MEETING

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OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

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AUDITORIUM

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JAMES F. PETERS, CSR, RPR
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Dr. Gina Solomon

Dr. Michael P. Wilson

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

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Ms. Dina Dobraca

Dr. Jianwen She, Chief, Biochemistry Section

Dr. Berna Watson

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. June-Soo Park, Environmental Chemistry Branch

ALSO PRESENT

Dr. Lesa Aylward, Summit Toxicology

Mr. Davis Baltz, Commonweal

Ms. Holly Brown-Williams, University of California, Berkeley

Dr. Dale Hattis, Clark University

Dr. Rachel Morello-Frosch, University of California, Berkeley

Mr. Tony Stefani, San Francisco Firefighters Cancer Prevention Foundation

Ms. Rachel Washburn, Loyola Marymount University, Los Angeles

INDEX

	PAGE
Welcome by OEHHA Acting Director Alexeef	1
Overview of the meeting by Chairperson Luderer	2
Program Update	
Presentation by Dr. Das	5
Panel Questions	28
Public Comment	32
Panel Discussion and Recommendations	39
Laboratory Update	
Presentation by Dr. She	40
Panel Questions	47
Presentation by Dr. Park	50
Panel Questions	54
Public Comment	71
Panel Discussion and Recommendations	72
Afternoon Session	78
Chemical Selection Planning	
Presentation by Dr. Krowech	78
Panel Questions	88
Public Comment	99
Panel Discussion and Recommendations	101
Biomonitoring Literacy: Developing Report-Back Materials with Input from Study Participants	
Presentation by Ms. Brown-Williams and Dr. Morello-Frosch	105
Panel Questions	125
Public Comment	144
Panel Discussion and Recommendations	150
Kaiser Permanente Collaboration: Biomonitoring Exposures Study(BEST)	
Presentation by Dr. Das	153
Panel Questions	165
Public Comment	176
Panel Discussion and Recommendations	177

INDEX CONTINUED

	PAGE
Looking Forward for Biomonitoring California - Program Planning	
Presentation by Dr. Das	177
Panel Questions	182
Public Comment	217
Panel Discussion and Recommendations	223
Public Comment	217
Wrap up	224
Adjournment	225
Reporter's Certificate	226

PROCEEDINGS

OEHHA ACTING DIRECTOR ALEXEEFF: Good morning. I'm George Alexeeff, Acting Director of the Office of Environmental Health Hazard Assessment. And I want to welcome the Panel and members of the public and staff as well as those listening on the audiocast to the Biomonitoring California to the Scientific Guidance Panel meeting on March 16th, 2011.

MS. HOOVER: Could you talk a little closer.

OEHHA ACTING DIRECTOR ALEXEEFF: Okay, will do.

So I want to thank the Panel for taking time out of their schedules to be here, as well as everyone else and thank them for taking their time to participate in this meeting.

In terms of some logistics, we do have to mention that we do have emergency exits in the back as well as in the front. And the restrooms are out the front and to your right.

The meeting is being transcribed and it's also being webcast. And then the microphones are always live, so for everyone to know that. And in a few weeks the transcript will be posted on the website.

And when we speak, please speak clearly into the microphone and give your name, if possible, so everyone listening can understand who's speaking.

So at our last Scientific Guidance Panel meeting, that occurred in Sacramento on November 2nd in 2010, at that meeting the Panel voted unanimously to recommend that manganese be added to the list of designated chemicals for the program.

Also, there was input provided on other agenda topics including program and laboratory updates, the Firefighter Occupational Exposures Project, the draft Public Involvement Plan, an introductory discussion of interpreting biomonitoring results using various comparison values, and chemical selection planning.

And if you'd like to look at a summary of the Panel's recommendations and input from the November meeting, you can visit the biomonitoring website at biomonitoring dot CA dot GOV.

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

CHAIRPERSON LUDERER: Thank you very much.

I'd like to also welcome everyone, members of the public, individuals who are listening on webcast, the staff and the Panel members.

I want to briefly review what the goals are for the meeting today.

The Panel will receive program and laboratory updates and provide input on those.

The Panel will provide input also on a screening approach for possible candidates for designation. And we'll discuss the example of non-halogenated organophosphate flame retardants to illustrate this proposed screening approach.

We will hear a presentation on the development of report-back materials for the Maternal and Infant Environmental Exposure Project, also called the Chemicals in Our Bodies Project, and provide input on that.

We'll receive an update on the program's collaboration with Kaiser Permanente, the Biomonitoring Exposures Study, or BEST, and provide input.

And we'll provide input on discussion questions designed to help the program plan for the future.

So after each presentation there will be an opportunity for Panel questions, also a public comment period, and then time for further Panel discussion and recommendations.

We also wanted to review how we'll be handling public comments today. If a member of the public would like to comment, please fill out a comment card, which can be obtained from the staff table outside the room and also from Amy Dunn, who is raising her hand with the purple cards there. And you can turn the cards into Amy.

Also, members of the public who are participating

via the webinar and would like to submit comments, can send an Email to the biomonitoring Email address, which is biomonitoring at oehha.ca.gov, during the meeting. And California Environmental Contaminant Biomonitoring Program staff will provide the comments to me. And then I'll read them aloud at the appropriate time during the public comment period.

To make sure that the meeting proceeds on schedule -- welcome, Dr. McKone.

PANEL MEMBER McKONE: I apologize. But I've been doing interviews for the crisis in Japan.

CHAIRPERSON LUDERER: So to make sure that all commenters have the opportunity to speak, public comments will be timed and will be subject to time limits. And the time allotted for these comments, we'll divide it equally among those individuals wishing to speak.

So please keep your comments focused on the agenda topics that are being presented that relate to that comment period. And there also will be an open comment period as the last item of the day for more general comments.

I just also wanted to remind everyone to please speak directly into the microphone and please introduce yourself before speaking. And this is for the benefit of the people who are listening and are watching via the

webinar and also for the benefit of the transcriber.

The materials for the meeting today are being provided in the meeting folder for the Scientific Guidance Panel members and via the website for the public. And there are also a small number of handouts and one folder for viewing at the staff table outside the auditorium.

Finally, we'll take two breaks today, one break for lunch at noon and then another break in the afternoon.

So we'll proceed to the first item on the agenda, which will be an update on the California Environmental Contaminant Biomonitoring Program activities. Dr. Rupali Das, Chief of the Exposure Assessment Section, California Department of Public Health, and lead of the California Environmental Contaminant Biomonitoring Program, and Amy Dunn, research scientist of the Office of Environmental Health Hazard Assessment, will be making the first presentation.

Dr. Das.

DR. DAS: Good morning. Thank you, Dr. Luderer.

While we get our technical issues straightened out today, let me also welcome members of the Scientific Guidance Panel, members of the audience who are attending here in Oakland, and those of you attending the webcast.

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: It's my pleasure today to provide you with a general update on the overall accomplishments of the program since our last meeting in November.

As you know, it takes a proverbial village to build and to continue and grow a project of this complexity. So the updates that I'm providing you today are really a representation of the work and the accomplishments of all the staff of Biomonitoring California, some of whom are in attendance today, but many of whom are not. And their work is invisible but represented in the accomplishments that I'll describe.

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DR. DAS: This is not the right presentation.

MS. HOOVER: No, that's looking forward.

DR. DAS: Yes.

That's the wrong presentation.

Can the audience see the presentation? Because from here I can't see the slides.

Okay. So the lights in the front will be turned off. But we have to wait for people who can do that to arrive.

Apologies for the delay and for the wrong presentation. But we have the right one up now.

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DR. DAS: So today I'll be providing updates on

the funding for the program, describing some staffing changes. And then something new, I'll be going through the timeline, walking you through our accomplishments of the program since its inception in 2006. And I'll be describing the strategies that the program has considered to obtain the statewide representative sample, briefly describing some of the accomplishments of the labs. But Dr. Jianwen She and Dr. June-Soo Park will really describe the lab's accomplishments in detail. And then I'll be providing an update on ongoing projects for which we're actively collecting samples. And then Amy Dunn will be describing some activities that we've done in terms of outreach and engagement.

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DR. DAS: So as you know, funding comes from two sources. We have a state source of funds, which is the Toxic Substances Control Account (TSCA). And the funding from that source has remained stable at $1.9 million a year, which continues to support 13 FTE in the three departments that are part of the program - California Department of Public Health, OEHHA, and the Department of Toxic Substances Control.

In addition, we have a CDC Cooperative Agreement, as you know, a five-year grant. We're currently in our second -- a five-year cooperative Agreement. Excuse me.

We're in our second year. And our funding, as you know, has been renewed at $2.6 million a year.

I'm happy to say that our project officer did change in January. Our project officer, Lovisa Romanoff, is visiting us this week. She's visiting the labs and our programs and is here with us today in the audience.

Lovisa, if you would just stand and wave.

(Applause.)

DR. DAS: Please join me in welcoming Lovisa. She's a research scientist at CDC; and, among other duties, is a project officer for all the three biomonitoring cooperative agreements, California and New York and Washington. She has a Masters Degree, MS, in chemical engineering from Sweden. And you can -- I can't pronounce the institute, but you can tell them -- oh, okay. All right.

In English, yes.

And has worked at a few institutions in Europe and in several labs at CDC as well as at the CDC Foundation, the nonprofit arm of CDC.

So thank you, Lovisa, and we're very happy to have you here.

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DR. DAS: So on staffing changes, we have hired a few new staff since our last meeting. There are two

environmental laboratory scientists that have been hired, and Dr. She will introduce them during his part of the presentation today. We have hired a new administrative assistant who will be starting next week.

And we have a new health educator with us today in the audience.

Amiko Mayeno, would you please stand.

Welcome, Amiko.

(Applause.)

DR. DAS: She will be the lead on several of our outreach activities for the program.

In addition, we have two visiting scholars in the labs, and Dr. She will introduce them as well.

We also have two vacancies. One of them is Diana Lee's old position. At the last meeting, if you'll recall, I announced that she would be retiring, and she did in January. And we have another vacancy in OEHHA as well.

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DR. DAS: So let me now walk you through the timeline. The formatting's appearing a little bit differently than it did on the screen. So apologies for it not looking perfect here.

But to remind you, Governor Schwarzenegger signed into law Senate Bill 1379 in 2006 and established the

California Environmental Contaminant Biomonitoring Program (CECBP), also known today as Biomonitoring California.

The next year, State General Funds in the amount of 5.2 million were contributed as a one-time amount of funds and went to support 13 FTEs and a one-time amount of funds going to support equipment. That year the biomonitoring listserv was established and the program website was created.

In terms of the listserv, the list of subscribers has been growing gradually but steadily during the last three and a half years, and currently there are 700 subscribers.

The program-specific web pages were set up in 2007 and initially had details about the panel, the program's three departments, and the goals of the program. Since then, new information continues to be added every month, and we have plans to improve the website and make it more user friendly as we go forward.

The first meeting of the Scientific Guidance Panel was held in 2008.

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DR. DAS: Also in 2008 we began work with CDC's, the Center for Disease Control and Prevention's, National Center for Health Statistics on a statewide sampling design. We'll be talking a little bit more about that as

the program -- as my presentation goes on.

We had three public input sessions and a workshop on chemical selection and held the three required Scientific Guidance Panel meetings.

We continued to -- that was the first year that TSCA funding became available to the program at $1.9 million a year.

Okay. I apologize. We have to take a little break, as the staff has to get into the podium to change the lights.

Thank you. I hope that you can see the slides better. And I apologize for that interruption.

Also in 2008, the program issued a request for information to researchers who had collected biological samples from California residents.

Just to remind you, criteria for selecting the collaborations included the following: The chemicals that the researchers wanted analyzed would coincide with lab capability in 2009. The samples would have been collected in the previous five years, and there were other collection and storage criteria that needed to be satisfied. But the samples come with basic demographic data that would be made available to the program, that they were of sufficient size; that they reflected California residents, especially susceptible populations;

and there were a few other criteria as well.

Three collaborations resulted from the issuance of this RFI: MARBLES, Markers for Autism Risk in Babies Learning Early Signs; CHAMACOS; and a collaboration with Columbia University. I'll be saying a little bit more about these three collaborations later. So I won't provide too much detail now.

In addition, we decided to collaborate with CYGNET, a Kaiser program studying samples from young girls. And I'll be saying a little bit more about this as my presentation goes on.

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DR. DAS: In 2009, we continued to hold meetings of the Scientific Guidance Panel, and our funding from the State remained stable, and we applied for and were awarded a competitive five-year CDC Cooperative Agreement in the amount of $2.6 million a year. That year we hired eight new staff with the CDC funds and obtained the equipment that you can see on the upper right-hand of the slide.

We also began our first pilot project where we actively collected samples from the Maternal and Infant Environmental Exposure Project (MIEEP), also known as the Chemicals in Our Bodies Project. This was a collaboration with Dr. Tracey Woodruff at UCSF and Dr. Morello-Frosch at UC Berkeley. And Dr. Morello-Frosch will be presenting

part of her work later today.

The labs also did an analysis of samples from Tulare County, which were collected by the Environmental Health Tracking Program, and helped with some outreach activities on another tracking project that was conducted in Imperial County.

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DR. DAS: In 2010 we continued to obtain new equipment with the help of our CDC funds, and we started recruitment for maternal-infant study in July of that year and hired five staff. That year we also started our pilot of an occupational cohort, the Firefighter Occupational Exposures, or FOX, project, which is a collaboration with Dr. Leslie Israel at UC Irvine's Center for Occupational and Environmental Health.

The labs analyzed the samples that were collected with the RFI researchers and the CYGNET samples. And recruitment began for the firefighter project approximately a year ago, last February of 2010. We started work on a public involvement plan that year as well.

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DR. DAS: Our work continues this year. We will -- are starting to revise and look at the results from the report-back template. You'll hear more about

that today. And we continue to obtain new equipment. And I'm very happy to say that we are unveiling our brochure "What is Biomonitoring," which you see before you. Members of the Panel have this brochure. And I believe it's available to the audience members as well.

Today is the first day we're releasing this brochure in public. I'm very proud of this work. A lot of our staff worked on it with Health Research for Action of the UC Berkeley School of Public Health. It describes what biomonitoring is and a little bit about our program.

This year we plan to start our next collaborative project with Kaiser Permanente Northern California Research Program on Genes, Environment, and Health - the Biomonitoring Exposure Study, or BEST. And our labs will continue to analyze the samples that we collect on the FOX and MIEEP studies.

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DR. DAS: In addition to all these accomplishments, we have another slide showing the accomplishments of the Scientific Guidance Panel's work with the program in terms of chemical selection. This slide shows the chemicals that the Panel along with the program members selected as designated or priority chemicals starting in December 2008 until the last meeting in November 2010.

I'm not going to go through this in detail. This is just to show you the chemicals, when they were selected. And you can peruse these at your convenience.

But as you can see, we've accomplished a lot, both in terms of chemical selection and, as the timeline shows, the program as a whole has really accomplished a great deal in the time since it's inception in 2006.

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DR. DAS: I want to move on now to talk about the program's work to approximate a statewide representative sample. As you know, one of the program's mandates is to biomonitor a statewide sample of California residents reflecting the State's diversity with respect to racial ethnicity, age, and economic status factors.

In 2008, Diana Lee, who has since retired, worked with CDC's National Center for Health Statistics to develop a statewide sampling strategy modeled after the National HANES Program. NCHS And Biomonitoring California staff developed a detailed plan and sampling design to acquire a representative sample of Californians. We identified the operational stages and staff roles required to support the program and also had a staffing plan and a model for costs.

The benefits for the program were that it complied with our legislative mandate. All of the

components of the program were designed to be scalable starting from a small project and expanding statewide. But to produce a statistically valid sample, approximately 3,000 participants would be needed annually. Over six years the program would sample Californians in 48 counties.

As you can imagine, limitations for this kind of a program were the costs. The costs to staff and support six to eight different participant enrollment locations throughout the State each year was approximately 9 to $10 million per year.

California also requires that a new program develop database structures and information technology specifics, and we did that. And the cost for -- the IT system, which included staff, multiple servers, field IT installations, and proprietary and custom software design was an impressive piece of work - Diana Lee prepared that as well - but also came at a very high cost.

While the costs of this type of statewide sampling are too high for today's financial -- fiscal climate, the methods can be deployed, we hope, after the current fiscal crisis is resolved. And perhaps elements of it can be used for smaller projects.

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DR. DAS: Because the costs of the HANES type

sampling were so high, we began to explore other kinds of collaborations to approximate a statewide sample.

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DR. DAS: The California Department of Public Health's Genetic Disease Screening Program collects blood and stores dried blood spots from over 99 percent of the nearly 500,000 infants born each year in California. We're in the process of exploring the feasibility of using dried blood spots for statewide population surveillance of prenatal exposures to chemicals. And Dr. She will present more information about the labs's work on analyzing dry blood spots.

In addition, 70 to 80 percent of pregnant women in California participate in California's Prenatal Screening Program, which results in 400,000 AFP specimens a year. These samples could provide information about chemicals in women of child-bearing age.

For both dried blood spots and AFP samples, we get very small volumes. The blood spots are much smaller in volume than the maternal serum. And both methods require pool sampling according to our current methods.

Our collaboration with Kaiser, which I'll describe in detail this afternoon, represents another approach to the statewide sampling. At the moment, this collaboration employs a regional sampling method. But if

successful, we anticipate this could expand out, possibly scaling up to a statewide sampling scheme. You'll hear more about this this afternoon.

The limitations of this kind of regional and statewide sampling is again the resources, because it does involve going out and collecting samples. And any collaboration that involves the program collecting samples will of course involve more resources than a collaboration where we collect samples that are collected by other researchers.

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DR. DAS: I want to briefly touch on the accomplishments of the labs. And you'll hear more about this in the next presentations.

Our completed lab collaborations include that with the CHAMACOS, where 50 samples were analyzed for phthalates; CYGNET, where 500 samples were analyzed for metals. This CYGNET was not part of the RFI but was a separate collaboration with the labs. MARBLES, 28 samples were analyzed for phthalates here. And the other RFI with Columbia University is currently in the planning stages. Discussion is going on to select the samples and the analytes.

In addition, we analyzed samples as a part of the collaboration with the tracking program. These were

samples collected in Tulare County. And samples for metabolite of organophosphate were analyzed by our labs.

As our labs begin to analyze samples and we begin to disseminate this information in meetings such as this and biomonitoring becomes more popular, our labs are actually starting to get requests from other researchers to analyze samples. So whereas the RFI went out and requested researchers for samples, our labs are starting to get requests independently of us going out to analyze samples. And so we are starting a process internally of developing criteria to evaluate these outside requests to select the ones that would be most suitable for our program. I think that's a great benefit and mark of achievement for our labs that this is happening.

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DR. DAS: I'll move on now to talk about our ongoing collaborations where we're actively collecting samples. The two active collaborations are MIEEP, Maternal and Infant Environmental Exposure Project, also known as the Chemicals in Our Bodies Project; and FOX, the Firefighter Occupational Exposures Project.

Our third collaboration is listed on this slide, but I won't be talking about it in this morning's presentation. You'll be hearing a lot more about it this afternoon. That is the Kaiser collaboration Biomonitoring

Exposure Study.

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DR. DAS: So just to remind you, the MIEEP pilot was identified -- the population of mothers and infants were identified by the Scientific Guidance Panel as a susceptible population worthy of study and also a community that would be worth studying since we didn't have the resources to go out and look at a statewide representative sample.

We began a collaboration with Dr. Tracey Woodruff at UCSF and Dr. Morello-Frosch at UC Berkeley in 2009. And this was not a hypothesis-driven study. But the number of participants and other aspects of the study were driven by resources. So the resources allowed us to collect samples from up to a hundred mothers and infants, and that was entirely driven by what was -- what we could do and not based on a hypothesis.

The purpose of this pilot, which was the first pilot where we actively collected samples, was to demonstrate our ability to capture samples in the field, and particularly in a labor and delivery setting which poses very specific challenges that we don't encounter in other settings, and to test protocols for sample collection, data collection and transfer, and sample management including collection in the field, transfer to

our labs, analysis, and then transfer of data back to our collaborators.

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DR. DAS: So to date, we have over 70 participants recruited. Our recruitment has been extended through April so that the mothers who are recruited into this project will be delivering by June.

At the last Panel meeting we were anticipating that recruitment would have been completed by now and we would have gotten many fewer participants. But we and our collaborators managed to extend recruitment through April. And our goal is still to get up to a hundred participants, resulting in a hundred moms and up to a hundred infant samples.

To date, we have received urine from 58 mothers, blood from 55 mothers, and cord bloods from -- 43 cord blood samples. So as you can see, our cord blood samples are fewer than the maternal samples. And this is a reflection of the difficulties in collecting samples in a labor and delivery setting.

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DR. DAS: So our Firefighter Pilot Study is something that we're also very proud of. Firefighters were identified as an occupational cohort that were highly likely to be exposed to several of the chemicals of

interest. And the Panel had expressed a desire to see us pursue a study in workers, and firefighters were determined to be a population that we're likely to see exposures.

The purpose of this pilot was to test protocols and procedures in worker cohort and also in a distant location. As you've already heard, this study is taking place in Irvine. So unlike the MIEEP project where we're getting samples from across the bay, for the FOX pilot we're getting samples from southern California.

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DR. DAS: So to update you on FOX, we're very happy to tell you that our enrollment and sample collection has been completed. This is quite an achievement, because we actually started sample collection about a year ago. So we're really proud of this accomplishment and I'd like to particularly thank and acknowledge Dr. Sandy McNeel --

Sandy, would you wave or stand up.

(Applause.)

DR. DAS: -- who's the project manager for this project and managed all the details from, you know, devising the survey instruments to making sure that staff collected the samples in the proper -- using the proper protocols and making sure that all the samples reached the

labs properly.

We have a lot of work to be done. But I think this is quite an achievement to tell you that we've completed sample collection and recruitment for this project in a year.

In addition to sample collection, we had a very small environmental sampling component for this project that was funded by a source that was independent of the biomonitoring funds. We collected dust from three fire stations that were in different parts of Orange County. And these were selected for various factors, including the number of firefighters, the type of incidents that the firefighters responded to, and geographical location.

This year, we will continue to analyze the biological samples that we've collected. The dust sample analyses are ongoing. And we hope to begin data analysis on some of the biological samples and the questionnaire data.

In addition, we will be field testing best practices for reporting results to firefighters, which we feel some of these practices will be a little bit different than reporting the results to the mothers in the MIEEP study.

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DR. DAS: And now I'd like to turn the mic over

to Amy Dunn, who will be talking to you about outreach and engagement activities.

MS. DUNN: Good morning.

We recently undertook several efforts to get stakeholder input into the design of the program's public involvement activities. I'll briefly describe efforts using the next few slides. You've heard about these efforts to some extent at previous meetings.

One is our first needs assessment survey of our stakeholders. And this one was with regard to stakeholder preferences for meeting with staff to provide input into program development.

The other -- the second area I'll cover is our outreach efforts to get ideas and suggestions on the draft Public Involvement Plan.

Then I'll mention some next steps that we envision in our public involvement activities.

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MS. DUNN: The survey on how you would like to participate in meetings with program staff had 95 respondents. About half of these were from government or academia.

One of our findings from the survey based on responses to a question about the location that people would prefer for in-person meetings is that most of our

listserv, or at least those responding to the survey, are based in northern California. Fewer than 15 percent indicated a preference for locations in southern California, which points to some work that we have ahead of us to expand our outreach into that area.

Another finding is a strong preference for teleconferences and webinars rather than in-person meetings, at least among those responding to the on-line survey. And you see that we're experimenting with webinars today. I apologize to those who are listening, because I've heard that the audio is not coming through very clearly.

We also found that daytime rather than evenings were preferred, as was a meeting format that split the meeting about in half between presentations and time for public comments.

Outreach for the public involvement plan was multi-faceted, including two teleconferences, an on-line survey, and comments via Email. The teleconferences included facilitated discussion of specific aspects of our public involvement efforts. We're grateful to all those who took the time to give us their feedback and ideas via these different mechanisms. We've compiled the comments, which include more than 200 specific suggestions on a range of topics, such as ideas for how to reach out to

more diverse groups, the best ways to share our findings with the public at large, and considerations in the development of materials to return results to individuals, among other topics.

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MS. DUNN: Finally, the next steps in the near term include reviewing all of this input that we've recently received from stakeholders and drawing on it as we revise the draft Public Involvement Plan. We're aware that on-line surveys miss some stakeholders. Thus, in addition to conducting additional needs assessment surveys on line, we intend to carry out in-person interviews to reach those we haven't been able to reach via on-line avenues.

We anticipate that the revised Public Involvement Plan will be completed in June of this year.

This concludes my report.

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DR. DAS: Thank you, Amy.

As I already mentioned, today represents the unveiling of our biomonitoring brochure. As I also mentioned, this was a work that a lot of our staff put time into. And we worked with Health Research for Action at UC Berkeley School of Public Health. The brochure describes what biomonitoring is and what it means to take

part in a biomonitoring project.

We plan to use this brochure as part of recruitment in our various projects. But, in addition, we hope that the brochure will be useful in a number of different settings and it will be widely disseminated. And we'd welcome the Panel's suggestions on any ideas you have for use of the brochure.

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DR. DAS: I'm happy to report that the legislative report that was due in January 2010 is now available at the OEHHA -- official website for the Biomonitoring Program. And the website is listed here. And we're currently preparing the next report, which is due in January 2012. As you will probably recall, a report is due to the Legislature every two years in January.

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DR. DAS: Finally, I would like to acknowledge all of the Biomonitoring California staff listed here. And not listed here are our collaborators, some of whom I've mentioned during my talk. But they are really critical in our success. And particularly I failed to acknowledge - and I would like to do so now - Dr. Leslie Israel and the firefighter liaisons that we had as part of the FOX collaboration and the Orange County Fire

Authority. Without their help and dedication to this project, I don't think we would have been able to complete the firefighter project. So I'd really like to acknowledge their help, in addition to our collaborators at UCSF, UC Irvine, and all of the researchers who provided our biological samples.

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DR. DAS: And now I'd like to offer the time for questions.

CHAIRPERSON LUDERER: Thank you very much, Dr. Das. It's really impressive to see that timeline and to see all the progress that the program has made over these last four years, especially with such limited resources.

And also congratulations on the biomonitoring brochure being released today.

DR. DAS: Thank you.

CHAIRPERSON LUDERER: It's very exciting.

So we have a few minutes now for Panel questions. Then there will be a public comment period and then there'll be more time for Panel discussions.

So do any of the Panel members have questions?

Dr. Wilson.

PANEL MEMBER WILSON: Hi. Mike Wilson.

Thank you, Rupa, for that presentation and I echo the Chair's congratulations on the work.

I'm wondering if you have a sense of when the work from the firefighter study will be available and when those analyses will be completed, if you have a projection.

DR. DAS: The analytes are being measured in different phases. So certain analytes are measured earlier than others. We anticipate that the results will be available on a rolling basis. And our plans for releasing their results -- we're developing some formal policies on those. But our current plan is to release the results to the participants ideally first and then to release the results in other audiences including the Panel, to public, and to scientific audiences.

We anticipate that the first set of results will be available within the year. And those could include the metals and the PFCs. That's an estimate. And then the other analytes would be available over the following year.

PANEL MEMBER WILSON: Great.

All right. Thank you.

CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: You say you're going to release the -- did I not push something?

You say you're going to release the results to participants first?

DR. DAS: Part of our program's mandate is to

return results to participants. And the informed consent process that participants went through indicates that -- gives participants the option of choosing to receive their individual results. And so our current plan is to give them their individual results before we talk about the overall results on the program to the public.

PANEL MEMBER CULVER: What information about the material -- pardon?

MS. HOOVER: Talk directly into the mike.

PANEL MEMBER CULVER: What additional information do you give the participant beyond just a number for a chemical? How much information about that chemical do they receive at the same time?

DR. DAS: That's an excellent question, Dr. Culver. And we are working on that. And I can't tell you exactly what other information will be available. However, one of the presentations this afternoon by Holly Brown-Williams and Dr. Morello-Frosch will be talking about a template that is being developed to guide the kind of information we provide to participants. We will use that template or some version of it to return results. What I think you're implying is that a number by itself may not be enough for participants. And we are working on what other information should be in there to make this information educational.

PANEL MEMBER CULVER: Will we get to see those templates?

DR. DAS: This afternoon I believe part of the presentation includes the template that was developed as part of the work that Dr. Morello-Frosh and Holly Brown-Williams did as part of the Maternal-Infant Environmental Exposure Project. So we will see that template.

PANEL MEMBER CULVER: Thank you.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

You may have mentioned this. But I was wondering if there is a formal dissemination plan for the brochure. I'm thinking in particular that this would be -- having such a plan would be a good way to maybe engage more people from southern California and more groups, occupational groups. Because I know one of the challenges in doing occupational studies is having, you know, a receptive organization to work with, like a union. And I think the brochure may be a good way to engage more people in this -- to let them know about the program. So just wondering if you were planning anything like that.

DR. DAS: That's an excellent suggestion, Dr. Quint.

Currently, as I mentioned the plans, we plan to

use the brochure as part of recruitment in our ongoing projects.

In addition, as part of our outreach and engagement activities, we'll consider a formal plan to disseminate the brochure. Amiko Mayeno and Amy Dunn are, among others, who are developing this -- outreach and engagement activities and we'll certainly take your comments into consideration, particularly the comments about reaching out to unions and other groups.

CHAIRPERSON LUDERER: Okay. If we have no other Panel questions, at this time do we have any public comments?

Okay. It looks like we have one person -- participant who is here and one that came in via Email. So I'd like to ask Tony Stefani of the San Francisco Firefighters Cancer Prevention Foundation to come forward.

MR. STEFANI: Thanks for the ability letting me comment. Greatly appreciate it.

My name is Tony Stefani. I'm a retired captain with the San Francisco Fire Department and the founder and president of the San Francisco Firefighters Cancer Prevention Foundation.

I'm basically here today to thank this Panel, to thank the California Department of Public Health, especially Dr. Das, for the occupational exposure project

that's going on currently in Irvine.

The fire profession right now is -- especially in major metropolitan areas is having a major problem with various forms of cancer. You no longer hear too much about firefighters actually dying on the job. We have an excellent program in place right now, an incident command system. And there's been various things that have taken place over the years where we've learned through fighting fires how to protect each other a little bit better at the scene of a working fire.

Our major problem right now is the ongoing problem with cancers, both in our active and retired firefighters.

Our foundation has put together a program for the early detection and prevention in firefighters in San Francisco. We've had one major study published so far, and that was in 2007 with the Urology Department at UCSF. And at that time Dr. Marshall Stoller and Dr. Kirsten Greene ran the project and found that we did have a higher rate of cancers of the genitourinary system, specifically transitional cell carcinoma. So on a yearly basis right now we offer active and retired firefighters a screening for that particular disease.

We are very interested in the study that's going on right now with the biomonitoring of the firefighters in

UC Irvine -- excuse me -- at Irvine, and would love to become involved in this type of study, to the point where we are willing -- our foundation is willing to help with the funding of this type of study. We think it's very important to give us the proper steps looking toward preventing cancer.

Our great concern right now is not actually fighting the fire itself but the exposures that occur during the overhauling process where we have a tremendous amount of off-gassing. We are really concerned about brominated and chlorinated compounds that are used in fire retardants in our State. We're really concerned about the PVC, the different types of plastics that are out there and the instability of these plastics and the exposures that they are occurring -- that are occurring right now to firefighters. Even though we wear protective breathing equipment, these chemicals are permeating the clothing of the firefighters.

There's now incidents of thyroid cancer. And the reason being that the profession looks at right now is because the thermo-protective masks that the firefighters are wearing, the hoods that they're wearing are not cleaned on a regular basis, their turn-out coats and pants are not cleaned on a regular basis, so they are continually getting exposures on an ongoing basis when

they put these pieces of clothing back on.

So this Biomonitoring Program, the Occupational Exposure Project with the firefighters we think is an excellent program. We'd love to see it broadened. We'd love to be that little spot across the bay that would be able to take part in a program like this.

And thank you very much.

(Applause.)

CHAIRPERSON LUDERER: Thank you very much for those comments. And I'm sure that the program staff will be interested in speaking further with you about that offer.

It looks like we have an additional comment from someone in the audience, Mr. Davis Baltz from Commonweal. So we'll take that comment and then I'll read the Email comment.

MR. BALTZ: Good morning, members of the Panel. Davis Baltz from Commonweal.

Just to refresh everyone's memory, we were a co-sponsor of the legislation that created this program and have been very pleased to track its progress since its inception. And Dr. Das's presentation summarizing the accomplishments of the program really pointed to a number of things that I think are significant: The dedicated staff of the program who have now produced this brochure,

the timeline outlining everything that's happened.

Who else would I like to acknowledge?

Diana Lee's contributions, although she's now retired and will be missed and hard to replace.

The collegial and professional Scientific Guidance Panel, you've really demonstrated a way of working together that has moved the program forward and hasn't been diverted into, you know, nonproductive conversations.

And then, lastly, the request that the program is now getting to analyze samples from other parties, I think that's very significant as well.

I'll be probably commenting on some other aspects of the program as this meeting goes on and for the workshop tomorrow. But in general, given the resource constraints that the program will face, I think continuing to generate data where you can is important. As we just heard, occupational studies seem to have a great deal of value. And perhaps we can figure out a way to expand the work of the FOX project to additional firefighters in the State. As we know, fire retardants, among others, is a key issue in California right now. And the more data that we can generate on the flame retardants in the general population as well as those who are fighting the fires for us I think would get us to a solution more quickly.

I also think that the exposures that you're exploring in the MIEEP project for young children as well as pregnant moms are important to pursue. As you know, NHANES is not measuring these in kids under six, their critical time of exposure. And this is a place where California can really contribute to the national conversation.

So I know that there are some thorny issues. We'll talk about reporting results later today as well as the issue of reference levels and their appropriate use. So I'll look forward to that conversation.

And thanks again to the village of Biomonitoring California.

(Applause.)

CHAIRPERSON LUDERER: Thank you very much for those comments.

I'd like to now read some comments that were Emailed in from Carl D. Ruiz, MPH, a research fellow, Regulatory Affairs at Henkel Consumer Goods in Scottsdale, Arizona.

Mr. Ruiz says: "Thank you for the opportunity to provide comments on the SGP meeting. Was reviewing the two-day meeting materials, and presentations, in particular the Biomonitoring California update presentation being made by Dr. Rupali Das of the CDPH and

Amy Dunn of the Office of Environmental Health Hazard Assessment, and noted that slide #24 has a copy of the biomonitoring brochure that CDPH will use to educate the public.

"I would like to comment that the brochure should also reflect the U.S. Centers for Disease Control and Prevention statement that 'the measurement of an environmental chemical in a person's blood or urine is an indication of exposure. It does not by itself mean that the chemical causes disease or an adverse effect.'"

And the source of that quote was 2009 Fourth National Report on Human Exposure to Environmental Chemicals from the Department of Health and Human Services CDC.

Mr. Ruiz goes on to say, "Informing the public that the presence of a chemical in one's body doesn't necessarily mean that it will cause disease or an adverse effect is important in order to fully disclose the truth; avoid unnecessary fear or anxiety, which can affect one's health; and communicate more clearly that the data obtained from biomonitoring studies are useful because they can be used in scientifically-based risk assessments, which can then determine whether or not such exposure presents a human health risk.

"Thank you for the opportunity to comment on this

important issue."

I think those were all the public comments.

All right. Then it's time for -- we have some time now for Panel discussion and recommendations.

Would any Panel members like to comment, have questions?

PANEL MEMBER WILSON: I'll make a comment.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson. I would just like to comment, thanking Mr. Baltz and Captain Stefani for your comments. And I think in particular the Panel and OEHHA are indebted to the firefighters union in making sure that -- in helping the project in Orange County get off the ground, and the cooperation of the firefighters association there. And, you know, look forward to further work with you and appreciate your presence here today.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: This is Gina Solomon. I just want to essentially second what Dr. Wilson said. I think that, you know, the firefighters project in southern California has shown that, you know, it can be a very effective collaboration. The excellent recruitment shows that, you know, it's feasible to replicate a firefighters project in other locations. And so it's definitely very much worthy of consideration to, you know, think about

expanding the project not only to San Francisco but perhaps, you know, it might be possible to identify a location in another part of the state.

And I'm kind of interested in whether firefighters who are doing wild firefighting might be encountering a somewhat different set of circumstances and whether it would be possible to include a group of firefighters who might be fighting wild fires as well.

CHAIRPERSON LUDERER: Okay. If we have no other questions from Panel members at this time, the next presentation will be introduced by Dr. Das, I believe. Right?

DR. DAS: Well, it's my pleasure to introduce Dr. Jianwen She, who is the Chief of the biomonitoring section in the Environmental Health Laboratory of the California Department of Public Health. His presentation will be followed by Dr. June-Soo Park of the Environmental Chemistry Lab of the Department of Toxic Substances Control.

Dr. She.

(Thereupon an overhead presentation was Presented as follows.)

DR. SHE: Thanks, Dr. Das. And good morning, everyone. I'm happy to update you on the progress --

MS. DUNN: Jianwen, you need to get right up to

the mic.

DR. SHE: I'm happy to update you on the progress EHLB has made since our last November meeting.

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DR. SHE: First of all, I would like to take a moment to introduce our new staff, Sung Choi, our LIMS specialist...

(Applause.)

DR. SHE: ...and the two visiting scholars from China, Professor Ruifang Fan...

(Applause.)

DR. SHE: ...and Mr. DaSheng Lu.

(Applause.)

DR. SHE: Professor Fan is from South China Normal University and is working on the hydroxy-PAH method development, and DaSheng is from Shanghai CDC and is developing a method for the analysis of a PCB and PBDE in dry blood spots.

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DR. SHE: Besides adding new staff, laboratory installed its second ICP-MS for urine metal panel and metal speciation analysis.

Lab also purchased a solid phase extraction workstation to automate sample preparation procedure.

--o0o--

DR. SHE: During the time we analyzed 41 samples for TCPy for Tulare II Environmental Health Tracking Program; 50 samples for phthalate for CHAMACOS studies; 101 samples for metals for FOX study; and a another hundred samples for metal for MIEEP study.

And we plan to begin analysis of urine samples for MIEEP and the FOX studies soon.

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DR. SHE: Currently, we have a few methods under development and validation.

Two methods under development are:

Metal panel in urine by ICP-MS; and

Arsenic and mercury speciation in urine by LC-MS.

And four other methods under validation are:

Environmental phenols in urine by LC-MS;

OP pesticides: Dialkyl phosphate metabolites (DAPs) by GC-MS and MS; and the hydroxy-PAHs in urine by LC-MS/MS, in addition to our previous development in GC high resolution methods; and

The most important we also start to analyze is PCB and PBDE in dry blood spot by high resolution GC-MS.

As Dr. Das mentioned, this dry blood spots and the maternal serums are very small volumes available. So we want to take a challenge to see how we can overcome the limitation and then to provide the technique to support

statewide programming and sampling plan.

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DR. SHE: DBS analysis is the most difficult method we are undertaking, and I like to talk about it in next few slides.

As you know, we face a few technical challenges for analysis of chemicals in DBS. For example:

Extremely small volume of blood. I use examples, current method one may use one milliliter of the blood or serum. The method we are talking about to use a few hundred or less than a hundred microliters of the blood.

And also we could have the potential contamination problems, extraction and recovery challenges, plus stability of the chemicals.

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DR. SHE: To reduce or avoid the impact of the stability issues, we selected persistent organic pollutants as the first group of the chemical to start. 14 PCB and 5 PBDEs were chosen for the method of development, and they are listed on this slide.

To solve the issue of small volume of blood in DBS assay, we maximized the sensitivity of the instrument and the method.

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DR. SHE: To assess the potential contamination

problem we have performed analysis of filter papers from previous years. We found the paper of the year of 1987 have the highest contamination. The papers of the year of 1996 have low and relative constant contamination. We concluded that we cannot use DBS before 1996.

--o0o--

DR. SHE: This table summarized the performance of DBS method, and we found it is promising. To help you to understand the results, we grouped 19 chemicals into four groups: Marked PCB or indicated PCB, include six of them; dioxin-like PCBs; other PCB; and the PBDEs.

For marker PCB, we can analyze four out of six at this moment. We do not think that we can analyze any dioxin-like PCBs from dry blood spots. For three other PCB we have no problem to analyze them. For five PBDEs we can analyze three at this moment.

The chemicals in the red color were the ones where we would have the problem at this moment. And they are the ones with the higher contamination in the filter paper or appear at a very low levels in the samples of general population.

As reminding you the third row is a 50 percentile from CDC report of numbers, which also gives a goal we try to reach with this method.

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DR. SHE: I need to go back.

The table also lists the two types of tests we did. So start from row 4, you can see that's our spiked test. Basically we spike so much, we look for the recovery and the precision.

Under the last two row is a really 1996 blood spots from genetic disease program they provide us. We look for the precision. We analyze 12 times. We get a very good precision on it. And also the level we found is much higher than CDC reported on levels from general population. But this is only one sample.

For real samples, as I mentioned, we checked the relative standard deviation. We also would allow purchase of materials to compare accuracy. Actually right now the experiment is still running, so we will have a result very soon.

You can see the RSD are good for both tests. We like to have the recovery number between 70 to 120 percent. Obviously a few of them cannot meet this criteria. We need to mention, for all of the tests, we used two spots which contain about 100 microliter of blood.

Our next step is to see if we can use one spot. If we can reach one spot, that's means we can do the individual samples. And we have confidence that we can do

individual samples for maternal serums. But I'm not sure we can do the dry blood spots and to address the stability issues of the method.

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DR. SHE: My last slide shows the performance of other methods.

You can see for hydroxy-PAH, we obtained very good precision. Out of ten of the chemicals we test, for five of them we get reasonable result compared with the CDC's quality control materials.

I wanted to thank at least our project office provide us the CDC quality control materials. This is a big help. We can compare all that with CDC.

For the environmental phenols, we get very good precision. We also test the sample from Germany quality control samples. We get a very good result on the BPA, Bisphenol A result.

For the other 13 chemicals, we still under evaluation. We use the CDC samples. My initial impression is that we get good result on most of them.

For the DAPs method, we get good precision. For six DAPs we have accurate result for DMTP and the DMDTP. But we still have the problem with other four for the accuracy. And we're still troubleshooting. We believe that our problem come from the standard we are using, not

from our procedure.

Before I conclude my presentation, I like to thank our lab team for their dedication and their hard work, especially our two visiting scholars from China.

And unfortunately DaSheng Lu work on DBS, he will leave at the end of next month. We cannot keep him. The Chinese CDC ask him to go back as quickly as he can.

Last but not the least, I want to thank Dr. Frank Barley for his outstanding leadership of inorganic groups. Dr. Frank Barley will retire at the end of April, and he will move to Oregon State to enjoy his retirement. And we hope that we can keep him at least in a consultant role for the program.

Thank you, everyone.

(Applause.)

CHAIRPERSON LUDERER: We're a little bit ahead of schedule. So if any Panel members have just quick clarifying questions before we move on to the next presentation.

Thank you.

PANEL MEMBER BRADMAN: I just want to go back to the recovery aspect --

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: Asa Bradman. If you could go back to the recoveries.

So I didn't quite understand here. With the PBDEs, it looks like some of them did okay. And I'm curious if there might be a way to improve the extraction to bring the recoveries, particularly for 47 and 99, up.

DR. SHE: This is a recovery from the spike experiment. So we spike the level that's similar of the general population. And right at this moment the lower recovery comes from the very high contamination from the filter papers. And we actually have a column before showing the ratio between the filter paper levels and the general population levels. For PBDE 47s the ratio is about 10. So that's means almost 10 times PBDE 47 show up in the filter paper than the general population.

So which cause the -- we cannot look at the blood at this moment. So we are working at this moment to see if we can improve our recovery of 47 and the 99, because of the importance in that.

PANEL MEMBER BRADMAN: Is it possible that the contamination on the blood spots, is it -- do you think it's intrinsic to the paper or it's being contaminated by handling and processing? And if it's the former, could we perhaps influence the choice of paper that's used for the blood spots.

DR. SHE: We do not have so much experience with filter paper on PBDE. But for the dioxin, for example,

people did a lot of research on the papers because of bleach. So we believe the structure of the paper have a lot of hydroxyl groups stand out. So we really don't know why this is low polar compound coming into the paper either from the -- kind of we think maybe from a manufacturer process instead of from absorbing.

So we need to find out more where this contamination comes from.

PANEL MEMBER BRADMAN: I'm just wondering if there might be some way that we could influence the quality of the paper that's used, either maybe looking for another brand or seeing if the manufacturing process can be altered, or some way of changing that so perhaps the background can be eliminated.

DR. SHE: That's a good point. We know the genetic disease program out of the paper, for example, from Whitman. And then they do a pre-screening for their tests, for example, immuno-acid test or the steroid test, that every -- when the other bigger batch come with rolls, they look for like every 2,000 pages that go to test if this paper meets that requirement.

The level include our chemical in their pre-screening procedure. Maybe that's something we can talk with them to see before they use the paper, is there anyway we can improve. That's a good suggestion.

PANEL MEMBER BRADMAN: I'm done.

CHAIRPERSON LUDERER: Okay. Why don't we go on to the second presentation, and then there will be more time for discussion and then comments afterwards.

This is Dr. June-Soo Park.

(Thereupon an overhead presentation was Presented as follows.)

DR. PARK: Good morning. My name is June-Soo Park. I come here again as the back-up speaker Myrto Petreas, who's not here. She's in Greece right now. Nice to see you again on the Panel.

I'm going to give a very quick and brief update about our laboratory side.

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DR. PARK: So we have one recent newbee, Dr. Sissy Petropoulou.

Sissy, is she here?

(Applause.)

DR. PARK: And Dr. Tan Guo.

(Applause.)

DR. PARK: And Dr. Suhash Harwani. He's not here with us today because he fly back to Chicago today to see his parents coming from India.

So also we have not only the person not only the staff. We have new equipment, LC-MS. It was installed a

couple of weeks ago. We have training coming next week.

And also we purchased four more SPE automated system to expedite our sample process. It's now being tested.

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DR. PARK: We have validated methods. This is same as before. PBDEs and the PCBs and organochlorine pesticide and perfluorinated chemicals.

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DR. PARK: We're still testing the method to measure some non-PBDE flame Retardants, like PBT, PBEB, HBB, and TBECH. I'm not going to describe full names. Probably doesn't mean much to probably most of us, I guess.

And this is the chemical list -- be found list, it can be analyzed in the GC method. But we have difficulties on the GC.

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DR. PARK: We also testing method using new LC-MS system. And they include tetrabromo bisphenol A, tetrabromobenzoate, phthalate, and the BTBPE.

Also, we are testing new method using GC to new LC-MS. The chemicals we are interested in listed the hydroxy-PCB and hydroxy PBDE metabolites. Also there's some environmental phenols like BPA and triclosan. I'm

only talking about the serum matrix here.

The main reason we want to switch the method -- we already established the method using the GC for this phenol compound. But we're really concerned. Using GC requires some derivatization involved with some potentially harmful derivatization reagent. So we didn't like it.

So hopefully this new LC method can work it out, so we can enjoy our work with a peaceful mind.

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DR. PARK: And we're also testing some method for the sample collection including a sample collection and a sample process and some long-term storaging. For this test we are using more than 60 samples collected from 11 volunteers here. And we're testing some serum separation tube against a red-top tube. We worked it out. We will save sometime in the extra effort. And the case is -- this is serum separation tube. We'll be safe, I mean safe from the -- safe for background levels of our analytes of interest, like lipid and organochlorine pesticide and the PCB, PBDE, and the PFC.

Particularly most concern -- our concern is the lipid and the perfluorinated compound. That we will find it out soon.

We are also testing some time before processing.

You know, sometimes when you are in the field you cannot process the samples right away. So it may -- you know, the sample wait like one day or two days. We are testing it, make sure it's okay. And also there's time. I think bottom one is kind of cut off. But we are also testing the -- after you, you know, receive the sample, you know, to store like more than years. So we also testing that's okay. So that would be compared to the like one-month storage.

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DR. PARK: So this is our plan. You know, we received some samples. We are going to aliquot all the samples for the purpose of analysis. But we start with the lipid measurement. And the next step we will measure perfluorinated compounds.

And then the PCB and organochlorine pesticide and the PBDE analysis is now on hold because we're kind of waiting, you know, for the other new BFRs. We want to see if some of the new BFRs can be analyzed with this group of -- you know, the compound we already validated method.

So if there's some method -- some of them will be analyzed with the compound that we are confident. Maybe some of them should go to the LC. So the new BFR analysis will be the last stage.

This is about it.

(Laughter.)

(Applause.)

CHAIRPERSON LUDERER: Thank you very much, Dr. Park and Dr. She.

We now have time for some more Panel questions. And then we also have ten minutes allotted for public comments.

I just wanted to say that I thought it was very exciting that Dr. Das also mentioned that the labs are now being asked by outside researchers about the possibility of measuring -- of analyzing samples, biospecimens. And I think this just shows that the capacity -- laboratory capacity for biomonitoring in the United States is not adequate at this point. And that's really one of the great benefits I think that this -- of this program, in additional to being able to do the mandate to do a biomonitoring of a representative sample of Californians, but building this laboratory capacity in California. And I think the fact that you are being asked by outside -- you know, other researchers whether their specimens can be measured is indicative of that.

So do any other Panel members have comments or questions?

PANEL MEMBER BRADMAN: Asa Bradman. I just -- with being in danger of being redundant, I want to echo

that as well, just looking at --

Dunn right into the mic.

PANEL MEMBER BRADMAN: I just want to echo that comment as well. Just the list of equipment that's been installed recently is impressive and really I think brings California close to, you know, CDC or at least being one of the -- it's going to be really the next major laboratory. And that's great that that's available.

And also, you know, one of the issues we talked at one of our first meetings here in this room was revenue and whether, you know, being able to provide those services can be another source of revenue to help support the program and help support the infrastructure. And I think that that can be an important component of this as well.

And I was pleased to hear earlier that there was some discussion too about what criteria -- or that there's a need for development of criteria to decide, you know, what to test and how to interact with outside people, and I think that's important.

Definitely there could be a source of revenue here. But we want to be careful that the work that's done fits into overall program goals, so we don't have, you know, the situation becoming more of a service lab but rather supporting public health goals.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I just wanted to also publicly thank CDC for all the training and help that they have given us in getting to this point in terms of our laboratory capability. And being able to do these samples also takes a lot of the pressure off of CDC, because I know there's a backlog of people samples that they have for analysis. But none of this would have been possible if we didn't get training and the support. So I just wanted to publicly acknowledge that.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Gina Solomon.

I agree with everything my fellow panelists have said.

I also was just harking back to a discussion we had a number of meetings ago about figuring out methods to test for unknowns. And I heard a presentation from some folks at the lab at San Francisco General Hospital. And they're using a time-of-flight mass spectrometer to look for unknowns and have actually, it appears, been having quite a lot of success. And I was wondering - it's a question to both labs - whether you're looking into that and whether that's something that might be a possibility at some point in the future. And I was actually thinking

about this, in part -- it related to the firefighters study, because firefighters would be exposed to all kinds of combustion byproducts of parent chemicals and it would -- it's probably a pretty complex mixture and it might be tough. If you're just kind of looking for the parent compounds, you might miss a lot.

DR. PARK: Yes, I remember last November meeting somebody -- one of -- a panel asked me about, you know, why we keep chasing the old, old chemicals, you know, the -- I probably answer the same things, you know, the -- but it's a known -- in relation to the green chemistry issues. Since we are getting first more -- getting more frustrated, you know, by knowing how industry react to also how regulation -- you know, the regulatory agency hopes that they reach.

So I think our group keep talking about this unknown identification in the environmental sample more and more. That's why our next instrument we hoping for or to get is for the -- either TOF on the -- which we will shop around and get some knowledge. We already have steps. You know, but who is capable?

So that the unknown identification in the environmental sample will be very important. Very important to -- if the green chemistry is not going forward with speed that we hope for, we have to give some

early warning to the public. You know, this is kind of a possible potential, you know, harmful chemicals. We don't know yet, but it is possible based on the structure base. Also the -- we can say yes because this is the size of the same structure, what it is. So if it can be toxic, we can -- we should let the public know about that.

So that's the kind of a next big step our -- the group is kind of pushing for.

DR. SHE: I completely agree with what Dr. Park already said. Just add one point. I'd like to comment on the firefight studies. For example, there are many new flame retardant -- phosphate for -- the flame retardant. People most of time are doing low water -- metabolite there are. Only very few labs like University of Nuremberg in Germany and other leading labs explore that metabolite. So the unknown or screening method would be very important beyond the target analysis.

So I thank you for that comment.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I just want to also echo that, because the new knowns -- or they're not exactly unknown. But the substitutes for some of the phthalates and other chemicals are already on the market. I think Dr. Krowech's presentation last time made us aware of the increasing

number of substitutes that are being developed. And I'm looking forward to our presentation later, because I think the screening of those compounds and knowing about them early will certainly -- you know, will benefit, because I review material safety data sheets on a regular basis and have identified a number of substitutes for some of the plasticizers and other chemicals, and virtually no information on them.

So I think this is a huge area of interest.

CHAIRPERSON LUDERER: Dr. Alexeeff.

OEHHA ACTING DIRECTOR ALEXEEFF: Yeah. Thank you for the presentation.

I was wondering if you could comment on processing time, because I know that's a big issue as well. And I wonder how you feel how that's coming along as well. Obviously your precision and the types of chemicals you will analyze is increasing. But how do you feel about the time to actually do the analysis?

DR. PARK: Are you asking the processing time for the sample analysis or of the sample collection?

OEHHA ACTING DIRECTOR ALEXEEFF: Actually the analysis.

DR. PARK: Actually analysis -- you know, the -- can you be a little bit more specific, you know, about how I feel --

OEHHA ACTING DIRECTOR ALEXEEFF: Biological sample in terms of cleanup, getting it ready to run and actually getting the analysis and being able to identify the chemicals. That obviously is a lot of work to get to the point where it could be done routinely. I'm just kind of wondering how you feel how you're coming along on that process.

DR. PARK: Well, we spend a lot of time, you know, to do -- to have very -- you know, concrete method. That kind of -- that's the kind of a time period we spend a lot of time and effort.

Then also you have the method. It's a production mode. So basically also the method is tested for all the accuracy and the precision. I think next step will be the production. You know, so I think that -- I don't see -- that's when really takes a long time. Method development is kind of the hardest part for us.

CHAIRPERSON LUDERER: Dr. Wilson.

DR. SHE: I want to --

CHAIRPERSON LUDERER: Oh, sorry.

Dr. She.

DR. SHE: I have one comment on George's previous question.

Analytical time, we are chemical dependent. For the inorganic chemicals first, possibly we can provide a

capacity to do all the samples we collect. Very reasonably, very quickly. You already see the slide we finish all the MIEEP and for the whole blood metals and FOX already. So we have not a capacity problem.

For the other chemicals we are analyzed, for example, like no persistent chemicals. You really I think right now with many procedure, we can handle a batch. I always said a batch included 15 to 20 samples. Maybe within like a three-week -- sorry -- within one week for one specific analytes.

And we also looking for the ways to improve the throughput for the POPS. For example, if the method we work out with DBS, we hope we can significantly improve the POPS production and then also reduces the cost on it. So substantially we use very small volume of samples. We simply follow the sample clean-up procedure.

DR. PARK: One more comment I'd like to do. Sorry about that.

We also -- don't forget about, you know, trying to detect some compound of emerging issues -- can be emerging issues. That's why it takes -- we can -- some other method. We can, you know, give a cue to analyze the samples. But we are kind of holding it, make sure the -- again, Dr. She mentioned that this is very fresh. It could be some one time or, you know, the second time -- if

you failed the first time, that's gone. So we make sure that we don't miss -- you know, the very important chemicals that we -- if you can measure. So that's kind of an effort that we are focusing right now.

OEHHA ACTING DIRECTOR ALEXEEFF: Thank you

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Yeah, Mike Wilson.

And I guess first I'd just like to echo Dr. Quint's appreciation to CDC for the support that has been ongoing. Obviously it wouldn't -- you know, we won't be where we are today without that support.

And as Dr. Luderer said, California's becoming -- beginning to be a place where people are seeking support for their own projects.

And I guess I'd like to underscore something that Dr. Bradman mentioned, that if that trend continues, I would want -- I want to make sure that both DTSC and OEHHA in establishing agreements for conducting sampling for outside parties, that we retain our focus on our public interest goals rather than sort of becoming a service program for these other efforts.

And that may mean that we would want to ensure that we have access to the data or the raw data that come out of those analyses and be able to use those and write about those in our public publications and so forth. If

that's within, you know, the scope of those contracts, I think it would be really helpful for our work and increasing our capacity. It's a great point Dr. Bradman raised.

And then the second is I guess for Dr. Park. I'm wondering if you could comment a little bit about your quality control and quality assurance measures in the lab. Dr. She mentioned some of the -- you know, the challenges they were having on recovery from their spiked samples and so forth. And I'm just wondering if you're having any similar problems in the DTSC labs or not. And if so, what steps are you taking at this point?

DR. PARK: We have quality control samples, also the procedures. I discussed a little bit about this last presentation, so I didn't discuss, you know, about the perfluorinated chemicals. For example -- that's one of the example. Now, do we have a one batch when we analyze it? We have blank. And we have our house control samples.

Before actually the method is set up, we did many cross-checks by asking the samples from first the CDC, with our staff and my staff went to the CDC to learn this PFC method from Dr. Antonio Calafat in her lab. And the staff informed that we had -- after we come back, we tested everything. And then when we are confident with

our own control samples, we asked -- CDC send their QC samples. We asked the New York State lab and we asked the Minnesota State lab, and we also one or two more our colleagues' lab, you know, to send us some QC samples to make sure we are in the same ball park.

So that's one of the QC procedures before we actually set up the concrete method. Then we have each batch. We have -- when we analyze samples, each batch contains a calibration standard, blank samples to mimic the actual samples, we use a bovine serum. And the second we have serum, standard certified reference material, also we have our in-house control samples.

So I think that kind of a procedure applies to the other chemicals too. POPs -- regular POPs, PCB, the PBDEs, also the method of development -- we are working on the new BFR, the same thing. Also the similar compounds will be -- you know, we'll have the same QA/QC procedures.

PANEL MEMBER WILSON: Thank you.

It sounds like you're confident with those measures. And I just think it might be helpful for the panel to have at some point, you know, just some sort of summary information on those measures so we can sort of get a sense of where the lab is and, you know, provide some input in that way in a more -- perhaps more substantive way.

DR. PARK: Okay. I will report for the next meeting.

PANEL MEMBER WILSON: Okay. Thank you very much, Dr. Park.

CHAIRPERSON LUDERER: I just have a quick question about the infant blood spots. I think that's actually very exciting that you have been able to develop this method that's so promising for the PCBs and the PBDEs, and that you're -- so you were confident that you'll be able to get down to sensitivity of using just one blood spot is extremely exciting right now.

You said they're combined from two. Was I understanding that correctly?

DR. SHE: Yes. We already did the one spot test in the laboratory. And right now we get very good precision on it. But we still a lot low. Before we tested certified material, we do our accuracy at this moment. One blood spots -- if that's incorrect, tell me if I'm wrong. I think in New York State also try to use one blood spots, right? They use small volumes. So we notice that did some study on the PBDE. The extraction rate is not so great. They're presenting in the MS-ACL meetings. So we work on -- I think we overcome the extraction recovery issue already in our lab. So with about a 50 microliter of the blood, we believe we can do

for certain chemicals, but not all.

CHAIRPERSON LUDERER: And then a related question is then, would you be -- when you have larger samples now, are you going to be able to use obviously smaller volumes of those samples? So would your plan be -- in order to be able to kind of save these precious samples that we've been talking about?

So your plan then would be for these chemicals, these PCBs and the PBDEs, you would be able to use smaller volumes, like a hundred microliters versus the one milliliter that you've been using before? Did I understand that correctly too?

DR. SHE: Yes, that's one of the largest way -- we think, okay, if we did not succeed to complete DBS method but we feel more confident we succeed on a method and may use less serums, which will be -- can be used for both our labs maybe in the future, to improve the throughput to reduce the cost. So I feel that also reserves the precious samples. The sample can be used for other studies too, yeah.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I realize I'm a little confused about a sort of an administrative issue, which is that in the past that it's been the DTSC lab that has, as I understand it, focused on the POPS, including the PCBs

and the PBDEs. Now it's clear that the DPH lab as well is doing analysis for PCBs and PBDEs. How is the work being divided between the two labs to avoid duplication and to make sure that both labs are, you know, using their resources most effectively.

DR. SHE: I can handle the comment.

Before we did a lot of dry blood spots, basically we discussed with Dr. Myrto Petreas. And we think this may be the best way to use the resource. We ? to the reasons and we have the dry blood spots handling experience.

And then we have basically a free chemist from -- don't use our state resource -- DaSheng Lu from Shanghai CDC, he come here in order to do the hair -- dioxin in the hair. He's a leader of the Shanghai CDC dioxin lab. I used to do the dioxin in the PBDE for many years.

Plus I have Frank -- talked to Frank Barley and me also work on the dry blood spots for many years. We developed a method in the dry blood spots.

So based on this experience, we feel like our lab leads this thing without dividing this POPS should it go to DTSC a lot. And the reason is it just happened that at this moment we have a resource with other program support, at least Dr. DaSheng Lu who did this. And long term definitely the two programs needed to work more closely to

see how we can even get better incomes from our investment.

So thank you for that concern.

CHAIRPERSON LUDERER: Okay. Thank you.

Are there any additional comments from Panel members?

We do need to take some comments from the public if we have any at this point.

MS. DUNN: We don't have any unless someone has a card.

No one.

CHAIRPERSON LUDERER: Okay. We have a few more minutes for Panel discussion if there are any additional comments or questions.

Okay. Otherwise then -- Dr. Solomon.

DR. PARK: I don't know if I have to put some disclaimer to what I said today. I always do when I go outside. So I think most of the things I said today is kind of limited to my opinion.

(Laughter.)

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: This is just a follow-up on the issue of looking for unknowns. Because there's a clear process for this Panel to designate and prioritize individual chemicals or even groups of chemicals, but

there isn't really a mechanism for us to prioritize or to sort of advise the Biomonitoring Program to look for unknowns and, you know, where that sort of fits in the priority structure against any of the individual chemicals on our list.

And so my question is: Is there a way that we could have that conversation and sort of think about -- because given the limited resources, you know, if there were to be a decision to purchase an additional piece of equipment, you know, would it be a high priority to purchase one of these instruments that can detect unknowns, et cetera?

So I'd just like to ask the program -- you know, OEHHA for how to do that and whether -- and ask the other panelists if that's something they might like to talk about more.

MS. HOOVER: Well, from OEHHA's perspective, certainly, you know, the Panel can always weigh in on that. And we've noted that over time that that's an important thing to keep in mind about emerging chemicals and unknowns. But I think it's actually more of a -- really it's more of a lab screening. And I know Jianwen has brought that up, in fact, exactly that issue about using a laboratory method to screen.

So today later Dr. Krowech's going to be talking

about a screening approach based on literature. But Jianwen brought up actually exactly what we're talking about, which is a screening approach using a lab approach, which would be very interesting. So we're definitely in support of that, if anyone wants to comment about the lab side of it.

DR. DAS: I can't comment on the lab side. But I can say that our current source of funds is the CDC Cooperative Agreement, and there are certain limitations on the use of those funds. They cannot be used for research. And so we certainly support the screening of unknowns, but it has to be sort of a programmatic issue that we decide. It can't be a research-based question in terms of screening for unknowns.

DR. SHE: And I do not think I have too much to add beyond what Dr. Park just said.

For the screening method, basically you kind of use a different tool set. For example, Dr. Park mentioned you needed to use -- some say you can measure either accurate to ? to lower the composition of the fragment and then to restructure in those additions.

Right now both labs have one tool can be done -- can be used for this, high resolution GC-MS plus we have the Q-trap. But both of these tools have a limitation. GC-MS, you can only use it for volatile

chemicals. A lot of chemicals today we work on is not volatile. So we do need it to expand our tool set. For example, TOF or the orbiter trap you can use easily to analyze this on all or to support a screening. So if the lab agrees to support this kind of screening with the laboratory approach, definitely we need some more set of equipment to do this.

MS. DUNN: Would you allow public comment?

CHAIRPERSON LUDERER: Yes.

Dr. Wilson, do you want to wait until --

PANEL MEMBER WILSON: Sure.

CHAIRPERSON LUDERER: We do have a public comment. It's Dr. Dale Hattis from Clark University.

DR. HATTIS: Yes. There is one possible approach that you might consider in addition to the -- the finding of an unknown in a bodily fluid and, that is, to look for DNA adducts or even hemoglobin-type adducts in some of your biological samples that you haven't previously analyzed.

For example, there is a hot phosphorus method that can detect DNA adducts very sensitively. And I don't know that anybody has yet done the exercise of trying to say, okay, can we account for all of the adducts that we can detect that way as a way of picking up something we didn't suspect yet in terms of a DNA-reactive chemical or

a precursor of a DNA-reactive chemical that we haven't yet identified? Now, that might be considered too researchy. But this is a administrative legal problem that I'll leave to other folks to deal with.

CHAIRPERSON LUDERER: Thank you, Dr. Hattis.

Dr. Wilson.

PANEL MEMBER WILSON: Sure. Mike Wilson.

I guess there's -- you know, I again think that it's extremely important for us to, if we are able to move in this direction of identifying unknowns and it's -- you know, it's clear that there's a way to do that, it sounds like we'll hear a little bit more this afternoon -- from doing a screening approach to samples and sort of seeing what pops up.

And I guess my question is, if it's also useful to use information that is similar to the Pesticide Use Reporting System in California, for example, if we actually have a sense from that information what are the high volume pesticides used in this State with the highest likelihood of exposure - and maybe this is a question for Dr. Das - if that information, you know, could be introduced in the decision making or prioritizing for potential unknowns and also if it would be useful in the program to have similar kinds of reporting on product ingredients and distribution in the State for products

other than pesticides?

MS. HOOVER: Hi. This is Sara Hoover at OEHHA. Sorry I didn't identify myself earlier.

So you're referring back to the work that we've been doing on an ongoing basis in terms of screening by volume as one element?

PANEL MEMBER WILSON: Yeah, and sort of one lens. And also in addition, if it's useful for the program to have additional information on ingredients and sort of usage of chemical products in the State.

MS. HOOVER: Yeah, I mean certainly every time we go to do a screening, that's one of the things that we look for, which is trying to just identify what chemicals are out there, what the volumes are. And you're right that that's difficult. There's gaps in that information clearly.

So we use commonly for non-pesticides -- like you pointed to the Pesticide Use Report, which we certainly use -- we use things like the U.S. volume, which of course has gaps. And Gail will be talking about that in her talk. So clearly, you know, it would be great to have more information on a wider range of products. Even just the chemical identity in products, knowing that would be very helpful.

So I can say, yes, I would agree with that. And

we definitely use that as one tool for screening.

PANEL MEMBER WILSON: Great. Thank you very much.

PANEL MEMBER BRADMAN: Yes, I just have kind of a --

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: -- personal anecdote here, which I think maybe underscores the importance of unknowns. It's something we haven't really talked about much before. But I'm involved in a study looking at air quality right now and we're looking at VOCs. And in most of our samples we're able to identify about between 28 and 50 percent of the total, you know, organic carbon load in our air samples. So the other, you know, 50 to 80 percent is at this point unidentified. So there's -- these are in child care facilities. So there's clearly a lot of stuff out there that we're not necessarily identifying even in environmental samples but that are probably getting into, you know, in this case, children's bodies. So there is kind of an argument to pursue this further.

MS. HOOVER: Sara Hoover again.

Yeah, I just wanted to echo that actually, because I did some work in Canada when I worked there for four years, and we did an open scan in an office building and identified and characterized many of the chemicals in

that scan. And most of them, you know, we'd never heard of and so I did a lot of research on what those were. Some of the highest unknowns turned out to be fragrance compounds actually. So that was interesting.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Great. Thank you.

Sara, I guess similar to Dr. Bradman's experience, where this next month, you know, trying to figure out how best to advise DTSC in implementing AB 1879, Mike Feuer's bill from L.A. and Joe Simitian's SB 509 on the toxic information clearinghouse. And one of the key issues that's facing the green ribbon science panel in that process is this question of the extent to which there should or should not be some form of reporting for products sold in California on ingredient -- whether it should be ingredient, whether it should be ingredient plus volume sold, ingredient plus volume plus distribution and use and so forth.

And so the extent to which that information can inform the biomonitoring process I think will be important for -- you know, for those deliberations. And so I guess it would be helpful to have a discussion about that.

And one thing, you know, I guess what I visualize would be a data -- a database that could be matched up against basic physical-chemical properties and a number of

others that could give us a sense of a prioritization of substances sold in California, used in ingredients that would be likely to persist in the environment and bioaccumulate and biomagnify and so forth.

And so I guess I agree that that would be, you know, useful information for the program.

MS. HOOVER: I agree with you.

CHAIRPERSON LUDERER: Okay. My microphone is falling apart, but hopefully you can still hear me.

So if we have no additional Panel comments at this time, I just wanted to summarize. But it seemed to me from the Panel discussion, there may be two major recommendations.

I think we heard from a number of Panel members that there's really broad interest in pursuing laboratory methods for identifying unknowns in biospecimens in kind of this effort to stay ahead of the curve and find out maybe what the next important toxicants might be.

And also I think several of the Panel members also brought up this issue of defining the criteria by which outside samples that would be measured by the laboratories would be chosen. So to keep those -- to make sure that that selection process would be -- would assure that the measuring of those samples doesn't detract from the goals of the Biomonitoring Program and that it

actually contributes to what the goals of the program are.

Then I think before we all leave for lunch, Fran Kammerer does have a reminder for us all.

STAFF COUNSEL KAMMERER: Thank you. Fran Kammerer, Staff Counsel, OEHHA. Just your friendly reminder to please refrain from discussing Biomonitoring Program matters away from this environment, to avoid an informal meeting. If you can keep your discussions to have here in the public.

Thank you.

CHAIRPERSON LUDERER: All right. We'll reconvene at noon. The clock on the wall is not correct, however.

MS. HOOVER: Yeah. So let's try to get started no later than what that clock says, which would be five to -- it's about seven minutes slow. So let's try to start back at 1.

CHAIRPERSON LUDERER: One o'clock, yeah. Sorry, I said noon I think.

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

CHAIRPERSON LUDERER: All right. I think we can go ahead and call the meeting back to order. I'd like to welcome everyone back from lunch.

And I'd like to introduce our next speaker. It is going to be Dr. Gail Krowech, who is a staff toxicologist with OEHHA. And she's going to outline a proposed screening approach for possible candidates to consider for designation, and illustrate the approach with an example.

Dr. Krowech.

(Thereupon an overhead presentation was Presented as follows.)

DR. KROWECH: Good afternoon.

The purpose of this agenda item is to follow up on Panel recommendations from the November 2010 meeting about choosing chemicals to bring forward as potential designated chemicals. So we're going to propose an approach for screening possible candidates for designation to bring to the SGP.

We'll illustrate the approach with the example of non-halogenated organic flame -- organophosphate flame retardants or, for short, PFRs, and obtain Panel input on both the approach and the example.

And I want to just say how this is different than

the policy we've been following in the past. In the past we've looked at broad categories that were of interest to the Panel and brought chemicals in those categories for potential designation.

So the proposed screening approach is designed to give the Panel a preview of possible candidates for designation and to help the program choose which candidates to bring forward.

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DR. KROWECH: As we go through the proposed approach, here's some of the issues we'd like you to think about: Is the proposed screening approach useful? Are there elements you'd like to add or delete? Does this approach provide enough information for the Panel to advise us on possible candidates for designation?

And for the example of the PFRs: Are there specific chemicals the program should consider bringing back for potential designation? Should the program consider preparing a document on the class of PFRs?

Here are the basic elements for the screening approach. We would search data on the extent and type of use for chemicals that the Panel has previously expressed interest in or the program has otherwise identified.

For chemicals with evidence of significant use, we'd conduct a brief search of the literature and

secondary sources for indicators of environmental persistence, bioaccumulation, toxicity. This step might also include using predictive software to generate estimates of relevant characteristics. And we'd also look for past environmental sampling and biomonitoring studies.

And then a summary of the corrected information would be brought back to the Panel for review and advice on possible candidates.

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DR. KROWECH: So this is one version of what a screening table could look like, with the name, type of use, and an indication of the extent of use. For volume of use we could use US EPA inventory update reporting on production import volume, the most recent of which is 2006.

If we're talking about pesticides, we might use the Pesticide Use Report. For trend we can look at past years in the same database or information from other countries if that's available and if it seems appropriate.

As indicator of persistence, we could identify measured data on half-lives. We can also use PBT Profiler, a screening tool which evaluates whether EPA's criteria on persistence, bioaccumulation, and toxicity are exceeded.

In the example that I've shown on this table,

I've used two pluses in red to indicate a high concern for persistence from the PBT Profiler.

As an indication of potential bioaccumulation we could use the measured or predicted log of the octanol water partition coefficient or $LogK_{ow}$. For an organic chemical a $LogK_{ow}$ greater than or equal to 5 generally suggests potential for bioaccumulation.

For an indicator of toxicity in humans we propose a brief search in secondary sources or the literature. For example, a positive neurotoxicity study would be an indicator of human toxicity. And notice that I've only used a checkmark here. And we chose this approach because of the difficulty of describing the nuances of available toxicity studies in only a couple of words.

We can also include a note that the chemical is found in environmental samples such as house dust, if that information is identified by a brief search.

And the last two columns would show if the chemical has been found in wildlife or people in past studies.

So this gives you a general idea of the proposed approach.

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DR. KROWECH: And now I'm going to illustrate how that approach could be applied with the non-halogenated

organophosphate flame retardants, or PFRs.

This example was chosen based on the Panel's input on possible candidates at the November meeting.

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DR. KROWECH: In addition to being used as flame retardants, a number of PFRs are also used extensively as plasticizers. Other uses include anti-foaming, wetting agents, anti-wear additives. And some example applications are listed here.

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DR. KROWECH: This slide just shows examples of PFR structures.

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DR. KROWECH: Okay. This is the first of three screening tables that we created for PFRs. The first two are aromatic PFRs and the third is not -- is a table of non-aromatic PFRs.

The volume is up on top. So this slide is of the most extensively used. Between 10 and 50 million pounds were reported to U.S. EPA in 2006.

I've shown the trend in brackets under the name of the chemical. And for where it says U.S., that refers to the inventory update reporting from U.S. EPA in past years. And Nordic is based on a report by the Nordic Expert Group covering the years 2002 to 2007.

And I came across this report, and it was an example of what's happening, you know, in another region. And I thought it would be useful for us to see that too.

The first chemical on this, triphenyl phosphate, or TPP, was discussed at the last SGP meeting. And of all the chemicals on this table, it has the most available information.

The plus in orange under "Persistence" represents moderate concern for persistence under the PBT Profiler.

And just to repeat something I said last time, TPP was found in high levels in house dust. And also some new information that I found, it was found in very high levels in wipe tests of computer screens and covers.

The other three chemicals on this list are all mixtures. And they all had a higher predictive persistence compared to TPP.

The second one down, isopropylated triphenyl phosphate, is a major component of Firemaster 550.

The next one, t-butylated triphenyl phosphate, is described as a flame retardant plasticizer for PVC plastics. Like isopropylated triphenyl phosphate, it also contains a percent of TPP.

And the last one on this list is Bisphenol A bis(diphenyl phosphate) reaction products. It's been talked about as a possible alternative to decaBDE in the

electronic enclosures. And in terms of past use for this compound, it wasn't reported -- it was reported as 1 to 10 million pounds in 2002. So it's increased dramatically.

In the "Persistence" column for this chemical, I didn't use the PBT Profiler, and noted the high concern based on a report prepared for Washington State on this chemical mixture.

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DR. KROWECH: This is another screen of aromatic PFRs, with reported volumes of 1 to 10 million pounds. And I just want to also note this isn't a complete list. This is just a representative group. And a table summarizes what I found for these chemicals.

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DR. KROWECH: And this is a list of non-aromatic PFRs. There's a little bit more information here.

In general, predicted persistence and bioaccumulation appear to be lower than for the aromatic PFRs. However, the first one on this list, tris(2-butoxyethyl)phosphate, has a lower predicted persistence concern and a lower $LogK_{ow}$, but has been detected in a number of studies.

And high -- just to mention one detail about this, high levels of this compound have been found in one study - it was particularly in a day care center - and was

traced to the presence of tris(2-butoxyethyl) phosphate in floor polish. And it's known to be 1 percent of certain floor polishes -- or had been. And its volume of use is decreasing both here and in the Nordic report.

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DR. KROWECH: So in this slide I wanted to show some of the examples of the range of toxicity information that I've been finding. And for this example I'm only going to use the chemicals that were listed in the first slide, which is a very high volume slide.

For triphenyl phosphate, one study found levels of TPP in house dust were associated with decreased fertility in 50 men at a fertility clinic.

For isopropylated triphenyl phosphate, neurotoxicity in hens was reported by U.S. EPA in their screening assessment of this mixture. They also noted data gaps for repeated dose toxicity, reproductive toxicity, developmental toxicity, and genetic toxicity.

And the last one here, t-butylated triphenyl phosphate, a lubricant oil containing 3 percent of this compound -- or this mixture was neurotoxic in hens. So in the table I left this as a question mark, because it's not clear what was causing the toxicity.

I also found some other interesting information related to the toxicity of PFRs and related to the data

gaps. Because of the lack of data, the Consumer Product Safety Commission has nominated several flame retardants for testing by the National Toxicology Program. And that nomination included six aromatic PFRs that CPSC considers representatives of this class. And so they're listed here, and all of them were in the tables that I showed below.

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DR. KROWECH: So this is a summary -- a brief summary of NTP's planned research on the aromatic PFRs.

They're going to do short-term screening evaluation of all of the chemicals in this -- in the class of the aromatic PFRs and look at effects of structure, toxicity of mixture, and include the endpoints of neurotoxicity, reproductive toxicity, steroidogenesis, and look at liver enzymes. And they'll look in detail at two of the aromatic PFRs, one of which will be triphenyl phosphate. And the other will be determined by the short-term screening. It will probably be either isopropylated triphenyl phosphate or the t-butylated triphenyl phosphate. And they'll do developmental toxicity studies and two-year cancer bioassays.

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DR. KROWECH: So I wanted to pause for questions, if there questions, about the PFRs at this point.

Okay.

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DR. KROWECH: All right. So turning back to the proposed screening approach. I wanted to note some limitations of the approach.

One, that volume doesn't reliably indicate the extent of use for emerging chemicals. The U.S. volume that I was relying on is out of date at this point. And also chemicals in imported products are not included.

It's also difficult to represent the subtlety of information in tabular form. Here's a few examples.

One is, since many of these compounds are mixtures, getting information about the mixture versus a specific isomer may be important. For example, for tricresyl phosphate, this is a mixture of isomers. Much of the toxicity information is relevant to one specific isomer.

Also I've used a checkmark for toxicity to indicate a toxicity concern but didn't provide details.

And in terms of environmental sampling, I've only listed what type of sample it was found in, house dust or indoor air. But it doesn't convey the levels, whether it was found once or repeatedly, or whether it's a recent study or older study.

And the similar issues similar issues are found

with biota and biomonitoring studies: When and where the sampling took place, whether there were changes in time, the study size, the frequency of detection all aren't included.

And then, lastly, a brief search like this may miss important information.

--o0o--

DR. KROWECH: So the questions for the Panel, even given these limitations:

Is this a useful screening approach for identifying possible candidates for designation?

Are there elements that you would add or delete?

Would a summary table be enough information for the panel to choose possible candidates for designation?

--o0o--

DR. KROWECH: And then in terms of the specific examples of PFRs:

Does the Panel want to see particular PFRs brought back for potential designation? Does the Panel want to see a group of these chemicals brought back?

That's it.

CHAIRPERSON LUDERER: Okay. Dr. Quint, do you have a comment?

PANEL MEMBER QUINT: Thank you, Gail. I thought it was a very interesting presentation, as it was the last

time.

For me, I think some information about -- maybe background information about whether or not the chemical is substituting -- and maybe this is implicit in what you're targeting -- whether or not it's a substitute for an existing designated chemical or chemical of concern based on either, you know, persistence or bioaccumulation or toxicity.

And some information on where it applies products. You know, how many -- what types of products the chemical may be found in.

And on the toxicity side, some sense of potential for exposure to the extent that you can get at that. I mean use is one thing. But if there is a potential for exposure either, I mean -- you know, through inhalation or, you know, food or something like that, some information on that would be really helpful.

And for me the toxicity check was not clear, whether or not it was concern or whether or not you'd actually found information. So if we could have some indication of whether or not there is -- because you might have a concern just based on structure activity. Or you may have concern because you've actually found something, as with the triphenyl phosphate. Because I had found that same information through another -- some more work that I

was doing.

So there's concern based on, you know, that it's a substitute for something or the structure raises a question. But there also may be concern because there is absolutely no information or there is -- two pluses, because, you know, there is sufficient information.

But I think this is an excellent way to make us aware of these emerging chemicals because I think it's a huge issue.

So thank you.

DR. KROWECH: Okay. That was very helpful. Thank you.

CHAIRPERSON LUDERER: Okay. Dr. Wilson and then Dr. Solomon.

PANEL MEMBER WILSON: Mike Wilson. Yeah, again, thank you, Dr. Krowech, for that presentation and for your work on this, that's been going on for a few years now beginning with the pesticide work. And we really appreciate it and appreciate the barriers that you come up against, the data gaps and so forth.

And I guess I have a question and then maybe a suggestion.

To your knowledge, has anyone -- or is there a database that has taken the 3,000 high production volume chemicals in the U.S. and put them through the PBT

Profiler? Has anyone done that?

DR. KROWECH: I haven't seen it. I don't know if they have, but I haven't seen it.

PANEL MEMBER WILSON: Um-hmm. You know, that in itself might be an interesting exercise that -- I haven't worked with that, you know, that program. I don't know if it's a difficult program to work with, you know, to run chemicals through. You probably would know that better. But we haven't done that work yet obviously. I mean it hasn't happened yet.

The other thing that hasn't happened is -- and we're actually putting this database together up at Berkeley, which is essentially a compilation of about 3,000 -- between 3,000 and 3500 substances that have been identified by authoritative bodies around the world as chemicals of concern. And it's sort of a master database of sort of a floor of what we know based on findings from authoritative bodies; and, again, surprisingly has never been compiled. Most of this information is in PDF form and so forth around -- in these different organizations around the world.

So we're putting that into a searchable database. And that might also be a place that, you know, could be a place to begin and sort of evaluating I think through the lens that you're proposing here, which is persistence and

bioaccumulation -- but that database might also be a place that could be -- you know, could be useful in sort of starting to set priorities.

DR. KROWECH: Yeah.

PANEL MEMBER WILSON: And then, you know, as Dr. Quint noted, we have this problem of -- we have information on what's used in high volume in the U.S. We have some information now on hazardous substances in authoritative bodies. But we don't really know what's used in California and what's sold in products. And that's, you know, a critical piece that -- we need to convey that that's an important piece of the puzzle, either from this body or, you know, from OEHHA that this is an important piece of information that we need to gather if we're going to set public health priorities around products.

And then I guess the last piece is that on the toxicity side, I agree with you that it's obviously, you know, oversimplified to have a check. And maybe there would be a way to expand that so that there could be a little bit more information without going -- without trying to be comprehensive, but at least to give a sense of, do we have sort of, you know, small, medium, or large amounts of information on this substance even in sort of those gross kinds of levels?

And the next sort of level is what's the quality of that information? But, you know, obviously it gets more complicated. But something a little bit more than a single check would also help us and sort of the reader of the information understand that there are large data gaps, for example, on toxicity or if this is a well characterized substance.

Is that -- am I being clear on that, that some sort of --

DR. KROWECH: No, I think that would be really useful --

PANEL MEMBER WILSON: -- some other sort of --

DR. KROWECH: -- and it could be added.

PANEL MEMBER WILSON: -- way of indicating that?

DR. KROWECH: Yeah.

PANEL MEMBER WILSON: Well, it's a lot of work. But this seems like a good -- I think it's a useful thing to do. It's a useful exercise. It's a useful way to begin prioritizing. And it's also a useful way for us and for OEHHA to signal where it needs new information.

DR. KROWECH: Um-hmm.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I want to thank you for putting together this proposal. I think it represents a lot of very good and careful thinking, and is definitely

something that could be of use, I would think, not only to this panel and this program, but also potentially more broadly, because it will gather together in one place in a really kind of readable format, you know, information that should be looked at together.

I agree about the checkmark for toxicity being perhaps the weakest point here. And it would seem possible to do something where you have some kind of indication for no data found at all, a different indication for concern based on structure activity relationships, something else designating that some minimal toxicity data were found indicating but, you know, it's very limited, and then something -- a fourth category that would be basically significant evidence of toxicity concern. You know, red-flag-category kind of thing.

And I'd hope that that would -- I mean I know that that will add quite a bit to the work. But I'm not actually asking for an in-depth evaluation of the quality of the studies and, you know, data but basically just sort of to give us a sense of what there is.

And, you know, just -- I hate to keep harping on it, but the whole sort of lab-based identification of unknowns through these TOF or other approaches could feed fantastically well right into this table as an additional column. Because what one could do or one could imagine

doing is using an instrument like that to run a, you know, subsample of studies -- of, you know, samples from -- you know, that we already have, see what comes up.

I'm guessing there are going to be long lists of chemicals that will come up on each participant. But using informatics, one could figure out which things show up most frequently at, you know, the highest concentrations. And that list could be narrowed down and could be included in something like this or it could in fact drive what one might then want to look for this information on. And so it could feed, you know, as sort of a whole different pathway into the prioritization process in a really nice way.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I just have one last comment about prioritizing based on volume. I mean you mentioned some problems with that in terms of just the accuracy of the numbers. But I also am concerned that some of the low volume chemicals -- if they have real toxicity concerns or concerns of persistence or bioaccumulation. These volumes change rapidly once they get on to the market. I mean you start off at 1 million and then, you know, in a couple of years you're up to 10. So I always hesitate to put a lot of stock in the fact that it's not a high volume chemical and

so therefore we shouldn't be concerned.

I think the driver should be more the source of, you know, as I said, toxicity and other concerns as opposed to volume per se, because, you know, the uses just expand once they get on to the market.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson.

And sort of picking up on that thought, I think it might be useful to -- in addition to having a persistence and bioaccumulation column, also have a column that is similar to what's occurring in the European Union where there's a very persistent and very bioaccumulative column. So in other words there's a cutoff point where the physical chemical properties of that substance indicate that it's very bioaccumulative, very persistent, based on some measure of half-life and so forth.

So it places it in a unique category. And such that, irrespective of toxicity, it's a substance that we know by its properties we're going to deliver into the next dozen or so years or more and so probably needs to be treated in a unique way and prioritized in that way.

DR. KROWECH: Okay.

CHAIRPERSON LUDERER: Are there any other questions from Panel members at this time?

No? Do we -- oh, Dr. Solomon.

PANEL MEMBER SOLOMON: I was just curious whether OEHHA nominates chemicals to the National Toxicology Program on any kind of regular basis, because it actually is a great -- you raised it in a context of the PFRs. And it actually is a great resource for some of these, and I'd just encourage that to happen whenever you guys stumble cross any chemicals that might fit their criteria and be of interest.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: I just have one last thing. And this may be really bizarre to say. But I think also if there was some way that we could -- you know, for people making these chemicals, if there could be some dialogue about whether or not there are toxicity data that could be brought forward. I say this because one of the chemicals that you talked about the last time, whose name I forget now, but it was a substitute plasticizer - I think it's a phthalate -- it's now being advertised as a phthalate-free plasticizer. And I searched and found no information, and then searched again for a different purpose and found a document by industry that indicated reproductive and developmental toxicity. That was completely found on Google, not on PubMed or anything else. And so, you -- but it was public information.

So there may be information available, and if we

ask, we could get it. I mean it's possible. So to have that as another avenue of -- you know, pursuing that as another avenue for getting information on some of these new substituted chemicals. Because some of these chemicals have been tested in some manner. But, you know, even chemicals that have -- for which there are EPA submissions under TSCA or listed when you do a search -- a literature search but the data are not available, you have to either purchase it or something like that.

So, anyway, however we can beat the bushes to get all of that information I think would be helpful.

PANEL MEMBER WILSON: Can I make one more comment? Sorry.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Very quickly. I'm Mike Wilson.

You know, the idea of sort of product information seems -- you know, may be difficult to achieve right now. But, you know, it turns out that Sweden has been doing this for 30 -- almost 35 years now, having a product registry. Anything that's sold in Sweden is registered by the -- you know, registered with the Swedish Chemical Inspectorate. And that information is compiled and assessed, and some of it's made public and some of it's retained within that agency and it's a very workable thing

that we probably need to put in place in California at some point. And this is just so critical in terms of this idea of identifying and prioritizing substances.

Maybe our guest from Sweden could comment at some point on that.

CHAIRPERSON LUDERER: All right. Do we have any public comment?

We are going to take more Panel comments after the public comment.

CHAIRPERSON LUDERER: Okay. We have two public comments.

So Dr. Dale Hattis from Clark University.

So we have ten minutes for comments. So if you could limit your comments to five minutes each please.

DR. HATTIS: Yes, I think it's a very good start to a framework for identifying chemicals and exposures of concern.

I would have you add one little thing to your "Chemical Use" column, and that is the concept that I think Tom McKone was a pioneer in promoting and that is the idea of the intake fraction, the fraction for a particular use of the chemical that's used that actually gets to a person. And so -- because this can differ by several orders of magnitude among different kinds of uses. Other things being equal, if a chemical is emitted

outdoors, you could count on about 1 in 10 of the fifth of it to get to a person just from the intake -- air dispersion phenomenon in the chemical intake. Whereas if it's emitted indoors in a house, then you can count on that ratio to be a few percent just because of the difference between the amount of air that's breathed in in relation to the amount of air that leaves the house.

So that's an important kind of -- another kind of thing is there are personal -- so essentially this helps to overcome this problem with the high volume. Volume is such a nice quantitative measurement. But, you know, it can be -- the amount -- the expectation for exposure can be radically changed by this -- you know, if you have a chemical that's used -- or a component of a chemical consumer product that's used in close proximity to people, you can predictably alter that.

A key example that I remember was many years ago when my children were very young I remember seeing a particular chemical that was in the baby wipes. And so -- and it was 2-bromo, 2-nitro 1,3-propanediol. So this sort of raised all kinds of red flags, because you have an aliphatic bromine, an aliphatic nitro grouped, and we have it in pretty close proximity to a putatively sensitive population, right? So it's those kinds of things that might be low volume that I think you want to

be in a position to pick up.

CHAIRPERSON LUDERER: Thank you, Dr. Hattis.

The second comment is from Davis Baltz of Commonweal.

MR. BALTZ: Davis Baltz, Commonweal. Thanks for that presentation.

In general, I really support anything that we can do to speed the process of being able to look at chemicals and get them designated as appropriate resources for the program permitting.

As you were giving your presentation, I was thinking about this other project that OEHHA's involved with, which is developing hazard traits for SB 509. And this may be more of a question than anything else, and we don't know how long it will be before the so-called Toxics Information Clearinghouse sort of sees the light of day. But a lot of the variables that you had in yours obviously will be captured in that. And once that's up and running, I think that could be a useful tool to sort of mine screening and otherwise incorporate or integrate the two.

And so that's my comment. Thanks.

CHAIRPERSON LUDERER: All right. Thank you to both of the public commenters.

Let's see. Dr. Bradman, you had a comment?

PANEL MEMBER BRADMAN: This is just very brief

and it kind of follows on what Dale said.

But I think it might be useful just to add the vapor pressure to this list here, and maybe an RFD if it's available. But I think the vapor pressure would be helpful.

And also, just as a rule, we shouldn't exclude compounds that are not persistent -- I mean that are persistent -- that are not persistent. Because, you know, as we know, there's a lot of nonpersistent compounds that we're exposed to on a regular basis. And even if they have short half-lives in the body, they're still substantial. And why that should be a criteria, it -- we should be careful when we look at these compounds that we think about exposure potential.

CHAIRPERSON LUDERER: Yes, Dr. McKone.

PANEL MEMBER McKONE: Since the work on intake fraction was invoked, thank you.

(Laughter.)

PANEL MEMBER McKONE: But I should point out, we actually -- when Dr. Wilson and I worked with the State on a screening list for pesticides, that was explicitly characterized. We didn't call it intake fraction. But we did an exposure potential, which was actually a multimedia fate exposure potential for the pesticides. And I do agree that looking carefully -- and it's more than just

vapor pressure. It's really looking at critical chemical properties. And there are papers, one of which I think I helped write, demonstrating that overall persistence is a really good indicator of exposure potential for a broad range of chemicals.

And the nice thing about intake fraction is it does vary over orders of magnitude. So it's a very effective binning or sorting process, in the same way that persistence varies over orders of magnitude. So it becomes something that -- if something only varied over one order of magnitude or a factor of five among 10,000 chemicals, they're all going to end up in about the same bin. But this really separates out those that you would expect to have a high exposure potential, so it's a worthwhile thing to apply as another level of screening and testing.

CHAIRPERSON LUDERER: Has the Panel addressed the questions that you had?

Okay, great. Thank you very much again.

Oh, Dr. Solomon.

PANEL MEMBER SOLOMON: Sorry. I just wanted to actually address the question that's up there right now.

(Laughter.)

PANEL MEMBER SOLOMON: Because I don't think we've had a discussion about whether we want to see any of

these PFRs brought back to us.

I would be very interested in at a minimum seeing the aromatic PFRs in more detail. What I see here is intriguing enough and, you know, indicative enough that we might want to pursue them, that I think it is worth taking a closer look.

I actually don't think it makes a lot of sense based on what I see here to just pick one or two or three chemicals from the list. So I think looking at them as a group makes sense.

I'm not as clear on the non-aromatics. But, you know, perhaps we could look at the aromatics first and think about those subsequently.

CHAIRPERSON LUDERER: All right. Any other comments from panel members?

All right. Then I think in the interests of time we should probably move on to the next presentation.

And so it's really a pleasure to introduce for the next presentation, will be given by Dr. Rachel Morello-Frosch, Associate Professor in the Department of Environmental Science Policy and Management, and by Holly Brown-Williams, Director of Policy at Health Research for Action. And both of them are also in the School of Public Health at the University of California at Berkeley.

And as many of you will probably recall, Dr.

Morello-Frosch and Ms. Brown-Williams made presentations on results communication to this Panel in July 2009. It's hard to believe it was that long ago already.

And today, their talk titled "Biomonitoring Literacy" will describe their collaborative work with Biomonitoring California to develop report-back materials for participants in the Chemicals in Our Bodies, or MIEEP, Project.

So thank you very much.

Dr. Morello-Frosch.

(Thereupon an overhead presentation was Presented as follows.)

MS. BROWN-WILLIAMS: Thank you very much. We really appreciate the opportunity to be back here and talk about some real work, working in partnership with the program on the pilot project that had been referred to as the Maternal-Infant Environmental Exposure Project and we're commonly calling with the participants now Chemicals in Our Bodies Project.

We wanted to start by just revisiting a little bit why we would want to do this kind of work, first of all. Of course the California program and any pilot projects that are done under it the results are required to be offered to participants if they want them.

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MS. BROWN-WILLIAMS: Also, prior experience in projects with individual and group report-back have been done that have shown a strong interest among participants and experience in providing the results to the participants. Health Research for Action collaborated with the CYGNET study group in California to do some focus groups with their parents of the girls in that study. Dr. Morello-Frosch has been involved in several household exposure studies that also in some cases include biomonitoring components and has a lot of experience with report-back there.

But we also wanted to raise just a larger contextual issue, that we feel like it is really important to keep in mind that the complex information that's coming out of biomonitoring and other environmental health studies should be accessible to the public and that there are ways to make the information accessible so that a wide range of, you know, educational backgrounds and cultural context, people in those groups can understand the information that we're providing.

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MS. BROWN-WILLIAMS: So when we talk about why biomonitoring literacy, we're really building on a body of work that's embedded in, you know, lots of health studies now around health literacy and making sure that people can

understand and act on health information.

It's also consistent though with sort of a growing focus that's appearing in the literature around public health literacy and making sure that the public in general is able to weigh in on larger societal issues around, you know, environmental and other factors that affect their health. And this definitely includes biomonitoring projects and other chemicals policies that might derive from them.

So we wanted to start out with just quickly reviewing, you know, what some of the key principles were for applying to a biomonitoring project, really finding out what people want to know, how much they understand, how they want to apply the information to their lives, and how to make it relevant to them; and to aim for, you know, the reading level that is going to capture the majority of the population, keeping in mind that whatever the educational levels are, the actual reading levels of the population are considerably lower than the grade they completed.

And some principles for preparing the information are really to group information into some logical clusters, to break up some of the complex information, to just generally make it both appear and be easier to read by using shorter sentences, simpler words, making sure

it's legible, trying to simplify graphics in a way that people can really understand them. And just -- both limiting the concepts but just really looking for conceptual clarity I think is the most important thing.

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MS. BROWN-WILLIAMS: So what Health Research for Action does in developing a lot of communication materials is we do a lot of participatory development. And one of the tools we use is usability testing, which is not intended to be a statistically significant approach, but it is intended to identify elements of the materials by working with your intended audiences to assess their comprehension, how they're responding to the materials, and work through that process to identify ways that you can change the materials to improve comprehension.

There are lots of ways that usability testing is used out in the field. It's been applied to both written materials, to web-based materials, and in other kinds of settings. We used a structured interview process, but there are other ways that people do it where they observe people using -- for example, navigating through a website.

We have -- actually I think I've covered everything on that slide.

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MS. BROWN-WILLIAMS: So for the Chemicals in Our

Bodies Project, our goal was to come up with a prototype and assess it through iterative testing with participants who had volunteered in the study, and to use this to inform the development of the materials. Our main goals were, you know: Are the main messages coming through in the materials? Are people with different educational levels understanding them? Is there anything that's confusing them or do they have ideas about ways to improve the materials? Is the way that they're, you know, interpreting the information meaningful? Are we missing key things that would be of interest to them?

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MS. BROWN-WILLIAMS: So we recruited from the population of women who have been enrolled in the Chemicals in Our Bodies Project, pregnant women at San Francisco General Hospital, when they were enrolled they were asked if they'd be willing to participate in an additional part of the research.

The participants -- here it's just highlighting some of the demographics. Here you can see that in general it was relatively low SES, very limited information about chemicals and health.

And the process that we used were we had a semi-structured interview that went from an hour to an hour and a half. The participants were asked to look at

the full packet of materials first and give us some general -- they were given time to read those materials, then asked them general questions about the materials. Then we walked through each document and asked them specific questions about them.

The process involves conferring and making changes in between the rounds and then moving on to additional participants to test the revised materials.

Once we finished -- we first conducted the usability test interviews in English. Then we moved to the Spanish. And then we assessed the changes that we made to the Spanish materials and went back to the English materials and made final revisions where that made sense.

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MS. BROWN-WILLIAMS: So when we developed the prototype to use in this project, we assessed nine different examples of report-back and we adapted the prototype that was used in the household exposure studies that was a collaboration between Silent Spring Institute, Brown University, and UC Berkeley, which Dr. Morello-Frosch was involved, because it met a lot of criteria that we had established. We really wanted to look for to start with a prototype that provided comprehensive information, that provided that information, a range of different formats, that had been tested and

evaluated in more than an English-speaking population.

And we had also -- when we conducted the focus groups with the CYGNET parents, while our purpose was not to evaluate different evaluation models, we did share a few different formats. And the format that was used in this project was perceived to provide the most comprehensive information and the parents favored that example.

So when we began to work with this prototype to adapt it for testing in this project, our first steps were to apply those health literacy principles in revising the materials, really organizing it into a logical packet. We revised a cover letter to really orient the reader to what they were going to find in the packet. Some of the most significant principles were really to consistently label things - it's very easy to sort of find yourself using different terminology as you go through with so many different documents - trying to simplify the graphics and the vocabulary, and in general just make the information easier to read.

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MS. BROWN-WILLIAMS: So at the end of this process Rachel's going to walk you through the process and the examples of how the materials were modified between the beginning and the end. But I'll just highlight some

of the successes.

Participants across the board really appreciated the fact that thought was going into preparing materials for them and that they would be given the kind of information that they were seeing in the sample materials. In the interests of time, I won't read all the quotes, but we wanted to give you some examples of the kind of feedback that we were getting from people. There's a lot of information that people did not know and they feel like they were getting more background information.

One of the requirements when we were adapting the materials was to include the exact test results of the participants. So we incorporated this into the hypothetical results that were tested. And our questions required them to look through the materials to answer a set of questions including what their own results were for selected chemicals. And nearly everyone was able to identify that.

Most could also identify whether they were lower or higher than other participants in the study. And while -- you know, as you can see from sort of a reaction there, they might see, "Well, you know, mine looks high. But then where do I compare to other?" So they're always looking for a way to put the information that they're getting in context.

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MS. BROWN-WILLIAMS: I think a really important point is that participants really did get the message that we don't have a health reference value for many of the chemicals. Both in the sample materials that they saw and in general that principle that safe levels are not established was well understood.

We wanted to know if they could navigate through the materials to find where they could get other information; that was very well understood. We went through and made some changes along the way into the chart that graphically displays their results, and that definitely improved their understanding of materials from the beginning test to the later stage tests.

Most of them -- oh, an important concern for us is that we were in our tests giving examples of two classes of chemicals - metals and pesticides. And we asked a question about, you know, in the -- when you're actually getting your results, there may be many other kinds of chemicals. How would you feel about getting more material than this? And most expressed a willingness to read more materials when they were mailed their actual results.

And because one of the documents touches on potential sources of exposure and some possible ways to

reduce exposure, they did understand, were able to navigate through and answer questions about ways they might have been exposed and ways they might reduce their exposures.

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MS. BROWN-WILLIAMS: Some of the key challenges. It is a lot of information and at the end of the day it is still complex information. So I mean that remains a challenge. But the important thing is that people did seem to be able to identify the key messages.

In general, asking people to compare to things that may already be references that they've never heard, such as national averages, we started using a term -- we changed the terminology but the levels of health concern, the concept, just moving between, you know, what's my level, how does it compare to these different reference levels was a challenge for some people.

Rachel can speak to this more as well.

But in general, the Spanish-speaking participants were less inclined to, you know, to comment that they didn't understand. So in some cases our changes were a product of both their feedback and just observing where they might be getting stuck and trying to address things to improve the -- that did improve the comprehension in the later stages. They also had lower literacy levels and

less knowledge of chemicals. Some of the people had never heard the term "pesticides" before. So it's just an important reality check.

For example, as Rachel will highlight in some of the materials, we didn't start with a definition of lead or cadmium, and people did not know what lead and cadmium were. And they said, "Well, why don't you start by telling me what these chemicals are." So we incorporated that information.

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MS. BROWN-WILLIAMS: So I'm going to turn it over to Dr. Morello-Frosch to walk you through the way that we modified the materials throughout the usability testing.

DR. MORELLO-FROSCH: So essentially I'm going to show you specifically in a second what we changed through the process of usability testing. But a lot of the things that we did were health literacy best practices, shortening sentences, adding more white space to make it more reader friendly, putting information in a question and answer format, making it easier to navigate within the documents that I'll show you, and simplifying and reformatting tables so that they're more transparent, and providing more clear explanations of the clear -- of the comparison values that we were trying to test with the participants.

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DR. MORELLO-FROSCH: So just to kind of get us all on the same page, in my experience in biomonitoring and personal exposure assessment studies and in addition to the work that we've been doing with the Chemicals in Our Bodies Project, these were kind of the basic questions people want to know when they get their results:

Quite simple. What did you find? How much? Is it high? Is it safe? Where does it come from? And what should I do?

And we have varying capacity to answer all of those questions. But with the materials that we've put together in the prototypes, we've tried to do the best that we can with the information that we have.

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DR. MORELLO-FROSCH: So imagine yourself as a study participant and you get a packet in the mail, and it would contain these four elements: It would contain a cover letter and then a summary of your results in text format, a results chart, and then a list of chemicals tested.

Each of 2, 3, and 4 are organized in chapters by chemical class. So you would get a summary of results, a results chart, and a list of chemicals tested for pesticides. You would get 2, 3, and 4 again for metals.

So we try and organize them in chapters by chemical class to make it clear.

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DR. MORELLO-FROSCH: So I'll go through this a little more slowly. You have these in your materials.

This is the cover letter that orients people again to the study, because time passes between when we actually take the samples and interview study participants to when we return their results to them. But explains to them what's in the packet. The table explains all the different parts, which is what I'm currently calling chapters.

We usability tested two classes of chemicals, metals and pesticides.

And then the letter explains a little bit about how they can compare their results. So we explained to them that they can compare their results to other mothers and babies in the study, to national averages, and to levels of health concern. Although we make very clear that in many cases levels of health concern are not available for many of the chemicals that we tested for. And then we provide a resource person, and they can call if they have questions.

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DR. MORELLO-FROSCH: And the second element is

the summary. Basically the bottom line. What we tested? How many pesticides we tested for in this case? What are they? Again, there were people who actually did not know what pesticides were, even though it's quite likely they're using them. And then, did we find pesticides? Sort of yes or no. And then again reminding them how they can compare and contextualize their results.

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DR. MORELLO-FROSCH: And then we'd provide them a little bit on the other side, information about the chemical class for that particular chapter. So where these chemicals are commonly found, what we might know about risks to human health, and potential ways to reduce their exposures, and then some resources.

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DR. MORELLO-FROSCH: This is the chart. And I'll show you in a second how it evolved through usability testing.

But essentially the blue circle shows to the participants their results. The gray circles are all the other participants in the study. The green line is the national average for other pregnant women in the U.S. based on NHANES data.

And then on the bottom you'll see a notation that says, "Your exact levels." We felt that one of the

requirements of the Biomonitoring Program is to provide people with their results. So we wanted to give people their actual numbers and not have them just rely on the scale in the chart itself to figure out what that was.

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DR. MORELLO-FROSCH: And then in many cases we'll be providing a list of the chemicals that we tested, with information on how it's used, the name -- the full name of the chemical that was tested, and then the types of pesticides that were potentially -- they could have been potentially exposed to if we found the metabolite in their urine.

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DR. MORELLO-FROSCH: Okay. So how did usability testing sort of change and help us evolve these materials as we went along testing them with study participants? So we're going to show you first the initial versus the final text summary of results for metals. And then I'm going to show you how the initial versus final results chart for metals in turn give you a sense of how these things evolve as you test them.

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DR. MORELLO-FROSCH: So this is what we started out with when we first showed this to study participants, the prototype.

We combined metals all on one page, very text heavy. You can see people are also being asked to read from left to right and from up to down -- up and down. A lot to take in on one page.

So we -- participants were having some challenges navigating through this, and we began to feel we needed to create some more space, white space on pages and spread things out.

So this is how we've ended up with the final prototype, where we have a lot more white space. We're having one chemical per page in terms of giving them information on what it is and whether or not we found it, which -- and making it more accessible and also making sure they're reading from left to right pretty much.

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DR. MORELLO-FROSCH: And then in the back providing the table that gives them more information on whether it's found potential risks and ways that they can reduce exposures. So now we have -- this has been broken up into two pages with a lot more white space.

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DR. MORELLO-FROSCH: So here's the chart that we started out with. And I've put arrows here just to highlight some things that we changed.

So we started out -- I just want to draw your

attention on the legend of the chart, we started out in terms of using the term "benchmark" to delineate, you know, what would be elevated blood lead level, for example. And that did not go over particularly well. People couldn't understand the notion of a benchmark. Sort of very challenging to convey what it meant in terms of helping participants contextualize their results.

The other thing is on the lower right part of the chart, if we didn't find something, we just left the exact level blank, which for some participants was confusing.

So we changed the chart a bit. The first thing we did was we changed the wording of "benchmark" and we called it a level of health concern, which became very clear then to people. It helped them distinguish the difference between what a national -- what an average is versus what a level of health concern is.

And then the other thing is, if we didn't find the chemical -- if they don't have a blue circle, we just make it clear in the part where it says "exact level" that it was not found. We also tried terms like "not detected" and different things. But "not found" seemed to be the most transparent terminology that participants appreciated.

The other thing is we just provided an extra label in the gray to make it clear that this is a legend,

so to draw their attention to that as their key for navigating the chart to understand what the different circle colors are and what they mean.

And then we put parentheses around the first two definitions to make it really clear; that if there's no blue circle, it means that we didn't find anything or -- and if there's no purple circle, we didn't find anything in the baby's umbilical cord blood.

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DR. MORELLO-FROSCH: So in summary, what do participants think of this stuff? They reacted very favorably to materials. They took about 15 minutes to review it. In the beginning you -- participants sit down and just read the materials and mark it up very quietly as long as they -- they're given as much time as they want.

They view these materials as a resource. This is something that they -- if they got this packet, they would keep it. A lot of them said they would share it with family members, they might share it with friends, they might share it with a health care provider. So this is something that they view as something they would hold on to for future reference.

They very much value seeing their results in comparison to the other participants in the study. That's very critical for them. And they really want context for

comparisons. More important than the actual number is the context compared to -- how you compare yourself to other things, whether it's other participants, the average, levels of health concern, if available, so on and so forth, and understanding what the differences is between those comparisons and what they mean.

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DR. MORELLO-FROSCH: Diversity of materials is extremely important. Some participants love text. They'll just read that text and that's kind of where they're going to stop. Other people prefer charts. They like to look at pictures. And participants like to have the flexibility to drill down and get more information if they want, but then also to just look at the information superficially and not feel compelled to have to go through it all if they don't want to.

Very often people look at these materials. They don't sit down and just pore through the whole packet all at the same time. That's been my experience in previous personal exposure assessment studies. They'll look at the materials and then come back to them and look at them more deeper. So it's something they're going to be looking at many times over.

And as I said, the actual chemical levels for them is not nearly as meaningful as how you contextualize

what they mean and what you're enabling them to compare it to.

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DR. MORELLO-FROSCH: So I think our recommendations based on this final prototype that we've arrived at is that these documents are very interconnected. We've really tried to make them so that the participants can really drill down. And so if we're going to make changes, we have to ensure that we make similar changes to the other documents to which they're connected.

The chapter format used in the prototype seems to really work with participants because it allows them to take the information in on chunks, focus on the chemical classes that they're most interested in; and mixing text with graphics is really key --

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DR. MORELLO-FROSCH: -- from a kind of health literacy point of view.

And so, just in conclusion, you know, this is a lot of information we're giving to participants. But they appear to really want it and appreciate it. And I think we can do a lot to enhance the biomonitoring literacy, both for study participants and ultimately for the broader public, by providing people with transparent and

accessible information but also ensuring that it's comprehensive and giving them flexibility to drill down and find out more if they want to.

And then we would recommend a health literacy review of the final packages to make sure that the information is as clear as possible.

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DR. MORELLO-FROSCH: So that is it, and we're happy to take questions. Thank you.

(Applause.)

CHAIRPERSON LUDERER: Thank you very much. That was a very interesting presentation really. And I'm sure Panel members have comments on it.

Who would like to start?

Dr. Culver.

PANEL MEMBER CULVER: Thank you for that presentation. Obviously you've done an awful lot of work.

Only two questions. How do you go about establishing the level of health concern to show a population that you're sampling?

And the second is, if you have a result that is obviously way above the distribution of other sample results that you have, what do you tell that person to do?

DR. MORELLO-FROSCH: So in answer to your first question, we in this prototype made no decisions about

levels of health concern. That's a decision that's going to be made by the Biomonitoring Program, which ones to use. The ones that we tested were ones that have been established like for lead. And so it's quite possible that there will be very few levels of health concern that we'll be able to show study participants when we are reporting back results. I think that would really depend what values there's a consensus on providing participants. So that was not a decision that we made as we were testing the prototype. The only one we really looked at was for the metals.

PANEL MEMBER CULVER: Who's going to come up with that level of health concern?

Who's going to come up with the --

DR. MORELLO-FROSCH: The Biomonitoring Program is going to be deliberating on making decisions about --

PANEL MEMBER CULVER: How is it going to do that?

MS. HOOVER: Well, obviously that's -- Sara Hoover, OEHHA. That's obviously a very difficult question. And we're having an entire day tomorrow to talk partly about how the program should approach this question. The workshop tomorrow is about understanding and interpreting biomonitoring results. One aspect of the workshop tomorrow is talking about comparison levels in blood and urine.

But just to tell you -- I mean we actually are already working on that. I gave a talk about that, you know, introducing that concept last time about what's out there, what's not out there. And it's pretty much to date the way we've been approaching even looking at this is just a chemical-by-chemical look, you know, like what's out there and what could we do, what's already established and so forth. But we don't have -- we haven't made exact decisions. I mean lead values are already available and we've been working on other chemicals. But it's an effort that's in progress right now.

Did you want to say anything else, Rupa?

DR. DAS: That's good.

PANEL MEMBER CULVER: Then my second question was, what you tell the person who has an obviously high value.

DR. MORELLO-FROSCH: So for the Chemicals in Our Bodies Project we're still in the process of collecting data. But it will really depend on what chemical it is that you find and --

PANEL MEMBER CULVER: Take lead.

DR. MORELLO-FROSCH: Okay. So for lead they're actually sort -- there's a pretty clear-cut process for contacting the participant and protocols for looking for the sources of lead that may explain why the person has

come up very high. We tend -- if we're finding high levels of things for, depending on the source, we have protocols in the study to reach out to the study participant and to try and find out what the source might be.

PANEL MEMBER CULVER: If you get a result of 45 micrograms per deciliter, what are you going to do?

DR. DAS: Rupa Das, California Department of Public Health.

The answer to your question, Dr. Culver, is really chemical by chemical. So as Dr. Morello-Frosch said, for lead the levels of concern have been established, although they're changing. The levels of concern are getting lower. But we are -- there's a fair amount of work that's already gone into lead to establish levels of concern for the pregnant women and children or for other adults. And there are programs at the State of California that are dedicated to managing high levels of lead. And so if we detect high levels of lead, we would refer to those programs. And those programs would then take action according to their normal protocol. So that's been established.

For other chemicals, we will have to make the decisions that you're addressing. And as was stated before, it will be chemical by chemical. But you're right

in that prior to communicating with individuals who've participated in these projects, we will have to make the decisions about what is a level of concern and what actions we're recommending. We plan to address those issues through workshops and other deliberations that we're having in the program before we communicate to the participants. We just don't have those protocols in place today, but we certainly will take you advice in proceeding with those.

PANEL MEMBER CULVER: I can foresee finding a result for a chemical, maybe a chemical well known, maybe lead, where you're going to have to refer that person to medical care, not just reduce your level of exposure.

And then how do you find a physician who is going to make some sense out of that number and provide the adequate level of care? Because you're now responsible for that person that you sampled. So you are responsible actually, I think morally anyway, for the ultimate care of that person. You better be sure that that care is going to be good.

DR. DAS: Yes, thank you for those comments.

Again, for lead, the programs -- there's a Childhood Lead Poisoning Prevention Program and the Occupational Lead Poisoning Prevention Program, if it's occupational and in an adult, that has a care system that

is in place to make sure that individuals with high lead receive the appropriate medical care.

For other substances where we can determine that there is a level of health concern, we will be sure to address the issue of referring to a health care provider who can appropriately address the issues. There are several referral mechanisms in place that we could draw upon; for example, the Pediatric Environmental Health Specialty Units or the appropriate facilities at the Centers for Occupational and Environmental Health.

So you're right in that most physicians aren't able to interpret or manage these elevated results. But there are mechanisms in place, and we will refer to those facilities as appropriate.

PANEL MEMBER CULVER: Thank you.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Sure.

(Laughter.)

PANEL MEMBER SOLOMON: This is fascinating and really amazing work. I've got to say, I'm very impressed.

And thank you for also presenting the before and after, because I just probably would have thought the before was just fine until I saw the after. And so it's nice to see. But the after is obviously much clearer. So great.

I'm curious the degree to which the participants found that -- well, I guess one question is that -- you presented these slides that were more information about pesticides or more information about lead. So I'm assuming that that was the drill-down that you referred to. And my question is about the degree to which the participants found that to be sufficient in terms of the sort of more in-depth layer of information or whether they were actually seeking even more detail and whether even greater drill-down might ultimately end up being necessary or not.

MS. BROWN-WILLIAMS: The design of the interview script is really intended to point people into the material. So what tended to happen is people looked back to see where they could get the information from the materials that were presented to them.

I would say that in general there were expressions of interest in getting more information. So, you know, we were limited in what we could -- what we are going to be able to provide them through the program. And even in terms of like other websites that might be a little bit more broad based in what they might communicate to the public about potential health risks and potential ways to reduce exposure, you know, those may be available through other mechanisms. People didn't really

distinguish kind of what we were providing to them, but there were general expressions of interest in learning more and immediately applying this to something in their own life.

So like one of the questions is around finding their level of DDT and then asking them questions that required them to navigate between materials. So, for example, from the results chart for pesticides, finding their level of DDT and then going into the list of pesticides tested to look up some more information about DDT. And, you know, one woman was accompanied by her husband, she said, "Oh, we're going to have to become vegetarians. This is in the fat of animals," you know. So it's like people immediately do look for, well, you know, something about this that they can kind of apply to their own lives.

So I mean I would say that in general people are interested in, you know, referrals to sources of information as much as we can provide. And the packet of materials is great.

And with the drill-down, I think what we're really meaning more is, for example, if you first see your summary of results and you don't consider yourself someone comfortable with graphical material, you might ignore that graph. But that wouldn't mean that you

would then miss important information about your own results or important health-related information.

So for drilling down was really ways of getting, you know, into other ways of getting that information. Or they might, you know, want to learn -- the graph can give them more information about reference values or other participants in the studies results than the summary of results when not everyone is likely to be as interested in that, but at least they have the option of getting that information.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

Again I echo Dr. Solomon's remarks. This is quite amazing work and very informative.

Is there an opportunity to ask people about specific products? I noticed you list -- they didn't understand pesticides so much, some of them didn't, and you listed fairly complex chemical names of chemicals that they may have exposure to. And I'm wondering if there's an opportunity -- with this really close interaction with the population, whether or not there's an opportunity to get more information about specific things that might be in their households or some -- for lead, for instance, is there an opportunity to find out whether or not anybody is working around lead or whether or not there may be a

take-home exposure or something like that? Because exposure is so missing from all of the biomonitoring, you know, information that we're collecting.

MS. BROWN-WILLIAMS: I'll let Rachel answer the second part of your question first.

DR. MORELLO-FROSCH: So as part of the MIEEP and Chemical in Our Bodies Project itself there's a pretty extensive exposure questionnaire that the -- the interviews that we were going to be interviewing the study participants -- we've been interviewing study participants. They also do a take-home questionnaire which gets at all kinds of products that they use in their home. It gets at also some potential occupational take-home exposures. So it gets at a lot of these issues that you raised, which is separate and apart from the report-back process itself.

PANEL MEMBER QUINT: I had another -- oh, and another question is whether or not any of the participants, since they're pregnant and they're -- you know, so there's exposure to their babies as -- potential exposure to their babies as well as themselves, whether or not anybody expressed the desire to talk to their health care provider about the information that they get in the report-backs? I mean was there any discussion of whether or not their physicians would get information or whether

or not they're going to -- of discussing what you give them with their health care provider? Which seems to me would be a logical thing if you're --

MS. BROWN-WILLIAMS: Yes, it does. I mean, as I recall, that did not really come up with people about, you know, "Is my doctor going to get this information?", or "Would my doctor have more information about this?" I know in the focus groups that we did with the CYGNET parents, there was a lot more interest expressed in that setting about either getting information through the primary care provider or having the opportunity to discuss the information.

You know, that may just be because, you know, due to the constraints of the time we had for these, we had to focus more on the comprehension of the materials. There's a whole other set of questions that we could have asked about kind of broader background that would be very interesting to know. But as I recall, there weren't, you know, specific questions about that.

I mean interestingly your first point was around, you know, the complex chemical names, and that was -- you know, a lot of our work was to try to move people more into the simplest form of the information, so they've been on the list of pesticides tested. We deemphasized the full chemical names and focused their attention on simple

three-letter abbreviations and descriptive information.

But people would love to have brand names, unfortunately. Just tell me what product not to buy.

(Laughter.)

DR. MORELLO-FROSCH: In terms of getting at the question of what they do with this information. When we actually do the report back, we are going to return to study participants to ask them sort of how they used that information, what action they are taking as individual -- we've done this before in other exposure studies -- what individual level of actions have they taken in terms of changing products or who they've shared this information with? Have they shared this with a health care provider or other family members or neighbors, or et cetera? Just to get a sense of what people's reactions to report-back are and what they're doing with the information.

PANEL MEMBER QUINT: Thanks.

CHAIRPERSON LUDERER: I think, Dr. Bradman, you had a question?

PANEL MEMBER BRADMAN: Yeah, I have a few comments and questions. And some of this might be for discussion tomorrow.

But just here's a real brief one. In terms of the babies, there was very little data for babies. Were the babies being compared to the mother or to other

babies, and the reason there were few circles is because there was few detections?

DR. MORELLO-FROSCH: Other babies. They're being compared to other babies.

PANEL MEMBER BRADMAN: Okay. So here's a series of questions.

One, is the ultimate plan to return results, in person or over the phone, along with the letter? Or was the goal here to produce a document that you could mail without any accompaniment? One issue I think for the Biomonitoring Program, you know, with relatively smaller studies it's possible to have one on one. In our work in Salinas we have one on one with hundreds of people. But if the numbers go up, I think that we've used the word "touch factor" might have to go down. And I wondered what your thoughts on that are and how this might work in that context.

DR. MORELLO-FROSCH: The idea was to produce a packet that could stand on its own. So the idea is to send the packet -- in this case we're actually going to evaluate the packet. So every participant's going to have touch time, because we're trying to see how well it's working.

PANEL MEMBER BRADMAN: Yeah, that I understand.

DR. MORELLO-FROSCH: But the goal is to get to a

packet that could stand on its own with minimal touch time, where if someone had questions, then it would be -- they would follow up with the program, but that wouldn't require an in-person session. So that's what we're trying to move toward.

PANEL MEMBER BRADMAN: Right.

Have you had any thoughts on conveying, you know, a sense of variability and also follow-up testing? And, again, this might apply for tomorrow. But we have found with some of our nonpersistent compounds over, say, even a three-day period, levels can vary by two orders of magnitude or more than two orders of magnitude. And so we've had a policy where if people had very high levels, we would offer to retest. Often with nonpersistent compounds, they'd be lower, there'd be kind of a regression to the mean phenomenon.

But I'm just curious. That's a little bit different from the issue of interpreting the level, which is also related because it's difficult to interpret something that jumps around all the time.

But, again, I'm wondering about follow-up testing and how to deal with variability.

DR. DAS: That's a really good point, and we are just starting to have conversations about that. I think it's really going to depend on the chemical and the

complexity of the analysis and the resources required and what the lab is willing to do. But that's certainly something that we have started discussion on, what should we do with these higher results in the clinical setting practices to repeat a test?

But I think the specifics of -- and the complexity of a particular test will partly determine that.

PANEL MEMBER BRADMAN: Then the last comment - and again this is another kind of hard issue but I'm sure will come up, so it's good to think about - on one of your slides -- I don't know if you have it in front of you -- but where you talked about, for example, if you had TCPy in your urine you were exposed to chlorpyrifos and then, you know, the issue of being exposed to pre-form metabolites. And for many of these compounds we're measuring a metabolite or some derivative, and of course that can reflect exposure to the parent compound or the pre-form metabolite or a mixture of both. And somebody's going to be concerned about using concrete language, you know, linking one to the other when there could be a disconnect. I don't know if you thought about that.

DR. MORELLO-FROSCH: Yeah. So this has been an issue that we've been talking about a little bit in some of our meetings which hasn't -- which I think we're going

to continue to deliberate on, because it's -- the question is, how do you finesse it in a way that's transparent to study participants, because they're not in a position particularly with a stand-alone packet to parse through all that. So you kind of have to decide how you're going to finesse that in the actual written materials in the end. So that hasn't been finalized. But, yeah, it's a big deal.

PANEL MEMBER WILSON: I have a question.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Rachel, I'm wondering if in your Cape Cod and in your Richmond studies if you did have results from those about the extent to which people have used this information with their health care provider or have provided it to their health care provider?

DR. MORELLO-FROSCH: Yeah. So some participants shared the information with health care providers, not even necessarily as "tell me what I should do," but more as an FYI, and just felt like it was useful information to share. So they didn't seem to have expectations that their doctor would have a clear-cut, you know, "this is what you should do and..." but more to let them know if they were participating in the study and that these were the kinds of chemicals that were found in their home. Some of them shared a little bit about decisions they had

made to change the kinds of products they bring in their home or decisions about not using home use pesticide products, for example.

That was the kind of -- those were the kinds of things that we saw in terms of the ways in which people were sharing this kind of information with health care providers.

PANEL MEMBER WILSON: I guess I wonder if it's useful as part of the results packets that goes to people to provide them with sort of a brief letter to their health care provider from the research group from OEHHA that says in language to the health care provider, "Here's what we're doing." And it's sort of irrespective of sort of the points that Dr. Culver was raising around lead and perhaps even some of the organophosphate levels, those where there are -- you know, there are health -- you know, there are established health levels and action levels and so forth. But with all of these others, where it's -- you know, we don't really -- you know, it's hard to know what it means. But as a way to -- something that they could give to the health care provider to give that provider a little bit of guidance and interpretation, you know, without going overboard, but fairly simple. It's just I'm wondering if it would be helpful. I guess it's a question.

DR. MORELLO-FROSCH: Yeah, it's a good question. I don't know. I mean I think that's kind of a decision for the program to deliberate in terms of the kinds of information -- you know, especially once the program is scaled up, what kind of information you want to go out to participants and then more broadly to other constituencies like health care providers.

DR. DAS: That's a good point. And we're considering doing that for the few chemicals where some kind of health level and action has been established. An example would be mercury, which is not as clear as lead, but there's more information than some of the other chemicals. So we're just starting to develop instruments that might be able to be given to a health care provider.

PANEL MEMBER WILSON: Right.

We certainly did that with the hexane exposures in the automotive repair industry, we wrote physician guidelines for understanding. But that was a much more clear health effect and there were sort of workers' compensation issues and really evidence of frank disease. It was kind of a different case, but it was very useful for people.

Yeah, Dr. Quint.

Oh, sorry.

MS. HOOVER: We normally like to allow for public

comment and then a little time for additional Panel discussion. But I obviously don't want to cut off a relevant comment. We're just already behind time.

So your choice, Chair.

CHAIRPERSON LUDERER: Maybe just have one more comment.

Dr. Quint, do you want to just --

PANEL MEMBER QUINT: Julia Quint.

I was just going to clarify. In the case that Dr. Wilson is talking about, the medical guidelines in the Occupational Health Program was -- the purpose was to help diagnose new cases of work-related illness; in this case, peripheral neuropathy. So you have a frank, as you said, linkage between the exposure and the chemical.

But I also think that there's an ongoing effort by many people to try to educate health care providers about environmental chemicals and -- you know, and not just lead and mercury and other things, but just to give them a growing appreciation that there are a number of chemicals that can impact health that consumers and others are exposed to. So this would provide an excellent opportunity to broaden knowledge. Not necessarily to make a direct linkage between health and the exposure, but just, you know, the same sort of information you're giving to the participants, health care providers need that as

well, because there's very little education about these issues.

CHAIRPERSON LUDERER: All right. Thank you again.

There are two public comments. One came in by Email and one is an in-person comment.

So why don't we start with Mr. Davis Baltz from Commonweal, who's here.

MR. BALTZ: I should sit on the other side of the room.

Davis Baltz with Commonweal.

Thanks for that great presentation. And I think, you know, the program is committed by statute and also because we think it's the right thing to do to convey results to participants. So you've really put your best foot forward with this work. And it shows that the program has a lot of tools at its disposal to convey results in an accessible and sensitive and as comprehensible a way as possible given our current knowledge. So if there are doubts - and I don't think that there were - that the program didn't have resources at its disposal to tackle this important issue, your work shows that there's actually quite a bit that they can draw on.

I was struck by, you know, the questions that

immediately come to people who have biomonitored the first one, sort of being, "Is it high?"

And I think as someone who's been biomonitored myself, it's a common and human reaction. You want to know how you stack up against everyone else. But as we know, these comparisons can give you a false sense of security. "Well, I'm less than the average, so everything is okay." But what if we ask the question, "Is it high compared to five years ago?", or "Is it high compared to ten years ago?" The answers could be quite different.

So we need to be careful. And this is where your work on biomonitoring literacy and health literacy in general become very relevant. In the studies that we've done at Commonweal, the more we talk with communities in advance about what biomonitoring can and can't do, the more willing they are to actually participate and to process the results in a way that doesn't cause panic, and enables them to move forward with this new important knowledge about what's going on in the world.

And the other question, you know, is it safe? For some substances like lead, and mercury to a lesser extent, and maybe some others, you know, we can say with relative confidence you're level is not a cause for concern or perhaps it is. And if it is a clinically significant level, of course we should report in a more

directive way, I suppose.

But in general we don't know the answer to most of these questions about chemicals, is it safe, because the information doesn't exist in the literature yet. So we have to be prepared to say, "We don't know." And study participants are for the most part grown-ups and they can accept this. And it's just something that is a fact of life.

I don't personally think that the Biomonitoring Program should be responsible for determining what a safe level is measured in the body of any of these chemicals.

If the program were to decide to take that on, I think OEHHA would be a good candidate agency to do the work. But this takes us down the road of risk assessment. And we'll be talking more about this tomorrow.

And irregardless of how the program decides to move forward on this, I think the key thing to remember is this program was implemented and -- or passed by the Legislature and signed by the Governor to provide regular and updated information on chemicals in Californians, both to create a baseline and then look at trends over time. And that should be kept in focus as the main objective of this program, so that Californians and the rest of the country and the world can see what's happening on a regular basis with chemicals in our bodies. And if we

start to say we can't release results until we know that there's a safe level, this program will grind to a halt and it won't meet the intent of the Legislature or the Governor.

So it's a difficult issue and there are things to be said on both sides of how and whether we should determine safe levels to the degree we have resources to do them. But the program should move forward and still generate information on a regular basis and publish it. And the conversation of what to do with that data is actually a subsequent conversation that is probably handled by others.

So thanks for the chance to comment.

CHAIRPERSON LUDERER: Looks like we have another public comment. Great.

Okay. This is Dr. Lesa Aylward, Summit Toxicology.

DR. AYLWARD: I just have two questions about the materials and issues that you might have addressed or not addressed.

The first is, since this is a maternal-infant study, did you convey any information to the participants about breast feeding, in light of the information that they now -- they would then have about having trace levels of chemicals in their bodies and what information -- what

decision process or thinking or recommendations one might make about deciding to breast feed or not breast feed? Are those issues addressed in the materials at all?

And the second question is -- I noted that you provided averages from NHANES based on the pregnant women from NHANES studies. Did you consider providing a reference range up to, you know, 95th percentile or some other range information as well? Because, for instance, for dioxins the 95th percentile might be a factor of 2 or 3 higher than the average, while for some of the phthalate metabolites it might be a factor of 10 or 15 or 20 higher than the average, so that that variation is significantly larger for some compounds than for others, and people would still be within what you might consider to be a reference range.

So breast feeding and reference range.

DR. MORELLO-FROSCH: Hello. Can you hear me?

Okay. So this part of it was just evaluation of the materials themselves. And since it was a prototype, we didn't discuss issues related to people's reactions or anything in terms of the material. Again, that's going to come upon the actual report-back process itself. This is really about focusing on how well materials work in terms of messages getting through and people navigating and understanding what they're looking at essentially.

So for this iteration we didn't look at ranges of average or the 90th percentile of the chemicals, because from a health literacy point of view -- I mean the average -- most of the participants have very low levels of literacy. So even explaining what an average is, it's extremely difficult.

So getting into percentiles, quantiles, these kinds of things, even more challenging. So we chose for the prototype not to do that.

DR. DAS: So those are good comments and we'll take those into consideration as we develop the report-back materials, which will be developed chemical class by chemical class, and we'll have to balance your comments with the comments that Dr. Morello-Frosch just made in terms of making the materials understandable to participants.

CHAIRPERSON LUDERER: Okay. We do have one more public comment that came in by Email.

So I wanted to thank the public commenters that just spoke and read this one from Caroline Silveira, Government Affairs at DuPont. And her comment is:

"What source are you using for levels of health concern? If you are stating in the materials that safe levels have not been established for most chemicals, isn't this a confusing and contradictory statement? Was it that

for the pesticides and metals you used in this prototype do happen to have established safe levels of concern? It seems that should be stated something like, 'For these particular substances for which you're blood or urine was tested, there are established levels of health concern and the source is whatever.'"

So did you want to respond to that possibly?

DR. MORELLO-FROSCH: Again, we were just trying to test the concept of level of health concern, not actually decide which levels of health concern to apply to these materials. That's going to be a longer process of deliberation that the Biomonitoring Program is going to have to decide.

So I think it's a very important question that the commenter asks, but is one that's going to be decided later. This was really about, can a participant understand the difference between the concept of a level health concern versus an average? Do they understand when they're comparing their results what those two things are and what they mean?

CHAIRPERSON LUDERER: Thank you.

All right. We're a little bit over.

Do the Panel members have any other comments or questions?

Dr. Bradman.

PANEL MEMBER BRADMAN: Well, I don't know if this is -- tell me if I should save this for tomorrow about some issues with the legality of reporting results back at all.

Is that something that we can comment on now or --

MS. HOOVER: Dr. Bradman, speak into the microphone.

PANEL MEMBER BRADMAN: Okay. Well, just this issue with new rules and regs around CLIA. And we had an experience where we wanted to expand the information we reported back to our participants. And we went to IRB and we were basically told that right now we can't expand biomonitoring results that we report back because there are both federal and state rules regulating the report-back of tests, and that the tests must be done -- if they're not done in a CLIA-certified lab or if they're not done under the supervision of a medical care provider, then you're not allowed to report individual results back. Now, there's some exceptions for research, although the exceptions are essentially what I just stated.

And it's kind of a strange situation because many of the tests that we do are not FDA-regulated diagnostic tests, so they would not normally be done in the context of a physician order.

And I know that most of the State labs are CLIA certified, although not all. I'm not sure about -- this is an issue that may need to be thought about. And I'm not sure if it applies to the discussion today. I apologize if I'm going off topic, but it's something to consider at some point.

CHAIRPERSON LUDERER: Dr. Das, do you want to respond to that?

DR. DAS: Okay. I'll just take a quick stab at that.

Part of the requirements of the initial CDC Cooperative Agreement were that the labs be CLIA certified. And so our labs are either CLIA certified or have the equivalent certification. And the tests that we have so far for the projects where we collect the samples, like MIEEP and FOX and Kaiser, will be done under the -- are done under the order of a physician.

So for right now it covers that.

PANEL MEMBER BRADMAN: The program is covered --

DR. DAS: The program is covered for right now, yes.

(Laughter.)

CHAIRPERSON LUDERER: All right. So thank you very much again, everyone, for a very interesting session.

We're going to take a break now. It was

scheduled to be a 15-minute break. Do we want to shorten it somewhat?

MS. HOOVER: Yeah.

CHAIRPERSON LUDERER: Come back at 3 p.m. by this clock.

PANEL MEMBER BRADMAN: Which clock?

CHAIRPERSON LUDERER: That clock or that clock.

(Thereupon a recess was taken.)

CHAIRPERSON LUDERER: Okay. I'd like to welcome everyone back and reintroduce Dr. Rupali Das, Chief of the Exposure Assessment Section of the California Department of Public Health and lead of the California Environmental Contaminant Biomonitoring program.

Dr. Das.

DR. DAS: Thank you, Dr. Luderer.

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: This afternoon I will be describing our newest collaboration with Kaiser Permanente. And that collaboration, as I mentioned this morning, is called the Biomonitoring Exposure Study, or BEST.

This is a presentation that was prepared together with Dr. Stephen Van Den Eeden. He could not be here today because he's in New York attending another meeting. Hopefully he is attending the webinar, or he will shortly

when he gets out of that meeting, and says that if he has any responses to questions, he'll be sending them to the listserv.

If there are any questions that I can't answer, then we'll get back to you.

As you recall, Dr. Van Den Eeden did present about a potential collaboration -- or at least about the Research Program on Genes, Environment, and Health in 2009.

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DR. DAS: As I just said, we're collaborating with the Kaiser Permanente Northern California, Division of Research, Research Program on Genes, Environment, and Health, or RPGEH. Funding for this program -- the BEST Program comes from the CDC Cooperative agreement. And as with the other projects that we're engaging in, in-kind support comes from both our collaborator, Kaiser, as well as from Biomonitoring California.

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DR. DAS: As you heard in 2009 when Dr. Stephen Van Den Eeden presented, the goal of the RPGEH is to build one of the largest and most comprehensive resources for research on the links between genetics and environment and the influences on health by linking both clinical data from the Kaiser system electronic medical records,

participant survey data, and environmental exposure data in the form of a questionnaire that's collected by RPGEH.

RPGEH is building a biobank, and currently has 160,000 biological samples that are primarily genetic -- for genetic analyses and 400,000 completed questionnaires. And they hope to have as many biological samples as completed questionnaires eventually.

And I should mention that those samples are all from active Kaiser Permanente members.

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DR. DAS: Let me start with an overview of BEST.

This is to be a pilot biomonitoring study in the Central Valley. And our goal is to recruit -- our current goal is to recruit a hundred male and female adults.

We will be recruiting jointly with the RPGEH Biobank program, the one that I described. And I'll describe how that will work in a few minutes.

As with our other pilots, we'll develop and test protocols and procedures that will be applicable to other studies. In this case, the sampling scheme is different than the ones we've followed for the other programs. And so we hope that this will be the model for something that could be then expanded to a larger regional and possibly a statewide study.

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DR. DAS: Collaborating with Kaiser offers a number of advantages. As I've described this morning, we're required by statute to biomonitor a statewide representative sample of Californians. And this statewide sample is to reflect the State's diversity with respect to race, ethnicity, age, and economic status.

Our collaboration with Kaiser allows us to leverage our limited resources to approximate a statewide sample. This particular collaboration allows us to expand to a geographic area that we haven't yet studied. So currently we have studies going on in the Bay Area and southern California. And this will expand to the Central Valley. The Central Valley is not only a different geographic area but likely has different exposures, as it is a major agricultural area.

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DR. DAS: The next few slides show data about Kaiser and its members. This slide shows where Kaiser members in northern California reside, and shows that they reside in both urban and non-urban locations.

These dots aren't necessarily individual houses, but they represent residence areas in which the Kaiser population resides.

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DR. DAS: This slide shows that Kaiser members

have wide variations of socioeconomic status. The data from this slide comes from a different study that Kaiser was conducting, and the blank counties are counties from which that study did not have a population drawn. And so Kaiser does have members in the blank counties, just for this study members were not drawn from those counties.

This shows the Neighborhood Deprivation Index that was developed by Messer in 2006, and is a composite index of census variables.

The Neighborhood Deprivation Index represents five sociodemographic categories, domains that were previously associated with health outcomes. And the factors that go into determining those categories include income, poverty, education, employment, housing, and occupation.

The counties that are shown in this map are census tracts of Alameda, Contra Costa, Marin, San Francisco, Yolo, Solano, Sonoma, Napa, Sacramento, Fresno, San Joaquin, and Stanislaus counties.

We will be drawing from some of these counties for our best collaboration.

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DR. DAS: This slide shows the educational level of Kaiser Permanente Northern California members compared to the general population in northern California. And you

can see that in general the education level of Kaiser Permanente members is somewhat equivalent. There's slightly lower proportion of Kaiser Permanente members who have less than a high school education and slightly more that have high school education. But in general they're fairly comparable.

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DR. DAS: And this slide shows a similar comparison of race and ethnicity of Kaiser members compared to the general population. Again, there are slight differences. But you can see that overall the Kaiser population is fairly comparable to the population in northern California.

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DR. DAS: There are some additional advantages to collaborating with Kaiser. As I mentioned, the RPGEH Biobank will take advantage of the electronic medical records. And this provides a comprehensive and continuously updated source of clinical data that we can merge with our biomonitoring data.

In addition, RPGEH has an incredible internal infrastructure. They do a lot of research projects and their staff are experienced in working both with research sets as well as with Kaiser members and with data.

And, finally, Kaiser itself has a strong and

longitudinal relationship with its members. And members tend to agree to participate in the research studies and stay with Kaiser for a long time, and this allows -- has the potential to allow for longitudinal follow-up.

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DR. DAS: So let me then move on to talking about BEST itself.

Our chemicals of interest are very similar to those of our other collaborations and include the brominated flame retardants; the newer brominated flame retardants; environmental phenols, such as BPA; the metals; pesticide metabolites of chlorpyrifos and pyrethroids, respectively TCPy and 3-PBA; and polycyclic aromatic hydrocarbon metabolites, at just 3-Phen.

The asterisks here represent chemicals on which we have questions in our exposure assessment questionnaire where we focus on exposures to those chemicals.

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DR. DAS: We'll move on to sampling and recruitment.

So as I mentioned, the sampling scheme for Kaiser is a little bit different for both Chemicals in Our Bodies Project as well as FOX. They were convenience samples. And so the people who came into one clinic or another clinic were essentially recruited into the study. Here

we'll be using a sampling scheme that will use as a denominator the Kaiser Permanente Northern California membership.

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DR. DAS: Our plan is to recruit Kaiser members who have been enrolled for more than a year and are members of Kaiser northern California. We'll stratify the members based on the location of residence; their age, two categories of age, less than 55 and older than 55; gender; and for categories race, African-American, Asian, non-Hispanic, white, and Hispanic.

And our current goal is to recruit a hundred participants. And so we'll end up with approximately three to four people in each of those smaller boxes at the bottom of this slide.

This will still not allow identification of individuals. Even though there is three to four people in each of those boxes, their identity will still be -- not be able to be identified based on these criteria.

The member rolls allow for a random sampling of participants. And we can calculate response rates for each of these boxes.

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DR. DAS: So all of this sampling scheme is not a convenience sample. Our goal of a hundred members is

based on resources. So it is possible that we would expand this to more than a hundred. But the total number of participants at this point is based on resources and not on a hypothesis-based question.

For the first ten participants, we're going to be going slow. We're obtaining feedback on the process, on the data collection instruments, the questionnaires. And how they perceive the recruitment process and instruments will then improve those instruments and then recruit the remaining participants.

So the way we're going to recruit is to first send a postcard and an introductory letter. The letter will introduce the project and describe what it's about and explain that it's a collaboration between Biomonitoring California and RPGEH. And participants will be asked to return the postcard indicating if they wish to participate or don't wish to participate. And in addition, they'll get a brochure describing biomonitoring.

Participants who return the postcard and say they don't want to participate will not receive a call. But everyone else will receive a call. So if the participants return a postcard and say that they want to participate or they don't return a postcard, they will receive a phone call to recruit them into the study.

And then we'll arrange a field visit.

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DR. DAS: And the field visit can occur either in the participant's home or at a Kaiser facility that's convenient to them. An interviewer/phlebotomist - the same individual is the interviewer and the phlebotomist - will consent participants and -- the participants will consent on a number of different things, as they have with other projects. They have the option of receiving individual results and they have the option of donating de-identified blood and urine samples for Biomonitoring California to our archive and, in addition, separately will consent to donating samples to RPGEH.

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DR. DAS: The interviewer/phlebotomist will collect the biological samples and questionnaire and participants will receive compensation. For the first ten participants, Amiko, our health educator, plans to go on the home visits with the interviewer to the participant's home or the facility to do some of the questioning and testing of our materials.

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DR. DAS: As with our other projects, there is an exposure questionnaire. This will be self-administered, and we'll focus on the following environments: Both home and work exposures will have some questions on

occupational exposures, some questions on diet, on home furnishings and personal care products.

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DR. DAS: You're probably familiar with this specimen collection and protocol. You've seen it for our other projects.

We'll be collecting urine, which will be used to analyze pyrethroid and organophosphate pesticide metabolites, metals, PAHs, and phthalates. Our lavender top tube will be used to analyze the metals and two red top tubes will be collected to analyze PCBs, brominated flame retardants, and perfluorinated chemicals.

In addition, on the right-hand side of the screen, there will be a red top and a yellow top and a saliva and urine aliquot collected for RPGEH that will not be part of Biomonitoring California. It will be collected at the same time, but it's going to Kaiser to be stored as part of their biobank.

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DR. DAS: As with our other projects, participants can elect to receive results. And our current plan is to return results in two phases. And that's primarily because the analysis occurs -- it ends up being in two phases. The early phase typically will include the metals and the PFCs, and the latter phase

includes the brominated flame retardants and other compounds.

After the results are returned, we plan to survey participants to evaluate how they understood the process and how they reacted to the results and to see how we can use those findings to improve our subsequent projects.

For selected results - some of our discussions this morning kind of alluded to this - if we find elevated results, results that we know are elevated, and those would be limited to probably the heavy metals, lead and mercury, we may return the results early if they indicate some kind of clinical action.

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DR. DAS: This is the timeline for the project. We have received IRB approval from both the California Department of Public Health as well as Kaiser Permanente Northern California IRBs.

As soon as that has been -- the instruments have been finalized, we will randomly select members to be recruited. Our initial recruitment will occur early summer. And our first ten participants will go through the process of consenting and donating samples during the summer. And then we hope to recruit complete recruitment by early next year. And then results return and feedback will take place over the following two years.

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DR. DAS: And I'd just like to acknowledge all our Biomonitor California staff and the staff at RPGEH for their assistance on this project.

And I'd be happy to take questions at this point.

CHAIRPERSON LUDERER: All right. Any questions from Panel members?

Dr. Solomon.

PANEL MEMBER SOLOMON: Thanks for that presentation. And I think as -- you know, this committee's already discussed collaborations with Kaiser in the past, and I just want to sort of reemphasize that it's a great thing that this collaboration's moving forward. And it's very impressive to see the degree to which the Kaiser population reflects the California demographics. I was actually a bit surprised to see that, and it's really useful information to know.

About this study, I actually had I guess three comments or questions. Two were about sort of that recruitment or subject selection protocol flowchart, that you're only including English-speaking participants. So I just wanted to sort of question whether it might be feasible to include Spanish-speaking participants, especially since this is in the Central Valley.

And then I was a little confused about the - and

maybe you can explain this again - the sort of under 55 year old and over 55 year old. And I'm trying to get a little more -- like for the under 55, 0 to 55 or 18 to 55? And why 55?

And then my other question -- sorry, that's three -- but is about the questionnaire and whether there might be any opportunity to review the exposure questionnaire.

DR. DAS: Okay. See if I can remember the three questions.

The first question, the Spanish-speaking. So we decided to conduct this initial pilot in English because -- again, Dr. Van Den Eeden would be the best person to answer this question. But his input to us was that the Kaiser population -- there are very few Kaiser members -- in spite of the reflection of the State in terms of ethnicity and the other factors that I presented, there are very few Kaiser members in the Central Valley who do not speak English, even if they are Spanish-speaking. But because we don't want to just capture English-speaking individuals, we certainly would like to expand this to include the Spanish-speaking population in the future. And if we do expand beyond a hundred even in the same geographic area, certainly that would be a priority for us to expand to Spanish-speaking

populations. And we'll take your comments and factor in if we do expand that.

Your second comment was about the sampling scheme and the age range and why 55.

This is an adult cohort and so it's above age 18, so it's 18 to 55 and then 55 and older.

And as far as why 55 was chosen, it was just a criteria because we could stratify in that way. I don't think there was a magic -- there was no specific reason that 55 was chosen. It was a way we could stratify by age and it was a way that, you know, we could use one of the factors to test stratification.

Dina, do you have any other input into -- I'm asking Dina if she has any input into why it was age 55.

MS. DOBRACA: Dina Dobraca, Environmental Health Investigations Branch.

Stephen Van Den Eeden would obviously be a better person to ask about why 55 was chosen. I just wanted to mention that the program will be receiving date of birth, so it's not as if when we do our analysis we won't know how under or over 55 someone was.

DR. DAS: I think -- Berna, did you want to respond to the question? You have to speak into the mike.

DR. DAS: Identify yourself.

DR. WATSON: This is Berna Watson from

Environmental Health Investigations Branch.

Although this doesn't apply to men, But 55 is taken as a cut-off for a reproductive-age woman as opposed to over-reproductive age. So since we are categorizing females like this way can separate two groups, we have done the same thing for the male.

DR. DAS: I think this is -- there could be various ways in which we could categorize age. I think this was sort of a simplified -- simple scheme to test our ability to stratify and sample based on those criteria.

And your third question, the questionnaire -- could you have input on the questionnaire?

The Panel has expressed interest in having input on the questionnaire in the past. I think once the Panel as a whole provides input, it become a public document. And so we certainly -- we would welcome your input. We just have to take that into consideration. Our questionnaire is based on the questionnaires that have been used in our prior pilots. It's changed since that and it reflects the chemical priorities that I indicated. It has been pilot tested in our other pilots.

CHAIRPERSON LUDERER: I just have a quick -- I mean a follow-up question on the sampling.

So you said they were going to be randomly sampled. Is that within each of those little boxes, you

know, that will be three or four people, they will be randomly sampled within that kind of subset of the population? Or the 100 and you're thinking that three will wind up, you know, based on the random sampling in each of those boxes?

DR. DAS: Maybe I should go back to that slide and explain.

So our denominator is the Kaiser Permanente Northern California database, which includes I don't know how many millions of people. And we will be first -- it doesn't matter which order you actually stratify by. So this is just the way it chose to select. You could start by stratifying based on ethnicity and work up. But the eligibility criteria, English-speaking, and that they've been members for a year. And after that -- we'll end up with a hundred total participants, and that is why we will have three to four in each of these boxes.

So if we expanded and said that we were going to have a thousand, then we would end up with probably 30 to 40 in each of the boxes.

Does that answer your question?

CHAIRPERSON LUDERER: So it is a stratified random sample.

DR. DAS: Yes.

CHAIRPERSON LUDERER: Any other questions from

the Panel?

Dr. Bradman.

PANEL MEMBER BRADMAN: I just have a technical comment on this slide where you showed the shipping.

DR. DAS: Okay.

PANEL MEMBER BRADMAN: Basically I -- I don't need to look at the slide. But one thing that we have found, that some compounds when they're shipped unfrozen, in other words collected and shipped then to a central lab in Berkeley and then aliquoted, that in some cases you could have 12 to 18 or 24 hours between collection and processing. And you might consider doing some pilot samples where, for example, you take your urine sample, freeze aliquots in the field maybe on dry ice, and then ship some and see if their integrity is maintained during the overnight shipping.

When we first started our work, CDC at that point with Dana Barr suggested aliquoting organophosphate -- you know, samples for organophosphate metabolite analysis within four hours. Then it went up to eight, and she did some experiments. And sitting overnight was fine. Obviously for metal that's not going to matter. But some of these other things may or may not be stable over a day after collection. Most of them, I bet, are. Certainly the things you're looking at in blood probably are. But

it's something just to check and it's a little QA/QC step that's nice to see.

DR. DAS: Thanks for that input.

What we have done for other projects is to freeze within a certain number of hours and then ship it frozen.

In this case there's an interim step in which the sample will be shipped, as it says here, to the Kaiser labs.

PANEL MEMBER BRADMAN: Right. So it's shipped overnight on ice gel. And, you know, that means it's being kept at around 35 or 40 degrees hopefully. And so there could be -- you know, there could be 18 hours before it's actually aliquoted and frozen. And you might just want to check that holding time.

DR. DAS: Okay. Will do.

CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

PANEL MEMBER KAVANAUGH-LYNCH: I'm having trouble understanding the rationale for this collaboration. I understand the potential. But this -- so these people -- you're going to be recruiting from Kaiser members, not from the RPGEH members?

DR. DAS: That's correct. Well, the Kaiser -- yes. Well, the RPGEH recruits from Kaiser members. RPGEH is a bio -- is in the Division of Research and it is a biorepository. It is not members -- I mean

they are a subset of members. So we will --

PANEL MEMBER KAVANAUGH-LYNCH: So some of these may -- some of the people you recruit to this may have joined the RPGEH cohort and some may not have?

DR. DAS: They may have donated samples to RPGEH in the past or questionnaires to RPGEH in the past, that's correct.

PANEL MEMBER KAVANAUGH-LYNCH: So the rationale beginning about it's good to collaborate with RPGEH because they have this, that, and the other thing actually doesn't pertain to this study, because these members are not part of the RPGEH cohort necessarily?

DR. DAS: Well, Dr. Stephen Van Den Eeden is with the RPGEH. And so our collaboration is with the institution. Our collaboration is not with the members who are part of that.

Dr. Van Den Eeden's institution is the research program on Genes, Environment, and Health in the Division of Research. So we're collaborating with the institution. Maybe that's the point of clarification.

PANEL MEMBER KAVANAUGH-LYNCH: No, I understand this is a collaboration with Kaiser and one of Kaiser's projects is the RPGEH and Kaiser members are recruited to join RPGEH, some do and some don't. People are being recruited into this study regardless, without regard to

whether they have become part of the RPGEH cohort or not. So the advantages you listed in the beginning, oh, they have this environmental questionnaire; oh, they've got -- their genetic material has been biobanked, actually does know pertain to this.

DR. DAS: They're being recruited into both simultaneously. So we will have access to --

PANEL MEMBER KAVANAUGH-LYNCH: Are you excluding people who have already -- are you excluding the 400,000 who have already joined?

DR. DAS: I don't believe so. That would be a question to check with Dr. Van Den Eeden.

The 400,000 have donated questionnaires and 160,000 have donated samples. But not all of them have donated blood samples. There are 160,000 saliva samples. But I think the blood collection is a new protocol.

Again, these are questions that Dr. Van Den Eeden would have to answer.

PANEL MEMBER KAVANAUGH-LYNCH: Okay. And then the other question, it seems to me that doing home visits to collect samples will eat up funds very, very quickly. And I know that previously RPGEH was planning to do their blood collection through their existing labs where an order was placed, so that the next time that patient came in to get a regular blood draw, they would also draw the

blood for the biobank and submit that at the same time, which would drastically reduce costs.

DR. DAS: According to Dr. Van Den Eeden, this is much less complicated than filling out a lab requisition. Again, this is a question for him to answer. But the resources we're putting into this, as you saw, are fairly modest for a population this size. But your point is well taken, if we try to expand out, doing home visits for a larger population, you may eat up a lot of resources.

So this is a pilot and we'll certainly explore other methods of sample collection.

And participants are given the option of having the phlebotomist come to their home or go to a facility. According to Dr. Van Den Eeden, however, that process that you described in terms of writing a lab requisition would not have worked well for this particular project.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I guess just building on what Dr. Kavanaugh-Lynch just asked. I'm not sure if this is what you were implying or not, but it actually could be quite interesting to limit the sample from this study to people who were already participants in RPGEH to leverage the -- you know, the potential for, you know, follow-on research studies that could use all of the information that's been collected through both studies. There may be

reasons why that doesn't make sense. But, you know, I also could see why that that might provide more information in the long run.

DR. DAS: Yeah, I can't comment on that because it's his decision. But I think part of the collaboration here will allow RPGEH to collect more participants -- more recruits into their biobank.

PANEL MEMBER SOLOMON: So then -- I'm sorry. Gina Solomon again.

So then does that mean that when someone is recruited into this biomonitoring study, they will then be included in the RPGEH?

DR. DAS: Yes, that's what this slide --

PANEL MEMBER SOLOMON: Oh, I see. Okay.

DR. DAS: They are being recruited into the RPGEH as part of this --

PANEL MEMBER SOLOMON: -- part of --

DR. DAS: This is a joint recruitment into RPGEH and Biomonitoring California. It's just that they have possibly not previously been recruited. But their biosamples are being collected both as part of RPGEH and Biomonitoring California. And that's what the right-hand side of this slide shows.

CHAIRPERSON LUDERER: I kind of have a related follow-up question. You know, we're talking about home

visits, and I think you just said it was going to be a phlebotomist. So is only a phlebotomist going to go into the home? Because obviously the other thing that could be done with a home visit would be a home environmental assessment, kind of getting at, you know, some of the questions that we've raised, you know, at various times about figuring out, you know, where are these chemicals coming from, you know. Obviously that does add a lot of expense if you were to try to do something like that, which might not be feasible. But I was wondering if that was sort of part of the rationale for doing that in this pilot study.

DR. DAS: Our current resources don't include a home assessment. The way we're trying to assess exposures in the home is through the exposure questionnaire, and that's self-administered.

But that's certainly a good point, that if someone's going to be visiting the home, they could also help to assess the home. I think then, as you said, it becomes -- it involves more resources. And we don't have the resources for that in this phase. But for the future, if there's a home visit, I think it certainly makes sense to consider that.

CHAIRPERSON LUDERER: Do we have any public comments at this point?

MS. DUNN: None.

CHAIRPERSON LUDERER: No?

Any additional Panel discussion or questions?

All right. Thank you very much, Dr. Das.

All right. So you're going to be also doing the next presentation, correct?

(Laughter.)

CHAIRPERSON LUDERER: Which will be "Looking Forward for Biomonitoring California."

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: So good afternoon again.

(Laughter.)

DR. DAS: This is my last presentation of the day.

And this presentation is really a set of questions for the Panel. We would like to get your input on some questions that we'd agreed to. And let me provide some background.

--o0o--

DR. DAS: As we look forward to the program -- you've seen our accomplishments over the last four to five years. And we are looking forward to planning the next few years, not only the three years remaining on our CDC Cooperative Agreement but also the program looking beyond

that. And so we'd like to get your input to help us guide our planning.

And we're asking for your input on three major areas:

Identifying populations for community studies;

Approximating a statewide representative sample;

And investigating environmental exposure sources.

And then we would also welcome your input on other issues that you would like to comment on.

So I'm going to read the questions to you and then ask for your input on all of them together.

--o0o--

DR. DAS: So in terms of identifying populations for community studies, we would like your input on some questions that I'll read in a minute. But examples of possible populations include the following:

We could continue a study of mothers and infants or firefighters, as we are currently doing.

We could also study another occupational cohort. One idea that has been proposed is health care workers because they are exposed to many chemicals as part of their work. But it could include other occupational cohorts that are similarly overexposed to certain substances.

Or another example of a possible population could

be a cohort with higher environmental exposures to particular contaminants that are not defined by occupation.

A final example is that of -- that's being proposed of a particular cohort, that of incoming medical students. Apparently Germany has this program where they biomonitor incoming medical students as they provide a stable population. And there's always a new population coming in. We thought that in addition to providing that kind of a stable population, biomonitoring this particular cohort serves to educate health care practitioners about the issue of biomonitoring.

Those are possible populations. But you may have other ideas.

The specific questions we'd like your input on is whether -- in addition to the other examples -- do you think any of the above examples are good ideas to pursue? Do you have other suggestions for populations that we should consider studying?

Or do you have suggestions for specific collaborators to help study these populations?

I should also mention that in addition to these particular communities, we have issued an RFI, as I mentioned this morning, and those are also other examples of communities that could be evaluated that wouldn't

involve the program going out and collecting samples.

I mentioned this morning that we had criteria for selecting those collaborators just to remind you what they were when we issued the RFI in 2008. Some of the criteria we used for selecting those collaborators were that:

The chemicals coincide with lab capability in 2009.

The samples were collected in the last five years.

There were some collection and storage criteria that needed to be met.

That basic demographic data were requested to be made available to the program.

And we were especially interested in susceptible populations.

At that time, we also asked collaborators to provide partial funding. And we had other requirements that were mentioned this morning by Dr. Wilson, such as the program would have liked to share authorship and other things.

Those are possible ideas to considering in terms of future collaborations.

--o0o--

DR. DAS: Our second question is to get your ideas on what our approach should be in approximating a

statewide sample.

This morning you heard about our efforts to scope out the possibilities for carrying out a CDC-NHANES-type sampling. As you heard, it's not feasible in the near term because of the expense that's involved.

The two possible cohorts -- or two possible options that we've identified that you've heard about include Kaiser-type collaboration, which is currently a regional collaboration, or pooled infant blood spots and pooled maternal serum or individual blood spots or serum analysis that are collected at birth.

We would like your input on the above options or other suggested approaches to approximate a statewide representative sample.

--o0o--

DR. DAS: And, finally, we have a question about investigating environmental exposure sources.

As we have discussed in the past, investigating environmental sources of exposure helps the program to interpret the source of biomonitored chemicals and also requires additional resources.

Our questions to you are: How should the program approach investigating environmental exposure sources of biomonitored chemicals? Should modeling be considered as a good avenue to explore? And does the Panel have

suggestions of researchers who might be interested in collaborating on environmental sampling or exposure modeling components of a project?

So these are the three questions. And we would like to have your input on all three.

CHAIRPERSON LUDERER: Thank you, Dr. Das.

Would it be helpful so that we address all the questions to kind of go through them? Or should we just --

DR. DAS: Go through them one by one maybe.

CHAIRPERSON LUDERER: All right. Should we start -- Panel members, any comments on the first set of questions regarding possible populations to biomonitor?

Dr. Bradman.

PANEL MEMBER BRADMAN: I don't know, this might start out a little bit random and be an iterative process.

But I just want to suggest that we try to pay attention to children, you know, age 0 to kindergarten or up to 18. A lot of the -- you know, of course NHANES, their lowest age level was age 6. And I know there's a lot of interest in this group, in all of us, in the pregnancy exposures and cord blood newborn levels. But I think there's also been a lot of concern and interest about how kids are exposed differently from adults and what they pick up. Certainly, you know, from lead and

also now PBDEs, that kids have much higher levels than adults. And if we could somehow -- I don't know if we view that group as a community or if within the context of community studies we can include children that haven't typically been studied who are in terms of the representative sample we also consider a full age range. I know early in the program there was some concerns about working with young children.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: With regard to this question, I think for me it boils down to whether we're talking about an "or" or an "and." Because I think that we have two fantastic collaborations going on right now, the one on the mothers and infants study and the other on firefighters, which have great potential to be expanded. And if selecting another population for community study means having to drop one of those two, I -- I'm not wildly enthusiastic about that, because I feel like there's still -- you know, there's a lot of promise to building on what we've already got at least for awhile. I mean at a certain point, yes, you know, you don't want to study every firefighter in the State. But doing a broader study of firefighters would have I think considerable merit.

If there's the potential for expanding the resource pool and adding a third community study, that's a

different question. And, you know, then I'd have all kinds of ideas, and I like some of the ideas that are presented here. And so I guess it would be helpful to have a sense of whether we're talking about adding a third community study or whether we would be talking about dropping a maternal and infant study and/or dropping the firefighters ongoing studies.

DR. DAS: I think we would -- we'd like to get your ideas on which way to proceed. So I think what you just said is you would -- what I heard you say is that you would like the current -- would like us to explore continuing the current collaborations as opposed to looking for a different collaboration to replace one of these ongoing collaborations.

PANEL MEMBER SOLOMON: Yeah, that's essentially what I've said. You know, I would be -- for example, with the firefighters study, I think there's potential to expand it to other geographic areas so that we would have, you know, at least three sites in the State, you know, with other groups of firefighters.

And in the case of the mother and infants, doing -- you know, whether with the same collaborators or with other collaborators, doing a mothers and infants kind of series of studies would be I think something that would be very helpful.

CHAIRPERSON LUDERER: Dr. Quint and then Dr. Culver.

PANEL MEMBER QUINT: Julia Quint.

MS. HOOVER: Sorry. Could I just say one other thing in response, just to clarify.

So I think that actually it would be great. We do have a decent amount of time for this item. We kind of would like to hear both, partly because this item is interest in near term. It's also trying to involve you, you know, as we look forward, even beyond when we don't have CDC funding anymore, you know. So a little bit of it is just really brainstorming. And then some of it, like what you just said about near-term building on. So I would like to hear both types of input.

PANEL MEMBER QUINT: Julia Quint.

I think it is important to build on existing studies if there is, you know, a reasonable hypothesis to do so. If another firefighter group presents an opportunity to study different things, as opposed to confirming what we did in the first one, I think that would be very worthwhile.

I am just concerned that -- in the beginning of this program there was a fair amount of participation from members of communities where there are a lot of toxic exposures, the more environmental justice issues that

people talked to this committee about, and for some people who have been advocating for biomonitoring for many, many years. And I would like to see us -- I'd like to see the program, to the extent that it makes sense in terms of the types of exposures, to really look at an urban community that, you know, is -- you know, where the members are exposed to either a lot of industrial exposures or impacted by a lot of traffic and things that have been written about and, you know, there are many papers. We have a researcher here who's done a lot of work, Dr. Morello-Frosch, on this subject.

So I think where it makes sense in terms of the chemicals that we have identified as being important. I know diesel has been exhausted, it's been identified, but we don't have a way to measure that now. But I would like to see some emphasis on those more environmental justice type communities. There's been a lot of activism, there's been a lot of participation, and different for advocating for, you know, biomonitoring and that sort of thing.

And increasingly we are now recognizing the social determinants of health and trying to integrate all of these different cumulative impacts on health. So I think it would be very good for the Biomonitoring Program to link with some of those other broad public health issues that are now being discussed.

So my preference would be to try to collaborate with people who are either researchers who are doing that work or with community members who've been active for many, many years in terms of their proximity and their, you know, exposures to -- this would be a more -- it could be rural or urban, but just communities that are unduly impacted by toxic exposures.

CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: I think my comments are really very much in support of what Dr. Quint said. Maybe I want to go a little bit further.

In my experience, in order to be able to study a population, you have to have a lot of money. And in order to get a lot of money, you have to have a question that is of importance to somebody. The firefighter study got money because firefighters were concerned about their exposure. So there's ready-made population with some support available.

I have a feeling that we're -- we've got a laboratory resource and we're looking for populations to sell our resource to. Might turn it around and advertise our availability, because there are populations out there being studied and there are people who are putting together grant applications. And it's always hard to get funding for a grant application. If some of those studies

need to sample the population that they want to study, then we could help them reduce the cost of their plan and come up with a collaboration that would be beneficial for both sides.

So I guess bottom line is I'm recommending that we make the availability of this tremendous resource that's being built here known more widely and see if we can't get some collaborations.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson.

And I guess my -- I'm of two minds about this. It seems that launching the project with the mothers and infants and launching the project with the firefighters was a heavily lift, and getting those protocols in place and the laboratory methodology and the shipping and the handling and all of those details; and that it would be cost effective to take advantage of that sort of thinking and the infrastructure that we've put in place. And so it seems that it would -- it makes sense to me that we would continue our work with those projects.

And I also, you know, agree with Dr. Quint's recommendation that -- and echoed by Dr. Culver, that we're also -- it's important for us to identify and to -- you know, to identify highly exposed subpopulations, if you will. And I think it looks like the Kaiser study is

doing that in the Central Valley. And it might make sense to expand that work into Kaiser's population in some of California's urban populations that what might be disproportionately exposed.

So I would sort of -- I'm on two tracks there.

CHAIRPERSON LUDERER: Any other comments from the Panel about this first set of questions?

Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I guess the one that I am possibly - and it's probably my own bias - the least interested in is the incoming medical students. I know that it provides a stable population or whatever the rationale was for it. But it seems that -- this is the opposite of the argument I made for a subpopulation that's vulnerable. I guess I'm looking at it in terms of with limited resources and ability do a statewide representative sample at the time.

I'm looking at, I guess you could say, to make the -- apply the resources as equitably as possible, because of -- while also trying to get a snapshot of the issues and problems in California as it relates to chemical exposures. And so if we use that lens, then, you know, people who are, you know, it's been said, disproportionately maybe exposed to chemicals either through a lack of being able to buy organic or whatever

the reasons or, you know, having occupations where they bring home chemicals or things like that, it would be important.

There are other occupational groups that have -- may have high exposures to some of the chemicals that we are concerned about who don't know about this program. That's why I think the outreach with the brochure to various occupational groups to get -- because you need a group that you can collaborate with because you need access. And for occupational groups it's hard.

So I think, you know, just having more outreach with groups that work with various unions or other occupational groups, janitors, for instance, or something like that, it would be very important to get them to know that this program exists, while also, you know, trying to identify those that have exposures of interest and concerns. Because in the occupational groups the exposures are going to be much higher, and so I think it's worth looking at.

And health care workers may be a group, but I think there are many others.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I confess I'm torn. I actually kind of like the incoming medical students, partly because it is a fantastic way to educate future

physicians about environmental health. And as we all know, that's a big problem, because most docs don't know much about it.

I actually think that incoming nurses would also be of great interest. So if we were going to do it and collaborate with a medical center, it actually wouldn't probably be that much harder to work with both the medical and the nursing schools, at least to UCSF. I can't speak for other schools.

The cohorts with high environmental exposures or environmental justice cohorts, in some ways I guess the mothers and infants study at San Francisco General, you know, fits that bill to some degree.

I think, you know, we've got to get into Los Angeles at some point. And it really would be -- you know, if there were any project ongoing in urban L.A. that involved, you know, some of the communities near the port - there are fantastic community groups down there - I don't know exactly what's ongoing in terms of infrastructure - that would be a collaboration that might well be worth jumping on.

The only other thing that I was thinking about is returning veterans. The VA has three centers around the country called the War-Related Injury and Illness Study Centers. And one of those three is at the Stanford -- the

Palo Alto VA. And this is a referral center for veterans with, you know, sort of -- with environmental exposures and also with unusual illnesses. And they're kind of trying to figure out what to do with this flood of people coming back from Iraq and Afghanistan with all kinds of health issues and who have had all kinds of exposures.

That doesn't really reflect exposures here in California, but it does reflect a pretty significant population that's returning to our State who have, you know, been -- sustained significant environmental exposures.

So I'm not sure honestly if that fits the criteria for our program. But it also sort of, I guess from a purely, you know, cold political calculus and, you know, sort of -- it's returning veterans. I think there's going to be some interest in what they were exposed to and that that will probably be something that will -- you know, if we had some tools and resources to bring to bear that were helpful in sorting out, you know, what the situation is with these folks, that would be of interest to a lot of policymakers and others. And the VA also has a lot of money. So it's just -- it might be worth chatting with the people at the Palo Alto VA. And I have contacts there.

CHAIRPERSON LUDERER: Okay. Shall we -- before

we move on, I also had a quick comment -- oh, Dr. Bradman.

PANEL MEMBER BRADMAN: One last thing.

I actually like the idea of health care workers, just to reiterate that, and particularly the full spectrum, including janitorial staff. I mean recently the Department of Public Health came out with a document on occupationally caused asthma and cleaners and other things with high VOC sources. And that wouldn't be just of course health care environments. But I think there's -- that's kind of a population that's not -- long neglected, very low paid, and suffers disproportionate exposures based on occupation.

So within that context of health care or other environments. And I still kind of want to put in that plug there for kids. I know kids are hard to study.

Also, the last question about, does the Panel have suggestions for specific collaborators? I think on the academic side there's kind of the usual suspects. But maybe we need to do more to look beyond the usual suspects, meaning beyond academia. And I don't have specific people to mention, like Gina said, looking south. But, you know, I think there's something to that, that we need to look beyond the usual suspects.

CHAIRPERSON LUDERER: Yeah. I mean I also actually had a quick comment about health care workers.

And I very much agree that if that population were to be studied, it should be broadly construed and include all the workers in health care settings, not only who we traditionally think of as health care workers.

But I guess also the point that I wanted to make is, if you're talking about, you know, nursing staff, in particular, and pharmacy staff, then one of the big concerns is exposure to antineoplastic agents and other drugs. And that's not something that, you know, is on our list of designated chemicals. But if you were to study that population, that is very important exposure.

So, you know, I don't know if that's maybe, you know, saying, well, I'm not sure whether that -- you know, it would I think not make a lot of sense to study that population and not look at those exposures. So that might be an argument against that population or an argument for a collaboration with someone that's already doing those kinds of measurements. I mean the person that comes to mind is Melissa McDiarmid, who's done a lot of, you know, both assessing the exposure side of things, looking at surface contamination, you know, with antineoplastic drugs and then also measuring biomarkers of exposure. So I mean if that were a population that, you know, the program wanted to pursue, I would certainly suggest talking to her.

PANEL MEMBER QUINT: Julia Quint.

I think also to possibly look at ethnic groups that are, you know, a major part of California that aren't represented in NHANES, like Asian Americans and the various subpopulation -- you know, various groups in that spectrum. Because we don't have any data, and that certainly is a big part of the California picture here.

And you'd have find a group or -- you know, exposures of concern or groups of concerns. But I think that would be worth going after.

PANEL MEMBER KAVANAUGH-LYNCH: I think I --

CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

PANEL MEMBER KAVANAUGH-LYNCH: Sorry.

-- see some advantages to the health care workers, but again not to incoming medical students. That's not going to be a California population. Most medical students who come to California -- most California medical students actually aren't Californians when they get here. And so you would -- and that probably not true for nursing schools. That might be a bit different. But just consideration as a California Biomonitoring Program, it would be more like a U.S. representative sample.

PANEL MEMBER QUINT: Julia Quint.

I think actually the UC schools give a preference to native Californians. So it's more difficult if you're

an out-of-state student. So I think, by and large, the populations of UC medical students are from California, at least according to my husband, who's on the admissions committee.

(Laughter.)

CHAIRPERSON LUDERER: All right.

PANEL MEMBER WILSON: Yeah, Mike Wilson.

I'm intrigued by Dr. Solomon's suggestion of returning veterans, in part because we have a -- because of the infrastructure that you described at Palo Alto, but also at VA in San Francisco, right? And UC Berkeley has a -- is a very active campus for veterans returning to school in terms of university campuses across the country. It was rated as the most friendly and supportive environment for returning veterans. And there's a number of interesting questions that I think it raises, but I think it's worth considering.

So thank you for raising it.

CHAIRPERSON LUDERER: All right. Should we maybe move on to the next set of questions at this point so we have time to discuss them all?

All right. Anyone like to start? This is having to do with an NHANES-type sample.

Dr. Solomon.

PANEL MEMBER SOLOMON: I was wildly impressed by

the presentation on looking at infant blood spots. It went way beyond anything that I thought was feasible. But it actually -- you know, it needs to go a lot further before it would be really useful for us for a statewide sample, because, you know, even with the persistent chemicals, some of, for example, the key PBDEs are -- you know, there's the contamination of the paper issue. With anything that's not a persistent chemical, I just can't imagine that it's going to be feasible. And there are a lot of things that our Panel -- that, you know, our Panel has prioritized that would just not be doable. And so I'm not sure it's worth that trade-off.

I would personally like to see maybe -- you know, if we had to give somewhere, I would rather give a little bit on the representative, you know, and random sample rather than on the number of analytes. I'd like to get, you know, as many chemicals as we can. Because I think, you know, our Panel has all discussed, well, we don't want to just be sampling for PCBs and -- you know.

And so unless the blood spot thing can -- you know, obviously it's great to look into it because it has potential. But I would put my money more on a Kaiser collaboration if we had to pick a direction to go that would be more statewide representative. And so -- and especially given the slides that Dr. Das showed about how

representative the Kaiser population actually is of the California population, that actually makes me feel quite a bit better. I still recognize that we would be missing stuff, you know, missing significant segments of the population by going through Kaiser, but I think on balance it might be the best way to go.

CHAIRPERSON LUDERER: As one of the southern California members of the Panel, I also wanted to point out that currently the Kaiser population is only northern California, you know. And I know that we talked about that when Dr. Van Den Eeden did his presentation, that there is an analogous research group with southern California Kaiser. And I mean I think if it could be combined to include both northern and southern California Kaiser, that that would be a great way to approximate a statewide representative sample.

Is there any further information about that since the last time we talked about it?

DR. DAS: Well, our efforts have gone towards pursuing this collaboration. And it takes considerable efforts just to get any one collaboration off the ground. So our efforts right now are really focused on getting this collaboration through. And we know we've established the collaboration, and now we actually have to implement it and get results.

But I think if we were to think of a second phase or an expansion, then I think collaborating with the southern California Kaiser Research Center or with Kaiser Hospital System would certainly be a preferable way to go, because someone else also expressed -- I can't remember which Panel member expressed a desire to expand into the L.A. area. I think it was you, Dr. Solomon.

But just to answer your question, we have not had those discussions yet.

CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: Do we know what a statewide representative sample would look like?

DR. DAS: Well, as explained this morning, we did work with CDC National Center for Health Statistics to get a sampling scheme what would it look like in terms of the specific strata, in terms of age, gender, ethnicity. That -- we don't have the criteria yet, but we have a system in place by which we could figure that out. It's just resource intensive to actually implement that sampling scheme.

PANEL MEMBER CULVER: Because I would think that Kaiser population would be quite different from the statewide population in terms of economic status.

DR. DAS: The slides that I showed at least for northern California, the northern California Kaiser

population for Kaiser is very similar to the northern California general population. I can't comment on the rest of the state.

PANEL MEMBER CULVER: Inn terms of income?

DR. DAS: Yes. The factors that I showed you included income. Income wasn't a separate slide, but income was included in one of the slides that I showed you.

PANEL MEMBER CULVER: Yeah, I didn't pick that up.

I've always considered that the Kaiser population was not a good one for general epidemiologic use because it was rather stratified on income. You have to be employed I think to be a member of Kaiser. Is that not true?

DR. DAS: I am not sure what the eligibility criteria are for Kaiser. But you're right, that Kaiser doesn't represent every individual. For example, even in the Central Valley, farm workers probably aren't represented in the Kaiser population even though they are employed.

PANEL MEMBER BRADMAN: And uninsured people obviously.

DR. DAS: Yes, right.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I guess what I, you know, after hearing the discussion, might want to propose along these lines if, you know, we're sort of thinking, you know, five years plus into the future would be to aim to incorporate southern California Kaiser and then consider, you know, perhaps a few partnerships with community-based hospitals or clinics that could help -- you know, sort of fill in the lower income, uninsured sort of portion of the population that would otherwise be missed.

Because, you know, we've -- we're sort of -- we already have a collaboration with San Francisco General. Several more like that, combined with a statewide Kaiser cohort, really would give us a pretty darn good, you know, estimation of a statewide represented sample, I would think.

CHAIRPERSON LUDERER: Actually I wanted to also make one other suggestion for a possible, you know, somewhat representative statewide sample, which would be the National Children Study participants that are being recruited by the California centers. So, you know, there's the Southern California Study Center Dr. Dean Baker and Jim Swanson are the PI's of. Obviously Dr. Bradman is involved with the National Children Study Center. Here in northern California I think the Northern California Study Center is Irva Hertz-Picciotto is the PI

of that. And then there's the UCLA, the L.A. Ventura Study Center with Neal Halfon.

So it's really distributed across the State in many different counties, you know, both rural and urban, that are being -- where participants are being recruited.

And samples are being collected from the children, which is something that Dr. Bradman had also brought up that, you know, I think it is -- I agree with that very much that it's very important, particularly because NHANES doesn't look at the children under 6, to maybe be able to do some biomonitoring in children, which is why also the infant blood spots are appealing.

But, you know, also samples are being collected from both -- from the mothers and from the fathers. So it's not only the mothers and infants or -- and children.

So I would just maybe suggest -- I spoke to Dean Baker about it. You know, he said he would be happy to explore that further with the program staff. And I'm sure the other PI's of the study centers would too.

DR. DAS: You know, I'd just like to respond to that. Actually a collaboration with the National Children Study was part of what we proposed to explore for year 3 of our CDC Cooperative Agreement. So it's just to explore the collaboration, not to actually begin the study.

And I've had some very preliminary discussions

with Dr. Baker. But I think based on your recommendation, we certainly, you know, will follow our previous plan and along with the other -- consider that along with the other suggestions that we received.

CHAIRPERSON LUDERER: Okay. No other questions or comments from the Panel members?

Okay. Do we have another set of questions?

Okay. So the topic at hand now is investigating environmental exposure sources.

Anyone like to start that discussion?

I could maybe just add that for the National Children Study there are environmental samples being collected as well. So that might be -- I know that that's evolving over time. And maybe Dr. Bradman can address that a little bit more. But that again might be a useful approach to begin looking at some of those questions.

PANEL MEMBER BRADMAN: I can comment on the National -- I would say right now the National Children Study is in flux. And of course they are enrolling people at the Orange County Vanguard Center. All of the other locations, there's nine counties in California, are really on hold while the program office is reevaluating the protocol. And we've been told that the study will start going into the field in 2012 or early 2013. And at that point they'd be enrolling pregnant women, and then of

course children will start arriving a few months after that. So it's going to be some years before it's actually operational in the field.

And there's also the potential for conflicts with the program office needs for, you know, following the protocol.

That said, you know, there's a close collaboration here with CDC. And certainly they would like to share the analysis. But I would say at this point the NCS is actually really in flux and it's not clear what the protocol's going to be. There certainly though is a potential to add on pieces to the protocol as long as it doesn't interfere with the primary protocol. So that could be a great opportunity to both biomonitor and conduct other kinds of adjunct studies. And there is going to be a mechanism to do that. The key will be to not increase burdens too much and not interfere with the main protocol.

But it's going to be some years down the road.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: More of a comment on the general topic.

Actually, you know, at first it may seem this might be, you know, relatively easy to do. It is for some substances. I guess lead as an example of where you could

look at the relationship between lead levels and emissions from -- or the use of lead in gasoline.

But I know that with the CHAMACOS program, we really attempted, with some success, to do this, business of doing source attribution, you know, where did the pesticide really come from? And it gets very complicated because there are so many competing pathways. If it's a very simple pathway from a source to a person to the level, then it's not so bad. But that actually seems to be rare that you have such a simple pathway.

And so I mean we've done some other work with NHANES data and the PAHs. And one of the things that helps that we're trying to do with NHANES is actually you have to find out where the people -- you have to get the identified data, so you have to go in and work in the restricted environment. Because if you're trying to relate a biomarker level to an ambient source, you really have to know where the person lived. If you're trying to -- you can't just do regional general trends.

If you're trying to relate it to a specific person and not only the air or environment they're in but also their diet or something about their house, then you really need a lot more information, some of which is just not there and is rarely ever collected, very few studies.

So I think it's -- my final point is on the issue

of sampling or modeling, I think we've found with again some limited work is that modeling isn't very useful because you can kind -- a model is hard to anchor. And sampling is just like a snapshot, you know, getting one scene out of a movie, right, and trying to figure out what the plot is.

But if you have the two of these, right, if you some modeling and then you have some sampling, the modeling gets constrained a lot by the sampling. The sampling helps you benchmark or anchor the result and get some better results. It doesn't validate it, you know, everybody says, "All right, I ran the model and then it matches one of our predictions." It's not really validating but it helps anchor.

So these are some of the techniques that have gone on that would have to be considered. But I think one should go cautiously into this effort. It isn't something where one would say, "Oh, well now that we have good biomarker data, we're going to go back and figure out, you know, exactly what source it was." These chemicals -- the biomarker data, it doesn't come with a return address so that --

(Laughter.)

PANEL MEMBER BRADMAN: I wanted to comment a little further in follow-up to that.

You know, I think these -- especially the community-based studies or possibly even a broader study could offer a good opportunity to look at environmental sources. From my understanding, that's not the focus of the legislation. And that if that were to be done, the resources might have to come from outside the program. And I would think actually that, you know, there would be competitive grants from NIHS or EPA and this would provide potentially a great opportunity for, you know, researchers, some of whom are in this room, others elsewhere, who would be interested in, you know, building something on. I think the key concern that I would have as a member of the Panel is just the obvious one - we wouldn't want to divert away from the biomonitoring. But I think there are opportunities here.

Also, there are a number of agencies in California and others like myself who are doing environmental studies. And maybe one way -- one thing useful -- something useful to do would be to look at those studies. You know, for example, we're monitoring chemicals in child care facilities. There's Dr. Morello-Frosch's study. There's other groups.

ARB regularly funds the exposure research in California. And could we use that to perhaps inform some of the monitoring? It could even inform questionnaires,

and then maybe could inform some sort of collaborative effort to try to find a stronger signal between source and exposure.

CHAIRPERSON LUDERER: Dr. Solomon, did you have a comment as well?

PANEL MEMBER SOLOMON: No. Dr. Bradman said absolutely everything I was thinking of saying but much more eloquently.

(Laughter.)

PANEL MEMBER BRADMAN: I got lucky.

(Laughter.)

CHAIRPERSON LUDERER: Dr. Alexeeff.

OEHHA ACTING DIRECTOR ALEXEEFF: Yeah, I just want to make a comment on this point, because, you know, the Program was created as an environmental contaminant biomonitoring program, with the idea that eventually components of CalEPA or various programs could go and address the environmental contamination sources in general; not necessarily specific for individuals, but more in general.

So I think if you could also, maybe not today, but think about these questions in that context as well. In other words, how can we identify general biomonitoring sources of these chemicals that are of concern? Or particularly if chemicals come up that are repeatedly

found, how can we go about identifying general sources of those chemicals?

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Yeah, I guess picking up on Dr. Alexeeff's point - and I guess it sort of falls in the cracks between environmental monitoring and modeling - and that's -- you know, the suggestions that we made for Dr. Krowech's presentation around the intersection of the Biomonitoring Program with the other work that OEHHA is doing, and DTSC, in developing the toxics information clearinghouse and identifying chemicals of concern and, you know, priority products and so forth that contain those chemicals, that we don't have the information yet in terms of, for example, a product registry.

So if we're looking at products being a source of contamination, we don't have that information yet. But, you know, we're moving in that direction. There's certainly interest. And there's an intersection I think that we're going to be able to build here around chemicals of concern and priority products that contain those chemicals that will begin to define a potential universe that would make sense for biomonitoring. And, again, there are researchers, you know, here in the Bay Area at Berkeley who are doing that kind of work.

But I guess I'm just advocating for linking these

kinds of questions about setting priorities and identifying sources with some of the other work that's going on under 509 and 1879 and so forth.

CHAIRPERSON LUDERER: Any other comments, questions, Panel members?

Dr. Solomon.

PANEL MEMBER SOLOMON: I actually -- I don't know if this is an appropriate time to raise this, but there's sort of a different issue that I was hoping to bring up and just sort of make the Committee and the Biomonitoring Program staff aware of. And so if we're sort of done with these questions, I'd love to just raise that briefly, which is -- is that okay?

MS. HOOVER: Yeah.

PANEL MEMBER SOLOMON: Well, in the last few months there have been calls from a lot of community groups on the Gulf Coast who were affected by the oil spill for biomonitoring. And I've been involved in this because I was sort of involved in the initial response to the oil spill. And I think there's some things that we might want to think about here in California, because it's conceivable that if there were some kind of an environmental release, some similar things might happen, and we should think about how this program might respond.

What actually has been happening on the Gulf

Coast, in my view, unfortunately is that individuals and some community groups have begun biomonitoring people for VOCs. These tests are being done now, although the exposures occurred some time ago. And there have been some widely publicized cases of individuals whose blood testing has come back elevated for certain VOCs that are also -- you know, that also happen to be constituents of petroleum.

And so, many people are now claiming that these biomonitoring results have proven that somehow the oil from the spill is still in people. And it's leading to sort of, you know, widespread anxiety and unfortunately sort of an opportunity -- the door is open for these various detox programs and so forth that people are now pursuing.

There are a number of private labs that are providing this VOC monitoring. And it's been actually rather difficult to kind of educate people about the half-life of VOCs in the environment; the half-life of VOCs in the human body; the fact that any VOCs that are being biomonitored now, if one actually believes, you know, these labs are -- and I'm not sure I have a lot of confidence in the results coming out of these labs. But even if one believes those, you know, the likelihood that it's related to the oil is not high -- not high. I want

to make sure that comes out. Quite low.

But there -- from the California perspective, if there were an environmental, you know, disaster or a major environmental release here, biomonitoring is something that people, you know, now know about and they can turn to and they can -- you know, and there would be, I would imagine, a need for our program to be out there quite quickly with some, you know, either providing biomonitoring - and that's something, you know, arguably that could have been done early on effectively in the gulf spill but unfortunately was not - and then also to educate people about sort of, you know, what the appropriate role of biomonitoring is.

And I'm not sure that today is the day to, you know, have this discussion. But since I'm totally embroiled in the middle of this right now in the Gulf Coast and kind of getting slammed by some of the community groups because I'm telling them -- I'm contradicting what they're saying, I just kind of wanted to raise it.

And maybe at some future time we could, you know, have some meeting time to talk about this, because I think that it's -- you know, it's better to have some plan in advance than to be scrambling at the last minute if we have to deal with something like this.

PANEL MEMBER McKONE: I'd like to speak to the

same issue. And partly because -- because there's a panic about radiation, I have to leave fairly soon because I'm doing a whole series of interviews. And I apologize. That's why I've been slipping out. I've been on radio all over the world today.

And what I've learned is, like with the whole incident of people buying up potassium iodine, the fear -- if there were a biomark -- well, there is a biomarker for radiation. There's actually a very good biomarker for radiation. I just hope people don't try and sell it illegally or something, because there is such fear. And anyone here if there were a Biomonitoring Program would probably be, you know, clearing their shelves of anything that would tell them their exposure to radiation.

But the point I want to make is is that -- I think Gina either -- somebody implicitly and some -- well, mostly implicitly -- explicitly raised the issue, should the Biomonitoring Program not only do this but also in a way set -- I wouldn't say standards, not in that sense -- but, you know, set the goals for what's good practice so it's a resource that people could come to?

One of the things I've learned, you know, very harshly is that there aren't very many resources out there where the media and the public can come just to get good basic information. I mean this came up with the oil spill

about what they're exposed to, what it means. And it's going to come up again and again. And, you know, I think we have to -- I agree very much, we have to think about not only doing it but how do we become a resource about how to do it right and how to give information and avoid a lot of misinformation that actually becomes abused, as it is in the Gulf.

With that, I probably have to run.

CHAIRPERSON LUDERER: Dr. Alexeeff.

OEHHA ACTING DIRECTOR ALEXEEFF: Yeah, I just wanted to comment on Dr. Solomon's comment. And, that is, you know, we have a fairly well structured emergency response program in this State. And the three programs involved in biomonitoring are also heavily involved in providing health and contaminant information. So I was wondering when you mentioned this, were you suggesting that we consider -- you know, because we have these various response plans, but we don't have a biomonitoring emergency response plan. And that is something that we could construct.

We could have the folks involved with the overarching -- like for CalEPA emergency response program and work -- you know, have them give a little presentation if we thought it was helpful and then talk about how could a biomonitoring emergency response plan be constructed and

become readily available in the event?

PANEL MEMBER QUINT: It's Julia Quint.

I think that would be a discussion worth having. And I think if we have that discussion, we should sort of separate the mandate of this program and the, you know, meager resources that we have so far to implement this program and to talk about what additional resources would be needed, if we were to, you know, have a biomonitoring emergency response aspect. Because it's different. It's not what this program, as I understand it, was designed to do.

Not that we shouldn't be doing it. But I think we should be clear about -- you know, that that would be additional to this, because otherwise you're raising expectations falsely, because we can barely do what, you know, we're doing now. So I think that would be a very worthwhile discussion given the involvement of the three programs in emergency response, but with that caveat that I just mentioned.

CHAIRPERSON LUDERER: Dr. Das.

DR. DAS: Yes, thank you.

I think they're all really good comments and especially with regard to what Dr. Alexeeff said in terms of the State's response teams. The Department of Public Health and our division particularly has such a response

team and collaborates with CDC. And CDC does have sort of a semi-biomonitoring program geared at emergency response. It's not the kinds of chemicals we're biomonitoring. They're more geared towards other chemicals that are -- that could potentially be used in terrorist-type incidents.

So I just wanted to make sure that any discussion we have factors that existing capacity at the federal level in which we tie into. And our program actually has had some collaborations with CDC to see if we could collect biosamples as part of an incident. Not the Biomonitoring Program but our division, the Emergency Response Program, has been collaborating with CDC.

So I think it's a very complicated discussion and we have to figure -- you know, will depend on what chemicals are being considered and what our capacity is. But I think the point being that there are existing programs that need to tie in. And also it's not our primary mandate but we might be called upon to respond.

PANEL MEMBER SOLOMON: I think there are really two pieces to this: One is, you know, the discussion about, you know, if there were some kind of an emergency, you know, do we have any ability to do some rapid biomonitoring and, you know, for what analytes and how might that work, which I think would be really interesting

to think about. Like, for example, in the Gulf it would have been -- I mean NIHS is now trying to do a cohort study of the Gulf workers. But there's no biomonitoring results taken, you know, early on from those workers. And it would have been great to have had, you know, even a small set of samples back then.

And then the other is the communications piece, like if there are people with a lot of questions about, oh, how can I get biomonitored for these chemicals, what -- you know, is there sort of a how is that -- how would that be dealt with? And I'm not even -- this may be something that needs to be just done by the program without input from our Panel. But if it would be useful to have a discussion, I think it might be interesting.

CHAIRPERSON LUDERER: Thank you.

We do have some time for public comments now allotted. Do we have --

MS. HOOVER: I wanted to also call for any public comment at this point. We had allowed for some open public comment at the end. So on this item or any open public comment.

CHAIRPERSON LUDERER: All right. So so far we have three here. And I think we have about 15 minutes at least, so if people could keep their comments to about five minutes.

The first commenter will be -- I mean this is someone who's present -- Rachel Washburn from Loyola Marymount University in Los Angeles.

MS. WASHBURN: Hi. Thanks for the time.

I just had a quick suggestion about communities to think about in the future collaborating with. Nail salon workers, urban women of reproductive age, Asians who maybe are another population that hasn't been sort of well represented to date and folks who are organizing and I know actually interested in biomonitoring.

CHAIRPERSON LUDERER: Thank you for that comment.

Next comment will be from Davis Baltz of Commonweal.

MR. BALTZ: Davis Baltz, Commonweal.

I was also going to say that, Rachel. And I think the California Healthy Nail Salon Collaborative would be the obvious first point of contact and, too, Koch is, you know, someone who's interested perhaps in seeing what might be possible.

Some other, you know, occupational groups, people who work with cleaning chemicals was mentioned. I think that could be worth pursuing. Agricultural workers would be another one.

But the current studies that are going now, the MIEEP and FOX studies, I agree with some of the comments

that were made that, you know, these are studies that are underway. They're sort of high profile populations that are important for California. And if there's a way to, you know, and with limited resources to build and expand on something as opposed to starting over, I would probably vote for continuing those over adding new ones. But of course they're all important.

I also would like to echo Dr. Bradman's emphasis on children. And, you know, the MIEEP project is working on that. Could we figure out someway to, you know, monitor cord blood on an ongoing basis? I know there's going to be a lot of consent issues and so forth. But I think, you know, those results are going to be very powerful for the public and for people to realize the value of the program.

Fence-line communities. I think - and, Allen Hirsch, you'll remember - a couple of years ago - and some of the staff as well - we did have a plan in place to actually biomonitor some notables in California which included a number of people from communities who were interested in biomonitoring EJ folks. And, you know, we never did go forward with that. But as you recall, people lined up pretty quickly to volunteer. And I think that, and my experience has been, communities are interested in this program, they're tracking it. And when the MIEEP and

FOX studies are published, I think there's a great opportunity there for the program to sort of have a little media splash but also to do outreach to communities and explain what their meaning is and hopefully generate some more interest for the program.

You know, we've got obviously communities here, West Oakland and Richmond, go down to Los Angeles, Vernon Commerce and the Port was mentioned. There's plenty of communities that, you know, would be appropriate to biomonitor.

If we're going to do any environmental media sampling at the same time, I think, you know, if we biomonitor fence-line communities, taking a look at the sofas that people have in their homes and taking a little snippet of the foam could be something that would be interesting. I think there's some pretty -- there's evidence now that if you have an older sofa in your home, the chances are that the dust that's coming off of the materials in that are going to be more ladened with the flame retardants than if you buy a new piece of furniture, although of course they will have it as well. So it could be an interesting additional piece of information.

But I also agree that the primary focus in a world of limited resources should be to keep the biomonitoring going. And if the environmental sampling

can go on at the same time, that's fine, but let's not sacrifice the biomonitoring.

Camp Lejeune in North Carolina has had a spike of breast cancer cases among men. And we have some military bases here in California to sort of follow on to the idea of looking at returning veterans. Maybe there's something going on at military bases that would be worth investigating. And that would probably also need to involve environmental sampling. But that's something to keep in back of our minds.

And then a couple out-of-the-box populations. The County Health Officers, could we convince them to participate in a study or offer it to them, and similarly the California Legislature. I know that came up in the past and it was sort of dismissed somewhat out of hand in part because it would be considered a gift, which would be inappropriate.

But I think if we could biomonitor our elected officials, I think we would raise the profile of the program and could have some very positive effects.

So then I guess the last thing on the emergency response, I think, you know, when Dick Jackson was here, he talked frequently about CDC being expected to respond in an emergency situation. And he had the one example in Mississippi where a pesticide was illegally applied

indoors. It was only supposed to be used outside. And, you know, a panic was about to set in because people didn't know whether their home was contaminated. And the Biomonitoring Program from CDC went in there on short notice and quickly identified the homes and the neighborhoods that there was a problem, put everyone else's mind at ease, and were able to evacuate the people who had been exposed. And I think that one exercise saved something like $50 million.

So there is a role for emergency response. And if something like that were to happen, I suppose, you know, California would go further in debt to pay for it, and it would come out of the General Fund or something.

But I think it is something important to think about.

So thanks for a chance to comment throughout the day. And I look forward to working with you in the future.

CHAIRPERSON LUDERER: Thank you very much.

The last public comment that we have is a comment that was submitted by Email. This is from Sharyle Patton, Commonweal Biomonitoring Resource Center.

And her comment starts out with a question:

"Discussions of possible cohorts for biomonitoring do not include the development of a window

or some kind of entryway, where those communities who have concerns about chemical body burdens might apply to be monitored. This selection I cohorts at this point seems very top down.

"Communities of concern include communities that share common exposures to a specific set of chemicals because of occupation, product use, geographical area, or perhaps communities based on similar health outcome. These would be communities that would approach Biomonitoring California for biomonitoring services and presumably may have access to funding to support some of a monitoring program's components given that lab costs would be covered.

"Dr. Quint's comments suggest that the creation of such a window might be worth doing.

"Will this ever be a possibility?"

Thank you.

Any additional comments from Panel members in response to the public comments or other questions that we've addressed today?

Dr. Bradman.

PANEL MEMBER BRADMAN: Yeah, I think that last comment is worthwhile and important to think about. I think Dr. Culver kind of suggested the same thing and that if there's a way to develop a mechanism to both actively

do outreach but also invite -- if there's some way that people feel invited to come in, you know, we might get more reception of the public and it might really improve the breadth and depth of the program.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I'm on the advisory committee for the nail salon, the California Healthy Nail Salon Collaborative. So I would be happy to work with the Committee and that group in whatever way possible if they're considered.

CHAIRPERSON LUDERER: Okay, great.

Thank you everyone.

If we don't have any more comments from the Panel members or -- are there any announcements that the staff would like to make, anything?

Okay. I just wonder if there's anything else that you wanted to --

MS. HOOVER: Nothing right now.

CHAIRPERSON LUDERER: All right. So I just want to remind you all that the next meeting is going -- that tomorrow we're having a workshop on understanding and interpreting biomonitoring results. And that will be in the same auditorium here at the Elihu M. Harris State Office Building in downtown Oakland. And the start time's going to be an hour earlier, so we'll be starting that

tomorrow at 9, not 10.

And then I also wanted to announce that the next Scientific Guidance Panel meeting will be in Sacramento. And that will be on July 14th.

All right. And with that, the meeting is adjourned.

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 4:57 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 28th day of March, 2011.

JAMES F. PETERS, CSR, RPR
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