MEETING

STATE OF CALIFORNIA

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

CAL/EPA HEADQUARTERS BUILDING

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BYRON SHER AUDITORIUM

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10:06 A.M.

JAMES F. PETERS, CSR, RPR
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APPEARANCES

PANEL MEMBERS

Dr. Ulrike Luderer, Chairperson

Dr. Asa Bradman

Dr. Dwight Culver

Dr. Thomas McKone

Dr. Julia Quint

Dr. Gina Solomon

Dr. Michael P. Wilson

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Dr. Joan Denton, Director

Mr. Allan Hirsch, Chief Deputy Director

Ms. Carol Monahan-Cummings, Chief Counsel

Ms. Amy Dunn, Safer Alternative Assessment and Biomonitoring Section

Dr. Mari Golub, Reproductive Toxicology and Epidemiology Section

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

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

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, Research Scientist

Dr. Jianwen She, Chief, Biochemistry Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. June-Soo Park, Environmental Chemistry Branch

ALSO PRESENT

Ms. Donna Brownsey, Breast Cancer Fund

Dr. Leslie M. Israel, U.C. Irvine, Center for Occupational and Environmental Health

Ms. Deborah Whitman, Environmental Voices

INDEX

INDEX CONTINUED

PROCEEDINGS

OEHHA DIRECTOR DENTON: We're going to go ahead and get started. This is the November 2nd meeting of the Science Guidance Panel for Biomonitoring. And my name is Joan Denton. I'm the Director of OEHHA. And I would like to welcome everyone.

I would like to welcome the members of the Panel, and thank you for taking time to participate in this important project.

I'd also like to welcome the members of the public who are here in the audience, as well as those that are listening on the webcast, as well as the staff of OEHHA and the Department of Public Health.

Just a couple of things on logistics. The restrooms, you go out the back doors. For those of you who are not familiar with the building, the closest restrooms are on the left. But there are also restrooms on the right towards the end of that side of the building.

And if we have an emergency, if the emergency signal sounds, then we'll go out the door and down the steps the way that you came in, and then exit through the front door.

So I'd like to again reiterate, as I alluded to in my opening sentence, that this is being webcast. And it's also being transcribed. So there will be a

transcript at the end of the meeting which will be posted on the website -- on our website. But this will probably take several weeks before it's up.

So because it's being webcast, we'd like to ask everyone to speak into the microphones, so that those people who are listening over the web can hear clearly.

Before I turn it over to our Chairperson, Dr. Ulricke Luderer, I just want to tell -- or just remind everyone what happened at our last meeting. The last meeting of the Panel was held on May 24th, and it was held in Oakland. And at that meeting the Panel voted unanimously to recommend that triclocarban be added to the list of designated chemicals for the program.

The Panel also voted unanimously to recommended adding the parabens that were already designated to the priority list. And those parabens include butylparaben, ethylparaben, methylparaben, and propylparaben.

And then, finally, we had discussion items on the agenda for which the Panel provided advice. And these topics included the format of designated and priority chemical lists, the Firefighter Occupational Exposures Project, and an overview of the draft Public Involvement Plan. So we added those chemicals as designated or as decided and voted upon by the Panel to the various lists. And we also had been implementing the advice of the Panel

which we got on the other agenda items.

But for a complete summary of the Panel's recommendations and input at that meeting, you can visit the website at www.biomonitoring.ca.gov -- biomonitoring.ca.gov.

So that concludes my opening remarks. And I'm going to turn it over now to Dr. Luderer to conduct the meeting.

CHAIRPERSON LUDERER: Thank you, Dr. Denton.

I'd also like to welcome everyone, all the members of the public who are here with us in Sacramento as well as those listening on the web via the webcast, as well as the Program staff and the Guidance Panel members.

I wanted to briefly talk about what our Panel goals are for the meeting today.

We will be first receiving program and laboratory updates, and the Panel will provide input on those updates. We also will be providing recommendations on one potential designated chemical and some input on future chemical selection activities.

The Panel will also begin discussing reference levels for Biomonitoring California and hearing presentations about that.

We'll also hear a summary of the draft Public Involvement Plan and respond to discussion questions about

that Public Involvement Plan.

And we'll receive an update on the Firefighter Occupational Exposures Project and provide input on that.

And each of these presentations will be followed by an opportunity for questions from the Panel as well as a public comment period, and then there will be time for further Panel discussion and recommendations.

I just wanted to say a little bit about the public comments and how we'll be handling those.

If you are here in the auditorium and you would like to make a comment, we ask that you please fill out a comment card, which you can obtain from Amy Dunn, who's sitting here to my right. She's holding up one of the comment cards. So please fill that out and turn them in then to Amy.

If you're listening via webcast and you would like to submit a comment, please do that by sending an email to the biomonitoring email address, which is biomonitoring@oehha.ca.gov, during -- any time during the meeting. And then those comments will be provided to me by the staff so that I can read them aloud during the appropriate comment period.

In order to make sure that the meeting continues on schedule and that all the commenters who would like to comment have the opportunity to speak, we're going to time

the public comments, basically divide the allotted time for public comments by the number of commenters who wish to speak.

Please, I also want to ask you to keep your comments focused on the agenda topic that's being presented during the -- prior to the comment period.

I also want to remind everyone to speak directly into the microphone and to introduce yourself please before speaking. And this is for the benefit of the people who are listening by the webcast and also for the transcriber.

As Dr. Denton already mentioned, the meeting's materials are provided in a folder for the members of the Guidance Panel and are also posted online at www.biomonitoring.ca.gov. There's also a sample Panel folder that you can view at the staff table outside the auditorium. And there's a small number of hard copies of the handouts there.

We also encourage you to go to the website for the latest revisions of the presentations that are going to be made at the meeting as well as related documents.

We're going to take two breaks today. One will be for lunch at around 12:30. And there will be another break in the afternoon. And a list of restaurants in the surrounding area is available on the welcome table.

So now, what I'd like to do is to introduce the first agenda item, which is an update on the California Environmental Contaminant Biomonitoring Program activities. And that update is going to be given to us by Dr. Rupali Das, Chief of the Exposure Assessment Section, California Department of Public Health, and the lead of the California Environmental Contaminant Biomonitoring Program.

Dr. Das.

DR. DAS: Thank you, Dr. Luderer; and good morning, Scientific Guidance Panel members and members of the public.

(Thereupon an overhead presentation was Presented as follows.)

DR. DAS: As Dr. Luderer said, I'm going to be giving an overall overview of the progress that's being made on the program since the last Panel meeting in May of this year.

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DR. DAS: And we're --

OEHHA DIRECTOR DENTON: Rupali, before you start, we do not have -- the monitors up here are not on for the slides.

DR. DAS: You have to turn the power on, I'm told.

ACTING CHAIRPERSON LUDERER: It's the right-hand button on the bottom of the screen.

DR. DAS: Okay. Everybody has their monitor on?

Okay.

ACTING CHAIRPERSON LUDERER: No, it's not working yet.

DR. DAS: Shall I go ahead?

Okay. Thank you.

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DR. DAS: So the topics I'll be covering today are listed on this slide. I'll be going over our new logo, the funding status, changes in staffing, just briefly covering the objectives on our CDC Cooperative Agreement, briefly describing our ongoing projects and saying just a few words about our new collaboration with Kaiser, and describing the outreach and engagement efforts that we've undertaken, and then our involvement in the National Biomonitoring System.

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DR. DAS: So we were very lucky to have the assistance of graphic artists in the Department of Toxic Substances Control as well as involvement from our staff in the three -- the other two departments, OEHHA and CDPH, and we developed this logo for the program. It's very innovative and we're very proud of it. This is the logo

that we've decided to adopt. And it can be used this way without text. And this is the text that the program has decided to use where we do want to use a tag line. So it can be used either way.

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DR. DAS: In terms of funding, the funding status is stable. We continue to have funds from the Toxic Substances Control Account (TSCA). And that level of funding is maintained at 1.9 million per year for the fiscal year, and continues to fund 13 FTEs.

And we're in year two of our CDC Cooperative Agreement. And we were renewed starting in September for 2.6 million, which is the same level that we were funded for the first year. And this year, the DTSC labs are included, and they've started to come on board with their activities funded by the Cooperative Agreement.

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DR. DAS: We continue to hire new staff because of either staff turnover or new positions being filled. And this is just a brief synopsis of the new staff:

Two environmental laboratory scientists, one staff programmer analyst, an administrative assistant that's in one of the laboratories. One of our positions was vacated, and so we are about to hire a health educator. We've actually hired one of the environmental

laboratory scientists that's listed as vacant here, and we have one more to hire. And we will be hiring a research scientist, a vacancy in OEHHA.

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DR. DAS: Just to remind you that our CDC Cooperative Agreement listed five objectives. I won't really be going over this, but just to remind you what they are.

The first two are really focused on lab objectives, to expand the lab capability and capacity, and to demonstrate the success of the lab quality management system. And in two lab presentations you will see that we have made progress on these objectives.

In addition, our goal is to assess and track exposure trends, to assess exposures in a representative group of Californians, and to collaborate with stakeholders and communities.

So while I won't be breaking down my presentation by objective, I think you'll see that we've made progress on all these objectives

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DR. DAS: Briefly, these are the ongoing projects. The first three listed here -- I'm sorry -- four projects listed here are primarily lab collaborations. And Dr. Jianwen She will be describing

the progress on those. But let me just go over them very briefly.

CHAMACOS collaboration: The Center for Health Assessment of Mothers and Children of Salinas is a lab collaboration where we're measuring urine for phthalates metabolites.

CYGNET. The cohort study of young girls' nutrition, environment, and transitions is a collaboration with a Kaiser CYGNET study where we're analyzing blood samples for metals.

The Environmental Health Tracking Collaboration. Dr. She will be covering what we've done so far primarily measuring the urine for metabolites of organophosphates.

And MARBLES. A Marker of Autism Risk in Babies - Learning Early Signs, collaboration with UC Davis where we're measuring urine for phthalates.

The two projects that you will hear more about today - one I'll be describing and one you'll hear about this afternoon - are MIEEP, the Mothers and Infants Environmental Exposure Project, also known as Chemicals in Our Bodies Project; and FOX, the Firefighter Occupational Exposures Project, that Dr. Leslie Israel will be describing in greater detail this afternoon.

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DR. DAS: So in terms of MIEEP, our Mothers and

Infants Environmental Exposure Project, we've made quite a bit of progress since our last meeting.

A field testing for the project instruments was completed in June at a Native American Health Center in Oakland. And testing was conducted in nine pregnant women that were very similar to our target population. The instruments were revised based on the field testing. And we received final approval from the Institutional Review Boards of both UCSF as well as the California Department of Public Health.

The research assistants were hired by UCSF and trained in both the field aspect of recruitment, interviewing participants, obtaining samples, and shipping - and that was done in collaboration with UCSF and the biomonitoring staff - and report back materials that will be used to report back individual results. Testing for that was begun -- the testing for English was completed and the Spanish testing will be completed soon.

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DR. DAS: Just to remind you of the way the Maternal Infant Project is going forth.

We're recruiting pregnant women at approximately 28 to 34 weeks gestation. And recruitment is occurring in a couple of different clinics affiliated with San Francisco General Hospital.

At the time of recruitment women are consented, enrolled. And there's a preliminary interview, and they're provided a take-home questionnaire -- a questionnaire that they take home and fill out at home. That questionnaire is collected at the second encounter, which occurs at 34 -- approximately 34 to 38 weeks gestation.

At that second encounter urine samples are collected and an in-person interview that's approximately an hour long is conducted by the research assistants at the clinic.

The third encounter occurs when the mother delivers at San Francisco General Hospital. At delivery maternal blood samples are collected, and following delivery umbilical cord samples are collected as well. And medical record abstraction occurs while the mom is still in the hospital.

The final encounter -- well, there won't be an in-person encounter as planned currently, but results will be returned.

Currently we plan to return results in two phases: One at approximately nine months to a year following the first encounter. And those results will be the blood metals and the nonpersistent metabolites in urine. And the final set of results we plan to return

approximately two years after the first encounter; and those will be the persistent metabolites.

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DR. DAS: At one of our earlier Panel meetings, we had discussed the need to give women information about the substances for which we were testing. The women are receiving educational materials. This is just a sample of the materials they're receiving. This material was developed by UCSF. The program itself was not involved in the development of these materials.

It's called Healthy Every Day. And there's an English version and a Spanish version. And it talks about many of the chemicals for which we were testing and provides some ideas on how to reduce exposure. And as I said, the program staff were not really involved in the development or review of these materials.

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DR. DAS: So let me give you a little bit more specific detail about MIEEP.

UCSF has recruited 40 participants so far. Our original goal before we actually started recruiting was 100 moms. So far they have recruited 40 participants. Twenty of them have given birth to date.

We in the program have received 20 maternal samples and 16 cord blood samples. So there were some

early births for which we were not able to obtain the cord blood samples. And I'll describe some of the reasons why in the next slide.

And we've received 31 take-home surveys so far.

Some other materials like the in-person interview and some of the other samples have not been received by us, but UCSF has collected them.

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DR. DAS: So UCSF feels that the recruitment is not going -- they haven't been able to recruit as many individuals as originally anticipated. There seem to be fewer births overall nationally as well as in SFGH. And so that's affected their ability to recruit pregnant women.

In addition, there've been time limitations at all phases. Many of these women are very busy with other kids or other things at home, and they might initially agree to participate but then don't follow through with complete enrollment because of their own time limitations. And so sometimes an appointment might be made and the woman won't show up. So that's affected recruitment.

And in terms of the ability to obtain umbilical cord samples, they're constantly trying to improve the protocols in the delivery room.

The collection of the umbilical cord samples

occurs -- is done by labor and delivery staff. So it might be the regular labor and delivery attending physicians or the residents or fellows that are rotating on that particular time period, and so there's a constant retraining that needs to occur for those staff as they're rotating on and off the labor and delivery ward. So that has affected some of the ability to collect the umbilical cord samples.

And the research assistants that UCSF have hired aren't there 24 hours a day, and so if a delivery occurs during off hours, that that sometimes can affect the ability to collect some umbilical cord samples as well.

However, in spite of these obstacles, we feel that we've had successful recruitment, sample collection, and shipping. We've really done a lot with limited resources. And so we're very happy that we have been able to collect all the data, both in terms of the questionnaires, the maternal and the umbilical cord samples.

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DR. DAS: So just to give you an example of the kinds of materials that our staff have developed for use by UCSF for the maternal-infant study, these are prototypes of protocols that we will modify and have modified for other studies -- other projects as well.

So this is just an example of some of the processing that occurs for the red top tubes. I won't go into it in detail, but our staff have developed very nice pictorial examples, combined with actual training of the RAs, to make sure that the specimen collection and processing goes according to protocol, so that we can ensure the quality of the analytes.

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DR. DAS: Similarly for shipping, it's really important that shipping occurs in a standard way so that we can get tubes that aren't broken or filled to their correct level, don't have clots in them or stored at the correct temperature. And so we've developed protocols for both storage and shipping. And those are followed by the staff as well.

We have had to work out several obstacles, but I think we're doing very well

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DR. DAS: So as I said, we have received several -- 20 maternal and 16 cord blood samples. The samples that we have received are the lavender tops. And those are being analyzed for lead, mercury, and cadmium.

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DR. DAS: And we have had ongoing discussions with the two programs in the State that deal with lead:

The Childhood Lead Poisoning Prevention Branch and the Occupational Lead Poisoning Prevention Program.

And this is actually a simplified, believe it or not, schema for reporting blood lead. Lead is one of the only substances for which we actually have health-based action levels to guide what we do based on the level of lead that's detected in blood. And its -- laboratories are required to report all lead results analyzed in the State of California regardless of the level. And that results in this complicated scheme.

So this just shows that the personal health information, the identifying information, is kept separate from the lab samples. Both are entered into a common database, but the personally identifying information is protected.

The reports go to the Childhood Lead Poisoning Prevention Branch, which is required to get all blood lead results from the State.

And from there, it's sent to the Occupational Lead Poisoning Prevention Program, to the pediatrician if the level requires it, and to other programs.

We have a similar schema for the Firefighter Occupational Exposures Project. It's simpler because it doesn't involve the childhood lead action levels and action by the Childhood Lead Poisoning Prevention Branch.

I can answer more questions about that if you want during the question and answer period. I just wanted to give you an idea that we do have a schema and that we're working with both branches to make sure that we're following both the State requirements as well as developing some of our own clinical action levels.

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DR. DAS: So as I mentioned, Dr. Leslie Israel will be covering the Firefighter Occupational Exposure Project in more detail this afternoon. But basically we have made progress in this as well. We completed field testing, we got IRB approvals. And you'll hear much more about this this afternoon.

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DR. DAS: Our new collaboration planned for year 2 of our CDC Cooperative Agreement is one with the Kaiser Research Program on Genes, Environment, and Health. We have had a couple of discussions with Stephen -- Dr. Stephen Van Den Eeden, who presented before this Panel at one of our earlier meetings, and we're discussing the details of the collaboration. And I hope at the next meeting that we'll have many more details. But our two potential pilot projects are a collaboration with the adult cohort where the RPGEH is collecting samples in certain populations in northern California, and a

pregnancy cohort that they have -- the research program has started collecting blood specimens on this year.

And I don't have enough details to provide you with much more. But this is something that we're really putting a lot of effort into this year and we'll have a lot more to report in the coming year.

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DR. DAS: In terms of outreach and engagement, we have a draft biomonitoring brochure. This is not a brochure about biomonitoring in general. It describes our program, Biomonitoring California.

And we've conducted usability testing in both English and Spanish. The field testing revealed that the brochure was very well received. It was understood. We made some changes based on suggestions. The changes were relatively minor.

The brochure is still in draft stage and needs to be approved before it's released to the public.

In addition, we are taking some efforts to improve the website. The website is currently hosted by OEHHA. The plans for the website revisions are under review by CECBP staff as well as staff from the Health Research for Action, who is doing a lot of the work and providing suggestions on improving the website. The focus is on improving access to the public and making

these -- making the website more friendly and accessible to the public.

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DR. DAS: And, finally, we -- biomonitoring staff have engaged with several organizations on a national basis to participate in the National Biomonitoring System, which is sort of a loose effort that's spearheaded by the Association of Public Health Laboratories (APHL). APHL has a five-year national biomonitoring plan where they hope to develop a network of public health laboratories that can -- at the national, local, and state levels that can respond to environmental health concerns with a focus on biomonitoring. But they have enlisted the involvement of two other organizations.

So APHL really has a focus on labs and their audience are laboratorians. But they recognize that biomonitoring involves much more than laboratories and has to involve epidemiologists, and so they have involved the Council of State and Territorial Epidemiologists (CSTE) and ASTHO, the Association of State and Territorial Health Officials. And so these three organizations bring laboratory, epidemiological, and public health expertise into biomonitoring efforts nationwide.

The goal is to provide nationwide guidelines for states who are developing biomonitoring programs. So this

isn't meant to be a top-down directory in terms of what to do. But as states take on biomonitoring efforts either through legislation or through investigations of individual incidents, it's helpful to have these guidelines that they can draw on rather than developing programs from scratch.

We have staff who actively participate particularly in the efforts related to APHL and CSTE. Diana Lee and Berna Watson and myself have been participating and writing parts of these guidelines and participating in meetings to develop these national guidelines.

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DR. DAS: So for next year, our largest focus in terms of a new effort is developing an MOU, Memorandum of Understanding, with Kaiser.

We will complete recruitment for both the Maternal-Infant Exposure Project and the Firefighters Exposures Project during this coming year. We will get data for both projects. And we'll have to embark on the complicated process of data management, lab analyses. And in the first part of next year we hope to release another request for information. If you'll recall, a couple of years ago the program issued an RFI, or request for information, asking investigators around the country that

had collected biospecimens on the California population if they would be interested in having our labs analyze biospecimens. And we hope to do that again in the first quarter of next year.

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DR. DAS: And so I'll be happy to take any questions at this point. Thank you.

CHAIRPERSON LUDERER: Do any Panel members have questions?

Dr. Wilson.

PANEL MEMBER WILSON: Thank you very much for that presentation. And congratulations on all the progress to date. It's really heartening to see.

I'm wondering if -- out of curiosity, what other states actually are contemplating biomonitoring programs, if you can comment on that.

DR. DAS: It's really variable, and I'm not sure I can comment on all the states.

Minnesota has legislation that was enacted after the 2006 legislation here. And it's a little bit different. It doesn't have all the elements that our state program does. But they're probably one of the states that are the closest to our program.

Diana, do you have more information on the other states?

It's really quite variable state to state.

MS. LEE: New York City is planning on carrying out another series of their New York City HANES. And I believe the Wadsworth -- the New York State Wadsworth Lab will be analyzing their samples.

And then also New York State's Department of Envir -- is it Department of Environment or Department of Public Health? -- is also getting more involved in biomonitoring as well but not on a state level.

The State of Wisconsin has collaborated with University of Wisconsin. And actually University of Wisconsin is collecting kind of an NHANES type study and banking samples collected, with the intent hopefully of being able to gather some laboratory resources to analyze them.

And there are smaller scale projects I believe and happening like in Washington, but not on the same scale necessarily.

Very few states other than Minnesota, as Rupa has indicated, have actual state legislation including biomonitoring as a state function. So California still retains that distinction. And Minnesota is hoping to beyond pilot projects

DR. DAS: And just to remind you, the three states that were funded by the CDC Cooperative Agreement

are New York, Washington, and California. So those three states, as Diana mentioned, have some sort of program going on, in addition to the others that she mentioned.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

Rupa, it's very impressive progress and excellent report. So thank you for that.

I'm just wondering if you have any idea of where we are in terms of budget constraints or deficit with regard to conducting a representative sample of California, keeping that as our mandate and, you know, our goal potentially. I'm not clear as to what -- which of these monies or, you know, pots of monies that we have, whether or not they could be used for that purpose eventually. And if so, what would be -- what's the remaining amount we would need to be able to do a representative sample?

DR. DAS: So I'll try to answer some of that. And might have to have Diana fill in, because she did so much of the initial legwork in order to determine what we would need to do a truly representative sample.

As you've indicated, the budget constraints are dictating what we're doing right now. And what we're doing right now is a number of different targeted

community studies, which is also allowed by the legislation. Our goal is to do a representative sample which is much more resource intensive. And I think what we're doing now is developing the capacity and capability in demonstrating that we actually can do larger programs.

I think the closest that we are coming right now to a representative sample is our collaboration with Kaiser. As we develop that collaboration, I think that has the possibilities of expanding to something that could be representative of -- it might be regional. It depends on how we collaborate with Kaiser. But we're collaborating with Kaiser right now in northern California. It's not -- doesn't include southern California at the current time.

In terms of the ability to really recruit and gather samples on a statewide representative sample, the initial estimates for sampling and even conducting a representative sampling strategy were quite high and I think beyond the capacity -- the resources we have right now.

So at the current time with the current resources, I don't see the ability to get a truly representative sample. However, I think we are moving toward that direction. I think our collaboration with Kaiser is really aimed at approaching as closely as we can

a representative sample.

So I know you have another question, but Diana might want to add some more.

PANEL MEMBER QUINT: While Diane is coming up, I just want to make it clear that I'm quite impressed and, you know, really appreciate this work that's being done now. This is not a criticism of the studies we are doing in the meantime. I just want to keep somewhere in my brain where we are in terms of, you know, what the fiscal constraints are and if we had -- you know, what that figure is.

MS. LEE: I think our original estimate's based way back when we did our legislative proposals was well over $10 million for doing a statewide sample, similar to how CDC operates NHANES by which they collect their environmental samples for analysis.

So we haven't updated those. But they're certainly expected to be higher given current fiscal times.

So, yes, definitely the Kaiser project that we're anticipating carrying out will give us a better idea of how we might use an existing sampling -- a population that we know something about to derive a representative sample. And then we're also hopeful that as our labs develop capacity to analyze newborn blood spots collected by the

Genetic Disease Branch, that we'll also be able to use some of those samples. But that's further down the line and that's certainly methodology that still needs to be developed.

But I think you can all appreciate the greater cost is in sample collection, and obviously maintaining the lab. So as we figure out creative ways to obtain our samples and piggyback on or collaborate with other people who are doing it routinely, it certainly helps decrease our costs overall.

DR. DAS: I just want to add one thing. You said which part of what we have will help us to attain the goal of reaching a representative sample. And I think the acquisition of lab equipment certainly has made a lot of progress towards helping us to achieve that.

As Diana said, with the -- the sample collection of course is something that we will need resources for. But we will demonstrate the ability to analyze those samples because of the lab equipment we've acquired.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I have a question about the recruitment for the San Francisco General Hospital study, because I think that -- I'm really encouraged to hear that that is moving forward. And it sounds like despite a number of logistical hurdles, it actually going

to be important and successful.

But the recruitment issue's a little worrisome, and I was wondering whether the -- sort of whether the plan is to hold to the goal of recruiting the full 100 participants. And if so, whether that may require additional resources given the fact that it's been harder to recruit than anticipated?

DR. DAS: So it's a very good question.

In order to recruit the original goal of a hundred moms, it will require additional resources, which we don't have at the current time. So our current intent is to not recruit a hundred women but to recruit as many as we can given the resources.

So, you know, in order to recruit a hundred, we would have to extend the time of recruitment. And it would mean putting additional resources into that.

PANEL MEMBER SOLOMON: Do you have projections at this point about how many women may be recruited over the time period that you do have?

DR. DAS: I think it's going -- well, I can't give you a definite number but I would say at least 50 and possibly 75. But 75 might be optimistic.

PANEL MEMBER SOLOMON: And is it okay to do follow-up questions?

Is there a possibility of identifying additional

resources to, you know, expand the study and the recruitment period?

DR. DAS: We can certainly go back and look at what the possibilities are. At this point, our -- the study -- you know, the project is being funded by our CDC Cooperative Agreement. In addition, UCSF, UC Berkeley, and we, with the UCSF being the principal investigator, have also obtained Wellness funds. And so UCSF actually has two pots of funds for that program. The Wellness funds are really not under our control. And they're being used for a portion of that project.

The CDC Cooperative Agreement funds at this point for year 2 have been accounted for. And so -- but we could certainly go back and look at what the possibilities are. I certainly agree, it would be -- the ideal situation would be to be able to recruit the hundred women that we had originally envisioned.

PANEL MEMBER SOLOMON: My final question I guess is that I was just curious if any power calculations have been done to look at the sample size question, because, you know, if one of our questions is, "Is this population of women systematically different in their exposures compared to the national NHANES survey population?" you know, it might be possible to get an estimate of how many participants would be needed in order to identify

differences if they do exist.

And so it would be actually really helpful to have those power calculations and then see if, you know, 50ish women will give us the information that we would need or if it's worth putting in the extra effort to identify the resources.

DR. DAS: Yeah, thank you for that suggestion. We have not done that, but we can go back and do those calculations.

CHAIRPERSON LUDERER: Are there any other questions from the Panel?

Okay. Then I think at this point we would like to find out if there are any public comments.

It looks like one Email comment.

All right. This is an Email comment that was sent in by Tim Shestek, - hope I'm pronouncing that right - from the American Chemistry Council. And his question is:

"Will a draft of the biomonitoring brochure be made available to the public for review and comment prior to its being finalized?" If not, why not? And also, can you comment on who has reviewed the draft and provided comments?"

DR. DAS: So the biomonitoring brochure is a description of the program -- of our State program. And

for that reason it will not be released to the public for comment. It's not a document that describes biomonitoring in general. So our plan was not to release it to the public, because the program staff are best able to describe what the program involves.

The brochure was developed jointly by the three departments - OEHHA, CDPH, with some involvement by DTSC in collaboration with Health Research for Action.

Field testing was conducted on a representative sample of participants chosen by Health Research for Action. And review was in -- it's ongoing. It hasn't been completed. But it's the Program staff and management that will review the brochure.

CHAIRPERSON LUDERER: Thank you.

We have another comment. Sorry, I don't know this person's name.

MS. WHITMAN: Hello. My name is Deborah Whitman, and I'm founder and president of a nonprofit called Environmental Voices. And basically what we do is provide research and education about toxic chemicals and how they affect your health and the environment.

And I just wanted to share something with you. That I suffer from multiple chemical sensitivities. And I'm a Kaiser patient and they've never seen anybody as bad as I am.

So I've been researching chemicals and how they affect your body for about 20 years now. And I would like to participate in whatever studies or information that you have.

And another organization that's a nonprofit is called the Environmental Working Group, who's done a lot of studies on chemicals and things like that.

So I basically just wanted to share this information and let you know that I'm interested in participating in anything that you have on this project. And I thank you very much for the work that you're doing.

CHAIRPERSON LUDERER: Thank you very much.

At this point, we have time for Panel discussion. So do the Panel members -- any Panel members have comments or questions they'd like to make at this time?

Okay. Looks like no further questions from the Panel.

So we could at this point move on to the next topic, which is the laboratory update.

DR. DAS: It is my pleasure to introduce Dr. Jianwen She, who's the chief of the Biomonitoring Section in the Environmental Health Lab of the California Department of Public Health, who will give the next presentation.

(Thereupon an overhead presentation was

Presented as follows.)

DR. SHE: Thank you very much, Dr. Das, for the introduction.

Good morning, Scientific Guidance Panel members and everyone.

I'm glad to have this opportunity to update you on what EHLB has done since our last May meeting -- since our May meeting.

Next one please.

--o0o--

DR. SHE: I'm very happy to report our progress for a year we completed the remodeling of two rooms for biomonitoring use. One room is for liquid chromatograph / mass spectrometry analysis and the one for GC, a gas chromatograph and mass spectrometry analysis.

We also installed three new instruments. You can see from the slide we installed two LC-MS/MS, plus one GC-MS/MS.

Our intended use of this new instrument is shown on the slide.

So one LC will be used for environmental phenols. Second LC will be used for organophosphate specific metabolites and pyrethroid metabolite analysis.

The GC will be used for organic phosphate common metabolite - dialkyl phosphate.

Next one please.

--o0o--

DR. SHE: We continue our sample management, Laboratory Information Management System, and the quality assurance activities.

With the LIMS customization, we can store specimen information, analytical results, and the patient information in a central location.

For the quality assurance, we conduct the stability studies of organophosphate pesticide and the phthalate metabolites. This stability study will provide guidance to our staff and the laboratory staff in the sample -- about the sample handling, collection and the processing.

Yeah, next one please.

--o0o--

DR. SHE: As Dr. Das mentioned, laboratory also participates in sample analysis for a few projects. So far we already finished three initial projects. One is for Tulare, which analyzes 77 urine samples from 34 participants for trichloropyridinol. And then we analyzed 500 blood samples for lead, cadmium, mercury from the CYGNET study. And then we finished 28 urine samples analysis for the MARBLES study.

And we have began work on CHAMACOS, MIEEP, and

the FOX sample analysis. In fact, we have already received and analyzed specimens from the MIEEP and the CHAMACOS participants.

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DR. SHE: In the Tulare study, for instance, we found that the level of the trichloropyridinol in 34 participants was similar to the level reported by NHANES. NHANES participated from the year 2001 and 2002.

This graph shows the geometric means of our study compared with the Hispanic, white and the non-Hispanic, white.

Our geometric means is slightly lower than the other two populations.

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DR. SHE: I simply remind you we evaluate the following methods:

We finished metals method validation in blood; phthalate metabolite, which included mEP and mBP, in urine; OP pesticides, which include trichloropyridinol and 3-phenylpropanoic acid, in urine. We finished the hydroxy-PAH, which include only one analyte, 3-PHEN, in urine. We finished the creatinine analysis for normalized analytes in the urine

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DR. SHE: Here is an example of our new method of

developed effort for the -- this graph is a chromatogram. It shows the separation of environmental phenols.

You can see in a relative short time, within 20 minutes, we can separate the nine compounds, include some of the designated chemicals, and also some of our priority chemicals like Bisphenol A.

Of course we have a lot of work to do to finish the validation of this method.

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DR. SHE: Here is what we will be doing in year 2 of CDC Cooperation Agreement.

We anticipate expanding upon existing methods.

For example, for hydroxy PAH, currently we have one analyte. In this year we plan to increase to eight.

For phthalate metabolites, currently we have two analytes. We'll be increasing to six.

OP specific metabolites, we have two analyte, will be increased to nine.

We're also continuing methods in progress. For example, like DAPs analysis, arsenic speciation, environmental phenols.

For environmental phenols we try to include about 14 analytes. For DAPs we plan to have six analytes.

The other thing we try to do is increase the capacity of the laboratory so we can handle more samples,

lay the foundation for the statewide monitoring program. So we need to do the procedural automation and to enhance our laboratory throughput.

Thank you.

CHAIRPERSON LUDERER: Thank you, Dr. She. It's wonderful to see the progress that the laboratory has been making.

Would you like us to take questions now or have both presentations and --

DR. SHE: Either way.

CHAIRPERSON LUDERER: All right. Any questions now for Dr. She from the Panel?

Dr. Solomon.

PANEL MEMBER SOLOMON: Very great progress from the laboratory. Thank you.

I noticed that you listed manganese as one of the validated methods. So is the lab really sort of ready to go up and running with manganese already?

DR. SHE: Actually, we analyzed manganese from the CYGNET study. Final -- under the sample we reported results. I think we are okay to report. But that's our new -- the three elements. We already originally have lead and cadmium and mercury. So we are -- okay.

MS. HOOVER: Yeah. Related to preparing for manganese, I was talking to Frank Barley in your lab, and

basically the way he phrases it is they have a validated method. They understand how to run it. But they still consider it on a trial basis, because they don't have a lot of experience with manganese, and there's a lot of complications with understanding laboratory results for manganese. So there's -- I'm just going to briefly touch on that. But I think you'll also hear a public comment about that. So the way Frank told me to present it is that they're running it on a trial basis as part of pilot projects. So that's the current status.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: Again, I'd like to add my thanks. I think you're making, you know, great progress. It's very exciting to see this building up.

My question's a little bit specific. But I'm curious about the hydroxy-PAHs, which it's just -- I don't know if you specified all of the ones. The eight that you're going to do, which ones will those be? And is there a sort of time line for what order they're going to be brought in, or are you just going to bring in eight?

DR. SHE: For the hydroxy-PAH?

PANEL MEMBER McKONE: Yeah, Hydroxy-PAHs. Currently you do the 3-phenoxy -- or 3 --

DR. SHE: Yeah.

PANEL MEMBER McKONE: And then you're going to

add eight more, it says.

DR. SHE: Yeah, we will handle more. The focus will be on the small ones, like a three ring and two ring. So we will handle naphthalene and the fluorene and -- oh, sorry, I read the parent compound. I should read the hydroxy metabolite.

So we --

PANEL MEMBER McKONE: Right. The parent compound's just fine. I mean I'm just curious about which order, which ones are coming in.

DR. SHE: We will handle eight metabolites from four parent compounds, which include 1-hydroxynaphthalene. 2-hydroxynaphthalene, 2-hydroxyfluorene, 3-hydroxyfluorene, 9-hydroxyfluorene, 3-hydroxyphenanthrene, 9-hydroxyphenanthrene -- 3-hydroxyphenanthrene we already have a method -- and the 1-hydroxypyrene. These are compounds we plan to expand it to.

PANEL MEMBER McKONE: Do you have any plans to go to the higher order rings, up to benzoapyrene, or is that --

DR. SHE: For the benzoapyrene, according to the CDC, they do not find it so much. But my information may be wrong. And some of these bigger rings may be a lot easier to detect in urine, and some of them might be in

the feces. But we will -- after these eight ones we will continue our research to see if we have results. And, yeah, we should end on it later -- at a later time.

PANEL MEMBER McKONE: Thank you.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

My question has to do -- again, very, very impressive and exciting.

Where are you in terms of your assessment of capacity? I mean are you up to your ears in samples or are you handling this volume comfortably? Or, you know, can you give me just a rough idea of, you know, the -- because you have a number coming, you finished a number. And is this sort of a comfortable amount of samples, or could you go much higher? I'm just trying to get some idea.

DR. SHE: All the output right now we have is from two instruments. But with the CDC grant, under the lab space doubling, I think we can go -- at least double the output. With automation, we can triple that very easily. We handle more stuff, so allow I think -- for lab capacity, we're supposed to be able to handle even a statewide program, at least from a EHLB lab's capacity, in one year or two year. If we talk about of thousands of sample levels.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: Just a brief question about the TCPY.

I'm wondering if you could give us the age ranges for the populations extracted from NHANES and also from the Tulare study.

DR. SHE: So --

PANEL MEMBER BRADMAN: Were they all adults?

DR. SHE: Yes, I'm trying to find my information on the -- oh, sorry.

In Tulare County's -- you asked for the age information?

PANEL MEMBER BRADMAN: Yes, thank you.

DR. SHE: First, that's 11 males and 23 females. That was 34 participants. Include 9 children, age 7 to 18. The general population from this 34, the age is from 7 to 79, with the average of 33 years old.

For the CDC NHANES study, sorry, I do not have the age information.

PANEL MEMBER BRADMAN: Okay. I just wanted to get a sense here of whether one of these emphasized children more than another or whether they're approximately similar.

It might be worth also comparing out the levels in the children. I know NHANES goes down to 6 to 11 as

their youngest age group. It might be worth -- the numbers are obviously going to get small for Tulare. But it would be interesting to compare children versus adults here.

DR. SHE: That's a very good suggestion. We should continue our data analysis in this direction.

PANEL MEMBER BRADMAN: Thank you.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you. And congratulations on the new equipment.

I have a specific question, then a general question.

I'll start with the general one, which is: With your quality assurance, quality control measures, if you're encountering any persistent problems with those? And if you feel confident with where the -- how the laboratory's performing on QA/QC and whether your QA/QC measures are within the range of those of CDC? That's just sort of the general question.

And then the second was around the stability study of the OP and phthalate metabolites, if that's -- if you could just give us a sense of what's happening with that, if that's a problem that you'll see you can resolve and sort of where your coefficient of variation is with that now.

DR. SHE: First, for general question about quality assurance, laboratory feel very confident. But of course for the new chemicals we have the challenge to find the, for example, PT samples. Some PT samples -- proficiency testing samples, we still like to find the most vendors or participants we can get to the different PT samples.

But regarding like a precision, accuracy, recovery, background contaminations, I think on the laboratory conduct the metal test, everything's under the control. For example, precision, accuracy levels are comparable of causing -- including the detection limits, very comparable to the CDC method.

And the challenge, like I mentioned, we needed to be able to evaluate more sample from outside. Some PT samples we get from CDC. Some we get from German GEQAs. We look for more samples, we can do more external assessment on our general quality assurance program.

Regarding the specific stability test, with the OP and the phthalate metabolite, we majorly conduct long-term storage test, different temperature effect on the storage, and freeze -- multiple cycle of freeze in the salt activities on the stabilities. And so far we found for some chemicals, for example, if long-term storage is not strictly under the condition, like minus 70, minus 20,

and might have the stability issues.

I missed the part you mentioned of the coefficient variation.

PANEL MEMBER WILSON: I think I -- my assumption from the slide was that there was a question in the laboratory method and there was some instability in measuring your standards. And so I think you've clarified that by saying that the question of stability has to do with the stability of the metabolite under storage conditions. Is that right?

DR. SHE: Oh, actually you're right. We also test under the laboratory analysis conditions. For example, we prepare a batch of samples which may take us one day. Under this typical analytical condition, samples under the room -- near the room temperature, we didn't find any significant change between if we're able to finish the sample within one-day's time.

Also, we tested the chemicals under the analytical conditions. For examples, triclosan, if we use atmospheric pressure chemical ionization, this chemical will break down. So we needed to look for the analytical conditions.

There are other things that you may already know, like basically -- BPA 209 where they compose on the GC, inject the port or repeat it on the GC columns break down

within the ion source. So we did evaluate the stability issues with the instrument under the sample process procedure.

PANEL MEMBER WILSON: Could I follow up with a final question -- thank you -- with the Chair.

Are you concerned that we could lose samples over time in storage? And maybe it's specifically with regard to OP or the phthalate metabolites.

DR. SHE: The long-term storage testing we conducted over one year so far -- could also lead to the -- other people did a special -- CDC published a few papers.

And if we store the samples at minus 20 or minus 70, I do not have a concern.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON LUDERER: Dr. Culver and then Dr. Bradman.

PANEL MEMBER CULVER: Thank you very much.

Once your methods are validated, are they going to be published? And if so, where?

DR. SHE: Right now, the lab published the -- actually no journal publication from this method. And we prepared the one for the OP pesticide method. And right now it's under review.

And we published some old methods like PBDE

analysis. I was invited to publish in the Science China, I published one in that journal.

Most of the publication we have done is only a presentation, you know, at scientific meetings. More like dioxin serious meetings; dioxin, we published a few. And all of the other ones the manuscript is still under the preparation and the review. But not a publication yet.

PANEL MEMBER CULVER: I wonder whether the methods that we use in our laboratory here are comparable with those that are used in clinical laboratories around the state. And if not, whether we can establish a relation between what our laboratories here provide and what is generally available to the clinical community.

DR. SHE: Our lab is a CLIA certified labs. We follow the CLIA laboratory improvement act. So in general principle, we are comparable. And so far I do not know so much a state clinical laboratory conducted a similar analysis with the same kind of analytes. But we will search on that area to see who's conducted the same kind of analysis. We will do the round-robin test. We have tried to plan to participate in some round-robin tests.

PANEL MEMBER CULVER: Thank you.

DR. SHE: Thank you very much.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: I just want to comment on

the storage stability issue. I mean really in any biorepository that's a concern, is the stability of the analytes. And some, you know, may not store well even at negative 80. I believe from CDC just from Dana Barr, I've heard informally that, you know, some compounds stored over years may decay slightly. And that I think just underscores the need for the kind of stability studies that you're doing. And really that should be kind of an ongoing part of any biorepository and biomonitoring Program.

Things like DDT and PBDEs, you know, that of course is probably stable over many years or decades. Things like manganese of course is a basic element. Other things may be less stable. There may be a difference between the parent compound and the metabolite. And I think among -- all of those who are involved in storing samples for analysis and future analysis have to consider that. And it's great that you are.

DR. SHE: Yes, thank you. We will continue the stability evaluations.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: I just want to respond to Dr. Bradman.

Is there a protocol that CDC has developed for evaluating the stability of, you know, metabolites and

others under storage conditions and should we be, you know, paying attention to that?

PANEL MEMBER BRADMAN: I mean I'd have to -- we'd have to ask CDC. But I know that they have conducted some studies. I don't know if they have a systematic protocol to evaluate that on a regular basis. And maybe that's something that should be considered, but we'd have to go back to CDC. And it probably varies by group as well.

DR. SHE: Actually that's right. And the information we get is a looks like that varied by the groups. We reviewed the CDC's publication that -- part of similar publication from different groups.

The general approach look similar. Some groups may look for the conjugated forms. Stability, someone look for the parents. Some want to look for even the free forms. So we try to summarize the common view from the people. We can try to create our own protocol. If CDC later on can give us some protocol, we definitely like to follow.

CHAIRPERSON LUDERER: Thank you very much again for that wonderful presentation.

And now we have another presentation.

DR. SHE: I'd like to take this opportunity to introduce Dr. June-Soo Park. Dr. June-Soo Park is our research scientist in the environmental chemistry

laboratory. He will give the update from ECL.

(Thereupon an overhead presentation was Presented as follows.)

DR. PARK: Well, thank you, Dr. She.

I'm actually the second back-up for this talk. Our original speaker, Myrto Petreas, had a family emergency. So she flew back to Greece last weekend. So hope our chief, Dr. Bruce La Belle, was here to present this one. But obviously he's not here.

So I'm going to do that.

My name is June-Soo Park. I'm going to give you the brief -- our laboratory update.

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DR. PARK: So we have validated many methods for the PBDEs. So Hopefully I don't have to explain all these chemicals, the full description. And the perfluorinated chemicals and the PCB and the chlorinated pesticides, also some phenol compound, for example, hydroxylated PCBs and PBD metabolites, triclosan, pentachlorophenol and so on.

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DR. PARK: And based on our validated method, we had many -- a couple of the different time groups, from some cohort study or some pilot study.

In 1960s one is some cohort study using the sample -- total sample number 495. Original sample size

is about 20,000 collected 50 years ago.

And the other time groups, the 1980s another cohort group.

And last one is the 2008-9. This is a pilot study conducted by us.

So as you can see just looking at our -- 4,4-DDT -- this DDT group nicely comes down. And the NHANES data in the between, covering the 1999 to the 2004.

And I also want you to look at the right side at the chlorinated pesticides oxychlorine, transnonachlor, hexachlorobenzene, and beta BHC. And, you know, they're coming down pretty dramatically up to 2008-9. By adding these NHANES data, you know, this -- you know, the decreasing trend looks more stepwise.

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DR. PARK: So PCB is the same -- not much difference between 1960s and 1980s, but it's dramatically decreased in the 2008 to 9.

The opposite way -- opposite story in the PBDEs. It started picking up on the yellow color bar in the 1980s and its order of magnitude increase in the contemporary serum.

By adding NHANES data here on the piece, you can see more stepwise decreasing in the PCBs, and the opposite way for the PBDE data.

One thing, you know, I want you to note or pay attention is the contemporary serum, how they change the levels -- how the levels have been changed between PCBs and PBDEs. Already -- you know the PBDE levels already exceeded PCB levels in this indoor environment. Even within our group, you know, we see this trend very often, you know, from the house cat, you know, also the human, also the house dust. So it's nothing surprising news.

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DR. PARK: And also the PCB and the PBDE metabolites are known as the potent thyroid endocrine disrupters. But they follows -- or in the lower levels they follows their parents' compound. This is only our -- the time groups, '60, '80, 2008 to 9, and hydroxy PBDEs also same, you know. We did not analyze in 1960 some samples because we don't expect, you know, any PBDEs or hydroxy PBDE exist back then.

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DR. PARK: So perfluorinated compound analysis. We adapted pretty much a similar manner, similar method from the CDC by using the automated solid phase extraction coupled with LC triple quad. But we, you know, conducted a very thorough QA/QC procedures, you know, including a laboratory-wide instrument background check. And recovers from our matrix spike control serums.

Also, the reference materials. These standard reference material. They don't have any certified values available yet. But you know they have some consensus about reference values for the representative perfluorinated compound, PFOS and PFOA.

Also, we did several inter-laboratory comparisons with CDC. Also, the New York State -- New York State Lab and the Minnesota State Lab by using -- by analyzing their QA/QC samples.

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DR. PARK: So this is an interesting result. I'm going to squeeze the NHANES data into our data. Little space, so I made a smaller -- a narrower bar graph there, but period stay same from 1999 to 2000, and the second period covering 2003 to 2004.

I want you to look at the right side, the PFOA data, first. Obviously from our time groups, we missed very important timing. When this PFOA levels hit the top based on the NHANES data, let's see, it was 1999 to the 2000. And since then it's coming down.

This kind of a trend -- same trend been reported from the many other -- not many other study -- very little study for this perfluorinated time trend. But I want -- they also report the similar trend as this.

I want to -- also I want to mention, because --

you know, most of the study reported only from the mid-1970. But we were able to measure 1960 samples. And to my knowledge, this is first 1960s perfluorinated compound data in the human serum.

But, you know, we expected -- you know, that based on this PFOA time trend, we expected a similar time trend for the PFOS too, as the other study reported.

But as you can see, 1960s data show the highest levels of over last 50 samples -- 50 years. So that's why I emphasize the previous -- you know, the QA/QC checks, you know, the old -- you know, the thorough QC checks, kind of convinced -- we convinced our laboratory side doesn't have anything to do with this 1960, you know, the huge peaks.

But there still remained -- there remained two possibilities, you know, still we can't get away from some artifact effect during the sample collection and storage back then. Whether -- that levels may be true, because we -- I haven't seen any 1960s data yet. Even though some study reported the 1970s is kind of a very low levels of PFOS. So I talked -- we talked to the -- you know, many colleagues in the conference or over the phone, and some -- you know, the PFC expert said, "Oh, it's impossible, you know, to have, you know, such a high concentration of, you know, PFOS in the 1960s." But some

other colleagues, you know, said differently.

Because back then, the people, you know, could have, you know, carelessly applied some Scotchgard, you know, the main source of this PFOS, you know, to their sofa or carpet or curtain to make some, you know, the stain resistant properties.

So at this moment, I think we put some question mark on our data. But obviously this is very interesting data.

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DR. PARK: And thanks to the CDC Cooperative Agreement, our new personnel, Dr. Suhash Harwani already started working with us. And Dr. Tan Guo, we expecting, you know, to have him on our board soon. And we working with a third candidate. And also we are meeting with the CDPH, Dr. Jianwen She's group, regularly, once a month, to discuss about this QA/QC, you know, how we can efficiently manage the samples by utilizing also the LIMS system.

We finished the shopping around for the -- to purchase this new equipment, LC triple quad. We found the best LC system can fit for our California Biomonitoring Program.

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DR. PARK: And more methods -- more methods for the, you know, the many other chemicals we working on.

And the one example is new or the alternative brominated flame retardant we sometimes call non-PBDE flame retardant.

By using the method we already have or validated, many many BFRs were resolved. For example, you know, the DBDP -- the decabromodiphenylethane, it's a very similar structure to the decaBDE and hexabromobenzene, you know, the alpha, beta-TBECH, and they were okay in terms of recoveries and the background-wise, but still, you know, we put these chemicals -- this method in some -- you know, the method validation category, because we need to test if our extraction method is sensitive enough to measure, you know, for two measures, you know, such as expected trace levels of these chemicals. So we are working on it.

Some other new BFRs are like the tetrabromobenzoate, phthalate, and the HBCD. They didn't give us a very good recovery from what we call the GC-MS method. So the they will be tested on this new LC triple quad system.

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DR. PARK: Also, we are planning to move the -- kind of change the method for our phenolic compound analysis to the LC method, because that way we can, you know, avoid some harmful derivatization process, which, you know, many of them -- none of our staffs want to do

that. And also we expecting, you know, some -- you know, serum samples for the analysis from the California study population soon.

So I'll be happy to take your questions or comments. Thank you very much.

CHAIRPERSON LUDERER: Thank you very much for that presentation. And, again, very impressive, all the progress has been made here on the laboratory side for both laboratories.

Do any of the Panel members have questions at this time?

Dr. Wilson.

PANEL MEMBER WILSON: Yeah, my question is about the question mark over the data from 1960 on the PFCs. It sounded like your concern was on the QA/QC that was conducted for those samples at the laboratory at the time. If that's -- and if that's so, what specific -- I'm just wondering if you could comment specifically what about their QA/QC methods are in question?

DR. PARK: No. No, the reason I mentioned our QA/QC procedure, I mean we went back to our -- all the QA/QC again, because the number was totally, you know, the unusual things based on, you know, the previous publications and our conversation with our colleagues.

So what else we did for that -- you know, the

high numbers, we originally analyzed -- we randomly selected from this 1960 cohort group about 20 samples. We initially analyzed this randomly selected 20 samples. Then what we had were these high numbers. So we checked all the QA/QC again including our laboratory background. We didn't see any problem.

In order to confirm these levels, we again randomly selected 20 more samples. We confirm the numbers real. Then we started talking with our -- you know, the researchers, you know, who knows some sample collection, you know, processes back in the 1950s. And also I started to talk with my colleague who was a PFC expert. You know, kind of there is still kind of controversial, you know, opinions. So some people -- it could be nothing or it could be really something.

So you put that number as true, but we are thinking of another grant proposal for this only.

So that's why -- we didn't doubt -- we didn't have any doubt about our QA/QC procedures. Again, as you see, you know, we thoroughly checked it. Even though we adapted the CDC method, we tried to do the many inter-laboratory comparisons with not only CDC; you know, Minnesota laboratory, State laboratory, also New York State laboratory, you know, as much resources we can use.

PANEL MEMBER WILSON: Can I follow up?

I just want to follow up, see if I understand that. You took a total of 40 samples from 1960 samples and reanalyzed them?

DR. PARK: Right. No, we initially analyzed 20 samples. Then we reselected another 20 samples.

PANEL MEMBER WILSON: Okay. And they came back fairly high. And those high levels are inconsistent with what you've been seeing from other laboratories and in discussions with colleagues for that period of time --

DR. PARK: No, no.

PANEL MEMBER WILSON: -- 1960s?

DR. PARK: As I emphasized before, the -- to my knowledge, there is no 1960s serum data for this PFC. What they published the -- if my memory's correct, they start like from 19 -- mid-1970s. So nobody traced back to the 1960s here. So this is very unique and a new result for us.

So, again, this could be something or it could be nothing.

PANEL MEMBER WILSON: I see. Okay.

CHAIRPERSON LUDERER: I just have a related question to that.

Among those 40 samples that you measured, what was the variability? Were there some that were very high that are driving this?

DR. PARK: You know, I give the median values -- you know, not the mean. But we expected a very large variation, but it wasn't. Actually it wasn't. You know, it's that error bars -- you know, the observed was kind of a -- not huge.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: Again, it's really -- these are informative presentations. And it's really fun to see. All the work that's going on are certainly interesting.

I wanted to bring up on the flame retardants, which I think is an important issue, I mean it's really rising to be more important, and people are very concerned about flame retardants. And then there's the likelihood that we're going to probably have even higher levels or more protection, more need for flame retardants. And so I think it's important we're looking at it.

But the interesting -- I think for us, you know, for all of us broadly, is community is -- it's hard to answer this question, because these are semi-volatile compounds but the market is very volatile - right? - it's moving around. And people are switching products, and it's really hard for us to predict.

So I guess the question is, how do we assure ourselves that we're looking for the right things?

Because, you know, one week you're hearing about organophosphates and then it's brominated compounds, then it's going to be this. And I think that's because there's a lot of uncertainty, so everybody's kind of posturing. One thing we know is that unless things change, you know, unless the furniture guidelines change, there's going to be a lot of some sort of flame retardant in products that are coming into our homes. So I think it's one of these things we have to look at.

So to get back to my question is, how do we really screen this to decide which chemicals to look at, you know, that are going to be in the marketplace when we're out there sampling?

DR. PARK: Well the -- you know, each -- almost be impossible. You know, you trace, you know, all the flame retardants or -- many other in the environment that are contaminants, you know. There are thousands, thousands of chemicals already, you know, probably out in the environment. Only thing, you know -- as an environmental chemist, it's kind of sometimes frustrating. We look -- I feel like we always kind of chasing, you know, whatever -- and whoever messed up the environment, we're kind of chasing always, you know, the -- you know, the production and the usage, it takes kind of a very short time. But, you know, chasing, you know, the --

whatever they -- you know, spread in the environment, it takes a long time.

Also, you know, it takes decades to prove that's really harmful also to give a negative effect to not only the ecology, also the public health. So it's kind of -- the kind of things I learned from the experience and the frustration.

So the only thing, you know, the best way we can approach is, you know, I think what our DTSC is doing, you know, some green chemistry initiatives, you know, to encourage the industry and the academy develop more of the eco-friendly, environmental friendly chemicals. So that's what we are going for.

But as for the environmental labs, you know, the -- that's why, you know, we'll be considering, you know, the next instrumentation will be like LC, time of flight, you know, we can screen the environmental samples, you know, so it will give us some information about some unknown compound. So, you know, instead of we keep, you know, chasing by using the target compound, I think that's kind of another approach from the environmental level to decide.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: I just have a general comment.

Just one thing interesting about this data, I think it really kind of just supports the rationale for a biomonitoring program, showing trends over time, and many of these trends are probably related to standards and use and regulations. And I just want to kind of comment on really the importance of this kind of information, both in understanding people's exposures and really understanding the value of this kind of program.

Thanks.

DR. PARK: Thank you.

CHAIRPERSON LUDERER: Dr. Denton.

OEHHA DIRECTOR DENTON: Just to follow up on that comment.

Will you and, Dr. She, will you have the kind of databases that will allow for future -- when you report future results of the biomonitoring, that you'll have data from 1960s and 1980s? Or is this just particular for, you know, the bioaccumulative compounds?

So do you have that kind of database that you'll be able to show this kind of information for the phthalates, for the metals, for the other chemicals that are going to be reported?

DR. PARK: I don't know about the other chemicals. But for the POPs, I just -- the present, not only the database we have, but also we tried to push

publications. So many other public, you know, know about our result. That's what our -- the Environmental Chemistry Laboratory is pursuing for.

That's what your question was?

OEHHA DIRECTOR DENTON: No, I was just wondering -- well, I was just curious, you know, for the future studies that you're going to be doing, measuring PBDEs and so forth, do you have the database, do you have the samples that you can compare the results that we'll be getting with data from 1960 or 1980?

DR. PARK: Yes, yes.

OEHHA DIRECTOR DENTON: Okay.

DR. PARK: Absolutely yes.

OEHHA DIRECTOR DENTON: Same with you, Dr. She?

DR. SHE: I guess you ask the archived samples, do we have archived samples to look back?

OEHHA DIRECTOR DENTON: Or a database that you can compare it with, of samples that you've measured before?

DR. SHE: I only can compare like a PBDE -- comment on a PBD. We did some earlier samples analysis. With the new ones we still don't have a database at least conducted by our labs. We did a lot of work on the PBDE with the ECL's lab.

And also I forgot to mention to Dr. Culver, when

you asked a question about publication, with older things we do publication in the EHPs, Environmental Science and Technology, we have many publications. We have a few publications in the field as highly cited papers. But with the new ones, come back to Dr. Denton's question, we don't have so many database at this moment.

DR. DAS: Rupa Das.

I just want to comment in response to your question, that the -- although there are samples that ECL may have to show these results in selected populations, in terms of a database that's comparable to the samples we're collecting now, they're not directly comparable. So the women in these studies were selected using different criteria. So we would have to go back and determine how comparable they are. So in general it's not the kind of database we're developing now. There are samples, and we can compare the samples, as has been done and presented to you. But those participants were selected using different criteria, so they may not be directly comparable.

CHAIRPERSON LUDERER: All right. Thanks, everyone. I think we do need to move on to our next topic now.

Thank you very much.

Sorry. Public comment.

Do we have just one?

We have ten minutes total for public comments.

Okay. So we have one actual -- a public comment that's on the previous presentation. So this one came in a little bit late to be read during the last comment period.

And this is from Sharyle Patton, Director of Health and the Environment Program for Commonweal. And she writes:

"Dear colleagues. The ongoing projects are truly impressive. Congratulations on your accomplishments. Establishing a baseline level of exposure for Californians is clearly important.

"However, the legislation calls for community monitoring as well. From the legislation, 'Additional community-based surveys shall be contingent on funding and shall be statistically valid and scientifically based.'

"Of course there are resource questions. But are there plans to continue doing biomonitoring at the community level? These kinds of studies are very important in identifying disproportionately exposed communities, whether these are demographic or non-demographic. California should remain a national leader for

community-based participatory research.

"Thank you for your response."

Dr. Das, would you like to comment on that?

DR. DAS: Rupa Das.

I've described the kinds of projects and studies that we plan on doing right now. Our Maternal-Infant Environmental Exposure Project is a type of community project. It's the community of mothers and infants. So I guess it depends on how we define "community". And as I described earlier, the Kaiser collaboration is sort of a represent -- is meant to be the proxy of a representative sample.

Beyond what I've described, we don't have current plans to go into the community and do sampling. But by doing these smaller targeted projects like the firefighter study, which is representative of a type of worker; mothers-infants study, representative of a type of population, we are approximating some estimate of a community-based study. And as resources become available, we'll plan to go out into the community and gather samples. And I really think the Kaiser collaboration comes the closest to that.

CHAIRPERSON LUDERER: Thank you very much.

Okay. I have one announcement, and then we do have one additional public comment.

The announcement is that apparently we were alerted that there was a mistake on the slides. And this was for the DTSC lab presentation. And the correct set of slides for this presentation will be posted soon, and we apologize for the error.

All right. Then we have a public comment from Deborah Whitman, President, Environment Voices.

Ms. Whitman.

MS. WHITMAN: Thank you again.

This is basically a question that I had. And, that is, Dr. She mentioned on slide 6 of his presentation that they were testing for some metals. The question I have is -- we understand that the U.S. Navy is conducting warfare testing and training programs in the Pacific Ocean. So they're doing programs in the ocean and over land in California, Oregon, and Washington. Some of the chemicals listed on their Environmental Impact Statement -- they're trying to expand their program actually. But they list aluminum, uranium -- there's just a huge list of all these chemicals.

We've been conducting our own tests. They're hair analysis tests. And we're finding in children specifically that the uranium is off the charts. On everything that we've tested we're finding off the charts, in sulfur, uranium, aluminum, lead; you name it, they are.

And so I was wondering, specifically are you doing any testing on aluminum, barium, uranium, and sulfur? And if not, I'd like to recommend that you consider those chemicals; and also to consider testing children, because we're finding the levels are higher in children as opposed to adults.

CHAIRPERSON LUDERER: Thank you for that comment.

Dr. She, would you like to respond to that?

DR. SHE: That's a good question.

Actually just like Sara pointed out, and the same as manganese, we did the uranium in the pilot test for this 500 CYGNET participate. We did a uranium 238.

But the other chemical -- elements you mentioned, we did not start. And depending on SGP's recommendation of the public interest, we may consider to do it in the future.

CHAIRPERSON LUDERER: All right. Thank you very much for the comments and also for the responses.

We're running just a little bit behind here. So we're going to move on to our next topic.

This is going to be a presentation of manganese as a potential designated chemical. And Sara Hoover, Chief of the Safer Alternatives Assessment and Biomonitoring Section, will be making this presentation.

(Thereupon an overhead presentation was

Presented as follows.)

MS. HOOVER: Good morning, Panel. Yeah, Sara Hoover, OEHHA. Sorry I didn't identify myself earlier about that comment on manganese.

So I'm going to be presenting some slides to you on manganese. Before I begin I just want to set the context of both the document and the talk. So just to remind you that the document is not intended to be a comprehensive review of manganese, by any means. It's actually a huge body of literature, so we tried to just provide you a sampling of information relevant to your consideration of it as a designated chemical.

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MS. HOOVER: And so the first slide I'll show you, just why are we even looking at manganese?

Manganese was suggested as a candidate in our surveys of State scientists and the public, which are posted on the biomonitoring website. The SGP has also expressed interest in manganese. And as Dr. She noted, laboratory capacity has been developed on a trial basis during a pilot project.

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MS. HOOVER: So to begin with, I just want to remind you about the criteria for a designated chemical.

So in deciding whether or not to add something to

the pool of designated chemicals, the Panel can consider exposure or potential exposure, known or suspected health effects, the need to assess efficacy of public health actions, availability of a biomonitoring analytical method, availability of adequate biospecimen samples, and incremental analytical cost.

And these criteria are not joined by "and".

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MS. HOOVER: So to begin with, just to say a little bit about manganese identity and uses.

It's an element and an essential nutrient.

In terms of uses, it has a wide variety of uses in industry, such as in metal alloys and in manufacturing of batteries. There are also fungicides that contain manganese. And in the past, it had been used as an additive in gasoline, a form of manganese.

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MS. HOOVER: In terms of exposure, basically the general population is pretty much primarily exposed to manganese via diet.

There are circumstances which indicate that environmental exposures, for example, via drinking water, can be significant. But I would say this hasn't been really well characterized as yet.

In terms of worker exposure, it has been shown

that they can get substantial exposures via inhalation, which can lead to health effects.

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MS. HOOVER: So this slide is just -- again, this is not a comprehensive review of California sources, but just some examples of sources.

So in terms of drinking water, CDPH actually summarized some exceedances of their notification level, which is 0.5 ppm for manganese, and that those -- actually exceedances occurred in 42 of 58 California counties. And this is data that spanned from 2001 to 2004 that they have posted on their website.

And the average of those reported exceedances was about 1 ppm, with a range of 0.5 to 35 ppm. This data, however, includes multiple sampling of the same wells and also includes inactive wells. But it just gives you a sense that it is occurring, these exceedances.

In terms of air, the Air Resources Board reported a statewide ambient level of approximately 24 nanogram per meter cubed. There were a couple sites measured in southern California that were shown to be higher in this MATES III study conducted by the South Coast Air District. But you'll see that even with those somewhat higher levels in those sites, compared to the workplace example, which is from the study of welders in San Francisco, it's quite

substantially higher in the welder exposure, up to milligram per meter cubed levels.

In terms of pesticide use, there are a couple manganese-containing pesticides that are in the top 100 pesticides used California:

Maneb - about 800,000 pounds applied in -- I believe this is 2008 data. And those were applied on lettuce, nuts, and other crops.

Mancozeb - 300,000 pounds. And that's applied on grapes, onions, tree fruits, and others.

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MS. HOOVER: So in terms of known or suspected health effects, Dr. Mari Golub actually reviewed and wrote the section on this. So I'm just going to briefly talk about it. If you have questions, she can respond to those.

Manganese is a neurotoxicant. It is an essential nutrient. So that's already established.

In terms of adverse health effects, it is a neurotoxicant in adults. It's been shown to induce manganism syndrome as well as motor and neurobehavioral effects. And there's an association with Parkinson's disease.

It's also -- there's also evidence that it is a developmental neurotoxicant; and there's been shown to

have effects on IQ and neurobehavior.

There's also an association of manganese levels with birth weight. And it can induce lung inflammation.

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MS. HOOVER: Now, this, again, it's not a comprehensive review of pharmacokinetics, but just a few points of interest, potentially of interest for biomonitoring.

So first, in general, manganese as an essential nutrient has generally homeostasis maintained in adults who are exposed to normal dietary levels. But you can see excessive exposures, as I've noted, via inhalation. And, in fact, manganese can be transported directly to the brain via the olfactory nerves.

There are some subpopulations that may be vulnerable to excessive exposure, such as neonates because of their less well developed biliary excretion and immature blood-brain barrier.

Iron-deficient individuals have been shown to have greater manganese absorption.

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MS. HOOVER: So, again, in the document, we gave you some samples of biomonitoring studies. There's actually more than what we even referenced in the document. So there's numerous studies that have looked at

manganese in various populations, including the general population, pregnant women and cord blood, infants and children, and workers.

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MS. HOOVER: And there's been a range of motivations for these studies, including an attempt to establish reference ranges. There was also some studies, particularly in Canada, studying the effect of the MMT use in gasoline. There have been a number of studies looking at worker exposures. And there have also been studies attempting to look at links between blood, urine, hair, or teeth levels and health effects.

So here I'm just going to give you some examples of some of the results.

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MS. HOOVER: So these are some examples of general population results. And I'm not really going to go over these. It's just to give you a sense of the range.

There's a Health Canada study in the general population compared to levels in Quebec, Germany, some information in children, Japan.

And then a little bit in the U.S. There was an earlier NHANES study looking at trace metals in urine. And a study in Maine of children which showed somewhat

higher levels.

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MS. HOOVER: So there's also been a number of studies looking at pregnant women and cord blood. And a number of studies have noted that pregnant women have elevated levels at term and that cord blood levels can be as high as double the levels in pregnant women. So this has been shown in studies in Oklahoma, Montreal, other study in Quebec, and in Paris.

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MS. HOOVER: In terms of laboratory methods: Manganese has been measured in blood, urine, hair, saliva, teeth, and nail clippings. And just -- as I mentioned, I just briefly touched on the fact that there have been some indications that it's been difficult to actually use levels in biological media to assess manganese exposure, for example, in workers.

So Cowan, et al., reviewed this issue, and they actually noticed that there was an effect on iron levels in workers exposed to manganese. So they looked at the blood manganese-iron ratio and they found that that's actually was appearing to be a more sensitive measure of exposure. And they specifically looked in erythrocytes and plasma, and they recommended looking further at this as a measure of -- a better measure of exposure for

manganese.

And actually Dr. -- I want to note Dr. Asa Bradman also has been looking at some of these issues, and he gave us a number of good references and background in helping us prepare for this.

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MS. HOOVER: In terms of laboratory methods within the biomonitoring program, EHL has been measuring manganese in whole blood on a trial basis, as I mentioned. This analysis actually can be bundled with other blood metals. And they're also looking at a method in urine, also on a trial basis.

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MS. HOOVER: In terms of the need to assess efficacy of public health action:

Manganese is an essential nutrient, but it's also a neurotoxicant.

It might be interesting to study the potential for excessive exposures, particularly in non-occupationally exposed populations.

It might be interesting to look at exposures that are particular to California.

And biomonitoring could help assess the extent and level of exposure in California and evaluate the need for further action.

So I'll start with any questions, which I may need to refer to my colleagues here.

CHAIRPERSON LUDERER: Thank you for that excellent overview of a very complicated topic.

Dr. Wilson and then Dr. Solomon.

PANEL MEMBER WILSON: Thank you.

Sara, I'm wondering both in your presentation and in the prepared materials if there are reference levels that are recommended nutritionally. And how does, for example, a finding of 24 micrograms per liter in blood in pregnant women compare to the nutritionally recommended levels?

MS. HOOVER: Well, I think I'm going to ask Mari to comment on this.

But the nutritionally recommended levels would be in food, right?

DR. GOLUB: It would be intake recommended levels.

MS. HOOVER: It would be intake recommended levels.

And, Mari, did you want to say anything about levels in pregnant women?

I mean, I guess I can say one thing, which is ATSDR gives what they call a normal range.

PANEL MEMBER WILSON: Right.

MS. HOOVER: But it's not clear -- they didn't actually report what that was based on. So that's why I didn't actually include that range. So it's not completely clear. But I'm going to let Mari say something about this.

DR. GOLUB: We all feel we'd like to spend several years looking into this. But as you look through the studies, the values in pregnant women are definitely elevated. There are studies showing increases during -- from the first, second, third trimester. And also there are many studies in different countries showing this same effect.

When you look at studies of neurotoxicity in worker populations, they do not include pregnant women. So the values in the populations that are often studied, excluding that group, are much more uniform.

We also know that they're very -- that the manganese levels are very elevated in the newborn, and that this gradually dissipates over maybe the first two years of life.

So when you actually look at the studies, the values fall out a little bit more clearly once you take these very clear and well studied population differences as regards to pregnant women and newborns into account.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Can you talk a little bit about the CDC's, you know, biomonitoring manganese that's not included in NHANES at this point. And I think that, you know, there have been some discussions within CDC about whether to include it. And I'm guessing that you've spoken with them and with their lab folks about their decision. So I'd just sort of like to hear what the outcome of some of those conversations may have been.

MS. HOOVER: I did not speak to CDC about that in particular. What I do know is that they -- they had that early study looking at trace metals in urine. They actually had manganese as a possible priority for inclusion in the reports, and then it didn't actually happen.

But I don't know if somebody at -- actually, Frank Barley, who developed the method, may have spoken with CDC lab, but I don't think Dr. -- I don't think Jianwen has.

DR. SHE: No.

MS. HOOVER: So I can't -- actually, we have a call into CDC to talk about a number of issues. And that's something that I could ask them about and get back to you on.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Two comments.

Thank you, Sara, for that good brief overview of a complicated subject.

You mentioned that some researchers have gone - and in your document also you explained - to looking at the ratio between manganese and iron because of some difficulties in interpreting results -- results of biological sampling; is that correct? I just wondered --

MS. HOOVER: Yeah.

PANEL MEMBER QUINT: -- if you could just mention what some of those difficulties are.

MS. HOOVER: Again, that's another body of literature. I think maybe Dr. Bradman could say more than I can on this. But I know that there have been issues, for example, in trying to -- like Cowan was trying to link the exposures they saw in the workplace to the levels they were seeing in workers. And they found that it was difficult to link measures of manganese in various media to the exposures they saw in the workplace. So they found that if they instead reported as a ratio to iron, they actually were able to more clearly show that association.

PANEL MEMBER QUINT: Okay. Thanks.

The other comment I have is, it sounds like most of the measurements in pregnant women have been -- I mean, in workers have not been in women, have been in men - or not pregnant women - is that correct? I think somebody

said that.

MS. HOOVER: Yeah, Dr. Golub was just saying that.

PANEL MEMBER QUINT: Okay. Dr. Golub said that.

I guess I'm concerned about potential exposures to pregnant women -- pregnant workers, because the standard -- the existing permissible exposure limit is very high. I mean, it's 200 micrograms per meter cubed --

MS. HOOVER: Yeah, I think that's --

PANEL MEMBER QUINT: -- yeah. And your chronic REL level is 90 nanograms per meter cubed, I think.

MS. HOOVER: Yeah, I think that's right.

PANEL MEMBER QUINT: So, you know, if -- and given that it seems for some reason pregnant women seem to -- you know, the levels seem to be higher, then I think that's very much a potential concern. So I want to make sure that we don't -- you know, when we look at excessive exposures, that -- and since inhalation, you know, is a route of exposure, that we keep the pregnant worker situation in mind, because, you know, this is -- and the permissible exposure limit is based on the threshold limit value from the American Conference of Governmental Industrial Hygienists, who admit that the level is probably not protective in their documentation.

So, as we talk about these concerns, particularly

the neurodevelopmental potential effects of manganese, then I think, you know, pregnant workers who may have that exposure, you know, this is potentially a hazard given the environmental -- you know, the regulation of the -- the amounts that they're legally allowed to be exposed. And I don't know how that relates to the biomonitoring data, but I think it's potentially of high concern. And I just want to put that somewhere in a public record.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: I just want to make a few comments, partly because this compound being here is based on a suggestion I made earlier.

We're planning to do a fair bit of work in manganese. And when this was originally brought up, we were just starting to learn about this. And we're planning a number of biomonitoring studies that will look at levels in a population of mostly low income Hispanic families in Monterey County, where about 3 or 350,000 pounds of the fungicides are used.

As I learn more about this, biomonitoring for manganese is challenging, because it's an essential nutrient and it's homeostatically regulated in the body. And I think that is -- that is a challenge and could affect interpretation -- well, certainly affects interpretation.

We're trying to look at levels in urine, in cord blood, in maternal blood. I should say maternal and child urine and breast milk; and also in different cross-sections of deciduous teeth in children, to try to get a sense of whether we can relate biological measures to the tooth levels, and the tooth levels may kind of represent a cumulative exposure, because manganese can substitute into the tooth minerals, and provide, you know, a marker of exposure in the same way lead, for example, has been measured in teeth.

So there's also evidence that hair may be a better measure of exposure, again for cumulative exposure.

So there's a lot of challenges here.

Based on the information on pesticide use in California, it does seem like that there is a lot of, you know, manganese fungicide use in California, about 21 percent molecular weight, for each of these compounds, which is a fairly high proportion. And I don't recall how that use compares to national levels, but I think it does make California unique. But we don't really know whether that use is actually exposing people and whether it's, you know, something that we can measure well. So I think that's a challenge here.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: I'm a little bit confused,

because we do -- it is a nutrient. But in the document it seems that there have been studies which show a link between environmental or general population exposures and neurotoxicity. So I'm wondering if, you know, in spite of the fact that it's a nutrient and there's homeostasis and all of that, it seems that in some situations people can be exposed to levels that correlate or - I'm asking a question - correlate well with toxic effects. I mean, are we -- is that a clear statement of -- it would be helpful, you know, in the document or somewhere to have some -- a summary showing levels and, you know, potential health effects, because I'm confused.

DR. GOLUB: We actually prepared a little slide on that --

PANEL MEMBER QUINT: Okay.

DR. GOLUB: -- in case that came up.

Yes, it is a nutrient, and there certainly are studies showing that lack of manganese has some effects. But manganese is an ultra-trace. There's only a few milligrams in the entire body. So it isn't that many people that come up short on manganese as a nutrient.

So this is a slide that we prepared to just try to line up some comparisons. And the only reason we selected these studies was because they gave us a chance to compare two groups. Many of the studies use very

complex models where they're looking -- they're doing regression analysis and they have controls, and you just don't get a two group comparison. So these are some studies that I selected.

The first two are occupational studies. And the first one in welders looked actually at visual evoked potentials and neurological exams. So I thought I'd include that, because it was somewhat more objective and more biomedically oriented.

And those populations, as you can see, there was about a doubling of the concentration in the affected group versus the control group.

And then the second one was alloy plant workers. Alloy plant workers are one of the most studied groups for the neurotoxic effects of manganese.

And in this case, they did a series of neurobehavioral tests, including things like steadiness and fine motor ability and so forth. And once again you see how elevated the levels were in the workers that showed the effects versus those that didn't.

Then moving on to a few of the neurodevelopmental ones. This recent article -- and I have to say in the past four weeks when we've been preparing for this meeting, every week we have a new study to look at. The work is coming out fast and furious on human populations

and manganese.

So in this particular study, that was a population selected for -- that were solicited for showing behavior problems in school or difficulties in school, nine-year olds. And they looked at -- and then they subsequently identified subpopulations that were diagnosed with ADHD. And this is the comparison of blood manganese -- these are all blood manganese levels -- in the children that were -- that subsequently were diagnosed with ADHD versus those that weren't. So here is a very small variation in the blood levels here.

Then the next study was a study of the Bayley scores in one-year olds. And at the same time that the test was given, blood manganese was sampled. It's comparing there the highest quintile with the three middle quintiles. So 20 to 28 is the three middle quintiles. Greater than 28 is the highest quintile. And they found lower Bayley scores in the children in the highest quintile. Interestingly, they also found lower Bayley scores in the children in the lowest quintile.

And then the final study is a study of intrauterine growth retardation. And in this case the blood sample, once more blood manganese levels, was in the cord blood. And the incidence of IUGR was the differentiating factor. And there was an elevated blood

manganese.

Note how much higher the newborn cord blood values are than the previous population values.

But there was an elevation in the newborns that were classified as IUGR.

So this is not exhaustive and it isn't really representative, but it does give you an idea of what those blood values look like, how much they deviate in affected populations versus nonaffected populations in these particular studies.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you for that clarification.

I think, you know, in reading the briefing document, there's no question that there's a fairly -- a substantial toxicity profile that can result from exposure to manganese. And I think, as you summarized in the paper, those included gonadotropic hormone effects, decreased birth weight, male reproductive effects, dysfunction, Parkinson's -- some association with Parkinson's, neurobehavioral developmental scores, and, as you said, IQ scores; and with fairly small margins of safety, it appears from what you're describing.

And so in reading the literature that you provided, I was, you know, frankly concerned that we --

there is evidence that we are, according I guess to the Air Resources Board data, directly dispersing about two million pounds of manganese into the environment, into California, and that maneb and the mancozeb are, as I remember from our earlier discussions, high volume pesticides in California. And I don't know what the trends are with those two pesticides, but -- I don't remember. I remember we looked at those specific substances.

But I guess my -- my point I guess is I'm -- in reading, you know, your briefing document and hearing the presentation, I'm concerned. And I think it's worthy of taking some action on, and that it meets -- that this meets essentially all of the criteria that Sara laid out early on.

So I guess my question there is, if we have a -- what is our charge here as a panel with regard to manganese?

CHAIRPERSON LUDERER: Sara, would you like to address that?

MS. HOOVER: Yeah. So first, just a reminder, we're going to have to do public comment. So we do have a public commenter that we want to hear from.

So, again, the only consideration before you today is whether or not you want to just add it to the

pool of designated chemicals. And so that would indicate, you know, that you do feel like it satisfies criteria. And you don't have to satisfy all the criteria, but it satisfies criteria for designation. And that would essentially give, you know, indication to the program that this is something you want us to continue to look into, and then possibly bring it back to you as a priority chemical in the future.

As I mentioned, right now it's just been done a little bit on a trial basis because of a request from a collaborator. But if you wanted us to go further, look more into it, bring it back to you, that would be -- this would be the first step in the chain. So today it would be a decision, if you want to, you could choose to recommend it to be a designated chemical for the program or you could ask us to bring you back more information. So it's really up to the Panel.

CHAIRPERSON LUDERER: All right. I think this would be a good time to do the public comment. And then we'll have more discussion from the Panel afterwards.

All right. It looks like we have two public comments. It looks like we have one from Dr. Jay Murray on behalf of the Manganese Interest Group.

So since we have two comments and ten minutes allotted, if the speakers would please hold their comments

to under five minutes each.

Thank you.

DR. MURRAY: Thank you. My name's Dr. Jay Murray. I am a toxicologist with a consulting practice in San Jose. And I'm here on behalf of the Manganese Interest Group.

You all received written comments very recently from the Manganese Interest Group. And I wanted to apologize for getting those to you at the last minute. We wanted to complement the background document, and that just was posted 12 days ago.

We also want to commend OEHHA and the Panel for what you're trying to accomplish in terms of improving scientific understanding of the public's exposure to environmental chemicals.

What I'm going to do is expand briefly on a few of the unique challenges that manganese poses, which Dr. Hoover alluded to, and give you some new information which I don't think you have.

You've heard from others that biomonitoring for manganese is not straightforward, it's complicated. You know that it's a nutrient. Dietary levels, by the way, are -- for the general population, are 2 to 3 milligrams manganese per day. It's in most fruits and vegetables, nuts. Vegetarians, for example, are up in the

neighborhood of 10 milligrams per day.

It's possible to have too much or too little, we certainly agree with that. And the dual characteristics here complicate biological monitoring for manganese because it's in the diet and because it's in all tissues.

Recently, there's some new information that I alluded to. These are pharmacokinetic and then physiologically-based pharmacokinetic studies that were conducted at the Hamner Institute by Mel Andersen, Harvey Clewell, Dave Dorman. And the results of that work -- I have a handout which I'll ask OEHHA to distribute on a break so that you have it. And it's a presentation on the results of the PBPK modeling and the human models. And OEHHA has kindly agreed to post it on their website.

This work, it includes the number of pharmacokinetic studies as well as the PBPK models. It allows you to predict what levels you'll find in blood and urine based on exposures by various routes at various levels.

We think the new data has utility because you can use the results to guide you in your decisions about biomonitoring and how best to accomplish that.

Dr. Bradman already mentioned the homeostatic aspects of this. The reason that's so important is that low and medium exposures to manganese -- the body has

homeostatic control mechanisms that keep blood levels within a certain range. Now, it's possible to overwhelm those homeostatic controls. And that's why you have individuals who have exhibited symptoms. But by and large, environmental exposures are going to be in a range which is much less than dietary exposure, and it's going to be very difficult to see any changes in blood levels due to those exposures.

The human PBPK modeling shows that dietary manganese variability is what really determines blood and brain tissue manganese levels. And according to those PBPK models, gender, old age, pregnancy, fetal development don't make those groups more susceptible to manganese tissue accumulation. What you really care about is manganese in the brain. And the higher levels in pregnant women and newborns, you know, we agree with that data, but I want to pose to you an alternative explanation. It's an essential nutrient. It's quite possible that those levels are elevated during pregnancy and in newborns for an important biological reason.

The other factor to take into account is that pregnant women I believe tend to eat healthier diets during pregnancy. So if you're increasing your intake of fruits and vegetables, you would expect manganese levels to increase.

Blood and urine, poor biomarkers, because manganese levels in blood varies throughout the day in the same person just due to differences in dietary intake.

And in worker studies it's been very difficult to identify workers exposed to manganese as opposed to the general public. And so it is not easy to use biomonitoring for manganese, even to distinguish the high exposures in an occupational setting.

You saw a slide that Dr. Hoover used for the welder study in San Francisco. If you look at the levels of exposure for the welders in that study, assuming 10 cubic meters in an eight-hour working day, the amount that those welders would have been exposed to assuming a hundred percent absorption is between 1 and roughly 4 1/2 milligrams per day. Now, contrast what to what I told you about diet, and you can understand why it's a challenge even in an occupational setting.

So just a few more things. I've highlighted some of the challenges and limitations of biomonitoring for manganese. You all are really in the best position to determine how manganese would fit into this program, how it stacks up against your other choices. And that's really your call. I just wanted to make sure that you had all the most current information. You'll see from the written comments and from the handout, it'll tell you

where to go to get this.

If you do decide to go forward with manganese, I urge you to make good use of the PBPK modeling and the pharmacokinetic studies that have been done at the Hamner Institute.

And, lastly, I encourage you to talk to the experts, the Mel Andersens, the Harvey Clewells, who are the people who created those PBPK models, and solicit their input in the design and interpretation of any biological monitoring studies that you decide to conduct on manganese.

Thank you.

CHAIRPERSON LUDERER: Thank you very much, Dr. Murray.

We have other public comment. This is from Deborah Whitman, President, Environmental Voices.

MS. WHITMAN: Thank you again.

First of all, I wanted to ask you to please wear my shoes. And I'm going to tell you a couple of stories.

And basically, from what I understand, that it's important to take blood tests when you're exposed to chemicals within, say, 24 hours when you're exposed. So I don't know if that's part of your studies or not, but I just wanted to share that.

The other thing is is that there's a word that

really has me upset. So if I get a little carried away, please forgive me. And that word was "pesticides".

The stories I'm going to tell you is recently we're doing studies on pesticides, because I've ended up in Emergency several times in the last few months, since March, being exposed to pesticides and herbicides.

I drove through King City and ended up in Emergency in Monterey, because the farmland -- I cannot drive through the farmland. I have to take Highway 1. And it just happened it was late at night and I couldn't drive Highway 1 that late at night. So I went through the farmland, ended up in Emergency. It's polluted all in that valley with those chemicals.

Two, they're spraying -- and we haven't determined yet because Yolo County Department of Ag threw away the sapling that I collected of what was sprayed over in the Yolo Causeway. It was either herbicide or pesticides. I ended up in Emergency trying to collect that sample. And I had on a mask that Kaiser gives me when I'm exposed to chemicals.

So I also set that chemical outside -- in plastic containers outside my door to take in to try to find a lab to study it. I had it there for three days and was still tasting whatever it was in my mouth and had the symptoms. I called poison control. They sent me to Emergency again

with poisoning. So they're toxic.

And if you're using this type of product in -- they're for pesticides and gasoline. I'm highly allergic to gasoline. I cannot use cooking stove or anything gas.

So what I'm trying to say is we're already living in a toxic world. It is horrible. This appears to me to be another chemical that you need to study. And I encourage you. I will volunteer, because I'll guaranty that there's no lab test or any types of equipment that will determine how toxic it is. I could probably tell you within 15 minutes if I went to an alloy plant whether it was toxic there or not. And I wouldn't charge you anything to volunteer. Of course I might end up six feet under, but, you know, it's worth it. We've just got to start studying these chemicals, and we have to see what it's doing to our children and our planet.

So I thank you very much.

Oh, and one other thing. I found out that they're using pesticides in the schools and they're spraying. And we're dealing with the Natomas School District, because that's where my grandchildren go. And their hair analyses are off the chart. My granddaughter at four years old had -- out of 21 chemicals tested, she had 12 of them off the chart, off the chart.

So we need to put a stop to these chemicals and

we need to continue the research that you're doing.

And I thank you again. And I encourage you to add this chemical to your list on your study.

CHAIRPERSON LUDERER: Thank you very much, Ms. Whitman, for those comments.

Sara, do you have a --

MS. HOOVER: Yeah, I just wanted to do a check with our transcriber if we should take the break. Are you okay to go a little longer?

Okay. So we're going to go a little bit of overtime, if you can wrap up your Panel discussion.

CHAIRPERSON LUDERER: Panel members?

I'm sorry. Comments or questions from the Panel?

Dr. Solomon.

PANEL MEMBER SOLOMON: I just have one more question for Sara Hoover, which is about MMT. It was mentioned in the briefing document the fact that this organomanganese compound isn't used in California gasoline. My recollection is that due to some NAFTA litigation, that it actually can be used nationally in the gasoline supply. But I'm not sure whether it is being. And, you know, this is just sort of a question about whether -- one of our informal criteria as a panel has been about sort of whether this might help us look at differences between California and the rest of the U.S.

And obviously we've looked at maneb and mancozeb as one difference. And MMT might be another.

MS. HOOVER: Yeah, I'd have to look that up for you. I mean my understanding is that it's not used in reformulated gasoline in the U.S. But I'd have to actually check on that fact and get back to you on that.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: I just have a quick question. Julia Quint.

We just got this handout on the PBPK modeling. And I'm wondering if OEHHA has had a chance to review this. I assume maybe not.

MS. HOOVER: No. But, again, I really want to emphasize that, you know, we don't need to review PBPK modeling in order to make a document on a designated chemical. I mean the pharmacokinetics, yes, are incredibly complicated. And so we didn't even attempt -- we did a very brief overview of pharmacokinetics. So we didn't actually even look for PBPK modeling.

So did you want to clarify your question?

PANEL MEMBER QUINT: Yeah, I want -- not the writing the document and for presenting it to us. I guess the question should be reframed. Do you intend to look at this as another piece of information?

MS. HOOVER: Well, I mean what I was trying to

indicate - and I completely support Dr. Murray's comments about the complexity of looking at manganese, and so does the lab - that if we go down this road certainly - and Dr. Bradman has commented on it as well - there's a lot of question about the best way to look at manganese. And so that would be a question that would be undertaken if the lab chose to pursue manganese. So that yeah, we would definitely look into that, particularly if the Panel -- again, this is just to put it in the pool of chemicals. And later we could bring it back as a possible consideration, and that could be part of what we look at is the complexity of the laboratory methods.

PANEL MEMBER QUINT: Okay. That's what I wanted to know. Thanks.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you.

I guess I have a process question to the Chair, maybe to the Panel: If we want to take some sort of action or continue the discussion now or if we're able to do that after the lunch? What's our -- what's our time frame?

MS. HOOVER: I mean I would suggest that you, if you can, you know, to try to wrap up your interim decision, which could either be, "Yes, go ahead and make it designated" because it meets the criteria, or "Please

bring it back to us at a future meeting." So I would encourage you to try to do that in the next like five to ten minutes maximum, because we really don't have spare time in the afternoon.

PANEL MEMBER WILSON: Okay.

CHAIRPERSON LUDERER: And I was actually going to ask if any of the Panel members have additional questions or comments, and also particularly if any of the Panel members would like to comment on that, whether they feel they would like to recommend designation or whether they feel that this is something that we should defer recommending designation or not.

PANEL MEMBER WILSON: Mike Wilson. You know, I appreciate the comments from Dr. Murray. And we also have evidence from the briefing document that there are -- well, we know there's a health-based notification level for California in drinking water of 0.5 milligrams per liter and that exceedances have been reported in 42 of California's 58 counties. We are seeing detections above the notification level in 5 percent of the State's drinking water systems. The Air Resources Board reports two million pounds emitted each year in the State. And we have about a million pounds of manganese-based pesticides dispersed each year in the State, at least according to the information we have here.

And we also have a fairly significant toxicity profile, particularly with respect to developmental neurotoxicity.

One of my concerns is that this is a -- particularly given the direct -- the potential direct exposure route from disbursement of maneb and mancozeb pesticides into agricultural areas, that this may have been a unique problem for California, as Dr. Solomon noted. And in my assessment of looking at the evidence here, it makes sense for us to move to designation. And I guess I would like to ask the Panel that we move in that direction.

CHAIRPERSON LUDERER: So Dr. Wilson would like to make a motion that the Panel designate manganese -- add manganese to the designated chemicals list.

Do any of the other Panel members have comments about that?

Dr. McKone.

PANEL MEMBER McKONE: Yeah, I tend to agree that there's a lot of information here that suggests moving forward. And I'm wondering -- the one thing though that bothers me in all of the discussions is that there's a lot of uncertainty about the blood level versus the exposure level. And I think that's going to be a real difficulty issue.

So I'm wondering if we could move forward with a recommendation to spend some more effort into that or to try to better understand. Because it's interesting that the nutrient guidelines are specified without understanding how those guidelines translate into a blood level, which is, you know -- and I mean for most nutrient substances we -- like salt we understand pretty well. But this one has these two complications, is, one, we don't know how the nutrient guideline translates into a blood level -- or apparently don't. I mean we haven't gotten good information on that.

And we don't know how the homeostatic mechanism really regulates, to what extent that kicks in. Obviously there's probably a range in which it controls, then becomes overwhelmed. But, again, that's left out.

So, again, these are -- I don't know if we can recommend to go forward but with the caveat that these are areas that should get some focus as we move ahead, or else the biomonitoring data will be difficult to interpret.

MS. HOOVER: Can I just say something about that?

Yeah, so you can certainly -- so as I said, if you just put it in the designated pool, you can ask us to do more research and then say whether or not you want us to bring it back as a potential priority chemical, and then we could look into more of these issues.

If you really want to defer, if you don't even feel comfortable designating, then, yeah, you could tell us, "Well, I want you to bring back this information."

So those are the two paths you could take. Either way we'd be happy to look into more information if -- however you do it.

PANEL MEMBER McKONE: Well, the motion is for designation.

MS. HOOVER: Yeah.

PANEL MEMBER McKONE: So all I'm saying is, yeah, designation with -- or we could add this request later. I -- okay.

MS. HOOVER: Yeah. I mean -- absolutely, yeah. Obviously, as I mentioned, it was just a brief overview, and we can delve into any particular issues that you'd like us to.

CHAIRPERSON LUDERER: Okay. I think Dr. Bradman and Dr. Solomon both had comments.

Dr. Bradman.

PANEL MEMBER BRADMAN: Thank you.

You know, I think I would -- I support Mike's comments and that it's worth designating this at the same time. And I appreciate the information submitted by the Manganese Interest Group and, you know, their point using this information and other information like it to help

design a biomonitoring program that would be interpretable, if that's a word, is key really to a future decision about whether this should be elevated from designated to priority. And, you know, it is a complicated scenario.

There's also, you know, questions about whether route-specific exposure is the key to some of these health effects, i.e., inhalation versus oral, and how do we interpret biomonitoring with respect to that. And given the widespread use of manganese in California, I think it does merit some attention. But we have to put in more thought ultimately about whether we can really interpret the laboratory data.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Yeah, I'm in agreement with both of my colleagues, that before considering elevating this to a priority, I think there would need to be a fair amount more work done, but that this, you know, does appear to meet the basic criteria for designated chemical.

I believe it's John Osterloh at CDC who has been the person working on manganese there. And we saw a couple of -- a few patients at UCSF in the Pediatric Environmental Health Specialty Unit, children with incidental elevated manganese levels who also happen to

live downwind of a steel-casting facility. And so we were investigating in that context the utility of blood manganese monitoring and encountered many of these questions and issues about the interpretability of the data. And certainly it was enough to give me some, you know, pause about, you know, how we would interpret results if we rolled this out as a part of the program. And I think that's part of what has caused CDC to go slowly on this too.

But it's certainly, you know, a chemical with significant toxicity in certain contexts and is one where there is a significant reason to look at it in the California context as we've discussed, and so I think that the pros outweigh the cons.

CHAIRPERSON LUDERER: Okay. So I think we have heard from the Panel that they are in favor of going ahead with voting now as a Panel for designating manganese. We've also heard that many of the Panel members expressed that there would be further research and information that would have to be brought to the Panel before we would feel comfortable recommending that it be moved to the priority list.

I just wanted to add actually one other issue related to that, which is the route-specific exposures that Dr. Bradman mentioned - and that I think would be

something that the Panel would like to hear more about as well - is the olfactory nerve uptake. Because that's a route of exposure to airborne manganese that would probably not be reflected in the blood levels, possibly not be reflected in blood or urine monitoring, and something that we might want to investigate further.

Okay. So I think we've said what the motion is. Do I need to state it again?

All right. So why don't we start on the end with Dr. Wilson. Would you like to vote on the motion, and then we'll move down.

PANEL MEMBER WILSON: So we're --

CHAIRPERSON LUDERER: The motion is to designate manganese, move it to the designated chemicals list.

PANEL MEMBER WILSON: Do we need a second?

CHAIRPERSON LUDERER: Sorry?

PANEL MEMBER WILSON: My apologies.

Do we need a second?

PANEL MEMBER BRADMAN: I second that.

CHAIRPERSON LUDERER: All right.

PANEL MEMBER WILSON: Aye. Mike Wilson.

PANEL MEMBER SOLOMON: Gina Solomon. Aye.

PANEL MEMBER McKONE: Tom McKone. Aye.

PANEL MEMBER QUINT: Julia Quint. Aye.

CHAIRPERSON LUDERER: Ulricke Luderer. Aye.

PANEL MEMBER BRADMAN: Asa Bradman. Aye.

PANEL MEMBER CULVER: Dwight Culver. Aye.

CHAIRPERSON LUDERER: The Panel has voted unanimously in favor of designating manganese.

And with that, we're, let's see, just a little bit behind the schedule. We had scheduled an hour for lunch. Should we try to make that a little bit shorter and get back on schedule?

MS. HOOVER: I just want to check with the transcriber. Are you okay coming back in 45 minutes, 1:30?

Okay. So let's try for -- back on schedule at 1:30.

CHAIRPERSON LUDERER: Okay. So we can meet at 1:30.

(Thereupon a lunch break was taken.)

AFTERNOON SESSION

CHAIRPERSON LUDERER: All right. I'd like to call the meeting back to order. Welcome, everyone, back from lunch for this afternoon's presentations and discussions.

The first presentation is going to be from Amy Dunn, Research Scientist III at OEHHA, who will present the draft Public Involvement Plan.

Amy.

(Thereupon an overhead presentation was Presented as follows.)

MS. DUNN: Good afternoon. I'm here today to go over the Public Involvement Plan.

And although I'm the one who's presenting the draft for public review and comment, I want to emphasize that this is work that's been done collaboratively with the Department of Public Health.

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MS. DUNN: These are the items that I'm going to be covering today:

I'm going to go through the key elements of our approach which we talked about in somewhat more detail at your last meeting when we talked about the overview. Just to remind you, I'll go through some of those items.

And then I'm going to focus in on the objectives

for each of the goals for the plan and some activities that illustrate what we mean by those objectives.

And then I'll show you the time line for finalizing the plan and describe some outreach we're planning for this fall to encourage comments on the plan.

And then there'll be time for discussion.

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MS. DUNN: So as we discussed last time, the approach that we're taking is guided by principles of Environmental Justice from CalEPA's Environmental Justice Strategy and Action Plan. And primarily our focus is to try to make sure that our efforts provide opportunities for all different types of members of the public to participate in our program and to be sensitive to the needs of different constituencies, and also drawing from public engagement principles to make our processes open, transparent, and accessible.

The goals for our activities have been drawn from the enabling legislation, Senate Bill 1379. And the specific objectives for each of those goals have been designed to help us achieve the goals. But in some cases, they're really just the beginning steps, and that we anticipate as the program evolves that these objectives will also change over time.

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MS. DUNN: This is a diagram that you saw last time. And as I mentioned, the legislation has given a direction to the development of our goals. And these form the basis for the objectives and activities that we are planning to carry out.

And underlying all of our activities are the core principles that I just mentioned.

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MS. DUNN: The four goals that we went through last time have changed slightly since your last meeting.

Goals 2 and 3 remain the same. But Goal 1, build public awareness and understanding of the program, is really just a little more concise way of saying what we had as our goal previously.

The second goal, as I said, and the third remain the same.

And the fourth goal has actually been broadened. Whereas before it was related solely to communicating individual results, we've broadened it to include both individual and more general population communication of our findings. And I'll go through those in more detail in a moment.

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MS. DUNN: So with regard to Goal 1, building public awareness and understanding of the program, the

first objective is to identify the needs of those who are interested in our program and actually to increase interest in our program. And one of things that we're doing to try to move forward in that is a needs assessment. So we're going to be carrying out a series of online surveys to try to get feedback from the people who are already aware of our program as far as what kinds of information they would like us to be providing and how they prefer to have that information communicated.

With regard to the second objective, maintaining and expanding our electronic communications, really our primary avenue right now is electronic. The webcast of these meetings, the website, and our Email listserv, those are the main ways that we are reached and reachable.

And one of the things that we are planning in the near future -- well, we're actually already started on, is improving the website, as Dr. Das mentioned earlier, to try to make it more user friendly and make the information that's there more easily accessible.

A third objective under this goal is to develop more informational materials with a focus on making information easy to read and culturally appropriate, such as the basic program brochure that we're developing.

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MS. DUNN: With regard to Goal 2, providing

opportunities for stakeholders to contribute to the program's design, implementation, and evaluation, one of the first steps in trying to achieve that goal is to build up the list of people who are aware of the program and to get more people involved. And one of the ways that we're -- we anticipate doing that is by reaching out to a variety of groups and encouraging people to join our listserv, since that's the way that we are able to -- with a low cost reach a large number of people.

A second objective is to find effective ways for engaging with stakeholders. The webcast is one way that we're doing that. But we're looking for other avenues. And one plan that we have is to create an online comment form that people who visit our website could give us feedback with regard to the kinds of information that they've found there or what they would like to find and can't find, or it isn't there and, you know, they'd like to see us develop it.

So we're hoping that that is going to bring in some more feedback on how we're doing.

And then a third objective is to begin to build community capacity. We're directed in the legislation to try to assist those who are interested in getting involved in the program by doing capacity building. But with our limited resources, it's a little challenging to find ways

to do that. So one of the first steps that we have in mind to carry out is to interview those who have experience with community capacity building on this kind of statewide scale and see if we can find ways that we can do that with the resources we have available to us.

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MS. DUNN: With regard to the third goal, achieving high participation rates in the target populations to be sampled, the first objective is to develop a recruitment strategy that's appropriate to the population. And an example of one of the kinds of things that we're doing is partnering with those who are trusted by the community. For example, in the Chemicals in Our Bodies project we're collaborating with the prenatal clinicians who, you know, see the women and are helping us to recruit.

With regard to the second objective, preparing suitable program materials, one of the efforts that we have underway, which you've heard about already, is field testing of the materials that we're producing to make sure that they work with the population that we're trying to reach.

And the third objective that we have as a starting point is to be sure to create and maintain points of contact that work for the population so that they have

easy access to information and staff as needed. And again, for the Chemicals in Our Bodies project, we have a toll-free phone number.

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MS. DUNN: The fourth goal, communicating biomonitoring results in an understandable manner, as I said, has expanded somewhat. We're still focused primarily on developing and testing methods for communicating results to participants. As you've heard in various presentations over the last several meetings, there's efforts underway in the pilot projects to assess the effectiveness of various approaches for communicating to individuals.

Drawing from those tests we'll be developing a best practices framework, which will also be informed by the research methods -- by the research that we're carrying out on methods that others have used successfully to communicate with participants, and also methods that have been used successfully to communicate results of biomonitoring studies more broadly to those who may not have actually been biomonitored but who are interested in the findings.

And we'll be interviewing others who have conducted those kinds of studies to try to get their thoughts on that.

And then, finally, we're working on developing an approach to identify and/or develop comparison values that can be useful in understanding the results that are found. And Sara will be talking more about that in the next presentation on biomonitoring reference levels.

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MS. DUNN: This is an updated time line from the one you saw at the last meeting, where we discussed the plan overview as shown on the left-hand side of the slide.

In September we released the draft plan and posted it on our website when we mailed links to the listserv.

And we're here in the center of the diagram right now, and hope to have some discussion at today's meeting.

And then in the next two months we'll be carrying out some efforts to try to encourage public comment on the plan that we've released in draft form.

And then we'll incorporate the input that we receive from the public and from the Panel and finalize the plan and post it on the website early next year.

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MS. DUNN: So what we have in store in the next couple of months is an online survey that will be, we hope, a quick and easy way for people to give us feedback on specific sections of the plan and provide feedback and

ideas about directions we should be looking at or where we're doing a good job and where we might be off base.

We also plan to hold public teleconferences, which are an opportunity for dialogue between staff and members of the public who are interested in our public involvement efforts.

In addition, at any time comments can be sent via Email to biomonitoring@oehha.ca.gov. And we have already begun to receive comments in that manner on the plan.

The deadline for public comment on the draft plan is December 15th of this year.

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MS. DUNN: I'd like to stop here and take any questions that you might have on the Public Involvement Plan.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you very much, Amy.

And I'm just -- I have a question about -- in general, but then maybe specifically with regard to the public teleconferences. If there is a media strategy or some, you know, thinking within the -- within OEHHA on how to reach sort of the key media outlets as a way to amplify the message?

MS. DUNN: Well, we haven't actually developed any kind of a media strategy. It's a little bit tricky to

have a -- have something that's newsworthy about the plan. But I'd be -- really welcome any suggestions you have about that.

PANEL MEMBER WILSON: Okay. Thanks.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Hi. Julia Quint.

I was wondering -- and I understand the reason for doing most of this online, because no resources to do a lot of the other methods if they're labor intensive.

I guess what I worry a little bit about, and I'm sure you have as well, is that some of the people we're trying to reach in terms of, you know, promoting understanding of the program are likely to be ones that, you know, don't -- may not have access to computers or don't check online to see what's going on.

So I'm wondering if you've thought about other methods like making use of some of the Panel members maybe to maybe do some outreach to key groups that might have access to community members to sort of help in promoting understanding of the program? I mean sometimes, you know, hearing from somebody in person about something through a group that they -- who's also working in the community and doing other work might be another way to promote understanding of what this is about.

And, you know, I know some labor groups who had

some reservations about biomonitoring. And I just would like us to think or maybe help you think more about how to increase outreach to some of the groups that aren't usually represented either in public comments or don't come anymore.

In the beginning we had much more interest in this subject. And that interest -- you know, as monitored by the people who come to make -- to the meetings, it seems to have fallen off sharply. So it would be good to think of ways other than the ones that are more -- you know, the most practical. And I would, you know, like to help you do that if you're interested.

MS. DUNN: I appreciate those suggestions. And we would -- we were hoping that the teleconferences would provide a venue for some people who might not be online. But they need to know about the teleconferences to be able to participate in them.

So I think the idea of doing outreach beyond what we're already doing to try to give people who aren't already plugged in a chance to join up in that way is at least one thing that we could potentially do.

We did -- as you're aware, earlier in the program, we did some workshops around the State. You know, we tried to do in-person outreach. And that ended up being really resource intensive for us. And so I think

we're -- we're trying to find something that is -- that meets the needs that we can meet with the resources that we have. So if you have, you know, people that we could reach out to, I'd really appreciate that. Anyone on the Panel and anyone listening or in the audience, if you have suggestions of people that we should be in contact with, I'd really appreciate getting those contact information.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Just along those lines, I mean we have -- fairly often we have inquiries from journalists, both here in California and across the country, that are interested in -- you know, who are interested in all kinds of aspects of chemicals policy, biomonitoring issues, green chemistry, this arena.

And so if we knew that OEHHA was prepared to field those calls and could -- you know, could respond to the journalists and provide the information and take interviews and so forth, we would be happy to direct them to you.

MS. DUNN: Well, we do get inquiries from journalists through the biomonitoring Email. So we have -- and we could continue. So that's a good way. You can always send them to bimonitoring@oehha.ca.gov, and then the appropriate person gets back to them. So we have done that, and we would certainly do that in the future.

And I wanted to also mention in relation to the point you raised earlier, that there are journalists who are part of our listserv. So there are some people who are keeping track of what we're doing.

CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: It seems to me that there may be a subset to this Public Involvement Plan. At the time when the cohort that is defined that is to statistically represent the State of California, at that time you will go out and start recruiting to that cohort. And you need to have a plan for how you're going to approach the public with regard to that specific activity.

Has there been a thought along those lines?

MS. DUNN: Yes. In fact, when we originally developed the plan a couple of years ago, that was our focus. But since the program has evolved a little bit, backing off on that because of our resource constraints, the plan has shifted to focus on what we're currently doing, which is these smaller pilot efforts. But we are trying with the resources that we do have to create a kind of a foundation that will enable us when we have the resources to do the statewide effort to have already tested out methods that work for recruiting people and for communicating with the public and, you know, having developed materials that the general public can, you know,

understand. And so we're trying to do the groundwork to be ready for that effort.

But the current plan, I think you're correct in saying that it doesn't really reflect that activity. But that's because we're not currently engaged in it.

PANEL MEMBER CULVER: I realize there's more of an immediate focus on the sort of subroutines that you are approaching now. But I hope we're not backing off on the original purpose of the program. We may have to take a longer view of it, but it still should be out there centrally in front of us, I would think.

MS. DUNN: Well, I think -- when I said backing off, I really just meant with regard to the public involvement efforts. So before when we originally developed the public involvement plan, we had a statewide focus, because that's what we expected to be doing right away. And so with regard to the public involvement activities, we don't really have the same kind of statewide focus since the sampling efforts aren't currently statewide.

So I didn't mean to speak for other aspects of the program, just the public involvement efforts.

PANEL MEMBER CULVER: While we're doing these other things, I still think we need to maintain that statewide focus. Otherwise we're just spinning our

wheels.

Sorry to speak so plain about it.

MS. DUNN: Yeah, I mean -- you know, honestly, we're -- we're fairly limited --

PANEL MEMBER CULVER: There's no point to biomonitoring if it isn't going to represent a population. This is not just a service to individual groups that are doing individual research.

The focus I think has to still be that statewide focus and never forget it, I think.

MS. DUNN: Well, and I -- I don't know if I was clear when I said before, but the things that we're doing within public involvement activities we really intend to be creating a kind of a basis for the statewide effort when it comes into play that we will already have developed certain mechanisms and certain materials, you know, informational materials. And, you know, we've been building the listserv and we're trying to build the listserv even more. And certainly that effort is a statewide effort. The listserv effort is -- well, it's actually -- you know, nationally, there's people beyond the state level who are part of the listserv.

PANEL MEMBER CULVER: Okay. Thank you.

CHAIRPERSON LUDERER: Should we take public comment at this point, and then we'll have some more Panel

discussion?

So we have 15 minutes allocated for public comment.

Do we have two?

CHAIRPERSON LUDERER: All right. I believe this is Deborah Whitman.

MS. WHITMAN: Deborah Whitman.

CHAIRPERSON LUDERER: Yes, Environmental Voices.

MS. WHITMAN: Well, this is your lucky day. That's all I can say. And when you get to know me a little bit better, you'll understand why I made that comment. The reason is I'm not only President of Environmental Voices and suffer from multiple chemical sensitivities for my entire life. I'm also a community producer with Davis Media Access Cable Television. In Davis, we have a radio station that's open to the public. In Sacramento they have Access Sacramento. There's access TV stations all over the U.S. and primarily in California though.

And this is something that I've been wanting to do for years, is to try to get some -- they're looking for programming and good quality programming. And I've been trying to get programs like this. You could put your board meetings on there. You could -- I could help you produce public service announcements. You could have

interviews. We have a studio at both locations where you can do interviews. The whole thing's free and it's open to the public.

So I encourage you to look into that. I'd be able to hook you up with the directors of both of those facilities and try to get some programming and things on that.

And there's also people looking for doing interviewing. So maybe get a group of your staff or something and set up an interview. And it goes on to cable TV in Sacramento and Davis. And I'm sure there's other -- there's up in Redding -- there's an access station up in Redding. So they're all over California. So I encourage you to do that.

Thank you.

Oh, and one other thing. There's a lot of groups with chronic fatigue, fibromyalgia, multiple chemical sensitivities. My research indicates that chemical exposures is the cause for all of these. It starts off with chronic fatigue. As you get more exposed, it turns into fibromyalgia. And as you get more exposed, it turns into multiple chemical sensitivities.

So I encourage you to contact those support groups - and I can also hook you up with some of those - to be part of your study.

And, anyway, I thank you very much again for the work you're doing.

CHAIRPERSON LUDERER: Thank you very much for your suggestions and comments.

And our next public commenter is -- is it Diane Brown --

MS. BROWNSEY: No, it's Donna.

CHAIRPERSON LUDERER: -- Donna Brownsey from the Breast Cancer Fund.

Sorry about that.

MS. BROWNSEY: No worries, no worries.

Good afternoon, members of the Science Guidance Panel. My name is Donna Brownsey, and I'm here representing my client, the Breast Cancer Fund.

I think most of you know that the Breast Cancer Fund was one of the sponsors of the authorizing legislation that established this program. And they've asked me to comment on the public participation plan this afternoon. But I just want to deviate for one second and just talk about how exciting it was to listen to the report on the lab efforts and all of the developments there. That's really -- for all of us who worked on this program many years ago, to see it in that stage of really implementation is very exciting. And I just wanted to share that with you. And also compliment you and express

our deepest gratitude for your service in making this program a success by bringing your expertise and also your commitment to these meetings and to the day in and day out of ensuring that this Biomonitoring Program will be a benefit to the people who live in the State of California. And I wanted to thank you for that.

The Breast Cancer Fund asked me to say that we sincerely appreciate the hard work that has clearly gone into the drafting of this Public Participation Plan. As you know, the authorizing statute for the program required public participation was based on a community-based participatory scientific model for conducting research.

This legislation was unique in that it mandated that the inclusion of biomonitoring subjects in the research and study design. We are pleased to see that the program has taken these matters seriously and is making every effort to include the public in what can sometimes be an esoteric process.

We especially appreciate the office's willingness to hire members of the community to conduct interviews and to help recruit participants.

Using and compensating the expertise of a particular community will be essential in assuring that the community needs are met while also meeting the scientific needs of the program. We are encouraged that

the program understands the importance of involving community members at the outset. And this will ensure the participation isn't just an afterthought and will be a key to gaining the trust of study subjects.

Lastly, we appreciate the diligence the office and the entire program has taken to ensure that results are communicated in a responsible manner. We look forward to our continued work with the program to ensure that the best strategies to communicate results to participants, and eagerly await the results from the four pilot studies discussed in this document.

We believe that testing these protocols among the different audiences and developing best practice guidelines is the best approach, and we appreciate the thoughtfulness with which this approach was developed.

We sincerely thank the program employees and look forward to exploring with you how to best maximize the public participation in the program. And I'm sure that they have extended the Breast Cancer Fund's considerable networking and contacts to help the program do outreach. Of all my clients, I am always so impressed by the Breast Cancer Fund's innovativeness and creativity in terms of, for such a small amount of resources, really because of their creativity and their commitment, their reach goes very far indeed in terms of networking with other

organizations who share the concerns about the exposure to toxic chemicals as well as to numerous health-focused and worker-focused groups. And so I know that they would share their contacts and their ability to network with the Department and with the program.

Thank you very much.

CHAIRPERSON LUDERER: Thank you very much, both of the public commenters.

Do we have any additional comments?

Okay, great.

Okay. Then we'll turn it back to the Panel for additional discussion.

No. Okay.

Did you have another slide to continue the presentation at this time?

MS. DUNN: I did have one additional slide.

And the question that I was hoping you might give us some thoughts on is -- well, there's a few questions up there. But I think we're trying to catch up on time, am I right?

MS. HOOVER: We're okay.

MS. DUNN: We're okay? Okay.

So the first question is, really I posed it during the presentation how do engage the public for feedback on the plan, and I think we've had some ideas on

that and I'd welcome more ideas. I think I'd like to just focus in on the second question.

As I mentioned earlier, you know, we did some outreach previously with regard to selecting chemicals for the program. And that did bring in both a lot of interest and a lot of really good ideas that we've been drawing from as we've moved forward with regard to chemical selection.

There are so many other areas that the program is working on right now. And because we have limited resources, I was wondering if you had suggestions about specific areas of the program where we might try to focus in on developing materials, doing outreach, trying to get members of the public up to speed and involved in what the program is doing in a particular area. I mean of course we'd like to do it on all program areas. But if we had to just focus on one particular area, what do you think would be of most interest to people or what would be most helpful to the program? If you have any insight on those questions.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: We're sort of like in this state of stupor after lunch. So could you --

(Laughter.)

PANEL MEMBER QUINT: -- just give us some

examples of the areas that you -- the program areas that you want us to sort of give you some feedback on.

MS. DUNN: Well, so, for example, we're engaged in some of these pilot studies, and we are -- you know, there is outreach that's happening in the communities themselves. But, for example, should we be focused on how people in a broader community would be interested in hearing about those findings, like focusing on results of communication? Or another possibility would be focus -- getting the public involved in how we choose the next set of pilot studies or, you know, giving us input on to what kind of occupational groups we should look at if we were going to do another occupational study.

Study design questions. That would be another type of area.

We could also continue to do chemical selection outreach, would be another kind of area.

PANEL MEMBER QUINT: I'll just throw out something, it's -- I mean one of the things I think it's -- there's so many -- a lot of initiatives going on in California right now. I mean all good, you know. But I think we now have the safer alternatives regulation that's out or green chemistry regulation that's being vetted. I guess the comment period ended yesterday.

I think in some ways it would be good to sort of

connect issues for people a bit. You know, on the one hand, some of the things that might be interesting to look -- to find out are chemicals that the public who has chosen -- who are engaged in commenting and attending and participating in the green, the safer alternatives initiative, you know, are there parallels to -- I mean there are parallels to the biomonitoring efforts.

So to somehow, you know, try to make some bridges with other chemicals policies, initiatives that are going on in the State. Because, you know, some of the -- it's a lot for a person and groups to keep up with. So some of the groups that are engaged in that effort may not necessarily have the resources or they don't remain engaged in this effort.

And to the extent that we can, you know, show the connections between, if there are -- to the extent that there are connections - and I think there are - between these efforts, I think it would be useful. And I really do believe that, you know, like the Breast Cancer Fund and other groups who are really good at engaging people in their industry groups who do this as well, I think working through groups just publicizing what the program is doing, what it has done -- I mean we were all so impressed with the progress that has been made in terms of the development of the methodologies in the laboratories. It

would be wonderful if more people shared, knew about what has happened since this legislation was passed and since this program started. And I'm not sure a lot of people do, because they don't tune in -- you know, they aren't necessarily on the webcast and people have too many things to keep up with.

So that would be one thing, just reaching out about the capability of --

MS. DUNN: Those are very helpful.

PANEL MEMBER QUINT: -- what we've developed so far would be great.

MS. DUNN: Those are very helpful. Thank you so much.

PANEL MEMBER BRADMAN: I have just a brief comment. And this I guess spills over a little bit into question 3.

You know, I think we're about to embark on a discussion with the bio-equivalents that we'll be talking about in the next presentation and then also in March. Now, I think that's going to be one of the most crucial pieces of the Biomonitoring Program in terms of setting a framework for how to interpret the results and health context. And I think it's going to be crucial to get input from, you know, all the groups that have previously been in touch with the program, but also to disseminate

widely and make sure you get input from, you know, those concerned about these issues from outside that. So I think that's going to be a really crucial and important piece of this program. And I can't overstate how important I think this in the next few discussions are going to be.

So as much input as you can get on that, I would make sure that those debates and questions about how to use the information is -- you get wide input on that.

MS. DUNN: Great. Thank you very much.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: I'll just be brief.

I just want to add to that. I think it's absolutely crucial. And I think this is an opportunity to sort of gain, you know, outreach to the medical community, people who will be in the position of talking to patients and others about results of biomonitoring. I mean some of the same groups that you have in your plan to do outreach to for various projects I think would also be good to start that outreach now, because a lot of the folks who are -- will be in the position of explaining what, you know, these results mean should be engaged early in these discussions of the reference values. And some of them are doing it already for various limited amounts of substances.

But I agree with Dr. Bradman, that this is probably one of the most crucial phases of the program.

PANEL MEMBER BRADMAN: Just to give a concrete example of that. Last week I was at the Academy of Breast Feeding Medicine. They had their meeting in San Francisco. And, you know, they were very interested in these issues. And they have their patients come to them, some of whom understand -- have understood publications, for example, about contamination as a message not to breast feed.

And I think that's the kind of communication that needs to be considered when you're talking about these, is to talk about -- get input on how to communicate messages that don't overstate or understate what -- the information that is found, and also make sure that things that we know are healthy, you know, like breast feeding, is not discouraged. That these are not necessarily health studies.

And there's information about exposure being garnered here. And there's probably going to be some sort of risk assessment. But that people should, you know, not mistakenly change, you know, some behaviors that we know are good.

So I -- and there's lots of groups out there. There's, you know, a lot of medical groups, nurses

associations -- a lot of people out there will be hearing about this information when the reports start coming out.

MS. DUNN: Great. Thank you very much.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Yeah, thank you.

I am reiterating to some extent both Dr. Quint and Dr. Bradman's comments. And, you know, from our experience in speaking with, you know, professional associations and occupational groups and students and so forth, the matter of chemical pollutants and industrial chemicals in umbilical cord blood and breast milk continues to be universally alarming, if at risk of overstating it.

But across these different sort of demographics and different demographic groups, if you will, including most recently training that we did at the Mandela Center in Oakland for entry level workers coming out of the prison system and getting into building trades and, you know, learning health and safety in the building trades. And we engaged with that group in a discussion of sustainability, global regeneration of ecosystems and Environmental Justice and so forth. And this issue was of great concern to that group of people, of what's happening in the next generation.

And so my sense is that as this

information -- as, for example, the study that we're doing with UCSF, as the results of that study become -- you know, they're appropriate for release to the public, it's going to be extremely important that OEHHA have the message properly framed. I think, as -- you know, as Dr. Bradman is describing how it's important that we take initiative and then be proactive in that, and not a reactive mode that can create these kinds of distorted messages or that can result in distorted messages.

And also I think, you know, particularly as we're seeing with the political changes and so forth over this next year, that it will be important, as Dr. Quint has suggested, and I just want to reiterate that, that the State of California is trying to do something on this question of -- in addition to monitoring what's going on, the State is really struggling with trying to identify and prioritize chemicals of concern. And making the linkage to those efforts I think is important and useful.

MS. DUNN: Great. Thank you very much.

CHAIRPERSON LUDERER: Okay. Did the Panel address the questions that you had and --

MS. DUNN: I really feel so grateful for all these great ideas. And I think we can really move forward with your suggestions. So thanks very much.

CHAIRPERSON LUDERER: All right. Well, thank

you.

All right. So as Amy already mentioned, the next item on our agenda is an introductory discussion on the biomonitoring reference levels. And Sara Hoover is going to present that for us.

(Thereupon an overhead presentation was Presented as follows.)

MS. HOOVER: Okay. So we're just starting this discussion. We've talked a little bit about this issue before. But we wanted to set aside some time on the agenda to start to get the SGP's input on this topic and also to help plan the workshop for March.

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MS. HOOVER: So in this brief agenda item, what I want to do is just say:

What do we mean when we say biomonitoring reference levels? It's just a general term we're using for now. And give examples of what we mean.

Briefly preview the March workshop.

And get initial SGP input.

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MS. HOOVER: So first just the Biomonitoring California context. As everyone knows, the program is actually required to return individual results upon request. And the results will be returned regardless of

whether comparison values exist. So we're expecting that it will be very likely that we'll get questions on the meaning of the results. So that's part of the motivation to try to look into this issue and get more comparison values.

Also, the program is directed to assess the efficacy of public health actions to reduce chemical exposures. So this would be another angle for wanting to have some comparison values to be able to evaluate the information better.

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MS. HOOVER: So what are we talking about with this general term? We're just using a very general umbrella term to refer to concentrations in biological media that could be useful for comparing to biomonitoring results, including things like measured levels in other relevant populations, levels in biological media that have been used to derive environmental guidance values or standards. So, for example, a blood lead level might be used as the basis for a drinking water guidance value, and that would be of interest to compare.

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MS. HOOVER: There's also an effort by Hays and co-authors to develop what they term biomonitoring equivalents. And these are existing guidance values that

are consistent with -- or, sorry -- levels in biological media that are consistent with existing guidance values. So they take existing guidance values that are already out there and back out what the blood or urine level would be consistent with those guidance values. And I'll give one example of that later.

Clinical action levels - levels that trigger particular follow-up actions for the clinical setting. So, for example, the CDPH Management Guidelines on Childhood Lead Poisoning.

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MS. HOOVER: And there's also levels for assessing biomonitoring results in workers. And these also may trigger follow-up actions. So these may be of interest. Such as the ACGIH Biological Exposure Indices.

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MS. HOOVER: So this is very rough, but I just wanted to give you an idea of the availability. So as you probably realize, most of the priority chemicals are actually derived from the designated pool, which came largely from CDC. So for about -- depending on how you count the priority chemicals. We don't have an exact number because some things are listed as classes. So approximately 80 percent have measured values in the U.S. population for comparison purposes.

In terms of other types of reference levels you can see that there's -- it's much less. So for biomonitoring equivalents, again depending on how you count it, it's about 10 percent and BEI is about 5 percent of priority chemicals. So you still have a lot of priority chemicals where you don't have that sort of information readily available.

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MS. HOOVER: Now, I just wanted to give a couple examples. And I want to preface this by just reminding you what I just said, which is there are some chemicals that are very well studied and actually have a range of, quote, reference levels available to choose from. Very rich database. And so I'm going to give a couple examples where there's a -- where there is some data to develop these kind of levels.

So one data based on human -- one example based on human data is cadmium. So, for example, the OEHHA public health goal actually specifies that the way the public health goal was derived was to prevent exposures from exceeding 1 microgram per gram creatinine in urine. And that's based on preventing proteinuria and therefore renal toxicity.

And then there's also biomonitoring equivalents available for Hays. And this is just one example based on

the U.S. EPA reference dose, which comes from a NOAEL in humans of 200 microgram per gram in the renal cortex. And I'm not going to go through the calculations that they do, but this leads to a biomonitoring equivalent based on the Hays et al. calculation of 2 microgram per gram of creatinine in urine and one 1.7 microgram per liter in blood.

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MS. HOOVER: And OSHA also has levels for cadmium. And it's actually a relatively complicated scheme. So this is just giving you a flavor of what they do.

So basically if an employee's exposed above the action level in air for more than 30 days per year, that would trigger medical surveillance. And then in that medical surveillance, if they find biological monitoring results of greater than 3 microgram per gram creatinine in urine or 5 microgram per liter in blood, that would then trigger additional requirements for further monitoring, exposure review. And depending on how high the levels are, possible removal from exposure.

So that's an example of a very well studied chemical where there's lots of different values to choose from.

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MS. HOOVER: In terms of an animal data example, I just picked one, dibutyl phthalate, which has biomonitoring equivalents for di-n-butyl phthalate, as mono-butyl phthalate. And this is from Aylward et al., 2009, which is a Hays colleague.

So the BEs for dibutyl phthalate were calculated for the Health Canada tolerable daily intake, the European Food Safety Authority TDI, and the U.S. Environmental Protection Agency reference dose.

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MS. HOOVER: And just to give you an idea of what the basis for these were, let's just summarize that.

So the Health Canada was a NOAEL for decreases in live offspring and increases in external defects and skeletal anomalies in offspring of mice exposed throughout gestation.

The EFSA TDI was a LOAEL for the loss of germ cell development and mammary gland changes in rats exposed via diet during gestation through lactation.

And the U.S. EPA RfD was increased mortality in rats exposed in diet for one year.

So you can see there's a range of the basis.

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MS. HOOVER: And this slide, I'm not going to go through it in detail, but I just wanted to give you a

flavor of the kind of calculation that's done for this.

So this is one way of interpreting existing guidance values. So starting with the type of guidance value that I have on the left side, then Hays et al. gives the point of departure that's actually identified in the assessment done by these agencies. So that's the first column, the point of departure in milligram per kilogram day.

Then the uncertainty factors that were applied for duration of exposure, severity of effect, and inter-species uncertainty factor is still applied in this scheme. By applying those uncertainty factors, the value of human equivalent POD is produced, also in milligram per kilogram day.

And then this human equivalent POD is multiplied by the estimated urinary concentration on a volume basis for the metabolite associated with a unit dose of the parent compound.

So by multiplying that factor by the human equivalent POD, you end up with the biomonitoring equivalent in urine in terms of milligrams per liter.

Then there's an additional uncertainty factor applied for intraspecies for inter-individual variability in the human population. And then this produced BEs in urine.

So there's also BEs on a per creatinine basis in the paper.

But this just gives you a flavor of the kind of calculation that was done by this group based on animal data. And you see you get a range of values. And we already know based on the previous slide that there's a range of -- the basis also varies for these.

So that's just sort of a -- I guess I'll just go ahead and go through the rest of the slides, and then we can go back and talk about any of these.

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MS. HOOVER: I just wanted to briefly preview what the workshop is about.

So the date that's planned is March 17th. And that's immediately following the March 16th SGP meeting. The location will be in Oakland.

The planned format is we'll be having presentations from invited speakers as well as some framing by Program staff, panel discussions and public participation.

And basically the purpose of the workshop is to explore the topic of biomonitoring reference levels for the program with the Panel, invited speakers, and the public.

And we'd really -- what we'd like to get out of

that workshop is guidance on how the program should proceed in this area.

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MS. HOOVER: Some of the possible topics that we've talked about for the workshop are:

First, just the purposes and applications of biomonitoring reference levels.

If we do choose a level, what would be the meaning of an exceedance and how to communicate that.

The implications for interpreting the information when the underlying basis for the reference level varies.

How do we account for the cumulative exposures and effects of the chemicals that we'd be measuring?

And probably one of the biggest questions is, what kind of approach might we take for data-sparse chemicals?

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MS. HOOVER: So for today, what I'd really like to do is just give all the Panel members a chance to give their general comments and just initial feedback about this topic, about the use of reference levels for Biomonitoring California, initial recommendations, concerns, challenges, just your initial opinions on that. And also I'd like feedback on the topics for the March workshop.

And with that, if you have any questions initially.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: This is a very interesting topic. I think it's important -- it's -- although the term used here, "biomonitoring reference levels," this approach actually dates way back to like the '30s and '40s if you look at the radioactive -- people who worked with radioactive materials focused on body burdens or the sort of steady state load relative to intake. So it's something that started -- it's much harder -- it's easier to do when you're looking at radioactive materials because you can actually measure the radioactivity of specific compounds. So that's why they did it.

But also if you even go into -- most of the pharmaceutical industry is actually aiming for a load or a blood load -- a steady state blood load. So even though you take a daily dose, you know, you take so many milligrams per day, it's really designed using pharmacokinetics to get the right steady state blood load.

So it's something we -- in a way, it's not something so new that we don't know how to do it. But we probably have to confront some of the uncertainties that exist for the type of compounds we're looking at.

The other example I'd give is in the dioxin

reassessment, the EPA really said, because dioxin accumulates and there's sort of a long-term body burden that builds up, both in rats and mice -- rats, mice, and humans, that it was easier to do the dose response based on blood levels or tissue load, basically body burden, instead of doing it on dose. Because dose was very difficult to characterize because of the accumulation.

So in a way it's a very logical approach in so many contexts that it would be really terrible not to do this, right, because we're missing a lot of knowledge.

So, you know, in terms of the feedback on -- I mean those are my comments on why it's a good idea.

So leading to suggestions, I think for the March workshop, it's important to make sure we broaden this out so that we bring in -- hopefully can find some of these people who have worked with nutrient loadings, with radioactive material -- something that can give us insight on what they've learned. Because I think one of the things we have to -- one of the problems with this is, although it looks really good, we may find that for many substances this is very problematic, right, there's going to be -- I mean for the substances I mentioned, like the radioactive materials, pharmaceutical, I mean these are things that they focus a lot and try to restrict the variability. Like for drugs, you don't want to pick

something where there's high variability, or you really to have to work to get the loading right.

So where this may fail is something where the -- like metabolism is controlling the level and there's enormous genetic variations in the factors that give rise to the metabolism by different pathways. So you'll take one group of people and you'll get one biological reference level. And then another group -- another gender, another age, another something else, and it will be totally different.

So we have to be very careful about going into this believing that there is such a simple translation in many cases. And we have to really look to explore that. So that's what I would suggest. Not to be, you know, cynical about it; be very cautious about where this works. Because we know in some areas it works well. But I fear that in other areas, it may not work at all.

And so we want to make sure we have that balance to sort of know where it's going to be reliable and know where it has some real pitfalls and dangers to scope out.

I'm hoping that's useful.

MS. HOOVER: Yeah, thanks.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: The thing that I guess I'm having the most trouble with in figuring how to approach

this is that as a Panel, when we've approached criteria for listing chemicals and designating chemicals, prioritizing chemicals, we've thought a lot about trying to stay kind of ahead of the curve, identify emerging potential hazards, new chemicals that may be coming on to the market to replace others, things that we want to sort of keep an eye on. Not necessarily because we think that they're super highly toxic, but because we think that they could be emerging concerns. And many, if not all, of those there's really no health-based level of concern, let alone, you know, biological index.

And so you allude to that at the end of your slides about what to do with data-poor chemicals. But I think we're going to be there with a lot of the ones that we care the most about in this program. And it makes me very nervous to be sort of taking, you know, some, you know, very poor data set and then doing not only the extrapolation to try to come up with something resembling a reference dose, but then taking that the step further that we would need to to come up with a biological equivalent.

And so, you know, I think that whether that means we don't do such an exercise with the data-poor chemicals or whether we try to do it with some major guesstimates, I think should be a significant part of the discussion.

CHAIRPERSON LUDERER: Dr. Bradman and then Dr. Culver.

PANEL MEMBER BRADMAN: I think this is going to be potentially very controversial, and that there's risks for the program to that. I do see the need for the program to be able to put the measurements in some sort of health context, particularly when you're returning results to individuals. And I have some concern about the interpretation of the results becoming controversial and that making the program controversial when the focus should be on biomonitoring. And maybe there's the discussion that needs to happen about what is the role of the Biomonitoring Program in risk assessment.

My concern is that there's going to be some sort of health or risk interpretation. And if it's done at a screening level, you know, there'll be a debate and concern about whether that rises to the level of a proper risk assessment and then whether, you know, anything that gets done in the context of this program by the State will then be out there in terms of and viewed as a law or a standard. And I think it has to be done very carefully.

A little nuts and bolts thing too. I think it would be interesting as part of the workshop to have some discussion about the merits of, you know, using a point of departure or kind of a probability or risk-based

interpretation for noncancer health effects versus something more like a reference dose. I mean if you look at the example here for the phthalates, you know, you really have different results, and they're based on different standards.

And then I think the use of that in terms of how you might look at cumulative exposures, I think there's some value to looking at mixed exposures particularly for compounds that as a group have similar mechanisms, you know. And there I think the point of departure is needed. But there's some -- you know, there's some technical issues that might worth discussing as a group and reviewing as a program.

But, again just back to my earlier statement, I'm concerned about this becoming a risk assessment effort. And, you know, we know from setting standards for diesel, for lead, that those become controversial. And I wouldn't want that - I don't know if people agree with me - but wouldn't want that to get in the way of the Biomonitoring Program doing biomonitoring.

It seems to me CDC in the way they do their measurements and then they leave the interpretation out for the general literature.

CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: I'd like to second

everything that Asa said.

You've mentioned several different things - reference dose, biological -- or biomonitoring equivalents, the BEI. I look at these as all being sort of transfers functions. And they're all a bit different and they have different purposes. So that if you're going to hold a workshop, I think the objective of the workshop would be to decide what transfer function you really want. And I think the description of the biomonitoring equivalent is probably closest to what would make sense to us.

But, again, this is dangerous ground. It's a quagmire. It may derail us. It's going to be hard enough for us to maintain the focus that we already have. But it's an interesting thing.

CHAIRPERSON LUDERER: Dr. Quint and Dr. Wilson.

PANEL MEMBER QUINT: Julia Quint.

I think it's a really interesting topic. And I just really want to reiterate, I guess, or emphasize the cautionary aspect of this. I think, as Gina -- Dr. Solomon pointed out, you know, we've -- it seems that biomonitoring has been measurements of exposure, and we have stayed away from health -- making interpretations of health risk that might be associated with the exposure as measured in biological media. And I think that it's

important to keep that separation.

It's also important to, you know, stay abreast of the new developing science. And this is definitely, you know, the work by Hays and others, this is already underway. So for that reason, I've always been anxious for us to look at what is being done in this area, because I think we have to. I think it's very important. I mean we may not want to interpret biomonitoring data in terms of health risks but other people are.

So there will be that -- the questions will be asked, and I think, you know, it's our -- we are responsible in communicating results to be able to answer certain questions that are posed.

I worry about things like -- you know, we are now much more aware in risk assessment of underlying conditions that add to health risks, you know, in genetic susceptibility, various vulnerable populations that have disease burdens that affect their -- you know, the risk of chemicals that they're exposed to. And this is no different.

So, you know, it's not as simple as an animal result and then interpreting that in terms of a BE or a bio -- you know, biomonitoring equivalent or something like that.

The other thing is cumulative -- you know, along

those lines is cumulative impacts. Again, this is chemical by chemical. What we're talking about is any one individual might have, you know, many of and do have many of these chemicals in their bodies. And so we have to be able to engage in the discussion of not only chemicals that have the same mechanism. But all these different chemicals, we have no idea of what the cumulative impact of those chemicals might be.

So I would, you know, just caution -- keeping up -- you know, exploring this, but keeping very separate what this legislation was meant to do. I mean it is a cautionary statement about chemicals policy and how chemicals have entered our environment and now entering our bodies and the potential for health impacts, without having the outcome of this workshop, the expectations being that we're going to come away with the methodology that will translate -- not that you've said any of that. But I'm just going down, you know, where people will naturally want to flow from this, is that we're going to come up with a number that will then say that the amount in your body is okay because, you know, it's not close to the reference dose or something like that.

I think that would be not good, especially given that you're saying, you know, only 10 percent of the chemicals have BEs, 5 percent have BEIs, and 80 percent --

you know, we have, you know, many more chemicals that have been measured. So, you know, it will take us a long time to get there.

I also worried -- one last thing. I really worry about the need for pharmacokinetic data in order to calculate these biomonitoring equivalents. My experience in working with chemicals is that we have those data for very few chemicals. I agree that it's really, really important for risk assessments, it's really important data to have. We just don't have it for a lot of chemicals. So there again, you know, we won't be able to have information even on the chemicals for which we have health effects data. So I think those are all really potentially problematic.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you. Mike Wilson.

I'm going to be echoing I think the concerns of my colleagues on the Panel. And I see this really as a fundamental epistemological question, which is really around the way we generate and use information.

And I think as the program is in the process of identifying the presence of industrial chemicals and pollutants in human blood and so forth, and the pathway -- we sort of are -- I think this question that you've raised here sends us along a different pathway and one in which

we are asking a question about how much harm is acceptable, if you will. We're sort of in a risk assessment framework.

And underneath that, there are all of these extraordinarily complicated questions, one being the problem of cumulative and mixed exposures, as we've heard on the Panel. A second being the uncertainties and assumptions that are inherent to PBPK models. The variability in biomonitoring results. And PBPK models, both inter and intra -- inter and intra-personal variability.

And the fact that we are -- you know, despite what look like robust tools, PBPK models, and that they give us a number on which we can sort of feel confident -- we think we can feel confident, the fact is we are -- in terms of the environmental health sciences and biomonitoring studies, we're not in the area of uncertainty. We're actually in the arena of ignorance. We really don't know what the long-term implications are and we don't know the orders of magnitude of those. And so I think it would be -- you know, it's just greatly overstepping, in a way, to rely on models where a possible conclusion might be that we could -- we would establish a safe exposure level based on the results of those models.

I don't think we're able to say that. And I

think it ends us -- puts us down a pathway of controversy and also into an area that's of questionable science.

I would encourage us to move as we have been moving, more in the -- continuing along the path of identifying the presence of levels of trends in chemicals and pollutants, and look with some skepticism at this approach, and keeping open the task of making sure that our process of identifying the presence of and levels of and trends in pollutants and chemicals is robust.

And I guess the second piece of this is that we're seeing from our colleagues in the European Union a very -- that they haven't gone down this pathway so much, at least to date.

The Royal Commission on Environmental Pollution finally took the position that rather than embarking on a risk assessment strategy around chemicals identified in people, they simply stated that steps should be taken to reduce the use of substances that appear in humans and in higher mammals.

The European Commission embodied that position essentially in law through the REACH regulation in classifying substances that are very persistent and very bioaccumulative as chemicals of a high concern, regardless of these questions of risk.

So those are my concerns. And again, I guess

they echo those of my colleagues.

CHAIRPERSON LUDERER: Dr. McKone. And then I know we have some public comments as well.

Or we don't. Okay.

PANEL MEMBER McKONE: Just an additional comment. And I think -- again, I think we agree. But I want to -- I think everyone's getting a little focused on the risk side of this, which I also agree is dangerous. But I don't want to lose the translation part of it that they're bringing up. And I think we really -- you know, we can't ignore the need for translation. It's very powerful, you know, translating from a blood level to an intake level.

And the reason that's important is because people -- you know, we're kind of talking about the right-hand side going from blood level to risk. But I'm thinking about the left-hand side going from source to what's in the blood. And if we don't have some mechanism of translation where possible, we may send people looking in the wrong pathway, like -- I mean for PAHs, you can do this exercise for PAHs and look at the blood levels and say, "Well, what had to go in to get that blood level?" And if you take the highest levels of air pollution in the country, you can get the NHANES numbers, because it's coming from other sources, not just from air.

So this is what I mean about having a translation

that says what had to go in, you know, within plausible amounts. Because I think that helps people find sources, and that -- I think that's within our purview.

But I do agree, once we start moving into this risk assessment, we're in the wrong kind of realm. We're going to get into some problems and more controversy. But I think the translation is something worth trying to preserve in this.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I agree that, you know, the exposure piece is -- because that's -- we started the biomonitoring as a measure of exposure. So, you know, being able to say where the exposures come from would be very important.

On the other side, when you give results to people - and this is my experience from just answering people's concerns over the phone for 15 years - is they really want to know what's happening with their health. I mean you can tell them how to reduce exposures. But when you give them a blood value, it's like going to the doctor and the doctor takes a measurement and the doctor tells them what is -- you know, what the lab value means. That's what people -- that's the context for most people, is, you know, "What does the value mean to my health," you know. Even though you talk about reducing exposure, they

want to know if it's going to make them sick.

So I think we have to appreciate the need for -- whether we give them that translation or stay away from it, I think it's important to understand that's what's uppermost on people's mind, because it has a clinical connotation as opposed to whatever scientific, you know, merging chemicals exposure sort of context that we're putting on it.

So I think we need to understand what this is and what this isn't, and then how we will use it in the context of what this program is mandated to do. And communication of risk is one of them.

So once we find out what this is, we can then -- we should and will have further discussion about whether or not informs or doesn't inform our risk communication efforts. But the risk communication I think for people who participate in this program will include wanting to know if their health is affected by having these chemicals in their bodies. It's just the way it works.

PANEL MEMBER BRADMAN: Yeah, I just want to echo Dr. Quint's comments. And I agree with that. And I think that's the tension that's going to be present in this program, is trying to think about how to communicate on an individual basis and how to communicate on a population basis. And the communication on the individual basis also

has to be linked to the consent process to make sure that there's a good understanding of what people are participating in and what they should expect at the other end as well. And that can be challenging.

But I think that -- well, I think we've all kind of expressed concerns about the risk assessment approach. And clearly I think we have good fodder for meeting in March.

CHAIRPERSON LUDERER: And we have one public comment; is that correct?

MS. DUNN: Yes.

CHAIRPERSON LUDERER: Okay. Great.

All right. Ms. Whitman.

MS. WHITMAN: Yes. I'm Deborah Whitman and President of Environmental Voices.

I just wanted to tell you I'm supposed to be in Santa Cruz right now on the beach. And I'm so glad I didn't go and I'm here instead.

So, anyway, I'd like to participate in the workshop. I have some other nonprofits that might be interested in having -- you know, submitting some input or helping out along that route too. So hopefully you'll contact me regarding that.

Instead of having lunch today, I spoke with Rosalind Peterson, who's the President of Agricultural

Defense Coalition. And they've been doing some water testing, pulling sample tests. And she asked me to request that you start studying SF-6, sulfur hexafluoride. They're finding spikes of these chemicals. Sulfur hexafluoride blocks oxygen to the heart, causes asphyxiation. It's also a greenhouse gas.

Arsenic -- evidently they're finding spikes of arsenic in water samples.

And she used to do testing for agriculture on a state and I believe federal level. I'm not sure.

And the other one is strontium. They're finding strikes of strontium, which is radioactive material.

So those were three that she suggested that you consider as part of your study.

And then the last thing was, there was somebody here talking about breast cancer. And these chemicals build up in our fat tissue. And it's my understanding that our breasts are primarily fat tissue. So I would recommend possibly that they look into doing studies on that area, maybe testing tumors in your intestines and different areas. I don't know that much about testing on health issues, but hopefully somebody out there might be looking into those areas as well.

So thank you again.

CHAIRPERSON LUDERER: Thank you very much.

MS. HOOVER: Yeah, I just wanted to thank everyone for their comments and say I'm aware of a lot of the challenges and issues that you raise. So we're going to be moving ahead cautiously, and that's kind of the purpose of the workshop, is to air out these issues more thoroughly.

Also just to let the public and listeners know, we'll be sending out more information about the workshop. So if you sign up for the listserv, you'll be aware of what's happening with it.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I guess I have a -- I have a question about the workshop, which is, are we framing the workshop as something that is just supposed to be talking about this issue of biomonitoring reference levels? Or are we thinking about the workshop as something that is around sort of how to provide context for the results and the different options that one might use for putting the biomonitoring results into context, of which biomonitoring reference levels would be potentially one? Because that's a different way of framing the workshop.

And I actually -- if it's still an option, and it were possible the frame it in that latter sense and sort of look more broadly at: Okay, here's the problem. We

have to figure out -- we're going to have all these numbers. We have to figure out how to interpret them for individuals and for groups. And here are the suite of options for ways we might do that, one of which is just sort of, you know, using means and standard deviations and so forth for, you know, the whole population that we studied and for NHANES and so forth and comparing it to that. And that has all a certain set of pros and cons.

Another option is to use, you know, this kind of calculation which has another set of pros and cons and might be useful for certain chemicals, less so for others.

And, you know, the other is to pretty much, you know, decline to give much context and say, well, you know, for these certain types of chemicals or situations we actually don't have any way of putting the results in context and then figure out how to explain that to people in a way that they might be able to, you know, deal with results like that.

Instead of just making the whole workshop around just this one technique.

MS. HOOVER: Yeah. No, it's definitely not around one technique certainly. And we are going to have -- the plan is to have that exact kind of wide ranging discussion about what -- and I was trying to give that flavor about it: Here's the context of Biomonitoring

California. Here's the challenges that we're going to face. How should we approach dealing with that?

And some of that work is already going on as part of the pilot projects definitely. And certainly there's cases where we will be returning results with no context, and that is explained to people: That we don't know what this means. Here is are the results.

So I think that that -- you know, there's definitely -- and I like the way that you described that discussion. So I'll, you know, be stealing some of what you just said for framing that initial discussion, because we want to have exactly that kind of broad discussion.

And then next to that we do -- like Dr. Quint was saying, we do want to be aware of, you know, the science and what's happening in the area. So we do want to talk about that as well.

So hopefully both things. It's only a one-day workshop of course, so we can only go so far.

CHAIRPERSON LUDERER: And if we don't have any additional comments from the Panel at this time, then this would be time for our short break.

I think we're a little bit ahead of our schedule at this point.

Should we plan on a 15-minute break?

MS. HOOVER: Yeah.

CHAIRPERSON LUDERER: Okay. So we'll reconvene at 20 after.

(Thereupon a recess was taken.)

CHAIRPERSON LUDERER: All right. I think it's a little later than we actually said we would start, so we should probably resume the meeting.

I'd like to welcome everyone back from our break.

And I would like to introduce my colleague, Dr. Leslie Israel from the UC Irvine Division of Occupational and Environmental Medicine, Center for Occupational and Environmental Health. And she's going to give an overview and update on the Firefighter Occupational Exposures Project.

(Thereupon an overhead presentation was Presented as follows.)

DR. ISRAEL: Good afternoon. My name is Leslie Israel. Thank you very much, Panel and Biomonitoring California, for inviting me to present and update on the FOX project.

Dr. Das had presented at your last meeting.

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DR. ISRAEL: And so what I'd like to do is move forward and give an overview of the collaborative efforts between UC Irvine COEH, the Orange County Fire Authority, and Biomonitoring California, and update you on the

project status regarding using the project time line and some of the steps where we're at

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DR. ISRAEL: So some of you may wonder how did this collaborative effort take place. So I'd like to just spend a few minutes discussing how that happened and the entities.

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DR. ISRAEL: As you all know, many of us are members of a Center for Occupational Environmental Health. And you all know that it is -- it was 1979 the COEH was established under a mandate from the California Legislature. It was really the DDCP episode that highlighted the necessity of utilizing the UC resources to meet the State's needs for addressing occupational and environmental health.

I really want to extend a special appreciation to Dr. Dwight Culver. He was extremely important in championing this effort in southern California. And Dr. Luderer, who, as she mentioned, is a colleague at UCI COEH, had suggested to Biomonitoring California that one of the clients we see may be appropriate for this pilot project.

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DR. ISRAEL: So Orange County Fire Authority has

a wellness and fitness program which Dr. Das had mentioned to you at your last meeting. And one of the components is the WEFIT medical evaluation. And it's a significant component. It was implemented in January of 2004. It's a nonpunitive. And the frequency are annual to biennial medical evaluation. And you can see the evaluation has a number of components, including the comprehensive history exam and various tests.

The results are communicated to the individual firefighter at the time when they exit from their evaluation -- prior to exiting their evaluation and also in a pretty significant lengthy report.

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DR. ISRAEL: So now I'd like to move on to the project time line. And Dr. Das had shared this with you last time. And both UCI and CDPH IRBs were approved in May. And dust samples were collected in May. And field testing instruments and procedures were tested and completed June-July. Dr. Sandy McNeel and other Biomonitoring California staff were very significantly involved in those steps.

Again, we did -- following the field testing, we did make some revisions. And those were submitted to the IRB and accepted so that we could begin recruitment this last month. And we hope to complete the recruitment and

collection of biospecimens by the end of February.

Again, data entry analysis we anticipate beginning some time January-February and then the results. And then of course the project report.

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DR. ISRAEL: What are the aims. Again, it's to assess levels of approximately 40 chemicals in blood and urine. And we are looking at collecting it from a hundred firefighters that belong to Orange County Fire Authority.

We are measuring a subset of these in the dust samples which have been collected.

And, again, the aim is to develop and test protocols and procedures that are applicable to a larger firefighter study and, as importantly, lessons that may apply to other occupational studies.

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DR. ISRAEL: The chemicals of interest have been mentioned today. But these are the bullet points:

The flame retardants, PFCs, metals, organochlorine pesticides, some pesticide metabolites, PAHs. And at the last meeting, the Panel recommended adding phthalates, and that has been added.

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DR. ISRAEL: So this is a diagram of the activities. And as you can see in the first column, the

field testing has been completed. And now we are moving on to firehouses. We completed the dust sample collections. And what's pending in that second column are the firehouse exposure source checklist. That's something that the firefighters will do, and we can discuss that later.

What I'd like to focus my brief presentation on is that third column. And that is UC Irvine in process.

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DR. ISRAEL: So at the top, the recruitment, consent, and enrollment.

So again, just as a reminder, the inclusion criteria are firefighters who are employed by the Orange County Fire Authority for a year or more and they're scheduled for their routine wellness-fitness exam. And that's done through OCFA through a coordinator.

And the recruitment is through a flier, which is great, because it's a one-page, two-sided flier and it just gives the bullets on what this is and what they need -- what's being requested of them.

The flier is being posted at the fire stations. It goes out in inter-mail. And it's also sent as an electronic reminder.

The OCFA Fire Authority newsletter is another document that also gives some recruitment information

about the FOX project.

Again, we consent and enroll during their WEFIT appointment.

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DR. ISRAEL: Informed consent. Again, the participant is given choices to participate in FOX project. They are given the option to receive individual results in addition to summary findings. And they are given the option of donating unused blood and urine samples that are collected, along with de-identified information for future studies.

Now, the last bullet, I'd like to inform you that participants receive no monetary compensation. And that's because they are on duty, and it is not permit -- the OCFA does not permit that.

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DR. ISRAEL: This pictorial shows the complicated processing of the specimens by the medical assistants and our nurse at the clinic.

And I'm just going to say that this is a very serious component of the project and we want to make sure that we are sending out quality specimens.

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DR. ISRAEL: Chief Sara Hoover spent some time discussing critical values/follow-up. And as was

mentioned, there will be further discussion on this. So at this point in time you can see that critical values' comparison with reference values, lead is pretty much the one that we have some information on.

As far as information on others, that will be determined.

Protocol for follow-up, again there's going to be review by UC Irvine and Biomonitoring California staff. And contact participant -- we would contact the participant by phone and mail if needed immediately if a result indicated that we needed to do so.

And then again Dr. Das and my information -- contact information will be provided.

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DR. ISRAEL: So the components of what they do while they're at the WEFIT exam as part of the FOX project is they complete an exposure questionnaire. And the purpose of it you can see. It gives -- it identifies occupational factors and work behaviors.

It also gets at information about chemicals targeted. So it asks them about what type of bedding they have, what type of furniture they're using at the firehouse, what type of pots and pans they're using. And, as I said, Dr. Sandy McNeel worked and did the focus groups on this with the firefighters.

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DR. ISRAEL: The other thing that they complete before they leave is a study evaluation questionnaire. Participants respond anonymously.

So on the exposure questionnaire, there is a number on it. On the study evaluation questionnaire, there is no number and no name.

It's about a five-minute questionnaire. And it's an opportunity for them to provide feedback on the recruitment, enrollment, specimen collection, and the exposure questionnaire components of what they completed that session.

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DR. ISRAEL: When they sign the medical consent, we also have them sign a record release so that we may abstract medical record information from their WEFIT questionnaire and chart. And some of the bullets of information we abstract are listed here. And I see that gender and education weren't listed, but they're also included.

So firefighter rank, special assignments, their activities, if they have other jobs, and also the dates of their evaluations through the current one, the one prior. And initial WEFIT Medical Evaluations along with chronic medical conditions, medications, tobacco use, and so

forth.

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DR. ISRAEL: So, again, I just want to review. We've completed the first column. We have the fire exposure source checklist to complete. And this third column I've just briefly gone through what is in process.

The results reporting. The time line that Dr. Das had presented back at your last meeting remains 6 to 8, 9 months for some of the results and then 18 months for others.

And then again, we will ask participant feedback on an online survey to find out about any questions they have about or concerns or comments on their result reports.

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DR. ISRAEL: So I would sincerely like to thank the collaboration that UC Irvine has had with the Biomonitoring California staff, Dr. Das, Dr. McNeel. And the other members of the staff have been terrific.

The Orange County Fire Authority is a very unique group. I've worked closely with labor and management since 2004, and they really do come to the table. And they appreciate transparency. And they're very excited about this project.

Again, I'd like to thank the others on the list,

the CDPH and others who have been involved.

I'd be happy to take questions.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Not yet.

(Laughter.)

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Thank you very much, Dr. Israel, for that very nice presentation.

You mentioned that you take -- you ask questions about work exposures. Do you also ask questions about home exposures or -- you know, because some of the chemicals, you know, could be associated with personal care products, like for the phthalates. And so I'm just wondering if you include a few questions on that as well.

DR. ISRAEL: So the FOX questionnaire, I'm actually going to have the Biomonitoring California people come up and address, because there was quite a bit of discussion about that. And so we do look at off duty/on duty. And we use that off duty/on duty analogy in our WEFIT questionnaire. So I'll let Dr. Das address that.

DR. DAS: Yeah, I think we had a little bit of discussion about the issue here, that the limitations we're working under are that firefighters are there for the WEFIT exam. As Dr. Israel explained, they're going through a very busy process at the clinic. And that is

the time we have to work with them.

We've been told by multiple people in Orange County and other counties that firefighters will not fill out a questionnaire once they leave their exam. And we have about 15 minutes for them to do so. And they're doing that while filling out other questionnaires as part of their wellness-fitness and doing treadmills and other things.

So within the 15-minute limitation, we restricted ourselves to activities at work. And so we're not able to ask those kinds of home-focused questions within that time limit.

Again, this is a pilot study and ideally, yes, we would get information about home. We'd also probably have a control population. But in this particular project, due to the limitations, we're not asking home-based questions or questions about home behavior.

PANEL MEMBER QUINT: One other follow-up question for either of you.

In terms of -- I usually think of firefighters as being heavily protected with PPE when they're fighting fires or whatever. And I'm wondering if -- you know, when you were thinking of the potential chemical exposures, I'm sure you thought of that. And I'm wondering if in any of these situations sometimes they -- do you ask questions

about whether or not they have -- what they're wearing? I mean are they supposed to be wearing PPE? And if you ask them if they don't, would they be like they aren't following, you know, good workplace practices or something? I'm just curious about that.

DR. ISRAEL: No, exactly. The exposure questionnaire that Biomonitoring California put together does include "When do you wear your respirator?" And there's actually quite detailed questions about when they're wearing it, how long they're wearing it.

The other thing I think that's interesting to note is the checklist that hasn't been done yet is going to look at exposures in the firehouse. Because, you know, the turnout gear is hanging there. And it's like where is it hanging and are they getting exposed to that turnout gear?

And so there's a lot of variables. And as much as we -- as Dr. Das said, we're really limited to sort of the firehouse and the workplace. We can look at those variables, which we are.

Do you have anything to add to that?

DR. DAS: No.

CHAIRPERSON LUDERER: All right. Dr. Denton and then Dr. Wilson.

OEHHA DIRECTOR DENTON: Just a follow-up to that.

I was curious about your doing indoor dust. And maybe you could kind of explain, is the dust coming or you're anticipating -- how are you going to tie that into the biomonitoring results? Is the dust coming off the clothing? I mean there are other sources of indoor exposure. But you guys, the measure of indoor is going to be the dust. So I'm curious about the thinking on that.

DR. DAS: So we are somewhat limited by the technology that's available. And so the dust sampling was done in three firehouses. We're actually recruiting firefighters from many more firehouses, I think 60 potential fire houses. The three firehouses were chosen based on geographical location, type of incident response, and other factors.

The dust sampling took place in the firehouses at various locations in the firehouse. And that's the -- we use methodology that's accepted in terms of dust sampling. So we did not vacuum the turnout gear or do any kind of personal sampling of firefighters.

So that's something that some colleagues are interested in doing and perhaps something we could look at in the future. But for the current time, we just sampled the firehouses -- different locations in the firehouses.

Oh, and the -- oh, yes. And we also collected vacuum bags that were in the vacuum cleaners that the

firefighters use normally. Because firefighters do their own maintenance in the firehouse. And so the vacuum bags that were in the vacuum cleaners that had been used in the firehouses were collected, and that is a standard methodology that the Environmental Chemistry Lab uses to analyze some of the chemicals we were interested in.

OEHHA DIRECTOR DENTON: So the thought is to tie in the biomonitoring results with these dust samples?

DR. DAS: It's a little unclear. We haven't made that decision. Again, it's only three firehouses. So I think our sample size is really small. I'm not sure how many firefighters are going to be coming from those three firehouses. We did not make the -- we didn't promise the firefighters or the union or OCFA that we would make the link between the firehouses, the dust samples collected in firehouses and the individual biomonitoring results. But the analysis of the dust samples will give us some indication about the sources of the chemicals that we analyze through particle size and other methods that other researchers have to identify sources of dust.

But whether we'll use the results to link them to biomonitoring, it's highly unlikely that we will be able to make that connection in this particular project.

And I also want to clarify, that the environmental sampling is not funded by the Biomonitoring

Program. It's sort of an extra effort.

DR. McNEEL: This is Sandy McNeel. And you actually covered what I had come up here to say. Other than, we saw the dust sampling as an opportunity to get a little better idea of potential sources of exposure particularly to some of chemicals that the firefighters may be exposed to in the field, with the consideration that they do additional -- they do initial cleanup of their turnout gear. Oftentimes at the site, then they jump in the truck, they go back to the fire station and they may do additional cleaning of turnout gear there. And so you have the potential for some of the chemicals, particularly for the groups that are doing Hazmat response, you know, that may find its way into the station. So we had an opportunity, you know, to look at some of that. And so we decided to take that.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: We may have discussed this earlier, I'm not sure, with Dr. Das. But do the three stations have diesel exhaust extractors.

DR. ISRAEL: OCFA has implemented diesel exhaust -- they've implemented that technology in all their firehouses

(Laughter.)

PANEL MEMBER WILSON: Okay. And then does the

questionnaire differentiate by job class? So firefighter and fire engineer versus fire captain?

DR. McNEEL: Right. That information is not included in the questionnaire, but it is abstracted from the WEFIT medical records. So, again, we used the approach of trying to gain as much information as we could from sources that were already available. Every firefighter goes through an initial questionnaire that asks for certain kinds of data. And then every year they -- or every time they have another exam, then there's a slightly different questionnaire to update some of the important factors, such as their job activities, their -- you know, their current positions. So we take position from the WEFIT abstraction.

PANEL MEMBER WILSON: Great. Good strategy, yeah. Great.

CHAIRPERSON LUDERER: Dr. Solomon and then Dr. Quint.

PANEL MEMBER SOLOMON: I just have two questions, the first for Dr. Israel. Thanks for a great presentation on this exciting study.

And I'm curious how the recruitment is going. I know it's a little bit early. But is it going to be difficult to recruit the hundred firefighters? And how long might that take?

And then my second question I guess is for the program, which is around the time period for returning results and -- I mean I know that it does take quite a bit of time to, you know, do the laboratory analysis and to get the results ready to return to the participants. But it does seem kind of like a long time lapse, and so I was just wondering for this study and the others whether there's any effort to get the results back to people more quickly.

DR. ISRAEL: So I'll respond.

Recruitment began October 18th -- Monday, October 18th. And we see WEFIT exams about twice a week and average anywhere from 5 to maybe 15 exams. It varies. Sometimes more. So as of 5 o'clock yesterday, we recruited and consented, enrolled and collected biospecimens on 18 participants.

DR. DAS: I just want to add to that. Rupa Das.

I think the recruitment's going very well. I don't think we'll have any trouble meeting the hundred target, and probably will do so before February. Although there's fluctuations when firefighters are scheduled. But when they are scheduled, I think we're seeing a very good participation rate.

In terms of results return, yes, we recognize it's a very long time and the participants are told that

it will take that long. It's possible if we have the information that we'd like to get all together sooner, that we would be able to return results sooner. But I think those guidelines are sort of the outer limits of how long it could take. I think as we move further into the program and have more experience returning results, interpreting results -- this also has to do with discussion we just had when Dr. Hoover presented about how to interpret results and package them and educate people about them. As we get more experience and have more -- a standardized format, it will become much easier and the results return will go much more quickly.

So at this point our limitations are the laboratory analysis and how to interpret. And I think we're making every attempt to reduce the time frame between sample collection and results return. These two projects being our first two, they might take a little bit longer. But we will certainly take your comments to heart and see if we can shorten that duration but maintain the -- take all the factors that we need to into consideration to return quality results that are meaningful to the participants.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I just had a quick question related to that. In

one of your slides you said that you would -- the comparison values to which the mercury and other compounds would be compared were to be determined. So is that a commitment that you are expecting to have comparison?

Let's see. Am I getting this right? Yeah, comparison with reference values. And it says "to be determined". So we're not committing to actually compare them; you're just --

DR. DAS: No, we're going to look into -- "we," meaning the program including OEHHA, are going to look into the values that are out there to determine whether we can come up with a level that's similar to the one we have for lead. I mean lead is the only substance for which we can guarantee we have some guidelines. For everything else I think we're going to look at what's out there to see if there is an actual level we can return.

Sara, did you want to add anything to that?

PANEL MEMBER QUINT: Yeah, the reason I ask that is because I know in the Occupational Health Branch many years ago we published medical guidelines that did have values, you know, as guidance to clinicians for various metals and things. But they were based on poisonings, not, you know, chronic health effects that we're concerned about here. So I was just wondering if there was some clinical reference values out there that clinicians are

currently using for some of these things. But, no.

Okay. Thanks.

DR. DAS: Well, I should qualify. There are some values that are floated out there, but they're, in general, not widely used by clinicians. So we'll be looking at those to see if they're relevant for this population.

CHAIRPERSON LUDERER: Actually I just had a quick question related to the sample -- you know, the turnaround time for results. And that is, is the plan as far as the analysis of the different chemicals that you're going to be measuring, are they going to all be done once all the samples have been collected? Or is there a plan to do them in kind of a rolling batched form? Just if you could give me more detail.

DR. DAS: I guess the simple way to answer that is it will be done in a batched way, but the number of samples in a batch will be -- is determined by the analyte and the lab. So I don't think we're going to wait till the very end. But the labs have told us that they would like to batch a certain number of samples before they run them, because that's just what works for them.

Jianwen, I don't know if you want to add anything to that.

DR. SHE: Speaking for environmental health

laboratory. And we are planning to do a few projects together maybe like a MIEEPs and then this FOX study. So we give like six months average time to return the results to the people to give further interpretations. And the laboratory turnaround time we estimate about six months.

CHAIRPERSON LUDERER: Yeah. I mean I guess one of -- actually this is a question for Jianwen She too. One of the things I was just getting at is, you know from a perspective of variability in terms of, you know, assay results, is it -- I mean it seems that it might actually be that a good practice is to measure them all together rather than measuring them in a rolling fashion. That was kind of what I was getting at.

DR. SHE: Yes. So the reason we batch up together because we run like a -- with each samples we need to have a 10 calibration points to run together, plus the laboratory controls and personal level, media level, high levels. And then we also introduce some duplicate. These are to be run together.

It would not make sense for to run only one sample plus 20 quality control samples. So we needed to batch them together.

CHAIRPERSON LUDERER: Any other questions from the Panel?

Okay. Dr. Israel.

DR. ISRAEL: Thank you.

I just wanted to make one comment. And, that is, that the hard copy -- there were two slides added to it that reflected the study evaluation and -- so you will get those posted when they post the slides.

Thank you very much.

CHAIRPERSON LUDERER: Thank you very much for providing us with that update. It's very impressive how much progress that's been made on this project.

Let's see. It looks like we're a little bit ahead of schedule. But should we move on to the comments? How many do we have?

MS. DUNN: One that you have up.

CHAIRPERSON LUDERER: That's the only one?

All right. So we have one comment. And this is Deborah Whitman, President, Environmental Voices.

MS. WHITMAN: Okay. Thank you for -- very much.

I just wanted to stress that I haven't really had enough time to review all the documents and things in the presentation. But -- and I wanted to thank UC Irvine for the study that they're doing.

I had one question though that came to my mind, and that's the issue of studying diesel and carbon monoxide. And I don't know if that's part of this study or if you can include it.

The reason is the Merit Manual states that carbon monoxide stays in the blood hemoglobin over 250 times longer than oxygen. And then diesel gets down deeper into your lungs. So those things I think need to be studied in part of this. I just think it's important to study maybe some of the firefighters that do wear their respirators and some of those that might stand back and not use them, and do a comparison that way.

And, again, to do blood tests within 24 hours of exposure would be very good.

I'd also like to encourage you to maybe do a study with forest -- firefighters that do the forests. The reason is, we're studying -- we're doing a study on the dying trees. We've been testing tree bark samples and we're finding -- the only chemicals I've been testing for because of funding reasons is aluminum, barium, strontium, titanium. And we're finding these chemicals in tree bark.

In addition, I'm concerned about other things like herbicides that are used when they do clear-cutting of trees, concern about like retardants - I guess that's what it is - when they spray. So my concern is is that when the wood burns and the grasses, are these chemicals coming up into the air and are they being exposed with different types of chemicals that you might see in a firehouse? So I wanted to bring that up.

And also I have a concern regarding their equipment and their trucks, and if you're including solvents and oils and things. Because I see them out there polishing their trucks and working on their trucks. And I also know that they run their trucks at the station, and I get -- I call them quite often, because I'm exposed to like carbon monoxide from people's fireplaces. And I have to tell them to shut off their trucks, because I'll get two or three trucks at my house and they run the diesel trucks there because they're not supposed to turn them off. And I'm highly allergic to diesel.

So those are some of the other issues that I wanted to bring up and hopefully you'll consider.

And then, lastly, I want to plug the Air Resources Board, because this is a video that's available to the public. It's free. All they have to do is call 1-800 IN SMOG. And it's an excellent video, the best that I've ever seen, about these chemicals and how they affect your health with asthma and fibrosis and everything else. So there you go. And I'll leave you a free copy.

CHAIRPERSON LUDERER: Thank you very much.

Do we have any additional discussion from the Panel members at this time?

Dr. Wilson.

PANEL MEMBER WILSON: My question about the

diesel exhaust extractors and the job classification was really that the areas that are the highest sort of exposure potential are during the overhaul phase, as you know, and during pump operations for the engineer standing at the pump -- you know, standing at the pump panel primarily to diesel exhaust. And then station exhaust, which sounds like has been controlled in Orange County pretty well. And then wildland firefighting where there's no respiratory protection at all. And of course during overhaul no respiratory protection is used at all. So I just wanted to make sure that those sort of exposure sources would be captured in the survey process.

DR. McNEEL: This is Sandy McNeel again.

And on the exposure questionnaire, we do ask questions, not only about when firefighters wear their PPE, but when they take it off, when they take their self-contained breathing apparatus off; and give them a couple of options, you know, for why they're removing it perhaps before an all-clear or a clearance statement is given.

So we're trying to get at that, as well as asking about different types of firefighting and/or other incidents that the staff are involved in.

So, we do ask about different types of fires in industrial, commercial complex, residential, wildland

fires. And so, again, considering that we're looking at a fairly small population here, we're hoping to get kind of an idea of what sorts of exposures in certain timeframes. We'll have the last year -- six months to a year from the WEFIT questionnaire, and we ask over the last month for the -- in the FOX questionnaire itself.

PANEL MEMBER WILSON: Thank you.

CHAIRPERSON LUDERER: Dr. Bradman just reminded me that -- Ms. Whitman mentioned the question of diesel exhaust, and we weren't sure whether you're aware of it, diesel exhaust is one of our designated chemicals that the Panel designates. So we thought you might be interested in knowing that.

At this point then our next topic is Chemical Selection Planning. And that's going to be -- that presentation's going to be given by Dr. Gail Krowech, who is a staff toxicologist with OEHHA.

Dr. Krowech.

(Thereupon an overhead presentation was Presented as follows.)

DR. KROWECH: Okay. Well, the purpose of this agenda item is to update the Panel on OEHHA's research on possible candidates for designation and to initiate discussion on general chemical selection questions.

In addition, we have one technical listing issue

we'd like to address.

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DR. KROWECH: So this is a slide of the candidates that have been researched so far. Some of them are more researched than others. But the idea is really just to give you an idea of what we have been looking at and to get some input on which areas to delve into more deeply.

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DR. KROWECH: And I'll start with the plasticizers, which the Panel has expressed interest in looking at what plasticizers are replacing the common phthalates.

And here's a list of some of them that I have found. I feel that perhaps I have scratched the surface. It's hard to know what else is out there. But looking at different sources, this seems to be many of them. I can put it that way.

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DR. KROWECH: And this next slide is a table of examples of high volume plasticizers that may be used as substitutes for the common phthalates. And I will be talking about three of these in a little bit more detail in the next few slides.

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DR. KROWECH: The first one is diethylhexyl adipate (DEHA). And that is -- the U.S. production import volume is between 50 and -- reported as 50 to 100 million pounds reported in 2006. It's used in food wrap film plastic packaging as well as many other applications.

In a recent study in northern California homes, it was found in the air of 100 percent of the homes in Richmond and Bolinas.

And there is a recent biomonitoring -- small biomonitoring study reported from China.

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DR. KROWECH: This next one is tri-2-ethylhexyl trimellitate, which looks an awful lot like a phthalate except that it has an additional ester side chain.

It's used in electrical cable installation, medical products, car interiors. And reported in food contact materials as well.

The Consumer Product Safety Commission, when they were looking at possible phthalates substitutes, thought that this plasticizer would be less likely to migrate from products because of its bulkier structure and high molecular weight.

There are some recent studies that indicate though that there still is leaching from medical tubing.

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DR. KROWECH: This is di 2-ethylhexyl terephthalate, which is a phthalate. It differs from the orthophthalates only in the location of the ester side chain.

And it's used in vinyl flooring, toys, coatings for clothing. It's sort of a general purpose plasticizer.

Its use in the United States -- the reported use has increased since from '86 to '94. It was reported from 10 to 50 million pounds. And that use has increased with the last three reporting periods.

It also recently had an expanded market in Europe. And there was a recent study of house dust in from Germany, which was part of the German environmental survey where they looked -- I think there were almost 600 homes that they looked at dust through vacuum bags. And in the period that they put together between 2003-2006, there was less than 20 percent of the samples had DEHT. In a small additional study in 2009, it had markedly increased to 94 percent.

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DR. KROWECH: Now, this plasticizer is not a high production volume chemical. It's DINCH, diisononyl cyclohexane - 1,2-dicarboxylate. And it is the non-aromatic analog of diisononyl phthalate.

It was introduced in Europe in 2002, at first

just for use in medical products and toys. But that use expanded in 2006 or 2007, now includes food wrap film and more food contact materials as well. And studies have shown that in food with high fat content, it does migrate from the plastic wrap.

In the same house dust study from Germany that I just discussed, they again looked at the levels of DINCH that they were finding in house dust and they saw dramatic increases in all the points that they looked at. And most recently the small study in 2009.

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DR. KROWECH: And maybe I'll stop for any clarifying questions on these plasticizers.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: It's very interesting to see all these new chemicals, testing my knowledge of organochemistry.

I guess -- I mean I think the question that we struggle with - and you do too - is how do we really sort through these or find -- because probably the ones in Europe, there must be some guidelines there for some preliminary toxicity testing on chemical properties.

But it is -- it's, you know, the classic example of the evil we know is being substituted by, you know, some -- I mean there's -- as much as we know, there's

always going to be some sort of need for an adaptive -- some sort of adaptive planning so that we don't flood the market, you know, with 30 percent of a new product -- or 30 percent of the market for vinyl floor is suddenly at a new -- whatever the compound was here. And then we go, "Oops," you know, and start all over again.

I mean I actually think not only is biomonitoring sort of a useful sentinel, but I think we have to think more about not getting to the point where we're biomonitoring these substances but, you know, trying to anticipate something about their behaviors. And I think that goes on. But I think it would be nice for us to find out a little more about what kind of upfront screening goes on for these things so we can set our own priorities or listen to your priorities and then comment on them.

DR. KROWECH: Okay. Thank you.

And that's really kind of, you know, what we hope to do with this session here, is to get your feedback on what we should be looking for -- how we should approach this, you know, as we go on in terms of looking at these this particular class and other ones.

PANEL MEMBER McKONE: Just to clarify. How do you want that feedback in terms of -- there are programs -- EPA in their -- has a toxic screening program that is intended for this sort of thing. Is that the sort

of -- or do you -- yeah, I mean you want to do this on a longer term basis. But there's certainly some things I'm aware of - and I'm sure there are more in other countries - but there are programs at EPA for exposure and toxicity screening just based on chemical properties or limited data. I know the European Union demands a lot more information on new substances. And most of these seem to be in commerce in Europe, so they probably have done some of that already.

So I think what we need to do is just kind of make sure we don't miss an opportunity to get that kind of information.

DR. KROWECH: Right. This is just sort of the beginning of looking at these.

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DR. KROWECH: Okay. This next chemical is also a plasticizer, but it's a non-halogenated flame retardant.

It's used in polyurethane foam. It's a component of Firemaster 550, which is the major substitute for PBDEs.

And as a plasticizer, it's used in the manufacture of polyester and in products such as paints and varnishes.

The U.S. volume in 2006 was reported as 10 to 50 million pounds.

There's a recent study in house dust of 50 men from an infertility clinic. And levels in house dust were significantly associated with decreased sperm concentration and increased serum prolactin.

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DR. KROWECH: If don't know if there are any questions about this chemical.

PANEL MEMBER McKONE: Just the last chemical.

DR. KROWECH: Triphenyl phosphate.

PANEL MEMBER McKONE: That's an OP, right? It's an organophosphate?

DR. KROWECH: Yes.

PANEL MEMBER McKONE: Okay. So I mean does that -- you know, I know there are lots of organophosphates. But did that raise a flag when it was --

DR. KROWECH: Well, originally I looked at organophosphate plasticizers because they were on a list of some of the plasticizers that are used as replacements. And I haven't seen triphenyl phosphate used in that way. But since it's a high volume chemical, it's important in California because of the PBDEs replacement. I wanted to at least do something on it and put it -- you know, put it in front of you and see, you know, what we all thought of it.

PANEL MEMBER McKONE: I think this comes back to what we talked about earlier, is one of the -- I guess I brought this up earlier about flame retardants. Because there's such a large demand for their use in California and elsewhere, it's something we really have to keep our eye on, because just to meet the standards it's going to take a very high volume. And to be a useful flame retardant, they have to be persistent. So, you know, we're going to keep running and -- we will find them in the environment unless, you know, somebody decides to go back and use wool, which is not so flammable, to make furniture.

DR. KROWECH: Okay. The next several slides --

CHAIRPERSON LUDERER: I think we have one more question.

DR. KROWECH: Oh, sorry.

PANEL MEMBER WILSON: Just very quickly. You know, I'm curious if there's any evidence that you've seen that the triphenyl phosphate has any of the properties, the neurotransmitter effects that the organophosphate pesticides produce.

DR. KROWECH: You know, I did not look at health effects at all. I didn't look at the toxicity. I just felt that as a first stab at these plasticizers was just to look at what was out there. So if the Panel is

interested in it, I can do that, look at it in terms of --

PANEL MEMBER WILSON: Yeah, thank you for bring it to our attention, for sure.

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

PANEL MEMBER BRADMAN: I just want to clarify. I presume at the end of this discussion your goal is to have some recommendations from us on which of these candidates --

DR. KROWECH: Absolutely.

PANEL MEMBER BRADMAN: -- to look at.

So I mean I think non-halogenated flame retardants is going to be a big one. But maybe we can wait for the discussion on that.

So I should say, no, I don't have any questions about this individual compound. But I do have a lot of discussion related to it when we get there.

DR. KROWECH: Okay. So the next several slides relate to emerging drinking water disinfection byproducts.

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DR. KROWECH: And by way of background, these are the disinfection byproducts from chlorine disinfection that U.S. EPA regulates: Four trihalomethanes and five haloacetic acids.

And regulation has driven a switch to alternative

disinfectants, such as ozone and chloramine.

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DR. KROWECH: And I'm going to give chloramination, chloramine, as an example because it's widely used in California water treatment as a secondary disinfectant.

So I'll start by: What is chloramine?

And when chlorine is added to water, it forms hypochlorous acid. Ammonia reacts with hypochlorous acid to form chloramines.

And chloramination, this process, produces significantly lower levels of regulated trihalomethanes and haloacetic acids.

And as I said, it's widely used in California.

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DR. KROWECH: However, compared to chlorination, it increases n-nitrosodimethylamine (NDMA), nitrogen-containing disinfection byproducts such as halonitromethanes, iodine-containing disinfection byproducts such as iodoacetic acid, and haloaldehydes.

Some of these depend whether or not their increase depend on certain conditions. But in general, they are increased.

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DR. KROWECH: CDC has done some studies on these

emerging disinfection byproducts and has published a method to look at halonitromethanes measuring nitromethane in blood. They also have a method for measuring iodine-contain trihalomethanes.

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DR. KROWECH: So, again, if there are any clarifying questions, I can answer them.

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DR. KROWECH: Okay. So I have done some preliminary looking around at two organotins - tributyltin and dibutyltin.

Tributyltin compounds in the past were used as biocides in paints on underwater surfaces to prevent the buildup of barnacles, for example.

Currently, the known uses are as biocides in textile products, such as carpets; in formulations used in hospitals and livestock facilities. And they're also used in wood preservatives.

One known exposure pathway is from diet, from fish and shellfish.

There are many concerns about tributyltin compounds. There's a lot of research showing that they are endocrine disrupters, that they are obesogens. Tributyltin methacrylate is listed under Proposition 65 as a developmental toxicant. And there's research on immune

suppression.

A biomonitoring study -- small biomonitoring study in Michigan in the late nineties found tributyltin in 70 percent of subjects.

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DR. KROWECH: And so this next slide is on dibutyltin compounds, which are primarily used as stabilizers for PVC plastics; and they're also used as catalysts for silicone production.

So exposure can be from drinking water from PVC pipes. Particularly pipes that have been cut seem to deliver a lot more dibutyltin.

And products prepared with something that had silicone in it. One example that was shown in a recent paper was baking parchment had 140 micrograms per gram dibutyltin. And the cookies baked on that parchment also had dibutyltin in them.

A study in New York, a recent study, showed dibutyltin in house dust with a very high range. And certain products that were PVC-based, when they looked at the dibutyltin levels in them, they were also very high.

Concerns about dibutyltin are neurotoxicity and immune suppression.

And, again, the same biomonitoring study found dibutyltin in the blood of 81 percent of subjects.

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DR. KROWECH: Are there any clarifying questions on this area?

CHAIRPERSON LUDERER: A quick question about tributyltin.

I have a vague memory that when we were looking at pesticides that are used in California, that organotins, or maybe it was tributyltin specifically, was on that list somewhere. Am I remembering that right?

DR. KROWECH: You know, I'd have to look it up. I'm not sure.

I think triphenyltin --

CHAIRPERSON LUDERER: Oh, triphenyltin. Okay.

DR. KROWECH: -- had been used. And I'm not sure that it still is used.

CHAIRPERSON LUDERER: Okay.

DR. KROWECH: I'll look that up.

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DR. KROWECH: Okay. Nonylphenol and nonylphenol ethoxylates is another area that we've looked at.

First of all, nonylphenol is not a single a chemical, but it's a mixture mostly of branched compounds. And its U.S. production import volume in 2006 was estimated to be between 100 and 500 million pounds.

Nonylphenol itself is used to make nonylphenol

ethoxylate. It's also used as stabilizers and antioxidants in plastics. And of course is a degradation product of nonylphenol ethoxylates.

Nonylphenol ethoxylates are used in detergents, cleaners, degreasers, pesticides - a wide variety of applications.

In terms of exposure, there's a house dust study in 2003 that looked at nonylphenol in Cape Cod, Massachusetts, and found nonylphenol and nonylphenol ethoxylates in 80 percent of the homes.

And a recent indoor air study in California found nonylphenol in more than 95 percent of homes. Also nonylphenol monoethoxylate was also found in greater than 95 percent of homes.

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DR. KROWECH: In terms of detection in biomonitoring studies, CDC measured 4-n-nonylphenol in urine in a study and found -- detected it in 51 percent of samples.

Since 2008-2009, there have been more studies that have detected nonylphenol in samples in adipose tissue, in blood, and in breast milk.

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DR. KROWECH: Any clarifying questions?

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DR. KROWECH: Okay. This last slide sort of puts together a lot of work that -- ongoing work that we have done in looking at the pesticides that -- top pesticides that are used in California in terms of the pounds applied. And I have just put five of them on this table that could be selected as ones to investigate further:

Glyphosate, because of the large volume. Also, there are a number of papers that are out now about endocrine disruption. And it has non-agricultural use.

Propanil, also very high volume. It's a dichloroaniline herbicide. A contaminant was recently studied by NTP, and they found -- the results just recently came out. It was clearly carcinogenic in both mice and rats. And it's a contaminant in all dichloroaniline herbicides, but it's highest in propanil.

Oryzalin is a Proposition 65 carcinogen.

Propargite is also a Proposition 65 carcinogen, as well as a developmental toxicant. And a recent study suggested a possible role for propargite in Parkinson's disease.

And, lastly, imidocloprid might be of interest because of the high consumer use as a pet pesticide.

--o0o--

DR. KROWECH: So here are the discussion questions, which -- the main one is: Are there particular

candidates that the Panel recommends we investigate further? And just sort of as a wrap-up every one that I've mentioned.

And also another way of looking at this is: Are there particular criteria that the Panel views as the most important for us in selecting candidates to bring forward; such as, should we look primarily at exposure, should we look at health effects? How should we -- what is the best way to approach our looking for candidates?

CHAIRPERSON LUDERER: Dr. Solomon, do you -- you just looked like you were --

PANEL MEMBER SOLOMON: I mean I for awhile have been very interested in the emerging disinfection byproducts; and I continue to be very interested in them just because I think that that's an important set of chemicals that is likely to be getting into people and that is likely to also be on the rise. And so it would be helpful not only to us but, you know, to U.S. EPA and other entities to begin to get a handle on that.

So that's a set of chemicals that I would be really interested in learning more about and potentially in designating.

And I have to say that organophosphate, I think there was a little buzz in the Panel here when the structure, you know, went up. And it just seems like it

would -- you know, just based on the organic chemistry of this chemical, it seems like it would be very interesting to learn more about it.

So those were the two that jumped out at me most strongly. But I think that there are a lot of really important candidates on this list.

And I actually did not -- I had not considered the organotins to be a significant current problem, because I thought of them as anti-fouling agents that were mostly going out of use. And so this was brand new to me. I'm still sort of digesting it. But maybe, you know -- it certainly got my attention.

So that's pretty much where I am on my thoughts.

DR. KROWECH: Okay.

CHAIRPERSON LUDERER: Dr. Quint.

PANEL MEMBER QUINT: Julia Quint.

I want to thank you for this really stimulating and well researched presentation.

In terms of criteria, I like both exposure and health effects. And I really like the way you've approached this in terms of, you know, the emerging substitutes, because I do think that, you know, it's really important to look at what's coming on to the market, as several of my colleagues have said.

And of those, the non-halogenated flame

retardants - and I think Dr. McKone talked about that - you know, there's all -- for things that we know are a safety issue or we know there's going to be a substitute because there's another concern that's compelling, you know, fires, I think that's -- it's very important to look at those. And as are the pesticides. I mean you had several pesticides on there that were, you know, of serious chronic health effects and in large volume use.

So I think the -- and I think you've done a good job of selecting which ones, you know, are potentially of interest. I think the thing will be is how to narrow this, because -- and I think the only way to narrow it is to have a -- frankly, to have a policy where you test before you market, in my opinion, because -- I mean basically this is what we're always involved in. And what I've been involved in forever is looking at the new chemical replacing an old chemical with different health effects. And, you know, there's a limit as to how many of these things you can keep up with.

And I think the triphenyl phosphate, I think I researched that for another -- something I was working on. And I think it does have -- is it an endocrine disrupter? I mean I seem to remember some unique toxicity about this chemical, I believe.

So my perspective, a quick, you know, sort of

pubmed toxnet review, I've always found helpful. I'm always researching chemicals that I have no idea what they are, and I'm always surprised sometimes about what I find. And I think one of those chemicals -- I think that particular chemical had some unique toxicity.

So, you know, I don't know how we will choose. I think within certain ones, like the pesticides, the very last one which we didn't have health effects data but it's being used on pets, I think potentially could be important. But if I had to rank those, I would go with the ones that we know have known toxicity and/or are in high volume use in California. Those two things to me make them very compelling.

But I just really appreciate the work. I think it's really good.

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

PANEL MEMBER WILSON: Yeah, Mike Wilson.

Thank you very much, Dr. Krowech, for that presentation. And, again, echoing Dr. Quint's reflection that we're trying to get out in front of what's emerging. And, again, it just raises this fundamental issue that we're struggling with in California of how do we generate a minimum data requirement for chemicals and products sold in California, and a minimum data set, if you will. And

if that's on the hazard side, it would be helpful. But it would also be helpful to have use and sales information, and we can get a sense of where the industry is headed.

And so I mean this sort of illustrates the nature of that problem. And it's probably a larger discussion about how or in what way either this Panel or OEHHA could communicate that problem, because we're seeing it, you know, in real life, in realtime unfold in front of us.

So I'm just -- I guess I'm just putting that out there as, once again, a pressing need that we need to tend to.

And then I have a specific question about the pesticides. If these were -- in looking at these, were these pesticides that appear to be growing in use in California, from looking at the DPR trend over the last several years? And then did you select these because of that or because of their volume in commerce -- or, you know, the volume -- I'm sorry -- their pounds applied or for their possible health effects? I'm just curious why those ones were selected.

DR. KROWECH: Basically from the pounds applied and health effects, except for the last one, which was just the consumer use. I didn't look at trends. I had in the past looked at trends and tried to find increasing ones. And so I actually just don't recall if any of these

were part -- were increasing or decreasing. And that would be something to do before we move forward on any of them.

PANEL MEMBER WILSON: If I could just follow up.

It seems that these -- these are fairly high volume, if I remember though, are numbers from, you know, previously, around pounds applied, six million pounds for the glyphosate and so forth. These seem like high use pesticides. Is that where they fall in your mind?

DR. KROWECH: Oh, absolutely. They came from the list of the most hundred -- you know, the top hundred pesticides in terms of the pounds applied. And glyphosate is, you know, way up there.

And also there's more than one product of glyphosate. And this is only -- actually it's agricultural use. So anything that is sold commercially is not included in that.

PANEL MEMBER WILSON: Okay.

CHAIRPERSON LUDERER: Dr. Bradman I think was next. Then Dr. Culver and then Dr. McKone.

PANEL MEMBER BRADMAN: I think that the big picture comments that have already been made I would agree with. That exposure and health effects are what we want to consider or what I would think is important. And then trends in California. I mean this kind of echoes our

earlier discussions.

On the more smaller picture level, you know, I think there's a lot of interest with the non-halogenated flame retardants. And that particular compound may be one, but there's others as well. And that's certainly consistent with growing use in California likely because of the PBDE phaseout.

With the pesticides, I think imidacloprid is something that we should consider very seriously. Again, the small picture issue. But it's used a lot in pets. It's also being used for structural pest control, so it's being used directly in homes. It's becoming a substitute for chlorpyrifos as a termiticide. So I think that's something that should be looked at closely.

And then with the other categories, again I think more information about use trends, and perhaps using some of the DPR data might help us prioritize. And then again, I think -- the assumption was also earlier that these are not currently being tested by CDC, and there's no plans to.

DR. KROWECH: Right, not that I know of.

PANEL MEMBER BRADMAN: Okay.

CHAIRPERSON LUDERER: Dr. Culver.

PANEL MEMBER CULVER: When we talked about criteria before, we also talked about biopersistence and

bioaccumulation. Do we have information about any of those properties with regard to these compounds?

DR. KROWECH: Some of them. And in terms of the plasticizers, I don't think any of them were considered bioaccumulative. So I tried to look at that. Although they had logged KOWs that would be consistent with that, but that hadn't been found.

So I haven't gone through and done that thorough of research in terms of the persistence and other factors, and in terms of really any of them. This was just really to sort of give you an overview. And then I think -- definitely before bringing anything forward as a potential candidate, we would go through and look at all of those factors.

PANEL MEMBER CULVER: It's a big job.

(Laughter.)

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: Yeah, actually hearing all of this, I wrote down a table. I'd like to propose something fairly specific to help us out, which is a table with -- let's see, I think I have five columns here -- as a way of organizing. Because we did this before with pesticides when we were looking at a lot -- I remember with Dr. Wilson and I and others tried to organize this. So it would be nice to have a table that for each

substance gave us the volume of use, which you have but it's kind of -- and the type of use, right, is it used residential, water, and then give us some help like how much and where.

Then any estimate of environmental persistence, first thing. A lot of these, like flame retardants, we know are persistent compounds, because they don't work as flame retardants if they don't stay where they are a long time. But they don't stay -- not all of it stays where it's supposed to.

And then some measure of either bioaccumulation or internal persistence.

So there's external -- you know, environmental persistence and then biological persistence. Which actually bioaccumulation is a proxy for biological persistence. So either one of those, if somebody knows something about the reservoir time in the body or...

And then again you have these exposure measurements. But it would be nice as we go across the column then to see, okay, these are indicators of exposure, but let's see what have people actually found, what levels have they found relative to the level of use. And then the -- so the next one would be summarizing any of these dust levels or blood -- any existing biomarker data or something that would indicate exposure relative to

use.

And then finally a summary of some measure of toxicity. And that actually could be maybe more than one column. I just have one column, because I'm an exposure scientist. I put toxicity over on the end.

(Laughter.)

PANEL MEMBER McKONE: But I think if we could look through that kind of organization. And it isn't -- I mean I think a lot of it is already here. But seeing it and going down, we could say, oh, look, here's high volume, high toxicity, low persistence. Here's something that -- oh, high volume, high persistence, high bioaccumulation. We would say, oh, this has got to go in. And it would help.

But in spite of my being very organized, I still would -- I'm biased towards the flame retardants simply because we know that they're used in large volume, we know they're used in a residential context, and we know it's a really critical issue. So if I had to do something today, I'd probably favor starting with those and then -- I mean I think they're good reasons for moving to the others.

But I think it would help us --

DR. KROWECH: Okay.

PANEL MEMBER McKONE: -- better to organize it a little more that way. And I'd be happy to help with a

little bit of that, at least the screening -- persistence screening --

DR. KROWECH: Great.

PANEL MEMBER McKONE: -- things like that.

OEHHA DIRECTOR DENTON: Dr. McKone, you know, we've been involved in the last six months, eight months in developing hazard traits for the green chemistry. We have -- gosh, how many hazard traits do we have? And these include exposure potential, this includes chemical properties, this includes toxicity. I mean we've thought through a lot of these things, you know, that -- your table. I mean that's exactly what we've been developing but in a much broader, you know, a much more I guess comprehensive way, you know, trying to think of all the hazard traits and the properties.

That clearinghouse -- that's going to be used to populate the clearinghouse that DTSC will be responsible for. And that's likely not to really materialize, you know, for a year or two. But I mean we could look at those -- I mean we've done a lot of thinking on exactly what you're, you know, mentioning. And maybe even look at potentially categorizing or looking at these chemicals in the light of those traits that we've already developed.

PANEL MEMBER McKONE: Yeah, actually that's the sort of thing I was thinking of when I went through --

because it's done in -- it's done in California. EPA is coming up with something similar. The people -- the international community doing life-cycle impact also does these sort of use persistence, fate persistence, biological persistence, and then toxicity.

Now, I'm not sure all of these are in those different databases. But if we look through them -- and it isn't a lot of work. You just have to look at these emerging databases. And we may get half of these covered without a lot of work.

CHAIRPERSON LUDERER: Okay. So I'm not sure that we've narrowed things down too much for you as a panel here. It sounds like there's a lot of consensus among the Panel members for the non-halogenated flame retardants in particular, but that many of the other classes of compounds that you discussed. So --

DR. KROWECH: Well, that would be a good start.

CHAIRPERSON LUDERER: -- I would think we would like to hear more about.

DR. KROWECH: That's great. Actually I have two more slides.

So the next is about priority chemicals. I just want to let you know that reconsideration of priority PAHs is planned. But I'd also like to ask if there are other already designated chemicals that the Panel would like to

see as potential priority chemicals -- or as priorities?

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: I think there was concern at the last meeting that we already had too many priority chemicals. And so, you know, I still -- I'm not sure -- at that point -- I haven't looked at the list recently. But at that point I wasn't seeing others that I thought urgently needed to be moved up. I think the only one that could fall into that category was -- I guess we designated triclocarban at the last meeting. And triclosan I think, as I recollect, is a priority. And they sort of -- in terms of uses and so forth, they kind of run together. So that might be the only one I would consider at this point.

DR. KROWECH: Okay. And we have one technical listing issue that Sara's going to talk about.

MS. HOOVER: So hopefully this will be really brief.

And just to explain what we mean by this. So, for example, the Panel has previously moved the entire group of phthalates that were already designated over to the priority list. However, the class of phthalates is not on the priority list.

So we realized that this -- what came up is that CDC has -- in their updated tables for the fourth report, they've reported on some additional phthalates, for

example, di-isodecyl phthalate, which we can automatically add to the designated list, but technically wouldn't fall in to the priority list because of how we -- because of how we prepared that priority listing for you. So we said those that were already designated.

So what we wanted to come back to -- we figured that the Panel would actually want the additional phthalates that appear on the designated list to also still be moved over because of the intent of -- or kind of the sense of the Panel was that group of chemicals was important. But we didn't feel like we could go ahead and do that without bringing this back to you and saying, "Do you agree that we would just automatically add?"

So it's a very specific case just where a group of chemicals being measured by CDC, the Panel moved that whole group over, and now CDC has added to that group, would the Panel want us to go ahead and add those rather than having to bring each one individually back as potential priority chemicals? So that's what this question is, just to get your approval for that proposal.

CHAIRPERSON LUDERER: Yeah.

PANEL MEMBER McKONE: I move that we approve.

PANEL MEMBER WILSON: Second.

CHAIRPERSON LUDERER: I see a lot of head nodding.

Should we take a formal vote or just --

MS. HOOVER: So I'll take that as a "yes".

Okay. Thank you.

CHAIRPERSON LUDERER: All right. Do we have any public comments on the last -- looks like we have one.

Do we have any others?

Just the one. Okay.

This is Deborah Whitman, President, Environmental Voices.

MS. WHITMAN: Thank you. And it's been a long day. I'll try to make this as quick as possible.

There's a -- first of all I wanted to go over the list of chemicals that we were kind of recommending, if they're not on your list, that you consider those again. We're talking about depleted uranium or uranium, a radioactive material; aluminum; strontium, which is radioactive; sulfur hexafluoride, it blocks oxygen to the heart and causes asphyxiation; arsenic, which we're finding these chemicals high in water saplings; barium; and titanium. The reason I'm including titanium is we're finding it in the tree bark. We haven't tested humans with the titanium yet, but it does build up in tissues with silica. And that's why we're doing it on the tree bark tests.

The other thing that I wanted to talk about --

you mentioned something about chlorine, and I haven't researched enough of that. But I want to tell you a little story with my experience with chlorine. My parents owned a swimming pool company in Redding called Shasta Pools, Patio and Things. They have one in Redding -- or did, in Red Bluff, and a couple other locations. But I worked there many years ago, and so did my mother, who also suffers from multiple chemical sensitivities. They used to have to lock their chlorine in a room near where we used to work.

And my stepbrother had a van that I wanted to buy. And he refused to sell it to me, and I couldn't figure out why. And he says, "Look at this." And he showed me the inside of the van and he showed me the chrome bumper on the van, and he said, "This van's toxic. See how it's corroded. It's from the chemicals that we used to haul."

So I've always been concerned about chlorine in swimming pools and felt that public swimming pools should have notices up there and studies should be done on that. So, you know, that's another issue.

Then this one might shock you. But I'm going to tell you I used to work at Franchise for the last 18 years. I worked 26 years with the State of California as an analyst, and primarily in contracts. I worked the last

18 years at the Franchise Tax Board.

And my very first contract with the Franchise Tax Board was to have toxic chemicals containers hauled out from a company that had to haul them out. And these were toxic chemicals that were used in the air handler system for all of our air there at Franchise Tax Board. That's when I started becoming the sickest, and I would complain that it was the toxic building. And they assured me that they've done all the tests for CalOSHA and there was nothing wrong. But there's all kinds of employees complaining about how toxic that building was.

Now, this building is toxic as well, because I used to also -- not only as a small business advocate for Franchise Tax Board, I was the recycle coordinator. I had to come to this building for meetings. And every time I'd come into this bidding and into this room, I get sick, and I'm getting sick now.

So I brought this up to people here at the EPA about checking the chemicals that you use in the air handlers or why this building's toxic. Basically I've had a manager tell me that they know that the State buildings are toxic, and that they can't do anything about it because of the cost to replace the system.

So, again, I'm going to stress that maybe you do a study on the employees in this building; the employees

at Franchise Tax Board, because their new building they just built is just as toxic as the old one that I used to work in.

So, anyway, I encourage you to check on that with these buildings, and especially the chemicals used in the air handling systems and the air systems.

Lastly -- let's see. No, it's not really last. Number 4 -- I did a lot of writing. Let's see. Yeah, I just wanted to mention too that I was going to move out of the State -- I had to retire because I was so sick that I couldn't work. And I still wanted to continue working at Franchise Tax Board. But I'd been sick for many years, only to find out that I suffer from multiple chemical sensitivities.

And so there's so many military bases in California that I found out have toxic waste sites. There's factories in California. There's agriculture burning that -- you know, I don't understand why the State of Vermont has agriculture and they don't allow burning there. My father was sick in Redding for two years, dying, and I would want to go up and visit him at the nursing home. And I couldn't do that because they were burning so much burning -- agriculture burning. They burned from about October through March that I couldn't drive up there.

So I encourage you -- this is October and November -- to maybe take a drive between here and Redding, and see how many fires that you see are burning. So that's another area of study that you might consider.

But I just wanted to state that after today and coming here, that I am so happy that you guys are taking this on and that you're looking into these issues. Because I'm finding out -- almost every woman that I talk to is suffering from illnesses that I can relate back to toxic chemical exposures. And I don't know why it seems to be affecting women more than men, but I think that's because men maybe do not complain as much as women do. I don't know.

But it's serious, and it's a lot more serious than most people even understand. And I've been trying to educate people about these issues for at least the last six years that I've been aware of why I was so sick. And because I don't have a Ph.D behind my name, nobody will listen to me. So I'm just glad that you guys are all Ph.D's and M.D.'s and taking this issue very seriously.

And, lastly, I just want to thank your staff, because I think they've done an excellent job with the presentations and the research that they've done. And I look forward to working with them in the future.

So thank you very much.

CHAIRPERSON LUDERER: Thank you very much for all your participation and comments today.

Okay. Do we have any final comments by the Panel members before we move on to our -- Sara.

MS. HOOVER: No, I was nodding to move on.

(Laughter.)

CHAIRPERSON LUDERER: All right. I'd like to -- yeah, we have two things. Dr. McKone would like to bring up a proposal for the Panel to consider.

PANEL MEMBER McKONE: May I? All right.

As many of you may know now, Larry Needham died on October 23rd. He had fought for two years with renal cancer. And, you know, he was a real pioneer in the field of biomonitoring. He spent 34 years at CDC and essentially built up the program that we now use as our model. So I think we owe him a great deal.

Also, he was -- he came out to California to join us for the SB 702 working group on -- what was it called then? -- Health surveillance, not health tracking. And some of us were on that committee with him, and he was really devoted, you know, to helping the state build a program on health tracking.

So he's done a number of things for the State, and I think he's been an inspiration for all of us. And it's a great loss. He was only 64 years old. And as I

approach 60, I realize that's a young age.

So I would like to propose that we issue some sort of a letter or a formal statement on behalf of this Panel, you know, to his family recognizing his accomplishments and offering our -- you know, our condolences, and then expressing how much we valued his work and his participation in our efforts to do health tracking and biomonitoring within the State of California.

CHAIRPERSON LUDERER: I think that's an excellent idea. And I think the other Panel members agree.

Would you be willing to take the lead and draft a letter?

PANEL MEMBER McKONE: Yes. It might take me a couple of days to get on top of it.

CHAIRPERSON LUDERER: Okay. Great.

And Dr. Das is going to -- I would like to reintroduce Dr. Das, who's going to make an announcement.

DR. DAS: Thank you, Dr. Luderer.

I wanted to announce some not very happy news. I want to announce that Diana Lee is planning to retire at the end of the year. And I just wanted to say a few words about her. Some of this comes from Dr. Michael Lipsett, who worked with her for a long time. And I'm sorry that Diana had to leave early and isn't here to hear this. But I just wanted to recognize her contributions to the

program.

And there's a lot, so I'm going to -- please pardon me, I'm going to read it.

Diana has played a central role in launching the biomonitoring program in which she has had a keen interest dating to well before the enabling legislation was finally passed in 2006. After its passage she worked closely with other CDPH staff to identify and organize CDPH's resources needed to establish and administer this program.

She had a major role in assembling, writing, and organizing our proposal to CDC that brought us over $2.6 million a year to California for five years and really is allowing us to do so much in this program.

She was pivotal in allowing us to start the maternal-infant exposure project. And you've seen the great strides we've made in that project, primarily due to her diligence.

There have been many, many behind-the-scenes tasks that she has done to help propel and maintain the program. For instance, the original legislation called for the establishment of a statewide representative sample of biomonitoring participants which would have been modeled after the CDC's Biomonitoring Program.

Diana managed a contract for a year and a half with the National Center for Health Statistics which

involved our working closely with the CDC managers responsible for NHANES. As a result, we actually have an excellent plan for a statewide biomonitoring program that is ready to go should the economy recover enough to support it.

She has helped to showcase the program by organizing biomonitoring panels and making presentations at national conferences, helping us to establish linkages with similar programs throughout the world.

Also having participated in the program even before its formal inception, she has an encyclopedic mental filing system of nearly everything related to biomonitoring in our department.

Of course administering a program in State government comes with lots of bureaucratic requirements, which Diana has helped us meet repeatedly without complaint and with incredible energy, including supervising an external contractor to identify and specify the massive IT requirements for a statewide program.

Diana has served as a mentor to our junior staff as well.

She's been a huge asset to the program. And I think I speak on behalf of all the staff in our department and in the program in general. And we will really miss her as a colleague and as a friend.

So I want to thank Diana even though she's not here.

Thank you.

CHAIRPERSON LUDERER: Thank you very much, Dr. Das. We also will miss working with her. It's really been a pleasure working with her these last few years, as we've worked together here on on the Scientific Guidance Panel. And will she be at the next meeting?

DR. DAS: I should have said that the reason I'm making this announcement at this meeting is that she will most likely not be here at the next meeting.

CHAIRPERSON LUDERER: Okay. The final item on our agenda then tonight is Dr. George Alexeeff is going to give a summary of the recommendations that the scientific Guidance Panel has made today.

DR. ALEXEEFF: Hello. I'm George Alexeeff of the Office Environmental Health Hazard Assessment.

So first, I will summarize the actions of the Scientific Guidance Panel. The Panel voted to add manganese to the designated chemicals list and recommended that we conduct more research in areas, such as pharmacokinetics before bringing it back to the Panel for consideration as a priority.

The Panel also voted that chemicals newly measured by CDC in groupings previously recommended as

priority by the Panel should be automatically added to the priority list.

And then the Panel also plans to write a letter to the family of Larry Needham regarding his accomplishments and offer condolences.

The Panel also gave recommendations regarding a number of the updates, including the public involvement plan, the biomonitoring reference levels, and workshop in the spring, chemical selection planning. And in particular on chemical selection planning, they recommended for further investigation, particularly non-halogenated flame retardants, and also emerging disinfection byproducts and pesticides, suggested that criteria be based on primarily exposure, such as high volume use or health effects, known toxicity, trends in California, biopersistence and bioaccumulation. And then there was a suggestion of recommending how we might present data, in terms of volume of use, type of use, persistence, bioaccumulation, exposure measurements toxicity and considering the hazard traits compiled by OEHHA for the green chemistry program.

Thank you.

CHAIRPERSON LUDERER: Okay. Before we completely adjourn the meeting, I just wanted to remind everyone again that the latest versions of all the presentations

that were made at the meeting today and supporting documents will be -- you can find at the biomonitoring website www.biomonitoring.ca.gov.

And I also wanted to announce that the next Scientific Guidance Panel meeting will be held on March 16th in Oakland, followed on March 17th by the biomonitoring reference level workshop that we discussed earlier this afternoon.

So thank you all for coming and I look forward to seeing you all again in March.

Thank you. The meeting is adjourned.

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 5:01 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 17th day of November, 2010.

JAMES F. PETERS, CSR, RPR
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