MEETING

STATE OF CALIFORNIA

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

JOE SERNA, JR., Cal/EPA HEADQUARTERS BUILDING

1001 I STREET

BYRON SHER AUDITORIUM

SACRAMENTO, CALIFORNIA

TUESDAY, FEBRUARY 9, 2010

10:02 A.M.

JAMES F. PETERS, CSR, RPR
CERTIFIED SHORTHAND REPORTER
LICENSE NUMBER 10063

APPEARANCES

PANEL MEMBERS

Dr. Edward Moreno, Chairperson

Dr. Asa Bradman

Dr. Marion Kavanaugh-Lynch

Dr. Ulricke Luderer

Dr. Thomas McKone

Dr. Julia Quint

Dr. Gina Solomon

Dr. Michael P. Wilson

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Mr. Allan Hirsch, Chief Deputy Director

Ms. Carol Monahan-Cummings, Chief Counsel

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

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

Ms. Fran Kammerer, Staff Counsel

Dr. Farla Kaufman, Research Scientist, Reproductive Toxicology and Epidemiology

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

APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Dr. Rupali Das, Chief, Exposure Assessment Section, Environmental Health Investigations Branch

Ms. Diana Lee, Research Scientist

Dr. Sandy McNeel

Dr. Jianwen She, Chief, Biochemistry Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Mr. Davis Baltz, Commonweal

Dr. Brian Bret, Dow AgroSciences

INDEX

INDEX CONTINUED

PROCEEDINGS

CHIEF DEPUTY DIRECTOR HIRSCH: Good morning. I'd like to welcome everyone both in the room and on the webcast to the first meeting in 2010 of the Scientific Guidance Panel for the California Environmental Protection -- or excuse me, California Environmental Contaminant Biomonitoring Program.

So I'd like to thank the members of the Panel and the public for taking time out of your schedules to join us. This will be a one-day meeting, in contrast to some of our past meetings, which have been two days, but we do have a full day's agenda before us.

My name is Allan Hirsch. I'm Chief Deputy Director for the Office of Environmental Health Hazard Assessment. Our Director, Joan Denton, had been scheduled until the last few days to be up here with you. And you might be interested in knowing that she is in Kings county today actually representing not just OEHHA, but CalEPA at a series of meetings on the reported cluster of birth defects in the Kettleman City area.

Actually, all three of our departments here OEHHA, DTSC, and DPH are going to be involved in some investigations of those -- of that birth defect cluster. And so Joan again is representing CalEPA at several meetings there. So she's doing very important work.

Before we get started, just some housekeeping items. The restrooms, for those who may need them, are you would exit the back of the auditorium, and then they are over to your left. And in the unlikely event of an emergency or a fire drill, we have the exits here are pretty well marked both on the back and the sides, and also exits here at the front of the auditorium too.

We tend to have fire drills in the spring, so this is not fire drill season here. And this meeting is being webcast and we have a transcriber here who is making a transcript of this meeting.

Our last Scientific Guidance Panel meeting was here in Sacramento on October 6th, 2009. The focus of that meeting was to get the Panel's advice on several items, which priority chemicals that the DTSC and DPH laboratories should develop analytical methods for first. We also heard a presentation on the Maternal Infant Environmental Exposure Project, also known as MIEEP. And also you talked about collaboration opportunities with the Kaiser Permanente Research Program on genes, environment, and health.

So today's meeting there will be -- we think it will go until five o'clock. And today's agenda is focused on program and laboratory updates, potential designated and priority chemicals. And you'll be looking at a

proposed new format for the designated and priority chemical lists. And then also you'll be receiving an update on the Maternal Infant Environmental Exposure Project.

And there will be also, as there always is, opportunities for panel discussion and questions and public comment throughout today's meeting.

So basically the goals of the meeting are to update the Panel and the public about Biomonitoring Program activities, obtain the Panel's recommendations on potential designated and priority chemicals, and on the proposed format for those chemical lists, and to obtain the Panel's input on the Maternal Infant Environmental Exposure Project.

So with that, I'll turn the meeting over to our Chair.

CHAIRPERSON MORENO: Thank you Allan.

Good morning, everybody. Good morning, Panel members and staff and public. Welcome to the February 9th meeting of the Scientific Guidance Panel to the Biomonitoring Program.

The goals have been stated by Mr. Hirsch, so I won't repeat them. What I'd like to remind everyone is how we're going to be handling public comment today. If a member of the public would like to make a comment, he or

she can fill out a comment card, which you can get from the staff table outside the room, and I'd ask that you turn in the cards to Amy.

Can you raise your hand.

Thanks.

Amy Dunn will collect those cards and hold them for when we have public comment.

Those that are listening -- members of the public who are listening on the webcast, if you would like to submit comments, you can send an Email to us at biomonitoring@oehha.ca.gov this morning during the meeting, and our staff here will take the Email and take the comments and they'll bring them to us here at the dais and we will share those comments during public comment.

We want to make sure that the meeting proceeds on schedule. And I want to make sure that everyone that wants to provide public comment has an opportunity to provide their comments. So we'll look at how many comments -- how many people want to provide comment and how much time we have for that time during the meeting, and we'll try to divide up the time equally among people who wish to speak.

I'd ask that if you provide public comment following one of the topics presented today, please try to limit your comments to the topic that was just presented.

Thanks.

Also, I'd ask everyone to please speak clearly into the microphone, and also introduce yourselves. That's for the benefit of people who are listening on the webcast, so they know who's speaking. And also for the transcriber so our transcriber knows who's providing the comments.

The materials that the Panel members have are also available for the public. And we have those available here in the auditorium for the public to review, if you'd like. And we will be taking two breaks. Since we got started at 10 o'clock, we'll taking our first break around 12:30 for lunch. And then we'll be taking a short break mid-afternoon. And we'll be concluding at five o'clock.

So that's all I have to share, before we get started on the rest of the program. Before I introduce the next speaker or the first speaker, which is Dr. Rupali Das, I just want to let everyone on the Panel know that I really enjoyed serving on the Panel. And it's been a tremendous honor to chair this distinguished group of researchers. But I find myself these days with significant number of competing responsibilities statewide and back at my county.

So I'm just letting you know that this will be my

last Scientific Guidance Panel meeting. I'll be resigning after -- well today will be my last day. And I really wish I could continue to work with you guys. I've learned a lot, and you've shared a lot with me. And I feel like I've done my best to contribute to the process. And also to Allan and all of your staff, the Department's and the Agency staff have done a fantastic job. It's a real pleasure to work with such qualified and dedicated people to make such progress in the current situation, the economic constraints that we have. It's just amazing to work with you guys, so that's all I want to say.

And with that, I need to hand it over to Allan.

CHIEF DEPUTY DIRECTOR HIRSCH: Well, we at the staff level got some advanced notice that you were going to say this. So perhaps I'm not in as much shock as perhaps some of the other people on the Panel here are. But I just wanted to say that, you know, the first chair of a Panel, and Dr. Moreno is our first chair, you know, tends to have a disproportionate influence on how that panel continues to be run. So, you know, we're very pleased, Ed, that you were able to set a very positive tone for this panel. The Panel, in your meetings, has been very productive. You've been cordial, focused on the science. And, you know, while that's reflection of the Panel as a whole, in particular it's a reflection, again,

of the way that you've run the meetings.

So we have every reason to think that that positive tone that you've set is going to continue on into the future, and we're very appreciative of that. And we also appreciate the support that you've shown for the program as we continue to deal with our fiscal challenges as well.

So, you know, we're sure that you're going to be continuing to be a great advocate for biomonitoring. I think you were a little modest to mention it, but one reason you're leaving is because you're now going to be, is it President or head of the CCLHO, the California Conference of Local Health Officers. So congratulations on that.

And, you know, again, in your future duties, I'm sure you'll be able to -- you will continue to support our biomonitoring efforts here.

Just one minor order of business related to that. We were thinking that probably at the Panel's next meeting on May 24th that that would be a good time for you to select a new Panel chair. You've got a full agenda today. And obviously Ed's news is just hitting you.

So our thought was that for the May 24th meeting, Dr. Luderer has been vice chair in the past and has been acting chair, so we figured we would convene -- if it's

okay with all of you, we would convene the next meeting with Dr. Luderer as the Acting Chair, and then, you know, during that meeting you can select a new Chair. So if that's okay with you, we though that would be a good way to go.

Okay, thank you.

CHAIRPERSON MORENO: All right. Thank you, Allan.

All right. So it's my pleasure now to introduce our first speaker, Dr. Rupali Das who is the Chief of the Exposure Assessment Section with California Department of Public Health, and lead of the California Environmental Contaminant Biomonitoring Program, and she's going to provide us a Program update.

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: Thank you, Dr. Moreno, and good morning to members of the Panel and the audience. I'm going to give the overview of the Biomonitoring Program and several other speakers today will elaborate on some of the issues that I touch on.

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DR. DAS: So I'll be touching on a few issues here. As we saw this morning, our full Program name takes a lot of time and it's difficult to pronounce. So we have

a new public name it's a little bit simpler. I'll be going very briefly over some staff changes, reminding you of the overall program goals; the funding status and how we are dealing with the reality of funding; and then remind you of our objectives under the CDC cooperative agreement and the progress we've made towards meeting some of those objectives.

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DR. DAS: So our new public name is Biomonitoring California. So throughout the presentation, you may here me referring to Biomonitoring California or to CECBP.

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DR. DAS: This slide shows some of the new staff who have been hired under the CDC cooperative agreement. And Dr. Jianwen She who will speak after me will actually go over this in a little bit more detail and introduce the staff, so I won't spend anymore time on this slide.

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DR. DAS: In addition, we have some changes in State staff. Robbie Welling, who is a research scientist with our Program moved to OEHHA. And we are in the process of recruiting a new research scientist to replace her. In addition, Kristin Gottschalk is a research scientist with OEHHA, who will be coordinating the Scientific Guidance Panel meetings and will interact with

you and is working with Sara Hoover on some other issues as well. Kristin, do you want to stand up.

Thank you.

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DR. DAS: So just to remind the Panel of the overall goals of the Biomonitoring Program. They are to determine the levels of environmental chemicals in a representative sample of Californians, either through a statewide sample or through community studies; to establish trends in the levels of these chemicals overtime; and to assess the effectiveness of public health efforts and regulatory programs to reduce Californian's exposure to these chemicals.

In addition, we are also committed to providing opportunities for public participation, in a way that's meaningful and sensitive to the diversity of the California population.

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DR. DAS: The lofty goals of that program, however, meet the fiscal realities. And the next two slides show you the fiscal -- the monetary aspects of the program.

Our core funding comes from the State and is stable at 1.9 million per year for the three departments. The funding source are the Toxic Substances Control

Account from DTSC. And funding is being maintained for this fiscal year 2009-2010. And we anticipate that it will remain stable for the next year 2010-11.

These funds support 13 FTEs at the State level. But we really couldn't get our work done without additional support from staff who are not directly funded through the TSCA funds. And we have the equivalent of about 4 FTE State staff providing support.

In addition, we're very lucky to have fellows from the Association of Public Health Labs, the Council of State and Territorial Epidemiologists, and CDC public health prevention specialists. These staff have been introduced to you in the past, and they're in the room with us today.

And as you already know, we do have mandatory furloughs three days a month that have affected our ability to complete the work. Although many of the staff do work through the furloughs, we're not able to get the same amount of work done. The furloughs are scheduled to end at the end of June of this year.

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DR. DAS: Our second major source of funding is the CDC cooperative agreement, which I spoke about last time. We were successful in obtaining that last year. This is a five-year cooperative agreement. And California

received 2.6 million out of the total of five million available under this grant. The other two states were New York and Washington.

The grant started funding on September 1st. And we anticipate that we'll be submitting a continuing application this spring.

Mark Davis, our CDC program officer, is actually in the room visiting us. Mark, could you stand up. He's visiting for this Scientific Guidance Panel today. And he'll be also visiting the two laboratories tomorrow.

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DR. DAS: To remind the Panel of our objectives that we specified under the cooperative agreement, we had five objectives specified. The first two expand laboratory capability and capacity. We had initially specified that we would complete 13,000 assays per year for up to 14 classes of chemicals in urine or blood. We had requested a slightly higher level of funding than what we got, so that number will likely change.

We also stated that we would demonstrate the success of a quality management system to transport, track, inventory, process, and analyze biospecimens, and to maintain archives.

Third, we specified that we would apply biomonitoring methods to assess and track exposure trends

in selected populations. For example, you'll hear about the Maternal Infant study in more detail this afternoon.

Next, we aim to assess exposures in a representative group of Californians, primarily through archived biospecimens. And finally, we plan to engage and collaborate with stakeholders and communities, especially where we'll be carrying out biomonitoring studies, and to test methods for developing outreach methods and educational materials.

I'll be talking about some of these objectives, and you'll hear more this afternoon as well.

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DR. DAS: Our first two objectives really have to deal with laboratory capability and capacity, and demonstrating success of the lab system. And Dr. Jianwen She and Dr. Myrto Petreas will be talking about that after me, so I won't dwell on that.

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DR. DAS: But there is one item I did want to mention under the labs, and that is method development. The first bullet describes the methods or lists the methods that are currently being developed. And again, the two speakers after me will talk about those in a little bit more detail.

I wanted to just mention the second bullet item.

At the last Panel meeting, members had indicated a strong interest in finding a little bit more about the availability of a biomarker for diesel exposure. And however due to competing work loads and the challenges posed by the availability of a biomarker for diesel - there isn't one currently - we've focused on some of the other methods, but we do plan to address this in a little bit more detail at a future meeting.

I just wanted to let you know we haven't forgotten about your request.

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DR. DAS: The third objective is to apply biomonitoring methods to assess and track exposure trends. And under this, there are three different projects that you've already heard about, but I just want to give you some updates. Our first study under -- or first project under the assessing and tracking exposure trends is our collaboration with Environmental Health Tracking, which was specified as a requirement of the grant. And we are lucky to be working with the tracking folks in our branch as well.

There were two studies conducted under the tracking focus. The first one in Tulare. The Tulare study focused on participants living near orange groves where chlorpyrifos was sprayed. There were approximately

30 individuals involved in that project. Urine is going to be analyzed for a metabolite of chlorpyrifos. There's a short questionnaire that will be administered, and air monitoring was conducted last summer under the first set of testing.

The urine results are not yet available, but the preliminary air monitoring suggests that the levels that were detected were very low. So the Tracking Program is planning to do a second phase of data collection this year, in which participants will be instructed to collect urine samples when they smell chlorpyrifos being applied.

Our second collaboration with Tracking is in Imperial county, where perchlorate was measured in urine and in food sample -- purchased food samples and in water samples. There were 31 individuals who were assayed in Imperial county. They provided 24-hour urine samples, locally grown produce and samples of water and also completed a food diary.

The Tracking Program and Biomonitoring staff are working on developing a method to communicate the results to individuals and to the community, and that will be done this spring.

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DR. DAS: The second collaboration under this objective is CYGNET, the Cohort of Young Girls' Nutrition,

Environment, and Transitions. Just to remind you, this is a study looking at the role of environmental, genetic, and other factors in a cohort of girls who were six to eight years old at the time the samples were originally collected, and continued to receive care at Kaiser. So this is a collaboration with Kaiser in the Bay Area.

The girls -- the clinics rather are in Oakland, San Francisco, and in San Rafael. So the samples were initially collected in 400 girls and they're continued to be followed every year. And our labs will be analyzing some of these samples for chlorpyrifos. I'm sorry. I lost track.

I'm sorry. We're starting with metals. We were suppose to do chlorpyrifos, but because we needed to coordinate with some of the other centers in other parts of the country, who are not planning to analyze chlorpyrifos, that's on hold. We're planning to analyze metals in blood for this cohort.

The PI for this study at Kaiser is Dr. Larry Kushi, and we are in the middle of almost done with completing the MOU with Kaiser.

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DR. DAS: Our third collaboration is on the Maternal and Infant Environmental Exposure Project, which you'll hear about in great detail this afternoon, so I

won't say too much about it. But just to remind you, this is a collaboration with UCSF, University of California, San Francisco, and UC Berkeley.

And the sample -- we're in the middle of developing the methods and running all the protocols and instruments through our Institutional Review Board. The materials have been submitted to the UCSF Institutional Review Board and will be submitted to the California Department of Public Health in a couple of weeks. You will be hearing a lot more about this this afternoon, so I'm actually not going to say too much more about this at this point.

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DR. DAS: A fourth collaboration that you haven't actually heard about, that I wanted to update you on, is something that was related to an issue that was raised at the last Biomonitoring meeting. The Panel members expressed an interest in having the Program look at some occupational cohorts.

And so we identified firefighters as a group of workers who potentially could be exposed to a lot of the chemicals of interest to the Biomonitoring Program. And so we had initiated conversations with Contra Costa County. And we were very encouraged -- our relationship was with the physician for the fire department. And we

were hoping to conduct a pilot study of 50 firefighters, looking at the analytes that are listed in blood and urine. This was to coincide with their annual physical, so it would have not involved -- the sample collection would have been pretty easy.

In addition, we had proposed environmental sampling in three fire houses for flame retardants and perfluorinated chemicals. However, unfortunately over the weekend we got news that this is on hold for right now, because the management at the fire department didn't support this going ahead. We are still trying to find out if we can have this go forward. But unfortunately, the news isn't as good on this particular collaboration as I wish it was.

But if this one doesn't work out, we are pursuing other collaborations, either in Contra Costa county or with other occupational groups. I can see there are some questions, but would you like to ask --

PANEL MEMBER WILSON: Keep going.

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DR. DAS: You can ask them at the end.

A fourth objective is to assess exposures in a representative group of Californians.

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DR. DAS: And under this objective, since we

don't have the funding to collect -- actively collect samples statewide, we have explored the feasibility of collaborating with researchers who have already collected samples and are looking at stored biospecimens and trying to perfect the storage -- looking at the utility of biospecimens for analyses, looking at ways to obtain them, store them, analyze them, and developing appropriate sampling strategies.

Some of these collaborations have been mentioned very briefly at other meetings.

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DR. DAS: Some of the ones that we're exploring now are a collaboration with the Genetic Diseases Branch of the Department of Public Health. We have met with them, and we learned that late last year, the branch actually received some stimulus funds to help automate their biobanking procedures for newborn blood spots and maternal serum.

This will facilitate tracking, handling, and retrieval of specimens and will enable web-based tracking system to link multiple data sets, including vital statistics, birth certificates, death certificates, et cetera that the genetic diseases branch has been collecting for a long period of time.

So our access to these specimens will require us

to develop methods to analyze newborn blood spots. This is also an area that both CDC and the Association of Public Health Labs supports, as well as maternal serum samples, but those samples are -- the samples that we will have access to are very small, one milliliter samples, so we'll have to develop some methods to be able to analyze smaller aliquots.

In addition, at the last meeting, you heard from Dr. Stephen Van Den Eeden, who described Kaiser's research program on genes, environment, and health. And we've had some additional meetings with Dr. Van Den Eeden to push this collaboration further. And we are very encouraged that we'll be able to piggy-back on some of their new specimen collection efforts, in addition to taking advantage of the vast biobank repository that Kaiser is able to maintain, because of their large patient population.

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DR. DAS: Our final objective is to collaborate with stakeholders and communities.

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DR. DAS: And we are accomplishing this objective through a contract with Health Research for Action in the UC Berkeley School of Public Health. This has a particular emphasis on activities relevant to targeted

biomonitoring investigations. Most relevant is the maternal infant project. And you'll hear actually more about this collaboration this afternoon.

We also plan to have a primer brochure that's a description of biomonitoring in general for the public, that's not focused on any particular investigation. We hope to have that starting to be developed and pilot tested this spring with the brochure ready for the public hopefully in July.

In addition, Health Research for Action will provide us some comments on the Program website, and suggest ways to improve it and post materials on the website.

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DR. DAS: So to summarize, I've just gone over our five objectives that we specified in the CDC cooperative agreement. This shows you that this cooperative agreement has really allowed us to leverage the resources that the State provides and accomplish a lot through laboratory collection of urine and blood, and also analyzing archived biospecimens through collaborations with multiple programs.

And we hope to continue to expand our net in terms of collaborating with researchers both who have collected biospecimens, as well as to collaborate with

other groups to actively collect specimens.

And this is very encouraging, but we will also need to continue to find resources to assist us, particularly with active collection of biospecimens.

In addition, the active collection of biospecimens will involve questionnaire administration and results communication. That also will require additional resources for each population that we look at.

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DR. DAS: And at this point, I'm happy to take your questions.

CHAIRPERSON MORENO: Thank you, Dr. Das. Questions from the Panel members?

Dr. Wilson, you had a question.

PANEL MEMBER WILSON: Thank you, Rupa. That was really interesting and informative. And I'm just -- I had a question about the firefighter study with Contra Costa county. A couple of things, if that was initiated by -- you know, by the State Health Department or did that come from either the union or management within the county?

And I'm just, you know, curious if you could just describe a little bit more about what happened and why that was derailed, if there's anymore information on that.

DR. DAS: The collaboration was initiated by us. It was -- firefighters are a population that has been of

interest for some of us in the Biomonitoring Program, because of their potential for exposure and because occupation ties into other interests that we have in our division.

And we knew of the physician who's the fire department physician. We've worked with him on other occupational issues related to firefighter screening. And he was very supportive of the collaboration as was the clinic manager, and initially some of the administration. But the decision to not let this go ahead at this time was one that was made at the top management level in the management side of it. It was never actually brought to the union, because our connection was through the physician, and the physician was sort of making the contacts. So that's, I guess, a summary of the course of events.

We're not -- we're hopeful that this may go forward, that it's not completely off the table. And one of the possibilities is that it may not be possible this year, but it's something we might want to revisit next year.

This time to do this study was particularly opportune because of availability of some extra funds that actually are separate from the two funding sources I described to you, as well as the firefighter physicals, a

lot of them coming at the same time, which would have allowed us to get a lot of the specimens in a short amount of time.

So this was a good time to do this. And if it doesn't go forward, because management doesn't support it, it doesn't mean that it's completely off the table. Both the physician and the clinic manager are supportive of pursuing this in the future, if it doesn't happen this year.

PANEL MEMBER WILSON: If I could just follow up briefly. I mean, you know, my experience, and also working with the San Francisco Fire Department on a respiratory exposure project, you know, has been that the management tends to be cautious in these kinds of questions, because it opens up potential workers' compensation issues and so forth.

But I think it's -- and I'd be actually happy to help you with this. That if they have a good understanding of what it is that the project entails and what its goals are and so forth, that it's not derailed completely, I guess I would suggest.

DR. DAS: Well, we would welcome any input you could give us and any assistance you could give us in moving this forward.

PANEL MEMBER WILSON: Yeah. Sure. Great. Thank

you.

CHAIRPERSON MORENO: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I'm also interested in the occupational cohorts that you're considering and some of the criteria. You mentioned the firefighters, and I think they are an interesting group to study. And you mentioned some of the reasons, you know, ease of sampling and the connections you've made. In terms of interventions, depending on what you find, I'm not sure if the exposures are occurring as they're fighting fires or whether or not some of the exposures are just from their surroundings et cetera.

But I'm interested in what you've -- some of the other possibilities that you're considering, because I know that it's a group that is important, if you can manage it, to study. And the potential for interventions, in terms of exposures and standard setting and all of that are -- you know, offer a lot of unique possibilities. So could you just say something about some of the other cohorts?

DR. DAS: Yeah, you raise very good questions, in terms of firefighters. Is their exposure coming from the fires or is it coming from general environmental exposures? I'm not sure that what we had planned would have been able to definitively answer that. And it really

was a convenience. I mean, you know, we were particularly interested in firefighters as an occupational group, but the sample collection really was partially because of convenience.

We are very limited in funds and resources. And so whatever we choose has to sort of fit in this -- has to be doable within our resources. But the other occupational groups that have been considered are hazmat workers. In addition, people have expressed an interest in other groups of workers that would be more difficult to reach, because they're not -- they may not be unionized and may not have -- we may not have the connections.

For example, janitors and cleaners was one group that was mentioned. Foam workers were another group that was mentioned. Recycling, E-waste recycling workers were mentioned.

Those were the main groups that we have entertained very superficially, but have not made any overtures to reaching out to recruit those, because we're focusing on firefighters. And as I said, we just heard about the latest developments this weekend.

But in the future, you know, we would appreciate some guidance from the Panel, both where to focus on, in terms of the groups of workers, but also how to access workers. And we feel that we would like to access a

unionized workforce. Although, we understand that the non-unionized workers often have the highest exposures in their jobs.

CHAIRPERSON MORENO: Dr. Wilson, you have another comment?

PANEL MEMBER WILSON: Just following up on Julia's comment. You know, from my experience working in the fire service, there is a really important question that I think this would begin to answer, and that's the exposures that occur at structural fires, where firefighters have removed their self-contained breathing apparatus and are inside the structure overhauling the building, finding hidden fires and so forth. And during that period, the products of combustion are still present and material is continuing to off gas and smolder. And from environmental sampling data, there's evidence of, you know, very high levels of exposure that occur during that period.

And the problem has been that we haven't had good information on firefighter exposure, and that solutions like air purifying respirators don't allow filtering of carbon monoxide. And so there's been this worry that firefighters wearing APRs during overhaul would be overconfident in the safety of those devices, and could be carbon monoxide poisoned.

And so the fire service has tended to default back to the use of self-contained breathing apparatus during all operations at a structural fire, but it's impractical, because of just the weight and bulk of that, you know, of that level of protection just comes off.

And so I think this -- you know, for that population, this is an important project that could be -- that could lead to an important intervention. And the second, I think, sort of source of exposure that's important in the fire service is diesel exhaust from the stations and from all, you know, various operations around the equipment.

DR. DAS: Right. Regarding diesel, the physician was interested, and actually expressed an interest in having a biomarker for diesel. So I think there is a lot of interest and awareness that that's an exposure that could occur.

And as you mentioned, the time when firefighters aren't wearing their equipment, it was one of the reasons we felt that they might be exposed to products of combustion.

PANEL MEMBER WILSON: Right. Thank you.

CHAIRPERSON MORENO: All right, if it's okay with the Panel, I want to open it up to public comment and then we can bring it back to the Panel after that for any

recommendations the Panel may have for staff.

So is there any -- Amy, were there any comments?

And were there any Emails sent in?

Our first speaker is Davis Baltz with Commonweal.

Good morning.

MR. BALTZ: Good morning, Dr. Moreno, members of the Panel. Davis Baltz with Commonweal in Bolinas, California.

I'd like to just start out, Dr. Moreno, and thank you for your service as Chair of this Panel. I didn't know that you were going to be stepping down. But in my experience of monitoring this Panel as well as experience with a number of other scientific review boards, I'd like to just make the observation that this Panel has really worked very well together, been very cooperative environment, and you've gotten a lot done, and you deserve a lot of credit for that. So wish you all the best in your future endeavors.

And I'd like to thank Dr. Das for the staff presentation, current updates on the Program, and I'd like to extend my thanks to the staff as well for the accomplishments that the Program has been able to make in this difficult economic environment, with the limitations of State funding to have been able to marshal additional funding and keep the Program moving forward on multiple

fronts. It is a job very well done. As a member of the public, I'd like to thank you for that. Working through furloughs and landing the CDC cooperative agreement is a real accomplishment too. And Mark Davis I know was introduced.

And so as someone who supports biomonitoring and its value for public health, here in California we're very grateful to CDC for their support.

Dr. Das mentioned, I was glad to see, sort of a reaffirmation of a number of the key objectives and goals of the Program. And the first couple ones related to the scientific integrity of the data that you will be producing. And that's very important. I think we've all understood that biomonitoring data can be very valuable, but it must be unassailable. And this Program is taking the steps through development of the laboratory capacity and the data management -- quality data management to ensure that when data is produced everyone will have confidence that it does reflect accurate exposures that Californians are being exposed too, which will then, as we know, enable subsequent conversations on what we should do with this data which we have confidence in.

I was also pleased to see the reminder that another set of activities that is important for this program is the community participation. And, as you know,

I've tracked this program from its beginning. And because of funding constraints, we haven't necessarily gotten to a point where there's a lot of opportunity for the public to weigh in. But I can tell you from my own work that people are watching this program carefully and are very eager to see and use the data when it does become available, and to start to provide input at appropriate times.

Your community studies in Tulare county and Imperial county, for example, one of the requirements of the program is to provide the opportunity for people to receive their results. And as someone who's been biomonitored myself, as well as my colleagues at Commonweal, I think, you know, we and other civil society actors would be happy to provide some comments on making results communication effective.

Similarly, the occupational cohorts, which were touched on, I was disappointed to hear this recent development with the firefighters, and glad to hear that Panel members would like to see the program continue to move ahead with that.

Other occupational cohorts were mentioned. I think, you know, the foam workers certainly could be one that I would be interested to see pursued. And similarly with the firefighters, one of the reasons is to tackle this thorny issue of exposure to fire retardants. We have

this sort of bizarre and unique situation in California where the Technical Bulletin 117 is likely exposing Californians to far higher levels of these substances than elsewhere in the country. At the same time, we have no evidence that we're preventing fire deaths by using these chemicals. So this is an activity of the Biomonitoring Program we'd really like to see move ahead, again on top of fire retardant exposure in California, and how it differs from national exposures.

So I expect I'll have a chance to comment again. And thanks again for the chance.

CHAIRPERSON MORENO: Thank you. We have -- that's it for the public comment, the people who are present. We have one Email that was sent in, and it's a question. This is from Tim Shestek, Senior Director, State Affairs, American Chemistry Council in Sacramento.

The question is, "Is there an update on the Program Report to the legislature that is required by the enacting statute?" And I understand that he may be referring to the legislation -- or the statue requires that the Biomonitoring Program issue a report to the legislature. So if you wouldn't mind providing an update.

Thank you.

DR. DAS: The report has been delayed, partly because of the furloughs. And we expect that it will be

released shortly, but it was supposed to be out to the legislature on January 1st with a requirement that it be release to the public 30 days after released to the legislature. So it hasn't yet gone to the legislature. We would expect that that will happen soon, and then 30 days after that released to the public.

CHAIRPERSON MORENO: Thank you. I'm sure you're working hard on that, so thank you for the update.

Okay. That's it for the public comment. I want to bring it back to the Panel members. This is again the presentation by Dr. Das. Any further discussion or recommendations to Dr. Das?

Dr. Luderer.

PANEL MEMBER LUDERER: Can everyone hear me?

I also wanted to actually thank Dr. Moreno for his excellent leadership of the Panel since its inception. And I think you've done a really amazing job of making sure, you know, that all opinions are heard, and also at the same time keeping us on task and moving through the scheduled -- through the schedule. So thank you very much. We'll miss you. I think I speak for most of the Panel.

And then I also wanted to applaud the idea that you have been pursuing the occupational cohort study. And I was also very sorry to hear that there are some issues

with it moving forward with the Contra Costa firefighters. And I really agree that there are many questions kind of remaining regarding firefighter exposures, some of the things that were talked about, exposures during knockdown, when less respiratory protection is often used, and also the potential in California for firefighters having greater exposures to flame retardants, which is a class of chemicals that's of great interest to the Panel as we've discussed at other meetings.

I wanted to suggest maybe whether you've considered the possibility of exploring collaborations with other firefighter cohorts. Just one suggestion might be the, that I'm familiar with, the Orange County Fire Authority, which is the fire authority that provides fire fighting services for most of Orange County in southern California. Actually, it already has a relationship with the University of California, Irvine, where every three years, 700 to 800 firefighters undergo wellness fitness examinations. And so this might be an opportunity to explore the possibility of a collaboration. So if you are interested, I can put you in touch with a physician whose the medical director for that.

DR. DAS: Yeah, we'd be interested in finding out about other potential collaborations and at least initiating the conversation, so that when some -- when is

an opportune time and some funds become available, then we are ready to move and study the -- or, you know, collaborate with that department. So I think that would be very helpful.

And just to let you know in terms of other fire departments, we had considered also the San Francisco Fire Department and didn't pursue it at the time. So we're not tied to Contra Costa county. We're willing to collaborate with other departments as well.

CHAIRPERSON MORENO: Dr. Wilson.

PANEL MEMBER WILSON: Mike Wilson. I guess I would just say that I think we appreciate the problem of accessing groups of workers that are not unionized, and that, you know, this issue came up is that are there other cohorts that we might -- that would be of interest. And I think, you know, there certainly are. And, you know, our experience at COEH has been essentially -- you know, it's just been -- the choke point has been access. As they're, you know, a non-unionized group of workers, it's just extremely difficult to gain access to those work places for these kinds of purposes in particular.

And, you know, you mentioned that -- and I guess I'm just stating that I'm sympathetic to that challenge, and that the fire department has a long tradition of unionization and, you know, fairly constructive labor

management relations as a consequence over many years. And so it's a stable cohort in that way, and a stable -- sort of -- there's a means of access that's accessible there that's not accessible in many other places of employment.

DR. DAS: Yeah, I appreciate those comments. And also because this program is in its infancy and we really want to demonstrate success and pilot test methods that can be applied to wider population, given our resources to reiterate what you said, I think it's really important for us to initially at least access all populations, including worker populations, where things are in our favor and they're easy to access and then to broaden it out to harder to reach non-unionized work forces, so that we can demonstrate success in all the different ways that I discussed.

CHAIRPERSON MORENO: Okay. Are there any other comments, recommendations by -- yes, Dr. Quint.

PANEL MEMBER QUINT: This is just a comment. I wanted to echo -- Julia Quint -- echo Mr. Baltz's comments about the program in general and the great success that you've managed in spite of work furloughs and, you know, getting the extra funding from CDC, you've really kept this program alive and relevant. And I just congratulate the staff and the departments on the excellent work that

you've done. I think it's been, you know, tremendous. So I just wanted to make sure that you knew that the Panel -- I'm sure you know this -- appreciates all of the effort.

Thank you.

DR. DAS: Thank you, Dr. Quint. I really appreciate that. And I want to say that I'm just a representative of the program here. But we have many great staff who are actually doing the work and the credit goes to all of them. And I also want to say too just to -- especially for Mark, since he's our program officer, that the CDC staff are not subject to furloughs.

(Laughter.)

DR. DAS: Don't worry, Mark.

(Laughter.)

CHAIRPERSON MORENO: All right. If there are no further comments or recommendations, Dr. Das I just want to maybe add two things. One is that I believe it's appropriate -- it would be appropriate for Panel members to continue to think of ideas and contacts for occupational cohorts and share with you.

And the other is just to let the Panel know if there's anything that we can do to assist you in further discussions with the Contra Costa Fire Department.

DR. DAS: We really appreciate that.

Thank you.

CHAIRPERSON MORENO: All right. Thanks.

Would you be so kind as to introduce the next speaker.

DR. DAS: Yes, we have two speakers from the laboratories. The first speak is Dr. Jianwen She. He's the Chief of the Biochemistry Section of the Environmental Health Laboratory Branch in the California Department of Public Health. And I will also introduce the speaker who will follow him, Dr. Myrto Petreas who's the Chief of the Environmental Chemistry Branch in the Environmental Chemistry Lab in the Department of Toxic Substances Control.

(Thereupon an overhead presentation was Presented as follows.)

DR. SHE: Thank you very much, Rupa for your kind introduction.

Good morning, Panel members. I'm happy to be here to report on our progress. Two major events happened during the last six months after I reported in July in 2009.

As you know, CECBP was awarded by CDC for $2.65 million to expand the laboratory capability and the capacity. And at the same time, CDC released a fourth report on human exposure to environmental chemicals.

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DR. SHE: Today, my update will focus on four areas. First, new staff and training; lab set up and the method development. As you heard before, everyone is concerned about quality, so quality assurance, of course, and also our collaboration with other partners.

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DR. SHE: With the CDC grant, we are able to hire four new staff. And also we plan to hire two more scientists and one laboratory information management specialist. I'm excited to introduce our new staff.

As I say your name, please stand up.

Shirley Cao. She's our new hired Quality Assurance Manager. She has more than nine years experience in quality assurance.

Yangzhu Long. Yangzhu is a Clinical Laboratory Scientist. She will be responsible for biorepository, set up, and sampling, and logging the materials.

And Dr. Sen. And Dr. Sen just graduated from UC Santa Cruz got Ph.D. in Biochemistry. He has been working in the inorganic section for the metal analysis.

We also hired Josephine, and she's busy in the lab. She's not here today. And she got her BS one year ago from San Francisco State University. She will also work in the inorganic section for the metal analysis. Right now, she's helped to develop a method to do

creatinine analysis.

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DR. SHE: All the newly hired staff we are sending to CDC for the trainings. For example, Shirley will be trained in the quality management areas. Yangzhu will be trained for biorepository, sample and standard handling, and materials screenings. And Dr. Sen and Josephine will be trained for method development. Of course, all of the new hires will get extensive in-house extensive training.

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DR. SHE: Last year, EHRB was able to establish organic lab from almost empty space, so you can see from the photograph. Actually, that's only a portion of the lab. So this actually is really a functional labs right now. We use it to develop the method for organic analysis.

Currently, with the CDC grant, we are expanding into two new laboratories. At the same time, we also are in the process of purchasing new equipment and sending people for further trainings.

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DR. SHE: CDC released its number four report. Right now, CDC's capacity can cover 212 analytes. As you can see from the graph, CDC grew from 2001, the first

report, 27 up to right now they can do eight times more. So the State program is still at its very beginning stage compared with CDC.

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DR. SHE: So come to the method development. We are able to finish two methods in the last year's timeframes. We finished the metabolite analysis trichloropyridinol for the chlorpyrifos, and 3-phenoxybenzoic acid for permethrin metabolite. We also finish a high throughput for metal panel analysis. We are able to analyze six elements right now.

All of the methods are through very strict quality assurance, quality control procedures. We run 20 runs as are required by CLIA.

Our number three method is phthalate metabolite. Right now we finished 13 batch of a run. We hope the method will be ready in April.

The last method we encountered some difficulty. This is also a method, compared to the other three, required more sensitivity. That's in PPT range. Other method occurred in PPB range.

So right now, we are collecting the validation data. And I hope the method will be ready in May this year.

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DR. SHE: What happened to Toyota we do not want to happen here.

(Laughter.)

DR. SHE: We don't want to have our data recalled. So those events reminded us of the importance of the quality assurance. So quality assurance include quality control and quality assessment. So my focus will be more focused on the quality assessment.

For example, we have three levels of QC run with each batch of samples. So we construct quality control charts over the long times to see the trend or the spike in our quality.

We also participate in an External Quality Control Performance Assessment Program. And we purchase reference materials, if it's available, to assess our qualities.

We are very happy to have from CDC Mr. Mark Davis. He give us a lot of samples in the last few months. We're able to run what CDC runs. And also, we get some samples from New York State to do inter-laboratory validations.

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DR. SHE: This is one example of our quality control chart on the lower level. We have three levels of quality control materials. This is QC low on the TCPy in

urine. For the 24 runs, you can see our quality control chart demonstrated we're able to get the accurate numbers which is the mean, and also how much we expect. And then also on the variations, that's a standard deviation there.

This simple graph took us almost three or four months, because that includes many samples running, 24 batches. Each batch can run like two, three days. Each batch included calibration standards, and then blanks, under the quality control materials. Each batch will go through a very detailed sample preparation and analysis procedure.

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DR. SHE: This is not good graph.

This is our inter-laboratory calibration graph. It's dark. You can see compared with the CDC, this X axis Is a CDC result. Y is our lab result. The two labs' correlation is excellent on the lead, blood lead analysis. We also did other analyses. This is one example.

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DR. SHE: So now we are ready to use our methods. The first two methods we used for the -- one is for the study Rupa already mentioned for Tulare county. We're able to analyze some samples for the TCPy's. We are not finished, because we still need to finish creatinine and then further cross checking with CDC on our data.

We also finished the 30 pilot samples for the CYGNET, which was shown in the previous graph.

With the collaborations, we're able to sign one MOU with the CHAMACOS studies, and then another two MOUs, one CYGNET and with UC Davis is still under review.

I want to thank Robin and Diana for the draft of these MOUs and also your hard work on them.

Thank you very much.

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DR. SHE: I'm ready to answer questions if you have any.

CHAIRPERSON MORENO: Would the Panel like to ask questions now or hear from Dr. Petreas first?

PANEL MEMBER WILSON: I have a question.

CHAIRPERSON MORENO: We'll take some questions.

Dr. Wilson.

PANEL MEMBER WILSON: Thanks very much for that presentation. And congratulations on your R squared of .99 with 30 samples. That's an accomplishment in itself. And I'm just curious if you could describe the three quality control measures. I think you described one being -- or maybe they're all blanks. And my question is if there's -- if you're running reagent blanks to ensure that there is not contamination from laboratory materials?

DR. SHE: Yes. And for the alternative analysis

at so low levels, background contaminations from lab environmental is very important issue we needed to avoid. For example, for some chemicals we do have the reagent blank, especially like the phthalate, because industry used it so much. And BPA, these are two chemicals laboratory have analyzed, heavy blank issues compared with others.

So we do need it to run all of the reagent blanks, chemical blanks to see where is the source. And on the other hand, we also tried to develop a technique able to separate this blank contribution from real samples. For example, we used pre-columns on the HPRC's before we analyze the samples. Any contribution from the solvent, you know the HPLC system will go through two columns. Our sample where it goes through only the second column, so which means the contribution, for example, for the BPA will elute the HPLC much later than the real samples. So you get a separation.

So we run the blank to look at the blank issues, and then we try to set up the technique to avoid the blank contribution.

PANEL MEMBER WILSON: And was that one of the quality control measures. And were there two others?

DR. SHE: There are many quality control measures. For example, also the calibrations. There's a

lot of instrument calibration. For each run, we needed to run seven calibration points to make sure our calibration is good.

And quality control, as you know, is a big assistance. There are more than three points. And then we also needed to control our standards. With daily check of the standards, we tried to, if possible, tried to purchase at least two standards from different sources for the comparison. We look for the response factor of each standard, and then we also look for relative response of the standards.

For this method, we'd like to see the relative response of the standards goes through the clean-up procedure. We still get relative response near two to one.

And there are other procedures.

PANEL MEMBER WILSON: Thank you very much.

CHAIRPERSON MORENO: Dr. Bradman.

PANEL MEMBER BRADMAN: I just want to comment on a point, in terms of QA/QC. And also just to confirm that we signed our MOU with Jianwen She this morning. We wanted to get it done by this meeting to look at phthalates in 50 urine samples from children participating in our study.

And also just to emphasize, and I know you're

thinking about this, but to kind of go on the record, the importance of field blanks as part of the QA/QC. And you know, I'm sure that you've thought about this, as part of these collection programs, including the CYGNET and Tulare study. I think it will be important to include field blanks to make sure that we're not, you know, introducing any contamination as part of the collection process. And I think that the comments from the Dow AgroSciences people kind of highlight that. And that is an important component of field research.

And I should mention in our collaboration, we'll be able to produce, you know, field blank samples that were collected -- blank samples that were collected exactly according to the procedure that we used to collect our unknowns, so we'll be able to determine whether there's any contamination from the collection process. But that's an important piece of this program, and I know you're thinking about it.

DR. SHE: Yeah. Thank you, Asa. That's a very good comment. With today's instrument you can detect very low levels. But what's happened garbage in, garbage out. So the field sample controlling is very important to control overall project qualities.

So I didn't run CYGNET. Dr. Frank Barley did that. So I'm not sure it provided fair blank samples.

But for Tulare county, we did collect the blank samples and then we run it.

CHAIRPERSON MORENO: Okay. I'd like to -- there might be more questions by the Panel members at this point, but we do need to move on to a presentation by Dr. Petreas. I'm going to leave enough time for Panel members to ask questions of her as well.

DR. SHE: Thanks.

CHAIRPERSON MORENO: Thanks.

(Thereupon an overhead presentation was Presented as follows.)

DR. PETREAS: Good morning, Panel members. So this will be the update for the DTSC laboratory. You may remember that I have shown this slide last time we talked about a year ago, showing what was the expectation, where would we be at the end of the year, 2009. And I had asked the question from the Panel to give us direction on which way we should go.

Given our resources, we could only do either of the two. Either continue with the persistent organic pollutants, the PBDEs that we were already doing and add the new BFRs in blood, or change course and do the perfluorinated chemicals, which would involve new territory for us, new instruments and new mode of action.

We had factored in the furloughs and the

numbers -- the adjusted numbers in red where by the end of the 2009 -- December 2009, we'd be able to do either 640 odd samples of blood for PBDEs and BFRs or a few more, 800, of the perfluorinated chemicals.

And I didn't get any clear direction, which was better for us, because we continued by inertia, and in a way tried to accomplish both. So I'm happy to say that we can tackle both methods with some adjustments. So we continued with the POPs, but we dropped the new BFRs. We had developed methods for two of them. We encountered some difficulties with the third one. And at that time, we stopped the development for BFR methods and we focused all our attention to the perfluorinated chemicals, and now we basically can do both almost.

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DR. PETREAS: And more specifically, the stats of method validation -- and I'm very happy that Jianwen described all the QC issues, so I Don't have to go into too much detail here.

But for the PBDEs, we were doing this series of chemicals in a different way before, but we transitioned -- after having trained staff at CDC, we transitioned and adopted the CDC methodology, which involves a high resolution mass spectrometer. So that part is done.

We're having a little trouble with the automation modules, which are also part of the CDC method. We're not very happy with their reliability. And given that we deal with like one milliliter of sample, we can't afford to lose anything. And we have some bugs. If we're working with the vendors to improve that, and we're testing against our manual method, which apparently is much more precise and more accurate and more reliable than the automated one. But we have high hopes, because we need the automation to improve our throughput.

In the meantime, we continue with sample analysis, so we can produce data on PBDEs using a hybrid of high resolution mass spec in the end, but using our manual processing before that.

For the perfluorinated chemicals, we did adopt from scratch the CDC methodology, because we didn't have any. This involves liquid chromatography which was new for us again. So far, given what Jianwen described in terms of quality control and charts and blanks and calibration, all our internal validation criteria have been met.

So these are all the 20 or so batches. And we're very happy. We're undergoing external validation. In the first round we did with a material that CDC sent us, we underestimated. So we want to see why. And for that we

requested to get a standard from CDC to see whether our standards are off. And at the same time, we're getting material standards and blood from our colleagues in New York State and Sweden, who are more experienced than us in PFC analysis -- in perfluorinated analysis. So with this feedback, we hope to be, you know, very soon be able to produce data.

We have our standard operating procedure drafted and in review, and we should be able to do something soon. And I want to credit our two staff. We only have two staff, remember, funded for this program. And Yunzhu Wang on the left has done all the work with the PBDEs. And Dr. Miaomiao Wang has done the PFCs. So we're really grateful for their work.

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DR. PETREAS: I also want to show our Fellow. APHL, Association of Public Health Laboratories, gave us a Fellowship. And we hired Dr. Harwani, who's been really valuable. You know, he's worked with the other staff on method developments in blood. He's been with us for almost a year and a half. And his Fellowship ends in June. We really want to get another Fellow, because really adding one person to the two makes a big difference. It's very valuable, and we hope to get another Fellow after that.

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Now, in addition to the two --

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DR. PETREAS: -- funded staff, we have other DTSC staff working on serum, not directly related with the program, but our experience in those areas gives indirect benefits to the Program.

So we have been collaborating for a long time with extramurally funded epidemiological studies who gave us access to specimens from California, in particular. And we have produced data on perfluorinated pesticides, PCBs, PBDEs, and then the metabolites of PCBs and PBDEs, phenols, including triclosan. And we have data on those.

I will talk a little more about the small pilot funded by UCSF on pregnant women. And we have produced data PBDEs and try to do also PFCs on those. And I'll get back to that now.

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DR. PETREAS: Another type of work I want to mention outside of serum work, at DTSC for other projects, we have developed methodologies for household dust. And we can measure PBDEs, PCBs, and plan to do also the new BFRs and the perfluorinated chemicals in dust. We have some preliminary data and are very very excited.

We also have a pilot Cat study in collaboration

with a veterinarian. Cats near the ground, they groom themselves. And again, our very preliminary data show very, very high levels in cats, which is interesting. And we can use them maybe as sentinels for environmental exposures.

We also look at plastics from consumer products to even plastic debris in the ocean, because this is a different idea of thinking how plastics serve as -- can absorb chemicals or can decompose and release chemicals in the environment, which give us a better handle on exposure assessments.

So should the program want to go into an exposure assessment, these are ideas we can work and incorporate.

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DR. PETREAS: Now, as far as the UCSF pilot study, this is in collaboration with the Dr. Woodruff and Zota from UCSF OBGYN. They gave us 25 samples from pregnant women. We did 18 of them so far, because we needed to catch a deadline for a proposal they wanted. And we only reported PBDEs so far.

And as you can see, our mean PBDE level is more than twice the NHANES geometric mean. So again, it confirms that Californians are higher than the rest of the country.

So to put this in perspective, I have a graph I

can show.

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DR. PETREAS: I don't have a pointer unfortunately. So these are data from serum from California women we have done over the last few years. And if we start from the complete left, basically you see nothing, because there was nothing measurable. These are samples for the 1960s. We did over, you know, several hundreds of them. And there was no PBDEs.

I'm only showing BDE-47, the most prominent of the PBDEs here, just as an example. So back in the sixties it wasn't present. And the next time we saw it was samples collected in the late nineties. These were Laotian immigrants to the Bay Area. These were reproductive-age women. And this is the second bar about 40 -- 50. This is the mean and standard error showing here.

The thick line around 20, 19.6 to be exact, is a geometric mean from NHANES 2003/4. That was the first time NHANES reported BDE-47.

So back in the sixties it wasn't present. And then every time after that, we are above the NHANES data. The third bar are the 18 samples from UCSF I just mentioned. So again they're very high. Interestingly, the very last graph, the bar, is blood from adult females

taken at the same time as the pregnant women, but they're not pregnant. And we can talk a little bit more about what this may mean.

I added here to the same graph the dotted line comes from the Zota paper of a year ago, showing when they were able to extract Californian data out of the NHANES and showed that the NHANES -- the geometric mean for California participants of NHANES was much higher, in fact, 36.2 versus 19.6.

And our contemporary data are clearly above the NHANES and some of them are above the California NHANES, but the older women, which is my point here, are not. And this is an interesting point. The last -- again, the last bar shows it's only nine of course, so there may be a change. There are nine woman who are not of reproductive age, a little older as a group. And these were collected as part of our method development. So this is part of our pilot to collect -- one of them -- blood for people to develop methods.

And so we see lower levels than the younger and also pregnant women. So that's something to keep in mind. We know it has been reported that younger people have higher levels of PBDEs than older people. This may be an explanation. Also, the fact that these are pregnant women, maybe different reason.

And I'm showing here in blue -- it's again the same graph. These are not California -- these are Mexican women, pregnant Mexican women, samples we collected in 1998. This was a study with UC Berkeley women from Chiapas, as part of a DDT kind of exposure, malaria control. But we measured PBDEs in them and they were much lower than the contemporary at the time, 1998, Laotian-born immigrants in the state. So you see a difference between Californian and, you know, Mexicans over the time there.

And going back to the UC -- we've very excited about the UCSF data, so I want to share that with you.

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DR. PETREAS: This is another way to present the data. This is from unpublished work from Zota and Woodruff, where they were again able to extract pregnant -- results from pregnant women from the NHANES. And that's the -- there were 75 pregnant women, I guess, from NHANES that they could identify. And their median was above the 50th percentile of the NHANES.

So even within NHANES, pregnant women were higher than the average, but then the UCSF group was even higher than that. So this is interesting, and it gives us an idea of probably what to expect when we do the Maternal and Infant Exposure study. So these are high levels and

we should be able to measure them pretty well.

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DR. PETREAS: So what's coming up?

Hopefully, we'll have a method with the perfluorinated chemicals validated very soon. And we'll apply the method to analyze contemporary and archived serum. They are not California data, as far as I know. So these are badly needed and will give us a base line on where we are.

And once we finish the PFCs, we plan to go back and revisit their methodologies for brominated flame retardants and try to expand our repertoire there. We are funded to do a small study in collaboration with the Occupational Health Branch of DPH, on measuring PBDEs and other BFRs in flight attendants. And we're again waiting to get going with our analysis of contemporary California men, PBDEs in those as part of the response to the Request For Information that we had issued two years ago. And we're working with Colombia University on that. So this is what we're supposed to be doing next.

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DR. PETREAS: And just in ending, I want to take this opportunity to invite you, if you're interested, we have these series of seminars, twice a month. And tomorrow's speakers is a Derek Muir for Environment

Canada. And Canadians have been really in the forefront of identifying chemicals of concern. And he's going to talk about how to identify the next generation of persistent bioaccumulative chemicals. So I think this may be something that the Program would be interested in. It will be in our building at 2 o'clock. Unfortunately, it cannot be telecast.

And also the next day we have another out-of-town speaker on biomonitoring of perfluorinated chemicals in Minnesota. That's 3M country. So she's going to talk about her study on PFCs, and it may be of interest. It's mostly a laboratory issue. So if anyone is interested in coming or if you want to be part of our mailing list, you know, let me know.

So that's my update.

CHAIRPERSON MORENO: Thank you, Myrto.

So we'll take questions from Panel members now for this presentation or either presentation.

Dr. Bradman.

PANEL MEMBER BRADMAN: Just a comment. One, your PBDE results are very interesting, and very similar to what we're finding in our cohort in the Salinas valley.

I just want to underscore and highlight your comment about measurements during pregnancy may be different than measurements at other times. In our

studies, looking at urinary metabolites in pregnant women, we've seen substantial differences during pregnancy and in the days just after.

And interestingly, in the samples collected in the days just after birth, the urinary metabolites were much higher than the levels during pregnancy. We don't quite know what that means from a pharmacokinetic point of view, but clearly there's a lot of changes going on physiologically during pregnancy and in the period after as well. We also tend to see a trend with slightly lower levels of persistent organic compounds over pregnancy, over time. It's very slight, but there seems to be a decline that may be related to changes in body fat and the equilibrium with levels in blood.

We also have had to deal with issues about changes in immunoglobulin binding proteins during pregnancy, changing during the course of pregnancy, and possibly changing some measurements related to either xenobiotics or thyroid or other factors.

So again, just to highlight, when we're doing measurements during pregnancy like, in a way, when we're doing measurements in children, we can't -- we have to understand there's a lot of changes going on, and the interpretation of those may not be so straightforward, and we have to be careful in our comparisons. And I think

that's an important point you raise and something that all biomonitoring projects should consider as they go forward when they're looking at that population.

DR. PETREAS: Yeah. I think it will be useful when we start the maternal infant study to know what to expect.

CHAIRPERSON MORENO: Dr. Solomon.

PANEL MEMBER SOLOMON: Yes, I just wanted to say that I'm very impressed that you managed to, within pretty much the original timeline, move forward with both methods, which I think, since our Panel was having difficulty picking one, you gauged correctly that we were hoping that there would be some way to move forward with both. That's fantastic.

And I'm also very glad to hear that you're still looking at the newer flame retardants, because those are still -- I mean, I think from our previous discussions, that there was a lot of interest in the Panel on looking at the newer ones as well. And I understand your decision to put those aside for awhile. And now if those are picked up again, that would be fantastic.

My question actually is for Jianwen She about the phthalates, because I noticed that they're in progress, and four phthalate metabolites are listed. And I remember at the previous meeting there were some discussion about

difficulties with some of the phthalates. And I was wondering if you could update us on that.

DR. SHE: And four phthalate. MEP, MBP, MBZP, MCCP. Right now, within the four of them, we are able to run all of the 13 batches. For two of them and MEP and we're able to get the standard reference materials from our German program. We're able to match their qualities, so our results match with them.

And MBP, we're able to match the result samples that Mark sent to us. So for these two, we don't think we have any further problem, but we needed to watch our stabilities.

For MCPP and MBZP. I think for MCPP the simple issue we cannot match relative response factors between the isotope labeled standard and the target compound. That's three times off there. We've tried to troubleshoot what's happening. We talked with Cambridge Isotope, and then I think that's where it will be a very easy issue, if they're able to have a different batch of standards for us to test. So we will overcome that issue.

For MBZP, it's looking like there's more issues there. The sample is not so stable after you extract out from the urine. So we still needed to work on much more on MBZP to figure out what happened.

And so that's a lot of the quality issues right

now to look at. So, you know, in summary, we solved two of them, and then we also solved the like Mark mentioned of this solvent contamination problem. With all of them, to some extent, they all have the contribution from the solvent, even from the system. We're able to use pre-column to separate the different peaks from the solvent and from the samples. But it's the other part that we still need to work on.

CHAIRPERSON MORENO: Okay, why don't we take one more question and then we'll go to public comment.

Anyone else, Panel members?

Dr. Wilson.

PANEL MEMBER WILSON: Yeah, thank you. Myrto, I had a question about the graphic comparing the 1960 cohort to the more recent ones.

And it's interesting that the doubling time would be consistent with what we've seen in Sweden in their breast milk study, of flame retardants over the last several decades, where they've seen this doubling time every five years. That trend would be consistent with the U.S. based -- the U.S. based finding, which I think that's -- is that adult female for the NHANES? Let's see. Your adult female in the far right, is that U.S.?

DR. PETREAS: Yes.

PANEL MEMBER WILSON: Okay. And, you know, then, of course, we're obviously much more rapid doubling time for California. And I'm just curious how confident you are in looking at the findings from 1960 in their -- in just sort of the technology of detecting these substances, if you feel confident in that as a baseline value.

DR. PETREAS: All of these samples were done in our lab.

PANEL MEMBER WILSON: I can't quite hear you. Thanks, Myrto.

DR. PETREAS: All these samples were analyzed in our laboratory the last few years. So it hasn't been reported elsewhere. This is our data with our system. And we had done, in fact, the sixties in the 1998 at the same time. So same exact technology same staff person doing it, we saw this difference.

I didn't get exactly what you meant about -- I want to point that both of the last bars, the adult female in the UCSF are the same year, 2009 from California.

And the only possible reason we see this difference, aside from chance, because you have very small numbers, may be the age or being pregnant. So I don't see a decline. It's the same time period, both of them were done in 2009, collected 2009.

PANEL MEMBER WILSON: Right, that's --

DR. PETREAS: So I don't see a decline that you see.

PANEL MEMBER WILSON: No, I don't think -- I probably misstated. I wasn't looking at a decline or talking about a decline. I was just struck by the -- just the high numbers that we're seeing for California. And it's an important finding. And thank you for clearing up that question from the 1960's data.

CHAIRPERSON MORENO: Okay.

PANEL MEMBER BRADMAN: Michael, you understand the CHDS samples have been stored since the sixties in a deep freeze.

PANEL MEMBER WILSON: Right. I hadn't understood that.

CHAIRPERSON MORENO: Okay.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON MORENO: Okay, thank you. I'm going to go head and open up for public comment before bringing it back to the Panel. Amy, are there any -- did anyone submit requests to speak?

MS. DUNN: There's no Email.

CHAIRPERSON MORENO: Okay, that's fine. Thank you.

And any Emails coming in?

Okay, so we'll bring it right back now to the

Panel. This is the opportunity for further discussion. And any recommendations that you might want to make to staff?

Okay, I don't see any. So I want to thank our presenters again. We do have a -- oh, yes, go ahead.

PANEL MEMBER LUDERER: This is for Dr. Petreas.

I do actually have a question about the same graph that we just were looking at related to the PBDEs in general. So, in general, are the PBDEs, if the samples are stored appropriately, you know -- I don't know if they're stored at minus seventy, then they are considered to be stable for that long period of time. I mean, five decades, if we're talking about from the sixties. I mean, do we have information about that?

DR. PETREAS: We don't have -- I don't have information for the PBDEs, but NIHS, Longnecker, had done work on organochlorine pesticides, and PCB stability. And there was no problem. So we assume it's the same. I mean, we had thought when we first saw the Swedish datum on milk, that was data from archiving from the seventies all the way to eighty something. And there was an increase.

So the question was did something happen to the old specimens and they degraded? I mean, I think data since then have shown that levels are increasing anyway.

So we believe that nothing had happened to those samples either. But nobody has -- I mean, it takes a long time to do this, so we have to keep our samples, analyze them 10 years from now, but this involves more handling every time.

PANEL MEMBER LUDERER: Yeah. And then the other question was about the adult females in the last borrow. Were those women in the same population as the pregnant women, so they were from, or was --

DR. PETREAS: No, we can't say they represent anything. These are convenience samples that we did for our method development, but they weren't pregnant and they were older.

PANEL MEMBER LUDERER: Thank you.

CHAIRPERSON MORENO: Okay. Any further comments or recommendations?

It doesn't appear that there are anymore. Okay, well then thank you again. And at this point we're going to go ahead and move on to our next presenter, Dr. Gail Krowech with OEHHA talking about potential designated chemicals.

Good morning.

(Thereupon an overhead presentation was Presented as follows.)

DR. KROWECH: Good morning. Okay, there is one

potential designated pesticide today. Pendimethalin.

MS. DUNN: I can advance the slides from here.

DR. KROWECH: Okay, that would be fine.

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DR. KROWECH: This slide shows the criteria for recommending additional designated chemicals, so I'll just list them here. Exposure or potential exposure to the public or specific subgroups, known or suspected health effects, need to assess the efficacy of public health actions, the availability of a biomonitoring analytical method, the availability of adequate biospecimen samples, and incremental analytical costs.

These criteria, just to review, are not joined by ands.

Next slide.

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DR. KROWECH: This is the structure of Pendimethalin. It's a dinitroaniline herbicide. It's one of the top 100 pesticides in California. And over one million pounds were applied in California in 2008.

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DR. KROWECH: In terms of use and exposure, Pendimethalin is used on agricultural crops, golf courses, landscape maintenance, residential lawn care.

The California Department of Pesticide Regulation

reported in its pesticide use report that over 1.4 million pounds were applied in 2008 in California. Uses nearly tripled within the last five years, and increased 29 percent between 2007 and 2008.

Pendimethalin was found in rainfall samples in four agricultural watersheds across the country in a U.S. Geological Survey study. And in terms of the California samples, Pendimethalin was found in 78 percent of the samples.

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DR. KROWECH: This slide shows a table of use in California from 2002 to 2008. You can see the large increase, particularly in certain crops alfalfa and almonds, oranges, and a decrease in cotton.

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DR. KROWECH: Pendimethalin is classified as a possible human carcinogen by the U.S. Environmental Protection Agency. Group C. This designation is based on thyroid tumors in rat cancer studies. And U.S. EPA considered this to be a high-dose effect. In a 1997 review, U.S. EPA concluded that Pendimethalin was not mutagenic in mammalian cells.

However, recent studies suggest that Pendimethalin may be genotoxic. There are knew studies that show chromosomal aberrations in mouse bone marrow

cells, and DNA strand breaks in Chinese hamster ovary cells.

There's also a study reported -- an in vitro study finding Pendimethalin is both estrogenic and anti-androgenic.

There are three epidemiologic studies from the agricultural health study cohort of studies of pesticide applicators, which suggests an association between Pendimethalin and certain cancers.

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DR. KROWECH: This slide shows the physical and chemical properties of Pendimethalin. And Pendimethalin has been identified as persistent, bioaccumulative, and toxic under the U.S. EPA Emergency Planning and Community Right to Know Act of 1986 or EPCR.

No past biomonitoring studies have been identified. In terms of analytical methods, the Program would need to develop methods. The likely biological matrix would be urine. And when methods are developed, they could be bundled with other dinitroanilines, such as trifluralin.

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DR. KROWECH: In terms of the need to assess efficacy of public health actions, this is a widely used pesticide. Recent findings suggesting potential

genotoxicity and endocrine disruption and findings from the epidemiological studies highlight the need for further studies. Biomonitoring would help assess the extent of exposure in California.

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DR. KROWECH: Are there any questions?

CHAIRPERSON MORENO: Thank you.

Questions for Dr. Krowech?

Yes, Dr. Quint and then Dr. Solomon.

PANEL MEMBER QUINT: Thank you, Gail. Julia Quint. I was very struck by the marked increase on certain crops. And I'm wondering is that related to more production of these particular almonds or whatever that we're producing or switched to a different -- you know, that switch to a different use? I mean, were we using something different on these crops before? Do you have any clue as to why we're using so much more?

DR. KROWECH: I think the difference might be -- the increase might be different in different cases. And so I think the difference in alfalfa has to actually do with a court case against something that had been used previously. And so this was replacement. I know with carrots, which are not even on this list, but it turns out that Pendimethalin was better -- you know, less damaging to their roots than what had been previously used. So I

think there might be differences depending on the crop.

PANEL MEMBER QUINT: Great, thanks.

PANEL MEMBER SOLOMON: This is Gina Solomon.

I was interested in some of the pharmacokinetics on this chemical. I did a little bit of digging, but not much. And one of the things that struck me is that, at least the couple studies that I saw, you know, ninety plus percent of administered dose was excreted within the first 24 hours, and was excreted largely in feces, which implies fairly poor bioavailability.

But that was -- I can't even remember what the animal model was. I'm sure a rat. And so then that made me wonder, you know, how likely it is that this chemical would be absorbed especially since herbicides are often not a major residue issue on food.

But then there was some recovered in urine. And so it suggested the potential to biomonitor for it in urine. I was just -- my concern was not so much about the feasibility of biomonitoring in urine as the, you know, sort of relative likelihood of exposure based on the pharmacokinetics. So I was just wondering if you had looked at any of that and could comment on that?

DR. KROWECH: I didn't do a thorough search. We don't generally do that. I didn't come across that. I do know that some of the suspected toxicity was thought to be

due to metabolism. So I really can't say more than that.

PANEL MEMBER WILSON: Thank you, Gail. Mike Wilson. And also, thank you for the briefing document. It was really concise and well put together, very useful.

And I had the same question that Julia Quint has raised about, you know, the sort of the second piece of that is, it's striking to me that a substance that is classified by U.S. EPA as a PBT would be approved for use in California. That classification is a fairly high bar under U.S. EPA., and it's not a large list of substances.

So I'm just curious if you had any communication with the Department of Pesticide Regulation and what their -- if they had an exposure justification or some other justification, perhaps as Dr. Solomon is raising for granting the approval for this substance in California.

DR. KROWECH: No, I haven't, so I don't know.

PANEL MEMBER WILSON: Do we have access to that process in DPR as far as you know?

DR. KROWECH: I think that we can ask and communicate. I do know that they consider -- actually, the only thing that I have communicated with them and know is that they really consider the carcinogen identification as a high-dose effect, as does U.S. EPA. So I think that was -- but in terms of PBT status, I don't know.

PANEL MEMBER WILSON: Okay, thank you.

DR. KROWECH: Yes. And someone from DPR did review the document.

CHAIRPERSON MORENO: Okay. Any other questions from the Panel before we open it up for public comment?

Okay. So, Amy, do we have anyone submitting a request to speak?

MS. DUNN: There are no via Email.

In the room, Davis Baltz.

CHAIRPERSON MORENO: No Emails. Okay, thank you.

Any other speakers?

Okay. Please introduce yourself.

MR. BALTZ: Davis Baltz with Commonweal.

Thanks for that great presentation. I think that, you know, Gina's question about what is the potential for actual exposure is an important one to explore. But given the staggering increase in the use of this substance, I don't think there's any reason not to at least designate it. So from a public interest organization, I hope that you would take that step to at least designate it today.

Thank you.

CHAIRPERSON MORENO: Okay. Anyone else wish to speak on this topic?

I don't see anyone else.

All right, then I'll bring it back to the Panel.

It's the Panel's opportunity for further discussion and to make any recommendations.

Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah, I think -- I mean, in review of this document, there were two very good reasons to at least, you know, seriously consider designating this chemical. One is that, you know, as our Panel has discussed in the past, we're looking for, you know, sort of one of our -- not in the statute, but as a panel priority-setting or designation-setting criteria had to do with chemicals that are increasing or decreasing in some significant way in California.

And here is a chemical that's brought to our attention that has been substantially increasing in use, and that in and of itself is a reason to, you know, consider looking for it.

The other issue, obviously, as I think Dr. Wilson pointed out, the persistent bioaccumulative toxicant designation also would make it something that we would be of -- that would be of interest.

I think I was so -- all of those certainly argue for designating the chemical. In terms of prioritizing it, I have to say that I was not totally blown away about the idea of making this a very top priority for the Program because of the experience with CDC and looking at

herbicides, and not tending to find a lot in the NHANES program.

The fact that herbicides tend not to be as commonly found as food residues. So we would be more looking for direct exposure kind of issues potentially water, though I didn't see drinking water. I think it hasn't really been looked for in drinking water, but maybe I'm wrong.

It seems like it could get into drinking water, so that would be a possible exposure pathway. And then this, what seemed to be, very low bioavailability in the pharmacokinetic studies that I looked at, that made me think well, you know, most of an ingested dose would probably not be absorbed. Though, clearly a fraction was being absorbed, thereby meaning that it would be biomonitorable.

So, you know, my take in looking at this was that this is probably worth having on our -- you know, being a designated chemical for our Program, maybe not being a top priority.

CHAIRPERSON MORENO: Thank you.

Further discussion?

Dr. McKone.

PANEL MEMBER McKONE: Probably this echoes Dr. Solomon's comments, but in a little bit different

perspective. You know, we did agree early on that we wanted to pick things that were on the rise, right. That's why we picked siloxanes, not because we believed that they had any evidence currently that they were highly toxic, but just that -- but in the case of siloxanes, they're used in the residential environment, so there was a lot of human contact.

And I do think the point is important that, you know, pesticides that show up are really in food. And food pathways are very important. And actually this is true for a lot of substances. I think even for many PAHs, that you see in the NHANES data, they really seem to be coming in by food pathway.

So I think to -- this one needs a little more work on the plausibility of the exposure pathways. If there is a water runoff pathway to nearby water systems, the high -- I'm looking at the chemical properties. It would suggest a bioaccumulation through food webs, aquatic food webs, but, you know, that may not -- we don't get that much of our aquatic food in California from surface waters. It would be ocean supplies. And so it would be a limited population that may be at risk, like people who fish locally in the areas that would get the runoffs. So the likelihood of finding those people, unless it's a very targeted survey, would be low, so we probably wouldn't see

it in the biomonitoring.

PANEL MEMBER BRADMAN: I just want to make a comment on this chemical, in terms of our experience looking at pesticide residues and house dust in the Salinas Valley.

From a physical chemical point of view, this is very similar to another compound we've looked at a bit called dacthal or chlorthal dimethyl, which has a fairly high Log KOW. And we're finding in general that compounds that have a fairly high Log KOWs tend to persist. They also tend to adhere to particles and end up in house dust. And we've scene, for example, dacthal. In Salinas, we find it in almost every dust sample. When we collect a sample from Oakland, we don't find it in any.

And I wouldn't be surprised if this is the kind of compound that would be showing up in residential environments from either drift or maybe physical transport on clothing or dust, not so much from vaporization and volatilization and resettling. But I would -- I think it's very likely that this is showing up in residential environments.

And it might be something to consider, again, as a designated chemical. And perhaps with more and different kinds of environmental data, it's something to look at in more detail in the future.

CHAIRPERSON MORENO: Okay. Dr. Luderer.

PANEL MEMBER LUDERER: Actually, the comment that I had was related to what Dr. Bradman just mentioned. I also wanted to say that I agree with all of the reasons that have already been given by Panel members for why it might make sense to designate this chemical, you know, the increase in usage in California. The persistence. I think, another reason is that it currently is not biomonitored by the CDC, and there really is no data. And then the final point that I wanted to make related to what Asa was just talking about, is the potential for residential exposure.

At least in the documents that we were given, it was mentioned that this is a used in residential lawn care, and landscaping. And so I know it's more difficult to acquire data about pesticide use through consumer products. And that's something that the Panel has talked about before, that this might be a route of exposure of concern, but that's more difficult to assess, because it's not captured in the crop pesticide use data.

And so I would, you know, add that as maybe another reason why we should consider designating this chemical. But I also agree that assessing additional information about potential levels of this chemical, for example in house dust and other environmental media, would

help to -- help us to decide in the future whether we might want to also prioritize this chemical.

CHAIRPERSON MORENO: Thank you.

PANEL MEMBER WILSON: Mike Wilson.

In my mind, this substance and as it has been flagged by OEHHA, is a, you know, perfect candidate for designation, and I would encourage the Panel to do so for the reasons that we've heard.

But, of course, you know, it's growing use, the fact that it's persistent and bioaccumulative, so we're increasing the likelihood of exposure over both time and space. And that it has toxic properties. It's, you know, we've learned in so many cases and, you know, PCBs are a good example, substances that were intended to be used in insulating equipment, for which there would be virtually no possibility of human exposure, and we're still finding them in the population with a lot of uncertainty about what the routes and the paths of exposure are and so forth.

So, in my mind at least, I would very much support designating this substance.

CHAIRPERSON MORENO: Dr. Quint.

PANEL MEMBER QUINT: I just want to add to the list of reasons to designate the fact that it's a suspected endocrine-disrupting chemical is really

important to me, in terms of, you know, concentrations that we might -- people might be exposed to that could be harmful.

And nobody mentioned -- we're talking about, you know, residues of these herbicides and runoffs and stuff like that. I suspect -- I don't know what the tolerance levels, in terms of the crops themselves as an almond eater, and a carrot eater. I suspect that that's controlled for, but do we know anything about residual levels of this herbicide on the crops themselves?

DR. KROWECH: I didn't see anything in this in the residue reports. So I think if it is, it's, you know, very, very -- well, it's not in there.

PANEL MEMBER QUINT: Yeah, the reason I ask that is because if, you know, up until now, it's considered toxic only at high doses. And it seems to me that toxicity database is developing. I mean, you've talked about genotoxicity data. We're talking about suspected endocrine-disrupting activity. So, you know, the tolerance levels may be set based on old data, so it's another reason for concern.

CHAIRPERSON MORENO: All right. Any other discussion by the Panel?

Okay. Is there an interest among the Panel to make a recommendation at this time?

Dr. Wilson.

PANEL MEMBER WILSON: I would make a motion that the Panel designate Pendimethalin as a designated chemical under the State's Biomonitoring Program.

CHAIRPERSON MORENO: Okay. Thank you.

Do we need a second on that?

CHIEF COUNSEL MONAHAN-CUMMINGS: (Nods head.)

CHAIRPERSON MORENO: Is there a second?

PANEL MEMBER McKONE: Second.

CHAIRPERSON MORENO: Dr. McKone seconded.

Okay, further discussion by Panel members on the motion?

And is everyone clear on the motion?

Okay. So I'll go ahead and take a roll call vote.

Dr. Kavanaugh-Lynch?

PANEL MEMBER KAVANAUGH-LYNCH: Yes.

CHAIRPERSON MORENO: Dr. Quint?

PANEL MEMBER QUINT: Yes.

CHAIRPERSON MORENO: Dr. Bradman?

PANEL MEMBER BRADMAN: Yes.

CHAIRPERSON MORENO: Dr. Solomon?

PANEL MEMBER SOLOMON: Yes.

CHAIRPERSON MORENO: Moreno yes.

Dr. Luderer?

PANEL MEMBER LUDERER: Yes.
CHAIRPERSON MORENO: Dr. Wilson?
PANEL MEMBER WILSON: Yes.
CHAIRPERSON MORENO: Dr. McKone?
PANEL MEMBER McKONE: Yes.
CHAIRPERSON MORENO: So the recommendation is approved unanimously.
Thank you.
At this point, that was the designation of the chemical. Any further discussion or guidance on prioritizing?
And keep in mind that the prioritization of this chemical was not on the agenda. My understanding is that we can't actually make that recommendation today as a priority chemical.
CHIEF COUNSEL MONAHAN-CUMMINGS: That's correct.
One thing I wanted to ask the Panel though is, and this will come up more in the subsequent discussions, but did you also intend to designate the metabolites of this chemical as well as any other markers, so that the Program could look for those as well?
CHAIRPERSON MORENO: Dr. Wilson, you made the motion.
PANEL MEMBER WILSON: That would be included in the motion.

CHIEF COUNSEL MONAHAN-CUMMINGS: So it's your intent to include the --

PANEL MEMBER WILSON: The substance and its metabolites necessary for detection.

CHAIRPERSON MORENO: Would it be more appropriate to have another motion to clarify, since we already voted on that.

CHIEF COUNSEL MONAHAN-CUMMINGS: It might not hurt.

CHAIRPERSON MORENO: So, Dr. Wilson, would you like to entertain another motion.

PANEL MEMBER WILSON: So to restate the motion, I would move that the Panel designate Pendimethalin as a designated chemical along with its metabolites.

CHIEF COUNSEL MONAHAN-CUMMINGS: Or other markers.

MS. HOOVER: Or any other relevant biomarkers or indicators for detecting this substance.

PANEL MEMBER WILSON: Or any other relevant indicators for detecting this substance.

(Laughter.)

CHAIRPERSON MORENO: Did you get that?

Great. All right, is there a second?

PANEL MEMBER LUDERER: Second.

CHAIRPERSON MORENO: Dr. Luderer.

Okay, I want to make sure everyone is clear on the motion?

Clear on the motion?

Any further discussion on that among Panel members?

No, okay. We'll go ahead and take a vote.

Dr. Kavanaugh-Lynch?

PANEL MEMBER KAVANAUGH-LYNCH: Yes.

CHAIRPERSON MORENO: Dr. Quint?

PANEL MEMBER QUINT: Yes.

CHAIRPERSON MORENO: Dr. Bradman?

PANEL MEMBER BRADMAN: Yes.

CHAIRPERSON MORENO: Dr. Solomon?

PANEL MEMBER SOLOMON: Yes.

CHAIRPERSON MORENO: Moreno, yes.

Dr. Luderer?

PANEL MEMBER LUDERER: Yes.

CHAIRPERSON MORENO: Dr. Wilson?

PANEL MEMBER WILSON: Yes.

CHAIRPERSON MORENO: And Dr. McKone?

PANEL MEMBER McKONE: Yes.

CHAIRPERSON MORENO: Wonderful. Okay, thank you.

If there are no further recommendations on this presentation, that concludes this portion of this morning's agenda. We were scheduled to break for lunch at

12:30, and it's 12 -- almost 12:10. So do we -- because of the way that the meeting was posted publicly, do we -- are we obligated to return at 1:30 or can we break early and come back early?

CHIEF COUNSEL MONAHAN-CUMMINGS: No, I think you break now and come back. You can break now and come back --

CHAIRPERSON MORENO: Come back early?

CHIEF COUNSEL MONAHAN-CUMMINGS: Sure.

CHAIRPERSON MORENO: Okay. So we're about 20 minutes ahead of schedule. So if we want to take the same amount of time, we would come back at 1:10?

MS. HOOVER: Let's do 1:15.

CHIEF COUNSEL MONAHAN-CUMMINGS: 1:15?

CHAIRPERSON MORENO: Okay, 1:15. So we're going to break now. We have one announcement before we break and then we'll break and come back at 1:15.

CHIEF COUNSEL MONAHAN-CUMMINGS: Okay. I just want to remind the Panel members also that you should not discuss items that are on the agenda with each other, while you're having lunch or anybody else. If you do, you would need to come -- when you come back you need to disclose that.

CHIEF DEPUTY DIRECTOR HIRSCH: Also, I have a pre-existing commitment from 1:30 till about 3. So my

chair will be empty, but if you need any guidance from OEHHA staff, Carol, our Chief Counsel, is right up in front, and Dr. Lauren Zeise as well.

CHAIRPERSON MORENO: Thank you.

All right, let's break.

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

CHAIRPERSON MORENO: All right, good afternoon. Ed Moreno. We're going to restart the meeting.

Okay. Welcome back, everybody. This is Ed Moreno. At this point, I'm going to reintroduce Dr. Rupali Das, Chief of the Exposure Assessment Section, of the Environmental Health Investigations Branch at CDPH, and lead of the Biomonitoring Program.

Dr. Das.

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: Thank you, Dr. Moreno and members of the Panel. I'm going to be sharing the podium this morning. It's going to be a tag team -- I mean this afternoon -- a tag team presentation. I'll start. Diana Lee will present the bulk of the middle portion and then I'll end the presentation.

And we'll be talking to you about the Maternal Infant Environmental Exposure Project, which we refer to so far as MIEEP, but have renamed it to give it a more public name, Chemicals in Our Bodies Project.

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DR. DAS: Okay. Is that you, okay.

All right, so this is just an overview of the topics that we've divided up this presentation into.

We'll be talking about the status of the current project, the design of the project. We'll be describing some of the questionnaires and other materials that we've developed and then going over the timeline.

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DR. DAS: So just to remind you, this is a collaborative project between three institutions, the California Environmental Contaminant Biomonitoring Program or Biomonitoring California, UC San Francisco, specifically the Program for Reproductive Health and the Environment with Tracy Woodruff and Jackie Schwartz, and UC Berkeley's School of Public Health and the Health Research for Action, which is in the School of Public Health. Rachel Morello-Frosch is with the School of Public Health and Holly Brown-Williams is with Health Research for Action.

There are three sources of funding that help us to achieve the objectives of this particular project. The CDC cooperative agreement provides a bulk of the core funding for this project. In addition, since we last met, UCSF got awarded a grant from the California Wellness Foundation, $250,000 over two years, to accomplish mostly the reach-back and questionnaire portions of the project. And, of course, our State resources contribute as well.

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DR. DAS: The aims of the project are to measure and compare levels of approximately 100 chemicals in the blood and urine from maternal infant pairs. And we would like to be able to get 100 maternal infant pairs. That's our goal; to identify the leading sources of exposure to a subset of these chemicals; to develop and test the communication and report-back methods and materials; and to conduct analyses of the associations between exposure and pregnancy and birth outcomes.

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DR. DAS: We'll be going over each of these in a little more detail. In addition, we are intending for this project to be a method to test a lot of the methods we hope to apply to a larger study that could be conducted statewide. Specifically, we're hoping to test the recruitment and enrollment procedures, the data collection methods, this biospecimen collection, managing, processing, developing some of the lab analyses, and finally report back -- reporting back results to participants.

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DR. DAS: So the chemicals of interest are shown here, and on the next slide. This slide shows the chemicals that will be analyzed by the Environmental Health Lab in the Department of Public Health.

The metals will be analyzed in whole blood. And the remainder of the chemicals will be analyzed in urine. These are the non-persistent chemicals.

Next slide.

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DR. DAS: The chemicals shown on this slide will be analyzed by the Environmental Chemistry Lab in the Department of Toxic Substances Control. And these are the persistent compounds. And these will be analyzed in serum.

Next.

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DR. DAS: So the specific components of the project include those shown here. The items shown in green are those that are funded primarily by the CDC cooperative agreement. And the items in purple are primarily funded by the California Wellness Foundation grant. And those in black represent contributions, in-kind, from project staff.

So recruitment, informed consent, and enrollment, exposure assessment through questionnaire administration. There will be two questionnaires. One will be administered in person by an interviewer at the clinic, and the other one will be a take-home questionnaire.

And then finally biospecimen collection will be

performed, as I described before. Maternal urine and blood will be collected as well as fetal umbilical cord samples.

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DR. DAS: In addition, we hope to conduct these components as well. The chemical analyses will be performed by the two labs, the Environmental Health Lab and the Environmental Chemistry Lab, as I described in a previous slide. The data analyses and report generation will be shared between the three different parties, Department of Public Health, UCSF, and UC Berkeley. And the report back will be primarily funded by the California Wellness Foundation, and will be done by UC Berkeley. And that includes a preliminary interview with the subjects, a feedback session using usability tests, and a results communication interview. And you'll hear a lot more detail about each of these components.

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DR. DAS: Next slide. You saw this slide last time. This was presented by Dr. Tracy Woodruff. This represents the population that we're targeting at San Francisco General Hospital. And the race is primarily -- the race of our mothers is primarily Latina, sixty percent, 20 percent African-American, 12 percent of the mothers are expected to be Caucasian, and eight percent

Asian and Pacific Islander.

This population tends to be low income and uninsured. While they are pregnant, they are eligible for Medi-Cal, which allows them some extra services. They tend to be low literacy, and more than half primarily speak Spanish or only speak Spanish.

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DR. DAS: This timeline is a very nice representation of the four time periods that we've divided up the project. And the timeline was developed by our Public Health Prevention Specialist, Ngozi Erondu, in the room with us.

And Diana was going to take you through the different components and the different timeframes.

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MS. LEE: So starting with the first encounter that we expect to have with the pregnant women, at around 28 to 34 weeks gestation, is when we primarily will be contacting them. And during this process we will be, not only recruiting, but we will be administering the informed consent and formally enrolling her, and then doing a preliminary interview, and an at-home questionnaire will be provided. So I'm going to explain these a little bit more in depth.

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MS. LEE: So the inclusion criteria shown on this slide indicate that we want to enroll women who are obviously receiving prenatal care at the Women's Health Center at San Francisco General, who plan to deliver at that hospital, who have low medical or obstetric risk, and are either Spanish or English speaking and equal to or over 18 years of age.

The UCSF staff will hire a Spanish speaking research assistant. And we've been informed that the optimal time to approach women is actually when they're in the waiting room. So this research assistant will actually be reviewing medical charts, the appointment logs, et cetera, and then have primary responsibility for approaching the women to explain the project and administer an informed consent.

The participant enrollment packet will be provided to each participant and will include a copy of the informed consent, the patient bill of rights, as well as an abbreviated information sheet that will describe the various components of the project.

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MS. LEE: Starting with the informed consent, we want to make sure that the informed consent is well understood. So this is to be personally described to the participant. And on these next few slides, we've actually

included examples of the language contained in the informed consent, starting with -- so that we really are able to set forth the expectations for both participant and the staff administering the project.

So we anticipate that we will be explaining the purpose of the project in these terms listed on the slide, that we will learn if certain kinds of chemicals in our environment are present in the bodies of pregnant women and their newborn babies. And we hope to understand where these chemicals come from and how we might be able to reduce exposure to them. We'll be looking at the ways pregnant women come into contact with these chemicals. And we ultimately want to find the best way to tell women about the types and amounts of chemicals that we will find in their bodies.

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MS. LEE: We clearly anticipate telling the participant what we expect to be able to share with them. That we expect to find at least some chemicals and in everybody's blood and urine. We will be able to learn and -- that the participant will be able to learn and receive information about the types and amounts of chemicals found in their body and also that they will be able to get some information about how to reduce their exposures.

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MS. LEE: We also want to be clear about what we will not be able to tell the participant, that we will not be able to tell you if the amounts of chemicals in your body are harmful for your health, and we will also not be able to tell you whether any health problems you have may be caused by the chemicals we find in your body. Again, setting hopefully very clear expectations on both the part of the participant as well as the staff.

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MS. LEE: All informed consents contain assurances, and ours certainly does as well. And we want to assure the participant that participating or not does not change any procedures or care during pregnancy or delivery. Taking part in this project is entirely your choice, and they can refuse to answer any questions or change their mind and stop participating at any time.

Also, we want to assure them that we will keep their information confidential and any identifying information will not be used in any meetings, reports, or articles.

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MS. LEE: There's information about the stipends. We anticipate that we'll be informing the participants taking part in this study where this project will take

roughly three to four hours of their time. We will provide a $25 stipend for the initial urine collection, and upon completion of the in-person interview, as well as $20 upon receipt of the completed at-home survey, and then $20 fore the blood samples.

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MS. LEE: At the end, we will ask the participant to indicate yes or no to these three statements. They have to indicate they want to participate in the Chemicals in Our Bodies Project, they want to know their own personal biomonitoring results, and that these may not be available for up to two years.

And they may indicate whether they want to donate their left-over blood and urine and personal information for use in future studies.

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MS. LEE: A subsequent part is if the participant indicates she would like to know her personal biomonitoring results, she's also asked to indicate whether she would like to be contacted later to participate in a feedback session interview, as well as a results communication interview, both components of the report-back component.

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MS. LEE: So I want to stop here for a second,

and just ask if there are any questions in particular about the informed consent?

CHAIRPERSON MORENO: Okay, thank you, Diana.

Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah, I just had a question about -- uh-oh, I don't have my glasses on. I think it's slide 16, which says what the participant can't learn. And I'm assuming that you're using the language here that you're sort of planning to use with the participants. And so I just worry a little bit about the language we will not be able to tell you, because that could be seen in two different ways. One is, there's no way of knowing and the other is well we'll know, but we won't be somehow allowed to tell you.

And when I translated it mentally into Spanish, I think the same problem would maybe even be more of an issue in Spanish, where it could sound like, you know, someone -- you know, we are forbidden from telling you or we are not allowed to tell you.

And so I just wanted to raise that question and make sure you've thought about it and think about whether there's better wording. In other words, you know, we will not know or no one will know. You know, it is unknown whether or something that doesn't sound as loaded.

MS. LEE: That's a very good point, and we'll

take that under consideration. All these documents have been initially submitted to UCSF's Institutional Review Board. And we will be submitting to our departments shortly. But we can always adjust -- I mean, continue revising them as well. And we do plan for some revisions to them, so I think we'll take into consideration, Dr. Solomon.

CHAIRPERSON MORENO: Dr. Quint.

PANEL MEMBER QUINT: In describing the cohort, you said that they were low income and on Medi-Cal. Are any of them working?

MS. LEE: Will be finding out. That is part of the questionnaire, that we will be assessing occupational status.

PANEL MEMBER QUINT: Because it changes a little bit the question about exposures, and rights and what they have a right to know and what their employee must tell them and all that sort of thing, you know.

So anyway --

MS. LEE: At the time that we recruit them, and you'll see this as we go forward in the presentation, we're actually recruiting them near the -- well, between 28 and 34 weeks. So it's starting their -- the end of their second trimester, the beginning part of their third trimester -- no, no, sorry. The end of -- it's in their

third trimester we're starting to recruit them. So we will be asking about occupational history during their pregnancy.

PANEL MEMBER QUINT: Right. Okay. Any other questions?

PANEL MEMBER BRADMAN: I have just a quick comment and question about recruitment. Does the Women's Health Center have a CPSP program, and would it be possible to have them hand out brochure or materials to potential participants, so if they're approached in the waiting room, it's not a cold call so to speak, or they could seek out -- that's something that we've done in Salinas and it really facilitates communication.

MS. LEE: Yeah, my understand -- yes, that San Francisco General is a comprehensive perinatal services provider and those are some of the health workers will be -- will have ultimate access to.

We've been told by both Tracy and Jackie that usually handing out written material isn't necessarily useful for recruitment and that the most effective way is really to approach the women while they're in the waiting room.

We hope to have some information material in writing that we can provide. We've also broached the idea of creating a poster, for instance, that can be displayed

in the waiting room. And we've been discouraged from doing that, but I will take back this feedback from you.

PANEL MEMBER BRADMAN: I think you're right, the poster won't be that helpful. But it's not so much handing somebody written materials, but it's also the verbal contact, and a brief description. And if you want more information, there will be somebody to talk to you.

I agree the paper itself isn't that helpful without the personal contact.

MS. LEE: Right. And while this newly to be hired research assistant will be very busy, during the recruitment phase, and then ultimately throughout the rest of the project as well. But that will be a prime focus of that position is to actively be in the waiting rooms to recruit women.

CHAIRPERSON MORENO: Dr. Wilson.

PANEL MEMBER WILSON: Thank you for that and for also providing us with the -- I think this was the IRB approval document.

MS. LEE: I think the sheet that we provided you is something called information for participants.

PANEL MEMBER WILSON: Right.

MS. LEE: That's something that's been prepared by the UCSF staff, that they intend to provide to the participant upon enrollment, so that it's kind of a

stepwise description of the steps that she'll be taking -- parts of the project that she'll be taking apart in.

PANEL MEMBER WILSON: It's great. It's very thorough. And I ended up in going through it translating it into a schematic, sort of similar to what was presented for us on the study outline.

But sort of a five- or six-step timeline that shows what the participant would be doing at that point. And then at the end there's this decision place to receive results or not, just as a suggestion for making it easy to understand and to communicate.

MS. LEE: We would love to see it.

PANEL MEMBER WILSON: Oh, yeah. And then the other is just in the slide number 14, which was learn if certain kinds of chemicals in our environment are present in the bodies of pregnant women and their newborn babies. I'm just wondering if it would be helpful to say, "...learn if certain kinds of chemicals in our homes, work places or environment...", to make it -- or if that would make it more concrete.

MS. LEE: That's an excellent suggestion. And we will, again, propose that for a potential modification.

PANEL MEMBER WILSON: Okay. Thank you, Diana.

CHAIRPERSON MORENO: Diana, Ed Moreno. I just have one request. Could you explain to me a little bit

more about what the intent is in asking if the subject would allow her sample to be stored and used for future research.

MS. LEE: I think it's to allow us to store the biospecimens, so that, say during this two-year timeframe, we may not have analytical methods, like cyclosiloxanes, for instance, developed by the end of this project, but they will become available in future years, that we can then use those samples as a source for analysis for future studies.

CHAIRPERSON MORENO: Okay. Thanks.

Other questions by Panel members?

Okay. At this point --

MS. LEE: I'm not done yet, though.

CHAIRPERSON MORENO: Oh, I'm sorry. I apologize.

(Laughter.)

MS. LEE: I'm just proposing to stop periodically during the presentation, so that I can provide opportunities for the Panel to weigh in on other issues.

But I do want to go through in the next series of slides more specifics about actual study administration.

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MS. LEE: So at the first encounter, we will be, after the initial consent is signed, we will be administering what is called the preliminary interview.

And this is to assess baseline knowledge and expectations of the participant regarding participation in the Biomonitoring component. This is actually a component of the report-back phase of the project.

And Dr. Rachel Morello-Frosch has actually drafted these questions and is proposing that this portion of this interview be audio recorded, so that they can listen to this and take them into consideration when they're doing their data analysis.

And I think when Dr. Morello-Frosch was here presenting before you in last July, she gave you examples of some of those questions.

So here's examples of those questions.

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MS. LEE: Why did you decide to participate in this project? What do you hope to learn? What might information about your exposure to chemicals mean for you or your family? And where did you get information about environmental health issues or chemical exposures?

So again, this is prior to her actually being biomonitored per se. This is at the first time right after she initially consents. And this information will help us design the report-back component, as well as education materials that will be used in this project.

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MS. LEE: Before I go further into discussing the two questionnaires that we use, I want to just digress a little bit, and describe the process that we utilize to develop the two questionnaires that we have.

And as you're aware, the measured levels of these chemicals that you see here, for instance, don't necessarily provide information about the sources of these chemicals. And as Dr. Rachel Morello-Frosch indicated chemicals don't come necessarily with a return address, as some of her participants have indicated. So we usually have to get at potential sources differently.

And one way of doing that is through questionnaires, and possibly even through environmental sampling. We're not going to be able to do environmental sampling in this study, so we did want to focus more heavily on the questionnaires.

And because of the constraints of time and so on, we also know that we're not going to be able to ask questions that necessarily focus on every single chemical that we'll be analyzing.

The two classes of chemicals, in particular, that we chose to emphasize in the questionnaire include pesticides and perfluorinated chemicals. But we also will be including questions that get at metals, flame retardants, phthalates, environmental phenols.

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MS. LEE: We again, thinking of participant burden and the literacy levels and language issues of the patient population, we wanted to have one of the questionnaires be administered in person, and one that would, again because of the kinds of questions that we were trying to ask, we felt would be better addressed if the participant had this -- could fill out the questionnaire at home.

And you'll see why in a minute, but we wanted to get at certain behaviors, products that she uses, et cetera.

We certainly wanted to have the questionnaire take no more than an hour, each of them, for filling out or for personal administration. And to help with the language issues, we also want the documents translated into Spanish.

Because with the analytes themselves, we also wanted to address things like timing of exposure to biospecimen collection. For instance, some of the chemicals like the pesticides, non-persistent pesticides, we know that we -- that the point of being able to actually capture them, their half-lives for instance, we want to get them information closer to the time of collection.

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MS. LEE: So with the questionnaire development, we have a technical work group, a small committee, comprised of both staff from CDPH -- California Department of Public Health, the Office of Environmental Health Hazard Assessment, as well as UCSF. And as with any study, we always start with the scientific literature looking at the chemicals per se, and researching the scientific literature.

So we wanted to specifically look at biomonitoring studies health assessments, exposure investigations, et cetera, related to the chemicals of interest. We also then contacted the researchers, the principal investigators to ask for samples of the questionnaires and their protocols. And some of the example questionnaires that we looked at are listed here on this website.

The CHAMACOS one, courtesy of Dr. Bradman, the National Children's Study, a questionnaire developed by the Occupational Health Branch specifically to look at occupational histories of pregnant women. Those available from NHANES. And one from Health Canada for the Maternal Infant Reproductive Environmental Chemical study. And one also from the University of British Columbia, some researchers there carrying out chemicals and health in

pregnancy.

To reduce participant burden, we also made a list of variables available from the prenatal newborn medical records that we could just abstract and not have to personally ask about. We compiled a number of these questions. And then we really wanted to ask ourselves how are these going to be used in any data analysis. So kind of an iterative process there. And then, of course, after compiling them, we have done an initial very limited field test with just some colleagues in our office, just to again to assess clarity of the questions, flow of the questions, and get a rough sense of how much time it took to actually administer these questionnaires.

And we have plans for once the questionnaires go through the individual -- the respective individual review boards, that we will do a more formal testing with participants with people that mirror the characteristics of our target population, so definitely with pregnant women, some in Spanish and some in English.

And then, as I indicated before, we expect that there will need to be some modifications of not only the questionnaires, but with your input now, possibly some of the language in the informed consent and so on, that we'll submit modifications to the IRBs again for final approval.

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MS. LEE: So I'm going to stop here and ask if there are any questions now regarding the questionnaire development process or any considerations of the questionnaire.

And before I go into the specific examples of both the in-person questionnaire and the at-home questionnaire.

PANEL MEMBER SOLOMON: I guess -- this is Gina Solomon. I have a question about the decision to focus on the pesticides as one of the groups of chemicals that's a high priority, because this -- in the study you're looking primarily at organophosphates, at least that's my recollection, which are not used much in urban settings anymore. And yet this is an urban population.

If this were an agricultural population, I'd think very differently. And so I would tend to expect that that there -- you know, lots of questions about what they use for household pests will not end up being as relevant.

And so then I was curious whether that means that you're going to be focusing on dietary history as a potential source of exposure to organophosphates, is that --

MS. LEE: We do have a dietary component in the personally-administered questionnaire. The decision to

focus on pesticides and perfluorinated chemicals was something that the technical work group made up, primarily of the State staff and UCSF staff decided were high priorities after kind of looking through a number of other issues.

And with the pesticides I think recognizing that again, we're -- this is still a pilot for us. And we hope to do something more expansive in other areas of the State, where maybe it's not urban. So we're piloting a number of the instruments and procedures with the intent that it be more applicable, not only in urban areas, but potential in rural areas as well.

Yeah, we're doing pyrethroids as well, not just organophosphates sorry.

CHAIRPERSON MORENO: Okay. Other questions?

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MS. LEE: So with that, let's go on to the details of the questionnaire. As I indicated, at the first encounter, we will be providing the participant with the at-home questionnaire itself and instructions. The chemicals that we particularly focus on for the at-home questionnaire, include the perfluorinated chemicals, flame retardants, parabens, and other environmental phenols, as well as phthalates.

And again, this is intended to give us

information on potential exposure sources posed in the home environment and focusing somewhat on cleaning and personal care products that she uses -- the participant uses during pregnancy.

The participant is instructed to either mail it back to us, and we do provide postage, or return it at her next visit.

So the next slide will give you an example of the instructions we provide specifically for personal care products.

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MS. LEE: Because we want this to be fairly straightforward, we ask that she just gather up all these products and then fill out a chart. And the example of the chart is given in the next slide.

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MS. LEE: So we've given an example here. And the survey administrator will -- I mean, the research assistant staff will actually go through this as an example, for instance. So here she would be instructed to fill out the brand, any pertinent name of product, and other information and kind of circle here you see where it can be found on a particular container. If she doesn't use a particular product, she's just to indicate it in the box.

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MS. LEE: The chart probably will be the most time consuming part of the questionnaire, the at-home questionnaire. The balance of the questionnaire really is -- the rest of the questions are given in this kind of format, where they just respond yes or no, and this one is asking specifically about stain resistance or water resistance.

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MS. LEE: The next question -- we've included examples of pictures to be more illustrative. And here this is asking about furniture in your house, like a sofa or chair that had exposed or crumbling foam and with pictures of exposed foam.

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MS. LEE: Any questions regarding the at-home questionnaire?

PANEL MEMBER QUINT: Julia Quint.

Are there any questions related to possible take-home exposures? I know this is the pregnant woman, but you know there are -- they're living in a place where somebody works and is -- you know, there may be a chance of bringing work dust or contaminants home on clothes that would be a potential exposure?

MS. LEE: Not so much on the at-home

questionnaire, but in the in-person one. And I'll get to that in a second, there are questions that allude to that.

PANEL MEMBER QUINT: Okay. But it would -- the exposure would be at home, because it's take-home exposure, but you're seeing that as not a part of the at-home questionnaire.

MS. LEE: Right. Partly because the at-home questionnaire is focusing on, as Dina Dobraca, one of our epidemiologists, who helped to develop the at-home questionnaire is focusing a lot on personal care products that pose potential dermal exposures, as an example. And then other things that are best assessed in terms of counting electronics and things like that, so that she's actually at home able to count them and do a tally, those kinds of things.

But the importance was, you know, we're not guaranteed. And again, this is again our piloting method that will actually get the at-home questionnaires back. So anything deemed of high importance, we wanted to ask in person.

PANEL MEMBER QUINT: The other question I had is about cleaning products at home. Is that a part of a different --

MS. LEE: Yes.

PANEL MEMBER QUINT: That's not the at-home

questionnaire.

MS. LEE: No, that's part of the at-home questionnaire too.

PANEL MEMBER QUINT: Okay. I missed it, I guess.

MS. LEE: I didn't include questions -- examples of all the questions examples, for brevity's sake, but they are included.

PANEL MEMBER QUINT: Okay, thanks.

CHAIRPERSON MORENO: Dr. Wilson.

PANEL MEMBER WILSON: Well, you may have answered it. I guess, you know, my question is if some piece of this is going to try to capture occupation at that time or prior to pregnancy. Would that be the in-person one?

MS. LEE: That's an in-person question.

PANEL MEMBER WILSON: Okay. So we'll wait.

MS. LEE: Because it was deemed high enough importance that it was -- we wanted to guarantee, you know, a high rate response rate to those questions that we wanted that asked in person, rather than rely on the at-home.

PANEL MEMBER WILSON: Right. Thank you.

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MS. LEE: Okay. So let's go on then to the second encounter, where -- and in between -- I just want to comment that we have plans to contact the woman by

phone, in between her first encounter, which is 28 to 34 weeks, and her next encounter, which would between 34 and 38 weeks. Again, to remind them of their important, for instance, for the -- and to remind them also to bring back the at-home questionnaire. So that's just kind of a phone contact we'll make in between.

But at the actual second encounter, we will be collecting the maternal urine sample. We'll be administering an in-person questionnaire. We collect the at-home questionnaire hopefully. And then we'll be going over kind of an educational handout and providing the stipends for the two questionnaires plus the urine sample.

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MS. LEE: So I'm going to just talk a little bit now about the actual in-person questionnaire, what we call the exposure assessment interview in the Institutional Review Board documents.

And in the in-person interview, we do focus on occupational history, hobbies and home activities, diet, behaviors, use of certain products, as well as asking questions that get at demographic information.

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MS. LEE: So this is the first question. And I'm not going to go through all the questions, but it's intended to be with a research assistant with a laptop.

And this is on the screen of the laptop. And she's verbally asking the participant these questions. So the participant doesn't see these questions. She's being asked to respond to them verbally. And the research assistant will be inputting it into the laptop.

So the first question, since you became pregnant, have you or anyone in -- sorry, excuse me. Let me ask it properly. Have you -- since you became pregnant, have you upholstered furniture at any of your jobs?

So the preface to this is there are other questions about are you currently working now, et cetera, et cetera.

But we decided for times really to make it fit within this hour timeframe, to capture the pregnancy part of exposure, not prior to pregnancy.

Any questions?

PANEL MEMBER QUINT: Julia Quint again. I'm just wondering, I know often people in these questionnaires will say, since your last menstrual period, instead of since you became pregnant. And, you know, I understood the distinction being as a lot of women don't know when they become pregnant. Sometimes you know. It's missed periods and that sort of thing.

So was there a decision that that was too complicated or -- yeah.

MS. LEE: Yes.

PANEL MEMBER QUINT: That's what I thought.

MS. LEE: Yeah, we wanted to use language hopefully that would just be clear. And actually looking at like the National Children's Study, the CHAMACOS and so on, I think that terminology, since you became pregnant or, you know, during your pregnancy, it seemed to be more user friendly.

PANEL MEMBER QUINT: Okay.

MS. LEE: And so if the participant responds yes, she's asked how many hours each week or each month. She does each of these activities on a job, recognizing that she may have more than one job also.

CHAIRPERSON MORENO: Diana, can you hold on one second.

Dr. McKone.

PANEL MEMBER McKONE: We're so far away, you can't see us.

(Laughter.)

PANEL MEMBER McKONE: I guess the question I have -- maybe we should save this till later, but has someone tested this with regard to how honest people are really going to be in responding to this? I mean, my fear is that these are pretty leading in the sense that somebody is going to -- they're going to say, oh, I

shouldn't have done that. I don't want to admit that I was removing paint. You know, the fear that the interviewer is judgmental, even though you try not to be, but it's sort of like they all sound like things you shouldn't be doing, when you're pregnant is the way it -- and so it's going to lead to a little bit of this sense that well, I'm not going to admit that I did this.

So how do you test against that?

MS. LEE: Well, that's where the issue of questionnaire validation comes in. And there are very few validated questionnaires.

So, yeah, we're relying on truth, to some extent. But again, if somebody has done this habitually, whether they've, you know, welded or soldered, you would expect maybe to see lead. So, again, this is tying two potential exposures that we might be able to back up through the biomonitoring efforts themselves.

PANEL MEMBER McKONE: I just -- to give you some background, one of our students was working on the issue of smoking in cars with children. And the questionnaires really failed to match at all the level of cotinine they were finding to correspond to it. And again, it's the issue of most people -- a lot of people in this situation have some fear of being judged by the questionnaire, so they will say no, I never smoke in my automobile.

CHAIRPERSON MORENO: Dr. Solomon.

PANEL MEMBER SOLOMON: This puts all of these questions in the context of a job, but some people may be doing these either as a hobby or in their own homes or having them done by other people in their own homes. So is that a whole other section of the questionnaire?

MS. LEE: That's the next question, the next slide.

PANEL MEMBER SOLOMON: If so, is just sort of makes me wonder is this the most efficient way of cramming every into an hour, because it's a lot of questions. And I'm sure you thought about alternative ways of doing this, where you do sort of more of an open-ended job history, and then classify potential exposures by job title and so forth. And there's all kinds of problems with that.

But this is going to tend to get a lot of noes for these. And then it makes me worry about the things that then get left off that might be relevant, but we don't think of them.

MS. LEE: That's a good point. We don't have a lot of open-ended questions, possibly because of the data entry issue and having to recategorize and so on. I think we do have some open-ended questions. We tried to capture again the kinds of questions -- and this question in particular, the occupational question, that would relate

to the chemicals that we're trying to focus specifically upon.

So going back to the list that was on one of the earlier slides, we don't capture all the occupations that might lead to some chemical exposure for instance.

PANEL MEMBER QUINT: Julia Quint.

Also, I'm not sure if it's embedded in this project, but the Occupational Health Branch, HESIS in particular, had a project with Tracey in the Program on Reproductive Health and the Environment through UC Berkeley. It's kind of a convoluted process.

But part of the goal of that project was to ask a limited number of occupational health and environmental health questions that could be perhaps inserted into an intake questionnaire by a clinician. So our goal was to see if we could get clinicians to start to begin to ask these questions.

So, you know, the sort of model that Gina is talking about certainly is a valid one. But, you know, if we're trying to do both here, that would be one reason to go this way.

And, you know, I was very struck by what Tom said. And this would make it longer, but I was wondering if you could put some -- you know, mix the questions up a little bit so it didn't sound to make them have some

questions that didn't -- weren't so negative that a person being interviewed couldn't necessarily target as being a negative sort of action on their part, with respect to an outcome of a pregnancy.

It would make the questionnaire longer, but it would be, not a foil question, but something that wouldn't necessarily get at an adverse exposure, and maybe, you know, so it all didn't seem like it was directed towards an exposure to a toxic chemical.

It would make the questionnaire longer, but it perhaps would mitigate some of what I understood Tom to be referring to, you know, like the tendency for somebody to say, Oh my God, I'm not going to admit that I painted while I was pregnant, because it probably would harm my baby?

So that's something to think about. I don't know if you could just stick a few in there that would not be so directed toward the answers we were trying to get, in terms of exposures to toxics.

MS. LEE: Do you have a particular example of a question.

PANEL MEMBER QUINT: No, I'd have to think about it. But it would be -- you would have to think about it a little bit, and not make it a two-hour interview instead of a, you know, a one-hour interview. But I'm just very

struck by what he said, because I think there is a tendency, if I were answering some of these questions and was pregnant, I'd be maybe not so honest. Even though I would want to be honest, I might not be honest.

MS. LEE: Oh, before I forget. We did actually start with the questions that you mentioned from the Occupational Health Branch, and widdled down from that, but they are kind of woven in as well.

DR. DAS: I just wanted to address some of the issues that were raised. We're not presenting you with the entire questionnaire, so you don't have the benefit of seeing what is actually here. So we do state in the beginning, "For the purpose of this questionnaire, please think of your pregnancy as beginning at the time of your last menstrual period."

And we do have some open-ended questions, such as what was your occupation, or the name of your job, what do you do at your current job, and a couple other questions that are open-ended. So it's not all multiple choice. These are meant to, as Diana said, to really target the chemicals of interest. And we felt that these were the best that would represent those exposures, but there are others that we can classify and sort of get to potential other exposures, even though we don't get to the specific jobs that are in this level of detail.

CHAIRPERSON MORENO: Any other questions?

PANEL MEMBER LUDERER: That was actually my question, whether there are questions included in the questionnaire that ask them what jobs and job titles they had during their pregnancy? I think that's useful information that you wouldn't want to miss and only have these kinds of very detailed specific questions.

MS. LEE: Right.

CHAIRPERSON MORENO: Dr. Bradman.

PANEL MEMBER BRADMAN: I was just going to comment. I know how -- actually, Rupa answered my questions as well, but I know how challenging these kinds of things are. And, you know, I'd be willing to make an offer to review the questionnaire. And I don't know if anyone else on the Panel would want to take the time to go through it, and we'll each have our own perspective and experience. But, you know, if you want more outside eyes, I'd be happy to do that.

MS. LEE: Thank you.

CHAIRPERSON MORENO: This is Ed Moreno. Can you remind us where in the IRB application process this survey is?

MS. LEE: All the documents so far have been submitted -- plus the study protocol have been submitted to UCSF's IRB -- Institution Review Board, which is also

going to be a joint one with UC Berkeley. And the ones being submitted to the California Department of Public Health's IRB is in the process of being put together now, so that we -- and based largely on what's already been submitted through UCSF's.

DR. DAS: This was a comment triggered by Asa, your very kind suggestion to review the questionnaire. If we give the members of the Panel -- or the entire Panel something to review or to comment on, we do have to release it to the public. And that is a consideration for us, that we would -- it's just something to consider, that whatever we give to the Panel, we have to release to the public, if it's in draft form or not.

CHAIRPERSON MORENO: Ed Moreno again. And Diana, you've had a -- I mean, it sounds like there's tremendous interest by Panel members to assist. How might, in reviewing the questions, might we be most helpful to you, considering where you're at with the IRB process.

DR. DAS: I believe because of the complicated IRB process, it would be very difficult to accommodate additional comments, because any changes we make to any document that's submitted to the IRB has to go back to the IRB. And UCSF's IRB process particularly is very onerous, in terms of marking up each change. So any change that's made has to go back to the IRB and delays the whole

implementation of the project.

So I would suggest at this point that you give us general input, based on what the categories and the types of questions we're presenting to you.

CHAIRPERSON MORENO: Okay. All right. Thanks. Would Panel members still like to see the survey though?

PANEL MEMBER BRADMAN: If it would be of use, but I totally sympathize with the IRB revision process.

CHAIRPERSON MORENO: All right. Thanks.

Diana, do you want to continue?

MS. LEE: Yeah. Just a couple more slides to give you an example and you we're asking about hobbies.

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MS. LEE: This is a question specifically again asking about similar exposures as the previous slide, but done in a home setting, by either the pregnant woman herself or someone else in her home, again asked in a similar way to capture ours per week or hours per month.

And accompanying some of these questions, we do have pictures to help illustrate the kinds of activities we're interested in. And this is hopefully self-explanatory.

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MS. LEE: And with respect to pesticide use, this is our questions that get at use in the last 30 days by

either the woman or someone in -- someone else in the home, chemicals for controlling flees, cockroaches, ants, termites, flies, et cetera, and in the home or control flees on pets or to kill weeds, insects, or other pests in their home or outside in their yards.

And again, if they answer yes in the last 30 days, they're asked how many times, and also whether they used it in the last 24 hours.

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MS. LEE: We also have questions about types of pots and pans, specifically again getting at the perfluorinated chemicals. And we provide illustrations about common pots and pans that can be used in the home, with the caveat that non-stick coatings are smooth, usually black or gray. And then we provide pictures of non-stick or Teflon cookware, including appliances.

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MS. LEE: And with respect to appliances, these questions were put together from the UCSF staff. Do you use a particular appliance like a rice cooker, electric grille or a fry pan. If yes, how old is it? Does it have scratches? How often do you use it? And do you wash it by hand or by dishwasher?

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MS. LEE: With respect to the diet history, we're

not asking for detailed recall, but we do ask about -- since they became pregnant, how often do they eat these particular food categories, and they can answer either by day, week, or by month. And we ask with the exception of fish or shell fish, we ask -- and canned foods and drinks, we ask about organic, as well as nonorganic, meat, poultry, milk and dairy products, rice, pasta noodles, fruits and vegetables.

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MS. LEE: So that was just kind of a smattering of some of the questions, and you've addressed other concerns about the questionnaire. But at the end, we feel we know for a fact that the woman is likely to have lots of questions, so we want to take the opportunity to answer her questions and provide and educational handout.

And in advance, I think we provided you with a draft that our field investigations coordinator, Rebecca Chung, has been working on. And the draft version is still going through some revision, but we are also working with our graphic artist to provide some illustrations. And this slide gives you an example of how we might incorporate graphics for this particular handout. And again, it would be also translated into Spanish.

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MS. LEE: So I'll stop here and ask for any

additional questions about our in-person interview or the educational handout.

CHAIRPERSON MORENO: Dr. Wilson.

PANEL MEMBER WILSON: Thank you, Ed.

So on the in-person interview, I'm coming back again to the question of occupational exposures. And for the woman who has spent the last, you know, five or ten years working in the building services industry of some kind using cleaning products every day, is that going to get captured here? Is it up -- in other words, if it happened -- if that occurred, and she left her job when she became pregnant?

MS. LEE: It is captured. I didn't prepare a slide about that, but we ask questions about before you became pregnant did they do certain activities, like upholster furniture, clean floors, windows, use, make or handle insecticides or weed killers, apply varnish, mix thinner, apply paints or lacquers, remove or strip paint, work with glues or adhesives, degrease tools, machines, or electronics, do welding or install carpet.

And then so -- but we're not asking about before pregnancy. We're asking only during their pregnancy.

PANEL MEMBER WILSON: Right. I'm just curious about that, if that's -- or maybe it's too late to do that, to try to capture that time period or maybe it

doesn't -- maybe it's not useful information.

DR. DAS: Is the question why we're not asking about these activities before pregnancy?

PANEL MEMBER WILSON: Yes.

DR. DAS: A couple of different reasons. This was a collaborative process, and it was, sort of, the consensus of the group and partly the length of the questionnaire. And the other is for the persistent chemicals, yes, it would be helpful to know what they did, but those chemicals are going to be found and probably reflect long-term exposure. For the non-persistent chemicals, we feel that the timeframe that we're capturing is going to reflect the timeframe that the measurements will reflect.

PANEL MEMBER WILSON: Okay.

CHAIRPERSON MORENO: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

But you are asking, I understood in that overview question, about job titles or occupation or something like that, but -- and perhaps there's some length of time the person that's been in the occupation? So you'll have some information on that.

MS. LEE: We do ask about time period, yeah.

PANEL MEMBER QUINT: I'm sorry?

MS. LEE: We do ask about time period.

PANEL MEMBER QUINT: That's what I thought.

MS. LEE: And then other substances we ask about include janitorial cleaners, dry-cleaning chemicals, nail polish, hair dyes. So other substances as well.

CHAIRPERSON MORENO: Dr. Wilson.

PANEL MEMBER WILSON: Yeah, thank you.

I appreciate getting the draft of the handout for, you know, what the women can do in a proactive kind of way. And, you know, it's -- you know, typically we don't do this kind of thing. You know, I mean we're more -- you know, we're sort of focusing on the things they should avoid, and the hazards and so forth. And so it's -- I think this is great.

And the only -- and I know this is a draft, but I did have a couple thoughts on it. One was if there was, if you are remodeling or consider remodeling a room or your home in preparation for a new member of the family basically that -- you know, Alameda County Lead Poisoning Prevention Group, for example, and probably the State one has some really good practical recommendations for dealing with, you know, the homeowner operated home restoration project or repainting -- refinishing and repainting. You know, that could be very easily put in here.

I guess that would be my main suggestion.

MS. LEE: So Rebecca will look into that.

CHAIRPERSON MORENO: Dr. Luderer and then Dr. Solomon.

PANEL MEMBER LUDERER: I also really appreciated being able to review that handout. And I think it's really nice to have these concrete steps that women can take to reduce exposures.

I did have just one kind of very specific comment about one of them, which was under the in-your-kitchen part of it, where you say, you know, "Do not use dishes or pots made outside the U.S. for food or drinks unless they have been tested and do not have lead in them."

And I'm wondering whether what you're really trying to get at there is things like ceramics that might contain lead in the glaze. And then you should be more specific, because I think first of all it would be very hard probably to find very many dishes or pots that are not made outside of the U.S. And, you know, most dishes and pots don't have any kind of material that comes with them saying that they've been tested, you know, and don't contain hazardous chemicals.

So I think that's just a little too general and probably maybe not very helpful. You might want to focus on hand-made ceramics or use some verbiage like that.

MS. LEE: Be careful, I'm a potter.

(Laughter.)

MS. LEE: So I think we have struggled with that, and I think we'll take it back. And do you want to say anything about that Rebecca.

MS. CHUNG: This is Rebecca Chung. I'm with the California Biomonitoring. All right, so that recommendation is consistent with California Department of Public Health, the Lead Branch -- the Childhood Lead Poisoning Branch, but we can certainly make it less broad to reflect that.

MS. LEE: Where possible, we did look at materials produced by State agencies and so on, and tried to use similar language so that we were consistent, if possible.

PANEL MEMBER SOLOMON: This is Gina Solomon.

Maybe it was just the impression I got, based on the way that the questionnaire was presented, but it appears -- it appeared as if the dietary history was sort of fairly broad, not super quantitative, and not a lot of detail there. And maybe I'm wrong.

But if I were to put my money on where like the vast majority of people's exposures are going to be coming from, I would put it on dietary factors for most of these chemicals. And, you know, studies on phthalates even, where, you know, maybe you'd expect less of that, it seems like it's mostly dietary as well.

And a lot of these really detailed questions about specific job practices, you know, do you upholster furniture as part of your job or do you mix and manufacture pesticides.

At least in a sample size of 100 San Franciscans we're going to have zero saying yes to those questions. And so I know it's kind of late to provide input and -- but, you know, my advice would be to focus much more on dietary and have more of a broad occupational history, but not like use time with lots and lots of specific questions where everyone is going to say no.

DR. DAS: Believe it or not, the occupational history is pared down compared to what we had originally in mind, and the dietary portion has been expanded probably for the same kind of thinking that you're pointing out. So the questions -- I can't remember what was presented, but we do ask about meat, poultry, fish, times per day, per week, per month, per year, eggs, milk, food in cans, drink in cans, and then organic fruits and vegetables.

So, you know, it's not a very extensive dietary history, but those are the questions that we ask.

PANEL MEMBER SOLOMON: And so for each of those things, you're getting a frequency, and then -- but you're not getting like details about what exactly what foods.

Like for canned foods, for example, the BPA resin linings are used on canned vegetables, but not in canned fruits. So if they're having canned fruit, they're probably not getting exposed to BPA. If they're eating canned beans or tomato sauce, they probably are. So it might be a little tricky without more detail to get things like that.

MS. LEE: Yeah. We ask a general question about food in cans in just that general category, so that it would capture, you know, meets, poultry, anything in cans basically.

PANEL MEMBER SOLOMON: Right. And then like some of the studies on phthalates have found some of the highest levels in spices, which is probably -- I don't know how that ends up being, in terms of exposure source, because people tend to use them in small quantities. So anyway, just a concern, but I'm glad to see that that's been beefed up and I'm getting some good frequency -- consumption frequency will be important. And then I guess the other thing is, in terms of like seafood, which kind of fish gets to be pretty important too.

DR. DAS: Yeah, regarding the question about BPA. BPA is not one of the chemicals we're focusing on, so we did not focus our questions to get details about BPA. And this is a pilot again. So we did have to sort of focus our attention on issues that we felt we wanted to focus in

for this population.

We did have these debates in our group about how much detail to put on each of these, including kinds of seafood. And for various reasons this kind of general history is what we ended up with. Again, partly driven by the focus of the chemicals that we were particularly interested in.

CHAIRPERSON MORENO: Dr. Quint, it looked like you had a question, and then Diana you still have some more to present, correct?

MS. LEE: (Nods head.)

PANEL MEMBER QUINT: That's okay. I just -- I heard some talk about remodeling or sprucing up before the baby and concentrating on lead. I just want to point out, there's a solvent that's a developmental toxicant that is used to strip paint, N-Methylpyrrolidone. So if we -- you know, it's widely used. And think about inserting something about paint stripping, you know, and use of that chemical, because it goes through the skin, et cetera, and I think it's a real potential hazard.

MS. LEE: Thank you.

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MS. LEE: All right. So going on, we're still at -- okay, let me rearm it. So earlier I said that if a woman asked specifically to have her results back, she is

then asked a subsequent question about whether she's willing to be contacted later on to participate in a feedback session. And this feedback section is part of the report-back component.

And in this case, it would be the usability test that the staff from Health Research for Action are planning on doing to develop a template that we can use to actually return results. So they'll come up with examples of a template, for instance, and then through a refinement, through these one-on-one kinds of usability test situations, they'll interview women individually and get feedback on their comprehension and then lead to the next version that will hopefully then indicate necessary changes to improve comprehension and usability.

So this slide is just to illustrate that between 34 and 38 weeks, roughly 16 to 20 women, not the same women, will be asked to participate in a series of usability tests. And there will be two done in English and then two done in Spanish.

And so it's an iterative process again. And that is a totally separate interview that will only happen for these 16 to 20 women, with a separate stipend to be provided.

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MS. LEE: So the next slide kind of gives you an

example of some of the questions that the staff would ask them. For instance, they'll show a hypothetical test result in different formats, and then ask them to explain what this figure tells them, what did you like or not like about how these results were presented, and is there anything you would like to know about your test results that this example doesn't tell you. Again, trying to get at comprehension and understand -- and user preference for the way this information is returned.

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MS. LEE: Okay. So going onward to the bulk of the -- all the women who follow through with delivery and so on that we can track, we will be collecting maternal blood, umbilical cord blood, and then providing stipends for that during the delivery period. And then while the woman is in the hospital, we've been told that that's the optimal time to try to look at the medical records and do data abstraction using those records.

So we'll aim for that period and know that we'll probably have to do some catch up, if we don't finish it all during the time the mother and the baby are in the hospital, those initial 48 hours.

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MS. LEE: This slide here just shows, you know, kind of a graphical format, the dispensation of the

specimens to be collected. The urine collection will happen again much earlier during -- before delivery. And these are the analytes to be tested for in the urine. The urine will be frozen at UCSF and then shipped to our lab in Richmond.

At delivery, the mother's blood will be collected and again indicates the blood will be analyzed for metals. And the serum will be separated at UCSF and then frozen and sent to, again, the Richmond Lab. And further aliquots will be taken, and then sent to the Environmental Chemistry Lab for analysis.

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MS. LEE: Similarly with the fetal cord blood, we will be doing some metals, as well as persistent organic chemicals in serum.

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MS. LEE: And I don't know if you caught it, but we are hoping to get a total of at least 30 ML's of whole blood that -- I mean red top -- blood collected in red top tubes that can be centrifuged. And one of those tubes will be stored or archived for -- and possibly used for splits as well.

We have a commitment from the Inorganics Lab that they will be able to do the blood metals roughly every two weeks, analyze a batch of blood metals. And this is to

enable us to catch high leads in maternal bloods, as soon as we can.

We have worked out a procedure where -- well, it's mandatory lead reporting in California. So if we see that a maternal blood is greater than four and a half micrograms per deciliter, as recommended by our Occupational Health Branch, there will be some follow up of those women.

Similarly, for fetal cord blood, if we find findings greater than 10 micrograms per deciliter, they will also be referred for follow up through their respective county system.

And with mercury, we're going to be defining a level probably close to the 5.8 micrograms per liter, unless we have better evidence that maybe we need to go lower for maternal blood.

The rest of the -- with respect to these kind of critical values, all the values will be reviewed by UCSF or State staff, and then there will be some contact with participant -- by phone and mail immediately, if needed, and then referral with Dr. Naomi Stotland at the Women's Health Center for ultimate referral to UCSF's Occupational Environmental Medicine Clinic for follow up as needed.

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MS. LEE: With respect to the other analytes,

that aren't, what we call, critical value follow up, we expect that some analyses of these analytes will take place sooner rather than later. And so there is actually two periods of report-back that we will be aiming for.

Some of the test results we anticipate returning with nine months to a year of delivery. And the next slide, I think, gives you a little bit more details about that.

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MS. LEE: So that roughly 50 women will be contacted for a one-hour report-back interview, results communication interview, that either Dr. Rachel Morello-Frosch or her staff will conduct.

And some of the results that we anticipate being able to return back sooner include possibly the phthalates, the organophosphate, pesticides, pyrethroid pesticides, and the blood metals for instance.

The bulk of the organic -- persistent organic pollutants will roughly take maybe up to two years to deliver. And those will be mailed back using the agreed upon template. Actually, the template developed early on in the project will be used for both report backs. So the initial nine month one to a year after delivery will gather more information about the understandability and so on, and how the participant, in particular, felt about

receiving her results, and then with direct follow up.

And then the last and subsequent result report-back at 18 months to two years after. They'll just be provided a mailed-back notification with a name and a contact that the participant can contact either at UCSF or the State staff.

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MS. LEE: So this is kind of diagrammed here. Ultimately, the data analysis for this type of report-back component is still being defined, and will be worked out jointly with staff at Health Research for Action, as well as Dr. Rachel Morello-Frosch.

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MS. LEE: And I think Dr. Das is going to continue with the balance of the data analysis.

DR. DAS: So we have started to define some of the elements of data analysis that we would like to complete. The data analysis will be shared between all three parties, the Department of Public Health, UCSF, and UC Berkeley.

And we are establishing, through an MOU, who will do what. We're trying to define all that before we actually start the study. At a minimum, we would like to look at some descriptive statistics. For example, the presence and distribution of levels of chemicals in

pregnant women, compare that with national data from NHANES. Also, the presence and distribution of levels of chemicals in infant cord blood. And then to compare the levels of maternal blood chemical levels to infant blood.

Next slide.

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DR. DAS: In addition, we'd like to look at some of these elements, demographic differences on chemical levels, associations between chemicals and the exposure sources, using the questionnaire data as a measure of exposure, the relationships between outcomes, birth outcomes and chemical levels.

We realize that this is a relatively small sample size, and our power to detect some of these differences may be pretty low. But since this is a pilot for a larger study, we hope at least to start looking at some of these elements.

In addition, the last bullet here is something that UCSF is particularly interested in developing a metric to look at the cumulative maternal infant exposures to chemicals using such elements as frequency of exposure, similar acting chemicals, and a toxicity-weighted summary measure of exposures is something they're hoping to develop.

Next slide.

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DR. DAS: And finally, this is an estimate of the timeframe of this project. As you've already heard, the IRB protocol has been submitted to UCSF's Institutional Review Board. And it will be submitted to the Department of Public Health's Institutional Review Board in a couple of -- by the end of next week.

In March and April, we will be receiving comments from both IRBs, and then responding to comments and sending the revised protocol. And we hope to start recruiting and begin getting the questionnaire and samples in May to June. Complete all the data and biospecimen collection by the end of the year, and then the lab analyses will take most of next year to complete, with report generation and report back going into the end of next year, 2011.

So at this point, are there any questions on this last part or any component of the project?

CHAIRPERSON MORENO: Thank you, Rupa. Does that conclude your presentation?

DR. DAS: Yes.

CHAIRPERSON MORENO: Further questions from Panel members?

Dr. Solomon.

PANEL MEMBER SOLOMON: I'm sorry. I have a

follow up from my previous dietary question, because I went back to remind myself what the priorities were, and noticed -- so it's pesticides and perfluorinated chemicals. And so I just wanted to be sure that there are questions about non-stick coatings. And so do you eat microwave popcorn and Chinese takeout and pizza and all those are in there?

DR. DAS: Yes.

PANEL MEMBER McKONE: Pictures.

DR. McNEEL: Pictures.

DR. DAS: Yes, pictures -- yes, we have those questions in there.

PANEL MEMBER SOLOMON: Okay, that's great. That's helpful.

CHAIRPERSON MORENO: Dr. Wilson.

PANEL MEMBER WILSON: Just a comment. Thank you for this really clear set of slides, the schematic graphic that you traced from the very beginning of the slide set to the end was really helpful for tracking your presentations. So thank you.

DR. DAS: Yeah, thanks to Ngozi our CDC prevention specialist for coming up with that.

PANEL MEMBER BRADMAN: I had a question.

CHAIRPERSON MORENO: Yes, go ahead.

PANEL MEMBER BRADMAN: On slide 49, my eyes are

finally changing. On slide 45, you talked about critical values for follow up. And you mentioned lead and mercury, and those particularly have some known standards. It sounds like you were going to use a process to develop some criteria to evaluate high levels for other compounds as well. I know there's a lot of challenges there. Is there more you can say about that or is that maybe something we can talk about at another meeting or --

DR. DAS: That's definitely something we will talk about at another meeting. That's something that's in development. And I don't think we have enough developed to discuss it at this point, but it's definitely something we will bring up at a future meeting.

PANEL MEMBER BRADMAN: I had another comment too. There was some written comments that were submitted by Dow Chemical and Dow AgroSciences about this project. And I'm wondering if there's anyone -- is there going to be a comment on that from Dow or -- okay.

CHAIRPERSON MORENO: Dr. Bradman, we'll open that up to public comment in just a minute.

DR. BRET: Well, I have no public comment. I'm just here representing my colleagues.

This is Brian Bret from Dow AgroSciences. I have no public comment. I'm here just representing my colleagues who are unable to be here themselves, and we

appreciate the opportunity to provide some comment and feedback and would look forward to work cooperatively and provide whatever assistance we can, particularly on our molecules, in particular and our experience with these type of studies.

Thank you.

CHAIRPERSON MORENO: Dr. Quint, do you have another question?

PANEL MEMBER QUINT: Julia Quint.

It's just a follow up to Asa's comment, a question about follow up. Even if you can't make, you know, quantitative -- can't do a robust comparison or to say anything about the values, you are comparing some of the values to NHANES. So I'm wondering if that's helpful is to say based on what the population at-large, you know, the values there, that, you know, you're in the 95th percentile or something.

I mean, that -- certainly, those types of comparisons could be made without having to say anything about, you know, what it means for a health outcome. But it is, sort of, an indicator that exposure should -- an attempt to reduce exposures, to the extent possible, should begin immediately, it would seem to me. So I'm wondering if any of that is planned?

DR. DAS: Yes, that's an excellent comment. And

that is something we do have planned to compare overall, and then individual results to the NHANES information. So both in terms of presenting it to the public, as well as communicating back to the individual, the one thing we do have is the national data of -- data from the National Biomonitoring Program, and the educational materials that we can develop, such as the example that you have to start to recommend to people some of the preventive measures that they can take.

MS. LEE: I think that's also the challenge that we'll have in trying to come up with a, hopefully, easily understandable template, for returning results when we're measuring up to probably over 100 chemicals, and how to portray that in a way that is understandable, where we have the woman's individual results and want to also show comparison say, either to an NHANES population or another, you know, pregnant women's study or whatever. I the comparisons -- and, of course, the group data, to compare to that will be a challenge.

CHAIRPERSON MORENO: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint. And I like your handout -- I didn't turn it on. I had my mouth there but no power.

(Laughter.)

PANEL MEMBER QUINT: Julia Quint. Yeah, I liked

your handout. And I was wondering if there was some brief kind of overview. You know, it's all about what people can do personally. And I think that that's very important, but the context for that, in terms of, you know, why we want them to do these things and why we're concerning about chemicals, even if it's a few statements, might be helpful, because we also want to raise consciousness without -- because, you know, people are pregnant, so they're concerned about, you know, their babies and what they can do to make them healthy and their part in it.

And I think something about, you know, our concern about chemicals in our environment and that, you know, this is something that lots of people are concerned about, and these measurements are being made or something like that, so that we don't -- I'm just always a little concerned when there's a lot of personal -- emphasis on personal actions, there should be, but also the context for that and why it's important. Because people should be able to eat what's healthy and all this sort of stuff and now we're overly concerned about fish and, et cetera.

MS. LEE: That's a very good point. And I think we're trying not to go on the point of information overload, but also trying to understand what can be conveyed logically.

PANEL MEMBER QUINT: Exactly.

DR. DAS: And that is also part of the whole effort by UC Berkeley and Health Research for Action. I think some of those messages will be developed trying to see what we can educate people on that they can understand, in terms of the overall reason for biomonitoring and what it means in terms of something beyond their personal behaviors.

CHAIRPERSON MORENO: Okay, Panel members, at this point, there may be some more questions, but I want to at least give the public an opportunity to provide any comments. And then we can bring it back to the Panel members.

So, Amy, were there any Emails on this topic?

MS. DUNN: No Emails.

CHAIRPERSON MORENO: Okay. And --

MS. DUNN: I believe we do have someone in the audience.

CHAIRPERSON MORENO: At this time, anyone in the public who's present wishing to speak now is the time to come forward.

Thanks.

And it looks like we have Mr. Baltz. Was there anyone else, so we can divide up the time evenly? Anyone else wishing to speak?

Okay.

MR. BALTZ: Thank you. Davis Baltz Commonweal. Well, I'm very enthusiastic about this project, and have been from the time that the possibility of it became apparent. And I want to commend the staff for all the work that they've done to bring it along. Since the last time we met, the California Wellness Foundation grant has come in, and that is enabling this work on the questionnaire development and the results communication, and that's going to be very important.

You've recruited some wonderful resources, Rachel Morello-Frosch and Holly Brown-Williams. And their expertise will really contribute a lot to this aspect of the project.

I wanted to just make a couple of comments on the questionnaire itself and some things that came to my mind while I was listening to the presentation. I have done a lot of interviewing myself through the years, and I completely understand the need to sort of put some parameters around how long an interview is going to last. But I do think that, to the extent that resources are available and a little more time can be devoted to tease out some of the issues or circumstances that the study contributors will find themselves in and can contribute to the interviewer, that you could come up with some valuable

information, would it be possible, for example, to conduct your in-person interview in the home? Extra expense of course.

But rather than do, you know, an hour long interview and have the study contributor also contribute an hour to filling out the at-home survey. If you could do the survey at home, you have this observational quality to seeing the non-stick or stick cookware and how scratched is it, as opposed to relying on someone's recollection. So that can obviously be very valuable.

You can also, you know, pick up whether there's flaking paint. You can pick up whether there's a lot of phthalate toys laying around that siblings might be using.

So doing an interview in the home presents a lot of challenges and extra expense, but -- and it's probably too late to even consider it, but I think you'll end with a more robust data set, if you can consider doing something like that.

During the recruitment phase, when you're actually approaching people in the waiting room or after they've agreed, it seems to me it might be helpful to also try to explain the public health value of this study that you're asking them to participate in to give them another reason to participate, that in addition to perhaps learning something useful that they can use personally,

they are contributing to something that's broader than their family and even their communities. So that in the future all families that are thinking about becoming pregnant or even families that aren't thinking about becoming pregnant, will benefit from their contribution to the study. It could, you know, help enable them to devote extra attention to filling out the surveys and so forth.

In a similar vein, I think, you know, explaining, for example, in the exposure assessment questions, why these questions are being asked. It's so that we can really zero in on how exposure is happening to these chemicals, so that people can kind of think a little more deeply about their responses.

I also had a comment on the dietary questions. To simply run down a list of food items and ask people do they eat this, do they eat that and how often, you may want to zero in on that ultimately so you really feel you've gotten a good idea of what their diet is. But I think it could be a good idea to have the first question in diet be open-ended and just have them describe to the interviewer what they eat in a typical meal, a typical day, or a typical week, and that will fill out some of the questions already that you have listed in bullet form, but also gives the interviewer a chance to follow up and delve a little more deeply into the exact components of the

diet.

For the questions about, did you use X chemical in the last 30 days, I think for the persistent chemicals, you're going to lose some information that way. You're concerned about chemicals that are going to be present for longer than 30 days, so I think you may want to think about asking have you used -- do you use these chemicals on an ongoing basis or since you became pregnant or since before the time you became pregnant, as some of the impacts that might happen would presumably take place before the mother even knew she was pregnant, but might have been exposed to a chemical that could be harmful.

I'd also then echo some of the comments that were made by the Panel members about really exploring the occupational history, not only of the pregnant woman during her pregnancy, but prior to pregnancy and the take-home exposures that her partner or another family member may have experienced and brought home on their clothes or elsewhere.

And then finally, I'd like to make a comment about the Dow letter, which I saw posted on the website. And, you know, they've pointed out a number of important factors to consider in biomonitoring studies.

For example, you know, if you could take repetitive samples, you would have more information to

work with than a single sample. Sometimes it's important, of course, to measure the metabolites, and especially if you maybe can't measure the parent compound. And for the urine samples, for example, yes, a 24-hour sample would be better than a single sample. But I think the important point is that the people who are designing this study have thought about these things. Any responsible researcher would know that. And you have to address the limitations and the context of these things within the study that you're conducting. And it should by no means prevent you from carrying out the biomonitoring study to begin with.

The reason we're doing this is to gather more information on human exposure to chemicals. And if we could do repetitive samples, that would be great. But in this study, in particular, we're talking about umbilical cord blood and it's simply not going to be possible. So we shouldn't downgrade the value of the data that we can gather just because we can't do it in a different way that might yield more data under other circumstances.

So sorry for being long-winded, and thanks for the chance to comment.

CHAIRPERSON MORENO: Okay. Any other public comment?

Okay, so we'll close the public comment portion and we'll bring it back to the Panel.

This is the opportunity for the Panel to discuss this topic and make any recommendations to the Program?

Anybody?

This is Ed Moreno. So, Dr. Das, in the discussion portion, Panel members did provide quite a bit of feedback on the survey itself. It appears to me that you're in the middle of IRB review for one institution and about to submit to the other institution. So it still seems though that the general comments provided by -- the comments provided by Panel members and the public could be of use in that -- you still have to, I understand, prepare educational material, and you'll have opportunities to engage the subjects -- a portion of the subjects in feedback activities as well. So the information we shared may be helpful there.

And also, you will be responding to IRB questions at some point in this process, so having this information may be helpful as well.

I just want to ask if there's any other way that the Panel could be of assistance at this point?

DR. DAS: Yes, thank you. We've been taking notes on the suggestions that you've provided and we will take them back for consideration and include the ones that are possible to include, both in the revised material that's submitted to our IRB, as well as the educational

materials, which are still under development. And the questions for reach-back, that protocol is still to be developed, so it's not too early to provide feedback in that regard.

I think the information that you've provided and the feedback is very helpful. And I can't think of any other way you can be of assistance at this point. But I think what you have provided is very helpful for us to consider.

CHAIRPERSON MORENO: Okay. Any final comments from Panel members on this topic?

Okay. Thank you, Dr. Das.

DR. DAS: Thank you.

CHAIRPERSON MORENO: At this point, we were scheduled to go to 3:30 on this topic, and then take a break. So I guess we could take a break early. We do have to take a break, because our --

THE COURT REPORTER: Court reporter.

CHAIRPERSON MORENO: -- court reporter -- thank you -- needs to take a break before we continue. So we were going to take a 15-minute break, so I think we can go ahead and take a -- is 15 minutes okay with Panel members and come back?

Is that right?

All right, so on that clock in the back of the

room, I've got 10 'til three, so about five after three we'll come back. Is that good?

All right, thanks.

(Thereupon a recess was taken.)

CHAIRPERSON MORENO: Okay. We're going to get started.

Welcome back. And this is Ed Moreno. I'd like to introduce the next speaker. This is a discussion of possible priority chemicals, and I'd like to reintroduce Dr. Gail Krowech.

(Thereupon an overhead presentation was Presented as follows.)

MS. DUNN: Is it working?

DR. KROWECH: No.

--o0o--

DR. KROWECH: Okay. So by way of review, the criteria for recommending priority chemicals are listed here. They are the degree of potential exposure to the public or to specific subgroups; the likelihood of a chemical being a carcinogen or toxicant, based on peer-reviewed health data, the chemical structure, or the toxicology of chemically related compounds; the limits of laboratory detection for the chemical, including the ability to detect the chemical at low enough levels that could be expected in the general population; and other

criteria that the Panel may agree to.

Again the criteria are not joined by an "and".

--o0o--

DR. KROWECH: And the Panel does not need to name additional criteria.

The potential priority chemicals for consideration today are polychlorinated biphenyls PCBs, those that are already designated; and benzophenone-3, which is 2-hydroxy-4-methoxybenzophenone, which CDC puts in the category as an environmental phenol.

--o0o--

DR. KROWECH: For PCBs, they've been banned since the late seventies. Current exposure is primarily via diet, foods with high fat content, such as meat, fish, dairy. There are high levels in certain fish, and fish advisories concerning PCBs in certain areas of California.

In the State science, scientists query on chemicals for biomonitoring. PCBs were cited as among the most important chemical contaminants in fish. And this is particularly important for the subgroup of subsistence fisherman. There are also high levels -- high levels of PCBs were found in adipose tissue in Californians

In terms of toxicity, PCBs are listed under Proposition 65 as causing both cancer and developmental toxicity. And they are also endocrine disrupting

chemicals.

--o0o--

DR. KROWECH: In terms of laboratory analysis, PCBs can be extracted with PBDEs from the same sample, and laboratory methods already are implemented. Data are available from the 1960s, 1980s and 2000s. And PCBs can be used as a point of reference for emerging persistent and bioaccumulative chemicals, such as PBDEs.

--o0o--

DR. KROWECH: Benzophenone-3 is the second potential priority chemical. And this chemical came to our attention because high levels of benzophenone-3 were found by CDC. And this is a chemical that for the first time the results were in the 4th report.

Benzophenone-3 is a common sunblocking ingredient in sunscreen, lotions, conditioners, and cosmetics. It's also used as UV stabilizer in plastic surface coatings, including food packaging.

There's likely high use of sunscreens in California, because of the sunny climate, outdoor lifestyle, and high rate of skin cancer.

Several studies have provided evidence that benzophenone-3 is an endocrine disruptor.

--o0o--

DR. KROWECH: In terms of laboratory analysis,

the State Lab has not yet developed methods. Analysis, when methods are developed, can be bundled with bisphenol A and/or other phenols.

--o0o--

DR. KROWECH: And this last slide is simply a duplicate of the table that was provided to you with the materials.

That's it. Any questions?

CHAIRPERSON MORENO: Yes. Let's start on this side.

Dr. McKone.

PANEL MEMBER McKONE: Yeah, is there any toxicity data, I mean, just briefly about benzophenone-3?

DR. KROWECH: There's several papers, the details of which don't escape me, but I can't remember -- I think that it increased cell proliferation in vitro. I'm not quite sure which cell lines. It might have been a breast cancer cell line, but there may be three or four papers on this?

PANEL MEMBER McKONE: So there's some hazard characterization, right --

DR. KROWECH: Yes

PANEL MEMBER McKONE: -- that would indicate -- I mean, at least hazard indicators for the compound.

DR. KROWECH: Yes.

PANEL MEMBER McKONE: No bioassays on reproductive cancer or neurotoxicity?

DR. KROWECH: No.

PANEL MEMBER McKONE: All right. Thank you.

CHAIRPERSON MORENO: Other questions?

Dr. Luderer.

PANEL MEMBER LUDERER: Yeah. I was just wondering if you could give us a little more maybe insight as to why say benzophenone-3 versus other sunscreen ingredients? I mean, is there a particular reason for choosing that one?

DR. KROWECH: Only because this is the one that CDC -- that's designated, you know, that's in our designated list. And CDC recently provided their data and showed high levels?

CHAIRPERSON MORENO: Okay. Dr. Quint.

PANEL MEMBER QUINT: Julia Quint. So in terms of alternatives, chemicals used as sunscreens, there are some that don't have -- we don't have concerns about, so there are safer alternatives, I guess, I'm asking --

DR. KROWECH: I don't know the answer.

PANEL MEMBER QUINT: -- to the extent that you know this?

DR. KROWECH: I don't know the answer to that.

PANEL MEMBER QUINT: Okay. Because I'm just

wondering, we're talking about, you know, use of this chemical to prevent skin canker. And I'm just wondering, you know, what else we're -- what else will be used in its stead, should we aim toward lowering exposures to it. But that's another concern, not maybe of the biomonitoring.

CHAIRPERSON MORENO: Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah. I'm not sure I'm totally persuaded on either of these. In the case of the PCBs, I think that the Panel has previously signaled that we're interested in sort of the chemicals of tomorrow, not so much the chemicals of yesterday. And also chemicals where we might expect to see something different going on in California versus other places.

And I'm not really persuaded that the PCBs are where we want to be going with this program. Of course, if -- I guess there's no huge downside to prioritizing them, since they're already basically being tested for in the laboratory and the method is already developed, so it wouldn't take much additional work. But anyway. So that's on the PCBs.

And on the benzophenone-3, I haven't looked in a lot of detail into the sunscreen issue, but benzophenone-3, my recollection is, is one of the selective UV blocking agents, which are tending to be replaced more and more by the ones that are both UVA and

UVB blocking, which -- you know, such as the titanium nanoparticle kind of sunscreens, which are the ones that actually, you know, we've been sort of focused on, in terms of potential health issues, not that -- I think that benzophenone-3 is fantastic. There is, you know, certainly some evidence of estrogenicity.

So I just sort of wasn't -- you know, I shared some of Dr. Luderer's questions about why this one should be pulled out and be particularly high priority at this point, especially -- I guess part of what's influencing me is I'm cognizant of the fact that we already have quite a long priority list, and I really like the things on that prior list. And once we start putting everything on the priority list, then nothing really feels like a priority.

CHAIRPERSON MORENO: Oh, Diana.

MS. LEE: Hi. I'd like to just comment on the polychlorinated biphenyls. We've received quite a bit of interest, especially from the UCSF staff, to include PCBs as a chemical analyte in the Maternal Infant and Environmental Exposure Project, specifically because of the potential impact on thyroid hormone. And they do want to look at multiple chemicals that have potential for thyroid disruption. So PCBs is high on their list, and it's something the State staff are also interested, in terms of looking at, with respect to data analysis.

So again, given that Dr. Myrto's lab already has these methods in place and has been analyzing them, we felt it was just kind of close the loop to include them as one of the priority chemicals.

PANEL MEMBER BRADMAN: This is a question maybe for Myrto, but if I remember correctly, the CDC Lab methods, which you're implementing, at least I know Andreas Sjödin produces PCBs, PBDEs and organochlorine pesticides in the same analysis. And that the only real extra work is data reduction.

DR. PETREAS: It's in the same sample, so you save precious blood sample. Several steps in the analysis. And the standards are expansive. So the incremental costs, I mean, in my mind, is worth it. But it does cost to add the standards, to do the extra injection in the instrument, the data managing and QC and everything.

But it's not like having a new analyte. You don't start from scratch. The first steps are common and then you start bifurcating and doing different procedures.

CHAIRPERSON MORENO: Dr. Wilson.

PANEL MEMBER WILSON: Thank you, Chair.

I guess I'm curious about the use of PCBs as a point of reference for these other substances, if that's something you can comment about?

DR. PETREAS: It's very common when data on PCBs PBDEs or other chemicals are presented, it's -- Myrto Petreas. Sorry. So it's very common to use at least PCB 153, which is the most common PCB, as a point of reference, saying now in this population PBDEs have exceeded PCBs. So it's something that's very useful. And for the incremental cost of producing and generating this data, it's traditional that people who measure them together, they always have this as a reference to see how things are -- PCBs are slowly dropping. Others are emerging, so it's nice to know when they intersect and where we are.

PANEL MEMBER WILSON: So if I could follow up on that.

PANEL MEMBER BRADMAN: Just one more thing related to that.

PANEL MEMBER WILSON: Sure.

PANEL MEMBER BRADMAN: It's also been useful, I know, in those working with PBDE data, for example, to look at another persistent compound and compare -- you know, look at the correlations, also look at potential sources. And for us, it's been a way to show that the sources of PBDE exposure are not the same as PCBs, because they're uncorrelated and because the PBDEs are probably coming from diet and house dust.

But by showing they're uncorrelated, you're kind of just confirming that there's new sources out there for these other compounds. That's another use.

DR. PETREAS: Yeah, that's exactly the point. In wildlife, for example, they correlate, because the food web for both PCBs and PBDEs. But in humans, because of indoor sources or spot, you know, exposures, you can see no correlations with the PCBs, which is again interesting.

So I think PCB would be a good market for diet. So other chemicals, PBDEs or the future other chemicals, who may not be entirely from diet, it's a good distinction.

PANEL MEMBER WILSON: And by designating it as a priority substance, that would then allow you to do that analysis simultaneously or at the same run, I guess?

DR. PETREAS: For the Program. We're doing it already. So the method is there and we're doing it already for other studies. So the methodolgy is available. But as far as the Program, I guess it has to go through this approval to be part of the --

PANEL MEMBER WILSON: I mean, do we have to prioritize it for the lab to do that work, to run those samples simultaneously with your PBDE samples?

MS. HOOVER: That's a question for our lawyer, I guess.

(Laughter.)

PANEL MEMBER WILSON: I think this gets to Gina's questions, you know, actually.

MS. HOOVER: I mean, my feeling is if this is -- this is the way that I've been looking at it. If they're doing a study that involves outside collaborators and outside funding. This isn't just the statewide Biomonitoring Program. You know, they're having outside collaborators. And so to me, you know, there's outside funding. So I think it's -- I mean, I don't know. I think that's a legal question, but I think that it's helpful. You know, it's helpful for the Program, because the Program, for a whole bunch of reasons, Gail mentioned State scientists have highlighted PCBs as an ongoing concern. I've had, you know, breast cancer advocates mention it as an ongoing concern.

There is also -- Gail didn't talk about everything, but there is also a dump of PCBs off the California coast that's still a problem.

So, you know, I think it's -- and the reasons that Myrto gave, we have this database of information. And it's like saying, okay, we're just not going to continued that now, but it's still an important chemical. It's not down to such low levels that it's irrelevant now. That's our view. So that would be my -- I mean, I know we

realize that -- you know, you've given us certain instructions. And we really brought this to you because of desires and needs of the program, to continue to measure the measured PCBs. Again, with benzophenone-3, it's just -- you know, very high levels were showing up, so we're pointing things to you on the designated list that may be of interest, you know, and that's why these are in front of you now. And we're working through the list that you've given us as well for the designated side of things. So just to clarify that point.

I don't know, Carol, did you want to add thinking or Lauren.

CHIEF COUNSEL MONAHAN-CUMMINGS: Well, what I -- is this on?

What I wanted to say is just to remind you all that you are and advisory panel, and so you're still just recommending priorities to the State agency.

MS. HOOVER: Carol, a little closer.

CHIEF COUNSEL MONAHAN-CUMMINGS: So you're recommending priorities, right. And so the State agencies can still decide which chemicals are priorities for them. And so, no, it isn't mandatory that you Identify these chemicals in order for them to test for them in the Biomonitoring Program.

But I think it does help them as they're choosing

chemicals, if this panel has identified something as a priority from your perspective, all right. So, you know, the advice helps, but it is not mandatory that it be on the priority list in order for them to study it, to make that decision.

PANEL MEMBER LUDERER: Ulricke Luderer.

I have a comment and kind of a question maybe for Dr. Petreas that relates to the PCBs. So one of the things that we've been talking about that various people have mentioned is this idea that, you know, one of the reasons for continuing to measure them is also observing kind of the trends over time, and that hopefully they're continuing to decrease over time as we biomonitor for them because they've been banned.

But in looking at the NHANES IV data that was provided to us prior to this meeting, one of the things I noticed was that for the non-dioxin-like PCBs quite a lot of them during the time periods that they were measured, so 99 and then 2001, 2002, 2003, 2004 they actually went up from '99 to 2001, and then kind of went back down to 1999 levels, so there didn't seem to be kind of a continuing trend with time. And I was wondering whether there's any maybe measurement related reason for that, or is that thought to really be, you know, a trend that's, you know, true and how could it be explained? I was

wondering if you had any comment on that.

DR. PETREAS: I haven't even seen that. I didn't notice this data. I mean, generally we know -- this is Myrto Petreas. And my comment is I haven't seen the data you referred to. And I never noticed that NHANES went up and down. I mean throughout the world, less well-designed studies than NHANES, maybe it's more small studies, show declines, and it's expected to show declines.

Our data from California from again disparate studies show declines over the decades. So we expect them to continue to drop, but they're still there, and they're still measurable, and they give us a good point of reference.

CHAIRPERSON MORENO: How about Dr. Quint and then Dr. Solomon.

PANEL MEMBER QUINT: Julia Quint.

It's very interesting to hear from you why you brought this issue to us, in terms of, you know, PCBs in particular, as a priority chemical. And I'm intrigued by the early results, I think, that you showed, Myrto, from the MIEEP Study. I guess, it was the -- not the -- I don't know what study it was. It wasn't that study, but of showing pregnant women having higher levels of PB -- yeah, it was one of the PBDEs, and also what Asa said about the lack of correlation between those two.

I think it's interesting the thyroid connection, the fact that, you know, you get the flame retardants up in pregnant women, and, you know, to look at the correlation between the PCBs and the flame retardants is quite interesting to me.

And I wouldn't have -- I came -- initially, I was thinking why PCBs, you know, why are you bringing this before us. So I just think it's -- I guess, I'm encouraging you to bring these issues before us even if you could go ahead and just measure them, because it's -- I've learned, you know, your reasoning behind it. And, you know, I think it would be a missed opportunity really now that I'm hearing this to not measure them or to not make them a priority or whatever we're doing here -- whatever decision we're making. And I didn't initially start out that way. I guess that's all I'm saying.

CHAIRPERSON MORENO: Dr. Zeise.

DR. ZEISE: Yeah, I think this has already been mentioned, the UCSF collaborators are looking at cumulative risk issues, and they have special expertise on the thyroids. So again, I think that that was another impetus for including PCBs in that study.

PANEL MEMBER SOLOMON: A couple things. One is that some of these issues around, you know, PCBs as a marker for diet and illustrating the sort of different

exposure pathways have been, by now, you know, established pretty well in a number of other studies. So I'm not sure that reestablishing them in the context of the greater Biomonitoring Program is necessarily a priority.

And I guess part of the thing is I'm thinking here about trying to separate out a little bit the ongoing, you know, study that's going on right now with UCSF, which I think, you know, there's very articulated reasons for including PCBs in that particular study. That's fine. I think especially the sort of cumulative exposure to thyroid toxicants is very important and interesting.

But in terms of sort of the overall direction of the Biomonitoring Program going into the future, it just feels -- it seems to me that it sends a signal that sort of -- you know, about the priorities of that program, that I don't feel very comfortable with, to have chemicals like the PCBs be on that sort of short list of priorities for the future.

And so what, you know, my inclination, though I could certainly be persuaded if there's sort of the idea that we need to designate -- you know, we need to put this on the priority list in order for the Program to be able to measure these chemicals, I would do that.

But it sounds like we don't need to. And what I

would say is go for it, you know, in the context of this UCSF maternal and child study, and in other settings where there are specific populations where it makes sense, because you already have the method, especially if you outside funding. But as the bigger Biomonitoring Program we hope, you know, one day it designs and gets off the ground and does the representative sample of Californians, I wouldn't really put my effort into putting PCBs into that program as part of it. I would focus on the other things that are already on our priority list. So that's, I guess, where I'm at. And I could vote either way on this particular issue, but, you know, that's sort of what I'd like to see, which is, you know, include PCBs and specific studies and specific populations where it makes sense, and leave them out of the big statewide ultimate program that we hope will be funded.

CHAIRPERSON MORENO: Okay. If there are more questions, we'll take more questions. If not, I want to open it up to public comment. And after that, we'll bring it back for discussion.

So, yes, we have one. Anyone else in the room wishing to provide comment at this time?

It looks like we have one person in the room. And were there any Emails coming in?

Okay, no Emails coming in on this topic. Okay,

go ahead introduce yourself.

MR. BALTZ: Davis Baltz, Commonweal.

You know, if we were in New York and we weren't prioritizing PCBs, I think it would really raise some eyebrows. I'm not saying that we should do anything based on what people in New York might think, but PCBs have been with us for a long time. They are a concern, and they're going to be from now on. And I think it would be prudent to go ahead and prioritize them. I don't think if we do raise the resources to ramp up and do the statewide representative sample any time soon, that doesn't mean that everything on the priority list gets biomonitored. There still has to be some selection process by staff.

But I think you might as well, if you have the opportunity now, to prioritize it to do it, because to come back later might just be a bureaucratic hurdle that would be complicated and, you know, distracting.

And similarly for the benzophenone-3, if this is showing up in high levels in Californians, I think it's a different set of questions you want to ask on whether you prioritize this. But this does sound like it is a chemical of the future. And particularly with skin cancer on the rise, more and more people are using sunblocks, so that's another one that, I think, if I were in a position to make a decision, I would prioritize that one as well.

So in summary, I think you have the opportunity to prioritize these two chemicals that have been proposed and I don't see a downside in doing so.

Thanks.

CHAIRPERSON MORENO: Okay. I'll ask again if there's anyone in the public here at the meeting that wants to provide any public comment?

I don't see any, so we'll close the public comment and bring it back to the. Panel

So Panel members, further discussion on this?

Dr. Quint.

PANEL MEMBER QUINT: I have a question. We were talking about the importance of diet and markers for -- I guess my question is, are there other chemicals, other than the PCBs, that would be good markers for, you know, dietary sources of, you know, pollution, I guess for lack of a better word? I mean -- and also that might have, you know, the cumulative sort of thyroid risks that UCSF is concerned about? This is not an area that I'm really that familiar with.

MS. LEE: I think with respect to the persistent organic pollutants, again because they tend to bind to fat, that they would be most prevalent in high foods that are high on the food chain with high fat contents of the animal products in particular, the dairy, dairy products

and poultry and meets and so on.

And I think there have actually been a few studies, and I think NHANES, in particular, looked at this too, with respect to PBDE exposures, as it related to diet, and found it most highly associated with like poultry skin and things like that.

PANEL MEMBER QUINT: No, I'm familiar with those two, but I meant, other than the PBDEs and PCBs, is there something else on our designated list that we haven't prioritized that we would think of -- I mean, this is kind of a broad question, but is there anything on the designated list that hasn't been prioritized that we would -- that would be the same type of -- would that present the same kind of data?

MS. LEE: Yeah, the DDT -- a number of the organic -- you know, the class of DDT, DDE chemicals, for instance, are another example of some of the persistent ones that are old time kind of hanger-onners that we haven't prioritized. And I think -- okay, so --

PANEL MEMBER SOLOMON: And the argument -- sorry. I think the argument that persuaded the Panel on DDE was the study showing that Mexican-Americans had far higher concentrations, which suggested, you know, sort of some issues that might be California specific that we would want to look into in the Biomonitoring Program.

MS. LEE: I think hexachlorobenzene is another one. And Myrto has left already, but HCB and -- is that designated one?

PANEL MEMBER LUDERER: Dioxins.

MS. LEE: Well, dioxins, yeah, we haven't done anything with that. Farla, is indicating acrylamide. It's not persistent, she says.

PANEL MEMBER BRADMAN: Just a comment about the benzophenone-3. Honestly, I would like to spend a little more time to think about that one. I don't know if we want to delay a decision, which -- but I know, given the talk about the NHANES data, I'd like to look at that and compare it to perhaps other data or perhaps look more carefully at the papers, just so I understand what's out there. I'm not saying I'd go either way, but just I'd like to see a little bit more information.

CHAIRPERSON MORENO: Dr. Kavanaugh-Lynch.

PANEL MEMBER KAVANAUGH-LYNCH: And I think one of the things I'd like us to consider when we're looking at benzophenone-3 is not so much that compound by itself, but that I could imagine wanting to biomonitor for sort of total estrogenic load, as a measure in biomonitoring, in which case, especially given the widespread exposure this might become an important component of that.

PANEL MEMBER SOLOMON: And just to add to that

comment, the other way to look at this issue would be to look at the sunscreens more generally, which might also be interesting, to see what other -- because there are cinemates and numerous other compounds in sunscreens, some of -- I'm not sure where they all stand, in terms of biomonitoring. And that might be a much bigger task. But in the longer run that could be an interesting thing for our committee to do.

PANEL MEMBER LUDERER: Ulricke Luderer.

I actually was going to also say that I think it would be more useful to look at sunscreens kind of as a category potentially, especially because they're -- I. -- think it's an area where there's a lot of substitution going on from -- you know, and it's in flux kind of the way the flame retardants are that we've been talking about.

But I also had one other comment about the PCBs, which is that kind of before -- you know, when I initially saw it on the list of potential priority chemicals, I had kind of the same response of oh, you know, PCBs have been around forever. We've been measuring them forever and they're declining and they're banned. And so, you know, maybe they shouldn't be on the priority list, but actually looking through some of the NHANES IV data that I just mentioned a little while ago, some of them seemed to have

been declining at least over the three cycles of NHANES that were in that report, but others really hadn't, and I think that's interesting.

And, in fact, some of the most high-use ones. I think somebody mentioned that PCB 153 was one of the very most prevalent ones. And that one seemed so show this different pattern.

And I don't know what the significance of that is or what the cause for that pattern is, but, you know, maybe there's more going on with the PCBs currently still than we think. And I think that might be an argument for putting them on the priority list.

PANEL MEMBER McKONE: Just a little insight on what's going on. It was actually described in the EPA's dioxin reassessment. And some of it's theoretical and some of it's fairly well documented, which is that dioxin-like compounds, including PCBs, have accumulated in soils and sediments where they can slowly come back out. And the initial drop is in atmospheric levels, but as the atmosphere drops, it starts driving out the, what they call, the reservoir sources.

And they expected to see it drop and then start leveling off, and then drop, and then level off again, because these things have accumulated in sediments, soils -- the near surface soil responds quickly, the

deeper soil takes a lot longer to push back into the atmosphere, but whenever you drop the atmosphere concentration, you get something that drives it out of the reservoir.

So we're probably seeing that. And in a way this would argue then that we probably don't want to get rid of it, because one way to see the impact of the reservoirs emitting is to look at the receptors, because the atmosphere is very hard to measure. The atmosphere is a mechanism of transport, but very difficult to measure, so probably we would see -- we would understand this better and be able to track it, if we were still tracking these compounds in humans.

PANEL MEMBER WILSON: Mike Wilson.

I am moving toward thinking that it's a smart thing to do to prioritize the PCBs for some of the reasons that people have been describing. And I guess where I'm beginning to shift on this, I think I had some of the original, sort of, feelings as the other Panel members did about, you know, why are we looking at legacy substances. But as I'm thinking about it and hearing from staff and panel members, it seems that these are legacy substances that provide important scientific information for what we're trying to do today in three different ways. And I think this may be is what the UCSF researchers are trying

to convey that, number one, they provide a point of reference, as Asa has said, for some of the emerging persistent bioaccumulative substances.

And that second, the PCB levels are relevant to this question of cumulative impact and sort of integrated risk assessment that we're trying to move toward, in sort of new ways of thinking about risk, given that they're still with us, and we're measuring emerging substances with them.

And then third, the health effects that may be resulting from thyroid effects -- impact on the thyroid or thyroid development or what is it, as that being an emerging health issue that also, you know, gets to this cumulative impact problem.

But the health problems that are specific to thyroid disruption or, you know, maybe Gina could talk about this a little more, those are health issues of concern. So I guess my tendency is that we would -- that we would prioritize PCBs for purposes of the program.

PANEL MEMBER SOLOMON: Sounding like I'm in a minority at this point, which is okay, we don't always have to be unanimous. But I guess just to summarize, I'm hearing a lot of good reasons that someone should be biomonitoring for PCBs in some places and some studies, but I'm still not hearing any good reasons why it has to

be the California Biomonitoring Program. CDC I don't think is likely to drop the PCBs any time in the near future.

And so there will be data looking at atmospheric flux and, you know, for whatever research we wanted to do on what's coming out of soil. And there will be data on PCB levels in the U.S. population to track ongoing declines or lack of declines. And I haven't seen any data suggesting that the concentrations of PCBs in Californians differs. I mean, the data I have seen suggests that, you know, pretty similar to NHANES levels. And so unless -- I'm sorry Myrto left, because she might know something that I don't know. But the data that I've seen from California is pretty consistent with national data.

So I'm just not meeting in my own head the criteria that I'd kind of set out for prioritizing chemicals, which is, you know, that it's something where we think that there are, you know, policy actions maybe driving current, you know, trends, either up or down, we sort of already know what policy actions did 30 years ago and that they are driving a trend generally downward.

And I'm not seeing any compelling reasons why the situation would be different in California than anywhere else. And I totally agree actually with the concern raised by the commenter, which is, you know, if I were in

New York State, I would for sure be biomonitoring for PCBs. I mean, you know, with the situation like they have in the Hudson River, they should be.

But in California, maybe not so much. So I'm not totally opposed to it, as I said, but I think I may take a principled stand and vote against prioritizing them, just to sort of communicate those issues, but I also think that it's a perfectly reasonable decision for our committee -- our Panel to vote to prioritize them.

CHAIRPERSON MORENO: Any further discussion on this topic by Panel members?

Okay. If not, is there a recommendation from a Panel member?

PANEL MEMBER WILSON: I'll make a motion -- Mike Wilson. I will make a motion that the Panel prioritize polychlorinated biphenyls for purposes of biomonitoring in California.

CHAIRPERSON MORENO: Is there a second?

PANEL MEMBER QUINT: Julia Quint. I second the motion.

CHIEF COUNSEL MONAHAN-CUMMINGS: Excuse me. This is Carol. Could you also say whether you're including metabolites and markers and all that stuff in the motion, so we don't have to do it twice.

PANEL MEMBER WILSON: My apologize. Mike Wilson.

So I would move that the Panel prioritize polychlorinated biphenyls and their metabolites for purposes of biomonitoring in California. And to the --

MS. HOOVER: Okay, so this kind of is prefacing our next topic.

PANEL MEMBER WILSON: Yes.

MS. HOOVER: And this is really just a point of clarity, just to be clear, because we kind of know what you mean when you say polychlorinated biphenyls, but when we were confronting this issue of formatting and what goes where, it just is easier for us if we have -- where is it Lauren?

We have a phrase that we created where it's, so it would be polychlorinated biphenyls, its metabolites, other biomarkers, and relevant indicator chemicals. So that way, it essentially gives the Program the leeway to measure it in whatever way we choose, and then it's just really transparent what we're including.

PANEL MEMBER SOLOMON: I thought you could only include the ones on the CDC list, so wouldn't it be just referencing prioritizing the designated PCBs as --

MS. HOOVER: Thank you, Gina, yes. Those that are already designated, yeah.

PANEL MEMBER WILSON: Okay.

CHAIRPERSON MORENO: Dr. Wilson, are you

accepting that as your amended motion?

PANEL MEMBER WILSON: It sounds like that's -- that we can't use the phrase of metabolites and biomarkers and relevant indicators.

MS. HOOVER: Okay. Now, this is sort of a lawyer question. Because actually the instruction that the Panel has given us in the past is that anything you put on the priority list, we are free to measure in any way that we so choose. And this, again, it's actually prefacing our next topic, and how we choose to represent the priority list. So up 'til now what we've done is on the designated list, we've included whatever CDC had or whatever the Panel designated, and we had it split between, what we called, parent chemical and target chemical for measurement.

And the reason is because in some cases, CDC -- because it's -- it's a little bit complicated, because CDC is a lab-based program. So they're naming things that they're interested in, which is maybe the metabolite. But what the public recognizes is the parent chemical. So we have actually made it a practice to try to translate that for the public, and actually show, not just this target that no one has ever heard of, but include the parent if it's known.

So we're actually trying to deal with this in a

more systematic way now, which is what the next item is, and we actually had to move it to the end, because of timing on the agenda.

So what we're proposing is that the appearance of the priority list would match the appearances of the designated list. Now, I don't know, Carol, do you have a comment on if there's any legal issue with incorporating that.

CHIEF COUNSEL MONAHAN-CUMMINGS: Well, the definition of designated chemicals in the statute, includes those substances that -- including chemical families or metabolites, that are included on the federal list.

So one would have to look at the federal list and see if the metabolites or related chemicals are on there. And if they are, then you can include that in your priority. But if they're not -- as a priority. If they're not, then you would have to designate those additional ones first -- or recommend designating them, and then include them as a priority.

Does that make sense?

PANEL MEMBER WILSON: Well, okay. It seems to me, if I understand it right, that we can make this motion that includes metabolites and biomarkers and relevant indicators and then by definition you have to -- you could

constrain that to the list of designated PCBs.

CHIEF COUNSEL MONAHAN-CUMMINGS: You could work that way.

PANEL MEMBER WILSON: Will that work?

CHIEF COUNSEL MONAHAN-CUMMINGS: Yeah.

PANEL MEMBER WILSON: So I will move that the Panel prioritize polychlorinated biphenyls, their metabolites, other biomarkers and relevant indicator chemical for purposes of the Biomonitoring Program.

CHAIRPERSON MORENO: Is that satisfactory?

CHIEF COUNSEL MONAHAN-CUMMINGS: Um-hmm.

CHAIRPERSON MORENO: So that's your -- thank you. That's your amended motion. Dr. Quint, are you okay with that?

PANEL MEMBER QUINT: Yeah. Julia Quint. I second that amended motion.

CHAIRPERSON MORENO: Make sure everyone is clear on that.

All right. And any further discussion on the motion?

If not, I'm going to go by roll call again and I'll start to my right.

Dr. Kavanaugh-Lynch?

PANEL MEMBER KAVANAUGH-LYNCH: I've been convinced by Gina, so I'm going to vote no.

CHAIRPERSON MORENO: Dr. Quint?
PANEL MEMBER QUINT: Yes.
CHAIRPERSON MORENO: Dr. Bradman?
PANEL MEMBER BRADMAN: Yes.
CHAIRPERSON MORENO: Dr. Solomon?
PANEL MEMBER SOLOMON: No.
CHAIRPERSON MORENO: Moreno yes.
Dr. Luderer?
PANEL MEMBER LUDERER: Yes.
CHAIRPERSON MORENO: Dr. Wilson?
PANEL MEMBER WILSON: Yes.
CHAIRPERSON MORENO: Dr. McKone?
PANEL MEMBER McKONE: Yes.
CHAIRPERSON MORENO: All right, so that passes six to two.
Thank you.
And at this point, there was a second discussion -- presentation, discussion on benzophenone-3.
PANEL MEMBER BRADMAN: I made a suggestion earlier that we hold off on that. Does that have to be a formal motion or is that just a decision on the --
CHAIRPERSON MORENO: No, I think you can give -- make a recommendation without -- that doesn't involve prioritizing this chemical.
DR. ZEISE: We can bring back to you, as a group,

sunscreens and do some additional analyses to help you with looking across the various chemicals that are used in sunscreens.

PANEL MEMBER BRADMAN: Okay, that would be great.

CHAIRPERSON MORENO: And I just want to make sure that other Panel members have an opportunity to add any other comments or suggestions to this general direction from the Panel.

PANEL MEMBER WILSON: You mean with benzophenone?

CHAIRPERSON MORENO: Yes.

PANEL MEMBER WILSON: Yeah, I support Asa's proposal.

CHAIRPERSON MORENO: Any other comments?

So we have consensus agreement on that.

Thank you.

All right, thank you very much for the presentation. Thank you for bringing that information to the Panel's attention.

So now we're going to move forward with the agenda, and we're going to have a presentation and discussion on designated and priority chemical lists.

Sara Hoover, Chief of the Safer Alternatives Assessment and Biomonitoring Section of OEHHA will make this presentation.

(Thereupon an overhead presentation was

Presented as follows.)

MS. HOOVER: So you had a preview just now of what this is about. Like I said, we had originally done some translation of the CDC list in order to bring clarity to the public. We've now revisited that and I'm going to talk about that.

Can you go to the next slide.

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MS. HOOVER: So the goals of this agenda item are first to just inform you of some additions to the designated list, and to just go over some of these things that we've been struggling with in order to create a clearer format for the designated and priority lists. And we just want to discuss it at this meeting, get your input from the Panel and the public on the proposed format, and wrestle with some of these issues. And then there might be some substantive issues that we would need to bring back to you in order to implement the format, which would happen at a later meeting.

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MS. HOOVER: So keep going. Just put them all on there.

So if chemicals are included in the CDC studies under the National Report on Human Exposure to Environmental Chemicals Program, then they're

automatically designated under the California program. And there's a couple additions under this criteria.

Carbaryl is a slightly special case. This chemical was actually overlooked. And the reason that that happened is because it was originally reported -- 1-naphthol is the same as 1-hydroxynaphthalene.

In the second report, CDC actually reported results on 1-naphthol as a metabolite of carbaryl under pesticides. In later reports, they only reported on 1-hydroxynaphthalene, but did reference both naphthalene and carbaryl as parent chemicals. So carbaryl actually has been included all along, it just was overlooked, because it was under PAHs. So we're moving forward to put that on the designated list.

In terms of parabens, there's a new CDC publication on butyl, ethyl, methyl, and propyl paraben. And so that is being biomonitored by CDC under this program, and so it falls under the designated classification, so we'll be adding those to the list as well.

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MS. HOOVER: So this is also partially what prompted this item was the fact that the CDC issued their fourth report. And they have a very nice -- they've now kind of taken the same approach in their table of

contents, where they're actually trying to list parent compounds in the metabolites or other biomarkers that they're using underneath that.

So we decided to try to adopt a similar format with some variation. Now, in some cases the Panel have added things to the list that CDC is not monitoring. So obviously we're going to retain the Panel designation for those. And other categories or titles of categories that CDC dropped, we felt like actually provided information, so we didn't drop them.

Now, as I mentioned -- and this may be -- we discussed this with our lawyer ahead of time, but we may need more discussion about this. We're proposing to format the designated and priority chemical lists in the same way. So as I mentioned previously, the designated list showed parent and target. The priority list just showed the chemicals. We noticed in some cases, and I'll show you an example of this, things got moved over based on a Panel discussion, and it may present some lack of clarity down the line.

So we were thinking that it would be simpler and clearer if something was designated -- or something was moved to priority that we would move it over as it appeared on the designated list and show it in the same way on the priority list. But there's issues -- there's

potential issues with that, so I'm going to get into that.

And so, as I said, we would show both parent chemicals and the metabolites or other indicators, other biomarkers on both lists.

Next slide.

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MS. HOOVER: So this is just a sample format, which isn't real clear on the slide, but you have it in your packet. And this is just a sample portion of the designated list. And the feature is that it's presented in a single column instead of double columns, and you have -- this one doesn't -- actually to go the next slide with the priority list.

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MS. HOOVER: And you have, for example, if there's a metabolite or other biomarker that's been identified, it's on the list, indented. Now, per the Panel's recommendations repeatedly, this doesn't mean that this the only thing that we could look at. It's just -- so the idea, the way that I'm looking at these lists is it's supposed to be providing useful information, and it's supposed to be providing as much information as we have.

If, in the future, we change methods or we find actual this is an excellent biomarker for diesel, that seems like an important thing to be on the list for

informational purposes.

Next slide.

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MS. HOOVER: So again, the changes under the new format is that things would be in one column instead of two. The metabolites or other biomarkers and other indicator-chemicals would be indented under the parent. The organization would generally follow the CDC Fourth report. So they've now regrouped and moved chemicals around. They have a category called Disinfection Byproducts, where they've moved the trihalomethanes. They moved p-Dichlorobenzene under VOCs instead of other pesticides.

So some of these issues you might want -- you might say actually that is a decrease in information and we wouldn't want to do that, and that's the kind of input we'd like to hear.

Next slide.

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MS. HOOVER: Some exceptions, as I mentioned. CDC has PBDEs listed differently in their index. And we would retain the way that we have it under the SGP designation for brominated and chlorinated organic compounds used as flame retardants. And then there's other categories that were never included by CDC. So, of

course, those are retained.

A few other exceptions that we decided on. Again, this is just proposed. We thought it was useful to retain tobacco smoke as a heading to give clarity about why cotinine is important, for example.

DEET. They moved DEET out of pesticides and listed it singly. And we felt that it was more informative to keep it in the pesticides category. And if you've had a chance to peruses the new format, we actually have a large section where all the different pesticides are groups, and there's -- all the different pesticides are grouped and categories underneath that are retained.

We also thought that given the type of lists it was, it would be useful to retain certain common names that are really widely used, like carbon tetrachloride. They changed it tetrachloromethane with carbon tet in parenthetical.

You know, these are minor issues, but that's some of the things we've been looking at.

Next slide.

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MS. HOOVER: So there's a bunch of things that come up, when we started to try to do that. So one of the examples I showed on the previous slide - I actually had that section - was PAHs. So in the discussion of PAHs

that the Panel had in prioritizing certain PAHs, you were referencing a table that the laboratory had provided about other chemicals that the laboratory can measure. And so the chemicals that were actually named were the metabolites and not the parents. And that's what got put on the priority list.

However, if you look at the designated list, for example hydroxybenzo[a]pyrene is listed under benzo[a]pyrene as the parent, which seems like useful information to me. Now, this is an example of a substantive issue that we'd have to bring back to you and get clarification about what you meant when you said we want you to put hydroxybenzo[a]pyrene on the list.

Another question that we're wrestling with a little bit is what if the metabolite itself is really the chemical of concern to highlight. And we had discussions about this with you before. For example -- and this is hypothetical, because this is not on the list. But for example if you had a chemical like 3,4-dichloroaniline that you're interested in, as a metabolite of other chemicals, how should that be represented in this new format?

We couldn't just have a hanging indent with nothing above it. Would we have to create a category? Or should we show it aligned left and just footnote it as an

exception?

We also confronted this with some non-specific metabolites. CDC has, in their long list, in some cases, just non-specific metabolites that they haven't linked to a specific parent.

There was a time when we were devoting tremendous resources to trying to look at all of these things and figure out all the relevant parents and link them. And we don't feel like that's a profitable activity for a non-specific metabolite. So how should that be shown?

At the moment, we just have them aligned left, and I believe they're noted or footnoted. But if they're not, we could do that.

Next slide.

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MS. HOOVER: There's also things that are measured that are actually parent compounds themselves, but are grouped under a broader category like Hexachlorocyclohexanes, including beta-HCH and gamma-HCH. So that, you know, should those be indented, even though they're not really metabolites or biomarkers, they're just another isomer. In the example we showed you, we put those in parenthesis, but maybe that's not really handy if you were searching the list. So that's another issue.

Similarly with various metal species, the way

that CDC shows it is they indented under the overall heading and that's how we showed it.

Next slide.

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MS. HOOVER: So as I said, in terms of follow up, we just wanted to get your thoughts. Do you like the new format? I think it's cleaner, but it does present other problems. We would take back your input and try to come back with something. And if there's some substantive change that would actually make a change to the priority list, we'd have to bring that back to you and get clarification from you.

That's it.

CHAIRPERSON MORENO: Thank you, Sara.

Questions for Sara?

PANEL MEMBER McKONE: Can you go back to your first slide, there's something there. I'm sorry, I guess it's the next one.

Oh, yeah. I knew it was on one of the slides. So in the naphthol -- or the hydroxynaphthalene that's associated both with naphthalene and carbamate, has CDC --

MS. HOOVER: Carbaryl.

PANEL MEMBER McKONE: I'm sorry, carbaryl. Have either your group or CDC assessed what relative fraction is attributable to each one in maybe like the median

range. I know it's highly variable. But how big of a contributor is either one to the 1-naphthol?

MS. HOOVER: I don't know the answer to that question. I don't know if anyone else in the audience does.

It would be interesting to know whether it's like only one or two percent additional amount or if when you add carbaryl you may actually be half and half.

PANEL MEMBER BRADMAN: Tom, I'm sorry, could you phrase that again, because I might have an answer to that.

PANEL MEMBER McKONE: So the question is when you look at a biomonitoring sample and a range of them and you see 1-hydroxynaphthalene, and you know it's coming from two, do we have any sense of what the relative contributions are, I mean, particularly in the mid-range?

PANEL MEMBER BRADMAN: The answer is yes. If I remember correctly, we have a paper submitted on this right now actually. Basically, there's 1-naphthol and 2-naphthol. And 1-naphthol and 2-naphthol come from naphthalene in approximately equal proportions. And 1-naphthol comes from carbaryl also.

So if you look at the ratio of 1-naphthol to 2-naphthol, You get some indication of the source. And there's an occupational setting that defined a ratio greater than two as indicating, at least in that case, an

occupational or some external source of carbaryl.

So I apologize, but to give an example from Salinas, you know, we found, in our population, we looked at the ratio of 1-naphthol to 2-naphthol in our population, also in the NHANES data, and we found an elevated frequency of ratios over two, for example, in our population, where carbaryl is used.

So you can gain some insight on exposure to carbaryl by looking at that ratio. And, you know, it may be specific to agricultural areas or maybe even within agricultural areas depending on the crop use. For example, we found that ratio higher when people were working on certain crops.

So there is some information there, but it has to be teased out of the data. Does that --

PANEL MEMBER McKONE: But there is a way to do it?

PANEL MEMBER BRADMAN: Yes.

PANEL MEMBER McKONE: So in other words, if I see 20 nanograms or whatever per liter of urine of 1-naphthol and 10 of 2-naphthol, probably the -- you would expect it to be closer to one.

PANEL MEMBER BRADMAN: Right. Or you could look at California and say, you know, 30 percent of the population has a ratio over two. Whereas, in NHANES it's

10 percent. So that suggests and additional source. Or you can look at an individual population.

PANEL MEMBER McKONE: Thank you.

PANEL MEMBER QUINT: Julia Quint.

That seems to bring up another interesting question though, is that are the data useful, in terms of, you know, trying to get at exposure, if you don't measure both?

MS. HOOVER: Yeah. No, I didn't talk about that, but they specifically talk about you need to measure both. You know, they talk about them together and they talk about 1- and 2-hydroxynaphthalene.

PANEL MEMBER QUINT: So we list one, but it's --

MS. HOOVER: Well, it's actually -- that actually is a question that I didn't ask, but it kind of is an interesting question under carbaryl. 1-hydroxynaphthalene is the metabolite, but you kind of need 2-hydroxynaphthalene. We didn't actually -- on your example, we show just 1-hydroxynaphthalene indented under carbaryl. But could that be misleading, you know, because you kind of need 2-hydroxynaphthalene.

PANEL MEMBER QUINT: Exactly, that's my question.

MS. HOOVER: So that my fall in the other biomarker or relevant indicator chemical category.

PANEL MEMBER QUINT: Exactly.

MS. HOOVER: So we could include it.

PANEL MEMBER WILSON: Is there anything, you know, related to this that we need to solve today?

MS. HOOVER: Related to this?

PANEL MEMBER WILSON: Yes.

MS. HOOVER: No, this is just interesting side conversation.

(Laughter.)

PANEL MEMBER WILSON: Oh, no, not what they're talking about, but your question.

(Laughter.)

MS. HOOVER: Okay, the larger questions of format?

PANEL MEMBER WILSON: Yes.

MS. HOOVER: I mean, I guess I want to hear your opinion about -- I mean, you've seen the old -- I didn't actually provide you copies of the old list, but you've seen the old lists. And there's some real problems with the formatting and lack of clarity and lots of lines and white space. And it's just not -- it's not a really handy format. So I guess that's one question is, do you like the new format? Is it worth it to pursue some of these picky little issues?

Now, in terms of the picky little issues, what I was going to propose, unless -- if you have a specific

preference, you know, like I think you should do X, Y, or Z about metabolites. I mean, that's one of my interesting points is, you know, what do you do if you want to highlight the metabolite as being of concern? Or do you want to include benzo[a]pyrene, if you've listed hydroxybenzo[a]pyrene. I would like to hear your opinions on that today. That would be very helpful.

In terms of the picky little issues, I've made a certain proposal in the attached. You could take a look at it, and we could come back with, you know, any substantive things that you really need to solve.

PANEL MEMBER SOLOMON: Okay. Gina Solomon.

I like the new list. I like the new format. I think this is going to be much more user-friendly and just easier for non-chemists to understand. So I think it is worth dealing with these problems.

I think it's a little tricky to sort of run through all the answers to all of these things. But I think that when a metabolite has been named, for example, the, you know, benzo[a]pyrene metabolite, I think it is worth listing the parent chemical. And if that requires bringing a bunch of these back to the Panel, sobeit, I think it's something that we could address fairly quickly, because it appears that that would have been just an oversight.

And when the metabolite is the chemical of concern, I think actually that's the case with a lot of chemicals, is that the metabolite is the active -- the biologically active chemical. I don't think that that precludes listing the parent chemical. I would, you know, in this hypothetical 3,4-dichloroaniline example, I would suggest listing the parents, you know, even if it's several different parent chemicals, and you, know noting that they all are metabolite -- you know, the reason that they -- you know, a necessary footnote, that the reason that they are listed is because they are metabolized to this active metabolite of concern.

The nonspecific metabolites are tricky, and I can't think really of a better way of dealing with them than just sort of lumping them into some kind of non-specific metabolite category.

MS. HOOVER: I mean, actually we started -- you know, Gail started to do a bunch of research in certain sections. And, you know, it's possible to parse them out. It can be complicated. And that's part of the problem is that we don't -- and even with this hypothetical example. The only reason I raise this is that typically we would be bringing you forward something where we would know the parents. But if just the metabolite was sort of divorced from the parents and considered, because we talked about

doing that. That was at a previous SGP meeting, where we wouldn't be bringing the parents. We would be bringing the metabolite, so that's why I was focusing on that.

I think, in general -- I mean, I agree with you. I think that it's important to have the parent, if known and easily accessible. I'm wondering, and this may be is a legal question, but we could also indicate -- it's almost like parents including, but not limited to. You know, it's -- because we're not necessarily going to have picked them all up. So that's my point is that if it's the metabolite that's of concern, you don't really want a subset of the parents, you want the parents that lead to that. But we might not have sufficient resources to figure that out completely. That's all I'm saying.

But maybe we could just take care of that in a footnote, you know, just indicate that these are the parents we've identified and their may be more, something like that.

CHAIRPERSON MORENO: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I was just actually going to say exactly what Gina said. I think this is much improved. I like it. It's informative. It's educational even. I think the isomers present a little bit of -- you know, you have to footnote that or something, because they need maybe to be

indented, but then it kind of --

MS. HOOVER: It doesn't fit our scheme.

PANEL MEMBER QUINT: It's not a metabolite, so that --

MS. HOOVER: Well, that might be another way of dealing with it, because I mean it makes more sense to me from a logical user-friendly point of view to just have them indented.

PANEL MEMBER QUINT: Exactly.

MS. HOOVER: And maybe we just need to footnote it, and say these are isomers. You know, these are related isomers.

PANEL MEMBER QUINT: Right.

MS. HOOVER: And so then our indent may have multiple means. We were trying to avoid that, but that would probably be the most practical solution.

PANEL MEMBER QUINT: Yeah. And I also like where you differed from CDC with the tobacco smoke, because I think, you know, your instincts are right. We want this to be accessible information for the public, and not, you know, a bunch of weird names of chemicals that nobody understands. You know, as much education as we can confer onto this process, I think the better off we are, and it's appropriate. So I like the decisions you've made where they didn't exactly fit what CDC was doing.

CHAIRPERSON MORENO: Dr. Luderer or Dr. Wilson.

PANEL MEMBER WILSON: I would concur with that. I think the way you're going about it is exactly right, that making it information rich and useful to the public and to, you know, community-based organizations and to businesses and so forth that are interested in this information, and, you know, providing the taxonomy back to the parent compound, and that might be the more common name, as Julia is, you know, stating.

And maybe -- and I think it makes sense, as you're saying, that there may be other parent compounds. And that could go in a footnote. And, you know maybe the specific metabolites -- well, I guess that's -- I think that would answer it for me. And I think that would be the direction we would want to go.

So I think the direction is right. I think it's a smart approach. I like it.

CHAIRPERSON MORENO: This is Ed Moreno.

I want to take this opportunity to open it up to the public, and then we'll conclude this after public comment with final recommendations from the Panel.

So, Amy, were there any Emails coming in from people on the webcast?

MS. DUNN: No email.

CHAIRPERSON MORENO: And anyone in the public

here today wishing to comment?

Okay. I don't see any. So I'll close the public comment -- here's someone from the public.

(Laughter.)

MS. HOOVER: I have actually one other question. You guys considered p-Dichlorobenzene as a pesticide, I believe, is that right Gail? Yeah. And now they moved it under VOCs. Do you have a problem with that? Should it be retained under pesticides? Any opinions on that specific one, because you actually discussed it as a pesticide and prioritized it in that -- was it prioritized or designated it? Prioritized.

Any comments on that one or do you have -- I mean, we could also footnote this is also used as a pesticide. You know we could do something like that.

CHAIRPERSON MORENO: Dr. Quint.

PANEL MEMBER QUINT: This is truly personal. Julia Quint. I don't think of it -- I mean, volatile doesn't do much for me. Whereas, I think of it more as a pesticide, you know. But that's just any orientation. I mean, there are lots of volatile organics, and I don't think of -- you know, so it is volatile and it could be there, but I think it's more useful, in terms of what we know about it as a pesticide, just personally.

CHAIRPERSON MORENO: Okay, I just want to

comment. We have closed public comment, so we'll continue with the Panel discussion.

Dr. Solomon.

PANEL MEMBER SOLOMON: I think, in general, the category VOCs doesn't mean a lot to many people, and it's a whole sort of garbage bag of different chemicals. And this would be a much bigger project, but it would be actually very interesting to sort of divide those up by end-use, cleaning products, you know, products in, you know, other cosmetics, products in chemicals in gasoline, degreasers, blah, blah, blah.

Short of doing that and of putting p-Dichlorobenzene into a sort of disinfectant category or something along those lines, I would tend to advocate leaving it in with pesticides, even though a lot of people don't think of toilet bowel deodorizers or mothball -- well, I guess mothballs people think of as pesticides. But people wouldn't think that a toilet bowl deodorizer is a pesticide so much, but it is.

MS. HOOVER: Okay, so based on that, I'll move it back to other pesticides in the next list for now, and consider the idea of adding more richness of information to some of the other categories.

CHAIRPERSON MORENO: Okay. Any other comments or recommendations? It sounds like the Panel likes the

format. You've gotten some recommendations on this.

Anyone else?

No.

Okay. Thank you for that presentation. Thank you for trying to help us clean up and better representing the list to the public and making it more useful.

Okay, we're going to move on to -- actually, I'm going to introduce Dr. Lauren Zeise, who is Chief of Reproductive and Cancer Hazard Assessment Branch, Office of Environmental Health Hazard Assessment, who is going to summarize the Panel's recommendation from Today.

DR. ZEISE: Hi. So we started off the morning getting an update on the budget, the collaborations, lab progress for the Program. And we heard back from the Panel continued support and encouragement for our collaborations with the Environmental Health Tracking cohorts, CYGNET, the MIEEP cohorts. We also heard continued encouragement and interest for an occupational cohort, particularly for firefighters. And there was some discussion of the advantages of using a unionized workforce.

We heard an offer of assistance from Mike Wilson and Ulricke Luderer to help locate a cohort. And we also heard of the useful -- again, from the Panel, of the usefulness of a diesel marker for firefighters and for

truckers. So again, reinforcing the idea of focusing on getting a good marker for diesel.

With regard to the lab reports, we heard very positive feedback for the current path of effort. Various suggestions and comments were made, including the importance of QA/QC for QA/QC of getting blanks in the field. The importance of considering pregnancy status. And, of course, we talked a lot about that in the afternoon. The continued encouragement to develop methods to analyze newer flame retardants.

And then the Committee by unanimous vote designated Pendimethalin, its metabolites, and other biomarkers and relevant indicator chemicals.

And then there was deliberation -- oh, so as we think about this particular compound, there's a lot of discussion on what would be important in considering the priority status of it. And that would include consideration of bioavailability, plausible exposure pathways, that would include things like the aquatic food web, food residues, potential residential exposure, including through dust.

So we had an extensive discussion of the MIEEP study, in progress on the MIEEP study, and we received a variety of suggestions on the study, on recruitment, questionnaire, in-person interview, educational materials,

and report-back. Some of the materials are a lot further along. And so the Program will take under advisement the comments and probably make limited changes to those things that are in the IRB process.

For the other items, there's much more opportunity for more extensive taking into account of the Committee's comments.

At a future meeting, we again agreed and reiterated that we would discuss clinical reference values. And that would include both methodologies as potentially some examples. Don't know if it will be as early as May, but that will be coming back to the Committee.

The Committee voted to add PCBs to the priority chemical list by a vote of six yes and two no. The program will bring chemicals and sunscreen back to the Panel for consideration. Benzophenone-3 will come back, along with possibly other chemicals and sunscreen and look at the whole issue of chemicals and sunscreen in a more holistic way.

And in bringing back benzophenone, we'll try to address this overall issue of estrogenic load, but it will take some thinking to see how we might go about doing that.

And regarding the list and its new format, we

heard that the Panel liked the new format. And so we'll proceed along with that. The direction is right, para-Dichlorobenzene went back to the pesticides. And in bringing the new format back and implementing, we'll probably have to come back to the Panel with a variety of substantive changes. So we'll go through the process of approaching the list one more time before finalizing it.

And so I'd like to thank the Panel for all their hard work, and Dr. Moreno for your good leadership, and wish you well. And I'd like to thank the staff for all their hard work as well.

CHAIRPERSON MORENO: Thank you, Dr. Zeise. So with that, that concludes the agenda.

Before we adjourn, I want to let the public know that the meeting presentations, the transcript, and the summary of our Panel recommendations will be available on the biomonitoring website as soon as staff has them available. And a notice will be sent to the biomonitoring listserv when those materials are available for public viewing.

I also want to announce that the next meeting is planned for May 24th, 2010 from 10 a.m. to 5 p.m. And that will be scheduled in the Bay Area, location to be determined. And that is it, so this meeting is adjourned.

Thanks.

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 4:31 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 19th day of February, 2010.

JAMES F. PETERS, CSR, RPR
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