

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

THE CALIFORNIA ENDOWMENT
OAKLAND CONFERENCE CENTER
7TH FLOOR, LAUREL ROOM
1111 BROADWAY STREET
OAKLAND, CALIFORNIA

FRIDAY, MARCH 13, 2015

10:04 A.M.

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

PANEL MEMBERS:

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

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

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

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

Thomas McKone, Ph.D.

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

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

Dr. George Alexeeff, Director

Mr. Alan Hirsch, Chief Deputy Director

Dr. Lauren Zeise, Deputy Director

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

Mr. Mario Fernandez, Staff Counsel

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

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

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

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

DEPARTMENT OF PUBLIC HEALTH:

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

Ms. Lauren Joe, Epidemiologist, Environmental Health Investigations Branch

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

Dr. Paula Johnson, Safe Cosmetics Program

Dr. Nerissa Wu, Chief, Chemical Exposure Investigations Unit

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

DEPARTMENT OF TOXIC SUBSTANCES CONTROL:

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

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

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

GUEST SPEAKERS:

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

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

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

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

ALSO PRESENT:

Dr. Simona Balan, Green Science Policy Institute

Ms. Nancy Buermeyer, Breast Cancer Fund

Ms. Lindsey Dillon, University of California, Davis

Mr. Alexander Hoepker, University of California, Berkeley

Mr. Tom Jacob, Chemical Industry Council of California

Ms. Olga Kalantzi, University of California, Berkeley

Ms. Susan Kreutzer

Dr. Veena Singla, Natural Resources Defense Counsel

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P R O C E E D I N G S

1
2 CHIEF DEPUTY DIRECTOR HIRSCH: Okay. Good
3 morning. My name is Allan Hirsch. I am Chief Deputy
4 Director for the Office of Environmental Health Hazard
5 Assessment. I'd like to welcome all of you to the
6 Scientific Guidance Panel meeting this morning. And I'd
7 like to welcome the Panel as well and thank all of you for
8 your interest in this Program and for coming out here.

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

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

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

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

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

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

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

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

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

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

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

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

25 PANEL MEMBER BARTELL: Thank you.

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

3 PANEL MEMBER BARTELL: Okay.

4 So shall I stand?

5 CHIEF DEPUTY DIRECTOR HIRSCH: Yes.

6 MS. HOOVER: You need the mic.

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

9 Maybe there's a little more room over here.

10 PANEL MEMBER BARTELL: Okay.

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

14 "I...", state your name.

15 PANEL MEMBER BARTELL: I, Scott Bartell, --

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

18 PANEL MEMBER BARTELL: -- do solemnly swear --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 will well and faithfully discharge..." --

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

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

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

8 CHIEF DEPUTY DIRECTOR HIRSCH: Okay.
9 Congratulations.

10 PANEL MEMBER BARTELL: Thank you
11 (Applause.)

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

23 (Laughter.)

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

1 CHAIRPERSON LUDERER: Can everyone hear me?

2 No. Okay. It's supposedly on.

3 All right. Hopefully, everyone can hear me now.

4 I'd like to welcome everyone to the Biomonitoring
5 California Scientific Guidance Panel meeting, the staff of
6 the Program, members of the public both who are here in
7 person and listening via the webinar, and, of course, also
8 the Panel members.

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

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

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

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

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

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

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

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

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

19 We are going to take two breaks today, one for
20 lunch around 12:30 and another one in the afternoon about
21 2:45 p.m.

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

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

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

14 So, Dr. DiBartolomeis.

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

19 (Laughter.)

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

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

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

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

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

7 (Laughter.)

8 DR. PLUMMER: Of course.

9 There we go.

10 DR. DiBARTOLOMEIS: That might work.

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

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

19 --o0o--

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

1 of this is General Fund.

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

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

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

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

25 We are going -- we have a scheduled briefing with

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

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

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

18 --o0o--

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

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

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

17 --o0o--

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

23 (Laughter.)

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

1 DR. DiBARTOLOMEIS: Well, so at the last November
2 meeting, I did talk a little bit about our priority
3 setting process, which we worked on for quite a bit of
4 2014, culminating in a big priority setting off-site in
5 October, I believe it was. And I already showed you these
6 Program vision points that we wanted to make, but I
7 thought it's always good to show them again. Don't
8 necessarily have to walk through them again, but I want to
9 remind people that that's -- the vision is kind of where
10 we are in terms of directing and thinking about where the
11 priorities would be in terms of achieving our vision, and
12 which is essentially a mission.

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

18 --o0o--

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

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

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

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

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

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

15 Okay. Thank you.

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

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

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

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

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

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

5 --o0o--

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

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

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

1 that came out of our deliberations.

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

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

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

18 --o0o--

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

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

24 (Laughter.)

25 DR. DiBARTOLOMEIS: Thank you.

1 (Applause.)

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

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

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

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

11 Dr. McKone.

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

14 CHAIRPERSON LUDERER: Okay.

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

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

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

24 (Laughter.)

25 DR. DiBARTOLOMEIS: No go ahead.

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

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

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

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

16 PANEL MEMBER MCKONE: Thank you.

17 CHAIRPERSON LUDERER: Dr. She.

18 (Thereupon an overhead presentation was
19 presented as follows.)

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

23 --o0o--

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

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

4 --o0o--

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

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

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

18 --o0o--

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

25 So the first column will show you the chemical,

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

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

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

17 --o0o--

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

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

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

5 --o0o--

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

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

21 --o0o--

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

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

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

13 --o0o--

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

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

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

1 Kaiser. And the PI is Dr. Assiamira Ferrara. And so far,
2 we already received 138 samples, and we reported data for
3 60 samples.

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

11 --o0o--

12 DR. SHE: This is a study actually I don't know.
13 But Dr -- and Dr. D. and Dr. Wu already mentioned. And I
14 think I do not need to -- I do not need to tell more about
15 this study. This is the MAMAS study. We already reported
16 100 samples from the 200 expected samples, we expect to
17 receive. So we finish half of them.

18 --o0o--

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

1 presented as follows.)

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

4 --o0o--

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

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

13 --o0o--

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

20 --o0o--

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

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

3 --o0o--

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

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

21 --o0o--

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

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

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

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

18 --o0o--

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

1 --o0o--

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

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

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

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

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

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

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

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

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

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

23 (Applause.)

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

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

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

8 Dr. Bartell.

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

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

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

9 PANEL MEMBER BARTELL: Thank you.

10 CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

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

13 (Laughter.)

14 CHAIRPERSON LUDERER: Yeah, go ahead.

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

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

1 in non-breast cancer patient women.

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

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

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

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

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

8 MS. HOOVER: Last November.

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

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

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

1 CHAIRPERSON LUDERER: Dr. Bradman.

2 PANEL MEMBER BRADMAN: Is this working?

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

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

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

1 about this bill? And I hadn't.

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

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

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

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

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

5 PANEL MEMBER BRADMAN: Then I have one other
6 comment and it's a little more technical and detail
7 oriented, just that I've actually -- we're sending 20
8 samples up to Chris Simpson's lab to test for
9 1-nitropyrene. These are from urine samples collected
10 from kids in East Oakland and Salinas. And I'll keep you
11 posted on that, but maybe there would be an opportunity to
12 somehow, if something goes forward, to collaborate on
13 that. And there might be a way to try to look at diesel
14 and those exposures.

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

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

22 PANEL MEMBER BRADMAN: Thanks.

23 CHAIRPERSON LUDERER: Dr. McKone.

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

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

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

10 CHIEF DEPUTY DIRECTOR HIRSCH: (Nods head.)

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

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

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

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

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

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

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

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

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

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

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

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

25 CHAIRPERSON LUDERER: Before we take more Panel

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

3 Great. Thank you.

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

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

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

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

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

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

18 And they're seeing that in the population about
19 30 percent would have this gene mutation. And the
20 patients they're seeing it's 95 percent. So whether or
21 not there could be something that we are chemically
22 sensitive to this, and then it is triggering particular
23 infectious agents in us.

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

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

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

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

22 Thank you.

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

1 definitely take your comments into consideration.

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

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

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

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

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

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

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

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

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

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

25 CHAIRPERSON LUDERER: Thank you very much for the

1 comment.

2 Dr. Petreas.

3 DR. PETREAS: Thank you. Myrto Petreas.

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

17 CHAIRPERSON LUDERER: Sara.

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

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

1 take that into account.

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

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

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

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

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

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

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

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

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

8 DR. PETREAS: Myrto Petreas.

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

13 CHAIRPERSON LUDERER: Dr. She.

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

25 Thank you

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

7 Any other comments from other Panel members?

8 Yes, Dr. Quintana.

9 PANEL MEMBER QUINTANA: Hi. Is this on?

10 My comments are for Dr. DiBartolomeis.

11 Hi. Jenny Quintana. Is this on now?

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

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

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

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

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

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

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

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

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

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

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

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

25 Lovisa Romanoff is a health scientist and project

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

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

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

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

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

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

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

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

15 Thank you.

16 (Thereupon an overhead presentation was
17 presented as follows.)

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

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

1 Program.

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

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

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

21 --o0o--

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

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

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

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

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

1 She disappeared.

2 Thank you.

3 --o0o--

4 DR. MORTENSEN: Thank you, Lovisa.

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

16 --o0o--

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

1 deficiencies.

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

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

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

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

7 --o0o--

8 DR. MORTENSEN: The exposure -- the exposure
9 report reflects the NHANES measurements that our
10 Environmental Health Laboratory measures in the samples
11 that come from NHANES. We do have a formal process for
12 adding new chemical measurements or groups of chemicals.
13 And there is a link on this website that will take you to
14 a Federal Register Notice. It was formally offered in
15 2002 -- or formalized in 2002. But basically the criteria
16 for consideration of a new chemical or chemical group are
17 these listed here. But bear in mind, we are looking at
18 the U.S. population in general. So we really focus on
19 wide -- chemicals or analytes that we think may be present
20 in the U.S. population widespread exposures.

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

1 investment of financial resources.

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

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

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

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

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

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

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

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

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

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

6 --o0o--

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

15 We have sort of an administrative change, but for
16 any of you who use NHANES data, you're used to finding
17 environmental phenols and parabens in one group and then
18 having to go to another group to find 2,4 and
19 2,5-dichlorophenol.

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

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

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

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

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

1 chemical DINCH, as it is known. We were measuring -- we
2 just started measuring in 2011-12, I believe, MHNCH. And
3 now we will be measuring a carboxy-MHNCH, which we think
4 might even be a better measure of exposure. So these two
5 metabolites will be available at -- we are sure in
6 2015-16. We're hoping we'll get approval to actually
7 measure and report those in 2013-14.

8 The additional dibutyl phthalate metabolites
9 shown here will also be measured hopefully in 2013-14, but
10 we are waiting for approval to measure and report those in
11 '13-'14, but we do have approval for '15-'16.

12 --o0o--

13 DR. MORTENSEN: Continuing. There are some
14 specific -- I still call them PFCs, so pardon my
15 non-chemistry language, but we are measuring some of the
16 specific isomers of PFOS and PFOA starting potentially in
17 2013-14, but certainly in '15-'16. We will continue to
18 report PFOS and PFOA, which are really summary types of
19 measures of these specific isomers. So we'll be reporting
20 all of these in the exposure report starting then, and
21 NHANES will have them of course on-line.

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

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

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

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

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

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

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

10 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

7 --o0o--

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

17 (Applause.)

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

21 Dr. Quintana.

22 PANEL MEMBER QUINTANA: Hi. Is this on?

23 Yeah?

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

1 (Laughter.)

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

4 DR. MORTENSEN: Cool.

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

8 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 DR. MORTENSEN: Oh, it is in there.

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

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

20 PANEL MEMBER MCKONE: And I'm looking through all
21 the data right now.

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

24 (Laughter.)

25 PANEL MEMBER MCKONE: I might fall asleep.

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

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

18 PANEL MEMBER MCKONE: And they ship the samples
19 out the same day.

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

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

1 sort out and -- yeah.

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

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

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

25 I guess I'm not necessarily sure I would always

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

17 DR. DiBARTOLOMEIS: This could be a long
18 conversation.

19 (Laughter.)

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

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

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

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

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

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

4 (Laughter.)

5 CHAIRPERSON LUDERER: Dr. Lipsett.

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

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

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

24 CHAIRPERSON LUDERER: Thank you, Dr. Lipsett.

25 And I know the Panel discussed a lot at the beginning too.

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

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

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

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

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

4 There were probably -- I think we had about
5 300 -- no, we did not have that many. We had 150 -- 100
6 to 150 children. And virtually all of them did
7 contribute, and we were really thrilled. And I'm sure
8 that a lot of this has to do with the enthusiasm of the
9 staff in the MECs, and the assistance from the parents,
10 because the folks who participate, you know, they're
11 really unsung heroes in many ways. And so we were really
12 excited that we got great samples.

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

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

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

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

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

22 PANEL MEMBER BRADMAN: I have one more question.

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

25 Okay. Our first public comment will be from

1 Alexander Hoepker, UC Berkeley.

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

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

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

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

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

4 MR. HOEPKER: In addition to measuring --

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

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

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

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

20 CHAIRPERSON LUDERER: Thank you.

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

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

1 California to do that great presentation.

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

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

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

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

22 (Laughter.)

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

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

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

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

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

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

25 Thank you.

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

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

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

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

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

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

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

14 Thank you very much.

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

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

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

25 (Laughter.)

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

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

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

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

25 And I think three cycles seemed like it could be

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

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

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

20 CHAIRPERSON LUDERER: Dr. Quintana.

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

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

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

11 CHAIRPERSON LUDERER: Dr. Mortensen.

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

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

1 Vanguard Center.

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

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

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

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

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

8 CHAIRPERSON LUDERER: In that range.

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

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

15 CHAIRPERSON LUDERER: Environmental samples as
16 well.

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

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

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

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

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

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

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

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

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

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

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

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

24 Thank you, Sara.

25 CHAIRPERSON LUDERER: This is Ulrike Luderer. I

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

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

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

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

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

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

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

13 (Laughter.)

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

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

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

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

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

5 STAFF COUNSEL FERNANDEZ: That's right.

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

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

14 1:30. All right. Thank you.

15 (Off record: 12:28 PM)

16 (Thereupon a lunch break was taken.)

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

2 (On record: 1:30 PM)

3 CHAIRPERSON LUDERER: All right. If everybody
4 could please take their seats so we could get started.5 Okay. I'd like to welcome everyone back from
6 lunch. Hope you're all well fed. And I wanted to
7 introduce our next speaker. It's a real pleasure to
8 introduce Dr. Kim Harley, who's going to be speaking about
9 results from the HERMOSA Study. And Dr. Harley is an
10 Adjunct Associate Professor in the Maternal and Child
11 Health Program, and an Associate Director of the Center
12 for Environmental Research and Children's Health, CERCH,
13 at UC Berkeley.14 She's an epidemiologist whose research examines
15 the impact of common hormone disrupting chemicals
16 including pesticides on our food, flame retardants in our
17 furniture and chemicals found in plastics on reproductive
18 health and development.19 And her research interests focus on the role of
20 these common exposures on fertility, timing of puberty,
21 obesity, and pregnancy health. Dr. Harley is currently
22 the Director of the HERMOSA Project, which is working with
23 Latina adolescents to determine their exposure to
24 hormone-disrupting chemicals in cosmetics and personal
25 care products.

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

4 Dr. Harley, welcome.

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

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

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

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

24 DR. SHE: (Nods head.)

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

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

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

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

20 --o0o--

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

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

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

16 --o0o--

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

25 --o0o--

1 DR. HARLEY: So what we did here is we enrolled
2 100 girls, 100 teenage girls. And they came in for a
3 pre-intervention visit, in which we gave them a detailed
4 questionnaire about all of the beauty products, cosmetics,
5 personal care products they'd used today and yesterday.
6 We took a urine sample, and then we told them a little bit
7 about endocrine disruptors that were found in makeup and
8 personal care products.

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

15 --o0o--

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

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

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

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

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

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

10 (Laughter.)

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

19 --o0o--

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

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

5 --o0o--

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

12 --o0o--

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

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

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

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

11 --o0o--

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

23 --o0o--

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

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

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

19 --o0o--

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

25 --o0o--

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

6 --o0o--

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

17 --o0o--

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

22 --o0o--

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

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

4 --o0o--

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

13 (Laughter.)

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

16 (Laughter.)

17 --o0o--

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

20 --o0o--

21 DR. HARLEY: First of all, if you look at who our
22 100 girls were, our participants in the study. They were
23 all teens. They were all either Mexican or
24 Mexican-American. Most of them spoke Spanish at home and
25 spoke English with their friends. And this was a

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

3 --o0o--

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

16 --o0o--

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

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

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

8 --o0o--

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

12 --o0o--

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

23 --o0o--

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

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

8 --o0o--

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

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

25 --o0o--

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

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

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

15 --o0o--

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

20 --o0o--

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

25 --o0o--

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

3 --o0o--

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

8 --o0o--

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

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

24 --o0o--

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

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

9 --o0o--

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

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

1 them.

2 --o0o--

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

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

19 --o0o--

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

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

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

12 --o0o--

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

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

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

5 --o0o--

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

10 --o0o--

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

13 (Applause.)

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

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

20 DR. HARLEY: Yes, thank you.

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

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

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

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

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

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

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

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

25 PANEL MEMBER MCKONE: The other thing in the

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

3 DR. HARLEY: About half and half.

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

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

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

1 stuff.

2 (Laughter.)

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

11 (Laughter.)

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

14 PANEL MEMBER BRADMAN: No.

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

25 DR. HARLEY: They were geometric means, not

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

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

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

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

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

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

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

18 DR. DiBARTOLOMEIS: Question about methodology.

19 Hi. So Michael DiBartolomeis.

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

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

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

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

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

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

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

7 (Laughter.)

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

10 (Laughter.)

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

23 (Laughter.)

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

1 more Panel discussion after that.

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

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

11 Thanks.

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

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

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

11 CHAIRPERSON LUDERER: Thank you.

12 The next comment is from Lindsey Dillon from UC
13 Davis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 CHAIRPERSON LUDERER: Laurel.

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

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

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

16 CHAIRPERSON LUDERER: Sara.

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

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

25 And the second question is if you can say

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

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

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

24 Your second question was what are the next steps?

25 So we are not following up with the 100 girls in

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

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

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

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

1 research with us.

2 CHAIRPERSON LUDERER: Personal care products for
3 the boys?

4 (Laughter.)

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

8 CHAIRPERSON LUDERER: Tom.

9 PANEL MEMBER MCKONE: Are you looking for input
10 on ideas?

11 We're full of that, right?

12 (Laughter.)

13 DR. HARLEY: Sure.

14 PANEL MEMBER MCKONE: Off-line.

15 (Laughter.)

16 CHAIRPERSON LUDERER: Any other comments,
17 thoughts?

18 Dr. Bartell.

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

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

7 DR. HARLEY: That's true.

8 CHAIRPERSON LUDERER: Dr. Kavanaugh-Lynch.

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

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

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

3 Thank you.

4 (Laughter.)

5 (Applause.)

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

10 (Laughter.)

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

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

14 Sara.

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

19 DR. HARLEY: (Nods head.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 CHAIRPERSON LUDERER: And that was actually going

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

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

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

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

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

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

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

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

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

1 100 girls as fast, if we had to do it with adults doing
2 the recruiting. But second of all, they really -- you
3 know, they helped us with the questionnaires asking about
4 what kind of products girls are using, because they know.
5 You know, they know what products girls are using and what
6 they're not using. And they found things that weren't on
7 our list that we needed to add onto our list, for example.

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

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

19 DIRECTOR ALEXEEFF: Hi. George Alexeeff.

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

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

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

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

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

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

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

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

1 a little bit of cheating, but not too much.

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

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

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

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

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

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

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

18 DR. ZAHEDI: I have --

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

25 DR. HARLEY: Yeah.

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

3 DR. HARLEY: Parabens are on the labels.

4 DIRECTOR ALEXEEFF: And why is that?

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

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

21 CHAIRPERSON LUDERER: Dr. DiBartolomeis.

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

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

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

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

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

19 (Laughter.)

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

23 DR. DiBARTOLOMEIS: Call her.

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

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

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

6 (Applause.)

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

10 (Off record: 2:34 PM)

11 (Thereupon a recess was taken.)

12 (On record: 2:51 PM)

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

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

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

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

10 So, Ms. Joe.

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

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

16 --o0o--

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

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

1 products that we encounter every day.

2 --o0o--

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

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

14 And for CTS's samples were from 2011 through
15 2014. The majority are white, all females, with a median
16 age in the sixties, and representing -- coming from all of
17 California.

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

25 And the study that made Expanded BEST all

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

7 --o0o--

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

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

20 --o0o--

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

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

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

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

17 --o0o--

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

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

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

4 --o0o--

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

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

17 --o0o--

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

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

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

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

12 --o0o--

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

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

25 Thanks.

1 (Applause.)

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

6 Dr. Bartell.

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

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

23 CHAIRPERSON LUDERER: Dr. Quintana.

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

1 MS. JOE: Yes.

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

4 MS. JOE: Right.

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

11 MS. JOE: Right.

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

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

21 MR. VOSS: Sure.

22 MS. JOE: Thanks.

23 MR. VOSS: Hi. Rob Voss.

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

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

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

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

12 CHAIRPERSON LUDERER: Dr. Bartell.

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

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

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

25 CHAIRPERSON LUDERER: Okay. I don't think there

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

4 (Thereupon an overhead presentation was
5 presented as follows.)

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

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

18 --o0o--

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

25 In terms of the polyfluoroalkyl substances, the

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

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

11 --o0o--

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

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

23 --o0o--

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

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

8 --o0o--

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

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

18 --o0o--

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

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

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

10 --o0o--

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

16 --o0o--

17 DR. KROWECH: Many of the new alternatives have
18 shorter carbon chains. This is because toxicity and
19 bioaccumulation typically increase as the length of the
20 carbon chain increases. So I've shown three structures
21 here. The first one is perfluorobutane sulfonic acid,
22 PFBS, with a four carbon chain. This was introduced in
23 2003 as a replacement for PFOS. And it is the one
24 alternative that is actually on the California
25 Biomonitoring designated list.

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

3 --o0o--

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

11 --o0o--

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

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

1 --o0o--

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

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

12 --o0o--

13 DR. KROWECH: And here are some examples. This
14 first slide shows examples from two studies. The samples
15 were collected from the U.S. population. The collection
16 period ranged from 2004 to 2009. So what they found were
17 some diPAPs. And basically what I've listed here is 6:2,
18 6:2/8:2 and 8:2. So three different kinds of polyfluoro
19 phosphate diesters. And these are used in food packaging.

20 And actually their level in 2004 seemed to be
21 almost on the order -- their total level seemed to be
22 almost on the order of PFOA, but it's decreased in the
23 2009 samples were much lower. Fluorotelomer sulfonic
24 acids are breakdown products of other PFASs used in food
25 packaging as well.

1 --o0o--

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

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

21 --o0o--

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

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

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

13 --o0o--

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

19 And two examples are the 6:2 fluorotelomer
20 alcohol, 6:2 fluorotelomer products and perfluorobutane
21 sulfonyl fluoride-based substances. The perfluoroether
22 carboxylic acids and sulfonic acids are also likely to be
23 highly persistent.

24 --o0o--

25 DR. KROWECH: In terms of the laboratory

1 considerations, Biomonitoring California has two LC-MS/MS
2 instruments for PFAS analysis. The method that's used
3 currently to measure the 12 PFASs can be expanded to
4 include additional compounds. Some PFASs might present
5 difficult analytical challenges.

6 The incremental cost of the additional PFASs
7 would include purchase of standards, cost of labor and
8 materials during method development and ongoing analysis.

9 --o0o--

10 DR. KROWECH: In terms of the need to assess the
11 efficacy of public health action, there is increasing use
12 of PFASs anticipated. For many PFASs, the extent of
13 exposure is unknown and more information is needed.
14 Including the class on the designated chemicals list would
15 allow the State to track the levels of important PFASs
16 over time.

17 --o0o--

18 DR. KROWECH: So the options for the Panel --
19 I'll just put this here, and then you can ask questions.
20 The Panel can recommend adding perfluoroalkyl and
21 polyfluoroalkyl substances as a class to the list of
22 designated chemicals; the Panel can defer, pending more
23 information; or, the Panel can recommend against adding
24 PFASs as designated chemicals.

25 And I'm happy to answer any questions.

1 (Applause.)

2 CHAIRPERSON LUDERER: Thank you very much, Dr.
3 Krowech.

4 Do we have any questions from Panel members for
5 either Dr. Krowech or Ms. Joe?

6 Clarifying questions, and then we'll -- we also
7 will see if we have any public comments.

8 Do we have any public comments?

9 Yes.

10 CHAIRPERSON LUDERER: I see blue slips.

11 MS. BUERMEYER: I thought guys had to ask some
12 questions.

13 CHAIRPERSON LUDERER: While we're getting those,
14 I actually do -- I have a couple of questions actually for
15 Dr. Krowech. And one is the EPA slide that you showed
16 with the 75 PMNs for telomers, were those 75 distinct
17 compounds?

18 DR. KROWECH: Yes.

19 CHAIRPERSON LUDERER: Wow. Okay.

20 DR. KROWECH: As far as I know.

21 CHAIRPERSON LUDERER: And then one more. And
22 then the PFASs that you mentioned that some of them might
23 present analytical challenges, and I was wondering if
24 either of the laboratory directors could comment on which
25 ones and why?

1 DR. PETREAS: Myrto Petreas from DTSC.

2 I would like to pass the buck to Dr. Wang and Dr.
3 Houtz --

4 (Laughter.)

5 DR. PETREAS: -- who are the real experts in the
6 lab and June-Soo, if you want to.

7 DR. WANG: So we have two instruments. One
8 instrument is designed as an on-line high throughput,
9 which is on-line SPE system. So it's limited on how the
10 sample -- basically, the serum been cleaned up on the
11 cartridge and then eluted into the mass spec. So if we
12 add new compounds, it would be a lot of -- depend on the
13 recovery of this, especially short chains on the short
14 cartridge, and it being retained on the cartridge and
15 eluted to column for analysis. So that's one concern.

16 Another concern is for the isomers, which we are
17 also interested in, the column we are currently using in
18 the system might not have capacity to separate the isomer
19 peaks from the major peaks. So that would be dependent on
20 another LC-MS instrument, which one of my colleagues is
21 also working on, Dr. Erika Houtz. She's not here. So
22 that's the major concern that we have on the instrument.

23 But we are very interested in adding the new
24 compounds into our current method. Then it would be a
25 great -- like also add our scientific curiosity. It would

1 be a great addition to our method.

2 CHAIRPERSON LUDERER: So for the high throughput
3 instrument, you might have to modify the --

4 DR. WANG: Modify the --

5 CHAIRPERSON LUDERER: -- use different columns.

6 DR. WANG: Yeah.

7 CHAIRPERSON LUDERER: Okay. Any other questions
8 from Panel members before we move on to -- Dr. Bartell.

9 PANEL MEMBER BARTELL: Yeah, another chemistry
10 question here. And not being a chemist, I'm wading into
11 dangerous territory. But I remember speaking with Antonia
12 Calafat at CDC years ago about PFOA, when she was running
13 some samples for one of our studies. And at the time she
14 was saying one of the big challenges with PFOA, which I
15 imagine applies to a lot of the other PFASs, that being a
16 surfactant it tends to stick to a lot of the lab
17 equipment. And so the recovery rates were really a
18 problem like getting good recovery, and just making sure,
19 you know, you don't have loss of material as it gets stuck
20 to your labware at different stages or your machine.

21 Is that something you guys have pretty much
22 solved? Do you get high recovery rates? You know, I know
23 you're already doing PFOA, PFOS --

24 DR. WANG: Yeah. Actually, PFOA is not a big
25 problem for us, like our background getting controlled,

1 because we have a delay column. So by attaching delay
2 column directly to the pump, gradient pump, so the
3 solvents, like interference, they got delayed probably
4 like less than one minute from our detection window.

5 So we -- generally, we can say that our
6 background are controlled pretty well. So it's -- yeah,
7 and also we have the isotope dilution, which always
8 helpful in the recovery.

9 PANEL MEMBER BARTELL: Okay. So at a very basic
10 level, if I'm hearing -- I'll paraphrase what I'm hearing
11 or interpreted, it sounds like they're not unique
12 challenges posed by adding these other classes of PFASs
13 that are unique to that class of compounds. It's just in
14 general adding any other chemical would require some
15 laboratory development?

16 DR. WANG: Yeah, general. Yeah. Actually, most
17 of the background that we see that, it has big delay
18 peaks, PFOA and PFNA. Nona. It's a nano one.

19 CHAIRPERSON LUDERER: Thank you.

20 Why don't we now take the public comments.

21 Okay. Thank you. All right. Our first public
22 comment is from Veena Singla, Natural Resources Defense
23 Council.

24 DR. SINGLA: Hi. Veena Singla, Natural Resources
25 Defense Council. Thanks for the very informative and

1 excellent presentations.

2 I wanted to comment in support of listing PFASs
3 as a class as designated chemicals. I think some of the
4 information presented did show how there's just this
5 incredible proliferation of these types of chemicals that
6 are being used in a pretty widespread way in products to
7 which people are widely exposed. So I think adding as a
8 class really makes sense in order to help capture the
9 landscape of current and future use that may be developing
10 with these types of chemicals.

11 CHAIRPERSON LUDERER: Thank you very much for
12 your comments. Our next comment is from Simona Balan,
13 Green Science Policy Institute.

14 DR. BALAN: Hi. I'm Simona Balan from the Green
15 Science Policy Institute. And just like Veena, I also
16 want to talk in support of recommending the entire class
17 of PFASs to be added to the Biomonitoring Program. We
18 have recently compiled a scientist consensus statement on
19 this class of chemicals. And since its presentation in
20 Madrid last year, it has been signed by over 200
21 scientists from 38 countries who are all concerned about
22 this entire class, and being problematic to human health
23 and the environment.

24 And we have also met with representatives from
25 DuPont, which is now Chemours, and we know that they are

1 replacing C-8, so the PFOA, the 8-carbon chain with about
2 30 different formulations of the 6-chain alternatives. So
3 the universe of fluorinated chemicals has really expanded.
4 And this seems to be the only logical way to deal with
5 them right now, to really treat them as a class.

6 And even though right now it might be hard to
7 measure all of them, we know that the scientific community
8 is working on this. And as analytical techniques become
9 available, we think that it would be great to have this
10 option to biomonitor any members of this class of PFASs,
11 because they are being used more and more in consumer
12 products.

13 So thank you for the opportunity to comment and
14 we hope you just add the whole class.

15 CHAIRPERSON LUDERER: Thank you.

16 Our next comment will be from Nancy Buermeyer
17 from the Breast Cancer Fund.

18 MS. BUERMEYER: Hi. Nancy Buermeyer from the
19 Breast Cancer Fund. Thank you for the opportunity to
20 comment. And I would like to echo my two previous
21 colleagues, and surprisingly enough, ask you to consider
22 this as a class for all of the reasons they've stated.
23 The flexibility to be able to move with the incredible
24 volatility of this market is an important one for the
25 Program. And, you know, we've all heard the stories of

1 unfortunate substitutions or regrettable substitutions and
2 we need to be able to stay on top of this. And the only
3 way to do that is to do this as a class instead of one
4 chemical at a time. So we would strongly urge the Panel
5 to designate this as a class.

6 Thank you.

7 CHAIRPERSON LUDERER: Thank you. Okay. We have
8 one comment that I'm going to read now that was sent in.
9 And it was provided to Panel members earlier. This is a
10 letter from the FluoroCouncil, the Global Industry Council
11 for Fluoro Technology.

12 I'm going to -- it's a rather long letter, so I'm
13 going to read key parts here. And the entire letter is
14 available on-line on the Biomonitoring California website.

15 "The FluoroCouncil is a global membership
16 organization representing the world's leading
17 manufacturers of fluoropolymers,
18 fluorotelomer-based products, fluoro-surfactants,
19 and fluoro-surface property modification agents.
20 The FluoroCouncil has a fundamental commitment to
21 product stewardship, and as part of its mission
22 addresses science and public policy issues
23 related to PFASs.

24 "All members of the FluoroCouncil were early
25 participants in 2010/2015 PFOA Stewardship

1 Program, the global partnership between the U.S.
2 Environmental Protection Agency, EPA, and
3 industry based on voluntary corporate goals to
4 reduce human and environmental exposure to PFOA
5 and higher homologs by eliminating those
6 chemicals from facility emissions and product
7 content by the end of 2015.

8 "The success of the Stewardship Program is
9 evident in decreasing levels of PFOA in humans
10 and the environment", and they cite data from
11 NHANES in their letter.

12 "In addition, through EPA's unregulated
13 contaminant monitoring rule, UCMR3, public water
14 systems monitor for PFOA.

15 "If the SGP decides to add PFASs as a class
16 to the designated chemicals list, we would
17 encourage a high level of transparency and public
18 engagement regarding both the selection of
19 specific PFAS compounds to be included in any of
20 the Biomonitoring California programs and the
21 analytical techniques to be used. Given the
22 complexity of this class of chemistry, it is
23 critical that the associated analytical
24 techniques are appropriate for the specific
25 substances and matrices to be tested, and meet

1 established criteria for accuracy, reliability,
2 and precision".

3 And it's signed Jessica Bowman, Executive
4 Director.

5 All right. So thank you for all those comments.
6 And now we have time for discussion and additional
7 questions by the Panel regarding this topic.

8 Dr. McKone.

9 PANEL MEMBER MCKONE: So actually this reminds me
10 a bit of the cyclic siloxane discussion, which had a lot
11 of parallels in the sense that it was a group of -- a
12 large group of chemicals with many different variations.
13 And it was also there -- were questions raised about
14 whether there was sufficient evidence of toxicity. And I
15 think in the end what really sort of tipped the decision
16 was the fact that it was a rising -- there were so many
17 increasing uses that it sort of met this criteria for
18 looking at a class of substances that had some evidence of
19 toxic or some sort of effects on human populations, but
20 also had this really rapid increase in use, so we would
21 expect to see increasing changes in exposure in the
22 population, and we had an opportunity to observe those.

23 And I think a lot of that plays in here. I don't
24 know how strong an evidence -- and again, I think this is
25 a decision we don't have to -- we don't have to have

1 strong proof of toxic endpoint to make a decision. I
2 think we need evidence that there are concerns about the
3 effects of these compounds. More importantly, it's a
4 class of compounds where it is difficult to identify
5 specific substances because of the switching and the rapid
6 dynamics of the market and how they're being used.

7 And they're very interesting, because it's an
8 opportunity for us not to look at what's been there, but
9 to see what's coming and watch it as it happens and
10 provide, you know, scientific insight.

11 So I would kind of make that point here.

12 CHAIRPERSON LUDERER: Very similar to the flame
13 retardants. It's in that regard as well that we've had
14 that discussion. And that's -- actually, you brought up a
15 good point, which Dr. Krowech actually showed that slide
16 also, the criteria for recommending additional designated
17 chemicals are not connected by "and", so they don't all
18 have to be met, and you mentioned that.

19 Do we have any other comments or questions from
20 the Panel?

21 Dr. Bradman.

22 PANEL MEMBER BRADMAN: Just a few comments. I
23 mean, given -- I mean, there's kind of known and
24 legitimate concerns about the toxicity of PFOS and PFOA.
25 And, you know, these compounds don't necessarily have the

1 same depth and breadth of evaluation. But I think by
2 analogy, we have concerns about them, and I think that
3 should be taken seriously. And this is not a toxicology
4 program, but I think these also meet the criteria of
5 having some concerns about their potential health effects.
6 And so that's another basis to consider adding them as a
7 class.

8 Also, in terms of the laboratory methods that
9 were discussed briefly on the write-up that we were
10 provided on page 13, it sounds like that the laboratory
11 could relatively easily at least add some of the longer
12 chain compounds fairly easily, and that maybe there would
13 be some challenges with some of the shorter chain
14 compounds.

15 But that said, it seems like the laboratory is
16 well equipped to develop methods to look at these so we
17 also meet that criteria, in terms of feasibility without
18 too much more cost. I guess I'm saying that both as a
19 statement and a question.

20 (Laughter.)

21 PANEL MEMBER BRADMAN: But maybe that's a point
22 we could hear about later.

23 Also, you know, I read this letter last night
24 from the FluoroCouncil, and I think this ties back to the
25 earlier statement about, you know, involvement in industry

1 in the meetings here and decisions. And I want to
2 emphasize that we really welcome input from all players in
3 the field of environmental health, including industry.
4 And I think this is a good example here, where there's
5 some good comments about these compounds and how industry
6 involvement has resulted in lower exposures.

7 And I think that's the kind of green chemistry
8 and health oriented or -- I shouldn't say health oriented,
9 preventive oriented environmental health that
10 biomonitoring can promote. And I think the point here
11 about transparency in terms of choosing methods while
12 choosing analytes and also having appropriate analytical
13 methods is really kind of fundamental to this Program in
14 terms of having public meetings. These are on the web.
15 The methods are published on the web. And speaking to
16 those in the room and also anyone who may be listening, we
17 would really welcome that kind of input. And that's
18 something that we -- that really is a strength of this
19 Program.

20 So I'm not quite ready to take it a step further,
21 but I think that these compounds, for a lot of reasons,
22 meet criteria why we would want to test for them in a
23 Biomonitoring Program.

24 CHAIRPERSON LUDERER: And Dr. Bradman addressed
25 several of the criteria and commented on how the PFASs as

1 a class meet several of those criteria. I think also the
2 need to assess efficacy of public health actions is
3 another criterion that these meet, in the sense that we
4 are phasing out certain -- the PFOA and PFOS, and now
5 these other ones are being used. And so in order to
6 really be able to see what's going on with these
7 substitutions, I think that's another one of the criteria
8 that's met.

9 Other comments from Panel or -- what we have to
10 decide here is whether we want to designate -- recommend
11 designation, recommend not designating, or request
12 additional information. Do we have specific comments from
13 Panel members about that?

14 PANEL MEMBER MCKONE: Oh. Should we have a
15 motion or do we have to discuss further?

16 CHAIRPERSON LUDERER: You can have a motion.

17 PANEL MEMBER MCKONE: I mean we could have a
18 motion and then discuss, right?

19 (Laughter.)

20 PANEL MEMBER BARTELL: Why don't we start with a
21 motion.

22 PANEL MEMBER MCKONE: Okay. So I'm going to make
23 a motion that the Panel recommend adding perfluoroalkyl
24 and perfluoroalkyl substances, PFASs, as a class to the
25 list of designated chemicals, period.

1 CHAIRPERSON LUDERER: Okay. Dr. McKone has
2 motioned that the class of chemicals perfluoroalkyl and
3 polyfluoroalkyl substances, PFASs, be included as
4 designated chemicals in the California Environmental
5 Contaminant Biomonitoring Program.

6 Do we have a second, any comments on that?

7 PANEL MEMBER BARTELL: Second.

8 CHAIRPERSON LUDERER: Dr. Bartell seconds.

9 PANEL MEMBER BRADMAN: I'm going to second as
10 well.

11 CHAIRPERSON LUDERER: You were going to second
12 also.

13 In that case, then we can have a Panel vote.
14 Should we start with -- I asked for discussion or do we
15 need -- does anyone have any additional comments or
16 discussion from the Panel?

17 Dr. Bartell.

18 PANEL MEMBER BARTELL: Just to be clear, I am in
19 support of this motion, but I think, you know, the one
20 argument against it is not knowing much about the toxicity
21 of these short chains, but I think as we've all said,
22 there's reason to be concerned or even to refer to them as
23 suspected health effects, which I think is the wording in
24 the written criteria, hence that may be sufficient, not
25 that we even need that point to be met, as I understand

1 it, to recommend this.

2 But I think my only misgiving, though I do
3 support it, is just that it seems like there's some hint
4 that the shorter chains are less toxic, but I don't think
5 there's a lot of toxicity data on that. And actually
6 adding these to biomonitoring might help spur some more
7 movement on doing studies on toxicity of these shorter
8 chain compounds.

9 So I think for those reasons in the balance, it's
10 probably still a good idea to move forward with adding
11 this to the designated chemicals. And that's my only
12 comment.

13 CHAIRPERSON LUDERER: Any other comments or
14 discussion?

15 All right. Then we can move on to voting on the
16 motion.

17 Dr. Kavanaugh-Lynch, why don't we start with you.

18 PANEL MEMBER KAVANAUGH-LYNCH: Aye.

19 PANEL MEMBER BARTELL: Aye.

20 PANEL MEMBER MCKONE: Aye.

21 CHAIRPERSON LUDERER: Aye.

22 PANEL MEMBER QUINTANA: Aye.

23 PANEL MEMBER BRADMAN: Aye.

24 CHAIRPERSON LUDERER: Okay. Unanimously the
25 Panel has voted to recommend the class of PFASs as

1 designated chemicals.

2 All right. So we are a little bit ahead of
3 schedule, which means we have more time for the open
4 public comment period.

5 So do we have some -- we don't have any
6 additional public comments.

7 Well -- oh, we do.

8 MR. HOEPKER: Hi. I'm Alexander Hoepker From UC
9 Berkeley, a chemist in training. This may not be in the
10 purview of biomonitoring, but I just wanted to throw it
11 out there, and it might also prompt some collaboration
12 with industry, and that is -- and it also feeds in with
13 green chemistry in general, to make recommendations for
14 substitutions, to avoid the problem of regrettable
15 substitutions, but clearly we had two problematic
16 substances that were substituted by a flurry of
17 fluorinated substances. And I can only wonder what would
18 happen say in 10 years time when these flurry of chemical
19 substances get replaced by other chemicals.

20 And so I was wondering if the Biomonitoring
21 California has an option to recommend chemicals or if
22 there's some provision for that.

23 Thank you.

24 CHAIRPERSON LUDERER: Does someone from the
25 Program perhaps want to respond to that? It's not --

1 DR. WILLIAMS: Meredith Williams from the Safer
2 Consumer Products Program in DTSC. And the whole Safer
3 Consumer Products Program is, as you heard last time,
4 designed to ask the manufacturers to ask two questions:
5 Is it necessary to have a chemical in a product, and might
6 there be a safer alternative?

7 And it outlines a comprehensive alternative
8 analysis process that would exactly address the question
9 that was raised, how do we avoid the regrettable
10 substitutes, what are the toxicities, what's known about
11 the alternative chemicals, what are the impacts,
12 environmental fate, et cetera? It's very comprehensive
13 across lifecycle -- product lifecycle.

14 So I think that that is an appropriate mechanism
15 to get those questions answered. It comes down to whether
16 or not we actually name a product with a chemical that
17 falls into this category, but it is very helpful in a
18 sense for us to be able to capture chemicals in classes,
19 rather than on an individual basis when we go to look for
20 those alternatives, both in terms of our regulatory
21 listings and in terms of then looking at alternative
22 analyses through that lens of chemical classes.

23 CHAIRPERSON LUDERER: Thanks very much.

24 Dr. McKone.

25 PANEL MEMBER MCKONE: Well, I'd like to point

1 out, first of all, in terms of whether it's in the purview
2 of this Panel, I actually think it's outside, because our
3 goal is to look at what's in people and do the best job of
4 tracking that.

5 But it doesn't say this isn't an important issue.
6 And I think almost everyone on here, in one way or
7 another, is involved in other activities that are very
8 important. I mean, there's the DTSC Green Chemistry,
9 there are international programs, there's a lot of work in
10 lifecycle assessment. But it's not only on chemicals, I
11 mean, I spend a lot of my time working on cleaner
12 alternatives for energy and providing energy services. So
13 it's very active area. It's very international. It's
14 academic and regulatory. So it's something going on, and
15 we certainly, I think, all support it. It's just, I
16 think, you know, when we meet, we don't want to go too far
17 out of our purview or we're going to -- you know, we're
18 going to dilute the power we have to really make
19 commentaries on biomonitoring.

20 CHAIRPERSON LUDERER: Thank you. Nancy Buermeyer
21 from the Breast Cancer Fund.

22 MS. BUERMEYER: Thanks for letting me get up
23 impromptu here. Obviously, the issue that was raised by
24 the gentleman from UC Berkeley is an important one, and I
25 just wanted to talk about how important we think the Safer

1 Consumer Products Program is and appreciate the comments
2 of Dr. Williams.

3 And I really think as I think has been done by
4 this Panel and by the leadership of the California
5 Biomonitoring Program is trying to integrate those two
6 programs. The information that this, the California
7 Biomonitoring Program, gathers I think is really
8 instructive to how DTSC makes the decisions about what
9 chemicals combinations they're going to look at.

10 And I also wanted to echo what Dr. Bartell said
11 about the more we know about exposure, the more that
12 drives the scientific research that we need. From our
13 perspective as an organization, we think we ought to know
14 that stuff before they get into the products, right, like
15 we think there ought to be reform of the Toxic Substances
16 Control Act so that we actually know the health issues
17 before we have exposure to large portions of the
18 population.

19 But given that that's not where we are right now,
20 that kind of exposure information really drives a lot of
21 that data. And we've seen that with biomonitoring data
22 showing huge exposure and how that has created an
23 avalanche of research on that -- of that chemical.

24 And I suspect we will see that we've seen that
25 some with flame retardants. We've seen some of that with

1 phthalates. And I think there's a potential to have that
2 happen here. So I really think that, while I agree, it's
3 outside of the purview of this body, I just wanted to
4 emphasize how important the work that this body does to
5 driving that sort of broader process of knowing the
6 toxicity, knowing the alternatives, and how do we make
7 products safer in the long term.

8 Thanks.

9 CHAIRPERSON LUDERER: Thank you. Sara Hoover --
10 or Dr. Williams.

11 DR. WILLIAMS: Meredith Williams again.

12 And I did want to say that our three-year
13 workplan explicitly called out biomonitoring results as a
14 method for us to make decisions about which categories got
15 included in the workplan, because that -- we had a degree
16 of confidence that we would be able to explain the
17 exposure.

18 And then as we go forward and choose individual
19 products from those product categories, we will again
20 circle back to biomonitoring. So this Program for us is
21 really fundamental to so much of our decision making, and
22 we're really excited to be in much stronger partnership
23 moving forward.

24 CHAIRPERSON LUDERER: Thank you.

25 Sara Hoover.

1 MS. HOOVER: Yes. Sara Hoover, OEHHA. I just
2 wanted to add a couple things of interest. First, we've
3 actually started some new efforts to work directly with
4 the Safer Consumer Products Program. So bringing -- you
5 may recall that last July, we had a consumer product
6 focused meeting when Dr. Williams was here. And we had
7 certain follow-up items, and we're working on those
8 follow-up items, like a systematic review of our list
9 compared to consumer product chemicals. And we've now
10 started a little work group with actual staff-to-staff
11 contact across the two programs.

12 So we're planning, you know, as we go forward to
13 work -- I mean, we've always been working closely at some
14 level, but we're making those links stronger. And we're
15 hoping -- this is all still tentative, but in July we're
16 hoping to have sort of another check-in on those efforts.
17 So that's one angle.

18 The other thing I'll just mention is the name of
19 my section in OEHHA is Safer Alternatives Assessment and
20 Biomonitoring Section. So even though in the
21 Biomonitoring Program we're not directly working on it,
22 it's an area that OEHHA is very interested in as well, and
23 we have other efforts along those lines. So it's an
24 important point that we want to make our data relevant to
25 that larger policy issue.

1 CHAIRPERSON LUDERER: Thank you very much. That
2 was -- that's really helpful that you added that.

3 Any other comments or questions from Panel
4 members?

5 I know Dr. Alexeeff didn't have the opportunity
6 to talk about what we did as a Scientific Guidance Panel
7 at the last meeting, so I thought I would give him the
8 opportunity to say a few words about that.

9 DIRECTOR ALEXEEFF: Also, I just wanted to
10 welcome Dr. Bartell. I can see he's already been
11 contributing, which is great.

12 (Laughter.)

13 DIRECTOR ALEXEEFF: So I look forward to your
14 contributions over the term here.

15 At our -- you know, at our last meeting, similar
16 to the things that we've discussed this meeting, you know,
17 we had laboratory updates, we had input, we heard the
18 findings of Biomonitoring California evaluation activities
19 of the CDC cooperative agreement. We had more CDC input
20 today. And last time we had a wide-range discussion about
21 the challenges in measuring exposure to diesel exhaust.
22 That clearly has been a chemical or a substance that's
23 been a very specific interest to this Panel. It comes up
24 regularly.

25 And the Panel reiterated their previous support

1 for the Program to identify a biomarker, and encouraged
2 pursuing the method development of 1-nitropyrene, which
3 has been used. We talked about that last time, and its
4 metabolites as a starting point.

5 And as always, we have a great transcript
6 preparer here. We're very fortunate to have him. And the
7 transcript is available on our website. And the
8 transcript of this meeting will be available on our
9 website of Biomonitoring California as well.

10 CHAIRPERSON LUDERER: Thank you, Dr. Alexeeff. I
11 also -- as Dr. Alexeeff just mentioned, we will have a
12 transcript of this meeting posted on the Biomonitoring
13 California website soon.

14 I also wanted to remind everyone that the next
15 Scientific Guidance Panel will be on July 16th in Oakland
16 also. And remind you all that this building closes at
17 5:00 p.m., and so we recommend that everyone not linger
18 for too long. I don't think that should be a problem.
19 That gives you an hour to get down to the first floor,
20 so -- and then with that, I would like to thank everyone
21 for coming and adjourn the meeting and see you all in
22 July.

23 (Thereupon the California Environmental
24 Contaminant Biomonitoring Program, Scientific
25 Guidance Panel meeting adjourned at 3:50 p.m.)

1 C E R T I F I C A T E O F R E P O R T E R

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

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

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 17th day of March, 2015.

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