MEETING

STATE OF CALIFORNIA

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

THE CALIFORNIA ENDOWMENT

OAKLAND CONFERENCE CENTER

7TH FLOOR, LAUREL ROOM

1111 BROADWAY STREET

OAKLAND, CALIFORNIA

FRIDAY, MARCH 13, 2015

10:04 A.M.

JAMES F. PETERS, CSR, RPR
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A P P E A R A N C E S

PANEL MEMBERS:

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

Scott Bartell, M.S., Ph.D.

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

Marion Kavanaugh-Lynch, M.D., M.P.H.

Thomas McKone, Ph.D.

Penelope (Jenny) Quintana, Ph.D., M.P.H.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

Dr. George Alexeeff, Director

Mr. Alan Hirsch, Chief Deputy Director

Dr. Lauren Zeise, Deputy Director

Ms. Amy Dunn, Research Scientist III, Safer Alternatives Assessment and Biomonitoring Section

Mr. Mario Fernandez, Staff Counsel

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

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

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

A P P E A R A N C E S C O N T I N U E D

DEPARTMENT OF PUBLIC HEALTH:

Dr. Michael J. DiBartolomeis, Chief, Exposure Assessment Section, Environmental Health Investigations Branch, Lead of Biomonitoring California

Ms. Lauren Joe, Epidemiologist, Environmental Health Investigations Branch

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

Dr. Paula Johnson, Safe Cosmetics Program

Dr. Nerissa Wu, Chief, Chemical Exposure Investigations Unit

Dr. Rana Zahedi, Research Scientist II, Biomonitoring and Biochemistry Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL:

Dr. June-Soo Park, Research Scientist Supervisor, Human and Environmental Monitoring Section Chief, Environmental Chemistry Laboratory

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

Dr. Miao Miao Wang, Research Scientist, Environmental Chemistry Laboratory

GUEST SPEAKERS:

Kim Harley, Ph.D., Associate Adjunct Professor, Maternal and Child Health; Associate Director for Health Effects, Center for Environmental Research and Children's Health, University of California, Berkeley

Lovisa Romanoff, M.S. M.P.H., Health Scientist and Project Office for State Biomonitoring

Mary Ellen Mortensen, M.D., M.S., Chief Medical Officer, Division of Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention

A P P E A R A N C E S C O N T I N U E D

ALSO PRESENT:

Dr. Simona Balan, Green Science Policy Institute

Ms. Nancy Buermeyer, Breast Cancer Fund

Ms. Lindsey Dillon, University of California, Davis

Mr. Alexander Hoepker, University of California, Berkeley

Mr. Tom Jacob, Chemical Industry Council of California

Ms. Olga Kalantzi, University of California, Berkeley

Ms. Susan Kreutzer

Dr. Veena Singla, Natural Resources Defense Counsel

I N D E X

I N D E X C O N T I N U E D

P R O C E E D I N G S

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Good morning. My name is Allan Hirsch. I am Chief Deputy Director for the Office of Environmental Health Hazard Assessment. I'd like to welcome all of you to the Scientific Guidance Panel meeting this morning. And I'd like to welcome the Panel as well and thank all of you for your interest in this Program and for coming out here.

Our Director, Dr. George Alexeeff, had a pressing matter that he had to deal with this morning, but he should be here for the afternoon session.

So I'd like to just basically let everyone know that this meeting is being transcribed by a Certified Court Reporter on the right side of the room. And also, this meeting is being broadcast via webinar, so audio will be available to people who are listening in on the Internet, and they'll be able to follow the slides as well. There won't be streaming video, but they will be able to see the slide presentations.

And so I think we're going to start out first with a little bit of a bring out the old and bring in the new. She's not here today, but I wanted to acknowledge and thank Dr. Julia Quint who was, of course, a member of the Scientific Guidance Panel here for a number of years. Dr. Quint -- actually, since 2008. Dr. Quint's strong

commitment to protecting worker and public health in the State is evident in her long-time contributions, first as Chief of the Hazard Evaluations System and Information Service at the Department of Public Health, and then later as a member both of the Scientific Guidance Panel and the Green Ribbon Science Panel that helped the Department of Toxic Substances Control set up their Safer Consumer Products Program.

So we're truly fortunate to have benefited from her enthusiastic participation at the SGP meetings and the valuable guidance and input that she gave to Biomonitoring California.

And as just one example, Dr. Quint's presentation at the July 2009 SGP meeting on biomonitoring in occupational settings helped put a spotlight on workers as an important population for the Program to study. And she continued to highlight -- to highlight worker concerns. So her wide-ranging knowledge of chemical hazards and extensive experience as a Public Health Scientist and Toxicologist are irreplaceable.

So we will genuinely miss Dr. Quint's involvement as a member of the SGP for Biomonitoring California and wish her the best in all of her future endeavors.

And so with that, I'd like to introduce and welcome the new Panel member who will be backfilling for

her, Dr. Scott Bartell. Dr. Bartell is an Associate Professor in Public Health Statistics and Epidemiology at UC Irvine. His research interest is environmental health methodology with an emphasis on environmental epidemiology, exposure science, and risk assessment. And one of his recent projects involved the linkage of fate and transport models and a pharmacokinetic model for the perfluorooctanoic acid, or also known as PFOA, with individual level residential histories and health outcomes for the CS Health Project and CS -- and C8 Science Panel Studies. Excuse me, that's C8 not CS.

He's also working on development of formal statistical methods for biomarker-based exposure estimation and for estimating the biological half-life from observational data in the presence of ongoing exposures.

And Dr. Bartell has served on numerous scientific advisory committees including for the National Research Council, the U.S. EPA, Centers for Disease Control and Prevention, The National Institute of Environmental Health Sciences, the U.S. Department of Energy, and the International Agency for Research on Cancer.

So welcome to the Scientific Guidance Panel. That's one more for you.

PANEL MEMBER BARTELL: Thank you.

CHAIRPERSON LUDERER: I guess, I get to administer the oath of office to you.

PANEL MEMBER BARTELL: Okay.

So shall I stand?

CHIEF DEPUTY DIRECTOR HIRSCH: Yes.

MS. HOOVER: You need the mic.

CHIEF DEPUTY DIRECTOR HIRSCH: We need to both be at a mic.

Maybe there's a little more room over here.

PANEL MEMBER BARTELL: Okay.

CHIEF DEPUTY DIRECTOR HIRSCH: So for the Office of the California Environmental Contaminant Biomonitoring Program Scientific Guidance Panel repeat after me.

"I...", state your name.

PANEL MEMBER BARTELL: I, Scott Bartell, --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...do solemnly swear..." --

PANEL MEMBER BARTELL: -- do solemnly swear --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...that I will support and defend the Constitution of the United States..." --

PANEL MEMBER BARTELL: -- that I will support and defend the Constitution of the United States --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...and the Constitution of the State of California..." --

PANEL MEMBER BARTELL: -- and the Constitution of the State of California --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...against all enemies foreign and domestic..." --

PANEL MEMBER BARTELL: -- against all enemies foreign and domestic --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...that I will bear truth faith and allegiance to the Constitution of the United States..." --

PANEL MEMBER BARTELL: -- that I will bear truth faith and allegiance to the Constitution of the United States --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...and the Constitution of the State of California..." --

PANEL MEMBER BARTELL: -- and the Constitution of the State of California --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...that I take this obligation freely..." --

PANEL MEMBER BARTELL: -- that I take this obligation freely --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...without any mental reservation or purpose of evasion..." --

PANEL MEMBER BARTELL: -- without any mental reservation or purpose of evasion --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...and that I

will well and faithfully discharge..." --

PANEL MEMBER BARTELL: -- and that I will well and faithfully discharge --

CHIEF DEPUTY DIRECTOR HIRSCH: -- "...the duties upon which I'm about to enter".

PANEL MEMBER BARTELL: -- the duties about which -- upon which I'm about to enter.

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Congratulations.

PANEL MEMBER BARTELL: Thank you

(Applause.)

CHIEF DEPUTY DIRECTOR HIRSCH: And then last, but not least, some housekeeping items. If you need to use the restrooms during this meeting, the restrooms are out the main entrance where you entered. I think you go one hallway beyond the main entrance, and they are on your right. And in the unlikely event of an emergency, there's -- there is an emergency stairway off to the right right before the main entrance. And the California Endowment staff tell me that in an emergency, they would dawn the orange vests and help lead you out. So probably won't need to test that, but that's what they say.

(Laughter.)

CHIEF DEPUTY DIRECTOR HIRSCH: So with that, I will turn the meeting over to our chair, Dr. Luderer.

CHAIRPERSON LUDERER: Can everyone hear me?

No. Okay. It's supposedly on.

All right. Hopefully, everyone can hear me now. I'd like to welcome everyone to the Biomonitoring California Scientific Guidance Panel meeting, the staff of the Program, members of the public both who are here in person and listening via the webinar, and, of course, also the Panel members.

I'd like to just quickly outline the goals for the meeting. We will receive Program and laboratory updates today and provide input on those. We'll also hear some updates on the activities of the National Biomonitoring Program and have a discussion with our guest speakers Lovisa Romanoff and Dr. Mary Ellen Mortensen from the Centers for Disease Control and Prevention. We're very excited about that presentation.

And also, very excited to hear a presentation from Dr. Kim Harley from UC Berkeley on the findings of HERMOSA intervention study of teenage girls. And that study examined chemical exposures related to the use of cosmetics in personal care products, and tested an intervention to reduce those exposures. And we'll have a discussion with Dr. Harley about how her work could inform possible future Biomonitoring California intervention studies.

Finally, this afternoon, we'll also consider perfluoroalkyl and polyfluoroalkyl substances, PFASs for short, as potential designated chemicals for Biomonitoring California.

As usual, for each of the agenda topics, we'll have time for Panel questions, public comment, and Panel discussion and recommendations. I'm just going to briefly review how we'll handle public comments. So if a member of the public would like to make a comment, then he or she should fill out a comment card, which can be obtained from the table in the side of the room there. And you can turn in the cards to -- oh, okay -- to either -- sorry. Okay. -- to not to Duyen -- okay to Amy or either one. Amy or Duyen. Okay.

And members of the public who are not at the meeting in person are invited to provide comments via email, and that's biomonitoringcalifornia -- biomonitoring@oehha.ca.gov. Biomonitoring California staff will then give me the emailed comments, so that I can read them allowed at the appropriate time during the meeting.

To assure that the meeting proceeds on schedule and so that all the commentators have opportunity to speak, we'll have to subject the comments to time limits, and we'll divide the time allotted for public comments

equally by the number of individuals who wish to speak on that agenda item. And we also ask the public commenters to please keep your comments focused on the agenda item that was being presented. And then there will be an open public comment session at the end of the day at which commenters can speak about any other topics that they would like.

I also want to remind everyone to please speak directly into the microphone and introduce yourself before speaking. And this is for the benefit of those people who are participating via webinar and also for our transcriber.

The meetings that were provided to the Scientific Guidance Panel members and were also posted on the Biomonitoring California website prior to the meeting today, there are a small number of paper copies on the table in the -- at the side of room for viewing here today.

We are going to take two breaks today, one for lunch around 12:30 and another one in the afternoon about 2:45 p.m.

So now it's my pleasure to introduce the first item of the day. We're going to hear Program updates and laboratory updates. Dr. Michael DiBartolomeis the Chief of the Exposure Assessment Section, California Department

of Public Health, and the lead of Biomonitoring California will start by providing a brief update on Biomonitoring California activities. And then we'll hear laboratory updates from Dr. Jianwen She, Chief of the Biochemistry Section in the Environmental Health Laboratory Branch in CDPH, and Dr. Myrto Petreas, Chief of the Environmental Chemistry Branch in the Environmental Chemistry Laboratory, Department of Toxic Substances Control.

And after each update, we'll have a few minutes for clarifying questions from Panel members. After all three speakers have presented their slides, we'll hear public comments and then we'll have time for further discussion about the presentations by the Panel.

So, Dr. DiBartolomeis.

DR. DiBARTOLOMEIS: Thank you, Dr. Luderer. And good morning, Panel. And welcome to our newest member of the Panel. You did very well and you passed the first test, which is probably the hardest test --

(Laughter.)

DR. DiBARTOLOMEIS: -- to actually be able to do that. I did it once too, but I don't know how I even did it.

We do have a pretty tight schedule, so we're going to be succinct in our updates, and they're going to be even a little bit shorter than they normally are, so

I'm going to go ahead and dive right in.

(Thereupon an overhead presentation was presented as follows.)

DR. DiBARTOLOMEIS: Oh, I thought you said it was going to -- just use this one. It's March 13th. It's a Friday. Put it together.

(Laughter.)

DR. PLUMMER: Of course.

There we go.

DR. DiBARTOLOMEIS: That might work.

All right. Sorry about that. So much for keeping on the tight schedule.

Just again, really three things I'm going to do today, some quick announcements, update you on a couple of our projects, and then I'm going to take off where I left off in November, and kind of advance this a little further into our Program priorities. I'm just going to sort of do this a little bit each time, so it's not overwhelming.

--o0o--

DR. DiBARTOLOMEIS: Program announcements, basically two things, Program funding. I just wanted to catch you up on where we are currently. We've always had the permanent State funds of $2.2 million per year. That hasn't changed any. Again, it's -- that's disbursed and comes from five different special funds. There's -- none

of this is General Fund.

We also have two additional temporary State funds, or limited term State funds, one is actually already in place, which is $0.7 million that were allocated for two years, this fiscal year and next fiscal year, in the Budget Act of 2014. And then there's a proposed $1.5 million augmentation for next fiscal year starting July 1st through 2017. That again is proposed. We're very hopeful that is going to also come through.

And so that is -- those are all -- that's all really good news. And again, just to remind you, we have the $1 million per year grant through -- federal grant through 2019 from our friends at CDC.

The other bit of good news, and I know you've all been waiting for this, the legislative report is done, approved, posted. You can go look at it, read it, use it for wallpaper, whatever you want to do. It's there for you. There's a picture of it kind of like a little munched up in the corner. So again, it was posted just this week on the 10th. There's the link, in case you're at home, or, you know, you want to link into that.

And there is a -- oh, so the slides got kind of mushed up here. So I apologize for that. I don't know what happened.

We are going -- we have a scheduled briefing with

the legislature on March 19th at the Capitol. It starts at 1:00 o'clock. And I know that Allan is going to be there. I'm actually going to be there sitting in the corner somewhere. So that -- I'll probably be able to report back on that in the next -- at the next meeting to see how that went.

Just one other word about the legislative report. It may not be that obvious. The time period that it covers is supposed to be 2012 to 2013. And it does cover the accomplishments and the work of the Program during that time period. However, if you go in there, you might be a little confused, because the budget information, the fiscal information, has been actually updated to pretty current, I think like up to February or so of 2015.

So it's a little bit confusing. The accomplishments are updated only to the end of 2013, but the budget is updated to pretty recently.

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DR. DiBARTOLOMEIS: With respect to project updates, I'll start with our BEST project. And again, I'll -- we usually split these out, Pilot and then the Expanded. With respect to the Pilot BEST, you can see that we have -- we're currently undergoing data analyses for the metals, perfluorinated compounds, brominated flame retardants and perchlorate. We are undergoing, and well

underway, with an evaluation of the results return. And I'm happy to report that we're up to 35 percent return on the surveys, and including 16 of those with come -- or, I guess, more detailed in-depth phone interviews. So we're gathering some really interesting information, which I don't know when we'll be able to present that, but that's going to be coming down the pike. And we are also in the process of posting some of these Pilot BEST results on the website. Let me know if you want to know which ones, but we're moving toward that direction.

From the -- on the Expanded BEST side, we have completed -- analyzed and completed and returned the first set of chemicals to the participants. We're currently analyzing the second set of chemicals. And the data analyses are underway for the first set of chemicals, which include metals in urine and PFCs.

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DR. DiBARTOLOMIES: Now, I'm going to throw a curve ball at you. We've been calling the Genetic Disease Screening Program Project the GDSP Project, but none of us really thought that was very clever, so we have a new name, MAMAS, which we do think is clever.

(Laughter.)

DR. DiBARTOLOMEIS: Measuring Analytes in Maternal Archived Samples. So please memorize that. That

will be on the quiz at the end of the day. We have received 460 -- the first 460 samples. That was actually received on the day of the last SGP meeting. I don't know if you recall, but I think I made that announcement, and -- Woops.

And these -- just sort of to recall, the 460 original samples are from 2012. And they were -- they're actually regionalized through Orange and San Diego counties, so they're limited to those two counties. We now have new samples coming in. Let's see, 540 -- well, if you look, you can see the breakdown of how the 460 samples are being analyzed. And we did receive the metals -- or many of the metals -- no, all the metals results. Partial metals, and we have the PFCs.

Okay. And we also have 540 more samples coming that are going to be more representative across the State. And, let's see, they're going to be split by -- we're going to actually be getting the full vials of samples instead of a lesser volume, so we'll be able to split them, and then also maybe even archive or save them for the future.

Let's see, we'll be doing PFCs and metals in 360 of those, and 180 will be used for POPs, or persistent organic pollutants.

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DR. DiBARTOLOMEIS: Well, so at the last November meeting, I did talk a little bit about our priority setting process, which we worked on for quite a bit of 2014, culminating in a big priority setting off-site in October, I believe it was. And I already showed you these Program vision points that we wanted to make, but I thought it's always good to show them again. Don't necessarily have to walk through them again, but I want to remind people that that's -- the vision is kind of where we are in terms of directing and thinking about where the priorities would be in terms of achieving our vision, and which is essentially a mission.

So the next slide -- next two slides I'm going to show you some ideas and what we thought as a Program of consensus -- a consensus vision of what kinds of projects we'd like to work on to try to meet these criteria for -- where the Program direction.

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DR. DiBARTOLOMEIS: So, of course, we're going to continue doing what we considered our statewide representative sampling surrogate, since we can't do the full blown California HANES kind of thing, and that would include MAMAS. But, of course, for example, the Teachers Study that we're in an agreement with -- a collaboration with is ongoing. The BEST is again one of those. So we

continue to look for opportunities where we can find samples of the State of California population that we can use as a means for adding to our statewide representative bio -- sorry, data bank for chemicals in people's bodies.

Then we also started to think about what could we do to help inform policy, to meet some of those other aspects of our vision, helping -- helping -- you know, working with our other State agencies, our sister agencies. So we -- the next two you could actually almost think of as one possibly, but we split them up because you can do consumer product biomonitoring and case studies without the intervention, but the intervention part, of course, is really intriguing because you can actually see the impact of a product being used and not being used versus kind of this consumer product biomonitoring case study where you may not actually see changes. You're just looking at a full -- you know, an amount of chemical in the body that could be due to the product.

So it turns out that we are actively working diligently toward designing a study that would be part of a pilot and in conjunction with work that's already being done or that's going to be done by Arlene Blum and her collaborators with flame retardants in cushions, and other household items, where we would be concentrating on not

only brominated flame retardants but phosphate-containing flame retardants, which we are very close to having a validated method for.

So that would be an intervention study where we could actually measure these levels of these chemicals in peoples blood. They're going to be looking at dust. Then there's an intervention where their household is kind of turned over into non-foam or non-flame retardant containing foams, and then after a period of time we can go back and look again and see not only if the dust level changes, which we expect are going to go way down, but we also anticipate that the blood levels will be going down in humans in urine levels. Yeah, flame retardants -- the OPs are urine, right?

Okay. Thank you.

And then the other -- we also -- in a bigger contextual -- and you'll see this on another slide. In the larger context, we want to emphasize environmental justice activities in our work. And I think we've mentioned this several times in the past. So we actually have a specific, what we call, sort of a nexus project where we're combining the OEHHA's and CalEPA's CalEnviroScreen data with our biomonitoring results. And we're actively. We have a working group that's actively doing this. And I'm sure at some point in the near

future, we'll be reporting back on that as well.

So that's sort of our first take on moving into that direction, but we're -- where we put that environmental just lens on -- justice lens on, in order to be thinking about targeting populations at greater risk.

And then finally, kind of like the other end of the spectrum, we want to also have like a longitudinal cohort sort of set up. And one of the ways we thought of doing this, and this actually started with Dr. Lipsett a few years ago, is to actually hook up with students that are in -- probably at UCSF, where they're in the School of Nursing, School of Medicine, Dental School or whatever, and where we can actually recruit young students, teach them about environmental health, collect their samples, and this would be kind of an ongoing you can -- it's pretty easy to track where health care professionals go. So you might conceive that you can keep tracking them for a period into the future. So we're going to give that a shot.

This is more or less a pilot, but we think it might actually give some results with very little sort of up-front money, because really what we're giving is some in-kind as well, in terms of teaching and providing education and support.

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DR. DiBARTOLOMEIS: For methods development, we've actually already expanded the metals panel, but I keep -- I'm going to keep this up there, because it's, you know, sort of a continuing activity of thinking outside the box on metals. I've already mentioned the phosphate flame retardants. We're well underway. And actually both labs have developed methodology for different reasons, but eventually we'll have like back-up systems and cross-training and that sort of thing.

Our bisphenol A analogs panel is also pretty far along. I think we're almost at the validation stage. We're getting close to that. I'm getting a nod from Jianwen, so I think that's right.

We are thinking about expanding phthalates or at least looking at phthalate substitutes and so we've -- and I think this might have been mentioned in the past, but we're -- you know, we're working down that road. We've always been wanting to do -- get into the fragrance world. So we continue to keep that as a high priority. And I know that musk methods have been started, but I know that they kind of hit this place where they stopped for a while, so we want to put that back on our targeted priority list.

And then, of course, we're going to continue with our targeted unknown screening that -- we do have a

working group that -- across the labs that is working on that. And I guess, at some point, we'll come back, because that's been on the agenda before and probably repeat that for a future meeting.

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DR. DiBARTOLOMEIS: And not to leave off the sort of number one priority that we've had for a long time, which is just to remind people we still have a CDC cooperative agreement. And the work in there is very high priority to the Program. And we're working those into as well as outside of these different projects. And everything they're doing in the CDC cooperative agreement matches perfectly with our vision.

So again, there's no kind of disconnect there. I already mentioned environmental justice. We do think we need to expand our outreach. We need to tell our stories better. We need to reach more audiences. We just have to do a better job of not only explaining what we do, but really making biomonitoring understandable to everybody, so that they -- at least if they hear or they're being biomonitored, they can understand what that is.

So there are a lot of different ideas. We have a working group that's - and I'm part of that one - that is working toward that. And at some point, we will come forward at a future meeting and likely give you some ideas

that came out of our deliberations.

Materials development is always going to be a high priority for the Program. We continue to want to update and improve the website, which is already getting great reviews. So we're really happy, but, you know, there's always going to be more we want to do. And, of course, our return packets for results return, we're continuing or always working on developing more materials and evaluating them.

We actually are working on or nearly -- we're indexing the methods and panels that we have in order for us to easier -- to be easier to track and explain what we do, and ultimately help us decide whether, at some point, we might want to drop some and add others and that sort of thing.

And then finally, we're always looking for new collaborations and new collaborative opportunities.

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DR. DiBARTOLOMEIS: So with that, I want to acknowledge again all the great staff of the Program. I'm really lucky to have all these great hard-working people.

And I also want to pay tribute to our favorite Vulcan, so Live Long and Prosper, everybody.

(Laughter.)

DR. DiBARTOLOMEIS: Thank you.

(Applause.)

CHAIRPERSON LUDERER: All right. Thank you, Michael. Is this still not working?

Okay. Thank you for that. Can you hear me?

Okay. Thank you very much. It's great to hear about the good budgetary news and also all the exciting new directions that the Program is taking with planned intervention studies, and the consumer products.

So we have time for a few clarifying questions from the Panel, and then more discussion afterwards.

Dr. McKone.

DR. PLUMMER: Actually, we're going to hold the comment until all three presentations are done.

CHAIRPERSON LUDERER: Okay.

PANEL MEMBER McKONE: I'm just going to forget this is on. Is it on?

Okay. On the MAMAS study, you mentioned that there were 540 in the first phase from Orange and San Diego. And then you talked about an additional 540. Where will they come from? Will it also be the same counties or different parts of the State?

DR. DiBARTOLOMEIS: Yeah, go ahead. I know the answer, but --

(Laughter.)

DR. DiBARTOLOMEIS: No go ahead.

DR. WU: I didn't mean to imply that Michael didn't know the answer.

Hi. I'm Nerissa Wu. The first 460 were from San Diego and Orange County. Those are biobank counties. We were restricted to samples that had already been stored by GDSP for the purposes of this biorepository.

Going forward, they have allowed us to go outside of biobank. So instead of the samples being archived and us pulling from biobank, we're going to be pulling from samples that are not being biobanked, so can cover all the non-biobank counties. And so it's allowed us to really represent the State more fully.

So we have stratified California to a northern tier, a southern area, then a Bay Area in order to try to get some geographic diversity.

PANEL MEMBER McKONE: Thank you.

CHAIRPERSON LUDERER: Dr. She.

(Thereupon an overhead presentation was presented as follows.)

DR. SHE: Good morning, Panel members. This morning, I will update the progress from the Environmental Health Laboratory in last three, four months.

--o0o--

DR. SHE: This will be a short update, so we basically quickly talk out of the five tasks on the method

development, I talk about two of them. And I also quickly report the kind of project that we're working on and the direction we are going.

--o0o--

DR. SHE: Two methods. One is the OP flame retardants. As you know, the older brominated flame retardants may show the trend goes down. That's the success of the regulations of the AB 302 in California, for example.

And then -- but the new ones organophosphate flame retardants maybe show the trend to go up, but we need to test them, so this requires a method. There's four chemicals. I'll show them. I will not read them anymore, so like we are working on.

And then for BPA substitute, and we know BPA may be slowly phased out, but the new chemicals show up like BPS, BPF, and the other two we are working on.

--o0o--

DR. SHE: So for -- to develop method, first we need to establish a target method detection limit. So our target method detection limit for the OP flame retardant is about 0.01 ppb, which is -- we compare with expected population levels from the other study. We think that's enough to detect the general population exposure.

So the first column will show you the chemical,

what they are with the full name. Second and third one show the two quality control samples we have, what kind of precision. I would call imprecision, because of the bigger the number is imprecise. The smaller number we're looking for it. It's better. Generally, we look for below 20 percent.

Last two columns is at two levels, 1 ppb and 10 ppb. We call it accuracy, which is the relative recovery. We look for relative recovery in between 70 to 113 percent. This is 100 percent -- close to the 100 percent would be better.

So we think this method, and from these parameters, we judge it's very good, but we needed to compare with our 30. Our 30 were standard materials, reference materials, which we will work on that to see our values have no bias.

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DR. SHE: For the BPA substitute for the four compounds, you can see are the same. We arranged the table the same way. So again, you can see the precision, except for BPS was acceptable. Also, the accuracy is very good.

For the BPS, right now, our laboratory do not have really good standards. And yesterday, we talked with CDC Program Officer and also the Medical Director. We

know that CDC may have -- they told us where to get it and maybe get it at a lower price. So I hope when the new standard come in, we'll have a good precision on this BPS too.

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DR. SHE: In summary, in the last six, seven years EHL able to develop 14 groups of chemical analytic methods, which cover a very wide range of the analytes. It's very hard to group them together, so each of them need a very unique method to measure it. And then overall have over 104 chemicals covered by the method.

Also, you can see the metrics come from the blood, plasma, urine, dry blood spots. So that's a very wide range of the metrics, plus a wide range of chemicals. The compilation is very complicated. So this one page slide summary reflects a lot of effort, including CDC's contribution and all of the Program's contributions, but especially by chemist sections and scientist contributions. So I'd really like to thank them, everyone for this contribution.

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DR. SHE: Using all of these methods, we conduct a few studies. For example, the BEST -- Pilot BEST Expanded BEST studies. So for Expanded BEST study -- we finished the Pilot earlier. We already reported last

column shows data released to the Program, which means the laboratory released the data to our EHIB staff that can conduct data analysis.

For example, we released the five groups of chemicals, blood total metals, urine total metals, creatinine, hydroxy-PAH, and OP-specific metabolites. We expect to release the other two groups of chemicals shown on column 2, environmental phenols and phthalates in urine. We already conducted the laboratory analysis. QA review is underway. And on the most right -- left column, there's two groups of chemicals we still need to finish laboratory analysis.

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DR. SHE: We have other three groups of ongoing projects. One is called CHIME. And this is Community Health Impacts from Mining Exposures. This study we collaborated with Dr. Peggy Reynolds from the Cancer Prevention Institute of California, and also Sierra Streams Institute.

We analyzed the 60 samples for 11 or 12 - Ryszard can correct me - group of metals, and then to examine the California gold miners exposure to the metals.

And the second group of chemicals -- second study we are conducting we call the Pregnancy Environment & Lifestyle Study. Short is PETALS. We collaborated with

Kaiser. And the PI is Dr. Assiamira Ferrara. And so far, we already received 138 samples, and we reported data for 60 samples.

And this study is a case controlled study of 300 cases with gestational diabetes mellitus and with 600 controls. And each sample we expect to get two specimens. So the total we'll have 1,800 samples. Each year we will analyze about 600 samples. So the goal of the study is to examine the relationship between the early pregnancy urinary BPA levels and the risk of the GDM disease.

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DR. SHE: This is a study actually I don't know. But Dr -- and Dr. D. and Dr. Wu already mentioned. And I think I do not need to -- I do not need to tell more about this study. This is the MAMAS study. We already reported 100 samples from the 200 expected samples, we expect to receive. So we finish half of them.

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DR. SHE: And also in the last three months the laboratory is able to publish two papers. One is from Dr. Gajek, Ryszard and Dr. Key-Young Choe. And their group published a method, determination of ultra-trace elements in human plasma or serum by ICP-MS. And this method, if you have questions, Dr. Gajek and Dr. Choe is in the audience.

And then also we developed and published second method is by Indranil Sen. He published and developed the validation of a method for arsenic speciation. And I thank them for their excellent laboratory work, plus the scientific publications.

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DR. SHE: For the future, we will continue to finish targeted unknown screening. We called it targeted. We don't think we should work on the untargeted screening before we do the targeted ones. So that's slightly easier for us to do. We also needed to make sure both the BPAA and the OP flame retardants method can be -- bring them to the production.

Yesterday, we also heard CDC have the -- now have the PT from the first group of BPA substitutes. Then if we test the PTs, we maybe should -- we have more confidence that our methods have no bias.

And then we complete reporting of the former ongoing project, the result.

Thank you.

(Applause.)

CHAIRPERSON LUDERER: Okay. Thank you, Dr. She. We'll hold questions until Dr. Petreas has finished her talk.

(Thereupon an overhead presentation was

presented as follows.)

DR. PETREAS: Good morning. So this is going to be a very brief update to catch up on time.

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DR. PETREAS: So our laboratory -- I'm going to talk only about the progress with sample analysis, and other activities that benefit the Program.

I should mention that we had no staff changes, but I notice Dr. Wang is here, so I want her -- she's Dr. Miaomiao Wang. I mean she's done a lot of work with all the PFCs all these years, so I want to acknowledge her contribution here.

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DR. PETREAS: So progress with the MAMAS. As of last week, we had completed all the PFC analysis thanks to Dr. Wang. And all the POPs analysis, we are waiting for the lipids to come from the clinical lab before we release them. But they finally came, so everything is done from this phase of the MAMAS.

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DR. PETREAS: Our next study is the Expanded BEST. And we had already reported that all the PFCs were completed. And now we're working on the POPs. So everything has been aliquoted. Extraction is completed, but now it's through the instrument. And with some

downtime, we have some delays there. But that's what we're working on now.

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DR. PETREAS: The Teachers, this is our largest study. It's a laboratory collaboration in contrast to the previous studies -- the two previous studies, which are designed by the Program. So this is in collaboration with the Cancer Prevention Institute of California. And we're going to have over 3,000 specimens from California women. So it's a tremendous population here.

We slowly move through the different classes of chemicals. So we have completed most of the PFC and PBDEs that are started. We work in batches. And now we're trying to catch up with the PCBs and organochlorine pesticides, which were of a lesser priority for our principal investigator, but now we're catching up with that. So this is a case controlled breast cancer study. So if -- and what we're showing here is everyone together. So it's just overall data from women without indication of disease status. This will come much later.

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DR. PETREAS: Again, based on the request from the last SGP, we also compiled all the methods that our laboratory performed. And I'm showing the same format as Dr. She showed. We're doing the PFCs or the PFAS, as we

call them from now on. We do the 12 PFCs. Plus now, we're going to discuss additional ones that we measure. And so for the PCBs, organochlorine pesticides, PBDEs, most of them are in serum, as you see, but we also do the organophosphate flame retardant metabolites in urine. The same compounds that Dr. She mentioned.

And as he said, this is -- there are no proficiency testing material. There's no standard reference material, but we're working with others, for example, with Dr. Heather Stapleton from Duke. And we're going -- we're exchanging samples of dust and urine. So we'll be sharing the urine from North Carolina along with our lab and Dr. She's lab to confirm that both labs do the same thing. So we still call it undergoing validation.

As far as the synthetic musks, yes, we started and we had maternity leave. But now we're back on track and hopefully we'll have more progress soon on the musks.

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DR. PETREAS: Our paper on the firefighters serum POPs was published. And the good news is that -- well, the bad news that we found very high levels of PBDEs in the firefighters. The good news is that some good housekeeping and following guidelines on personal protective equipment and washing your hands may reduce exposure. So this is very interesting.

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DR. PETREAS: As a companion study to the serum and the biomonitoring phase, we had the Fire Station Dust Study. And this was the master thesis for Beverly Shen, who worked in our lab. The paper now is in review at ES&T. And again, we found the highest PBDEs ever reported in the firehouse dust. And it was much higher.

We have already published the other -- the brominated flame retardants beyond PBDEs, which again were much higher in the firehouse dust than in California homes sampled at the same time.

And now we're analyzing the same dusts from the FOX study and the houses for OPFRs and bromo- and chloro-dioxins. So we'll have data soon on that.

What's very interesting is that the firefighters are very interested in our study, so we're going to have a second fire station dust study. This will be funded by the International Association of Firefighters. The intent here is to refine the exposure assessment questionnaire and apply this -- this study will be conducted beyond California, so we saw what's happened in California. Is California unique? Is there something that they could be exposed to in other states?

So they are deciding on which other districts throughout the country would be sampled. And the plan is

that we collect dust from the fire stations as before, but also trucks and equipment that we had not considered the first time and we think that it's a data gap.

And we'll expand the analysis beyond the PBDEs, of course, other BFRs, OPFRs, dioxins in a different stage, PAHs and the perfluorinated compounds, as well as non-targeted eventually.

A subquestion is what could be in the turnout gear? These are the gear firefighters wear and use. And we have some preliminary data that this may contain bromine, which may be something with flame retardants.

And the other important question is does dust get tracked back from the fire activities back into the fire station, and that's why we have all these high levels?

So we have a great team with the firefighters. Commonweal. I want to acknowledge Sharyle Patton here for putting us in touch and bringing everything together, our lab, and of course UC Berkeley where Beverly will be working with Kathy Hammond as her advisor to conduct this other study. So we're very excited and we're starting soon. And hopefully, we'll have more updates at another time.

(Applause.)

CHAIRPERSON LUDERER: Thank you very much to Dr. Petreas and Dr. She for those laboratory updates. It's

exciting to see all the new methods development progress that's been made and the progress on the different studies.

We have -- why don't we take some clarifying questions, if there are any, from the Panel members, and then we'll take public comments, and then we'll have time for more discussion from the Panel.

Dr. Bartell.

PANEL MEMBER BARTELL: Yeah. As a new Panel member here, maybe you can just help fill-in some background information for me. I'm just wondering on the analytical chemistry here a lot of these chemicals that you're measuring are similar to what's covered in NHANES or other CDC programs. And I'm wondering to what extent you can sort of borrow or use protocols from those labs at CDC, since some of these chemicals they've been doing them for a while or do you find that you really have to develop new analytical techniques for the particular types of samples you're collecting here that are somehow different?

DR. SHE: Actually, the CDC's contribution is enormous. So we actually follow the path you mentioned. So when we started, we had sent the staff to CDC. And like Lovisa send us all the protocols and the PT samples. We tried to follow the CDC's past without reinventing the wheel.

And on the other hand, because the two laboratories set-up is completely different. CDC set up their lab much earlier, so we may not exactly can copy what they do. We would need to buy new instruments, and then we also need to fit it in our work flow, so certain modification is necessary. So that's -- basically, we follow CDC with some laboratory modification to fit in our specific resource.

PANEL MEMBER BARTELL: Thank you.

CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

PANEL MEMBER KAVANAUGH-LYNCH: Are non-clarifying questions and comments allowed?

(Laughter.)

CHAIRPERSON LUDERER: Yeah, go ahead.

PANEL MEMBER KAVANAUGH-LYNCH: I just had actually three points. So one is on the priority initiatives, I'm like thrilled to see them. I think they're like right on track, just great.

I wanted to mention in the biomonitoring intervention study, I know of a project under development to come to the California Breast Cancer Research Program for -- seeking funding, in which they are doing an intervention on cosmetics, and providing women with replacement cosmetics for a month, and then actually doing -- looking at biological effects on breast biopsies

in non-breast cancer patient women.

And so I think that's another opportunity. And that tying in the biomonitoring with the -- with the consumer products, with the intervention, and then with the biological activity is like the next step, which I'm really thrilled to see coming to us for funding and would encourage you to collaborate with.

And then my third was the environmental justice project, I love that also. And I think one thing I didn't see in here, but I'm sure it hasn't fallen off your plate, is looking at a biomarker for diesel. And that I think would be a great enhancement to that environmental justice project.

DR. DiBARTOLOMEIS: This is Michael DiBartolomeis. I actually neglected to mention the sort of -- the next tier of methods development. Those were the ones that were either already underway or had made it high on our list because we're ready to move on them. We have things in place. The diesel is in the runner-up category or the next tier. We still have some work to do trying to figure out what it is that we would be biomonitoring. And so that is still -- it's in the hierarchy. It's just sort of in the on-deck circle, if that makes any sense. So it's not forgotten. It hasn't dropped off.

We've also -- just to mention a few others. You know, blood -- dried blood spots, VOCs, a few others. You know, we're still contemplating those, so -- but the ones I presented are the ones that we're really actively pursuing at this point.

DR. SHE: And on diesel -- for the diesel and also like two back -- like SGP --

MS. HOOVER: Last November.

DR. SHE: -- last November, we had invited Dr. Chris Simpson to present laboratory part. At least since the laboratory move very slow and compare the other components, we decided to do -- like Laurel, me, Sara, we contacted Dr. Simpson after he returned. And two days ago, he sent us 12 standards for potential biomarker what his lab is doing.

And then -- so once -- like Dr. D. mentioned, once the Program decided which marker to do, the laboratory at least be ready in certain things, because this standard is very hard to find. He's the one to only have this metabolite from 1-nitropyrene and other chemicals.

So that's an update. So once the Program need it, we tried to fit -- take the challenge, because the current method used 100 milliliters of urine, we needed to look to see, but at least we have the standards on hand.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: Is this working?

Okay. I have really just two comments. One, Michael, you talked about the MAMAS project, which is using the archived samples from the Genetic Disease Screening Program. I just want bring it to the attention of the Panel, and the group as a whole, a recent bill that was submitted by Mike Gatto from Southern California, and he's proposing essentially basically eliminating the storage of blood spots -- newborn blood spots. You know, basically he's framing it as kind of the Government having DNA of all children, and that being an invasion of privacy. And that's a bill that's actually going to be introduced. It's come up now at the UC Office of President.

And I'm just concerned about, you know, the biomonitoring and public health implications of not having archived material. And I just, I guess, want the Program and maybe the Panel to consider, you know, what the implications are of that bill and how it might apply, not just to blood spots, but also archived maternal samples, and whether we should take an opinion on that?

DR. DiBARTOLOMEIS: Again, Michael DiBartolomeis. Well, you were beaten to the punch today by the Chair. Dr. Luderer came up to me and said do you know anything

about this bill? And I hadn't.

And in the Department of Public Health more than likely a bill like that would go to the Genetic Disease Screening Program for analysis. I can't comment on anything about legislation anyway in a public setting. And I certainly -- the Biomonitoring Program can't take a position on a bill like that.

It doesn't stop the Panel from talking about what the implications might be. What I will do is go back -- go through my chain and find out if we can at least get on to the tracking or watch or even do a secondary analysis or whatever from the Program standpoint, from the Division of Environmental Occupational Disease Control. So that's all I can say about it, but you guys can certainly talk about what your concerns would be, if that were to arise.

PANEL MEMBER BRADMAN: And maybe that's not necessarily something we have time for today but it's something to consider.

CHIEF DEPUTY DIRECTOR HIRSCH: Well, the other -- sorry. The other thing I could say is I will echo what Michael said. I think the Office of Environmental Health Hazard Assessment would take a look at that bill, and as individual departments, the Department of Public Health, OEHHA, DTSC too could. We can always analyze these bills. And bill analyses are confidential, but they go to the

Governor's office, and they advise the Governor on what kinds of positions they could take on those bills. So, I mean, it sounds like something that our three departments just as individual departments would want to weigh in on.

PANEL MEMBER BRADMAN: Then I have one other comment and it's a little more technical and detail oriented, just that I've actually -- we're sending 20 samples up to Chris Simpson's lab to test for 1-nitropyrene. These are from urine samples collected from kids in East Oakland and Salinas. And I'll keep you posted on that, but maybe there would be an opportunity to somehow, if something goes forward, to collaborate on that. And there might be a way to try to look at diesel and those exposures.

DR. SHE: Jianwen She again. That will be a great opportunity to help us validate the method, just like we did with HERMOSA with you. That's very helpful.

And also Dr. Simpson planned to send his laboratory manager to here also help us to make sure we do the right thing. So with the extra sample you have, we'll be -- even be more helpful to validate the data directly.

PANEL MEMBER BRADMAN: Thanks.

CHAIRPERSON LUDERER: Dr. McKone.

PANEL MEMBER McKONE: So I have -- I want to do one follow up to the point about legislation and watching

it. And so I want to make sure, you know, that the Panel should have -- certainly have somebody informing us. And I believe that even though the State can't take a position, we're in a position where we could craft a letter. As Panel members right, we're Governor and legislative appointees, so we can make commentary, right, where State staff cannot comment on legislation?

So as long as we're informed about it, we have an opportunity to do that, I assume?

CHIEF DEPUTY DIRECTOR HIRSCH: (Nods head.)

PANEL MEMBER McKONE: I guess so I have one quick question, and then a comment, which I'll save the discussion if we're short of time.

So the first one is on the turnout gear. How do you -- I'm just curious how one samples turnout gear?

DR. PETREAS: Dr. Petreas. So the turnout gear is the pants and the heavy jackets that they wear. We had, again thanks to Sharyle Patton, a suit brought to the lab, an unused suit. And we tested it with the XRF gun, which measures elements. So we could see bromine, possibly from some flame retardant, on the lining of the pants, but we couldn't cut a piece. It was a new suit. We couldn't take to analyze.

So this was -- we wish we could do that eventually. And firefighters may be interested in that in

the future. So we know that there are four manufacturers in the country, but the supply maybe comes from different countries, the material that they sew here.

So that's the good thing that working with the Firefighter Association we can get all these answers and design more -- you know, a smarter study, if you want to assess exposures to firefighters, because they have very high levels and cannot be explained with --

PANEL MEMBER McKONE: I mean, it's actually, not just for you, but more of a broader question or commentary. So there were a couple things I heard that I want to tie to other issues. One is in the flame retardant, where -- the Arlene Blum sort of motivated study where you take somebody's furniture and you take it away, right, and then you do the cross-over to see how they change.

And what I thought was interesting is you look at the dust -- I mean, the proposal is look at the dust and then look at the urine. And my thought is, well, there's a lot of things between dust and urine. And the same thing when you sample -- but -- well, let me -- so the comment I have is that I haven't heard a lot about skin as a biomarker medium. And I know we can't do it now, but I've been in some lengthy discussions with Charlie Weschler and Bill Nazaroff who have been looking at

passive uptake. And Charlie has actually got some ideas. He's retired from AT&T Bell Labs, but he works a lot in the Danish Technical University at Rutgers. But there's just this discussion in this community about how we could better use skin as a biomarkers.

And one of the things that comes up is, you know, skin wipes can be all over the map, partly because they aren't calibrated. And we know that the chemistry is such that you have to calibrate against the lipid. So when you take a skin wipe, you should be not looking at just chemicals, but also the lipid composition.

So I just bring this up to say maybe it's a topic of where we're missing -- I mean, I know we miss a lot between dust and urine. And one of the first pathways from dust to urine might be skin. And there's active and passive uptake in skin. And we're really sort of skipping this a lot.

And, you know, I find it a fascinating issue, because I mean we have a lot of skin, 1.8 square meters per person. And it's all in contact with the environment at some level, and we still haven't really figured out how to use it effectively. And there's some research I think we could tap into that might do that. So that's just a comment, not -- something for future discussion.

CHAIRPERSON LUDERER: Before we take more Panel

discussion, I wanted to make sure that we have time for the public comments, and it looks like we have a few.

Great. Thank you.

All right. Our first public comment will be from Susan Kreutzer. And we have ten minutes, so please try to keep your comments to about three minutes each, since we have three comments.

MS. KREUTZER: Hi. This is my first time to be to this meeting, and the first time to even hear about you guys. I had someone contact me, and saw that I was in an article in the Chronicle. And so I wanted to come today and just throw out a couple things to see if this group has ever looked at this.

I'm a patient that has myalgic encephalomyelitis, which has been in the paper recently, because the Institute of Medicine just came out with a report. And some of you may know of this illness that was referred to as chronic fatigue syndrome, that -- it was a name that was given by the CDC in 1988 when there was an outbreak up Incline Village in Lake Tahoe. And we had AIDS going on at the same time. And the CDC was very concerned that there could be more of a panic really, that we could have had some other kind of virus or something else going on. So that was 30 years ago.

And it's a very complicated area, but one that I

was wondering if this group had looked at any possibility of the chemical input into this particular disease that we believe affects over a million people in the United States, maybe up to 4 million and 17 million people worldwide. And there is a -- at Stanford they're doing a lot of work, but a lot of this is on the infectious disease side. There is a doctor by the name of Dr. Andreas Kogelnik with the Open Medicine Clinic Institute and Foundation working with Ron Davis at Stanford, who's in the genome area.

And in the patients that they're looking at with this illness, they're seeing about a third of them that look like they have some kind of chemical toxicity or sensitivity. And what they've seen is there is a gene mutation called -- I believe I have this correct -- is MTHFR. And for the scientists, if I've screwed that up, I apologize for that.

And they're seeing that in the population about 30 percent would have this gene mutation. And the patients they're seeing it's 95 percent. So whether or not there could be something that we are chemically sensitive to this, and then it is triggering particular infectious agents in us.

But it just seems like it would be a really interesting area to be studying. And what I've seen as a

patient, there seems to be a lack of collaboration or people even aware of what different scientists are doing, even what they're doing up at UC Davis in the vet school, where they're looking at the animals and then trying to compare that with humans. And so I've just been working on trying to get people together to look at that.

So that's really what my comment is here today. One of the things that we are looking at for a cluster outbreak that happened up in Tahoe, and then we've -- studying -- this is just a group of patients -- studying this around the world is the -- and I will probably screw this up -- is cyanobacteria, which is the blue-green algae, and whether or not that is sweeping in areas.

And they think that that -- excuse me, just not feeling that well today -- so whether that comes in. And there are times when, you know, that's naturally occurring, but they're also seeing that fertilizers contribute to that, and whether those events are coming into areas and could be causing cluster outbreaks, and we're missing that and not studying those people. So that's really what I was coming here today to say.

Thank you.

CHAIRPERSON LUDERER: Thank you very much for those comments and suggestions. And I know the Program has not worked on that topic in the past, but we'll

definitely take your comments into consideration.

So next we have Veena Singla from the Natural Resources Defense Council.

DR. SINGLA: Good morning. Veena Singla with Natural Resources Defense Council. Thanks so much for the Program updates. It's always -- it's really great to see the fantastic work that's going on in the Program.

And I wanted to respond a little bit to Dr. McKone's comments on active and passive uptake through skin. I agree. I think that's very interesting, especially in the context of the firefighter studies, given some of the previous studies showing the very large increases in uptake in phthalates specifically in firefighters during the heat and humidity they experience during their work.

I was looking at phthalate uptakes through their neck hoods and the neck skin. So I think that would be very interesting to consider as well in this context.

And also, I wanted to mention that I was really glad to see the progress on the development of the methods for BPA alternatives. I think it's very timely, given the number of new studies that have come out recently showing possible similar endocrine disrupting effects of BPS and BPF, and potential neurodevelopmental effects as well. So very glad to see the progress there.

CHAIRPERSON LUDERER: Thank you very much for those comments as well.

And our last commenter is Tom Jacob from the Chemistry Industry -- Chemical Industry Council of California.

MR. JACOB: Thank you. It's been awhile since I've been around to observe this group. And I would like to just comment on the progress that you've made since the initiation of this with very limited money. It really is impressive.

But I had a specific question with respect to a number of the projects that were iterated. There was mention of coordination with various groups. And I was just curious whether there's been any outreach to, or coordination with, the involved industries, for example, in the personal care products realm or the consumer products realm, where you have potentially leverage points that could allow you to tap into or at least connect with the technical expertise within industry through groups such as the Personal Care Products Council or the Consumer Specialty Products Association and the like.

None of the industry connections were mentioned, and I'm just curious whether there is a -- are any outreach or coordination underway.

CHAIRPERSON LUDERER: Thank you very much for the

comment.

Dr. Petreas.

DR. PETREAS: Thank you. Myrto Petreas.

We have contacts with industry in terms of flame retardants. And as a matter of fact, because of recent legislation in California requiring labeling products as containing or not containing flame retardants, we met -- it was a small meeting with industry and government people, where I made a little presentation. And ever since, I get a lot of contacts from industry offering more information about history of use of flame retardants, different manufacture -- different types, and, you know, promises for more collaboration and offers to stay in contact. So we take this very -- it's very encouraging, because they have a lot of information we don't have, so we look forward to that.

CHAIRPERSON LUDERER: Sara.

MS. HOOVER: Yeah. Hi. Sara Hoover of OEHHA.

I just wanted to comment with regarding coordinating industry with regard to our documents. Very often, as we're prepping certain documents, we get contacted by industry groups. We actually meet with those industry groups. We get input, data information, that we take into account as we look at chemical groups for chemical selection. So that's another angle of where we

take that into account.

DR. DiBARTOLOMEIS: It's Michael DiBartolomeis. I might as well throw my ideas into the ring. Actually, at the time the Biomonitoring Program was established in statute, two other programs were either being established or had already been. The Safer Consumer Products Regulations and the Green Chemistry Initiative, and then of course the Safe Cosmetics Program were all around the same time. And it's been my idea certainly to bring the element of integration into the -- as the lead of the Biomonitoring Program.

And to that end, we are working collaboratively with the Department of Toxic Substances Control on ways to integrate the biomonitoring activities with the implementation of the consumer product regulations. And that, of course, does involve heavy back and forth with the industry through panels and other types of work, as you're probably aware.

The same thing with the Cosmetics Program. When I was creating that and running that program, we had quite a bit of interaction with the Personal Care Products Council and some of the smaller trade associations. And actually Paula -- Dr. Paula Johnson is here who is the new lead of the Cosmetics Program, so obviously you can see we do a lot of integration. And so your points are actually

right on. At some point, you know, this -- the idea would be to be looking at collaboration as a much more holistic, you know, kind of thing.

You know, at this point, a lot of our collaborations are with researchers and academics and, you know, Kaiser Permanente and those sort of things. For obvious reasons, they have cohorts, they have resources to help, but we're working toward that.

CHAIRPERSON LUDERER: Okay. Thank you, Michael. We have time for some more discussion from the Panel. I just wanted to get back to the topic that Dr. Bradman had brought up regarding the proposed bill regarding the use of blood spots and just let everyone know if that if you're interested in looking at the text of the bill it's AB 170, so that people can educate themselves about that. And I think that would be something that the Panel is very interested in. I would agree with that.

I also wanted to just comment on something that Dr. Petreas had brought up talking about the FOX study and the observation that hygiene seemed to be associated with decreased exposures to some of the compounds that you found were elevated in firefighters. And I think that kind of really naturally I think would lead to maybe another idea for a intervention study, and particularly an occupational intervention study, which you hadn't

specifically mentioned. You are talking about looking at dust from multiples sources now, not just the fire station dust.

But is there any thought or discussion about possibly doing an intervention study with firefighters and trying to do some biomonitoring to see whether the interventions are successful?

DR. PETREAS: Myrto Petreas.

At this stage, we're only considering dust. We brought up the issue of biomonitoring, but the Association of Firefighters doesn't want to consider at this stage. So first we do the dust and then we see.

CHAIRPERSON LUDERER: Dr. She.

DR. SHE: The comment on this I think so far the dust studies majorly focused on the persistent organic chemicals. To do an intervention to see the quicker results low persistent chemical is more important. The reasons persistent chemicals have a diverse input source, longer half-life. So intervention study is a lot easier done, but -- and I think I'd like to talk with Dr. Myrto Petreas on other study to see that if they considered the intervention study. For example, we find BP 3 is a very high level. These are chemicals to do the intervention study you can quickly see the result.

Thank you

CHAIRPERSON LUDERER: Thank you. I mean, one other possibility would maybe to do a cohort study where you'd track new recruits, you know, before they've got the firehouse exposure and then maybe do interventions in some firehouses and see whether they have less of an increase with time on the job.

Any other comments from other Panel members?

Yes, Dr. Quintana.

PANEL MEMBER QUINTANA: Hi. Is this on?

My comments are for Dr. DiBartolomeis.

Hi. Jenny Quintana. Is this on now?

Yea. My comments are for Dr. DiBartolomeis. And I have a couple comments on his future directions. And first of all, I'd like to talk about the results return that he mentioned. I think that the California Biomonitoring Program is helping efforts, not just in California, but the United States and around the world in terms of best practices how to return results to communities. And it's a really important and forward-looking part of this Program. And I want to commend this Program for doing that.

But my comment was to really kind of marry this concern with best practices for results return with the environmental justice component, and to really explicitly look at the best practices for disadvantaged communities

or minority communities and look at that explicitly, because that's extremely important for environmental justice part of results return.

And my other comment was in the context of the fact that this Program has had reduced funding and has done wonderful things. I did want to comment about the goal of statewide representative sampling, which was currently not carried out as originally envisioned with a much larger budget. But I wanted to encourage that in that we do things like the MAMAS study or the BEST study that very explicitly look at how does this fall short of the goal of representative sampling to very explicitly see who isn't in the BEST study in that same geographic area as -- you know, to have effort put to that -- to that part as well.

And I wasn't actually sure about the MAMAS study. The selection of those first samples was it a random sampling, stratified sample, or is that being done on those samples? And if so, it may be that anything that's in a biorepository is already not representative of who could be in that study. There's ethnic differences and accepting biorepositories, et cetera.

DR. WU: Sure. I mean the MAMAS study we know is an imperfect surrogate for statewide representative sampling. MAMAS with the biorepository is -- the source

of those samples is a prenatal screening program for California. And about 70 percent of pregnant women in California are screened through the prenatal sampling. So it's a pretty good -- it's a pretty good sampling of women who are pregnant. So already it's imperfect.

But that first 460 samples again was selected based on -- and it's a pilot study just to really assess the feasibility of using biobank, and we had some limits because of that, but we are moving towards this more statewide without our limits of biobank to represent the State.

We've made efforts to represent across races and geography. And we have some limited information about the mothers and we'll try to take those things into consideration to get as close to a statewide sampling as possible.

CHAIRPERSON LUDERER: Okay. We're actually over time. Are there any -- I think we need to go on.

So it's really a great pleasure to introduce our next agenda item. Thank you to the speakers from this morning already.

Dr. Ms. Lovisa Romanoff and Dr. Mary Ellen Mortensen from the CDC who will provide updates on activities of the National Biomonitoring Program.

Lovisa Romanoff is a health scientist and project

officer for State biomonitoring. And Ms. Romanoff is the program lead and the project officer for this cooperative agreement at the Division of Laboratory Sciences, National Center For Environmental Health of the Centers for Disease Control and Prevention, the CDC, in Atlanta, Georgia.

Lovisa has been involved in biomonitoring activities since 2002. Her early research focus was on biomonitoring of PAH metabolites, as well as developing methods for human exposure assessment of nonpersistent pesticides.

Lovisa earned her Bachelor and Master of Science degrees in Chemical Engineering from the Royal Institute of Technology Stockholm, Sweden, and a Master of Public Health from the University of South Florida.

Dr. Mary Ellen Mortensen is Chief Medical Officer in the Division of Laboratory Sciences at National Center for Environmental Health, where she serves as an expert in pediatrics, medical toxicology, and biomonitoring.

A major aspect of her duties involves overseeing updates and revisions to CDC's National Report on Human Exposure to Environmental Chemicals and the updated tables. And in her role as the laboratory division's liaison with the National Health and Nutrition Examination Survey, NHANES, she developed a successful feasibility study to collect urine from young NHANES participants that

has resulted in urine collections beginning with age 3, where previously it was only starting at age 6.

She has been the CDC lead for a pilot study to measure a panel of environmental chemicals in pregnant women and infants enrolled in the National Children's Study, and was a member of the Interagency Coordinating Committee of the NCS, the Nation Children's Study, and a consultant to the NCS for biological sample protocols. And she is CDC's liaison to the American Academy of Pediatrics Council on Environmental Health, which provides policy and technical advice to the AAP and environmental health education to the AAP membership.

So it's really a pleasure to welcome Ms. Romanoff and Dr. Mortensen this morning.

Thank you.

(Thereupon an overhead presentation was presented as follows.)

MS. ROMANOFF: I had to bring my phone with some notes on it.

Good morning. I'm Lovisa Romanoff. And as you just said, I'm from the Division of Laboratory Sciences at CDC's National Center for Environmental Health. I'm the program lead and project officer for State Biomonitoring. I've been the project officer for the past five years. And so I'm very familiar with the Biomonitoring California

Program.

It's always great to come out here and do site visits and visit with the scientists and hear about their accomplishments. And I think that they've made a lot of progress over the past five years, first through the cooperative agreement that just ended in 2014, and then now as part of the new cooperative agreement that we just began in 2014.

I'm here today to tell you a little bit about the National Biomonitoring Program and give you some NHANES updates. I've been part of the Scientific Guidance Panel in the past -- or meetings in the past, but I've never been on the agenda, so thank you so much for including us here today.

My part will be fairly small. I have the good fortune of bringing Dr. Mary Mortensen with me today. She is our Chief Medical Officer in the Division. And she really is the person behind the national exposure report, which I believe many of you have seen and work with. And she's also our liaison with NCHS working on NHANES work.

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MS. ROMANOFF: So just a very brief update. Our background of the National Biomonitoring Program. So the National Biomonitoring Program is one of our division's core programs. We have other activities in the Division,

but this is really one of our most important programs.

The goal of the program is to provide laboratory science and to detect -- to improve the diagnosis, detection, treatment, and prevention of disease resulting from exposure to environmental chemicals.

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MS. ROMANOFF: The objectives of the Program is mainly to assess the exposure of the U.S. population. And this is done through our work with NHANES. And on average, we -- this is where I needed my phone for the numbers, because I wanted to give you the number of environmental and nutritional indicators that we do measure in our division, and it's 345.

And then we also do specific studies where we provide biomonitoring measurements on specific populations, and collaborate with partners on studies to investigate the relationship between human exposure and adverse health effects.

On average, annually we do about 100 of those studies a year. And I know that we have actually partnered with some of our Panel members on some of those studies.

We continuously work on new and improved biomonitoring methods. We add analytes to methods continuously. And then as technology updates, we move

into more automated procedures since we have a very high throughput in our laboratories.

We also provide support for CDC emergency response that involves exposure or potential exposure to environmental chemicals. And then finally, and this ties back into the Biomonitoring California Program, where we provide analytical and technical expertise support. We provide training and technology transfer to our partners, both State and local laboratories. And many of the scientists in the Biomonitoring California Program have visited our labs in Atlanta to get training on existing methods.

We also have established a proficiency program for biomonitoring methods. Some of the compounds that are included in the measurements that the laboratories at the State level and also CDC does, there are no proficiency programs available for some of the compounds, so we've tried to bridge that, and make some of them available able to our State partners, as I'm sure has been explained to you. Jianwen was just talking about us now including BPS and BPF in that program, which I don't believe is available anywhere else.

So that is just a very brief update. Dr. Mortensen will talk more about NHANES and our partnerships with NHANES.

She disappeared.

Thank you.

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DR. MORTENSEN: Thank you, Lovisa.

I'm Mary Ellen Mortensen with the Centers for Disease Control. And I want to start by thanking you for the invitation to be here, and also to the marvelous hosts from the Health Department, the Environmental Health Lab, and DTSC - I'm learning new acronyms - who have been fantastic in sharing their experiences and have just absolutely an awesome program. I don't even know how else to describe it. But it's been such a pleasurable two days of tours and discussions, and with some great input for me personally, in terms of trying to make the exposure report a more usable and improved product, if you will.

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DR. MORTENSEN: So actually, I'm going to start, because many people don't understand the relationship between NHANES and the exposure report and the National Biomonitoring Program. The two are very closely linked, but they are not the same thing. NHANES is the National Health and Nutrition Examination Survey. It's been going since 19 -- let me see if I can get back one slide -- 1971 when Congress authorized it actually to evaluate the nutrition in the U.S. because there were pockets of severe

deficiencies.

It became a continuous survey, releasing data in two-year cycles after 1999. It's a very complex, stratified, multi-state representative, all of those kinds of adjectives which I know all of the advisory committee members know very well.

There are about 10,000 participants at 30 locations who are interviewed, surveyed, examined, sampled, and so on every two years, so -- and, in fact, to be a participant in the NHANES survey is about a two-day commitment of time. It's, in many ways, very invasive. They come to the home. You go to the mobile exam center, which is shown in this slide, and spend quite a bit of time being -- talking to people and being examined and getting -- giving samples.

I think -- from my personal perspective, from the exposure report's perspective, and from DLS's perspective, is this, the mobile examination centers, or the MEC, that are so critical to us being able to measure these environmental analytes, these contaminants, if you will, the environmental measures that we are able to make because we get pristine samples, we get samples that are collected through very carefully designed and executed protocols by experienced staff. We do pre-screen all of the materials that are used for collecting any samples

that are going to be measured for metals, and we have had discussions and done some limited pre-screening for other materials, but really it's the metals that require pre-screening, so that what you measure in the sample is what was in the person and not in the environment around them.

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DR. MORTENSEN: The exposure -- the exposure report reflects the NHANES measurements that our Environmental Health Laboratory measures in the samples that come from NHANES. We do have a formal process for adding new chemical measurements or groups of chemicals. And there is a link on this website that will take you to a Federal Register Notice. It was formally offered in 2002 -- or formalized in 2002. But basically the criteria for consideration of a new chemical or chemical group are these listed here. But bear in mind, we are looking at the U.S. population in general. So we really focus on wide -- chemicals or analytes that we think may be present in the U.S. population widespread exposures.

Considerations also include the availability and the feasibility of an analytical method, and to a certain extent, the costs of those, because we do pay for the collection of the samples. And, of course, developing new methods doesn't only take time, but it does require some

investment of financial resources.

So because there are -- among my clinical colleagues, there sometimes are questions about, well, such and such new chemical is out in commerce. Why don't you just start measuring it in NHANES?

Well, it's a little more complicated than that. And again, I'm sure many of you know that, but I put this slide together as sort of a series of steps that we follow and have to follow before we can add a new chemical to NHANES and to the exposure reports.

First of all, we, as I mentioned, need a justification in the criteria for inclusion more on the previous slide. Then we have to think about what is the best analyte to measure and what is the best matrix.

And sometimes that requires some preliminary -- for new chemicals, preliminary studies in animals to determine what the metabolites are, for example, if we think that measuring urinary metabolites would be optimal.

Then the method has to be developed or modified, because we do try to develop multi-analyte panels, so that we can get the biggest bang for the buck, if you will, and measure the most chemicals in a single sample in a single method.

Sometimes there is no reference material available, so that limits us. We do work with NIST and

other organizations who develop reference materials, but that takes time, and it is very costly.

Once we have a method, we need to do a feasibility study, because we think we're going to find it in the majority of the population, but we may or may not. So this is often where we propose a study to NHANES to use surplus samples that they have archived. And that proposal has to go through an entire review process, through IRB approval. And we have to provide them with evidence that, yes, we do indeed have an analytical method that's up and running.

So once we get the results of the feasibility study, which is usually limited to a subsample in the -- of the population, not the entire sample as used. But once we have the data to show us that, yes, there's widespread exposure, we're detecting it in a large percentage of the population, we then have to notify NHANES that we want to make this part of the regular ongoing NHANES survey. And that requires that we submit a letter of intent.

And there's quite a lengthy lead time. And, for example, to get a measurement -- a new measurement in the NHANES 2017-18 cycle, we have to submit the Letter of Intent by middle of 2015.

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DR. MORTENSEN: So it's just not as quick as we would like it to be. So for any of you who are not laboratorians, are not familiar, this is a little bit of an explanation as to why. So NHANES though, as I'm sure you are aware those of you who use the data, has made some changes in their sampling design, which we think is terrific, because it has expanded the number of racial ethnic categories now that are available.

As of 2011-12, the -- actually they call it non-Asian -- non-Hispanic Asian, which I find to be kind of awkward, so I simply refer to the category as Asian -- racial ethnicity group has been added. Then a little earlier they actually had been oversampling all Hispanics. So there is now sufficient numbers in the category of Mexican-American and all Hispanics, so that those two categories can be analyzed, in addition to the non-Hispanic white, non-Hispanic black, and Mexican-American that have been actually available for quite awhile.

The point that was mentioned earlier, I think in my introduction, one of the things I worked with NHANES on was to try to lower the age at which urine is collected, because young children hard to get samples, but they're very much an underevaluated, if you will, population. So we were really excited that the feasibility study was

successful and that they are actually in the process now of starting to collect urine from three year olds and up. And that will be a full sample. It's not that many children, but at least it's 100 percent of children willing to give a urine sample who are participants.

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DR. MORTENSEN: With regard to some of the new measurements, we took quite -- there has been a lot of method reevaluation and revision. And DEET and the metabolites are actually themselves in a new method. So there should be some data released fairly soon which will be the results of the 2007-2008 samples, but we think that we'll be very rapidly adding additional more current cycles to those data when they're released.

We have sort of an administrative change, but for any of you who use NHANES data, you're used to finding environmental phenols and parabens in one group and then having to go to another group to find 2,4 and 2,5-dichlorophenol.

So for reasons of simplicity since they're all measured in the same group, we report them at the same time, we have discussed with NHANES consolidating those into single group, which we are going to call personal care and consumer product chemicals and metabolites. It's kind of a long name, but it is descriptive, since this is

kind of a mixed -- chemically mixed group in some respects. 2013-14 you'll see that posting of those chemicals under that category.

And starting also in 2015-16, we will be reporting blood cobalt and chromium for ages 40 and up. This category or these two blood metals were being measured as a result of requests from the Food and Drug Administration. And the reasoning for that is that the advisory committees on hip joints and failures of the artificial hip joints, many of the physicians -- many of the clinicians were anxious to get some standardized -- some reference ranges for these two blood metals, which they feel is an -- are important, at least as a source of information, not solely, but to add to the information to evaluate potential hip failures.

So we had some reservations and rather had hoped they would be happy with urine cobalt and chromium, because there is quite a split between people with failing hips and normal individuals, in terms of those values, but they felt that they also wanted blood cobalt and chromium, so that's why these two metals are being added to the panel starting in 2015-16.

There are a couple of groups that we have been measuring all along, or for many years. And we have another phthalate alternative metabolite. The alternative

chemical DINCH, as it is known. We were measuring -- we just started measuring in 2011-12, I believe, MHNCH. And now we will be measuring a carboxy-MHNCH, which we think might even be a better measure of exposure. So these two metabolites will be available at -- we are sure in 2015-16. We're hoping we'll get approval to actually measure and report those in 2013-14.

The additional dibutyl phthalate metabolites shown here will also be measured hopefully in 2013-14, but we are waiting for approval to measure and report those in '13-'14, but we do have approval for '15-'16.

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DR. MORTENSEN: Continuing. There are some specific -- I still call them PFCs, so pardon my non-chemistry language, but we are measuring some of the specific isomers of PFOS and PFOA starting potentially in 2013-14, but certainly in '15-'16. We will continue to report PFOS and PFOA, which are really summary types of measures of these specific isomers. So we'll be reporting all of these in the exposure report starting then, and NHANES will have them of course on-line.

We have, unfortunately due to some resource limitations, had to reduce the sample size in the blood metals for 12 year and older ages. And it will be a one-half rather than a full sample. I was particularly

unhappy that this was necessary, because we had just, as of 2011-12, begun reporting speciated mercury in blood. And it's unfortunate that we've had to drop the sample size down by 50 percent in adults. So that will be affected.

There are a number of urine and serum tobacco biomarkers that will be released for 2013-14. And these are listed here. I'm not going to name them, because people have access to the slides, but these have been -- the methods for these have been developed in conjunction with the FDA's Center for Tobacco Products as part of their work in tobacco control and evaluation of smokers. And so these metabolites will be reported.

And they will be measured in a sample of adults -- principally in the sample of adults who are smokers versus non-smokers, which we currently have in the report.

From time to time, we do stop measuring some chemicals. The formal process is described in the Federal Register Notice that's listed here, but largely these criteria can be categorized as we find a better way to measure exposure. Maybe it's a new metabolite, maybe the only metabolite was not a good indicator. Also, if we're not detecting a chemical or a group of chemicals, actually all the chemicals in a group for three cycles, we will

stop measurement and redeploy those resources. And then also for some chemicals, when the levels are not changing, they're very consistent, we find that it's probably not of value to continue with the measurements. We may simply elect to stop measuring those, except for chemicals such as those that have established biomonitoring thresholds, like blood lead, or for which there are specific health concerns, such as blood mercury.

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DR. MORTENSEN: Let me see. These are the chemicals that we are not going to be reporting after 2010. Either beryllium and platinum are chemicals -- are metals that we have not detected in urine in more than three cycles, I believe, but we just have not found them to be present, not at the concentrations we can measure.

The phytoestrogens have been stable. The dietary sources of these chemicals, these compounds have essentially not changed, so we didn't feel that there was value in continuing to measure them. Some of the others are -- the rest of these are chemicals that we were not detecting in the urine samples. These are all urinary metabolites. So we aren't measuring those any longer.

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DR. MORTENSEN: The last thing I would like to mention is that we are contemplating a fifth report -- a

fifth national report. As those of you familiar with the fourth report, we were doing updated tables. Our goal is to get compilations of the data that is publicly available put together and out to the public as fast as we can. And the updated tables seemed to be the most expeditious way to do it.

It's an enormous document. And for those of you who have insomnia, I can recommend sit down with it, just read through the tables --

(Laughter.)

DR. MORTENSEN: -- numbers and numbers and numbers, and I'm sure you won't need a sleeping pill.

But the fifth report that we are contemplating would be an electronic version. It would look probably a lot like the fourth report -- I'm sorry, the updated tables. Unlike the fourth report, which had a lot of text, those that text those contextual summaries, if you will, of the chemicals and chemical groups, we have removed. And actually, they are all available on-line. But we call them biomonitoring summaries and we separated them out, because we felt that it would just make a document too enormous to try to keep including that. And there's some other administrative considerations that make this a pretty good solution for us to get these updated tables out fairly efficiently.

So the fifth report would be more like an updated table. But right now, the 1,100 page document that we put out in February can't be emailed. It's so ginormous. And I worry that people with slower connections may have trouble downloading it.

We also thought, well, you know, maybe there's some natural breaks. We have discussed and actually one of my agendas for coming out was to talk with the folks in the Health Department and the Environmental Health Lab and the groups here who are users of the reports to see would it be okay? What do they think about separating these segments or these sections into volumes, so that the U.S. population data, which is at the front of the updated tables, make that one volume, have a separate volume that deals -- that provides the tables on the adult smokers and non-smokers, and then have a third volume for pooled samples, which are largely the persistent organic pollutants at this point.

There could be a fourth volume to pull out the data tables, which are chemicals we no longer measure. But we don't want those to get lost, so that might not be a very smart thing to do. I was thinking of that as a -- we brought that up as a suggestion simply to reduce the file size of the PDF.

We think we'll stay with the PDF format, at least

have that, because it seems to be a format that works across all kinds of platforms. And over time, people have the ability to open it with a publicly available Adobe viewer.

So those are some thoughts that we've had, and bounce these ideas off the folks, and gotten some great suggestions to the health -- from the Health Department, and the labs and DTSC.

The last item I would just point out, we also ran into a problem. We've got so many cycles of data for some of these chemicals that the tables are three or four pages long, even more when you have urinary metabolites and you have to show the uncorrected and the creatinine corrected.

So we made the decision to -- for all the tables to essentially have data up to 2010 in the first table, and then refer people to a subsequent table, which follows it, for the 2011-12 and subsequent data. Hopefully, I'll retire before we run out of room. But that's exactly what we've done.

And, of course, my concern was confirmed when one of the lab chiefs called after the table -- the February release and said, I see the data up to 2010 -- '09-'10, what happened to '11-'12, did you guys -- oh, she didn't -- users who know -- who go to it and look just didn't even think to keep going to see if there was a

subsequent page. We're going to try to address that with a little note on the tables, but these are kind of the changes that we've tried to make this as user friendly. We have limited venues to get feedback, but any suggestions are welcome to improve the usability. And I thank you for the opportunity to be here.

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DR. MORTENSEN: And this is kind of what the website looks like with the most recent updated tables. I apologize. Somehow the website link web address did not get included on this. I thought I had it, but it is CDC -- www -- www.cdc.gov/exposure report. I have it as a link on my favorites, so I never think about what it says, so pardon that -- so pardon my omission, and I do thank you very much for the opportunity to be here and be happy to answer any questions.

(Applause.)

CHAIRPERSON LUDERER: Thank you very much. That was a really great presentation. We have time for clarifying questions first from the Panel.

Dr. Quintana.

PANEL MEMBER QUINTANA: Hi. Is this on?

Yeah?

Okay. First of all, I want to say I did read the updated tables. I didn't fall asleep.

(Laughter.)

PANEL MEMBER QUINTANA: They came out. I was very excited to see them.

DR. MORTENSEN: Cool.

PANEL MEMBER QUINTANA: My students are actually doing a take-home mid-term using part of it, so I hope they don't have problems with their slow connections.

(Laughter.)

PANEL MEMBER QUINTANA: So I want to commend you for having the adult smoker versus non-smokers data in there, because I think that will be extremely valuable as a way to help communicate results to participants. For example, if you have chemicals which are in tobacco smoke but also in other types of occupational exposures, like firefighting or exposed to traffic. And you can say, oh, your levels are higher than some people in our study, but about half those of active smokers. That helps people put things in perspective, so I think that data is extremely valuable.

And I was wondering if you had thought about a similar approach for other highly exposed populations as a way to help frame what are typical levels of certain biomarkers. And then my last question to you, on a separate note, is when I was looking at the updated methods, I was just wondering if you had discussions at

the CDC and NHANES about including Native Americans, more oversampling for that population, because I'm not an expert in that area, but I do know they have many different exposures, often very different water sources, local water that may be contaminated, for example. And I thought that must have come up in discussions and I was curious how that played out?

DR. MORTENSEN: I'll try to answer those. Thank you very much for your comments, and I'm happy to hear that the data are useful. It's always a good thing.

With regard to the Native Americans, they're not specifically excluded, but they are not a group that is oversampled. There are challenges in working with each of the different tribal nations, and handling of particularly biological samples. As far as I know, and I've not been involved in discussions about changing the study design, but I think there have been some discussions to try to do it.

Now, the NHANES is only conducted in the continental U.S., so Alaska and Hawaii are not part of the survey sites, so that would exclude certainly Alaska native population, which for obvious reasons you couldn't really haul those tractor/trailer trucks through the winter of Alaska or even in the summer.

So there are some issues, but it is -- it is

something that is -- I can raise it, because I think it's been discussed. They have tried to work with -- I don't know to what extent, but it is a population that does not get oversampled, you're absolutely right.

And part of it has to do with the limitation in the number of participants who can be included in a given year, and the desire to keep it as a representative national sample.

The other question -- I'm sorry, your second question before that?

PANEL MEMBER QUINTANA: It was more a comment about the value of having highly exposed populations separated out in the tables for comparison purposes.

DR. MORTENSEN: Right. One of the limitations of NHANES is that exposure information per se is pretty limited, other than tobacco smoke.

Most of the questions are still geared toward health and nutritional behaviors. And there is occupational information collected, but other than that, use of products, things like that, just have not been part of the survey.

Now, if someone could come up with sufficient financial resources, we could put in a request and work with them to make changes in the questions. But they are also at a point where the burden on the participants is

such that, if they were to add questions, they would have to remove other questions. And they do that from time to time, but really I think you have to think about NHANES as providing you a snapshot picture of the general population exposure with some people highly exposed, some people not exposed, and it's really not feasible to really sort out those exposure levels. It's just a limitation of being a national survey.

CHAIRPERSON LUDERER: Dr. Bartell and then -- oh, Dr. McKone and then Dr. Bartell.

PANEL MEMBER McKONE: I'll be quick. I guess comments. One is you said you apologized that there was no link. There is a link.

DR. MORTENSEN: Oh, it is in there.

PANEL MEMBER McKONE: I have your PDF. And as a matter of fact, I clicked on it and downloaded everything in a couple minutes.

DR. MORTENSEN: Oh, awesome. Oh, so it did work as a link. Okay. I just didn't --

PANEL MEMBER McKONE: And I'm looking through all the data right now.

DR. MORTENSEN: Excellent. Uh-oh, I don't want you to fall asleep.

(Laughter.)

PANEL MEMBER McKONE: I might fall asleep.

Actually, the other is a comment too. You showed the trailer complex. And I just want to say in the early days of the Panel, like when we first started, we were invited -- the CDC was set up. I mean, the NHANES trailers were in San Francisco, and we went over and got a really nice tour. I think it was like a half-day tour. I mean, we really went through each stage. And it's just a fascinating process. And it's really worth doing. I mean, if the trailers are around the area again, we should probably take an opportunity if we can get somebody to let us in to look at it, because it's -- you really don't understand the process. You can look at the data tables, but it's fascinating to see how it's actually done and controlled and managed, and how much stuff gets packed into those trailers.

DR. MORTENSEN: It is remarkable. And they upload the data every night to the servers.

PANEL MEMBER McKONE: And they ship the samples out the same day.

DR. MORTENSEN: And ship the samples after they, you know, process them, aliquot. It is just remarkable and --

PANEL MEMBER McKONE: Right, because part of the trailers are a lab. That was the other thing that fascinated me is there's an active lab to get everything

sort out and -- yeah.

DR. MORTENSEN: It is really a crown jewel of NHANES, and I think unfortunately under-recognized, particularly when it comes to widespread recognition in the federal government.

PANEL MEMBER BARTELL: Actually, this is as much a question and perhaps more a question for the California Biomonitoring folks, but it was spurred by something you said about, you know, the national sampling goal of NHANES, which is very important. I think in thinking about this distinction when we're asking about sort of high risk populations, it brings you to not only different goals, but much different sampling designs than when you're trying to do a representative ample, either in NHANES for nationwide, or, as we talked about earlier, with a statewide sample in California.

And I thought this was actually interesting. It kind of was implicit in some of the presentations earlier today, that a number of the California Biomonitoring Program's activities that are ongoing right now are not, in fact, designed to be statewide samples. But there was some mention that maybe that was a long-term goal or at least, you know, thought of as an ideal thing would be to do statewide.

I guess I'm not necessarily sure I would always

agree with that. I think sometimes you learn a lot by actually focusing on high-risk populations instead, which actually brings you to different, you know, sort of study goals, different study designs. And so this is partly a comment, but also a question for the California Biomonitoring folks. To what extent, if any, does the Program have the ability to decide between these two goals? You know, are you -- do you have mandates from legislation that say this has to be statewide sampling and so you view these collaborations as maybe sort of pilots and that you want to work towards that or is the idea of maybe doing some specific high-risk sampling actually also one of your goals? And I guess the question is not only legislative or Program mandates, but also does your cooperative agreement with CDC allow you flexibility in deciding which of those goals to pursue?

DR. DiBARTOLOMEIS: This could be a long conversation.

(Laughter.)

DR. DiBARTOLOMEIS: And there are probably 25 people in this room who can answer this question. So very briefly, yes, in the statute, we are mandated to look at the State as a representative, as well as look at targeted populations, so it's both.

This is a little taboo of a subject, but it's

factual. We have never had the resources to do what would be an equivalent of an NHANES in California. So we have -- as we've mentioned, and you're picking up on, we do these things that are kind of surrogates for it, MAMAS, which has deficiencies, BEST, which has its deficiencies. So they're not really -- not only are they not representative statewide, we're also not doing the kind of survey instrument kind of thing that -- we do questionnaires, but not to the extent that NHANES is doing.

So it's really cost prohibitive at this point, but it is a long-term goal, because, A, it's still mandated. We realize it's there. And we still get, you know, I guess advocates who really want that done. And there is obviously a scientific need as well. You know, to just -- you can't really compare what's going on with California with the NHANES in a very -- in a detailed way because of the regionality and -- you know, even in California, we have regions obviously.

So the other major statutory obligation, I guess I would say, and mission of the Program is to also inform policy development and past and future practices. So you can see how if we were to use targeted versus -- and statewide and then, you know, couple it with consumer products and that sort of thing, that meets that mission.

So I'd be more than happy at some point to actually spend time with you on the phone and talk more through this, but I'm being told to --

(Laughter.)

CHAIRPERSON LUDERER: Dr. Lipsett.

DR. LIPSETT: Michael Lipsett. I'm formerly with the Biomonitoring Program.

And when the Program was initiated, we actually did work with the CDC people who were responsible for designing NHANES to develop an approach that could be scalable in California to do this same kind of sampling. And so we actually do have that study design. You know, it's archived now. It was -- as Michael said, it's really cost prohibitive to do that.

But also with respect to the legislative mandates, the bill that finally went through was the fourth attempt by Commonweal and the Breast Cancer Fund and the legislature to get it through. Earlier iterations really focused on more highly exposed communities. And I think that's -- that was part of the intention of the advocates, but I think that the administration at the time wanted to also have, you know, a statewide sample as well. So we have both of those mandates.

CHAIRPERSON LUDERER: Thank you, Dr. Lipsett. And I know the Panel discussed a lot at the beginning too.

There was the whole question of could one obtain NHANES data for California participants, but that's not possible because of the small numbers and concerns about participant privacy and being able to identify individual participants.

I did have another -- I would love to hear a little bit more about the three-year old urine sampling. That's very exciting. I was just curious what is the percentage of three-year olds from whom you attempt to get samples that you're successful?

DR. MORTENSEN: Right. Well, once again, I have to credit the staff in the mobile exam centers who were trying to get the kids to cooperate and explain it. It was a feasibility study in a -- just a convenience sample of the MECs. And essentially, they were almost 100 percent successful in getting children to give it a try, and most of the time succeed in getting an adequate urine sample.

Now, we had worked with them because we actually -- part of the feasibility was that we took the urine samples and made a series of measurements of the various urinary chemicals that we measure, so -- among -- which included the metals. So the technique involved, we had the little -- I'll call them the urine hats. They fit in the toilet boil. We had to pre-wash those with acid

and package them individually. And then the staff would use those to collect the urine and put it into the container. And then it was sent off and handled as usual.

There were probably -- I think we had about 300 -- no, we did not have that many. We had 150 -- 100 to 150 children. And virtually all of them did contribute, and we were really thrilled. And I'm sure that a lot of this has to do with the enthusiasm of the staff in the MECs, and the assistance from the parents, because the folks who participate, you know, they're really unsung heroes in many ways. And so we were really excited that we got great samples.

We are going to make -- the data will not be made available on-line -- you know, published to the NHANES website. It is in their research data center. So it's available to people who make a proposal to analyze the data to the RDC, but it is not going to be publicly available, because it's not a representative sample. That wasn't the intent. It was really a feasibility study.

So I would say that there is -- in reference to your comment about the inability to look at regional data, you're absolutely correct, the publicly available data is not -- you don't know where it was collected in the U.S. However, there is a process to propose a study to the NHANES to get access to those data. It's very carefully

controlled access. And nothing but the results of an analysis of those data can be taken with the investigator who does the analysis. And it's reviewed to make sure that there is no possibility of disclosure, but it is possible, and there have been a few studies that looked at regional exposures to certain chemicals that have been published, but they are very -- they're carefully looked at to make sure there's no breaching of confidentiality, because that is so critical to participation.

So the RDC is going to have the data from the three- to five-year old urine study, but we've -- we've looked at it, and actually the detection frequencies -- I believe there will be an abstract at the ISEE meeting that Dr. Calafat has looked at a number of the analytes measured in her lab. So that would be these consumer -- what did I say it was called, the Personal Care and Consumer Products category of chemicals, and largely detection frequencies, but by then we may have more information available. So thank you for your interest.

CHAIRPERSON LUDERER: Okay. Do we have -- yes, we do have public comments.

PANEL MEMBER BRADMAN: I have one more question.

CHAIRPERSON LUDERER: Okay. We'll have time after the public comments for more questions. Thanks.

Okay. Our first public comment will be from

Alexander Hoepker, UC Berkeley.

MR. HOEPKER: Thank you for the presentation. I had a quick question about endocrine-disrupting chemicals. Is that part of the report of the CDC? In particular, I'm referring to EDC activities as opposed to measuring individual chemicals. So being a catch-all approach essentially that's targeting known EDCs, but also ones that have potentially not been identified as such.

CHAIRPERSON LUDERER: Dr. Mortensen, would you like to answer that?

DR. MORTENSEN: I'll take a try. When we talk about endocrine disrupting chemicals, there's quite a broad spectrum of individual chemicals. A number of those are measured individually. And in the analysis of NHANES data, there is an identifying -- sort of an identifier with the individual. So you could potentially select a number of chemical groups or chemicals if you wished to measure those, and you could link them across individuals. Not every chemical is measured in every individual in NHANES. So you might find that, for example, PBDEs were measured in one group and maybe the phthalates were a different subgroup.

But for the urinary metabolites, frequently you can actually look at several chemicals and determine that they were measured in the same individuals. I'm not sure

if that was the question you were getting at, because we measure individual chemicals within a group and several groups of chemicals.

MR. HOEPKER: In addition to measuring --

MS. HOOVER. You've got to use the mic.

CHAIRPERSON LUDERER: I think the question was whether, in addition to measuring the actual chemical concentrations, you measure their endocrine activity?

DR. MORTENSEN: Oh. Oh, oh. I see. I'm sorry. I'm sorry. I misunderstood.

Actually, those kinds of effect biomarkers are not part of the measures that we do. There is information about health and there are a number of clinical chemistry measurements that are made in the NHANES participants. And at one point, for example, they were measuring TSH and free T4, I believe it was, or they had some indicators of thyroid function, but that's not a consistently available indicator. So it kind of depends on what effect measure you're interested in looking at.

CHAIRPERSON LUDERER: Thank you.

Our next commenter is Nancy Buermeyer from the Breast Cancer Fund.

MS. BUERMEYER: Thank you very much, and thank you for the opportunity to comment. And welcome and thank you for coming all the way from Atlanta to sunny

California to do that great presentation.

We use the NHANES data a lot at the Breast Cancer Fund. We think it's incredibly important data. I have spent the last week writing some comments on phthalates in children's toys that has keyed largely on the changing suite of phthalates and relative antiandrogenic effects, and whether, based on all of that, we should ban DINP from kids' toys.

So you guys are front and center and a really important conversation in our world. And obviously, really appreciate the work you do and look forward to continuing to do that and have the sort of national and the State work complement each other.

In terms of suggestions that would make my world as a lobbyist -- as an advocate easier would be any information you guys could provide as a standard manner on the frequency of detection above the level of detection.

So we sometimes get those numbers out of the data, but it's not easy to come by at least. I've read your tables, and it took me awhile to find the 2011-2012 data. It's true, but I found it, so it's all good.

(Laughter.)

MS. BUERMEYER: But that kind of information would be really helpful, as well as any information you could breakdown about how many phthalates you found in a

particular person. So like what percentage of the population had five phthalates or more? What percentage of the population had 10 phthalates or more?

And everyone I've talked to who actually gets into the interstices of the data says it's really complicated, so I don't even try. But to the extent any of that could be brought forward, that would be super helpful, particularly as we try to move the conversation in science towards cumulative effects of chemicals that have similar impacts. So those would be my thoughts for you guys.

And thanks again to the Panel for having them here and for all the work that the Panel does.

And on the -- just briefly on the front of statewide versus smaller populations, the question that Dr. Bartell asked, yes, the law said they should do it, and the advocates have not yet been successful in getting enough money for them to do what we asked them to do in the law.

So we continue to work to try to fund the Biomonitoring Program at a level that would really fully realize the potential that this amazing resource -- of this amazing resource that we have. And we'll keep working on that.

Thank you.

CHAIRPERSON LUDERER: Thank you. And Dr. Mortensen, you had some responses to the questions.

DR. MORTENSEN: Thank you. Dr. Mary Mortensen. And I just -- I appreciate your comments. They're really well taken, but I did want to clarify something, the issue of detection frequencies. We've talked about putting those in the data tables and have decided not to do so, because the limits of detection can change as methods improve, as we change a method. And so that could be misleading, because if you have a much lower detection limit, suddenly you may have a detection frequency that goes up and people go, "Oh, my goodness", without understanding the role of the LOD, or the limit of detection, in that factor.

However, the NHANES website does provide a documentation file, which would allow you to essentially estimate in the sample the frequency of detection of a given analyte because they have a code for it in the variable, and I can give you details later.

But you can get a feel for the frequency of detection in the sample, and you can look in subsequent NHANES cycles to get an idea of where the detection frequency is going. So that was the one.

And the other one -- oh, with regard to presenting data on how many phthalates were found in how

many women, for example, we actually -- that kind of a detailed analysis of NHANES is something that we look to the public -- to the authors of publications. And there are publications that really have looked at the -- the number of phthalates, for example -- phthalate metabolites that are found in women.

And so I would urge you to check -- do a literature search really. It's the best way. And if you use NHANES as one of the key words and phthalates, you'll probably come up with some of those studies, but that's -- that's really beyond the kind of analysis that our data tables can undertake, so -- but there are publications, plenty of them, on the subjects like that.

Thank you very much.

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

PANEL MEMBER BRADMAN: Yeah, I have a couple comments.

Okay. I just wanted to applaud your including three year olds and doing that sampling. That's something that I used to say with more frequency at these meetings that I think, as a group, this Program is leaving out younger kids, and I haven't said that for a year or more. So I think it's time to repeat that.

(Laughter.)

PANEL MEMBER BRADMAN: Our group, we've actually successfully collected urine samples starting at six months of age, and many samples from kids two, three, four, five, six. And one limitation we've had with the NHANES data is having that as a comparison group for the measurements we've done with younger kids.

Also, I kind of want to highlight a really important use of the NHANES data for us, in general, and that's for returning results to participants. In fact, a number of years ago, our IRB kind of made it a condition that our approval to return results was having a national reference sample, and being able to provide some interpretation.

And, in general, I know many of the groups here and at Berkeley and other biomonitoring groups use the NHANES data for, as a reference sample, and return results. And that's really an important purpose of it and really valuable. So I just want to highlight that.

And then I was interested by the criteria for dropping chemicals. And I can see how that could be kind of a loaded issue sometimes. I'm thinking also say, for example, flame retardants, and we see some evidence that PBDE flame retardants are declining, and there's been changes in use, of course, in the last decade.

And I think three cycles seemed like it could be

a little short to really say document a decline, if those levels continue to decline, or there's some evidence they are declining. So I'm wondering, is it fixed at three cycles or how do you deal with that when you're dealing with something with kind of big policy implications?

DR. MORTENSEN: Thank you. It's Mary Mortensen again. And I may not have made it entirely clear. The three cycles really pertains to non-detectable concentrations in all the chemicals within a group.

So, for example, flame retardants, if they hit non-detectable in all categories for three cycles, things would have probably changed substantially from the current time. But just a decline in and of itself wouldn't -- it would be unusual for that to be a sufficient reason for us to stop the measurement of a chemical group, especially one in which there is so much interest and concern, and actually with other studies of highly exposed populations, the need to continue to have national reference ranges. So I'm sorry if I didn't make that clear.

CHAIRPERSON LUDERER: Dr. Quintana.

PANEL MEMBER QUINTANA: Hi. This question, I'm not sure if it's for the staff or for Dr. Mortensen, maybe the folks at UC Irvine. But getting back to representative population sampling, when you were being introduced, you were commented that you had worked with

the National Children's Study in the past. And I was just thinking that there are archived samples, biological samples, urine, blood, as well as of course dust and everything else from the Vanguard Center that was run through UC Irvine. And that was a population-based random sample, at least of neighborhoods.

And so I was wondering if any discussion had taken place with the staff at petitioning to get those archived samples and examine the full suite of chemicals in the samples?

CHAIRPERSON LUDERER: Dr. Mortensen.

DR. MORTENSEN: Dr. Mortensen. I'm probably most familiar with the National Children's Study, because I did work with them for quite awhile. And absolutely, the Vanguard -- the seven Vanguard Centers that started enrolling and collecting samples in around -- in late 2009 collected samples up for about two years. And then pretty much sample collection I think ceased as they tried to determine better ways to recruit and retain enrollees, participants.

So there -- CDC did do a pilot study with the National Children's Study, in which we did measure a suite of environmental chemicals in samples that came from each of the seven, rather a convenience sample or just a unselected group of about 500 total, 75 samples per

Vanguard Center.

And those data are actually in the NCS data repository, the results are. And at this point with the wind down of the NCS, there has been discussion of making the archived samples, which are in a biorepository, and have been maintained -- we worked with them on the protocols for collection and maintenance. So I think that they have done a really nice job with that.

But I don't know the mechanism or when and how that's going to become available, because the program office of the National Children's Study is being disbanded. And most of the contracts with folks who work with the contractors that worked with the -- with the National Children's Study are going to come to an end probably in September, if not sooner.

So I don't know what mechanism -- nothing has been said about how they're going to make it available, except that NIEHS, I think, has been given some authorization to work with -- use some of the funds to develop some analytical capabilities around the country. There is a program they call CHEAR. I believe the RFA came out about a month ago -- or no a few weeks ago. And part of that may include archived samples, but it is unclear what -- who's going to manage and how that -- those archived samples would be managed.

So I think it's possibly something to stay tuned or to ask about. And I'm not entirely sure who to tell you to ask, except folks at NIEHS who deal with the extramural programs.

PANEL MEMBER QUINTANA: I think in California something on the order of 150 subjects in the Vanguard Center, 175 or fewer.

CHAIRPERSON LUDERER: In that range.

PANEL MEMBER QUINTANA: Yeah, so it's not a huge number of samples, but it is at least California, even though it's all southern -- Orange County, but it is a sample.

DR. MORTENSEN: Right. Right, it is. And they've got urine and serum, and I think saliva samples.

CHAIRPERSON LUDERER: Environmental samples as well.

DR. MORTENSEN: Environmental samples, right. They did quite a series.

CHAIRPERSON LUDERER: I mean, I don't know about how you can access the biorepository, but that CHEAR that it called for proposals, I think part of what they're asking for is proposals about how to do that, so -- yeah.

DR. MORTENSEN: You may be right, because this is not something that NIEHS has traditionally done. And so it is an open question, but I know they do want to make

those samples available and the data that had been collected and warehoused.

PANEL MEMBER QUINTANA: But for the staff of the California Biomonitoring, you have not made a request at this point or have you considered requesting those samples?

DR. DiBARTOLOMEIS: There are different ways I can answer this. I'm just going to give you a quick answer for now, because it's a little premature, but we are hooking up with UC Berkeley to write a proposal to be one of the lab networks for this CHEAR Project, so we would actually be an analytical laboratory.

We -- I can tell you the other thing is when we had a half hour, 40 minute conversation with the NIEHS contact, she herself said basically what Mary is saying and others, they don't really know how they're going to implement this yet. So I think it's really just premature to get into a detailed discussion.

Nevertheless, it is definitely on the radar. And I think we'll be able to report something back at the next meeting. I think that's probably the best thing to do at this point.

CHAIRPERSON LUDERER: Do any Panel members have more comments or questions for Dr. Mortensen?

MS. HOOVER: Hi. I was waiting to make sure no

one else had any last comments. So I was going to -- this is Sara Hoover of OEHHA. I just did want to mention, since we're a very difficult acronym challenging Program, that OEHHA was also involved in meeting with Mary. And the reason why I wanted to mention it is because there were actually very excited about our website materials, our on-line results database, our fact sheets. And so we're talking about staying in touch going forward and working together more closely in sharing materials. And they might link to our materials, if possible, that kind of thing. So that was it.

DR. MORTENSEN: My apologies. I was trying to kind of lump everybody. And I am sorry I did not point -- make the note about the excellent work done in the communication end, because it's something that we have been terribly frustrated and very dissatisfied with what we have to date. And it's -- as we work on a fifth report, the communication and trying to improve the available information to people, particularly the lay public who want to know something about these chemicals, where they might get exposed, what concentrations might mean is excellent. And they've done so much work, we don't want to reinvent the wheel.

Thank you, Sara.

CHAIRPERSON LUDERER: This is Ulrike Luderer. I

might take this opportunity just to make a comment and echo something that Dr. Bradman said about the amazingly huge utility of having a database of nationally representative concentrations of these different analytes. And I can say that from a occupational and environmental medicine physician perspective. I use them in the clinic all the time.

And I was actually very interested in your comment that the blood cobalt and chromium are going to be added, because very often I've seen many patients that have come in with blood levels and there wasn't a nationally representative comparison.

So I did have one question about the chromium, which is, is that total chromium or is it speciated?

DR. MORTENSEN: Thank you for that question, because I did neglect to point out, it is total chromium. I did want to also point out we had a very difficult time during the feasibility phases of getting samples that were not contaminated by the needles. And, in fact, we even thought about -- we even considered teflon-coated needles at one point, because it just seemed impossible to get samples that did not contain a large amount of chromium from the stainless steel needles.

The solution -- so it's really a word of caution in interpreting blood -- any blood chromium results, that

it should probably be drawn into a second vile. In other words, you put the needle in the person, you draw a tube, you either discard or used it for something else, and then you draw a second tube -- continue to draw into a second tube to reduce the amount, because apparently the chromium that leaches out or comes out of the needle in the materials is really in -- it's in the initial phase of the blood coming through that it picks up the chromium. But it is total chromium.

CHAIRPERSON LUDERER: Okay. Do we have anymore quick comments or do we have to wrap-up? We have to wrap-up.

(Laughter.)

CHAIRPERSON LUDERER: I'm sorry if anyone did have anymore quick comments or questions.

All right. Before we break for lunch, I do -- I wanted to invite Mario Fernandez, attorney for OEHHA, to give a reminder about Bagley-Keene. And I also wanted to let everyone know that we have an hour for lunch. So Mr. Fernandez.

STAFF COUNSEL FERNANDEZ: All right. Thank you, Dr. Luderer. Very briefly, I just ask that you, during lunch break, you do not discuss the information that was provided during the meeting. And if you want to talk about it further, please do so after we've reconvened.

This will give the public an opportunity to participate in the discussion. And that's it. Thank you.

PANEL MEMBER BARTELL: That's directed at us not everybody else.

STAFF COUNSEL FERNANDEZ: That's right.

CHAIRPERSON LUDERER: So it is 12:28, so we'll reconvene at 1:30.

Yes, and I wanted -- I was going to do that. So I wanted to recommend to Panel members and audience members that there is a quick dining option available at the and Oakland 12th Street City Center Shopping Plaza near the BART station, so that we are able to actually come back on time and not delay the afternoon events.

1:30. All right. Thank you.

(Off record: 12:28 PM)

(Thereupon a lunch break was taken.)

A F T E R N O O N S E S S I O N

(On record: 1:30 PM)

CHAIRPERSON LUDERER: All right. If everybody could please take their seats so we could get started.

Okay. I'd like to welcome everyone back from lunch. Hope you're all well fed. And I wanted to introduce our next speaker. It's a real pleasure to introduce Dr. Kim Harley, who's going to be speaking about results from the HERMOSA Study. And Dr. Harley is an Adjunct Associate Professor in the Maternal and Child Health Program, and an Associate Director of the Center for Environmental Research and Children's Health, CERCH, at UC Berkeley.

She's an epidemiologist whose research examines the impact of common hormone disrupting chemicals including pesticides on our food, flame retardants in our furniture and chemicals found in plastics on reproductive health and development.

And her research interests focus on the role of these common exposures on fertility, timing of puberty, obesity, and pregnancy health. Dr. Harley is currently the Director of the HERMOSA Project, which is working with Latina adolescents to determine their exposure to hormone-disrupting chemicals in cosmetics and personal care products.

And she's also the Associate Director of Health Effects for the CHAMACOS Study of immigrant farmworker women and their children living in the Salinas Valley.

Dr. Harley, welcome.

(Thereupon an overhead presentation was presented as follows.)

DR. HARLEY: Thank you. Thank you for having me here today. I'm really excited to present our work to the Panel and to everyone else here.

Our study is the HERMOSA Study, which stands for Health and Environmental Research on Makeup of Salinas Adolescents, which is a big mouthful. And we never call it that. We call it HERMOSA, which means beautiful in Spanish, and that reflects our study population. We were working with Latina girls, and talking about makeup and personal care products.

Before I get started, I did want to take the opportunity to thank some of our collaborators that are here. In particular, all of our analysis of phthalates and phenols were done by Jianwen She's lab, the Environmental Health Laboratory at the State Health Department. And I know a couple of the chemists that worked on it -- Rana, yes?

DR. SHE: (Nods head.)

DR. HARLEY: Rana Zahedi and Qi Gavin. Yeah. So

they played a huge part in this study, and we're really happy to have them on board and to do our analysis of our chemical exposures.

So I'm the Research PI of this study. I should mention this study is funded by the California Breast Cancer Research Program. And it's a community research collaborative. So one of the things that's really important about this study is that it's a joint project between a research PI and a community PI. And I'm actually not used to presenting this by myself very much, because my Community PI is Kimberly Parra, who works for Clinica de Salud del Valle de Salinas down in Salinas, and usually she presents with me.

And also -- we also have one of the teens that we worked with on the study present too. So this is just me. Usually, it's a much bigger crowd, but I do want to stress that Kimberly and I are really equal partners, and she handles the community side and I handle the scientific side.

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DR. HARLEY: So this study was really interested in potential endocrine disruptors that we find in personal care products, and I'm sure everybody here on the Panel is familiar with. Specifically, we were looking at phthalates, which can be found in fragrances, in nail

polish, and a lot of personal care products. And then we were looking at -- oh, and they're also found in plastics. And then we were looking at three phenols. So we were looking at, well, the group of phenols known as parabens, which are preservatives found in makeup. They're also found in food.

We were looking at triclosan, which is an antibacterial agent that's found in liquid soap and in one brand of toothpaste. And we were looking at oxybenzone, also called benzophenone-3, which is a sunscreen agent. So these are the three -- there are these four chemicals, the phthalates and the phenols that we were interested in, that we can measure in urine and we know are present in personal care products, and also have been shown to have endocrine disrupting properties.

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DR. HARLEY: So the aims of the study were first of all to characterize levels and sources of phthalate and phenol exposure from personal care products in young Latina women to see if we could lower the concentrations of these phthalates and phenols in the body by using alternate products, to empower local youth in scientific research methods, and also to work with local youth to develop health and education advocacy skills.

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DR. HARLEY: So what we did here is we enrolled 100 girls, 100 teenage girls. And they came in for a pre-intervention visit, in which we gave them a detailed questionnaire about all of the beauty products, cosmetics, personal care products they'd used today and yesterday. We took a urine sample, and then we told them a little bit about endocrine disruptors that were found in makeup and personal care products.

Then for three days we gave them low-chemical products to use and asked them not to use their own products. And they came back three days later for their post-intervention visit, in which they gave another urine sample, so we could see if the levels of these chemicals had gone down between the first visit and the second one.

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DR. HARLEY: Here's just a schematic of our data collection. We actually did a home visit, first of all, to get consent from the girl's parents. And we also used this as an opportunity to take photographs of all of the personal care products she used, so that when she came in for that first office visit, we had the photograph right there to help trigger her memory and to help us also know what brand of products she used most often.

Then we scheduled her first office visit when we took the urine sample. For the three-day intervention,

she was asked to use no nail polish, no perfume, and to only use the products that we had given her. And then she came back three days later for her follow-up visit. And we tried to schedule the first visit and the follow-up visit at the same time. So if she came in at 10:00 o'clock on Monday, she came back at 10:00 o'clock on Thursday to try and get rid of some of that diurnal variability.

--o0o--

DR. HARLEY: You may -- we may wonder what I mean when I say our low-chemical alternatives. What we did here is we just looked for brands that advertised or pledged that they didn't use phthalates or phenols in their products. So we identified them through internet searches. We started with the Campaign for Safe Cosmetics webpage. They have a compact for -- with companies that companies have signed saying that they won't use -- they're pledging not to use chemicals in their products. So that gave us a first set of companies to work with. We went to the skin-deep database from Environmental Working Group, we went to drug stores, we went to health food stores, we looked on-line, so that we could come up with a group of companies and a group of products that were pledging to be low chemical.

We really wanted to prioritize products that were

locally available. This study took place in Salinas, and I'll get to that soon. But we wanted to prioritize products that you could buy there, that weren't too expensive, that would be accessible to girls in the community, and we also -- although we were really looking at products that didn't have phenols and phthalates, we wanted products that were lower in chemicals across the board. So just because they don't have phthalates and phenols in them, we didn't want them to have, you know, formaldehyde or any other sort of chemical that we weren't measuring, but still we wouldn't want in our products.

So the way that we narrowed it down, we then chose -- we looked at the ingredient list. Parabens, triclosan, and BP-3 are all items that are listed on ingredient lists. So we chose products that didn't have these in them. With the phthalates, it was a little bit trickier, because phthalates aren't listed on ingredients, so we had to choose brands that said that they didn't use phthalates. And when that wasn't possible, we chose options that had no fragrance or parfum on the ingredients label.

But I want to stress that we did not conduct independent tests for the presence of phthalates or phenols. That was beyond the scope of this project. We really had to look for brands that said that they didn't

use them, didn't list them on their ingredient list, and trust that that was really true.

And we wanted this to be the same sort of experience that a consumer would have, if a consumer was trying to choose low-chemical products.

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DR. HARLEY: So after -- when the girls came in for their first visit, this was really their favorite part. After we gave them the questionnaire, we took them to our beauty bar, and they received a whole bunch of products. So all girls received shampoo, conditioner, body wash, soap, all these things on the list here. If they were Colgate Total users, which contains triclosan, we gave them a different kind of toothpaste to use. Otherwise, they were allowed to keep using their regular toothpaste.

And then all the girls got to choose four makeup items. So we had liquid and powder foundation, mascara, eye liner, lip gloss, lip stick, lip balm. If they were sunscreen wearers, they got to choose that. We gave them a little makeup bag, and they got to take all of their different products home with them. And we instructed them to use only these products for the next three days.

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DR. HARLEY: So we took -- as I mentioned, we

took the urine samples at the first visit. And then when they came back three days later, and I mentioned that these analyses were conducted by the Environmental Health Lab at the California Department of Public Health, these analyses were done. It was solid phase extraction, followed by high-performance liquid chromatography-isotope dilution tandem mass spectrometry. And luckily the chemists are here, so if people have questions about that, I don't have to answer them.

(Laughter.)

DR. HARLEY: And they used a variety of QA/QC collection, looking at precision, accuracy, method blanks, and quality control samples. We were interested in controlling for urinary dilution. We have creatinine measured and we also have specific gravity. And most of these analyses we -- or all of these analyses we controlled for specific gravity to account for urinary dilution.

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DR. HARLEY: This is the panel of phthalates that were measured that are -- were measured in our urine samples by the Health Department. I highlight the two at the top, the diethyl phthalates and the dibutyl phthalates. These are the two that we were most interested in, because these are the phthalates that are

found in personal care products. They devolve to three metabolites, MEP, MBP, and MIBP, which you can see were detected in almost everybody. But these are the three phthalate metabolites that we focused on for this study.

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DR. HARLEY: And then this is the panel of phenols that were measured in those urines. And we were interested in the triclosan, the BP-3 and then the four different parabens that you can see there. We also had bisphenol A measured, but that was not really of interest, because that's not found in personal care products.

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DR. HARLEY: So I want to back up a little bit and talk now about the community that we were working in. At the beginning, I told you the aims of this study. And one of them -- the first two aims were to look at exposure in 100 girls in this community. But the last two aims were really to empower youth in this community and teach them environmental health literacy and teach them about scientific methods.

So we've been working -- our group has been working in Salinas for more than 15 years now. Salinas is about two hours south of here. It's an agricultural community. It's not a rural community. It's really a small city that has a lot of urban problems. It's got a

very large Mexican immigrant, very low income population, a lot of poverty. Salinas has the highest youth homicide rate in California. We see very high teen birth rates in this community, and we know that a lot of Latina girls are dropping out of school, partly because they're having babies.

Really, we're looking at a community with not a lot of opportunity for their youth. And so this is the backdrop against which we wanted to do this study. And this is why we really wanted to work in this community.

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DR. HARLEY: So in this community for the last five years, we've been working with a group of environmental health leaders, some youth that are from the local high schools that have been part of, what we call, the CHAMACOS Youth Council. And we've been training them in environmental health literacy and advocacy. And they've done some different projects with us, but we were really ready to do a real scientific kind of biomonitoring exposure study with them. So these are the people that we hired to really help do this study and design this study with us.

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DR. HARLEY: So what we do with the YCC with our youth group, they meet twice a month, and they talk about

different environmental health topics. And one of the topics they talked about - this was probably two, three years ago - we talked about the idea of chemicals that are in personal care products. And this was really eye opening for them, because really they'd never thought about it before. It wasn't something they'd known about.

You can see we have a speaker from the Breast Cancer Fund, from the Campaign for Safe Cosmetics, that's Sarada Tangirala, I think is her name. She came down to speak to our youth. And this was a topic that really resonated with them, because, as I mentioned, they had no idea that there were chemicals in cosmetics. And they were talking and thought about how teens -- teen girls in particular are using a lot of these products, and that teen girls are in this phase of rapid reproductive development, breast tissue development, that this could be a really time of -- critical window of exposure. So this was a topic that they were interested in.

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DR. HARLEY: And we worked with them and with the California Breast Cancer Research Fund, after we got funding, to really involve them in all stages of the study. So they were involved from the beginning in helping us design the study.

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DR. HARLEY: They came up with the name, HERMOSA, and designed the logo. And here we can see some different logo options and voting on what we're going to end up with. And I should mention the woman in the top -- in the middle picture is Kimberly Parra, my co-PI.

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DR. HARLEY: We also had them test out our alternative products. So we had several alternative products that we thought we could use, but we had the youth in our youth group try them all out to see which products would actually be acceptable, and that teenagers might actually want to use. And they took them home and came back with all sorts of comments and reviews about all the different products we had, and which ones were terrible, and which ones we could actually move forward with.

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DR. HARLEY: And then we hired them. We hired them as UC Berkeley research assistants for the summer. I gave them summer jobs to actually do the data collection on this study --

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DR. HARLEY: -- which means that they were involved in recruiting the 100 girls, enrolling them, scheduling their appointments. When they came in, they

did the interviews. They collected the urine samples. They really were involved from start to finish in conducting this study.

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DR. HARLEY: And after the summer was over, we sent the urine samples up to the Health Department Lab. We also had a field trip in which the youth got to come up, see the biomonitoring lab, learn about how the different machines worked, meet the chemists, and really kind of walk through the process, which was great. And the thing that impressed them the most was expensive those mass spectrometry machines are.

(Laughter.)

DR. HARLEY: I wouldn't even let them go near them.

(Laughter.)

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DR. HARLEY: So now I want to tell you a little bit about the results of our study.

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DR. HARLEY: First of all, if you look at who our 100 girls were, our participants in the study. They were all teens. They were all either Mexican or Mexican-American. Most of them spoke Spanish at home and spoke English with their friends. And this was a

low-income group. Fifty-eight percent of them were living below poverty.

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DR. HARLEY: Now, I want to talk a little bit about the results from that first visit. So when they came in for that initial visit and gave us their urine samples, you can see here, this is just the number of detectables. So you can see that for triclosan, BP-3 and the three phthalates we're interested in, almost everybody had -- you know, more than 90 percent of the girls had detectable levels in their urine. For the parabens, methylparaben and propylparaben, again we had about 90 percent detection. And then the other two butyl and ethyl paraben was more like 50 percent. But, in general, these chemicals were very widely detected.

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DR. HARLEY: So as I mentioned, when they came in for that first visit, we got detailed information about all the personal care products they'd used in the last 24 hours. So I just want to show you what we found with those urine samples from that first visit and their association with some products that the girls had been using in the last 24 hours.

We can see here looking at triclosan, that the girls who had used Colgate Total toothpaste, at least four

times in the last 24 hours, had significantly higher levels of triclosan in their urine. That was the strongest thing associated with triclosan, but we also looked at their hand soap use. We saw that girls who used liquid soap today or yesterday had higher levels of triclosan in their urine. It was not statistically significant, but it was quite a bit higher.

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DR. HARLEY: If they used bar soap today or yesterday, they had lower levels of triclosan, not statistically significant.

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DR. HARLEY: We specifically asked them if they used antibacterial soap today or yesterday and we didn't see any association with this, which sort of makes me think that people just don't know if they're using antibacterial soap or not. And a lot of the soap we use is in a public bathroom or is some place else, and we just don't really know what it is. So it was interesting to me that the liquid soap we saw an association with, but not specifically trying to get at whether it was antibacterial or not.

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DR. HARLEY: So then we looked at BP-3, which is found in sunscreen. And we can see a strong association

with whether they used sunscreen or not. So girls who's used sunscreen in the last 24 hours had significantly higher concentrations of BP-3 in their urine. We were interested in both foundation and lip balm, because some foundation and some lip balm have SPF in them, but we didn't really see an association of BP-3 levels with use of those two products.

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DR. HARLEY: Then we were looking at phthalates. So here I'll show MEP, which is the phthalate with the highest -- phthalate metabolite rather, with the highest levels. Our hypothesis was that we would see a big difference between girls who wore perfume and those who didn't, perfume, fragrance, spray-on deodorant, things that had fragrance in them, and we were really surprised, because we actually don't see a difference by fragrance use. It's possible that ME -- I mean, we know that MEP is increasingly being taken out of products, so that may be why, but we didn't see a difference with that.

We did see that girls using solid deodorant had higher levels. And we saw an association with girls who had used lotion or moisturizer in the last 24 hours, they had higher levels of MEP in their urine than girls who hadn't used those products.

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DR. HARLEY: Then moving on to the parabens. I'll show you the results for propyl paraben. The results for methyl paraben are almost identical. First of all, just in general, we asked how often the girls wear makeup. Girls who wear makeup every day have significantly higher levels of propyl paraben and methyl paraben in their urine compared to girls who wear makeup less often.

And when we looked at what they had specifically worn in the last 24 hours, we see higher concentrations of parabens in the urine for girls who have worn foundation, blush, or mascara in the last 24 hours.

We looked at a bunch of different types of makeup. And these were the three that really popped out as being the -- having the strongest association.

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DR. HARLEY: But the real question you probably want to know is did the levels of these chemicals in their urine go down during the three-day intervention that we did?

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DR. HARLEY: So here's what we saw for triclosan. Remember, this is just three days. We see -- this is about a 35 percent decrease in urinary concentration of triclosan over the course of the study.

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DR. HARLEY: BP-3 we saw a similar, about a 35 percent, decrease in urinary BP-3 levels.

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DR. HARLEY: Phthalates didn't go down as much. We only saw a decrease in MEP. We didn't see a decrease in MBP or MiBP. That's about a 28 percent decrease in the MEP levels over the course of the study.

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DR. HARLEY: And here's parabens. These went down about 45 percent. The methyl paraben and the propyl paraben went down 45 percent over the three days of our study. But I want to point out that butyl paraben and ethyl paraben, although they were very low, did actually go up over the course of our study. And I don't have a real explanation for this, except to say I wonder if these products that are advertising that they don't have parabens in them are actually just doing a regrettable substitution of taking out the methyl paraben and propyls and putting in the butyl and ethyl parabens instead.

And we haven't analyzed any of these products yet to find out if that's happening, but it's, you know, a hypothesis. Of course, as I mentioned, the levels are very low of these two types of parabens.

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DR. HARLEY: And I do want to mention, remember,

we measured, let's see, was it six other phthalates, and we also measured BPA in our phenol panel. We -- our hypothesis was that those chemicals wouldn't go down at all over the course of the three days. And when you look at our levels, they basically stayed the same, So those were not affected over our three-day intervention, which gives weight I think to the fact that the ones that we thought would go down actually did.

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DR. HARLEY: We also talked to the girls in our study about, you know, what they learned during the course of our study. Most of them said that they learned something new about chemicals and cosmetics. Again, we really found that teenagers don't have any idea and really are not thinking about chemicals in cosmetics at all. They've got a lot of things to think about, and this isn't one of the things they were thinking about.

Thirty percent of our girls said that after the first visit they went home and checked the ingredient list on the cosmetics they had at home. And 93 percent said that they would like to buy beauty products without endocrine disruptors. Now, this doesn't mean that they all rushed out and did that, but they all said that they would be interested in, and they would like to have, beauty products that didn't have endocrine disruptors in

them.

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DR. HARLEY: One of the things we did, we did this -- the HERMOSA study was done two years ago -- two summers ago. And then last summer, once we had all the results back, one of the things that's really important to us in all of our research is that the research participants get to know the results of the study first, and that research participants, if they want to know the levels of their own exposure are able to find that out.

So we hired our youth again to put together a presentation about the findings, present it to the study participants, and then to help give the levels back to the participants. So here you can see on the right just an example page of what we gave back to participants to show her levels before and after the intervention, and how that compared both to all teens in NHANES and all teens in this study population.

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DR. HARLEY: Our youth research assistants in our youth group have also been involved in a lot of advocacy and outreach activities that kind of grew out of this project, and were informed by this project. They have made a bunch of educational materials. One that is very popular is their DIY handouts. They are like little

recipe cards. And it's a bunch of different, you know, shampoos, and face products, and things you can make. You know, the strawberry face scrub that's made with strawberries and brown sugar. Everybody loves those at health fairs, and they like to do those demonstrations.

We also have a little wallet guide that's in English and Spanish, that you can take with you to the store to choose products. They've been doing a lot of health fairs and community events. And they're also posting on social media, particularly Instagram is the one that they like the most.

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DR. HARLEY: So, in summary, what we found is that we were able to reduce levels of these phthalates and phenols by 25 to 45 percent by switching products for three days. That phthalate levels were the ones that were the hardest to reduce. And that we were able to empower youth by training them to be scientific researchers. And the youth have developed educational materials and are informing their community about our findings. They also have a petition on change.org, and they're coming up with their own activities that they want to do to further knowledge about this study.

Oh, they're also -- they were interviewed -- three of them were interviewed last week on an NPR station

for Latina U.S.A. I'm sorry, I can't remember the exact name, but they've been on local television. So it's been really great for them and to see them representing their community.

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DR. HARLEY: So I just wanted to finish by thanking our staff and our collaborators. Down in the corner there, you'll see Dr. Bradman, who's one of our co-investigators on this study.

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DR. HARLEY: And also, of course, thanks to our funder. I'm happy to take questions.

(Applause.)

CHAIRPERSON LUDERER: Starting out with some clarifying questions from the Panel. Thank you for that really great presentation.

PANEL MEMBER McKONE: I think it is Latina U.S.A., the program on NPR. It's on every Saturday or something.

DR. HARLEY: Yes, thank you.

PANEL MEMBER McKONE: One of the interesting things here, and I don't know if you can comment on it, is not just youth, but I think a lot of people fail to understand how science works, and that's why they don't trust it. And they either over -- and I'm just wondering

if you noticed, did they -- I mean, you surveyed their attitudes about what they would do, but did anyone sort of observe how they began to understand scientific process and that it is not, you know, perfect, that it has -- not that I'm complaining about your results, but, you know, this is the whole thing about confidence. And I find so many people, even very well educated people who should know better, don't understand limitations of any kind of a study. Either they overread it or they ignore it, but they don't know how to use it. So I'm just curious if you saw that kind of an effect.

DR. HARLEY: No, that's a really good point. We did do a survey with the kids before -- the youth, before and after, just the youth in our youth group to see, you know, a whole bunch of different things in terms of self-efficacy and community engagement. And we did ask them some science questions and see how those things improved. We saw some small improvements.

But a lot of what we got was much more qualitative and anecdotal. So we have -- one of the things that I heard you say again and again was, you know, I didn't think I could do science. You know, I thought science was something that people in white lab coats did. In fact, this is one of the things they said in one of the TV interviews. You know, I always thought that science

was something that people in white lab coats did, and I couldn't understand it, and it was not relevant to me.

And being part of this study made me realize that it's really accessible, it can be interesting, and it can be, you know, something that can help my community. So that was sort of, you know, one of the things that they really learned.

The other thing that we really had to work with them though on is, you know, we talked about these chemicals as endocrine disruptors. And we had to tell them, well -- but you can't run out and tell everybody that, you know, this shampoo is going to give you breast cancer. Like we really need to be sure that we're being clear about what we know and what we don't know.

So when you're talking to girls about it, you can say that these chemicals have been shown to act like hormones or to mimic hormones, and we don't know how that may affect your health in the long run, but we think it would be a good idea to try to reduce our exposure. You know, just trying to make sure that we're sticking to the facts, and we're not, you know, alarming people. And that's sort of a hard balance to walk, but I think it's really important, especially when you're returning people's results to them.

PANEL MEMBER McKONE: The other thing in the

picture of the volunteers, I noticed you had actually a substantially large number of males.

DR. HARLEY: About half and half.

PANEL MEMBER McKONE: Yeah, half and half. And was that hard to achieve -- or did you target that? And again, from what I -- I mean, my kids are grown up, but from my experience science isn't -- among boys is not always that -- especially this kind of science, right? Health science is not as attractive to young teenage boys as --

DR. HARLEY: So we were working with our existing youth council, which is about half boys and half girls. And that was -- you know, when we struck on this topic, it was a little bit hard to make sure we could include the boys. I mean, because it was so obvious what all the girls in our study could do, and they were -- we really had the girls doing the interviewing with other girls, because we felt like they're asking a lot of personal questions. It would be -- it would just be nicer to be having a girl interview you.

So we had to find things for the boys to do. And they were doing a lot of the health education and the aliquoting of urine or, you know, that kind of stuff, but it was -- you know, it was hard. Like, we needed to make sure everybody was involved and everybody was learning

stuff.

(Laughter.)

DR. HARLEY: But they were -- the boys -- it's interesting, the boys were just -- were almost as -- you know, pretty much as interested as the girls, because I don't know if you've noticed, but boys are using a lot of products these days, and a lot of them smell really strong. I think if you're talking about the phthalate exposure and you walk by a middle school locker room these days, there's plenty of that going on for the boys, too.

(Laughter.)

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

PANEL MEMBER BRADMAN: No.

DIRECTOR ALEXEEFF: I had a question. George Alexeeff. Thank you for the presentation. It was really good. I was just wondering on the statistical analysis, I know you were comparing the means of before and after. Did you look at to see like, for example, you know, like the highest exposures and what happened to that particular individual when they switched? Like did they go down dramatically or was it not really that different amongst the actual individuals? In other words, how much variability was there in the change?

DR. HARLEY: They were geometric means, not

means, just to be clear, but not that that's that important. What we actually saw when we look at the whole distribution, there's a lot of girls that didn't change that much, because they were in the low area. The people that really changed were those ones that were the outliers, that were really high. We saw that those high -- that high group really pulled down.

And then -- you know, and we returned the results, so girls could see if their levels went down. And it was sort of disappointing for some of the girls that were kind of in the low levels, because you know, not that much happened. But the girls in the high levels, that's where we see -- we see the drop.

CHAIRPERSON LUDERER: I actually have a question. You know, you saw that -- or you didn't see an effect with the fragrance question, but you did with the lotions. I mean, do you think what's driving the lotion is the fragrances in lotions or do you have any thoughts about that?

DR. HARLEY: Or if there's some sort of -- if there's some sort of absorption through the skin. You know, I don't know. It's true that we really found the strongest association for phthalates -- the strong association we saw was with lotions and moisturizers and not where we really expected it, which was the fragrances.

I have a few thoughts about that with the fragrances. Partly, we have a lot of fragrances in our life. And we did ask the girls when we went to their home visit, we did look for things like air fresheners, and we asked about air fresheners. We asked about, you know, dish soap. And, you know, we tried to get at as many other sources of fragrances as we could, but it just, for whatever reason, the MEP didn't show up.

But I do know, if you look at NHANES, the MEP levels are really going down just in the last, you know, three, four, five years. So it feels like the MEP is starting to come out of some of these products. Yeah, I don't know about the lotion, but I do wonder about possibly dermal absorption. I just don't know.

CHAIRPERSON LUDERER: I have another question actually, but it looks -- do you have a comment or question, Dr. DiBartolomeis?

DR. DiBARTOLOMEIS: Question about methodology.

Hi. So Michael DiBartolomeis.

Just really quickly. I'm assuming this had to do with the half-life of the chemicals, but how did you choose three days? And what would have happened if you'd done a time course? Would it have been possible that you could have actually seen even lower -- you know, bigger changes?

DR. HARLEY: Thanks for asking that. That's a good question. We chose three days partly for feasibility. When we originally planned this study, we thought we would do it for a week. And then we started working with teenage girls, and we thought, okay, we really need compliance here, and we figured that for three days, they could actually do it.

And what I imagined happening was if we asked them to do it for seven days, they'd be really good for those first few days and then they'd start to cheat as they got -- the week got longer, so we went with three days. But it does definitely beg the question, and we don't have the data to know, you know, this is how far they went down in three days, would they go down farther if we continued this study longer?

However, I will point out that most of these metabolites are -- we're measuring exposure in about the last 24 hours, which is why we felt like we were safe with three days, that that should be enough to really see a difference.

CHAIRPERSON LUDERER: I had another question which is related to it. So you mentioned that your youth council members were sort of we never thought of chemicals in cosmetics or personal care products before, and I wonder if they reported back or I'm sure you talked about

what the challenges were in recruiting participants, because presumably they had never thought of that either, and was it difficult to convince them, you know, to do this?

DR. HARLEY: It was so easy to do recruitment on this, because we were giving away free makeup.

(Laughter.)

DR. HARLEY: It was real easy. And also I have to say --

(Laughter.)

DR. HARLEY: I also have to sort of attribute part of this to our staff -- to our girls. We had one girl I think she recruited maybe 50 of those participants. I mean, they just -- they did it through their personal networks. We had a Facebook page. We had texts. We did it -- a lot of it was kind of sending out texts to their -- all of their friends and having their friends send the texts out and just trying to get enough people interested. But they got a gift card for a store purchase for their participation, and they got a makeup bag full of makeup, so they loved it. We could have -- yeah, we could have had more girls.

(Laughter.)

CHAIRPERSON LUDERER: Why don't we take the public comments at this time, and then we'll have time for

more Panel discussion after that.

Okay. So our first public comment is from Paula Johnson, the California Department of Public Health Safe Cosmetics Program.

DR. JOHNSON: Hi. Thank you. It's such a great study. So thanks for that presentation. And I was just curious if you had any indication of whether or not the girls would continue to use alternate products or if they gave any feedback, if they were -- if they were less effective or more expensive, and so they wouldn't?

Thanks.

DR. HARLEY: That's a good question. We did struggle a lot with trying to find products that were affordable and locally available. So wherever possible, we tried to get things that you could just get at, you know, Target or Walmart in Salinas, so that -- for that very reason to make sure that they could keep using them. There were some products that they loved that I'm sure they're still using. Particularly, there's a lip balm that they loved.

We did talk to them about it. I think I have the data somewhere, but I'm afraid that I don't have it right at my fingertips, if they would consider -- continue using these products. And there was -- you know, some said that they would.

Some of the products, there were a few things that were hard to find, so some of the products were expensive. I'm thinking of we were able to find a low-cost mascara, but liquid foundation was really difficult. So there's things that it's just not really realistic for them to keep using, but there definitely were several products that we could -- you know, they were just kind of mainstream brands that they could keep using. And that was really our goal was to get things that they could really use in the future.

CHAIRPERSON LUDERER: Thank you.

The next comment is from Lindsey Dillon from UC Davis.

MS. DILLON: So thank you. That was wonderful. My question was basically the same, if you ran like a cost differential from like the store brand products, and if you did a longitudinal study of maybe what they continued using or not? So sorry. You don't have to answer that.

DR. HARLEY: It would be great to do a longitudinal study. A colleague of mine at Brown University is thinking about doing something like that, but yeah, we didn't have that.

I can tell you it's more expensive. I mean, we all know it's more expensive to try and find those low chemical products. And that is a big issue.

CHAIRPERSON LUDERER: All right. We have another comment from June-Soo Park, Department of Toxic Substances Control.

DR. PARK: I'm not a public. I'm a member of the biomonitoring group, but I decided to make some comment, because I'm really concerned about these girls, because I'm a father of two teenage girls too.

You know, I didn't really pay attention to the numbers. I'm a laboratorian, so I'm -- first, I like to acknowledge all the analysts to who made this great job. Particularly, BP-3 and the phthalate levels, it's amazing. You know, at lunch time, you know, I did go and look into the firefighter data for the BP-3.

So I wrote down here. So BP-3 -- these girls have, you know, five times higher than the firefighter when they use the sunscreen. Even they didn't use sunscreen, about two times higher -- a little less than two times higher. Also, the monoethyl phthalate. They're higher than the workers. I don't know what's going on there, but I -- I just want to -- you know, the -- Harley, I don't know if you noticed -- you compared the data we have, but this is amazingly high levels. So I think even much higher in U.S. population -- you know, your maximum levels is already, you know, higher than their range. So I think I'm very concerned about those girls.

DR. HARLEY: That's a really good point about comparing to some of the other Biomonitoring Program data. I have compared to NHANES, and our median levels and our geometric means are actually pretty similar to what you see in NHANES, yeah for the phthalates and -- yeah, we -- I believe -- I'm trying to remember if we looked at teenage girls. But even compared to the NHANES population in general, but we did compare them specifically to teenagers in NHANES, and it's in the same ballpark.

I can't speak exactly to the maximum levels. The maximum levels may be higher, but certainly the range is pretty similar.

DR. PARK: Okay. I think my mistake then.

CHAIRPERSON LUDERER: Okay. We have one more public comment from Olga Kalantzi UC Berkeley visiting scholar.

MS. KALANTZI: Hello. Olga Kalantzi. That was a really interesting presentation. I'm wondering on the intervention part, if you have or if you plan on following up to see whether some of these girls are actually going to be using safer products not containing EDCs, because it would be interesting to know.

And also going back to what the previous people have said with regards to cost, because some of the products that I saw, at least in the pictures, are maybe a

little bit more expensive than others. Did you think that maybe you could suggest to them using more natural products. So instead of saying using a more EDC-free moisturizer using something like almond oil or things that like a homemade soap or homemade shampoo instead of the actual other products?

DR. HARLEY: Yes. Thank you for mentioning that. That really was part of it when we were addressing the cost issue. That's why we had the youth make those little recipes. And they had such a good time finding recipes that they liked. But that idea that you can just find things in your kitchen that you can use rather than having to go out and buy a lot of these products. We had -- you know, one idea, for example, is you can rub beets on your cheeks as a way -- instead of using blush. That was one of the things that we saw or you put it on your -- I guess it was -- not, it was for your lips. Beets on your lips.

There was all sorts of ways that -- you know, workarounds that you could do, you know, natural products as opposed to buying products. But that was part of it. Definitely, what can you make and, you know, as opposed to what do you have to buy.

CHAIRPERSON LUDERER: Laurel.

DR. PLUMMER: I think it's really interesting that, you know, Salinas having at least referred to Target

and Walmart as kind of two options. I think it just popped into my head that wouldn't it be cool if, you know, your youth group could actually like talk to those, you know, companies, and say for areas like Salinas, they could start having different products. I think that would be like an awesome thing for them to work on.

DR. HARLEY: They did a letter writing campaign. And they sent letters to the CEOs of those stores, and other stores, to a bunch of drug stores, just saying, you know, we're a group of teens from Salinas, and this is what we found, and this is what we think. And we really encourage you to stock more low-chemical products in your stores. That was also the gist of the change.org petition, yeah, to make sure the stores can stock that -- those goods for them.

CHAIRPERSON LUDERER: Sara.

MS. HOOVER: Yeah. Thanks, Kim. Really interesting.

Two questions for you. I was curious, you mentioned that some of the girls had really high levels. And I wondered if you did any follow up on, you know, sort of how high and why? Like the people who were very high, if you could track back specifically why they were high in particular chemicals?

And the second question is if you can say

anything about other studies you're planning or follow up after the study?

DR. HARLEY: Okay. So two separate questions. The first one is that we're preparing this for publication right now, and hope to get it out soon. But that's one of the things that we're really interested in looking at is who are those girls that were really off the charts. And I mentioned this quickly, but when we went to their homes to do their consent with their parents, we actually brought with us three plastic -- four plastic bins, and gave each one to the girl, and said -- you know, one said hair products and one said face products. And she went to her bathroom and her bedroom and she put all those products in the bin. And we came back, we had an iPad, and we took a picture.

So for every girl we know all of -- we know not just whether she used mascara yesterday, we actually know the brand of mascara. So that's really the next step is to see if there's some specific brands, or if we can get -- if we can sort of dig down a little more on what products it is in those girls that are really high. So that's sort of what we're in the process of looking at now.

Your second question was what are the next steps?

So we are not following up with the 100 girls in

our HERMOSA study. And that was one of Olga's question was it's true. It would be great to see if this had long-term behavior changes for them, but we've -- those girls have moved on, and we're not following up with them, so we don't know that from our study.

We are moving forward with our youth group though, because we really feel like this has been a great model in terms of teaching youth scientific methods, teaching them environmental health literacy, having them work on health education and advocacy projects.

Most of the youth that worked on the HERMOSA Study have graduated now from high school or they're graduating right now, and many of them are actually at UC colleges now, which makes them the first generation in their families to go to college, which has been really rewarding for us. But we have a new crop, so we -- when they graduate, we've enrolled new kids. And the new group are all saying, well, what study are we going to do?

So we're trying to put together what the next project will be. It won't be on makeup. It will be something else, but it will -- we're really hoping to do a follow-up biomonitoring type project in this community, where the next group of youth get to do the same thing with us, where they help design the study, they, you know, are hired as the interviewers and really get to do the

research with us.

CHAIRPERSON LUDERER: Personal care products for the boys?

(Laughter.)

DR. HARLEY: We're thinking pesticides. It's pretty relevant in our community. Our community is very interested in pesticides.

CHAIRPERSON LUDERER: Tom.

PANEL MEMBER McKONE: Are you looking for input on ideas?

We're full of that, right?

(Laughter.)

DR. HARLEY: Sure.

PANEL MEMBER McKONE: Off-line.

(Laughter.)

CHAIRPERSON LUDERER: Any other comments, thoughts?

Dr. Bartell.

PANEL MEMBER BARTELL: Yeah, a brief comment. Just because it came up, I think, you know, the issue of like Walmart, and what products they carry. There was an announcement -- I think several announcements from Procter & Gamble, Johnson & Johnson, Walmart in the last two or three years that they intend to phase out parabens and hormone-like phthalates. And I'm sure this is on the

radar for California Biomonitoring, hopefully already, but it definitely, I think, has bearing on, you know, thinking about prioritizing chemicals. So just for, you know, kind of this Panel, it's something I think to keep in mind. It's a rapidly moving target sort of what chemicals are being used in these products.

DR. HARLEY: That's true.

CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

PANEL MEMBER KAVANAUGH-LYNCH: I'll try it. Is it -- yes, okay. I just wanted to make two comments. One is I just wanted to emphasize if you thought this presentation was good, you should see it when the community partner and the teens are participating. It is truly amazing. And I'm getting tears in my eyes. This is why I love funding and why -- actually, why I just want to emphasize, you know, we're doing a lot of community collaboration within the Biomonitoring Project -- or Program, but it's more than just icing. It really changes the world when you do it, when you -- when it's not just scientists in white coats in the labs doing research and monitoring, what's happening in our world, when we get communities involved.

They change the questions. They take the results and go out and do letter-writing campaigns and other actions that most of us who sit in our labs don't get

involved in. It's really powerful stuff, and you make me so proud.

Thank you.

(Laughter.)

(Applause.)

DR. HARLEY: You're right. This is a much better talk when I have a 19 year old with me. I will totally admit that when I have a 19 year old doing half this talk, it's better.

(Laughter.)

DR. HARLEY: They're all in school right now.

CHAIRPERSON LUDERER: All right. Do we have any other comments or questions from the Panel?

Sara.

MS. HOOVER: I think from what you were saying, I heard you say, I think, that you personally returned the results. Did you have one of your teen council actually meet --

DR. HARLEY: (Nods head.)

MS. HOOVER: Okay. So I know that's your model, so that's great.

And the second question was for your results return materials, did you get specific feedback on understandability of the approach you used?

DR. HARLEY: So the first question is yes it was

our teens that were returning the results with -- you know, we had adult staff around, but they -- the teens were really doing it one-on-one.

In terms of feedback, we -- the teens helped us design them, design the forms to hand back to make sure that they were understandable. And we did a little bit of sort of focus grouping with them before we handed them back. We didn't do any evaluation after the fact of the girls to see, you know, how well they understood them.

So that wasn't part of it, but we did try to put a lot of thought into how to make this understandable and also not to make it scary.

CHAIRPERSON LUDERER: So I have another question. You mentioned that there were some girls that had really low levels of most of the chemicals that you measured. Did you look at -- I mean, were there any girls who didn't wear makeup, use personal -- much -- you know, many of these products? Did it correlate with that or not?

DR. HARLEY: Certainly with the makeup, the strongest association was with the parabens. So we definitely had a bunch of girls who don't wear makeup. And those girls tended to have, on average, we saw that they had lower paraben levels in their urine. In terms of the other products, you know, everybody uses shampoo. Everybody uses soap. So those not so much, but the

parabens, because they seem to be so specific to makeup, we saw a pretty strong signal with those.

PANEL MEMBER McKONE: So I have to make one comment about I think the power of this kind of community study. And I don't know if it's clear, but it looks to me like they learned a very important issue about science. And I'm really concerned, because I see so many people who think science is starting with an answer and then cherry-picking the data and the papers you want.

Now, you see this with climate change, with vaccines, with everything else, people start with the answer and they think science is proving your answer. And they're learning that it's about collecting the data, developing scenarios and hypotheses across a broad range, and then seeing where the data takes you.

And I think that's such a powerful lesson, because I think so much of our -- not just our youth, but the whole country is really misunderstanding science right now, and thinking it's answer first and not data first.

DR. HARLEY: One of the things that I personally did is I went down to Salinas twice. We had two different sessions with the youth where we tried to give them an opportunity to look at the numbers and analyze the data. And it's a little bit hard, because you want to make it not -- you know, you want to keep it understandable. But

we had, you know, one of the sessions where I said, okay, we're going to look at oxybenzone. So tell me what do you hypothesize? Before we look at the numbers, tell me what you think you're going to see. And then we actually -- it was just sort of almost like an Excel spreadsheet, like let's figure out what the mean is of the two groups. And in some cases, we saw what we thought we were going to see, and some cases we didn't see what we thought we were going to see.

But that's what science is, right? I really wanted to just talk -- walk them through that sort of simple process of coming up with a hypothesis and then seeing if your hypothesis is proven or not.

CHAIRPERSON LUDERER: Thank you again very much. Do we have any other -- well, I thought we addressed them, but -- we did have some discussion questions, which I think we have already kind of talked about a lot of these, but -- so one is if you could maybe summarize again what you thought were the challenges that you faced in designing and carrying out the study, like what were the biggest challenges? I mean, you've already talked about that.

DR. HARLEY: Compliance was one of the things that we were really concerned about. And I did mention that, and that's why we made it only be three days. And

that is a big issue. I mean, I guess this isn't really the answer to your question, but you -- there's two ways to think about how to do this kind of study. One is do a study like this and then come back a month later or a year later and see how it's changed the long-term behaviors of the girls. What we tried to do instead was let's just do a short-term study just to see if it's even feasible, just to see if just changing these products is going to make a difference. So that's what we were really focusing on, and so we don't have that long-term piece of it. That's for a different study.

The other thing I would say, I mean, one of the things that's really distinctive about what we do is that we work with the youth to bring them into the study, to be -- to, you know, help us design and help us implement the study. And there's so many ways in which that makes the study so much richer, and it makes the findings go so much farther.

But there's ways in which that's so challenging too. I mean, it certainly would have been easier for us to have two of our already experienced interviewers just go out to the homes and get the data. We could have done it in half the time, but that would have missed, you know, half the point of the study. So that's something that we're really committed to doing, to including them and

having it be a youth empowerment study as well as just an exposure study.

CHAIRPERSON LUDERER: And I mean I think you've already touched on some of this also, but some -- you know, how -- if you were, you know, to -- designing a future study, you know, what are some of the key lessons that you think about as far as the sampling and the intervention, you know, the timing? You already mentioned why you used three days this time, and, you know, didn't use a follow up and aren't doing a longer term follow up, but, you know, if you kind of had the option to design the study of your dreams.

DR. HARLEY: One of the things that made this sort of really feasible was that we were looking at chemicals that we know have a really short half-life. So we were looking at chemicals that we know are going to be washed out of the body in 24 or 48 hours. So we were able to do a study like this. I don't know how you would do this with something like, you know, some sort of persistent chemical that it's just going to take so much longer to see some sort of change. So we were lucky in a lot of ways by the topic that we were studying. I think you'd have a harder time if you were trying to look at flame retardants or something else.

CHAIRPERSON LUDERER: And that was actually going

to be the next question, which is, you know, if you -- you know, the Program is, you know, talking about designing a study to look at, you know, intervention study and one of the possible types of chemical classes that's being considered is flame retardants, and, you know, products that have flame retardants and what recommendations you would have for the Program going forward with that type of an intervention study?

DR. HARLEY: It's a hard study. I think that if you're looking at something that's persistent like that, you may need to look at sort of intermediate markers. So maybe what you do is you look to see if you can over -- you know, with behavior changes or over time see if levels in the dust, for example, in the home, go down. And you might expect to see that before you actually see changes in the body.

So it's hard. It's really hard with persistent chemicals. You need a much longer time window before you're going to see changes, unfortunately for all of us.

CHAIRPERSON LUDERER: Dr. Bradman, did you have something?

PANEL MEMBER BRADMAN: I think one of the important things of intervention studies is that they show exposure pathways. And we tend to think of intervention studies as, you know, can we prevent exposure? But I

think importantly though they really show us where exposures are coming from. And then whatever decisions we make about risk and hazard, they offer a place to intervene. And here, you know, it really directs, I think, us to say, well, maybe there's opportunities to take these materials out of these products, and hopefully not replace them with other materials that would be just -- you know, it would have similar concerns.

And there's kind of an upstream intervention from a relatively short study that would really change the profile of exposure, you know, potentially nationwide. I mean we see that with phthalates. And I think that's one of the really important pieces of intervention studies, and that we should think of them also as exposure studies, but they're controlled and they have really demonstrable results. So I think it's really important work.

PANEL MEMBER KAVANAUGH-LYNCH: So you made this comment that you could have done it in half the time if you'd used your own professional interviewers. My question is do you think you uncovered information using the youth who were part of the community as the interviewers that you might not have uncovered if you were using professional interviewers?

DR. HARLEY: I think that's totally true. First of all, they recruited them. So we wouldn't have gotten

100 girls as fast, if we had to do it with adults doing the recruiting. But second of all, they really -- you know, they helped us with the questionnaires asking about what kind of products girls are using, because they know. You know, they know what products girls are using and what they're not using. And they found things that weren't on our list that we needed to add onto our list, for example.

So they -- and they definitely helped with that process of what kind of questions do we want to ask. And they also helped a lot with the process of which products should we offer to the girls. You know, they were like they are not going to use this product. You cannot give them this shampoo. They are not going to use it, you know, try this one instead, that kind of thing.

So yeah, they definitely -- I think they really added to the effectiveness of the methodology. Like I think they improved the science in that way, just because they could bring the context.

DIRECTOR ALEXEEFF: Hi. George Alexeeff.

I was wondering, I'm looking at the tables that you had, you know, pre- and post-intervention numbers. And so on a number of the post-intervention levels -- I mean, I don't know how high these levels are, but they are relatively still high. So I'm just wondering if you've, you know, thought about what the sources of the exposure

could be. I know you mentioned air fresheners, but it wasn't clear to me if you thought maybe that was a source of exposure or not. And, you know, it seemed like, for example, looking at, well, triclosan for example, or BP-3 and those -- and even the MEP on the phthalates there seems -- there definitely is reduction, but there is kind of a high baseline.

DR. HARLEY: Yeah, right. It's true. I mean, we -- they dropped quite a lot, but they didn't go away, right? So it's really interesting with -- for example, with triclosan, we took out their antibacterial soap, we took out their Colgate Total toothpaste. We really made the levels go down, but they didn't go away completely. So, you know, what is that additional source of exposure, because there's definitely still exposure happening. And it's possible that's residual exposure because, you know, it has -- it's, you know, left over from before the intervention.

It's possible that there's other sources, but it's hard to think -- with triclosan, for example, I mean, it's in some clothing, but it's hard to figure out what the other sources would be. For parabens and for phthalates, that's much easier, because, you know, there's so many things that have fragrance that the phthalates could be coming from and we know that, you know, a lot of

canned food, a lot of processed food have parabens in it. So there's certainly other places where that can be coming from, but it's -- yeah, it's an excellent point that you're making, but we got rid of a lot of the exposure, but we didn't get rid of all of it. We didn't even get rid of, you know, half of it. There's still kind of half of it left there, and whether that's coming from some other source or it's residual sticking round in their bodies.

CHAIRPERSON LUDERER: Regarding the triclosan, they were all in school, right? I mean, I wonder what type of hand soaps they have in the school bathrooms or wherever else --

DR. HARLEY: We gave them a little thing of -- squirt bottle of liquid soap to carry in their purses. They weren't in school, because it was summer vacation, but we asked them to -- and we knew that was going to be tough, but we asked them to carry around liquid soap. And we did ask them when we came back, we asked them if they cheated? You know, like tell us -- you know, be honest with us, tell us, you know, did you use this, did you use that?

So we have -- they were -- the compliance was actually very good, but we do know -- you know, people said, yeah, I used some other soap or whatever. There was

a little bit of cheating, but not too much.

DR. ZAHEDI: Hi. Rana Zahedi from California Department of Public Health. I was wondering if those kids helped with the house tasks, and if they wash the ditches by hand using those -- was there any question regarding that?

DR. HARLEY: Yes, we asked them -- so we really were focusing on what they'd done in the last 24 to 48 hours, but we asked them if they had done the dishes. I think we only asked about hand washing the dishes. We didn't ask about the dishwasher. We asked about housekeeping. We asked about whether air fresheners were used. So those are all things that can be put into our multi-variable models. We've looked at them a little bit, but we can explore those a little more.

We tried -- before we went into this study, we tried to think, you know, what are all the possible sources. I'm sure we've forgotten some, but we tried to think of as many as we could.

CHAIRPERSON LUDERER: I wanted to ask you one more question, which is what -- you know, you were mentioning that some of these parabens are being phased out as preservatives, and, you know, the MEP is falling because there's less use of DEP. What do you, you know, from your work in this area, see as the sort of up and

coming things that we should be paying attention to that are going to be replacing these?

DR. HARLEY: That is always the challenge, isn't it? We're always playing catch-up. You know, that's a -- you kind of caught me off guard. I'm trying to think what we're seeing in the fragrances. We were wondering if we were going to see the MBP coming up as the MEP went down, but not seeing that so much. I would -- you know, I'm sorry, I would have to kind of go back to the literature and see what we're using as replacements for the MEP.

The parabens we were concerned because we saw those other two parabens increase, that if those are going to start to rise as the other parabens go down. I don't think we're seeing quite the decrease in parabens that we're seeing in phthalates. Phthalates are the one that seem to be on the radar -- the public radar and seem to be going down faster.

DR. ZAHEDI: I have --

DIRECTOR ALEXEEFF: Yeah, another question about, you know, when you were talking about the ingredients. And I wasn't -- I don't remember exactly what you said. And I was trying to remember that, you know, I assume BP-3 and triclosan would be on the label. Those are required to be labeled.

DR. HARLEY: Yeah.

DIRECTOR ALEXEEFF: But did you say that neither phthalates nor the parabens were on labels or --

DR. HARLEY: Parabens are on the labels.

DIRECTOR ALEXEEFF: And why is that?

DR. HARLEY: The reason that phthalates are not on the labels is because fragrance is proprietary. So they don't have to say what their fragrance is. They can just say fragrance or parfum and they don't have to say what's in it. So we don't know -- if it says fragrance or parfum, we don't know that it's phthalates. We suspect that it's likely to be phthalates, but we certainly found products that smelled nice, but we -- you know, we had shampoo that was from companies that said right on the bottle, it said no phthalates, you know, no parabens and we said, okay, we're going to trust you. This smells nice. We're going to assume that you have some sort of natural fragrance.

So the fact that it says fragrance doesn't mean that it has phthalates, but, you know, it's a good indicator.

CHAIRPERSON LUDERER: Dr. DiBartolomeis.

DR. DiBARTOLOMEIS: Actually, I think this is pertinent. The Safe Cosmetics Act does require the manufacturers of cosmetic products, personal care products to report chemicals that cause cancer or reproductive

toxicity or birth defects to the Department of Public Health. And fragrances have to be reported in the sense that the company that is using the fragrance formulation has to know, from going back to the fragrance manufacturer, whether or not any of these chemicals are in those products.

And so they are required to report them. Now, are they? You know, we might be able to find out. Did you -- so I guess my question would be did you cross-check the products with the Safer Consumer -- sorry, safe cosmetic products database to see if they had reported any of those fragrances in the -- as -- they might not tell you exactly what the fragrance number is, but they have to say that there is or is not a chemical.

If not, then there is some noncompliance going on, and that would be really interesting, I would hope, for Cosmetics Program to think in terms of enforcement.

DR. HARLEY: We didn't cross-check, but we will.

(Laughter.)

DR. HARLEY: Thank you for bringing that up. I didn't even know that that was an option. All I knew is that the -- on the label it doesn't have to say --

DR. DiBARTOLOMEIS: Call her.

DR. HARLEY: I will. Before we leave, yeah, I'd love to look into that in more detail.

CHAIRPERSON LUDERER: All right. Do we have any -- no other questions or comments from the Panel?

So then I think we can go on our break a little bit early. Thank you again so much for the presentation and answering all the questions.

(Applause.)

CHAIRPERSON LUDERER: So our break will be 15 minutes. So, yeah, 2:50 then. Everyone, please reconvene at 2:50.

(Off record: 2:34 PM)

(Thereupon a recess was taken.)

(On record: 2:51 PM)

CHAIRPERSON LUDERER: Okay. If everybody could go ahead and take a seat, so we can get started. Apparently, we're already behind again here, or -- no, I think we're still on time.

Okay. Great. I just want to call the meeting back to order, and welcome everyone back from the break. So I'm very pleased also to present this next agenda item. We're going to be -- it's going to be about consideration of perfluoroalkyl and polyfluoroalkyl substances, PFASs, as potential designated chemicals. And we're going to have two presenters. Ms. Lauren Joe, Epidemiologist in the Environmental Health Investigations Branch at CDPH. And Ms. Joe will present a brief overview of biomonitoring

results for perfluorinated chemicals, PFCs, from past Biomonitoring California studies.

After Ms. Joe's talk, Ms. Gail -- Dr. Gail Krowech - pardon me - Staff Toxicologist in the Safer Alternatives Assessment and Biomonitoring Section of OEHHA will give a presentation on information relevant to the Panel's consideration of perfluoroalkyl and polyfluoroalkyl substances in -- as potential designated chemicals.

So, Ms. Joe.

(Thereupon an overhead presentation was presented as follows.)

MS. JOE: Thank you, Dr. Luderer. Good afternoon, everyone. Thank you for sticking around. I'll jump right into it.

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MS. JOE: These are the 12 PFCs that we measure, and they were designated in 2009. They're the same PFCs measured by NHANES. And in the next presentation, like Dr. Luderer mentioned, Gail will speak about PFASs. That's the larger class of chemicals underwhich these PFCs belong.

But for now, I'll just mention that PFCs are used to make materials more resistant to things like oils, stains, water, and grease. So they're very common in

products that we encounter every day.

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MS. JOE: Before I get into our results, I want to give some basic details of the Biomonitoring California studies that we're going to look at, because they each have different populations of interest, and that's important when comparing results in this manner.

So the first, and most contemporary data, comes from our California Teachers Study, which is a lab collaboration that Dr. Petreas has talked about in the past. There were over 1,000 samples. And the N's presented on these slides refer to the number of samples that were analyzed for PFCs.

And for CTS's samples were from 2011 through 2014. The majority are white, all females, with a median age in the sixties, and representing -- coming from all of California.

Then there's the Expanded Biomonitoring Exposure Study with 337 samples from -- collected from 2013. And in the design of the study, we oversampled for Hispanics, and Asian/Pacific Islanders. There is a median age in the forties. And this is a collaboration with Kaiser Permanente Northern California with a focus on the Central Valley.

And the study that made Expanded BEST all

possible was our Pilot BEST. That was the first time we collaborated with KPNC. And there are 110 samples collected in 2011 through '12. And the race ethnic breakdown was pretty much evenly distributed across white, black, Hispanic and Asian/Pacific Islander. And there was a median age in the fifties.

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MS. JOE: There's our Firefighter Occupational Exposures Project, or FOX, 101 firefighters. The samples are from 2011 -- 2010 to '11, majority white, mostly male with a mean age in the forties. And the firefighters were from one county in Southern California.

And finally, there's the Maternal and Infant Environmental Exposure Project, or MIEEP. This was the very first Biomonitoring California study that was completed and done. And there were 77 maternal serum samples collected in 2010 to '11, majority were Latina pregnant females in their third trimester of pregnancy from San Francisco General Hospital.

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MS. JOE: To summarize detection frequencies across these studies, for the four most prominent PFCs, PFOS, PFOA, PFNA and PFHxS detection frequencies were almost 100 percent across our studies. With the exception of MIEEP, PFOA had a detection frequency of less than 65

percent. And we also did not report PFHxS in MIEEP because of some matrix interferences because of using maternal pregnant women serum.

On the other side of the spectrum, there's PFBS, which had very low detection frequencies in -- across the studies. With the exception of an Expanded BEST, PFBS was not measured or reported due to some laboratory interferences -- instrumental interferences.

And the detection frequencies varied for the other PFCs. And part of that is due to the different laboratory limits of detection. For example, in PFDoA, the laboratory LOD was very low, the lowest of all of the studies. And it was the only study that had a detection frequency for that PFC of greater than 60 percent, though the levels were very low, and we'll see that in a couple slides.

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MS. JOE: These are the geometric means in nanogram per milliliter. And I'm only going to show geometric means for the chemicals that had a detection frequency greater than or equal to 60 percent. And for non-detects, we imputed using the LOD divided by the square root of 2.

So clearly, we see that FOX has the highest geometric means for many of these. These are the four

prominent that I mentioned before, except for PFNA the levels are more Similar to one another, though FOX is still -- still has the highest geometric mean.

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MS. JOE: These are the rest of the PFCs, but not showing PFBS because of the low detection frequencies. And again, we see FOX is high for several of them, though there is some variation. For example, in methyl PFOSA, CTS has the highest geometric mean followed by Pilot BEST and then FOX.

And I can't definitively say the reason behind this, but we do know that each of these studies come from different time periods, different locations in California. And the distributions by age and race and gender are all different. So this is what we see so far from our studies in California, but how do they compare to the nation?

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MS. JOE: And our Biomonitoring staff addressed this question in a recently published article in the Journal of Environmental -- Occupational and Environmental Medicine. We're very proud of this excellent work. And many of the authors are here in the audience today. So kudos.

When they went to compare FOX to the nation using NHANES data, it was important to make sure they used an

appropriate subgroup from NHANES. So for FOX, that was men above the age of 20. And what they found was PFC levels in FOX did not vary that much compared to NHANES, except for PFDeA, where geometric means were three times greater in FOX compared to NHANES. It's highlighted in yellow.

And I highlighted a couple other PFCs in green to show that the limits of detection in FOX were very low, much lower compared to NHANES, which resulted in a higher detection frequency and the ability to calculate and characterize these PFCs at very low levels.

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MS. JOE: And so just a very brief overview. Our next steps we're going to go and do similar comparisons using NHANES with our Expanded BEST and Pilot BEST looking at the appropriate gender, age, and race ethnic groups. We also, of course, will examine those demographics within each study, and include the analysis of exposure questionnaire data, which includes different potential routes of exposure, as well as potential confounders like smoking.

So that's all I'm going to talk about today. A very brief overview, but there's more to look forward to in the future.

Thanks.

(Applause.)

CHAIRPERSON LUDERER: Thank you very much. It's always really nice to see results from some of these studies that we've been following for several years. We have time if there's a quick clarifying question.

Dr. Bartell.

PANEL MEMBER BARTELL: Yeah. Just wondered regarding these two plots comparing PFC concentrations across the different studies just looking at, I think, it's the geometric mean from each study. You know, a lot of these look like just eyeballing them and thinking about the variability one might expect that might not be statistically significant, differences might be within the range of random variability for some of these PFASs. Have you actually looked formally to see if any of these differences really are unlikely to be the result of random variation?

MS. JOE: Yeah, that's a great question. And we're doing some of that statistical analysis now, some of the meta-analysis, but I didn't want to go over that in detail today. But we are keeping that in mind. Thank you for that comment.

CHAIRPERSON LUDERER: Dr. Quintana.

PANEL MEMBER QUINTANA: I had a question about comparing your results to NHANES.

MS. JOE: Yes.

PANEL MEMBER QUINTANA: And I was just curious about so many chemicals go up as -- we age and --

MS. JOE: Right.

PANEL MEMBER QUINTANA: -- for example one of the studies was higher in the teachers group who are much older than the firefighters. And I'm just curious when you talked about the firefighter data comparing it to NHANES, it sounded like you compared the firefighters to everyone over 20 --

MS. JOE: Right.

PANEL MEMBER QUINTANA: -- in NHANES, which includes people much older. Are you trying to match it to the exact age of the firefighters for a more detailed analysis or --

MS. JOE: Not the exact age, but possible similar distributions of age within those two populations. And I wanted to give Rob Voss - he worked on this project - an opportunity to comment, if he wanted to, anymore than that?

MR. VOSS: Sure.

MS. JOE: Thanks.

MR. VOSS: Hi. Rob Voss.

Yeah, we tried to get the closest match we could, but we did that by choosing those over 20 as the

comparison. We didn't cut back the higher end of the distribution, so the NHANES group does include several -- the sizeable proportion that are older than our firefighters, so that, you know, that might be a future thing we could look at. But we just chose to cut it at 20 and look at 20 above in NHANES for the purpose of that.

PANEL MEMBER QUINTANA: I was just thinking that it might actually mask a difference that was maybe even greater than it looked.

MR. VOSS: Yeah, it's possible. We could look at that. Thanks.

CHAIRPERSON LUDERER: Dr. Bartell.

PANEL MEMBER BARTELL: Sorry. Just a very quick follow-up. The broad data in NHANES are available. And there are methods by which you could actually do direct age adjustment. If you -- if the intent is actually to compare, you know, any one of these study populations with NHANES adjusting for the actual -- not just the rough age range, but the specific ages in your population.

So it's -- you know, you have to actually delve in and do some -- a little bit of statistical analysis, but it is indeed possible.

MS. JOE: Right. Thank you. Yeah, more tinkering with the NHANES that raw data.

CHAIRPERSON LUDERER: Okay. I don't think there

are anymore clarifying questions right now. So Dr. Krowech will give her talk and then there will be time for more questions and discussion.

(Thereupon an overhead presentation was presented as follows.)

DR. KROWECH: I'm going to talk about now the entire class of perfluoroalkyl and polyfluoroalkyl substances or PFASs.

So first to define these two subgroups, a perfluoroalkyl substance is one in which all of the hydrogen atoms attached to carbon atoms have been replaced by fluorine atoms. So all of the chemicals that Lauren has just talked about are in this group. A polyfluoroalkyl substance is one in which all of the hydrogen atoms on at least one of the carbon atoms have been replaced by fluorine atoms. And I'm going to show examples on the next slide.

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DR. KROWECH: So here are examples of both groups. For the perfluoroalkyl substances, I put both PFOA and PFOS. And you can see that each of the carbons on the carbon chain are fully fluorinated. The exception is in the functional group. So PFOA is a carboxylic acid and PFOS is a sulfonic acid.

In terms of the polyfluoroalkyl substances, the

first example is a fluorotelomer alcohol. This one -- and I'm just going to explain the nomenclature, because it will show up again, is an 8:2 fluorotelomer alcohol, which means that 8 of the carbons are fully fluorinated and 2 have hydrogen atoms attached to them.

The bottom structure is a 6:2 polyfluoroalkylphosphate diester. So again, this uses the same nomenclature of 6 on each part of the ester, 6 carbon atoms are fully fluorinated, and 2 have hydrogen atoms attached to them. So it's a 6:2 diPAP.

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DR. KROWECH: So why consider PFASs as a class for biomonitoring?

Large numbers of PFASs are known to be used as alternatives to PFOS, PFOA, and other long-chain perfluorinated compounds that are being phased out. Many other PFASs, as well as breakdown products, may also be in the environment. And the extent of human exposure is not well known. Having the entire class of PFASs designated on the Biomonitoring California list would facilitate broad laboratory screening and allow the Program to look at key emerging chemicals in this group.

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DR. KROWECH: So this slide just defines what designated chemicals are. And they're chemicals that can

be considered for biomonitoring by the Program. Chemicals are designated based on inclusion in CDC's National Reports on Human Exposure to Environmental Chemicals program. That's how the perfluorinated chemicals became -- came on our designated list, and also by recommendations by the Scientific Guidance Panel for Biomonitoring California.

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DR. KROWECH: These are the criteria for recommending additional designated chemicals. I'm just going to go over them:

Exposure or potential exposure, known or suspected health effects, the need to assess the efficacy of public health actions, the availability of a biomonitoring analytical method, the availability of adequate biospecimen samples, the incremental analytical cost. And these criteria are not joined by ands.

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DR. KROWECH: To look at PFASs some more, they're used in a wide variety of applications. And I've listed here some of the major ones. They've been used as processing aids in manufacturing of fluoropolymers. For example, PFOA was used in the manufacturing of polytetrafluoroethylene, which is used to make non-stick coatings for pans. Polytetrafluoroethylene itself is not

a PFAS. And PFOA does not become -- did not become part of that chemical, but it was used as an aid in the manufacturing.

PFASs are used in surface treatments of textile and carpets to provide water and grease-resistant properties. They're used in food contact material for grease resistance of paper plates and food packaging containers. They've also been used in chrome plating and in firefighting foams.

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DR. KROWECH: With the phase-out of PFOS, PFOA, and other long chain perfluorinated compounds, numerous alternatives have come into use. And these are some -- examples of some of the alternatives that were mentioned in Wang et al., and I just wanted to show them here.

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DR. KROWECH: Many of the new alternatives have shorter carbon chains. This is because toxicity and bioaccumulation typically increase as the length of the carbon chain increases. So I've shown three structures here. The first one is perfluorobutane sulfonic acid, PFBS, with a four carbon chain. This was introduced in 2003 as a replacement for PFOS. And it is the one alternative that is actually on the California Biomonitoring designated list.

The next one is 6:2 fluorotelomer alcohol. Fluorotelomer alcohols are major raw materials for surface treatment products. And many of them break down as well into fluorotelomer alcohols.

The third chemical at the bottom is a perfluoroether carboxylic acid. This particular one is used -- is a replacement used as a processing aid in fluoropolymer manufacturing.

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DR. KROWECH: This is an excerpt from a page on the U.S. EPA website on alternatives for PFOA and related chemicals. And I put it on here just to show the volume of use of some of these newer compounds. And I bolded this last sentence, "To date, over 75 premanufacture notices have been received for telomers based on shorter chain alternatives".

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DR. KROWECH: In terms of exposure or potential exposure, food is regarded is the major source of PFASs. This can be from PFASs that get into the environment or from migration of PFASs in food packaging from the chemical getting into oily, greasy foods. They can be found at very low levels in drinking water. They're in consumer products, such as carpets and textiles, and liquid carpet treatments, floor waxes. And from their

migration out of these consumer products, they can be in indoor air and dust.

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DR. KROWECH: Some of the concerns about the shorter chain PFASs is that their removal by water treatment systems is generally more difficult compared to their longer chain homologs. And they are also released more easily from biosolids compared to longer chain PFASs. And short chain PFASs may be more easily taken up by plants.

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DR. KROWECH: In terms of known or suspected health effects, there are many studies on PFOS and PFOA and some on other long chain perfluorinated compounds. There are very limited toxicological data on newer PFASs.

There are potential concerns though. And some of them include indications of endocrine activity, such as estrogenic activity, and effects on steroidogenesis, which is based on some in vitro studies. There have been a few studies that showed covalent binding of fluorotelomer alcohols to cell proteins. And one of those studies was in an in vivo study in rats. And it also showed covalent binding of a 6:2 diPAP, the phosphate diester, and liver toxicity was seen in laboratory animals after exposure to two perfluoroether carboxylic acids.

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DR. KROWECH: In terms of past biomonitoring studies, as Lauren mentioned, PFOA, PFOS, PFNA, and perfluorohexane sulfonic acid are found in nearly all people tested. Recent U.S. data indicate that levels of some phased out PFASs, including PFOS and PFOA, are decreasing.

Many PFASs not on the Biomonitoring California designated list have been identified in recent biomonitoring studies, and I'm just going to show some of them. They're very low levels.

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DR. KROWECH: And here are some examples. This first slide shows examples from two studies. The samples were collected from the U.S. population. The collection period ranged from 2004 to 2009. So what they found were some diPAPs. And basically what I've listed here is 6:2, 6:2/8:2 and 8:2. So three different kinds of polyfluoro phosphate diesters. And these are used in food packaging.

And actually their level in 2004 seemed to be almost on the order -- their total level seemed to be almost on the order of PFOA, but it's decreased in the 2009 samples were much lower. Fluorotelomer sulfonic acids are breakdown products of other PFASs used in food packaging as well.

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DR. KROWECH: And this slide shows two different they're from two different -- they're from two different studies. The first one is from a study of ski wax technicians. And they were exposed to very high levels of fluorotelomer alcohols. In this study, which found many other compounds, but I'm just showing the fluorotelomer alcohol metabolites as one example, they were able to find these fluorotelomer alcohol unsaturated carboxylic acids and fluorotelomer carboxylic acids. So the metabolites that had been found in the in vitro studies were found here.

The study in firefighters in Australia actually compared firefighters in a control population, and found some perfluoroalkyl sulfonic acids that we haven't been measuring. They didn't give levels, and some of the PFASs that they found were, as I said, exclusively or significantly greater in firefighters compared to controls, but the perfluoropentane sulfonic acid was not. It was found equally in both populations.

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DR. KROWECH: In terms of bioaccumulation, bioaccumulation has been shown to increase with increasing chain length in studies in rainbow trout. Bioconcentration factors in fish though might not be the

most relevant metric for PFASs. For instance, PFOA was not bioaccumulative in rainbow trout. The polyfluoroether carboxylic acids and sulfonic acids are also not bioaccumulative in fish, so more research is needed to gain some information on their bioaccumulation potential.

Short chain PFASs though are less bioaccumulative in animals and humans. In humans, longer chain PFASs, the half-lives are measured in years, such as PFOS is 5.4 years. A very small study of the PFBS, the 4-carbon chain compound, showed that estimated a half-life of approximately 26 days. However, the short chain PFASs might accumulate to a greater degree in plants.

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DR. KROWECH: In terms of persistence, the short chain perfluoroalkyl carboxylic acids and sulfonic acids are similarly persistent as their long chain homologs. Many PFASs will breakdown to the short chain perfluoro carboxylic acids and sulfonic acids.

And two examples are the 6:2 fluorotelomer alcohol, 6:2 fluorotelomer products and perfluorobutane sulfonyl fluoride-based substances. The perfluoroether carboxylic acids and sulfonic acids are also likely to be highly persistent.

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DR. KROWECH: In terms of the laboratory

considerations, Biomonitoring California has two LC-MS/MS instruments for PFAS analysis. The method that's used currently to measure the 12 PFASs can be expanded to include additional compounds. Some PFASs might present difficult analytical challenges.

The incremental cost of the additional PFASs would include purchase of standards, cost of labor and materials during method development and ongoing analysis.

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DR. KROWECH: In terms of the need to assess the efficacy of public health action, there is increasing use of PFASs anticipated. For many PFASs, the extent of exposure is unknown and more information is needed. Including the class on the designated chemicals list would allow the State to track the levels of important PFASs over time.

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DR. KROWECH: So the options for the Panel -- I'll just put this here, and then you can ask questions. The Panel can recommend adding perfluoroalkyl and polyfluoroalkyl substances as a class to the list of designated chemicals; the Panel can defer, pending more information; or, the Panel can recommend against adding PFASs as designated chemicals.

And I'm happy to answer any questions.

(Applause.)

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

Do we have any questions from Panel members for either Dr. Krowech or Ms. Joe?

Clarifying questions, and then we'll -- we also will see if we have any public comments.

Do we have any public comments?

Yes.

CHAIRPERSON LUDERER: I see blue slips.

MS. BUERMEYER: I thought guys had to ask some questions.

CHAIRPERSON LUDERER: While we're getting those, I actually do -- I have a couple of questions actually for Dr. Krowech. And one is the EPA slide that you showed with the 75 PMNs for telomers, were those 75 distinct compounds?

DR. KROWECH: Yes.

CHAIRPERSON LUDERER: Wow. Okay.

DR. KROWECH: As far as I know.

CHAIRPERSON LUDERER: And then one more. And then the PFASs that you mentioned that some of them might present analytical challenges, and I was wondering if either of the laboratory directors could comment on which ones and why?

DR. PETREAS: Myrto Petreas from DTSC.

I would like to pass the buck to Dr. Wang and Dr. Houtz --

(Laughter.)

DR. PETREAS: -- who are the real experts in the lab and June-Soo, if you want to.

DR. WANG: So we have two instruments. One instrument is designed as an on-line high throughput, which is on-line SPE system. So it's limited on how the sample -- basically, the serum been cleaned up on the cartridge and then eluted into the mass spec. So if we add new compounds, it would be a lot of -- depend on the recovery of this, especially short chains on the short cartridge, and it being retained on the cartridge and eluted to column for analysis. So that's one concern.

Another concern is for the isomers, which we are also interested in, the column we are currently using in the system might not have capacity to separate the isomer peaks from the major peaks. So that would be dependent on another LC-MS instrument, which one of my colleagues is also working on, Dr. Erika Houtz. She's not here. So that's the major concern that we have on the instrument.

But we are very interested in adding the new compounds into our current method. Then it would be a great -- like also add our scientific curiosity. It would

be a great addition to our method.

CHAIRPERSON LUDERER: So for the high throughput instrument, you might have to modify the --

DR. WANG: Modify the --

CHAIRPERSON LUDERER: -- use different columns.

DR. WANG: Yeah.

CHAIRPERSON LUDERER: Okay. Any other questions from Panel members before we move on to -- Dr. Bartell.

PANEL MEMBER BARTELL: Yeah, another chemistry question here. And not being a chemist, I'm wading into dangerous territory. But I remember speaking with Antonia Calafat at CDC years ago about PFOA, when she was running some samples for one of our studies. And at the time she was saying one of the big challenges with PFOA, which I imagine applies to a lot of the other PFASs, that being a surfactant it tends to stick to a lot of the lab equipment. And so the recovery rates were really a problem like getting good recovery, and just making sure, you know, you don't have loss of material as it gets stuck to your labware at different stages or your machine.

Is that something you guys have pretty much solved? Do you get high recovery rates? You know, I know you're already doing PFOA, PFOS --

DR. WANG: Yeah. Actually, PFOA is not a big problem for us, like our background getting controlled,

because we have a delay column. So by attaching delay column directly to the pump, gradient pump, so the solvents, like interference, they got delayed probably like less than one minute from our detection window.

So we -- generally, we can say that our background are controlled pretty well. So it's -- yeah, and also we have the isotope dilution, which always helpful in the recovery.

PANEL MEMBER BARTELL: Okay. So at a very basic level, if I'm hearing -- I'll paraphrase what I'm hearing or interpreted, it sounds like they're not unique challenges posed by adding these other classes of PFASs that are unique to that class of compounds. It's just in general adding any other chemical would require some laboratory development?

DR. WANG: Yeah, general. Yeah. Actually, most of the background that we see that, it has big delay peaks, PFOA and PFNA. Nona. It's a nano one.

CHAIRPERSON LUDERER: Thank you.

Why don't we now take the public comments.

Okay. Thank you. All right. Our first public comment is from Veena Singla, Natural Resources Defense Council.

DR. SINGLA: Hi. Veena Singla, Natural Resources Defense Council. Thanks for the very informative and

excellent presentations.

I wanted to comment in support of listing PFASs as a class as designated chemicals. I think some of the information presented did show how there's just this incredible proliferation of these types of chemicals that are being used in a pretty widespread way in products to which people are widely exposed. So I think adding as a class really makes sense in order to help capture the landscape of current and future use that may be developing with these types of chemicals.

CHAIRPERSON LUDERER: Thank you very much for your comments. Our next comment is from Simona Balan, Green Science Policy Institute.

DR. BALAN: Hi. I'm Simona Balan from the Green Science Policy Institute. And just like Veena, I also want to talk in support of recommending the entire class of PFASs to be added to the Biomonitoring Program. We have recently compiled a scientist consensus statement on this class of chemicals. And since its presentation in Madrid last year, it has been signed by over 200 scientists from 38 countries who are all concerned about this entire class, and being problematic to human health and the environment.

And we have also met with representatives from DuPont, which is now Chemours, and we know that they are

replacing C-8, so the PFOA, the 8-carbon chain with about 30 different formulations of the 6-chain alternatives. So the universe of fluorinated chemicals has really expanded. And this seems to be the only logical way to deal with them right now, to really treat them as a class.

And even though right now it might be hard to measure all of them, we know that the scientific community is working on this. And as analytical techniques become available, we think that it would be great to have this option to biomonitor any members of this class of PFASs, because they are being used more and more in consumer products.

So thank you for the opportunity to comment and we hope you just add the whole class.

CHAIRPERSON LUDERER: Thank you.

Our next comment will be from Nancy Buermeyer from the Breast Cancer Fund.

MS. BUERMEYER: Hi. Nancy Buermeyer from the Breast Cancer Fund. Thank you for the opportunity to comment. And I would like to echo my two previous colleagues, and surprisingly enough, ask you to consider this as a class for all of the reasons they've stated. The flexibility to be able to move with the incredible volatility of this market is an important one for the Program. And, you know, we've all heard the stories of

unfortunate substitutions or regrettable substitutions and we need to be able to stay on top of this. And the only way to do that is to do this as a class instead of one chemical at a time. So we would strongly urge the Panel to designate this as a class.

Thank you.

CHAIRPERSON LUDERER: Thank you. Okay. We have one comment that I'm going to read now that was sent in. And it was provided to Panel members earlier. This is a letter from the FluoroCouncil, the Global Industry Council for Fluoro Technology.

I'm going to -- it's a rather long letter, so I'm going to read key parts here. And the entire letter is available on-line on the Biomonitoring California website.

"The FluoroCouncil is a global membership organization representing the world's leading manufacturers of fluoropolymers, fluorotelomer-based products, fluoro-surfactants, and fluoro-surface property modification agents. The FluoroCouncil has a fundamental commitment to product stewardship, and as part of its mission addresses science and public policy issues related to PFASs.

"All members of the FluoroCouncil were early participants in 2010/2015 PFOA Stewardship

Program, the global partnership between the U.S. Environmental Protection Agency, EPA, and industry based on voluntary corporate goals to reduce human and environmental exposure to PFOA and higher homologs by eliminating those chemicals from facility emissions and product content by the end of 2015.

"The success of the Stewardship Program is evident in decreasing levels of PFOA in humans and the environment", and they cite data from NHANES in their letter.

"In addition, through EPA's unregulated contaminant monitoring rule, UCMR3, public water systems monitor for PFOA.

"If the SGP decides to add PFASs as a class to the designated chemicals list, we would encourage a high level of transparency and public engagement regarding both the selection of specific PFAS compounds to be included in any of the Biomonitoring California programs and the analytical techniques to be used. Given the complexity of this class of chemistry, it is critical that the associated analytical techniques are appropriate for the specific substances and matrices to be tested, and meet

established criteria for accuracy, reliability, and precision".

And it's signed Jessica Bowman, Executive Director.

All right. So thank you for all those comments. And now we have time for discussion and additional questions by the Panel regarding this topic.

Dr. McKone.

PANEL MEMBER McKONE: So actually this reminds me a bit of the cyclic siloxane discussion, which had a lot of parallels in the sense that it was a group of -- a large group of chemicals with many different variations. And it was also there -- were questions raised about whether there was sufficient evidence of toxicity. And I think in the end what really sort of tipped the decision was the fact that it was a rising -- there were so many increasing uses that it sort of met this criteria for looking at a class of substances that had some evidence of toxic or some sort of effects on human populations, but also had this really rapid increase in use, so we would expect to see increasing changes in exposure in the population, and we had an opportunity to observe those.

And I think a lot of that plays in here. I don't know how strong an evidence -- and again, I think this is a decision we don't have to -- we don't have to have

strong proof of toxic endpoint to make a decision. I think we need evidence that there are concerns about the effects of these compounds. More importantly, it's a class of compounds where it is difficult to identify specific substances because of the switching and the rapid dynamics of the market and how they're being used.

And they're very interesting, because it's an opportunity for us not to look at what's been there, but to see what's coming and watch it as it happens and provide, you know, scientific insight.

So I would kind of make that point here.

CHAIRPERSON LUDERER: Very similar to the flame retardants. It's in that regard as well that we've had that discussion. And that's -- actually, you brought up a good point, which Dr. Krowech actually showed that slide also, the criteria for recommending additional designated chemicals are not connected by "and", so they don't all have to be met, and you mentioned that.

Do we have any other comments or questions from the Panel?

Dr. Bradman.

PANEL MEMBER BRADMAN: Just a few comments. I mean, given -- I mean, there's kind of known and legitimate concerns about the toxicity of PFOS and PFOA. And, you know, these compounds don't necessarily have the

same depth and breadth of evaluation. But I think by analogy, we have concerns about them, and I think that should be taken seriously. And this is not a toxicology program, but I think these also meet the criteria of having some concerns about their potential health effects. And so that's another basis to consider adding them as a class.

Also, in terms of the laboratory methods that were discussed briefly on the write-up that we were provided on page 13, it sounds like that the laboratory could relatively easily at least add some of the longer chain compounds fairly easily, and that maybe there would be some challenges with some of the shorter chain compounds.

But that said, it seems like the laboratory is well equipped to develop methods to look at these so we also meet that criteria, in terms of feasibility without too much more cost. I guess I'm saying that both as a statement and a question.

(Laughter.)

PANEL MEMBER BRADMAN: But maybe that's a point we could hear about later.

Also, you know, I read this letter last night from the FluoroCouncil, and I think this ties back to the earlier statement about, you know, involvement in industry

in the meetings here and decisions. And I want to emphasize that we really welcome input from all players in the field of environmental health, including industry. And I think this is a good example here, where there's some good comments about these compounds and how industry involvement has resulted in lower exposures.

And I think that's the kind of green chemistry and health oriented or -- I shouldn't say health oriented, preventive oriented environmental health that biomonitoring can promote. And I think the point here about transparency in terms of choosing methods while choosing analytes and also having appropriate analytical methods is really kind of fundamental to this Program in terms of having public meetings. These are on the web. The methods are published on the web. And speaking to those in the room and also anyone who may be listening, we would really welcome that kind of input. And that's something that we -- that really is a strength of this Program.

So I'm not quite ready to take it a step further, but I think that these compounds, for a lot of reasons, meet criteria why we would want to test for them in a Biomonitoring Program.

CHAIRPERSON LUDERER: And Dr. Bradman addressed several of the criteria and commented on how the PFASs as

a class meet several of those criteria. I think also the need to assess efficacy of public health actions is another criterion that these meet, in the sense that we are phasing out certain -- the PFOA and PFOS, and now these other ones are being used. And so in order to really be able to see what's going on with these substitutions, I think that's another one of the criteria that's met.

Other comments from Panel or -- what we have to decide here is whether we want to designate -- recommend designation, recommend not designating, or request additional information. Do we have specific comments from Panel members about that?

PANEL MEMBER McKONE: Oh. Should we have a motion or do we have to discuss further?

CHAIRPERSON LUDERER: You can have a motion.

PANEL MEMBER McKONE: I mean we could have a motion and then discuss, right?

(Laughter.)

PANEL MEMBER BARTELL: Why don't we start with a motion.

PANEL MEMBER McKONE: Okay. So I'm going to make a motion that the Panel recommend adding perfluoroalkyl and perfluoroalkyl substances, PFASs, as a class to the list of designated chemicals, period.

CHAIRPERSON LUDERER: Okay. Dr. McKone has motioned that the class of chemicals perfluoroalkyl and polyfluoroalkyl substances, PFASs, be included as designated chemicals in the California Environmental Contaminant Biomonitoring Program.

Do we have a second, any comments on that?

PANEL MEMBER BARTELL: Second.

CHAIRPERSON LUDERER: Dr. Bartell seconds.

PANEL MEMBER BRADMAN: I'm going to second as well.

CHAIRPERSON LUDERER: You were going to second also.

In that case, then we can have a Panel vote. Should we start with -- I asked for discussion or do we need -- does anyone have any additional comments or discussion from the Panel?

Dr. Bartell.

PANEL MEMBER BARTELL: Just to be clear, I am in support of this motion, but I think, you know, the one argument against it is not knowing much about the toxicity of these short chains, but I think as we've all said, there's reason to be concerned or even to refer to them as suspected health effects, which I think is the wording in the written criteria, hence that may be sufficient, not that we even need that point to be met, as I understand

it, to recommend this.

But I think my only misgiving, though I do support it, is just that it seems like there's some hint that the shorter chains are less toxic, but I don't think there's a lot of toxicity data on that. And actually adding these to biomonitoring might help spur some more movement on doing studies on toxicity of these shorter chain compounds.

So I think for those reasons in the balance, it's probably still a good idea to move forward with adding this to the designated chemicals. And that's my only comment.

CHAIRPERSON LUDERER: Any other comments or discussion?

All right. Then we can move on to voting on the motion.

Dr. Kavanaugh-Lynch, why don't we start with you.

PANEL MEMBER KAVANAUGH-LYNCH: Aye.

PANEL MEMBER BARTELL: Aye.

PANEL MEMBER McKONE: Aye.

CHAIRPERSON LUDERER: Aye.

PANEL MEMBER QUINTANA: Aye.

PANEL MEMBER BRADMAN: Aye.

CHAIRPERSON LUDERER: Okay. Unanimously the Panel has voted to recommend the class of PFASs as

designated chemicals.

All right. So we are a little bit ahead of schedule, which means we have more time for the open public comment period.

So do we have some -- we don't have any additional public comments.

Well -- oh, we do.

MR. HOEPKER: Hi. I'm Alexander Hoepker From UC Berkeley, a chemist in training. This may not be in the purview of biomonitoring, but I just wanted to throw it out there, and it might also prompt some collaboration with industry, and that is -- and it also feeds in with green chemistry in general, to make recommendations for substitutions, to avoid the problem of regrettable substitutions, but clearly we had two problematic substances that were substituted by a flurry of fluorinated substances. And I can only wonder what would happen say in 10 years time when these flurry of chemical substances get replaced by other chemicals.

And so I was wondering if the Biomonitoring California has an option to recommend chemicals or if there's some provision for that.

Thank you.

CHAIRPERSON LUDERER: Does someone from the Program perhaps want to respond to that? It's not --

DR. WILLIAMS: Meredith Williams from the Safer Consumer Products Program in DTSC. And the whole Safer Consumer Products Program is, as you heard last time, designed to ask the manufacturers to ask two questions: Is it necessary to have a chemical in a product, and might there be a safer alternative?

And it outlines a comprehensive alternative analysis process that would exactly address the question that was raised, how do we avoid the regrettable substitutes, what are the toxicities, what's known about the alternative chemicals, what are the impacts, environmental fate, et cetera? It's very comprehensive across lifecycle -- product lifecycle.

So I think that that is an appropriate mechanism to get those questions answered. It comes down to whether or not we actually name a product with a chemical that falls into this category, but it is very helpful in a sense for us to be able to capture chemicals in classes, rather than on an individual basis when we go to look for those alternatives, both in terms of our regulatory listings and in terms of then looking at alternative analyses through that lens of chemical classes.

CHAIRPERSON LUDERER: Thanks very much.

Dr. McKone.

PANEL MEMBER McKONE: Well, I'd like to point

out, first of all, in terms of whether it's in the purview of this Panel, I actually think it's outside, because our goal is to look at what's in people and do the best job of tracking that.

But it doesn't say this isn't an important issue. And I think almost everyone on here, in one way or another, is involved in other activities that are very important. I mean, there's the DTSC Green Chemistry, there are international programs, there's a lot of work in lifecycle assessment. But it's not only on chemicals, I mean, I spend a lot of my time working on cleaner alternatives for energy and providing energy services. So it's very active area. It's very international. It's academic and regulatory. So it's something going on, and we certainly, I think, all support it. It's just, I think, you know, when we meet, we don't want to go too far out of our purview or we're going to -- you know, we're going to dilute the power we have to really make commentaries on biomonitoring.

CHAIRPERSON LUDERER: Thank you. Nancy Buermeyer from the Breast Cancer Fund.

MS. BUERMEYER: Thanks for letting me get up impromptu here. Obviously, the issue that was raised by the gentleman from UC Berkeley is an important one, and I just wanted to talk about how important we think the Safer

Consumer Products Program is and appreciate the comments of Dr. Williams.

And I really think as I think has been done by this Panel and by the leadership of the California Biomonitoring Program is trying to integrate those two programs. The information that this, the California Biomonitoring Program, gathers I think is really instructive to how DTSC makes the decisions about what chemicals combinations they're going to look at.

And I also wanted to echo what Dr. Bartell said about the more we know about exposure, the more that drives the scientific research that we need. From our perspective as an organization, we think we ought to know that stuff before they get into the products, right, like we think there ought to be reform of the Toxic Substances Control Act so that we actually know the health issues before we have exposure to large portions of the population.

But given that that's not where we are right now, that kind of exposure information really drives a lot of that data. And we've seen that with biomonitoring data showing huge exposure and how that has created an avalanche of research on that -- of that chemical.

And I suspect we will see that we've seen that some with flame retardants. We've seen some of that with

phthalates. And I think there's a potential to have that happen here. So I really think that, while I agree, it's outside of the purview of this body, I just wanted to emphasize how important the work that this body does to driving that sort of broader process of knowing the toxicity, knowing the alternatives, and how do we make products safer in the long term.

Thanks.

CHAIRPERSON LUDERER: Thank you. Sara Hoover -- or Dr. Williams.

DR. WILLIAMS: Meredith Williams again.

And I did want to say that our three-year workplan explicitly called out biomonitoring results as a method for us to make decisions about which categories got included in the workplan, because that -- we had a degree of confidence that we would be able to explain the exposure.

And then as we go forward and choose individual products from those product categories, we will again circle back to biomonitoring. So this Program for us is really fundamental to so much of our decision making, and we're really excited to be in much stronger partnership moving forward.

CHAIRPERSON LUDERER: Thank you.

Sara Hoover.

MS. HOOVER: Yes. Sara Hoover, OEHHA. I just wanted to add a couple things of interest. First, we've actually started some new efforts to work directly with the Safer Consumer Products Program. So bringing -- you may recall that last July, we had a consumer product focused meeting when Dr. Williams was here. And we had certain follow-up items, and we're working on those follow-up items, like a systematic review of our list compared to consumer product chemicals. And we've now started a little work group with actual staff-to-staff contact across the two programs.

So we're planning, you know, as we go forward to work -- I mean, we've always been working closely at some level, but we're making those links stronger. And we're hoping -- this is all still tentative, but in July we're hoping to have sort of another check-in on those efforts. So that's one angle.

The other thing I'll just mention is the name of my section in OEHHA is Safer Alternatives Assessment and Biomonitoring Section. So even though in the Biomonitoring Program we're not directly working on it, it's an area that OEHHA is very interested in as well, and we have other efforts along those lines. So it's an important point that we want to make our data relevant to that larger policy issue.

CHAIRPERSON LUDERER: Thank you very much. That was -- that's really helpful that you added that.

Any other comments or questions from Panel members?

I know Dr. Alexeeff didn't have the opportunity to talk about what we did as a Scientific Guidance Panel at the last meeting, so I thought I would give him the opportunity to say a few words about that.

DIRECTOR ALEXEEFF: Also, I just wanted to welcome Dr. Bartell. I can see he's already been contributing, which is great.

(Laughter.)

DIRECTOR ALEXEEFF: So I look forward to your contributions over the term here.

At our -- you know, at our last meeting, similar to the things that we've discussed this meeting, you know, we had laboratory updates, we had input, we heard the findings of Biomonitoring California evaluation activities of the CDC cooperative agreement. We had more CDC input today. And last time we had a wide-range discussion about the challenges in measuring exposure to diesel exhaust. That clearly has been a chemical or a substance that's been a very specific interest to this Panel. It comes up regularly.

And the Panel reiterated their previous support

for the Program to identify a biomarker, and encouraged pursuing the method development of 1-nitropyrene, which has been used. We talked about that last time, and its metabolites as a starting point.

And as always, we have a great transcript preparer here. We're very fortunate to have him. And the transcript is available on our website. And the transcript of this meeting will be available on our website of Biomonitoring California as well.

CHAIRPERSON LUDERER: Thank you, Dr. Alexeeff. I also -- as Dr. Alexeeff just mentioned, we will have a transcript of this meeting posted on the Biomonitoring California website soon.

I also wanted to remind everyone that the next Scientific Guidance Panel will be on July 16th in Oakland also. And remind you all that this building closes at 5:00 p.m., and so we recommend that everyone not linger for too long. I don't think that should be a problem. That gives you an hour to get down to the first floor, so -- and then with that, I would like to thank everyone for coming and adjourn the meeting and see you all in July.

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 3:50 p.m.)

C E R T I F I C A T E O F R E P O R T E R

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, 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 March, 2015.

JAMES F. PETERS, CSR, RPR
Certified Shorthand Reporter
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