

MEETING  
STATE OF CALIFORNIA  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT  
ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM  
SCIENTIFIC GUIDANCE PANEL

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APPEARANCES

PANEL MEMBERS

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

Dwight Culver, M.D.

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

Thomas McKone, Ph.D.

Gina Solomon, M.D., M.P.H.

Michael Wilson, Ph.D., M.P.H.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Dr. George Alexeeff, Acting Director

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

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1 any.

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

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

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

21           (Thereupon a problem with the sound  
22 system occurred.)

23           (Laughter.)

24           CHIEF DEPUTY DIRECTOR HIRSCH: Okay. I'll just  
25 finish -- we'll finish this quickly again. So they

1 discussed highlights of the workshop that was held in  
2 March on understanding and interpreting biomonitoring  
3 results and they advised the program to not pursue  
4 individual risk interpretations of biomonitoring results.

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

9           And so if you wanted more information about that  
10 meeting, we have a transcript of it now that's up on our  
11 website [www.biomonitoring.ca.gov](http://www.biomonitoring.ca.gov).

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

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

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

1 and discuss issues of common interest.

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

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

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

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

24           In order to assure that the meeting proceeds on  
25 schedule, and I guess we're already a little behind

1 schedule here, all the commentators will have an  
2 opportunity to speak, but we'll time the comments,  
3 basically divide the amount of time we have by the number  
4 of people who wish to speak.

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

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

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

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

22           So now I'd like to announce our first agenda item  
23 for the day, which is the Biomonitoring California Program  
24 and Laboratory Update. And it's a pleasure to introduce  
25 Dr. Rupali Das, Chief of the Exposure Assessment Section,

1 in the Environmental Health Investigations Branch at the  
2 California Department of Public Health and lead of  
3 Biomonitoring California.

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

10 Dr. Das.

11 (Thereupon an overhead presentation was  
12 Presented as follows.)

13 DR. DAS: Good morning. Thank you, Dr. Luderer.  
14 And welcome, members of the Scientific Guidance Panel and  
15 audience members here in the room and those listening on  
16 the webcast. It's my pleasure to give you an update of  
17 the overall achievements of the Program since our last  
18 meeting with the Panel.

19 --o0o--

20 DR. DAS: Today, I'll be providing an update on  
21 the funding, describing some staffing changes, providing a  
22 very brief update on our pilot projects, the Maternal  
23 Infant Environmental Exposures Project, the Firefighter  
24 Occupational Exposures Project and the Biomonitoring  
25 Exposures Study. And you'll hear more about a couple of

1 these projects later on as well. Describing a few other  
2 activities, and you'll get a brief glimpse as to what's  
3 coming next.

4 --o0o--

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

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

17 --o0o--

18 DR. DAS: I just wanted to remind you about the  
19 CDC cooperative agreement objectives, because it's been  
20 awhile since we put them all up on the screen. We had  
21 five objectives that we specified in the cooperative  
22 agreement. First to expand laboratory capability and  
23 capacity. Second to demonstrate the success of the lab  
24 quality management system. Third to apply biomonitoring  
25 methods to assess and track exposure trends, and that's

1 certainly consistent with our State mandate. Fourth, to  
2 assess exposures in a representative group of Californians  
3 also consistent with our State mandate. And fifth, to  
4 collaborate with stakeholders and communities. That's a  
5 third common element with our State mandate.

6 --o0o--

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

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

21 If you would please stand, Dr. Ken Aldous and Dr.  
22 Patrick Parsons are in the room today. And Blaine Rhodes  
23 and Denise Laflamme, sorry. This is actually not my  
24 updated presentation. That's why I was thrown off a  
25 little bit. And Lovisa Romanoff and Antonia Calafat from

1 CDC are here in the room as well. So I'd just like to  
2 extend a very warm welcome to them for being here with us.

3 (Applause.)

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

7 --o0o--

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

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

21 Laura has extensive grant writing skills and  
22 experience in reproductive health endpoint studies. With  
23 Drs. Brenda Eskenazi and Asa Bradman she has been an  
24 integral partner in several CHAMACOS projects. Her  
25 experience and interests make her an excellent addition to

1 our biomonitoring team. And we're very happy to have her.

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

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

5 (Applause.)

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

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

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

22 (Applause.)

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

1 his presentation.

2 --o0o--

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

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

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

18 --o0o--

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

24 To remind you, this is a collaboration between  
25 Biomonitoring California, UCSF, and UC Berkeley. This was

1 a convenience sample of mother-infant pairs recruited at  
2 San Francisco General Hospital, mothers who delivered --  
3 who were receiving prenatal care at SFGH were recruited  
4 into the study.

5 --o0o--

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

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

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

20 --o0o--

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

25 This was also a convenience sample and we

1 recruited firefighters who were undergoing wellness and  
2 fitness evaluations at the UC Irvine COEH clinic. We  
3 enrolled 101 firefighters.

4 --o0o--

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

11 --o0o--

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

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

23 --o0o--

24 DR. DAS: We enter data from all these different  
25 documents. We have an informed consent document, an



1 QA/QC purpose, our quality assurance and quality control  
2 purposes for all the questionnaires. We've also done some  
3 accuracy and precision checking for the data entry and  
4 have done some logic checks and validation.

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

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

16                           --o0o--

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

21                           --o0o--

22           DR. DAS: This is a reminder that this is a study  
23 that's taking place in the California Central Valley.  
24 It's a stratified random sample, a regional representative  
25 sample of residents in California's Central Valley,

1 consisting of adult Kaiser members, living in seven  
2 Central Valley counties listed at the bottom there and  
3 indicated by the blue in the middle of the map of  
4 California.

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

8 --o0o--

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

17 This recruitment strategy is a little bit  
18 different than the other two projects that were  
19 convenience samples with participants recruited in  
20 clinics. Because BEST involves either going to a  
21 participant's home or their office or having them come to  
22 a Kaiser clinic, there is an additional element of  
23 arranging for a visit, and then arranging for sample  
24 collection. So the whole process is a little bit more  
25 involved than for the convenience samples of MIEEP and

1 FOX.

2 --o0o--

3 DR. DAS: In addition to the projects that  
4 described and the sample analyses, we continue to do other  
5 activities that are very important for us. And these  
6 include chemical selection. We've been developing  
7 potential designated -- a potential designated document  
8 for non-halogenated aromatic organophosphate flame  
9 retardants, and are continuing to screen candidates for  
10 potential designation, for example, additional pesticides.

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

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

24 And finally, we are in the process of revamping  
25 the Biomonitoring California website. This includes

1 revising the look and content to make it more user  
2 friendly, to allow people to come and find what they want  
3 readily, to improve readability, and to increase the  
4 relevance for general audiences. And I think you'll be  
5 very pleased with the results. We hope that that will be  
6 ready for rolling out to the public in 2012.

7 --o0o--

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

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

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

25 If you'll recall in 2008, the Program issued the

1 first RFI, and we collaborated with three different  
2 research groups to analyze samples that they had  
3 collected. And we are almost ready to issue the next RFI.

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

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

17 --o0o--

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

1 (Applause.)

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

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

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

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

13 Dr. McKone.

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

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

24 We can describe the results of that meeting in  
25 another -- of our last two-day meeting in another SGP

1 meeting. That's not on the agenda. But staff are here to  
2 talk to you. And if you have specific questions, we'd be  
3 happy to answer them.

4 PANEL MEMBER MCKONE: All right. Thank you.

5 CHAIRPERSON LUDERER: Okay. If there are no  
6 further questions, we can proceed to the next  
7 presentation.

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

12 (Thereupon an overhead presentation was  
13 Presented as follows.)

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

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

19 --o0o--

20 DR. SHE: Rupali already mentioned laboratory  
21 have two new staff. Mr. Anthony Zhou, you can see the  
22 picture. He's not in the audience. He graduated from UC  
23 Berkeley. And he has some chemistry background, and also  
24 computer program language background. And then he is  
25 major with PAH sample preparation, and also a lot of the

1 cap with -- prepare the -- check the inventory and also do  
2 the -- some computer database related work in the lab.

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

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

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

16 (Applause.)

17 DR. SHE: Thank you, Doctor.

18 --o0o--

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

23 This purchase completed the Environmental Health  
24 Laboratory's setup for quantitative analysis funded by CDC  
25 cooperative agreement.

1                   --o0o--

2           DR. SHE: For the laboratory method, we still  
3 talk about three different category, under development,  
4 under validation and application, and in production.

5                   --o0o--

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

14                   --o0o--

15           DR. SHE: As I mentioned, Dr. Dashen Lu started  
16 the dry blood spots and the very low volume blood spots  
17 analysis for PBDEs and the PCBs. And then he left at the  
18 end of May. So we don't have so much progress. Gladly we  
19 have Dr. Simon join us, so he can pick up and continue.

20           Dr. Sen Nil he's working on the arsenic  
21 speciation. His method is almost ready for validation and  
22 Dr. Sen is in the audience if you have further questions,  
23 he can help to address.

24                   --o0o--

25           DR. SHE: So this slide shows the separation of

1 six species of the arsenic. And I think the -- he also  
2 went to New York, Washington State, so we're able to  
3 collaborate with the other State biomonitoring programs,  
4 learn from them, share the experience. The Washington  
5 State is also here and they may also answer some  
6 questions.

7 --o0o--

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

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

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

25 For the OP pesticide, we're able to do TCPy, and

1 the 3-PBA, we reported before. We are in the process to  
2 expand them, the list.

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

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

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

22 --o0o--

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

1 90 urine samples.

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

8           We are right now also reviewing MIEEP samples  
9 result.

10                   --o0o--

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

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

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

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

1 qualities.

2 --o0o--

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

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

17 --o0o--

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

25 But the first we need a standard list, develop a

1 checklist. So some of these items can be automated. We  
2 call it automated data review, ADR. So we tried  
3 programming. So again, make the data review process most  
4 standardized and automatic.

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

9 Construct calibration curve control chart for  
10 slope and intercept.

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

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

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

25 --o0o--

1 DR. SHE: Thank you.

2 CHAIRPERSON LUDERER: Thank you, Dr. She. It's  
3 very impressive to see all the progress that you and your  
4 colleagues have made in spite of the unfilled positions.

5 Does any of the Panel members have clarifying  
6 questions?

7 Dr. McKone.

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

14 DR. SHE: We look only at parent compound.

15 PANEL MEMBER MCKONE: Just the parent compound.

16 DR. SHE: Just the parent compound.

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

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

25 PANEL MEMBER MCKONE: And then my other question

1 is, and this is my ignorance, but the PCBs aren't they  
2 often in the same -- I mean, are they in the same realm as  
3 the dioxins, or is that -- I know we haven't really talked  
4 a lot about dioxin-like compounds. But if they're there,  
5 if somebody wanted them, is it a lot of extra work to get  
6 them or is that not really --

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

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

20 PANEL MEMBER MCKONE: And I guess just a  
21 follow-up, so because these are very small samples -- I  
22 mean the anticipation is that you could do a lot more  
23 samples for less effort than ones that would require full  
24 serum and a lot of quantity, right? I mean, that was --  
25 the intent -- it says these are blood spots, dry blood

1 spots and low volume. So is there a broader coverage we  
2 could get, hopefully, you know, with enough funding?

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

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

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

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

21 PANEL MEMBER MCKONE: Thank you. Thank you very  
22 much. That's a very interesting presentation.

23 DR. SHE: Thank you.

24 CHAIRPERSON LUDERER: Dr. Wilson.

25 PANEL MEMBER WILSON: Thank you, Dr. She for that

1 presentation, and for all your good work once again. And  
2 I just have a couple questions about on your -- you  
3 mentioned the field break -- I'm sorry the blanks. And I  
4 assume they're both sort of field and laboratory blanks.  
5 And I'm just curious if you could say something about if  
6 you've had any indication that there are other sources of  
7 contamination, or what have you, in your blanks or, you  
8 know, indications of any trouble in the analytical method  
9 through the blanks?

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

16 So we found for the MIEEP project some device we  
17 used for very low contamination, which is fine, because  
18 compare the levels, we do not think that's significant.

19 And due to today's instrument is so sensitive,  
20 you should see something anyway. So there's a low --  
21 absolute low. So you see something as long as they are  
22 not a significant find.

23 And for the field blank, you see for the MIEEP  
24 project we analyzed 90 samples, so far we analyzed five  
25 field blank. The project collected more than five field

1 blanks. We do not see any interference for DAPs. We do  
2 not see for the phthalate. We did not see for -- we did  
3 not see for hydroxy-PAH. But for the environmental  
4 phenols, sometime we see some peak show up. So far, we  
5 did not see is a major issue with -- for one blank, we  
6 notice some levels there. And it's about -- we look at  
7 about eight -- I would say -- I forget the unit, the  
8 numbers is eight, but our sample number is like 3,000.

9 So we do not think that it's significant at this  
10 moment here. But we did see some peaks for the  
11 environmental phenols.

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

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

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

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

22 DR. SHE: Yeah, we can -- for the FOX project, we  
23 can only control the laboratory contamination issues and  
24 protection issues. We cannot control any pre-analysis  
25 contamination -- potential contamination issues, because

1 we do not have the blank.

2 PANEL MEMBER WILSON: Okay. Thank you.

3 CHAIRPERSON LUDERER: There will be an  
4 opportunity for more Panel questions at the end.

5 PANEL MEMBER BRADMAN: I have a couple.

6 CHAIRPERSON LUDERER: Dr. Bradman, do you have a  
7 quick clarifying question.

8 PANEL MEMBER BRADMAN: Well, one thing to  
9 clarify, I think, Tom, with the blood spots, they're often  
10 routinely collected from infants, so there's potentially  
11 tens of thousands of blood spots available. So they offer  
12 a lot of opportunity.

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

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

1 manufacturer.

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

8           PANEL MEMBER BRADMAN: Right.

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

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

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

1 papers in the future.

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

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

15 DR. SHE: Yeah. We would like to learn more  
16 about it as a PBDE-free serum that you mentioned, if we  
17 can get it. Regarding the NIST, certified materials, NIST  
18 1957 have certified the values, or at least the reference  
19 value. If they not certify, they give you reference  
20 values.

21 And we use that in our method. We actually -- a  
22 lot of times, we match it very well. NIST certified the  
23 values that have a very low -- very low tolerance levels,  
24 tolerance range, which is very good. So if you can parse  
25 that one, possible better than any other PT program. The

1 other PT program have a wider range. If you parse it,  
2 don't mean so much. You must still have different result,  
3 if two laboratory posit. The NIST, so far, I think we  
4 able to get within 3 ICD. I think it's very good.

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

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

12 (Thereupon an overhead presentation was  
13 Presented as follows.)

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

16 --o0o--

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

23 PANEL MEMBER WILSON: Dr. Petreas, if you can --  
24 if you could speak directly into the mic, it would be  
25 hopeful.

1 DR. PETREAS: Okay.

2 PANEL MEMBER WILSON: Thank you.

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

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

14 --o0o--

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

22 Joon Soo a background in chemical oceanography,  
23 had the post-doc in atmospheric chemistry. And  
24 nevertheless, he did a great job with human blood. And,  
25 in fact, he's the one who's pioneered the hydroxylated

1 metabolites of PCBs and PBDEs in our lab. And he was the  
2 lead scientist for a long time and now he's the section  
3 chief.

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

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

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

23           She's done great work. So when this position  
24 appeared, she was the best candidate, and we hired her.  
25 And she's now transitioning into working on MIEEP.

1           So we made some progress here. And we're happy  
2 and we hope to fill the two vacancies before another  
3 freeze comes.

4                           --o0o--

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

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

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

25                           --o0o--

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

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

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

19 --o0o--

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

25 In fact, I should say that for each of our

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

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

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

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

19                           --o0o--

20           DR. PETREAS: Using the LC-MS we're looking at  
21 other BFRs, Tetrabromobisphenol A, high volume BFR,  
22 2,4,6-tribromophenol and 2,4-dibromophenol. These are  
23 BFRs that can be addressed by LC-MS. And the same method  
24 can include Bisphenol A.

25           So the method now has been validated on bovine

1 serum. And we started testing some archived human serum.  
2 The current field studies, the FOX and the MIEEP were not  
3 supposed to be -- we don't have to look for these  
4 chemicals at this stage. But the next field study we  
5 should have these methods on line.

6 --o0o--

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

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

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

23 --o0o--

24 DR. PETREAS: And the important thing I guess  
25 here is that the analyses are on schedule as we had

1 planned. So we're moving along fine.

2 --o0o--

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

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

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

24 And, of course, the challenge of staffing is  
25 still there. We have vacancies and people on leave.

1                   --o0o--

2           DR. PETREAS: Well, we're fortunate to have good  
3 relations with our colleagues. And, for example, we have  
4 long-term relationships with some Swedish universities.  
5 And currently we have Dr. Anna Kärrman passing  
6 her -- spending her post -- I mean, sabbatical. Thank  
7 you -- her sabbatical with us. And she's helping us with  
8 the PFC methods. So working with our staff and  
9 transferring technology there.

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

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

24                   --o0o--

25           DR. PETREAS: So I think with that, that's my

1 update. If you have any questions, I'd be happy to answer  
2 them.

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

9 Dr. Wilson.

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

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

24 PANEL MEMBER WILSON: There were -- sorry.

25 DR. PETREAS: The fact is that these are high

1 control. They're there. They're in the dust. We are  
2 getting exposed. We haven't looked at all the  
3 compartments. I mean I don't know where they may end up.

4 PANEL MEMBER WILSON: Wasn't the -- aren't  
5 brominated flame retardants in the most recent panel from  
6 CDC. I don't know if any of the panelists could tell me  
7 or not, but. And I'm -- and was that --

8 DR. PETREAS: No, PBDEs.

9 PANEL MEMBER WILSON: PBDEs, yes?

10 DR. PETREAS: Yes. PBDEs, yes. BFRs, no.

11 PANEL MEMBER WILSON: BFRs no, right. Okay.

12 Great. Well thank you.

13 DR. PETREAS: In fact, one of my sources is Dr.  
14 Houdin, who said that he doesn't think they should be  
15 absorbed by the GI tract. But again, we don't have  
16 toxicology information to know how they get partitioned  
17 and metabolized.

18 PANEL MEMBER WILSON: Interesting. Great. Thank  
19 you.

20 CHAIRPERSON LUDERER: All right. Why don't we  
21 move on to public comments. Do we have any public  
22 comments?

23 MS. DUNN: None through Email, but one in the  
24 room.

25 CHAIRPERSON LUDERER: So we have 10 minutes

1 allotted for public comment. Although, we are about 10  
2 minutes behind also our schedule.

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

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

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

20 That said, of course, from the beginning of this  
21 program, it's never had the funding that would enable it  
22 to reach all of its statutory mandates. So obviously in  
23 this current climate, that will continue to be a  
24 challenge. And certainly from the public interest side of  
25 watching the development of this program, we'll do

1 everything we can to mobilize additional resources as we  
2 can and protect those that in place.

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

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

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

24 One of the objectives in the CDC cooperative  
25 agreement that Dr. Das put up was collaboration with

1 stakeholders and communities. And to the degree that the  
2 representatives from CDC here can take back this message  
3 from the public interest community, we are absolutely  
4 delighted with the way that the staff has worked with  
5 communities by making public comment periods available and  
6 being available to answer our questions. And so from our  
7 point of view, certainly that objective has been far  
8 exceeded.

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

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

1 this year. And there is actually quite a bit of interest.

2 So thanks for the chance to comment.

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

6 Dr. McKone?

7 No.

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

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

14 Thank you.

15 (Thereupon an overhead presentation was  
16 Presented as follows.)

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

24 Prior to joining CDC in 1996, she was a Fulbright  
25 Scholar and a Research Associate at Emory.



1 about are trace concentrations in this biological fluid,  
2 versus the normally large concentrations of the chemicals  
3 in the environmental levels.

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

9 --o0o--

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

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

22 We require, and those are the ones that are  
23 listed on the right side of this slide, looking in here,  
24 we actually would like to have biomonitoring methods that  
25 use small amounts of samples. And this is because the

1 sample biological assessments are precious. And there are  
2 small samples, and they may not be easy to obtain. So  
3 we'd like to get as many measurements as possible with  
4 very little amounts of sample.

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

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

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

1 NHANES.

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

6                               --o0o--

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

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

23                               --o0o--

24           DR. CALAFAT: So I think I had said several times  
25 that analytical chemistry and biomonitoring are going

1 together. However, I think that there are also important  
2 differences between analytical chemistry and  
3 biomonitoring, in, what I call, an analyte versus a  
4 biomarker.

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

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

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

24 --o0o--

25 DR. CALAFAT: Certainly, you want to pick the

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

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

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

20           However, we you need to keep into consideration  
21 that these matrices contain a very large amount of  
22 endogenous components. And these components may affect  
23 the results -- the analytical results that we are  
24 obtaining. And a case that is very clear and evident that  
25 has been known for several years is in phthalates, because

1 many of these matrices contain enzymes esterases raises  
2 that can break down the phthalates, which is ubiquitous in  
3 the environment, and therefore they can lead to some  
4 contamination that we have no way to control for.

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

7 --o0o--

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

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

23 As you can see, there was considerable  
24 variability, not only between days and between  
25 participants, but also within individuals and within the

1 same day.

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

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

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

20           What is important here to -- oh, thank you. What  
21 is important here to realize is that there were very -- in  
22 both cases, the concentrations were variable in the urine,  
23 but there was a different pattern in this variability.  
24 While for the compound that is present in personal care  
25 products, the source of the variability was mainly driven

1 by the participant. You either use or you don't use the  
2 product. And when you do, you tend to use it on a regular  
3 basis, and at the same time every day.

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

14 --o0o--

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

1 of BPA for these eight participants.

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

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

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

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

25           We analyzed both urine and serum for Bisphenol A.

1 And what we observed, it was -- and you can see it in  
2 here, in my opinion, beautiful graphs that show a very --  
3 the units are different. On the left side is the urinary  
4 excretion of BPA. On the right side, you have the  
5 concentration of BPA in the blood. And you can see, they  
6 mimic, very nicely, the curves. They go together. When  
7 you have increasing concentrations in the blood, then you  
8 have increasing concentrations in the urine. It's just  
9 that the urine increased. It was about one hour behind  
10 the increase in blood concentrations.

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

16 --o0o--

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

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

25 And the answer is that it may, it may not. It

1 just really depends on the biomarker. It's going to  
2 depend on the exposure scenario. And it's going to depend  
3 on the population. So if we think about exposures that  
4 are chronic to nonpersistent chemicals, maybe one spot  
5 sample is good enough. If we're thinking about the  
6 nonpersistent chemicals that go to which we are exposed  
7 through episodic events, then maybe the one spot sample is  
8 adequate. It's better than having none. Don't get me  
9 wrong, but may not be the best approach, it's simply just  
10 all that we have. But it would be important in those  
11 particular cases to collect additional information, such  
12 as the time of collection of the sample, as well as the  
13 last time that the person had voided his or her bladder.

14           So can we really overcome this variability? And  
15 I don't think so. We could think about collecting  
16 multiple urine specimens per person. But this would  
17 certainly increase the cost of the study, not only in  
18 terms of analysis, but also in terms of storage. And  
19 without even going into that, it could just decrease the  
20 compliance of the participants.

21           So one potential approach is like maybe pooling  
22 several spot specimens. But then we're going to go into  
23 how many do we want to pool. Certainly, I think that  
24 collecting more than one sample, if at all possible, is  
25 better than collecting one. But collecting one is better

1 than collecting none.

2 --o0o--

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

12 --o0o--

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

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

25 We had several years ago a study that showed that

1 women that went for a delivery, a C-section delivery, had  
2 much higher concentrations of DEHP metabolites -- this is  
3 the compound the PVC plasticizer in their urine -- while  
4 the concentrations of the other phthalates, metabolites  
5 were totally unremarkable.

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

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

19                           --o0o--

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

1 know the -- all the sources and routes of exposure for  
2 some of the chemicals.

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

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

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

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

21                               --o0o--

22           DR. CALAFAT: So to conclude, I would like us to  
23 remember that biomonitoring is one tool for exposure  
24 assessment that requires complex analytical methods and is  
25 because you're measuring trace levels versus the higher

1 normal environmental levels, and it integrates all  
2 potential sources and routes of exposure.

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

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

18                           --o0o--

19           DR. CALAFAT: And I couldn't finish without  
20 thanking the people who really have done the work, and  
21 have been working with me for many years. The work that I  
22 presented today is the work from the Personal Care  
23 Products Laboratory, but we at CDC were about, in our  
24 division, about 400 very dedicated people to  
25 biomonitoring, as well as the people in our sister agency,

1 the National Center for Health Statistics who are  
2 collecting the samples that we use for NHANES.

3           And I'll be happy to answer any questions you may  
4 have.

5           Thank you.

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

9           Dr. McKone.

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

19           And I think one of the things we have to struggle  
20 with is on the one hand, you can almost use it as a source  
21 of frustration, and say look it's so noisy, I can't do  
22 anything with it. But actually most of these things there  
23 is a way to sort of dig deep. I think -- I guess the  
24 question is, is there a way to use this to tell us when a  
25 sample is useful or how many samples we need.

1           What I'm thinking of is like when you take a  
2 sample of any chemical in the population where you worry  
3 about, is you're just taking a snapshot of a highly  
4 dynamic situation. But sometimes if you take enough  
5 snapshots, like if you could take a million snapshots, you  
6 know you would get useful information. You would see a  
7 trend. You could see something. But maybe you don't need  
8 a million. The question is how many do you need to  
9 realize you're getting rid of the noise and actually  
10 seeing a trend, I guess, is what it leads to? And it's  
11 not just for biomonitoring. It's something we really have  
12 to deal with.

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

25           It may also be whether you're only simply

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

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

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

24 In the world of radiation, they've actually found  
25 a cumulative lifetime genetic or a heritable chromosome

1 damage, so that you really can do a lifetime running  
2 cumulative dose. I mean, so I kind -- hopefully we can  
3 set this as a goal. I know it's hard to do now, but the  
4 more persistent the marker, I think the more -- and then  
5 if we have a persistent marker and a short-term marker,  
6 right, then we can really start telling a better narrative  
7 about what people are seeing, both long term, and then  
8 what kind of daily oscillations they have due to things  
9 like diet or something that may be in their environment.

10 DR. CALAFAT: Yeah, for --

11 PANEL MEMBER MCKONE: It's probably not a  
12 question, but it's just a --

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

21 So we're moving from the blood into the urine,  
22 but the urine is not yet perfect. So it would be nice if  
23 we could, for example, look for some markers, like  
24 hemoglobin adducts, that would extend -- you know, you  
25 could say at least this is for 120 days. There is

1 research ongoing in that particular field, but it's just  
2 not moving as quickly as one would want.

3 PANEL MEMBER MCKONE: Thank you.

4 CHAIRPERSON LUDERER: Dr. Solomon.

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

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

22 And so I guess my question for you is whether  
23 this -- you know, this oscillation and the nonpersistent  
24 biomarkers is sufficiently problematic that it raises any  
25 questions about the sample size in NHANES and whether that

1 information is still, you know, useful for sort of  
2 creating points in time, or descriptive statistics about  
3 the overall U.S. population?

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

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

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

21 And in some cases, we cannot change the exposure,  
22 because we don't even know where these chemicals are  
23 coming from. So in these -- if you think in this  
24 scenario, I think having one sample is really much better  
25 than having none at all.

1           PANEL MEMBER SOLOMON: Just a follow-up question  
2 to that, with regard to the research studies, it seems  
3 that the issue there would tend to be non-differential  
4 misclassification of exposure, which would tend to  
5 systematically bias all of the research studies on  
6 chemicals like BPA toward the null.

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

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

24           DR. CALAFAT: Yes, you are absolutely right. At  
25 the same time, I also want to remind you that many times

1 what you have is one specimen collected from that  
2 specimen, then you have to do your measurements and then  
3 you're trying to evaluate exposure to different chemicals.

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

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

15 CHAIRPERSON LUDERER: Dr. Wilson.

16 PANEL MEMBER WILSON: Great. Thank you, Chair.

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

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

1 described.

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

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

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

25           Regarding -- so this is what I meant by pooling.

1 But this is only one idea that could save some costs and  
2 could provide some information, valuable information, but  
3 at the same time, you would be missing -- you know, you  
4 wouldn't have the information from the day one, day two,  
5 day seven. It would be day one through day seven.

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

16           CHAIRPERSON LUDERER: Dr. Bradman.

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

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

24           DR. CALAFAT: Certainly.

25           PANEL MEMBER BRADMAN: Right now, most of the

1 papers that have been published focused on adults. And I  
2 think we need to look at different ages. We have done one  
3 study with three to six year olds and find similar levels  
4 of variability. I don't know whether we would see that,  
5 for example, in six-month olds or newborns or there might  
6 be different trends at different ages.

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

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

18           And then I think we can think in terms of risk  
19 assessment perhaps on an acute basis. But if there's any  
20 attempt to think about chronic exposures, that's a whole  
21 'nother challenge there. Although, I want to emphasize  
22 that in discussions here on the Panel we've kind of  
23 decided that, at least the Program here itself won't be  
24 focused on risk assessment and interpretation of the  
25 results, but I'm sure others will. And I think the points

1 you raise need to be considered, when that data is looked  
2 at.

3 DR. CALAFAT: Thank you.

4 CHAIRPERSON LUDERER: Dr. Solomon.

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

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

25 CHAIRPERSON LUDERER: Dr. Wilson.

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

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

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

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

24           PANEL MEMBER WILSON: Understood. Thank you.

25           CHAIRPERSON LUDERER: Dr. Alexeeff.

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

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

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

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

19           DR. CALAFAT: Yeah. I mean, this one is the one  
20 when you're taking the spot samples collected on that  
21 particular day, so every single spot sample. And then  
22 you're looking at what is the intra-day variability, how  
23 much -- you know, like if you collected the sample in the  
24 morning or you collected the sample in the evening. I  
25 know you can see there are the differences -- the main

1 difference in there is, again, there's more variability  
2 for the compound that is coming from the diet, at least in  
3 this population -- these are adults -- rather than the  
4 compound that is coming from the use of personal care  
5 products, because that's -- you tend to use them on a  
6 regular basis every day X amount of times.

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

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

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

25           DR. CALAFAT: It was the type of food. It was --

1 in this particular, unlike the other study that -- where  
2 those eight CDC colleagues who conducted business as usual  
3 for a week, so everything that they did they -- and they  
4 provided the sample. In this particular one that's why I  
5 said the controlled setting. There were 20 adults that  
6 they housed in a facility was for one day. And then they  
7 were given a choice between three breakfast, three  
8 lunches, and three dinners.

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

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

18           CHAIRPERSON LUDERER: Thank you. And I did have  
19 one more question, which is related, I think, and that is,  
20 you know, you mentioned the different sampling strategies,  
21 you know, the spot samples versus 24-hour versus pooling  
22 within an individual. And I think one thing that's very  
23 important in helping to decide which of those strategies  
24 might be the best has to do with understanding the  
25 toxicology of the particular chemical as well, which I

1 don't think we've mentioned.

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

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

22           CHAIRPERSON LUDERER: Do we have any other  
23 questions from the Panel members at this time?

24           If not, we can take public comments, and then  
25 we'll have time for more discussion at the end from the

1 Panel.

2 Do we have any public comments?

3 MS. DUNN: None from Email but Davis Baltz.

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

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

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

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

1 going to be releasing updated tables.

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

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

16 Dr. Zeise.

17 DR. ZEISE: Hi. Lauren Zeise from OEHHA.

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

24 So I'm wondering a couple things. One, are there  
25 any other adduct kinds of markers on the horizon for

1 chemicals that you're considering now. And another is  
2 whether or not you would be potentially, where it is  
3 important, reporting on ratios of different markers within  
4 an individual and looking at those distributions. I think  
5 that could be very informative for, for example, risk  
6 assessors.

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

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

15 DR. ZEISE: (Nods head.)

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

22 DR. ZEISE: (Nods head.)

23 DR. CALAFAT: This is something that I can just  
24 bring up to the Division, and then just to see how -- if  
25 this is something that may happen in the future. If not,

1 then, you can always get the information, because don't  
2 forget that all the data that we put in the exposure  
3 reports, the raw data so-called are on the website, on the  
4 NHANES website.

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

10 DR. ZEISE: Thank you.

11 CHAIRPERSON LUDERER: Any questions or comments  
12 from Panel members?

13 No.

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

17 If not, we can take lunch early.

18 Okay.

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

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

1 And, Carol, did you want to --

2 CHIEF COUNSEL MONAHAN-CUMMINGS: No need to.

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

7 (Laughter.)

8 MS. HOOVER: See you at 1:30.

9 (Thereupon a lunch break was taken.)

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1 AFTERNOON SESSION

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

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

8 Dr. Das.

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

19 The first presentation will be from Washington  
20 State. And I will introduce Blaine Rhodes. And after  
21 he's done, then I will introduce Dr. Ken Aldous. Blaine  
22 Rhodes is the Director of the Office of Environmental  
23 Laboratory Sciences at the Washington State Public Health  
24 Laboratories in Shoreline, Washington. He manages five  
25 laboratories with 25 scientists, and is the principal

1 investigator on the Washington Environmental Biomonitoring  
2 Survey or WEBS. And he wants to say that he's very proud  
3 of the project staff.

4 Blaine.

5 (Thereupon an overhead presentation was  
6 Presented as follows.)

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

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

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

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

23 --o0o--

24 MR. RHODES: In 2003, we applied for funding, but  
25 did not get it. And in 2009, we reapplied when the

1 request for funding proposals came out. And be careful  
2 what you wish for, we got the grant and had to build an  
3 entire structure from scratch, which is different from  
4 our -- the other two programs. What we received is a  
5 five-year grant, and the promise, at least, of level  
6 funding throughout the five years.

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

14                           --o0o--

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

21           A lot of these suggestions came from our --  
22 inside the Department and also from a nascent Scientific  
23 Advisory Panel, which became our Scientific Advisory  
24 Panel, a group of people we've worked with for years all  
25 around the State in various governmental positions.

1           So at the same time, we're going to compare all  
2 those results to NHANES. And coincidentally, we could do  
3 a great number of urine metals at the same time. So we  
4 just -- once you get them into the instrument, out they  
5 all come, so we add those on.

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

10                           --o0o--

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

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

21           Two to three field management in Non-Infectious  
22 Conditions Epidemiology. We call it NICE in Washington.  
23 We have two or three management staff for the field. And  
24 those people are full time and they did a magnificent job.  
25 Senior Epidemiologist Statistician is part time. We did

1 get a CSTE fellow this year, and clerical support. We got  
2 two toxicologists from the Division of Environmental  
3 Health part time. And that's, once again, another entity  
4 you cannot live without.

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

7 --o0o--

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

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

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

22 --o0o--

23 MR. RHODES: And then selected 70 block groups.  
24 And then from each block group 27 housing units. And then  
25 sent sample -- sent letters to the housing units and then

1 sent the collection teams out to enroll them in the  
2 program, and it didn't always work.

3 --o0o--

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

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

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

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

25 (Laughter.)

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

4 --o0o--

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

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

20 (Laughter.)

21 MR. RHODES: Then the households were asked to  
22 fill out two questionnaires, and asked for permission to  
23 archive their urine sample for five years, if they gave  
24 permission. And actually over 95 percent gave permission,  
25 so we ended up with freezers full of extra samples.

1           Now, we're trying to figure out what to do with  
2 them, but that's -- fortunately, we have a great group of  
3 people in our Scientific Advisory Panel to help us.

4                           --o0o--

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

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

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

22                           --o0o--

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

1 speciating the arsenic.

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

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

15 --o0o--

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

25 For metals, only if they're greater than

1 occupational BEI values, cadmium, cobalt, thallium,  
2 uranium. And then we did six metals for the water.  
3 Manganese, which is not part of NHANES, but it certainly  
4 is near and dear to EPA. So we did that for them.

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

9 --o0o--

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

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

25 The other thing we have is Hanford. And I

1 thought possibly that there might be some uranium leakage  
2 there, but fortunately there is none.

3 --o0o--

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

8 --o0o--

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

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

21 --o0o--

22 MR. RHODES: Next year's, we are -- we have --  
23 we're validating the pyrethroid method. And we have both  
24 urban and rural areas, and it will be interesting to see.  
25 One would surmise there will be a difference, but we won't

1 know until we test. Organophosphate pesticides method is  
2 still in development. And other general population  
3 studies are in discussion. We have the samples, should we  
4 need them.

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

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

15 --o0o--

16 MR. RHODES: The high arsenic study, we already  
17 screened 313 households, collected 173 urine samples, and  
18 82 drinking water samples. And all the results have been  
19 analyzed and reported back. We have not -- we're still  
20 doing the statistical analysis on them, so I can't report  
21 anything on that yet.

22 The pesticide applicators, we're recruiting  
23 people for that. This is one of the areas where we get  
24 into the question of what if we actually find something.  
25 There's the liability question that jumps up when you

1 start doing these kinds of studies. And we're working  
2 with the legal department to get those ironed out, because  
3 biomonitoring can have consequences that we have to make  
4 sure about.

5 --o0o--

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

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

23 --o0o--

24 MR. RHODES: Based on the Advisory Committee  
25 recommendations, we are looking at the measuring of

1 mercury in seafood consumers and Asian populations, which  
2 we also have a heavy one. Analyze year one and year two  
3 for bisphenol A metabolites, and for the panel of  
4 phthalates and prepare laboratory analysis of NNAL, which  
5 is another smoking metabolite other than cotinine, when  
6 we -- if we get resources and people.

7 --o0o--

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

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

13 Dr. Culver.

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

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

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

25 MR. RHODES: I'll have to get back to the portal

1 and let you know. It's above the standard -- we flirt  
2 with the EPA numbers a lot.

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

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

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

15           PANEL MEMBER CULVER: Thank you.

16           MR. RHODES: Thank you, sir.

17           CHAIRPERSON LUDERER: Dr. Solomon.

18           PANEL MEMBER SOLOMON: Yes. Thanks for a very  
19 interesting presentation. It was a little hard to see the  
20 tables of metals results. Way too small on the handout  
21 and the slide flashed by a little bit on the rapid side.  
22 But I'd love to hear a little bit more about mercury,  
23 because you mentioned that you're going to be doing some  
24 follow-up studies on hair levels. I think that it makes a  
25 lot of sense in our coastal States to have some serious

1 focus on mercury, because I think that's something that  
2 the NHANES data don't -- I mean, that they may not reflect  
3 your State and our State.

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

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

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

18 As far as the speciation of -- we're not going to  
19 speciate the mercury off the hair. We'll do total mercury  
20 off that. But as you said, our environmental health  
21 people keep track of mercury in the waters of Puget Sound,  
22 and in the fish. So we are going to be seeing if it's  
23 coastal. There are also some cinnabar bluffs containing  
24 bluffs out in the middle of the State that could generate  
25 some mercury in water and/or vegetation.

1           PANEL MEMBER SOLOMON: One follow-up. Are you  
2 going to be collecting urine and hair from the same people  
3 or will this be different people?

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

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

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

22           CHAIRPERSON LUDERER: Dr. Wilson.

23           PANEL MEMBER WILSON: Thank you, Chair. Thank  
24 you for the presentation. And I just have a couple  
25 questions.

1           One was following up on Dr. Solomon's question  
2 about the comparison slide, and maybe you could put that  
3 up, if you could. Would that be possible?

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

6           PANEL MEMBER WILSON: That's it.

7           MR. RHODES: There it is.

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

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

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

14          MR. RHODES: Significantly.

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

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

25          PANEL MEMBER WILSON: Yeah. And then could you

1 say a little bit about how you weighted the census tracts  
2 by population to get a representative sample?

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

9 (Laughter.)

10 PANEL MEMBER WILSON: Fair enough.

11 CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

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

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

19 MS. LAFLAMME: Hi. Good afternoon. My name is  
20 Denise Laflamme. And so we reported back results to  
21 participants with a one-page letter. And we reported back  
22 their total arsenic result for all participants, and we  
23 only reported back high values for those selected metals  
24 that we had comparison values to. So if they were -- if  
25 they had a high cobalt compared to the occupational value,

1 we would report their high cobalt. But if they didn't, we  
2 wouldn't report on cobalt. And then we also reported  
3 their drinking water results, also in the results letter.

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

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

20           One thing that we're looking forward to, and we  
21 were hoping for at the time, was to have the speciated  
22 arsenic results along with the total arsenic results, so  
23 that when people called, we could look to see if they  
24 were -- if their -- our total arsenic level is more  
25 attributed to seafood-related arsenic forms versus, you

1 know, the inorganic arsenic forms. So we've been a little  
2 bit delayed on that analysis. And then also that has made  
3 it a little complicated in speaking to participants when  
4 they have questions.

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

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

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

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

20 Arsenic is a really big issue in our State, not  
21 from just naturally occurring sources. We've had several  
22 industrial smelters in Washington State, and that have --  
23 in the Tacoma area there's the ASARCO Smelters. And  
24 there's one in Tacoma and then also north of Seattle in  
25 the Everett area. And the widespread environmental

1 arsenic contamination has been associated with historic  
2 activities at those smelters.

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

11           MR. RHODES: Thank you. Good job.

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

16           Thank you again.

17           MR. RHODES: Thank you.

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

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

25           As a researcher at the Wadsworth Center, he has

1 developed and improved analytical instrumentation and  
2 methods for the detection of lead in blood, and the  
3 measurement of dioxins and other trace elements and  
4 persistent organic compounds in biological and  
5 environmental samples. He has published over 100 papers  
6 in the field of analytical chemistry, and instrumental  
7 methods of analysis.

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

12 Dr. Aldous.

13 (Thereupon an overhead presentation was  
14 Presented as follows.)

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

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

23 --o0o--

24 DR. ALDOUS: And I just want to show you a little  
25 bit of background as to Wadsworth Center. In case you

1 didn't know, we're the State principal lab in Albany. We  
2 have four areas. The Bigg's Lab is where most of the  
3 environmental chemistry and biomonitoring is taking place.  
4 We also have a Griffin Lab, which used to be called the  
5 State Farm. And the State Farm is where Patrick Parsons  
6 keeps his goats for getting lead intoxicated blood. So we  
7 have the Axelrod Institute and also the Center for Medical  
8 Sciences.

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

12                           --o0o--

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

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

23           We just had an Email from the Commissioner today.  
24 And although right now they are about eight miles apart,  
25 as of today, they're going to be merged into the downtown

1 campus, because of our State's fiscal situation, and also  
2 the reduction in the number of staff in those two areas of  
3 the Health Department.

4 --o0o--

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

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

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

24 --o0o--

25 DR. ALDOUS: It's just some history of

1 biomonitoring at Wadsworth. We applied in 2001 for the  
2 planning grant, which many States and State consortia did,  
3 25 in fact. Only three were awarded in 2003. We were  
4 successful. And although we didn't -- we were not funded  
5 at the level that we expected, we did do some interesting  
6 work in those five years of biomonitoring.

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

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

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

24           And we also started some pilot projects on some  
25 of these analytes, which became more important as we went

1 into this last five-year cooperative agreement. So we  
2 were funded in 2009, one of the three State labs that are  
3 here today.

4 --o0o--

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

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

17 --o0o--

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

25 We also started to work with the city of New

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

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

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

22 Again, a great use of biomonitoring.

23 --o0o--

24 DR. ALDOUS: So these are our current specific  
25 aims, to expand the number of sample -- of analytes that



1 were collected. And couple of things I wanted to point  
2 out about this was these samples were distributed to a  
3 number of labs. Wadsworth had some of them. Some went to  
4 CDC. Some went to another Johns Hopkins and other  
5 universities.

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

13 --o0o--

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

19 Now, some of these people consented to have  
20 additional target compounds analyzed at the time when the  
21 samples were collected. There was some publications there  
22 from those studies that I placed at the bottom. So we  
23 used LC-MS/MS for our serum cotinine. It was a method  
24 that was developed at CDC, and we transferred it. All the  
25 analyses that we intend to do on this archive of samples

1 will be similar to the ones that have use for the national  
2 program, so that we can hopefully compare the data.

3 --o0o--

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

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

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

20 --o0o--

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

23 We want to maintain our trained staff. We want  
24 to hire additional staff. We need access to sensitive  
25 instrumentation. We really need clean rooms. We need

1 biohoods and we need to obviously develop and validate our  
2 methods for those that aren't already in that State.

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

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

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

17                           --o0o--

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

1 sample pre-treatment and preparation of samples.

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

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

12 --o0o--

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

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

25 --o0o--

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

9 --o0o--

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

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

20 --o0o--

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

1 study.

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

4 --o0o--

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

16 --o0o--

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

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

25 --o0o--

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

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

13 --o0o--

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

17 --o0o--

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

23 So this is our current Biomonitoring Program.

24 --o0o--

25 DR. ALDOUS: We're expanding the number of

1 analytes that we will have measured for organic and  
2 inorganic compounds in the New York City HANES. We're  
3 starting to work on depleted uranium. We have that method  
4 in development. We have the methyl mercury method in  
5 development where we're looking for a study of Asian  
6 populations.

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

12                           --o0o--

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

18                           --o0o--

19           DR. ALDOUS: This is our staff. We have six  
20 people paid off the grant. And Dr. Parsons, Dr. Kannan,  
21 and Dr. Jansing are all State employees. We do have some  
22 school of public health students. So I just want to  
23 acknowledge Department of Health and Mental Hygiene from  
24 New York City, our State Center For Environmental Health  
25 and funding assistance from CDC.

1                               --o0o--

2               DR. ALDOUS:   And I want to be sure to mention Dr.  
3 Kannan, who we call Kannan because we can't pronounce his  
4 first name.

5               (Laughter.)

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

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

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

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

19              MS. DUNN:   None.

20              CHAIRPERSON LUDERER:   Thank you.

21              All right. Mr. Davis Baltz from Commonweal.

22              MR. BALTZ:   Davis Baltz, Commonweal.

23              Thank you for those presentations. I actually  
24 just wanted to ask a couple of questions. I noticed in  
25 New York there was no mention of reporting results back to

1 participants. And I wonder if you do that? And if so,  
2 how you've managed that?

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

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

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

22           MR. RHODES: In Washington, we do report the  
23 total arsenic, no matter what. And we've reported all the  
24 six water levels, but we only reported the other metals if  
25 they were outside of the norm. So we didn't want to get

1 anybody scared, by the fact that they're there, because  
2 they're there in everybody. We just wanted to make sure  
3 they knew what we were looking for, and they would get  
4 something back if they needed it.

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

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

20           But you can only go -- either you get legislation  
21 or you get your consent forms worded a certain way or  
22 something like that. There are ways to minimize the  
23 problems, but -- and so we're working on those, especially  
24 as we get into higher -- you know, special populations  
25 that might have a higher level.

1 DR. PARSONS: Good afternoon. My name is Patrick  
2 Parsons. I'm the inorganic half of the team from New  
3 York.

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

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

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

18 But for other things, it's not quite so simple.  
19 So, for example, if we are doing a biomonitoring study and  
20 we're measuring something like maybe the rare earth  
21 elements, we don't know what those numbers mean, because  
22 we have no clinical reference range to interpret them.  
23 And so in a study like that, we would tell people in the  
24 informed consent form, that they would not get those data  
25 back.

1           For the organic analytes, there may be some for  
2 which we have a reference interval. And so they could get  
3 them back. But for others, there may be no information.  
4 It may be that the biomonitoring study is designed to put  
5 a reference range in place. And so in that situation, you  
6 know, in that situation we would tell people that we would  
7 not report the data back.

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

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

15           Dr. Wilson.

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

22           DR. PARSONS: Okay. So in the United States, the  
23 Clinical Laboratory Improvement Amendments of 1988 govern  
24 what clinical labs, whether they are government owned or  
25 commercial laboratories, can report to human subjects.

1           So any human specimen that is tested is covered  
2 under CLIA, with some rare exceptions. And so if you are  
3 going to test a specimen, and you are going to report  
4 those data back to the subject, then you're covered by  
5 CLIA, which means that your laboratory has to be  
6 accredited.

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

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

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

21           CHAIRPERSON LUDERER: Dr. Bradman.

22           PANEL MEMBER BRADMAN: I'm not quite sure if I  
23 have a question or a comment. I do have a question about  
24 depleted uranium. But back to this reporting back issue,  
25 at least in Berkeley, our IRB has taken a different

1 approach. Although this issue is starting to arise, and  
2 they've prevented us from reporting some results back  
3 that -- if you have a research test, you don't necessarily  
4 need to have a clear clinical reference range.

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

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

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

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

24 But I think the thing that gives me most  
25 heartburn when I'm setting up a biomonitoring

1 collaboration is what would happen if I report a result  
2 back through a PI or collaborator to a human subject and  
3 we tell them it's elevated, and then the following week  
4 there is a lawsuit, and I'm dragged into court and I have  
5 to stand up and explain why I did that, was I legally able  
6 to report that result?

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

16           MS. HOOVER: Dr. Luderer.

17           CHAIRPERSON LUDERER: Yes.

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

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

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

24           CHAIRPERSON LUDERER: Dr. Lipsett.

25           DR. LIPSETT: Yeah. Hi. Michael Lipsett,

1 Department of Public Health.

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

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

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

23           CHAIRPERSON LUDERER: Dr. Das.

24           DR. DAS: Rupa Das, California Department of  
25 Public Health. I just wanted to add to what Dr. Lipsett

1 said, and to emphasize that we do not -- for the chemicals  
2 that have no clinical reference values, which are most of  
3 the chemicals that we're measuring, we do not plan to  
4 state that they are elevated, nor do we plan to make any  
5 definitive statements about the health implications of  
6 those levels. Just to put context to what Dr. Lipsett  
7 said.

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

10 Yes, Dr. Das.

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

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

1 reference value.

2 Does that answer your question?

3 PANEL MEMBER WILSON: Yeah. Thank you.

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

6 Okay. No.

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

9 MS. HOOVER: Just one second.

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

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

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

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

21 We were scheduled to have Dr. Tracey Woodruff  
22 present this next presentation. Dr. Woodruff is not able  
23 to be here. Carrie Dickenson will present in her place.  
24 Carrie is a researcher who works with Dr. Woodruff on the  
25 Maternal Infant Environmental Exposures Project. And

1 we'll let her introduce herself.

2 (Thereupon an overhead presentation was  
3 Presented as follows.)

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

11 --o0o--

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

16 --o0o--

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

22 --o0o--

23 MS. DICKENSON: The UCSF study personnel include  
24 Dr. Tracey Woodruff, Dr. Naomi Stotland, who's an OBGYN at  
25 San Francisco General Hospital, and the co-investigator on

1 this study. Jackie Schwartz and myself who are the study  
2 coordinators. Jessica Trowbridge, who's the data manager,  
3 and Cynthia Melgoza Canchola who's the research assistant.

4 --o0o--

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

13 --o0o--

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

23 And then Rachel Morello-Frosch from UC Berkeley,  
24 who I believe has previously presented her part of the  
25 project, developed the report-back materials to

1 understand -- for participants to understand their  
2 chemical biomonitoring results.

3 --o0o--

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

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

18 --o0o--

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

22 --o0o--

23 MS. DICKENSON: So the interview-administered  
24 survey, which took between one and one and a half hours to  
25 administer by the research assistants and happened before

1 the delivery the several different sections included food,  
2 water, and cooking. And some of those questions for that  
3 section would be how many times a day, week, month or year  
4 do you eat red meat, for example.

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

10 We also asked about pesticides. So in the past  
11 30 years, did you or any anyone else in your home use  
12 chemicals or pesticides? We asked about occupation, the  
13 name, hours of work, et cetera, reproductive history,  
14 tooth fillings, and certain demographic questions.

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

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

21 --o0o--

22 MS. DICKENSON: There was also an at-home survey.  
23 And some of the sections were the personal care products,  
24 hair care products, make-up, body or face products,  
25 cleaning products. And then we also asked about the home

1 electronics, the bedroom, et cetera. Some of the typical  
2 questions, you know, is your mattress treated for stain  
3 protection or water resistance? Do you sleep with a  
4 regular foam or memory foam pillow? Do you own any  
5 clothing that is wrinkle resistant or stain resistant?

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

10 --o0o--

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

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

24 So we're looking at newborn care and the  
25 biophysical baseline. So we're collecting all of that

1 information in addition to the interviews in the survey.

2 --o0o--

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

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

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

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

23 And then what would happen after that was that  
24 the nurse practitioners or midwives would then go into one  
25 of the rooms and pick up a maternal blood and an umbilical

1 cord blood collection kit to be used in the delivery room.  
2 And then from there, they would communicate with our  
3 research assistants, who would then collect the specimens,  
4 process them according to Biomonitoring California  
5 instructions, and then we would store them before shipping  
6 them for analysis.

7 --o0o--

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

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

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

24 --o0o--

25 MS. DICKENSON: Here's some of our recruitment

1 statistics. Recruitment started in July 2010, and ended  
2 in June 2011. There are approximately five participants  
3 recruited each week. In total, we enrolled 92  
4 participants. Approximately 65 percent of our eligible  
5 participants were approached by the study team. Around 50  
6 percent have approached participants in enrolled.

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

12 --o0o--

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

17 And then some reasons that we've also included  
18 here for the missed collection, is that women were -- they  
19 delivered before they were actually able to have the  
20 interview and collect the urine. And then they delivered  
21 before they were able to see their charts or before the  
22 nurse practitioners realized that they were part of the  
23 study. There was some, you know, miscommunication  
24 happening there, so the blood was missed, or there was an  
25 emergency or a scheduled C-section, so the cord blood was

1 not obtained.

2 --o0o--

3 MS. DICKENSON: So some of the preliminary  
4 results that we've received so far is that the -- all of  
5 the blood lead levels were reported to the San Francisco  
6 Department of Public Health for any additional follow up.  
7 And Karen Cohn really was instrumental in helping reaching  
8 out to our participants. And she sent them a letter,  
9 which offered a voluntary home assessment, and brochure.

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

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

20 --o0o--

21 MS. DICKENSON: So the next steps for the project  
22 are the data validation and analysis, which we're working  
23 on with Biomonitoring California, and then presenting and  
24 publishing the results from the study.

25 --o0o--

1 MS. DICKENSON: And I'd just like to acknowledge  
2 the California Wellness Foundation, the CDC, and Louise  
3 Dimattio and Ocean Berg who are the nurse managers in  
4 labor and delivery. Kathleen Flanagan and all of the 5M  
5 and 6C clinic staff at San Francisco General Hospital.

6 Thank you.

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

10 Dr. Solomon.

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

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

1 have had -- you know, received anything from the hospital  
2 itself.

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

8 CHAIRPERSON LUDERER: Any other questions from  
9 Panel members?

10 Do we have any public comments?

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

13 CHAIRPERSON LUDERER: Okay. Thank you very much.

14 MS. DICKENSON: Thank you.

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

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

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

25 MS. DUNN: And just to remind people, some of the

1 mics might be live during the break, so if you're having a  
2 private conversation, move away from the microphones.

3 (Thereupon a recess was taken.)

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

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

14 (Thereupon an overhead presentation was  
15 Presented as follows.)

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

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

25 --o0o--

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

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

11 --o0o--

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

17 Now, actually in this particular case, the  
18 firefighters were not actual participants of the study.  
19 There were two, but most of them -- the remaining  
20 participants were not actual participants in this study.  
21 In the overall FOX study, they were just participants in  
22 the usability testing. So this usability testing is an  
23 iterative process that allows us to improve upon the  
24 drafts we have prepared. So after we interview the  
25 participants, we improve the materials and then go back

1 for another round of interviewing, so that we can quickly  
2 identify confusing and difficult concepts.

3 --o0o--

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

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

11 --o0o--

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

18 --o0o--

19 MS. MAYENO: So this next slide shows how the FOX  
20 materials have gone through quite a process of  
21 development. It actually started in -- woops. It started  
22 in 2009, in January of 2009, when we started discussions  
23 about the Maternal Infant Environmental Exposure Project  
24 materials to return results. And then by 2011, February  
25 2011, Health Research for Action with Holly Brown-Williams

1 as well as Rachel Morello-Frosch -- Dr. Rachel  
2 Morello-Frosch had conducted usability testing for the  
3 Maternal Infant Environmental Exposures Project.

4           Woops. There we go.

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

9                           --o0o--

10           MS. MAYENO: So the usability testing recruitment  
11 was done at the firefighter's wellness and fitness  
12 appointments, as well as at the fire stations. There were  
13 17 male firefighters that participated in all the  
14 interviews out of 19 that we had invited to participate.  
15 The two that didn't participate were -- just had other  
16 appointments and couldn't stay for the interviews.

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

20                           --o0o--

21           MS. MAYENO: So for this -- the usability testing  
22 we did was on the first set of chemicals we're planning to  
23 report back on in this first phase. Later we'll be  
24 reporting on the other chemicals that we have -- we've  
25 been testing for in the FOX population.

1           So we are -- we prepared materials on the four  
2 metals in blood cadmium, lead, manganese, mercury, and the  
3 12 perfluoro-chemicals in blood.

4                           --o0o--

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

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

19                           --o0o--

20           MS. MAYENO: So this is an example of the text  
21 version of the results. We had -- we prepared text --  
22 like the MIEEP study, we prepared text and graphic  
23 versions of the results. And here you can see the --  
24 basically, it was all text. And then we also showed them  
25 a version that had a table added to the text.



1 participant. Of course, these aren't real results, but  
2 these are mock results that we had shared with them.

3 And they had absolutely no trouble understanding  
4 these results or interpreting -- and they also liked them  
5 a lot better. They preferred them over the circle graphs  
6 that we showed you previously.

7 --o0o--

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

19 --o0o--

20 MS. MAYENO: And this is what we have.  
21 Basically, it's still being formatted, but these are  
22 basically the graphs we chose for the -- to use for the  
23 returning the results to the FOX participants. So in the  
24 upper left-hand corner, you can see it's similar  
25 information that the other graphs gave. It compares their

1 result to the national median and to a level of concern  
2 where we had one.

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

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

16   --o0o--

17           MS. MAYENO: Another thing that we shared with  
18 them was the fact sheet. So as you remember hearing about  
19 probably in the March SGP meeting, where Rachel  
20 Morello-Frosch and Holly Williams-Brown had presented  
21 about the MIEEP materials, they developed some beautiful  
22 materials that included fact sheets for each chemical.  
23 And we -- the firefighters very much liked the fact  
24 sheets. And we also developed more of them under the  
25 guidance of OEHHA, more fact sheets on the

1 perfluoro-chemicals that we didn't have previously;  
2 manganese and mercury that we didn't have previously. So  
3 now we have all of those fact sheets.

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

10                   --o0o--

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

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

19                   --o0o--

20           DR. McNEEL: Thank you, Amiko.

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

1 we could not tell them the health relevance of their  
2 results.

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

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

10                   --o0o--

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

20                   --o0o--

21           DR. McNEEL: So in response to the firefighters'  
22 concerns, we did take a look at the kinds of things that  
23 they were interested in. And we wound up developing a new  
24 fact sheet that will be included in the participant's  
25 results package. And this is a short document that goes

1 into greater detail about why we did choose to look at  
2 firefighters in this particular study, including the fact  
3 that firefighters have a good potential for increased  
4 exposure to environmental chemicals as a direct result of  
5 their jobs, and also that there are only a few studies  
6 that have looked at firefighter exposure to these  
7 chemicals. And in addition, that their participation will  
8 contribute to a Statewide database that we are in the  
9 process of building.

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

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

19 --o0o--

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

25 And we're currently analyzing data from the

1 firefighter exposure questionnaires and the fire station  
2 checklist that will help us answer hopefully some of the  
3 questions that we've received.

4 --o0o--

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

19 --o0o--

20 DR. McNEEL: Our next steps for the FOX project  
21 are to get approval from our two institutional review  
22 boards to actually distribute these finalized documents to  
23 our participants. And then once we have approval for the  
24 document templates, we'll merge the data from our  
25 databases onto the specific documents for results return,



1 understandable way to our participants.

2 --o0o--

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

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

8 Dr. Culver.

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

11 DR. McNEEL: Yes.

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

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

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

24 That level of concern was chosen based on  
25 consultation with the Occupational Health Branch. That is

1 the lead level at which the Occupational Health Branch  
2 would -- has decided they would send a letter to working  
3 people to let them know about the services that they  
4 provide, and, if necessary, would do follow-up looking at  
5 their place of work as a potential source of exposure.

6 PANEL MEMBER CULVER: Has that been published?

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

9 PANEL MEMBER CULVER: That level of --

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

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

16 DR. DAS: Yes.

17 PANEL MEMBER CULVER: Okay. Thank you.

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

1 in the future.

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

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

20 CHAIRPERSON LUDERER: I mean one thought that  
21 does come to mind is, which obviously would add a whole  
22 additional layer of complexity, would be to have  
23 participant reports be individualized, you know, for  
24 individuals -- you know, basically the format that would  
25 make the most sense to them.

1 I mean, I know that's -- would, as I said, make  
2 things much more complicated, but it does, you know, sort  
3 of down the road in thinking about how participant report  
4 back might evolve, it does kind of lead you to think that  
5 maybe is a direction that one needs to go.

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

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

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

22 CHAIRPERSON LUDERER: Any other discussion,  
23 questions, comments?

24 Dr. Das.

25 DR. DAS: Rupa Das, California Department of

1 Public Health. I actually wanted to add something to my  
2 response to Dr. Culver. Your question was the level of  
3 concern 10 chosen with the age and gender in mind. And  
4 the level of concern was chosen with the age and gender in  
5 mind. It is a level of concern we are using for FOX,  
6 because we chose this as an occupational cohort, and  
7 that -- and the answer I gave before is correct that the  
8 Occupational Health Branch has chosen that level to use as  
9 the threshold for sending a letter.

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

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

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

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

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

25           DR. DAS: If they were women of reproductive age,

1 we might choose a lower level of concern. Our population,  
2 as I said, two out of the 101 were women in this case.

3 CHAIRPERSON LUDERER: Dr. Wilson.

4 PANEL MEMBER WILSON: Yeah. Thank you, Chair.  
5 Mike Wilson.

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

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

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

20 PANEL MEMBER WILSON: Yeah. And so in looking at  
21 the fact sheet that you put up, it was -- those sources  
22 were primarily home -- looked like home-based and sort of  
23 consumer product sources.

24 DR. McNEEL: Right, yes.

25 PANEL MEMBER WILSON: You know -- and, of course,

1 my concern on the metals, particularly the lead, would be  
2 the occupational exposure is occurring during overhaul,  
3 when there's no respiratory protection being used, and,  
4 you know, at least in, you know, residential structure  
5 fires. And so, you know, and -- but I'd be happy to talk  
6 with you, you know, in some more detail about that. And  
7 that there may be specific recommendations that could be  
8 made with that particular work practice.

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

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

17           In response to your first comment, we are trying  
18 to collect some data about timeframes during which  
19 firefighters may not be wearing their respiratory  
20 protection during overhaul. This is a pilot. So  
21 we'll -- if anything, we may generate some hypotheses, but  
22 we'll have to look at the data that comes back from --  
23 particularly from our metals analyses and see if there's  
24 something more we need to look into there. But, yes,  
25 that's certainly a concern.

1 PANEL MEMBER WILSON: Yeah. Thank you, Sandy.

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

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

13 PANEL MEMBER WILSON: Exactly. Okay. Yeah.  
14 Thank you.

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

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

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

23 All right. Thank you very much.

24 Sara.

25 MS. HOOVER: I thought since we have a little

1 time, I'll go ahead and add some more about our research  
2 for the fact sheets in response to Dr. Wilson's comment.  
3 So we actually did a lot of research trying to look  
4 specifically at firefighter exposure for all of these.  
5 And we did a lot of work with Amiko, with the Occupational  
6 Lead Branch, looking at, again, the potential for  
7 firefighter exposure.

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

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

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

1 PANEL MEMBER WILSON: Great.

2 CHAIRPERSON LUDERER: Thank you.

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

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

8 CHAIRPERSON LUDERER: Thank you.

9 Is there any additional discussion from among the  
10 Panel members?

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

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

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

25 And then we're going to be determining where to

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

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

9 And that next meeting is going to be on March  
10 15th.

11 MS. HOOVER: 16th.

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

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

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

21 Thank you.

22 (Thereupon the California Environmental  
23 Contaminant Biomonitoring Program, Scientific  
24 Guidance Panel meeting adjourned at 4:01 p.m.)

25

