APPEARANCES

PANEL MEMBERS
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Ms. Carol Monahan-Cummings, Chief Counsel
Mr. Allan Hirsch, Chief Deputy Director
Ms. Amy Dunn, Safer Alternative Assessment and Biomonitoring Section
Ms. Sara Hoover, Chief, Safer Alternative Assessment and Biomonitoring Section
Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch

DEPARTMENT OF PUBLIC HEALTH
Dr. Rupali Das, Chief, Exposure Assessment Section, Environmental Health Investigations Branch
Dr. Sandy McNeel, Research Scientist
Ms. Amiko Mayeno, Field Investigations Coordinator
Dr. Jianwen She, Chief, Biochemistry Section
APPEARANCES CONTINUED

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Dr. Kenneth Aldous, New York State Department of Health
Mr. Davis Baltz, Commonweal

Mr. Davis Baltz, Commonweal

Dr. Antonia Calafat, Centers for Disease Control and Prevention

Ms. Carrie Dickenson, University of California, San Francisco

Ms. Denise Laflamme, Washington State, Public Health Laboratories

Dr. Patrick Parsons, New York State Department of Health

Mr. Blaine Rhodes, Washington State Public Health Laboratories
<table>
<thead>
<tr>
<th>INDEX</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome by Allan Hirsch, Chief Deputy Director, Office of Environmental Health Hazard Assessment</td>
<td>1</td>
</tr>
<tr>
<td>Overview of the Meeting, Ulrike Luderer, Chair, Scientific Guidance Panel (SGP)</td>
<td>3</td>
</tr>
<tr>
<td>Program and Laboratory Updates</td>
<td></td>
</tr>
<tr>
<td>Presentation: California Department of Public Health (CDPH), Environmental Health Laboratory (CDPH), Environmental Chemistry Laboratory (Department of Toxic Substances Control)</td>
<td>5, 21, 37, 37</td>
</tr>
<tr>
<td>Panel Questions</td>
<td>20, 20, 29, 46</td>
</tr>
<tr>
<td>Public Comment</td>
<td>48</td>
</tr>
<tr>
<td>Panel Discussion and Recommendations</td>
<td>51</td>
</tr>
<tr>
<td>Biomonitoring for Exposure Assessment: Challenges and Future Directions</td>
<td></td>
</tr>
<tr>
<td>Presentation: Antonia Calafat, Ph.D., Chief, Organic Analytical Toxicology Branch, National Center for Environmental Health, Centers for Disease Control and Prevention</td>
<td>51</td>
</tr>
<tr>
<td>Panel Questions</td>
<td>68</td>
</tr>
<tr>
<td>Public Comment</td>
<td>85</td>
</tr>
<tr>
<td>Panel Discussion</td>
<td>86</td>
</tr>
<tr>
<td>Afternoon Session</td>
<td>90</td>
</tr>
<tr>
<td>Presentations by Washington and New York State Biomonitoring Programs</td>
<td></td>
</tr>
<tr>
<td>Washington Environmental Biomonitoring Survey</td>
<td>91</td>
</tr>
<tr>
<td>Blaine Rhodes, Office Director, Environmental Laboratory Sciences, Washington State Public Health Laboratories</td>
<td></td>
</tr>
<tr>
<td>Expanding the Capability and Capacity for Biomonitoring at the Wadsworth Center, NY State Department of Health</td>
<td>112</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Kenneth M. Aldous, Ph.D., Director, Division of Environmental Health Sciences, Wadsworth Center, New York State Department of Health</td>
<td>112</td>
</tr>
<tr>
<td>Panel Questions</td>
<td>103, 127</td>
</tr>
<tr>
<td>Public Comment</td>
<td>127</td>
</tr>
<tr>
<td>Panel Discussion</td>
<td>131</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Update on Maternal and Infant Environmental Exposure Project (MIEEP or Chemicals in Our Bodies Project)</th>
<th>138</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation: Carrie Dickenson University of California, San Francisco (UCSF), Program on Reproductive Health and the Environment</td>
<td>138</td>
</tr>
<tr>
<td>Panel Questions</td>
<td>147</td>
</tr>
<tr>
<td>Public Comment</td>
<td>148</td>
</tr>
<tr>
<td>Panel Discussion and Recommendations</td>
<td>148</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary of Results Return Testing in the Firefighter Occupational Exposures (FOX) Project</th>
<th>149</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation: CDPH</td>
<td>149</td>
</tr>
<tr>
<td>Panel Questions</td>
<td>162</td>
</tr>
<tr>
<td>Public Comment</td>
<td>169</td>
</tr>
<tr>
<td>Panel Discussion and Recommendations</td>
<td>169</td>
</tr>
</tbody>
</table>

| Open Public Comment Period | 171 |
| Wrap up | 171 |
| Adjournment | 172 |
| Reporter's Certificate | 173 |
CHIEF DEPUTY DIRECTOR HIRSCH: Okay. I think we're going to get started now. For the record, I'm not George Alexeeff. My name is Allan Hirsch. I'm Chief Deputy Director of the Office of Environmental Health Hazard Assessment. I'd like to welcome all of you here on the Panel and in the audience to the meeting. George is in the building. He should be here in just a few minutes. He got pulled aside on something. So we're going to start. And again, he should be here shortly.

So again, I'd like to welcome all of you, and thank you for coming. And if you're watching via the webcast, welcome to our meeting here. I'd like to thank the members of the Panel for taking time out of your very busy schedules to come to Sacramento, and take part.

Just a few logistics here. Restrooms are located here on the second floor of the building, outside of the rooms here. The easiest way is to leave the rooms and go left. And you should find them. They're off to your right after that.

In the unlikely event there is a fire drill or an emergency, the easiest way out is to go out the exits, turn right walk down the stairs, and leave the building on the first floor. We had a series of fire drills I think about four to six weeks ago, so hopefully there won't be
any.

And also again, the meeting today is being webcast and is being recorded and transcribed as well. We have a court reporter here up front. So there will be a transcript of the meeting posted on the website. Our goal is to have them up usually about a month after the meeting.

Okay. And then I'll just give a quick overview of the last SGP meeting. It took place here in Sacramento on July 14th. The Panel commented on the overall program and laboratory updates. They provided input on an updated chemical selection screening tool to help identify candidates for potential designation. We heard a presentation on methods for non-targeted screening of biological samples to identify previously undetected environmental contaminants. And they recommended that the Panel explore ways to use these methods for priority setting and confirmatory analyses.

They discussed highlights of the March workshop -- don't need to hear myself twice.

(Thereupon a problem with the sound system occurred.)

(Laughter.)

CHIEF DEPUTY DIRECTOR HIRSCH: Okay. I'll just finish -- we'll finish this quickly again. So they
discussed highlights of the workshop that was held in March on understanding and interpreting biomonitoring results and they advised the program to not pursue individual risk interpretations of biomonitoring results.

Lastly, they provided input on Panel recommendations for the Program to be summarized by our Chair, Dr. Luderer, and sent to the Program for inclusion in the 2012 report to the Legislature.

And so if you wanted more information about that meeting, we have a transcript of it now that's up on our website www.biomonitoring.ca.gov.

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

CHAIRPERSON LUDERER: Thank you very much. And good morning, everyone. I'd like to welcome all the members of the public, the Program staff, the speakers, as well as the Scientific Guidance Panel members to the meeting.

As you've heard today, we have a number of goals. We're going to receive program and laboratory updates and provide input on those. We're going to hear from national biomonitoring -- the National Biomonitoring Program and discuss challenges and future directions in biomonitoring exposure assessment, and we're also going to hear about the Washington and New York State Biomonitoring Programs
and discuss issues of common interest.

    We're going to receive an update on the Maternal
and Infant Environmental Exposure Project. And discuss
progress of that Project, as well as a report on results
of usability testing of results return materials in the
Firefighter Occupational Exposures, or FOX, project, and
provide input on that.

    And after each presentation, as always, we'll
have an opportunity for Panel questions and then a public
comment period, and then time for further Panel discussion
and recommendations.

    For the public comments, if you would like to
make a comment, please fill out a comment card, which can
be obtained at the staff table with the handouts, and you
can turn that into Amy Dunn who is holding the comment
cards up there. And we'll also allow -- it's also
possible for members of the public who are participating
via the webcast to submit comments. And you can send
those by Email to the Biomonitoring Email address, which
is biomonitoring@oehha.ca.gov during the meeting.

    The Biomonitoring California staff will provide
those comments to me, and then I'll be able to read them
aloud at the appropriate time.

    In order to assure that the meeting proceeds on
schedule, and I guess we're already a little behind
schedule here, all the commentators will have an
opportunity to speak, but we'll time the comments,
basically divide the amount of time we have by the number
of people who wish to speak.

So please keep your comments focused on the
agenda topics that were being presented. And then there
will also be an open public comment period at the end of
the meeting, the last item of the day for general comments
about the program.

I also want to remind everyone to directly speak
into the microphone and please introduce yourself before
speaking. This is for the benefit of people who are
participating via the webcast, as well as for the benefit
of the transcriber.

So the materials for the meeting were provided in
the meeting folder to the Panel members and via the
website for the public. There are also a small number of
handouts and one folder for viewing at the staff table,
which is in the back of the room.

We'll take two breaks today, one for lunch at
around 12:30, and one in the afternoon.

So now I'd like to announce our first agenda item
for the day, which is the Biomonitoring California Program
and Laboratory Update. And it's a pleasure to introduce
Dr. Rupali Das, Chief of the Exposure Assessment Section,
in the Environmental Health Investigations Branch at the
California Department of Public Health and lead of
Biomonitoring California.

Dr. Jianwen She, Chief of the Biochemistry
Section in the Environmental Health Laboratory Branch at
the California Department of Public Health, and Dr. Myrto
Petreas Chief of Environmental Chemistry Branch, in the
Environmental Chemistry Laboratory at the California
Department of Toxic Substances Control.

Dr. Das.

(Thereupon an overhead presentation was
Presented as follows.)

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

And welcome, members of the Scientific Guidance Panel and
audience members here in the room and those listening on
the webcast. It's my pleasure to give you an update of
the overall achievements of the Program since our last
meeting with the Panel.

--o0o--

DR. DAS: Today, I'll be providing an update on
the funding, describing some staffing changes, providing a
very brief update on our pilot projects, the Maternal
Infant Environmental Exposures Project, the Firefighter
Occupational Exposures Project and the Biomonitoring
Exposures Study. And you'll hear more about a couple of
these projects later on as well. Describing a few other activities, and you'll get a brief glimpse as to what's coming next.

--o0o--

DR. DAS: I'm happy to report that our funding remains stable. As you know, we have two sources of funding. Our State funding comes from the Toxic Substances Control Account, or TSCA. And our funding is maintained at 1.9 million for this fiscal year. As you know, that funding supports 13 -- the equivalent of 13 FTEs across three departments.

We are also very fortunate to have the CDC cooperative agreement, which funds many of our activities. We're currently in year three of the five-year cooperative agreement. And our funding for this year remains stable at 2.6 million a year.

--o0o--

DR. DAS: I just wanted to remind you about the CDC cooperative agreement objectives, because it's been awhile since we put them all up on the screen. We had five objectives that we specified in the cooperative agreement. First to expand laboratory capability and capacity. Second to demonstrate the success of the lab quality management system. Third to apply biomonitoring methods to assess and track exposure trends, and that's
certainly consistent with our State mandate. Fourth, to assess exposures in a representative group of Californians also consistent with our State mandate. And fifth, to collaborate with stakeholders and communities. That's a third common element with our State mandate.

--o0o--

DR. DAS: There were three recipients of the CDC cooperative agreement, California, New York, and Washington State. Since the last meeting, we have made significant progress towards forming a State biomonitoring network of the States that were funded by the cooperative agreement. We've had approximately quarterly telephone calls.

And over the last couple of days, we had our first in-person meeting. It went very well. It was primarily meeting between lab staff to exchange ideas, share common issues, and look for solutions. The meetings took place in the Berkeley and Richmond labs. And we're very happy to have some of the staff here in attendance today.

If you would please stand, Dr. Ken Aldous and Dr. Patrick Parsons are in the room today. And Blaine Rhodes and Denise Laflamme, sorry. This is actually not my updated presentation. That's why I was thrown off a little bit. And Lovisa Romanoff and Antonia Calafat from
CDC are here in the room as well. So I'd just like to extend a very warm welcome to them for being here with us.

(Applause.)

DR. DAS: You will hear from Dr. Aldous and Blaine Rhodes later today about the programs in their States.

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DR. DAS: We have several new staff. Some of the lab staff will be introduced during the lab updates. Sabrina Crispo-Smith is a lab scientist in the Environmental Chemistry Lab in DTSC.

Dr. Laura Fenster is a new epidemiologist joining us in the Environmental Health Investigations Branch. She is in the position previously occupied by Diana Lee. Laura has an MPH in health education and a Ph.D. in epidemiology from UC Berkeley. She has worked in various positions in the Division of Environmental and Occupational Disease Control, both in the Occupational Health Branch, as well as in the Environmental Health Investigations Branch over a number of years.

Laura has extensive grant writing skills and experience in reproductive health endpoint studies. With Drs. Brenda Eskenazi and Asa Bradman she has been an integral partner in several CHAMACOS projects. Her experience and interests make her an excellent addition to
our biomonitoring team. And we're very happy to have her.

So I'd like to extend a warm welcome to her.

Laura, would you please stand for those of you who don't know her.

(Applause.)

DR. DAS: We're also very fortunate to have Jeff Fowles, a toxicologist, who's just joined our program recently. Jeff and I first worked together in the Air Toxicology and Epidemiology Section of OEHHA many years ago. Since then, Jeff has gained considerable experience working on food residue standards, toxicity classification of hazardous stances and surveillance for acute chemical injuries for governmental agencies and research organizations in New Zealand. And he's also worked as a regulatory toxicologist and in product safety positions.

Jeff received his Ph.D. in toxicology for Oregon State University, and is currently the only toxicologist in our Branch, and provides considerable resource for many people, including those of us in the Biomonitoring Program.

So, Jeff, if you would please stand and welcome.

(Applause.)

DR. DAS: We also have Anthony Zhou who's a laboratory assistant in the Environmental Health Lab. And Dr. She will introduce him in a little bit more detail in
his presentation.

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DR. DAS: Sadly, we are saying good-bye to a number of staff as well. Dr. Frank Barley, who was our inorganic chemist for metals, provided a lot of expertise in the metals analysis, has retired, but continues to provide some assistance to us as a retired annuitant.

Dr. Robert Ramage went to another program in the State. Josie Alvaran, who was a specimen management specialist and really helped the lab and the Epi and the field staff work together in a very smooth fashion, has moved on to another position as well.

And our CDC Public Health Prevention Specialist, Ngozi Erondu, was with us for two years, and has gone on to -- will soon join a Ph.D. program at the London School of Tropical Health and Hygiene. And so we are sad to see her go, but very happy for her future career.

--o0o--

DR. DAS: I'd like to now give you a brief update on the Maternal Infant Environmental Exposures Project. You will hear from the UCSF PI, Dr. Tracey Woodruff this afternoon. So this is just a brief reminder of what the project is all about.

To remind you, this is a collaboration between Biomonitoring California, UCSF, and UC Berkeley. This was
a convenience sample of mother-infant pairs recruited at San Francisco General Hospital, mothers who delivered -- who were receiving prenatal care at SFGH were recruited into the study.

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DR. DAS: And to let you know where we are today, these were the different phases of the project: Recruitment, data collection, data management, and results return.

The check marks indicate the elements that we've already completed. We are done with recruitment. We're done with the collection of all the data, including the biological specimens, as well as the questionnaire. And we are in the process of analyzing the samples in the labs and doing such things as abstracting medical records and entering the data.

You'll hear a little bit more detail about that, and a little bit about the results this afternoon from Dr. Woodruff.

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DR. DAS: The Firefighter Occupational Exposures Project, or FOX, is a collaboration with the UC Irvine Center for Occupational and Environmental Health, and the Orange County Fire Authority.

This was also a convenience sample and we
recruited firefighters who were undergoing wellness and fitness evaluations at the UC Irvine COEH clinic. We enrolled 101 firefighters.

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DR. DAS: Similarly to MIEEP, we have the different phases of the project. We are done with recruitment, data collection, and have entered the data, and are currently analyzing the data and analyzing samples. And you'll hear a little bit about the results return work that we've done for FOX this afternoon.

---o0o---

DR. DAS: I wanted to tell you a little bit about the data sources for FOX. When you saw in the previous slide that we're entering data, it looks like one box, and we can just check it off. But actually, there are many different elements for both MIEEP and for FOX, in terms of data entry.

And so to give you an idea of what data entry means or when we talk about data management what we're talking about, this slide shows the different parts of -- different sources of data that go into our data management process.

---o0o---

DR. DAS: We enter data from all these different documents. We have an informed consent document, an
exposure assessment questionnaire. For FOX, we abstract some medical records from the WEFIT, or wellness and fitness questionnaire, that's obtained by UC Irvine.

There is a lead reporting form that we are required to fill out as part of the State requirements. For FOX, we also asked the participants to fill out an evaluation survey after they were recruited to tell us a little bit about their experience, about participating in the study.

We have a participant log. The fire station checklist is a list of items that firefighters at each station were asked to fill out asking about the environmental conditions in their fire stations. There's also additional fire station information and the laboratories have their own set of data that they need to enter, and we need to merge with the Epi data that we collect.

The computer logos indicate information that is automated.

--o0o--

DR. DAS: This slide shows a little bit more detail about the data management steps. We have entered data from all the source of the environmental data, and the questionnaire information are from all the sources for the participants. We have completed double data entry for
QA/QC purpose, our quality assurance and quality control purposes for all the questionnaires. We've also done some accuracy and precision checking for the data entry and have done some logic checks and validation.

And we will soon be linking data from various sources to create a full data set, and checking the consistency of variables from different sources.

For the FOX project, we were fortunate to have some resources outside the biomonitoring funding to collect some environmental samples. We collected dust samples from 20 fire stations and analyses are in progress for the chemicals listed here. The polybrominated diphenyl ethers, or PBDEs, polycyclic aromatic hydrocarbons or PAHs, and the polychlorinated biphenyls or PCBs.

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DR. DAS: The Biomonitoring Exposures Study, or BEST, is a collaboration with Kaiser Permanente Northern California Research Program on Genes, Environment and Health.

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DR. DAS: This is a reminder that this is a study that's taking place in the California Central Valley. It's a stratified random sample, a regional representative sample of residents in California's Central Valley,
consisting of adult Kaiser members, living in seven Central Valley counties listed at the bottom there and indicated by the blue in the middle of the map of California.

Our goal is to recruit 100 participants. We are in the process of recruiting the participants. We hope to complete data collection soon.

--o0o--

DR. DAS: This slide shows where we are with the BEST Project. We are in the process of recruiting participants. We did an initial phase of participant recruitment, and then refined the data collection instruments and processes, and have recently embarked on the second phase of recruitment and sample collection. And we will soon be completing the other phases as we have done for the other projects.

This recruitment strategy is a little bit different than the other two projects that were convenience samples with participants recruited in clinics. Because BEST involves either going to a participant's home or their office or having them come to a Kaiser clinic, there is an additional element of arranging for a visit, and then arranging for sample collection. So the whole process is a little bit more involved than for the convenience samples of MIEEP and
DR. DAS: In addition to the projects that described and the sample analyses, we continue to do other activities that are very important for us. And these include chemical selection. We've been developing potential designated -- a potential designated document for non-halogenated aromatic organophosphate flame retardants, and are continuing to screen candidates for potential designation, for example, additional pesticides.

We've also been working on the public involvement plan. It is currently in management review, and we're drawing on the many helpful suggestions we receive from stakeholders who reviewed the draft plan. These include ideas on new ways to reach interested audiences. For example, we're evaluating the possibility of establishing a social media presence, as a way of engaging additional stakeholders.

We'll also be reaching out to groups with potential interest in the Program by sending notes through other email lists, such as those operated by State agencies, including the CalEPA Environmental Justice listserve.

And finally, we are in the process of revamping the Biomonitoring California website. This includes
revising the look and content to make it more user
friendly, to allow people to come and find what they want
readily, to improve readability, and to increase the
relevance for general audiences. And I think you'll be
very pleased with the results. We hope that that will be
ready for rolling out to the public in 2012.

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DR. DAS: In the coming months, we hope to return
results to participants in both the MIEEP and the FOX
studies. In the slides where I was describing where we
are, you saw that we're analyzing the results and
establishing the results return materials.

Early in 2012, we aim to return the first set of
results to both the firefighters and to Maternal Infant
Environmental Exposures Project participants. And you'll
hear a little bit about the FOX results returned,
usability testing this afternoon to show you some of the
work we've done to make these materials understandable to
participants.

We've also done a considerable amount of work
towards issuing a second Request For Information to
outside researchers to ask for interest in having
Biomonitoring California's analyzed samples collected by
other researchers.

If you'll recall in 2008, the Program issued the
first RFI, and we collaborated with three different research groups to analyze samples that they had collected. And we are almost ready to issue the next RFI.

We also are going to be rolling out a second phase of the Biomonitoring Exposures Study or BEST, that's the collaboration with Kaiser. The BEST II, as we'll refer to it, will also take place in California's Central Valley. Our plan is to include Spanish speaking participants. This was a recommendation from the Scientific Guidance Panel and something that we feel is very relevant and appropriate for the State of California.

And finally, as is a requirement of the mandate, we are preparing a report to submit to the Legislature. Our requirements are to submit a report every two years. And the next one is due in January 2012. The report is currently in management review.

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DR. DAS: Finally, as I've said before, it takes a village to run a biomonitoring program. And I wanted to thank all the terrific staff whose work I've outlined in the last few slides, and who the next few presenters will also describe. So I want to give a big round of thanks and applause to all the many staff who contribute to the wonderful work we're doing in California. So I want to applaud them also. Thank you.
(Applause.)

DR. DAS: This makes my job so much easier to have such terrific staff.

If you have any questions now, I'd be happy to answer them. I'd also like to thank you, Scientific Guidance Panel members, and our collaborators who are essential in completing our projects.

If you have any questions, I'd be happy to answer them, at this point, before we go on to presentations from the lab.

CHAIRPERSON LUDERER: Any questions from any of the Panel members?

Dr. McKone.

PANEL MEMBER McKONE: I guess this is a clarification. You brought up the meeting with Washington and New York. Are we going to hear much more about that or is it something we can do on our own mingling at breaks?

DR. DAS: We are just -- we are actually -- we met with them over the last two days. And so we did not have on the agenda an item to describe the outcome of that meeting. You will be hearing from Washington and New York States about their programs.

We can describe the results of that meeting in another -- of our last two-day meeting in another SGP
meeting. That's not on the agenda. But staff are here to
talk to you. And if you have specific questions, we'd be
happy to answer them.

PANEL MEMBER MCKONE: All right. Thank you.
CHAIRPERSON LUDERER: Okay. If there are no
further questions, we can proceed to the next
presentation.

DR. DAS: The next speaker will be Dr. Jianwen
She who is the Chief of the Biochemistry Section in the
Environmental Health Lab of the California Department of
Public Health.

(Thereupon an overhead presentation was
Presented as follows.)

DR. SHE: Thanks, Dr. Das, for your introduction.
Good morning, Science Guidance Panel and to everyone.

I want to update the Panel -- I'd like to update
the Panel and the audience about the progress since July
meeting.

--o0o--

DR. SHE: Rupali already mentioned laboratory
have two new staff. Mr. Anthony Zhou, you can see the
picture. He's not in the audience. He graduated from UC
Berkeley. And he has some chemistry background, and also
computer program language background. And then he is
major with PAH sample preparation, and also a lot of the
cap with -- prepare the -- check the inventory and also do the -- some computer database related work in the lab.

We also have Dr. Simon Ip. He's hired by Association of Public Health Laboratory as a fellow. Right now, he -- he work with us to continue the work Mr. Dashen Lu left for the dry blood spots and also Dr. Bob Ramage left and then Dr. Simon will continues some work of the hydroxy-PAH on the high resolution.

As Dr. Das mentioned, Dr. Frank Barley left us, and Dr. Bob Ramage left us. And then Josie left us. So we have three vacancies.

I forgot to mention, Dr. Simon got his Ph.D. from Hong Kong Science and Technology University. He get his BS from UC San Diego. Dr. Simon actually is in our -- in the audience. Will you please stand up.

(Appplause.)

DR. SHE: Thank you, Doctor.

--o0o--

DR. SHE: I also want to talk about the laboratory setup. We purchased and installed the last piece of big equipment in our lab. The LC-MS for perchlorate and the organophosphate pesticide analysis.

This purchase completed the Environmental Health Laboratory's setup for quantitative analysis funded by CDC cooperative agreement.
DR. SHE: For the laboratory method, we still talk about three different category, under development, under validation and application, and in production.

DR. SHE: Two inorganic methods right now under development. One is a metal panels in urine by ICP-MS. And the second one is a perchlorate analysis. For perchlorate analysis, with a new instrument, we already have the -- previously, we purchased a Ion-chromatograph. We tested the linkage and the hand shake between the instrument. So very soon we will start the development work.

DR. SHE: As I mentioned, Dr. Dashen Lu started the dry blood spots and the very low volume blood spots analysis for PBDEs and the PCBs. And then he left at the end of May. So we don't have so much progress. Gladly we have Dr. Simon join us, so he can pick up and continue. Dr. Sen Nil he's working on the arsenic speciation. His method is almost ready for validation and Dr. Sen is in the audience if you have further questions, he can help to address.

DR. SHE: So this slide shows the separation of
six species of the arsenic. And I think the -- he also went to New York, Washington State, so we're able to collaborate with the other State biomonitoring programs, learn from them, share the experience. The Washington State is also here and they may also answer some questions.

--o0o--

DR. SHE: We are very glad for all of the organic method. Most, of course, we set up in the CDC grant application we bring to the productions. So the -- but I started with metal panels. We already have this one I reported before.

We have four metals mercury, cadmium, lead, manganese. And for the phthalate we're able to analyze right now six of them. We have a problem with MMP. I'm very glad Dr. Antonia Calafat, she is here. I think the CDC also have some question about analysis of the MMP. So we will not do the MMP at this moment.

For the six of the DAPs, we have a problem with DMP, the first one. We're able to do five of them at this moment. We don't know what's the reason why we cannot do DMP, but other labs can do. We still need to search. Dr. Dongli Wang is here, also in the audience. He may answer some questions regarding that methods.

For the OP pesticide, we're able to do TCPy, and
the 3-PBA, we reported before. We are in the process to expand them, the list.

For the environmental phenols we're able to do all of the searching of them. We exchange the samples with CDC. We make the most of them. And also Dr. Antonia Calafat gave us some new suggestions. Some of the analytes she think were dropped out by CDC. She can maybe give us some more details when the questions come up.

We're able to do 10 hydroxy-PAHs. And as I mentioned, right now our chemist left, but we have two methods. We have high resolution GC-MS method and we also develop a method by a visiting professor from China use the LC-MS/MS. Both methods give very reasonable, comparable result. And the performance, for example, like detection limit and precision are very comparable. So at least we have one method still have chemist running -- chemist still with us. And Dr. Fan will go back to China at the end of February. But we hope we can continue the work with Dr. Simon.

We also tried to recruit the new candidate that replaced Dr. Bob Ramage.

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DR. SHE: This regarding the project progress. The laboratory finished all of the sample analysis for MIEEP project. You can see that's 140 blood samples and
90 urine samples.

   The first column, you see the chemist -- the chemicals, we are able to finish them. And the last columns show our progress on the FOX samples. We just finish the 101 blood samples for metals. The other four categories we still aliquot a sample. Very soon we will start the sample analysis.

   We are right now also reviewing MIEEP samples result.

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   DR. SHE: For the future work, of course, we need to finish all of the FOX samples as soon as we can. And complete method validation for dry blood spots for PBDE and PCB. And then continue to use dry blood spots for other analytes. For example, New York use for PFCs and then for -- CDC use it for perchlorate. So we will explore them if we're able to finish PBDE and PCB.

   Finish metal panels in urine. Complete arsenic speciations. We want to finish the method development for perchlorate. Right now we also try to expand especially OP and the pyrethroid metabolite list.

   We also like to automate sample preparation, which currently we are using a manual preparation.

   We also like to automate report generation data review process, so make sure our data is of high
qualities.

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DR. SHE: This slide shows which chemicals we tried expanding. Again, according to Dr. Antonia, some chemicals they move to different method like DEET. That's the first one. CDC right now use different method. And a lot of the chemical is -- Atrazine -- number -- are treating metabolite, ATZ, number -- four rows from bottom, ATZ. CDC used different method. So we may not able to expand with current method for these two chemicals. But the remaining we are still working on. So if we finish the expansion of the panel for organic, we have four panels almost.

We also for phthalate we're able to exchange samples with New York, with Dr. Kannan and Dr. Ying Guo our agreement on the analytical result is very good.

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DR. SHE: As I mentioned, laboratories also working on the standardized data review process, because right now it take too much time to review all of the data. And we'd like to standardize what's the peer chemist supposed to review, what the quality control person to review. The releaser like should provide what he need to check.

But the first we need a standard list, develop a
checklist. So some of these items can be automated. We call it automated date review, ADR. So we tried programming. So again, make the data review process most standardized and automatic.

And, for example, we have a draft list already, for example, check up the validation of calibration curve, slope, and they intercept, which can be done by computer program.

Construct calibration curve control chart for slope and intercept.

Do a metric plot of internal standard or calculate the recovery of internal standard. The reason is the current LC-MS always have the ion suppression or ion enhancement, so we need to make sure our standard response is under control. Construct the control chart for the recovery of target compound.

We not review the next three lines. But for example, for chromatograph what we suggest to check, make sure the peak is integrated correctly, retention time is correct. So all of these items in the checklist we are being reviewed peer chemist or the quality control person. Finally reviewed by the chemist also provides.

The idea is because they're standardized and they're automatic.

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DR. SHE: Thank you.

CHAIRPERSON LUDERER: Thank you, Dr. She. It's very impressive to see all the progress that you and your colleagues have made in spite of the unfilled positions. Does any of the Panel members have clarifying questions?

Dr. McKone.

PANEL MEMBER McKONE: This may reveal my ignorance about chemistry, but I'm going to ask it anyway. You said you're under development. You have PBDEs and PCBs from very low volumes of blood. First of all, I guess my first question is, are you looking at the parent compound or metabolites?

DR. SHE: We look only at parent compound.

PANEL MEMBER McKONE: Just the parent compound.

DR. SHE: Just the parent compound.

PANEL MEMBER McKONE: Is that what CDC -- did they -- I thought they do some metabolites, at least for PBDEs -- for --

DR. SHE: They possibly use serum sample to do the metabolite, because of volume, yeah. Myrto's lab was working on some hydroxy metabolite of PBDE, yeah, but they need a little bit larger volume. We work on very small volumes.

PANEL MEMBER McKONE: And then my other question
is, and this is my ignorance, but the PCBs aren't they
often in the same -- I mean, are they in the same realm as
the dioxins, or is that -- I know we haven't really talked
a lot about dioxin-like compounds. But if they're there,
if somebody wanted them, is it a lot of extra work to get
them or is that not really --

DR. SHE: There is the dioxin-like PCBs, for
example, coplanar PCB-77, 126, 169, 81, they are very low
volume. They have a toxicity-like dioxin, 2,3,7,8
substituted dioxins. So that you really analyze with
dioxins together.

But since the concentration is so low of the
dioxin, you need a large volume. So we able -- you know,
this method we analyzed so-called mark PCB, major six --
major mark, like 28, and 153, 118. This bigger -- the
concentration is higher for this method, and low for the
coplanar PCB. Myrto, can address if she has a plan to do
it or not. But we are not able to do this with dry blood
spots or low volume of samples.

PANEL MEMBER McKONE: And I guess just a
follow-up, so because these are very small samples -- I
mean the anticipation is that you could do a lot more
samples for less effort than ones that would require full
serum and a lot of quantity, right? I mean, that was --
the intent -- it says these are blood spots, dry blood
spots and low volume. So is there a broader coverage we
could get, hopefully, you know, with enough funding?

    I mean, is the intent to get broader coverage or
is it -- this is just something you want to get, so we
don't need a lot of blood?

    DR. SHE: Sorry. I need to clarify the
questions. Broad coverage for the --

    PANEL MEMBER McKONE: I mean broader in terms of
number of samples, so you could do a lot more people for
less cost, because you only need a dry blood sample. You
don't need to get serum and store it.

    DR. SHE: Yes. That's our goal. The goal is
that, at least for laboratory part, we try to simplify
clean-up procedure, because volume is so small the
interference is small. So we do not need the like of
traditional clean-up method. We can short the clean-up
method, so it will allow us to do the high throughput.
And then, of course, collect the samples, we are have --
can be done in different ways. You do not have so much
cost as tradition collection. Yeah, so that's our goal.

    PANEL MEMBER McKONE: Thank you. Thank you very
much. That's a very interesting presentation.

    DR. SHE: Thank you.

    CHAIRPERSON LUDERER: Dr. Wilson.

    PANEL MEMBER WILSON: Thank you, Dr. She for that
presentation, and for all your good work once again. And I just have a couple questions about on your -- you mentioned the field break -- I'm sorry the blanks. And I assume they're both sort of field and laboratory blanks. And I'm just curious if you could say something about if you've had any indication that there are other sources of contamination, or what have you, in your blanks or, you know, indications of any trouble in the analytical method through the blanks?

DR. SHE: Yes. Before I talk about a field blank, we also have a laboratory blank under the containers. So the some containers, like urine collection cups, were pre-screened by CDC. But the test tubings for the aliquots is pre-screened by us. Since we right now have a full method, we can pre-screen ourself.

So we found for the MIEEP project some device we used for very low contamination, which is fine, because compare the levels, we do not think that's significant. And due to today's instrument is so sensitive, you should see something anyway. So there's a low -- absolute low. So you see something as long as they are not a significant find.

And for the field blank, you see for the MIEEP project we analyzed 90 samples, so far we analyzed five field blank. The project collected more than five field
blanks. We do not see any interference for DAPs. We do not see for the phthalate. We did not see for -- we did not see for hydroxy-PAH. But for the environmental phenols, sometime we see some peak show up. So far, we did not see is a major issue with -- for one blank, we notice some levels there. And it's about -- we look at about eight -- I would say -- I forget the unit, the numbers is eight, but our sample number is like 3,000. So we do not think that it's significant at this moment here. But we did see some peaks for the environmental phenols.

PANEL MEMBER WILSON: And are you running blanks on the FOX study, as well? I didn't see it on your slide.

DR. SHE: The FOX study, I think Sandy or Dr. Das can address. I do not think that collected a field blank.

DR. DAS: Rupa Das, California Department of Public Health. For the FOX study, the field blanks were not collected. So we are not analyzing them.

PANEL MEMBER WILSON: And so you're using the same blanks, laboratory and analytical blanks, I guess for both studies?

DR. SHE: Yeah, we can -- for the FOX project, we can only control the laboratory contamination issues and protection issues. We cannot control any pre-analysis contamination -- potential contamination issues, because
we do not have the blank.

    PANEL MEMBER WILSON: Okay. Thank you.
    CHAIRPERSON LUDERER: There will be an
opportunity for more Panel questions at the end.
    PANEL MEMBER BRADMAN: I have a couple.
    CHAIRPERSON LUDERER: Dr. Bradman, do you have a
quick clarifying question.
    PANEL MEMBER BRADMAN: Well, one thing to
clarify, I think, Tom, with the blood spots, they're often
routinely collected from infants, so there's potentially
tens of thousands of blood spots available. So they offer
a lot of opportunity.

    Then my next question is, if I remember correctly
last time we talked about blood spots, there was some
concern about contamination from the paper for some of the
target analytes. And I wonder if that had been looked at
any more, and if -- or that's still a technical challenge
there?

    DR. SHE: We did not have progress since the end
of May. And then I hope Dr. -- right now, Dr. Simon is
start here. He's experienced analyst very likely, so
he'll be able to design a study to give -- to evaluate it.
And, you know, the past our conclusions for the recent
field paper -- field papers used to collect the dry blood
spots, we think the contamination may be happened at the
manufacturer.

So during the storage times, we do not think that's further contaminations. We did 30 days test. We were able to repeat from the first day and the last day. We didn't see the PCB or PBDE value changed. Although the time is still very short compared to some of the dry blood spots maybe stored for a few years.

PANEL MEMBER BRADMAN: Right.

DR. SHE: So we will try to address that issue further.

PANEL MEMBER BRADMAN: Right. And I guess I just wonder, if it was an issue with the paper and the manufacturing process, I wonder if we're able to validate. These tools are potentially extremely valuable. There might be a way for the State program to influence the manufacturing process for the paper, and maybe get a substrate that wouldn't have that contamination.

DR. SHE: Yeah. That's maybe something the -- between the program of the newborn screening and the Biomonitoring Program should talk about this. And the reason that we receive a package of a field paper from Agilent, that claim was kind of a new technique committed and contaminant free. We still evaluate that package to see if that's something we can give that device to the newborn screen program, if they're willing to use the
papers in the future.

PANEL MEMBER BRADMAN: Right. Then the last comment about blanks for PBDEs, I think that's a really challenging one, just because it's hard to get PBDE-free serum. I know Andreas at CDC has suggested using New Zealand bovine serum as potentially a relatively PBDE-free blank. We're actually going to be experimenting with that in our group in the next month or so.

And then also I believe there's an NIST reference material. I don't think it's certified for PBDEs, but there are some values for it. And that's also a potential medium that could be used to see if there's any addition of PBDE relative to the -- not certified, but expected levels during handling and processing.

DR. SHE: Yeah. We would like to learn more about it as a PBDE-free serum that you mentioned, if we can get it. Regarding the NIST, certified materials, NIST 1957 have certified the values, or at least the reference value. If they not certify, they give you reference values.

And we use that in our method. We actually -- a lot of times, we match it very well. NIST certified the values that have a very low -- very low tolerance levels, tolerance range, which is very good. So if you can parse that one, possible better than any other PT program. The
other PT program have a wider range. If you parse it, don't mean so much. You must still have different result, if two laboratory posit. The NIST, so far, I think we able to get within 3 ICD. I think it's very good.

CHAIRPERSON LUDERER: All right. Thank you again, Dr. She. Why don't we move on to the next presentation and then we'll have more opportunity for questions.

DR. DAS: The next presenter will be Dr. Myrto Petreas, who is the Chief of the Biochemistry Branch in the Environmental Chemistry Lab of DTSC.

(Thereupon an overhead presentation was Presented as follows.)

DR. PETREAS: Hello, everyone. So this is the update for the DTSC laboratory.

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DR. PETREAS: I will cover where we are in terms of staffing, where we are in terms of our capabilities to analyze the chemicals on the priority list. Our status with the field studies, the FOX and the MIEEP studies. And also address some challenges we face and opportunities we took. And I'm starting with --

PANEL MEMBER WILSON: Dr. Petreas, if you can -- if you could speak directly into the mic, it would be hopeful.
DR. PETREAS: Okay.

PANEL MEMBER WILSON: Thank you.

DR. PETREAS: So just to repeat, I'll start with staffing, because that was a very hot topic last time when we met in July. And I have here the slide I had given last July, where it was pretty alarming that out of our 10 State funded positions, four were vacant, including the section chief. And at the time our vacancies were swept away by the Department of Finance, so it was very worrisome.

And also of the six remaining positions, the two that were funded by the Biomonitoring Program both of the staff were on long leave. So things were very worrisome.

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DR. PETREAS: So fast forward to now and we have some good news. First of all, we managed to fill the section chief position. And Dr. June Soo Park, whom you have met - he has given updates in this Panel before - has been appointed as a section chief to replace Dr. Kim Hopper who has retired two years ago. So the section was empty for a long time.

Joon Soo a background in chemical oceanography, had the post-doc in atmospheric chemistry. And nevertheless, he did a great job with human blood. And, in fact, he's the one who's pioneered the hydroxylated
metabolites of PCBs and PBDEs in our lab. And he was the
lead scientist for a long time and now he's the section
chief.

As far as the other positions -- of course, he
was placed into the chief position, but vacated his own
position. So it was a musical chair. We haven't filled
any position yet, but I'm happy to announce that today
we're actually interviewing for one of the positions. We
got permission from our department to fill two of the four
vacancies. So we're trying to fill the first one today.

Now, of the two Biomonitoring Program funded
positions, one of them came back with a healthy baby from
maternity leave, so she's back. But we're still waiting
for the other person who's been out since Christmas. So
only less than 0.7 person years of these two people were
used for the program.

Another piece of good news is we got our fourth
environmental laboratory scientist funded by the CDC
cooperative agreement. It's Dr. Sabrina Crispo-Smith, who
is also a chemical oceanographer from the University of
British Columbia. We had hired her a year ago to work on
a project funded by NIHS on human blood.

She's done great work. So when this position
appeared, she was the best candidate, and we hired her.
And she's now transitioning into working on MIEEP.
So we made some progress here. And we're happy and we hope to fill the two vacancies before another freeze comes.

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DR. PETREAS: Where we stand in terms of methods. Not much changed since last time we met. So we are in production, and we have methods for PCBs, organochlorine pesticides, PBDEs, and perfluorinated chemicals, PFCs. So we're in production with those.

In terms of the other brominated flame retardants, just to remind you that when we say flame retardants, they belong to very different chemical classes, and they require different methodologies, different instrumentation.

And last time we met, I was telling you that we have a method to measure some of these BFRs, but we couldn't find them in any of the samples we had tested so far. So we're wondering is it possible they're not absorbed. They're metabolized with something else, and we're looking at the parent compound. Whereas, we should have been looking at the metabolite. So far there are no published reports on measurements in human serum. In talking with colleagues throughout the world, we don't know what's happening.

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DR. PETREAS: So we took a decision to stop tweaking them, because we're doing our PBDE methods, trying to incorporate as many of these BFRs as possible in that method, and trying to change the little parameters here and there to make sure we get the good recoveries and good quality control.

And we did that with we bovine serum, where we spiked. But we couldn't find anything in real samples. So we decided to examine the first 30 samples from the MIEEP study, and see whether that method could give us any BFRs. If not, we would drop the effort to make sure we include them.

And the decision was that results were not very promising, so we're not going to pay too much attention on these BFRs at this stage. We want to proceed and complete the MIEEP study, and then revisit and see whether we have to do something different. So that's where we stand with the BFRs.

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DR. PETREAS: And specifically, these are the ones that we attempted. And we do have very good -- we have a method. And to address Dr. McKone's question, yes -- or Dr. Bradman's question. Yes, we are using the New Zealand serum as a blank.

In fact, I should say that for each of our
methods, we have different blanks, because they're not all -- for the PFCs we have a different source for our serum. And when we're looking for the phenols, we looked at the chicken serum, goat serum, cow serum, what have you, sheep serum. And I think the best one is goat at this point. It's very hard to find a serum source without all of these chemicals in the background.

So nevertheless, these are the BFRs that we can see by our high resolution mass spectrometry method, but trace levels of them can be found in real samples.

The exception is the hexabromobenzene, which we see some low levels. But again, we're not sure, and we had a discussion yesterday with our colleagues from CDC and New York and Washington, on whether we're looking at the wrong compound here.

Okay. In terms of BFRs, the next goal foal is to use the LC-MS to address a hexabromocyclododecane, HBCD, which should be measurable in blood.

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DR. PETREAS: Using the LC-MS we're looking at other BFRs, Tetrabromobisphenol A, high volume BFR, 2,4,6-tribromophenol and 2,4-dibromophenol. These are BFRs that can be addressed by LC-MS. And the same method can include Bisphenol A.

So the method now has been validated on bovine
serum. And we started testing some archived human serum. The current field studies, the FOX and the MIEEP were not supposed to be -- we don't have to look for these chemicals at this stage. But the next field study we should have these methods on line.

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DR. PETREAS: So this is the progress we have with the two studies. We had started with FOX and we completed the PFC analysis. And then we were directed to put more emphasis on the MIEEP, in terms of priorities. And we have -- you can see here the different blocks -- parts of the analytical process.

So extractions, which are the first phase, have been completed for all the MIEEP samples. And some of them, the PFCs and PBDEs have gone through the instruments and now we are in the process of data review and then will be transferring the data to the data repository.

I have a note here that, yes, we have 106 samples, even though there 101 participants. The lab receives blind samples, so we don't know who is who. We had 106 vials, and we analyzed all of them. Some of them were repeats.

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DR. PETREAS: And the important thing I guess here is that the analyses are on schedule as we had
planned. So we're moving along fine.

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DR. PETREAS: Now, again, the challenge is the
time of priorities. And having limited equipment and
limited staff, how do we decide how much time to spend on
method development and improvement versus production and
sample analysis. And the example was with some of the
BFRs, we decided to use the current method without anymore
changes and see if we can measure anything.

Having completed the PFC analysis of both
studies, we decided to now improve the methodology by
addressing and measuring the branched PFOS to improve the
accuracy of measurements, and also hopefully in the future
have a method that can address maybe sources of the
different PFCs. So this requires adopting a method and
revalidating, but it's a good time now that we have
completed that part of the studies.

Hydroxy metabolites. As I said Dr. Park had
developed a method using GC-MS and that requires
derivatization to make them volatile and used by GC-MS.
Now, we want to transfer as many of these analytes into
LC-MS, but that requires time and validation. So it's a
matter of priorities when we're going to do that.

And, of course, the challenge of staffing is
still there. We have vacancies and people on leave.
DR. PETREAS: Well, we're fortunate to have good relations with our colleagues. And, for example, we have long-term relationships with some Swedish universities. And currently we have Dr. Anna Kärrman passing her -- spending her post -- I mean, sabbatical. Thank you -- her sabbatical with us. And she's helping us with the PFC methods. So working with our staff and transferring technology there.

Also, I have Linda. Linda Linderholm from Stockholm University. She's working -- she's funded by UCSF to look at hydroxy BDEs which was part of her dissertation, and helping our staff again comparing and transitioning the method to LC-MS.

We also are working with UCSF. You met Dr. Gerona, who came here last time. And our staff are in contact with them and visited each other to work on BPA and serum analysis, free and conjugated. And, of course, we have our program-wide coordination with our sister lab, and also with a network of the biomonitoring funded labs, New York, Washington, CDC. We had very fruitful meetings the last two days, and we set the foundation for follow ups and more discussions. So it's up to us to follow up.

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DR. PETREAS: So I think with that, that's my
update. If you have any questions, I'd be happy to answer them.

CHAIRPERSON LUDERER: Thank you, Dr. Petreas. It's encouraging to hear that you're able to fill some of those vacancies. Do any of the Panel members have any clarifying questions before we move on to public comments and then we'll have more time for Panel discussion and recommendations after that.

Dr. Wilson.

PANEL MEMBER WILSON: Thank you, Chair. And I'm just curious on the BFRs, you know, with the challenge you're having around identifying them in serum, what the CDC has done on this?

DR. PETREAS: We had the discussion yesterday. And I can summarize saying that, probably we're looking at the wrong form of the chemical. If these chemicals are not absorbed, or if they're metabolized, maybe we shouldn't be looking at that. And we should be very careful not to conclude that these chemicals are not present in humans, because maybe we're not looking at the right form of the chemical. But we don't have much information on the, I guess, distribution and metabolism of these compounds, which is a big question.

PANEL MEMBER WILSON: There were -- sorry.

DR. PETREAS: The fact is that these are high
control. They're there. They're in the dust. We are getting exposed. We haven't looked at all the compartments. I mean I don't know where they may end up. PANEL MEMBER WILSON: Wasn't the -- aren't brominated flame retardants in the most recent panel from CDC. I don't know if any of the panelists could tell me or not, but. And I'm -- and was that -- DR. PETREAS: No, PBDEs. PANEL MEMBER WILSON: PBDEs, yes? DR. PETREAS: Yes. PBDEs, yes. BFRs, no. PANEL MEMBER WILSON: BFRs no, right. Okay. Great. Well thank you. DR. PETREAS: In fact, one of my sources is Dr. Houdin, who said that he doesn't think they should be absorbed by the GI tract. But again, we don't have toxicology information to know how they get partitioned and metabolized. PANEL MEMBER WILSON: Interesting. Great. Thank you. CHAIRPERSON LUDERER: All right. Why don't we move on to public comments. Do we have any public comments? MS. DUNN: None through Email, but one in the room. CHAIRPERSON LUDERER: So we have 10 minutes
allotted for public comment. Although, we are about 10
minutes behind also our schedule.

And the public comment will be Mr. Davis Baltz
from Commonweal. Thank you.

MR. BALTZ: Okay. Thank you very much. I'll try
to be very brief. I'm Davis Baltz from Commonweal. We're
an NGO, Bolinas, California. And for those who aren't
familiar with us, with the Breast Cancer Fund, we were the
co-sponsors of the legislation that created this program,
and it's been our pleasure to follow the progress of it
ever since.

So first of all, I'd just like to compliment the
staff of Biomonitoring California for their continued
progress under sometimes difficult circumstances.
Thrilled to hear that the funding is stable for at least
one more year at current levels. I know that's been a
challenge. I'd like to welcome the new staff, and hope
that the rest of the vacancies can be filled as soon as
possible.

That said, of course, from the beginning of this
program, it's never had the funding that would enable it
to reach all of its statutory mandates. So obviously in
this current climate, that will continue to be a
challenge. And certainly from the public interest side of
watching the development of this program, we'll do
everything we can to mobilize additional resources as we can and protect those that in place.

Happy to see the continued progress on MIEEP and the FOX studies. And as I think I've said before to this Panel, I think communities in California, although they don't show up in large numbers for these meetings, they're very interested in this program in the community studies that are being conducted. And when results are ready to public, I think you'll see quite a large increase in the participation and how these -- the results can be used by communities in productive ways.

In these three presentations, I'm happy to see, despite the challenges with the PBDEs and other flame retardants, this is a key priority for us. And I know from talking with other colleagues, that getting a handle on how California is exposed to and might respond to the levels of flame retardants in biospecimens is absolutely critical. We have, as many of us know, this unique situation in California, which needs to be addressed.

And then finally for this little piece of my comment today, I would just like to know that CDC is here as well as New York and Washington programs, welcome all of you. Anxious and eager to hear your presentations.

One of the objectives in the CDC cooperative agreement that Dr. Das put up was collaboration with
stakeholders and communities. And to the degree that the representatives from CDC here can take back this message from the public interest community, we are absolutely delighted with the way that the staff has worked with communities by making public comment periods available and being available to answer our questions. And so from our point of view, certainly that objective has been far exceeded.

Looking forward to hearing how New York and Washington are developing their programs. And this idea of a State biomonitoring network, I think has a lot of promise to capture efficiencies as the expertise and insights of various programs can work together.

Commonweal is in a new project this year of training environmental health advocates in environmental health science. We just completed our last training yesterday. And we're being introduced to a number of communities in California that we haven't gotten to know before, including many in the Central Valley. And I know for the BEST project, Dr. Das mentioned, that you're hoping to reach some new communities including Spanish speaking ones. And with the new contacts we're making, I think we might be able to introduce you to some people who would be interested. We've raised biomonitoring as part of our curriculum in the trainings that we've been doing
this year. And there is actually quite a bit of interest.

So thanks for the chance to comment.

CHAIRPERSON LUDERER: Thank you very much for
those comments. We now have time for Panel discussion and
recommendations.

Dr. McKone?

No.

Okay. It looks like we have no additional
questions. I think we asked all our questions along the
way already after each presentation.

Shall we move on then and get back on schedule,
perhaps to our next presentation. Dr. Das, are you going
to make the introductions.

Thank you.

(Thereupon an overhead presentation was
Presented as follows.)

DR. DAS: It's my pleasure to introduce Dr. Antonia Calafat of CDC. She is the Chief of the Organic
Analytical Toxicology Branch at the Division of Laboratory
Sciences of the National Center for Environmental Health
of CDC in Atlanta. Dr. Calafat earned her Bachelor's,
Master's and Doctoral degrees in Chemistry from the
University of Balearic Islands in Spain.

Prior to joining CDC in 1996, she was a Fulbright
Scholar and a Research Associate at Emory.
Dr. Calafat, it's my pleasure to have you speak today.

DR. CALAFAT: Good morning, members of the Panel, members of the audience, and of the audience online somewhere.

It is my pleasure to be here today and talk about the work that we're doing at CDC on biomonitoring, and just to present some of the challenges and future directions in which we think biomonitoring may be going.

I don't think I need to praise the wonders of biomonitoring to this audience. But I just want to say and remind you that biomonitoring is only one of the -- is a tool for exposure assessment. It's only one of the tools that we may use.

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DR. CALAFAT: It is the assessment of internal dose by measuring the concentrations of the parent chemical or its metabolites or just reaction products in biological specimens. Urine and blood are the ones that are most commonly used.

It is important to note that biomonitoring integrates all potential sources and routes of exposure. And this is a topic or it is a point that I'm going to be referring to later on in the presentation. And it's also very important to remember that what we'll be talking
about are trace concentrations in this biological fluid, versus the normally large concentrations of the chemicals in the environmental levels.

One other thing that people sometimes forget is that with biomonitoring, we do not measure exposures. We measure concentrations. And we translate these concentrations into exposures. And here is where I think there is one of the major challenges in biomonitoring.

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DR. CALAFAT: Biomonitoring certainly starts or has an importance with the analytical method that is being used. For the chemists in the room or in the audience, then there are different -- do we have a pointer? I guess not -- there are different just characteristics that are necessary for any analytical chemistry method that you want to use for measuring elements or compounds in fluids, in biological fluids.

However for biomonitoring, there are some additional characteristics that I think are extremely important, because they may help you understand what are some of the challenges that we face with biomonitoring.

We require, and those are the ones that are listed on the right side of this slide, looking in here, we actually would like to have biomonitoring methods that use small amounts of samples. And this is because the
sample biological assessments are precious. And there are small samples, and they may not be easy to obtain. So we'd like to get as many measurements as possible with very little amounts of sample.

At the same time, we would like to have the specimens that then we can use to analyze for multiple analytes, not only one analyte, because you have little specimen. You want to go with as much as you can with that little drop of blood or a small amount of urine.

So as a result, these methods are going to be multi-analyte. And what this means is that eventually you're going to have to end up with a compromise method. And by compromise method, what I mean is that there's going to be a method in which each are biomonitored that you measure in this particular method may not be responding as well as it would be if you have a method in which you're only measuring analyte X. So you measure 10 analytes, you may have to find some of them are going to respond worse than others, and some better than others. You need to stick with the best performance, the one that gives you the best compromise performance.

It certainly has to be a high throughput method, and it will require automation. Otherwise, you wouldn't be able to apply biomonitoring methods to provide service. For example, the ones that we do at CDC, specifically
NHANES.

And biomonitoring cannot be successful without very strong quality assurance, quality control program that involves, among many other things, participation in interlaboratory comparisons.

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DR. CALAFAT: I'm not going to spend a lot of time on this slide. Although, I could talk forever about chemistry. But just saying that there are certain steps that we need to start thinking about when we develop a biomonitoring method. And certainly the matrix, the nature of the chemical, and the instrumentation that you have available in the laboratory, they are going to influence the choice of the analytical method.

In a perfect world, and I would like to say that when we chemists can make the strongest impact in developing a very good analytical methods is in the first two steps of the slide. That would be like the sample preparation and the pre-concentration of the sample, where we can get, you know, like very clean extracts being blood or urine that then we can just use to analyze for many, many different chemicals.

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DR. CALAFAT: So I think I had said several times that analytical chemistry and biomonitoring are going
together. However, I think that there are also important differences between analytical chemistry and biomonitoring, in, what I call, an analyte versus a biomarker.

In both cases, you are going to need to validate the method. You are going to -- that is going to require having facilities, instrumentation, personnel, and analytical standards. Without them we cannot do any type of quantification.

At the same time, if we're thinking about biomarkers. And hear comes one of the challenges of biomonitoring into an interpretation of biomonitoring. We need to have additional information about the metabolism and toxicokinetics of the target analyte. That will impact the biomarker selection, as well as, depending on the nature of the chemical, an understanding that there's going to be variability in the concentrations measured.

There are going to be matrix factors that we're going to have to take into consideration, as well as sampling factors. I'm not going to have time to cover everything together in detail, but I'm going to try to give you just a flavor of what I think are the most important points in each one of these parameters.

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DR. CALAFAT: Certainly, you want to pick the
most abundant and relevant compound for the target population when you select your biomarker of choice, because you want to minimize exposure and misclassification. We have heard before that we are having -- that there is a method existing for measuring some brominated flame retardants. But they cannot detect these biomarkers in these analytes in the serum.

Well, maybe serum is not the best matrix to look at these compounds. Maybe these compounds are excreted in the feces. So the fact that we're looking in the wrong compartment may send the wrong information.

So, in general, as the matrix, in terms -- this leads me to the matrix choice, that we have, in general, selected urine for biomonitoring of non-persistent chemicals, and blood for biomonitoring of persistent chemicals. There may be some other matrices, like dry blood spots on some of them. And they may be -- like, for some specific populations, breast milk can be a very valuable biomonitoring matrix.

However, we you need to keep into consideration that these matrices contain a very large amount of endogenous components. And these components may affect the results -- the analytical results that we are obtaining. And a case that is very clear and evident that has been known for several years is in phthalates, because
many of these matrices contain enzymes esterases raises
that can break down the phthalates, which is ubiquitous in
the environment, and therefore they can lead to some
contamination that we have no way to control for.

And we also have certainly some stability and
collection issues that I'm going to be covering shortly.

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DR. CALAFAT: One thing that has been quite a bit
discussed recently is the variability in urinary
concentrations of the nonpersistent chemicals. And I just
wanted to show you a few slides that are discussing this
variability in concentrations, and how are we going to be
able to address this situation when we try to interpret
biomonitoring data.

In this slide there is just an example of a study
that we did at CDC, in which very dedicated CDC employees
provided for a month -- sorry, for a week -- that was long
enough -- for a week every single void volume -- urine
void that they produced. And they -- we measured these
urine samples for a different suite, if you want, of
environmental chemicals. These are the data in particular
for BPA.

As you can see, there was considerable
variability, not only between days and between
participants, but also within individuals and within the
same day.

So this brings like the question into our multiple collections per person needed to categorize exposure. And these may be -- you know, this is particularly important in the case when you have a known persistent chemical, such as BPA, to which you are exposed to episodic exposures or events, for example, diet. So how can we address -- assess exposure to such a chemical.

Interestingly enough -- oh, and I apologize, because you really cannot see much in here, but I never thought there was going to be so much light in your room.

This is the same urine samples collected from the same group of participants, but we looked at phthalates instead. And we look at metabolites of one particular phthalate, DHP, which is a compound that is present in PVC plastics and to which we think that exposure happens mainly through diet, and monoethyl phthalate, a metabolite of diethyl phthalate, which is a phthalate that is used mainly in personal care products.

What is important here to -- oh, thank you. What is important here to realize is that there were very -- in both cases, the concentrations were variable in the urine, but there was a different pattern in this variability. While for the compound that is present in personal care products, the source of the variability was mainly driven
by the participant. You either use or you don't use the
product. And when you do, you tend to use it on a regular
basis, and at the same time every day.

For the compound that is coming through the diet,
the DHP metabolite, MEHHP, the situation was very similar
to the graph that I showed you before for BPA. The main
difference was, you know, within the person. So we -- at
least adults, we certainly eat every day, but we tend to
eat different things every day. So there's going to be
exposure to these chemicals, but then what you -- the
concentration -- or the ability that you have one day may
have very little to do with the variability that you have
the next day.

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DR. CALAFAT: This brings me to another point.
People who are detractors of BPA -- oh, sorry, of
biomonitoring of nonpersistent chemicals in urine tend to
say that maybe we shouldn't be using single spot samples,
that we need to collect 24-hour specimens. Although, I do
agree that a 24-hour specimen is going to give you the
best information about exposure that happened that
particular day within the past 24 hours, it's not true or
it may not true, at least for certain chemicals, that
these 24-hour collections are going to be reflective of
past or future exposures. And this again is the example
of BPA for these eight participants.

And as you can see, if you average the total intake exposure through this every day in micrograms for each participant, you see that there are considerable differences. And those differences may vary depending on the participants. So in other words, maybe a 24-hour collection is not the way to go.

To make even things worse, then when we think about these nonpersistent chemicals, we tend to think that well maybe if we can just go on, then look in the blood, then -- and have a method that is really sensitive enough, then we're going to be able to get some useful information.

Unfortunately, a nonpersistent chemical, which is excreted in the urine, the concentrations are going to be variable in the urine, but they're also going to be variable in the blood. This is a study, another study that relates to BPA that we did in collaboration with two other federal agencies.

And in this case, the participants consumed that we -- they consume a diet, regular diet of different types. And they provided every -- they provided like hourly urine concentrations -- or urine samples, urine one day, and they also provided bloods specimens.

We analyzed both urine and serum for Bisphenol A.
And what we observed, it was -- and you can see it in here, in my opinion, beautiful graphs that show a very -- the units are different. On the left side is the urinary excretion of BPA. On the right side, you have the concentration of BPA in the blood. And you can see, they mimic, very nicely, the curves. They go together. When you have increasing concentrations in the blood, then you have increasing concentrations in the urine. It's just that the urine increased. It was about one hour behind the increase in blood concentrations.

But the concentrations in the serum were about 50 times lower than the concentrations in the urine. That's suggesting that it's going to be much more difficult to capture exposure to a nonpersistent chemical by measuring it in blood, rather than measuring it in urine.

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DR. CALAFAT: So how can we think about sampling strategies that would be good for these nonpersistent chemicals?

Remember that many times you only have one specimen, but you're going to be looking at multiple biomarkers. So is it fair to say that one simple -- one single sample can be used to characterize the individual's average exposure for a certain time period?

And the answer is that it may, it may not. It
just really depends on the biomarker. It's going to depend on the exposure scenario. And it's going to depend on the population. So if we think about exposures that are chronic to nonpersistent chemicals, maybe one spot sample is good enough. If we're thinking about the nonpersistent chemicals that go to which we are exposed through episodic events, then maybe the one spot sample is adequate. It's better than having none. Don't get me wrong, but may not be the best approach, it's simply just all that we have. But it would be important in those particular cases to collect additional information, such as the time of collection of the sample, as well as the last time that the person had voided his or her bladder. So can we really overcome this variability? And I don't think so. We could think about collecting multiple urine specimens per person. But this would certainly increase the cost of the study, not only in terms of analysis, but also in terms of storage. And without even going into that, it could just decrease the compliance of the participants.

So one potential approach is like maybe pooling several spot specimens. But then we're going to go into how many do we want to pool. Certainly, I think that collecting more than one sample, if at all possible, is better than collecting one. But collecting one is better
than collecting none.

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DR. CALAFAT: There is variability. And I think the examples I showed before clearly illustrated that. However, despite this variability, biomonitoring can show that there are tremendous exposure differences. These are data from NHANES 2005/2006 on methyl paraben. And as you can see, is regardless age, women had much higher concentrations, and I think I can say here, exposures to methyl paraben than men do, either being children, either being adults.

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DR. CALAFAT: One other important consideration about biomonitoring is just before the data samples get into the laboratory, is it possible that the collection protocols are affecting the interpretation of biomonitoring data?

And many times we have the convenience of collecting samples in clinical settings. And in clinical settings, often the participants may be exposed to some -- maybe using some devices that they're not using normally. And they may have, for example, IVs that they contain PVC, and PVC is known to contain plasticizers, such as DEHP and BPA as well.

We had several years ago a study that showed that
women that went for a delivery, a C-section delivery, had
much higher concentrations of DEHP metabolites -- this is
the compound the PVC plasticizer in their urine -- while
the concentrations of the other phthalates, metabolites
were totally unremarkable.

There is another study, a later study, recent
study from a French group that confirmed the results that
we found, that this time the women had gone for delivery
and had a catheter in their bladder. And in those
particular cases, they found that the concentrations are
not only of the phthalates, of DEHP metabolite, but also
BPA they were higher than the concentrations in other
women that did not have those type of devices.

So biomonitoring data, the point I'm trying to
make here, is that it will reflect through exposures, but
maybe these are the exposures that happen in a particular
setting, not exposures that had to do with the general
environmental exposures we think about.

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DR. CALAFAT: And wrapping up quickly now just to
say that collection and storage also do matter. And I
remember I said initially that biomonitoring integrates
all the sources and routes of exposures. So
unfortunately, external contamination could be one of
those. And this is particularly important when we don't
know the -- all the sources and routes of exposure for some of the chemicals.

And this is true for many chemicals that we are -- are currently in commerce. When these chemicals are ubiquitous everywhere, and they're at trace levels. Remember in the environment, they tend to be in much higher concentrations.

So as I said before, the collection procedure may be the source. So we need to think about -- we need to provide information into how are the specimens collected, and how are data stored before we analyze them for biomonitoring purposes.

Although we cannot completely rule out external contamination, I think that by a consistent use of field blanks and, for example blanks QCs, then we can have a good idea of whether or not potential contamination may have occurred.

So I think it's really very important to -- when we're talking about biomonitoring specimens to talk about the how, when, and where these specimens were collected.

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DR. CALAFAT: So to conclude, I would like us to remember that biomonitoring is one tool for exposure assessment that requires complex analytical methods and is because you're measuring trace levels versus the higher
normal environmental levels, and it integrates all potential sources and routes of exposure.

Although many analytes can be measured, not all these analytes are good exposure biomarkers. So if we want to do a good biomonitoring program, we need to first start by selecting the appropriate biomarkers, and having a knowledge about the metabolism, and then how the matrix that we choose for biomonitoring may impact those measurements. We need to think that maybe we're going to need multiple samples. Maybe we're going to need multiple samples to evaluate exposure to a particular chemical. And we need to think about how this collection and handling procedures may affect the integrity of the specimen for biomonitoring.

However, I think that if used properly, biomonitoring certainly will improve any exposure assessment.

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DR. CALAFAT: And I couldn't finish without thanking the people who really have done the work, and have been working with me for many years. The work that I presented today is the work from the Personal Care Products Laboratory, but we at CDC were about, in our division, about 400 very dedicated people to biomonitoring, as well as the people in our sister agency,
the National Center for Health Statistics who are collecting the samples that we use for NHANES. And I'll be happy to answer any questions you may have.

Thank you.

CHAIRPERSON LUDERER: Thank you very much, Dr. Calafat. That was a fascinating presentation. And do any of the Panel members have questions at this time?

Dr. McKone.

PANEL MEMBER McKONE: I don't know if this is a question, but it's -- I just want to comment, I guess, on -- you know, I really think the issue about the variation and how to use that. I mean, it's not unique to biomarkers. It shows up, I think, in a lot of public health exposure risk issues, which is whatever you look at, if you look more closely, there's granularity. And everything oscillates. If you look at people's activity patterns.

And I think one of the things we have to struggle with is on the one hand, you can almost use it as a source of frustration, and say look it's so noisy, I can't do anything with it. But actually most of these things there is a way to sort of dig deep. I think -- I guess the question is, is there a way to use this to tell us when a sample is useful or how many samples we need.
What I'm thinking of is like when you take a sample of any chemical in the population where you worry about, is you're just taking a snapshot of a highly dynamic situation. But sometimes if you take enough snapshots, like if you could take a million snapshots, you know you would get useful information. You would see a trend. You could see something. But maybe you don't need a million. The question is how many do you need to realize you're getting rid of the noise and actually seeing a trend, I guess, is what it leads to? And it's not just for biomonitoring. It's something we really have to deal with.

DR. CALAFAT: Yeah. I wish I had that answer that I could give you a number, but I do not. But what I can tell you is that I think that the number of samples that you need to collect it will depend on the purpose of the study, and the design of the study. It will depend on the population that you're studying. In some cases, it may be that there are differences. It may be different the number of samples that you need to collect from an adult population versus, you know, a population of children. That if the chemical is coming from the diet, they may have a very uniform or bland diet on a daily basis, if you want.

It may also be whether you're only simply
interested in looking at exposure trends or exposure patterns. That's something that may be -- you're doing with that section of the study, like in NHANES, that is very useful. Like, in the example that I show for the parabens, that you can see when exposure is really the driving force and you have sufficient sample size, then once sample is enough, because you may have a person that used that product, for example, and you collected the sample immediately after. And there may be another person who also used the product, but you collected the sample before, and then it kind of averages out, so you get a good idea for an average exposure with only one sample.

If you're interested in looking at health effects, then it may be more important to just see whether you can get some samples within the time period that you think the effects may be developing, if known. The problem is sometimes you don't even have this information.

PANEL MEMBER McKONE: And just to follow up. I guess the other issue for me is it gives us a motivation to look for more persistent markers. And I know that's a -- I mean, the analogy I think of is diabetes, right, blood sugar and all over the place, but I guess the A1C marker is a much longer term constant.

In the world of radiation, they've actually found a cumulative lifetime genetic or a heritable chromosome
damage, so that you really can do a lifetime running cumulative dose. I mean, so I kind -- hopefully we can set this as a goal. I know it's hard to do now, but the more persistent the marker, I think the more -- and then if we have a persistent marker and a short-term marker, right, then we can really start telling a better narrative about what people are seeing, both long term, and then what kind of daily oscillations they have due to things like diet or something that may be in their environment.

DR. CALAFAT: Yeah, for --

PANEL MEMBER McKONE: It's probably not a question, but it's just a --

DR. CALAFAT: I mean, it's -- no, it's actually an excellent point, because you're trying to just expand the window of exposure as much as possible, or -- and then that's, for example, the case when I'm saying that for a nonpersistent chemical, probably urine is better than blood, because in blood it's so short lived that chances are that you're going to miss the exposure if it's something episodic.

So we're moving from the blood into the urine, but the urine is not yet perfect. So it would be nice if we could, for example, look for some markers, like hemoglobin adducts, that would extend -- you know, you could say at least this is for 120 days. There is
research ongoing in that particular field, but it's just not moving as quickly as one would want.

PANEL MEMBER McKONE: Thank you.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Thank you. That was an excellent presentation, and very elegant work. And I guess I was sort of dividing the problem with nonpersistent biomarkers into two categories. One is how to use these in the setting of research studies. And the other is how to use them in the setting of descriptive statistics around the sort of -- you know, the U.S. population and the NHANES type context?

So if with regard to the second one, you know, we -- it seems to me that if we're looking at a fairly large population, and we do take a snapshot, that that information should still at least -- if the population -- if the sample size is large enough, should still be reliable enough, because in theory we're capturing each person at some point in their oscillation. And they're all sort of -- would even out with a big enough sample size.

And so I guess my question for you is whether this -- you know, this oscillation and the nonpersistent biomarkers is sufficiently problematic that it raises any questions about the sample size in NHANES and whether that
information is still, you know, useful for sort of
creating points in time, or descriptive statistics about
the overall U.S. population?

    DR. CALAFAT: In my opinion, the fact that we
have only one sample for NHANES doesn't detract the
valuable information that we're getting from NHANES. As I
said, it's ideally -- maybe more samples would be better,
but at least I would advocate to have one.

    So I'm happy that we had one. And I think that
if you think on a population basis, then there are issues,
and obviously then you may say, you know, maybe we are --
particularly when you're looking into the high end, into
the higher percentiles, then you can say, well, maybe this
person was in the higher percentile now, but they wouldn't
have been before.

    Well, that maybe the person who was now in the
lower percentile was in the higher percentile later. So
it evens up, in my mind. So that's the best way that we
can do for -- I mean, we cannot change the chemistry of
the compounds.

    And in some cases, we cannot change the exposure,
because we don't even know where these chemicals are
coming from. So in these -- if you think in this
scenario, I think having one sample is really much better
than having none at all.
PANEL MEMBER SOLOMON: Just a follow-up question to that, with regard to the research studies, it seems that the issue there would tend to be non-differential misclassification of exposure, which would tend to systematically bias all of the research studies on chemicals like BPA toward the null.

So it's sort of amazing that there have been associations seen in some of those studies. But the only situation I could think of which would not bias towards the null, might be if, for example you know, what part of the group were systematically sampled in the morning and the rest systematically in the afternoon, and this was something which, you know, people -- participants tend to use after showering in the morning a product or something, and, you know, there might end up being some systematic split in terms of the exposure that would create an artifactual association.

And so it seems like those are the kinds of issues maybe researchers should be thinking about, if they want to avoid problems. But otherwise, it seems like, if anything, we're just ending up with a bias towards the null, which needs to be taken into consideration when these studies are looked at.

DR. CALAFAT: Yes, you are absolutely right. At the same time, I also want to remind you that many times
what you have is one specimen collected from that
specimen, then you have to do your measurements and then
you're trying to evaluate exposure to different chemicals.

For some of them, maybe collecting the sample in
the morning would have been better than collecting the
sample in the afternoon or in the evening, because they're
coming from different sources.

So I think we're doing the best we can with what
we have. I totally agree with you, that even in those epi
studies, then, if anything, it just would be biased mainly
toward the null, so they just -- that's what we say every
time that we have biomonitoring included in what --
included in one of these epi studies when there are some
potential findings or associations.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Great. Thank you, Chair.

And my question is, you know, similar to those of
the other panelists. And it's -- you know, the problem
that we run into in assessing exposures and occupational
settings, for example, is -- and the problem of pooling
results is that we miss the highly exposed subgroups that
are then ultimately those most at risk.

And, you know, you've demonstrated that with the
differences between the sexes with the methyl paraben.
And so -- and yet, then we have the problem that you
described.

And so my question is if, in fact, NCEH is starting to pool samples and/or if you've -- you know, you have sufficient information to characterize variability around specific metabolites, and if that information could be used by the California program, the sort of coefficient of variation around it, we could actually use that information?

DR. CALAFAT: Yeah. Well, when I meant pooling is pooling from the same person, not different people. So it would be when you just think about if you say, well, collecting more than one sample per person. And then you may be able to collect multiple samples, but then the analysis are pretty pricey. So what we meant to just -- let's say if you're able to collect your -- to expand somehow your collection, period, within two weeks, two months, whatever is really adequate for the intended purpose of your study, maybe then what you could do is just pull those specimens, and then try to say, well, this is kind of like an integrated measure of the concentrations that we have throughout three months.

Again, that would be kind of a stretch, and then you would have to think how do you do this pooling of strategy.

Regarding -- so this is what I meant by pooling.
But this is only one idea that could save some costs and could provide some information, valuable information, but at the same time, you would be missing -- you know, you wouldn't have the information from the day one, day two, day seven. It would be day one through day seven.

Regarding NHANES, we are, for the most part, not doing pools. There are still individual samples, because they're -- in some cases, we may be doing pools, and we have done in the past, when there wasn't enough specimen left for analysis. And then we thought that it was important to provide some information. We did, for example, pools with PFCs in 2001-2002 when there was no more serum left. And it was after there had been some changes in the manufacturing of these compounds. But for the most part, we continue to do individual samples.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: I just have a few comments here. And I just want to underscore how important this kind of work is.

One thing I think it really points to is a real need for doing more research on intra- and inter-individual variability. And I also want to suggest that we extend that to different age groups.

DR. CALAFAT: Certainly.

PANEL MEMBER BRADMAN: Right now, most of the
papers that have been published focused on adults. And I think we need to look at different ages. We have done one study with three to six year olds and find similar levels of variability. I don't know whether we would see that, for example, in six-month olds or newborns or there might be different trends at different ages.

And, of course, some of those very young ages were also concerned about for both risk assessment and epidemiology.

Which brings me to my next point. One is we talked about the utility of these for epidemiologic analysis, but the same issues also arise around risk assessment. I think when we think of nonpersistent measurements -- or measurements of nonpersistent compounds in urine, the utility there is to get -- or the real use there, I think gives us information on population-wide exposures.

And then I think we can think in terms of risk assessment perhaps on an acute basis. But if there's any attempt to think about chronic exposures, that's a whole 'nother challenge there. Although, I want to emphasize that in discussions here on the Panel we've kind of decided that, at least the Program here itself won't be focused on risk assessment and interpretation of the results, but I'm sure others will. And I think the points
you raise need to be considered, when that data is looked at.

DR. CALAFAT: Thank you.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Regarding future directions. At the last meeting of this Panel, we had a presentation on non-targeted screening for contaminants using TOF mass spec method, and there was discussion of the orbitrap as an instrument that might be helpful for doing more improved nontargeted screening. And I'm just curious whether you're doing that and what you're thinking about in that direction?

DR. CALAFAT: I mean, we have not -- we are continue to do what we think we do best. That is doing this type of quantitative analysis for -- to provide information for the general U.S. population. I think that this other information is very important, and I don't see them, one excluding each other. I just think these are too parallel, if you want pieces of information or research, just directions, that should be both followed. Whether this is done at CDC or in any other agency, I guess that I certainly don't know. But I don't see one excluding the other. I think both of them are important and they have -- each one has a place.

CHAIRPERSON LUDERER: Dr. Wilson.
PANEL MEMBER WILSON: Yeah. Thank you. I guess I'm going to follow up my question, and it may be off base here. But I'm just curious in your experience, if you've gotten a sense that there's a minimum sample size from which you can generate a reasonable understanding of the variability, you know, based on the work that you've done, and, you know, my interest is in if we can -- if it might be of use here in California.

DR. CALAFAT: Again, I think it really would depend on the chemical that you're trying to look at. It would depend on the population, as Asa said. And it may just be -- it's not the same thing looking at an adult population than looking at a population of infants or young children.

It may also depend on the intended purpose of your study. So I really don't have the magic answer. I think that at last having one is better than having none. But as to how many you can collect, then ideally then one would say collect as many as possible.

But I think it's really just too complex, because of the wide range of chemicals that we're looking at, and the different uses and situations that I just don't feel I can give a number.

PANEL MEMBER WILSON: Understood. Thank you.

CHAIRPERSON LUDERER: Dr. Alexeeff.
ACTING DIRECTOR ALEXEEFF: Yes. Good morning.
Thank you for the presentation. I had a question on one
of your slides, the one that had to -- that was called
variability in urinary concentrations, phthalates as a
case study.

DR. CALAFAT: Uh-huh. Do you want me to go back?

ACTING DIRECTOR ALEXEEFF: So you talk about
three types of variability in that slide, and one is
between persons and one is within persons. But then you
also mentioned the spot sample intra-day variability. So
I'm trying to understand that third one what that means.

We've had a number of questions raised to us when
we were looking at exposures and based upon NHANES data on
spot samples and questions were raised, well, it's just a
spot sample, and a question like that. So I was just
wondering what you could explain about that variability,
which also it seems to be smaller than the others, is that
the case or is that just --

DR. CALAFAT: Yeah. I mean, this one is the one
when you're taking the spot samples collected on that
particular day, so every single spot sample. And then
you're looking at what is the intra-day variability, how
much -- you know, like if you collected the sample in the
morning or you collected the sample in the evening. I
know you can see there are the differences -- the main
difference in there is, again, there's more variability for the compound that is coming from the diet, at least in this population -- these are adults -- rather than the compound that is coming from the use of personal care products, because that's -- you tend to use them on a regular basis every day X amount of times.

So there's not going to be that much difference versus the one that you're going to get from the chemical that you are getting from the diet within the same day.

CHAIRPERSON LUDERER: I actually have a question related to the variability and the utility of doing these frequent samples. I mean, I think a lot of the data, including the slide you have up now, as well as your other slides, really beautifully highlighted kind of the need for these kind of detailed studies, where you have repeated samples during a short window of time, if you're trying to determine what the exposure sources were for these nonpersistent types of chemicals.

And one thing that particularly intrigued me was another slide, which I think is a few later, which was the BPA, the serum in urine. And I was just wondering whether you had any information about why the peak after breakfast was so much lower than the peaks after lunch and dinner. Is it the type of food or the amount of food?

DR. CALAFAT: It was the type of food. It was --
in this particular, unlike the other study that -- where those eight CDC colleagues who conducted business as usual for a week, so everything that they did they -- and they provided the sample. In this particular one that's why I said the controlled setting. There were 20 adults that they housed in a facility was for one day. And then they were given a choice between three breakfast, three lunches, and three dinners.

And then those were selected from different types of commercial foods. And they -- the idea was just to collect information on the levels of BPA. This was study done uniquely for BPA to see the levels between -- throughout the day, after the consumption of these particular food.

So depending on the breakfast or the lunch that they got, then they may have got higher or lower exposures to BPA.

CHAIRPERSON LUDERER: Thank you. And I did have one more question, which is related, I think, and that is, you know, you mentioned the different sampling strategies, you know, the spot samples versus 24-hour versus pooling within an individual. And I think one thing that's very important in helping to decide which of those strategies might be the best has to do with understanding the toxicology of the particular chemical as well, which I
don't think we've mentioned.

You know, it may be that the cumulative exposure
is more important than the 24 -- you know, doing repeated
sampling over time and pooling them or 24-hour urine would
be appropriate, but it may be that the peak value is
really the critical from a toxicological perspective. And
so I think it has to always be thought of in that context
as well.

DR. CALAFAT: Yeah, certainly. And then it would
also help if we know the exposures are coming from. In
some cases, we do. But for many of the chemicals, we do
not. And then that's what I said that biomonitoring is
only one of the approaches. It's not meant to be the one
that has the answers for everything, but it is one that is
meant to be used with some others including, for example,
ambient biomonitoring, or even personal monitoring, and
collecting customer information, so you can get -- when
you integrate the information that you're getting from
these four different compartments, if you want, then you
can get the best picture of exposure -- assessment of
exposure for that particular study.

CHAIRPERSON LUDERER: Do we have any other
questions from the Panel members at this time?
If not, we can take public comments, and then
we'll have time for more discussion at the end from the
Panel.

Do we have any public comments?

MS. DUNN: None from Email but Davis Baltz.

CHAIRPERSON LUDERER: Great. We have a comment from Davis Baltz from Commonweal.

MR. BALTZ: Davis Baltz, Commonweal. It's a question actually for Dr. Calafat. And thank you for all of the work. It's been invaluable, you know, for those of us who are working in this field. And my question is, which you may not be able to answer, in terms of the next national exposure report, can you give us any insight into its timeline, and also whether there will be any significant increases in the analytes that will be examined or anything else in that regard?

DR. CALAFAT: Thank you. There is going to be a next exposure report or our next update is going to be coming shortly early in 2012. It's going to involve mainly most of the chemicals that have been measured before -- I just cannot -- some of the chemicals that have been measured before.

I think the approach now is because the number has increased so much from the first time when we started with only 27 of them. That is really hard to get the different labs all coordinated. We feel the different obligations that we all have. So the idea is that we're
going to be releasing updated tables.

For example, the fourth exposure report that was release, I believe it was in 2009. 2010, we had some -- early 2011, I believe it was, some updated tables. Now, there's going to be another report that is going to be only on the web. It's not going to be a paper report, I believe. But it's not going to have, that I think of, any data that have not been reported before, except maybe some of the metals. Maybe some of the metals are going to be coming out. And maybe some of the speciated arsenic may be. But I'm not positive. I really -- I'm sorry. I can find out for you and just let you know. I don't have the answer now.

CHAIRPERSON LUDERER: I think we have time now for some more discussion and questions from Panel members.

Dr. Zeise.

DR. ZEISE: Hi. Lauren Zeise from OEHHA.

For some of the nonpersistent chemicals, I'm thinking of acrylamide and glycidamide. You have hemoglobin adduct information. And the ratio of the acrylamide to glycidamide adducts is also a very important consideration within an individual in thinking about risks.

So I'm wondering a couple things. One, are there any other adduct kinds of markers on the horizon for
chemicals that you're considering now. And another is
whether or not you would be potentially, where it is
important, reporting on ratios of different markers within
an individual and looking at those distributions. I think
that could be very informative for, for example, risk
assessors.

DR. CALAFAT: Some of the chemicals that have
potential application with looking at adducts, PAHs are
some of them. So this is an ongoing research that we're
doing now, but we don't have a method yet. But when we
do, then we think that this would provide important
information.

As for the providing individual ratios, do you
mean like in exposure reports or do you mean --

DR. ZEISE: (Nods head.)

DR. CALAFAT: This is something that probably we
could just think about if there is. I mean individual --
if you're just getting a range of individual ratios, I
guess that this is what you're saying. In the same way
that you have tables with the concentrations and then you
could have ranges of ratios.

DR. ZEISE: (Nods head.)

DR. CALAFAT: This is something that I can just
bring up to the Division, and then just to see how -- if
this is something that may happen in the future. If not,
then, you can always get the information, because don't forget that all the data that we put in the exposure reports, the raw data so-called are on the website, on the NHANES website.

So anyone can just collect information and then just do their own analysis. And actually many people do so this is something that you could always do, if you were interested without having to wait for us coming out with the report.

DR. ZEISE: Thank you.

CHAIRPERSON LUDERER: Any questions or comments from Panel members?

No.

Are there any specific questions that the Program staff would like the Panel to address regarding any of the morning presentations.

If not, we can take lunch early.

Okay.

So we'll take lunch early. Shall we still leave an hour for lunch and come back a bit earlier.

MS. HOOVER: Why don't we just say that we'll start promptly at 1:30, so this gives us a little more -- sorry. Sara Hoover, OEHHA. Yeah, let's try to start promptly back at 1:30, so this gives us enough time to do that.
And, Carol, did you want to --

CHIEF COUNSEL MONAHAN-CUMMINGS: No need to.

MS. HOOVER: Okay. So today, we won't have the normal Bagley-Keene warning, because we're not having real Panel decisions. So you can -- well, behave as you'd normally behave during lunch. Let's put it that way.

(Laughter.)

MS. HOOVER: See you at 1:30.

(Thereupon a lunch break was taken.)
AFTERNOON SESSION

ACTING DIRECTOR ALEXEEFF: Okay. Let's call the meeting back to order here.

CHAIRPERSON LUDERER: All right. Well, I'd like to welcome everyone back. And I'd like to reintroduce Dr. Rupa Das, who will introduce the next item and the next two speakers, Blaine Rhodes and Dr. Kenneth Aldous.

Dr. Das.

DR. DAS: Thank you, Dr. Luderer. As I mentioned over the last two days, we've been meeting with the two other States who received the CDC cooperative agreement funds, Washington State and New York State. This was a great opportunity to share ideas. We timed this visit to coincide with the Scientific Guidance Panel meeting, so they could both attend. And while they are here, you could hear about their programs, which are different from each other and different from ours, but we all have lessons to learn from them.

The first presentation will be from Washington State. And I will introduce Blaine Rhodes. And after he's done, then I will introduce Dr. Ken Aldous. Blaine Rhodes is the Director of the Office of Environmental Laboratory Sciences at the Washington State Public Health Laboratories in Shoreline, Washington. He manages five laboratories with 25 scientists, and is the principal
investigator on the Washington Environmental Biomonitoring Survey or WEBS. And he wants to say that he's very proud of the project staff.

Blaine.

(Thereupon an overhead presentation was Presented as follows.)

MR. RHODES: Thank you. Let me raise this to the right level. Is this good?

So distinguished Chairperson and Panel members, and ladies and gentlemen in the room and in the ether. I'm the first speaker after lunch, and thereby have the mission, should I decide to accept it, to try to keep you all awake. I can't guarantee anything.

The Washington Environmental Biomonitoring Survey, we call WEBS, and that's because webs are individual junctions and connections that form a pattern that cover a large area. And we thought that was fairly indicative of this particular project.

Washington State did not have any previous official biomonitoring or legislative Biomonitoring Program. We were working -- we had some occupational type programs and others, but we had no structure built.

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MR. RHODES: In 2003, we applied for funding, but did not get it. And in 2009, we reapplied when the
request for funding proposals came out. And be careful what you wish for, we got the grant and had to build an entire structure from scratch, which is different from our -- the other two programs. What we received is a five-year grant, and the promise, at least, of level funding throughout the five years.

The goals of the grant are right off of the grant -- the grant application, increase our biomonitoring capability. We already have the chemical terrorism lab, so we were looking at what we could do with that equipment, et cetera; provide State level biomonitoring laboratory data to compare with the national data; and conduct surveillance of analytes important in our State.

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MR. RHODES: So the grant years one and two we -- from a -- we wanted to do a general population study. We wanted a background, just like NHANES, except in Washington State. Measure levels of total arsenic, speciated arsenic, metabolites of organophosphates and pyrethroid pesticides.

A lot of these suggestions came from our -- inside the Department and also from a nascent Scientific Advisory Panel, which became our Scientific Advisory Panel, a group of people we've worked with for years all around the State in various governmental positions.
So at the same time, we're going to compare all those results to NHANES. And coincidentally, we could do a great number of urine metals at the same time. So we just -- once you get them into the instrument, out they all come, so we add those on.

The other activities, of course, was to establish the Scientific Advisory Committee formally and identify and develop any add-on projects like the other metals or something that came along with what we were doing --

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MR. RHODES: -- naturally, without adding too much more work.

Our staff is nine plus FTEs. The ones with stars on them do not -- are not full times. They're just part times. I'm the PI. Then we have a couple of chemists, elite chemists, and a Chem 1, plus another chemist this year. We have a WEBS laboratory coordinator, which is not a technical person, but a person who takes care of all the -- dealing with the field people. It was a very handy thing to do. It was probably the best hire we made.

Two to three field management in Non-Infectious Conditions Epidemiology. We call it NICE in Washington. We have two or three management staff for the field. And those people are full time and they did a magnificent job. Senior Epidemiologist Statistician is part time. We did
get a CSTE fellow this year, and clerical support. We got
two toxicologists from the Division of Environmental
Health part time. And that's, once again, another entity
you cannot live without.

And informatics, we had to adapt our lab LIMS to
the biomonitoring and create databases in epidemiology.

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MR. RHODES: So all of that adds up to 9.3.

Our general population sample was from randomly
selected census block groups. And if you look at the
little dots, we started, and of course it takes six months
to spool up a project, so the hires, et cetera. We got
going on this about six months in the first year, and
continued about six months into the second year.

That's why the year one and year two of the grant
that's actually a whole one-year sampling, so we were
trying to take care of the problems of seasonality. If
you look at those little dots, they actually represent the
same number of households or the same number of
population. Some of our population is pretty spread out
there, when you get into eastern Washington.

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MR. RHODES: And then selected 70 block groups.
And then from each block group 27 housing units. And then
sent sample -- sent letters to the housing units and then
sent the collection teams out to enroll them in the program, and it didn't always work.

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MR. RHODES: We got about 37 to 40 percent acceptance rate, and that's just the way it is. Some people just don't want to take part. That's fine. It's a voluntary activity, but it was very important to start out with the local health jurisdictions. We don't -- the State has got to work very closely with the locals.

And especially in the case of the tribes. Any Indian tribes we work with, we have to work very closely with the locals, because they trust the locals. They don't trust the State.

The field teams were all trained by personnel, our personnel, our laboratory coordinator and a coordinator from NICE. And they picked up frozen urine samples. We only actually ever rejected two samples on the basis of shipping. That's how good those teams were, and how well they worked.

We had Spanish speaking field staff translators for other languages. And, of course, all procedures and approvals are approved by the Washington IRB. And that's another -- that's, you know, one of those little statements that is quite a bit of work.

(Laughter.)
MR. RHODES: But, you know, it's totally -- it's what the IRB is there for, and we're very happy to work with them.

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MR. RHODES: So a single urine sample, let's talk about spot samples. It's a spot sample. It's a single urine sample. Hopefully, they do the first void in the morning. It's done at their own discretion, so you can't really control it. Down to six years old. Six years old was the youngest we would take.

We also collaborated with a National Environmental Health Tracking Network group from Washington. And they paid for us to pick up tap water samples and analyze the metals in the tap waters. It was a target of opportunity. They came to us. They paid for the procedure, and it gave them geospatial information on drinking water across the State on a random basis. So that was a big plus on our parts. It's also a CDC project, so it got us some points there, didn't it?

(Laughter.)

MR. RHODES: Then the households were asked to fill out two questionnaires, and asked for permission to archive their urine sample for five years, if they gave permission. And actually over 95 percent gave permission, so we ended up with freezers full of extra samples.
Now, we're trying to figure out what to do with them, but that's -- fortunately, we have a great group of people in our Scientific Advisory Panel to help us.

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MR. RHODES: Laboratory testing. As I said, field staff trained in collection and shipping by WEBS trainers. That was one of the things we did. The laboratory staff was trained at CDC in their methods, the NHANES methods, some of which are undergoing revision even as we speak.

That's one of the things of being out here on the edge of technology, things change. They're always in flux. These are not methods that are set in stone. So you have to be adaptive, as you go through these things.

But we really need to compare the results to NHANES, so we need to have basically what they -- we had the same methods. And then we did -- most of the instrumentation is dual use. Although, a couple of them have actually been completely taken over by the production work in the biomonitoring. We've bought other ones for the -- our other laboratorians.

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MR. RHODES: Laboratory testing. And that's a picture of my lead chemist, Caroline West. Total metals is a fairly known quantity. Speciated metals, so we're
speciating the arsenic.

And especially since we have a lot of shell fish and shell fish eaters in our area. So we need to find out what arsenic is what. And it's at the edge of the envelope. We've had difficulties and we're working through them and we're actually back in production now.

CDC is still, as I said, working on pesticide metabolite methods, and we'll be working right with them. And we actually had to -- or developed our own creatinine capability, because -- testing capability, because we couldn't afford to send them out to a clinical lab. So we do them all by tandem mass spec, which is a little bit like squashing a fly with a bazooka, but it actually works very well and we are CAP certified in the procedure.

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MR. RHODES: Our participants get feedback within eight weeks, if at all possible. In some cases, the pesticide just hasn't been possible. But the reportable values, we've reported to them their total arsenic. Lead, if it's greater than an equivalent to blood lead screening value, that there are equivalence between, so my epidemiologists tell me, between the blood and urine. And if it's high enough, that it would be an equivalent blood lead of 10 or better, we'll report that.

For metals, only if they're greater than
occupational BEI values, cadmium, cobalt, thallium, uranium. And then we did six metals for the water. Manganese, which is not part of NHANES, but it certainly is near and dear to EPA. So we did that for them.

Pesticides, we're going to compare our results with the 95th percentile of NHANES, because that's the reference number we have. And, of course, there's the toll free number to epidemiology for any questions.

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MR. RHODES: Our general population and survey results, and this is a page from the report, which shows all the metals and the 50th, 75th, 90th and 95th percentile on a logarithmic scale. You can see most of our numbers in Washington State are pretty close to NHANES. There are a couple of places were lower and one place was particularly higher.

These are the two I was really looking at. In total arsenic, we're about twice as high, in both cases. And then in uranium, since we have uranium mines up in the east of the State, I thought we would be a lot higher, and we're actually right smack dab in the middle of them, because the geology is such that the uranium didn't travel across the State, so we only have a very small pocket of high radon, high uranium areas.

The other thing we have is Hanford. And I
thought possibly that there might be some uranium leakage there, but fortunately there is none.

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MR. RHODES: So those are the kinds of things we've been looking at. The ordinate, by the way, is in nanograms per milliliter or parts per billion or whatever you want to think of it.

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MR. RHODES: We did 1,422 urine samples. That's enough for a truly random sample in a State of six million people. 502 drinking water samples. And like I said, our household volunteer rate was 37 percent. The results are creatinine corrected, and we compared them to NHANES which had 2,627 samples in the metals. And we feel pretty confident about our results.

Washington Tracking Network has not put the drinking water information on the portal. It's all geospatially labeled, so they should be able to put -- that I'm really looking forward to seeing, being also in the environmental health business.

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MR. RHODES: Next year's, we are -- we have -- we're validating the pyrethroid method. And we have both urban and rural areas, and it will be interesting to see. One would surmise there will be a difference, but we won't
know until we test. Organophosphate pesticides method is still in development. And other general population studies are in discussion. We have the samples, should we need them.

    Special population studies have begun. There's the high arsenic groundwater area on Whidbey Island, which is a very, very pretty island out in Puget Sound. But I didn't get to go out and take any samples, so I didn't get a vacation that day.

    And also, occupational exposure to pyrethroid pesticides, we're going to have a baseline. It will be interesting to see if we can see an actual rise, a statistically significant rise in -- in some people who might be more heavily occupationally exposed.

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    MR. RHODES: The high arsenic study, we already screened 313 households, collected 173 urine samples, and 82 drinking water samples. And all the results have been analyzed and reported back. We have not -- we're still doing the statistical analysis on them, so I can't report anything on that yet.

    The pesticide applicators, we're recruiting people for that. This is one of the areas where we get into the question of what if we actually find something. There's the liability question that jumps up when you
start doing these kinds of studies. And we're working
with the legal department to get those ironed out, because
biomonitoring can have consequences that we have to make
sure about.

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MR. RHODES: Our Advisory Committee, which has
met three times and is due for another meeting pretty
quick is composed of a great number of real good
neighbors. We have the University of Washington, which is
six miles away. We have a number of professors and
alternates from there, Washington State University, which
is clear across the State. We have a person who flies in.
Department of Ecology and the Department of Labor and
Industry, and that's a very interesting group, because
they do a lot of occupational medicine. Both have a
representative.

Then we have a couple of east and west local
health people. The Washington Toxics Coalition, as a
public health group or a public interest group. The
Department of Health Tracking, they're tracking -- Glen
Patrick is on it. And the U.S. EPA has a place at the
table when they decide to fill it.

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MR. RHODES: Based on the Advisory Committee
recommendations, we are looking at the measuring of
mercury in seafood consumers and Asian populations, which
we also have a heavy one. Analyze year one and year two
for bisphenol A metabolites, and for the panel of
phthalates and prepare laboratory analysis of NNAL, which
is another smoking metabolite other than cotinine, when
we -- if we get resources and people.

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MR. RHODES: So thank you very much. I'd be
happy to take questions, comments?

CHAIRPERSON LUDERER: Thank you very much, Dr.
Rhodes. It was a very interesting presentation. And we
have time now for some Panel member questions.

Dr. Culver.

PANEL MEMBER CULVER: I think your program is
very interesting and I'm looking forward to your results.
I'm interested in the emphasis you placed on arsenic. Why
did you come up with that emphasis?

MR. RHODES: The emphasize placed on arsenic was
because partially of the geology and it's high in the
groundwater, and we wanted to see if that -- that's an
exposure. We wanted to see if that translated over to
high levels.

PANEL MEMBER CULVER: How high is it in the
groundwater?

MR. RHODES: I'll have to get back to the portal
and let you know. It's above the standard -- we flirt with the EPA numbers a lot.

The other thing is a lot of shell fish eating. We have great shelf fish growing there. And along the coast people eat shell fish, and they get doses of arsenic. Now that's total arsenic, and that's why we're speciating.

PANEL MEMBER CULVER: Have you indications that arsenobetaine is toxic?

MR. RHODES: No. No. And that's why we wanted to separate it. If we can get -- if we get high arsenic numbers -- and we got a number of high arsenic numbers for people in this study, we'd like to be able to say but don't worry about it, it's arsenobetaine?

PANEL MEMBER CULVER: Thank you.

MR. RHODES: Thank you, sir.

CHAIRPERSON LUDERER: Dr. Solomon.

PANEL MEMBER SOLOMON: Yes. Thanks for a very interesting presentation. It was a little hard to see the tables of metals results. Way too small on the handout and the slide flashed by a little bit on the rapid side. But I'd love to hear a little bit more about mercury, because you mentioned that you're going to be doing some follow-up studies on hair levels. I think that it makes a lot of sense in our coastal States to have some serious
focus on mercury, because I think that's something that the NHANES data don't -- I mean, that they may not reflect your State and our State.

So can you talk a little bit more about what you're planning to do there and especially also on the speciation issue?

MR. RHODES: Well, the speciated -- the mercury issue is that we are -- we don't have enough -- quite enough funding to go out and get blood, because in the State that requires a phlebotomist. So urine is an excellent vehicle for us and hair is an excellent vehicle for us.

Hair does reflect mercury. There's a lot of -- there's a lot of debate on how well, but we are going to look at that anyway, because, as you said, it was done in -- a study was done in NHANES. We would like to see how that reflects.

As far as the speciation of -- we're not going to speciate the mercury off the hair. We'll do total mercury off that. But as you said, our environmental health people keep track of mercury in the waters of Puget Sound, and in the fish. So we are going to be seeing if it's coastal. There are also some cinnabar bluffs containing bluffs out in the middle of the State that could generate some mercury in water and/or vegetation.
PANEL MEMBER SOLOMON: One follow-up. Are you going to be collecting urine and hair from the same people or will this be different people?

MR. RHODES: This will probably be a different cohort.

PANEL MEMBER SOLOMON: Because on the urine mercury or the hair, you know, issue, we've had some situations in California in the last year associated with skin creams and exposure to inorganic mercurial compounds, which would presumably be showing up in urine or could complicate issues with regard to interpretation of hair mercury. So I'm just interested in if you're looking at that at all.

MR. RHODES: That's a very good point. And actually that was just -- that's something we learned at this very meeting with both California and with New York. So we're going to have to be very careful in how we prepare those samples, because otherwise something external could certainly give you artifacts. So -- and like I said, that's one of the great things about this two-day meeting, we've learned a lot.

CHAIRPERSON LUDERER: Dr. Wilson.

PANEL MEMBER WILSON: Thank you, Chair. Thank you for the presentation. And I just have a couple questions.
One was following up on Dr. Solomon's question about the comparison slide, and maybe you could put that up, if you could. Would that be possible?

MR. RHODES: I think so. Let me see what I can do here.

PANEL MEMBER WILSON: That's it.

MR. RHODES: There it is.

PANEL MEMBER WILSON: Okay. And can you make it into a slide.

MR. RHODES: Yeah, I'm working on that.

PANEL MEMBER WILSON: There we go. So, yeah, it looked like your arsenic was quite a bit higher in the -- relative to NHANES?

MR. RHODES: Significantly.

PANEL MEMBER WILSON: Yeah. And was there anything else that you identified or not? It looks -- from these other ones, I can't quite read them actually.

MR. RHODES: Generally, no. We didn't see a great deal of difference with any of the other metals that we looked at. And as I said, I was expecting for uranium to be higher, but it wasn't. And this will all be published fairly soon. We just don't have it -- this was hot off the press, so I threw a page into my presentation. We will have it on the web soon.

PANEL MEMBER WILSON: Yeah. And then could you
say a little bit about how you weighted the census tracts by population to get a representative sample?

MR. RHODES: I cannot. That was epidemiology. And -- but we can easily get that information for you, and send it on to probably -- through either your -- through Dr. Rupa Dali or Jed, either one. But Rupa probably is the one who will know how to use it. So I'll have my epidemiologist call your epidemiologist.

(Laughter.)

PANEL MEMBER WILSON: Fair enough.

CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

PANEL MEMBER KAVANAUGH-LYNCH: I was wondering if you could comment on your experiences with informing participants of their values. And, you know, did you get any phone calls? Did people respond well or not?

MR. RHODES: I'll have the person who took the phone calls answer that. This is Denise LaFlamme. She's the field manager for the program, and an epidemiologist.

MS. LAFLAMME: Hi. Good afternoon. My name is Denise LaFlamme. And so we reported back results to participants with a one-page letter. And we reported back their total arsenic result for all participants, and we only reported back high values for those selected metals that we had comparison values to. So if they were -- if they had a high cobalt compared to the occupational value,
we would report their high cobalt. But if they didn't, we wouldn't report on cobalt. And then we also reported their drinking water results, also in the results letter.

And I do help staff, the toll free line. And we have gotten, you know, intermittent calls from participants wanting to know more information about their results. And I either tried to answer their questions. We have an arsenic -- usually, their questions are around arsenic, because maybe their level is higher -- you know, is -- we report it back as high to them. And we have an arsenic toxicologist on staff. And we refer questions about like retesting and sources of exposure to our arsenic toxicologist.

We also collect -- at the same time, we collect questionnaire data specifically asking about their diet in the previous three days before their urine sample collection. And frequently, I can look at that and determine if they had a high seafood diet in the previous three days. So that helps to explain their level.

One thing that we're looking forward to, and we were hoping for at the time, was to have the speciated arsenic results along with the total arsenic results, so that when people called, we could look to see if they were -- if their -- our total arsenic level is more attributed to seafood-related arsenic forms versus, you
know, the inorganic arsenic forms. So we've been a little bit delayed on that analysis. And then also that has made it a little complicated in speaking to participants when they have questions.

But if I could just take a moment to respond to the weighting question. Yeah, the census tracts were weighted by population. So the census tracts that had the higher populations had a greater chance of being selected as part of the random sample. Is that what you were getting at? Did you want the specific --

PANEL MEMBER WILSON: No, essentially that was it. That was essentially it, but that you went through a process of assigning weights to different census blocks based on population

MS. LAFLAMME: Yes, based on population. That's correct. And our biostatistician did that for us.

And then if I could also follow up, and I think it's a very important point. And this is -- I think Blaine had forgotten about this originally.

Arsenic is a really big issue in our State, not from just naturally occurring sources. We've had several industrial smelters in Washington State, and that have -- in the Tacoma area there's the ASARCO Smelters. And there's one in Tacoma and then also north of Seattle in the Everett area. And the widespread environmental
arsenic contamination has been associated with historic activities at those smelters.

And then also the interior of our State there had been a lot of use of lead arsenic pesticides around the apple orchards. Also another possible source of arsenic are environmental exposures to arsenic in our State. So the natural sources of arsenic, definitely, but then also these contributions from historical pesticide use and industrial activities really was why we were interested in arsenic as well.

MR. RHODES: Thank you. Good job.

CHAIRPERSON LUDERER: Thank you. There will be more time for additional Panel discussion and questions after the next presentation. So perhaps, at this point, I'll let Dr. Das introduce our next speaker.

Thank you again.

MR. RHODES: Thank you.

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

It's now my pleasure to introduce Dr. Ken Aldous. Dr. Aldous received his Bachelor of Science in chemistry in 1967, and his Ph.D. in analytical chemistry in 1970 from Imperial College of Science and Technology, University of London.

As a researcher at the Wadsworth Center, he has
developed and improved analytical instrumentation and methods for the detection of lead in blood, and the measurement of dioxins and other trace elements and persistent organic compounds in biological and environmental samples. He has published over 100 papers in the field of analytical chemistry, and instrumental methods of analysis.

His present position is Director, Division of Environmental Health Sciences at Wadsworth and he is principal investigator on CDC funded programs for human biomonitoring and chemical threat preparedness.

Dr. Aldous.

(Thereupon an overhead presentation was Presented as follows.)

DR. ALDOUS: Thank you, Rupa. Dr. Luderer, and members of the Panel, thank you for -- thank you very much for inviting us to present at this meeting. It's been great to meet together as three States. And I hope that this talk will be of interest.

I've titled it expanding the capability and capacity for biomonitoring in New York. That's because it's the title of our funding.

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DR. ALDOUS: And I just want to show you a little bit of background as to Wadsworth Center. In case you
didn't know, we're the State principal lab in Albany. We have four areas. The Bigg's Lab is where most of the environmental chemistry and biomonitoring is taking place. We also have a Griffin Lab, which used to be called the State Farm. And the State Farm is where Patrick Parsons keeps his goats for getting lead intoxicated blood. So we have the Axelrod Institute and also the Center for Medical Sciences.

We're going to focus on the Division of Environmental Health Sciences, which is the division that both Pat and Dr. Kannan and I are in.

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DR. ALDOUS: This is the organization of the Public Health Program in New York State. We have the Office of the Commissioner, who directly supervises the Office of Public Health. And there are four centers within the Office of Public Health.

And the two of importance for biomonitoring are the Center for Environmental Health, which has the Environmental Public Health Tracking Program, and the Wadsworth Center, which is where we are, which is the Center for Biomonitoring.

We just had an Email from the Commissioner today. And although right now they are about eight miles apart, as of today, they're going to be merged into the downtown
campus, because of our State's fiscal situation, and also the reduction in the number of staff in those two areas of the Health Department.

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DR. ALDOUS: This is the Wadsworth Center and the director's office. Dr. Sturman, who you may know, is our lab director. And there are basically six divisions. The Environmental Health Sciences Division, on the extreme left, is broken into four labs. And in terms of biomonitoring, we have two lab sections. One supervised by Dr. Parsons, which is the Inorganic and Nuclear Lab, and the Organic Analytical Lab, Dr. Kannan. We also have a Molecular Toxicology and an Environmental Biology Lab.

I just wanted to mention that indeed we are a consolidated lab. We do environmental testing as well as clinical testing. We are parts of the federal network, including the LRNC, which is the Lab Response Network for Chemical threats. We've part of the FDA Food Emergency Response Network, the EPA's Environmental Response Lab Network.

As I say, we're the principal State lab for safe drinking water, and we are also a CLIA-exempt State, and we have CLIA accreditation for our clinical analyses.

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DR. ALDOUS: It's just some history of
biomonitoring at Wadsworth. We applied in 2001 for the planning grant, which many States and State consortia did, 25 in fact. Only three were awarded in 2003. We were successful. And although we didn't -- we were not funded at the level that we expected, we did do some interesting work in those five years of biomonitoring.

We were able to purchase a high resolution mass spectrometer. We had ability to fund one analytical staff person. And during that period of time, we collaborated with our tobacco control program. And it was at the time when cigarette smoking was banned in public places, and we were able to, with the help of CDC, develop a cotinine in serum method, and also cotinine in saliva method for monitoring the impact of that legislation. And that's one of the values of biomonitoring as you well are aware.

We also, during that period of time, collaborated with New York City. And they were in the midst of doing the City Health and Nutrition Examination Survey, which was modeled on the national program.

And we started to analyze some of the samples that were collected as part of that survey for trace elements for cotinine, because that was again of interest and some organophosphorus pesticides.

And we also started some pilot projects on some of these analytes, which became more important as we went
into this last five-year cooperative agreement. So we were funded in 2009, one of the three State labs that are here today.

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DR. ALDOUS: We did have a planning grant, and it started out as an inventory of the State. We looked at various projects. We had input from numerous parties that were interested in biomonitoring. And we eventually brought together a biomonitoring steering committee. We came up with a plan, and this was the plan that was put forward and was funded for the first five-year project.

Since then, we've obviously applied for the ongoing funding. We've had applications going to ATSDR. And we also leveraged State funding, but we have not really got any biomonitoring budget initiative with the State of New York.

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DR. ALDOUS: So these are some of the major projects I just touched upon. The impact of State legislation on exposure to smoke. We worked, as I say, with our community health tobacco program. We did 1,800 self-administered sample collections for saliva cotinine, and showed that for non-smokers, the background level had actually dropped significantly after the ban.

We also started to work with the city of New
York, and we analyzed some of the samples that they collected for trace elements for -- in blood for urine mercury and for serum cotinine. We also took part in an angler study with Dr. John Vena, and published some of that data, which I've listed at the bottom.

An interesting thing that we did during that period of time was we started to look at the advantage of using newborn screening blood spots. We do about a thousand a day. And as you know, that's a great resource for looking at the exposure to newborns. So we looked at our archive of these. And we took the last 10 years, and we were looking for the perfluorinated compounds. We pooled samples.

This was where we were interested in looking for trends. So we were not interested in specific babies, but we were interested in where these compounds -- how they tracked with time over 10 years. It was very interesting that when 3M pulled them off the market in 2000, 2002, that was the peak of the values that we detected. And after that point in time, we saw a decrease in the levels in newborn blood spot -- blood from babies.

Again, a great use of biomonitoring.

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DR. ALDOUS: So these are our current specific aims, to expand the number of sample -- of analytes that
we can measure in the CHANES archived samples.

When we put forward our application for this last period of time, we said we want to hit the road running. We want samples. And one of the big problems with biomonitoring is developing the program and getting samples. It's a very costly part. Our funding was really for the lab. And so we need to work with our epidemiology people to help us develop projects, and also collect -- help collect the samples.

So we wanted to again try and fill in the blanks for all the NHANES targets in this population of samples that were collected in 2004 from New York City.

We have some other projects which I'll talk about in a moment. One is for depleted uranium, one for methyl mercury, and some pilot studies that we're working on. And we really want to develop collaborative biomonitoring studies with our environmental public health tracking people. That's something that I felt very strongly about, and we've tried to do that over the last year.

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DR. ALDOUS: So this is the -- for those that aren't aware of it -- the New York City Community HANES. It was done in 2004.

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DR. ALDOUS: This is layout of the samples that
were collected. And couple of things I wanted to point out about this was these samples were distributed to a number of labs. Wadsworth had some of them. Some went to CDC. Some went to another Johns Hopkins and other universities.

This was a big project. It was basically modeled on the national program. One thing that they did was they placed a number of samples into a repository. I think this is a real great thing that we should be doing, because now they're offering for some target compounds that may still be stable and are available for analysis from this repository.

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DR. ALDOUS: So this City HANES was a population based cross-sectional survey of about 2,000 adults. It was conducted in 2004. We measured serum cotinine, and blood metals were measured, and urine mercury was measured in the population.

Now, some of these people consented to have additional target compounds analyzed at the time when the samples were collected. There was some publications there from those studies that I placed at the bottom. So we used LC-MS/MS for our serum cotinine. It was a method that was developed at CDC, and we transferred it. All the analyses that we intend to do on this archive of samples
will be similar to the ones that have use for the national program, so that we can hopefully compare the data.

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DR. ALDOUS: So these are the objectives for the CHANES archive samples. We want to complete our analyses of about a thousand sera for PCBs, organochlorine pesticides and PBDEs. We want to complete the analysis of urine samples for hydroxy-PAHs. And we're in the process of validating methods for phthalate metabolites, bisphenol A and perchlorate.

So those are what we intend to do for organics. For inorganics we're looking at completing the analysis of urine metals. And we're developing methods for selenium in whole blood and also manganese using sector field ICP-MS.

We're also developing the mercury speciation method, using GC isotope dilution ICP-MS. And we intend to analyze about 400 samples. We're also doing arsenic speciation for the same reason that Washington is.

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DR. ALDOUS: So what are the requirements for reaching these goals?

We want to maintain our trained staff. We want to hire additional staff. We need access to sensitive instrumentation. We really need clean rooms. We need
biohoods and we need to obviously develop and validate our methods for those that aren't already in that State.

We need to access -- to get access to standards and reference materials. This is one of the things that we've been talking about over the last two days, is if we're going to all be on the same playing field, we want to be able to exchange materials, so that we can be sure that our methods are comparable, and we can be able to then have the data compared from lab to lab.

We're interested in being able to do studies where there are thousands of samples. And so we have to increase our sample throughput. We want to be able to obviously get ongoing training at CDC, and we want to develop projects with our collaborators.

We are interested in pilot studies. And if pilot studies lead to larger programs, then all the better.

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DR. ALDOUS: Some of the challenges. I think these have all been laid out. There's a large inertia to develop a study, obtain IRB approval, and get the funding to do that. There's a great cost to sample and data collection. The samples we get are complex. And typically for biomonitoring we're looking at low concentration a target compounds. So that adds a lot of pressure on the work that we have to do, in terms of
sample pre-treatment and preparation of samples.

We have to be very careful about contamination, not only in the lab, but during sample collection. The data you get is only as good as the sample that's initially collected. And we need standards and reference materials.

Instrumentation is expensive to operate and maintain. We spend a lot of funds on maintaining very expensive pieces of equipment to do this sort of work. And without some of our other funding from other CDC projects, this would be very difficult.

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DR. ALDOUS: So this is our current resources. We have trained -- we do have trained staff. We do have facilities. We have some duel use instrumentation, because of our work with the Chemical Threat Program. Although, we are doing so many proficiency tests and surge drills, the amount of time now on that instrumentation has been reduced significantly.

The fact that we have a network now and from just these three States, this is great for collaboration, for support, and to get expertise developed across this network. And we hope that this will continue to allow us to grow as a network.

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DR. ALDOUS: I'm just going to go through -- I think I've just got time to go through some of the methods that are sort of ongoing and being developed. We have a situation, close to Albany where we have a population that was exposed over the years to depleted uranium. And we're interested in looking at that problem. And that will allow us to develop our capability to do sector field ICP-MS efficiently.

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DR. ALDOUS: This project is a community-based project. We have a group that is a concerned group with this facility, which used to be called National Lead. It's been -- it's not been used. The area was cleaned up about several years ago, 25 years ago, since the exposure. But there was a huge amount of depleted uranium released into the environment.

So we have this program now to look at citizens that have -- residents, and also people that worked at that plant.

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DR. ALDOUS: So our program right now is to validate a method for uranium isotopes in urine. And this is an ongoing project that we have just started, and we're hoping to get through our outreach, and get our IRB approval to start sample collection for this particular
study.

We have, before the end of 2011, that may be a little optimistic at this point.

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DR. ALDOUS: The other thing that we're looking at is blood mercury speciation. This is a technique that again is being developed by Dr. Parsons' lab. It's a fairly complex method. It is based on an EPA method for isotope dilution ICP-MS. And it will allow us to measure a number of species of mercury. And the reason we want to do that is that when we did our original study of the blood mercury from the NHANES, we had a distribution of levels that were above our State level for reporting to the heavy metals registry. So, you see, we have 438 samples that exceeded five micrograms per liter.

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DR. ALDOUS: Obviously, when we do total mercury, we're including some of the other forms of mercury, including methyl mercury and ethyl mercury.

So with the ability to do speciation, we can go back, look at those 438 samples and see if we can speciate and determine whether these high levels were a function of organomercury in those people that potentially are eating fish.

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DR. ALDOUS: So target organic chemicals. These are some of the things that we're looking to do in the future, or we have already in reasonable shape. As I say, persistent organic pollutants, organophosphate pesticide metabolites, PAH metabolites. These are things that we would like to have up and running and have data from the CHANES cohort.

Those in yellow at the bottom are the sort of things that Dr. Kannan has on the radar and is starting to use some of our school of public health post-graduate people to determine if we can get methods up for some of those targets.

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DR. ALDOUS: We have equipment. We have instrumentation. High resolution GC-MS, regular GC-MS. Liquid chromatography with mass spec.

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DR. ALDOUS: This is an interesting system, because it's what's called dual column switching, which increases our throughput by using two chromatographic columns. We can switch from one to the other to improve our throughput from sample to sample.

So this is our current Biomonitoring Program.

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DR. ALDOUS: We're expanding the number of
analytes that we will have measured for organic and inorganic compounds in the New York City HANES. We're starting to work on depleted uranium. We have that method in development. We have the methyl mercury method in development where we're looking for a study of Asian populations.

In fact, Dr. Parsons just got funded to do a fairly extensive study of mercury exposure in the Asian population. And we want to have our pilot study to develop methods for emerging contaminants and to develop collaborative biomonitoring with public health tracking.

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DR. ALDOUS: So I usually throw this slide in at the end, because public health tracking must include data on environmental hazards. Human exposure health effects, the most health relevant method of determining human exposure to environmental hazards is biomonitoring.

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DR. ALDOUS: This is our staff. We have six people paid off the grant. And Dr. Parsons, Dr. Kannan, and Dr. Jansing are all State employees. We do have some school of public health students. So I just want to acknowledge Department of Health and Mental Hygiene from New York City, our State Center For Environmental Health and funding assistance from CDC.
DR. ALDOUS: And I want to be sure to mention Dr. Kannan, who we call Kannan because we can't pronounce his first name.

(Laughter.)

DR. ALDOUS: And Dr. Parsons who are really the people that are running the biomonitoring program. My information is there at the bottom for if people want to contact me. So I think that was the last slide.

CHAIRPERSON LUDERER: Thank you, Dr. Aldous for that interesting overview of the New York State Biomonitoring Program. Do we have questions or comments from Panel members?

We also need to take some public comments at this time, if we have any, and then we can come back to the Panel and have some more discussion after that.

Do we have any -- we have one. Do we have any from the web participants?

MS. DUNN: None.

CHAIRPERSON LUDERER: Thank you.

All right. Mr. Davis Baltz from Commonweal.

MR. BALTZ: Davis Baltz, Commonweal.

Thank you for those presentations. I actually just wanted to ask a couple of questions. I noticed in New York there was no mention of reporting results back to
participants. And I wonder if you do that? And if so, how you've managed that?

And in Washington I hear that you only report back individual results if they exceed a certain threshold, but you also made mention of the liability question. And so maybe I'd ask both of you, if you'd comment on what your concerns are there and how your discussions are proceeding.

DR. ALDOUS: So the CHANES program is modeled on the NHANES program. And the only results that would be reported back would be if they exceeded certain values. And for the situation in New York City with mercury, we did have some issues, which if you want the full story, Dr. Parsons will give it far better than I, but the level in blood and also in urine was quite high for one particular participant. And we did call that person, I believe, through the people at New York City just to be sure that they had some medical intervention.

So typically for these surveys we're not supplying the data back to the participants. And I think that's made clear in the consent form.

MR. RHODES: In Washington, we do report the total arsenic, no matter what. And we've reported all the six water levels, but we only reported the other metals if they were outside of the norm. So we didn't want to get
anybody scared, by the fact that they're there, because they're there in everybody. We just wanted to make sure they knew what we were looking for, and they would get something back if they needed it.

As far as the liability question goes, if you're working with a subpopulation, and say an occupational population, and there's something that shows up, they may turn around and sue their employer or somebody else. And they may not have much of a case. That's the question, at what point -- and then we get called into court and we're embroiled in a large battle. And all we can do is tell what science we used.

And then that -- there are a lot of legal questions that come up. So what we're trying to do is make sure that -- and I'm still working with people who know legality and the casework for this, that the science doesn't get stopped or held up, because people are afraid to do anything because of this. So it's a question and it's a pertinent question of these times.

But you can only go -- either you get legislation or you get your consent forms worded a certain way or something like that. There are ways to minimize the problems, but -- and so we're working on those, especially as we get into higher -- you know, special populations that might have a higher level.
DR. PARSONS: Good afternoon. My name is Patrick Parsons. I'm the inorganic half of the team from New York.

So reporting test reports to individuals is a little tricky. Because of regulatory concerns at the federal level, it's clear. And in our State, we have State regulations that govern what we can report to individuals.

And it really comes down to a question of whether you have a clinical reference range that would explain to people if they are elevated or not. And so for some things that's fairly straightforward. So if we're measuring blood lead or blood mercury, or urine mercury, there is a well-established clinical reference interval.

And so for participants in those studies, they can get those data, and they can get them from us because the lab is accredited under CLIA and under the State regs.

But for other things, it's not quite so simple. So, for example, if we are doing a biomonitoring study and we're measuring something like maybe the rare earth elements, we don't know what those numbers mean, because we have no clinical reference range to interpret them. And so in a study like that, we would tell people in the informed consent form, that they would not get those data back.
For the organic analytes, there may be some for which we have a reference interval. And so they could get them back. But for others, there may be no information. It may be that the biomonitoring study is designed to put a reference range in place. And so in that situation, you know, in that situation we would tell people that we would not report the data back.

So I think it really depends on the specific study and the analytes that we're testing for. And again, I think that because of the regulatory concerns, that really does dictate, you know, what can be reported back and what cannot.

CHAIRPERSON LUDERER: Thank you. Do we have any questions, comments from the Panel?

Dr. Wilson.

PANEL MEMBER WILSON: Yeah. Thank you, Chair. I have a follow-up question to the previous speaker. And that was your point about that there are regulatory concerns that constrain the reporting to participants. And I'm just wondering if you could provide a little more detail or maybe an example.

DR. PARSONS: Okay. So in the United States, the Clinical Laboratory Improvement Amendments of 1988 govern what clinical labs, whether they are government owned or commercial laboratories, can report to human subjects.
So any human specimen that is tested is covered under CLIA, with some rare exceptions. And so if you are going to test a specimen, and you are going to report those data back to the subject, then you're covered by CLIA, which means that your laboratory has to be accredited.

Number two, your methods have to be validated to CLIA 88 standards and in our State, to New York State standards. They're pretty rigorous. And you have to have a clinical reference range. And if you don't have those things, then you can't report back. It's actually illegal.

PANEL MEMBER WILSON: And the reference range being that you have an indication of what those findings actually mean from a health perspective or from a population-based perspective, is that what that means?

DR. PARSONS: Yeah, from a population base perspective, you've got to be able to define whether it is elevated or whether it is, for want of a better word, normal.

CHAIRPERSON LUDERER: Dr. Bradman.

PANEL MEMBER BRADMAN: I'm not quite sure if I have a question or a comment. I do have a question about depleted uranium. But back to this reporting back issue, at least in Berkeley, our IRB has taken a different
approach. Although this issue is starting to arise, and they've prevented us from reporting some results back that -- if you have a research test, you don't necessarily need to have a clear clinical reference range.

In other words, you're doing something that's not an FDA approved diagnostic test, but if it's done in a CLIA lab, and you're working with the physician, you can return the results.

And this is -- I know right now, at least in the University of California IRB system, this issue is under flux right now. And there's both State and federal rules. And at least here, I don't know if it's going to fall out quite as strictly as you describe in New York.

DR. PARSONS: You raise a very interesting issue, because on the one hand there are -- there's the regulatory apparatus that exists. And, for us, that's both federal and State. And then there's the IRB issues. And sometimes they don't always converge.

In our State Health Department, our own IRB is very well acquainted with the regulatory apparatus, and, in effect, would make sure that whatever we do is consistent with State law and with federal law. So that may be a conflict in other places.

But I think the thing that gives me most heartburn when I'm setting up a biomonitoring
collaboration is what would happen if I report a result back through a PI or collaborator to a human subject and we tell them it's elevated, and then the following week there is a lawsuit, and I'm dragged into court and I have to stand up and explain why I did that, was I legally able to report that result?

And that just makes me feel uncomfortable. So I will tell collaborators that I'm perfectly willing to share results with subjects provided, you know, the test is properly validated, I have a clinical reference range. And if all those things are met, then we're good to go. But if I don't know, you know, what I'm reporting out what it means in terms of human health or, you know, interpreted against a population exposure then, I think that we don't share that. Does that answer your question?

MS. HOOVER: Dr. Luderer.

CHAIRPERSON LUDERER: Yes.

PANEL MEMBER BRADMAN: I'll delay my completion about depleted uranium.

DR. PARSONS: That's a whole different -- because that's an isotopic ratio then. That's unitless.

PANEL MEMBER BRADMAN: Well, I'll save that for later.

CHAIRPERSON LUDERER: Dr. Lipsett.

DR. LIPSETT: Yeah. Hi. Michael Lipsett,
Department of Public Health.

Yeah. We've had extensive interactions with the CMS people who were responsible for administering CLIA with respect to reporting back results. And I would agree with the gentleman from New York with respect to tests that are -- where you do have -- that do have clinical implications. And you know what the potential -- or what the health impacts are likely to be for individuals.

But for quite a few of the chemicals that are part of this program, and some of the ones that Dr. Bradman was talking about, we don't know what the health implications are. And they -- CMS will not actually issue CLIA certification for a number of these chemicals. They are not covered under CLIA, and we're not -- we don't have the same sort of restrictions on reporting those back, as long as we're not reporting them in a way where we're -- that involves any kind of clinical management of the patient.

But it is a very tricky kind of issue. We had interactions with CMS going on over several months to try and make sure that we understood what the legal implications of this were.

CHAIRPERSON LUDERER: Dr. Das.

DR. DAS: Rupa Das, California Department of Public Health. I just wanted to add to what Dr. Lipsett
said, and to emphasize that we do not -- for the chemicals that have no clinical reference values, which are most of the chemicals that we're measuring, we do not plan to state that they are elevated, nor do we plan to make any definitive statements about the health implications of those levels. Just to put context to what Dr. Lipsett said.

PANEL MEMBER WILSON: Mike Wilson. So how does that then get reflected in the informed consent process?

Yes, Dr. Das.

DR. DAS: Our informed consent asks -- well, first of all, we are required by the legislation to return results to participants in a meaningful manner if they request them. So our informed consent asks participants if they wish to receive results. And if they don't wish to receive results, then we don't return them, but the majority of participants so far have agreed to receive results.

And so they indicate on the consent form, if they wish to receive them. And then the meaning -- in order to meet the mandate and to return them in a meaningful manner, that's what we, as a Program, are working out what is meaningful and how to return them, but not to make any definitive statements about health implications or state that they're elevated when we don't have a clinical
reference value.

Does that answer your question?

PANEL MEMBER WILSON:  Yeah.  Thank you.

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

Okay.  No.

We do have a break scheduled.  Let's see, a 15 minute break.

MS. HOOVER:  Just one second.

Sara Hoover, OEHHA.  We're just checking on our next presenter.

If we do take a break now, we should shorten it.  Okay.  So actually our next speaker is here, and so we're going to continue.  It's actually a substitution for Dr. Tracey Woodruff.

No, we're not going to break.  We're going to continue now with this next presentation and the break will be after that.

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

We were scheduled to have Dr. Tracey Woodruff present this next presentation.  Dr. Woodruff is not able to be here.  Carrie Dickenson will present in her place.  Carrie is a researcher who works with Dr. Woodruff on the Maternal Infant Environmental Exposures Project.  And
we'll let her introduce herself.

(Thereupon an overhead presentation was
Presented as follows.)

MS. DICKENSON: Thanks very much. My name is
Carrie Dickenson. I'm with the program on Reproductive
Health and the Environment at the University of
California, San Francisco. And as Rupa mentioned, I am
giving the presentation this afternoon on the Chemicals in
Our Bodies Project on behalf of Dr. Tracey Woodruff, who's
the director of the program.

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MS. DICKENSON: Thank you. So this is an update.
I'm just going to go through the project goals, our
recruitment, and sort of where we're at in the project
itself at this point in the stage.

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MS. DICKENSON: So this is a joint project of the
University of California, San Francisco, Biomonitoring
California, and the University of California, Berkeley.
The PIs are Dr. Tracey Woodruff, and Dr. Rupali Das, and
Dr. Rachel Morello-Frosch.

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MS. DICKENSON: The UCSF study personnel include
Dr. Tracey Woodruff, Dr. Naomi Stotland, who's an OBGYN at
San Francisco General Hospital, and the co-investigator on
this study. Jackie Schwartz and myself who are the study coordinators. Jessica Trowbridge, who's the data manager, and Cynthia Melgoza Canchola who's the research assistant. 

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MS. DICKENSON: So we have four project goals. The first is measuring and comparing levels of over 100 different chemicals in between 75 and a hundred maternal infant pairs; identifying leading sources of exposure to a subset of these chemicals; and developing and testing approaches to provide biomonitoring results to participants; and finally, to evaluate the association of chemical exposures and pregnancy and birth outcomes.

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MS. DICKENSON: The research design and methods, we recruited an enrolled between 75 to 100 maternal infant pairs, all of which were delivered at San Francisco General Hospital. We interviewed women on potential sources of exposure to chemicals, their diet, home environment, workplace, et cetera. And we collected biological specimens. Urine, we collected before delivery. Maternal and umbilical cord blood we collected at delivery.

And then Rachel Morello-Frosch from UC Berkeley, who I believe has previously presented her part of the project, developed the report-back materials to
understand -- for participants to understand their
chemical biomonitoring results.

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MS. DICKENSON: In terms of the eligibility, we
recruited English and Spanish speakers 18 years and older.
There due date was within the recruitment timeline, but
primarily they were late to second trimester into the
third trimester.

Our requirement was that they delivered at San
Francisco General Hospital. We do not recruit women who
had high risk pregnancies. Some of the recruitment sites
were RAs recruited individuals for participation in the
study, included the Centering Groups in San Francisco, at
Homeless Pre-natal and the Good Samaritan, the OB
Continuity Clinics, Nurse Practitioners Clinics, the
Midwives Clinics and the Family Planning Centers all at
San Francisco General.

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MS. DICKENSON: So the questionnaire focused on
three different chemical areas, pesticides, perfluorinated
chemicals, and BPA.

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MS. DICKENSON: So the interview-administered
survey, which took between one and one and a half hours to
administer by the research assistants and happened before
the delivery the several different sections included food, water, and cooking. And some of those questions for that section would be how many times a day, week, month or year do you eat red meat, for example.

The home section included information or questions pertaining to nail polish use, dyes, paint, installation insulation and furniture. So since you became pregnant, have you used any nail polish or nail polish remover?

We also asked about pesticides. So in the past 30 years, did you or any anyone else in your home use chemicals or pesticides? We asked about occupation, the name, hours of work, et cetera, reproductive history, tooth fillings, and certain demographic questions.

And in terms of the reproductive history part, a typical question, for example, would be for birth control, have you ever used a Mirena or other type of IUD?

So that's just an example of some of the questions and the different sections that we asked participants about.

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MS. DICKENSON: There was also an at-home survey. And some of the sections were the personal care products, hair care products, make-up, body or face products, cleaning products. And then we also asked about the home
electronics, the bedroom, et cetera. Some of the typical questions, you know, is your mattress treated for stain protection or water resistance? Do you sleep with a regular foam or memory foam pillow? Do you own any clothing that is wrinkle resistant or stain resistant?

So this was a question -- a survey participants did at home, and they mailed either to us or Biomonitoring California. So this is in addition to the survey that I was talking about earlier.

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MS. DICKENSON: And then so we also did chart abstraction. And so this took place after the delivery. So we looked at the prenatal charts, the labor and delivery charts, and the birth center charts. And in terms of the prenatal charts, some of the information that we were abstracting was age, ethnicity, medical history, previous pregnancy, emotional status, education, et cetera.

In terms of the labor and delivery charts, we looked at past obstetric history, medications, past medical history, health history, and then the initial newborn exam. And then the birth center chart was really the baby's chart.

So we're looking at newborn care and the biophysical baseline. So we're collecting all of that
information in addition to the interviews in the survey.

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MS. DICKENSON: In terms of the biological specimen collection, we had the maternal urine, which I mentioned, which was collected at the time of the exposure assessment interview. And some of the analytes that we were measuring in the urine are listed here.

And then the maternal and umbilical cord blood -- I'm sorry, the maternal urine was collected by the research assistants after the interview itself, and then stored in a freezer before it was sent to the labs at Biomonitoring California.

And then the maternal and umbilical cord blood was collected at the delivery. And again, these are the additional analytes that we were measuring in these two biomarkers.

And so what would happen is once a participant checked in for the delivery, they would give the nurses or the nurse practitioners, or their OB a flier that says that they were part of the study, or there would also be a sticker in their chart indicating that they were part of the study.

And then what would happen after that was that the nurse practitioners or midwives would then go into one of the rooms and pick up a maternal blood and an umbilical
cord blood collection kit to be used in the delivery room. And then from there, they would communicate with our research assistants, who would then collect the specimens, process them according to Biomonitoring California instructions, and then we would store them before shipping them for analysis.

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MS. DICKENSON: So each participant received several different pieces of educational materials at the end of the study. So this is a picture here of one of the UCSF documents that we created called Health Every day. And that just is a brochure which basically outlines 25 things that can be done every day to keep chemicals out of your body.

And then in addition to the Healthy Every day document, we had several green cleaning recipes and instructions on the safe removal of ants cockroaches and mice. A lead brochure. The Environmental Working Group's guide on PFCs and triclosan, the Dirty Dozen and NRDC's Fish Guide.

And so all of this material is available in English and Spanish. All of our research assistants are bilingual in both languages.

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MS. DICKENSON: Here's some of our recruitment
statistics. Recruitment started in July 2010, and ended in June 2011. There are approximately five participants recruited each week. In total, we enrolled 92 participants. Approximately 65 percent of our eligible participants were approached by the study team. Around 50 percent have approached participants in enrolled.

And then some reasons that I wanted to mention for individuals not enrolling were they were disinterested, they didn't have enough time to participate, and there was no child care or transportation.

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MS. DICKENSON: So in terms of the specimen collection success rates, we collected 83 percent of the maternal blood, 98 percent of maternal urine, and then 67 percent of the umbilical cord blood.

And then some reasons that we've also included here for the missed collection, is that women were -- they delivered before they were actually able to have the interview and collect the urine. And then they delivered before they were able to see their charts or before the nurse practitioners realized that they were part of the study. There was some, you know, miscommunication happening there, so the blood was missed, or there was an emergency or a scheduled C-section, so the cord blood was
MS. DICKENSON: So some of the preliminary results that we've received so far is that the -- all of the blood lead levels were reported to the San Francisco Department of Public Health for any additional follow up. And Karen Cohn really was instrumental in helping reaching out to our participants. And she sent them a letter, which offered a voluntary home assessment, and brochure.

And then we had one individual who had elevated mercury levels. And working through RCHR at UCSF, we were able to conduct a home visit with Karen Cohn from San Francisco Department of Public Health. And then consultants from U.S. EPA Region 9 to determine the source of exposure.

During the home visit, we were able to determine the source of exposure. And we are now working or have been working with Dr. Mark Miller to provide health education to the participant and do any follow up.

MS. DICKENSON: So the next steps for the project are the data validation and analysis, which we're working on with Biomonitoring California, and then presenting and publishing the results from the study.
MS. DICKENSON: And I'd just like to acknowledge the California Wellness Foundation, the CDC, and Louise Dimattio and Ocean Berg who are the nurse managers in labor and delivery. Kathleen Flanagan and all of the 5M and 6C clinic staff at San Francisco General Hospital.

Thank you.

CHAIRPERSON LUDERER: Thank you very much. That's a very interesting presentation. Do we have questions from the Panel members?

Dr. Solomon.

PANEL MEMBER SOLOMON: Yes. Given what we heard this morning the presentation from Dr. Calafat, the fact that the phthalate and BPA blood draws and urine samples were done after the participants entered the hospital, I guess, you know, could be an issue. Were you able to determine whether these moms had already had any medications given or IVs or anything prior to the samples being collected?

MS. DICKENSON: Right. That's a great question. Unfortunately, because of the fact that they were coming in at all hours of the day and night, we weren't able to know for sure exactly if the women had received their IV prior to the blood collection. The urine itself was taken, you know, several weeks -- up to several weeks before the delivery. So at that point, they would not
have had -- you know, received anything from the hospital itself.

But we do have all of the chart abstraction information, as well which I had mentioned, which has a lot of information with regards to what type of medication the individual could have been taking previously, as well as what was administered at the hospital.

CHAIRPERSON LUDERER: Any other questions from Panel members?

Do we have any public comments?

MS. DUNN: (Shakes head.) We have no comments through Email. I don't know otherwise.

CHAIRPERSON LUDERER: Okay. Thank you very much.

MS. DICKENSON: Thank you.

CHAIRPERSON LUDERER: Okay. We have a 15-minute break scheduled. We will -- it looks -- it's 3:15, so we'll reconvene at 3:30 -- oops sorry. I can't see the clock from here. Sorry, 3:20.

MS. HOOVER: So just before -- Sara Hoover, OEHHA. Just to verify, no more discussion at all from the Panel about the project? No questions I know, but no check-in on any discussion, right? I just wanted to double check that.

So, yeah, 3:20, we'll reconvene.

MS. DUNN: And just to remind people, some of the
mics might be live during the break, so if you're having a private conversation, move away from the microphones.

(Thereupon a recess was taken.)

CHAIRPERSON LUDERER: Okay. We need to resume. If all the Panel members could sit down.

All right. So welcome back. I'd like to go ahead and introduce our next speakers, Amiko Mayeno, who is the Health Educator with Biomonitoring California, and Dr. Sandy McNeel, Research Scientist with the Environmental Health Investigations Branch at the California Department of Public Health. And they will be giving the next presentation: Summary of results - return testing in the Firefighter Occupational Exposures Project.

(Thereupon an overhead presentation was Presented as follows.)

MS. MAYENO: Good afternoon, everybody. Thank you for giving us this opportunity to present what we learned from interviewing firefighters in Orange County this summer.

We are very excited to share some of the insights we gained on how best to report results to -- the chemical results to firefighters in the FOX study, as well as the insights we gained around best practices on returning results in general.

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MS. MAYENO: The results communication team responsible for developing the materials for the FOX results package, included the Department of Public Health, Office of Environmental Health Hazard Assessment, UC Irvine Center for Occupational Environmental Health, and the Orange County Fire Authority.

This team was a very, very collaborative team and worked hard together to develop the materials and to usability -- to develop -- prepare for the usability testing and revising materials based on that testing.

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MS. MAYENO: So I'm going to talk more about what the usability testing did. But before that, I wanted to explain what we mean by usability testing. So in this context, we're referring to interviewing participants to get feedback on drafts of materials that we have designed.

Now, actually in this particular case, the firefighters were not actual participants of the study. There were two, but most of them -- the remaining participants were not actual participants in this study. In the overall FOX study, they were just participants in the usability testing. So this usability testing is an iterative process that allows us to improve upon the drafts we have prepared. So after we interview the participants, we improve the materials and then go back
for another round of interviewing, so that we can quickly identify confusing and difficult concepts.

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MS. MAYENO: So why did we do this usability testing?

Again, it was to ensure that the results communication materials were clear and meaningful for FOX participants, and also to inform the development of the overall template that can be used for returning results to a broader range of Californians.

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MS. MAYENO: So the outcomes of this testing were pretty similar to what we intended. But additionally, we also learned what else firefighters wanted to know. So we learned a lot more than we had bargained for going in. We learned about things we hadn't thought of earlier before we went into the testing.

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MS. MAYENO: So this next slide shows how the FOX materials have gone through quite a process of development. It actually started in -- woops. It started in 2009, in January of 2009, when we started discussions about the Maternal Infant Environmental Exposure Project materials to return results. And then by 2011, February 2011, Health Research for Action with Holly Brown-Williams
as well as Rachel Morello-Frosch -- Dr. Rachel Morello-Frosch had conducted usability testing for the Maternal Infant Environmental Exposures Project.

Woops. There we go.

By June 2011, we had taken those materials and revised them for the FOX in preparation for the usability testing for the FOX. And in August 2011, we conducted the usability testing in Orange County.

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MS. MAYENO: So the usability testing recruitment was done at the firefighter's wellness and fitness appointments, as well as at the fire stations. There were 17 male firefighters that participated in all the interviews out of 19 that we had invited to participate. The two that didn't participate were -- just had other appointments and couldn't stay for the interviews.

So the interviews were one hour long. And they were either in individual or small groups. There were three rounds of interviews.

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MS. MAYENO: So for this -- the usability testing we did was on the first set of chemicals we're planning to report back on in this first phase. Later we'll be reporting on the other chemicals that we have -- we've been testing for in the FOX population.
So we are -- we prepared materials on the four metals in blood cadmium, lead, manganese, mercury, and the 12 perfluoro-chemicals in blood.

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MS. MAYENO: So what we intended to communicate, we were trying to find out how clearly we were doing this. We intended to communicate the individual chemical tests results, provide a context for understanding those results, such as the level of concern and something to compare their results to, such as the national population level or the FOX participant levels, other FOX participant levels.

And as well as providing chemical background on each individual chemical, including potential exposure sources, possible health concerns, and possible ways to reduce exposure. So now I'm going to show you some of the first drafts, the earlier drafts we showed to firefighters in the usability testing.

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MS. MAYENO: So this is an example of the text version of the results. We had -- we prepared text -- like the MIEEP study, we prepared text and graphic versions of the results. And here you can see the -- basically, it was all text. And then we also showed them a version that had a table added to the text.
MS. MAYENO: So this is pretty similar to the text, but we just added a table that summarized their levels and what they could compare their levels to, including the range of the firefighters in the study, the national median, as well the national 95th percentile. And if we had one, a level of concern. So in this example of lead, of course, we had a level of concern.

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MS. MAYENO: So this is also -- we also showed them graphs of -- we showed them some samples of the graphs that we had prepared. This is very similar to what had been prepared for the MIEEP project, and -- but when we showed them this particular graph, some people had trouble -- some of the firefighters had trouble interpreting the chart, and actually found it somewhat confusing.

So in response to those reactions, we went ahead and showed them, in the last round of testing, we showed them this draft.

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MS. MAYENO: And this had been prepared -- this is a histogram of all the results of the participants. You can see the gray bars represent individual participants. The blue bar is the actual level of the
participant. Of course, these aren't real results, but these are mock results that we had shared with them. And they had absolutely no trouble understanding these results or interpreting -- and they also liked them a lot better. They preferred them over the circle graphs that we showed you previously.

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MS. MAYENO: So just another note, this graph, the basic histogram, was developed by the Environmental Health Tracking Program at the California Department of Public Health. But we did get some feedback that they still felt it was busy. And when we brought it back and we discussed it after the usability testing, one of our partners from UC Irvine felt that it might be a little too disclosing of each individual's level, and some of the firefighters might feel like their privacy wasn't being totally respected. So in response to those two concerns, we developed these drafts.

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MS. MAYENO: And this is what we have. Basically, it's still being formatted, but these are basically the graphs we chose for the -- to use for the returning the results to the FOX participants. So in the upper left-hand corner, you can see it's similar information that the other graphs gave. It compares their
result to the national median and to a level of concern where we had one.

And then in the lower other graph on the right-hand side, lower right-hand side, you can see that you -- the participant can see their level as it compares to levels of other participants within the FOX study. Of course, these are not actual results, but we just wanted to share this with you, so you could see what we were doing.

And you can see also that this does not give as much detail, in terms of every single person's results. So they cannot compare their results like they could in these different graphs with the other individuals in the study, but they could just compare it to the range as well as the median of the other FOX participants.

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MS. MAYENO: Another thing that we shared with them was the fact sheet. So as you remember hearing about probably in the March SGP meeting, where Rachel Morello-Frosch and Holly Williams-Brown had presented about the MIEEP materials, they developed some beautiful materials that included fact sheets for each chemical. And we -- the firefighters very much liked the fact sheets. And we also developed more of them under the guidance of OEHHA, more fact sheets on the
perfluoro-chemicals that we didn't have previously; manganese and mercury that we didn't have previously. So now we have all of those fact sheets.

But the main changes we made was that we changed it -- they liked -- they preferred the question/answer forms. So we made it more into a question/answer format. And they also wanted more resources on how they could do their own research on a given chemical, so we provided more resources for them.

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MS. MAYENO: So in summary of the main changes we made to increase clarity, we added tables to all of the different chemicals. We developed new results graphics, and we changed the fact sheets to question and answer format, and expanded the resource section.

And now Sandy McNeel is going to take over and she's going to talk about what else did firefighters want to know.

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DR. McNEEL: Thank you, Amiko.

As we've mentioned, during their interviews, the firefighters brought up some issues that we had not initially taken into consideration with regard to the results that would be returned to individuals. And many of them asked why we were testing them for chemicals, if
we could not tell them the health relevance of their results.

Now, in addition, the frequently asked questions indicated that exposures to many of these chemicals were primarily through use of general everyday kinds of products rather than their firefighter occupational activities.

They were also interested in knowing how the data from the study would be used.

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DR. McNEEL: Now, in addition, they were also interested not only in their own results, but they also wanted to know if data from this study would show a difference in chemical levels by factors such as a firefighter's chronological age, the years that they had worked as either a volunteer or employed firefighter, or their duties and job classifications, such as firefighter or engineer or Captain, as well as duties such as hazardous materials response.

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DR. McNEEL: So in response to the firefighters' concerns, we did take a look at the kinds of things that they were interested in. And we wound up developing a new fact sheet that will be included in the participant's results package. And this is a short document that goes
into greater detail about why we did choose to look at firefighters in this particular study, including the fact that firefighters have a good potential for increased exposure to environmental chemicals as a direct result of their jobs, and also that there are only a few studies that have looked at firefighter exposure to these chemicals. And in addition, that their participation will contribute to a Statewide database that we are in the process of building.

Now, this fact sheet also gave them some reminders about what they could actually learn from the study, and also some general recommendations on how to minimize their exposure to environmental chemicals while they're on their job.

We also modified the cover letter to emphasize the importance of their contribution to building our knowledge about environmental chemicals in firefighters, and through them other Californians.

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DR. McNEEL: Now, in addition to the changes that I just mentioned, we're also considering the best way to put the various pieces of our data puzzle together to form a cohesive report of the aggregated data that we'll make available to the participants at a later date.

And we're currently analyzing data from the
firefighter exposure questionnaires and the fire station checklist that will help us answer hopefully some of the questions that we've received.

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DR. McNEEL: So the final package that will be sent to our FOX participants in this first set of results returns are a cover letter, the one-page document why we're studying firefighters. And then for each of the four metals, and for the 12 PFCs as a group, each of those will have a laboratory results page that will include the individual participant's results in both a table and a text format, as well as an information sheet to provide some more background about the chemicals, each individual chemical, and a graphic display that will include the individual participant's results as well as comparisons again to the other individuals in the FOX study, as well as to the NHANES population, and a level of concern, if there is one established, for that particular chemical.

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DR. McNEEL: Our next steps for the FOX project are to get approval from our two institutional review boards to actually distribute these finalized documents to our participants. And then once we have approval for the document templates, we'll merge the data from our databases onto the specific documents for results return,
print those out, review them for accuracy, and get them into the mail to our participants.

Then once that's completed, we'll begin the job to expand our template library to include additional chemicals or classes of chemicals that will be returned in the second phase of our results return process, after those additional chemicals have been analyzed and undergone result validation.

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DR. McNEEL: Now, we have learned an awful lot from usability testing that has already occurred with the MIEEP project, and also through what we have done on FOX, but we are not done yet. We realize that there's still a number of issues that we would like to look into further, particularly to continue looking at how best to provide a context to our participants, so that they understand how they compare with others, both in their own study group and also how they compare to people sampled in the national survey.

We also want to continue refining and improving the ways we present data to our participants, both through tables and also using graphic displays, because we know that some people prefer images to numbers on tables. And including improving all of our basic information to make sure that all of these are presented in the most
understandable way to our participants.

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DR. McNEEL: So with that, I would like to thank the Panel and everyone here in the room and on line for your attention and we'd be happy to answer questions.

CHAIRPERSON LUDERER: Thank you very much, Dr. McNeel. Any questions from Panel members?

PANEL MEMBER CULVER: Is this on? Do you hear me?

DR. McNEEL: Yes.

PANEL MEMBER CULVER: Okay. First of all, this is really a fantastic outcome of your efforts. I applaud your analyzing all of the various facets of this study and making changes as you've gone along. And I think that this has been a very helpful thing for our future interests.

I have one little kind of specific question. And that is whether the level of concern that you picked for lead was related to the age and gender of the firefighters?

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

That level of concern was chosen based on consultation with the Occupational Health Branch. That is
the lead level at which the Occupational Health Branch would -- has decided they would send a letter to working people to let them know about the services that they provide, and, if necessary, would do follow-up looking at their place of work as a potential source of exposure.

PANEL MEMBER CULVER: Has that been published?

DR. DAS: Has the level of -- that level of concern of 10?

PANEL MEMBER CULVER: That level of --

DR. DAS: No. This is a decision made by the State Occupational Health Branch as a threshold for their action, specifically sending a letter to workers with a level higher than 10, 10 or higher rather.

PANEL MEMBER CULVER: That is now their policy in this State?

DR. DAS: Yes.

PANEL MEMBER CULVER: Okay. Thank you.

CHAIRPERSON LUDERER: I actually have a question I think maybe both of you and Ms. Dickenson regarding the difference that you observed in the graphical -- the kind of preference for the graphical presentation of the data between the participants in the MIEEP study and the FOX study, and whether -- you know, what your thoughts are on that, and kind of, you know, the implications for developing these kind of materials for other populations
in the future.

MS. MAYENO: Amiko Mayeno, California Department of Public Health. Yeah, in terms of the -- I mean, I think that it wasn't comparable, in terms of how the testing was done with the MIEEP, and it was with the FOX, because we were comparing different types of visuals. So their experience was the participants didn't have too much trouble understanding the graphs. But there was some confusion that we noted in the firefighters, which was interesting, because there's definitely an overall higher educational level within the firefighters.

But we do think that because there's two different populations we were looking at and there was different methods that we were using, that it's important to continue to look at this issue as we look into -- for example, we're looking at doing usability testing for the Kaiser study, and looking at those issues with a broader range of population, that span a larger demographic spectrum.

CHAIRPERSON LUDERER: I mean one thought that does come to mind is, which obviously would add a whole additional layer of complexity, would be to have participant reports be individualized, you know, for individuals -- you know, basically the format that would make the most sense to them.
I mean, I know that's -- would, as I said, make things much more complicated, but it does, you know, sort of down the road in thinking about how participant report back might evolve, it does kind of lead you to think that maybe is a direction that one needs to go.

DR. McNEEL: Sandy McNeel, California Department of Public Health.

We have talked in the past, as far as the future ways that we would like to be able to return results to participants, including having some type of secure on-line method by which people could access their own individual results. And if wishes were horses, and we had all the IT support and everything else that it would need to do that, you know, it would be possible to think about having multiple different types of graphic displays or different tables that could be automatically populated from our data sets.

But probably until that kind of thing happens, we're looking at trying to come up with something that we can use to try to standardize our approach of again kind of aiming toward what we would do for a Statewide survey.

CHAIRPERSON LUDERER: Any other discussion, questions, comments?

Dr. Das.

DR. DAS: Rupa Das, California Department of
Public Health. I actually wanted to add something to my response to Dr. Culver. Your question was the level of concern 10 chosen with the age and gender in mind. And the level of concern was chosen with the age and gender in mind. It is a level of concern we are using for FOX, because we chose this as an occupational cohort, and that -- and the answer I gave before is correct that the Occupational Health Branch has chosen that level to use as the threshold for sending a letter.

However, our cohort is primarily male, 98 percent male. And so with a female population, a reproductive age population, we would choose a different level of concern, as we have for the maternal infant project.

And so while I think your question was focused on FOX, our choice of the level of concern really is somewhat dependent on the age, gender, and the fact that this is a working population.

PANEL MEMBER CULVER: That was why I asked my question the way I did. And I thought your answer was very helpful and very adequate.

DR. DAS: Thank you. I just wanted to add to it.

PANEL MEMBER CULVER: Although I'm not sure that I am able to support 10 for women exposed at the workplace.

DR. DAS: If they were women of reproductive age,
we might choose a lower level of concern. Our population, as I said, two out of the 101 were women in this case.

Chairperson Luderer: Dr. Wilson.

Panel member Wilson: Yeah. Thank you, Chair.

Mike Wilson.

I was -- I'm not sure if I quite caught it, but that on the section on what you intended to communicate, was it that there was no possible occupational sources of exposure for these substances?

Dr. McNeel: No. In this particular study, we are looking at some potential occupational sources, but we had no way to look at home or non-occupational sources for any of the chemicals that we're looking at. So we are not proposing a source for where the firefighters were likely to come into contact with these chemicals.

Although, in the frequently asked questions, we do provide information about the most common sources of exposure, some of which may be occupational, but most of which are not.

Panel member Wilson: Yeah. And so in looking at the fact sheet that you put up, it was -- those sources were primarily home -- looked like home-based and sort of consumer product sources.

Dr. McNeel: Right, yes.

Panel member Wilson: You know -- and, of course,
my concern on the metals, particularly the lead, would be the occupational exposure is occurring during overhaul, when there's no respiratory protection being used, and, you know, at least in, you know, residential structure fires. And so, you know, and -- but I'd be happy to talk with you, you know, in some more detail about that. And that there may be specific recommendations that could be made with that particular work practice.

And then I guess the follow-up question would be, if there's somebody from the -- not only from the fire authority, but from the firefighters union who has been involved on the health and safety side who's participated in some of the discussions at this point?

DR. McNEEL: Yes. We have made sure to involve both union and management sides of the Orange County Fire Authority.

In response to your first comment, we are trying to collect some data about timeframes during which firefighters may not be wearing their respiratory protection during overhaul. This is a pilot. So we'll -- if anything, we may generate some hypotheses, but we'll have to look at the data that comes back from -- particularly from our metals analyses and see if there's something more we need to look into there. But, yes, that's certainly a concern.
PANEL MEMBER WILSON: Yeah. Thank you, Sandy.

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

I just wanted to acknowledge your comment about overhaul being a likely source of exposure to lots of chemicals, including heavy metals, such as lead. We do mention that in some of our educational materials that exposure can occur during overhaul. And so we mention that that is a possible source of exposure. But I think that one of the points is that we can't differentiate between occupational and non-occupational sources of exposure just by biomonitoring.


CHAIRPERSON LUDERER: If there are no other questions or comments from the Panel members at this time, this would be a good point for public comments. Do we have any comments from the web participants?

MS. DUNN: We do not have any, either web nor in the room, I don't believe.

CHAIRPERSON LUDERER: Thank you. Is there any additional discussion from among the Panel members?

All right. Thank you very much.

Sara.

MS. HOOVER: I thought since we have a little
time, I'll go ahead and add some more about our research
for the fact sheets in response to Dr. Wilson's comment.
So we actually did a lot of research trying to look
specifically at firefighter exposure for all of these.
And we did a lot of work with Amiko, with the Occupational
Lead Branch, looking at, again, the potential for
firefighter exposure.

So anywhere we had that kind of information, for
example, we did determine that PFCs can be in certain
types of fire fighting foam, that was put into the fact
sheet. The reality is that most really high lead
exposures, they're pretty -- they're getting to be more
well characterized.

And so the fact sheet, we're not only talking
about obviously occupational exposure for firefighters,
because if they were to have for example a high lead or
high mercury, it might be from something completely
unrelated to their occupation. So we tried to focus on
not just that, but also on the key known sources of
exposure for all of these chemicals.

So that -- you know, it's not strictly an
occupational study. It's actually a study that integrates
all their sources of exposure. So we wanted to make sure
they got education about where it might be coming from.
So that was the approach we took.
PANEL MEMBER WILSON: Great.

CHAIRPERSON LUDERER: Thank you.

Next on the agenda is an open public comment period. Do we have any requests to speak or any comments from the web audience?

MS. DUNN: We have no comments from the web audience or in the room.

CHAIRPERSON LUDERER: Thank you.

Is there any additional discussion from among the Panel members?

Okay. Looks like we are going to be -- Sara, yes.

MS. HOOVER: Just before you close, can I ask a question about the March meeting, unless you wanted to say anything else about this meeting.

So I just wanted to let people know, which Dr. Luderer would be talking about, the next meeting is going to be in the Bay Area. And I just wanted to kind of have an open invitation if any of you or anyone in the listening audience knows of a webcasting facility in the Bay Area that the State might be able to use. We have really limited ability to do that in any of the venues that we're aware of that we don't have to pay for in the Bay Area. So I just wanted to put that out there.

And then we're going to be determining where to
have it. We may end up not having any webcasting for the March meeting in the Bay Area. So I just wanted to put that plea out, if anyone has ideas. We're still researching it ourselves. But if anybody has thoughts, we'd be happy to get that information.

CHAIRPERSON LUDERER: Okay. I'm sure any Panel Members, if they do have any ideas on that, we'll get back to you.

And that next meeting is going to be on March 15th.

MS. HOOVER: 16th.

CHAIRPERSON LUDERER: 16th, sorry. 16th in the Bay Area. And the exact location will be announced later, as Sara just said.

I also wanted to let everyone know that a transcript of this current meeting should be available on line in about a month.

And with that, I would like to adjourn the meeting and thank you all for attending. And for the stimulating presentations and discussion today.

Thank you.

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 4:01 p.m.)
CERTIFICATE OF REPORTER

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, and Registered Professional Reporter, do hereby certify:

That I am a disinterested person herein; that the foregoing California Environmental Contamination Biomonitoring Program Scientific Guidance Panel meeting was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, and thereafter transcribed under my direction, by computer-assisted transcription.

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

IN WITNESS WHEREOF, I have hereunto set my hand this 28th day of November, 2011.

JAMES F. PETERS, CSR, RPR
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