

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

JOE SERNA JR., CAL/EPA HEADQUARTERS
1001 I STREET
COASTAL HEARING ROOM
SACRAMENTO, CALIFORNIA

THURSDAY, DECEMBER 4, 2008
2:07 P.M.

JAMES F. PETERS, CSR, RPR
CERTIFIED SHORTHAND REPORTER
LICENSE NUMBER 10063

PETERS SHORTHAND REPORTING CORPORATION (916) 362-2345

APPEARANCES

PANEL MEMBERS

Dr. Edward Moreno, Chairperson

Dr. Asa Bradman

Dr. B. Dwight Culver

Dr. Marion Kavanaugh-Lynch

Dr. Ulricke Luderer

Dr. Thomas McKone

Dr. Gina Solomon

Dr. Michael P. Wilson

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Dr. Joan Denton, Director

Mr. Allan Hirsch, Chief Deputy Director

Dr. George Alexeeff, Deputy Director, Scientific Affairs

Ms. Carol Monahan-Cummings, Chief Counsel

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

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

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch

PETERS SHORTHAND REPORTING CORPORATION (916) 362-2345

APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Dr. Peter Flessel, Chief, Environmental Health Laboratory
Branch

Ms. Diana Lee, Research Scientist

Dr. Michael Lipsett, Chief, Exposure Assessment Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Mr. Davis Baltz, Commonweal

PETERS SHORTHAND REPORTING CORPORATION (916) 362-2345

INDEX

	PAGE
Welcome by Director Denton	1
Overview of the Afternoon's Activities by Chairperson Moreno	4
Program Planning: Resource Issues, Collaboration with Other Researchers and Survey Options	
- Presentation by Dr. Lipsett	8
- Panel Questions	17
- Public Comment	46
- Panel Discussion	52
Laboratory Capacity	
- Presentations by Dr. Flessel and Dr. Petreas	60
- Panel Questions	75
- Public Comment	91
- Panel Discussion	92
Recess	109
Reporter's Certificate	110

1 PROCEEDINGS

2 OEHHA DIRECTOR DENTON: Good afternoon, everyone.
3 We're going to get started. We're about six or seven
4 minutes late, but that should be no problem.

5 My name is Joan Denton and I'm the Director of
6 the Office of Environmental Health Hazard Assessment. And
7 this is, I guess, our fourth meeting of the Biomonitoring
8 Science Guidance Panel. It's actually a two-day meeting,
9 this afternoon and all day tomorrow.

10 I'd like to start by maybe starting with Gina.

11 Gina, if we could just run down the group here
12 and you could introduce yourselves, the members of the
13 Panel.

14 PANEL MEMBER SOLOMON: I'm Gina Solomon. I'm a
15 senior scientist at the Natural Resources Defense Council
16 and an associate clinical professor of medicine at UCSF.

17 PANEL MEMBER BRADMAN: Asa Bradman at the Center
18 for Children's Environmental Health Research at UC
19 Berkeley.

20 PANEL MEMBER WILSON: Mike Wilson, research
21 scientist at the Center for Occupational and Environmental
22 Health at UC Berkeley.

23 CHAIRPERSON MORENO: Ed Moreno. I'm the Health
24 Officer for Fresno County and Director of the Department
25 of Public Health in Fresno County.

1 PANEL MEMBER CULVER: And I'm Dwight Culver,
2 University of California, Irvine, Occupational
3 Environmental Medicine.

4 PANEL MEMBER MCKONE: I'm Tom McKone with the
5 School of Public Health at the University California at
6 Berkeley and also with the Lawrence Berkeley National
7 Laboratory.

8 PANEL MEMBER LUDERER: Ulricke Luderer, Associate
9 Professor at the Center for Occupational Environmental
10 Health, UC Irvine.

11 OEHHA DIRECTOR DENTON: Okay, thank you. Thank
12 you, all, to the Panel members as well as the staff who
13 have prepared this meeting, for coming today. This is a
14 two-day meeting, as I mentioned before. And the purpose
15 of today's meeting will be -- we will be consulting --
16 staff will be consulting with the Panel on program
17 planning, including laboratory activities. And then
18 tomorrow we'll be talking to the Panel and getting your
19 recommendations on potential designated chemicals.

20 Before I turn it over to Dr. Moreno, I wanted to
21 mention just a couple of announcements.

22 The restrooms. If you go out these doors, there
23 are restrooms to the left and there are restrooms to the
24 right. So you can take your choice. The left is kind of
25 easier to access because they're right over here by the

1 Byron Sher auditorium. If you go to the right, they're
2 past the elevators, women's to the left, men's to the
3 right.

4 Also, if there should be a fire alarm, we will
5 just exit the room and go down the stairs and exit the
6 front of the building.

7 Just a little bit of background. The last
8 Science Guidance Panel was held on October 24th, and we
9 held it in two locations over a teleconference, in Oakland
10 and in Irvine. And the focus of that meeting was on
11 statewide sample design options and laboratory activities.

12 So today's meeting will last until 5, although I
13 told Dr. Moreno that we need actually to be out of the
14 room by five o'clock. The meeting is scheduled though
15 from 2 to 5.

16 Sara.

17 MS. HOOVER: We got an extension to 5:30. So
18 they'll let us stay --

19 OEHHA DIRECTOR DENTON: Okay. Well, then we need
20 to be out of the room by 5:30.

21 MS. HOOVER: -- but needs to be cleared out.

22 OEHHA DIRECTOR DENTON: Okay. That's good.

23 And then tomorrow the meeting is from 9 to 4.
24 And there are agenda items, handouts in the back of the
25 room.

1 So today's agenda -- this afternoon's agenda,
2 which will run from 2 to 5 or 5:30, as I mentioned,
3 involves program planning and laboratory capacity. And
4 Dr. Michael Lipsett and Dr. Myrto Petreas and Dr. Peter
5 Flessel will be carrying on that discussion.

6 And then tomorrow there will be a number of
7 presentations on the potential designated chemicals that
8 the Panel asked us to follow-up on.

9 Throughout the meeting there will be
10 opportunities for the Panel to discuss these items with
11 us, as well as the presentations, as well as public
12 comment.

13 Okay. I think that's about it.

14 So I'll turn it over to Dr. Moreno.

15 CHAIRPERSON MORENO: Hi. Thank you, Joan.

16 I want to welcome back our Panel members for this
17 meeting and Program staff. And also I noticed there's
18 people from the public. So welcome. And also anyone
19 that's watching on the webcast, welcome.

20 At this time, I want to briefly go over what some
21 of the goals are for this meeting. Joan's already
22 mentioned a few.

23 In particular, we're going to be looking at -- or
24 learning more about the Program, the Biomonitoring Program
25 planning activities so far, which include presentations on

1 any issues dealing with resources, as well as
2 collaboration with other researchers and some presentation
3 discussion on some survey options.

4 We're also going to be looking at laboratory
5 capacity. And we look forward to that presentation today
6 and some discussion.

7 And tomorrow we will get into -- or the Panel
8 will get into hearing updates on the chemicals that the
9 Panel had requested more information on for consideration
10 and making a recommendation to add to the designated list
11 of chemicals.

12 In terms of -- oh, and after each presentation,
13 our Panel will have an opportunity to ask questions of the
14 presenters today. And we'll follow that with public
15 comment. But we will be -- following public comment, we
16 will be bringing it back to the Panel to have further
17 discussion as necessary based on additional comments
18 provided by the public.

19 The way we're going to handle public comment
20 today is -- we do have again cards available. And if you
21 wish to make some comments, we ask that you please fill
22 out the card, write your name on the card and what topic
23 you want to comment on.

24 And where can people turn in those cards?

25 Great. Thank you.

1 I ask that anyone listening and viewing on the
2 webcast, if you have comments, please Email them to
3 biomonitoring@oehha.ca.gov. And I'll be -- those comments
4 will be shared with me and I'll be able to share those at
5 this meeting.

6 And, finally, one request is that the public try
7 to focus the comments to the topic that we're currently
8 discussing.

9 Panel members, you do have the materials in your
10 binders for discussion today.

11 And the general public can also access those
12 documents on the website.

13 And we are going to take at least a ten-minute
14 break this afternoon. And we will be finished -- we're
15 scheduled to go till 5 o'clock. The latest we can stay is
16 5:30. And we need to get out of the room by 5:30 today.

17 So that's it. Before we get started, I'm going
18 to ask Ms. Carol Monahan-Cummings to make a few comments
19 regarding the public process.

20 OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Thank you,
21 Dr. Moreno. Carol Monahan-Cummings, Chief Counsel for
22 OEHHA and counsel for this committee.

23 I just want to take just a minute to remind you
24 about -- the first meeting you had I mentioned to you that
25 this group is subject to the Bagley-Keene Open Meeting

1 Act, and we provided you all of these materials on the
2 Meeting Act. And I wanted to point out that those are
3 kind of the minimums for ensuring public participation.
4 And so for -- in terms of this group, obviously it's
5 always open to the public and we have public comments and
6 you just discussed that.

7 In terms of having subgroups or workgroups, in
8 the future -- I know you've done that already, and that's
9 totally fine. But in the future what I would like to
10 recommend to you is that when you do create subgroups or
11 subcommittees or workgroups or whatever, that you consider
12 having those meetings be open to the public as well. I
13 know sometimes the logistics of that are a little bit
14 difficult. But in order to be very transparent and ensure
15 that the public has as much access as possible and input
16 as possible for this program, you should consider having
17 those meetings open as well.

18 Any questions on that?

19 Okay. Thank you.

20 CHAIRPERSON MORENO: All right. Thank you for
21 that clarification.

22 At this time, we're going to go ahead and move
23 with the further -- move on with our agenda, and we're
24 going to go ahead and hear from -- regarding program
25 planning, the resource issues, collaboration with other

1 researchers and survey options. And, at this point, Dr.
2 Michael Lipsett will take over the presentations.

3 Dr. Lipsett is the Chief of the Exposure
4 Assessment Section of the Environmental Health
5 Investigations Branch at the California Department of
6 Public Health.

7 Dr. Lipsett.

8 (Thereupon an overhead presentation was
9 Presented as follows.)

10 DR. LIPSETT: Thank you, Dr. Moreno and members
11 of the Panel. I appreciate this opportunity to provide an
12 update of the Program.

13 And could you -- the mouse doesn't seem to be --
14 oh, there it goes. Okay, I'm sorry.

15 --o0o--

16 DR. LIPSETT: Okay. As you know from previous
17 meetings, we have been planning for the greater part of
18 the last year to undertake a statewide survey involving
19 2,000 or more participants over a two-year cycle to
20 participate in the Biomonitoring Program. This would be
21 modeled after the CDC program. And we've been working
22 pretty closely with the people in the National Center for
23 Health Statistics to develop an appropriate sampling
24 strategy.

25 Under direction from the administration, we had

1 been -- we're planning to incrementally increase the
2 resources to phase in this program over five to six years
3 and, at the same time, to plan to undertake smaller scale
4 community studies.

5 --o0o--

6 DR. LIPSETT: However, given the current fiscal
7 catastrophe here in Sacramento, we need a little bit of a
8 reality check. And I'd alluded to this during our last
9 meeting in October, that we have base-level funding for
10 the three departments that are listed on this slide, 12
11 positions total, an ongoing budget of a little over 1
12 million for our department, 600,000 for OEHHA, and about
13 300,000 for the Department of Toxic Substances Control.

14 Last summer the Legislature moved our Program
15 from the General Fund to a special fund that's
16 administered by DTSC called the Toxic Substances Control
17 Account in an attempt to try to -- is this working okay
18 for you?

19 DR. ALEXEEFF: Yes.

20 DR. LIPSETT: -- in an attempt to try to reduce
21 the burden on the General Fund. However, in terms of
22 looking to undertake full program implementation to do
23 this statewide survey, it's not really going to be
24 feasible given the lack of additional funding; and given the current
25 budgetary situation, I think it's unlikely that we're

1 going to be seeing any additional funding soon.

2 Therefore, we're going to need to examine other
3 survey options.

4 --o0o--

5 DR. LIPSETT: Now, our Plan B for this was to
6 undertake some smaller scale biomonitoring studies. The
7 initial purchase and installation of laboratory equipment,
8 as mentioned previously, will be done early in 2009. And
9 we will be able to use this to collaborate with
10 researchers and possibly in the future to undertake some
11 targeted community studies.

12 In terms of the collaborations, we distributed a
13 request for information for researchers throughout
14 California to submit an application to have some samples
15 that they had previously archived to be analyzed by the
16 laboratories in this program. And we've discussed this
17 briefly at the last meeting. At that time, we had
18 received no applications.

19 --o0o--

20 DR. LIPSETT: However, since then, we have
21 received a number. But the idea was to -- not only to
22 undertake some biomonitoring that would be useful to
23 further the goals of this program, but to add value to
24 some of these existing epidemiologic or exposure
25 assessment studies, and to be able to explore the

1 feasibility for the laboratories of analyzing certain
2 chemicals on a larger scale. The idea was to be able to
3 analyze these data, to generate them, to be made public in
4 2010.

5 --o0o--

6 DR. LIPSETT: So since the last meeting, we
7 received ten different project descriptions or
8 applications from six different research institutions.
9 Unfortunately, there was limited supplemental funding that
10 was indicated that these researchers would have available
11 to support these analyses. We received eight responses
12 indicating that the researchers had previously archived
13 samples of blood and urine to analyze, and two in which
14 these blood and urine samples will be collected at some
15 point in the future.

16 --o0o--

17 DR. LIPSETT: The analytes that the researchers
18 had requested that they look at are listed on this table.
19 These are all within the -- will be within the
20 capabilities of the laboratories to analyze during 2009,
21 and you'll hear more about that from Drs. Petreas and
22 Flessel in the next presentation.

23 --o0o--

24 DR. LIPSETT: Now, we're in the process now of
25 evaluating these responses to the RFI using these

1 that we were not -- well, we needed some additional
2 clarification from some of the responses. This is going
3 to take place within the next few weeks. We'll make a
4 selection among these in early January and contact the
5 people who submitted these applications shortly
6 thereafter. And we hope to begin the analyses in spring
7 of 2009.

8 --o0o--

9 DR. LIPSETT: Any panel members have any
10 questions about the RFI, at this point?

11 Okay. I'll proceed.

12 --o0o--

13 DR. LIPSETT: Okay. The other thing that we're
14 actively discussing and starting to plan for, at this
15 point, is to undertake some community studies. And I
16 wanted to review briefly for you what "community" means
17 under the legislation that set up this program.

18 It refers not only to geographic communities but
19 to nongeographically-based populations that may share
20 common exposures because of similar occupations; or these
21 may be populations that have a common health outcome that
22 may be linked to chemical exposures; or experience similar
23 exposures because of consumption, lifestyle, product use
24 or shared ethnicity, age or gender.

25 --o0o--

1 DR. LIPSETT: Now, one of the things that we
2 haven't really discussed with the Panel is that the CDC
3 has committed to us to undertake two sets of analyses of
4 chemicals under a Memorandum of Understanding with the
5 laboratories. One is to analyze up to 10 chemical groups
6 of samples from 500 subjects. The other is to analyze a
7 single chemical in samples from 200 participants.

8 --o0o--

9 DR. LIPSETT: And for an initial type of
10 community study, we were hoping to try to leverage this
11 offer of CDC analytical assistance, and on this slide
12 presented some examples of the kinds of community types of
13 studies that we could potentially undertake.

14 We could collaborate with a clinic, say, with a
15 university OB-GYN clinic, say, to obtain paired
16 maternal-child or maternal-cord blood specimens.

17 We could look at one or more occupational groups
18 who have exposures that encompass the CECBP priority
19 chemicals, such as firefighters, nail salon workers,
20 people who work with flame retardants, such as furniture
21 foam workers.

22 We could undertake a study of a specific
23 geographic area, say, near heavy traffic or a specific
24 industrial source; or choose a health-affected group.

25 Now, the specific sampling design, including the

1 interest potentially in funding some of these activities.
2 But we would need to really get very specific about the
3 design and costing-out of one or more of these in order to
4 be able to submit a formal proposal to that foundation or
5 to any others.

6 So any input or discussion that you have on these
7 topics, we would really appreciate.

8 Thank you.

9 CHAIRPERSON MORENO: All right. I'll bring it
10 back to the Panel and ask the Panel if they have any
11 questions.

12 PANEL MEMBER WILSON: Sure.

13 Michael, could you just talk a little bit more
14 about the first bullet on collaborating with clinics to
15 obtain maternal-child biospecimens, what those
16 biospecimens might be and the actual number of samples
17 you're considering and so forth.

18 DR. LIPSETT: Well, if we were to try to focus
19 exclusively on that as a community study, one example of
20 that might be to, say, collaborate with a medical school.
21 For us, in terms of the ease of doing that, it would
22 probably be UCSF to, say, get maternal and then cord blood
23 samples -- paired samples to try to look at what the
24 difference -- what kinds of levels of specific chemicals
25 you might identify in each of these. And one might put

1 down specific eligibility criteria, say, for different
2 racial or ethnic groups, say from also different
3 geographic criteria, say from San Francisco or the
4 peninsula, Marin, where you would be able to encompass as
5 well a lot of economic variability too. And one could try
6 to have this represent a kind of exposure type of study.

7 You know, one thing that -- one aspect that might
8 be very useful from something like this would be that it
9 could help feed into the whole green chemistry initiative,
10 for example, where we would be able to identify, you know,
11 what -- not only what adults are exposed to but what
12 infants are being born with. One would assume, depending
13 on what those are, if they're bioaccumulative, these might
14 become chemicals of concern for the green chemistry
15 process.

16 But at the number you -- back to the number. If
17 the CDC's willing to do 500 samples, we would probably get
18 250 paired samples.

19 PANEL MEMBER WILSON: Okay.

20 CHAIRPERSON MORENO: Okay. Joan has a question
21 and then Dr. McKone.

22 OEHHA DIRECTOR DENTON: Michael, we talked about
23 bringing visibility to the Program, given the resource
24 constraints, that it would be good to get some products
25 out, some results out, you know, demonstrable results of

1 the Program, say, coming up this next year, to give some
2 visibility that this is a program that's producing
3 something and that would, you know, be maybe more amenable
4 to our pleas for resources.

5 Are there any aspects or any of these -- any
6 particular -- you know, from this list, do you see that
7 there's more potential in that arena in any particular
8 ones of this laundry list of studies that we get results
9 out earlier and maybe bring visibility to the Program?

10 DR. LIPSETT: I think all of them are going to
11 take some time to design the study. And I think in terms
12 of having really early results, that would be more likely
13 to be done with the banked samples that the labs are going
14 to analyze for the responders to the RFI. I think to
15 undertake any of these we would need to design it, go to
16 one or more foundations to try and get some support for
17 it, and then go out into the field. We're probably not
18 looking at results from any of these really till -- I
19 don't want to make any concrete predictions, but probably
20 towards the end of 2010 or early 2011, something like
21 that, for any of them.

22 OEHHA DIRECTOR DENTON: Even the banked samples?

23 DR. LIPSETT: Not banked samples -- but for the
24 RFI -- the labs are going to be talking about that later
25 today, that that should be early next year. I mean,

1 they're going to start early next year, and that would be
2 available in early 2010.

3 CHAIRPERSON MORENO: Dr. McKone, you had a
4 question.

5 PANEL MEMBER MCKONE: I'm just trying to clarify
6 if I understand it. It sounds like, you know -- of course
7 in an ideal world with lots of money, you would -- the
8 original plan was to really have a probabilistic sample of
9 the state organized the way CDC would do it. But the
10 ideal world is not there --

11 DR. LIPSETT: Right.

12 PANEL MEMBER MCKONE: -- because of finance.

13 So what we're trying to do is take opportunities
14 and other studies that can be used.

15 My question is, have you spent some time thinking
16 about -- I mean, this is not going to be quite what we
17 originally talked about doing, which was a really nice
18 probabilistic sample. But in some ways this may fill
19 in -- it may fill in a lot of the pieces of that. It may
20 actually work almost as well in some cases. Have you
21 thought about how to take instead of what you want to do,
22 but what we have an opportunity to do and make it fit as
23 much into the plans, so that it's still quite useful in
24 terms of the concept that was originally developed?

25 Does that make sense? I mean, have you spent

1 some time thinking about what -- would there be really big
2 gaps or maybe some small gaps that would accrue from this
3 sort of approach?

4 DR. LIPSETT: Well, if I understand you
5 correctly, in terms of the fitting back into the concept,
6 you're talking about having a more representative
7 statewide type of sample?

8 PANEL MEMBER McKONE: Right. I mean, we're not
9 going to have that. But is there some way to -- in other
10 words, it's not what we want, it's kind of what we can
11 get. But can we make what we can get into what we really
12 wanted by some, you know, statistical hard work or
13 something like that?

14 (Laughter.)

15 DR. LIPSETT: Yeah. Well, I've listed here a
16 number of examples of the kinds of studies that could be
17 done. There are some other possibilities too. I mean,
18 there is a maternal alpha-fetoprotein specimen bank that
19 contains hundreds of thousands of samples from women
20 statewide, but the sample volumes are very small. I mean,
21 it may be possible to select a certain number from that.
22 You know, it's clearly limited to pregnant women, which
23 obviously that would be a group that would be of interest
24 to the Program and presumably to policy-makers.

25 But it would be a potentially more limited number

1 of analytes that one could look at in those samples, at
2 least initially with -- I mean, for our laboratories
3 because the sample volume is so small, I mean just a
4 couple of ml. But that might be another possibility of a
5 kind of study that we could undertake as well, and might
6 meet more of the kinds of criteria that you're thinking
7 about.

8 I mean, does that answer your question or is
9 that --

10 PANEL MEMBER MCKONE: I think it does. I mean,
11 I'm also sort of probing a bit to see, you know -- I mean,
12 for me, and I think for some of the Committee, we would
13 like as much as possible to make sure we're making
14 progress on the original goal even though we can't do it
15 exactly that way. And I think, you know, maybe one of the
16 things that needs to be done is not only looking at the
17 opportunities, but also some sort of value of information
18 for what you have and how that relates to more ideal
19 information.

20 You know, I'm not sure I've really formulated
21 this. But I think it might somewhat be sort of a
22 simulation exercise that someone could go through to see,
23 well, how likely is it that you would capture a truly
24 probabilistic sample if you didn't do it that way, but
25 instead took an opportunity sample. I mean, that's sort

1 of where I'm thinking. It might be a useful exercise to
2 go through. Not very expensive to do that, because
3 that -- it's sort of the simulation exercise, just sitting
4 around, sort of working out some way to ask -- and we'd
5 probably need a biostatistician or someone to work on that
6 who's thought through these sorts of things.

7 DR. LIPSETT: Okay. Well, we don't have that
8 kind of statistical resource, but possibly OEHHA does.

9 I mean, Lauren, do you want to address that?

10 Ms. Lee: We do have those still, the contract
11 with CDC. And that's going to run for at least another
12 year. And they do -- they have offered us continuous
13 statistical input and consultation. So it's possible we
14 could direct our contract resources with them to help
15 design a community-based type study, again using a
16 probabilistic method.

17 PANEL MEMBER MCKONE: Yeah, that'd be -- I mean,
18 if doesn't cost a lot, I mean, that might enhance the
19 value of information that's derived from these -- moving
20 them toward our goal of having a more probabilistic --

21 DR. LIPSETT: Yeah. You know, I think it might
22 be useful for us to talk with you about more specifically
23 what you're thinking of, because in terms of utilizing the
24 resources from CDC, we were going to have them help us
25 with some additional planning, say, if we wanted to do a

1 small area study, a geographic community study to take
2 some of the principles that had been discussed at the last
3 meeting by Dr. Curtin and try and involve that.

4 So before committing CDC resources to undertaking
5 this additional exercise, I think we need to be really
6 clear on what it is that you think -- what it is that you
7 think would be the outcome of this kind of analysis and
8 how that would help in the decision-making process.

9 PANEL MEMBER MCKONE: I mean, you want to do more
10 off-line or you want to --

11 DR. LIPSETT: Yeah.

12 PANEL MEMBER MCKONE: -- make that part of our
13 discussion --

14 DR. LIPSETT: Well, it's up to you. I mean, I
15 think in terms of -- I mean, if you -- yeah, I think it'd
16 probably be better to do it off-line.

17 PANEL MEMBER MCKONE: You know, without getting
18 technical, I'm just sort of thinking of some of the
19 Bayesian methodology where you can develop, you know, a
20 prior -- then you can -- when you target samples and then
21 say how likely is it that I would see what I sampled in a
22 small subsample given that the bigger subsample has this
23 characteristic. So, I mean, that's sort of what I'm
24 thinking, some Bayesian and Bayesian Monte Carlo, which
25 has been used in other fields when you can only do a

1 little bit of surveillance and you want to put the
2 surveillance in the context of what you think is happening
3 in the -- actually, if you want to see a great example of
4 this, you just look at all the analysis of the elections
5 that went on and how people could take certain trends
6 and -- you know, could take early trends in exit polls and
7 then turn it into a national pattern.

8 So it's sort of an -- it's inverse modeling. But
9 it's not anything innovative. I don't think -- it's not
10 something that we would have to -- if we found the right
11 people who know how to do this, they could say how likely
12 it is that a small community sample actually could
13 represent a bigger picture of the state.

14 DR. ZEISE: What I'd like to suggest perhaps,
15 because I think -- I mean, we have been also just
16 pondering the possibility of trying to get at some of the
17 goals of the statewide sampling with alternative means.
18 And I think it would be useful to try to explore this
19 issue a bit further. And we could also explore it within
20 OEHHA if there's not sufficient funding in the CDC, and
21 also maybe with some academic partners.

22 So I'd like to suggest that we come back -- that
23 we look at this issue and come back to it.

24 DR. LIPSETT: Yeah, I think we can continue
25 discussion off-line.

1 Okay. Thanks.

2 PANEL MEMBER WILSON: I'd like to actually follow
3 that --

4 CHAIRPERSON MORENO: Yeah, Dr. Wilson, you have
5 more comments?

6 PANEL MEMBER WILSON: Sure. And I guess -- I
7 think it's relevant to your question here about, you know,
8 sort of input on options for the community studies, in
9 that, you know, looking at this set of options, that one
10 of the questions that comes to mind is, is there any one
11 of these that would be most useful in terms of its
12 generalizability?

13 And I think that sort of gets to Tom's point, you
14 know, that -- and if that's our objective, then the way we
15 set up the sampling criteria is important of course. And
16 you'd mentioned that, for example, in the first one around
17 the maternal-child biospecimens that there might be a set
18 of criteria -- you know, inclusion criteria for the
19 participants. And I think what I hear Tom saying is maybe
20 it -- rather than that, maybe it makes sense to design a
21 sample that would be -- you know, a random sample that
22 would perhaps be more generalizable. And so I guess my
23 question then is if -- and more useful, as you're saying,
24 to the larger objective.

25 And so I guess the question is -- I know at our

1 last session we really grappled with the biostatistics
2 issues and the representativeness of the samples. But I
3 guess if we were to obtain 250 matched samples of
4 maternal-child biospecimens, does that give us the power
5 if we were to do it in a random way to make a statement
6 that could be generalized? Do we have the statistical
7 power within 250 matched samples to, in fact, say
8 anything?

9 Do we know that yet?

10 DR. LIPSETT: Well, I guess it would -- we
11 haven't done those kinds of power calculations. But my
12 guess is with those numbers, depending on what the
13 chemicals are, what their concentrations were, what the
14 coefficient of variability is in terms of the lab methods,
15 I mean, all these things would need to be factored into
16 it. But we might end up with, you know, somewhat wide
17 confidence intervals. But if it's done in an
18 appropriately, you know, randomized probabilistic type of
19 way within that target population, we probably would be
20 able to make some reasonable generalizations.

21 PANEL MEMBER WILSON: Right. That seems -- as
22 well, I would concur. I think that might be more valuable
23 actually.

24 CHAIRPERSON MORENO: Okay. And Dr. Solomon has a
25 question. But if I could just get some clarification

1 before Dr. Solomon asks.

2 So in your presentation, what you presented was
3 that there's the RFI process. And in looking at -- if I
4 understand, looking at participating with researchers who
5 already have been banking samples, correct? That was one
6 of the --

7 DR. LIPSETT: Right.

8 CHAIRPERSON MORENO: Okay. And if we do that,
9 could you explain to me what the considerations are for
10 that group of samples that we'd be testing in terms of how
11 they were -- the selection process that that researcher
12 used to identify those participants and to collect those
13 samples and how that prior criteria that were used would
14 be taken into consideration in trying to analyze them for
15 the purpose of a small study for the Biomonitoring
16 Program.

17 DR. LIPSETT: So are you asking in terms of
18 whether those -- the banked samples were collected from
19 people who were recruited in a way that might be
20 representative of the population of the State of
21 California?

22 CHAIRPERSON MORENO: Right, do you have
23 information -- have you had a chance to look at that and
24 determine -- have you come to some, I guess, conclusions
25 as to how the selection criteria would impact the ability

1 to use that for the purposes of the Biomonitoring Program?
2 Because what I'm thinking is if it was a randomized
3 representation of the population, be it pregnant women or
4 whoever, if that is close enough to the criteria that the
5 Biomonitoring Program would be using in the future, then
6 that would be -- could that be useful?

7 In the future, we can make some presumptive --
8 not presumptive -- but some early findings with the
9 limited resources we have. And then as we go to --
10 funding is available and we started expanding the
11 Biomonitoring Program, we could include that group that we
12 studied in 2009 into the larger group. Is that possible?

13 DR. LIPSETT: Yeah. Well, without getting into
14 the specifics of each one of these proposals -- the
15 applications that were received, I can say that a number
16 of the populations from whom these samples were obtained
17 were not recruited in that way. I mean, you could say
18 something about, say, that kind of population and who they
19 might represent within the State of California. But
20 it would not -- they're not necessarily generalizable to
21 the population as a whole.

22 CHAIRPERSON MORENO: Okay, thanks.

23 Dr. Solomon.

24 PANEL MEMBER SOLOMON: Yes. I heard two things
25 really in that presentation. One is that we're very short

1 on money, and the other is that we're pretty short on
2 time; if we're hoping to get any kind of results by the
3 end of 2010 optimistically, that we really would have
4 to - correct me if I'm wrong - you know, sort of go with
5 one of these strategies and really try to push forward
6 fairly quickly.

7 And so what that tells me is that Panel members,
8 you know, that maybe our role could best be to help sort
9 of try to figure out what, you know, without complicating
10 things too much, what -- you know, which of these
11 alternatives or if there's another alternative that isn't
12 here in front of us, you know, might meet the criteria for
13 being, you know, relatively inexpensive, relatively
14 efficient, especially in terms of participant recruitment.
15 Because looking at the bulleted alternatives here, I think
16 some of them would be more complicated in terms of
17 recruitment than others. And I think some of the
18 alternatives that were proposed, you know, random sampling
19 strategies, might even be yet more complicated in terms of
20 recruitment.

21 So, if we think about that and try to weigh those
22 concerns against, you know, obviously the desire to have a
23 representative sample ultimately, you know, frankly, I'm
24 not sure if we should be striving for representativeness
25 yet. I feel like we should be striving for something

1 that's doable. So it's just my observation.

2 I also have a question or just a clarification on
3 the chemical list.

4 My understanding is CDC will be doing these
5 analyses. So does that mean that in terms of the
6 analytes, we would be looking only at the CDC list of
7 chemicals and not considering anything that, for example,
8 the Panel might be designating over the coming, you know,
9 day or in the future?

10 DR. LIPSETT: Well, I think given what their
11 offer is, we ought to take them up on doing ten -- not
12 just ten chemicals, but ten particular chemical groups.

13 But in terms of going forward with, you know, the
14 process that was envisioned with the legislation, it would
15 be good to have specific priority chemicals that you would
16 have recommended to us that we would have identified as
17 being really important for California to be -- and to make
18 sure that whatever the CDC analyzes, that the bulk of
19 them -- or the bulk or all of our priority chemicals be
20 encompassed in that list. Although we know that there may
21 be some that they may not be able to do.

22 PANEL MEMBER SOLOMON: So just in follow-up, does
23 that mean that it would be helpful for us to identify
24 priority chemicals in the course of this meeting?

25 DR. LIPSETT: I don't think that that's -- I've

1 talked about this with some of the other staff. And I
2 think that because that particular decision was not
3 noticed -- and, Carol, maybe you want to comment on this.
4 Is this something that they could proceed with in terms of
5 designating priority chemicals or not? I was under the
6 impression that it was designated chemicals only at this
7 meeting.

8 OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: I'm not
9 sure that I understand the question. I'm sorry.

10 DR. LIPSETT: The question was whether the Panel
11 could go beyond adding to the list of designated chemicals
12 and could actually recommend priority chemicals.

13 OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Tomorrow
14 or today or --

15 DR. LIPSETT: During the course of this meeting.

16 OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: I would
17 recommend against that, just because it isn't on the
18 agenda. So it's probably better for you not to do that.

19 One thing to keep in mind though is you're
20 providing advice and it's not a binding decision of the
21 group. And so if you wanted to provide some advice about,
22 you know, we think that we're looking at X chemical as a
23 priority for -- you know, yeah, but we want to discuss
24 that at the next meeting or something, you could do that.
25 But I wouldn't recommend doing anything that's outside the

1 agenda. It's not worth the trouble that can be caused.

2 CHAIRPERSON MORENO: Dr. Solomon, anything else?

3 PANEL MEMBER SOLOMON: No.

4 CHAIRPERSON MORENO: Okay. Other --

5 DR. ALEXEEFF: George Alexeeff. I just had a
6 couple clarifying questions, and maybe -- I hope I'm not
7 the only one confused. But maybe you could clarify this.
8 Because Dr. Wilson was talking about the number of
9 samples, and so there's a couple things I just wanted to
10 clarify.

11 With regard to the RFI goals, does the sampling
12 that you're envisioning in that, does that influence
13 anything with regards to the other options in terms of
14 workload or choices or things like that? Are these --
15 you're envisioning that both things are doable? That's
16 what I'm asking.

17 DR. LIPSETT: Well, with respect to the RFI, the
18 main load -- the workload on that is mainly at the
19 laboratories, the DTSC and the CDPH laboratories.

20 With respect to designing, the community study,
21 for example, that will be something that would be mainly
22 the Environmental Health Investigations Branch staff and
23 people from OEHHA, with some input from DTSC as well. So
24 there may be some overlap of time from some of the
25 laboratory staff. But the bulk of that work would be done

1 by non-laboratory people.

2 DR. ALEXEEFF: Okay. That's one thing I wanted
3 to clarify.

4 And then with regards to what Dr. Wilson said
5 about the number of samples. Because I was looking in
6 the -- in the actual overhead and it talks about 500
7 samples, and you referred to 250 paired samples. So I was
8 just wondering if you could clarify that. Am I mixing --

9 DR. LIPSETT: That's 250, one from a mother, one
10 from a child. So times two would give you 500.

11 DR. ALEXEEFF: All right. But that is actually
12 listed under the community study, correct?

13 DR. LIPSETT: Right. As an initial attempt to
14 leverage the CDC's offer of assistance, to provide this
15 laboratory assistance. Because our laboratories will --
16 you know, they're still installing the equipment. They're
17 going to be working on analyzing materials from the
18 response to the RFI. They're going to be developing new
19 methods. And, you know, by the time we go out and
20 actually collect samples from people with any one of these
21 particular options, presumably the laboratories will be
22 done with much of the work in response to the RFI and will
23 be able to do -- well, they would not be doing the
24 analysis for this but they may be able to undertake some
25 additional analyses, say, of priority chemicals, for

1 example, that the CDC would not be doing for us.

2 DR. ALEXEEFF: All right.

3 CHAIRPERSON MORENO: Okay. I want to give Dr.
4 Luderer an opportunity to ask a question. But before
5 that, we're going to be taking public comment in a few
6 minutes, so I want to remind everyone to fill out their
7 cards, and if staff could bring the cards up.

8 Thank you.

9 Dr. Luderer.

10 PANEL MEMBER LUDERER: So I wanted to ask a
11 question having to do -- you know, addressing this issue
12 that some of the other Panel members have also brought up
13 about, you know, how might it be possible, you know, to
14 leverage some of these other types of collaborative
15 options in order to still address that goal of having a
16 population-based sample, you know, of the State of
17 California, which is kind of the original goal of the
18 legislation. And I wondered whether you've explored any
19 possibilities to maybe collaborate with studies that are
20 population-based studies that already include a large
21 population within California, so that it's a
22 population-based sample.

23 I mean, the thing that comes to my mind initially
24 would be something like the National Children's Study,
25 which has not yet started but is about to.

1 And there are many sites within the State of
2 California where they will, you know, be recruiting a
3 population-based sample of California women, some prior to
4 conception, some after conception, and obtaining lots of
5 biospecimens; you know, whether there might be some way of
6 collaborating with that study, you know, in a way that
7 enables maybe, you know, analyses to be done that might
8 not be able to be done as part, you know -- and to also,
9 you know, kind of analogous to what you're doing with the
10 CDC, where the CDC NHANES program is enabling you to maybe
11 do some analyses that you wouldn't have the funding to do
12 otherwise kind of on the other side of this collaborating
13 to have access potentially to a population that's a
14 probabilistic sample within the State of California. You
15 know, it's just an idea.

16 DR. LIPSETT: So the idea would be then to try to
17 piggyback on something like the National Children's Study.

18 PANEL MEMBER LUDERER: Yeah.

19 DR. LIPSETT: And this is something that I'm
20 certainly willing to explore. I know a number of the
21 investigators in California. And there may be some room
22 in terms of what their flexibility might be. But to the
23 extent that we -- say, if we want to develop
24 exposure-specific questions for specific chemicals, which
25 is one of the things that we wanted to do, that may or may

1 not fit into the protocol that they want to undertake. Or
2 if all we would want to do would be to obtain, you know,
3 an extra couple of tubes of blood, well, that may be a
4 problem as well with children. But it's something that I
5 think is worth talking to some of these investigators, and
6 I'm certainly willing to do that.

7 PANEL MEMBER BRADMAN: I can comment a little bit
8 on that too. I'm actually PI of Kern County with the
9 National Children's Study. And the protocol is very
10 prescribed, and there is a process to develop ancillary
11 studies. They have to fit in with the goals of the NCS.
12 But there is a process, and it might be possible to do
13 something. The next steps would be to talk with some of
14 the center directors in California, like Jim Swanson and
15 Neal Halfon.

16 But, again, the protocols are very proscribed,
17 and making change to it is not easy. However, there could
18 be opportunities to use that infrastructure to recruit
19 other kinds of participants.

20 I wanted to step back though and get back to some
21 of the requests for kind of input here. In looking at
22 this list of possible community studies, I look at that
23 and say, you know, they're all important and these are all
24 areas that need more attention and should get more
25 attention. I think it would be wisest though to do

1 community-based studies that are meaningful to larger
2 populations. And I wouldn't want to -- you know, I hate
3 the idea of excluding, for example, certain kinds of
4 occupational studies.

5 But I think if we were to focus, for example, on
6 children and mothers, that's a sample that's -- a
7 population that is really a strong -- you know, is
8 strongly connected to the well-being of our society. And
9 that generating more information on that and coming from
10 the State I think is a strong statement and commitment of
11 the State to try to understand what are the health risks
12 and what are the exposures that are going on in that
13 population. And if you were to choose other strategies
14 again, I would think looking at populations that -- again
15 generating information that's meaningful to the whole
16 population.

17 On the question here about descriptive or
18 hypothesis-driven studies, I would actually focus on the
19 descriptive. And maybe there's some other people who have
20 different opinions here. I think the danger of focusing
21 on hypothesis-driven research is if you don't answer your
22 question, you're kind of left with a null finding.
23 Whereas, with the descriptive research you're really
24 categorizing what people are exposed to and developing
25 some sort of health interpretation. And it would be -- I

1 think it would be a challenge to create, you know, certain
2 public policy issues if you're doing research that is
3 potentially related to public -- you know, public policy
4 decisions and the results are null or they're null because
5 the design wasn't quite right, and you kind of open up a
6 whole can of worms that I think could raise challenges for
7 the Programs.

8 Then the last thing where I had some thoughts
9 that we haven't really touched on is the whole issue about
10 communicating results. And there is a small literature on
11 that. And there are some people here in the Bay Area I'm
12 sure would be happy to, you know, describe what they've
13 gone through. I'm sure I'd be happy to describe what
14 we've gone through with returning results back now to
15 about half of all our participants on pesticide results in
16 children.

17 And in my experience, it's not difficult and it's
18 not complicated. I know there's been a lot of ethical
19 issues. We had to fight with the ARB to actually have
20 permission to turn results back. However, after going
21 through a relatively simple process and sitting down with
22 people, doing it in person, explaining what they mean --
23 or if you're not doing it in person, have a venue for
24 responding personally to individual results -- it's kind
25 of a moot issue. People want to know. People don't freak

1 out. And it overall tends to be a positive experience.

2 DR. LIPSETT: Okay. Well, Dr. Bradman, I think
3 we might want to subcontract with you for that process.

4 (Laughter.)

5 DR. LIPSETT: Because I've read most of the
6 published literature on this. And it is an area that
7 we're -- there haven't been a lot of people who've done
8 what you've been able to do. I mean, it's just been
9 undertaken. And I guess one of the concerns that we've
10 had is just in trying to communicate information,
11 especially, say, involving children. And I'm actually
12 quite impressed to hear that you've had that level of
13 success.

14 But, say, with some of the PBDEs that you'd find
15 in high levels in kids where you have some toxicology that
16 suggests that there may be potentially significant issues,
17 you know, later on for these kids and being able to do
18 that in such a way as to not generate undue anxiety in the
19 parents is -- I think it's -- well, I'm going to defer to
20 your experience on it. But it would seem to me to be a
21 priori something that's not really that straightforward.

22 PANEL MEMBER BRADMAN: Well, there's discussion
23 we could have that about, and if you want to have it now.
24 But I mean I think there's specific steps you can take in
25 terms of offering retesting and follow up. And that tends

1 to assuage people's concerns, also if they understand that
2 the testing is being done in a research context. Because
3 many of the things we're testing for are not -- they're
4 not -- there's no clinical definition of what they mean,
5 you know. And, of course, lead and a few others have
6 exceptions. But in general, it's -- but, again, I think
7 that's another discussion.

8 DR. LIPSETT: Okay. Well, thank you.

9 Could I ask the other Panel members actually to
10 reflect back on what Dr. Bradman said about
11 hypothesis-driven versus exposure-assessment type of
12 research.

13 CHAIRPERSON MORENO: Why don't we start on this
14 side and we'll work our way down with comments.

15 PANEL MEMBER MCKONE: Yeah, actually I had made
16 notes almost to the same effect, that -- and a little bit
17 different reasoning, I guess. But I thought if you do
18 the -- start doing the hypothesis-driven studies, it takes
19 away from the sort of uniqueness of this program and
20 starts looking like another health study, and I think
21 there may be a danger to doing that.

22 But also I agree with Asa's point too, is that if
23 it's a hypothesis-driven study, it'll move in a certain
24 direction. And the more we can keep it descriptive, I
25 think the more it feeds into our original intent of having

1 a representative sample of the State of California. So I
2 would probably second that point.

3 PANEL MEMBER WILSON: I would -- oh, Ed.

4 CHAIRPERSON MORENO: Anyone else?

5 No, go ahead.

6 PANEL MEMBER WILSON: Yeah, I would concur with
7 that, that particularly at this point in the development
8 of the Program, that a descriptive study opens the
9 possibility of further questions and inquiry. Whereas, in
10 a hypothesis-driven one, it tends to give us an answer
11 that's -- you know, can be fairly constrained. And so I
12 would also support this, you know, a descriptive approach.

13 And also, in just looking at the set of options
14 here, I think what's interesting, what I hear on the Panel
15 here, is sort of a back and forth on the matters of
16 recruitment expense and efficiency sort of balanced
17 against what is going to be most valuable with respect to
18 public health -- and public health information.

19 And I think I would -- you know, I concur with
20 Asa, that looking at the question of maternal-child
21 biospecimens, that as an option, probably addresses all of
22 those criteria in terms of -- I mean in terms of ease of
23 recruitment, expense, efficiency, and broad value. And,
24 you know, my experience in, you know, gathering
25 occupational health samples, for example, is extremely

1 difficult to do, number one, in a non-unionized workforce,
2 in that your access to those workers hinges on the
3 employer's consent really in a non-unionized, you know,
4 facility or workforce.

5 And with a unionized workforce you have more
6 options. But, again, you -- and there's more access in
7 that you have some independence there. But, again, it's a
8 fairly -- it's difficult to say much about that finding
9 for the general population, right? It's going to be
10 specific for that occupational setting or that population
11 of workers.

12 And as valuable as that is -- you know, as
13 valuable as it is, but I think in terms of public health
14 value, this -- a maternal-child biospecimen is probably
15 higher, gives us more information.

16 The other is that on the health-affected group
17 approach, again, definitely worth doing; but I worry about
18 how that's -- how the findings are communicated and that
19 if it was, you know, autism or breast-cancer-affected
20 participants, these were the inclusion criteria, we then
21 collected these samples. It's not possible for us to
22 really say that there's any real linkage there, I mean at
23 this point. And so in terms of the risk communication, I
24 think that's -- we just need to think about where we're
25 headed with that.

1 And so my instinct is to sort of -- that that's
2 probably not a good approach to look at health-affected
3 groups. And again back to your first option.

4 DR. LIPSETT: Thank you.

5 CHAIRPERSON MORENO: Any Panel members on this
6 side?

7 PANEL MEMBER KAVANAUGH-LYNCH: I had the same
8 response when I saw the list, particularly that it
9 included breast cancer, where there has been a significant
10 lack of success in surveying breast-cancer-affected women
11 for chemicals of interest. And where we think that -- you
12 know, where the latency is a big issue or maybe decades
13 where time of exposure and dose of exposure and multiple
14 exposures may all play a role, which are things you are
15 not going to be able to address in a small community
16 study, I think the risk of coming up with something that
17 only upsets people and disappoints people is high.

18 Whereas, a more observational study allows you to
19 have absolute results: We set out to observe something.
20 We observed things. Here's what we observed. Now, what
21 you can do with it is sort of the next step, and here are
22 the questions that these raise that then allow themselves
23 to -- are subject for future research studies, is, I
24 think, the way to go. And especially if you want
25 something that is quick, as Gina was just talking about,

1 you know, if we want something that -- where we have --
2 you absolutely can deliver something that's of interest to
3 people in a short period of time, I think what you can do
4 is observations.

5 PANEL MEMBER SOLOMON: And I fully concur with my
6 colleagues on the Committee, both about, you know,
7 focusing on descriptive as opposed to hypothesis-driven
8 studies at this point and the appeal of the maternal-child
9 biospecimen approach certainly among the options here as a
10 good way to go for the reasons that other people have
11 outlined.

12 CHAIRPERSON MORENO: All right. So I think
13 you're hearing consensus on a question you asked the
14 Panel. I'm interested in something that we can -- this
15 Panel and the Program can publish and put forth. And to
16 raise interest, to demonstrate that this is a good
17 product, we need more of this, we need more funding. This
18 could be bigger and better. And we're going to get more
19 of this when the funding is available.

20 So you got the answer you're looking for on that
21 one?

22 DR. LIPSETT: I got the discussion I was looking
23 for, yes.

24 (Laughter.)

25 DR. LIPSETT: Thank you. This is very helpful,

1 very helpful.

2 CHAIRPERSON MORENO: Okay. If you don't mind --
3 we are a little over our schedule. At this time, we're
4 going to open up to public comment. And I have one
5 request to speak from Davis Baltz.

6 MR. BALTZ: Thank you very much for the
7 opportunity to speak today, members of the Panel. I'm
8 Davis Baltz with Commonweal, a nonprofit in Bolinas,
9 California. And with Breast Cancer Fund we were
10 co-sponsors of the legislation that created this program.

11 You know, as has been said, the statute calls for
12 both a statewide representative sample and community
13 studies. So, you know, we don't have the money right now
14 to do the statewide representative sample, and I think
15 we're all clear on that. But it's not going to be a
16 setback for the Program to go ahead and do the community
17 studies. So let's not look at this as sort of the second
18 choice. Of course, we want to scale up and do these
19 regular statewide studies. But in the interests of
20 generating some data and some interest in the Program, it
21 is important to move forward.

22 I have also heard the talk about the
23 maternal-child pairs. And I think for all the reasons
24 that have been discussed already that that would be a good
25 choice, especially since we have this offer from CDC to

1 provide the analysis.

2 But as Gina pointed out, you know, time is of the
3 essence here too. And I don't know if this would pass
4 muster with any of you. But if we want to generate some
5 discussion in California about what these results might
6 mean and what it can mean for Californians, why don't we
7 offer the lab capacity here in this state in a pilot to
8 test every member of the Legislature. Not all of them
9 will take us up on the offer. But I guaranty you we will
10 get some prominent media attention and discussion. And I
11 think that could translate into some support financially.

12 Another idea that I floated before is, absent
13 that or maybe in addition to, let's offer a biomonitoring
14 test to county health officers. This way every county is
15 represented. And if we also get a good sampling of the
16 Legislature, I think you could say that this would be a
17 representative sample of California.

18 (Laughter.)

19 MR. BALTZ: Now, concerning the funding,
20 Commonweal has actually gotten a grant recently to do some
21 public education around biomonitoring, and we've been
22 doing that since this legislation was passed. But we have
23 some more targeted money. And as I've said to you before,
24 we're committed to helping raise the profile of this
25 program and help it develop. If there is some way that we

1 can approach some foundations as well and take on some
2 piece of this that would be helpful, we're ready to do
3 that.

4 And one thing that comes to my mind is, you know,
5 a year or two ago at Boston University some -- there was a
6 consensus process on biomonitoring. It's a model that I
7 think is commonly done in Europe, where a cross-section of
8 people who don't necessarily have a technical background
9 in an area are brought together and they go through an
10 intensive period of discussion with presentations to learn
11 about an issue and then come forward with those sort of
12 lay findings that reflect for the society's interest.

13 And I think if we could combine some limited
14 community study with this process that would inform how we
15 can communicate results and again raise the profile of the
16 Program, this would be kind of an interesting thing for
17 our foundation to fund, especially if it was a partnership
18 with communities, the Government program, and maybe some
19 academicians as well.

20 The last thing I'll say is, Dr. Lipsett mentioned
21 the green chemistry initiative, and I think it's worth
22 starting to look at the Biomonitoring Program as a
23 component of green chemistry. Certainly we know there's a
24 bit of momentum right now in California for green
25 chemistry despite our budgetary problems. The fact that

1 DTSC has been the driver for the green chemistry
2 initiative, it's Director Gorsen has been a champion of
3 it, and the laboratory at DTSC is involved in this
4 program, I think we need to make a better effort to
5 convince all the parties that biomonitoring, in fact, does
6 advance green chemistry.

7 We're going to have the implementation this year
8 of AB 1879 and SB 509, sort of the first planks in the
9 green chemistry platform, if you will. And, you know, we
10 don't have the official report yet on what the green
11 chemistry initiative is ultimately going to encompass.
12 But from point of view of someone who works in the
13 nonprofit sector, I think any green chemistry initiative
14 that ultimately will be supported will need to retire some
15 bad actor chemicals. And there are a number out there
16 that we certainly have enough information on to act.

17 So if we can fold in biomonitoring results into
18 this process of the development of the green chemistry, I
19 think it would be worth doing and maybe would smooth out
20 some of the potential hurdles we face of this cross-agency
21 collaboration, especially in light of the funding for the
22 Program going to the TSCA account at DTSC.

23 So thank you, as always, for the chance to
24 comment.

25 CHAIRPERSON MORENO: Thank you.

1 Any questions from Panel members for Mr. Baltz?

2 Yes, we do.

3 PANEL MEMBER WILSON: Davis, I appreciate your
4 mention of the green chemistry initiative. I think -- I
5 concur with that, that one of the challenges under AB 1879
6 is going to be to identify and prioritize chemicals of
7 concern and without getting paralyzed. And I concur. I
8 think this is an interesting lens, the State's
9 biomonitoring program, as a way for the State to move
10 quickly and to identify substances that are relevant in
11 California and so forth. So I appreciate that comment.

12 I'm wondering if you could just comment a little
13 bit more about the Program you described at Boston
14 University.

15 MR. BALTZ: What they did was they identified I
16 think about a dozen -- I can't remember the exact number,
17 but it was probably not more than a dozen -- citizens in
18 greater Boston who expressed an interest to participate
19 but basically didn't know much about biomonitoring. And
20 so they came together over more or less a year-long
21 process. And they gathered on two or three weekends and
22 heard presentations from experts on biomonitoring, both
23 the laboratory side, communication-of-results side, sort
24 of, you know, the kind of experts that you are sitting on
25 this panel. And then with some skilled facilitation, they

1 developed a report on their findings basically on
2 biomonitoring, what they felt its value to society would
3 be, and recommendations for policy-makers for how they
4 should move forward with advancing biomonitoring.

5 PANEL MEMBER WILSON: Thank you.

6 CHAIRPERSON MORENO: Okay. Other comments,
7 questions?

8 Yes, Dr. Solomon.

9 PANEL MEMBER SOLOMON: I think the suggestion to
10 biomonitor some high profile people - I don't know if it
11 would be legislators or who - but is a provocative one.
12 And if the lab is actually going to be opening, so to
13 speak, in early 2009, it does seem like a good opportunity
14 to have an official lab opening event and to potentially
15 invite some folks to tour the lab. And there will be a
16 need to collect some samples at that point from some
17 volunteers.

18 So I'd like to suggest that we -- to staff that
19 you think about what sort of falls within the bounds of
20 what is doable in terms of a lab opening event. And that,
21 you know, we would certainly, you know, as
22 panelists -- those panelists who are located nearby I
23 think would be very happy to come participate in any such
24 event if it were held.

25 MR. BALTZ: You know, throughout the time the

1 legislation was before -- was enacted, we stressed in all
2 the committee hearings that we felt it was very important
3 for the Biomonitoring Program to, you know, be science
4 based and that that should be the priority so that any
5 results couldn't be attacked for being sloppy. And we
6 continue to agree with that. And I don't think there's
7 necessarily, you know, a contradiction between having a
8 lab opening event with a little media attached and still
9 have a very rigorous science analysis, despite the fact
10 that the people who may be in the study aren't going to be
11 the representative sample that ideally that we would like.

12 We've been talking with a number of communities
13 about biomonitoring, and a number of them have expressed
14 interest in sort of stepping forward and volunteering to
15 be biomonitored if this could be something that the
16 Program would be interested in; again, not necessarily
17 representative of California in a statistical sense but a
18 number of different communities whose constituencies are
19 affected by chemical exposure and then could be
20 spokespeople for generating public support, which then
21 could come back up through their legislative
22 representatives.

23 CHAIRPERSON MORENO: Okay. Any other questions?

24 Thank you.

25 Dr. Lipsett, I just want to go over, before we

1 break, what I understand that we covered this portion of
2 the meeting.

3 The current status of the RFI review is that
4 additional information would be requested of the
5 responders and that selection will take place in January
6 of 2009; is that correct?

7 DR. LIPSETT: Yes.

8 CHAIRPERSON MORENO: Which means this Panel will
9 be expecting additional information as a result of that
10 work at the next meeting, or after this meeting?

11 DR. LIPSETT: Okay. The --

12 MS. LEE: Excuse me. Before public comment is
13 closed, I'd like to report that there is a comment being
14 submitted by Rebecca Sutton from the Environmental Working
15 Group who indicates: "The Environmental Working Group
16 supports the idea of maternal-child sample pairings as
17 part of the California Biomonitoring Program. Thanks for
18 the opportunity to attend the conference via webcast."

19 CHAIRPERSON MORENO: Thank you. And that will be
20 added to the record.

21 Thank you.

22 DR. LIPSETT: The answer is yes, we can provide
23 that information at the next Panel meeting or we could
24 also ask Carol if it's okay to Email the Panel members, or
25 would it be something that may need --

1 CHAIRPERSON MORENO: -- actually I think --

2 DR. LIPSETT: We'll do it at the next meeting.

3 CHAIRPERSON MORENO: Can we receive that
4 information in compliance with the Bagley-Keene Act,
5 however that is most appropriate, and staff can then
6 determine --

7 OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: We'll talk
8 about that.

9 CHAIRPERSON MORENO: Yes, thank you.

10 And did you also get sufficient input from the
11 Panel on the community studies and ancillary activities?

12 DR. LIPSETT: Yeah, I think that -- yeah, I think
13 this is a very helpful discussion.

14 And actually I'd like to ask Dr. McKone again
15 to -- regarding your earlier suggestion about looking at
16 these different types of studies with respect to the kinds
17 of information that would be generated that could be
18 applied to the, say, initial conceptualization of the
19 Program in terms of a representative sample.

20 Do you still feel that you'd want to undertake
21 this kind of simulation exercise, given the kinds of
22 feedback you've heard from the rest of the Panel?

23 PANEL MEMBER MCKONE: Yeah, I think there was a
24 consensus that -- I mean, I was really speaking to the
25 issue of making it generalizable. So to some extent, we

1 could take the community sampling and have it -- determine
2 to what extent it gives us insight about the broader
3 representativeness of the state population. I still think
4 that's feasible. It's just sort of a standard inverse
5 modeling. I know it's not standard for a lot of people,
6 but it -- I don't think it's that -- I mean, it's
7 something we should look at.

8 DR. LIPSETT: Okay.

9 PANEL MEMBER McKONE: Because it might actually
10 enhance the value of limited information.

11 DR. LIPSETT: Great.

12 Okay. Thank you.

13 CHAIRPERSON MORENO: All right. Thank you.

14 So with this, I think we're going to take a
15 ten-minute break. So it's -- I'm looking at that clock
16 back there -- it's 3:25. So we'll be back at 3:35.

17 Okay. Thanks.

18 (Thereupon a recess was taken.)

19 CHAIRPERSON MORENO: All right. I'd like to call
20 the meeting back to order, if the public can have a seat
21 and our Panel members come back to the dais.

22 Thank you.

23 Welcome back, everyone.

24 I'm just going to regress just for a moment to
25 our prior presenters, just for a second.

1 Dr. Lipsett, there was some interest I believe
2 from some Panel members for a brief reminder of the
3 statute that enacted this program and the intent, to
4 remind us what we're trying to achieve as we continue with
5 these discussions today.

6 DR. LIPSETT: Well, in looking at the statute, in
7 both the preamble and what's contained in the bill, it was
8 intended to set up a biomonitoring program for California
9 that had a number of components, one of which was to
10 undertake a statewide representative sample to try and set
11 a baseline level of specific chemicals that we would
12 identify within that population. The participants would
13 be allowed to have their results upon request. This is
14 another aspect of it, that there be meaningful
15 opportunities for public participation; that there be
16 technical input from a scientific guidance panel; and that
17 within the statewide survey, in addition to trying to set
18 a baseline level of specific chemicals, that we would look
19 for trends over time that could be used to help us assess
20 regulatory and other kinds of public health interventions
21 to reduce exposures over time. And then, in addition, the
22 bill called for community studies as well, contingent upon
23 funding.

24 Does that cover it? Or would you like additional
25 information? I'm not looking directly at the bill, but I

1 certainly could provide more if you'd like additional
2 information.

3 OEHHA DIRECTOR DENTON: Michael, I think Dr.
4 Culver's -- is what question is the Biomonitoring Program
5 seeking to answer? What question? What are the levels of
6 chemicals in Californians on a statewide basis as well as
7 a community? I mean, what is the -- kind of what is the
8 question or questions that the Program is seeking to
9 answer?

10 DR. LIPSETT: Okay. Well, there are a number of
11 uses to which biomonitoring data could be put, and they're
12 spelled out in the preamble to the legislation. But the
13 main question is: What is it that people are exposed to?
14 What is it that people actually have within their body,
15 within their blood and urine, other -- and their tissues?
16 Because as is indicated in the bill itself, there are like
17 nearly a hundred thousand chemicals that are in use --
18 registered for use in this country for which we have very,
19 very little information in terms of their potential health
20 effects. And we have even less information about the
21 exposure patterns in the population.

22 And that is one of the principal ideas behind
23 this, is to try and get an idea of what it is that people
24 in California are exposed to. And those data can be used
25 by researchers, they can be used by public health

1 officials. There are a variety of uses for this. But the
2 idea was to just generate information that, at this point,
3 doesn't exist.

4 CHAIRPERSON MORENO: All right. Thank you.

5 Before we move on to the next portion of our
6 agenda, I just want to remind people that this is being
7 webcast. And those of you that are watching the webcast,
8 we will be going till 5 o'clock today. And if you have
9 questions for the -- that you'd like us to share here at
10 the meeting, you can Email us at
11 biomonitoring@oehha.ca.gov. And those of you that are in
12 the public who are present today, also a reminder that we
13 have the purple cards here for you to fill out, and we'll
14 have opportunity for public comment after this next
15 presentation.

16 Another reminder to our Panel members and our
17 staff, I'll do my best to identify the speaker. But if I
18 forget, please identify yourself, because we are keeping
19 record of who's providing comment at this meeting. So
20 that's one reminder.

21 And I believe our lead counsel has a suggestion
22 for -- or a reminder for Panel members for this evening.

23 OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS: Right. I
24 was told that you all are going to dinner this evening.
25 Probably at least a quorum of the group would be together

1 at dinner. And so I just wanted to remind you that it's
2 important not to discuss the matters that are on the
3 agenda or may come on the agenda for this Panel when
4 you're having dinner. So if you can stay on different
5 subjects -- I know that's hard because the reason that
6 you're together is because of this group. But it's best
7 to avoid those discussions so that any discussions you do
8 have can be made in a public forum.

9 CHAIRPERSON MORENO: All right. Thanks for that
10 reminder.

11 Okay. Dr. Lipsett, would you like to make the
12 introductions of our next presenter.

13 Thank you.

14 DR. LIPSETT: Our next presenters are the lab
15 chiefs for this program. For the Department of Public
16 Health is Dr. Peter Flessel, who's the Chief of the
17 Environmental Health Laboratory Branch.

18 And just I wanted to add a note about Dr.
19 Flessel, that this will be his last Panel meeting because
20 he is retiring at the end of this month after many years
21 of dedicated State service.

22 And he will be accompanied in this presentation
23 by Dr. Myrto Petreas, who is the Chief -- the Branch Chief
24 for the Environmental Chemistry Laboratory of the
25 Department of Toxic Substances Control.

1 Thank you.

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

4 DR. FLESSEL: Dr. Moreno, Panel members. Thank
5 you very much.

6 We're going to provide you with an update on
7 laboratory capacity. I'll begin. Myrto will take over.

8 The content of today's presentation is largely
9 derived from the conversations -- initiated by the
10 conversations that we had after the last meeting when
11 several of you asked us questions about, "Well, what could
12 you really do given the funding that exists right now?"
13 And so what we tried to do is to put together
14 presentations that would tell you about our current
15 staffing and equipment progress, and then to ask some sort
16 of soft questions about what we think we can do, in what
17 timeframe, and to what extent.

18 --o0o--

19 DR. FLESSEL: So I'll start by bringing you an
20 update on our scientists involved in the Program. These
21 are the five individuals that are supported by the
22 Biomonitoring Program. From left to right, Paramijit
23 Behniwal; Bob Ramage; Frank Barley; and Jianwen She, who
24 is here in the room; and Meralda Rafol, who is our admin
25 person to support the staff -- the laboratory staff.

1 Those four individuals are the laboratorians.

2 --o0o--

3 DR. FLESSEL: We are making real progress in
4 getting our equipment in place:

5 The upper left, the sample prep instrument that
6 we'll use to automate and increase our throughput of
7 samples.

8 The upper right is an ICP/MS for metals testing.
9 We're very happy to have that in place now.

10 On the bottom is a manufacturer's photograph of
11 the Hi Sensitivity LC-MS/MS that we'll use for organics
12 testing. This is currently in the box. And we are
13 waiting for final renovations to the laboratory. The
14 Devil is in the details, as you know, always. And it's at
15 this point getting another 208 line to handle the power
16 requirements. But we're almost there as far as our
17 organic testing capacity. And we're definitely on our way
18 as far as our metals testing capacity.

19 --o0o--

20 DR. FLESSEL: So one question that we started to
21 ask ourselves is: What is the number of samples that we
22 could analyze with base funding, assuming minimal sample
23 management? The numbers that I put up there are under
24 these conditions. Maybe a thousand whole blood samples, a
25 thousand serums, a thousand urines.

1 Now, the important caveat, to sort of stop and
2 explain, is that minimal sample management means that we
3 only log the samples, test them and report them. That's
4 very different than what we had set out to do in the full
5 program.

6 If you followed the full implementation of
7 rollout as it was planned, we actually had projected four
8 PYs to do sample management: A research scientist and two
9 senior lab assistants to actually do the hands-on work,
10 and then an IT professional to essentially support the
11 LIMS, the Laboratory Information Management System, that
12 we'd need to handle the samples.

13 Think about what real sample management would
14 involve if we're out there collecting the samples. If
15 we're a part of that, we have to provide the sampling
16 materials; we have to make sure that everything that goes
17 into the field has been quality controlled to avoid any
18 contamination; we have to make sure that the labeling
19 systems are appropriate for the field so that when the
20 samples come back in, we can use those labels to enter the
21 laboratory into -- the samples into the laboratory, we can
22 do the aliquoting of the samples and send them around to
23 the various laboratories that are going to do the tests,
24 and then we're going to create the archive. That's a lot
25 of work.

1 On the other hand, if we only receive, log, test
2 and report samples, we can handle a good bit more.

3 --o0o--

4 DR. FLESSEL: What then under these conditions of
5 minimal sample management could the Public Health
6 Laboratory do given the base funding that we have? This
7 is our best case laboratory capacity estimate.

8 These are the things that we might be able to do
9 in the timeframe that's shown on the slides here.

10 So with regard to metals in whole blood - lead,
11 cadmium, and mercury - we're actually there. I mean, this
12 is not something that we set out to do in terms of the
13 Biomonitoring Program. We've been doing metals testing
14 for a long time. So it was pretty easy for us to extend
15 our metals testing to create a standard operating
16 procedure that will really be in place in the next month
17 or so. And once it's up, we feel we could run a thousand
18 samples a year.

19 And then we've thought that arsenic would be an
20 interesting addition to this metals panel, and we could do
21 that. We could add arsenic to a panel probably by
22 mid-spring. And once it's up and running, we could do a
23 thousand of these tests in whole blood per year.

24 And then we could extend this metals work by
25 choosing to look at speciated mercury or speciated

1 well, gee, that's too optimistic. But something like the
2 late spring we should be in a position to run the OP
3 pesticides in urine.

4 And, in fact, I told you last time about the
5 Tracking study out in Tulare County. We're actually doing
6 a little pilot study in support of the Tracking Program
7 involving some -- its biodrift. The issue is how much of
8 this stuff that's applied gets into people in the
9 community around the field? And so this was sort of dual
10 use for biomonitoring and this Tracking Program activity.
11 And so we got a jump-start on that. And we hope that
12 we'll be able to continue to do that.

13 The other two options there are much
14 more -- they're softer opportunities; namely, we haven't
15 gone very far in developing methods for, on the one hand,
16 phthalates and Bisphenol A. It's possible, however --
17 we've done enough thinking to know that we can do a
18 phthalate panel and Bisphenol A together in the same
19 analysis, at least we believe we can. And that if we
20 chose to do that and put effort into it, we could probably
21 be ready to have a method in place by the fall, October
22 '09. And once it's there as a standard procedure, we
23 could run about a thousand samples per year.

24 Another alternative would be to look at the
25 polycyclic aromatic hydrocarbons, a panel of those.

1 Again, we could -- if this was the choice of the Program,
2 with your support, we could set up and have that panel
3 ready to go some time in the fall, probably October,
4 November maybe, a thousand samples per year, assuming that
5 we're not collecting the samples, we're not doing all that
6 sample management.

7 --o0o--

8 DR. FLESSEL: So now I'll let Myrto talk about
9 activities in her lab.

10 PANEL MEMBER SOLOMON: Could I ask a clarifying
11 question there? Is that okay?

12 So with regard, for example, to the organics, if
13 the Panel were to suggest a different set of chemicals,
14 let's say, you know, the pyrethroids as another group of
15 interest, would that be sort of doable instead of one of
16 these on the same timeline or is --

17 DR. FLESSEL: It would have to be either/or, yes.

18 PANEL MEMBER SOLOMON: Great.

19 DR. FLESSEL: Well, obviously these would end up
20 approximately --

21 PANEL MEMBER SOLOMON: I was just wondering if
22 these were --

23 DR. FLESSEL: -- approximately the same timeline.
24 So we haven't done as much thinking about pyrethroids as
25 we have about the phthalates, BPA, and PAH and the OPs,

1 but we haven't gone very far into it. We've largely been
2 focused on getting the instruments in, getting them
3 installed, and then starting to collect a lot of the
4 materials -- the testing materials that could be used for
5 basically any panel of organics.

6 PANEL MEMBER SOLOMON: So if you were to get sort
7 of general direction from the Panel about the sort of
8 nonpersistent organics in the near term, then that would
9 allow you to sort of figure out which pathway to pursue in
10 terms of your two groups of chemicals that you think that
11 you'll be up and running with?

12 DR. FLESSEL: That's right. That's why it's
13 really important to get input from the Panel at this
14 point, because we're really at that decision point.

15 DR. PETREAS: I'll follow the same format as
16 Peter, starting with our staff. These are our two staff:
17 Yunzhu Wang, who's a chemist, on the left; and Dr.
18 Miaomiao Wang, research scientist, on the right. They're
19 standing proudly in front of our new instruments.

20 Now, unlike what Peter described for the Public
21 Health Laboratory, which got a whole section funded
22 through the Program, we only got these two staff. So we
23 had to fold them into our existing staff, because
24 otherwise it wouldn't be viable. The staff need
25 supervision, guidance, data review, quality assurance and

1 so forth.

2 So by including them with a group of experienced
3 staff acting as mentors, we can have something done.

4 Now, the group that adopted these two new
5 scientists is the quite experienced group that has been
6 performing biomonitoring studies for many years. And we
7 have a lot of experience doing chemicals -- persistent
8 chemicals in many different matrices, from soils and
9 sediments to biota, wildlife, human tissues and so forth.

10 This group is still active and will stay active
11 in the area of emerging contaminants, as it applies to
12 many initiatives of DTSC. So it's busy with DTSC
13 programs, but provides the door, I guess, to start with
14 the new biomonitoring program.

15 The existing staff are State staff and also
16 contract staff funded by extramural grants from federal
17 government. And we have students that work in the lab.

18 And we're also lucky to get the fellow -- a
19 post-doctorate fellow for free funded by the Association
20 of Public Health Laboratories. It's a one-year
21 appointment, maybe expanded to a second year. And we'll
22 have this person -- he started a month ago and he started
23 working on the serum methods so he can help to get us
24 going in the beginning.

25 We should note, however, that these are the two

1 staff that we have. So whatever we promise that we can do
2 or commit we can do, we have to keep in mind that it's
3 limited. And if something goes wrong, we cannot even stay
4 with the commitment. We need -- really we need more
5 staff, because without more staff, we can only probably do
6 the things that I'll show you later and not all these other
7 interesting things I hear or the chemicals that we'll be
8 talking about tomorrow. It's either/or. So we cannot do
9 the legislators and the RFI specimens or, or, or. We have
10 to really choose what we can do.

11 But I should say, because of our past history and
12 the experience of our staff, any work that we do for DTSC
13 can very well feed into this program. Even data we
14 produce from our other studies can fit into this program.
15 So there's synergy by having this new staff involved with
16 the existing staff.

17 --o0o--

18 DR. PETREAS: Now, our equipment. This is the
19 high resolution GC/MS that was installed very recently.
20 And as of Monday, we started the one-week-long training.
21 So this is the first piece of equipment that came.

22 We're expecting also the liquid chromatograph
23 LC-MS that Peter showed. We expect also some of the
24 sample preparation equipment that will help automate and
25 increase our throughputs. But things are not there yet,

1 and we already are about three months behind schedule from
2 what we thought we would be a few months ago.

3 --o0o--

4 DR. PETREAS: I just want to give you just some
5 background on the other activities that we're doing, for DTSC,
6 that eventually will feed into the implementation of the
7 Biomonitoring Program.

8 Historically, we have been doing studies of
9 persistent organic pollutants, or POPs, in all kinds of
10 media, as I said, from soils and sediments to wildlife and
11 human tissues. And we have built this capacity and
12 capabilities over many years with trial and error. But we
13 know where we stand if it comes to do organochlorine
14 pesticides, OCPs, PCBs, and PBDEs. So with this -- with
15 the current methodology and the current technology, we can
16 do about 500 samples of serum per year using a little over
17 two staff; primarily contract staff doing the bulk of the
18 work, but overseen by State staff who also do most of the
19 instrumentation.

20 We have good quality data and we're confident
21 about this area.

22 Now, we're also expanding, adding more to our
23 repertoire. So we add some of the new brominated flame
24 retardants that can be extracted from the same serum
25 sample. So we hope to expand our methods that I'm listing

1 set up this month, and training will be this month.

2 In February, we expect to set up and get training
3 on the LC/MS.

4 And between January and April, we plan to set up
5 and use the automated sample preparation equipment that
6 will help us optimize and increase our throughputs.

7 Again, these are assumptions, because we're
8 not certain in terms of a timeline, because when things can go
9 wrong, will go wrong.

10 And parenthetically, I should say that all this
11 equipment that we're sort of getting, the sample
12 preparation improvement and the LC/MS and GC/MS, are ideas
13 we got from CDC. And there they're used very efficiently, very
14 productively.

15 The difference, however, between CDC and us is that in
16 CDC if one instrument fails, they go to the next one.
17 They have banks of instruments and they have a resident
18 engineer to help repair their instruments. In our case,
19 if something fails, we have to get authorization and
20 approval, and it takes time and money and -- it's not so
21 easy. So if something can go wrong, will delay things.

22 So our best estimates at this point -- oh, and
23 also, I forgot to say that we plan to send the staff for
24 training at CDC, both labs, we'll send them when we're
25 ready, sometime in the spring.

1 So if we were to go and continue expanding on our
2 POPs, our best estimate is in the spring we'll have a --
3 set up new equipment, change our methodology to take
4 advantage of the new automated equipment, with a goal to
5 have a method that will allow us to develop and -- to have
6 a capacity for 800 samples per year for the POPs by late
7 fall. Again, this is an optimistic -- and I've been
8 criticized by some of our staff saying that this may be
9 promising too much. But that's a goal. So we have a goal
10 and try to get there.

11 So we need to get the decision pretty soon
12 whether we're going to go with POPs or something else.

13 --o0o--

14 DR. PETREAS: So again following Peter's example
15 of a table, again best best best case, as I said, we could
16 possibly do about 800 -- start to be able to do 800
17 samples per year starting in October of the things that we
18 are more familiar with, the PCBs, the PBDEs and the OCPs,
19 and possibly some of the new brominated flame retardants.

20 Or we can put our attention to the perfluorinated
21 chemicals, use the LC/MS. Apparently, these are more easy
22 than the POPs. We haven't done them, so everything is
23 difficult in the beginning.

24 But probably we can be able to do about a
25 thousand samples per year by the end of spring -- late

1 fall.

2 But keep in mind that we cannot do both. So it's
3 either the POPs or the perfluorinated. And it's not -- I
4 mean we can never do both, in October '09 or October '10
5 or ever, unless we get more staff.

6 So the idea is we use the synergy of the entire
7 group of the lab to get the Program started. But at
8 steady state we have two staff who should be there
9 producing and generating data and getting new methods for
10 new chemicals. And so that's a big limitation we have.

11 --o0o--

12 DR. PETREAS: And, in summary, I guess
13 representing both of our views here is we made progress,
14 the initial staff are on board, and the equipment are
15 arriving. Some of them are already here.

16 Word of caution. Repairs are costly and take
17 time. And we have -- the new equipment has a one-year
18 warranty. After that, it will cost money.

19 So, again, we need operating expenses, we need
20 staff. And that's why we tried to work with external
21 partners.

22 Both labs will probably get the fellow that we
23 have from the Association of Public Health Laboratories.
24 So this will add hopefully one body to help with Peter's
25 lab.

1 Now, again, to reduce the time and the effort for
2 sample management, we can work with some samples
3 from the RFI, which come from one freezer to the next.
4 And the idea again and the intent here is to be able to
5 produce something as soon as possible so we keep the
6 Program alive and generate some good data.

7 So with that, we can have questions.

8 CHAIRPERSON MORENO: Thank you for the
9 presentations.

10 Questions. We'll start on the right here.

11 Dr. Luderer.

12 PANEL MEMBER LUDERER: Thank you both for the
13 presentations.

14 I have a question which -- just a clarification I
15 guess. What I'm hearing is that the limitation right now
16 in terms of the number of samples that both of your labs,
17 you expect to be able to analyze, you know, in the time
18 frames that you said, are more limited by staff than by
19 the equipment; so that if you had more staff, both labs
20 could potentially analyze more samples; is that -- was I
21 understanding that correctly?

22 DR. FLESSEL: Well, I would say it's -- for us
23 it's probably -- we're pretty much -- it's neck and neck.
24 So if you have more staff but you don't have the
25 equipment, then you're in trouble too. So I would have to

1 say that, yes, for her, no, for us.

2 PANEL MEMBER LUDERER: And then if I might, just
3 one follow-up question.

4 One of the things that you were talking about was
5 that if equipment goes down, the expense of repairing it
6 and not having a back up. And I was -- one thing I was a
7 little confused about, the LC-MS, are there going to be
8 two of them, one in each lab, or are you going to be using
9 the same one? And if there are two, you know, could one
10 serve as a back-up if there was a problem?

11 DR. PETREAS: There will be one in each lab, and
12 they will be dedicated to different types of chemicals.
13 So even if they were in the same lab, you can't switch
14 from one to the other easily.

15 PANEL MEMBER LUDERER: Okay.

16 CHAIRPERSON MORENO: Dr. Culver.

17 PANEL MEMBER CULVER: I'm concerned with the
18 one-year warranty.

19 DR. FLESSEL: So are we.

20 PANEL MEMBER CULVER: Is it possible to get a
21 maintenance contract?

22 DR. PETREAS: Yes, but they're very expensive.
23 It's about 10 percent of the value of the --

24 PANEL MEMBER CULVER: But should that be budgeted
25 in?

1 DR. FLESSEL: Well, that's right.

2 PANEL MEMBER CULVER: You're staring into
3 catastrophe.

4 DR. FLESSEL: That's right. Thank you very much.

5 That's a very important point. So that's why we
6 put it up there.

7 The way it ought to be done is to have these,
8 what are called, preventive maintenance contracts in place
9 at the end of the warranty period. Because then you get
10 on the phone, you get the guys out there almost
11 instantaneously. Furthermore, you don't have the
12 breakdowns that you're going to inevitably have because
13 you're doing preventive maintenance.

14 So the answer is yes. But, as Myrto said, the
15 costs are large. It's basically, estimate, around 10
16 percent of the capital costs. So we have between the two
17 of us well over a million dollars worth of laboratory
18 equipment, so we're talking a hundred, a hundred fifty
19 thousand dollars for the preventive maintenance contracts,
20 which we can't do at this point. So we're protecting
21 short term.

22 DR. PETREAS: Also, the plan was that --

23 DR. FLESSEL: Per year.

24 DR. PETREAS: But if the Biomonitoring Program is
25 deployed for over several years, in subsequent years,

1 we'll request money for preventive maintenance.

2 CHAIRPERSON MORENO: Yes.

3 PANEL MEMBER McKONE: I'm just wondering.

4 Strategically it would make more sense to do fewer samples
5 and have higher reliability with the equipment. I don't
6 know if that's possible. In other words, instead of doing
7 a thousand samples, do 800 and take the money saved -- I
8 don't know if it works that way. But I would think
9 there's some critical trade-offs here. Because I know --
10 I mean, I have people who run labs. And it's a disaster
11 when the equipment's down, because we just sit there for
12 weeks until we get it fixed, and nothing gets done.

13 So I'm just wondering if, given that, you know,
14 there's some likelihood of the equipment failing anyway
15 and then instead of getting a thousand, you could only get
16 800, why not assume that that's possible and then take
17 that expected loss and use it as kind of an insurance
18 policy.

19 DR. PETREAS: Well, the thousand was a goal we
20 have for when we were going to do the statewide survey.
21 That was a goal, that we should be able to do a thousand
22 samples. So we tried to see how can we get there.

23 PANEL MEMBER McKONE: Right. So that's not
24 tradable in terms of doing fewer samples but having higher
25 equipment reliability?

1 DR. PETREAS: For the time being, we're not
2 having a statewide survey, so we have smaller studies. So
3 we'll see how we go with that.

4 DR. FLESSEL: I would say, yes, Tom, you're
5 right. It's like you have a car. You drive it 20,000
6 miles a year, you're probably going to turn it over and,
7 you know, sell it sooner than if you drive it 5,000 miles
8 a year.

9 On the other hand, driving it's really important.
10 With a lot of the instrumentation that we have, keeping it
11 going is really important. So it is a trade-off.

12 We were making estimates based on instruments up
13 and running, performing well all the time. That's how we
14 got those numbers. We could back off -- probably will
15 have to back off those numbers just because of the reality
16 of running the operation.

17 I don't know that you really want to manage a lab
18 in which you say, "Now, we're not going to do a lot of
19 sample analysis this month because we want to save the
20 instruments." I don't -- I think we want to push them and
21 we want to push the sample prep and we want to do as much
22 throughput as we can and make sure that the samples that
23 we're analyzing are important every step of the way.

24 CHAIRPERSON MORENO: We have questions down this
25 side.

1 Dr. Solomon and Dr. Bradman.

2 PANEL MEMBER SOLOMON: Yeah, thanks for those
3 presentations.

4 About some of the trade-offs among chemical
5 groups, I was just -- just have a few questions about
6 that.

7 One is, with regard to the POPs, is there any
8 possibility of picking sub-categories of POPs, say, if the
9 Committee decided that we didn't care about the PCBs, but
10 we cared about the flame retardants? Would that still
11 make it impossible to also look at perfluorinated
12 chemicals because of the either/or?

13 DR. PETREAS: It's a very different technique.
14 First of all, from beginning -- it's a totally different
15 sample. Now, the POPs, the way we have them, it's a
16 multi-residue analysis. So in the same extract we try
17 to measure the pesticide, the PCBs, the PBDEs and probably
18 others. If we drop the PCBs, it doesn't save us much
19 because it's the same process. The quality assurance
20 would be less -- fewer standards -- internal standards,
21 but we don't save much.

22 Now, the perfluorinated require totally different
23 extraction from the beginning. They're saying it's much
24 easier than the POPs. But we haven't done them, so for us
25 it would be difficult to start, but eventually it should

1 be much simpler. POPs are the Cadillac, they're very
2 difficult, laborious, tedious, expensive. Anything else
3 compared to the POPs is easier.

4 PANEL MEMBER SOLOMON: And in follow-up, there's
5 some categories of chemicals or individual chemicals on
6 the CDC list or that we're considering tomorrow as
7 potential designated chemicals - and I'm not actually sure
8 which of your labs they would fall under - the
9 cyclosiloxanes specifically and also some of the phenols
10 like triclosan. Would those fall sort of more in the
11 persistent, Myrto, in your lab?

12 DR. PETREAS: We are looking at some -- we looked
13 at some siloxanes. We talked with people who have done
14 them. They're easily found in environmental samples. We
15 had some difficulty in blood to see them the first time we
16 tried. Maybe the levels were very low or -- it
17 wasn't easy. But we have the standards and we'll look
18 into those.

19 Again, these are things that DTSC asks us to do,
20 so we're doing them aside from the Biomonitoring Program.
21 But once we have a method, if it's applicable we can use
22 it.

23 PANEL MEMBER SOLOMON: And how about the phenols?
24 Like triclosan is basically a chlorinated diphenol ether.
25 So it might be similar.

1 DR. PETREAS: We're doing chlorophenol and we're
2 doing some other hydroxylated metabolites. So they could
3 be in that fraction, but we haven't looked for triclosan
4 yet.

5 PANEL MEMBER SOLOMON: Okay. And presumably if
6 any of those categories of chemicals were included, that
7 would be instead of either the POPs or the perfluorinated
8 chemicals?

9 DR. PETREAS: In fact, we would start the POPs.
10 But then you have to separate, fractionate. And we use
11 the organic fraction to do what we do. But we should do
12 the other fraction to look at the more soluble -- water
13 soluble ones. So that's again bifurcation and more steps.

14 PANEL MEMBER SOLOMON: Thanks.

15 PANEL MEMBER BRADMAN: I just have a brief
16 comment and then a question. The comment is related to
17 Gina's question.

18 One, for the OPs in urine, is that specific
19 metabolites or nonspecific?

20 DR. FLESSEL: Well, we're thinking about both.
21 It's much easier to do the nonspecific materials because
22 you don't have to worry about getting the standards for
23 all of the specific ones. But we're trying to take it
24 using both approaches.

25 PANEL MEMBER BRADMAN: Okay. And then this next

1 question is kind of a -- almost a procedural question, and
2 maybe perhaps more applicable for tomorrow. But, you
3 know, we are tasked for putting together a list of
4 designated chemicals and then priority chemicals. But
5 should we be constrained by what the laboratory says they
6 can do? I mean, it looks like really you're in a start-up
7 phase. The list at CDC, the number of analyses is bigger
8 than what we have right here. And then we may be adding
9 on some other kinds of chemicals that are specific to
10 California. And it seems to me there could be some
11 tension between what we consider, you know, a priority
12 chemical -- a designated chemical or priority chemical and
13 what the lab resources are.

14 So I'm not sure how we are supposed to think
15 about that if there are laboratory constraints, at least
16 in the present. I mean, maybe in the future those will be
17 solved.

18 DR. FLESSEL: This is -- what are laboratory
19 constraints? The Program wants your guidance. We're
20 not -- Myrto has a situation where she's doing things for
21 her DTSC bosses, and so she's marching on those
22 independent of what the Biomonitoring Program suggests.
23 But certainly for us, we want to hear -- the Program wants
24 to hear from the Panel about those chemical panels that
25 you think are most important. And because we haven't gone

1 that far. OPs, yes, we've spent some time in. we're
2 happy that we have it. The metals we've had basically in
3 hand. But beyond that, we're really in the preliminary
4 stages. And if you don't want phthalates and PBA -- if
5 you don't want PAH and you really want something else,
6 then you need to tell the Program that.

7 CHAIRPERSON MORENO: If I could just make a
8 comment in response to your questions. Ed Moreno.

9 My understanding is that the first charge of this
10 Panel is to make recommendations for the designated list.
11 And my understanding is that that's what we do regardless
12 of the resources. We feel that -- this Panel feels that
13 it's important that Californians be tested for the
14 following list of chemicals and that's the recommendation.

15 But the second charge, it does -- I believe
16 prioritizing does take into account several factors,
17 including fundamentally. And what we're talking about
18 here is resources. So among the designated list, here and
19 now what can we start with as priorities? But that
20 designated list will serve as the designated list for
21 years to come as we move -- as resources become more
22 available, then we'd go back and look at the situation on
23 a yearly basis and we can start adding to the priority
24 list. That's my understanding.

25 PANEL MEMBER WILSON: I have a question.

1 CHAIRPERSON MORENO: Yes.

2 PANEL MEMBER WILSON: I guess also I have a --
3 first, a procedural question, which again is -- I
4 understand that you have then methods developed and all
5 the quality control laboratories, not methods, set up for
6 these substances. And I guess the question is -- you
7 know, we've been having these discussions about priority
8 substances and that might be unique to California.

9 At what point, looking at this calendar, do you
10 need to know from this Panel what those -- what we
11 consider to be the priority chemicals and how long in some
12 range does it take to develop the methods and QC for
13 those?

14 DR. PETREAS: It depends on how close the
15 chemicals we do now, are to the new chemicals, where they can be
16 added to the method, or is to be completely different
17 technology.

18 PANEL MEMBER WILSON: Yes. So I guess in the
19 latter case, if we're in, you know, sort of a -- as you
20 describe it, something that's fairly different. What is
21 the timeframe that it has?

22 DR. FLESSEL: Well, that can be a year. That's
23 not unusual.

24 PANEL MEMBER WILSON: Right.

25 DR. FLESSEL: Especially when you're going at it

1 for the first time.

2 PANEL MEMBER WILSON: Right.

3 DR. FLESSEL: But, Michael, I hope you haven't
4 misunderstood us. We don't have these SOPs ready to go.
5 The timeframes that we proposed were for getting to the
6 point where we could say to you, "Yes, bring me your
7 sample. We can start today to do these tests." The
8 nearest term for us is to run metals starting soon after
9 the first of the year. OPs maybe in late spring. And
10 then October we're talking about some of those other
11 organic panels. So if you -- yes, it's important that we
12 have a good idea and that the Panel and the Program come
13 to some consensus on that other issue. So we're talking
14 about potentially designating chemicals tomorrow. But
15 then, at some point pretty soon, we need to cut to the
16 chase and say, "Oh, but these are the ones we, as a team,
17 think we ought to actually be analyzing for with the
18 limited resources that we have.

19 PANEL MEMBER WILSON: Right.

20 DR. FLESSEL: Two stories though.

21 CHAIRPERSON MORENO: Okay. I'd like to hand over
22 to Dr. Denton.

23 OEHHA DIRECTOR DENTON: Both of you talked in
24 terms of a thousand samples, 500 samples. How does that
25 translate as far as individuals? If you have a thousand

1 samples, are those including -- are those duplicates and
2 so you're actually doing 500 individuals? What's the
3 breakdown of samples versus individuals?

4 DR. FLESSEL: Right. I think that -- we talked a
5 little bit about this earlier. But think about our
6 participants. So, Joan, you're a participant. We're
7 going to get from you several blood specimens for several
8 analyses, and we're going to get a urine sample. So maybe
9 five sample analyses per participant is maybe a
10 multiplier.

11 And, no, we're not thinking about the duplicate
12 issue at all. We're just talking about -- if you're
13 thinking about numbers of samples, you should think --
14 remember that each participant will deliver more than one
15 sample.

16 DR. PETREAS: For each panel of sample of
17 analysis, one participant will give one sample. So if we
18 do Bisphenol A in urine, it will be one sample from every
19 participant. The same participant may give blood for POPs
20 or siloxanes or something different.

21 DR. FLESSEL: We're not getting your point. Say
22 again. We'll listen carefully.

23 OEHHA DIRECTOR DENTON: I think we're still
24 confused.

25 Okay. So back on your slide, you have so many of

1 an analysis of POPs, have something for so many -- let's
2 see, maybe I could...

3 Okay. So for OP pesticides, a thousand samples
4 per year, what does that mean in terms of how many
5 individuals will you be able to test for OP pesticides?

6 DR. FLESSEL: A thousand.

7 OEHHA DIRECTOR DENTON: One thousand.

8 DR. FLESSEL: Sure, a thousand urine specimens --

9 OEHHA DIRECTOR DENTON: So 1,000 --

10 DR. FLESSEL: You could be sampling -- you could,
11 say, for instance, measure variations in a single
12 individual over a course of time. So you might be looking
13 at a hundred people with 10 samples per person over time.
14 But a thousand samples means a thousand urine specimens
15 analyzed for OP pesticides.

16 OEHHA DIRECTOR DENTON: So a thousand different
17 individuals or a thousand times the same person?

18 DR. FLESSEL: If you like, yeah.

19 DR. PETREAS: A thousand vials.

20 DR. FLESSEL: A thousand samples to run.

21 CHAIRPERSON MORENO: I have a question. I just
22 want to make sure I got the numbers correct. I'm trying
23 to keep tally of the number of samples that each lab can
24 do and what was offered. It looks like the Department of
25 Public Health lab can do a thousand samples, which could

1 mean a thousand individuals, right?

2 And then Department of Toxic Substances Control
3 can do 800 to a thousand?

4 DR. PETREAS: Estimates.

5 CHAIRPERSON MORENO: I'm sorry?

6 DR. PETREAS: Estimates.

7 CHAIRPERSON MORENO: Estimates.

8 Now, was there also an offer that we heard that
9 the CDC had offered to do a number of samples?

10 DR. FLESSEL: That's in addition to everything
11 that we've talked about.

12 CHAIRPERSON MORENO: Was that 500?

13 DR. FLESSEL: It's 500 for all ten panels. And
14 then it's 200 for a single chemical.

15 DR. LIPSETT: Right. That's a one-time
16 commitment on their part, not an ongoing.

17 This would be an ongoing capability.

18 CHAIRPERSON MORENO: Okay. Thank you.

19 Other questions?

20 Yes.

21 PANEL MEMBER KAVANAUGH-LYNCH: I'm trying to
22 match what you're saying now with the lab capabilities and
23 developing them over time and then what we heard about
24 earlier with looking at the RFI responses. And is -- what
25 I don't see on the criteria for RFI responses is looking

1 at either -- I see analytes requested fit with lab
2 capabilities, but not analytes fit with things that we may
3 have chosen that we want you to develop capabilities in.
4 Is that one of the things that may be -- those may be one
5 of the criteria? That make sense?

6 DR. FLESSEL: Well, I would just say, I was
7 delighted that there was such a good match between the RFI
8 candidate chemicals and the ones that we had been thinking
9 about - that was fortuitous - except for the pyrethroids.

10 DR. PETREAS: Well, we had listed in the RFI
11 which chemicals we can do. So the responders, I guess,
12 had to match.

13 DR. FLESSEL: That's why it worked so well.

14 (Laughter.)

15 PANEL MEMBER KAVANAUGH-LYNCH: But my question --
16 yeah. My question is, if we develop a list tomorrow, what
17 is -- will there be any relationship between the list we
18 develop tomorrow and what you're capable of and what we
19 might choose from the RFI?

20 DR. PETREAS: Timing issue.

21 DR. FLESSEL: Yeah, there are three levels of
22 discussion there. There are a lot of discussions
23 involving program and the panel and the laboratory
24 capability that would drive that. So I don't think you
25 can cut through it all that quickly.

1 DR. LIPSETT: Well, see, we hope that there is a
2 good correlation, if we drew a Venn Diagram, that there
3 would be substantial overlap.

4 CHAIRPERSON MORENO: At this time, I'd actually
5 like to open up for public comment. And I think we still
6 have a little bit of time for more Panel discussion after
7 public comment. But I want the public to be able to share
8 their opinion on what's been discussed on the second
9 section of this afternoon's agenda.

10 I still have Mr. Baltz's request to speak. But
11 are there additional requests? And before we move back to
12 the Panel, are there any Emails received on this topic?

13 MS. LEE: We received a comment from Diana
14 Graham, who indicated her appreciation for the webcasting
15 of this meeting.

16 CHAIRPERSON MORENO: All right. Thank you. We
17 appreciate you tuning in.

18 Okay. Mr. Baltz.

19 MR. BALTZ: Davis Baltz with Commonweal again.

20 Thanks for the presentations.

21 I'd just like to second what I heard from the
22 Panel that it's the obligation or one of the duties of the
23 Panel to designate chemicals now that are of concern to
24 California and we would like to see biomonitored, even if
25 the resources don't exist now and maybe some time in the

1 future it's important to sort of recognize that these are
2 chemicals of concern for California and get them in the
3 queue even if the queue is quite long.

4 I don't know if -- and if we come to a point
5 where we have to choose now in the short term between POPs
6 and the perfluorinateds, that will be a tough decision.
7 There does seem to be some market movement towards
8 voluntary retirement of some PFC chemicals. So that might
9 indicate that we should focus on the POPs. But that's
10 going to be a thorny one.

11 And then just the last thing, I also want to
12 thank Peter Flessel for his years of service, and wish you
13 well in your retirement.

14 DR. FLESSEL: Thanks.

15 CHAIRPERSON MORENO: All right. If there are no
16 more comments from the public, I'll bring it back to the
17 Panel for another opportunity to discuss on this topic.

18 Dr. Solomon.

19 PANEL MEMBER SOLOMON: Yes, I actually also want
20 to thank Peter Flessel for everything, for doing so much
21 over so many years, and for his -- as well as for the
22 presentation today.

23 I'm actually trying to sort of wrap together our
24 two discussions of this afternoon, because it seemed like
25 the Panel felt pretty strongly that looking at

1 maternal-child pairs is a good first step. And
2 understanding also that this is an iterative process, so,
3 you know, we'll be designating some chemicals tomorrow
4 presumably or potentially and then looking at maybe
5 additional ones in the future, and similarly sort of
6 thinking about priority chemicals in an iterative way, but
7 trying to get the ball rolling now.

8 And so, you know, in light of the fact that we're
9 looking at kids and maternal, you know -- and fetal
10 exposures, it seems to make some sense to think about as
11 priorities, chemicals that are, you know, developmental
12 neurotoxicants or endocrine disrupters that would be of
13 particular concern in that population.

14 And there are quite a few to choose from,
15 probably too many, you know, when you put together the CDC
16 list and the ones we're looking at tomorrow. But some of
17 them have actually been quite well studied. And my
18 particular bias is that, you know, if a chemical or group
19 of chemicals has been pretty well studied in populations
20 of mothers and children, especially, you know, here in
21 California, that we may not want to repeat that.

22 And so looking at ones that are newer or that
23 haven't been as well studied would be appealing to me.
24 And so, you know, I -- obviously, there are quite a few
25 metals that would be developmental neurotoxicants. But,

1 you know, some of them, such as lead, have been quite well
2 studied.

3 And there are other -- there are pesticides that
4 are potential developmental neurotoxicants. Some have
5 been quite well studied in some populations in California.
6 Some of the endocrine-disrupting chemicals, in contrast,
7 maybe not quite as well studied in Californians yet. So
8 it might be an interesting direction to go. Thyroid
9 disrupters, such as the flame retardants, some of the
10 estrogenic agents, such as the phthalates and PBA, which
11 were mentioned by Dr. Flessel. Maybe some of the
12 phenols -- chlorinated phenols that are also potential
13 thyroid disrupters would be of, you know, possible
14 interest if we're thinking about some priorities.

15 Not to walk away from the metals, because I think
16 there's still things to learn certainly with mercury here
17 in California where I'm guessing we'd find some
18 interesting things.

19 DR. LIPSETT: Could I respond briefly to your
20 comment, Dr. Solomon?

21 To the extent that we would be relying for the
22 initial analysis on the CDC laboratories, whatever would
23 be done would -- in that particular set of analyses would
24 be what's within their universe. But they offer to do ten
25 panels of studies, not ten single chemicals. And so we're

1 talking about substantial numbers of chemicals. We
2 might -- you know, before we actually get to that point,
3 we might want to review what their capabilities are and
4 make some decisions based on that in relation to your
5 discussions of designated chemicals and potential priority
6 chemicals for California.

7 CHAIRPERSON MORENO: Dr. Wilson, did you have a
8 comment?

9 PANEL MEMBER WILSON: You answered it actually,
10 Michael, clarifying what the CDC is going to do. So,
11 yeah.

12 PANEL MEMBER BRADMAN: I have two comments. One,
13 I also wanted to thank Peter. For all the time that I've
14 known you and worked together at different times, it's
15 been a pleasure.

16 And the other thing I just want to comment, just
17 to underscore laboratory issues are incredibly complex.
18 And just kind of a reminder to all of us the challenges
19 that they -- that the labs here face. Just from personal
20 experience and my own time measuring things and working
21 with CDC and others, it seems like everything's a
22 trade-off in terms of volume of material available, how
23 you process it, making sure the QA/QC is good, having
24 problems with one set of analyses but not with another, or
25 having to make trade-offs with cost. Do you want to

1 get -- there's one chemical you really want to get, but it
2 means a whole separate extraction, a whole separate
3 analysis, perhaps using new or different procedures that
4 aren't compatible with other things -- other analytes.

5 So just to underscore, it's really a -- it's a
6 very challenging process to narrow down an analyte list
7 and then actually to run them.

8 So I guess I wanted to make sure that you know we
9 appreciate that.

10 MS. LEE: Hi. I have another comment from
11 Miglena Wilbur from the Department of Pesticide
12 Regulation. And her comment is -- or question rather is:
13 Is there a minimum time of California residence for survey
14 participants?

15 DR. LIPSETT: That isn't a topic that we've
16 discussed at this point.

17 CHAIRPERSON MORENO: Okay. Thank you.

18 Dr. Alexeeff:

19 DR. ALEXEEFF: George Alexeeff.

20 I wanted to ask a question to -- well, actually
21 to Dr. Lipsett, Flessel, and Petreas, and commenting on
22 what Dr. Solomon was saying on the time issue.

23 And I know you gave some times in these
24 presentations. And I'm wondering if the timing is -- if
25 you were thinking of the time, is that if we told you

1 today do this particular chemical, it would take you that
2 amount of time to get up to speed? Because as Dr. Solomon
3 pointed out earlier, there's a requirement of prioritizing
4 the chemicals that are designated. So I'm just wondering
5 if we had a meeting in January or February where we
6 discussed prioritizing chemicals and designated -- helped
7 that -- you know, made a decision, perfluorinated or POPs
8 or whatever, would you still have the time to -- would
9 these times still be fairly relevant or would that be
10 pushing you back two months or something like that?

11 DR. PETREAS: Well, luckily or unluckily, our
12 instrument is not here yet. So generally that won't make
13 much difference. But soon after that, we need to know.
14 And, again, some things would be easy to do. And the only
15 estimate we made is for the POPs because we have a good
16 handle on them, and the fluorinated because we heard it's
17 simple. If you give us a third option, we have to start
18 calculating from the beginning and things may be not so
19 good.

20 DR. FLESSEL: I would say from my perspective,
21 those estimates are really soft. I mean there are a lot
22 of things that can stretch them out. So if you told us in
23 January or February you wanted to, say, to work on that
24 PAH panel, we could probably bring it in by the end of the
25 year. But still. I mean, nine months is the same as 12

1 months shooting from here.

2 DR. ALEXEEFF: And I was wondering also with
3 regard to the CDC analysis, if there was a timing issue on
4 that?

5 DR. LIPSETT: Not from the standpoint of methods
6 development. Because whatever they have listed on their
7 panels of analytes, they already have methods for, they're
8 already doing these kinds of analyses for the NHANES
9 group.

10 PANEL MEMBER BRADMAN: I will underscore though,
11 with CDC there's always a time factor in terms of getting
12 your results back.

13 DR. LIPSETT: Yeah. That's a different question
14 though.

15 (Laughter.)

16 CHAIRPERSON MORENO: Any other questions from
17 Panel -- I'm sorry.

18 Go ahead, Joan.

19 OEHHA DIRECTOR DENTON: Michael, I have a
20 go-back. I remembered our last Panel meeting that the
21 individual from CDC said that 2,000 statewide samples were
22 plenty for doing a statewide survey.

23 If we were to look at the amount of samples that
24 can be done including the CDC, it seems like we have
25 anywhere from -- we could have anywhere from 1,200 to

1 1,500 individuals that could be represented in what we
2 have available now.

3 Why is that not then adequate to do a statewide
4 survey?

5 DR. LIPSETT: Well, it would depend on what you
6 would want to get out of a statewide survey. If you
7 wanted to do the kind of random sample, a
8 probability-based survey that we talked about before, that
9 aspect of it is very expensive and time consuming and we
10 don't have the resources to do that at this point. And I
11 don't -- I don't think that we would be as likely to get
12 foundation funding to be able to do something like that,
13 at least based on my looking at a variety of different
14 foundation websites and the kinds of things that they seem
15 to be interested in, which is more community-based,
16 community-focused types of studies.

17 But the numbers of staff that will be needed to
18 do that that we would have to hire under contract would be
19 much, much, much greater than what we would have to do
20 with one of these -- a community-type of study.

21 And, in addition, in terms of trying to get a
22 representative sample then of, say -- I mean,
23 theoretically we could do something like that given
24 adequate resources. But the numbers of staff that would
25 be required are just not something that -- that we think

1 would be feasible to do at this point.

2 OEHHA DIRECTOR DENTON: So it's not the
3 analytical laboratory capability that is the issue for the
4 statewide sampling at this point in time; it's more the
5 contract staff or the State staff that would be needed to
6 design a survey, conduct the survey, get the samples. Is
7 that the portion that makes statewide sampling at this
8 point in time not feasible?

9 DR. LIPSETT: Well, it's partly that. It's
10 also -- it's the time dimension that's involved.

11 The Canadian Government last year and this year
12 is doing a national biomonitoring survey similar to what
13 NHANES does. They began planning for that, I think it
14 was, around 2001 and they went out into the field six
15 years later. This is what we had been planning to do with
16 the statewide survey as well, but it would take a number
17 of years to roll out. And if we were really interested in
18 doing -- undertaking some activities that would generate
19 some results earlier, I think that undertaking these
20 community studies would be a better way to go at this
21 point, and more realistic just in terms of the likelihood
22 of getting external funding for them as well.

23 DR. FLESSEL: Joan, I wanted to add a footnote to
24 what Michael just said. The point that I wanted to make
25 is that these numbers, we're assuming that we really

1 didn't do any of that sample management stuff that really
2 is labor intensive. This is just if we put our ears back
3 and do samples. You bring me the samples, you put them
4 down, I log them in, I analyze them, and I send you the
5 results on an Excel spreadsheet.

6 So when I showed these slides with a wise
7 colleague, he said, "You know what they're going to think?
8 As soon as you put that up there, they'll think, 'well,
9 look, we can do the statewide study with these kinds of
10 numbers,'" right?

11 So

12 OEHHA DIRECTOR DENTON: They do go back and --

13 DR. FLESSEL: Right. It's not quite that true.
14 We wanted to -- you're right though. You're on to the
15 point that the analytic capacity is there, but there's a
16 lot you have to build around it to make it work.

17 PANEL MEMBER WILSON: I know we've been having
18 these discussions about potential designated chemicals and
19 you've been participating in that. It's been really
20 valuable. And I guess, first, a question. And, that is,
21 if -- do you feel that your understanding of the sort of
22 the state of the art of analytical methods for
23 biomonitoring samples is such that at tomorrow's
24 discussion over these designated chemicals that you might
25 be able to give us a sense of, you know, specifically what

1 the laboratory challenge is going to be and the potential
2 timeframe in developing the methods to assess each -- you
3 know, assess these? That's the first.

4 And then the second is, thank you, Peter, for
5 everything, for helping get this off the ground and moving
6 it forward. You know, we all so appreciate what you've
7 done.

8 DR. FLESSEL: Thank you, Michael.

9 I would just say that, as you know, since you've
10 been part of the many -- the work group that's been
11 thinking about the potentially designated chemicals,
12 there's been a lab component to that discussion. And so
13 we've been thinking about the feasibility of doing the
14 analysis. We haven't been thinking about it that
15 critically. So to be able to tell you tomorrow, well, is
16 that going to be 12 months or is that a year and a half or
17 is that 8 months, I don't think so. But we can certainly
18 sort of in broad outline say, yeah, that's feasible or
19 that's not feasible. The timeframe is a little harder to
20 put a finger on.

21 PANEL MEMBER WILSON: Okay. Thank you.

22 CHAIRPERSON MORENO: More questions?

23 PANEL MEMBER SOLOMON: Well, I'm going to go out
24 on a limb here a little bit with regard to the CDC
25 chemicals. Because I was just -- you know, after our

1 discussion about their willingness to look at ten
2 categories and I looked through what they can do, and they
3 can do about 20 categories, and so presumably we have to
4 pick, you know, half of these as ones that we might want
5 to consider, not necessarily even as priority chemicals,
6 but ones that we would want to consider for this sort of
7 community study that we would do.

8 And it seems like there could be -- you know, I
9 don't know what other community members -- I mean, what
10 other Panel members might think, but, you know, it seems
11 worth looking at the metals, in part because of interest
12 in mercury and fish consumption in California and how that
13 might be relevant.

14 And I think the phthalates are of broad interest,
15 especially in a population of infants and fetuses.

16 The specific OP metabolites would also be of
17 interest in this group.

18 And I think the pyrethroids as well just because
19 of how wide spread they're becoming for household use.

20 And the environmental phenols, include Bisphenol
21 A and also triclosans, have some important consumer
22 product-related exposures.

23 PBDEs obviously are very interesting in
24 California because we're curious whether they're
25 declining. And we hope to see that.

1 And even if we can't ourselves do the
2 perfluorinated chemicals, I think it would be great to ask
3 CDC to do it.

4 And perchlorate obviously is of enormous interest
5 in California. Though if we're -- you know, depending on
6 exactly where the population lives, that might or might
7 not show much, though there's clearly dietary exposures.

8 And then there would -- that would be eight
9 categories and we'd still have room for a couple more.
10 And the couple more could include various things. I
11 think -- actually I think cotinine would be extremely
12 interesting, because I'm guessing that the levels would be
13 pretty low, and I think that's an important thing to, you
14 know, document from a public health perspective.

15 And other possibilities would be another category
16 of pesticides or potentially the VOCs. But, you know,
17 it's just my 2 cents and where I might go if I were sort
18 of checking my way down the CDC list and putting together
19 a proposal for funding on this.

20 DR. LIPSETT: Yeah, I think that the Panel will
21 have an opportunity in the future to weigh in on this. I
22 mean, if you want to discuss this now, that's fine. But I
23 think we need to get further along in terms of having a
24 study design, talking with CDC, talking and trying to get
25 something set up. And that's not going to happen in the

1 next month or two. You'll have another opportunity to
2 talk about this at greater length if you like.

3 CHAIRPERSON MORENO: This is Ed Moreno.

4 I think what I'm hearing from Dr. Solomon, and
5 others probably are feeling the same way, is that we're
6 getting enough information now. We need more information,
7 but we're getting enough information now that some of us
8 are thinking already about prioritizing.

9 We do need to get through the designation portion
10 first, I believe. And that's what's on the agenda for
11 tomorrow. But I was -- what I'm thinking is that perhaps
12 tomorrow, that's towards the end of the meeting, perhaps
13 we can have -- Panel and the Program staff can begin to
14 have some discussion about planning for the agenda for the
15 next meeting, to make sure that that agenda will meet the
16 needs of the Panel members and meet the needs of the
17 laboratories to try to -- begin to focus their direction
18 and their efforts and get us as soon as possible to where
19 we need to be to begin the Program.

20 So those are my thoughts. And I think that
21 would -- would that be reasonable to include in tomorrow's
22 discussion?

23 DR. ZEISE: Dr. Moreno, in the afternoon, there
24 is "the next steps" piece on chemical selection, and I
25 think it would fit nicely into that place on the agenda.

1 We had been planning to have that discussion.

2 And I guess the other thing is we haven't -- I
3 think the statute is flexible enough, as others have
4 mentioned, that the designated chemical pool can change
5 over time and the priority chemical pool can change over
6 time. And I think from what I've heard from some of the
7 comments around the CDC 500 study is that really is kind
8 of a feasibility study in thinking ahead about what might
9 be priority chemicals. So maybe not for the first batch
10 but maybe for future batches.

11 CHAIRPERSON MORENO: All right. With that, I'm
12 going -- if there are no more comments from Panel
13 members - okay - I'm going to go ahead and ask that Dr.
14 George Alexeeff give some -- or summarize what was just
15 discussed today and close this meeting, allow us to -- I
16 guess it will be recessed till tomorrow.

17 So, Dr. Alexeeff.

18 DR. ALEXEEFF: Well, today we had essentially
19 three presentations - one from Dr. Lipsett, one from Dr.
20 Flessel, and one from Dr. Petreas.

21 In term of the -- Dr. Lipsett gave an overview of
22 the current status of the Program and the resource needs
23 and the current resource status. And we had sort of
24 focused the discussion on what could be accomplished with
25 the current funding level that we have.

1 In the discussion of laboratory capacity -- oh,
2 actually in -- I think what's important to point out, Dr.
3 Lipsett discussed the issue -- the two types of studies
4 that we were looking at to address with regards to the
5 current capacity of funding. One was this RFI study and
6 the goals as we go into that. And they have put out an
7 RFI. They've received some interest in that. They will
8 be providing -- reviewing it and providing some comments
9 back in January, either at the next meeting or probably
10 through some public medium about what the results of that
11 analysis was.

12 In addition to that, there was discussion of
13 community-based studies. And, in particular, there was a
14 list of possible types of studies that could be conducted
15 from a community standpoint. And there was sort of a
16 sense of the committee given to the staff here that
17 community studies would be very meaningful with regards to
18 if they're reflective of the larger population.

19 And I would think that -- also Dr. McKone sort of
20 just mentioned this as well, but more and more of a
21 statistical kind of point to try to look at the study,
22 study design, so it should be as reflective as possible of
23 the population at large.

24 There was a discussion of whether or not this
25 type of community study should be hypothesis- or

1 descriptive-driven. And descriptive-driven seemed to be
2 the focus. Primarily hypothesis-driven studies are pretty
3 much more focused on research. And this would be more
4 helpful for the types of things we're looking at.

5 In particular, one particular design was this
6 maternal-child sort of component linking, which would be
7 very helpful for our understanding of some chemicals.

8 And with regards to laboratory capacity, we had a
9 lot of discussion about the types of chemicals that could
10 be analyzed and the timelines. And there was, depending
11 upon the laboratory, somewhere between 500 and a thousand
12 samples that could be analyzed per year, but that
13 additional funding would be needed if there was a lot of
14 management required of the sampling.

15 And I would say that's it for now.

16 CHAIRPERSON MORENO: All right. Well, thank you.

17 Well, with that, I also want -- before we recess,
18 I think we're -- we're not adjourning today, we're
19 recessing till 9 o'clock tomorrow morning; is that
20 correct?

21 OEHHA CHIEF COUNSEL MONAHAN-CUMMINGS:

22 (Nods head.)

23 CHAIRPERSON MORENO: This is an ongoing meeting.

24 Before we recess, I do want to also thank Dr.
25 Flessel. I haven't had a chance to work with you other

1 than my capacity as the Chair of this distinguished Panel.
2 And your insightfulness and your honesty has allowed this
3 Panel, I believe, to quickly move through the difficulties
4 that you face and in a way that we understand it, and it's
5 very helpful. So thank you very much.

6 And with that, we'll recess till tomorrow here at
7 9 o'clock.

8 Thank you.

9 (Thereupon the California Environmental
10 Contaminant Biomonitoring Program Scientific
11 Guidance Panel meeting recessed at 4:56 p.m.)

12

13

14

15

16

17

18

19

20

21

22

23

24

25

1 CERTIFICATE OF REPORTER

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

5 That I am a disinterested person herein; that the
6 foregoing California Environmental Contamination
7 Biomonitoring Program Scientific Guidance Panel meeting
8 was reported in shorthand by me, James F. Peters, a
9 Certified Shorthand Reporter of the State of California,
10 and thereafter transcribed into typewriting.

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

14 IN WITNESS WHEREOF, I have hereunto set my hand
15 this 15th day of December 2008.

16

17

18

19

20

21

JAMES F. PETERS, CSR, RPR

22

Certified Shorthand Reporter

23

License No. 10063

24

25