

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

JOE SERNA, JR., Cal/EPA HEADQUARTERS BUILDING  
1001 I STREET  
SIERRA HEARING ROOM  
SACRAMENTO, CALIFORNIA

TUESDAY, OCTOBER 6, 2009  
10:00 A.M.

JAMES F. PETERS, CSR, RPR  
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APPEARANCES

PANEL MEMBERS

Dr. Ulricke Luderer, Acting Chairperson

Dr. Asa Bradman

Dr. Dwight Culver

Dr. Marion Kavanaugh-Lynch

Dr. Thomas McKone

Dr. Julia Quint

Dr. Gina Solomon

Dr. Michael P. Wilson

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Dr. Joan Denton, Director

Ms. Carol Monahan-Cummings, Chief Counsel

Mr. Allan Hirsch, Chief Deputy Director

Dr. George Alexeeff, Deputy Director, Scientific Affairs

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

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

Ms. Fran Kammerer, Staff Counsel

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

Dr. Rachel Roisman, Public Health Medical Officer, Safer Alternatives Assessment and Biomonitoring Section

APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Dr. Michael Lipsett, Chief, Environmental Health  
Investigations Branch

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

Ms. Diana Lee, Research Scientist

Dr. Sandy McNeel

Dr. Jianwen She, Chief, Biochemistry Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Mr. Davis Baltz, Commonweal

Dr. Stephen Van Den Eeden, Kaiser Permanente, Research  
Program on Genes, Environment, and Health

Dr. Tracey Woodruff, University of California, San  
Francisco, Program on Reproductive Health and the  
Environment

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1 of California, Irvine, Occupational and Environmental  
2 Medicine.

3 PANEL MEMBER BRADMAN: Asa Bradman at the  
4 University of California at Berkeley at the Center for  
5 Children's Environmental Health Research.

6 PANEL MEMBER QUINT: Julia Quint, retired,  
7 California Department of Public Health.

8 OEHHA DIRECTOR DENTON: Well, thank you members  
9 of the Panel, members of the audience, those of you on the  
10 webcast. This is the meeting of the Science Guidance  
11 Panel for the California Environmental Contaminant  
12 Biomonitoring Program.

13 Just a few announcements on the logistics and  
14 then what's the plan for the meeting today. And then I'll  
15 be turning it over to the other speakers.

16 So just an announcement on logistics. If this  
17 the first time that you're in this room, the emergency  
18 exit is right down the stairway that you I'm sure noticed  
19 or came up as you entered the room, which is right  
20 outside. So if there's an emergency alarm then we'll just  
21 go down those stairs and out the building.

22 The restrooms. There is a set of restrooms on  
23 the right -- on my right over there by the elevators, as  
24 well as over on the left. If you go clear to the end past  
25 the hearing rooms, there's also another set of restrooms

1 over there.

2           So I mentioned it, but I want to remind everyone  
3 that the meeting is being webcast and also transcribed.  
4 And there will be a record and there will be the  
5 transcript of the meeting posted on the Internet in a few  
6 weeks.

7           Also, for those of you in the room who will be  
8 speaking, we'd like to ask you to speak directly into the  
9 microphones, so that both our reporter, as well as those  
10 on the webcast can hear what's being said.

11           So just to give you an overview of where we are  
12 in this process, the Panel met on July 28th and 29th in  
13 Oakland. And the focus of that meeting last summer was on  
14 chemical selection, laboratory capacity, and communicating  
15 biomonitoring results.

16           So today -- what's going to happen today, we'll  
17 give you a preview of the meeting. There are actually  
18 four things that we're looking and we'll be discussing  
19 with the Panel today. First of all, we'll be updating the  
20 panel, as well as the public on program activities of the  
21 Biomonitoring Program.

22           Secondly, we're going to be discussing priority  
23 chemicals that have been selected and also soliciting  
24 recommendations from the Panel on them.

25           The third is that we want to update you on the

1 collaborative projects with other organizations that we've  
2 been engaged with.

3           And then finally, we want to obtain the Panel's  
4 recommendations on future directions of the program.

5           And throughout these discussions, as laid out in  
6 the agenda, there will be opportunities for both panel  
7 discussion and questions as well as public input.

8           Now that takes care of my official remarks. And  
9 while I was making them Dr. Solomon entered the. So Dr.  
10 Solomon, we went through and introduced ourselves. So  
11 would you like to just introduce yourself.

12           PANEL MEMBER SOLOMON: Yes. I'm Gina Solomon  
13 with the Natural Resources Defense Council and the  
14 University of California at San Francisco.

15           OEHHA DIRECTOR DENTON: Okay, so that rounds  
16 out -- so all of the members of the Panel are now present.

17           Now, before I turn it over to the Chair -- well,  
18 I should say Dr. Moreno is ill today, so we don't have Dr.  
19 Moreno here. But Dr. Ulricke is going to -- has  
20 graciously accepted the charge of sitting in for him today  
21 in that capacity. So before I turn it over to her, I know  
22 that Sara has a brief announcement that she would like to  
23 make and then we'll turn it over to Dr. Luderer.

24           MS. HOOVER: Hi there. My name is Sara Hoover  
25 and I'm the Chief of the Safer Alternatives Assessment and

1 Biomonitoring Section of OEHHA.

2           And I have some bad news and some good news. And  
3 the bad news is, is that Dr. Rachel Roisman is going to be  
4 leaving the Program. Today is her last day with the  
5 Biomonitoring Program at OEHHA.

6           The good news is, is that she's actually joining  
7 the Department of Public Health, so we'll still be seeing  
8 her around. She's going to be a public health medical  
9 officer in the Occupational Health Surveillance and  
10 Evaluation Program. And that's kind of her real career  
11 choice is occupational health. So she's very excited  
12 about this opportunity.

13           She's going to be working on general occupational  
14 health surveillance and pesticide related illnesses, as  
15 well as some of emergency preparedness.

16           So I just want to really thank Rachel for all the  
17 excellent work she's given us over the past year and a  
18 half. And we look forward to working with her in her new  
19 role. So I just want to let you know that any questions  
20 you would normally direct to Rachel, if you could just  
21 direct them to me, and I'll be leading the Program for  
22 now.

23           So thanks, Rachel.

24           (Applause.)

25           ACTING CHAIRPERSON LUDERER: Thank you, Dr.

1 Denton and Sara.

2 No, it was on.

3 I'd like to welcome everyone, all the Panel  
4 members, everyone in the room and all the people attending  
5 via the webcast as well. And I'm just going to briefly  
6 give some additional information about the Panel goals and  
7 how we'll be handling public comments today.

8 So as Dr. Denton already outlined, the goals for  
9 the meeting for the panel today are to provide  
10 recommendations to the California Environmental  
11 Contaminant Biomonitoring Program on priority chemicals;  
12 to provide feedback on collaborative projects with other  
13 organizations; and to provide recommendations on future  
14 directions for the CECBP.

15 So each of the presentations on these topics will  
16 be followed by time for Panel questions, as well as a  
17 public comment period, and then time for further Panel  
18 discussion and recommendations.

19 And we ask that if you're a member of the public  
20 who would like to make a comment, that you should fill out  
21 a public comment card, which can be obtained at the staff  
22 table outside the room. And you can turn the cards in to  
23 Rebecca Chung who is just raising her hand there on my  
24 right.

25 If you are listening via webcast and you would

1 like to submit comments, you can send an Email to the  
2 Biomonitoring Email address, which is  
3 biomonitoring@oehha.ca.gov during the meeting -- and  
4 biomonitoring is one word -- and the CECBP staff will  
5 provide the comments to me and then I will be able to read  
6 them aloud at the appropriate time.

7           To ensure that the meeting proceeds on schedule  
8 and that all commenters have the opportunity to speak, we  
9 are going to time the public comments for each of the  
10 comment periods. And the time that we'll allot for each  
11 individual to speak will be equally -- we'll divide that  
12 comment period equally among the individuals. We also ask  
13 that the individuals who want to comment would please keep  
14 their comments focused on the agenda topic that is being  
15 discussed at that time.

16           Finally, I want to remind everyone, including  
17 myself --

18           (Laughter.)

19           ACTING CHAIRPERSON LUDERER: -- to speak directly  
20 into the microphone and to introduce yourself please  
21 before speaking.

22           And this is for the benefit of the people  
23 listening on the webcast as well, and also for the  
24 transcriber.

25           So the meeting materials that were provided to

1 the Panel members today are also available as handouts,  
2 and they're also on the website for the public to access.

3 And finally, we will take two breaks today, one  
4 in the morning. We'll take one for lunch around 12:30 and  
5 one in the afternoon. That's actually three breaks.

6 And finally, I'd like to introduce Dr. Rupali  
7 Das, the Chief of the Exposure Assessment Section at the  
8 California Department of Public Health, and lead of the  
9 California Environmental Contaminant Biomonitoring  
10 Program, who will talk about program advances.

11 Dr. Das.

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

14 DR. DAS: Good morning, Panel members and members  
15 of the audience and those who are attending via webcast.

16 Thank you for your introduction.

17 I'll be providing you an update on the activities  
18 of the California Environmental Contaminant Biomonitoring  
19 Program or CECBP.

20 --o0o--

21 DR. DAS: So the topics that I'll be talking  
22 about today is to introduce to you some new staff on our  
23 Program, to give you an update on the funding status for  
24 the Program, to talk about the CDC cooperative agreement,  
25 and to talk about other Program activities as well.

1                   --o0o--

2                   DR. DAS:  So I have the pleasure of introducing  
3 three new staff who actually all started yesterday just in  
4 time for this meeting.

5                   The first person is Ngozi Erundu.  She is a CDC  
6 Public Health Prevention Specialist.

7                   Ngozi, if you would stand.

8                   Thank you.

9                   Ngozi recently arrived from Atlanta to begin a  
10 two-year assignment with the Department of Public Health  
11 as a Public Health Prevention Specialist.  She's an  
12 epidemiologist and will be working primarily with a number  
13 of the field investigations that we have planned for the  
14 Biomonitoring Program.

15                   Robin Christensen has been hired as a Project  
16 Coordinator for the CDC Cooperative Agreement, which I  
17 will be speaking about.  She will be provide  
18 administrative and programmatic support for the labs and  
19 field activity.  Robin has an MPH from Harvard, and her  
20 interest lies in programmatic approaches to improving  
21 community health at the local level.

22                   Most recently she managed a project that worked  
23 to increase the capacity of California's domestic violence  
24 shelter programs to respond to and serve families with  
25 disabilities.

1 Thank you, Robin.

2 Rebecca Chung has been hired as a field  
3 investigations coordinator also for the CDC cooperative  
4 agreement.

5 She will help to facilitate and manage some of  
6 the biomonitoring field investigations and results  
7 communication activities.

8 Rebecca has an MPH in Health Promotion and Health  
9 Behavior from Portland State University. Her recent work  
10 experience includes developing built environment  
11 indicators for Oregon's Environmental Public Health  
12 Tracking Program and working with the Oregon Environmental  
13 Council's Eco Health Child Care Program to develop  
14 educational materials for the general public.

15 So please join me in welcoming our three new  
16 staff.

17 (Applause.)

18 --o0o--

19 DR. DAS: I'd now like to provide you an update  
20 of the funding status for our Program.

21 The budget for 2009/2010 fiscal year remains at  
22 baseline level. This is 1.9 million that comes from the  
23 Toxic Substances Control Account that's administered by  
24 DTSC or the Department of Toxic Substances Control. And  
25 that funding goes to the three departments under the

1 program, Department of Public Health, OEHHA, and DTSC.

2 The funding is stable for at least the next  
3 fiscal year. Our funding -- our State positions are all  
4 filled. That's 13 State positions that are funded through  
5 these TSCA funds. We're also fortunate to have in-kind  
6 contributions, the equivalent of four State FTE, who are  
7 not specifically funded through these funds, but provide  
8 in-kind support; and several fellows, including a Fellow  
9 from the Association of Public Health Labs, a Fellow from  
10 the Council of State and Territorial Epidemiologists or  
11 CSTE, and Ngozi, who's a CDC Public Health Prevention  
12 Specialist.

13 As you know, we have mandatory furloughs at the  
14 State, and there have been some workload adjustments, not  
15 affecting the people who have been hired through the CDC  
16 cooperative agreement.

17 --o0o--

18 DR. DAS: As most of you may have heard, CDC  
19 awarded our Program a five year cooperative agreement.  
20 This was a very competitive process with many of the  
21 states applying. There were three states funded  
22 California, New York, and Washington. Of the five million  
23 available for this grant, California is receiving 2.6  
24 million for the first year. And funding for the  
25 subsequent years, it will be subject to progress and



1 about this later. And finally, to engage and collaborate  
2 with stakeholders and communities. And I'll talk in a  
3 little bit more detail about each these objectives. The  
4 first two, first.

5 --o0o--

6 DR. DAS: Ninety percent of the funding that we  
7 received from the CDC will go to support lab activities,  
8 that is staff and equipment. That translates to about  
9 1.25 million going to the labs. The remaining balance,  
10 about 10 percent of the funding, will help with biosample  
11 collection for targeted exposure investigations and public  
12 outreach and participation related to these  
13 investigations.

14 We plan to hire seven staff into the labs. And  
15 the labs are actively recruiting currently. This will  
16 include a staff program or analyst to expand the  
17 Laboratory Information Management System or LIMS; a  
18 Quality Assurance Officer to enhance the lab QA/QC  
19 measures; and a Sample Management Officer to handle sample  
20 handling and tracking.

21 These three positions will eventually be shared  
22 between the two labs, the Department of Public Health and  
23 the DTSC.

24 In addition, the CDPH labs will hire four staff  
25 the first year to develop methods and increase through-put

1 for inorganic and nonpersistent organic chemicals.

2 We expect that the DTSC lab will be CLIA  
3 certified, as California -- sorry Clinical Licensing  
4 Assessment, a certification that's required of labs and  
5 that was required under the CDC cooperative agreement. We  
6 expect that the DTSC lab will be CLIA certified by year  
7 two of the cooperative agreement. This will enable them  
8 to use the resources that we obtain through the CDC grant  
9 and to hire contract staff and purchase equipment.

10 The laboratory staff will be trained by CDC. And  
11 this is a requirement of the cooperative agreement as  
12 well.

13 --o0o--

14 DR. DAS: The CDPH labs will specifically focus  
15 its methods and through-put on chemicals or classes of  
16 chemicals shown on this slide. This list is consistent  
17 with the priority list of chemicals recommended by the  
18 Panel: Metals in blood and urine, perchlorate,  
19 organophosphate pesticides, pyrethroid pesticides,  
20 Bisphenol A, phthalates and polyaromatic hydrocarbons.

21 --o0o--

22 DR. DAS: The CDPH lab plans to do over 8,000  
23 assays by the end of year five of the cooperative  
24 agreement. The DTSC lab is, as I mentioned, seeking CLIA  
25 certification, which is a requirement of the cooperative

1 agreement and plans to do analyses of polybrominated  
2 diphenyl ethers or PBDEs, other brominated and chlorinated  
3 flame retardants, perfluorinated chemicals,  
4 cyclosiloxanes, and other chemicals that will remain to be  
5 determined.

6           As you can see on the slide, some of the methods  
7 that this lab will use are being developed or are yet to  
8 be developed.

9           And DTSC labs plan to conduct over 5,000 assays  
10 for these persistent chemicals in serum by the end of year  
11 five of the cooperative agreement.

12           Are there any questions that pertain to anything  
13 I've spoken about, the lab components or the CDC  
14 biomonitoring cooperative agreement?

15           ACTING CHAIRPERSON LUDERER: Dr. McKone.

16           PANEL MEMBER MCKONE: I think just a comment.  
17 And I think we all feel this way. This is really good  
18 news to get the money from the CDC. When I saw that  
19 announced, I went yes.

20           (Laughter.)

21           DR. DAS: Thank you.

22           PANEL MEMBER MCKONE: You know, just like, now  
23 you've got some lab. So I think the whole Panel here  
24 really feels that that was quite an achievement and you  
25 should be congratulated.

1 DR. DAS: That was a joint effort of the whole  
2 Biomonitoring Program, so the kudos should be shared by  
3 all the staff.

4 Thank you.

5 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

6 PANEL MEMBER SOLOMON: Just to clarify. So the  
7 8,000 chemicals by the end of the five years is  
8 basically -- it's not 8,000 per year. So it would be say  
9 roughly 2,000 a year after year one kind of rate of  
10 through-put, is what the labs are aiming at?

11 DR. DAS: We have lab staff. Dr. She would you  
12 like to answer that question.

13 DR. SHE: I think that you are right. The lab  
14 capacity I hope we can handle almost 2,000 samples per  
15 year.

16 DR. DAS: Dr. Roisman is actually going to be  
17 describing the lab analyses in some detail during her  
18 presentation. So I think your question will be answered  
19 in more detail in the next presentation.

20 Dr. Culver.

21 PANEL MEMBER CULVER: As you ramp up your  
22 laboratory capacity, what are your plans for biospecimen  
23 storage?

24 DR. DAS: Yes. The biospecimens will be stored.  
25 Dr. She, would you like to answer that one also.

1 DR. SHE: Currently, CDPH lab already have  
2 freezer farm. We have five deep freezers, which kind of  
3 store all of the samples for a few years, at least the  
4 capacity we already have.

5 So we will use this grant to try to expand it a  
6 little bit, maybe buy two deep freezers to handle this  
7 current capacity. So the samples we store in the CDPH  
8 lab, and then we will transfer to the DTSC lab in the  
9 future.

10 ACTING CHAIRPERSON LUDERER: Dr. Quint.

11 PANEL MEMBER QUINT: Julia Quint.

12 Were the specific chemicals specified during the  
13 whole grant period, or I guess what I'm asking, is there  
14 any flexibility with regard to which chemicals we pursue?

15 DR. DAS: Yes, absolutely. The chemicals were  
16 not specified in the CDC cooperative agreement, and so we  
17 have flexibility. And we hope that the Panel will provide  
18 us some guidance on which chemicals to pursue. And I  
19 think we'll be discussing that today.

20 ACTING CHAIRPERSON LUDERER: Thank you.

21 DR. DAS: Okay.

22 --o0o--

23 DR. DAS: So now on to Objective 3.

24 Objective 3 addresses the lab support for  
25 specific field investigations that will allow the Program

1 to assess and track trends for selected chemicals among  
2 targeted populations. And we'll primarily focus on three  
3 specific collaborations.

4 --o0o--

5 DR. DAS: This describes the first collaboration  
6 with the Environmental Health Tracking Program. The CDC  
7 RFA specifically indicated that collaboration with the  
8 Tracking Program should be part of the proposal.

9 And currently, we're collaborating with the  
10 Tracking Program on two existing projects. The first is  
11 in Tulare county, and the second is in Imperial county.  
12 And I described this during the last scientific guidance  
13 panel meeting.

14 For the Tulare county project, we will be  
15 analyzing metabolites, chlorpyrifos and others that are  
16 non-specific metabolites that are yet to be determined.

17 For the Imperial county project, we will be  
18 storing split urine samples that will be analyzed both by  
19 our labs as well as CDC labs for perchlorate and metals in  
20 urine. And we hope to develop the capacity to analyze  
21 split samples with an expedited timeline.

22 In addition, we hope that we will develop  
23 additional collaborations with the Tracking Program over  
24 the years of the cooperative agreement.

25 --o0o--

1 DR. DAS: Our second collaboration is with  
2 CYGNET, the Cohort of Young Girls' Nutrition, Environment,  
3 and Transitions.

4 At the last meeting, one of our presenters for  
5 the results communication panel, Holly Brown-Williams,  
6 described the CYGNET study being carried out by Dr. Larry  
7 Kushi at Kaiser and others.

8 And just to refresh your memory, this study  
9 primarily looks at the role of environmental genetic and  
10 other factors following a cohort of over 400 girls between  
11 the ages of six to eight years, who received care at  
12 Kaiser clinics in Oakland, San Francisco, and San Rafael.

13 CYGNET researchers collected and stored baseline  
14 blood and urine samples in 2005. CDC labs have already  
15 analyzed serum for some analytes, but the urine has not  
16 yet been analyzed.

17 The CYGNET researchers indicated their  
18 willingness to provide the stored samples to the  
19 Biomonitoring Program. And so the CDPH lab will be able  
20 to analyze these stored samples for metals and  
21 organophosphate pesticides to provide descriptive  
22 information about exposures experienced by pre-adolescent  
23 girls in the study population.

24 Urine samples collected yearly from 2005 to the  
25 present can also be analyzed for some analytes to look at

1 the trends over those years.

2           The Biomonitoring Program will be working on a  
3 Memorandum of Agreement with CYGNET principal  
4 investigators in the near future.

5           (Thereupon the Chairperson of the State  
6 Water Resources Control Board entered  
7 the room.)

8           OEHHA DIRECTOR DENTON: To my left is Charles  
9 Hoppin who is the Chair of the State Water Board. And he  
10 is saying that everything we're saying is being heard over  
11 in the next room, apparently through some kind of  
12 technical thing. So is there anybody that's -- do we have  
13 a technical person here

14           MS. HOOVER: I'll have to call.

15           OEHHA DIRECTOR DENTON: We'll have to call them.

16           SWRCB CHAIRPERSON HOPPIN: Thank you.

17           OEHHA DIRECTOR DENTON: How have you found it  
18 interesting.

19           (Laughter.)

20           SWRCB CHAIRPERSON HOPPIN: I have a very short  
21 attention span. I have a hard time talking to one person,  
22 let alone talking to someone and listening. It's like  
23 being at a family reunion.

24           (Laughter.)

25           ACTING CHAIRPERSON LUDERER: I think we should

1 just continue.

2 PANEL MEMBER MCKONE: Perhaps we could just work  
3 with out mikes?

4 MS. HOOVER: No, because of the webcast.

5 ACTING CHAIRPERSON LUDERER: We could take a  
6 break now.

7 Do we have any idea how quickly we can get the --

8 MS. HOOVER: Yeah, how about a five minute break  
9 say.

10 ACTING CHAIRPERSON LUDERER: Okay, five minutes  
11 then. So we'll reconvene at 10:40.

12 (Thereupon a recess was taken.)

13 ACTING CHAIRPERSON LUDERER: Can everyone please  
14 take your seats, so that we can reconvene.

15 Dr. Das, would you like to continue your  
16 presentation.

17 DR. DAS: I'm going to continue with my  
18 presentation. To just remind you, I was talking about  
19 Objective 3, which addresses lab support for specific  
20 field investigations.

21 The third support -- third project for which the  
22 CDC's cooperative agreement will provide support is the  
23 Maternal and Infant Environmental Exposure Project, which  
24 you will hear about more this afternoon. The CDC  
25 cooperative agreement includes resources for a subcontract



1 Francisco General, as well as the others, if the deep  
2 storage will -- what's the time period that those would be  
3 allowed to be preserved under the storage conditions.

4 DR. SHE: Deep storage, I mean, is minus 70  
5 degrees. So within this group of chemicals, may be easy  
6 to compose once it's possible like hydroxy-PAH, these  
7 groups. And CDC thinks that can be started at least even  
8 in the extract -- after extracted from the urine or stored  
9 for up to 18 months at least, for the chemical forms.

10 So that's why it always varied. I don't find  
11 that it's agreed how long that can be stored, so that's  
12 something we still need to locate above 18 months. So at  
13 least 18 months for some usually decomposed chemicals.

14 PANEL MEMBER WILSON: If I can follow up. It's  
15 possible to store these samples for much longer, isn't  
16 that right?

17 DR. SHE: I mean after you extract it in the  
18 chemical form it's 18 months. If we use the original  
19 sample in the urine, it can be reserved much longer, but  
20 for how long I do not have the definite answer.

21 PANEL MEMBER WILSON: And what of whole blood or  
22 plasma, is that -- is it possible to store those samples  
23 for a longer period of time?

24 DR. SHE: I do not have that -- Myrto, you want  
25 to answer.

1 DR. PETREAS: Good morning. Myrto Petreas, DTSC.  
2 Serum, I can talk about serum. Once it's  
3 separated, it can be stored really for many, many years  
4 from what others have done. What we usually do, we also  
5 measure lipids, because the lipids may change more than  
6 some of the chemicals. These are very persistent  
7 chemicals that we'll be looking for. So it's more concern  
8 about the lipids changing. So that's an indicator.

9 And I assume with urine samples, creatinine or  
10 specific other things are going to be tested to ascertain  
11 that there was no significant physical change to the  
12 samples. And I believe whole blood can be stored. Plasma  
13 as a problem, but we're not dealing with plasma here.  
14 Plasma can be stored, but it can be thawed more than once  
15 or twice, because it does give problems to the analysis.

16 So I don't think we'll have any problems with  
17 whole blood or with serum for at least five to ten years.  
18 And that's how long people have gone back without finding  
19 any problems.

20 PANEL MEMBER BRADMAN: It also depends a little  
21 bit on what your target analytes are. Obviously, metals  
22 can store indefinitely. Some of the less persistent  
23 chemicals like pesticides, there actually have not been  
24 too many dissipation studies of how well things store.  
25 And then there also can be issues if you have a sample and

1 you thought it and take an aliquot for analysis and then  
2 refreeze it. And then some years later you take another  
3 aliquot, then the sample going through the freeze-thaw  
4 process could affect the target analyte.

5 DR. PETREAS: Well, the plan would be to have  
6 small aliquots, so you don't thaw the sample more than  
7 once or twice.

8 PANEL MEMBER BRADMAN: Right. That's ideal

9 DR. PETREAS: And also contaminate by dipping  
10 your pipette.

11 ACTING CHAIRPERSON LUDERER: Any more questions  
12 from Panel members?

13 Dr. Culver.

14 PANEL MEMBER CULVER: It seems to me that  
15 decisions about storage should be made now. And planning  
16 for the facility in which to store those should be planned  
17 for now. Is that underway?

18 DR. DAS: Yes, the planning is underway. And  
19 actually one of the lab staff that are to be hired, the  
20 Sample Management Officer will be dealing specifically  
21 with these types of issues. And so that person will be on  
22 board before the samples are collected and that planning  
23 is under way.

24 ACTING CHAIRPERSON LUDERER: Dr. Denton.

25 OEHHA DIRECTOR DENTON: Dr. Das -- this is Joan

1 Denton. This may be covered in a future presentation, but  
2 given now that you're going to be able to do 2,000 samples  
3 a year with the CDC money, how does that -- you know, the  
4 whole question has been statewide versus community-based  
5 studies. Where are we on that question? Is the Program  
6 going to start with statewide or what is the thinking  
7 about that?

8 DR. DAS: Well, currently, the CDC funds are  
9 sufficient to support this pilot program, the Maternal  
10 Infant Exposure project that I described -- that will be  
11 described in more detail. And the vast majority of that  
12 funding is going to the labs. As far as a statewide  
13 sample, we currently don't have the resources to look at a  
14 truly statewide sample. We're hopping with different  
15 pilot programs and by leveraging our resources with  
16 samples that have already been collected that we will be  
17 able to get representative samples from around the state.  
18 But currently, we don't have the resources to do the kind  
19 of statewide program that was originally envisioned.

20 ACTING CHAIRPERSON LUDERER: Dr. Quint.

21 PANEL MEMBER QUINT: Julia Quint. It's my  
22 understanding that the CDC grant money is specifically not  
23 for a statewide sample, but for specific populations. Am  
24 I not understanding that correctly? I thought what I  
25 read --

1 DR. DAS: I'm not sure if the RFA specifically  
2 said that it was not to be for a statewide sample, but it  
3 does not provide us the resources to get a truly statewide  
4 sample.

5 PANEL MEMBER QUINT: Right, even if you wanted  
6 to.

7 DR. DAS: Yes.

8 PANEL MEMBER QUINT: Okay, thanks.

9 DR. DAS: Did you want to add something Diana?

10 MS. LEE: Hi. This is Diana Lee with CDPH.

11 And the RFA specifically indicated that the  
12 chemicals to be addressed under the RFA, should be of  
13 those of concern to the local jurisdiction, the State  
14 jurisdiction. And it didn't specifically indicate that we  
15 couldn't do a statewide type of sample, but it indicated  
16 pretty broad flexibility.

17 However, the main purpose of this funding was to  
18 enable the laboratory capacity and capability to be  
19 expanded. And so we didn't choose in the proposal to  
20 really emphasize a lot of sample collection de novo, so to  
21 speak. And as you all know, laboratory equipment and  
22 staffing became our first priority, to enable the labs to  
23 expand the number of chemicals they could analyze as well  
24 as to increase their through-put.

25 So the decision was made to maximize those

1 resources to the extent possible and to assess how we  
2 could use those resources to analyze existing biosamples  
3 that we could have access to. And Dr. Das will go into  
4 more detail about that and build on some of the existing  
5 collaborations that we've described previously.

6 DR. LIPSETT: I wanted to amplify that a little  
7 bit more. Michael Lipsett, CDPH.

8 The RFA asked us to address the issue of  
9 examining trends in chemicals in the state. And to that  
10 end, we are going to be trying to piggy-back on some  
11 existing sample collection efforts as Diana mentioned.  
12 And this is some of what Rupali will be talking about a  
13 little bit later. We don't have money in the proposal.  
14 Even though it seems like a lot from CDC, there's not  
15 money in there to go out and do an extensive statewide  
16 sample collection. It's just too prohibitive.

17 So I hope that answers your questions.

18 ACTING CHAIRPERSON LUDERER: Okay. If there are  
19 no more questions from Panel members, you can continue  
20 with the presentation.

21 --o0o--

22 DR. DAS: So I actually skipped one slide here.  
23 So the kind of input we're looking for from the Panel  
24 today asset pertains to the maternal infant study is to  
25 get your recommendations on chemical analytes to include



1           We recognize that few, if any, resources are  
2 available to implement a statewide biomonitoring sampling.  
3 And so following the model of the National Biomonitoring  
4 Program, our program has begun to explore the feasibility  
5 of accessing stored biospecimens.

6           We will assess how feasible it is for the labs to  
7 obtain stored biospecimens and to determine the utility of  
8 the biospecimens for chemical analysis, the costs to  
9 obtain and analyze the analytes, and the appropriate  
10 sampling strategies.

11           As we indicated at the last Panel meeting, the  
12 initial contacts have been made with staff at the Genetic  
13 Diseases Branch, and we'll continue these discussions and  
14 share our findings at future meetings. And this  
15 afternoon, Dr. Stephen van den Eeden from Kaiser, will be  
16 speaking to you about the biobank repository being  
17 established by Kaiser's research program on genes,  
18 environment, and health.

19           And we expect that our project coordinator Robin  
20 will be assisting with facilitating many of these  
21 assessments.

22                           --o0o--

23           DR. DAS: Our Fifth and final objective,  
24 indicates that we will engage and collaborate with  
25 stakeholders and communities. We place a particular



1 analytes of the biospecimens, namely blood and urine,  
2 primarily coming from programs or collaborators who are  
3 already collecting biospecimens and/or storing them. And  
4 in addition, we are collecting -- we'll plan to collect  
5 biospecimens through the maternal infant project.

6 --o0o--

7 DR. DAS: Are there questions regarding anything  
8 I've spoken about so far?

9 ACTING CHAIRPERSON LUDERER: Dr. Wilson.

10 PANEL MEMBER WILSON: Yeah. Thank you. Mike  
11 Wilson.

12 And I guess, you know, the question is it seems  
13 to me that as the funding kicks in and the project starts  
14 to move forward that there's opportunity -- it seems like  
15 a great opportunity for undergraduate and graduate  
16 students to become involved with the project, both in the  
17 sample collection and in the analysis and so forth. And  
18 so I'm wondering if that's been -- if there's  
19 opportunities to do that at this point.

20 DR. DAS: That's certainly a very good  
21 suggestion. There are many aspects of the project where  
22 students could get involved and we will look into that.

23 PANEL MEMBER WILSON: Yeah.

24 DR. DAS: We have fellows, but we will start  
25 looking into students who could help with various aspects

1 of the project.

2 DR. KAUFMAN: That's something that we've been  
3 talking about for a very long time. This is Farla  
4 Kaufman, OEHHA.

5 And it was what we were discussing when we had a  
6 statewide program envisioned. However, because of all the  
7 activity to enable us to acquire the grants, that's  
8 something that hasn't had enough attention. But now, it  
9 definitely is. And the issue of graduate students and  
10 add-on studies and certainly exposure assessment and  
11 possibly getting somebody to do some environmental  
12 sampling, they're all things that we're discussing, and  
13 would really appreciate any of your help with that.

14 So it's something that's next on the agenda right  
15 now.

16 DR. SHE: Also, the laboratory likes that idea.  
17 The laboratory kind of use like a graduate student to bear  
18 some collaboration to bring a bright, smart person to  
19 working in the lab on the project. That's something we  
20 talk for a long time. So now we have the space and we  
21 have equipment to host the student who comes over.

22 PANEL MEMBER WILSON: Okay. If I could just  
23 follow that up. We just are on cusp of announcing what  
24 will be the Berkeley Center for Green Chemistry that sort  
25 of brings together the College of Chemistry and

1 Engineering with School of Public Health, College of  
2 Natural Resources, the School of Business and the law  
3 school all focused on the, sort of, the technical problems  
4 in health, and environmental aspects and then legal  
5 aspects of green chemistry and chemicals policy.

6           So that what we're seeing already is a lot of  
7 student interest in this area. And so it's sort of, I  
8 think, a natural conduit in working with the program in  
9 supporting the work that you're doing.

10           DR. DAS: Yes. As you can -- as you've heard,  
11 there's a lot of interest in having students. And thank  
12 you for suggesting that. And we hope we'll be able to use  
13 your resources in helping to recruit some students in  
14 various aspects of the Program.

15           ACTING CHAIRPERSON LUDERER: Excellent. It looks  
16 like there are no more questions.

17           DR. DAS: So my final slide is just to tell you  
18 about what we plan to do. We'll continue to work on the  
19 chemical selection. We'll talk about that today. We hope  
20 to develop a public participation plan. We have started  
21 hiring new staff, and we will continue to do so,  
22 particularly in the labs. And as we mentioned in our last  
23 meeting, we are -- according to the legislation, we have a  
24 report due to the legislature on January 1st, and we are  
25 in the process of preparing that and submitting that up

1 our chain.

2           And that concludes my presentation. Are there  
3 any final questions?

4           ACTING CHAIRPERSON LUDERER: Thank, Dr. Das.  
5 Dr. Quint.

6           PANEL MEMBER QUINT: Julia Quint.

7           With regard to the report to the legislature, is  
8 there an opportunity for the Panel to make -- I don't know  
9 the form that that report will take. But I'm wondering if  
10 there's an opportunity for the Panel to make comments or,  
11 you know, say something about -- have input in some way  
12 into that report?

13           For instance, you know, I think most Panel  
14 members are really very impressed with the work that's  
15 been done so far, fully supportive of, you know, continued  
16 funding, but would also like to see full funding, so that  
17 we could actually do a statewide program. And I'm  
18 wondering if the legislative, you know, report that you  
19 make, if there's an opportunity to include some of those  
20 recommendations from the Panel, should the Panel decide to  
21 make those, if that would be an opportunity to include  
22 that into the report?

23           DR. DAS: We would welcome your recommendations  
24 as far as the future directions of our Program. And I  
25 think we look to the Panel members to help us chart our

1 future course. And I think we would definitely like to  
2 have your recommendations to include as part of the  
3 legislative report.

4 ACTING CHAIRPERSON LUDERER: And there will be a  
5 more detailed discussion of that this afternoon, correct?

6 DR. DAS: We will have a discussion as the last  
7 discussion today on your recommendations for the future of  
8 the Program.

9 ACTING CHAIRPERSON LUDERER: Thank you.

10 If there are no additional questions from the  
11 Panel, at this time, we'd like to take a public comments,  
12 if there are any now.

13 Have we received any comment cards?

14 Are there any comments via the Internet?

15 DR. McNEEL: No, we've received no messages  
16 through the Email.

17 ACTING CHAIRPERSON LUDERER: So we have ten  
18 minutes scheduled for public comments. We're a little bit  
19 behind our schedule. It looks like we've only received  
20 one; is that correct?

21 Okay. So I'd like to invite Davis Baltz from  
22 Commonweal to come up.

23 MR. BALTZ: Davis Baltz with Commonweal. For  
24 those who don't know we're a health and environmental NGO  
25 in Bolinas, California.

1           First, I'd just like to add my congratulations to  
2 the Program for landing this CDC cooperative agreement. I  
3 know a tremendous amount of work from all the staff went  
4 into it. It's really a great accomplishment forward for  
5 the Program. So congratulations on that.

6           And also, you know, acknowledge CDC's long-time  
7 interest in biomonitoring and as funds have become  
8 available to support the states to complement what's  
9 happening at the federal level, dating back to Dick  
10 Jackson's tenure when the NHANES Biomonitoring work just  
11 got under way. And Dick, of course, served on this Panel  
12 in its early days as well.

13           A couple of quick comments about the presentation  
14 from Dr. Das. Look forward to following the  
15 collaborations in Tulare and Imperial counties. And I  
16 know you mentioned that you would be open for some other  
17 ideas. Hopefully, continue to provide those as we go  
18 along.

19           But a couple of things right off the bat. I  
20 think given California's unique situation with flame  
21 retardants, it would be important to craft some sort of  
22 collaboration, where we can really start to gather some  
23 data on how Californians are exposed to these substances  
24 in ways that we may not see in other parts of the country.

25           And it also would really, I think, be valuable if

1 the Program can design a collaboration in the workplace,  
2 so that it's clear that the Biomonitoring Program covers  
3 and encompasses and is concerned about occupational  
4 exposures.

5           And then finally on the CYGNET study, I know  
6 we're not having a presentation on that today, so I just  
7 wanted to bring up since we are -- that study will be  
8 looking at young women entering puberty and their risk for  
9 breast cancer, I didn't see a list of -- an entire list of  
10 chemicals that might be looked at. But obviously, those  
11 that are estrogenic will be at the top of the list. I'd  
12 like to again recommend that Bisphenol A be included the  
13 list of chemicals that are looked at.

14           The new EPA Administrator, Lisa Jackson was in  
15 town this last week and made an important address, sort of  
16 laying out some principles that the EPA is going to be  
17 following as they look at comprehensive chemicals policy  
18 reform in Washington. And she specifically mentioned  
19 Bisphenol A, both in her public remarks in San Francisco  
20 as well as a briefing call earlier in the day.

21           So this is a chemical that I know we've all  
22 looked at quite a bit and many of us still have concerns  
23 about. So any additional data that we can acquire through  
24 the Biomonitoring Program about Bisphenol A exposure, I  
25 think, would be helpful to come to some reasonable

1 decisions on how we should be managing these chemicals.

2           So thanks again, and probably talk to you later  
3 today.

4           ACTING CHAIRPERSON LUDERER: Thank you very much  
5 for those comments.

6           All right, so the next item on the agenda is for  
7 Panel discussion. And we have that scheduled until 11:15.  
8 Some of the items that Dr. Das brought up that she  
9 was -- that was specifically requesting panel input on  
10 were to determine the chemicals of interest particularly  
11 for the mother and infant study, and input from the Panel  
12 regarding questionnaire development and testing.

13           So I'll open up the Panel discussion.

14           Dr. Quint.

15           PANEL MEMBER QUINT: I have a question. Can you  
16 point us to where we should -- should we be looking at the  
17 list of priority chemicals in terms of input or, I mean,  
18 we have chemicals that we have prioritized. And so I'm a  
19 little bit confused as to what we're doing right now.

20           DR. ROISMAN: This is Rachel Roisman with OEHHA.  
21 I'll try to offer some clarification.

22           So there are a couple of different points in the  
23 agenda today where we're going to be asking for your input  
24 on chemicals. The next presentation is going to be  
25 focused on the priority chemical list and getting your

1 input on that. And that's going to be, you know, for  
2 chemicals that, as a program, we should focus on  
3 generally, and then in regard to the CDC cooperative  
4 agreement.

5 After lunch, there will be a discussion -- a  
6 presentation about the MIEEP, project, Maternal and Infant  
7 Environmental Exposure Project, and we'll be asking for  
8 your input at that time about the chemicals specifically  
9 for that study. So your input on chemicals will come up a  
10 couple of different times today.

11 PANEL MEMBER QUINT: Julia Quint. I guess my  
12 question was for the project, are we going outside of the  
13 chemicals that we have already sort of targeted or are we  
14 working within the list that we have -- you know, of the  
15 designated and prioritized chemicals.

16 DR. ROISMAN: Well, I think one issue that will  
17 come up when we discuss the maternal infant project is  
18 who's going to be doing the analysis, whether it will  
19 be -- whether we'll be using the CDC MOU that we've  
20 discussed at meetings awhile ago, and/or using our lab's  
21 resources. And so depending on obviously if we're talking  
22 about our labs, then we'd be working within the priority  
23 chemical list. But if we're using the CDC MOU, then we  
24 have access to a different -- they do some chemicals that  
25 aren't on our priority list, and they don't do some of the

1 chemicals that are on our priority list, so that would be  
2 a slightly different thing. But that discussion will  
3 probably be had in more detail in the afternoon.

4 PANEL MEMBER QUINT: Thanks.

5 MS. LEE: And just -- this is Diana Lee again.  
6 Diana Lee with CDPH. And just as a point of  
7 clarification, and to help you kind of think about this.  
8 So for Rachel -- in the past, we've mentioned that the  
9 labs do have an existing MOU with the CDC labs that allows  
10 analysis of up to 10 chemical classes for roughly samples  
11 from 500 participants.

12 And so the original thought was that we could use  
13 that MOU to carry out the laboratory analysis at least for  
14 the maternal infant exposure study that we want to carry  
15 out. And then we applied for the CDC funding and received  
16 that. And part of our proposed work plan through that is  
17 to have our State labs carry out some of the analysis for  
18 the analytes that would be of interest.

19 So the question, you know, that will come up that  
20 bears thinking of is that for this initial pilot of  
21 roughly 100 women, do we want our State labs -- or do we  
22 want the analysis to be carried out solely by our State  
23 labs, which is a more limited panel of analytes -- or a  
24 limited number of analytes, and save the full 500 from the  
25 MOU for the larger study that will then ultimately give us

1 more power, so that's something to consider.

2           And there is a draft list of analytes of interest  
3 now that we certainly want the panel to consider, that  
4 primarily are coming from the priority list of chemicals  
5 that Rachel will be again reviewing with you shortly.

6           Does that help?

7           ACTING CHAIRPERSON LUDERER: Dr. Quint.

8           PANEL MEMBER QUINT: Julia Quint. Do we know  
9 anything about the demographics of the population that we  
10 would recruit into the study? Because some of, you  
11 know -- some of that information about the study  
12 participants might guide some of our decisions about what  
13 we biomonitor

14           DR. DAS: This is Rupali Das from CDPH.

15           Dr. Woodruff will be talking to you about the  
16 population of the clinic this afternoon, so you will have  
17 that detail after lunch.

18           ACTING CHAIRPERSON LUDERER: Dr. Bradman.

19           PANEL MEMBER BRADMAN: Asa Bradman.

20           I actually also wanted to clarify what input  
21 you're interested with respect to the questionnaire  
22 development and testing right now?

23           DR. DAS: I did have that up there as a bullet  
24 point, but I don't think we were planning to discuss that  
25 in detail today. The reason it was up there on the slide

1 is to describe why we didn't have a questionnaire for you  
2 at this presentation.

3 (Laughter.)

4 PANEL MEMBER BRADMAN: Right, but I wondered --

5 DR. DAS: We're more interested in asking you  
6 about the chemicals today.

7 PANEL MEMBER BRADMAN: Okay. I wondered if you  
8 wanted some advice about that development process?

9 DR. DAS: About the questionnaire development?

10 PANEL MEMBER BRADMAN: Yeah.

11 DR. DAS: If you have some advice, we'd be happy  
12 to take it. But the reason it was up there was really to  
13 describe why we didn't have the questionnaire for you.

14 (Laughter.)

15 PANEL MEMBER BRADMAN: Okay, thanks.

16 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

17 PANEL MEMBER SOLOMON: I'm having a little  
18 trouble giving advice about which chemicals to pick for  
19 these efforts, because I think that the ones that you  
20 might want to go for are -- I'm sort of sharing some of  
21 Dr. Quint's issues, which is that they're determined in  
22 large part by the study population and the study that  
23 you're trying to do.

24 And so the fact that we're sort of doing these  
25 smaller efforts means that we might be actually looking at

1 different panels of chemicals for different ones. And I  
2 think that if we're looking at, you know, teenage girls or  
3 pregnant women, we certainly do want to be looking at  
4 estrogenic chemicals, and in the case of pregnant women,  
5 thyroid disrupting chemicals, of which we have many  
6 examples on the list here. And some of the neurotoxicants  
7 for the pregnant women.

8           And if we're looking at collaborations and  
9 expanding, you know, opportunities with the Tracking  
10 Program and coming up with additional ideas there, we're  
11 looking for some things that totally different. We're  
12 looking for chemicals that might be mappable basically,  
13 because that's kind of what they do. And so we'd be  
14 looking maybe at pesticides or some of the drinking water  
15 contaminants where they could test some of their overlays.

16           So the questions are totally different, and it's  
17 a little difficult then to sort of say well, here's the  
18 list.

19           DR. ROISMAN: Rachel Roisman with OEHHA. I  
20 apologize, because I think we've obviously made this more  
21 confusing than we intended to. But in the afternoon,  
22 there will be a discussion about the maternal infant  
23 program, and we'll give you a lot more detail about what  
24 that study is going to look like and what the chemicals to  
25 be analyzed could be, whether we use our labs or CDC labs

1 or a combination. And there will be an opportunity for  
2 you all to provide us input at that point. So we didn't  
3 mean to imply that this is your only opportunity to give  
4 input or that we will be giving you a lot more information  
5 about that program.

6 So this is more -- was intended to just be a very  
7 general sort of update about the Biomonitoring Program and  
8 then more specific detail about the cooperative  
9 agreements, since that's a new and fairly significant  
10 change in the Program.

11 ACTING CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

12 PANEL MEMBER KAVANAUGH-LYNCH: Hi. Mel  
13 Kavanaugh-Lynch. I had also a couple of questions.

14 Well, let me make my suggestion. I know that the  
15 CYGNET study has ancillary studies looking at built  
16 environment questions, which could make it a very good  
17 opportunity to look at diesel exhaust, which is on our  
18 list to be developed. So one of my questions is, is that  
19 something that might be developed as part of the CDC  
20 grant?

21 And then I also know that there will be  
22 opportunity to possibly extend that cohort for another  
23 five to seven years, which may make the phenols, and  
24 particularly BPA, very interesting to look at because we  
25 could look at sort of pre-regulation and post-regulation

1 amounts very possibly. But it almost sounds like from the  
2 description of the study that it's already been determined  
3 what's going to be looked at in the area of those young --  
4 in this context.

5           So is there opportunity to discuss that and  
6 will the diesel measurement be something that could be  
7 developed in the next couple of years?

8           MS. LEE: Sorry, this is Diana Lee with CDPH.

9           So yes, we are actively engaging in conversations  
10 with the principal investigators of the CYGNET study. And  
11 when we originally were preparing the proposal, we  
12 approached them with respect to the potential for access  
13 to their studies. And at that time, they clarified what  
14 the baseline samples that they've collected in 2005 have  
15 currently been -- what analysis has currently taken place  
16 by the CDC labs. And from -- and then we kind of  
17 discussed what our labs were proposing, in terms of  
18 additional methods and/or capability and capacity. And of  
19 the ones that our labs were proposing, they said, well, we  
20 would be interested in such and such and such.

21           So what Dr. Das had in her slide were based on  
22 those preliminary discussions, and, in particular, the  
23 organophosphates, pesticides in urine for instance, and  
24 metals in blood and urine possibly.

25           So they are still -- we're still continuing this

1 discussion with them. And, as you know, it's a  
2 multi-center study, that's also, you know, being carried  
3 out in Cleveland as well. And so some of these analytical  
4 issues are also being discussed with them. And our  
5 cooperative agreement resources will be reserved  
6 specifically for looking at California's cohort, for  
7 instance. And then they're mediating with their other  
8 centers as well.

9           So it's a little bit more complicated and we're  
10 going to follow, you know, this discussion with them. And  
11 you know, we will definitely be developing the MOU with  
12 them to address the specific analytes as well.

13           So we definitely will share your comments with  
14 them, and I know that the initial analysis of BPA has  
15 already taken place for the baseline samples, for  
16 instance. And then, as we indicated, they've been  
17 collecting urine samples yearly since then and then  
18 storing them.

19           And those are the primary samples that they think  
20 they can make accessible to us. And what additional  
21 analytes will be carried out in those specimens are still  
22 somewhat fluid.

23           DR. DAS: I think one of your questions was, can  
24 the methodology to analyze diesel be developed; is that  
25 correct?

1           Would you be able to answer that?

2           DR. SHE: I missed the question about the diesel.  
3 And I think Dr. Peter Flessel, when he was still here, he  
4 made a very good presentation. Some chemicals if that's  
5 in the polyaromatic hydrocarbons, we can do it. Some of  
6 the markers for like IGN, we cannot do in this lab. So if  
7 that's a chemical related to the markers, if the Program  
8 would require the laboratory what kind to look for the PAH  
9 and the other hydroxypyrenes, some of these chemicals. I  
10 don't know if that's -- I missed the question part.

11           ACTING CHAIRPERSON LUDERER: Is there a comment  
12 here or public comment?

13           DR. McNEEL: This is Sandy McNeel with CDPH. I'm  
14 monitoring the Email. And we've had multiple requests for  
15 speakers to speak into the microphones. Unfortunately,  
16 Davis' comments were not audible over the webcast. So I  
17 would just like to remind everybody to speak directly into  
18 the microphone and get within about two inches of it.

19           Thank you.

20           ACTING CHAIRPERSON LUDERER: Dr. McKone.

21           PANEL MEMBER MCKONE: Tom McKone into the  
22 microphone

23           (Laughter.)

24           PANEL MEMBER MCKONE: This is a comment more, but  
25 you know, this idea of watching big events happening,

1 coming and going. With regard to transportation, there's  
2 a lot of fuel switching that's likely to go on with  
3 alternative fuels. There are programs in place, both  
4 nationally and certainly in the State for ultra-low sulfur  
5 or reformulated gasolines.

6 So I think we don't want to lose track of some of  
7 these markers of transportation, because we will be able  
8 to witness, you know -- or witness whether there is a  
9 change in a marker of exposure as we see the fuel  
10 composition change and the regulations on emissions change  
11 in time.

12 ACTING CHAIRPERSON LUDERER: Dr. Wilson.

13 PANEL MEMBER WILSON: Mike Wilson again. And I  
14 have to come back to this question of storage. I guess I  
15 need to be educated about what -- it sounds like that it's  
16 possible to -- that it's technically possible to have long  
17 term storage for metals, perhaps, in blood or in cord  
18 blood samples, but that there's a problem with volatiles,  
19 for example, that you may lose that over time.

20 I guess, I feel that it's really important that  
21 whatever we can do to, you know, place samples in  
22 long-term storage, we should be doing that, if it's  
23 technically possible, because of the problem of, you know,  
24 what we don't know that we don't know. And that may  
25 become apparent in subsequent generations, something along

1 the lines of what we've seen at DES and now with DDT and a  
2 number of others.

3 I don't know if members of the Panel or OEHHA  
4 could educate us about what is technically possible with  
5 regard to storage of cord blood samples, for example.

6 Any takers?

7 (Laughter.)

8 PANEL MEMBER BRADMAN: Well, I can just say from  
9 our experience in working CDC that many of the compounds  
10 are stable over a long time. And again, it depends on the  
11 individual chemical that you're looking at. But at  
12 negative 70, many of the target analytes, particularly  
13 persistent organic pollutants, can be stable. For  
14 example, the CHDS study out of Oakland, you know, they're  
15 looking at samples that are 40 years old.

16 PANEL MEMBER WILSON: Did you say 40?

17 PANEL MEMBER BRADMAN: Forty. And again, it  
18 really depends on the analyte. I think there's a general  
19 need, and this is something that CDC and NIST and others  
20 should support, where there are studies of storage  
21 stability and dissipation, and, you know, looking at  
22 issues of, for example, sample breaking down in, you know,  
23 after it's been extracted in the instrument. But I mean,  
24 in general, many of the compounds we're looking at are  
25 stable for a long time. But there is a lack of data for

1 many as well. But POPs are, you know, decades at negative  
2 70.

3 DR. SHE: Lab did a literature search on the OP  
4 metabolite and we found in the literature too it can cover  
5 from three years until indefinite times. So I agree with  
6 what Asa said, it depends on the chemicals. That's a gap  
7 on the data we need to collect. Consider many chemicals  
8 like we talk BPE is only bringing to the attention  
9 recently. So we all want to have solid data to support  
10 how long this can be stored. But we'd definitely like to  
11 work on this area to find out what's the best way to store  
12 them, how long they can be stored.

13 PANEL MEMBER WILSON: I think it's sort of --  
14 again, following up on Dr. Culver's point, that it just  
15 seems critically important to me at the outset, as we're  
16 thinking about that issue, because it may affect how each  
17 aliquot is distributed. It may be that each sample is  
18 split into four separate samples. One or two of which are  
19 placed in long-term storage with the expectation that they  
20 would not be accessed, for example.

21 DR. SHE: I agree with you, so these are areas  
22 definitely the lab and the Program need to pay more  
23 attention in order to do a. Plan and when we hire the  
24 people looking for what's the best way to aliquot the  
25 samples and to store the portion for the long term and

1 shorter term use.

2 PANEL MEMBER WILSON: Right, exactly.

3 PANEL MEMBER BRADMAN: There is, Mike, too, and  
4 maybe this is something that could be presented here in  
5 review. There is actually an international society for  
6 biological and exposure repositories. And they've been  
7 setting up QA/QC guidelines and standard protocols and  
8 procedures for collecting and storing samples for future  
9 studies. That might be something worth reviewing as part  
10 of this effort.

11 You know, some of the principles that we use in  
12 our work is to divide samples between freezers, so if a  
13 building collapses or you have a power outage, back-up  
14 power, alarm is on, computers -- so, I mean, on freezers  
15 if the temperatures start to rise, you're notified by an  
16 automatic calling system, so somebody can go in and get  
17 some dry ice or have a back-up freezer. I mean, those are  
18 principles of storage that I think -- I'm sure the lab  
19 here is familiar with, but maybe could be concretized in  
20 some way.

21 PANEL MEMBER WILSON: And are those just to  
22 follow that up, are those sort of protocols that are laid  
23 out by this international body?

24 PANEL MEMBER BRADMAN: Yes.

25 PANEL MEMBER WILSON: So that seems to me to be

1 something that would be important, as we're launching our  
2 program here in the state, that we -- you know we're  
3 confident with those protocols.

4 DR. PETREAS: I was going to weigh in on exactly  
5 the same QA/QC issues.

6 Myrto Petreas, DTSC.

7 I was going to bring up the same QC issues. In  
8 addition, I can tell you in our experience for the last  
9 maybe 15 years, we've been storing our samples in minus  
10 20, not even minus 70. And we have not seen any  
11 breakdown. We've as QC -- lab QCs, we have bovine serum,  
12 which we spike with all kinds of persistent chemicals,  
13 organochlorine pesticides, PCBs, and PBDEs. And every  
14 time we analyze a batch of real samples, we draw one of  
15 these frozen ones. We haven't seen any degradation in the  
16 last seven or eight years that we've been doing this, and  
17 it's only minus 20. So I'm sure that the minus 70 will be  
18 really robust.

19 ACTING CHAIRPERSON LUDERER: Dr. Das.

20 DR. DAS: I wanted to Reiterate that we will be  
21 hiring a Sample Management Officer that will deal  
22 specifically with these issues. So as we hire them, you  
23 know, hopefully you'll be able to provide some advice and  
24 we'll collaborate with you on developing some of these  
25 procedures. But we are paying attention to the need to

1 develop these policies before we start collecting samples.

2           ACTING CHAIRPERSON LUDERER: Dr. Culver, did you  
3 have a comment?

4           PANEL MEMBER CULVER: Well, I would like -- could  
5 all of this be addressed sometime after your expert is on  
6 staff?

7           DR. DAS: Yes. We definitely will make it a  
8 point to put this issue on an agenda of a future meeting  
9 after this person is hired.

10           ACTING CHAIRPERSON LUDERER: Ulricke Luderer.

11           I just wanted to actually follow up on something  
12 that Mike Wilson was talking about related to coming up  
13 with procedures for how the samples will be dealt with,  
14 not only the storage, but I think another topic that would  
15 be good to talk about in the future would be procedures  
16 for how archived samples could be accessed. And, you  
17 know, how, for example, by outside investigators, would  
18 that be possible, or by the Program, you know, how that  
19 would be prioritized of what kinds of subsequent analyses  
20 would be done on these archived samples.

21           So I think that's something that probably would  
22 really benefit from being discussed ahead of time and  
23 having a procedure in place for that.

24           Do any of the Panel members have additional  
25 comments?

1 MS. LEE: Diana Lee with the California  
2 Department of Public Health. I want to stress that the  
3 initial efforts of the Program are going to be accessing  
4 biospecimens collected by other researchers and  
5 collaborators, so that first rights to any samples will  
6 need to be cleared by these researchers.

7 And we're only doing a very limited collection  
8 of, what I, call de novo sample collection under the  
9 auspices of the CECBP. But you're right, that those  
10 issues of access to archived biospecimens has come up  
11 already in our discussions, and we will need to address  
12 them.

13 ACTING CHAIRPERSON LUDERER: I just wanted to ask  
14 how we're doing on time. We're kind of off schedule, but  
15 can we take a few more questions from the Panel or  
16 comments from the Panel?

17 MS. HOOVER: Sara Hoover, OEHHA.

18 Our original schedule was to start Rachel's  
19 presentation 15 minutes ago, so we're a bit behind.

20 ACTING CHAIRPERSON LUDERER: Okay, then I think  
21 we can hold questions for the subsequent question period  
22 from the Panel at this point, and maybe proceed with that  
23 next presentation.

24 So the next presentation will be a discussion of  
25 the priority chemicals list, and Dr. Rachel Roisman will

1 be presenting that.

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

4 DR. ROISMAN: Yes. And I'll just start actually  
5 by making an announcement to people listening on the  
6 webcast, that if they're having issues with the webcast or  
7 have questions about the meeting, to please send an Email  
8 to [biomonitoring@oehha.ca.gov](mailto:biomonitoring@oehha.ca.gov).

9 And as a little background to this presentation,  
10 so I think the complicating factors that, you know, we are  
11 not just talking about a statewide biomonitoring program,  
12 because that's not what we're able to do right now. So  
13 you know, the issue of priority chemicals and even  
14 designated -- well, chemicals for the Program is more  
15 complicated, because we're talking about them in chemicals  
16 in very different contexts. And all of these pilot  
17 studies and the small community-based projects that we're  
18 doing. And, you know, when we're collaborating with other  
19 researchers.

20 And so I think the question about what chemicals  
21 we should look at has become a lot more complicated. And  
22 that's why we keep coming back to you and we will continue  
23 to keep coming back to you to get your input about  
24 chemical selection for the Program as a whole, but also in  
25 these particular contexts. And for each study, there's a

1 different -- we're looking -- you know, we're working with  
2 different collaborators who have their own interests, and  
3 we're looking with different populations. And so the set  
4 of chemicals that we look at is probably going to vary.

5           So the purpose of this particular discussion is  
6 to get your input about the priority list, in general,  
7 and, you know, in particular, how it's going to be -- how  
8 the labs are going to develop with the extra support  
9 that's coming through the CDC. And then, for instance,  
10 later this afternoon, we'll talk to you more specifically  
11 about this Maternal Infant Environmental Exposure Project  
12 and try to get your input about chemical selection for  
13 that particular study.

14           But the reality is that the nature -- the way the  
15 Program is right now, we're going to have to ask for your  
16 input over and over again about these chemicals in these  
17 various contexts.

18                           --o0o--

19           DR. ROISMAN: So I'll just start once again with  
20 this slide that you've seen before, which gives you an  
21 overview of how we come up with the chemicals that are  
22 included in the Biomonitoring Program. So designated  
23 chemicals, it's a fairly large pool of chemicals that  
24 include everything that's biomonitored by the CDC as part  
25 of NHANES, as well as additional chemicals that the Panel



1 chemicals be included as priority chemicals in the  
2 Program.

3 --o0o--

4 DR. ROISMAN: So so far on the priority chemical  
5 list, we have two chemicals classes in their entirety,  
6 cyclosiloxanes and brominated and chlorinated organic  
7 compounds used as flame retardants. And then we have 76  
8 chemicals substances, mostly individual chemicals, but,  
9 for instance, the mixture diesel exhaust is included in  
10 this group.

11 And the reality is that even with the CDC  
12 cooperative agreement, the labs don't have the resources  
13 to develop methods for all of these priority chemicals at  
14 the same time. And so there does need to be some  
15 decisions that are made about which methods will be  
16 developed first.

17 --o0o--

18 DR. ROISMAN: This is a summary of the priority  
19 chemicals based on the groups that they fall into, so the  
20 metals cadmium, lead, mercury and arsenic, environmental  
21 phenols, perchlorate, diesel exhaust, cotinine, the two  
22 classes that I mentioned before, cyclosiloxanes and  
23 brominated and chlorinated organic compounds used as flame  
24 retardants, three of the polycyclic aromatic hydrocarbons,  
25 and then organophosphate insecticides, pyrethroid

1 pesticides and phthalates. And again not every member of  
2 those classes is included as a priority chemical.

3 A couple of additional pesticides, DDT,  
4 para-Dichlorobenzene benzene, and 2,4-D. And then finally  
5 the perfluorinated compounds, again not every member of  
6 that class, but the ones that are biomonitored by the CDC.

7 --o0o--

8 DR. ROISMAN: And again as a reminder, the way  
9 that we've been operating is that the Program  
10 determines -- the Panel recommends the parent compound  
11 that's of interest, and the Program determines the  
12 appropriate target compound. And this may be a parent, an  
13 isomer, a key metabolite or something else. And this is  
14 likely to change as method development proceeds.

15 --o0o--

16 DR. ROISMAN: So just to tell everybody what the  
17 materials were that we put together for this discussion,  
18 there is a table that's been posted on the website and  
19 provided to the Panel in advance of the meeting. And it  
20 mirrors tables that we've provided in the past about, at  
21 that time, potential priority chemicals. And now it has  
22 all the priority chemicals. The emphasis in the table is  
23 on laboratory considerations, which lab does the analysis,  
24 whether it's a blood or urine, biospecimen, the timeline  
25 for lab capability, and some background material whether



1 has current capability include lead, cadmium, and mercury.  
2 One pyrethroid metabolite, 3-phenoxybenzoic acid, which is  
3 common to three of the priority pyrethroids, as well as to  
4 some other pyrethroids that are not priority chemicals.  
5 Chlorpyrifos, this is a specific OP metabolite for  
6 chlorpyrifos. 11 of the PBDEs and DDT.

7 --o0o--

8 DR. ROISMAN: So on the table we also talked  
9 about which chemicals the labs have -- expects to develop  
10 capability for measurement within 12 months. We're  
11 calling this "soon". And this includes the DAP  
12 metabolites, which are non-specific metabolites for all of  
13 the priority organophosphates, perchlorate, the  
14 environmental phenols, triclosan and BPA, arsenic, one of  
15 the PAHs, 3-Hydroxyphenanthrene, 10 of the brominated or  
16 chlorinated flame retardants, four of the phthalate  
17 metabolites and 12 of the perfluorinated compounds. And  
18 these are detailed on the table, but I'm just summarizing  
19 them here.

20 On the table there are also several chemicals for  
21 which the lab expects to develop capability for  
22 measurement in more than 12 months, which we're saying is  
23 later. And this includes diesel exhaust, other pyrethroid  
24 metabolites, two of the phthalate metabolites,  
25 cyclosiloxanes, and two of the PAHs.

1                   --o0o--

2           DR. ROISMAN:  So just to flesh out this now soon  
3 and later and also give you a little bit more information  
4 about not just lab capability but capacity, I'm going to  
5 show you the table that were included in the CDC -- the  
6 application for funding through the CDC.  And these may  
7 not show up great on the slides, but they are available at  
8 the end of this -- your copy of the slides, you have a  
9 full-page version of the table.  And that's also available  
10 in the back.  And all of this will be posted on the  
11 website after the meeting.

12           And I'll just preface it by saying, you know,  
13 these were estimates to begin with, and they also are  
14 based on full funding --

15                   --o0o--

16           DR. ROISMAN:  -- from the CDC for all five years.  
17 We already know that in year one we requested 2.9 million,  
18 we got 2.65 million.  So these numbers are already based  
19 on more money than we know that we're receiving for year  
20 one, and assumes full funding for years two through five.

21           So this first table is for the DPH labs.  And the  
22 letters in there are telling you whether the method is in  
23 development.  That's what "M" stands for.  "P" is  
24 partial -- I guess partial capacity, meaning that it can  
25 measure, you know, maybe 250 to 400 or 500 samples.  And

1 then "F" is for full capacity, which generally means, you  
2 know, measuring, you know, certainly more than 400  
3 samples.

4           And there are other distinctions between, you  
5 know, partial and full than just the number of the assay  
6 capacity. So what this tells you is, you know, where the  
7 DPH labs think that they'll be, assuming they continue to  
8 get full funding from the CDC over the next several years  
9 in regards to measuring metals, both in blood and urine,  
10 perchlorate, the organophosphate pesticides, which  
11 includes the specific metabolites, and then the DAP  
12 metabolites are listed separately, the pyrethroid  
13 pesticides, Bisphenol A and the phthalates.

14           And then at the bottom, it shows you the total  
15 assays per year, which I know was a question brought up by  
16 one of the Panel member earlier today about, you know, how  
17 man samples were talking about in each year of the  
18 agreement.

19           Are there questions about this table?

20           ACTING CHAIRPERSON LUDERER: Actually, I have a  
21 clarification of the table which relates to the question  
22 that we had -- I think that Dr. Solomon had earlier, which  
23 here at the line across the bottom of the table, suggests  
24 that the number of samples that can be assayed per year is  
25 going to be increasing in each year of the grant. And

1 earlier it sounded more like it was 8,000 for the total  
2 five years and 2,000 per year. So could you clarify that.

3 DR. ROISMAN: I'm going to do better, and I'm  
4 going to defer to Dr. She.

5 DR. SHE: We mentioned like --

6 DR. McNEEL: Jianwen, put it right up to your  
7 mouth.

8 DR. SHE: -- two thousand samples that means per  
9 analyte groups, so that's a new -- can end up together.  
10 And on this table we list a thousand. But a lot of our  
11 analytes, especially like metals and some of the analytes  
12 like urines, we think we can go up to 2,000 samples. So a  
13 realistic number we are between 1,000 and 2,000.

14 For some of them, if the process takes longer, we  
15 think maybe not exactly at 2,000 mark. But some of them,  
16 like metals, we probably will have low limitation on the  
17 capacity.

18 ACTING CHAIRPERSON LUDERER: Just to follow up on  
19 that. So if you're doing more than one analyte group --  
20 you know, say you said 2,000 you could do metals, but does  
21 that mean that then you can't do another -- some other  
22 analyte? I'm just looking at the totals here at the  
23 bottom.

24 DR. SHE: The other ones I think if you take  
25 1,500 we have a good estimate. On the average, we can

1 handle all the analyte in our lab around 1,500. We have a  
2 safe estimate.

3 ACTING CHAIRPERSON LUDERER: Thank you.

4 Any other questions from Panel members?

5 MS. LEE: This is Diana Lee from CDPH. I just  
6 want to again remind the Panel that this cooperative  
7 agreement is for five years. At the end of which, there  
8 is no necessary guaranteed funding to continue the staff,  
9 et cetera, and have resources to maintain the equipment  
10 being obtained through this initial five-year cooperative  
11 agreement.

12 So for the purposes of the proposal, we certainly  
13 indicated that at the end of the five-year period, we  
14 intend to meet this objective of doing roughly 14,000  
15 assays combined by the two labs, for 14 classes -- or  
16 chemicals, I believe, is what we indicated. So that's at  
17 the end of the five year period that we expect to achieve  
18 this.

19 --o0o--

20 DR. ROISMAN: So I will go on to the next slide,  
21 which is the same idea, but this is for the DTSC labs.  
22 And the, I think, important thing to notice here is at the  
23 bottom there on the left, there's room for a new  
24 chemical/chemical class, is something where method  
25 development would be started in year five.

1           And so the chemicals that we're dealing with  
2 here, the PBDEs, other flame retardants, the hydroxylated  
3 PBDEs, perfluorinated chemicals, and cyclosiloxanes and  
4 then again this new chemical.

5                               --o0o--

6           DR. ROISMAN: I'll just back up and ask if there  
7 are any clarifying questions about this table?

8           Okay. So on the priority chemicals table that  
9 you got in advance of the meeting, there are some  
10 chemicals that are not -- where method development is  
11 currently not planned for various reasons. And I thought  
12 that I should highlight these just so that you're aware of  
13 them: Cotinine is a marker for tobacco exposure;  
14 para-dichlorobenzene, one of the pesticides we talked  
15 about at the last meeting; 2,4-D, another pesticide from  
16 the last meeting; seventeen of the chlorinated or  
17 brominated flame retardants; two of the phthalate  
18 metabolites; and two of the perfluorinated compounds.

19           So the questions that we -- two of the questions  
20 that we have for your discussion is, you know, is there an  
21 additional chemical that you'd like to see the DTSC lab  
22 develop method for in year five of the CDC cooperative  
23 agreement. And are there priority chemicals for which  
24 method development is not planned for which you'd like to  
25 see methods developed.

1           And again, you know, this discussion is really  
2 about the program as a whole and how we're using the CDC  
3 funding. And we'll have a separate discussion about, you  
4 know, some of the specific pilot studies that we're going  
5 to be doing and which chemicals should be included in  
6 that. But if there -- you know, this is the current plan  
7 for method development from the labs. So this is a good  
8 opportunity if you have input about that to let us know  
9 what you think, and also just to provide you with a  
10 reality check in terms of when -- you know, how far in the  
11 future some of these priority chemicals methods, you know,  
12 aren't going to, even with this additional funding,  
13 can't -- the methods can't be developed for several years  
14 from now.

15           So I hope this has given you more information  
16 about that.

17                           --o0o--

18           ACTING CHAIRPERSON LUDERER: Thank you, Dr.  
19 Roisman. Because we're a little bit behind schedule,  
20 maybe we can take a few clarifying questions now and then  
21 have the public comments and then do the Panel discussion,  
22 if that's all right with everyone.

23           Do you have a question, Dr. Kavanaugh-Lynch?

24           PANEL MEMBER KAVANAUGH-LYNCH: Mel  
25 Kavanaugh-Lynch. So I just have a questions about diesel,

1 because it's listed on the table as later, but not  
2 planned, but I don't see it in any of the plans.

3 DR. SHE: I guess maybe a lot of people can  
4 correct me like, Mike.

5 Diesel biomarker is very complicated issue. And  
6 some of the people monitor the certain markers and then  
7 Peter presented it before. And at this moment, the lab  
8 only has three chemists in the lab. At this moment, they  
9 all already do other things. But if the Panel thinks that  
10 this marker and also can recommend which marker we should  
11 focus on, then the lab can try to redirect or to come up  
12 with a plan.

13 MS. HOOVER: I just want to -- I think it's  
14 probably clear. But I think one of the issues is it's  
15 still not clear exactly how to measure diesel exhaust and  
16 have it be specific enough. So I think as what you were  
17 saying previously is that you certainly could do certain  
18 PAHs that would be related to diesel exhaust. But you do  
19 not currently have a method under development that is a  
20 specific fingerprint for diesel exhaust; is that correct?

21 DR. SHE: Right.

22 MS. HOOVER: So that's the situation.

23 ACTING CHAIRPERSON LUDERER: Dr. Quint.

24 PANEL MEMBER QUINT: Julia Quint.

25 I think when Peter made the presentation, I think

1 that you referred to several times, there were promising  
2 leads for certain specific fingerprints for diesel. And I  
3 think one of the things that some of us might be  
4 interested in is instead of a brand new chemical is to  
5 really spend time, you know, seeing whether or not this,  
6 you know, specific chemical -- and I don't remember the  
7 name -- but, you know, to make sure that we would  
8 concentrate on that, not trying to preempt what you  
9 would -- you know, your preference.

10 And that's the confusion. Because I don't  
11 remember the specifics of Peter's presentation, but it did  
12 seem promising that there was a specific marker for  
13 diesel. And if we could talk about, you know, what it  
14 would take in terms of CDC resources to pursue that as,  
15 you know, opposed to a brand new chemical, I think many of  
16 us would be delighted to endorse something like that,  
17 because diesel is so important.

18 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

19 PANEL MEMBER SOLOMON: Gina Solomon.

20 I'd just like to pile on. I agree, and my  
21 recollection is that Dr. Flessel spoke with someone, I  
22 think, at Battelle who was working on this issue. And  
23 there was at least some potential interest in a  
24 collaboration, I believe, from there. And so it would be  
25 great to follow up on that lead. I believe that had to do

1 with the nitro-PAHs as a biomarker, which, in my view,  
2 seemed a little bit more promising than the IGE kind of  
3 approach.

4           And so, you know, if there were a collaboration  
5 that could be created there, and additional funding  
6 perhaps could be sought around that, that would be  
7 wonderful.

8           DR. ROISMAN: Rachel Roisman with OEHHA. I just  
9 want to clarify that the new chemical is actually under  
10 DTSC. And so this would be a DPH thing. So you may -- it  
11 may be necessary for you to look at the table of the DPH  
12 chemicals that are part of the CDC cooperative agreement,  
13 and say, you know, which -- if there's some of those that  
14 are less of interest to you than diesel and to ask them  
15 to -- I don't know if that's necessary from the lab's  
16 point of view.

17           DR. LIPSETT: Michael Lipsett. Yeah, I'm sorry I  
18 had to step out of the room at the beginning of this  
19 discussion, so I may be repeating some stuff that you  
20 already heard.

21           PANEL MEMBER MCKONE: Speak up, Michael.

22           DR. LIPSETT: We did submit a pre-proposal to  
23 ARB. Did you already mention this, Jianwen or not?

24           DR. SHE: No, I did not.

25           DR. LIPSETT: This is something that the Air

1 Resources Board is very interested in as well.

2 And Jianwen and I and I think Peter was involved  
3 in this before he retired. We submitted a pre-proposal to  
4 ARB to help develop a biomarker or at least to work on  
5 this with some initial funding from ARB. But there was  
6 work that was very similar to what we were proposing that  
7 was further along with another research group in  
8 California. And I think Battelle might have been involved  
9 in this as well.

10 But we can follow up with the Air Resources Board  
11 and find out, you know, where they are on this and present  
12 that information to you at the next meeting if you would  
13 like.

14 PANEL MEMBER MCKONE: Just a clarifying question.  
15 What specifically, is this just markers of diesel or would  
16 it be other broader markers of traffic and  
17 transportation-related exposures?

18 DR. LIPSETT: They were particularly interested  
19 in diesel markers.

20 PANEL MEMBER MCKONE: Certainly high priority.  
21 But is there any likely effort to go -- and again, it's  
22 back to this point I brought up. We're kind of watching,  
23 you know -- certainly the State is encouraging a shift in  
24 fuels, right. We're seeing a shift to low-carbon fuels.  
25 There's a range of things out there. There are a lot of

1 con -- I know the ARB -- actually I think I'm involved in  
2 some of this. I'm familiar with what they're trying to do  
3 to understand the different spectrum of emissions.

4           And I just -- I don't know if these other groups  
5 are targeting some of this, and if there's other  
6 opportunities. I'm not aware of a lot. I know I'm aware  
7 of the studies of changing emissions, that is putting  
8 vehicles in test chambers, looking at different engines  
9 and fuels. But is anyone going to capture the other side  
10 of this equation, which is what happens in the receptor  
11 population with these shifting emissions.

12           And it may not be something we can capture.  
13 Certainly, the diesel I would argue is the highest  
14 priority, because that's the biggest likely burden of  
15 disease element in transportation fuels. But if there are  
16 other opportunities it would certainly be interesting.

17           DR. LIPSETT: Well, we can check with ARB's  
18 Research Division to find out where they are headed on  
19 this. They do have a lot more in the way of resources to  
20 be able to support these kinds of methods development.  
21 And we can just give you a status report on that at the  
22 next meeting.

23           ACTING CHAIRPERSON LUDERER: I just wanted to  
24 actually also clarify what Dr. Roisman was bringing up,  
25 that -- is it -- so you're really -- there's only room

1 really for the panel to make recommendations for new  
2 analyses from the DTSC lab?

3 DR. ROISMAN: Well, it's my understanding  
4 that -- or at least that you would have to probably knock  
5 something off the list for the DPH lab if you want to move  
6 something like diesel up there. That's my understanding,  
7 so that there isn't enough money in the proposal to just  
8 add on -- even if it's fully funded, to add on something  
9 else to what the labs could do.

10 ACTING CHAIRPERSON LUDERER: If there are no  
11 other clarifying questions from the Panel at this point,  
12 perhaps we could take the public comments and then have  
13 more of a discussion after that.

14 All right.

15 Are there any public comments or requests for  
16 public comments?

17 Any via Email? No.

18 All right. Well, then we can continue with our  
19 discussion among the Panel members, if there are no public  
20 comments.

21 MS. LEE: Our work plan for CDC is still somewhat  
22 fluid. And we will be submitting updates and progress  
23 reports and so on. So as we prepare our proposal for  
24 subsequent years, we could include a recommendation that  
25 the panel is particularly interested in a certain chemical

1 and see if we could get additional resources to help  
2 develop those methods too. So I think it's still good to  
3 go on record to indicate that interest and document it as  
4 such.

5 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

6 PANEL MEMBER SOLOMON: I'm just wondering why the  
7 organophosphate dialkyl phosphate metabolites are on the  
8 list. Those are non-specific metabolites. My  
9 understanding is CDC is moving away from using those and  
10 is moving towards using specific OP metabolites. And so  
11 if we were going to chop something off the list, that  
12 would be my vote.

13 DR. SHE: So you mean the DAPs?

14 DR. ROISMAN: It's on.

15 DR. SHE: Actually, I do not know CDC is moving  
16 away from it. So we based it on the 2003 CDC's finding.  
17 DAP is a common metabolite, so it can reflect the total  
18 aggregated exposure. But if the CDC moves away,  
19 definitely the Panel can look at this given the new  
20 recommendation.

21 DR. ROISMAN: One complicating factor, and  
22 correct me if I'm wrong, but I believe that there's also  
23 some -- it's a little bit tricky, because I think  
24 something like the DAP metabolites is something that, for  
25 instance, the Environmental Tracking Program or other

1 collaborators are relying on the DPH labs to be able to  
2 provide that for them. So I think that they're also  
3 developing those methods for reasons other than the  
4 Biomonitoring Program, is that true?

5 DR. SHE: We do not have the firm commitment to  
6 do the DAPs for the Tulare county, because that changes  
7 their proposal. They only ask us to do TCP, so that we  
8 can -- that's a lot of problem.

9 PANEL MEMBER SOLOMON: If I may follow up. It's  
10 Gina Solomon again. The problem with the non-specific  
11 metabolites is that there are some organophosphates that  
12 are very highly toxic, and some that are far less toxic  
13 that all breakdown to the same metabolite. And so if you  
14 detect the metabolite, it's a little bit hard to sort of  
15 back project the toxicity to which that person was likely  
16 to have been exposed, because you don't know which parent  
17 compound is represented.

18 And so the more specific metabolites are  
19 preferable, I think, for that reason. And I think it was  
20 a good choice for the Tracking Program to focus on TCP and  
21 chlorpyrifos for their project. So that's just a thought.

22 And speaking of the Tracking Program, going back  
23 to diesel, it would be great collaboration with the  
24 Tracking Program, because they're doing some studies where  
25 they're mapping near highway, you know, sort of -- they

1 did some work in Oakland where they looked at asthma  
2 hospitalizations and ER visits and proximity to freeways.  
3 And those are -- you know, diesel exhaust sort of  
4 exposures are at least potentially mappable, and  
5 biomonitoring could actually be a part of that in, I  
6 think, a pretty interesting way.

7 ACTING CHAIRPERSON LUDERER: Dr. Wilson.

8 PANEL MEMBER WILSON: Yeah, Mike Wilson.

9 I just want to add my support to, you know,  
10 efforts to identify a reasonably specific biomarker of  
11 diesel exposure, and that, you know, as we're seeing the  
12 trajectory in terms of California's growth development in  
13 the Port of Oakland and Long Beach and so forth, this is  
14 going to be a continuing issue for California, I think.

15 So, you know, absolutely whatever we can do to be  
16 focusing on that, I would like to see us do that. And the  
17 other is that one other comment and then a question, that  
18 under the AB 1879, DTSC has been charged by the  
19 Legislature to identify and prioritize chemicals of  
20 concern in California.

21 And it's sort of working its way through to do  
22 that. And, in fact, next week the green ribbon panel is  
23 deliberating on the specifics of that process, and it's  
24 possible that there will be other substances that come to  
25 our attention in the next year or two. And so I'm just

1 sort of flagging that as another source of input and data  
2 that would be potentially useful for what we're doing and  
3 in terms of this question of -- this open slot here on new  
4 chemicals for the DTSC lab.

5           And then my question is, if there is -- over the  
6 course of the five years, if there is -- what the public  
7 reporting, sort of, system is contemplated, in terms of  
8 the results, and also if there is a schedule for  
9 publishing the results in, you know, Environmental Health  
10 Perspectives, for example, if that's part of the five-year  
11 plan?

12           DR. DAS: In terms of reporting the results, what  
13 we've been working on now is to develop a plan to report  
14 results back to individual participants. That's our first  
15 goal, that that is mandated in the legislation.

16           As a part of that, I think we will also have to  
17 develop a plan to report the results publicly. And that's  
18 something we will work on. As far as publications, we  
19 definitely plan to have publications, but we don't have a  
20 specific plan right now, where we are planning to publish  
21 in certain journals, but I think that's a very good  
22 suggestion. The issue of publications has come up in  
23 regards to the UCSF study, but we haven't developed them  
24 in a lot of detail.

25           PANEL MEMBER WILSON: Thank you.

1           PANEL MEMBER BRADMAN: This is Asa. I'm not  
2 necessarily making a plug for DAPs here, but I just want  
3 to kind of outline some of the complexity there.

4           Many of the OP pesticides are not measurable.  
5 There's no pesticide-specific metabolite for many of them.  
6 And some of them are quite toxic like oxydemeton-methyl.  
7 DAPs are kind of a classic problem, because they reflect  
8 so many different chemicals with such different toxicity.

9           CDC is developing a method for all OPs in blood.  
10 The detection limits are fairly high. And I suspect that  
11 many of the assays they will get will be non-detectable,  
12 because the detection limits are high. I think the issue  
13 of, you know, dropping DAPs or not, bears more discussion,  
14 but it's something to seriously consider, because they're  
15 hard to interpret. They do provide information on general  
16 trends.

17           And certainly the dominant pesticides in  
18 California, some of the, you know, chlorpyrifos, diazinon,  
19 you know they're very heavily used in agriculture. The  
20 use has been eliminated in residential environments, and  
21 there is potentially an opportunity there to track changes  
22 in exposure. So that's something that may warrant  
23 discussion.

24           I also wanted to ask, it's not clear to me how  
25 some of these decisions were made to not plan for doing

1 certain analytes. And I'm sure that had to do with  
2 capacity, but maybe you could clarify that. And I would  
3 agree, just to step back a little bit, that diesel should  
4 be a high priority for the Panel and for the State. And  
5 anymore discussion on that is warranted. I don't know if  
6 we want to actually take a vote on that. And then, I  
7 think, also tobacco smoke and cotinine is something to  
8 consider. I know it's done nationally, but it's certainly  
9 an important public health issue, and it's also another  
10 opportunity to track changes in exposure, hopefully as a  
11 result of changes in legislation.

12 ACTING CHAIRPERSON LUDERER: Yeah, I was  
13 actually -- just to follow up on what Dr. Bradman was  
14 saying, I was going to suggest that it seemed as though  
15 the Panel was beginning to come to a consensus that diesel  
16 is important, and that we might want to make a  
17 recommendation about diesel, and whether we should do that  
18 as a formal vote, and whether that needs to be tied to  
19 together with a recommendation for dropping another  
20 chemical in order to be able to make the recommendation  
21 that diesel be -- the method be developed for diesel.

22 I also have had a request from a Panel member for  
23 a break, and we actually have lunch scheduled at 12:30. I  
24 don't know whether we can -- is it all right with everyone  
25 on the Panel to wait till 12:30 or do we need --

1 PANEL MEMBER WILSON: Sure.

2 ACTING CHAIRPERSON LUDERER: Dr. Lipsett.

3 DR. LIPSETT: Yeah. I wanted to respond to Dr.  
4 Bradman's question about the decision related to cotinine.  
5 And you may or may not recall that when Peter Flessel was  
6 here, he did address this question. And that is that  
7 basically if we want to be able to analyze cotinine, that  
8 will take a dedicated piece of equipment just for that  
9 analysis.

10 And it was basically felt that that would compete  
11 with too many other possible analyses that we would want  
12 to do. And so that decision was made really early on  
13 within the CDPH laboratory. With respect to the DAPs, I  
14 mean, we can confer with the lab people and get back to  
15 you at the next meeting about that.

16 And then with respect to diesel. You know, I  
17 think all of us think that it's an important priority. As  
18 I said before, we will confer with ARB at least with  
19 respect to where they are on this, because they may be  
20 further along in the their research funding of this. And  
21 in any case, they will be aware of other efforts that are  
22 being undertaken nationally and internationally in this  
23 regard.

24 ACTING CHAIRPERSON LUDERER: Thank you.

25 DR. ROISMAN: Rachel Roisman with OEHHA.

1 I'll just add one thing, which is I know that the  
2 CDC is also looking at other tobacco biomarkers, including  
3 NNAL. And I don't know anything about that analysis or  
4 whether it require its own machine, but that could be  
5 something that we would look into as possibly a less  
6 resource intensive way of measuring tobacco exposure, if  
7 that would be of interest to the panel.

8 ACTING CHAIRPERSON LUDERER: Dr. She.

9 DR. SHE: If the Panel wanted to do the -- Dr.  
10 Quint mentioned that the paper that's published in 2007 by  
11 the first author I think is Japanese, and use the  
12 1-nitropyrenes. And then if I remember correctly, that  
13 necessarily required a lot of urine samples to do it, so  
14 we said at that moment we concluded that method maybe a  
15 research level paper. And then for the routine  
16 biomonitoring needed some work done, because otherwise we  
17 required so much samples to do that 1-nitropyrene.

18 So I'd like the Panel to give us a clear  
19 direction which marker possibly can be used, so lab can be  
20 focused on it.

21 ACTING CHAIRPERSON LUDERER: Is there a comment?

22 MS. HOOVER: Well, I think there's a pause before  
23 the mike goes on. Sara Hoover, OEHHA.

24 I think what Dr. Lipsett said is that we will  
25 follow up on what the options are, what ARB is working on

1 in that regard, and we will brief you, because obviously,  
2 you're not necessarily going to be able to give us  
3 guidance on the appropriate marker to pursue at this  
4 point. So we'll report back to you on what is in the  
5 works and what might or might not be possible, and then we  
6 can have further discussion on diesel.

7 ACTING CHAIRPERSON LUDERER: Great.

8 Are there any other items that the Panel members  
9 would like to discuss?

10 PANEL MEMBER WILSON: This is Mike Wilson.

11 Do you want to entertain a motion on that to hear  
12 from the Panel as a decision?

13 ACTING CHAIRPERSON LUDERER: Do we need a motion  
14 today if we're going to come back with more information?  
15 I'm thinking maybe we should wait and have additional  
16 discussion at the next meeting. We don't need a motion  
17 for you to bring back more information to us, correct?

18 MS. HOOVER: We'll do it.

19 (Laughter.)

20 PANEL MEMBER WILSON: Sobeit.

21 OEHHA DIRECTOR DENTON: Dr. Luderer, I had a  
22 question. I'm wondering if it would be possible to find  
23 out that information today and bring it back to the Panel  
24 this afternoon. I mean, ARB is in this building, the  
25 Research Division is in this building. The next Panel

1 meeting is, what, three or four months away.

2 (Laughter.)

3 OEHHA DIRECTOR DENTON: I mean, you might be able  
4 to come back and say, you know, they're not planning on  
5 looking at it or they have a huge research project that's  
6 in the works or something.

7 DR. LIPSETT: Okay, we may be able to get some  
8 information about this. It's possible that I can find out  
9 during lunch.

10 OEHHA DIRECTOR DENTON: It might be worth at  
11 least a try.

12 DR. LIPSETT: Okay, that's fine.

13 OEHHA DIRECTOR DENTON: And then we'll have  
14 something to work from at this meeting.

15 DR. LIPSETT: Yeah, I'll try to do that, but  
16 there's no guaranty that the people who are responsible  
17 for that are going to be available to talk about it. But  
18 sure, I'll do that during lunch.

19 ACTING CHAIRPERSON LUDERER: Dr. Solomon. Sorry.

20 DR. ROISMAN: Also, I mean, it sounds clear to me  
21 that there's a lot of interest in the Panel in developing  
22 diesel. And, you know, the cooperative agreement laid out  
23 a plan for five years. The funding was only requested and  
24 provided for the first year.

25 So in several months, we will be preparing and

1 submitting a proposal for the next year. And it seems  
2 clear to me that, you know, you are encouraging us to  
3 really make sure that making, you know, a diesel biomarker  
4 a part of that proposal for, you know, the next year or  
5 the next several years, if I'm -- if that's incorrect, let  
6 us know, but it just sounds to me like that's of great  
7 interest to the panel, and something that you'd really  
8 like to see included as a significant part of the proposal  
9 in coming years.

10 PANEL MEMBER WILSON: I guess --

11 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

12 PANEL MEMBER SOLOMON: A couple things. One is  
13 with regard to diesel, there might be other sources of  
14 funding too, NIOSH funding or, you know, even NIEHS  
15 funding on methods development, so that, you know, if it  
16 doesn't work within the CDC proposal, it just might be  
17 worth looking at other things.

18 But my main question was about the 17 chlorinated  
19 or brominated flame retardants that are not planned. And  
20 I was looking down the list and trying to remember the  
21 memo that -- and the, you know, which of the flame --  
22 whether any of these are ones that were of particular  
23 concern, and that our problem -- you know, potentially  
24 increasing in California.

25 And it seemed like the dechlorine plus at a

1 minimum was one that I recall seems to be rising. And  
2 maybe, Sara, you can remind us about some of the others

3 MS. HOOVER: Gail Krowech.

4 PANEL MEMBER SOLOMON: Oh, sorry, Gail, you were  
5 the one who -- sorry, spaced out. Because it would just  
6 be good to know if there's anything we're missing

7 DR. KROWECH: Gail Krowech, OEHHA.

8 I think the tris, 1-chloro-2-propyl phosphate is  
9 one that's currently being used, in furniture foam and  
10 showing up a lot. So what's labeled here as TCPP. Also,  
11 the two brominated chemicals in Firemaster 550. I think  
12 that that has been reformulated to Firemaster 600. I'm  
13 not sure if both of them are in there, but that also has  
14 had high use.

15 And I think also decabromodiphenyl ethane has  
16 been -- had use and we should look more at that as a  
17 replacement for deca. So that would be another one.

18 DR. PETREAS: If I can add from the lab  
19 perspective. This is Myrto Petreas, DTSC. Remember, this  
20 is not a class of chemicals. It's a group of very, very  
21 different chemicals. So when we start it, we were doing  
22 the PBDEs and we started adapting our method to encompass  
23 a few more at the time. So they're not planned. Mostly,  
24 they're phosphates, which require totally different  
25 behavior, totally different instrumentation needed.

1           So as we stand now with the current resources,  
2 it's not planned. Maybe some of the new chemicals in the  
3 future.

4           ACTING CHAIRPERSON LUDERER: Dr. Wilson.

5           PANEL MEMBER WILSON: Mike Wilson. Maybe I'm  
6 overly focused on protocol. I guess I would like to  
7 provide a really unequivocal response to Dr. Roisman's  
8 question from the Panel about that we are -- in the form  
9 of a motion, that we are recommending that staff take  
10 steps to identify a biomarker of exposure to diesel and  
11 develop a lab method for its identification in  
12 biomonitoring studies.

13           And, I guess, I defer to the Chair, but I guess I  
14 would like to see that posed in the form of a motion and  
15 made clear from the Panel.

16           ACTING CHAIRPERSON LUDERER: Do we have any  
17 objections or discussion from the other Panel members  
18 about that. I think it certainly adds -- I said, I think  
19 it's clear that the Panel seems to be coming to a  
20 consensus and feel that it's important, so we certainly  
21 could take a vote to recommend that. I think that would  
22 be a reasonable. If someone would like to second.

23           PANEL MEMBER WILSON: I guess I'll just state --

24           ACTING CHAIRPERSON LUDERER: Would you like to  
25 state it more specifically.

1           PANEL MEMBER WILSON: The motion would be that  
2 the Panel recommends to -- that Program staff take steps  
3 to identify a biomarker of exposure to diesel exhaust, and  
4 the development of a laboratory method for its  
5 identification in biomonitoring studies.

6           ACTING CHAIRPERSON LUDERER: Okay. Dr. McKone.

7           PANEL MEMBER MCKONE: I'll second that, because I  
8 agree. I think that we just discussed it and the minutes  
9 suggest that we were all in favor. It's much more  
10 powerful to just we unanimously gave the marching orders.

11          ACTING CHAIRPERSON LUDERER: All right. Shall we  
12 take the formal vote then?

13          Everyone raise your hand if you support the  
14 motion.

15          (Hands raised.)

16          ACTING CHAIRPERSON LUDERER: Unanimous support  
17 for the motion proposed by Dr. Wilson.

18          PANEL MEMBER WILSON: Thank you

19          ACTING CHAIRPERSON LUDERER: Okay. Any other  
20 discussion, questions by Panel members?

21          CHIEF COUNSEL MONAHAN-CUMMINGS: Excuse me, I  
22 don't have my Bagley-Keene Act with me, but my  
23 recollection is when you're doing a vote when there's  
24 people that aren't present in the room that you have to do  
25 it by roll call. So, sorry. It's probably not that

1 important, but if you could just say your name and then  
2 yes or no, and then we'd just go ahead and get that on the  
3 record.

4 ACTING CHAIRPERSON LUDERER: Okay. Shall we  
5 start with Dr. McKone.

6 PANEL MEMBER MCKONE: Tom McKone, aye.

7 PANEL MEMBER WILSON: Mike Wilson, aye.

8 MEMBER KAVANAUGH-LYNCH: Mel Kavanaugh-Lynch,  
9 aye.

10 PANEL MEMBER QUINT: Julia Quint, aye.

11 ACTING CHAIRPERSON LUDERER: Ulricke Luderer,  
12 aye.

13 PANEL MEMBER CULVER: Dwight Culver, aye.

14 PANEL MEMBER BRADMAN: Asa Bradman, aye.

15 PANEL MEMBER SOLOMON: Gina Solomon, aye.

16 ACTING CHAIRPERSON LUDERER: Any additional  
17 discussion by the Panel?

18 Dr. Quint.

19 PANEL MEMBER QUINT: I just want to reiterate the  
20 importance of diesel exhaust to workers. And I think it  
21 provides a good opportunity to follow up on what Davis  
22 Baltz emphasized in his comments, that some of these  
23 special studies be directed to occupational exposures.  
24 And I think there has been a lot of activity, not only in  
25 the ports, but in West Oakland, with the truckers or

1 unions and communities working together on diesel exhaust.

2           So this would represent another opportunity to  
3 incorporate an occupational component into the  
4 Biomonitoring Program. So I just want to make sure we  
5 don't lose sight of that as we go forth with diesel.

6           DR. KROWECH: I wanted to make a correction on the  
7 flame retardants.

8           Gail, Krowech, OEHHA.

9           I just wanted to mention that the tris,  
10 chlorinated tris compound that I mentioned, I actually  
11 said the wrong one. The one that is showing up a lot and  
12 used in furniture foam is the Tris 1,3-dichloro-2-propyl  
13 phosphate.

14           DR. ROISMAN: Rachel Roisman, OEHHA.

15           I also wanted to encourage the Panel to keep in  
16 mind that there is still this, sort of, new chemical group  
17 in the DTSC labs as part of the CDC agreement. And if  
18 there are chemicals that are, you know, not currently  
19 planned for development, for instance, the phosphate flame  
20 retardants or others that you would particularly like to  
21 see, the Program focus on this would be very helpful for  
22 us to receive that input from you.

23           ACTING CHAIRPERSON LUDERER: Dr. Solomon.

24           PANEL MEMBER SOLOMON: Well, one obvious  
25 candidate then might be some of these tris phosphate

1 chemicals, recognizing that they are a different chemical  
2 class, so it's going to be a fair amount of work for the  
3 lab, but that those might be of interest.

4           And then the other that popped out at me is not  
5 planned is the short-chain chlorinated paraffins, which  
6 actually, you know, Mr. Baltz mentioned that Lisa Jackson  
7 listed some priorities that EPA has identified in her talk  
8 last week. And actually the short-chain chlorinated  
9 paraffins are now toward the top of EPA's priority list,  
10 and might be something where some information development  
11 could be useful here in California as well.

12           ACTING CHAIRPERSON LUDERER: To follow up on that  
13 question, would some of the phosphate -- brominated and  
14 chlorinated phosphates be able to be bundled or would  
15 there -- would they need to be analyzed separately, and  
16 maybe add on also the issue of the short-chain paraffins.

17           DR. PETREAS: Myrto Petreas, DTSC.

18           When we put this in the proposal, it was tied to  
19 obtaining the new instrument, the time of flight mass  
20 spectrometer. And this is to really look at truly unknown  
21 chemicals, not to go out after certain ones that we  
22 already know about, but what could be there that nobody  
23 has ever thought about.

24           So that was the intent. And that's on the last  
25 year of the project, so we have way time by that time to

1 maybe have other priorities. But the intent was to really  
2 look at unknowns, new chemicals.

3 Now, in response to your question or rather the  
4 phosphates, we haven't looked into them. I'm sure there  
5 will be methods, and many of them can be grouped together.  
6 But certainly they're not grouped with the PBDEs that  
7 we're doing now or -- for example, the HBCD hexabromo  
8 cyclododecane, requires totally different instrumentation,  
9 but it goes together with the TBBPA. So there's certain  
10 ones that can be grouped together, but so far we haven't  
11 had resources to look into them.

12 ACTING CHAIRPERSON LUDERER: Dr. She and then Dr.  
13 Wilson.

14 DR. SHE: Jianwen She, CDPH Lab. Some of this  
15 phosphate flame retardants I agree with what Dr. Petreas  
16 said, that you cannot bundle them together. Recently, I  
17 think Professor Tom Webster from University of Boston, he  
18 suggests some of these chemicals should be looked at the  
19 urine, look at the metabolite. So that maybe quite  
20 different than the PBDE. You're looking for the theorems.

21 ACTING CHAIRPERSON LUDERER: Dr. Wilson.

22 PANEL MEMBER WILSON: This is just a clarifying  
23 question. Are we seeking input now on determining  
24 additional chemicals of interest or are we just focusing  
25 on flame retardants?

1 MS. HOOVER: I mean, you know, basically your  
2 input on chemicals of interest. And, I mean, I think what  
3 Dr. Petreas mentioned is also very interesting, so your  
4 input on that as an approach. To me, that sounds like a  
5 very promising thing to do. So just general discussion  
6 and also maybe more discussion of -- the other thing, and  
7 I'm not sure if we said this, but just to be clear, this  
8 is commenting on the CDC proposal, but we're also talking  
9 about, you know, looking further out as well.

10 So supposing we come across another source of  
11 funding, we would like to know, okay, if you have more  
12 funding, we'd be really interested in these chemicals. So  
13 we have that, you know, as information that we can use in  
14 forming proposals. That would be very helpful as well.

15 PANEL MEMBER WILSON: Great. So I guess what I  
16 would add to that is that, you know, one of the things  
17 that Lisa Jackson also pointed out, you know, very clearly  
18 in her remarks here in San Francisco, where there's  
19 structural problems with the gathering of information on  
20 both hazard and exposure in the U.S. that are the legacy  
21 of the Toxic Substances Control Act, and that the  
22 Administration is, you know, quite focused on addressing  
23 those data gaps. And that that's going to happen  
24 potentially fairly soon.

25 And California, of course, under AB 1879 is, at

1 least by statute, expected to do that as well. And so I  
2 would, you know, suggest that as, you know -- you know,  
3 that as information begins to become more robust, both on  
4 hazard and exposure and perhaps uniquely for California,  
5 that there will be, I think, opportunities for us to begin  
6 focusing on additional chemicals of concern that, you  
7 know, become clear.

8           And that it's, you know, in the next -- even in  
9 the next year or two. And so I guess I want to -- I don't  
10 want to close off the possibility that we, you know, have  
11 the possibility of focusing on those substances that rise  
12 to the top as data becomes, you know, more robust, as  
13 those processes, both federally and here in California,  
14 roll out.

15           ACTING CHAIRPERSON LUDERER: Dr. Quint.

16           PANEL MEMBER QUINT: Julia Quint.

17           I was going to mention another source of  
18 information or something that's unique to California, and  
19 again it's the continuing, you know, substitution of  
20 chemicals, based on, you know, subsequent -- based on  
21 reducing VOC limits. You know, we have a unique situation  
22 where we are actually -- the market is responding to  
23 California's, you know, need to make the air clean,  
24 especially in southern California.

25           So we are on almost a continual basis, new

1 chemicals are being introduced. We just had one, dimethyl  
2 carbonate down in the south coast that was introduced that  
3 potentially could have had long-term health problems.

4           So I think for us, particularly in California,  
5 you know, we have a situation where we need to pay  
6 attention to new chemicals that are being substituted in,  
7 because the local air quality management districts are  
8 making regulations that prohibit or ban use of existing  
9 chemicals in certain industrial, you know, sectors.

10           You know, and it is unique to California.  
11 Certain chemicals are used -- they continue to be used in  
12 other parts of the country that can't be used here. So  
13 that's just another thing for us to pay attention to  
14 that's unique.

15           ACTING CHAIRPERSON LUDERER: Dr. Wilson.

16           PANEL MEMBER WILSON: Mike Wilson.

17           And to follow that up, you know, I'm just  
18 completely in agreement with Dr. Quint on this, that in  
19 particular we have very little understanding of the  
20 substances that are forming the material basis and the  
21 chemical basis for clean energy technologies, for new  
22 building technologies, LEED standard and so forth. And  
23 the information that we are becoming -- that is becoming  
24 clear is that there are a whole set of toxic materials  
25 that are used in those technologies.

1           So, for example, you know, we dealt with, in  
2 fact, with Dr. Quint with HESIS with hexane acetone blends  
3 used in the vehicle repair industry, and the sequelae for  
4 that being automotive repair mechanics with peripheral  
5 neuropathy and so forth here in the Bay Area.

6           So it's now -- what we've learned is that the  
7 adhesive that's used in insulating mechanical systems in  
8 commercial buildings for water and air ducting, water  
9 pipes and air ducting. That adhesive is formulated with  
10 hexane and acetone and about 10 percent toluene, and used  
11 indoor spaces with poor ventilation, and that those work  
12 practices requiring ventilation -- requiring insulation  
13 and weatherization and so forth, the demand for that kind  
14 of work is going to grow.

15           And so it's just an example of new chemical  
16 hazards that we're going to witness that are probably  
17 going to be emerging first in California with our climate  
18 change initiatives and so forth, that we need to be paying  
19 attention to I think in this program as well. We're going  
20 to see these rolling out in the next couple of years even.

21           MS. HOOVER: Sara Hoover, OEHHA.

22           I just wanted to let people know that Gail  
23 Krowech is our lead for chemical selection. And I think  
24 it would be really great if any of you here like -- you  
25 know, if a new chemical is being introduced, if you could

1 send that information to Gail. And for the listening  
2 audience her Email is gkrowech, G-k-r-o-w-e-c-h  
3 @oehha.ca.gov.

4 So please feel free to continue to send those  
5 suggestions. And we'll be tracking, you know, emerging  
6 chemicals over time and certainly can bring those  
7 chemicals to the Panel as they rise to the attention in  
8 California.

9 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

10 PANEL MEMBER SOLOMON: I just wanted to speak to  
11 what Dr. Petreas mentioned, because I thought it was very  
12 helpful to understand what DTSC's vision is for the end of  
13 the five-year grant period.

14 So just to clarify, my understanding is that then  
15 you would be basically -- does this mean you would be  
16 screening blood for unknowns and then trying to figure out  
17 what those unknowns are? And if so, I think that's a  
18 great use of the money and would actually sort of  
19 provisionally withdraw my suggestions for other chemicals  
20 to put in the queue. Though, of course, I still do think  
21 that it would be great to, you know, look at the short  
22 chain chlorinated paraffins and some of the other flame  
23 retardants, but that would, you know, require additional  
24 resources. And I think that looking for unknowns is  
25 probably more interesting and important.

1 DR. PETREAS: Myrto Petreas, DTSC. The short  
2 answer is yes, that's the intent to screen for unknowns.

3 ACTING CHAIRPERSON LUDERER: Ulricke Luderer.

4 I actually also wanted to say the same thing,  
5 that I think that that would be a great use of the funds  
6 to be able to identify true unknowns. I mean, this is  
7 something that the panel at several meetings had  
8 discussed, that this is something that we think would be  
9 important and would like to be able to do. And it had  
10 sounded like it wouldn't be possible, but I think that  
11 would be great.

12 DR. PETREAS: To clarify. It would be to look  
13 for unknowns for which method development may be needed  
14 after that. But it's looking ahead.

15 Myrto Petreas.

16 ACTING CHAIRPERSON LUDERER: Any other questions  
17 or comments from Panel members?

18 Okay, and it's just about the time that was  
19 scheduled for lunch. So I think we can, at this point,  
20 then, since there's no more discussion items from the  
21 Panel members, break for lunch. We have one hour  
22 scheduled for lunch. It's 12:33, why don't we say 1:35  
23 we'll return and start with the afternoon session.

24 Thank you.

25 (Thereupon a lunch break was taken.)



1 fund development of diesel biomarkers. And they are  
2 actually still in the process of wanting to identify  
3 unique chemical signatures for diesel airborne markers,  
4 much less biomarkers.

5           It's still very much of a regulatory priority for  
6 ARB, but it does not sound like we are going to be getting  
7 any funding from them to do this sort of work in the near  
8 future.

9           One of the other things that they did mention  
10 too, and this goes along with Dr. McKone was saying  
11 earlier, is that there is going to be kind of a paradigm  
12 shift in diesel exposures. With the new controls that ARB  
13 has instituted as of 2007, in terms of having particle  
14 filters and new NOx controls, the emissions that we're  
15 going to be seeing for newer diesels are going to be much  
16 much lower over the course of the, you know, next 10, 15  
17 years.

18           And so any kind of biomarker that we would have  
19 wanted to look at that would have been good, say a few  
20 years ago, may no longer be appropriate to try and  
21 identify in the future.

22           But this brings me to another point that I wanted  
23 to make. I understood that you passed a resolution while  
24 I was upstairs having lunch with ARB --

25           (Laughter.)

1 DR. LIPSETT: -- about diesel. And I'm going to  
2 give you a, sort of, unofficial personal opinion about  
3 this, because we haven't, as a Program, had an opportunity  
4 to discuss this fully.

5 But I think asking the Program to develop a  
6 method to look for diesel biomarkers is a big research  
7 project that we, at least for the foreseeable future,  
8 really don't have the bandwidth to do. It's going to be a  
9 huge process to be able to ramp up and develop methods for  
10 chemicals that we know are going to be -- that we know we  
11 want to identify, priority chemicals that you've already  
12 recommended to us.

13 And I think in terms of trying to develop a  
14 diesel biomarker, we have to figure out well, what is it  
15 that we want to even look at, much less develop the  
16 markers for.

17 And this is the kind of thing that I think that  
18 the Program would have a lot of difficulty trying to  
19 incorporate and it would have to come at the expense of  
20 developing other methods to identify chemicals that you're  
21 really interested in. And I don't mean any disrespect to  
22 the Panel by this, but I think you're asking something  
23 that really would be very, very difficult for us to try  
24 and undertake.

25 And there's one other thing I wanted to add to

1 this too. The other pre-proposal that was submitted to  
2 ARB last year was one that involved looking at people who  
3 are undergoing controlled exposures to diesel exhaust,  
4 which would be an ideal way to look for potential diesel  
5 biomarkers. I don't know what happened to that. It was a  
6 collaborative of a couple of research groups in  
7 California, and I think Battelle.

8 And that is something that I could look into and  
9 try and find out where that is, and we could report that  
10 to you at your next meeting.

11 But again, I think this is something that really  
12 is beyond our capabilities at this point to undertake.

13 ACTING CHAIRPERSON LUDERER: Thank you, Dr.  
14 Lipsett.

15 DR. McNEEL: Your mike is off

16 ACTING CHAIRPERSON LUDERER: Oh, I pushed it,  
17 sorry.

18 Do we have any time for any quick response from  
19 the Panel? Yes, okay. Any Panel members like to respond.

20 Dr. Quint.

21 PANEL MEMBER QUINT: Julia Quint.

22 Thank you, Michael, for that perspective, because  
23 we aren't -- there are many limitations in government  
24 service. And taking on a research -- development of a  
25 research methodology I'm sure it would really stretch

1 staff.

2 I did participate -- you know, agree to the  
3 motion. I thought we were asking to look into whether or  
4 not a method existed, and whether or not it could be used,  
5 as opposed to development of a method. So I think there's  
6 a little confusion, at least on this panel member's -- for  
7 me, about what we actually were asking of staff.

8 So maybe we should just clarify that, because  
9 Peter -- you know, it's been awhile since Peter gave us  
10 his very good presentation on what was available and some  
11 of the difficulties. And I, frankly, don't remember any  
12 of the particulars.

13 So I think we could, you know, all benefit from  
14 just getting a status report on where things are and what  
15 other people have done, because -- anyway I don't --  
16 that's -- because I agree with you.

17 DR. LIPSETT: Yeah, I think a status report on  
18 where things stand, and research into what would be an  
19 appropriate biomarker is something that is eminently  
20 doable, and we can report back to you at the next meeting  
21 about that.

22 But actually embarking on a research project, I  
23 just want to make sure that that's really clear that we  
24 don't really that have capability.

25 ACTING CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

1           PANEL MEMBER KAVANAUGH-LYNCH: Well, I apologize,  
2 because I feel like I opened this can of worms earlier.  
3 But the reason I did is because I saw diesel exhaust on  
4 our list as a method to be developed later, and not under  
5 "not planned", but later. And most of the other things  
6 that are listed as "later" are on this chart of things  
7 that are going to be done during CDC. So I was really  
8 asking well, how come that's the one that's not on there?

9           I might suggest that maybe that should get  
10 changed from later to not planned. I mean, if that is  
11 indeed the case on the public documents.

12          DR. ROISMAN: That's accurate.

13          DR. LIPSETT: You know what, why don't we address  
14 that. We need to talk about this internally, and then  
15 address it when we give you the update at the next  
16 meeting. Does that sound fair?

17          PANEL MEMBER KAVANAUGH-LYNCH: Yeah.

18          ACTING CHAIRPERSON LUDERER: Dr. Wilson.

19          PANEL MEMBER WILSON: Okay. Well, yeah, Mike  
20 Wilson.

21                 My intent in making the motion was that sort of  
22 consistent with what Dr. Quint was saying that  
23 recommending that staff identify biomarker of exposure and  
24 a laboratory method. But I think the word "develop" is in  
25 there. And so that would require obviously a research

1 project to develop it. And as you said, this is going to  
2 exceed what -- you know, it's going to require too much to  
3 do that.

4 So I don't know if you want to just restate it,  
5 if you want to do that, you know, to the Chair to make it  
6 clearer.

7 Ulricke.

8 ACTING CHAIRPERSON LUDERER: Dr. Alexeeff.

9 DR. ALEXEEFF: Hi. George Alexeeff with OEHHA.

10 So we could take out the word "develop" and this  
11 is what -- if we did do that, this is what the motion  
12 would be. "The Panel recommends that Program staff take  
13 step to identify a biomarker of exposure to diesel exhaust  
14 and a laboratory method for its identification of  
15 biomonitoring studies.

16 PANEL MEMBER WILSON: I think that's a fine  
17 clarification.

18 ACTING CHAIRPERSON LUDERER: Are you making a  
19 motion to change? Is that a motion to change the  
20 recommendation?

21 PANEL MEMBER WILSON: Yeah. My motion would be  
22 to accept the text that Dr. Alexeeff has read.

23 ACTING CHAIRPERSON LUDERER: Would someone like  
24 to second the motion?

25 PANEL MEMBER MCKONE: I'll second it.

1           ACTING CHAIRPERSON LUDERER: Then do we need --  
2 Dr. Kavanaugh-Lynch.

3           PANEL MEMBER KAVANAUGH-LYNCH: Okay. I'm not  
4 going to apologize for this. All these other things we  
5 are developing methods. So to say we don't want to  
6 develop a method, I'm having a problem with the wording.  
7 And because we are developing methods for other things.  
8 So it's perhaps because those have identified methods that  
9 could be developed, I just would suggest that we clarify  
10 the wording.

11           PANEL MEMBER QUINT: Define develop.

12           DR. LIPSETT: I think that the ambiguity here is  
13 that for those other chemicals that we're going to be  
14 developing methods for, we know what we're looking for.  
15 For diesel, we don't know specifically what would  
16 represent a unique chemical signature for diesel exposure.  
17 So that's the part that may be difficult initially.

18           And as I mentioned with this other pre-proposal  
19 that had been submitted to ARB, where there were  
20 individuals who were -- who had blood samples drawn before  
21 and after being exposed to diesel in a controlled  
22 environment, that's like an ideal way to try and identify  
23 a biomarker. We don't have those kinds of samples  
24 accessible to us at this point. And we'd have to try and  
25 figure out a way to get people, sort of, before and after

1 exposure. I mean, it's a very expensive proposition, very  
2 time consuming, very heavy-duty research project, that, as  
3 I said before, we simply don't have the capacity to do at  
4 this point.

5 PANEL MEMBER KAVANAUGH-LYNCH: So is the  
6 clarification development of a biomarker versus  
7 development of a method for measurement of something you  
8 already -- of the marker you already have identified?

9 DR. LIPSETT: I think that's right. I mean, we  
10 know what we're looking for with these others, like with  
11 the PBDEs. We know what penta -- the PBDE 47 is. I mean,  
12 those methods are already developed. But say for some of  
13 the newer flame retardants, we know what it is we're going  
14 to be looking for. With diesel, we don't know. We have  
15 to identify what is the appropriate chemical first.  
16 That's the research project. Then once you know, then  
17 developing the methods would be something that would --  
18 presumably the labs would be able to do, but we don't know  
19 what the appropriate biomarker is at this point.

20 ACTING CHAIRPERSON LUDERER: Dr. Quint.

21 PANEL MEMBER QUINT: Julia Quint. I think that's  
22 the point of confusion for me, and not remembering Peter  
23 Flessel's talk is, you know, part of the stumbling block  
24 here. Because I thought that we did have identified a  
25 reasonable -- not that it's been widely used, but that the

1 research had pointed in a certain direction and there was  
2 a lot of promise, in terms of a particular specific  
3 biomarker.

4           So I was -- my understanding was that, you know,  
5 that there was such a fingerprint for diesel that was much  
6 more specific, but you know --

7           DR. LIPSETT: Yeah, I think he was talking about  
8 specific nitro aromatics. But there were three potential  
9 sets of biomarkers that he was talking about that people  
10 were looking into.

11           PANEL MEMBER QUINT: Right.

12           DR. LIPSETT: But none of them really has been  
13 identified as having a unique diesel profile, to our  
14 knowledge. And again, we can have a more extensive  
15 discussion about this at the next meeting, when we  
16 actually know what we're talking about. I mean, when  
17 we've looked and sort of scoured the literature and talked  
18 to researchers in other parts of the country, who may be  
19 looking at this kind of thing.

20           PANEL MEMBER QUINT: But I think the point that  
21 Dr. Kavanaugh brought up is the point of clarification,  
22 when we use the word, "develop" a method, that we are more  
23 precise, in terms of defining what that means. You know,  
24 developing a method for something that has already been  
25 identified, because we're talking about, you know, unknown

1 peaks down the line in year five and things like that. So  
2 I think it's really important somewhere for there to exist  
3 a better definition of what development of a method means  
4 more precisely, at least for some of us, as we come up  
5 with all of these chemicals.

6           Anyway.

7           DR. LIPSETT: Okay.

8           DR. ROISMAN: Rachel Roisman, OEHHA. It sounds  
9 very clear to me that you definitely want to hear an  
10 update at the next meeting about where. And at that  
11 point, it will have been just over a year since we last  
12 talked about diesel in detail. So we could certainly give  
13 you an update about where things stand, and discuss the  
14 feasibility of us, you know, continuing to pursue it. And  
15 I think that that's certainly reasonable.

16           I did want to ask the Panel to consider, we do  
17 have some guest speakers who are going to be speaking this  
18 afternoon. And I know at least one of them has to leave  
19 before the meeting is over. There may be more time to  
20 talk about this at the end of the day, but --

21           ACTING CHAIRPERSON LUDERER: So the question  
22 then, at this point, really, I think would be to the Panel  
23 whether we agree with the revised recommendation and we  
24 can just agree to that now or whether we should go on  
25 until the end, to have more of a discussion about this at

1 the end of the day. Does anyone object to deciding now?

2 PANEL MEMBER SOLOMON: I would propose that we  
3 must move on to other issues.

4 ACTING CHAIRPERSON LUDERER: All right. Does  
5 everyone agree to moving on?

6 All right, we'll move on.

7 So then to actually get back to our agenda for  
8 the afternoon. And we apologize for being off schedule.

9 The first presentation of the afternoon is on the  
10 Maternal Infant Environmental Exposure Project. And Dr.  
11 Tracey Woodruff, Associate Professor at the University of  
12 California, San Francisco will be presenting that.

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

15 DR. WOODRUFF: Thank you. Good afternoon. My  
16 name is Tracey Woodruff. I'm from the University of  
17 California, San Francisco. I'm in the Department of  
18 Obstetrics, Gynecology, and Reproductive Sciences. And I  
19 run the program on Reproductive Health and the  
20 Environment. And I'm going to be presenting to you today  
21 the Maternal Infant Environmental Exposure Project, which  
22 was already mentioned this morning in Rupa's presentation.  
23 It's a very exciting collaboration that we have ongoing  
24 with the State with UCSF and with UC Berkeley.

25 The project intends to fulfill some of the goals

1 of the biomonitoring legislation. It's community based in  
2 that we are focusing on pregnant women and their infants,  
3 and we will be looking at a population within the San  
4 Francisco city.

5 It will also focus on identifying potential  
6 sources of exposure for some constituents or chemicals  
7 that we will be biomonitoring for. And there will also be  
8 a component that is currently planned for reporting back  
9 results to the individuals in the study.

10 The other thing I wanted to mention about this  
11 study, is because we're planning it now, it's a  
12 prospective study. And so that also makes it very  
13 exciting and interesting. And, as you heard, this morning  
14 there has been a lot of great work on the part of the  
15 staff from California. They've secured some money from  
16 the CDC for a cooperative agreement to bring in resources  
17 into the Biomonitoring Program.

18 There is some subset of those resources that will  
19 go towards the funds that will be used to basically do the  
20 pilot study for the MIEEP project. And so I'm going to  
21 talk through a few more of the specifics on some of the  
22 protocols that we have planned for the MIEEP project with  
23 a few more of the details that we have been discussing.

24 I will note that this is all currently in  
25 progress, so we have an outline of how we are going to be

1 moving forward on this research project, but the details  
2 are still being worked out.

3 --o0o--

4 DR. WOODRUFF: I'd also like to point out that  
5 there are two sources of funding for this project. And  
6 the two sources of funding currently fund different  
7 aspects of the research project.

8 The first, as I mentioned, is from the CDC  
9 cooperative agreement. It is also because the State  
10 obviously has very restricted resources, the staff from  
11 the State have gone out to seek funding from other  
12 sources.

13 And it is through their great effort that they  
14 have made contact with the California Wellness Foundation.  
15 We have submitted a proposal by invitation to the  
16 California Wellness Foundation to supplement the CDC  
17 money, which will be used to enhance some of the work that  
18 we're going to be doing -- we're proposing to be doing  
19 under this research protocol.

20 So just to orient you to what we'll be doing,  
21 what is currently if there is funding for in place, and  
22 then what we are hoping to do under the funding from the  
23 Wellness Foundation are the pilot study objectives on this  
24 slide.

25 The CDC cooperative agreement will fund a

1 biomonitoring pilot study of what we're hoping is at least  
2 50 mothers and their newborn infants for exposure to toxic  
3 chemicals. And I'll talk a little bit more in detail  
4 about that.

5           The Wellness Foundation will expand upon this  
6 basic structure to implement -- develop and implement a  
7 questionnaire to attempt to identify sources for select  
8 chemicals that are being biomonitored in the study. There  
9 will also be a protocol developed informing participants  
10 of their biomonitoring results.

11           And as we have put into the wellness foundation,  
12 we are hoping to spend some portion of the time, not only  
13 developing the analysis of the results for use by the  
14 State, but also to digest that a little bit to inform  
15 policymakers, opinion leaders and others in the state  
16 about what we find from the pilot study and what are those  
17 implications for environmental health of residents in  
18 California.

19                           --o0o--

20           DR. WOODRUFF: So the pilot study approach is  
21 to -- we are working with the San Francisco General  
22 Hospital Women's Health Center. UCSD is very fortunate to  
23 be associated with the General Hospital. It is run by  
24 UCSF. And so we are working with faculty as well and the  
25 department of OBGYN to work with us on the study.

1 I'll describe this in a little more detail on a  
2 later slide. But San Francisco General serves a very  
3 ethnically diverse population, and they are primarily  
4 lower SES. So we're very excited about the potential for  
5 what we're going to be embarking on in this study.

6 The cooperative agreement also funds collection,  
7 processing, and shipping of biological specimens for women  
8 who are enrolled in the study. Our plan is to enroll  
9 women, which I'll talk a little bit more, during our third  
10 trimester.

11 One of the challenges in doing this type of study  
12 is we're trying to decrease the time from when we start  
13 the study to when you actually get to hear about the  
14 results. And obviously people are hopefully pregnant for  
15 nine months. So if we try and capture them towards the  
16 end of the pregnancy, we are hoping to shorten some of  
17 that time between the beginning of the study and when we  
18 might see some results, because there's many steps along  
19 the way that we have to complete before we can actually  
20 tell people what we found from this.

21 We'll be collecting a urine sample during the  
22 third trimester. You'll note that we are targeting 100  
23 women to enroll into this study. The other complicating  
24 factor about doing this study, is you cannot predict when  
25 someone is going to have a baby. So this means that

1 there's a little bit of a moving target on our resource  
2 allocation. We have enough resources to do this study,  
3 but we probably don't have enough resources to have  
4 somebody on call 24/7 when people might be having their  
5 babies. We have to be into the clinic, into the delivery  
6 room after the baby is delivered to collect the samples  
7 that have to be processed within four hours.

8           So you can see this has some logistical  
9 challenges to it, which we'll be working out through the  
10 pilot study. But we're anticipating that that may reduce  
11 the number of cord bloods we collect.

12           We'll then, as part of the CDC measure and  
13 compare levels of chemicals in the pregnant women and  
14 their infants. This came up this morning. The analysis  
15 is current -- has been planned to be done by the state,  
16 and possibly by CDC. There's some flux in who may be  
17 doing the analysis for this pilot study. We can talk  
18 about that. And then there will be data analysis and  
19 report generation.

20                           --o0o--

21           DR. WOODRUFF: Now, the Wellness Foundation, for  
22 which we have been -- the State was invited to submit a  
23 proposal to supplement the work that's being done through  
24 the CDC cooperative agreement. UCSF is the PI on that.  
25 It will add these three other pieces to the CDC work.

1 That would be develop a questionnaire on sources of  
2 exposure to select chemicals.

3 The goal of the -- well, I'll talk about this in  
4 a minute, but the goal is to have a questionnaire that  
5 will be administered for no more than an hour to the women  
6 who are enrolled in this study.

7 That means that we have to -- there's lots of  
8 chemicals that we can analyze, but we can't ask about all  
9 the sources, because there's just not enough time to do  
10 that. So that means there has to be some choices made in  
11 what will be the focus of the questionnaire.

12 The other exciting feature of this, which is a  
13 prominent part of the application to the Wellness  
14 Foundation is to develop a protocol for informing  
15 participants of their biomonitoring results. I'll talk a  
16 little bit more about this in one of the other slides, but  
17 there will be two phases of this project that this piece  
18 of the project is being run by UC Berkeley. Rachel  
19 Morello-Frosch is the PI on this. She has a lot of  
20 expertise in how to do report-back of results. There will  
21 be some usability tests and then we also plan as part of  
22 the project to do in-home visits that will have some type  
23 of interview and some feedback on how that goes.

24 Also, part of the Wellness Foundation will be  
25 results communication. We hope to publish this in the

1 peer-reviewed literature. There will obviously be reports  
2 that will be part of working with the State. There is  
3 interest, obviously, to identify what are the best  
4 practices for communicating results. As we learned  
5 through as the study unfolds, and there will be  
6 communication to -- some of the key constituents were  
7 interested in the results of the study, including  
8 policymakers and other audiences.

9 --o0o--

10 DR. WOODRUFF: So this is a rough estimate of  
11 what the population looks like that is served by the  
12 General. The General serves only residents of San  
13 Francisco. As I said earlier, the population is quite  
14 diverse. Over 60 percent are Latina, 20 percent African  
15 American, about 12 percent Caucasian, a little less than  
16 10 are Asian or Pacific Islander.

17 The General has about 1,200 births per year. The  
18 patients tend to be low income. They tend to be  
19 uninsured. They're not -- it's not all uninsured, but  
20 there are a large number of patients who go there who are  
21 uninsured. The population is relatively low literacy, so  
22 this will be a challenge for developing the questionnaire.  
23 And more than half are primary Spanish speakers.

24 So, as you can imagine, this is going to be  
25 something slightly different than what other biomonitoring

1 studies perhaps have been doing in the past.

2 --o0o--

3 DR. WOODRUFF: So the process that we have  
4 proposed, as I said, is to recruit women during the third  
5 trimester, so this will decrease the time that it takes us  
6 to get to the collection of cord bloods. Essentially, we  
7 will identify women through -- we are working with Dr.  
8 Naomi Stotland who is one of the attending physicians at  
9 the clinic. We will be looking through the patient  
10 records to identify women in their third trimester. We  
11 will identify when they're coming in. We will approach  
12 them, ask them to participate in the study.

13 On the second visit prior to when they deliver,  
14 we will have them come in and complete a one hour  
15 interview, based on the questionnaire that's developed.  
16 We will also collect a urine sample at that time. The  
17 questionnaire implementation is contingent upon the  
18 funding from the Wellness Foundation.

19 We will then be marking the charts and having a  
20 follow up at delivery, so when they come in for delivery,  
21 we will hopefully be able to catch them at delivery. We  
22 will go into the delivery room, collect a blood sample,  
23 which will be taken actually prior to delivery as part of  
24 normal routine care, and collecting the cord blood after  
25 the baby is delivered.

1           The other complicating feature, which I've  
2 mentioned, is that the bloods and urines will all be  
3 initially processed at UCSF and shipped to the State for  
4 further processing, but the processing that we do at UCSF  
5 will have to occur within four hours of collection to  
6 ensure that we accurately capture the particular analytes  
7 that we're interested in. So that's another wrinkle in  
8 how we implement the protocol.

9           After we collect the biological samples, they  
10 will -- as I said they'll sent to the State. The State  
11 will do their post-processing. The State will analyze  
12 them for particular analytes, which I will be talking  
13 about the draft lists that we have proposed currently.  
14 Some of them may be sent to CDC. It can take anywhere  
15 from three months to over a year to get back the results  
16 on the analytes, depending on which analyte.

17           One of our goals, as I said in the beginning for  
18 this study, is to try and decrease the time from when we  
19 start to when we might start getting results from the  
20 pilot study.

21           So in that scenario, there are some analytes that  
22 are going to be more attractive to analyze than others.  
23 And I'll note those when I go through the list.

24           There has been some discussion as Diana brought  
25 up, that we may only use the State lab for this pilot

1 study. And that would then change the types of analytes  
2 that we would be able to analyze, since the lab only has  
3 capacity for a certain set of panels, which were discussed  
4 this morning.

5 Now, the participants will be asked if they would  
6 like to receive their results back. That would be one  
7 last contact with the participants for the report back.  
8 This piece of the project again is contingent on funding  
9 from the Wellness Foundation.

10 This part of the project will be done in two  
11 phases. There will be one phase where the materials will  
12 be developed and tested on a group of women that are  
13 demographically similar, but hypothetical. So there will  
14 be hypothetical results, and there will be non-pregnant  
15 women. And the results will be tested twice. Given the  
16 first time and then how the results were received will be  
17 analyzed and they'll be retested. And then the final  
18 report back will occur with the actual participants in  
19 their homes if they desire.

20 --o0o--

21 DR. WOODRUFF: So the next steps for where we are  
22 going with this study is the first thing -- well, one of  
23 the first things we need to do is to determine the  
24 chemicals of interest. You've already had some discussion  
25 about this this morning. I will show you a slide which is

1 in your handout, which has the draft list that we proposed  
2 to the California Wellness Foundation.

3 We haven't made any final decisions on this list  
4 of chemicals. Obviously, your feedback will be very  
5 important in this. And then again if we decide that the  
6 pilot study will collect biological samples, and those  
7 sample will be analyzed all by the State, that will  
8 necessarily limit the number of samples that we are able  
9 to -- the number of analytes we're able to look at.

10 Some of the criteria we've been considering when  
11 we're thinking about which chemicals to select are very  
12 similar to ones that have already been mentioned. Public  
13 health importance, chemicals that pose a risk to early  
14 development. Will we be able to look at those chemicals  
15 and compare them to data that's been collected through  
16 NHANES? And then because we have this diverse population,  
17 is it possible that we may see racial and ethnic  
18 differences for some of the chemical analytes that we're  
19 proposing to analyze.

20 We've also -- I've given you an outline of how  
21 we're going to be proceeding with the study. We have to  
22 develop a more complete protocol for that. We, of course,  
23 have to go through IRB, which will make some time.  
24 Developing the questionnaire will, of course, be very  
25 challenging because we have to select which chemicals are

1 we going to focus on, and then develop the questionnaire  
2 has to be tested obviously, because we need to make sure  
3 that it meets the literacy needs of the population that we  
4 will be interviewing, and then we have to translate it  
5 into Spanish.

6           We need to define data analysis plan. As you can  
7 imagine it's very complicated. We only have 50 women, 50  
8 infants and 10 panels with over 100 chemicals. As you can  
9 see, that the number of pieces of data that we have to  
10 analyze grows in complexity quite quickly. And so coming  
11 up with different ways to do the data analysis is another  
12 one of our challenges.

13           And then we also have the recruitment materials.  
14 Of course, when we recruit these women, we need to give  
15 them information about the study, what we will be finding,  
16 and then other types of things that they may be interested  
17 in, because obviously if we're talking about chemicals,  
18 that pregnant women are exposed to and their babies, they  
19 may have some questions about just these chemicals, in  
20 general, and what are some of the things that they should  
21 be concerned about.

22                           --o0o--

23           DR. WOODRUFF: So here's the draft list of  
24 chemicals that we had put forth in the Wellness proposal.  
25 This represents a mix of chemicals that can be analyzed by

1 the State and by CDC, if we so choose -- if the State so  
2 chooses to invoke the cooperative agreement arrangement  
3 they have with CDC. It's cotinine, environmental phenols,  
4 heavy metals. We have a category of high-use pesticides:  
5 PCBs, perchlorate, nitrate, thiocyanate, phthalates,  
6 PBDEs, perfluorinated chemicals. And then we reserved a  
7 spot for something that is new or emerging chemical of  
8 concern that we thought would be interesting to look at,  
9 but we hadn't anticipated as part of this panel.

10           The things that are starred are those analytes  
11 that the State can analyze. So, for example, under the  
12 environmental phenols, as you heard this morning, they can  
13 do Bisphenol A and triclosan. CDC is also doing  
14 benzophenone-3 as part of that environmental phenol panel.

15           And under the high-use pesticides, the State can  
16 do some organophosphates and some pyrethroids. And then  
17 also, the other thing is that we have PBDEs as number 8,  
18 but as the State said, this also could be just a larger  
19 group of flame retardants in general, so that could also  
20 be modified.

21                           --o0o--

22           DR. WOODRUFF: So some of the challenges of doing  
23 this are that we're working across three  
24 different -- well, I'm going to say the state is one  
25 institutions, but there are many institutions actually

1 within the state. But let's just say the State is one  
2 institution and then UCSF -- and, of course, UCSF has its  
3 own internal institutions, and then UC Berkeley. So we  
4 have to work across multiple institutions to make this  
5 study happen because of the complexities of the study  
6 design.

7           Obviously, participant recruitment and  
8 questionnaire administration is going to be another area  
9 where it well challenging. And then collecting the cord  
10 blood and processing, we're still working through how that  
11 is going to happen.

12           I would also point out that UCSF, we have to work  
13 with the clinic staff. The clinic staff are primarily  
14 there to facilitate interactions with patients. We have  
15 been very fortunate that we have great clinicians at the  
16 general, who have been very excited to work with us on  
17 this study. And so we feel that that's really going to  
18 help facilitate the study. But we have to be mindful  
19 about working with their own constraints, not only  
20 budgetary, but their patient flow constraints.

21                           --o0o--

22           DR. WOODRUFF: So this just lists the key  
23 collaborators. Of course, there's all the stuff who are  
24 from the CECBP Program. UC Berkeley, the primary PIs are  
25 Rachel Morello-Frosch, as I mentioned, and Holly

1 Brown-Williams, who's also been working with us on this  
2 project. And then from UCSF myself, Jackie Schwartz, who  
3 will be coordinating the study at our end, and Dr. Naomi  
4 Stotland who is the co-PI and clinician who is working  
5 with us from the General.

6 And then I'd also like to mention Dr. Rebecca  
7 Jackson, because she manages clinic flow at the prenatal  
8 clinic, and is a very important participant, even though  
9 she's not receiving any resources from any of the funding.

10 --o0o--

11 DR. WOODRUFF: And with that, I'd be happy to  
12 entertain any questions or suggestions for the study.

13 ACTING CHAIRPERSON LUDERER: Thank you for that  
14 wonderful presentation. It sounds like a very exciting  
15 study. And I'm sure all the Panel members agree with me  
16 in thanking you and all the CECBP staff who have also  
17 worked so hard on putting this together.

18 I believe Dr. Culver had a question.

19 PANEL MEMBER CULVER: What are the scientific  
20 questions that the full study is intended to answer?

21 DR. WOODRUFF: Well, right now, the focus of the  
22 study is primarily to ask the question what are the levels  
23 of chemicals in pregnant women and their infants in a  
24 population within the State of California.

25 PANEL MEMBER CULVER: Why?

1 DR. WOODRUFF: Well, that is part of what -- this  
2 was entered into as part of the mandate from the  
3 Biomonitoring Program. We do not currently have any other  
4 types of scientific sort of more other hypothesis driven  
5 studies from this population. I mean, there's obviously  
6 many different questions we could ask about the  
7 population, whether particular types of birth outcomes  
8 that might be related or certain types of clinical  
9 measurements that we might be interested in looking at.  
10 But the focus has -- on this project is to just ask the  
11 question what are the levels of chemicals in the pregnant  
12 women and the infants.

13 Diana looks like she wants to say something.

14 (Laughter.)

15 MS. LEE: This is Diana from CDPH. This is  
16 following up on presentations previously, in regards to  
17 pilot kinds of community investigations, in particular,  
18 that the program could carry on, and providing descriptive  
19 information as opposed to hypothesis testing studies. So  
20 as you recall probably, there was a recommendation from  
21 the Scientific Guidance Panel to further explore how a  
22 paired maternal infant kind of study could be carried out.

23 And we've been reporting on progress towards  
24 obtaining, you know, resources to carry that out. And the  
25 CDC cooperative agreement allows some initial funding for

1 the biospecimen -- for the participant recruitment and  
2 biospecimen collection. And we have reported in previous  
3 meetings about our proposed collaborations, discussions  
4 with the UCSF Program on Reproductive Health and the  
5 Environment.

6 PANEL MEMBER CULVER: This is a methodology  
7 study. It would be kind of nice if it also had a  
8 scientific purposely.

9 MS. LEE: At this point, I think we're hope that  
10 when we mount the full 500 person study, that that will  
11 include more of a scientific basis. This pilot is really  
12 intended to allow us to develop the field protocols, test  
13 our instruments et cetera, in preparation for the larger  
14 study, as well as gather some initial descriptive data on  
15 the chemical exposures.

16 ACTING CHAIRPERSON LUDERER: Dr. Quint.

17 PANEL MEMBER QUINT: Julia Quint.

18 I think this will be a very important pilot study  
19 for all the reasons that I think the Biomonitoring Program  
20 is important, because -- and I was delighted to see that  
21 one of the things one of the objectives is to inform  
22 policymakers and opinion -- people -- you know, to tell  
23 people about this study in a way that we can start to help  
24 to ensure prevention. I'm not sure what you will find.  
25 It will -- you know, certainly as much as a pilot can do

1 that will answer questions about what's -- you know,  
2 what's in people's bodies.

3           And to the extent that these exposures are higher  
4 than what you would find in NHANES for a general  
5 population, we can start to have maybe some targeted  
6 outreach about how to reduce exposures.

7           So I think for me, I mean, in a public health  
8 sense, I think it could provide very important  
9 information, and information that fraction, you know,  
10 something that people could do to help improve health over  
11 a period of time, and for policymakers to address things  
12 that people don't have the power to really change by  
13 themselves.

14           And it's not focused on whether or not there's  
15 going to be an adverse outcome in the future. But some of  
16 these things in terms of development and, you know, events  
17 down the line, we don't capture well in surveillance  
18 programs. So I think this is the beginning of doing  
19 hazard identification and then hopefully prevention. So  
20 for me, I don't know if that's scientific, but it  
21 certainly has a big public health potential.

22           DR. WOODRUFF: Right, I mean I would -- it's a  
23 little tricky because, you know, 50 is good number, but  
24 it's hard to say if we'll be able to see anything  
25 definitive. I would say one of the other things that we

1 are interested in looking at and obviously will be of  
2 interest to the scientific community, as well as the  
3 public, is what are the levels that we find in the  
4 infants, and what's the relationship that we see between  
5 the levels in the pregnant women and the infants. So it  
6 gives us some type of idea about the possibility -- the  
7 implications for in utero exposures.

8 ACTING CHAIRPERSON LUDERER: Dr. McKone.

9 PANEL MEMBER MCKONE: Tom McKone.

10 This is sort of a comment. And I don't know how  
11 much you can really address it. But you know, the infant  
12 is within the mother and the mother is within the home.  
13 And you're really looking at the infant and the mother,  
14 but skipping the next you know, there's a boundary  
15 chemically. And, you know, I know the questionnaires will  
16 give you insight, but is there anyway of even partnering  
17 with somebody who could put in -- you know, there's some  
18 of these passive meters that will soak up the very low  
19 vapor pressure chemicals over a week or so. I mean, there  
20 are wipes, dust samples, which aren't as good. I mean,  
21 ideally if you had a passive monitor in the home, you  
22 might be able to see some of these chemicals, and maybe  
23 not for this study, but for the longer term.

24 Because I know it's very frustrating to use  
25 questionnaires to infer, you know, what the chemical

1 composition of the next layer is. It's a very important  
2 layer. The residential environment can be very important  
3 as a source for may -- I mean many of the chemicals on  
4 your list are probably very easy to detect in the  
5 residential environment.

6 DR. WOODRUFF: Yes, that's an excellent point.  
7 And as you alluded to it also requires some extra  
8 resources to be able to either go into the home or ask  
9 people to take things home that they could, you know, do  
10 something with, either through Sampling or wipes or  
11 whatever.

12 It has been something that we've discussed, as  
13 kind of a add-on feature. I'm not -- you know, given that  
14 we've been very focused on just putting together this  
15 study and trying to figure out how we're going to get in  
16 the clinic and do all those types of things, we haven't  
17 really had enough, I guess as Michael Lipsett would say,  
18 bandwidth to sort of focus on that other people of it,  
19 which clearly is important, because it gets to the  
20 prevention part.

21 It will be great to be able to measure these  
22 chemicals in people. But if we don't really know where  
23 they're coming from, it will be -- we'll have a little bit  
24 of a tricky problem in trying to recommend, particularly  
25 when we're talking about the report-back about well, what

1 can people do to reduce their exposures.

2           So we're mindful, but we don't currently -- I  
3 wouldn't -- we don't have any immediate plans to do that,  
4 but it's certainly something that we are thinking about, I  
5 guess is how I would put it.

6           DR. KAUFMAN: This is Farla Kaufman, OEHHA. And  
7 we talked a little bit about this this morning. And, Tom,  
8 when you talked about at one or two previous meetings,  
9 about modeling some of these issues, I mean, that really  
10 resonates.

11           So if we could get the resources, the graduate  
12 students, the studies, the people interested as Tracey  
13 said we haven't had the bandwidth. We haven't had the  
14 resources to focus on those kinds of issues. Now, we're  
15 starting to say we really need to do this now that we have  
16 a little bit of breathing room. And we would definitely  
17 appreciate any resources, any, you know, directions that  
18 you could help with, people who might be interested in  
19 working on it with us, because I think it's -- it's also  
20 just a perfect opportunity for people out there. It's a  
21 wonderful project, and it would be ideal to get involved  
22 be able to get those samples, the environmental samples,  
23 people looking at modeling of specific exposures from that  
24 and the questionnaire.

25           ACTING CHAIRPERSON LUDERER: Dr. Solomon and then

1 Dr. Quint.

2 PANEL MEMBER SOLOMON: Yes. Thank you so much  
3 for that presentation. And I'm very enthusiastic about  
4 this study. It's exactly along the lines of what this  
5 panel was, I think, envisioning and recommending when we  
6 suggested, you know, moving forward with maternal infant  
7 pairs as a high priority for a pilot project.

8 And my question -- I actually have two questions.  
9 One is you mentioned, in terms of the report-back that the  
10 full sort of all bells whistles report-back was contingent  
11 upon it, that, you know, additional Wellness Foundation  
12 funding.

13 And I just wanted to hear a little bit about what  
14 the report-back would be like in the event that that  
15 funding doesn't come through. I certainly hope it does.  
16 But, you know, as you know, as part of this Program, we do  
17 have to provide report-back anyway. And so just sort of  
18 curious what that would look like.

19 The other question I had is about -- and this may  
20 be a bandwidth issue as well -- whether there's a plan to  
21 do presentations to reach out to some of the local  
22 community groups, Environmental Justice groups, et cetera,  
23 that work in the catchment area of SFGH?

24 DR. WOODRUFF: Did you want to -- you seem like  
25 you want to answer the first one about the report-back, or

1 do you want me to say something about the report-back.

2           The current plan right now is under the CDC  
3 funding is only to do biological specimen collections. So  
4 there wouldn't be any report back, unless we get the  
5 Wellness Foundation funding.

6           And then in terms of the community-based groups,  
7 yes, I agree with you. That's very important. We've been  
8 trying to -- I mean, our first take on this was to go to  
9 the some people at the clinic. There's a clinic across  
10 the street that serves -- that the Department of OBGYN  
11 also works with that serves some of the people in that  
12 population. And it's possible that they may be a  
13 resource. But we haven't quite figured out exactly which  
14 groups to work with. And, of course, I think that's an  
15 important aspect that you're talking about is that would  
16 be a good feature is to when we go out to talk about the  
17 results is to include some of these groups that are served  
18 by the general.

19           MS. LEE: Yeah. And the Wellness Foundation will  
20 obviously supply the resources and do a more in-depth  
21 report-back along the lines of -- similar to what Rachel  
22 Morello-Frosch reported in the last meeting, and building  
23 on some of her efforts as well. But regardless of whether  
24 we get the Wellness founding, the legislation does require  
25 us to do a report-back. So it could be something so

1 simple as just a mail -- a letter for instance with a  
2 phone number and a contact, if they have questions.  
3 That's the minimum we would do, but we would still have  
4 some report-back procedure.

5           And with respect to the context with community  
6 groups and so on, that will be something that Rebecca  
7 specifically will be following up on as we plan this study  
8 too. She doesn't know that yet.

9           (Laughter.)

10           ACTING CHAIRPERSON LUDERER: Dr. Quint.

11           PANEL MEMBER QUINT: Julia Quint.

12           You mentioned the breakdown in terms of  
13 demographics, at least racial and ethnic. Do any of these  
14 women work or do you know the proportion that work in  
15 addition -- because that's obviously going to be an  
16 important source of exposure or it could be.

17           And then the second question I had is about for  
18 the Latina population, how many might be newly immigrated  
19 or if immigration is an issue, in terms of body burden,  
20 that could also impact, you know, which analytes are  
21 present or which ones would be of interest. So you  
22 probably aren't nearly there yet, but I don't know if the  
23 General collects information like that.

24           DR. WOODRUFF: In terms of the occupational  
25 exposures, I think Julia knows, but the Panel may not know

1 is we have a small amount of funding from the HESIS  
2 program to do an occupational survey actually at the  
3 General with this population. So we should actually have  
4 some idea about what the state of occupational exposures  
5 within a small sample of women from the pre-natal clinic.

6 Our preliminary discussions with the clinicians  
7 there is it's not very -- I wouldn't say it was very  
8 quantitative. It's sort of more anecdotal.

9 As you can imagine a lot, there's not a lot of  
10 manufacturing, but probably a lot of services -- service  
11 sector type of jobs.

12 Your second question was the --

13 PANEL MEMBER QUINT: About the immigrant --

14 DR. WOODRUFF: Oh, the immigrants, yeah. I don't  
15 have a sense of what the breakdown is. That is  
16 probably -- will be one of the features that -- when the  
17 questionnaire that's being put together, we'll ask --  
18 we'll focus somewhat on some sources, but we'll also be  
19 collecting some of these other pieces of demographic  
20 information that we can't get from the medical chart,  
21 basically.

22 ACTING CHAIRPERSON LUDERER: Tracey, I have a  
23 quick question. What's your timing on this project?

24 DR. WOODRUFF: Well, our goal is to be starting  
25 recruitment hopefully within six months. So, you know, to

1 set everything up so that we can get into the clinic in  
2 six months. It's a little bit ambitious, because there's  
3 a lot of details that have to worked out, but that's what  
4 we're hoping. And then the time -- depending on how the  
5 funning works, we'll spend somewhere between three to six  
6 months collecting -- we'll, we have to spend more than  
7 three months collecting biological samples, but somewhere  
8 in that timeframe.

9           And then the Wellness Foundation is a two-year  
10 funding. So we'd be able to stretch the timelines a  
11 little bit if we were able to get that.

12           PANEL MEMBER BRADMAN: I just have a quick  
13 comment. I think this could be a resource issue. But it  
14 looks like you plan to measure some things in blood, cord  
15 blood, but also some things in maternal urine.

16           DR. WOODRUFF: Yes.

17           PANEL MEMBER BRADMAN: And I don't know if you've  
18 considered also collecting a newborn urine sample. And  
19 then you would be able to compare the urine measurements  
20 with the newborn urine samples. We've done it. It's not  
21 too hard, but it is another sample that requires its own  
22 protocols and effort.

23           DR. WOODRUFF: Yeah. Do you collect it in the  
24 room?

25           PANEL MEMBER BRADMAN: We collected a couple days

1 after.

2 DR. WOODRUFF: A couple days after, so you have  
3 to go to their home.

4 PANEL MEMBER BRADMAN: Right after birth can be,  
5 you know, it's a time when we tried to stay away from  
6 people to not interfere.

7 (Laughter.)

8 DR. WOODRUFF: We're going to be right in there  
9 though, yeah, okay.

10 (Laughter.)

11 PANEL MEMBER BRADMAN: But a group at Columbia  
12 has done it as well, and it's been pretty successful  
13 actually. And that would add a nice pair there.

14 DR. WOODRUFF: Yeah, there is an issue between  
15 the urine, the blood, because you measure different things  
16 in different biological media. We can talk about it.  
17 Again, it's sort of a resource thing. It would have to be  
18 done in the hospital is the issue, because once they  
19 leave, it's many more resources to go out and do the  
20 collection. You know, some women spend a day or so in the  
21 hospital, so I don't know.

22 PANEL MEMBER BRADMAN: It can be done with a  
23 urine bag and it's actually not that difficult.

24 DR. WOODRUFF: Okay. We'll, we're meeting  
25 tomorrow to talk about the protocol. We'll put that on

1 the list.

2 (Laughter.)

3 ACTING CHAIRPERSON LUDERER: I think we have Dr.  
4 Culver and Dr. Wilson who both want to -- Dr. Culver, why  
5 don't you start.

6 PANEL MEMBER CULVER: I'm still looking for  
7 additional objectives or questions that your study could  
8 answer. And because prenatal exposures and childhood  
9 cancer are very important issues, could you perhaps use  
10 questions related to that, as part of your selection of  
11 the chemicals that you would do biomonitoring for?

12 DR. WOODRUFF: So would the suggestion be that we  
13 select one of the criteria from when we're selecting the  
14 chemicals as to -- I guess that would be -- that's the  
15 criteria that is currently -- that the Panel considers is  
16 whether it's a carcinogen or reproductive and  
17 developmental toxicant? Is that --

18 PANEL MEMBER CULVER: Chemicals related -- that  
19 could possibly be related to childhood cancer.

20 DR. WOODRUFF: Yeah, we could consider that as  
21 part of our criteria for selecting the chemicals.

22 ACTING CHAIRPERSON LUDERER: Dr. Wilson, I think  
23 had a question.

24 PANEL MEMBER WILSON: Yeah, thank you. And  
25 Tracey we're just thrilled that you're heading this up at

1 UCSF with your team at the General. And I'm wondering if  
2 you could -- could you clarify again how you're going to  
3 approach the question of occupational exposure among the  
4 participants?

5 DR. WOODRUFF: Well, I think we're going to  
6 include some -- our hope is to include some questions on  
7 the questionnaire that will be administered under the  
8 Wellness Foundation funding. That's part of that hour  
9 long questionnaire that the women will come in to do when  
10 we collect the urine sample.

11 And then we would have some questions related to  
12 asking them about what their occupation was and whether  
13 there was any potential for occupational exposure. I  
14 can't tell you exactly what those questions are going to  
15 look like, because the questionnaire has yet to be  
16 developed, but I believe we will have something on the  
17 questionnaire related to that issue.

18 PANEL MEMBER WILSON: You had mentioned that  
19 there was some funding from HESIS to do some aspect of  
20 that. I didn't quite understand what that was.

21 DR. WOODRUFF: Yes. So we have some separate  
22 funding from HESIS to develop -- or look at the  
23 development of an occupational questionnaire for prenatal  
24 patients, which we're pilot testing actually in this  
25 population at the San Francisco General.

1           So we're hoping that there will be overlap  
2 between these two projects that we can actually use the  
3 questionnaire that we've already developed in draft. And  
4 we're going to be testing it, so we can see how well it  
5 works. It's a little bit long, I think, for the purposes  
6 of the MIEEP study, but it could help us sort of narrow  
7 down on which questions might be most effective in  
8 identifying important occupational exposures. That's what  
9 I meant in terms of the overlap between the two projects.

10           PANEL MEMBER WILSON: Thank you. And obviously,  
11 you know, really interested in those questions, and they,  
12 you know, tend to get neglected.

13           So anything you can do to hang on to those would  
14 be appreciated, I think.

15           DR. WOODRUFF: Oh, yeah. I mean, we'll have  
16 something. It's just how detailed we'll get is sort of  
17 where we aren't quite sure yet, because we aren't sure how  
18 much detail we need, or what kind of -- we aren't quite  
19 sure what the occupations are of the women who are coming  
20 into the pre-natal clinic. And so it could be that, you  
21 know, there may be one area to focus that would be most  
22 efficient, in terms of capturing their occupational  
23 Exposures. So that's why it's a little bit up in the air  
24 still about, in terms of what we'll be doing.

25           PANEL MEMBER WILSON: Okay. Yeah, I guess, you

1 know, it's interesting in that might be a place where  
2 students could help, if it meant sort of gathering  
3 information from sort of MSDS information, and these  
4 things that could sort of help you get better data.

5 DR. WOODRUFF: Yeah. We actually have a student  
6 from Berkeley working on that occupational health  
7 questionnaire.

8 PANEL MEMBER WILSON: Thank you.

9 ACTING CHAIRPERSON LUDERER: Dr. Solomon has a  
10 question, and then I think we need to see whether we have  
11 public comments that were submitted, because we also have  
12 a 10-minute public comment session scheduled.

13 Dr. Solomon.

14 PANEL MEMBER SOLOMON: Yeah. Just to follow up  
15 on one of the points that Dr. Culver made about sort of  
16 getting value out of the study. I was just wondering,  
17 since you have such a great list of thyroid disruptors  
18 here, among the chemicals of concern, what about -- is  
19 there any possibility of getting TSH and T-4 in these  
20 newborns?

21 DR. WOODRUFF: Well, actually I do a screen at  
22 birth, so I suppose we could work with the genetic  
23 screening branch to get those results. So, yeah, I guess  
24 that is possible.

25 PANEL MEMBER SOLOMON: Because if you could

1 get -- I mean, if you could get them to draw them anyway,  
2 and then --

3 DR. WOODRUFF: Well, but they're already doing  
4 the screening, right, so we ought to be able to get that.

5 PANEL MEMBER SOLOMON: And then give you the  
6 results, then that would be --

7 DR. WOODRUFF: Right. So we'd have to work with  
8 them to see if they'd be willing to share those results  
9 with us. So yeah, obviously that would be very  
10 interesting. But I want to caution that we only have 50.

11 (Laughter.)

12 ACTING CHAIRPERSON LUDERER: Okay. I'm just  
13 going to ask now if there are any public comments in --  
14 are there any public comments? Any from by Email?

15 No.

16 Just one.

17 The comment will be from Mr. Davis Baltz from  
18 Commonweal.

19 MR. BALTZ: Are we on? Yes.

20 Davis Baltz of Commonweal. We also thank you  
21 very much for that presentation. It's very exciting to  
22 see this coming along so quickly from an idea to look at  
23 maternal child pairs just a few months ago to now really  
24 being on the brink of implementation.

25 And I think, you know, a number of the things

1 that you are going to undertake with the Wellness money  
2 are going to be very valuable, the development of the  
3 questionnaire, the protocol for informing participants of  
4 their results, and just the whole results communication  
5 issue. You will recall that the statute does require the  
6 program to report back results if desired to study  
7 contributors. And that was our controversial aspect of  
8 the bill when it was in the legislature.

9           We felt it was important to keep in there. And  
10 it was retained. So it is going to be something that will  
11 be sensitive and important to get right. And what you  
12 learn with this pilot project will be put to good use I'm  
13 sure by the Program as they go on to conduct other either  
14 smaller studies or something statewide.

15           I want to focus for a second on one of the  
16 objectives that was listed in the slides as informing  
17 policymakers, opinion leaders and others about the study  
18 results, and their implications for environmental health  
19 in California.

20           I think we need to be rather -- it's something of  
21 a delicate issue, I feel. And for someone who represents  
22 a public interest organization, I'm all for drawing as  
23 many conclusions as we can that lead us towards  
24 prevention, as Dr. Quint was mentioning.

25           But I think it's important to keep in mind that

1 the Biomonitoring Program needs to rest on a foundation of  
2 science that can be unimpeachable and respected by all  
3 parties. So once the data is collected and reported, it's  
4 important that we have these conversations with  
5 policymakers, but it's not necessarily the role of the  
6 program itself to go out and do that education.

7 I think it falls -- it may be better to leave it  
8 to other entities to carry on the conversation that the  
9 data generates. So I just want to put in a cautionary  
10 note on how policymakers will be informed of the results  
11 of this study or other things that the Program undertakes,  
12 so that, as we are trying to get the funding for the  
13 Biomonitoring Program, we avoid any, you know, accusations  
14 or implications that the Program has become politicized  
15 and is using the results to push a certain policy agenda.

16 ACTING CHAIRPERSON LUDERER: Thank you, Dr.  
17 Woodruff. Would you like to respond to that?

18 DR. WOODRUFF: Tracey Woodruff, UCSF.

19 I'm very mindful about what you were saying, in  
20 terms of providing that interpretation of the data. And I  
21 think we're looking at it -- I know from our perspective  
22 we're looking at it -- I now from our perspective we're  
23 looking at it as how do we make sure that these complex  
24 ideas can be understood, because if you've looked at some  
25 of these biomonitoring studies, and probably many of you

1 have, it's a little bit hard to just look at all these  
2 numbers and just have thousands of pieces of data, and  
3 then not be able to at least be able to say, oh, is  
4 this -- how does this level compare -- for example, one  
5 question might be, "How do the levels compare to what's  
6 found in NHANES?"

7           That's just a very simple thing that has no  
8 interpretation, but may be important for people who want  
9 to know. And we want to just be able to essentially  
10 translate that information into understandable language,  
11 rather than, well the median is A, and the median here is  
12 B. People don't understand that.

13           I think that's where we're aiming towards, in  
14 terms of how we make the information a little more  
15 accessible to people who care about what it says.

16           ACTING CHAIRPERSON LUDERER: I know we're behind,  
17 and there -- do we have some information about whether we  
18 need to move on to the next speaker? Is there someone  
19 that needs to leave or do we have time for more Panel  
20 discussion at this point?

21           DR. WOODRUFF: I'm fine, it's not 3.

22           (Laughter.)

23           DR. ROISMAN: We would still like to get the  
24 Panel input on the chemicals to be included in this study.

25           ACTING CHAIRPERSON LUDERER: Any Panel members

1 who would like to start on that issue?

2 DR. WOODRUFF: Yeah, I just would -- we have a  
3 list that we put in the proposal to the Wellness  
4 Foundation. It's on Slide 9 there. I just -- this is  
5 where we're leaning. So you should just take a look at  
6 that and see if you have any comments about that,  
7 particularly in light of the trade-offs that we are going  
8 to be considering between the State lab versus the CDC  
9 lab, and who can measure what.

10 PANEL MEMBER SOLOMON: May I?

11 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

12 PANEL MEMBER SOLOMON: It's Gina Solomon with an  
13 opinion.

14 I like your list very much, but, you know, we  
15 will have to make decisions about this State versus CDC  
16 lab or decide to go with the CDC lab and then supplement  
17 it with a few assays done by the State lab, which also  
18 might be possible. And I think that's kind of where I'm  
19 leaning, because I think that this is an important study.  
20 I don't know that -- well, I guess we'll have to hear  
21 about the Kaiser study.

22 But there aren't a lot of others like right now  
23 in the pipeline that I'm aware of that would be competing  
24 for the CDC cooperative agreement resources. I'd love to  
25 hear from staff about that.

1           There's a good one to use the CDC cooperative  
2 agreement for. It would give us cotinine, which I think  
3 would be helpful, which we wouldn't be able to get  
4 otherwise, and a few another things. But I would love to  
5 supplement it with some of the other flame retardants,  
6 because I think that it would be missing a big opportunity  
7 to just get the PBDEs, given the current situation in  
8 California. And so, you know, the perfect world would be  
9 to do this list with added flame retardants that the DTSC  
10 lab could offer.

11           ACTING CHAIRPERSON LUDERER: Dr. Quint.

12           PANEL MEMBER QUINT: Julia Quint.

13           I guess the one -- I like your list as well. I  
14 guess the one that I -- because I don't know much about  
15 exposure pattern, is perchlorate, and if we think that  
16 given where the sample population -- the study population  
17 is coming from, whether or not perchlorate would be a  
18 chemical of a possible exposure of concern. And that's  
19 reflecting what I don't know about perchlorate.

20           You know, I kind of tend to see the exposures as  
21 being related to contamination in certain areas. And I'm  
22 just wondering if these folks live in a place where we  
23 would expect that exposure.

24           DR. WOODRUFF: I think it depends -- this is  
25 Tracey Woodruff. I think it depends on whether the

1 drinking water is one source, but you can also get it from  
2 the food supply. So it could be, because it can --  
3 there's a study by, I think it was, FDA that found that  
4 perchlorate was in a lot fruits and vegetable and dairy  
5 products.

6           So it's not completely -- I mean, I agree with  
7 you, because you kind of think of it as a contaminant in  
8 the drinking water supply in southern California, and  
9 we're looking in San Francisco, which gets their water  
10 primarily from Hetch Hetchy.

11           But if there is some kind of significant dietary  
12 component, which is a little bit what they found in  
13 Atlanta when they did their sort of pilot study. If you  
14 remember you've heard Ben Blount talk about it. He  
15 basically went in the bathroom and collected people's  
16 urine samples, and found perchlorate in all the people  
17 that he just casually sampled in their lab.

18           It could be that we'll find it in this  
19 population. I'm not completely sure, but it does -- it is  
20 plausible, I guess.

21           PANEL MEMBER QUINT: Right.

22           OEHHA DIRECTOR DENTON: This is Joan. Just one  
23 thing to add to that. Also, infants are the sensitive  
24 population of concern for exposure to perchlorate.

25           ACTING CHAIRPERSON LUDERER: Dr. Solomon.

1           PANEL MEMBER SOLOMON: I think the FDA study  
2 indicated that somewhere around 80 percent, 85 percent of  
3 perchlorate exposure is probably coming from food these  
4 days, and not so much -- from the water supply. There  
5 isn't perchlorate in San Francisco water.

6           But what we'd probably actually be getting is a  
7 measure -- a surrogate measure fruit and vegetable intake,  
8 which in this population, you know, we might actually find  
9 pretty low levels unfortunately, because of the relative  
10 lack of access to fresh produce.

11           And so I don't know what that would tell us. But  
12 I think Dr. Quint's point is a good one. This might not  
13 be the optimal population for looking at these analytes.  
14 But, I mean, in terms of if you're going to pick any  
15 maternal child population, it might not be the most  
16 exposed, but we certainly are looking for exposures in  
17 infants, in general. If we were doing this in southern  
18 California, it might be more interesting.

19           ACTING CHAIRPERSON LUDERER: Dr. Lee.

20           MS. LEE: Sorry, it's not Dr. Lee. It's Diana  
21 Lee at CDPH.

22           I just want to remind the Panel, that invoking  
23 the MOU with CDC is then decreasing the amount of  
24 resources we have for the larger study. The MOU enables  
25 us to tap them for a community study of up to 500

1 participants, for up to 10 chemical panels, and one  
2 chemical-specific study that would involve say 200 people.

3           So the Program is considering -- and because we  
4 received the co-op agreement, that one consideration would  
5 be for our labs, the State labs, using their co-op  
6 agreement resources to do the analysis for obviously a  
7 more limited slate of chemicals possibly, and to save the  
8 full 500 from the CDC MOU to use with the larger study.  
9 So that is a consideration I would encourage the Panel to  
10 consider.

11           ACTING CHAIRPERSON LUDERER: So then to clarify,  
12 in just looking at this draft list, it looks like the  
13 chemicals that could not be done, if the State labs were  
14 to measure, would be cotinine, triclosan -- no  
15 benzophenone. Triclosan can be measured by the State  
16 labs. And that's really it. It's really just those.

17           Oh, yes, nitrate and thiocyanate.

18           MS. LEE: Yeah, and it's a more limited panel  
19 certainly of pesticides, in terms of both the  
20 organophosphates and pyrethroids.

21           ACTING CHAIRPERSON LUDERER: Okay. All right.

22           PANEL MEMBER SOLOMON: One other question. Given  
23 the State timelines, some of these are not -- the labs  
24 aren't up to speed -- up, you know, and running yet with  
25 them. And so that would presumably mean that the samples

1 would sit for maybe a year or more or after they're  
2 collected until the labs are ready and able to run them,  
3 is that correct?

4           Because that would then lengthen the time between  
5 when the samples are collected and when the results could  
6 be reported back.

7           DR. SHE: I can speak for CDPH lab. Currently,  
8 we can analyze heavy metals, and we also can analyze OP  
9 metabolites. And we will be able to measure phthalate.  
10 The other ones on the list, you know, from the urine  
11 samples like you mentioned will possibly be stored for one  
12 year before we can really analyze them.

13           So I don't know about Myrto.

14           DR. PETREAS: Myrto Petreas, DTSC. I can  
15 envision like a stepwise release of results from the lab.  
16 And it's up to the principal investigators to decide when  
17 they are going to communicate, you know, piecemeal or the  
18 whole thing. But certain analysis will be very swift,  
19 others will take much longer.

20           MS. LEE: One possibility that's been discussed  
21 with Dr. Rachel Morello-Frosch is that some of the  
22 chemicals that are more readily -- could be more readily  
23 analyzed, say the metals, for instance, and the phthalates  
24 possibly, and one of the OPs, for instance, could be  
25 reported on more immediately, as part of the testing of

1 this phased return process. And it would possibly provide  
2 some guidance to us, because the metals do have some  
3 health reference values, for instance, like mercury, and  
4 the phthalates do not, for instance.

5           And so it would be a way to kind of look at  
6 setting up a format for reporting the balance of the  
7 analytes that could be forthcoming later on, in terms of  
8 those with known or more certain health reference values,  
9 as opposed to those with more uncertain health base values  
10 possibly.

11           DR. PETREAS: Myrto Petreas, DTSC.

12           Something else. This is unusual, in our  
13 experience, that a sample will be coming continuously. I  
14 mean, we're used to going to the freezer and take a rack  
15 of 20 vials. It's not efficient for us to do one sample.  
16 So we have to really batch them, either those, unless we  
17 have another study ongoing. And I doubt that we'll be  
18 covering all of these chemicals on an ongoing basis. So  
19 this is not like a quick turnaround.

20           MS. LEE: And I think given the tentative  
21 timeline that Tracey laid out, that if, in fact, they were  
22 able to start patient recruitment in say six months, it  
23 might not be until the end of next summer or later that  
24 all the biospecimens would be collected and then analysis  
25 would probably be initiated by the labs at that time. And

1 by then, the labs would be further along in some of their  
2 methods and could probably do more analytes, according to  
3 our work plan now.

4 And I agree that probably the results  
5 communication would not be done until all the specimens  
6 were analyzed, because I'm assuming that we'd want to  
7 compare results by an individual amongst an entire group,  
8 and give them some reference as to where they stand within  
9 the study population, for instance.

10 These are still just ideas that we're floating  
11 out there.

12 OEHHA DIRECTOR DENTON: This is Joan. Do we have  
13 any idea how fast CDC's turnaround time will be?

14 MS. LEE: It's 9 to 12 months is there  
15 recommended -- sorry, excuse me, 9 to 12 months for most  
16 analytes. Some could take up to two years. Maybe Asa  
17 could provide more clarification.

18 PANEL MEMBER BRADMAN: Well, it depends on who  
19 the analyst is. How do I frame this? Some of the people  
20 are very clear and stick to their schedule. Some don't.  
21 I know for PBDE's you get very good results and you get a  
22 clear estimate of when you get results back.

23 Also, for the Bisphenol A, you'll bet very clear.  
24 For the non-persistent pesticides, it's a little more  
25 flexible on when they'll come back.

1 Right now, CDC has a lot of competition with the  
2 NHANES. And also they're going to be getting samples from  
3 the National Children's Study. So it's really important  
4 to, when you interface with CDC, is make it clear what  
5 their commitments are and what timeframe they can really  
6 meet, because they're under a lot of pressure as well.

7 And I think that their timeframe will be variable  
8 in the next year, depending on what their requirements  
9 are, based especially on those other efforts.

10 MS. LEE: That's what we were told.

11 PANEL MEMBER BRADMAN: I know personally that I  
12 think it would be valuable for data to come out of the  
13 State laboratories. And I don't know if Program people or  
14 other panelists also see value in that, but I think I  
15 would encourage that as a focus especially for analyte  
16 classes or groups of chemicals that are already available  
17 and on line at this point.

18 ACTING CHAIRPERSON LUDERER: Ulricke Luderer.

19 I just wanted to agree with that. I think there  
20 would be a lot of value in that, in the data actually  
21 coming out of the State labs. And I also wanted to say  
22 that I think that this list of chemicals, these are, you  
23 know, all excellent choices. You know, there are, as Dr.  
24 Solomon already mentioned, multiple chemicals that are  
25 known to affect the thyroid access and that are

1 developmental neurotoxicants and reproductive toxicants  
2 from many animal studies. In some of these chemicals such  
3 as the phthalates, there are some human data.

4           So I think that this is an excellent list of  
5 chemicals. And while I would like, I guess, also to see  
6 all of them measured, I think that there would be a lot of  
7 value to having the State labs do the measurements and,  
8 you know, perhaps it would be possible by the end of the  
9 study period to have some more of these analytes on line  
10 as was already mentioned.

11           Dr. Wilson.

12           PANEL MEMBER WILSON: Yeah, Mike Wilson.

13           Tracey, is this a set of 10 that is constrained,  
14 that it couldn't really be added to?

15           DR. WOODRUFF: No. This is a draft list, so it's  
16 still flexible. Obviously, we are constrained because the  
17 labs can only measure so many things, but this is where we  
18 put our initial draft list together, and there's really as  
19 you see there's a lot of commonalities between the panel's  
20 priority list and what the CDC can measure and what  
21 California can measure. I mean, we're really talking  
22 about some of the chemicals around the margin, I think, as  
23 where we have more flexibility about what we put in.

24           PANEL MEMBER WILSON: You know, I mean  
25 the -- when the Environmental Working Group did their cord

1 blood report, there were four other classes that they  
2 included that I'll just throw out there. One was  
3 polychlorinated naphthalenes, where they have found 50  
4 different congeners. And then brominated dioxins and  
5 furans, chlorinated dioxins and furans and then  
6 polyaromatic hydrocarbons.

7 DR. WOODRUFF: Yeah. Well, I would also add that  
8 the CDC is now measuring many more chemicals that are even  
9 things that we've discussed today, because they also do  
10 parabens and VOCs, which have been released on their  
11 website. And those haven't really been in the mix, in  
12 terms of the discussion. But you're right, there are  
13 other things that are outside that haven't made it onto  
14 this list. It's hard to choose, right?

15 PANEL MEMBER WILSON: Yeah. I mean, these ones I  
16 think are -- I'm not sure what the sources of the  
17 polychlorinated naphthalenes are, but these others are  
18 more pollutants, industrial pollutants as compared -- I  
19 mean, like the PAHs and the dioxins and furans being  
20 pollutants as compared to sort of product-based  
21 substances.

22 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

23 PANEL MEMBER SOLOMON: Well, PAHs are relevant  
24 because of traffic and also dietary sources. And even if  
25 we can't get cotinine, I guess, they're getting some

1 measure of smoke, though not an ideal one.

2           The other one I just wanted to mention is at the  
3 last meeting, we had some discussions about DDT  
4 metabolites. And despite -- you know, there were some  
5 issues about well, DDT isn't around anymore and levels are  
6 going down. But some folks pointed out persuasively that  
7 the NHANES showed, you know, quite significantly higher  
8 levels in Latinos, compared to Caucasians and African  
9 Americans. And this is a very Latina population. And so  
10 it just made me think about whether that's worth tossing  
11 in the mix; that, you know, if our hypothesis is correct,  
12 we might expect to see relatively high DDT metabolites in  
13 this population of women.

14           DR. WOODRUFF: This is Tracey Woodruff. I guess,  
15 you know, if we move towards this going with just the  
16 State labs. So, for example, then you couldn't do  
17 continue. It could be well, maybe we'll add in -- DDT, I  
18 think, can be done at the State lab. So it could be that,  
19 like you're suggesting, we add in things to fill in those  
20 spaces where we have to drop things.

21           So I think that your other point about sort of  
22 things that have been banned a long time ago, is kind of  
23 the slot where the PCBs are right now. I mean, you could  
24 PCB -- not dioxins but PCBs or DDT or that sort of are --  
25 was banned a long time ago. Also, the thyroid hormone

1 disruptor. So it fulfills multiple criteria, I guess,  
2 some of the chemicals on there.

3 CHAIRPERSON LUDERER: Diana.

4 MS. LEE: One last area for the panel that I  
5 would ask for some consideration, since we'll be further  
6 discussing this is, Tracey has already indicated that  
7 there's no way the questionnaire would focus on all the  
8 analytes of interest. So are there key ones in particular  
9 that you want us to focus on as we try to develop the  
10 questionnaire that gets at some of the potential sources  
11 of these compounds.

12 ACTING CHAIRPERSON LUDERER: Dr. Wilson or Dr.  
13 McKone.

14 PANEL MEMBER MCKONE: Tom McKone. Yeah, I  
15 think -- we didn't really look at the questionnaire. But  
16 one of the questions I had, now that this comes up is, is  
17 the questionnaire only a sit down with them and ask  
18 questions or is there some sort of a household survey that  
19 could be tied into it? It's not at their home, right, so  
20 you can't go in and comment on whether they had vinyl  
21 floor or not? I mean, like vinyl might be a huge fraction  
22 of phthalates in vinyl or what kind of toys there are, or  
23 general conditions.

24 I mean, these things -- or if you could even look  
25 at their diet over the last week or so. Those would be

1 things that would give you insight on possible sources,  
2 and the location of their home, proximity to roadways, et  
3 cetera. Is that -- well, some of that you can ask them in  
4 in a question and answer period, where they're not at  
5 their home. But if there's an opportunity to go to their  
6 home and do a home survey, you probably could load in a  
7 lot more indicators of exposure than you could just with  
8 questions.

9 DR. WOODRUFF: Right. So the current plan is to  
10 do it on site at UCSF, either in the clinic or outside the  
11 clinic.

12 Do you think it would be effective if people were  
13 asked to bring something home and then bring it back.  
14 Like so if there wasn't resources to go into their home  
15 but they had to go home and fill something out and bring  
16 it back.

17 PANEL MEMBER MCKONE: Well, it's hard to answer  
18 in a few minutes. I mean, this is the sort of thing we  
19 should brainstorm for awhile.

20 But, you know, I'd be uncomfortable, probably, in  
21 terms of chemistry. There are these ideas that you can  
22 develop a really lipid monitor and you could make it look  
23 like something they can hang up or a toy. But then it's  
24 the -- you get into all kinds of calibration problems.

25 I know, I actually would defer a bit to Asa on

1 this. I know in CHAMACOS, the ability to survey homes and  
2 actually look around and see what condition the home is  
3 in. And particularly build -- I mean, some of these  
4 things are associated with building materials, and knowing  
5 how much furniture or what type they have would help us  
6 understand, you know, contributions to flame retardants.  
7 The age of the home. I mean, there's a number of factors  
8 that could narrow down some hypotheses about the sources  
9 of the chemicals, which again would be hard to get from a  
10 survey away from their home, because then you have to  
11 think of how to elicit to somebody who's not really there.

12 PANEL MEMBER BRADMAN: I think these efforts are  
13 always really challenging. I mean, and if you can't go  
14 into the home, the quality of the information it's hard to  
15 assess. I mean, you could try. This is a pilot study.  
16 And you could have a simple take-home checklist or you can  
17 just do a checklist, you know, as part of the question, in  
18 terms of floor type, you know, how many room carpeted, how  
19 many rooms not, is it wood floor, is it a vinyl, linoleum.  
20 That's probably all you could really get. And you could  
21 make some crude comparisons to see if that's meaningful.

22 There are some efforts, as part of the National  
23 Children's Study, to come up with a subject administered  
24 questionnaires and information. It might be worth  
25 contacting some of the people -- planing people in the NCS

1 and see what they've come up with. And there is some talk  
2 about having home samplers, relatively simple samplers,  
3 that people can administer themselves.

4 And, you know, again, this is pilot study. It  
5 might not be that much more work, something else to track  
6 and do for -- have people come home and do something like  
7 that. I would bet the NCS would be interested in possibly  
8 collaborating on some test project like this.

9 In our experience, it's helpful to have somebody  
10 to go into the home, who speaks the language and can do  
11 the inspection.

12 DR. PETREAS: This is Myrto Petreas, DTSC.

13 A simple thing that we're doing now is vacuum  
14 cleaner bag. We can ask them to bring their vacuum  
15 cleaner bag. We're doing a study now with UC Berkeley.  
16 Pat Buffler and Steve Rappaport, following up on their  
17 leukemia study, getting vacuum cleaner bags from homes of  
18 children, with and without disease. We have the method  
19 already developed. So it would be easy to look for  
20 certain of these chemicals in the home environment as  
21 integrated over time and space in the vacuum cleaner bag.  
22 So short of going to the house, it's something that the  
23 house can come to you.

24 PANEL MEMBER BRADMAN: Right. That's an idea.  
25 And you can also collect those and store them. I mean,

1 it's another \$300 to \$500 a sample to get those tested.  
2 But you could put them in a freezer and then maybe get  
3 some additional funding.

4 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

5 PANEL MEMBER SOLOMON: This takes a somewhat  
6 contrary viewpoint. Since this is a study of pregnant  
7 women, not of kids, one could argue that, you know,  
8 household dust and such things might be a slightly smaller  
9 relative contribution. And some of the -- you know, at  
10 least in the case of phthalates, which is an area I've  
11 looked into a bit recently for sources of exposure. It  
12 seems like the consensus is moving more toward food  
13 being -- diet being the dominant source.

14 So one could imagine doing, you know, sort of  
15 your basic questionnaire, that will get a handle on, you  
16 know, some lead exposure issues and pesticide uses, and  
17 use of anti-bacterial soaps for triclosan. So those are  
18 all easy ones.

19 Then just go in deep into a dietary history  
20 survey. And maybe not dealing with anything else,  
21 because, you know, it's really hard to get lots and lots  
22 of information about, you know, how old is your sofa,  
23 where did you get it, you know. It's not going to help us  
24 all that much, even though it would be great. You know,  
25 what about your curtains and do you have carpet with a

1 carpet pad underneath. You know, and then people may not  
2 be able to recall all the products -- consumer products  
3 they use and what brands they are and so forth.

4           And I could just see that turning into a  
5 complete, you know, nightmare. But, you know, a three-day  
6 dietary recall is a fairly standard straightforward, you  
7 know, survey. And then you would be getting the urine the  
8 same day. And so you'd really be getting a pretty good  
9 reflection, specifically for some of the short lived  
10 things, like phthalates, you know, what they took in. And  
11 I might think that would be the biggest bang for the buck  
12 with the least amount of resources expended.

13           MS. LEE: This is Diana Lee with CDPH.

14           But one of the things we have played around with  
15 is a take-home type of questionnaire, where they would be  
16 able to identify some of the personal care products, for  
17 instance, they use or be able to identify how many  
18 electronics or the type of pillow they use or something  
19 like that.

20           And so these are things that we've been -- had in  
21 the process of developing. And we may still pilot that,  
22 but we are concerned about the take-home burden, so to  
23 speak, that the questionnaire would ensue, and then having  
24 them return that questionnaire to the study centers, for  
25 instance. But if that's something you want us to continue

1 kind of looking into, we can certainly do that.

2 ACTING CHAIRPERSON LUDERER: Are there any  
3 additional comments from the Panel. Have we addressed --  
4 I hit it and the light didn't go on.

5 Have we addressed the major questions at this  
6 point that you had for us, to the extent that we could  
7 move on to the next presentation?

8 MS. LEE: Any comments from the public?

9 ACTING CHAIRPERSON LUDERER: We had that.

10 DR. ROISMAN: Rachel Roisman with OEHHA.

11 I was just going to suggest considering a change  
12 in the schedule, since we have gone over, we could take  
13 our break now, and then come back and do the last two  
14 agenda items -- last three agenda items.

15 ACTING CHAIRPERSON LUDERER: Okay, that sounds  
16 like a good idea. So the break was scheduled for 15  
17 minutes. Do we want to make it maybe a little shorter?

18 MS. HOOVER: Ten. And also just to clarify, the  
19 last item we think it doesn't need to take as long as it's  
20 scheduled for, so we can make up a bit of the time as  
21 well.

22 ACTING CHAIRPERSON LUDERER: Okay, great. So  
23 we'll reconvene at 3:20.

24 (Thereupon a recess was taken.)

25 ACTING CHAIRPERSON LUDERER: All right. I think

1 we need to get started again. It looks like all but one  
2 of the Panel members is here.

3 All right. We're going to get started again with  
4 the next presentation of the afternoon. So our next  
5 agenda item is going to be the CECBP Collaboration with  
6 Kaiser Permanente Research Program on Genes, Environment  
7 and Health. And this is going to be presented by Dr.  
8 Stephen Van Den Eeden, senior investigator in the Division  
9 of Research at Kaiser.

10 Thank you.

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

13 DR. VAN DEN EEDEN: Thank you very much. I just  
14 wanted to thank Michael Lipsett and Paul English for a  
15 little over a year ago discussing this whole process with  
16 me. I'm involved in their Environmental Health Tracking  
17 Program Technical Advisory Group with Dr. Quint and Dr.  
18 Solomon. Also I'd like to thank Dr. Das for inviting me  
19 and congratulations to your group. I think this really is  
20 a pretty fantastic advance forward.

21 I also wanted to give a two second introduction,  
22 not to Kaiser, because presumably everybody has at least a  
23 halfway decent idea of Kaiser, but actually our research  
24 division. We've been in existence since the early  
25 sixties. It was actually a nascent effort at creating an





1 research, epidemiology. Those sorts of things. We also  
2 have a whole group actually that's focusing solely on LC  
3 issues, ethical/legal/social implications. So they're  
4 looking at those kinds of things.

5           When you consent people for these kind of  
6 studies, what do they understand? What do they retain?  
7 Those sorts of things.

8           I'm going to move quickly --

9                               --o0o--

10           DR. VAN DEN EEDEN: -- in terms of time.

11           I kind of alluded to all these things. We have  
12 the infrastructure in place to do a lot of these kinds of  
13 things.

14           I wanted to comment about one of the things that  
15 Dr. Wilson mentioned. You know, when you put stuff into  
16 long-term storage, you want it for two reasons. One is,  
17 you don't know what you want to look for 20 years down the  
18 line.

19           The other reason obviously is health related,  
20 that you want to, you know, link that to long-term health  
21 data. And I think that's one nice advantage of Kaiser and  
22 research within Kaiser is we basically have a fairly loyal  
23 membership. And so we have people -- we are just  
24 finishing a study where we looked at birth records from 30  
25 years ago and health outcomes now, kind of thing. So it

1 allows you to do some very interesting research.

2 --o0o--

3 DR. VAN DEN EEDEN: Just I'll go quickly. You  
4 know, we had a phase where we got some money to just kind  
5 of get this up and going. Some of it which was the whole  
6 consenting process and things like that. I won't really  
7 go into that. If you have questions, feel free to ask me.

8 --o0o--

9 DR. VAN DEN EEDEN: We have a -- we've created  
10 disease registries within our electronic databases. And  
11 it pretty much spans the kinds of areas that, you know,  
12 most people are interested, and certainly the prevalent  
13 diseases, and a lot of not-so-prevalent diseases. I think  
14 two things to note is we're doing not just diseases.  
15 You'll notice in the upper right hand part of the column,  
16 we're creating a healthy aging component to this. And  
17 I'll talk about this in another second or two.

18 But we're also creating a pregnancy cohort, which  
19 follows up nicely with Dr. Woodruff's talk.

20 --o0o--

21 DR. VAN DEN EEDEN: So where are we right now  
22 with this?

23 We've done a survey to all adult members in  
24 northern California. It was a -- we included some  
25 translation versions for those that desired it and wanted

1 it. It's a five-page questionnaire, so it's fairly short  
2 compact. It doesn't get, you know, deep into lots of  
3 areas that we would like. But we felt like if we had  
4 something shorter, we'd get a higher response, which I  
5 think was the case. And it got at the important standard  
6 epidemiologic co-factors that I think we all typically  
7 want to know about.

8           Right now, we have about 400,000 questionnaires  
9 in hand. And we're developing procedures to continue that  
10 process with on-line kinds of things and in-clinic  
11 completion and that sort of thing.

12           I should add that of those 400,000, over 140,000  
13 of them come from minority groups.

14                           --o0o--

15           DR. VAN DEN EEDEN: So we're in, what we're  
16 calling, the Phase 2 of the granting process. And we've  
17 gotten additional monies from the Robert Wood Johnson  
18 Foundation and Kaiser Permanente to move ahead. And we're  
19 moving ahead with establishing a biorepository and to work  
20 with the Environmental Health Tracking System, and a group  
21 from UCSF and Berkeley to create essentially a built  
22 environment kind of database, and try to merge that with  
23 our population information.

24           We're also working on building out a  
25 biorepository. All the questions that you were asking

1 earlier, we've been wrestling with for a year and a half  
2 now, how you do this. We flew individuals from the UK  
3 Biobank, which is probably considered the Cadillac of, you  
4 know, large cohort kinds of biorepository systems in to  
5 consult with us, and figure this out.

6 And the long and short of it is, there's no right  
7 answer. You just kind of do the best you can with the  
8 best available information.

9 --o0o--

10 DR. VAN DEN EEDEN: What we've accomplished to  
11 date is -- well, what we're -- the plans right now are by  
12 the end of next year to have 200,000 DNA samples that are  
13 either blood or saliva, and by 2013 to have 500,000 sample  
14 biorepository.

15 Our current effort has been to buildup a DNA  
16 repository. And we have over 135,000 signed consents and  
17 over 110,000 saliva samples in hand.

18 We are now working on the next step, which is to  
19 develop -- to exploit the Kaiser infrastructure, in terms  
20 of blood collection. You know, in our Oakland area, there  
21 was probably like seven clinical laboratories that they  
22 can go to in each of the medical office buildings, and  
23 that sort of thing. And what we're trying to do is  
24 exploit that infrastructure, so that we can arrange and  
25 consent ahead of time to obtain a blood sample, put it

1 into our full electronic medical record, and the next time  
2 they go in, either for a regular visit or just because  
3 they're interested enough to participate, a research blood  
4 draw would be drawn and that would go into our  
5 biorepository.

6 --o0o--

7 DR. VAN DEN EEDEN: So again, we think we're  
8 going to get at least 100,000 new blood samples, possibly  
9 more through 2013. I won't go through -- anybody who's  
10 done field work knows that collecting blood is a very  
11 expensive proposition. And to be able to exploit this  
12 infrastructure just drives down the cost, you know,  
13 enormously.

14 So that's really what we're trying to do. The  
15 other thing about someplace like Kaiser is that there are  
16 ways to target individuals for a variety of reasons. You  
17 may just want them geographically -- if you're doing  
18 biomonitoring, geographically distributed. And we'd be  
19 able to identify the appropriate information. You may  
20 want them for disease state or a condition like pregnancy.  
21 We have that infrastructure in place, that we know exactly  
22 when they're going to have a visit next time, because it's  
23 in the appointment system and that sort of thing.

24 The other thing I want to mention about this, and  
25 this articulates with the background research that we've

1 been doing, or the other research we've been doing for the  
2 last, you know, 40 years, we have already biorepositories  
3 essentially. We already have over 10,000 specimens laid  
4 down from other studies, that could be exploited as part  
5 of this effort that could be very informative.

6 We have a case-control study of Parkinson's  
7 disease with serum, where we have 700 individuals with  
8 newly diagnosed Parkinson's Disease and 700 controls. You  
9 know, there's biomonitoring and health outcome research  
10 that could be done simultaneously. And I think that's one  
11 of the real advantages, again, of Kaiser is you can  
12 accomplish multiple goals at the same time.

13 The other thing is we have a cohort that started  
14 in the sixties, where we have 214,000 serum samples laid  
15 down from 1964 through '91, with the bulk of them in the  
16 late sixties early seventies. We're doing studies on  
17 thyroid selenium and thyroid cancer in that group. We're  
18 looking at OCs and PCBs and liver cancer and aflatoxin.  
19 We're actually looking at aflatoxin in this to look at  
20 liver cancer. About 40,000 of those individuals are still  
21 current members of Kaiser.

22 You know, we're interested in seeing what  
23 exposure now and exposure, you know, 30 years ago looks  
24 like. We'd be able to go ahead and do that.

25 --o0o--

1 DR. VAN DEN EEDEN: So our process that we're  
2 trying to put into place is that when we have a targeted  
3 individual -- and targeted just may be a random, you know,  
4 member of Kaiser -- is that we contact them and recruit  
5 them. We get an informed consent. Our research staff in  
6 the electronic medical record would place the order for a  
7 blood draw, a research blood draw. The next time they  
8 visit the lab, they have the blood drawn and the specimen  
9 is processed at our regional lab. We have a regional lab  
10 that sees 20,000 specimens a day. It's highly automated,  
11 to say the least, kind of thing. And they're very  
12 supportive. And it would be the kind of thing, instead of  
13 going over to the CBC station, the blood draw, the tubes,  
14 whatever, would go to the research bench and be processed  
15 as we would need to have it processed. And be put into a  
16 the biorepository.

17 So, again there's nice opportunities to take  
18 advantage of Kaiser's situation.

19 --o0o--

20 DR. VAN DEN EEDEN: Having said that, there are  
21 always issues. Nothing is easy. We had to get about --  
22 talk about multiple groups needing sign-off, there's about  
23 42 groups in Kaiser that always has to say something about  
24 something. And we've, you know, working on getting all  
25 those. There's IRB issues. The whole consenting process

1 we've been through and sat down with them to work out how  
2 we consent these individuals. I should add, somebody  
3 asked me earlier. This consent is a consent for general  
4 use. It's not to do a specific study, and to link to  
5 their medical record information.

6           So we get that upfront kind of thing. Because  
7 these blood draws would be done in the Kaiser system, it  
8 becomes a medical practice issue. So where I'm a Ph.D.  
9 epidemiologist, when I do my studies in the field, I'm  
10 able to get the blood draw. We have certified trained  
11 staff who do blood draws in the field. But when this  
12 happens in the Kaiser facilities, it becomes a medical  
13 practice issue. You know, where I can't -- I'm a Ph.D.  
14 I'm not that kind of doctor. I can't order a blood draw  
15 within our system, so we're setting up those kinds of  
16 issues.

17           Kaiser has some co-pays, so we have to resolve  
18 when they -- everybody who does something within Kaiser  
19 has to register that they've had a contact. So we have to  
20 resolve the wiping out of co-pays, when they're there for  
21 the blood draw. And it's there. It just needs a little  
22 more work. We're finishing it up.

23           The other thing is maintaining research  
24 confidentiality. One of the things we routinely do is  
25 say, when we do research, because it tends to be outside

1 of the formal facilities and practitioners is we say your  
2 information will not go into your medical record. The  
3 only exception to that is when we're doing testing that is  
4 of clinical -- known clinical value. If you do a CVC and  
5 you get an out-of-normal range test, we are obligated by  
6 the IRB to tell that individual and to ask them, do you  
7 want us to inform your primary care doc kind of thing.

8           So once they're in the system, we're working on  
9 segregating the information, so that it isn't part of  
10 their formal medical record. And part of that is, you  
11 know, obviously being driven at least initially out of the  
12 genetic kinds of things, where we don't want genetic  
13 information that's sitting there, and part of a medical  
14 record that might get sent off for a job or something like  
15 that. So we're working on that.

16           And then recording of results. Although, that,  
17 frankly, is probably going to be a little bit easier,  
18 because certainly most of the kinds of things that we do  
19 here and most of the kinds of assays that we've done to  
20 date are not clinical assays, not completely, but mostly.

21           --o0o--

22           DR. VAN DEN EEDEN: Kind of individual level  
23 factors that we would have to bring to bear are the  
24 questionnaire data from at least these 550,000  
25 individuals. We have -- I consider the clinical

1 environment to be individual level. Some of the strongest  
2 exposures known to individuals come from pharmaceuticals.  
3 We obviously have a very complete record of what kind of  
4 pharmaceuticals people are overall receiving and taking.

5           Devices we've -- you know, there was questions  
6 about silicone. We were able to link to our database and  
7 do a study on silicone and health outcomes, autoimmune  
8 disease. I mean, it's those kinds of exposures that if  
9 you're interested in, and they're attached to normal  
10 medical care, we would be able to look at.

11           We're also, as I mentioned, working with the  
12 individuals from UCSF and UC Berkeley to create a GIS  
13 database around the built environment. And that's, for  
14 the most part, pretty well done. We, of course, have  
15 census information that we've linked. And then we're  
16 still working with the Environmental Health Tracking  
17 Program to see where we can draw synergy with that -- a  
18 good example again might be the Parkinson's case control  
19 study, where we linked to pesticide use information  
20 geographically, and we can coordinate with disease with  
21 possibly serum exposure, and that sort of thing.

22           The other thing about those kinds of studies is  
23 we often have a very longitudinal record of where people  
24 lived from our databases, so that, you know, you can move  
25 them in time and assign exposure, at least a little more

1 precisely kind of thing.

2 --o0o--

3 DR. VAN DEN EEDEN: New active grants. I won't  
4 go into this. We're doing a genome-wide study of prostate  
5 cancer. We're going to be drawing blood on 1,500 African  
6 American men with prostate cancer, and 1,500 African  
7 American men without. We're doing a very large  
8 multi-ethnic study of bipolar disease. Betty Kahn at our  
9 place is looking at LACE, and factors that influence  
10 survival and breast cancer. And then we recently, within  
11 the last number of days, received recovery money from  
12 these grant opportunities or Go Grants to genotype a  
13 hundred thousand individuals.

14 --o0o--

15 DR. VAN DEN EEDEN: This takes a village. And we  
16 literally have a village working on it. These are only  
17 the -- literally the sort of scientific level individuals.  
18 The staff that's working on this is probably another 35  
19 individuals.

20 --o0o--

21 DR. VAN DEN EEDEN: And then really kind of get  
22 to the point today why I'm here, what are the  
23 opportunities here. You know, we're setting up our blood  
24 draw to talk about what we're going to get. Discussions  
25 with certainly the staff, your recommendations on what

1 that might look like. We've had active discussions about  
2 whether to collect urine. That becomes a little more  
3 difficult. Certainly in our laboratory setting, it's  
4 routine, you know, urinalysis is a routine laboratory kind  
5 of thing. So we'd certainly be able to do that.

6           When you start talking about 100,000 individuals  
7 and, you know, 100,000 urine samples, it's a resource  
8 issue. Do you have space to process it, and freeze it,  
9 and keep it, and that sort of thing.

10           We've also talked a lot with folks at NIEHS,  
11 National Institute for Environmental Health Sciences,  
12 about ways that larger studies like this can try to get  
13 some home environment kinds of information from the kinds  
14 of things that people have talked about, either, you know,  
15 sending us a sample from their vacuum bag or a swipe  
16 behind the refrigerator, that sort of thing, up to and  
17 including, you know, a self-collected soil sample. There  
18 are actually some protocols out there on, you know, going  
19 outside your door and doing certain, you know, directions  
20 and collecting a sample and keeping that. We've had  
21 discussions about trying to do, at least on a pilot basis,  
22 some things like that.

23                           --o0o--

24           DR. VAN DEN EEDEN: And then really we're very  
25 interested in -- and we is not just RPGEH, but I think the

1 whole group of researchers. It's already being  
2 manifested, as a matter of fact, through the CYGNET study.  
3 That's Dr. Kushi, who's the PI of that is in the office  
4 next to me, kind of thing.

5           Our folks are very interested in collaborating to  
6 the best we can. And again, I think there's many  
7 opportunities where we can have multiple purposes. We  
8 curve have biomonitoring efforts, when they're in an  
9 existing study sample, where, you know, we'll get some  
10 idea of the distribution and levels out there, but they're  
11 going to have maturation rates for six to eight year olds.  
12 There's hypothesis-driven studies right there, kind of  
13 thing.

14           We have studies that are going in on  
15 multi-generational -- three generations, where we have  
16 samples with the CHDS sample. We have the third  
17 generation folks within Kaiser. We have a grant in to  
18 look at levels from pregnancy, the first pregnancy, to  
19 levels in the current group of women.

20           And we're working up a proposal now to look at  
21 male infertility. You know, there's a lot of estrogen  
22 disruptors and that sort of thing. We're also actually  
23 very interested in chemicals that disrupt the androgen  
24 pathway, that sort of thing. So a lot of opportunities  
25 here. And I think that's it.

1           ACTING CHAIRPERSON LUDERER: Dr. Denton.

2           OEHHA DIRECTOR DENTON: Just to make sure, if the  
3 Program worked with you as an investigator for Kaiser, can  
4 there be sharing of the blood samples or urine samples?  
5 That is, for some of these individuals, could those  
6 samples be sent to a CDPH lab or a DTSC lab for further  
7 analysis of these target chemicals?

8           DR. VAN DEN EEDEN: Absolutely. So typically,  
9 most of our assay work -- and again unless it's clinical,  
10 you know, unless you want a CVC, a hemoglobin A1C or a C  
11 Reactive Protein or something, unless it's clinical, it  
12 all goes outside of our place.

13           OEHHA DIRECTOR DENTON: And how about the  
14 information, the patient information, the location that  
15 they live, you know, their age, their sex, that kind of  
16 thing. Is that confidential that's held within Kaiser?

17           DR. VAN DEN EEDEN: There are ways that it can  
18 happen. So we can certainly -- you know, if we put in a  
19 protocol that we're interested in this group of people and  
20 we need to know where they live, and we go to our IRB, and  
21 they say this is a legitimate research project, put in the  
22 appropriate DUA, Data Use Agreement, that basically says  
23 that, you know, the State individuals will keep it within  
24 the minimal number of individuals. It will be, you  
25 know -- it's not something that our IRB will just let be

1 put up on the web for example. So it would allow us to  
2 share, you know, so that a targeted effort would be able  
3 to be done.

4 OEHHA DIRECTOR DENTON: So one last question, is  
5 that happening now with the Program? Rupa, are you --  
6 what's the status of the collaboration with Kaiser?

7 DR. DAS: Well, we invited -- this is Rupa Das  
8 from CDPH. We invited Dr. Van Den Eeden here to present  
9 the background on the Kaiser Research Program. We've  
10 entered into conversations with him to look at the  
11 possibility of collaborating and getting samples, possibly  
12 starting next year. And we actually haven't had much  
13 chance to speak, since we had those initial conversations,  
14 where maybe, Stephen, you should describe where it's gone  
15 from there. And so we've entered into some initial  
16 conversations. We're hoping that once it gets past the  
17 Kaiser IRB or whatever it has to go through Kaiser that we  
18 would start looking at ways to collect field samples, and  
19 collaborate and then analyze them. But I think Stephen  
20 should answer some of the internal Kaiser questions.

21 DR. VAN DEN EEDEN: Yeah, you know, our take -- I  
22 mean, we have studies that samples come in and all the  
23 information goes, because it's a multi-site study, and  
24 there's a coordinating center and all that.

25 And, you know, the bottom line is that if you're

1 approaching somebody to be involved in a study, and we  
2 know ahead of time that we're going to share, we consent  
3 them to do that. And essentially once it's consented, you  
4 know, the IRB is fine with that. I mean, it's not a  
5 barrier. And it's basically just being up front with  
6 them.

7           Now, with existing samples that we have, that  
8 becomes more problematic, because we never consented them  
9 to say, oh, we're going to do -- now, we might be able to  
10 send samples over and have them analyzed, but they would  
11 be blinded samples. You know, we could do lots of the  
12 analysis that they might be interested in, where do people  
13 live when they were drawn. And, you know, we can do all  
14 that. But in prospective collection, if you consent them  
15 that you're going to do this, it's essentially not an  
16 issue.

17           ACTING CHAIRPERSON LUDERER: Dr. McKone.

18           PANEL MEMBER MCKONE: Thank you. First of all,  
19 this is very interesting. I think it offers a lot of  
20 opportunities. One that I'd like to pursue a little bit,  
21 and it sounds like, you know, unlike the NHANES, which is  
22 a random sample every time it's done. It's longitudinal  
23 in time, but not in person. And it sounds like this  
24 actually offers an opportunity that no one else really has  
25 to do some longitudinal tracking of what's in the blood,

1 and how that's associated with the evolution of somebody's  
2 health or lack of health.

3           And is that -- I mean, am I correct in saying  
4 that you probably are fairly unique in having the  
5 longitudinal time series ability to some extent?

6           DR. VAN DEN EEDEN: Yeah, I think that is  
7 absolutely, true. I mean, we've done, you know, retention  
8 analyses, how long do people stay within Kaiser. And  
9 it's -- you know, it's a funny shape. So, you know, from  
10 birth till age 20, we have very strong retention -- into  
11 the eighties, 80 percent. You know, so if they're born in  
12 Kaiser, 80 percent of them when they're like 18 are still  
13 a member of Kaiser. And not surprisingly, after they  
14 become adult, you know, who knows where they go, who knows  
15 what kind of -- I mean, we are an insured population,  
16 those sorts of things. But then it goes right back up  
17 when you get into about the 45 and 50 year range that you  
18 see that those people are, again, very long-term members,  
19 that they stay for a very long time.

20           PANEL MEMBER MCKONE: So just to pursue this a  
21 bit. In theory, you could get blood samples at different  
22 periods, right, from the same individual and, you know,  
23 again, this is probably confidential, but still within the  
24 system. You know where they live.

25           DR. VAN DEN EEDEN: Yes.

1           PANEL MEMBER MCKONE: A lot about, you know, what  
2 they do, and even potentially how their diet changes, if  
3 that's recorded.

4           DR. VAN DEN EEDEN: That's correct.

5           PANEL MEMBER MCKONE: It's really a remarkable  
6 resource in capturing the kind of longitudinal -- things  
7 we've never been able to get.

8           DR. VAN DEN EEDEN: And the research program  
9 we've had this discussion like -- you know, we probably  
10 couldn't repeat if we get 500,000, we probably couldn't  
11 repeat that. I mean, the biorepository for 500,000  
12 probably runs about four million a year just to like  
13 barely keep running. I mean it's a very expensive process  
14 kind of thing.

15           But, you know, for targeted individuals, you  
16 know, you certainly could do that. And I don't know  
17 whether it was -- it was probably with Michael. I mean,  
18 I've had those discussions about, you know, who are these  
19 individuals, and might there be some of those individuals  
20 we approach right at the beginning and say, look, we want  
21 to go through every, you know, every four years or every  
22 five years or whatever the timeframe would be, to do  
23 exactly that.

24           And again, for some existing things, you know, we  
25 have populations right now that we have biorepositories.

1 So we can go -- you know, right now we can go back to  
2 people that have been drawn 10 years ago. I mean, we have  
3 some of that capability right now, at least for two points  
4 in time.

5 PANEL MEMBER MCKONE: Just one more quick. But  
6 on the other hand, I mean, you still sound like you're  
7 working on the problem of household samples. You don't  
8 really know a lot about their environment, other than -- I  
9 mean, we know location. We know exactly what neighborhood  
10 somebody would be in for this data set.

11 DR. VAN DEN EEDEN: Right.

12 PANEL MEMBER MCKONE: And probably diet to some  
13 extent, but then how -- indoor air quality, dust  
14 samples --

15 DR. VAN DEN EEDEN: That's right.

16 PANEL MEMBER MCKONE: Those things are not really  
17 in the system.

18 DR. VAN DEN EEDEN: That is correct.

19 DR. DAS: This is Rupa Das from CDPH. I just  
20 wanted to add something. One of the things we were hoping  
21 to get out of the Kaiser collaboration is to assess the  
22 feasibility of looking at this as some version of a  
23 statewide sample. You know, again to answer your  
24 question, Dr. Denton, this isn't something that we've  
25 completely planned yet. But given Kaiser's wide reach and

1 all the resources that Stephen talked about, this would be  
2 one way of looking at a possible statewide sample. And we  
3 would have to figure out how we would want to sample this  
4 population using our CDC and NCHS resources, perhaps to  
5 come up with a sampling plan.

6 But that's the hope that we will start out with a  
7 pilot study, but then possibly utilize this as one  
8 possibility of a statewide sample.

9 DR. VAN DEN EEDEN: You know, even a pilot within  
10 northern California covers at least 21 counties, which is  
11 not a bad start probably.

12 OEHHA DIRECTOR DENTON: Just one of the things.  
13 This is Joan.

14 You know, if universal health care becomes a  
15 reality, I would think that there would be a great influx  
16 of members into Kaiser from many demographics. So that's  
17 a whole other thing that may materialize in the future,  
18 and for which this whole thing could capitalize on.

19 DR. VAN DEN EEDEN: Right. And that's actually  
20 some of the groups that we've talked about going after, as  
21 part of getting questionnaire data and that sort of thing,  
22 is all the new members that come in. I mean, it's many  
23 thousands of every kind of thing is getting them engaged  
24 in almost a research mentality as well, that it's good for  
25 health. It's -- you know, to be part of research.

1           ACTING CHAIRPERSON LUDERER: Dr. Culver.

2           PANEL MEMBER CULVER: You also have a cancer  
3 registry?

4           DR. VAN DEN EEDEN: We do. Our cancer registry  
5 within our Kaiser Permanente northern California feeds all  
6 the information to the State registry.

7           PANEL MEMBER CULVER: And you can link your  
8 cancer registry to your biorepository?

9           DR. VAN DEN EEDEN: Absolutely, and in real time,  
10 which is --

11          PANEL MEMBER CULVER: Could be interesting.

12          DR. VAN DEN EEDEN: Yeah.

13          ACTING CHAIRPERSON LUDERER: Dr. Solomon.

14          PANEL MEMBER SOLOMON: I think this is great.  
15 Thank you for coming and giving this presentation. And  
16 it's absolutely the kind of thing.

17          MS. HOOVER: Your mike.

18          PANEL MEMBER SOLOMON: Oh, sorry. This is  
19 absolutely the kind of thing that, I think, makes sense  
20 for this program. And it's a great collaboration  
21 opportunity.

22                 You did mention that some of Kaiser's research  
23 efforts in this area have been funded by Kaiser, Kaiser  
24 Foundation, I assume so far. And I was just wondering  
25 whether additional funding might be available from that

1 source to help support collaboration like this or at least  
2 some of the Kaiser data collection end of it?

3 DR. VAN DEN EEDEN: You can imagine I'm not  
4 authorized to speak on their behalf.

5 (Laughter.)

6 DR. VAN DEN EEDEN: But, in fact, the answer is  
7 yes. I mean, I think, you know, there's a very strong  
8 growing sense within places outside of the Division of  
9 Research and the research community, because we're -- 45  
10 million is a lot of money, but that's speck to what gets  
11 spent, you know, in the whole region.

12 But there are people that are very, very  
13 interested in this. And it wouldn't surprise me if we  
14 would be able to negotiate some support for this.

15 ACTING CHAIRPERSON LUDERER: Any other questions  
16 from other Panel members?

17 Dr. Kavanaugh-Lynch.

18 PANEL MEMBER KAVANAUGH-LYNCH: Thanks for the  
19 presentation. So my understanding of the status now is  
20 you've got DNA in a couple hundred thousand, and you're  
21 trying to get that to be -- or 100,000, and trying to --  
22 and you have this very brief questionnaire. But you  
23 actually have no serum to use for biomonitoring or urine  
24 for biomonitoring.

25 DR. VAN DEN EEDEN: That's what we're putting

1 into place right now. That's correct.

2 PANEL MEMBER KAVANAUGH-LYNCH: And you have no --

3 DR. VAN DEN EEDEN: Other than -- excuse me.

4 Other than existing studies. But for the research -- for  
5 the RPGEH that is true.

6 PANEL MEMBER KAVANAUGH-LYNCH: And part of your  
7 goals for Phase 2 is build database of environmental  
8 exposures. Can you tell me more about how you're going  
9 about that?

10 DR. VAN DEN EEDEN: Well, it's essentially tight  
11 linkage with the Environmental Health Tracking Program.  
12 So the work that Paul English and that group is doing,  
13 because, you know, for us to do it would be to reinvent  
14 the wheel. I mean, they've gotten grants to do this. So  
15 they've got a GIS database that has, you know, all the  
16 pesticide use report, air pollution data, the tracking.

17 PANEL MEMBER KAVANAUGH-LYNCH: So it's nothing on  
18 individual environmental exposures?

19 DR. VAN DEN EEDEN: Other than the brief stuff  
20 that we've obtained in the questionnaire, that's correct.

21 PANEL MEMBER KAVANAUGH-LYNCH: Okay. And is  
22 there any plan to ever do that?

23 DR. VAN DEN EEDEN: Yes. You know, this  
24 is -- when you go -- you know, when you go big, you often  
25 can't go deep to put it succinctly. And we made a

1 decision to go big, and so we haven't gone deep at this  
2 point. With the general idea that what we would be doing  
3 is, I put up there one of our studies is a case control  
4 study of prostate cancer in African American men.

5 So our plan is to go back to those individuals  
6 and conduct an interview with the cases and the controls,  
7 where you've gotten the resources to go deeper into the  
8 kinds of questions that you want to obtain information on.

9 ACTING CHAIRPERSON LUDERER: I have a question.  
10 Yeah, this is really an amazing, unique resource that I  
11 think, there are -- it sounds like there are lots of  
12 opportunities where the CECBP could interface. One  
13 question I have kind of gets back to the idea of maybe  
14 using this to do some form of a statewide sample.

15 So from what -- from your -- and I'm wondering if  
16 you could clarify for me. The RPGEH right now is northern  
17 California only or is there an analogous process also  
18 going on in southern California as well?

19 DR. VAN DEN EEDEN: Not really is probably the  
20 shortest answer. We've been in discussions. Our mens  
21 cohort we're going out to collect a biospecimen from them.  
22 Right now, it's going to be saliva, because -- for a  
23 variety of resources essentially.

24 So we'll have that, but Kaiser regents have  
25 operated autonomously. They don't -- you know, data

1 systems haven't been talking and that sort of thing.

2           We've now gone to a common electronic medical  
3 record. And there's much more integration of the research  
4 groups, in terms of like, okay, let's do this.

5           So there would be certainly opportunities to  
6 collaborate with folks down there, you know, all of which  
7 I know to say okay, why don't we get 500 individuals from  
8 southern California spread out, kind of thing or a  
9 thousand, whatever. And so it certainly can happen. But  
10 right now, it's northern California.

11           ACTING CHAIRPERSON LUDERER: Kind of a related  
12 follow-up question. The biospecimen repositories that you  
13 have from previous studies, you know, going back decades,  
14 is that -- is there a similar repository that includes  
15 southern California specimens or a statewide repository or  
16 is that northern California also?

17           DR. VAN DEN EEDEN: Off the top of my head, I  
18 believe virtually all of them are northern California  
19 only. I can't think of any that involves the  
20 collaboration.

21           ACTING CHAIRPERSON LUDERER: Dr. Wilson.

22           PANEL MEMBER WILSON: Yeah, thank you for your  
23 presentation. And it's, you know, just -- I think we  
24 really appreciate the interest and willingness of Kaiser  
25 to engage with the State on this.

1           And I guess, you know, the question is if some  
2 portion of the 100,000 new blood samples that you're  
3 hoping to obtain each year up to 2013. If some portion of  
4 those were, you know, to enter the biomonitoring  
5 laboratory process, if the data that, you know, come out  
6 of that process would be of use to Kaiser in the work that  
7 you're doing. And if so, if that I'm sort of following up  
8 on Gina's question who the back door, if that would -- if  
9 they would be in Kaiser's interest to help support that  
10 process through the Foundation.

11           DR. VAN DEN EEDEN: Yeah, you know, I guess I  
12 would answer it in two ways or, you know, what the sample  
13 group is. So if it's some kind of random sample of  
14 individuals. You know, a thousand gets pretty hard to do  
15 a lot of outcome research, because they're just a number  
16 of outcomes that happen in a thousand individuals, and any  
17 particular outcome is not going to be very high. But  
18 within the context of other studies, this case control  
19 study of African American men, where, you know, to me it's  
20 a win-win. It's like we, you know, are able to provide  
21 samples, look at environmental factors, how it might  
22 relate to prostate cancer, and look at levels in the serum  
23 of a set of individuals that are essentially randomly  
24 sampled within the Kaiser membership. I mean, it seems  
25 like there's a lot of information that gets able to be

1 used by everybody in real informative ways.

2 PANEL MEMBER WILSON: I mean, it seems to me  
3 that, you know, from the things that we've been talking  
4 about over the months here that, you know, for example,  
5 would those blood samples obtained each year, are those  
6 going to be linked then to these surveys or  
7 questionnaires?

8 DR. VAN DEN EEDEN: Yes.

9 PANEL MEMBER WILSON: And there would be sort  
10 of -- I noticed that there were -- maybe I didn't see it,  
11 but that there was no occupational health aspects or  
12 occupational exposure questions that were included in that  
13 questionnaire. And it's obviously something we're  
14 interested in.

15 And so is the development of those questionnaires  
16 continuing or where are you with that?

17 DR. VAN DEN EEDEN: Well, we have actually  
18 extensive experience in obtaining occupation health  
19 information. I mean, our Parkinson's study spent an hour  
20 with each individual obtaining occupational information.  
21 So, you know, we pretty much know how to do that at the  
22 deepest way you can do it within a questionnaire kind of  
23 format kind of thing, where you collect information on  
24 occupation, tasks, materials.

25 And then we've been using an industrial hygienist

1 to look over the material, that those responses and rate  
2 those kinds of exposures. Because, you know, the bottom  
3 line is most people don't know what they're exposed to.

4 And so, you're at least retrospectively typically  
5 stuck with inferring exposure in these kinds of studies  
6 kind of thing.

7 And what we're working on right now is actually  
8 trying to come up with a shorter form of that, so that you  
9 won't take up an hour's worth of time -- and that's  
10 interviewer time kind of thing.

11 PANEL MEMBER WILSON: Right. Well, thank you  
12 very much. This sounds very promising.

13 ACTING CHAIRPERSON LUDERER: All right. Thank  
14 you very much.

15 We have time now, 10 minutes, for public  
16 comments. And I wanted to ask whether we received any by  
17 Email or comment cards? Are there any individuals who  
18 would like to comment?

19 Well, then we have time for more discussion.

20 (Laughter.)

21 ACTING CHAIRPERSON LUDERER: Any Panel members?  
22 Dr. Wilson.

23 PANEL MEMBER WILSON: Well, you know, one of the  
24 things that occurred to me was if in the IRB process, I'm  
25 just thinking just about, you know, the actual sort of

1 operations of obtaining some of the samples. One of the  
2 things we ran into was participants that were nervous  
3 about providing samples to State agencies. Whereas, they  
4 were fine to do it with the university, but were nervous  
5 about State agencies. So I don't know if that's an inform  
6 consent issue or not, but just in terms of thinking about  
7 moving forward.

8 DR. VAN DEN EEDEN: We've not had, what I would  
9 call, significant problems. And we've done some  
10 collaborations with the CDC and sent samples to them. I  
11 mean, it's sending it to the federal government. So at  
12 least in our experience that's not been a significant  
13 problem.

14 I also think we have sort of this other kind of  
15 advantage, which is Kaiser people approaching Kaiser  
16 members. And even though we're going to be collaborating  
17 and we will be sharing information, I think there's a  
18 level of trust there that works out well.

19 PANEL MEMBER WILSON: Understood.

20 ACTING CHAIRPERSON LUDERER: Dr. McKone.

21 PANEL MEMBER MCKONE: This is kind of technical,  
22 but I think this might be of interest, but have you had an  
23 opportunity, since you've worked with CDC, do you do  
24 quality control studies with them to look at how your --  
25 because you say you contract the samples out. You're

1 looking for sometimes the same things they are. How  
2 often -- or has there been an opportunity to do  
3 consistency, because I think that's something we do worry  
4 about, is, you know, how much consistency we will get  
5 across different labs. I mean, that's why the people here  
6 are going for training at CDC, so we follow the same  
7 protocols.

8 DR. VAN DEN EEDEN: Well, I won't speak for all  
9 30 research studies at our place, but certainly the  
10 studies I've been involved in we use some pilot samples,  
11 where we send them down and get results, and then send  
12 another -- the same split sample down. And if we have  
13 enough, we include it even in our regular samples when  
14 we're actually running the study to see that we get, you  
15 know, at least one or two points in time we get, you know,  
16 at least reliable output.

17 ACTING CHAIRPERSON LUDERER: Has the Panel --  
18 have we addressed the questions that you would like us to  
19 on this topic or should we move on to the next  
20 presentation? Or do you want any particular  
21 recommendations on this?

22 DR. DAS: Again, the purpose of this presentation  
23 was just to inform you about Kaiser's work. And we don't  
24 really have any questions or issues for you to address on  
25 this topic.

1           ACTING CHAIRPERSON LUDERER: Thank you very much.  
2           Dr. McKone.

3           PANEL MEMBER MCKONE: Yeah, Tom McKone.

4           Can the Panel sort of offer an endorsement that  
5 this is a good direction to pursue? I mean, I don't if --  
6 again, it's like we said this morning, I mean, in a way we  
7 feel sort of odd just being silent. Maybe we should be  
8 sometimes.

9           (Laughter.)

10          PANEL MEMBER MCKONE: But I think it's helpful if  
11 we go on record with some sort of statement that we really  
12 think is a very useful direction and encourage both Kaiser  
13 and the State to continue to build a collaboration.

14          DR. VAN DEN EEDEN: I would just add that that  
15 would probably be useful should I go to talk to our  
16 Foundation people about some support.

17          PANEL MEMBER MCKONE: Do we have to do this by a  
18 vote or just sort of by acclamation? I mean, I think the  
19 sense of the Panel is that we should really strongly  
20 endorse.

21          STAFF COUNSEL KAMMERER: You could take a vote.

22          ACTING CHAIRPERSON LUDERER: So would we like to  
23 make a motion? Would you like to articulate what you just  
24 said again?

25          PANEL MEMBER MCKONE: Yes. Let me see if I

1 remember what I just said. I make a motion that the Panel  
2 strongly endorse the Kaiser California collaboration and  
3 continue to explore ways to expand this.

4 PANEL MEMBER WILSON: I would second that.

5 ACTING CHAIRPERSON LUDERER: All right. We can  
6 start.

7 PANEL MEMBER MCKONE: Tom McKone, aye.

8 PANEL MEMBER WILSON: Mike Wilson, aye.

9 PANEL MEMBER KAVANAUGH-LYNCH: Mel  
10 Kavanaugh-Lynch, aye.

11 PANEL MEMBER QUINT: Julia Quint, aye.

12 ACTING CHAIRPERSON LUDERER: Ulricke Luderer,  
13 aye.

14 PANEL MEMBER CULVER: Dwight Culver, aye.

15 PANEL MEMBER BRADMAN: Asa Bradman, aye.

16 ACTING CHAIRPERSON LUDERER: Unanimous among the  
17 present Panel members.

18 All right.

19 So the next -- actually, the second to last  
20 agenda item for the afternoon is a presentation by Dr.  
21 Rupali Das on CECBP future directions.

22 Dr. Das.

23 (Thereupon an overhead presentation was  
24 Presented as follows.)

25 DR. DAS: Thank you. Actually, what I wanted to

1 do first is just to show you this slide, which was  
2 actually one of the last slides of my morning's  
3 presentation, just to summarize what we plan to do over  
4 the next ensuing few months. We're going to proceed with  
5 chemical selection, develop a public participation plan,  
6 continue to hiring staff, and prepare the report that's  
7 required to be submitted to the legislature under the  
8 terms of the legislation.

9           And I think what would be beneficial to us is to  
10 have from the Panel some recommendations -- overall  
11 recommendations for the Program to pursue over the next  
12 few months and beyond that, that we can put into the  
13 legislative report. Let me give you some details about  
14 what our program efforts entail.

15           Given the state of funding which I summarized  
16 this morning, we plan to pursue opportunities for external  
17 funding and collaborations with outside researchers who  
18 have collected biospecimens to leverage our existing  
19 resources to enable us to get -- to do both pilot studies  
20 and to pursue some sort of statewide sample, even though  
21 it's a little bit different than what was originally  
22 envisioned in the legislation.

23                           --o0o--

24           DR. DAS: As I described, we plan to conduct  
25 activities that were specified in the CDC cooperative

1 agreement. We have five different objectives that I  
2 described to increase lab capability and capacity, and to  
3 continue outreach efforts to identify and engage in  
4 additional stakeholders -- in addition to researchers  
5 other stakeholders.

6 --o0o--

7 DR. DAS: We plan to maintain and expand  
8 electronic resources, which include the website, the  
9 listserv and other electronic resources that might be  
10 involved in various ways.

11 We'll continue meeting with the Panel, and to  
12 support the Panel's guidance, in terms of selecting  
13 designated and priority chemicals. And through our  
14 collaborations with Health Research for Action and others  
15 to develop results communication methods and materials for  
16 participants, health care providers, and other groups.

17 And finally, we hope to start developing  
18 biomonitoring reference levels that can be used to help  
19 interpret the lab analyte levels that we obtain through  
20 the Biomonitoring Program.

21 So that's only a summary of what we plan to do.  
22 I think what we would like to see is some discussion from  
23 the Panel members as to whether you support this, whether  
24 there are additional efforts that you think we should be  
25 pursuing, and what we should expect to put as our goals in

1 the ledge -- and recommendations for the program in the  
2 legislative report.

3 ACTING CHAIRPERSON LUDERER: Dr. McKone.

4 PANEL MEMBER MCKONE: Tom McKone.

5 I just want to see if I could expand a bit on  
6 developing biomonitoring reference levels. Does that mean  
7 you're actually going to sort of try and define a baseline  
8 of what's in the population or references? I mean, I  
9 wasn't real clear, I guess.

10 DR. DAS: Okay, let me let OEHHA answer that  
11 question.

12 PANEL MEMBER MCKONE: I mean, it sounds like a  
13 good idea, but I'm not sure exactly if I fully  
14 comprehended it.

15 MS. HOOVER: Well, this is just a very fledgling  
16 effort basically, Tom. So the idea is to -- you know, as  
17 I think Diana and Rupa mentioned, there's something to  
18 compare, in terms of health bases for things like lead and  
19 mercury. There's not for other types of chemicals. So we  
20 want start to investigate. That's one of the hires I'm  
21 planning, a staff person who can actually work on trying  
22 to look at what does it -- you know, the idea of  
23 interpretation when you see -- not just a comparison with  
24 other populations like NHANES, but actually trying to  
25 interpret what does it mean if you have X amount of a

1 chemical in your blood or in the urine. So it's that  
2 concept.

3 PANEL MEMBER MCKONE: A kind of benchmark then.  
4 Not a baseline. I mean, a baseline would be sort of  
5 what's the typical population, but this would be more of a  
6 benchmark idea. That this would be maybe a level of  
7 concern or something that we considered an indicator.

8 DR. ALEXEEFF: This is George Alexeeff.

9 So I think what we want to do is, you know, we  
10 have a large toxicology capacity in OEHHA. And we want to  
11 incorporate that along with physiologically-based  
12 pharmacokinetic modeling and other attributes to look at  
13 what levels might be of concern in various biological  
14 specimens.

15 There is some work already done by ACGIH, and  
16 some other organizations. We can look at those and see  
17 how they might work for this Program.

18 And then as we heard in one of the first  
19 presentations to this group a year or two ago, there's  
20 looking at both individual levels that might be of concern  
21 and population levels that should be something of concern.  
22 So we're going to look at all those types of issues. But  
23 it's just as Sara mentioned, it's something we're just  
24 initiating now.

25 PANEL MEMBER CULVER: So your reference levels

1 would be population based?

2 DR. ALEXEEFF: Well, I think we wanted to look at  
3 as I think it was the German organization. I can't  
4 remember the group. They had both population based and  
5 individual based. We want to look at that at their  
6 program and little bit more carefully and see how that  
7 works.

8 ACTING CHAIRPERSON LUDERER: Dr. Das, did you  
9 have something else?

10 I thought maybe you wanted --

11 DR. DAS: No.

12 ACTING CHAIRPERSON LUDERER: Dr. Wilson.

13 PANEL MEMBER WILSON: Yeah. My question is on  
14 the same issue. My understanding of the ACGIH is that  
15 those are biological exposure indices that correlate with  
16 exposure concentrations, but not with health outcomes,  
17 which is, I think, somewhat simpler, but I worry a little  
18 bit about interpreting biomonitoring findings and health  
19 outcomes at sort of where the state of the science is now,  
20 given sort of the uncertainties and problems of cumulative  
21 exposure, et cetera.

22 DR. ALEXEEFF: This is George Alexeeff. That's a  
23 good point. We'll be looking at those, but part of it,  
24 you're right, is to understand -- well, just as a simple  
25 example, we've developed a number of reference levels for

1 air exposure. And the program we're talking about has  
2 developed information on how air exposure translates into  
3 urine levels. So those are the kinds of things we wanted  
4 to look at, and see if we can make the connection of urine  
5 levels with the air reference levels, for example.

6 PANEL MEMBER WILSON: That seems to make sense to  
7 me. I guess where I worry is if it takes the next step to  
8 risk or not risk, or if there's an actual effort to  
9 conduct a risk assessment based on a biomonitoring  
10 finding. So is it that? Are you thinking of that or the  
11 former?

12 MS. HOOVER: Lauren was just saying, that's done,  
13 for example, with mercury. You know, you can -- I mean,  
14 it depends on -- this is a fledgling effort, I will  
15 repeat. We haven't actually started it. It's something  
16 we want to do. We're planning to hire staff for. It's  
17 something that they're actually is work in the literature  
18 on, and there's been some review of that work by staff.

19 So, you know, any and all comments of your  
20 initial thoughts on it are welcome. You can send them to  
21 me.

22 PANEL MEMBER BRADMAN: I mean, just from a risk  
23 communication point of view or just returning the results,  
24 I mean the most common question you get from people is  
25 what does this mean. And, you know, in our experience, we

1 often say that we don't know what it means. This is for  
2 research. We're learning about, you know, what it means.  
3 And we're obviously -- in an epidemiologic study, we're  
4 not looking at cut points.

5 But that is a question that you'll be asked when  
6 you return results. And to the extent that there's  
7 information out there and a capacity to understand it, you  
8 know, I think it's a good idea to try to go -- you know,  
9 to make that effort. It's fraught with a lot of issues.

10 And it could bring -- you know, sometimes the  
11 setting of those kinds of benchmarks or concentrations can  
12 get politicized or controversial and it may even take away  
13 from some of the scientific effort of just, you know,  
14 producing reliable information about exposure.

15 But on a personal basis and scientifically, I  
16 think it's worth doing just to address that concern of  
17 participants.

18 MS. HOOVER: Yeah. I mean, I agree with what you  
19 just said. And it really is for informational purposes.  
20 I mean, that's the concept of where it all came from.  
21 It's our participation and the kinds of expertise that we  
22 have, it's something that we actually can contribute to,  
23 and devote some efforts to. Because of the background  
24 that OEHHA has, we have a chance of, you know, actually  
25 moving that forward to some degree as much as possible.

1           ACTING CHAIRPERSON LUDERER: Dr. Quint.

2           PANEL MEMBER QUINT: Julia Quint.

3           I think it is essential to do it, because it's  
4 already being done in the literature by folks who are  
5 compare biomonitoring data to -- they're calling it  
6 biomonitoring equivalence. And they actually are  
7 comparing, you know, body burden data to mainly ACGIH,  
8 American Conference of Governmental Industrial Hygienists,  
9 levels, the threshold limit values.

10           And Michael is right, I mean, the ACGIH has done  
11 this for years. And the biological exposure indices are  
12 compared with their threshold limit values. So they are  
13 air measurements that are then compared to the amount of  
14 chemical in the urine or the blood.

15           But, you know, the interpretation of that number  
16 in terms of whether or not there's a health concern is  
17 based on, you know, the air measurement, which is not  
18 based on solid toxicology. So basically, it's a false  
19 sense of assurance in the workplace, that if you have a  
20 certain amount of chemical in your urine, that, you know,  
21 it isn't a health concern. But the number they're  
22 comparing it to is not a legitimate number for most  
23 things, in terms of the issues we're talking about here,  
24 which are, you know, long term or chronic exposure.

25           So I think, you know, in the absence of -- I

1 mean, I don't think we're in the position of doing nothing  
2 here. I think we have to look at this as scientifically  
3 as possible, with all the limitations, because there are  
4 already reports in the literature interpreting those data  
5 in a way that I don't think -- that I think raises a lot  
6 of questions.

7 ACTING CHAIRPERSON LUDERER: Dr. Culver.

8 PANEL MEMBER CULVER: Yeah, to further discuss  
9 that particular issue. The BEIs --

10 MS. HOOVER: Dr. Culver, can you speak into the  
11 mike.

12 PANEL MEMBER CULVER: I'm sorry, the BEIs that  
13 you referred to set by ACGIH are for an occupational  
14 population. The population has to be defined before you  
15 start looking at numbers. And that's why I'm concerned  
16 with our Biomonitoring Program here, is that we be sure  
17 that we identify the population that those numbers relate  
18 to.

19 Hopefully, most of our numbers will be relatable  
20 to the overall California population, broken down by age,  
21 sex, and socioeconomic status and things of this sort.  
22 But always we need to have that divider to which any  
23 number is associated and a little extra.

24 PANEL MEMBER WILSON: Mike Wilson again.

25 I think it's interesting. It gets in to sort of,

1 you know, how we interpret these numbers, and then how  
2 that -- what that -- I think as Asa Bradman pointed out,  
3 how did the numbers then get used in terms of public  
4 policy and so forth.

5           A couple of things. One, the mercury -- I mean,  
6 the mercury is probably a good example that as our  
7 understanding of its health effects has changed over time,  
8 the, you know, safe levels have dropped by orders of  
9 magnitude over the last, I think, it's, what, 30 years or  
10 so.

11           And sort of based on that, that evidence and with  
12 a number of other -- you know, evidence of a number of  
13 other substances, the way the European Union is moving on  
14 substances that are -- substances that are very  
15 bioaccumulative, very persistent, VPVBs.

16           The Royal Commission on Environmental Pollution  
17 and then subsequently the European Commission took the  
18 position that those substances are inherently problematic  
19 by the nature of their physical properties. That by the  
20 nature of their persistence and bioaccumulative properties  
21 we're delivering them into future generations.

22           And so they chose -- with those substances, they  
23 chose not to follow a risk assessment paradigm actually,  
24 and decided that they would -- that those substances  
25 should be -- efforts should be made to steadily and

1 continually remove them from commercial use.

2           And then, of course, -- so that's a select body  
3 of substances.

4           MS. HOOVER: Mike, can I pipe in here for a  
5 second.

6           PANEL MEMBER WILSON: Yes, of course.

7           MS. HOOVER: So that's actually why we are  
8 calling them biomonitoring reference levels. So it's  
9 not -- we actually have that exact issue in mind. So  
10 we'll be looking at those type of things. But I really  
11 need to pipe in here that we can't have this conversation  
12 at this meeting right now about reference levels.

13           What we really need in this section is just sort  
14 of broad recommendations from the Panel about what you'd  
15 like to see, and sort of as specific as possible, because  
16 it's -- for the purpose of this item is specific  
17 recommendations from the Panel to be incorporated into the  
18 lege report.

19           But I do want to say that we definitely plan,  
20 potentially even a two-day meeting on reference levels,  
21 bringing in people who are doing biomonitoring equivalence  
22 now, bringing in other people who have looked at these  
23 issues. So this will definitely get a very big airing and  
24 we'll be asking for more detailed input on the issue as  
25 well.

1           So anyway, you can finish your point, but I just  
2 wanted to pipe in with that.

3           PANEL MEMBER WILSON: Yeah, thank you. And I  
4 guess my point would be that as that work is going forward  
5 that there may be substances that, you know, warrant a  
6 different form of assessment, I guess, if you will.

7           DR. DAS: Thank you. So, yeah, I just want to  
8 reiterate what Sara said, that the item that we're  
9 discussing here is to have your specific recommendations  
10 for what should go into -- what we should put into the  
11 legislative report going forward, what should the  
12 recommendations be for the Program. And just to remind  
13 you, I have these items here, and you could look at these  
14 specific items and agree or change them or add something  
15 or add something that is missing here.

16           And again, just to remind you about the first  
17 item here, given the current state of funding and our  
18 inability to pursue a statewide sample, as was originally  
19 envisioned in the legislation, we are planning to continue  
20 pursuing other funding opportunities and collaborations  
21 with researchers.

22           But your input into that point and the other  
23 points, it would be really appreciated.

24           ACTING CHAIRPERSON LUDERER: Well, maybe I could  
25 just sort of summarize the discussion that we've had so

1 far. We've talked a lot about one of the points that you  
2 had, which is about developing the biomonitoring reference  
3 levels. And I think what we heard from the Panel members,  
4 although there was -- you know, there were various caveats  
5 of things that need to be kept in mind and potential  
6 pitfalls that generally the Panel thought this was an  
7 important endeavor for you to undertake.

8           So I think, unless there's disagreement from  
9 Panel members, that that would be one of our  
10 recommendations.

11           One of the things I wanted to ask about,  
12 regarding your point number one that you just brought up  
13 is whether we, as a Panel, can recommend that the State  
14 fully fund the statewide biomonitoring effort, that that  
15 would be our ideal scenario. You know, although we're  
16 extremely impressed by all the -- you know, what you've  
17 been able to leverage, or the collaborations with MIEEP  
18 and Kaiser RBGEH, and getting the CDC funding, that that  
19 would really be the ideal scenario.

20           OEHHA DIRECTOR DENTON: Dr. Luderer, Dr. Moreno  
21 signed a letter that you could request be put into an  
22 attachment in this report, which did exactly that, that  
23 went to the Agency Secretary. So that could be attached  
24 within the report or to the report or as an appendix or  
25 something.

1           ACTING CHAIRPERSON LUDERER: Dr. Solomon.

2           PANEL MEMBER SOLOMON: Yeah. I very strongly  
3 agree with the points that were just made. And I think  
4 that, you know, we now do have some more funding in hand  
5 for the Biomonitoring Program from CDC. And so, it would  
6 be interesting to just think about how -- you know, what  
7 the additional increment of funding that would be  
8 necessary to allow this Program to now scale up from  
9 really, I think, being in great -- you know, really solid  
10 shape for doing some small pilot projects to really being  
11 able to do what it was -- you know, what is in the  
12 legislation, which is a statewide representative sample.

13           And so, you know, what would the numbers look  
14 like? What would it take? And, you know, I don't know if  
15 that's something that we could ask staff to prepare for  
16 us, but I certainly think that we should, as a Panel,  
17 continue to push for what was in the legislation.

18           So in addition to the small pilot projects that  
19 are commendable, that we should be keeping the ultimate  
20 goal in mind and doing everything we can to remind the  
21 legislature of it.

22           ACTING CHAIRPERSON LUDERER: Dr. Quint.

23           PANEL MEMBER QUINT: Julia Quint.

24           I think along with the initial letter that Dr.  
25 Moreno signed, I think, many months ago now, that we

1 should also have very strong language from the Panel  
2 saying how extremely pleased we are with the  
3 resourcefulness of the staff in, you know, identifying all  
4 these additional funding opportunities and moving forward  
5 so, you know, rapidly with some of the suggestions that  
6 Panel members made about, you know, smaller studies that  
7 could be done.

8           And the interest in this study, the coming forth  
9 of Kaiser as a potential collaborator, I think, we can't  
10 state too strongly how pleased we are with the Program  
11 thus far, so that it's not interpreted that if we don't  
12 have, you know, a statewide sample that we have gained  
13 nothing from this, because, you know, that certainly isn't  
14 the message we want to convey.

15           And also just one other thing, it's been  
16 mentioned a couple of times, but I would really like for  
17 us to also consider an occupational study, either as part  
18 of a, you know, more environmental study or as a separate  
19 effort, because I think it's really important for  
20 California and for a number of reasons that we recognize,  
21 you know, the extent to which workers are exposed to a  
22 number of chemicals of concern.

23           ACTING CHAIRPERSON LUDERER: Dr. Wilson.

24           PANEL MEMBER WILSON: Mike Wilson.

25           I would just add to that, that there are things

1 that the Panel can say that staff wouldn't be able to say.  
2 And that that would be, in terms of our just, you know,  
3 making for the record in that report our unequivocal  
4 support for the work that you've been doing, and the way  
5 you've been able to expand the resources that we do have  
6 in all these other areas is just terrific work. And we  
7 want to get behind it and make that clear in the report.

8 I guess, so I'm saying is in addition to  
9 recommendations, you know, we want to do this as well.

10 DR. DAS: Thank you for your comments. I think a  
11 letter stating that would be helpful to include with the  
12 legislative report, like we will include Dr. Moreno's  
13 letter as well.

14 So I think if you could provide us with that,  
15 that would be very helpful.

16 ACTING CHAIRPERSON LUDERER: So we're talking  
17 about another letter with the endorsement of the efforts  
18 that have been made so far, that Dr. Quint summarized. So  
19 obtaining external funding through CDC collaborative  
20 agreement, and the UCSF UC Berkeley MIEEP collaboration,  
21 and the Kaiser RPGEH collaboration. And then should we,  
22 with this letter, include the recommendation for full  
23 funding, in addition to having the letter from Dr. Moreno  
24 already.

25 Okay, I agree.

1           And then some of the other points that other  
2 Panel members have brought up that would be included would  
3 be to encourage an occupational pilot study among the  
4 pilot studies that are already -- in addition to the pilot  
5 studies that you're already involved in, as well as the  
6 Panel being supportive of the importance of developing  
7 reference levels based on some of the findings, and  
8 bringing in the toxicological expertise of OEHHA.

9           Are there any other points?

10          Dr. Quint.

11          PANEL MEMBER QUINT: Julia Quint.

12           I don't know if this is -- you know, how these --  
13 the form that this legislative report will take. I think  
14 they take many different forms. But I was wondering if it  
15 would also be helpful -- one of the things that's come out  
16 of this, and, you know, the way in which the staff, and  
17 with the Panel's help, have identified other  
18 collaborators. What's quite obvious to me is the added  
19 value that the Biomonitoring Program has brought to other  
20 research areas, for instance, the Program on Reproductive  
21 Health and the Environment, you know, Environmental Health  
22 Tracking. All of these things now -- the Green Chemistry  
23 Initiative. All of these things have sort of overlapping  
24 kind of public health benefits.

25           And I think what's happening, since we haven't

1 done the statewide sample, one of the things that has  
2 happened, is that we're seeing more connections between  
3 these, you know, in some cases academic research  
4 initiatives. On the other hand, some of the other  
5 statewide initiatives.

6           And because some of us sit on a lot of these  
7 different panels, I think we see, you know, the  
8 connections between them.

9           So I guess one of the things I was thinking is  
10 whether or not we could ask other researchers or other  
11 people, our collaborators, to also write in support of  
12 just what I said, you know, the benefit of the  
13 Biomonitoring Program, the value added to some of their,  
14 you know, research or other efforts, you know, that are  
15 going on.

16           I was thinking of Kaiser for one. I was thinking  
17 of Tracey, because I work with the Program Reproductive  
18 Health and the Environment. And I think, you know, the  
19 mother infant pair program is really going to add to our  
20 efforts there. So it's something to think about. I mean,  
21 you don't want to have too many supporting letters, I  
22 guess. But it really has made a big difference for a lot  
23 of other efforts. And I think it's really important to  
24 point that out.

25           ACTING CHAIRPERSON LUDERER: Do any of the Panel

1 members have other comments, additional items?

2 PANEL MEMBER BRADMAN: I'm just. I have a  
3 question about the process. I mean, who's going to write  
4 the letter? Does Bagley-Keene apply? Yeah, okay, it  
5 sounds like you're thinking about that too.

6 ACTING CHAIRPERSON LUDERER: Perhaps, we could  
7 get some legal opinion on that.

8 STAFF COUNSEL KAMMERER: As far as the process  
9 itself goes, I'm not too sure. I would think the Chair of  
10 the Panel would write the letter.

11 As far as Bagley-Keene goes, this is a public  
12 letter, so it should be okay. You'll be writing it, and I  
13 understand it will be a public process, so that should be  
14 fine.

15 Any other questions as far as Bagley-Keene goes?

16 ACTING CHAIRPERSON LUDERER: So is it permissible  
17 then for, say, a draft to be written and circulated among  
18 the Panel members? Is that how it would be done or how --

19 STAFF COUNSEL KAMMERER: The problem with that is  
20 you do have a Bagley-Keene issue. The drafts -- if the  
21 draft is circulated, the draft would have to become  
22 public. I do believe. I'm not so sure about that.

23 But I do know that once you have the final  
24 document, as along as it's public. You do have an issue  
25 of a meeting when you have a draft going around. If it's

1 a clarification thing, it should be fine. But if you  
2 have information that could lead towards a decision of the  
3 Panel, then that is information that should be discussed  
4 in front of the public. But if it's just minor, you know,  
5 issues that are not decision making, it should be fine.

6 OEHHA DIRECTOR DENTON: Dr. Ulricke, I recall  
7 with the letter that Dr. Moreno signed, there was a  
8 subcommittee. There can be a subcommittee of the Panel  
9 that's less than a quorum. And I think Dr. Asa Bradman  
10 was one of the members. I don't remember if Gina was.  
11 But there could be, you know, select members that could  
12 work with the Chair to draft the letter. Albeit, not the  
13 whole Committee, but there could be.

14 STAFF COUNSEL KAMMERER: Yeah that's correct, as  
15 long as it's less than --

16 OEHHA DIRECTOR DENTON: What, there could be  
17 three? Maybe three members?

18 MS. HOOVER: We can also just double check with  
19 Carol too, before you actually form your subcommittee. So  
20 we'll verify with her about procedures.

21 OEHHA DIRECTOR DENTON: Maybe we could know at  
22 the meeting today if we do form a subcommittee, which of  
23 the Panel members would be willing to be part of the  
24 subcommittee. And then if we don't need one, then we  
25 don't. If we do need one, then we have our members.

1           ACTING CHAIRPERSON LUDERER: I'd be happy to be  
2 on the subcommittee.

3           OEHHA DIRECTOR DENTON: Did Ulricke is on the --  
4 any others?

5           ACTING CHAIRPERSON LUDERER: Any other?

6           PANEL MEMBER WILSON: I would. Mike Wilson.

7           OEHHA DIRECTOR DENTON: And Dr. Culver maybe we  
8 ought to --

9           PANEL MEMBER BRADMAN: That's fine.

10          OEHHA DIRECTOR DENTON: Okay. And then if we can  
11 have a 5th, a 4th.

12          PANEL MEMBER BRADMAN: Yeah, I think you can have  
13 four, because we have nine members.

14          OEHHA DIRECTOR DENTON: Well, no, you have Dr.  
15 Moreno as well.

16          PANEL MEMBER BRADMAN: Correct, yeah.

17          OEHHA DIRECTOR DENTON: So if we can have five,  
18 then we have -- yeah, we have Asa.

19          Dr. Ulricke, Dr. Wilson, and Dr. Culver, and then  
20 with Asa as a pinch hitter, if something happens.

21          (Laughter.)

22          DR. DAS: Could I just remind you when you write  
23 the letter and you include the recommendations, to just  
24 indicate your support for these brief bullets that are  
25 summaries of our recommendations also.

1           ACTING CHAIRPERSON LUDERER: Yes, both sets of  
2 slides.

3           OEHHA DIRECTOR DENTON: This is Joan. Just one  
4 more point of clarification. Back to the total funding of  
5 the Program. The estimate a couple of years ago was 10  
6 million. We have 1.6 that we have from the TSCA funds --  
7 1.9. Then from the CDC we have 2.6. So that kind of  
8 gives you a ballpark.

9           DR. DAS: The CDC funds are for five years.

10          OEHHA DIRECTOR DENTON: For five years and it's  
11 conditional on reapproval, as is TSCA. TSCA kind of goes  
12 from year to year too. So it kind of gives you a ballpark  
13 of the numbers.

14          ACTING CHAIRPERSON LUDERER: So the 10 million  
15 was per year for doing a full statewide --

16          OEHHA DIRECTOR DENTON: Correct, for having -- at  
17 least 10 million I think for a fully funded program.

18          ACTING CHAIRPERSON LUDERER: And then another  
19 question is what's the timeframe for submitting this?  
20 It's by the end of the year, but you obviously want the  
21 letter sooner.

22          DR. DAS: The report is due to the legislature on  
23 January 1st, but we need to send it up through our  
24 management November 1st. And just to remind you, the  
25 legislative report will be made public within 30 days of

1 submission to the legislature.

2           ACTING CHAIRPERSON LUDERER: All right. We have  
3 one more agenda item, which is Dr. Alexeeff's summary, but  
4 we were going to also revisit very briefly the  
5 recommendation that we had made regarding developing a  
6 biomarker for diesel exhaust.

7           DR. ROISMAN: Rachel Roisman, OEHHA.

8           We were also going to propose -- given that we've  
9 just had a discussion where we solicited some  
10 recommendations from the Panel that Dr. Alexeeff is  
11 willing to forego his final piece, his summary piece. And  
12 since time is a little bit short, we can just use that  
13 time to finish up the diesel discussion and then adjourn  
14 the meeting.

15           ACTING CHAIRPERSON LUDERER: Thank you.

16           So could you perhaps read back the text again of  
17 what we had recommended and what the proposed revision was  
18 to remove the word "develop" I believe.

19           DR. ALEXEEFF: George Alexeeff with OEHHA.

20           So this is the proposal that was adopted. "The  
21 Panel recommends that Program staff take steps to identify  
22 a biomarker of exposure to diesel exhaust and develop a  
23 laboratory method for its identification in biomonitoring  
24 studies.

25           ACTING CHAIRPERSON LUDERER: And the proposal is

1 to remove the word "develop".

2 DR. ALEXEEFF: After the discussion, there was  
3 some concern about the word "develop". And if you take  
4 the word "develop" out, the motion still makes sense to me  
5 anyway.

6 ACTING CHAIRPERSON LUDERER: So we need to have a  
7 vote as to whether the Panel is in agreement with the  
8 revised version of the recommendation?

9 PANEL MEMBER WILSON: Well, I forwarded the  
10 motion, so I would amend the motion to state that, "The  
11 Panel recommends that Program staff take steps to identify  
12 a biomarker of exposure to diesel exhaust and a laboratory  
13 method for its identification in biomonitoring studies."

14 ACTING CHAIRPERSON LUDERER: Dr. Culver.

15 PANEL MEMBER CULVER: Because that's a really  
16 challenging effort to conduct to develop a -- to develop a  
17 biomarker for diesel exhaust, I wonder whether an initial  
18 feasibility effort would be in order.

19 ACTING CHAIRPERSON LUDERER: Dr. Solomon.

20 PANEL MEMBER SOLOMON: I think we're spending way  
21 too much time on this. In my opinion, we've sent a very  
22 clear signal to staff that diesel needs to be bumped up on  
23 the priority list. That it shouldn't be kind of left by  
24 the wayside. I think staff has gotten the signal. I  
25 would just move on. Our role is advisory. Whatever the

1 wording of the resolution may be or may have been, staff  
2 can pay attention to it or ignore it, because we are only  
3 advisory. So I'd say let's not spend more time on it. I  
4 think the main point has come across.

5 ACTING CHAIRPERSON LUDERER: All right. Are we  
6 required to vote or is that -- yes?

7 OEHHA DIRECTOR DENTON: Well, you voted on the  
8 last resolution. So the last resolution sort of stands,  
9 but with the caveat that there's been a lot of discussion  
10 and sort of a lot of rethinking of the proposal.

11 I mean, one thing you could do is you could  
12 simply revisit the resolution after you hear back from  
13 Program staff next time about what the feasibility and the  
14 methods and so forth are, because I'm sure that will weigh  
15 in on what your recommendations will be. So you could do  
16 that.

17 Is that --

18 ACTING CHAIRPERSON LUDERER: That sounds  
19 reasonable.

20 DR. ALEXEEFF: This is George Alexeeff.

21 My comment is, it does say take steps. So as we  
22 take steps, we can let you know what step we're on.

23 (Laughter.)

24 PANEL MEMBER WILSON: Fair enough. I'll withdraw  
25 the motion.

1           ACTING CHAIRPERSON LUDERER: All right. We do  
2 have at least one more request for a public comment. We  
3 have a public comment period on this last session. Do we  
4 have any additional ones by Email?

5           No, okay.

6           So the commenter will be Davis Baltz from  
7 Commonweal.

8           MR. BALTZ: Davis Baltz with Commonweal.

9           I know we're running a little late, so I'll be  
10 very brief. First of all, I'd like to say I was enrolled  
11 as a Kaiser member at four months old. My saliva  
12 collection kit, it's on my desk at home.

13           And if you need to consent me right now for  
14 anything else, I'm ready.

15           (Laughter.)

16           MR. BALTZ: A lot of great ideas for  
17 collaborations. The Kaiser presentation was very  
18 interesting. And I think that we've got a lot of ideas  
19 already on the table, and others have been suggested for  
20 other pilots or community-based studies.

21           I'd like to again, since my comments didn't get  
22 heard over the webcast earlier, reiterate that an  
23 occupational exposure study would be very valuable for the  
24 state. But these small studies don't take the place of a  
25 representative statewide sample. And so to really fulfill

1 the mandate in the legislation, we need to find the  
2 funding, so that we can do this kind of study so that we  
3 establish baseline for the state and then track trends  
4 over time.

5 So I support this idea of the Panel sending a  
6 letter emphasizing that. And if it's useful to staff,  
7 Commonwealth would be happy to write a letter too.

8 In terms of some of the next steps that you're  
9 planning. The public participation and the outreach to  
10 engage additional stakeholders, I think this is something  
11 else that we would like to be involved with if it would be  
12 useful. I've continued to keep a lot of my colleagues  
13 informed about the progress of the Program. And I know  
14 many of them are interested to get involved at the  
15 appropriate time.

16 I think the budgetary constraints have sort of  
17 put a lot of things on hold, including, you know, the  
18 opportunity for other community groups and interested  
19 stakeholders to come and get involved. We, you know, had  
20 an idea for awhile a few months ago of maybe having a  
21 short pilot of some influential Californians and some  
22 community members. It didn't pan out, but we had actually  
23 lined up several people who were willing to come forward  
24 and actually be biomonitored. So they and their  
25 organizations are still interested in this.

1           So I'll still be involved as you know, and look  
2 forward to supporting the Program as it continues to  
3 develop.

4           Thanks a lot.

5           ACTING CHAIRPERSON LUDERER: Thank you. We have  
6 another comment.

7           STAFF COUNSEL KAMMERER: This is comment.

8           Dr. Luderer, Fran Kammerer for OEHHA. It was  
9 brought up that if the Committee appoints a subcommittee,  
10 if it designates a subcommittee, then it becomes an action  
11 of the Committee and it does violate Bagley-Keene if they  
12 meet.

13           However, what we can do here is that suggestions  
14 can be made. And since Dr. Luderer has been here the  
15 entire time, she's aware of the opinions, she could write  
16 the letter. And if you have any suggestions, and you  
17 could talk to one or two members of the Committee, as long  
18 as it's not a designated subcommittee.

19           (Laughter.)

20           ACTING CHAIRPERSON LUDERER: Thank you. I think  
21 that completes our agenda.

22           I'd like to thank everyone for coming, Panel  
23 members, and staff, members of the public, everyone who's  
24 listening on the internet.

25           Dr. Alexeeff.

1 DR. ALEXEEFF: I could present a two-minute  
2 summary.

3 ACTING CHAIRPERSON LUDERER: Great.

4 PANEL MEMBER MCKONE: It wouldn't be a meeting  
5 without it.

6 DR. ALEXEEFF: These will be the highlights.

7 Okay. So Dr. Das provided an overview of the  
8 Biomonitoring Program and activities, introduced new  
9 staff, the funding status, an overview of the CDC grant.  
10 Panel members recommended that procedures for storage of  
11 biosample be developed. Also, that they recommended that  
12 we develop procedures for archiving samples. And they  
13 were very interested in more resources, not only funds,  
14 but also students assisting in the project.

15 Dr. Roisman provided an overview of the current  
16 priority chemical list, provided estimates of the capacity  
17 of the labs to analyze a number of the priority chemicals.  
18 And also there was some discussion about the value the  
19 dialkyl metabolites. And staff will be coming back to  
20 that issue later.

21 There's discussion about cotinine and the value  
22 of Measuring that. And staff will be discussing that with  
23 the Panel at a future meeting.

24 There was also interest in looking for an  
25 occupational component in future studies.

1           There was a motion on diesel exhaust.

2           (Laughter.)

3           DR. ALEXEEFF: Dr. Woodruff discussed the MIEEP  
4 study. And also Dr. Eeden discussed the Kaiser Research  
5 Program on Genes Environmental Health. The panel  
6 expressed endorsement of further collaboration with these  
7 activities, and with other similar activities.

8           So thank you.

9           ACTING CHAIRPERSON LUDERER: Thank you.

10          And then I would like to close the meeting, and  
11 we will meet again on February 9th for the next meeting.

12          Thank you.

13          (Thereupon the California Environmental  
14 Contaminant Biomonitoring Program, Scientific  
15 Guidance Panel meeting recessed at 4:52 p.m.)

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