

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

THURSDAY, JULY 16, 2015

10:00 A.M.

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

A P P E A R A N C E S

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Dr. Lauren Zeise, Acting Director

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Mr. Mario Fernandez, Staff Counsel

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

Dr. Laurel Plummer, Staff Toxicologist, Safer Alternatives
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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

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

Mr. Rob Voss, M.P.H., Research Scientist, Chemical Exposure Investigations Unit

Dr. Nerissa Wu, Chief, Chemical Exposure Investigations Unit

DEPARTMENT OF TOXIC SUBSTANCES CONTROL:

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

GUEST SPEAKERS:

Antonia Calafat, Ph.D., Chief, Organic Analytical Toxicology Branch, Division of Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention(CDC)

Mr. Karl Palmer, Chief, Safer Consumer Products Branch, California Department of Toxic Substances Control(DTSC)

ALSO PRESENT:

Ms. Nancy Buermeyer, Breast Cancer Fund

Mr. Alexander Hoepker, UC Berkeley, Center for Green Chemistry

Lovisa Romanoff, M.S., M.P.H., Health Scientist, Project Officer for State Biomonitoring, Centers for Disease Control and Prevention

Dr. Veena Singla, Natural Resources Defense Council

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1 P R O C E E D I N G S

2 DR. PLUMMER: Good morning, everybody. We're
3 just going to gather now and start the meeting. So if
4 everyone could take their seats.

5 Okay. So I'm just going to give some
6 introductory announcements. Welcome, everyone. Nice to
7 see you today. Today's meeting will be webcast, so I want
8 to remind everyone to speak directly into your
9 microphones. If you're going to give public comment, you
10 can come up to the podium and speak at this microphone
11 here. This is for both the people on the webcast and also
12 for our transcriber.

13 Today, the meetings -- the meeting materials were
14 provided to our SGP members and also posted on the
15 Biomonitoring California website. And there's some copies
16 over by the entrance where Leah is sitting. Today, we'll
17 take two breaks, one around 12:50 for lunch, and another
18 at 3:00 p.m. And just to point out, the restrooms are
19 past the reception desk and the first hallway on your
20 right. The emergency exit is you can go out either of
21 these doors and it's right, basically in the hallway right
22 behind us here. And one other announcement, there is
23 WiFi. It's -- there's no password for it. So if you need
24 that.

25 And with that, I would like to introduce Dr.

1 Lauren Zeise, Acting Director of the Office of
2 Environmental Health Hazard Assessment.

3 ACTING DIRECTOR ZEISE: Thank you. So good
4 morning, everyone. I'd like to welcome you all to the
5 Scientific Guidance Panel for the California Environmental
6 Contaminant Biomonitoring Program, also known as
7 Biomonitoring California.

8 And I'd just like to start off by thanking you
9 all for your participation in this important meeting. I
10 am sitting in the seat that George Alexeeff normally sits
11 in. And so as we start this meeting, I'd just like to --
12 we would like to take a few moments to honor and pay
13 tribute to George.

14 So for those of you who don't know, George passed
15 away a couple of weeks ago from pancreatic cancer. And he
16 was our much respected, much loved Director of OEHHA. And
17 we're all very, very sorry about his passing. George was
18 a really truly wonderful person and dedicated his
19 professional life to public health. He was a very strong
20 advocate for Biomonitoring California.

21 And he understood that -- how important it was to
22 have information -- biomonitored information on people.

23 (Phone interference.)

24 ACTING DIRECTOR ZEISE: It looks like we have
25 some interference.

1 Okay. All right. So he really understood how
2 effective it was to have biomonitored information to move
3 forward public health policy. And again, he was a very
4 strong advocate for the Program.

5 So those of you who know George, he had a great
6 sense of humor. And actually, there's one event that
7 keeps coming to my mind when I think about that, and that
8 was George unexpectedly showing up at an OEHHA gathering
9 dressed as a previous Governor impersonating that Governor
10 and saying, "I'll be back".

11 (Laughter.)

12 ACTING DIRECTOR ZEISE: So that was George. And
13 he was so much fun. And he would easily liven up a
14 meeting, a very serious meeting with some silly jokes. He
15 had this quirky sense of humor and this infectious smile,
16 so just really wonderful.

17 And he was a very effective manager and boss. So
18 if there was a problem, he'd look for solutions. He
19 wouldn't waste time thinking about excuses for the
20 problem, but he was really focused on getting a solution
21 for the problem.

22 And he had a very special skill for bringing in
23 and mentoring young staff. And he was very proud about
24 the young and talented staff he brought to OEHHA. So
25 during the memorial, which was last Sunday, and over the

1 course of thinking about George, we learned a lot about
2 his personal life. And we came to discover that his
3 personal life was just as wonderful as his professional
4 life.

5 And, you know, he was someone who taught Sunday
6 school every Sunday for 15 years, and he sent his wife
7 flowers every week to her office. We were astounded by
8 that fact. And he was just a wonderful dancer and just a
9 lot of fun.

10 So, you know, we miss George more than we can
11 express. And we'll forever appreciate his contributions
12 to OEHHA, the Biomonitoring Program, and all of his many
13 public health initiatives that he championed.

14 Now, I'd like to invite Michael DiBartolomeis to
15 say a few words about George. I think he might have a
16 funny story actually.

17 DR. DiBARTOLOMEIS: Well, good morning, and thank
18 you, Lauren. We do know George mostly as a colleague, a
19 leader, a scientist, a mentor. I'm going to tell you a
20 story of George the friend. Some friends -- and George
21 somehow could make friends with just about everybody. In
22 fact, I don't know if he had anybody he wouldn't have
23 called a friend. And we're not talking about the
24 superficial smile, forget the person's name kind of
25 friend. I mean, we're talking about somebody he --

1 George, when he befriended you, he really befriended you.

2 So I'm going to tell you a story about my
3 friendship with George. It's personal and I have never
4 told anybody. So this is the first time I've ever told
5 this story. It seems much more relevant.

6 But first, I'd like to give you a little bit of
7 background. Stories need the foundation. We did hear
8 that George, of course, is -- has another -- had another
9 life. And one -- and part of his other life, besides his
10 crazy legs for dancing -- I mean, this guy was a non-stop
11 dancer and music aficionado.

12 (Laughter.)

13 DR. DiBARTOLOMEIS: He was also a fanatic. And
14 what I mean by that is he loved the San Francisco Giants,
15 and we went to a couple of games together, as a matter
16 fact. And one of the games I went to with him Barry Bonds
17 parked one into the water in the bay, and he was like a
18 about a 10-year old kid giggling and jumping up and down.
19 So picture that.

20 I happen to grow up outside of Boston, so I am a
21 long-time suffering Boston Red Sox fan. And for those of
22 you who didn't see Fever Pitch or don't know the Red Sox
23 history, in 1918 they sold probably the best baseball
24 player every, Babe Ruth, to the New York Yankees. And we
25 all know what he did for the New York Yankees. And up

1 until that point, the Red Sox were probably the best team
2 in baseball. They went on an 86-year drought and never
3 won the World Series after they sold Babe Ruth.

4 So fast forward, 2004. Red Sox went to the
5 playoffs, and they were playing Yankees. And they went
6 down three games to none, so they had -- they were 0 and
7 3. That's it. Everybody kiss them goodbye. Well, one
8 base steal later, and four wins in a row, they ended up
9 into the World Series. It's pretty miraculous.

10 And in October, they were in the World Series in
11 Boston, George was in Boston as well. And he was there
12 with his daughter. I think his daughter was graduating or
13 doing her thesis defense or something along those lines.
14 The Red Sox won the World Series in four straight games.
15 Of course, I was elated.

16 And got back, probably three or four days, I get
17 an envelope interoffice agency -- interagency office
18 envelope in the mail, not marked, just my name. And
19 inside was a T-shirt that said Reverse the Curse, or the
20 Curse is Reversed.

21 (Laughter.)

22 DR. DiBARTOLOMEIS: Sorry. And that was the
23 curse of the Bambino or Babe Ruth. And then there was
24 from the hotel USA Today was the front page, just to prove
25 that the Red Sox really did win.

1 (Laughter.)

2 DR. DiBARTOLOMEIS: And just a note from George
3 saying, "I thought you might like these as a memento".

4 So I'm telling you this, not because -- I mean,
5 these are just funny gifts. But here's a guy who was, you
6 know, almost second in command of a department and
7 government, complicated family life, he's with his
8 daughter, and he had the time to think about me. And I
9 still remember it the day I opened up that envelope,
10 that's what I thought about, and I still -- it's crystal
11 clear to me, that is a true friend. Somebody who really
12 thinks about you when all other things are going on in
13 their lives.

14 So he's -- George was a listener, and that's what
15 you want in a true friend. He thought of you, and that's
16 what you want in a true friend. And when you needed a
17 laugh, and a good story, George was always there to
18 produce it. And that's what you want in a good friend.
19 So I'm telling you that we all know him as the leader and
20 the colleague, and all that, but he's really a true friend
21 as well. He's going to be missed.

22 So as far as I'm concerned, George Victor "Crazy
23 Legs" Alexeeff --

24 (Laughter.)

25 DR. DiBARTOLOMEIS: -- is going to be sorely

1 missed as not only a colleague, but also as a friend.

2 Thank you.

3 ACTING DIRECTOR ZEISE: Thank you, Michael. We
4 have a table set up over here with a tribute to George,
5 and it includes a letter of thanks from the Governor, a
6 resolution from the State Senate, pictures, and other
7 items in his honor. So I encourage everybody to visit the
8 table and take a look and remember George. So thank you.

9 So now we're going to return to the important
10 work of our meeting, and I'm going to start with a recap
11 of the SGP meeting, which was held in Oakland on March
12 13th, 2015. So, at that meeting, the Panel heard the
13 Program and laboratory updates and provided input. It
14 received an in-depth update from Dr. Mary Mortensen and
15 Lovisa Romanoff at the CDC about the national biomonitor
16 program.

17 We discussed what -- the Panel discussed with Dr.
18 Kim Harley of UC Berkeley the results of the HERMOSA
19 biomonitoring study. That was an intervention study of
20 phthalates and phenols in personal care products.

21 And the Committee also unanimously recommended
22 that the class of chemicals known as Perfluoroalkyl and
23 Polyfluoroalkyl Substances, PFASs, be added to our
24 designated chemical list, is that right? Designated
25 chemical list, not priority list. So more information on

1 the March meeting is available on our biomonitoring
2 website at www.biomonitoring.ca.gov.

3 Again, I'd like to welcome everyone to our
4 meeting, and now I will turn the meeting over to our Chair
5 Dr. Ulrike Luderer.

6 CHAIRPERSON LUDERER: Thank you, Lauren. And I
7 wanted to thank Lauren and Michael for those really moving
8 tributes to George. On behalf of the Scientific Guidance
9 Panel, I just wanted to say that George really touched all
10 of our lives, and that we will miss him greatly. He was a
11 really inspiring leader and mentor. He was dedicated to
12 public service. He had a keen intellect and a wonderful
13 sense of humor, amazing smile, and our thoughts and
14 deepest sympathies go out to his family and to his
15 friends.

16 And I know that we'll be thinking of him during
17 our meeting today, and I believe there can be no better
18 way to honor his memory than to carry on the work that he
19 was so passionate about. And I do need this tissue.

20 (Laughter.)

21 CHAIRPERSON LUDERER: So then I went to review
22 the Panel goals for the meeting. We're going to today
23 discuss with Dr. Antonia Calafat of the CDC her work on
24 phthalates and phthalate alternatives. We're going to
25 hear a detailed update on the Program study that's called

1 Measuring Analytes in Maternal Archived Samples, or MAMAS.
2 We'll hear a presentation from Karl Palmer of the
3 Department of Toxic Substances Control, Safer Consumer
4 Cosmetics -- Consumer Products Program, and discuss how
5 the SGP and that program can inform one another.

6 And finally, we'll consider the chemical class
7 ortho-phthalates as potential designated chemicals for
8 Biomonitoring California.

9 And as always, there will be time allotted for
10 each topic for Panel questions, public comment, Panel
11 discussion and/or recommendations.

12 I just wanted to remind everyone how we'll be
13 handling the public comments. If you would like to make a
14 comment, please fill out a comment card, which can be
15 obtained on the table to my right in the entrance of the
16 room, and you can turn the cards into Amy Dunn who is
17 standing there holding some of those yellow cards.

18 Members of the public who are not at the meeting
19 today in person can -- are invited to provide comments by
20 email at biomonitoring@oehha.ca.gov, and I will read
21 the emailed comments a loud during the meeting.

22 Public comments are subject to time limits and
23 the time allotted will be divided by the number of people
24 who wish to speak on that agenda item. Also, I wanted to
25 remind you to please keep your comments on the agenda

1 topics that are being presented, and there will be an open
2 public comment period as the last item of the day.

3 So now it's my pleasure to introduce Dr. Antonia
4 Calafat, who will describe her research on phthalates and
5 phthalate alternatives. Dr. Calafat serves as Chief of
6 the Organic Analytical Toxicology Branch at the Division
7 of Laboratory Sciences, National Center for Environmental
8 Health of the Centers for Disease Control and Prevention,
9 the CDC. She earned her bachelor, masters, and doctoral
10 degrees in chemistry from the University of the Balearic
11 Islands in Spain. Prior to her career at CDC, she was a
12 Fulbright Scholar and a research associate at Emory
13 University in Atlanta.

14 And she currently leads the CDC Biomonitoring
15 Programs for Assessing Human Exposure to Environmental --
16 to pesticides, polycyclic aromatic hydrocarbons,
17 persistent organic pollutants, such as polyfluoroalkyl
18 compounds and polybrominated diphenyl ethers, and
19 chemicals added to consumer and personal care products,
20 such as phthalates and phenols.

21 She has developed and maintained extensive,
22 collaborative research with leading scientists in the
23 fields of exposure science, epidemiology, toxicology, and
24 health assessment. And her research has made important
25 contributions to CDC's National Biomonitoring Program.

1 So welcome, Dr. Calafat.

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

4 (Applause.)

5 DR. CALAFAT: Thank you. Thank you for the kind
6 introduction. It is really indeed my pleasure to be here
7 today to talk about the work that people at CDC have done.
8 I'm here only as the spokesperson. So then without them
9 and their hard work, then I wouldn't be here.

10 So I'm going to be talking today about the
11 phthalates and phthalate alternatives.

12 --o0o--

13 DR. CALAFAT: And I'm just going to give you a
14 very brief overview of the generalities about the exposure
15 to phthalates. How are we looking at changes in exposure
16 to phthalates, because it's very evident that changes in
17 the market practices, you know, in the make-up of the
18 products. And this is certainly impacting the exposures
19 that we are all experiencing.

20 And how we have been using NHANES, the National
21 Health and Nutrition Examination Survey, great resource.
22 Just a program that has the biomonitoring component, and
23 how we can use this NHANES to assess the changes in
24 exposures, also to look at how we can look at archived
25 samples. And then it's nice to see that later on you're

1 going to be looking at these MAMAS, you know, like a
2 program to just again using archived samples to assess
3 exposures, and then to look for trends in emerging
4 chemicals.

5 And I'm going to be talking about the example of
6 DINCH, which is a non-phthalate product but is used as a
7 phthalate alternative. And there is another program, not
8 here in the United States, but abroad, because there
9 are -- we are not here alone in the world, and they have
10 also very important programs that have been going on for a
11 while. And I'm just going to highlight very briefly the
12 German Environmental Specimen Bank, because it just
13 corroborates the findings that we are also seeing in
14 NHANES.

15 I'll be spending some time looking at the
16 selection of phthalate biomarkers, because as I said, you
17 know, we live in an evolving world, the constant changes
18 in exposure, and then we want to make sure that we are
19 selecting the right biomarkers, we are providing the right
20 information, and just going to be providing two examples
21 of those.

22 We also are looking at phthalates, not because we
23 simply want to, but because these are chemicals of
24 concern. They have some toxicological properties, and
25 they're bioactive in animal studies certainly. And there

1 is evidence that it's also happening, having some activity
2 in humans. So I'm going to be giving an example of a
3 chemical that seems to have quite -- be quite toxic, yet
4 the evidence is that exposure, and luckily for us, among
5 humans is not very prevalent, at least for now. And then
6 I'm just going to be talking about some future work.

7 --o0o--

8 DR. CALAFAT: This is like -- kind of like the
9 summary of what are phthalates. Phthalates are widely
10 industrial -- used industrial chemicals. And phthalates
11 encompass a wide range of chemicals within different
12 compounds within that family. Some of them, the larger
13 ones are being used as plasticizers mainly of PVC. And
14 PVC is used in so many different products, you know, like
15 they're used in like, you know, linings, it's used in
16 tubing, the amount of certain phthalates is what makes
17 like a very rigid pipe, or a very flexible tubing.

18 So they also use some of these phthalates in
19 medical devices, in blood bags. The smaller phthalates
20 are used in some other applications in commerce being
21 consumer -- mainly in consumer and personal care products,
22 in fragrances. When you see something in a product that
23 say fragrance, chances are that it contains some of the
24 phthalates. They can be used in paints and lacquers, and
25 in certain medications -- in the coating of certain

1 medications.

2 As I said before, we're looking at phthalates,
3 because they have -- there's clear evidence that they have
4 adverse health effects in animal studies. And there is
5 emerging data suggesting that phthalates also have some
6 potential adverse human effects in people, humans
7 obviously.

8 And how do we look at exposure to phthalates?
9 We're looking at metabolites of phthalates. And on the
10 right side of the slide, you can see there is the
11 structure of the phthalates, that ones outside how the
12 phthalates are used in commerce. Then it's not
13 everywhere, but it is very easy to go from what is used in
14 commerce into what happens in the body. Then the
15 phthalates metabolize, they break down, and then we get
16 what we have, within that box - and I don't have a
17 pointer, but I guess everybody can see it - then these are
18 the two different type of metabolites that we look when
19 we're assessing exposure to phthalates.

20 --o0o--

21 DR. CALAFAT: It's very easy to say, but maybe
22 more difficult to do, because really the human exposure
23 scenario is quite a complicated matter. We don't have the
24 control conditions that apply in animal studies in the
25 human -- in human exposures. We have very many, and many

1 times, even unknown sources and routes of exposure. We
2 actually are not sure about the dose that we're exposed to
3 for how long, how frequently, and when did it happen?
4 Yesterday, today, two minutes ago.

5 And we are really not exposed to one chemical,
6 which is what has been used traditionally in traditional
7 toxicology, but to cocktails, mixtures of chemicals. So
8 how are we really going to assess these exposures?

9 Biomonitoring is certainly one of the important
10 tools that you can be using for assessing exposure to
11 phthalates and to many different chemicals today. I'm
12 only going to be talking about phthalates.

13 --o0o--

14 DR. CALAFAT: So at CDC, we have within the
15 phthalates, a biomonitoring program. We have like four
16 areas that I think are important to highlight. The first
17 one would be assessing exposure to phthalates and
18 alternatives. And the use of NHANES, as I'm going to be
19 showing shortly, is incredibly important for that purpose.

20 NHANES looks at -- has -- collects important
21 information about associations -- I mean, about health
22 conditions. Most of the time -- well not most of the
23 time -- always self-reported. And it could be used for
24 just associations or determined associations between
25 exposure to phthalates and health effects. However,

1 NHANES is a cross-sectional study, so we always like to
2 partner with some other investigators. And some of them
3 are actually even in the room today. And then just to
4 look at the interactions between exposure to phthalates
5 and some health effects.

6 We spent quite a bit of time into the research
7 that we like for improving, what I call, like improving
8 biomonitoring practices. And in that regard, then we
9 develop analytical methods. I'm a chemist by training,
10 and I became an exposure scientist here when I joined CDC.
11 We identify -- as part of this research and development,
12 we identify and validate exposure biomarkers, including
13 some that are these replacement chemicals. I'm not seeing
14 you guys. I'm turning, I guess.

15 (Laughter.)

16 DR. CALAFAT: And then we also work with some
17 other federal partners to develop standard reference
18 materials. And as part of our biomonitoring cooperative
19 agreement with the states, we work on capacity building in
20 the states. And that's -- I guess that's why we're here,
21 and I'm here, in California because you do have indeed a
22 truly wonderful Program. And we are working with the
23 State to, in what I call, performance testing.

24 --o0o--

25 DR. CALAFAT: In terms of biomonitoring methods,

1 we really have to remember that biomonitoring has a core
2 in analytical chemistry. And, in general though,
3 analytical chemistry methods are going to have four main
4 requirements. They have to be sensitive, specific and
5 selective, accurate and precise, meaning you have to have
6 a method that can allow you to detect very small amounts
7 of levels of a particular chemical, differentiate between
8 this chemical and everything else that is in the matrix,
9 being accurate, so we want to be sure that this is what
10 we're measuring and precise.

11 However, this again is what is general analytical
12 chemistry, but we also have some specific just
13 requirements for biomonitoring, being that you want to
14 have a method that uses minimum sample volume. And this
15 is important because in addition from an analytical
16 perspective, reduces solvent use and waste. So improve
17 the safety, you know, like conditions of the analysis is
18 also important on where you're sitting, because when
19 you're just going and trying to collect samples, then
20 sometimes samples are not very easy to obtain. And then,
21 you know, like blood is available, but some people may not
22 like to give a lot of blood, so -- and even urine, we
23 think, oh, this is abundant, but try to get urine from a
24 very small child. So that may not be that easy.

25 So you really want a method that uses minimum

1 sample volume, that measures many compounds at the same
2 time, and is high throughput. So in this way then we
3 increase efficiency. From that very small amount of
4 sample, we want to measure as many things as we can.

5 We want it to be reproducible. I want the method
6 to give me the same result today that it is going to give
7 me in a month, that is going to give me in years. So you
8 have to have as part of that, to ensure reproducibility,
9 you want to have a very strong quality assurance/quality
10 control program that just you can use for accountability.

11 And finally, obviously, you want to do all of
12 this, and then we don't have enough hours in a day to do
13 all of that unless the method is highly automated. And
14 that means that you're going to have like kind of an
15 upfront cost that you're going to have to cover.
16 Biomonitoring is not cheap by any means, but at the end
17 it's going to be cost effective.

18 But because of all these requirements that I have
19 mentioned, and then particularly because of the fact that
20 you want to include as many chemicals as possible, as many
21 compounds as possible, your method is going to be a best
22 compromise method. So every time that you're measuring
23 more than one chemical, you're going to have something
24 that you're going to have to compromise on, because all
25 these requirements you would like them ideally to apply to

1 every single chemical.

2 Needless to say, that's impossible, but you just
3 have to get the best compromise method that you can live
4 with. And that's going to become important later on.

5 --o0o--

6 DR. CALAFAT: I said the methods have to be
7 accurate, and then biomonitoring is a targeting -- is a
8 targeted strategy. So we know very well what we're
9 looking for. So because we do then, we want to determine
10 the levels that we have of those chemicals. And in order
11 to do that, we need to have standards. These standards
12 are many times custom made, and then we just need to make
13 sure that those standards are accurate. If they tell you
14 that the standard is 98 percent pure, it better be 98
15 percent pure, because if not then, your accuracy -- your
16 methods are not -- I mean, your accuracy may suffer.

17 Other points that are -- factors that are going
18 to impact the accuracy of the methods are going to be the
19 analytical method that you select. And then it just -- it
20 may depend on the chemical that you want to look at. Then
21 you're going to have to pick one thing or another. We're
22 blessed in time now that technology has advanced so much
23 that you have to have a wide portfolio of the needs that
24 you could choose, but you better pick well.

25 You need to have well-maintained instrumentation.

1 And, as I said, biomonitoring is not cheap. It's pretty
2 pricey, and instruments are not -- are expensive, and
3 maintaining them may be even more, so -- and you have to
4 have trained personnel. So you have to have people who
5 are trained to do the measurements, because again, you
6 want them to be reproducible day in and day out. And I
7 often say that at CDC when we get a new person then -- and
8 you'll look at them in the eye and you say, you know,
9 we'll talk again in a year, because that's when I think
10 that then it's going to take you about a year to get
11 familiar and comfortable really with everything that is
12 involved.

13 They look at you kind of just saying this woman
14 is crazy. But I think that at the end of the year, they
15 would agree with me that I wasn't that much off anyway.
16 And then in order to test the accuracy that are different
17 progress that you can look at, that you can use, not too
18 many for phthalates, but I'm just going to highlight one.
19 It's a German program that includes several metabolites of
20 various phthalates, four of DEHP, and then three other
21 metabolites. And actually that program was incredibly
22 important and instrumental in identifying a source of bias
23 in certain standards. And that was something that
24 researchers in Canada found out when they had purchased
25 different standards, and then they participated in this

1 external assessment program, and they started failing for
2 some compounds, which is something that was unusual
3 because they were doing pretty well before.

4 And then they could go back and then identify
5 that the source of the bias was some of the standards that
6 some of the chemical manufacturers had -- or the companies
7 that make the standards had sold, and the solutions were
8 not -- the compounds had degraded in solution. So that
9 prompted, you know, kind of like interesting just trying
10 to say, okay, well, we better look at what is important
11 where we're doing -- develop a method, because sometimes
12 we take things for granted. And you may be doing
13 everything right, but if your standards are wrong, then
14 you're going to be in trouble.

15 And actually, as a result of all these
16 investigations, even at CDC, we discovered that the
17 standards that we purchased back in the late 1990s, that
18 they were purchased from a company no longer in
19 business -- not sure whether this was the reason, but no
20 longer in business. And it turns out that several of the
21 compounds that we purchased from them turned out not to be
22 as pure as we thought they were going to be. And as a
23 result, we actually had to issue a correction.

24 Luckily for us, we hadn't always been using the
25 same standards, because they were nothing -- nothing else

1 available. And then -- but we had to issue a correction
2 for all the results that -- of NHANES since 1999. That
3 was even before my coming to working on this at CDC,
4 just -- and everybody who was working with us that we
5 provide the results within a certain time frame, then they
6 had to correct their results.

7 --o0o--

8 DR. CALAFAT: Because of the importance of
9 accuracy, then we partnered with NIST, with the National
10 Institute for Standards and Technology, in developing
11 standard reference materials. And years ago, then we, for
12 a different project, we were working on NIST procuring
13 standard reference materials actually for PAHs. That's
14 why we got samples from urine from smokers and
15 non-smokers, because we thought that, you know, like
16 smokers are going to have higher concentrations of these
17 PAHs than non-smokers, and they just go ahead and
18 characterize these materials.

19 Then we talked to NIST and then decided that in
20 addition to PAHs, we were going to measure some other
21 compounds, including actually phthalates. So as of last
22 year, NIST has a couple of standard reference materials
23 that have reference values for 11 phthalates, which are
24 the ones that we detect most frequently in NHANES. So
25 these can be used. You purchase these frozen urine

1 samples, and then you develop your method, and then you
2 could check the accuracy of your measurements using the
3 standard reference materials.

4 --o0o--

5 DR. CALAFAT: And lastly, in terms of what we're
6 doing with the states, including California as part of our
7 cooperative agreements, then we have been, in terms of
8 building capacity, we provided technical support since
9 2009, as part of just training. And we had some
10 investigators from the states coming to CDC and being
11 trained for the methods, site visits, and advisory
12 services we also provide.

13 And in 2012, as a request from the states, and
14 because we also thought that was important for us to just
15 help making sure that everybody was getting comparable
16 results, we started, what we call, a quality assurance
17 program and providing performance testing materials for
18 different chemical classes, including phthalates and other
19 plasticizers.

20 --o0o--

21 DR. CALAFAT: So with all of this, now we have a
22 pretty -- we're pretty pleased with the methodology that
23 we have for measuring phthalates. And it wouldn't do us
24 any good to develop a method. We were doing nothing with
25 it, but we have been just using the method to assess

1 exposure to phthalates in many different populations. And
2 this is just an example of to show that how prevalent
3 exposure to phthalates is in the United States.

4 These are data. The latest NHANES released data
5 from 2011/2012 that showed that pretty much everyone in
6 the U.S. population, juvenile population six years of age
7 and older is exposed to various different phthalates.

8 --o0o--

9 DR. CALAFAT: But are we supposed to -- these
10 phthalates -- I mean, is it always the same thing or are
11 we seeing changes? And actually -- and I apologize for
12 the way the slides are. The title is almost jumping,
13 but -- the -- we actually noticed that exposure to certain
14 phthalates are changing. What we measure are not
15 exposures. We're measuring concentrations, but NHANES is
16 only one sample -- one spot sample. But it seems pretty
17 evident for me that then if you're looking at the data
18 that goes from 2001/2002 until to 2011/12, so these are
19 six cycles of NHANES. We're talking about 12 years worth
20 of data.

21 And then every cycle we have about 2,500 people.
22 So here we're talking about 15,000 people that we have
23 sampled throughout the years, more samples than we even
24 want to acknowledge. Then you see that there are an
25 increase -- a decrease in the concentrations of the

1 metabolite of dibutyl phthalates shown in green in on the
2 slide. We measure monobutyl phthalate and we have
3 observed an about 60 percent decrease in 2012 compared to
4 2001/2002, if we categorize exposure based on these
5 concentrations.

6 However, while this concentration is decreasing,
7 there seems to be a parallel increase in the
8 concentrations of the metabolite of diisobutyl phthalate.
9 Both of these phthalates are four carbon phthalates.
10 They're isomeric. Their structures are very similar. So
11 is it possible that dibutyl phthalate, which is one of the
12 regulated phthalates, concentrations have been going down
13 because the industry had removed these chemicals from
14 products, and then have replaced the dibutyl phthalate
15 with diisobutyl phthalate, we seem to see an increase in
16 concentrations about 120 percent.

17 --o0o--

18 DR. CALAFAT: But this is not restricted only to
19 the small phthalates. And these are the small phthalates
20 that would be used in like more in the personal care
21 products, would be used in lacquers and paints, would be
22 use in certain medications.

23 But what about the larger phthalates? What about
24 the DEHP ones, a phthalate that many people are familiar
25 with. And another phthalate that has been -- has been

1 regulated has been some legislative action. And this --
2 in this slide, then we're seeing that, again, we're
3 measuring the concentrations of some metabolites. And so
4 although here it says DINP and DEHP, what we're really
5 measuring is not the parent compound, but the metabolites
6 of the parent compound.

7 But because they're a mouthful, then I thought
8 that it was easier to just display like this for the
9 non-chemist audiences. So anyway, we're seeing -- since
10 2005 and 2006, we're seeing a decrease in concentrations
11 of the DEHP metabolites, so exposures to DEHP, that have
12 decreased about 70 percent, a little short of 70 percent.

13 At the same time, we see -- and those are the
14 bars that are shown in the light gray, I guess. And at
15 the same time, we're seeing an increase in the
16 concentrations of the metabolites of another phthalate.
17 Instead of having eight carbons, like DEHP, DINP has nine
18 carbons. Again, very similar -- I mean, well --
19 relatively similar structure, relatively similar
20 performance in products. So is it possible that as DEHP
21 is moving out of the market, DINP is getting more in
22 there, so as a result, we're getting more exposure?

23 --o0o--

24 DR. CALAFAT: So we thought, well, that's
25 interesting, but what could be also happening is are we

1 also restricted to moving one phthalate into another or --
2 and with other compounds that could be replacing the
3 phthalates as well.

4 And then one example is of a known phthalate
5 plasticizer is similarly structured, but not -- I mean, it
6 seems the same, but believe me it's, then is a
7 non-phthalate and it's called DINCH. And it was
8 introduced as an alternative to phthalates in Europe in
9 2002. And it was a replacement, particularly for DEHP and
10 for sensitive applications, so mainly used in toys for
11 kids, in medical devices, and as well as in food
12 packaging.

13 And then, like for phthalates -- exactly as for
14 phthalates, then we are using -- we could use metabolites
15 of DINCH as biomarkers of exposure. And in this graph
16 then, you can see that DINCH metabolizes into different
17 compounds. And each one of them actually is much more
18 complicated, but let's just say for the sake of the talk
19 right now, that you go to the very bottom of the slide and
20 you see that there is one compound that makes about 24
21 percent of the chemicals. So one would say let's go ahead
22 and measure this compound, use it as a biomarker.

23 The problem in here is that this is a nonspecific
24 biomarker. So what is depicted here as CHDA is a
25 metabolite of DINCH, but could be a metabolite of many

1 other compounds. So looking at this may not be really a
2 very good indication that there is exposure to DINCH
3 unless you measure something else.

4 So instead, we chose to use, as a biomarker, what
5 is called OH-MINCH. That is about 11 percent of the dose
6 of DINCH. So this is the biomarker that in the next
7 slides that I'm going to be showing the data we generated
8 at CDC was based on the results for that particular
9 compound.

10 --o0o--

11 DR. CALAFAT: I'm doing well with time?

12 So it turns out that the exposures to DINCH seem
13 also to be changing. So we had collected some samples,
14 and those are convenience samples of adults here in the
15 United States. And then we collected samples that
16 they're -- partly, the samples are used as part of our
17 method development. And then we had samples collected at
18 six points in time between 2000 and 2012. And what is
19 interesting here, the table is -- kind of has a lot of
20 data, but would be enough for you to remember that in
21 2000 -- the samples collected in 2000 and 2001 we did not
22 detect any -- the DINCH metabolite at all, which makes a
23 lot of sense, because it wasn't introduced in the market
24 until 2002. So if we have seen it before, we are in
25 trouble.

1 So -- but then, as we move down, then 2007, '09,
2 '11, and '12 what we're seeing is an increase in the
3 frequency of detection, and in the upper end kind of an
4 increase in the concentration, suggesting that we indeed
5 may be seeing an increase in concentration to this
6 metabolite, because it's -- now that it's in the market,
7 the exposures are increasing.

8 What was very reassuring is that similar results
9 were observed in Germany.

10 --o0o--

11 DR. CALAFAT: And in here, what I'm showing, are
12 the example of the environmental specimen bank data from
13 Germany. And the sampling design is quite different from
14 the design in NHANES. Those are 24 hours urine collection
15 from college students in four different areas in Germany.
16 They collect 60 samples per year, and they measured four
17 different metabolites. And then they summed them also --
18 the different metabolites that we had in that cartoon.
19 They measured them. They summed them all. And what they
20 saw was very similar to what we saw too.

21 In the samples collected in 1990, 2000 and --
22 sorry, 1999 and 2003, they did not detect. There was no
23 evidence of any exposure to DINCH, while the
24 concentrations and the frequency of detection in 2006,
25 '09, and '12 increased. And the labels were different

1 because the methods are different.

2 So we're working to getting our method a little
3 more sensitive. They were only measuring DINCH. We are
4 measuring DINCH with all the other phthalates, so here
5 comes the compromise I spoke about. Our data from NHANES
6 2011/2012, there are spot samples from everyone six years
7 of age and older. We only measured one metabolite and we
8 detected this DINCH metabolite in 25 percent of the
9 samples, at a wide range of concentration going between
10 non-detectable and our limit of detection, was 0.4 parts
11 per billion to about 170 parts per billion.

12 So very different strategy, sampling designs,
13 different populations, but the data seem to suggest that
14 exposures in Germany to DINCH are going up, exposures in
15 the United States are going up as well.

16 --o0o--

17 DR. CALAFAT: So this is another way just to say
18 that it seems that DINCH and other phthalates may be
19 replacing DEHP, and that -- the fact that these compounds
20 are replacing DEHP, which has a very defined structure.
21 And those compounds, on the other hand, are isomers. They
22 have branches here and there. And the branches may be in
23 different parts of the molecule, which is tricky in
24 itself, because it makes it more difficult to look to just
25 track the metabolites and measure the concentrations.

1 So we're moving from looking at very defined
2 compounds that they have a single nice beautiful peak,
3 that's what we like to see, chemists, into something that
4 is a little bit of a mess, because it's a combination of
5 many different compounds bunched together.

6 Starting with NHANES 2013-14 and the data from --
7 these data are going to be released later this year. And
8 CHS doesn't have the sampling weights yet for NHANES
9 '13/'14. That's why the data cannot be released yet, but
10 we will have -- in addition to the metabolite that I
11 mentioned before, the hydroxy-MINCH, the OH-MINCH, we are
12 also going to be providing results for the carboxy-MINCH.
13 It was only about two percent of the dose, but then we're
14 trying to add as many compounds as possible from the same
15 parent.

16 --o0o--

17 DR. CALAFAT: So I said it before, that the
18 strict monitor exposure to phthalates, because the
19 exposures are constantly evolving, and we really don't
20 know exactly what the market is going to show. But
21 because of this, then we need to have methods to identify
22 new biomarkers. And we have been pretty successful at
23 using in vitro metabolism. When we have a compound that
24 we think is going to be in the market, then we do a short
25 study to identify whether -- which ones are the major

1 metabolites -- in vitro metabolites, then we have
2 partnered with some investigators, particularly at EPA, in
3 doing some very crude, I would say, animal studies -- that
4 then, you know, the animals are dosed with a high level,
5 high dose of the chemical that we want to look at. And
6 then we try to identify the new biomarkers.

7 And in some cases, we have been lucky in having
8 some human studies for these compounds, that they don't
9 happen here in the United States, but in Germany they have
10 been able to dose themselves, the investigators, and then
11 just do like a time course study that is based on a few
12 individuals, but these are people, not rats. So that --
13 this is very important information.

14 It's important when we monitor the changes in
15 exposures that again we select the right biomarker, and to
16 have access to these archived urine samples, because they
17 can be either general population sample. They even can be
18 convenience samples, just to see whether we can identify
19 the exposure trends.

20 --o0o--

21 DR. CALAFAT: I say I have said these many, many
22 times, but I'm going to repeat it again, if -- it's one
23 thing that is very important to remember is that we could
24 measure -- as a chemist, I should be able to measure
25 pretty much anything, if I have a standard. Otherwise,

1 I'm a lousy one. And it says that if I can only measure
2 five, and I do not measure 15, then I'm the worst chemist.
3 But because -- but we can measure many things in a sample,
4 but we really have a -- we need additional information to
5 make sure that that measurement is really truly an
6 exposure biomarker and not a pure just chemical analyte.

7 --o0o--

8 DR. CALAFAT: And this is one example that I
9 think -- didn't show very well -- one example that I think
10 that illustrates very well the point I made before. So I
11 meant -- I talked before about diisononyl phthalate. This
12 is a phthalate that has nine carbons, and it metabolizes
13 in many different metabolites, but there are two of them
14 that we have been monitoring in NHANES. One is the
15 mono-isononyl phthalate that only represents about two
16 percent of the dose, very much liked the DINCH. There's
17 some that are very small. And then another metabolite
18 that represents about 10 percent of it.

19 Well, what happened is that data from NHANES
20 2005/2006, if you look on the boxed area in -- on the
21 slide, then you can see that we measured both compounds.
22 Those are metabolites of the same precursor, but then we
23 only found that about 13 percent of people had detectable
24 concentrations of the minor metabolite.

25 On the other hand, about 82 percent of people had

1 non-detectable concentrations of that compound, but had
2 detectable concentration of the more sensitive biomarker.
3 So what does this mean?

4 That if we had totally relied on the measurements
5 of the minor biomarker, we would have said that 82 percent
6 of the people who were indeed exposed to the chemical were
7 not exposed. So you would have misclassified exposure of
8 this number of participants, number of people if you are
9 not looking at the right biomarker.

10 So it is important to look at the most sensitive
11 biomarker, and if possible, and you can incorporate it in
12 the method, then measure as many chemicals from the parent
13 compounds as possible.

14 --o0o--

15 DR. CALAFAT: Okay. I should be done.

16 This is another example that kind of illustrates
17 the evolution that we have been following in terms of
18 phthalates, and this is the dibutyl phthalate in -- so
19 these are four-carbon phthalates. And we have -- these
20 are isomers. And you can see, you know, there is
21 likely -- they're similar. They have four carbons in the
22 alkyl chain, and they metabolize into, what we call,
23 MnP -- MnBP and MiBP. And we have been measuring these
24 compounds, these different analytes since 2001. So those
25 represent about more than 80 percent in one case and about

1 70 percent of the dose in the case of diisobutyl
2 phthalate.

3 But these compounds are similar, but as I said,
4 there is likely difference, so they metabolize
5 differently. So in the case of diisobutyl phthalate on
6 the right side of the slide, then the mono-isobutyl
7 phthalate may metabolize further into an oxidated
8 metabolite that, until now, we had not measured. The
9 standards were not available, but we were lucky enough to
10 get some standards from Holger Koch who's -- are our
11 friends in Germany. They have done a lot of work, and we
12 have been working together for -- I mean, since 2002, so a
13 long time.

14 So they were kind enough to provide us with
15 standards from the compound that represents 20 percent of
16 the dose of diisobutyl phthalate on the right side, and
17 then the metabolite that represents about seven percent of
18 the dose of monobutyl phthalate on the left side.

19 We're going to be measuring these four different
20 metabolites in now -- in NHANES starting with NHANES 2013
21 and '14. And there's also in this slide -- I put it up
22 here, because remember I said we measure concentrations.
23 So when we measured the concentration on MnBP, or MBP
24 short, MiBP, and you see the levels, then it may be
25 misleading if you don't know that one represents 85

1 percent of the dose, but the other is only 77 -- 70
2 percent of the dose. So the exposures may be higher.

3 I mean, again, we measure concentrations. We
4 don't measure exposures. You need much more information
5 to go and get what indeed was the exposure.

6 --o0o--

7 DR. CALAFAT: So in terms -- I said also I wanted
8 to provide an example of toxicology and exposure. And
9 dipentyl phthalate is one of the -- in animal studies is
10 one of the most toxic compounds. So we did a study to
11 determine metabolite -- the metabolism of these compounds
12 in rats, and then we got -- again, we didn't do the rat --
13 the animal work that was done at EPA by Earl Gray. And
14 they had nine rats, and they gave them one single oral
15 dose of the dipentyl phthalate, pretty large, probably 100
16 milligrams per killogram. And then they obtained -- they
17 collected the urine 24 hours after the dose and 48 hours
18 after the dose.

19 And then what we observed is we identified three
20 major metabolites and -- in the 24 hours and 48 hours. So
21 we thought, okay, let's just go and use these metabolites
22 to try to assess exposure to dipentyl phthalate. On the
23 right side of the slide, you can see that these different
24 metabolites correlated pretty well, suggesting that the
25 source of exposure was the same, which again we knew in

1 this case those were the rats and we knew what we gave
2 them.

3 --o0o--

4 DR. CALAFAT: So when we moved into the people,
5 then we had -- we had about 45 samples -- human samples
6 that we collected anonymously in 2009, those were adult
7 samples. And then we found a pretty low detection
8 frequency for the specific metabolite of dipentyl
9 phthalate. And we observed that there was no correlation
10 between the different metabolites suggesting that it's
11 possible then that what we saw were exposures to some
12 other phthalates not really to the dipentyl phthalate, and
13 that exposure to dipentyl phthalate it doesn't seem to be
14 that prevalent at least in the United States at least back
15 then.

16 --o0o--

17 DR. CALAFAT: So what exposure biomarkers should
18 be measuring? We need to think. Again, this is going to
19 be dictated by your analytical method in large part. So
20 can we more analyze, when do we stop? You know, like have
21 we -- can we have 20 analytes 30, 40? It just -- it gets
22 to the point that your method is not going to be stable
23 anymore.

24 So it's going to depend on the method, but you
25 really would have to do quite a bit of research to

1 determine what is important to measure. And then the
2 compromise within the method is how many -- if I can put
3 10 compounds -- and I'm just throwing a number -- then
4 which one of the 10 that would be -- give the most
5 important information. Because maybe you tried to put 12,
6 then your method is just going to crash, and then you're
7 not going to have reliable information.

8 It may depend on the instrumentation that you
9 have. And then there is one example of the diisodecyl
10 phthalate. This is a compound with 10 carbons. And it is
11 an isomer, so similar, that is called DPHP. This had a
12 defined structure. And then the issue is that in order to
13 differentiate it from the exposure of the DIDP, then you
14 would need various specific instrumentation that is quite
15 expensive and may not be worthwhile looking into, because
16 while looking at the exposure to DIDP, and this is an
17 isomer that has this big -- instead of the single peak has
18 this big block, then you're already capturing that.

19 Remember to think about the toxicokinetics of the
20 chemical, and then in terms of what is -- what is the
21 chemical that is more abundant and is it specific or not,
22 and then look at the target population. So it depends on
23 the study that you're looking into then, your exposures
24 may be population specific. So if you have exposure that
25 you have, it could be even age dependent. You know, you

1 may have children that they may be exposed to more dust,
2 for example, than adults are. And then, you know, like is
3 this something that is important for me to look at? And
4 then if there are some compounds that you think that they
5 may be partitioning more, do you want to look at those in
6 a population of children not in adults?

7 And certainly in the nature of exposure it's very
8 different to look at background exposure versus specific
9 populations. That may happen from an accident
10 contamination -- I mean, accidental contamination on even
11 occupational exposures.

12 --o0o--

13 DR. CALAFAT: So as -- wrapping up and giving
14 like my kind of take-home messages, we know Americans are
15 really exposed to phthalates. There's no doubt about it.
16 But the market changes are just impacting the formulations
17 and that are being used in products. And this, in turn,
18 is impacting the exposure to phthalates, to both
19 phthalates and non-phthalates.

20 These exposures are going to be changing all the
21 time, so we need to make sure that we can address them. I
22 already mentioned that we need to -- when we think about
23 biomonitoring, we need to think about the toxicokinetics
24 of the chemicals that we're looking at, and making sure
25 that the method that we have is adequate for the intended

1 purpose of the study. So it may be that then one size
2 doesn't really fit all.

3 And then I think it is also important that we
4 think about banking of urine, because this can be
5 incredibly useful in identifying trends evaluation, and in
6 thinking even about chemicals that they may not be on the
7 radar right now.

8 --o0o--

9 DR. CALAFAT: We're going to continue NHANES and
10 the studies on the targeted populations, because we really
11 want to track the exposures to these legacy phthalates and
12 the replacement chemicals. And then we also want to fill
13 in the data gaps to understand better the temporal trends
14 and more importantly why are these temporal trends
15 happening, what are the underlying reasons? We are a
16 public health agency, and we're interested in preventing.
17 So, if at all possible, we want to prevent exposures
18 before they happen. And we want to identify and
19 incorporate these different phthalates and replacement
20 biomarkers.

21 --o0o--

22 DR. CALAFAT: And my last slide will be to give
23 credit to the people who have done the work that I
24 presented today. And Manori Silva, we've been working
25 together since 2002. And she's been instrumental in the

1 Biomonitoring Program. Ella and Jim, and the past lab
2 members as well, NCHS, our sister, I guess, agency. We're
3 part of CDC all for collecting NHANES, and my dear
4 collaborators for their support throughout the years.

5 --o0o--

6 DR. CALAFAT: Thank you, all.

7 (Applause.)

8 CHAIRPERSON LUDERER: Thank you very much, Dr.
9 Calafat. That was a very interesting presentation.

10 We have time now for some questions from the
11 Panel, specific questions to Dr. Calafat. And then we'll
12 take public comment and then we'll have more time for
13 discussion.

14 Dr. Cranor.

15 PANEL MEMBER CRANOR: Yes. Thank you very much.
16 That was very informative. And I liked your message at
17 the end. And I just want to pursue that a little bit.
18 You said you're in the public health business, and you're
19 seeking to prevent diseases, and I think that's terrific.
20 I think the problem with biomonitoring has been how to do
21 that in a more proactive or quicker way.

22 And I liked your work with DINCH, because that
23 seems to be appearing unanticipated. And so I guess I
24 have two or three questions related to this. We talked a
25 little before the meeting about it, but I'll repeat it.

1 Are there -- do you have -- partly you have a plan here
2 for looking at whole classes of substances.

3 DR. CALAFAT: Um-hmm.

4 PANEL MEMBER CRANOR: And that seems to be a good
5 idea and seeing if new things appear. And then you have
6 DINCH as outside the class. That's one question.

7 The second question would be -- and it's outside
8 your scope, but a terrific thing to do would be when you
9 see things appearing, is there some kind of obvious
10 connection to a toxicology program to test the toxicity of
11 this new thing, what is it like compared to the other
12 things that we have?

13 So could you talk about those two things?

14 DR. CALAFAT: Yeah. In terms of the -- looking
15 at different compounds and grouping them, so the grouping
16 we -- in fact, we are doing grouping. I mean,
17 analytically, you group the chemicals by the structure, by
18 the chemistry, and by the properties, because this is
19 how -- these are the properties that we need to take
20 advantage of to separate them to strike them from the
21 urine in this case, and then to detect them. So that
22 would be one grouping.

23 So that's while actually we had changed our
24 grouping on the phthalates, because actually we measured
25 DINCH as part of the phthalates panel that we call, even

1 though DINCH is not a phthalate. So we changed the name.
2 It used to be the phthalates panel, and I think now we
3 call it plasticize -- phthalate plasticizers and
4 alternatives. So just to give us enough room so we can
5 include some additional chemicals.

6 You may also group the chemicals based on their
7 toxicology or their activity. So it really -- the
8 grouping of the chemicals can be incredibly helpful, but
9 it doesn't have to be only one type of grouping. The
10 grouping is really going to depend again on the intended
11 purposes of what -- how you want to use the group data.

12 So in terms of toxicology, it may just be very
13 different, because you may have -- you know, in addition
14 to phthalates, you may have something else that you could
15 group in there.

16 In terms of the -- what are these other chemicals
17 out there? I said biomonitoring is one tool.
18 Biomonitoring is a targeted -- provides targeted
19 measurements. So we know what we're looking for. That is
20 the non-targeted approach that you could go and look into.

21 I think for the non-targeted approach, because
22 you don't really know exactly what you're looking for,
23 that's the beauty about it, is I think I probably would
24 start not with humans -- human samples. Those are pretty
25 complex. And the levels are very low. So that's one

1 thing that I actually didn't mention, but I guess it goes
2 without saying. You know, that's why we want to have
3 these methods so sensitive. We are looking at trace
4 levels, when we have so much more of everything in a urine
5 sample than the chemical we want to look for.

6 So I would say that if I want to look at
7 non-targeted approach, if I want to see what is upcoming,
8 I will look for an environmental sample, just -- that
9 sample, for example. The levels will be so much higher,
10 so you're not going to be fighting the analytics of your
11 system. So then look at the levels of these chemicals in
12 the environment.

13 Granted, in the dust, you're not going to see the
14 metabolites, for example, of phthalates. You would see
15 the parent compound. But then once you get the big hits,
16 then you can go ahead and then just try to identify what
17 are the right metabolites for me to look whether these
18 chemicals are present in humans.

19 So, in my opinion -- and I do not know that much
20 about non-targeted approach, and we cannot do non-targeted
21 approaches, so we are set with a targeted approach. I
22 think that that may be more successful than trying to get
23 very low concentrations of a chemical, that there may be
24 big hits, but believe me, outside, they're going to be so
25 much larger than what you're going to find in people. I

1 don't know if I did answer your question.

2 PANEL MEMBER CRANOR: Thank you.

3 CHAIRPERSON LUDERER: Dr. Quintana.

4 PANEL MEMBER QUINTANA: Hi. Thank you for your
5 presentation.

6 I was struck by something you said about these
7 German samples that were available, because as you
8 mentioned, the NHANES samples are spot urine samples. And
9 some of the issues of looking at metabolites like this,
10 which I believe have a very short half-life --

11 DR. CALAFAT: Um-hmm.

12 PANEL MEMBER QUINTANA: -- are how accurate are
13 spot samples in predicting that person's actual kind of
14 stable exposure? And I was curious about these German
15 samples which have 24-hour urines, 60 samples a year.
16 That's a really amazing resource, right?

17 DR. CALAFAT: Yeah, but it's only collected once.
18 So there's 60 samples.

19 PANEL MEMBER QUINTANA: Oh, oh. Sixty.

20 DR. CALAFAT: Yeah, no, no, no. I mean, yeah,
21 then after now -- you know, I say yeah, no, there's 60
22 people, 60 students.

23 PANEL MEMBER QUINTANA: Oh. So there's not --

24 DR. CALAFAT: And each one provides 24-hour
25 samples.

1 PANEL MEMBER QUINTANA: So they're not --

2 DR. CALAFAT: No, they're not -- they're not
3 serial samples throughout the year.

4 PANEL MEMBER QUINTANA: Do you know of any
5 resource where there are multiple samples per person that
6 might get at how accurate these samples are at prediction?
7 I think that would be an important piece to add to these
8 analyses.

9 DR. CALAFAT: It's very important. I mean, and
10 you're -- there has been actually a lot of research done
11 in the past 10 years or so, I would say, regarding like
12 what we call the temporality of the exposures or the
13 variability in concentrations.

14 And I would say that, again, you know, this is
15 something that you have to factor in your study design.
16 The variability is going to be dependent, not only on the
17 half-life of the compound, which is certainly important,
18 but also in how frequent is the exposure. So most of the
19 exposures to these particular chemicals are episodic.

20 So, you know, you have it's going up and down.
21 But when it's going up and down very frequently, you kind
22 of build up -- and I hate to use the term, but kind of a
23 pseudo steady state. So you build some -- a certain
24 concentration, even though the half-life of the compound
25 is short. So the half-life may be six hours, but I'm

1 exposed every other -- every other hour. So you're going
2 to have building up and down, up and down in your body.
3 So that's also very important how frequently is the
4 exposure. Unfortunately, many times, we don't know this
5 information. We certainly don't have this information,
6 except you have like an intervention study.

7 At the same time, it's true that there is
8 variability in concentrations. And even within the
9 phthalates, there's variability in concentrations. But,
10 for example, a phthalate that would get mainly from
11 exposure through food, once -- most of the large
12 compounds, the large phthalates, that come in from dietary
13 sources.

14 We eat every day, but we eat something different
15 every day, at least adults. You know, that may be a
16 different story in children or neonates, or something like
17 this, but -- so based on what you have eaten, you're going
18 to have certain concentrations of the chemical maybe today
19 in the morning, in the afternoon not, or something in the
20 evening. And they may change from day to day.

21 So these chemicals tend to have a very poor
22 reproducibility. And when the people go and look at these
23 intraclass correlation coefficients they tend to be very
24 low, maybe 0.1, maybe 0.2 if you're lucky.

25 The story is very different when you're thinking

1 about chemicals that are coming from use of products. So
2 you tend to use the same products day in and day out. You
3 may not use the same products I use, but certainly we have
4 a certain routine. And then for those products, and those
5 certain chemicals, certain phthalates, then the
6 reproducibility is going to be so much better.

7 So if you're looking at diethyl phthalate, which
8 is the one that is used in fragrance products, and is the
9 one that it has been used kind of as a marker for exposure
10 to all personal care products, it's pretty reproducible,
11 in some cases. I mean, not only just restricted to
12 phthalates, think about triclosan, for example. You use
13 an antibacterial soap. You use it everywhere around the
14 house and everybody in the household does.

15 So the inter -- the variability is going to
16 depend on the chemical, is going to depend on the nature
17 of the exposure. And ideally, we would like to collect as
18 many samples as possible. Twenty-four hour samples
19 provide very good information about what happened
20 yesterday. But it doesn't mean that they're going to
21 give -- be good at representing what's going to happen in
22 one week, in one month, and what happened six months ago
23 when you were interested in looking at.

24 Yet, the compliance may go really down when you
25 have 24-hour samples. So my approach, and it's something

1 that I've been working with different people and I have
2 been telling them, maybe this is what we should be going
3 and doing, is pooling samples.

4 So many times people now they have, through
5 pregnancy for example, they collected one sample in the
6 first trimester, in the second trimester, in the third
7 trimester. It may not fit all the study designs. It
8 depends on what you want to look at. You want to look for
9 a healthy thing that happens in the first trimester, don't
10 pull me a sample in the third trimester, because it's not
11 going to work.

12 But when you identify your window of -- the
13 window that you want to look at, maybe try to collect more
14 than one sample, and try to collect samples throughout the
15 day. We said -- you know, sometimes we say, you know, we
16 like first morning voids. A first morning void is a spot
17 sample. It just so happens to be the first one in the
18 morning. And if it's the first one in the morning, make
19 sure it's really the first one in the morning. If that
20 person voided in the middle of the night, it's not really.
21 I mean, your analyte has already left.

22 So just collect samples at different times during
23 the day, because I think that they're going to capture
24 better the average exposure. And what we are looking into
25 is an average exposure. Like for NHANES, for example,

1 it's true we're collecting one spot sample, but when the
2 driving force that -- of what you're seeing in the urine
3 is the exposure, it doesn't matter if it's a spot sample.
4 You have enough sample size.

5 I may have caught someone before the exposure
6 happened, and then so I missed that exposure that happened
7 an hour later, but I got somebody else. So it kind of
8 averages out. And I think it's still useful to
9 characterize the average exposure. I don't know if that
10 answers it.

11 PANEL MEMBER QUINTANA: Yes.

12 DR. CALAFAT: So pooling samples may be
13 interesting, but certainly I would suggest more than one
14 is better than none. But, I mean, more than one is better
15 than one, but one is better than none.

16 (Laughter.)

17 CHAIRPERSON LUDERER: Dr. Schwarzman.

18 PANEL MEMBER SCHWARZMAN: Thank you so much for
19 your presentation. I'm curious about another aspect. I
20 think the story of DINCH is a very interesting sort of
21 cautionary tale for us, as we think about chemical
22 selection and what we're looking at and looking for. And
23 it raises for me this issue of choosing chemicals based on
24 function rather than chemical identity.

25 So here, we have a bunch of phthalates that are

1 used, the short chains interchangeably, the longer chains
2 interchangeably for different uses. And then there comes
3 along a non-phthalate plasticizer, and it raises this
4 issue of how do we make sure that we're looking for
5 substitutes that are used for the same function, but may
6 not belong to the same chemical class?

7 And California has the flexibility or has used
8 the flexibility in the past. I'm looking at the list of
9 designated chemicals and one of the categories is
10 brominated and chlorinated organic compounds used as flame
11 retardants. So that's where an instance in which a bunch
12 of chemicals that are -- may not belong to the same
13 chemical class, except that they contain halogens, but
14 they belong to the same functional class.

15 And it's an interesting idea that I think this
16 panel will continue to wrestle with about chemical
17 selection and using functional class to designate some
18 chemicals in some instances. And that's obviously
19 something that you did in choosing to look for DINCH. And
20 I was hoping that you could talk a little bit about your
21 view on that and how CDC chose DINCH and how you're
22 approaching that issue?

23 DR. CALAFAT: Going. That's a very good
24 question. And then I would say start small and build on,
25 you know, what you have to move forward. So when we

1 were -- when we started our phthalates program, I believe
2 we were measuring seven phthalate metabolites. Actually,
3 of these seven, we have taken out now two of them, because
4 one of them we didn't see at all. So after many years of
5 looking at it, it wasn't it.

6 There other one actually was the wrong biomarker.
7 So we were able to look at it in this -- I mean, because
8 we had the standard, but after we learned more about the
9 chemicals, then it couldn't be -- the body wouldn't have
10 formed it. So we would have sent the wrong information.

11 Within the years then, we learned more about the
12 chemical and started adding in new metabolites. Then you
13 know when there is public concern and then legislators
14 start looking into certain chemicals that changes may be
15 upcoming. We don't know exactly when, but then you have
16 to be kind of alert, if you want, and get information
17 about what is new in the market, what is coming up. If a
18 compound is being taken out, something else is going to
19 replace it.

20 And then when you have a program that has
21 different chemical classes, and there is chemical groups,
22 then -- and we are really lucky that we have plenty of
23 instrumentation, very talented staff, and the support -- I
24 mean, certainly Congress support will be going down, but
25 Congress support.

1 (Laughter.)

2 DR. CALAFAT: And so you can make sure that you
3 find the place for that new chemical.

4 So like DINCH went and worked beautifully into
5 the phthalates method. In terms of the organophosphate
6 flame retardants, then we're starting a panel on flame
7 retardants -- urinary flame retardants, and actually
8 includes more than the organophosphate. It includes some
9 others that are non-organophosphate based, but that are
10 flame retardants. And actually, I think it is good that
11 we can sort them within these categories.

12 It doesn't mean that we're going to be able to
13 hit every single compound in that category, but at least
14 if you get a few of them that you can use as the markers,
15 that's a starting point that helps you to work on that, at
16 least to say, okay, well if you choose well, and hopefully
17 you're going to have a few compounds that you're going to
18 see whether there's exposure or not.

19 So based on that, then you can just go and say,
20 okay, we're only keep on looking and then keep alert and
21 then try to find out what is coming next, and see whether
22 that new compound is going to work. For our purposes, it
23 sometimes is not as much as the functionality, or the use
24 of the chemical as to whether it fits within our method.

25 For example, BPA is a plasticizer. We could

1 measure BPA with the -- I mean, we're calling it a
2 plasticizer, maybe one would say, okay, why don't you put
3 it with the phthalates, and you put it with the DINCH.
4 Yet, we had the BPA in another panel, because those are
5 the phenols and BPA is a phenol, so -- but try to have the
6 tools that would allow you to look at different chemicals,
7 but understanding that unfortunately we're not going to be
8 able to get them all, and not -- certainly not all of them
9 at once.

10 CHAIRPERSON LUDERER: Dr. Fiehn has a question
11 and then we'll take some public comments.

12 PANEL MEMBER FIEHN: Thank you. I wonder
13 if -- how you view things, protocols to be combined? Some
14 of these chemicals have similar chemical properties. And
15 like, you know, Log Kow and so on. And, you know,
16 thinking about costs and thinking about effectiveness of
17 programs, it might be really useful to say, well, we go
18 from 10 targets to 40 targets. And with the appropriate
19 internal surrogate markers, we could even then still get
20 very reliable information, even if our recovery from a
21 certain specimen drops from say 85 percent to 65 percent
22 or so, you know, so at least we have some idea at a wider
23 range of compounds.

24 As you say, you know, industry chemicals change
25 all the time. Still yet we want to, you know, look over

1 yearly trends, over long, let's say, decades and so on.
2 And I don't think it's -- it can be cost effective to say,
3 you know, we have here five compounds, and here we have
4 five compounds, and here we have five compounds. For each
5 of those, we would have very dedicated methods, and then
6 we, you know, look at thousands of chemicals.

7 I think we have to adopt standards or ideas how
8 to do something we call, in my area, widely targeted
9 approaches. Maybe you want to comment on that
10 perspective.

11 DR. CALAFAT: I mean, I think it really depends
12 on what you're trying to use the method for. If you're
13 thinking about the national survey, I wouldn't recommend
14 going the way you're going, because your method is not
15 going to be stable, if you're putting 40 compounds. I
16 mean, I can tell you.

17 You're not going to get the -- we use internal
18 standards, and we -- it is much better than using no
19 internal standards. But the internal standards are really
20 helping in detection part. So you're right about the
21 recovery, but then in the part with the detection that we
22 use mass spectrometry, that may not be the case. And you
23 may be facing tremendous -- and I may be very -- getting
24 very technical, but I think you understand where I'm
25 going -- matrix effects.

1 So you may not have been able -- in order to keep
2 a very small compound and one that was very large, you may
3 not have been able to clean your sample enough, because
4 your -- the compound that you wanted the little one would
5 have left. And then that would turn out into a sample
6 that is pretty dirty. And if you have to do many
7 injections, because this is a national program that has a
8 lot of -- I mean, number of samples, that may not be very
9 cost effective, because you're going to have to do a lot
10 of maintenance of the instruments.

11 At the same time, I say before, not one size fits
12 all. Then you may want to have, like one kind of
13 screening method, if you want, that then you can just look
14 for certain samples, I mean, for a small number of
15 samples. That I think is important to try to bank
16 samples.

17 If you remember, we had the data from DINCH that
18 is from NHANES that are about 2,500 people. But we pretty
19 much got kind of the same result looking at between 50 and
20 100 samples that they're convenience samplings in
21 different times, you know, in different years.

22 So it's -- you may be able to get some
23 information, and for -- in one study design, that you may
24 not be able to get for a larger study. So I'm not
25 advocating that you would say you can only measure five

1 compounds in a method. This is not what I'm saying.

2 What I'm saying is that you need to develop a
3 method that you can feel confident that is going to be
4 reproducible, because what you want to make sure is that
5 the results that you're providing -- and these are results
6 that may be used for policy -- may have policy
7 implications, may have, you know, a bunch of different
8 implications that you want to make sure that then you can
9 vouch for those data now, and you can vouch for them in
10 five years.

11 But I'm not saying -- you're going to know your
12 method. You know what you can put in there. And then at
13 the same time, often, because you're looking at these
14 trends if you want, when one chemical goes out, then -- I
15 mean, after you have seen that that chemical didn't change
16 for years, may it's time to say, okay, they'll just cycle
17 it off and then put something else in there.

18 So these methods have to be dynamic all the time.
19 So I guess that's why I like a lab. It's always
20 constantly changing and evolving. So I don't think there
21 is one way of saying this is it, but I would just say know
22 your method and trust your chemist.

23 (Laughter.)

24 CHAIRPERSON LUDERER: I think that's a great
25 segue to our public comments.

1 So I think I saw some yellow cards, and we do
2 have some people who wish to comment.

3 DR. CALAFAT: Turn around now.

4 CHAIRPERSON LUDERER: And then we'll have you
5 come back for more discussion afterwards.

6 All right. Thank you. So all right, we have 10
7 minutes and two commenters. The first commenter will be
8 Nancy Buermeyer from the Breast Cancer Fund.

9 MS. BUERMEYER: Thank you very much. Again,
10 Nancy Buermeyer of the Breast Cancer Fund.

11 Thank you as always to the Panel for your
12 incredibly hard work on these issues and for letting us
13 come up here and make comment about it. And a very
14 special thank you to Dr. Calafat and Lovisa for making the
15 trip in from Atlanta. It's an incredible treat to have
16 you here. My scientists in particular were very excited
17 to know that Dr. Calafat was going to be here, as she is,
18 as we like to call her, the mother of biomonitoring.

19 (Laughter.)

20 DR. CALAFAT: That's very nice.

21 (Laughter.)

22 MS. BUERMEYER: And as an advocate, I will say
23 that this data that comes out of both the CDC and the
24 State of California is invaluable in our efforts in making
25 the case for controls on exposure to these chemicals. If

1 we can't show to policymakers that not only are the
2 chemicals in the environment but they're actually getting
3 into people, it makes our case in refuting the chemical
4 industry that much more difficult.

5 And so thank you for your ongoing work. The
6 NHANES data gets used all the time in the work that we do.
7 I did want to mention that the chart that you put in one
8 of your slides on the frequency of detection was super,
9 super useful. And I don't remember seeing that in the
10 general charts that show the geometric mean and the N
11 samples.

12 And I don't know if that's because over time the
13 level of detection gets impacted by the level of
14 detection -- the level of -- yeah, whether the more
15 sensitive methods. But as an advocate, being able to say
16 that 100 percent of people are exposed to DINP when I'm
17 trying to argue to keep DINP out of toys, wicked useful
18 and really hard to figure out as an advocate, particularly
19 when you're looking at multiple metabolites for a
20 particular chemical.

21 So I would put my pitch in for you guys to do
22 that more often, because I think -- I know it can be done,
23 but my sense is it's a complicated thing to go into the
24 interstices of the data and do it and well beyond my
25 capabilities.

1 So thank you for doing it here. Keep it up for
2 this and other chemicals. And just generally thank you to
3 the programs, both the national and the California Program
4 and for your -- the Panel's guidance in pulling these
5 things together.

6 And I look forward to talking more about
7 phthalates later in the program.

8 Thanks.

9 DR. CALAFAT: So thank you. Actually, that data
10 is easy to get out. I mean is -- we don't put it on the
11 exposure report tables. Is it okay?

12 I feel much better.

13 (Laughter.)

14 DR. CALAFAT: But if you go into the NHANES
15 website -- on the NHANES website where the data are
16 posted, there is a place that is called the document file.
17 So in that document file it describes the variables of the
18 name of the chemicals. And then it's going to give you
19 how many were detectable, and how many were not. So the
20 numbers I took where I just went into the metabolite, and
21 then just had, okay, this is the number -- the total
22 number of samples. This is how many samples were
23 detectable.

24 And I believe that the code is zero for -- I
25 can't remember. I email -- now, I can't remember. I

1 don't want to say something that is wrong. But that one
2 is very easy. If you want to do it by subset, so going
3 into like our age or sex or race ethnicity, then you would
4 have to go into the data -- the raw data and calculate it
5 yourself.

6 MS. BUERMEYER: And does it show for different
7 metabolites?

8 MS. HOOVER: Can you talk into the mic?

9 DR. CALAFAT: What she's asking is that whether
10 it shows for every metabolite, yes. It would show for
11 every metabolite that we measure, because each one of them
12 has a name assigned to it, and then each one of them
13 they're going to show the frequency table.

14 MS. BUERMEYER: Just one more real quick
15 question. So if you find -- so if there's four
16 metabolites for a particular parent compound, will you
17 detect each of those metabolites in the same number of
18 samples. Like if you have it, will you have all four
19 metabolites?

20 DR. CALAFAT: Not necessarily. So -- but if I
21 find -- if I have four metabolites, for example, DEHP and
22 I measure four metabolites and one of them was 100
23 percent, is 100 percent detection, yes.

24 MS. BUERMEYER: Okay.

25 CHAIRPERSON LUDERER: We have quick question.

1 Dr. Bartell.

2 PANEL MEMBER BARTELL: Yeah. Just to follow-up
3 on that topic of discussion. You know, I think, if I'm
4 not mistaken, one of the complicating factors, and maybe
5 Antonia can comment on this, in interpreting some of the
6 time trends, in terms of percent detected, as you alluded
7 to, is that there can be changes in the limit of
8 detection.

9 And so I was hoping you might actually clarify
10 for us, Antonia, in your slide number 14, you had the
11 table for OH-MINCH showing, you know, trend over time and
12 detection frequency. And there's a footnote there saying
13 LOD 0.4 micrograms per liter. So was that the same LOD
14 throughout all the years and were those all tested at the
15 same time?

16 DR. CALAFAT: Yes. Those samples were archived
17 samples. And then until we had the method, we didn't
18 analyze them. We analyzed them all at the same time, so
19 it was the same method that was the detection limit for
20 all of them, yeah.

21 PANEL MEMBER BARTELL: Thank you. And I think
22 that's an important distinction if you were going back
23 trying to put together a table like this looking at past
24 NHANES, you might -- you know, you'd have to look very
25 carefully to see if that limit of detection changed

1 throughout that period of time.

2 DR. CALAFAT: Yeah, because certainly a detection
3 frequency -- we talked about it earlier today. That
4 really depends on your limit of detection. You could have
5 100 percent. I mean, really, we could have the best
6 method possible with very, very good sensitivity, we could
7 have 100 percent for everything.

8 CHAIRPERSON LUDERER: Thank you. We have another
9 public comment, and this is from Veena Singla from the
10 Natural Resources Defense Council.

11 DR. SINGLA: Hello. Good morning. Veena Singla
12 with the Natural Resources Defense Council.

13 I just wanted to echo Nancy's thanks to all of
14 you. And it's wonderful to see you, Dr. Calafat, in
15 person after reading so many of your papers.

16 (Laughter.)

17 DR. SINGLA: And I just wanted to highlight one
18 point that Dr. Calafat had mentioned, in terms of
19 exposures to specific populations may be different. And
20 she had highlighted young children as one example in terms
21 of their exposure to indoor dust. I also wanted to
22 mention the risks to occupational populations, especially
23 with exposure to phthalates from personal care and beauty
24 products for low income and minority women who may work in
25 beauty salons and nail salons, and also people who work in

1 cleaning professions and are exposed during their work to
2 cleaning products that may contain phthalates.

3 And that the risks for these specific populations
4 for phthalate exposures could be much higher than the kind
5 of average or general population, which was presented in
6 the graphs today.

7 Thank you.

8 CHAIRPERSON LUDERER: Thank you very much for the
9 comments. Now, we have time for additional discussion
10 with the Panel and with Dr. Calafat. And, Dr.
11 DiBartolomeis, would you like to speak? Yes.

12 DR. DiBARTOLOMEIS: So just a question for Mother
13 Calafat.

14 (Laughter.)

15 DR. DiBARTOLOMEIS: Actually, I could have asked
16 this yesterday, but I had forgotten. Since CDC is out
17 ahead in a lot of ways in developing methods, maybe even
18 for the first time worldwide, it's hard to say, you know,
19 may individual researchers are working on this as well.
20 And from time to time, we run into this problem too.

21 There is no performance testing validation for
22 new methods that are out there on the cutting edge. So
23 what do you advise or how do you guys internally validate
24 your own internal methods? Is it just, you know,
25 something internal or do you have a third party that you

1 go to or other scientists? Would you mind -- you know,
2 because we have that -- this situation comes up for us.

3 Thanks.

4 DR. CALAFAT: Well, to make a long answer short
5 is we have not. There is not a body that would just go
6 and say this is -- this method is kind of certified.
7 Something I have been thinking a lot for many years, you
8 know, you wouldn't do an epi study without proper IRB.
9 And it's -- but there's really nothing -- oh, you're back.
10 I need to talk to you there. Sorry. I just got
11 distracted.

12 (Laughter.)

13 DR. CALAFAT: So we start the method and then we
14 just do everything that we know that could be -- and we
15 try to think about everything that we should think about
16 before we say the method is ready to go.

17 This doesn't mean that we get it perfect every
18 time, and we have nothing to contrast with. In certain
19 cases, you know, like as you start working on something
20 and then somebody works on the same thing, you know, like
21 my interactions with Holger in Germany, they have been
22 working on DINCH, and then we were working on DINCH, and
23 then it's reassuring to see that you're seeing -- getting
24 similar results. But there are very few, very few
25 programs that would evaluate the performance of your

1 method.

2 There are some that test your accuracy, but
3 that's it. And then -- but in addition to accuracy, then
4 you have again, you know, like is that is your method
5 reproducible. So you may be just lucky. And sometimes --
6 I mean, I remember sometime someone said, I want the
7 results that you get from everyone, not from your best
8 chemist. And then, you know, like it's something that
9 this hasn't been captured yet.

10 And I don't know what we would need to do. But
11 certainly I think as the field is moving and going -- I
12 mean, it's just progressing, we really need to start
13 thinking about what's the next step. So if a lab comes
14 and says, you know, I can do these measurements. Can I
15 trust the measurements? So that's something that now is,
16 in many cases, we actually do not know.

17 DR. DiBARTOLOMEIS: Thank you.

18 CHAIRPERSON LUDERER: Dr. She.

19 DR. SHE: Thank you very much, Antonia. I think
20 everyone feels your talk is so important, but especially
21 important for the laboratory person as a chemist.

22 So I like you emphasize the foundation of an
23 analytic chemist to the Biomonitoring Program how
24 important the PM is. And to go from there and then you
25 also talk about -- when you talk about the criteria for

1 method, you emphasized compromise. So that compromise is
2 a word of the analytic chemist that I appreciate so much.

3 For example, when we do an intervention study,
4 this criteria you put there, accuracy maybe not so
5 important compared to precision and the reproducibility.
6 So compromise of a set of criteria of laboratory we need
7 to be very flexible. And that also depends on the study.
8 These studies look for case control. All this like you
9 already point out, is look for compare with national
10 studies.

11 Also, I like to comment on Dr. Oliver's
12 discussion and your discussion. Dr. Oliver mentioned
13 wide -- so we look for each -- same goals from different
14 angle. How we can use a wide target to increase
15 throughput? You already mentioned the screening method.

16 So as a laboratory, we also face the same thing.
17 For example, can we use two-tiered method, one is based on
18 the screening, and then with the confirmation. So all of
19 this approach I think we like your comment.

20 And my specific comment is on page 18 -- page 8,
21 sorry.

22 DR. CALAFAT: The standard reference materials.

23 DR. SHE: Yes. And for -- okay. Standard
24 references materials. For example, the Program
25 participated in so many PT program, also related to Dr.

1 Mike these questions. Like we participate German G-EQUAS,
2 part of the CDC programs.

3 Now, we know NIST have new standards. If we look
4 at the criteria for past standards, for example, number 4,
5 DEHP, I calculate about 1.6 percent accuracy. So then you
6 look for the next one MEP, the bottom -- number 3 from the
7 bottom up, is about three percent.

8 So that's really require laboratory to look. And
9 CDC play a very central role to bring Biomonitoring
10 Program more systematic instead of opportunity study.
11 California did a lot of opportunity study in the past.
12 For example, we did PBDE. Dr. Myrto Petreas is a leader
13 in this area, so -- but this study is more opportunity.
14 CDC's role make it systematic.

15 But internationally, so these three PT programs,
16 how -- which one we past fit in which study? I think CDC
17 can play that role international and more systematic.

18 For laboratory past the PT, like the NIST, we
19 need to know our precision, so that affects other parts
20 like throughput. I like your comment.

21 Thank you.

22 DR. CALAFAT: So this again goes into what we
23 said that biomonitoring is one of the tools. We have many
24 other tools. And then -- and when you develop the method,
25 you need to know what is -- what your method is going to

1 be used for. And then -- and sometimes you may have to
2 tweak your method, so -- and we know that. That's why I
3 think it's important biomonitoring is not only -- is not a
4 discipline that is -- again analytical chemist that we can
5 talk and then ad nauseam about chemistry.

6 But it involves -- it's a partnership with your
7 other investigators. And then, you know, determining in
8 terms of the sampling, how are we going to get the best
9 sample, how many chemicals we want to look at. And then
10 in terms of accuracy it's again -- is accuracy the most
11 important thing in this particular method or not?

12 For our purposes accuracy is a key. It's key.
13 It has to be accurate. And if we know that it is not
14 accurate, then we just need to take any necessary steps to
15 make the method as accurate as possible. And this may
16 imply that then you may be losing in terms of how many
17 things you're going to be able to look at, because that's
18 one part that is very hard to compromise for us.

19 But it may not be the same chemist in a different
20 study. So in terms of what PTs do you give more weighting
21 to, which I think is what you were mentioning, I actually
22 think that when your method is solid and fine, you're
23 going to be okay in all these measurements.

24 And in terms of just it doesn't worry me that
25 much that you would say, you know, I'm saying is 10.6 plus

1 minus 0.5. I mean, this is something that NIST did, and
2 this was -- I mean, it was based on repeated measurements
3 of the same material. So, granted, some methods may have
4 better precision than others We know that.

5 But it doesn't bother me that instead, you know,
6 you would get something that is 12 or something that is
7 eight. I mean, to me, that's not that critical, because
8 if you're using this for an epi study to categorize
9 exposure, then that's probably not going to make a big
10 difference where this person is going to be categorized.

11 However, if instead of 10.6, you tell them it's
12 1.6 or 100.6, then I have a big problem, because then that
13 is totally off base. So again, that -- when I'm saying
14 you need to understand your method and then know what it's
15 is used for, and talk to each other. So, you know,
16 hopefully maybe one day, we're going to be able to offer a
17 program that is really comprehensive. If it's something
18 that we -- I mean, I know I'm not speaking only for
19 myself, but for Lovisa that we would love to be able to
20 do. It's just that we have certain constraints that we
21 need to go through before. But, believe me, the intention
22 is just to move in that direction.

23 DR. SHE: Thank you very much.

24 CHAIRPERSON LUDERER: I actually have a question,
25 which kind of relates to, you know, the way that in

1 Biomonitoring California, you know, we're looking at the
2 California population specifically, and then we go to
3 NHANES. And I was very interested in your -- with the
4 DINCH story, you know, the CDC data, and then comparing it
5 with the German data.

6 And so one of my questions is I was wondering if
7 you could speak a little bit more -- I mean, one of the
8 things that's striking from the two sets of data that you
9 presented, the U.S. data from your lab, and the German
10 data, is how much higher the detection frequency is in
11 Germany for the same years.

12 And so I guess I have kind of multiple questions
13 about that, but, you know, one is, if you look at just
14 hydroxy-MINCH in the German data, is it more similar to
15 what you're seeing here or do you think there's really
16 some difference in exposure, maybe it started to be used
17 earlier in Germany? If you could sort of elaborate on
18 that, that would be great?

19 DR. CALAFAT: So that point goes into what Scott
20 had said before. I'm really comparing apples and oranges.
21 Comparing apples and oranges in terms of the study design,
22 as well as in the method, that analytical method. So when
23 it's truly comparable is when you would say you use a same
24 method or at least a method that may be different, but has
25 the similar -- the same sensitivity for the target

1 analytes.

2 So in that particular case, they used a different
3 approach. And if I'm not mistaken, they were only looking
4 for the DINCH metabolites. And the three different
5 metabolites that they looked at the, carboxamide, the
6 oxon, and the hydroxy. We only look at the hydroxy. And
7 it was part of the method that in NHANES that had an LOD
8 of 4.5 -- 0.4 parts per billion. Their detection limit
9 was lower. I don't remember on top of my head, but it's
10 lower.

11 At the same time, in my experience with
12 phthalates, we have seen differences. And with Germany in
13 particular, there -- the changes like that we saw with
14 DEHP, and DINP in the United States or DBP and DIBP, the
15 butyls and DEHP. They had happened before in Europe.

16 So the trend in decreasing concentrations of one
17 compound then going up on the other, they started earlier
18 there. So I cannot rule out -- just based on the
19 information that we had from this limited comparison, I
20 cannot say whether there is a higher exposure to DINCH in
21 the German population than it is in the United States
22 right now.

23 But again, I couldn't rule it out, maybe or not.
24 But in addition to that, you need to factor differences in
25 analytical methods, sensitivity, and the study design.

1 CHAIRPERSON LUDERER: Dr. Cranor.

2 PANEL MEMBER CRANOR: A follow up to that
3 question. It occurred to me that just now we know that
4 Europe is trying to do a better job than the United States
5 is trying to do, in terms of cleaning up their chemical
6 substances and getting the more toxic things out of
7 commerce.

8 And they probably -- they may have gotten them
9 out better than U.S. Comparative data could be very
10 interesting here to sample what's showing up in Europe
11 versus sampling what's showing up here. And I don't know.
12 I don't have a suggestion about what you might find or
13 what you might do with it, but is anybody doing that?

14 DR. CALAFAT: So we have done it in separate
15 studies working with investigators in different parts of
16 Europe or in the Middle East. We have a study in Israel
17 as well, a long time ago.

18 And that we can say -- and that was using our
19 own -- our methods, so the same method what use for
20 NHANES. And what I can tell you is that they were clear
21 parents that were different. So as I said, you know, like
22 within the German data that something was similar in
23 samples that we analyzed from Spain, samples that we
24 analyzed from France that just kind of -- it is very
25 possible that the chemicals that are used in one

1 particular region of the world they're very different to
2 others.

3 For example, just DINP, the diisononyl phthalate,
4 we tend to use the mixture that from one particular
5 manufacturer in the United States versus there is a
6 different manufacturer in Europe. And because this is one
7 of these chemicals that I said is isomeric, so it has
8 different structures depending on what you put in the
9 reactor, then it may be easier to -- there is likely
10 different chemicals and the biomarkers may also be
11 slightly different.

12 So I do believe they are differences in patterns
13 of exposure, because the products that are being used in
14 one particular part of the world may not be exactly the
15 products that are used somewhere else. So that brings --
16 I mean, that means something that one day, if I have time,
17 then I could try to pull together the data from the
18 different studies that we have done and see really the
19 pattern, but there is the United States. And then if I
20 say Germany, then it would apply to pretty much the other
21 countries that we have work in the -- in western Europe.

22 PANEL MEMBER CRANOR: Thank you.

23 CHAIRPERSON LUDERER: Okay. Comments, questions
24 from Panel members?

25 I have one more question, which is regarding the

1 DINP. You know, you showed the two different metabolites,
2 the MNP and the MCOP. And I was wondering if you could
3 comment on whether it's known whether some of those
4 differences in the detection frequencies of those
5 metabolites are due to potentially in differences in
6 metabolism among -- you know, within the population,
7 polymorphisms or some other, you know, differences in
8 metabolic pathways.

9 DR. CALAFAT: Yeah. That's -- actually, MNP is
10 very easy to form, you know, is a very simple -- is a
11 simple hydrolysis. So it's something that happens in the
12 body very quickly, but also may happen in the environment.
13 So that's also one reason why MNP may not be the best
14 biomarker, because it could be an environmental degradate,
15 and it could come from external contamination. In the
16 case of the phthalates, we take pride in saying we're
17 looking at metabolites. We're eliminating contamination,
18 but not really with these monoesters. In terms of -- and
19 then versus MCOP. That's an oxidative product that
20 requires a P450 mechanism, so it can only happen in the
21 body, as far as I know.

22 And there may be differences in metabolism.
23 However, whether we're going to capture them, I'm not 100
24 percent sure that we would because there's also so much
25 variability in the concentrations. And then it may also

1 depend what you're seeing is -- you know, if it's
2 something that has happened, a very recent exposure. And
3 again, it depends on how -- when was the exposure. So if
4 it's a very recent exposure, I imagine that nothing else
5 had happen before. So the body had time to make MNP, but
6 didn't have time yet, because the half-life is longer, to
7 make the other compound.

8 So -- but this would be very different if it was
9 exposure that happened more frequently, because -- so it
10 is a very different picture, but there probably are
11 differences in metabolism. I'm just not sure we can
12 capture them.

13 CHAIRPERSON LUDERER: Mr. Fiehn.

14 PANEL MEMBER FIEHN: Yes. One, a little
15 different comment I guess than the analytical questions
16 that we had is obviously for the government, as well as
17 for the public, it's not only important to biomonitor
18 exposures, but also to see, you know, how to get quickly
19 information and in an accumulated way, like in databases
20 or so, about effects and associated effects.

21 And I just did, while we were talking here, a
22 very quick, you know, survey on the internet just to see,
23 you know, how -- you know, which compounds are associated
24 with which affects. It doesn't mean causal, of course,
25 but just associated. And it appears that, you know, from

1 the comments I found on the Internet that people said, oh,
2 we need more research; oh, we need more research; oh, we
3 need more research.

4 And that is both in like rats as well as in
5 ongoing human studies. And I do not see here a concerted
6 effort by agencies. I don't say which agencies, but, you
7 know, Congress funded agencies, that includes NIH or
8 whatnot, to kind of collect complementary information to
9 complementary health based or toxicity outcome
10 information, phenotypic information associated with
11 exposures, because that's what we really need eventually
12 to make informed decisions. So do you know better -- do
13 you have better information than that?

14 DR. CALAFAT: No. I mean, I know that we -- in
15 terms of NHANES, for example, which is the program I'm
16 quite familiar with, it fulfills one particular role, but
17 is not the answer to everything.

18 And NHANES collects information and there have
19 been quite a few studies that show associations with
20 health effects. What we do at CDC is mainly biomarkers of
21 exposure. We are not looking into biomarkers of effect.
22 There are some, but -- and for certain chemicals, but we
23 just have not got there yet.

24 If there's no exposure, there shouldn't be an
25 effect, so I just think that we are -- we're doing some

1 useful work in there. And we are not a regulatory agency,
2 as you well know, but we take pride in thinking that the
3 data that we generate can be used for -- by other agencies
4 to make policy or major changes.

5 Because we know that NHANES doesn't have the
6 answer to everything, that's why we partner with
7 investigators. And there is smaller studies - these are
8 not large population studies - in identifying certain,
9 you, know populations with some health effects that then
10 can provide -- try to provide the link between
11 biomonitoring and health effects. But in terms of wide
12 government approach that would spin-off out of NHANES, I
13 don't think so.

14 PANEL MEMBER CRANOR: That was the question I
15 asked implicitly earlier. So thank you.

16 CHAIRPERSON LUDERER: Any other questions,
17 comments from the Panel or others?

18 Okay. Well, thank you again, Dr. Calafat, for
19 that wonderful presentation.

20 (Applause.)

21 DR. WU: Can I say goodbye to our CDC colleagues?

22 (Laughter.)

23 MS. HOOVER: Just to let the audience listening
24 on-line know, we're just saying goodbye to our wonderful
25 CDC contributors. We really appreciate them coming out,

1 and we'll be seeing CDC again in November. Just a little
2 preview.

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

5 CHAIRPERSON LUDERER: All right. Thank you
6 again. And now it's a pleasure to introduce Dr. Nerissa
7 Wu and Robert Voss, who will give us a detailed look at
8 the Program study that's called Measuring Analytes in
9 Maternal Archived Samples, or MAMAS, including some
10 preliminary results from the study.

11 Dr. Wu is Chief of the Chemical Exposure
12 Investigations Unit in the Environmental Health
13 Investigations Branch of CDPH, and Robert Voss is a
14 Research Scientist in Dr. Wu's unit.

15 So, Dr. Wu.

16 DR. WU: Thanks. Good morning, everyone. I'm
17 actually going to spend a little time talking about our
18 Program overall, the Program updates and announcements
19 that Michael DiBartolomeis usually gives. I will give
20 some project updates on our other non-MAMAS projects and
21 then we're going to focus more specifically on MAMAS, the
22 Measuring Analytes in Maternal Archives Samples, the
23 Biobank project. But it will be a brief overview, because
24 then Rob Voss will come up and give some actual data,
25 which we're very excited to present.

1 --o0o--

2 DR. WU: So Program announcements, starting with
3 the budget. The last time we were here, we talked about
4 this proposed \$1.5 million dollar augmentation that had
5 been proposed for the new budget. Unfortunately, since
6 that time, a new fiscal analysis was done, and this
7 proposal was cut in half. But the good news is that the
8 most recent budget was signed with \$800,000 of an
9 augmentation included for the biomonitoring budget.

10 So our budget going forward now includes our
11 permanent State funding, our CDC five-year cooperative
12 agreement, for which we are just finishing up the first
13 year. We just got official word that we can go on to year
14 two, so that's awesome. We have one two-year
15 augmentation, which started in 2014, which is scheduled to
16 expire in June 2016. And this new \$800,000 two-year
17 augmentation, which just started up and is scheduled to
18 expire in June 2017. Now, these two temporary
19 augmentations do overlap for one year, but then one of
20 them expires and our budget correspondingly goes down.

21 Personnel updates. We have a new person joining
22 EHL, Dr. Chang, who is here -- Dr. Chang has joined EHL to
23 work on PAH and non-targeted screening. So, welcome.

24 --o0o--

25 DR. WU: And there are actually no other

1 personnel changes. I just wanted to give a shout-out to
2 our overall staff, because they work very hard and they're
3 great to work with.

4 --o0o--

5 DR. WU: So project updates. Pilot BEST, we have
6 our ongoing data analyses. Our epi staff looking at
7 demographics markers and some exposure pathways. And
8 we're also continuing to work on our evaluation of results
9 return, so we hope to have some results to bring back to
10 you on that soon.

11 We've also posted new results on the website for
12 PCBs, PAHs, organochlorine pesticides, pyrethroid
13 pesticide metabolites. There is ongoing demographic and
14 exposure pathway work also being done for those, so there
15 will be more to come on the Pilot BEST results on our
16 website.

17 For Expanded BEST, we have gotten our lab results
18 for a second set of chemicals, environmental phenols,
19 PAHs, phthalates, pesticides, and metals, all urinary
20 analytes. And then we have the POPs, the persistent
21 organic pollutants in serum. So we have the round 2
22 results return planned for August. And 217 of the 218
23 Expanded BEST participants should be receiving a
24 results -- their results packets in August. And as with
25 Pilot BEST, we do have some ongoing epi analysis, so there

1 will be more to come as we find some more results.

2 --o0o--

3 DR. WU: We have two proposed studies in the
4 works, which fit really well with the Program priorities
5 that we've talked about here, the connection between
6 consumer products and exposure, and also our focus on
7 environmental justice and disproportionately exposed
8 communities.

9 We have the Flame Retardant and Environmental
10 Exposure Study or FREES, which we talked briefly about
11 last time. This project has moved forward quite a bit
12 since then. We'll be collaborating with UC Davis, Dr.
13 Deborah Bennett, and some project partners on the Couch
14 and Foam Cushioning Replacement Study. So UC Davis will
15 be recruiting participants who are planning to replace
16 foam furnishings in their home. And at time equals zero
17 and at subsequent points in time, UC Davis will go in and
18 collect dust samples and take a look at how flame
19 retardants change in their dust over time.

20 So we, as part of the FREES study, will be
21 recruiting a subset of those participants and doing
22 biomonitoring at those same time intervals, so that we can
23 track the reduction in flame retardants in their bodies
24 after they replace the foam in their homes.

25 So this is really exciting to be able to look at

1 a specific household product and the impact that it has on
2 our participants. This is -- it's a small study, but we
3 hope to gain enough information so that we can then go
4 work on a larger more generalizable population.

5 --o0o--

6 DR. WU: We also have the Asian/Pacific Islander
7 Community Exposures Project, or the ACE project. And this
8 grew out of a collaboration with a number of San Francisco
9 advocacy groups with whom we worked closely on the issue
10 of fish consumption and mercury exposure. APA Family
11 Services, which serves Asians in the San Francisco Bay
12 Area approached us about biomonitoring. And this
13 conversation grew into a collaborative study to look at
14 Chinese, Vietnamese, Filipino, and Lao populations in San
15 Francisco and to do a lot of outreach and education,
16 biomonitoring, and some intervention work with some
17 follow-up biomonitoring.

18 It's a proposal we wrote up to NIH. And
19 unfortunately, at this point, we have not been funded by
20 NIH, but we're looking for other funding sources, and also
21 looking at different ways to retool the study, and scale
22 it in ways that we can proceed with it.

23 This is a really important study. It's
24 something -- this is a data gap that we know exists.
25 NHANES has undersampled Asians historically. And even

1 though the numbers have been made up in recent cycles,
2 there's still very little information on specific Asian
3 subpopulations, and, of course, specifically the
4 California Asian population. So this is a study that
5 would really enable us to look at those populations and
6 look at exposure pathways relevant to those populations.

7 --o0o--

8 DR. WU: So to focus on MAMAS, the Measuring
9 Analytes in Maternal Archived Samples, I was here a year
10 ago talking about in detail about how Biobank works, so I
11 won't go into as much detail now, but I will just give you
12 a review, and I'm happy to answer questions about it.
13 About 70 percent of pregnant women in California
14 participate in the State Genetic Disease Screening Program
15 prenatal screening. It's about 350,000 women each year
16 who go through this program, have a blood draw in the
17 first and/or the second trimester either in their
18 clinician's office or in a phlebotomy center. Those
19 samples are sent to the GDSP labs for analyses for genetic
20 diseases.

21 And once they're -- once information has been
22 sent out to families. And if the women live in one of the
23 Biobank counties listed up here, those samples are put
24 into the Biobank and made available to researchers who
25 work on issues related to screening or to women's and

1 children's diseases.

2 --o0o--

3 DR. WU: We've had ongoing discussions with GDSP,
4 and they've actually opened up their program to allow us
5 to access samples from current pregnancies and prospective
6 pregnancies, and from the non-Biobank counties, which
7 gives us a lot more potential for sampling across
8 California.

9 --o0o--

10 DR. WU: So this slide summarizes the different
11 phases of MAMAS that we're going through. Last November,
12 we were able to get 460 samples from the Biobank. And
13 this is from San Diego and Orange Counties. These are
14 pregnancies from 2012. The purpose of doing this first
15 round of the pilot was really to evaluate how the Biobank
16 would work for us, what was the process of getting
17 samples. This is a new process for us as well as for
18 GDSP. Take a look at what the condition of those samples
19 was like, and was there anything about these samples that
20 would impact our ability to use them?

21 We did find out the volume is quite small, so we
22 weren't able to do more than one analytical panel per
23 sample. And Rob is actually going to come up and talk a
24 little bit more about the results we have from that batch
25 of samples. In the meantime, we've gone ahead and

1 designed the phase 2, which will be 540 samples. We're
2 going to be getting these from across California, and it's
3 a little easier to see on this slide --

4 --o0o--

5 DR. WU: -- the different geographic tiers across
6 California. Los Angeles, San Bernardino, and Riverside
7 counties, the Bay Area, as represented by Alameda and
8 Contra Costa counties, and the northern tier of the State
9 which is in 19 counties up in the northern part of
10 California.

11 --o0o--

12 DR. WU: So we'll be getting these samples. And
13 because they're not from Biobank counties, there's a
14 little more volume, and we're able to do two analytical
15 panels per sample, and these are from current pregnancies,
16 so we can look at current exposures.

17 So I'm actually going to stop there with that
18 very brief overview, because we're going to let Rob have a
19 little more time to present some of our sample results.

20 MR. VOSS: Thanks. It's nice to be here to share
21 these results with you. I hope I'm not taller than this
22 microphone and you can all hear me.

23 --o0o--

24 MR. VOSS: Let's see, so as Nerissa said, our
25 first -- these are results from the first phase of our

1 MAMAS study. These are 460 samples from pregnant women in
2 San Diego and Orange Counties. We specified the specific
3 racial distributions you can see on the slide here. And
4 beyond that, these samples are taken from non-smokers --
5 non-smoking mothers in singleton pregnancies. And they
6 were all drawn in the second trimester of pregnancies, so
7 some consistency there.

8 But as Nerissa pointed out, only approximately 70
9 percent of California mothers participate in genetic
10 disease screening through this Program. So our sample
11 here is only representative of those who participate.

12 --o0o--

13 MR. VOSS: The specific chemicals we looked at in
14 this phase were metals, perfluorochemicals, and persistent
15 organic pollutants. And you can see how we apportioned
16 our samples in the first column there.

17 The second phase of MAMAS, because we have more
18 sample volume, we'll be able to roughly double the samples
19 in each of these panels. And, of course, that will
20 represent more of the State.

21 I want to mention that for comparison's sake,
22 it's not always possible to get the ideal NHANES
23 comparison because sometimes they don't oversample for
24 pregnant women, and don't get enough pregnant women in
25 each particular panel in a particular year that you might

1 be interested in.

2 And for persistent organics, they've only been
3 reporting pooled samples in recent years, so we can't
4 compare directly to those. So that's worth remembering.

5 --o0o--

6 MR. VOSS: So jumping to results. Here are the
7 PFCs that we detected in the MAMAS sample compared to two
8 previous studies. And these are sorted in descending
9 order of detection in the MAMAS group. So at the bottom
10 of the chart here, you can see for a few of these
11 chemicals we're finding them in fewer participants in this
12 study than in previous studies. So perhaps that is the
13 beginning of a trend. We'll have to wait and see.

14 --o0o--

15 MR. VOSS: But for -- looking at two specific
16 PFCs that were found in all of the MAMAS, here, we're
17 looking at levels in MAMAS, and in three previous cycles
18 of NHANES that represent the decade prior to 2012 when we
19 got the MAMAS samples.

20 And for these NHANES values here, we're looking
21 at females for all ages, regardless of pregnancy status.
22 So the values represent that. And you can clearly see the
23 downward trend over the last decade or the decade previous
24 to our sampling, downward trend nationally, and we can
25 clearly see that the MAMAS are pretty equivalent to the

1 NHANES cycle that was most contemporary to them. So
2 that's indicating that, you know, we're pretty much
3 sitting in line with national trends, as far as these two
4 chemicals go at least.

5 --o0o--

6 MR. VOSS: Turning to our metals results. For
7 these five metals, we can report results. And as you can
8 see, they're pretty much detected in all of our MAMAS
9 samples. Unfortunately, we had some pretty significant
10 contamination issues with the metals analysis. And that's
11 going to affect results for a lot of the other metals that
12 we commonly have in our panels. And unfortunately, we're
13 not going to be able to report on those for this round,
14 and it's likely that that will continue into the future.
15 So we'll have to -- we're still working on exactly how to
16 proceed with metals analysis, but for now, we have these
17 metals to look at.

18 --o0o--

19 MR. VOSS: And looking here in a little more
20 detail at mercury by race categories in the MAMAS sample
21 as compared to in NHANES cycle of roughly the same time
22 period. I need to point out that the NHANES values there
23 are measured in blood, and the MAMAS values come from
24 serum, so we can't directly compare the levels.

25 --o0o--

1 MR. VOSS: But what we can look at are the
2 distributions in the various race categories, and we can
3 clearly see that the MAMAS group mirrors the pattern of
4 distribution in the national sample with the Asians
5 clearly being -- having higher mercury.

6 I'd like to point out, at this point, that the
7 MAMAS samples that we have there represent 2012. They
8 were drawn in 2012, but we got them from Biobank in
9 November of last year, as Nerissa said.

10 So really what we're looking at here is results
11 from samples that the Program obtained six months ago. So
12 I think this is kind of an exciting development to point
13 out that, you know, potentially we can use this stream of
14 samples from GDSP to do monitoring and look at results, at
15 least at the level of distribution by race within a fairly
16 short time period, if that's something we decide is a
17 Program priority, and we want to continue to pursue it.
18 So that's a nice potential for the study.

19 --o0o--

20 MR. VOSS: And the final panel that I'll talk
21 about are persistent organics. And here, I'm showing the
22 detection frequencies in MAMAS for all the congeners that
23 we found in at least 40 percent of the MAMAS. And these
24 detection frequencies are less than the pregnant women
25 subsample in 2003 NHANES, and the geometric means, which

1 I'm not going to go into detail on, also less than the
2 pregnant subsample of 2003 for NHANES.

3 And that's to be expected, given the general
4 trends for these chemicals. However, we have an
5 interesting anomaly an exception here to that trend being
6 BDE-183 which we found in 74 percent of the MAMAS group,
7 which was a surprise to us, as we had not previously found
8 that chemical, that congener in very many of our
9 participants in previous studies. So that's something of
10 interest we can look at a little more here.

11 --o0o--

12 MR. VOSS: For the commonly looked at BDEs shown
13 here, the MAMAS group is generally you can see coming in a
14 somewhat higher than Hispanic mothers in San Francisco in
15 the MIEEP study, and coming in lower than the firefighters
16 the FOX study, and they're roughly equivalent study to the
17 California Teachers Study values.

18 But again, we can look at BDE-183 there at the
19 bottom, which we did not find in very many participants in
20 any of those previous studies. So again, kind of a new
21 development here that is of interest.

22 --o0o--

23 MR. VOSS: And so to explore that a little bit
24 further, just to see a little bit more what we can say --
25 or what we can see about this flame retardant or

1 this -- yeah, the BDE-183, and also just to explore the
2 capability of the MAMAS project in general.

3 So here, I'm showing distributions of these three
4 persistent organics by race categories in MAMAS. The top
5 row there, the top section, DDE, I'm really just showing
6 for context and to kind of show some validation of the
7 MAMAS methods. And you can clearly see that the MAMAS
8 sample seems like it's robust enough and representative
9 enough to capture this known trend in distribution of DDE,
10 where Hispanics are higher than whites are for this
11 chemical. So that's validating for the MAMAS project, and
12 good to see for the project at least.

13 (Laughter.)

14 MR. VOSS: For BDE-47, a commonly looked at
15 chemical, we don't see any real differences in the MAMAS
16 group. So we're not quite sure what to make of that as we
17 might expect to see racial differences, but we don't. And
18 then for BDE-183, we can see it looks like it might be
19 slightly higher in the MAMAS sample for Hispanics than for
20 the white group.

21 So this is very preliminary. You need to point
22 out that we only had 20 samples in each of those race
23 categories. So, you know, clearly this is very
24 preliminary work here, but it does highlight the ability
25 of this project perhaps to look at things in a pretty

1 short time frame. And so this might be what looking for
2 emerging chemicals of concern could look like doing this
3 project in the future. We could be looking at these sorts
4 of results within a short time frame if that's something
5 we choose to do in the Program.

6 --o0o--

7 MR. VOSS: So to summarize. The project seems to
8 have some benefits. It seems to be a way to pretty
9 inexpensively get rather large sample sets that are
10 racially and geographically representative of California,
11 so that's very nice.

12 And in addition, the GDSP project offers kind of
13 a continuous sampling stream, so if we want to take
14 advantage of that, we can use that to do monitoring in
15 pretty short turnaround times, if we choose.

16 And then it's important to remember the project
17 is always going to have some challenges. We're always
18 going to be limited to small volumes of serum for
19 analysis, and it's always only going to be pregnant women.
20 So that limits some of the work we can do and limits how
21 representative this can be of the entire State.

22 Additionally, it's important to note that we're
23 never -- because of the way we get these samples, we're
24 never going to be getting -- able to get anything like a
25 detailed exposure assessment history. So this is never

1 going to be a project where we can do detailed
2 epidemiology of that sort, but it does have other
3 benefits, which are -- offer advantages.

4 --o0o--

5 MR. VOSS: And that's pretty much what I have.
6 Just to summarize future directions, we're going to be
7 getting our phase 2 samples coming in over the next year,
8 and we'll be merging those together with what I've shown
9 you today to, you know, hopefully see if some of the
10 results we've seen today hold up. And this is exciting
11 for the State, because, you know, as you can see from the
12 map, this is exciting for the Program, because this gets
13 us sort of -- you know, it's a big step towards something
14 like statewide representation. We're not there yet, but
15 this is the largest geography we've covered in a project
16 yet, so that's exciting for us.

17 And then we have to decide how we might want to
18 use this project in the future. We've seen that it could
19 be useful for looking at chemicals over a shorter -- short
20 time frame. So maybe it's a sentinel monitoring type of
21 project. We could use it to look at changes in chemicals
22 in the population over time in California. Those things
23 are yet to be decided, but -- and there may be other ways
24 to use this project as well, but those are the things
25 we'll be thinking about and deciding in the future.

1 with GDSP and do prospective types of studies. We
2 don't -- obviously, we're limited in our analytical
3 capabilities. We only have serum, so we couldn't do a
4 phthalates study. But yes, we could work in partnership.
5 They have a lot of outcome data in the GDSP registry and
6 database, so that kind of study is absolutely possible.

7 CHAIRPERSON LUDERER: Dr. Schwarzman.

8 PANEL MEMBER SCHWARZMAN: Thanks. I actually
9 have a second question based on that of, if you could
10 elaborate, what kind of outcome data is in the GDSP? I'd
11 be curious to know what kind outcome data is available.
12 And then I have my first question, if that's okay?

13 DR. WU: I have to rely on my memory, because I
14 haven't been in GDSP for a number of years. But they have
15 their genetic outcomes, so they have things like trisomies
16 and they have the neural tube defects information. They
17 also have the metabolic disorder outcomes. And then I
18 think on their newborn screening form they have just a --
19 they would have things like -- I'm trying to think of what
20 else. They have anything that can be noted at birth.
21 They often get that written down on the newborn form.

22 It is not necessarily perfect data, because
23 obviously these things are observed at different points of
24 a newborn's life, and the reporting is not complete, but
25 the registry is pretty thorough.

1 PANEL MEMBER SCHWARZMAN: And interesting, or
2 almost ironic, twist that it's a genetic screening. I
3 mean, that's it's a screening program that's meant to
4 detect genetic effects. And so they're looking at
5 different things than we would be interested in from an
6 environmental exposure sort of perspective. So it's just
7 lucky if some of those outcomes might match, things that
8 we're interested in, but I think fairly low probability
9 that the outcomes they're investigating are ones that we
10 would be specifically interested in about exposures.

11 DR. WU: That's right. I mean, maybe the best
12 way to do a study like this would be to partner with a
13 clinician or a hospital system that has much more detailed
14 outcome data and can also follow the newborns for a longer
15 period of time.

16 I mean, that's definitely a direction that would
17 be interesting to go in, but partly this was -- this is
18 just very preliminary, can we use the MAMAS samples, how
19 can we collaborate with GDSP, but it does open the door
20 for a lot of possibilities.

21 PANEL MEMBER SCHWARZMAN: Thank you so much for
22 taking that. My initial question was the -- some of
23 the -- you showed us mainly the differential outcomes
24 based on race, and I'm wondering if you showed us that
25 data because that's what was most striking in terms of

1 distinguishing features -- the variables that affected the
2 outcomes the most or is it the main thing that you have to
3 look at, that is did it also vary by geographic location?
4 I assume you don't have occupational information,
5 socioeconomic status information. Is there any -- what
6 other variables are available, and did you show us the
7 race, because that was the determining variable or because
8 it's what's available?

9 MR. VOSS: Yeah, more the latter. Very limited
10 demographics that we get. I showed -- let's see, can I
11 zip all the way to the front. We have a variable
12 indicating Medi-Cal usage, and then age and ethnicity, and
13 that's really it. So geographically we do have that. But
14 for this particular subsample, it's all Orange County and
15 San Diego County mothers. So geography wasn't very
16 interesting, but certainly could be a contributor to some
17 of the outcomes I showed.

18 CHAIRPERSON LUDERER: Dr. Cranor.

19 PANEL MEMBER CRANOR: Three questions. A couple
20 of them are really quick. Do I read your acronym
21 correctly that DDD -- DDE is the metabolite of DDT?

22 MR. VOSS: Yes. The environmental breakdown
23 product.

24 PANEL MEMBER CRANOR: Yes. Well, that's shocking
25 that it's 100 percent.

1 MR. VOSS: Yeah, well, that's pretty normal in
2 environmental samples that we see that.

3 PANEL MEMBER CRANOR: Is that right?

4 MS. BUERMEYER: Normal and yet still shocking.
5 (Laughter.)

6 PANEL MEMBER CRANOR: That's right.

7 MR. VOSS: Right. Not to take away from your
8 first adjective, but it is a pretty consistent finding.

9 PANEL MEMBER CRANOR: Okay. Thank you.

10 Oh, I wanted to comment on your apology. I don't
11 know that you should need to apologize. So you may not
12 give perfect representation across the State, but you're
13 sampling a terribly important subpopulation --

14 MR. VOSS: Very true.

15 PANEL MEMBER CRANOR: -- the mother and their
16 children. So I wouldn't apologize for that so much.

17 MR. VOSS: Oh, well, thank you.

18 (Laughter.)

19 MR. VOSS: We'll take that.

20 DR. DiBARTOLOMEIS: Take it back, Rob.

21 (Laughter.)

22 MR. VOSS: I do -- you know, it does -- we do
23 need to point out, of course, that -- I mean, it's
24 never -- it's always only going to be mothers, females,
25 mothers, obviously a very important population.

1 PANEL MEMBER CRANOR: Right.

2 MR. VOSS: But, you know, if males are exposed
3 differentially to some particular chemical, this project
4 will never capture that. So that's more what I was
5 getting at.

6 PANEL MEMBER CRANOR: I guess the third question,
7 do you plan to broaden the things you're looking for? You
8 only did a few things here.

9 MR. VOSS: Right. We did these, as Nerissa said,
10 as more of a capability study to see what we could do. We
11 would certainly be open to broadening, I think, to
12 anything we can look for in serum, and in the volumes of
13 serum that we're able to get. So we're not going to be
14 able to get whole blood. We're not going to be able to
15 get urine, so there may be things that we can't look at.

16 PANEL MEMBER CRANOR: Would there be a way -- a
17 fourth question then. Would there be a way to target
18 things that we already suspect are causing problems in
19 children during the developmental period?

20 MR. VOSS: I think we can choose to look at
21 whatever we feel is the most interesting avenue to pursue.
22 The only caveat being it has to be something we can --
23 we're capable of finding in serum.

24 PANEL MEMBER CRANOR: The researchers in the
25 developmental origins of disease, which I've read a

1 certain number of, are finding a variety of things, and
2 you could learn from that literature and maybe target
3 based on that.

4 MR. VOSS: Certainly. Thank you.

5 CHAIRPERSON LUDERER: Dr. Bartell, and then Dr.
6 Quintana.

7 PANEL MEMBER BARTELL: I just wanted to echo the
8 earlier comment about, you know, it would be -- you got
9 really a fantastic resource here. I realize this is early
10 in the stages. And for you guys, it's almost more, you
11 know, piloting whether you could actually, you know, have
12 sufficient sample volume to do these kind of analyses.
13 But I think already even, just with the samples you've
14 collected here, this would be fantastic to find a way, if
15 you can work with GDSP, to link those data to
16 demographics -- a little more detailed demographic data to
17 whatever possible extent you can without the outcome data.

18 And I don't know to what extent you've had
19 discussions with them about that, but I guess I would
20 encourage you to open up those discussions more and just
21 see if there are ways to even just take advantage of the
22 information they already collected. I mean, ideally even
23 collect maybe some other health outcome information as
24 suggested earlier.

25 But one idea for doing that in a way that may be

1 relatively -- relatively easy at this stage might be to
2 see if you can link that information with birth
3 certificate data, since the birth certificates actually
4 have a lot of the variables we're talking about, the
5 socioeconomic status, in terms of occupation of the
6 parents. And you could, I think, get at least some of the
7 information and even some of those health outcomes.

8 Sometimes, I think -- I'm not sure in California,
9 but some states there are some indications like
10 preeclampsia on the birth certificate. So you may be able
11 to find some information, you know, just from existing
12 records if you, you know, can get permission to sort of
13 link those.

14 MR. VOSS: Yeah, I'm sure we'll be pursuing that.
15 And it's -- I think it's in the -- it's not so much a
16 technical issue of could we do it, it's more in the
17 getting of the permissions to access those data, but yeah,
18 definitely good ideas.

19 CHAIRPERSON LUDERER: Dr. Quintana.

20 PANEL MEMBER QUINTANA: Hi. I saw in your slides
21 that you are working with very small volumes, as you said,
22 you know, close to a ml. So I know that there's always
23 going to be competing interests and what to analyze, but I
24 would encourage you to analyze things like cotinine and
25 other things related to tobacco use, for example, which

1 have a huge impact on birth outcomes, that can be done in
2 quite small volumes I think nowadays, because it can help
3 explain maybe some of these other biomarkers that do track
4 a little bit with tobacco use or even excessive
5 second-hand smoke exposure.

6 So I know it's a competing problem, but it might
7 get around a little bit of the problem of not having some
8 questionnaire data of some very important other exposures.

9 MR. VOSS: Right. Yeah, that's an interesting
10 idea. I think -- I don't know if it came across, but we
11 will be getting slightly greater sample volumes in the
12 future, if we get them directly from GDSP. But yeah,
13 that's a great idea, and we'll be looking for ways to
14 maximize what we can do with what we have.

15 CHAIRPERSON LUDERER: I actually -- I have a
16 question, which is about the 70 percent of women are
17 participating in this program. Do you have any
18 information about whether those 70 percent differ from the
19 other 30 percent in any kind of systematic important ways?

20 MR. VOSS: Right. Well, I know that they tend to
21 be -- that wealthier women perhaps will look for other
22 avenues to get screening. And then older women,
23 potentially higher risk pregnancies, might also be shifted
24 to non-state screening diagnostic centers. So those are
25 the two primary things.

1 I don't know if there's general, like,
2 demographics of GDSP information available beyond that.

3 DR. WU: It is available, but I don't want to
4 misspeak, because it has been awhile since I've looked at
5 those data. But Rob is correct, that it is more older
6 women, more high risk pregnancies, if there has been a
7 history of a birth outcome, then those women are going to
8 go more quickly to diagnostic than to go through the State
9 screening program. There's also a lot of development in
10 fetal cell DNA. So I think GDSP itself is looking at how
11 their demographics are going to shift and how utilization
12 is going to shift, because as people decide to go for kind
13 of fancier screening, the statewide program utilization
14 may decrease and become less representative.

15 CHAIRPERSON LUDERER: Is there any geographic,
16 you know, major geographic? I mean, I guess urban/rural
17 probably from what you're saying.

18 DR. WU: I can't recall. Sorry.

19 CHAIRPERSON LUDERER: Do we have other questions
20 from Panel members before we take public comments, and
21 then we'll have more time for discussion with the Panel
22 also?

23 All right. Do we have any public comments?

24 MS. BUERMEYER: I'll say something.

25 (Laughter.)

1 CHAIRPERSON LUDERER: Great. Thank you. All
2 right. We have two commenters. The first one will be
3 Veena Singla from the Natural Resources Defense Council.

4 DR. SINGLA: Thank you. Yes. Veena Singla,
5 Natural Resources Defense Council. Thank you for a very
6 interesting, informative presentation. It's great to see
7 the progress with this project.

8 And I had two comments. One on the future
9 possibilities and directions in terms of which chemicals
10 to target. I wanted to suggested targeting chemicals with
11 known prenatal toxicity concerns, so well known things
12 like organophosphate pesticides, and also chemicals which
13 emerging data is suggesting a lot of prenatal toxicity
14 concerns like some of the environmental phenols, as well
15 as the phthalates.

16 And in terms of the MAMAS phase 2 and the wider
17 geographic representation that will be able to be achieved
18 there, I think that's -- that's really great that there
19 will be samples from more counties in California.
20 However, I was concerned to see that the Central Valley
21 counties with the most intensive pesticide use are no
22 longer represented in the phase 2 samples, though they
23 were in the Biobank samples, so particularly Fresno, Kern,
24 Kings, and Tulare Counties.

25 So I wanted to note that I think it's really

1 important to try to capture some samples from populations
2 in the agriculturally intensive counties, as this is a
3 unique and high risk population within California.

4 DR. WU: Just a quick response. That's a really
5 good point about Central Valley. We had moved away from
6 Central Valley for phase 2, in part because we were trying
7 to -- we were working to test out this new paradigm with
8 GDSP. But the other thing is that many of the counties in
9 the Central Valley, because they are captured by Biobank,
10 we can't get those samples until they have been banked for
11 one or two years. So it limits our ability to do any
12 prospective work, and it also limits the sample volume
13 that we're able to get.

14 CHAIRPERSON LUDERER: The second public comment
15 is from Nancy Buermeyer from the Breast Cancer Fund.

16 MS. BUERMEYER: Thank you. Nancy Buermeyer from
17 the Breast Cancer Fund. Dr. Luderer took my question
18 about the 30 percent, so thanks --

19 (Laughter.)

20 MS. BUERMEYER: -- I think. But I just wanted
21 to -- now, I have a new question. So does that mean that
22 the samples from the first round didn't come from the
23 Central Valley or from the Fresno area?

24 DR. WU: They did. They're from San Diego,
25 Orange County.

1 MS. BUERMEYER: So not from this center little
2 area.

3 DR. WU: So yeah, we took them -- so the seven
4 Biobank counties, most are in Central Valley and two are
5 San Diego and Orange County. I think we selected San
6 Diego and Orange County because we had not done any
7 studies in the south except for FOX. But again, we
8 could -- I mean, we have to think about our Program
9 priorities, but what we're going to use these samples for.

10 We could go back to using -- to grabbing some
11 Central Valley samples, but in this -- in MAMAS 1, no, we
12 did not. We took them from south.

13 MS. BUERMEYER: Okay. Thank you.

14 And then just to echo what Dr. Cranor said,
15 please don't apologize for it being pregnant women.

16 (Laughter.)

17 MS. BUERMEYER: One of the things that the
18 advocacy community has done a lot is to focus on
19 children's products, as the sort of frame for working in
20 policy work, which is important, because children are
21 vulnerable populations, and they're sympathetic folks to
22 protect. But what we know, everyone in this room knows,
23 is that these prenatal exposures are probably more
24 important than exposures to toddlers. And so being able
25 to capture some of these exposures are really important,

1 and would encourage all that can be done to incorporate
2 these other data: Occupation, outcomes, birthweights, all
3 these things that we've been talking about.

4 So that would be great. And thank you for
5 working on this project. It will be great. Useful
6 information for us.

7 CHAIRPERSON LUDERER: A comment or response?

8 DR. FENSTER: This is just an addendum -- I'm
9 Laura Fenster. I work with the California Biomonitoring
10 Program. I also -- I just want to remind the Panel and
11 the public that we do have an ongoing study in
12 collaboration with Kaiser in the Central Valley. And we
13 are looking at, not health outcomes and it's not pregnant
14 women, but we are looking at many metabolites that were
15 mentioned, phthalates, organophosphate data.

16 We just received some of that data from the lab,
17 so we will be looking at our exposure questionnaire and
18 levels in -- by race and other demographics. We'll look
19 forward to presenting that data in the future, just so
20 that that gap in the State, until Nerissa says, we will
21 have more data potentially. We are trying to look at that
22 population.

23 In that study, in the expanded version, we did
24 oversample Hispanics and Asian-Pacific Islanders, and
25 there's also about 20 percent of African-Americans in that

1 study as well. So we will be able to look by race,
2 ethnicities, and we did collect data on the occupation as
3 well.

4 CHAIRPERSON LUDERER: Thank you very much.

5 Dr. She.

6 DR. SHE: Jianwen She, Chief of Biochemistry
7 Section EHL.

8 And I'd also like to follow Dr. Laura Fenster
9 said. Actually, California Biomonitoring Program may not
10 have direct linkage between the exposures and the health
11 effect, but we do have laboratory collaboration. For
12 example, we work with Kaiser. Kaiser looking for the
13 environmental exposure and the health effect of pregnant
14 women. Hope this also can provide some sideline
15 information on the health effects.

16 And actually, I'm very interested to also notice
17 other laboratory chemists confined in the laboratory tend
18 to miss big picture. So today, I notice some big picture.
19 For examples, when Dr. -- when Rob present page 19 slide,
20 obvious from NHANES and MAMAS, mercury is lowest. And
21 then for the Asian women, I do not know -- I cannot see
22 the color, but I remember the Asian is low.

23 So my question is when we program -- propose
24 study, I need to be kind of educated for the Asian-Pacific
25 Islander community exposure, especially look for the Asian

1 population. If you know overall this Asian population at
2 least the mercury is low. So I just wonder when NIH
3 rejected this study and what suggestion they give to us
4 that affect us --

5 DR. WU: It's high.

6 DR. SHE: Huh?

7 DR. WU: Asian is high.

8 DR. SHE: Oh, Asian is high.

9 Oh, that's lower -- Sorry. It's higher.

10 (Laughter.)

11 MR. VOSS: We're reading from left to right.

12 DR. SHE: Oh, sorry. I thought that I -- thank
13 you very much.

14 (Laughter.)

15 MR. VOSS: Sorry to confuse you.

16 DR. WU: Sorry. It is a good point that Asians
17 are actually disproportionately high in mercury and
18 arsenic, which is one of the reasons -- one of the reasons
19 we want to focus on the Asian population.

20 DR. SHE: That's actually common to my normal
21 knowledge, but not surprising, because mercury comes from
22 fish eating. My knowledge is mercury is high, because San
23 Francisco Bay is EPA declared mercury impact, so I -- but
24 I needed to read the slide more carefully in the future.

25 (Laughter.)

1 CHAIRPERSON LUDERER: Yeah. Myrto Petreas.

2 DR. PETREAS: Myrto Petreas with the
3 Environmental Chemistry Lab. I want to respond to the
4 comment from Dr. Singla, that it would be very nice to do
5 the phenols and the pesticides, but unfortunately we only
6 do them in urine, and here it's serum. So our lab does do
7 them, but not in blood.

8 CHAIRPERSON LUDERER: Thank you very much. Do we
9 have other discussion, questions, comments from Panel
10 members?

11 I do have another question, which is about you
12 mentioned the contamination problem with the metal panel.
13 And I was wondering, do you -- I think you said it was
14 from the tubes not from the needles that were used for
15 drawing the samples?

16 MR. VOSS: It seems to be from the collection
17 tubes. We've done a --

18 MS. HOOVER: Mic, Rob.

19 MR. VOSS: What's that?

20 MS. HOOVER: Mic.

21 MR. VOSS: Oh, sorry. Yeah. It seems to be from
22 the collection tubes. We've done a couple preliminary
23 studies, one with DI water and another with purchased
24 serum, and it definitely seems to be something that's
25 coming from the gel media in the collection tubes.

1 CHAIRPERSON LUDERER: Do they use the same tubes
2 from the same manufacturer for the Program statewide or --

3 MR. VOSS: I think -- do they provide the tubes,
4 GDSP?

5 DR. WU: Yes.

6 MR. VOSS: Yeah, so they use the same tubes
7 statewide. And they're -- you know, it's optimized to get
8 samples for genetic disease screening, so it's obviously
9 not a priority for them.

10 CHAIRPERSON LUDERER: And finally, the reason I
11 was asking is do you think that that -- that these tubes
12 may pose a problem for other analytes in addition to
13 metals.

14 MR. VOSS: Well, we haven't found any yet, but I
15 guess that's going to be something we'll have to continue
16 to look at for sure.

17 Myrto.

18 DR. PETREAS: Myrto Petreas.

19 We did preliminary work. Before we decided to
20 embark on these MAMAS, we did visit the clinical lab that
21 was doing the analysis and took samples that they used,
22 because, as we know, their interest is those genetic
23 markers. They don't care about dust. They don't care
24 about exposure to the UV light or anything. So many of
25 these samples sit on autosampler for days or hours. They

1 have to be repeated. Many different pipettes are dipped
2 into them.

3 Nevertheless, the concern was about the POPs,
4 PBDEs and PFCs. And we tested them. The limited samples
5 that we took from them didn't show anything unusual. And
6 then we gave them our samples to be left along with the
7 others, and we didn't see anything picked up then, but
8 very limited, one lab, one time.

9 CHAIRPERSON LUDERER: I have to pause and wait
10 for the light to come on, so that's why I did that.

11 Dr. Kavanaugh-Lynch.

12 PANEL MEMBER KAVANAUGH-LYNCH: There we go. At
13 the risk of stating the obvious, this is a really huge
14 potential in so many ways, as has already been stated.
15 The -- focusing on pregnant women and children is limited,
16 but a very, very high value. And we know -- I think we --
17 we suspect that this Program may never, but certainly not
18 in the short term, have the money to do statewide
19 sampling, as was initially proposed in the legislation.

20 And this is as close as you can get. And really,
21 I mean, to get this close, essentially for free, for the
22 sampling piece, is -- is of huge benefit. And so I
23 just -- I greatly support everything the Program is doing
24 to pursue this as a potential. I mean, the -- I guess the
25 reality is you can't do -- you can't screen for everything

1 in every sample, and that's probably the biggest downside
2 is that you -- the volume is so limited.

3 But I just think there's no limit to the amount
4 of effort you should put into this, because it has --
5 really has the greatest potential of anything I've seen.

6 MR. VOSS: Thank you for that. I certainly never
7 meant to diminish the importance of looking at pregnant
8 women.

9 (Laughter.)

10 MR. VOSS: And I didn't mean to diminish in what
11 we're doing in that respect. I just do want to point out,
12 you know, it is -- it is what it is. But certainly, it
13 seems like it's a really great resource for getting
14 samples from, you know, a large part of the State, getting
15 them quickly and at least getting racial diversity into
16 our sample pool, whether or not it serves as the only way
17 that we do statewide sampling, you know, I certainly hope
18 that we can move to doing more statewide sampling, where
19 we'll be able to get more information. That's my personal
20 opinion, but certainly this is an extremely useful tool or
21 it appears that way, at this point.

22 DR. WU: I just want to add that the samples are
23 much less expensive than a full recruitment and
24 biomonitoring study would be, but they are, unfortunately,
25 not free. We have explored the issue of one State program

1 paying another, and we -- the Biobank has written into
2 their legislation that they do need to charge for these
3 samples, even for a State program, at least in the
4 foreseeable future.

5 There is another advantage, in that we don't have
6 results return with these. We don't -- we can't return
7 the results to participants, and we have a fairly broad
8 IRB proposal, so that we can do things like targeted
9 unknown screening or additional environmental chemicals as
10 they come along, and we become aware of them.

11 And I think as we gather data and show the
12 utility of this, it allows us to explore more
13 collaborations with GDSP and also their clinician partners
14 out there who will see the usefulness of our data.

15 CHAIRPERSON LUDERER: Dr. Schwarzman had a
16 question and then Dr. She.

17 PANEL MEMBER SCHWARZMAN: Thank you. You're
18 raising this point about the sort of collaboration with
19 GDSP and what else might be possible. And this other
20 issue of what is not possible to analyze in serum samples
21 makes me want to at least just sort of raise an out-there
22 possibility for future collaboration of given the volume
23 of urine that's collected from pregnant women, it seems
24 not that big a stretch that, at some point in the future,
25 there might be a way to collaborate with the GDSP program

1 about getting samples that are not currently collected now
2 that would not be used for genetic screening, but that
3 could serve a different purpose.

4 And I can see how that's a far-out-there goal,
5 and -- but it may be a very significant role for the pilot
6 study, in that you've been able to demonstrate such
7 interesting findings by the pilot study, that it may
8 provide an opening to explore other sample collection
9 possibilities that would be much more feasible than if the
10 Biomonitoring Program on its own were just to set out to
11 collect samples. So it sounds like you already have
12 thoughts in that direction.

13 DR. WU: Yeah, I agree. There's actually a
14 really good model for that kind of study, Project Baby's
15 Breath, which was administered by Dr. Marty Kharrazi,
16 who's in our Branch at CDPH, where they have urine and
17 cord blood and prenatal samples and newborn outcomes. And
18 they followed the participants for quite a long time and
19 have reams of data that have come out that. So that's a
20 great model for us to look at.

21 We're really -- this is our -- we're all very
22 excited about this data. It's a real just step into the
23 water, but I think there is a world of possibility out
24 there to partner with GDSP.

25 CHAIRPERSON LUDERER: Just a follow up on that

1 real quick and then Dr. She. I mean apropos of a world of
2 possibilities and things that, you know, other things that
3 might be done, I mean, it's very exciting to have this
4 step towards a representative sample. And the thing that
5 came into my mind was I know that the lab has done work on
6 the newborn blood spots and measuring analytes in those.
7 And might it be possible in the future to link those and
8 to look at mother/infant pairs?

9 DR. SHE: Exactly, you and me on the same topics.
10 That's what -- I'm very glad you bring up. And then
11 laboratory develop newborn screening spots and method like
12 four years ago. As we are aware, contamination may be a
13 potential problem. But as you see, serum also faces the
14 same problem for metals, potentially for other chemicals.

15 Using newborn screening program from the blood
16 spots, more and more people pay attention. It's right now
17 maybe the mother to linked to the health effect is
18 indirect. Maybe the kids linked to the birth defect is
19 more direct.

20 For example, we know that kids have a twin. And
21 then genetic reason cannot explain why one kid have a
22 disease onset, another one doesn't have. To look at this,
23 consider this unique information a biomonitoring program
24 can provide beyond the genetic reasons. Phenotype,
25 genotype, and environmental part and lifestyle is a cause.

1 So I really like to follow our Chair's suggestion
2 for the Panel to look at this technical issue. I do not
3 think that's critical. We already resolved the most. We
4 published.

5 And also, consider the -- you can collect the
6 urine from mother or blood, but very hard to collect any
7 sample from kids.

8 Thank you.

9 CHAIRPERSON LUDERER: I don't see any other hands
10 up from Panel members.

11 All right. I think we had a really great
12 suggestion. And thank you very much for that wonderful
13 presentation and those very exciting data.

14 All right. Thank you.

15 (Applause.)

16 CHAIRPERSON LUDERER: Okay. Now, we are --
17 before we break for lunch. Mario Fernandez, the attorney
18 for OEHHA, is going to give us a reminder about
19 Bagley-Keene.

20 STAFF COUNSEL FERNANDEZ: Thank you, Doctor. I'd
21 ask that during our lunch break that the Panel members
22 please refrain from discussing the agenda items until we
23 reconvene. And we just want to ensure that everyone has
24 an opportunity to participate in the discussion.

25 Thank you.

1 CHAIRPERSON LUDERER: Thank you very much.

2 I also want to remind everyone, including the --
3 especially perhaps the Panel members, to choose a quick
4 dining option --

5 (Laughter.)

6 CHAIRPERSON LUDERER: -- which is available in
7 this Oakland 12th Street City Center Plaza near the Bart
8 station. So that's very close. We -- we're going to plan
9 an hour and 15 minutes for lunch, so should we have people
10 come back at quarter to 2:00 instead of 2:00.

11 MS. HOOVER: Quarter to 2:00, yeah,

12 CHAIRPERSON LUDERER: 1:45.

13 MS. HOOVER: Yeah. I just urge people to be back
14 by 1:45, and then we'll start promptly at 1:50. Okay. So
15 give us five minutes to gather and mill about.

16 (Laughter.)

17 CHAIRPERSON LUDERER: Okay. Great. We will see
18 you promptly at 1:45.

19 (Off record: 12:32 PM)

20 (Thereupon a lunch break was taken.)

21

22

23

24

25

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

2 (On record: 2:01 PM)

3 CHAIRPERSON LUDERER: All right. I'd like to
4 welcome everyone back from lunch. And somehow we managed
5 to start exactly at the time we had originally planned, so
6 that works out.

7 I'd like to call the meeting back to order. And
8 it's a pleasure to now introduce Karl Palmer, who is Chief
9 of the Safer Consumer Product Branch in the Department of
10 Toxic Substances Control. And he will be presenting an
11 update on the California Safer Consumer Products Program.

12 Karl is responsible for DTSC's efforts to
13 implement the Safer Consumer Products Regulations. These
14 regulations establish processes to identify and prioritize
15 hazardous chemicals in consumer products, and for
16 evaluating options for safer alternatives.

17 And Karl's team also administers DTSC's other
18 laws regarding toxics in products and helps lead DTSC's
19 efforts to expand pollution prevention practices, green
20 chemistry strategies, and sustainability initiatives
21 throughout California.

22 Welcome, Karl.

23 (Thereupon an overhead presentation was
24 presented as follows.)

25 MR. PALMER: Thank you. It's a pleasure to be

1 here.

2 Before I start, I just wanted to take a personal
3 moment and direct to Lauren, on behalf of my colleagues at
4 DTSC, our great sadness and sympathies at the loss of
5 George Alexeeff. As you know, many of my colleagues have
6 known him since grad school. Many of us worked with him
7 over the years. And my program is entirely housed on the
8 12th floor at the CalEPA building, along with a huge
9 amount of OEHHA staff. So we have the great pleasure of
10 working with them and seeing George's impact on hiring
11 great people and mentoring them. And so our hearts and
12 thoughts are with you.

13 ACTING DIRECTOR ZEISE: Thank you.

14 MR. PALMER: So thank you, Panel, for inviting
15 me. And it's a pleasure to be here. My Deputy Director,
16 Meredith Williams, was here a year ago and gave an update
17 on the basics of our program. And today, I'm going to
18 give a little refresher on some of the core parts of our
19 program, and really an update of what we're doing to
20 implement our new regulations on safer consumer products.

21 And I'm going to primarily focus on our
22 relationship with Biomonitoring California, and how
23 important it is that that collaboration moves forward to
24 the effectiveness of our program and our goals.

25 --o0o--

1 MR. PALMER: So what's our mission?

2 The California legislature in 2008 passed a law,
3 kind of known as the green chemistry law, which mandated
4 the Department adopt regulations which put in place a new
5 framework that looked at how we can promote the reduction
6 of toxic chemicals in consumer products.

7 And the intent was to reduce exposure to people
8 and the environment from those toxic chemicals, and to do
9 a few key things, to look at the entire lifecycle of those
10 products and all the potential exposures that come from
11 those chemicals and products, and to put in place a system
12 that looked holistically at how we can reduce the threats
13 from those products throughout the lifecycle of that
14 product, and importantly make sure that we don't put in
15 place restrictions or constraints that push the
16 manufacturers to substitute chemicals that might be a
17 regrettable substitute, something that might be as bad or
18 worse.

19 So that was the framework and the mission we were
20 given. In 2013, we adopted -- end of 2013, we adopted our
21 regulations. And now we're in the process of implementing
22 those regulations.

23 --o0o--

24 MR. PALMER: I'm going to go -- give you a brief
25 overview of what the -- how the regulations work. There

1 are really four main parts of the regulations. The first
2 part is identifying chemicals that we're concerned about.
3 And we call them candidate chemicals. I'm going to talk a
4 little bit about that, how we get them, the importance of
5 biomonitoring in that process.

6 The second part of the process is for DTSC to
7 identify specific consumer products that contain one or
8 more of those chemicals, and then to identify that product
9 specifically, and go to the manufacturers, the people that
10 make that product, and put it into commerce in California,
11 and say we want you to take a look at this issue, and this
12 chemical or chemicals, and your product and the potential
13 exposures across the lifecycle. And we want you to do a
14 robust alternatives analysis that uses lifecycle thinking
15 and looks at alternatives, but it looks at all the impacts
16 across the use, production, and ultimate end of life of
17 that product.

18 And then once the manufacturers do that, they
19 come back to DTSC and say here's how we think we can make
20 our product safer, and here's the things we're going to
21 do. At that point, DTSC is charged with the
22 responsibility to look at that proposal and say is this
23 good enough? Does this make sense, based on good science,
24 on the data available, on the concerns that we have about
25 that chemical product combination. And if not, what are

1 some other things that need to be done. And we have the
2 authority to impose, what we call, regulatory responses on
3 that manufacturer. And that is -- could be a range of
4 anything from saying, well, we need more information,
5 either DTSC needs more information to make some
6 determinations, maybe the consumer needs more information
7 about potential risks or harms from the use of that
8 chemical.

9 We might require that they fill data gaps. They
10 need to go do additional research. Ultimately, we have
11 the authority to say we're going to restrict the sale of
12 that product in one shape -- way, shape, or form to
13 Californians to prevent harm.

14 That's the broad overview. We're really in the
15 midst of the first two steps of that process, and that's
16 what I'm going to highlight.

17 --o0o--

18 MR. PALMER: But let me just talk a little bit
19 about our candidate chemical process. In our regulations,
20 we pointed to 23 other lists that were established by a
21 variety of authoritative bodies throughout the world,
22 OEHHA's Prop 65 list, EPA's various lists, Canada, the EU,
23 et cetera.

24 And what we did was we said all these
25 chemicals -- really smart people have found that there are

1 hazard traits to these chemicals that may pose some kind
2 of problem, either to people or the environment. So those
3 were the chemicals we're looking at.

4 There's a few notable exceptions. And probably
5 most predominantly is that we don't have the authority to
6 look at pesticides, also prescription drugs and a few
7 other things. So that narrows the list of potential
8 chemicals we might look at. Those lists are divided into
9 two basic kinds of lists, ones which are really hazard
10 trait lists that look at the intrinsic properties of those
11 chemicals and say here is why there's a concern. There's
12 some endpoint or hazard trait of concern. And the other
13 lists are really looking at things that show exposure,
14 that show that these chemicals are either in people or in
15 our environment. Biomonitoring California and NHANES are
16 the two primary ones on that.

17 And I want to blow up that biomonitoring bubble,
18 because appropriately, this is really one of the most
19 important lists of all of these lists, and for a couple of
20 reasons from my perspective, is that all of these lists,
21 with the exception of a couple which we reference specific
22 reports that had a date on them, all of them are living
23 lists. Depending on whose list it is, it may change, you
24 know, frequently or infrequently. But when those lists
25 change, those chemicals automatically go onto our list or

1 they drop off of our list. So they're living lists.

2 And so when Biomonitoring California adopts a
3 chemical onto the priority list, not the designated
4 chemical list, but the priority list, those chemicals
5 automatically are subject to our regulatory process.

6 Now, the other important part of that is that
7 particularly because some of this is about chasing
8 information and getting data is that -- so it's important
9 what chemicals are on the list. And one of the key
10 aspects that the legislature wanted us to do is make sure
11 that we don't move towards regrettable substitutes.

12 So when we look at one chemical that we know has
13 certain hazard traits and we might focus on that, we
14 really don't want to push someone to a similar chemical
15 that just isn't on someone's list. So this body has the
16 ability to look at lists, and as was discussed earlier
17 this morning, look at classes of chemicals, consider those
18 things at like functional use. What do we want to look at
19 and why, and don't just focus on one chemical, because, as
20 we know, there are often lots of different versions that
21 could also be a problem.

22 So this is a very powerful and important part of
23 our process, because it really sets the menu of what we
24 can look at in determining what products and what
25 chemicals are we concerned about and why, and how can we

1 get them through our process with the ultimate goal of
2 getting manufacturers to make safer products.

3 So once we know what the chemicals are, how do we
4 pick which products to look at?

5 This -- we've had a lot of questions about this
6 process. And both the legislature and our regulations
7 give us an extremely broad set of criteria to look at.
8 They all make sense. You know, should it be greenhouse
9 gases we're concerned about, exposure to people, children,
10 sensitive subpopulations, the environment, all those
11 things?

12 But the umbrella criteria are really that we have
13 to show that there's potential for that chemical to have
14 an exposure to -- through that product. So does this
15 product we're looking at have that chemical and is there a
16 potential for exposure, and does that exposure potentially
17 lead to significant or widespread adverse impact?

18 Now, that's a pretty broad mission, and -- but we
19 take that very seriously. And I'm going to talk a little
20 bit how we refine that and how we're picking what we look
21 at.

22 --o0o--

23 MR. PALMER: And -- but before I do that, I want
24 to tell you the first things we looked at in the process.
25 The first products that were put into the hopper, if you

1 will, of this Safer Consumer Products Program, there's
2 three of them.

3 And we came out in March of last year and said
4 these are the things we're going to look at. The first
5 one are children's sleep products with foam in it that
6 contain the flame retardants TDCPP or TCEP. The second
7 one are paint strippers that contain methylene chloride.
8 And the third product is spray polyurethane foam systems
9 with this isocyanate MDI. These are all a mouthful, but
10 it's really fairly straightforward, and -- when you look
11 at our rationale.

12 For the children's products, you know, we have
13 good data from dust studies and from biomonitoring that
14 these chemicals get into people and children. And we know
15 that these chemicals are not required to be in those
16 products, and it's questionable whether they serve the
17 functional use that they're intended for. So that seemed
18 like a good thing to pick.

19 Methylene chloride paint strippers. Again, the
20 hazard traits of methylene chloride are well documented,
21 and we have routinely, you know, people that die from
22 using this product. And so that's a concern.

23 And then the last one, spray polyurethane foam
24 systems. This is a mouthful. And what we're really
25 talking about are spray polyurethane foam products that

1 combine A and B side. They're sprayed as -- to create a
2 foam for insulation purposes, either in roofing or in
3 insulation.

4 And our concern is primarily with workers,
5 because at the time they're spraying these, and before
6 everything polymerizes, there's a lot of potential
7 exposure to MDI. And our concerns about asthma -- it
8 being an asthmagen in sensitivity.

9 So we're going to put those three products as the
10 first ones through our system, if you will.

11 --o0o--

12 MR. PALMER: And so this year, later this summer,
13 we hope to come out with our notice for rule-making on
14 each one of these products. We have to adopt these by
15 rule. So we'll have another process where we put all the
16 data on the table, and our understanding of our concerns.
17 And then we'll adopt them in regulation in which will
18 start the alternatives analysis process.

19 Concurrently, we've been spending a lot of time
20 developing guidance on how to do an alternatives analysis.
21 The specifications for that are in our regulations. This
22 is going to be a toolkit of best practices, of resources,
23 of examples that will help people who have to do this
24 analysis, figure out how to meet our requirements, and how
25 to hopefully get through a process of identifying safer

1 alternatives.

2 So that's where we are with those products.

3 --o0o--

4 MR. PALMER: In April of this year, we came out
5 with our priority product workplan. This is really a
6 roadmap of our thinking and our focus for the next three
7 years on what products and chemicals we're going to look
8 at. And the -- we put this as a requirement in
9 regulations to -- for a couple of reasons. One, we wanted
10 to make sure that people understood what our thinking was
11 and why. And we wanted to have the dialogue with all the
12 manufacturers of these -- in these different sectors of
13 the many different types of products that we might want to
14 focus on.

15 Because information is really the coin of the
16 realm here, is this is an opportunity for stakeholders in
17 these sectors to come meet with us and tell us their story
18 about why they think we should be looking at this or not
19 looking at that, why people from advocacy can say this is
20 the data we have, this is what we're concerned about, and
21 how we can work with our colleagues both in State/federal
22 government and the scientific and academic community to
23 increase our knowledge about what is the space we should
24 be and what things should we pick? So we put out the
25 workplan. There's seven broad categories.

1 --o0o--

2 MR. PALMER: And I'm going to talk about those,
3 but I wanted to give you a little bit of thinking about
4 how we're going to narrow this down. And what we put
5 importantly in this workplan, what we call, our policy
6 priorities. How are we going to sift through some of
7 these many criteria and concerns that we might have and
8 pick a few things?

9 So these are the top things we were looking at.
10 We want to make sure that we have documentation of clear
11 exposure pathways. We called out -- the biomonitoring
12 results are going to be a significant part of informing us
13 about what we should look at. We similarly are concerned
14 about documentation of chemicals in the indoor
15 environment. Most Californians spend most of their time
16 indoors.

17 We also, in our regulations, pay particular
18 interest to certain sensitive subpopulations. And
19 primarily we're concerned in this round with children and
20 workers.

21 And then also, the last two priorities are a
22 function of us being concerned about the environment. The
23 first three products we've put into the process were
24 really focused on human exposure concerns. These identify
25 that we're going to be looking at things that get into the

1 environment, particularly the aquatic environment, and we
2 want to see what floats to the top, so to speak, on that.

3 (Laughter.)

4 MR. PALMER: Or sinks to the bottom.

5 (Laughter.)

6 MR. PALMER: So these are going to be the filters
7 by which we have a lot of these conversations, and when we
8 start looking at these broad categories. And let me tell
9 you what those categories are.

10 --o0o--

11 MR. PALMER: And you'll see why it's important
12 that we start figuring out a way to sift through some of
13 these things.

14 So our first category is beauty, personal care,
15 and hygiene products, things that you put on and in your
16 body, both because of concern to human exposure and
17 because many of these things are washed into the aquatic
18 environment.

19 Our second category is household products and
20 office furniture furnishings products. Specifically in
21 this category, we identified that we're going to be
22 looking at two classes of chemicals. We're going to be
23 looking at flame retardants and we're going to be looking
24 at chemicals used for stain repellents and water
25 repellency.

1 So we've narrowed that category somewhat. The
2 next category, building products, we narrowed as well to
3 focus on paint products, adhesives, sealants, and
4 flooring. And note that all of these categories, even the
5 subcategories, are extremely broad. There are multitudes
6 of chemicals and products in each one of these categories.

7 Cleaning products, similarly, thousands of
8 different types of products. A little more specifically
9 and more focused, we have a category for fishing and
10 angling equipment. Specifically, our concern there is
11 primarily lead and lead in small fishing weights and
12 devices, like jigs that can be ingested by waterfowl, and
13 that's our primary concern.

14 Office machinery, consumable products is not very
15 descriptive, but our focus there is really looking at inks
16 and toners, and receipts -- thermal paper receipts.

17 And lastly, the clothing category as well with
18 concerns both for human exposure, but also largely with
19 impacts on the aquatic environment. So those are our
20 categories. And as you can see, there's a lot to work
21 with there.

22 --o0o--

23 MR. PALMER: And our intent and our next steps
24 are going to be is to take this workplan and start having
25 workshops, start meeting with different sectors that

1 produce these products, start meeting with advocacy groups
2 that have information and interest, start talking to our
3 colleagues in academia and looking at research, and see
4 what information we can start sorting through.

5 I put the biomonitoring area in there, because
6 it, again as I pointed out earlier, it's an important part
7 of our policy priorities to identify the data that is
8 available from biomonitoring, and see how that overlays
9 with our priorities and our categories, and start sifting
10 and sorting.

11 I wanted to give you a little bit insight of how
12 we're going to do that. We're a relatively small program,
13 but we have a team, our chemical product evaluation team,
14 which is comprised largely of scientists and engineers,
15 who we've divided these categories into teams, and each
16 category has a team of scientists and engineers who are
17 tasked both by looking at all of our concerns and all the
18 data in that category based on our chemical list, and
19 based on our policy priorities. So we're going to be
20 looking, if you will -- sorry for the --

21 --o0o--

22 MR. PALMER: -- nauseating graphics, but -- so
23 each team is going to be looking across all of the policy
24 priorities and seeing what we can document and collect.
25 And really, I like to say to my staff, this is a

1 discernment process. There's not an algorithm that says
2 how we're going to go from A to B to C in every case.
3 It's really starting to collect information, seeing where
4 that leads us, collect more information, see where that
5 leads us, onward and onward.

6 At the same time, across the teams, we're
7 taking -- we have individuals that are tasked by looking
8 at each policy priority. So we have policy priority
9 teams. So the people that are looking at biomonitoring in
10 these categories get together and start looking at that,
11 so they can share some of their expertise and knowledge,
12 both in these categories, but also looking towards the
13 future to see what comes up that might inform us about the
14 next workplan and things that might be significant that we
15 don't want to miss in our research. So that's happening
16 concurrently as well.

17 So I wanted to talk a little bit about our
18 collaboration with Biomonitoring California.

19 --oOo--

20 MR. PALMER: Importantly, we've met recently --
21 we have a commitment and we have ongoing meetings with
22 Biomonitoring California management, DTSC, OEHHA, and
23 CDPH. And at my level, the branch chief level, we're
24 really trying to get good information and find the people
25 that know how it fits in our process. We've -- we're

1 embarking on that journey, and it's going to be very
2 productive and helpful for us. And they will be tapping
3 into our folks on the team looking at biomonitoring and
4 looking into each category.

5 Concurrently, OEHHA is looking at databases that
6 have product information and trying to cross-check that
7 with the biomonitoring data that we have, and see what
8 rises to the surface on that, and how that might focus at
9 least how we start looking, and looking in the future.

10 And then we're also really blessed here in
11 California both at ECL and DPH to have incredible staff
12 and equipment and capability in our labs that will also be
13 engaged in this process to help inform us in our program,
14 not only how to help evaluate the data and look at its
15 value, its strengths and weaknesses, but also to have the
16 discussion about how we might look about the future, how
17 might we look to develop other looks at things that
18 answer -- might answer questions that we have.

19 So in the future, we're going to have the
20 back-and-forth dialogue about, you know, all the
21 information coming into biomonitoring and to us and
22 saying, hey, maybe biomonitoring should be looking at
23 this, and then we should be looking at the stuff that
24 biomonitoring is.

25 So it's going to be, I think, a very fruitful

1 relationship, and a very important one for our success.
2 We also hope that we'll be able to have discussions about
3 potential horizons on where we might go for intervention
4 studies and input into how we can help with ongoing
5 studies as well. And ultimately, we would hope that as
6 our program progresses and we see manufacturers changing
7 the way they make their products and shifting to safer
8 chemicals and away from hazardous chemicals, that we would
9 be able to use biomonitoring data to actually affirm
10 that -- their success, that we are, you know, limiting
11 exposure to chemicals.

12 We know that there's not always a smoking gun, a
13 direct line between, you know, a product and a chemical
14 and what you find in biomonitoring, but I think it's a
15 potentially very powerful tool to show success and to help
16 guide us in the future.

17 --o0o--

18 MR. PALMER: So that's primarily our mission and
19 our plan and what we're doing actively. I put this slide
20 up. Meredith, my boss, uses this slide, and we like it,
21 because, you know, no one has really done this regulatory
22 approach that we're trying to do here in California. So
23 we're using a new approach, and much like -- you know,
24 whether it's America's Cup or safer chemicals, you know,
25 we're using all the technology we can. We're trying

1 things out. We're going to make mistakes. You know, we
2 may hit and capsize here and there, but we're going to get
3 up.

4 And we're really blessed to have with
5 Biomonitoring California a great crew that's also on the
6 same journey. We're very appreciative of that, and we
7 look forward to continuing our success. So that's it in a
8 nutshell.

9 (Applause.)

10 CHAIRPERSON LUDERER: Thank you very much. That
11 was really interesting. It's great to hear about the
12 progress that you've been making in your program and also
13 to talk about various ways that the programs can
14 intersect, Biomonitoring California and the Safer Consumer
15 Products Program.

16 So we have 10 minutes or so allotted for Panel
17 questions, and then we'll have public comment, and then
18 again Panel and speaker discussion.

19 Dr. Cranor.

20 PANEL MEMBER CRANOR: A quick question about your
21 first products. You spoke about looking forward. When I
22 look at your -- at least your first product, I wonder
23 if --

24 MS. HOOVER: Carl, can you use the mic?

25 PANEL MEMBER CRANOR: Pardon?

1 MS. HOOVER: It just wasn't pointed at your
2 mouth.

3 PANEL MEMBER CRANOR: Too loud?

4 MS. HOOVER: No. No. There you go.

5 PANEL MEMBER CRANOR: Sorry. All right.

6 I wondered about your first product whether
7 that's already on the way out. And you spoke about
8 looking forward and I think that's a great idea, because I
9 think there's too little of that, but I wonder if the --
10 are these flame retardants and are they already on the way
11 out, I guess that would be the question?

12 MR. PALMER: That's a good question. I think
13 they are and I hope they are. Keep in mind that, you
14 know -- and we had great input from CEH, who's done a lot
15 of work on this, but we hope they're on their way out.
16 We've worked with the Juvenile Products Manufacturers
17 Association, who want them to be out, but not everyone is
18 a member. And there's a lot of products that are imported
19 throughout the world. So there are oftentimes people who
20 want to do the right thing and are moving in the right
21 direction, but we're capturing everyone.

22 And so part of this -- our design is to use the
23 market for innovation and to have a level playing field.
24 So while we hope that everyone gets out, we're going to be
25 looking to make sure that everyone gets out.

1 PANEL MEMBER CRANOR: The reason I asked the
2 question is because there might be a better way for you to
3 use your time than working on things that are already kind
4 of on the way out and maybe the market is going to --
5 maybe or maybe not going to take care of it. And so
6 that's the reason I raised the question.

7 MR. PALMER: And that's certainly a concern of
8 ours. And if you look at the mix of the first three
9 products, you know, some of the factors that came into
10 that decision making are interesting. So, for example,
11 methylene chloride paint strippers, there are the market
12 alternatives right now. They have challenges in terms of
13 their efficacy and cost and things likes that, but we
14 thought that was a good thing to look at, because there
15 are some significant impacts from that product.

16 And then in spray polyurethane foam, we knew
17 going in that there is not, at least currently, an
18 off-the-shelf way to make foam of a similar function. So
19 this is really a green chemistry -- truly a chemistry
20 challenge, and we recognize that.

21 And the other thing I want to point out is that
22 we are not presuming necessarily any one outcome. We're
23 not saying we want to ban this. We're saying we want to
24 take a look, and we want to see what options there are.
25 And so in the case of spray polyurethane foam products, we

1 don't know that there's an alternative. We know you might
2 be able to use a different type of product, fiberglass,
3 cellulose.

4 But they're going to be evaluating not only the
5 potential risks, but also its benefit and its
6 functionality. So they're going to be looking at its
7 efficacy in terms of R-value and length of service. And
8 all those things are on the table. So we don't really
9 know where it's going to go.

10 But your point is a good one, we are concerned
11 about our bandwidth and our focus. Our mantra in adopting
12 the regs and implementing the program is trying to be
13 meaningful, practical, and legally defensible. So those
14 are good things that we are always keeping in mind.

15 CHAIRPERSON LUDERER: Dr. Quintana.

16 PANEL MEMBER QUINTANA: Hi. First, I want to
17 thank you for putting workers at the heart of this effort,
18 as well as children, because I think they have the fewest
19 protections really of any group, unless they can be
20 brought to bear, you know, in terms of consumer sentiment,
21 and what have you, on preventing exposures. So I think
22 that's a great thing.

23 I was interested in what you said in your last
24 slide about potential intervention studies, because I
25 think when you have a situation where you might have a

1 relatively abundant compound and biomonitoring studies,
2 but lots of different sources, I think those can be very
3 helpful to figure out where they're coming from. And I
4 think it really dovetails with consumer interest in
5 preventing exposures, because when I talk to people about
6 this Program that I just meet, you know, other moms or
7 whatever, what they always want to know is what can I do?

8 They want to know, you know, what -- can I buy
9 something different? Can I buy those expensive whatever
10 products is it better? You know, so they instantly think
11 of interventions when they think of this Program of
12 California Biomonitoring. And so I think that really
13 dovetails nicely.

14 MR. PALMER: Yeah, thank you. And we're just
15 starting to have those conversations. But certainly, if
16 you look at the HERMOSA study and you look at other things
17 that shed a lot of light on the importance of some of
18 these things and the challenges. I mean, when you look at
19 beauty products, the rate of use, the volume, the
20 potential exposures, and our culture, you know, consumers
21 want to know what choices they have and how to make good
22 choices.

23 And our focus is largely upstream from that.
24 It's really talking to the manufacturers about chemicals
25 and design in hopes that those choices are made simpler by

1 having safer products, not having to require a consumer to
2 know to read the label and figure it out, which is tough.

3 CHAIRPERSON LUDERER: Any other questions,
4 clarifying questions from Panel members?

5 Do we have -- we have some public comments
6 though, I see. And then we'll have you back for more
7 discussion afterwards.

8 MS. BUERMEYER: You should just recycle.

9 (Laughter.)

10 CHAIRPERSON LUDERER: All right. Nancy Buermeyer
11 from the Breast Cancer Fund.

12 MS. BUERMEYER: Thanks very much. Again, Nancy
13 Buermeyer, the Breast Cancer Fund.

14 I wanted to thank Karl for being here and talking
15 about this program. It's a program that the Breast Cancer
16 Fund has been invested in for a very, very long time. We
17 were one of the organizations that helped write the
18 legislation, and then the regulations, which I heard was
19 kind of a bear. I managed to miss that process, but I
20 understand it was quite an involved process.

21 And we are very excited about seeing it get up
22 and running. And I'm hopeful that your slide about the
23 Oracle sailboat is about how fast you're going to be going
24 at the end of the year.

25 (Laughter.)

1 MS. BUERMEYER: You're going to get those things
2 running through there really fast. Well, your working on
3 it, right?

4 I also wanted to comment on the sort of shopping
5 your way out of the problem. You know, I think we also
6 find in our website that the thing that gets the most
7 traffic is our tips on how you reduce your own exposure.
8 And that's an important thing. It's -- people, and
9 particularly moms, want that. It's a way to bring people
10 into the conversation.

11 But I think it's really important that we not use
12 it to blame the victim. I mean there just is no way to
13 avoid a lot of these exposure. And I think that's why the
14 upstream approach is incredibly important that -- you
15 know, so that consumers don't have to have a Ph.D. in
16 chemistry to figure out whether the products that they're
17 using with their families are safe. And in the case of
18 cleaning products, one of the things we've been working on
19 is a bill in the legislature to try to get the ingredients
20 of cleaning products disclosed, so that you even have the
21 information, if you knew what the chemicals were to figure
22 out whether something is safer or not.

23 So I think there's a lot of different pieces to
24 this puzzle. And I think that this program has a really
25 important role to play. And obviously, the Biomonitoring

1 Program provides a key piece of the puzzle to make those
2 selections, which brings me to my question for Dr. Palmer.

3 There's a slide here about executing the
4 workplan, and it talks about data call-ins and stakeholder
5 meetings and workshops. And it all gets mixed up into the
6 priority chemical -- priority products.

7 Can you just expand that out a little bit, like
8 what kind of data call-ins are you talking about? It
9 sounds like you have scoping teams. I just would be
10 curious how that's going to work and how stakeholders can
11 be involved.

12 MR. PALMER: Sure. Thank you, Nancy. It's going
13 to a variety of ways. Our -- we have limited authority to
14 actually collect -- to require information to be given to
15 us. But the call-in term is in our regulation. It
16 essentially is we can ask manufacturers for information.
17 They don't necessarily have to give it to us, but if they
18 don't give it to us, then we're going to let everyone know
19 that we still want this information. So the power of
20 public pressure, you know, to be transparent is there.

21 But probably more importantly is that once we
22 came out with the workplan, these sectors are paying
23 attention, and they're starting to respond when we have a
24 question, whether it's my staff just calling up saying,
25 you know, where is -- do you use this chemical or where do

1 I get this data?

2 And then in the public sector, as we start going
3 through this process, we're going to choose what we
4 workshop for example. We might have a workshop on a
5 specific sector, or some component of that sector, or
6 chemicals within that sector, or we might decide we need
7 to have a workshop that's really based more on the
8 functional use of certain types of chemicals across the
9 various categories, because we have great latitude to pick
10 chemicals and products across this spectrum, but there's a
11 lot to learn.

12 So we're also happy to hear from people who have
13 suggestions on how we might do that or where we should
14 have this dialogue. And it will all be very transparent.
15 I mean, we obviously meet with lots of people, but we're
16 going to be putting all this information out as we start
17 moving forward and saying this is how we're refining our
18 focus. So it will be a lot of different ways.

19 MS. BUERMEYER: Do you have any sense of timing?

20 MR. PALMER: Timing. Yeah, I think that what
21 we're focusing on right now is trying to kind of sort
22 through chemical information to see -- in those categories
23 where we have information on chemical presence in
24 products. That will then sort of inform us probably this
25 fall about should we have some workshops on that and

1 should we start pulling the thread on specific areas more?
2 We don't really know. Again, it's -- we don't have a set
3 schedule for workshops. We don't have a target. What
4 we're trying to do is get some, you know, additional
5 products in the next six months queued up and make this an
6 iterative process.

7 That workplan is a three-year workplan. And by
8 the end of the second year, we have to have the next one
9 done. So the other thing is -- we're interested in is
10 finding out other things that might be of interest down
11 the road. So even if it's not in one of those categories,
12 but there might be some compelling information, we'd like
13 to know that as well.

14 CHAIRPERSON LUDERER: Thank you. Okay. We have
15 another public comment. This one is from Alexander
16 Hoepker from UC Berkeley, Berkeley Center of Green
17 Chemistry.

18 MR. HOEPKER: Thank you very much. My name is
19 Alex Hoepker. I'm from UC Berkeley, post doc there with
20 the Center of Green Chemistry.

21 I have a question about sort of the pathway of
22 identifying upstream chemicals of concern, especially in
23 regards to dissemination of information. And I'm thinking
24 very particularly about the private sector here. So as
25 you workshop finding solutions for alternatives, will that

1 information be publicly available, especially thinking
2 about IP issues?

3 And then my other question was among exclusions
4 were pesticides, and I was wondering what the reason for
5 that was?

6 Thank you.

7 MR. PALMER: Well, the simple answer is that
8 we -- when we require information -- when someone gets in
9 the process, they have to give us information. They can
10 claim trade secret protections under California law, and
11 that's reflected in our regulations, and we have to
12 protect that. Otherwise, everything is going to be
13 transparent. We will be posting all of our documents, all
14 of our decision documents, all the data that we get, with
15 the exception of that. And that burden is really on them
16 to make that -- assert that privilege and then for us to
17 evaluate it. We'll see.

18 The second part, why were pesticides excluded?
19 And they were excluded because the California legislature
20 said they would be.

21 (Laughter.)

22 MR. PALMER: And, I mean, you know, from a
23 practical standpoint, I mean, there are a lot of pesticide
24 issues out there, but that would have opened up even --
25 many more options and challenges in terms of more things

1 to look at. And we've got a lot on our plate right now,
2 so not to discount it. That would be a good thing to look
3 at.

4 CHAIRPERSON LUDERER: Dr. Cranor.

5 PANEL MEMBER CRANOR: One follow-up question I'm
6 not sure I understand the answer to yet. I actually
7 happened to be at a conference with your colleague,
8 Meredith, a month ago or something. And her description
9 of it suggested maybe that the end-product might be a
10 regulatory action. You're today not suggesting that.

11 But what worried me then, and maybe you can
12 disabuse me of this now, is that these things are in the
13 market. When we have post-market laws, it's so slow, and
14 so hard to do something. Are there features of your
15 program that can speed things up, so that we don't have to
16 go through these very long, slow, agonizing processes?
17 And then here, of course, if you'd take something that's
18 already on the way out, it's to no avail. So could you
19 say a little bit more about that?

20 MR. PALMER: Sure. Let me say a couple things.
21 One, I'm sure Meredith was right, because she's my boss.
22 So whatever --

23 (Laughter.)

24 MR. PALMER: But, no -- but specifically yeah, we
25 do have the ability to impose a regulatory requirement,

1 and we will if we need to. At the same time, we might not
2 need to if someone makes a change, and it's a good change.
3 And, you know, that would be ideal. It would be less of
4 a -- it would be more timely. It would be hopefully
5 effective. But part of the objective is to send messages
6 to these sectors that you should be looking at our
7 candidate chemical list.

8 I mean, I think most responsible manufacturers
9 are going to look at that list and say am I using any of
10 these chemicals? Do I need to use all these chemicals?
11 Are there alternatives? Can I -- because frankly, they
12 don't really want to talk to me and Meredith ever.

13 (Laughter.)

14 MR. PALMER: So -- and we see there are some
15 leaders out there in different sectors who are showing
16 that these things can be done. The community of practice
17 around alternatives assessment is building. For many
18 manufacturers it's a question of not can you do it? It's
19 can you expand your existing practices to incorporate
20 other factors that we're concerned about that maybe you
21 didn't have to be concerned about because the market
22 didn't dictate it or a regulation didn't dictate it.

23 So I think those messages are being heard, and
24 people are paying attention, because the market is always
25 going to be nimbler than we are. And yet, we're hearing

1 from a lot of people that they get it, that they're --
2 they should be working on it. And so we're hopeful that
3 people will make work to move faster.

4 PANEL MEMBER CRANOR: I mean, I guess that's
5 encouraging, because if you have to go through a
6 regulatory process, it's often very slow, and very
7 painful. So you're optimistic that you can accomplish a
8 lot via market mechanisms and persuasiveness, rather than
9 having to turn to the regulatory product at the end?

10 MR. PALMER: No, I would phrase it that, I mean,
11 I'm a regulator. And I think it's very important to have
12 a clear message and a clear boundary and set some
13 standards. At the same time, I think that that provides
14 the opportunity for people who wanted to be progressive
15 and look forward to move faster than we do, and have the
16 back-stop of making sure that there's a level playing
17 field, and that we have standards that are met when we
18 identify our problem that needs addressing.

19 So it's this combination of that. There will
20 always be winners and losers in the market, but, you know,
21 I think it's really important to have us there to say, no,
22 there is a line here and --

23 PANEL MEMBER CRANOR: I see. So in the end, it's
24 the regulatory outcome that you feel you'll have to impose
25 at some point?

1 MR. PALMER: Yeah, I mean, I'm sure we will at
2 some point for some people. I mean, most -- one of the
3 most common questions I get when I talk about this, and
4 Meredith as well, is what does compliance look like?

5 You know, by and large, most companies want to do
6 the right thing. They want to be in compliance, and they
7 want to know what that looks like. So part of this is
8 that education process of saying this is a very different
9 regulatory program that certainly anyone at DTSC and most
10 environmental and health agencies, we're not setting a
11 specific standard, we're not saying you -- here's the
12 concentration, here's not the action level.

13 We're saying here's the potential problem. You
14 tell us what -- how -- what you're going to do with it.
15 It's a very foreign concept for folks. It makes them very
16 uncomfortable that uncertainty. And we're there to say
17 there is going to be certainty that we're going to be
18 looking and we're going to be holding you accountable, but
19 we're also going to support if you do good things.

20 PANEL MEMBER CRANOR: Thank you.

21 CHAIRPERSON LUDERER: Dr. DiBartolomeis, you have
22 a comment?

23 DR. DiBARTOLOMEIS: Michael DiBartolomeis, CDPH.

24 So I'm going to challenge you a little bit on the
25 concept --

1 (Laughter.)

2 DR. DiBARTOLOMEIS: I know -- on the concept that
3 just because something is written into legislation, there
4 isn't some open to interpretation.

5 So on the pesticide issue, clearly I understand
6 why they took pesticides that are used in agriculture or
7 even structural pest control off the list. Theoretically,
8 they're for covers and the State law has covered that
9 fairly well, and there's a whole process in place.

10 But I'm going to submit to you that something
11 like triclosan, which is technically a pesticide, is
12 probably more -- is more problematic because it's in
13 consumer products, which would be your neck of the woods.
14 And then I would think the intent of the legislation was
15 not to exclude those sort of chemicals.

16 Now, I -- so technically, it may be excluded, but
17 I'm kind of wondering if you could push the envelope on
18 that. So I'm just wondering, you know, where would you
19 put triclosan in that, because to me it's in that gray
20 area?

21 MR. PALMER: Well, actually, Michael, we don't
22 think it really is gray. We think it's complicated.
23 Triclosan is on our candidate chemical list. And we feel
24 that, depending on its use and what type of product and
25 its application, we could look at it, I mean --

1 DR. DiBARTOLOMEIS: So you're agreeing with me
2 then.

3 (Laughter.)

4 MR. PALMER: And you have to -- I am agreeing
5 with. Yeah, I know, write that down.

6 (Laughter.)

7 MR. PALMER: Yes, because it really depends on
8 the -- you know, we reference FDA and all these other
9 hierarchies -- regulatory hierarchies and some of them
10 don't fit the exclusion. So we do feel that we could get
11 there in certain circumstances.

12 CHAIRPERSON LUDERER: Dr. She.

13 DR. SHE: Karl, I think this is very important
14 point you give, and try to maybe join -- bear the linkage
15 between the two programs. And I'm finding interest -- so
16 from the policy level, regulator's level, you see the need
17 to bring the programs together. From a scientific point
18 of view, I think the programs must work together to solve
19 the public health issues.

20 For example, I use your slide -- your slide
21 number four, you have exclusion. You basically exclude
22 metabolite breakdown compounds. Metabolite breakdown for
23 the non-persistent chemicals, and that's only seen by
24 monitoring.

25 And then monitor parent compound for this

1 non-persistent may be problematic. So from a
2 biomonitoring point of view, from an environmental point
3 of view, so you think two programs complement each other.
4 So and -- so I think now is the time to find the correct
5 part to work together may put a different level of
6 requirement of a program to think together. I use FREES
7 study we propose together which include dust, blood, and
8 urine. And then we need to see Biomonitoring Program
9 breakdown what each lab can do better for certain things.

10 So parent compounds, for example, DTSC is a good
11 resource. For urine metabolite, I like you also -- you
12 already started a communication with us, but laboratory
13 can also be part of this communication to see we have
14 literally, without reinventing the wheel, we can provide
15 help.

16 For example, some chemicals, very hard to measure
17 the parents, but metabolite maybe the easy way. And so we
18 can breakout the boundary of the two programs and merge
19 them together literally in the scientific process.

20 MR. PALMER: Well, thank you. I agree. I mean,
21 let me clarify that the exclusion for metabolites is not
22 that we can't go to biomonitoring and take measurements of
23 metabolites, it's that we wouldn't list that as the
24 chemical of concern in the product.

25 So -- and our definition of chemical, if you go

1 to our regulations, you might enjoy reading that.

2 (Laughter.)

3 MR. PALMER: It's pretty much open to a broad
4 interpretation of things that we could capture including
5 degradation products.

6 DR. SHE: Thank you.

7 CHAIRPERSON LUDERER: Dr. Schwarzman.

8 PANEL MEMBER SCHWARZMAN: Thank you so much for
9 your presentation. And I appreciate hearing all the ways
10 in which you think that biomonitoring can inform the Safer
11 Consumer Products program, and it's something that we've
12 talked a lot about in those panel meetings.

13 But I also want to flag, in this setting, I'm
14 just grateful that there's so much communication happening
15 now between these BDOs of the two programs, because I
16 think an issue that we were talking about earlier with
17 regard to like DINCH being this example of a non-phthalate
18 alternative that comes in that is relevant for looking at
19 a currently biomonitored group of chemicals.

20 It seems to me thinking about what the Safer
21 Consumer Products program can bring to biomonitoring,
22 that's one of the large areas, and that I would -- that I
23 think we should keep our eye out for is ways -- places
24 that the Safer Consumer Products program is learning about
25 alternatives that are coming down the line or ways that

1 the market is shifting or where industry is looking to
2 move away from impending regulation or just the shot
3 light -- spotlight shining of the Safer Consumer Products
4 Regulation.

5 Even if there isn't regulatory action taken on
6 chemicals of concern that that might provide clues to the
7 biomonitoring world about directions that we should look
8 for maybe outside of a chemical class, but a functional
9 substitute, and for something that I'm glad to hear you
10 talking about these sort of forward-looking studies or the
11 potential for that anyway, that we should be keeping our
12 eyes open too as the Safer Consumer Products Branch learns
13 about potential substitutes or industry shifts, that
14 that's something that the biomonitoring group should
15 really consider for additions to our chemical list.

16 CHAIRPERSON LUDERER: Other questions or comments
17 from Panel members?

18 Dr. Kavanaugh-Lynch.

19 PANEL MEMBER KAVANAUGH-LYNCH: Just out of
20 curiosity I was wondering where food contaminants and food
21 packaging might have ended up in your priority list or if
22 it's there at all?

23 MR. PALMER: If you look at our workplan, we did
24 not include food packaging. We had some interest who had
25 given us a lot of input saying that they thought that

1 would be a priority. And I would just say, you know, we
2 appreciate that input. And I think there was a lot of
3 good input, and there's a lot of arguments why we might
4 look at that.

5 So two things. One, we're going to keep doing
6 this. So just because we're not looking in this round,
7 doesn't mean we're going to look at the next round. The
8 other thing I want to point out is that we have in our
9 regulations provisions which allow anyone to petition the
10 Department to specifically look at either a chemical or a
11 product chemical combination. And that then sort of
12 shifts the burden onto the petitioner to provide the data
13 that would support that argument and our look at that.

14 And we will address any of those formal
15 positions -- petitions, and -- so that is an opportunity
16 as a check and balance, if you will, that as good
17 information is developed, that we could certainly change
18 course or address something, if appropriate.

19 CHAIRPERSON LUDERER: I actually have a kind of a
20 comment about it that relates to the food packaging, but
21 also to some of -- two of the categories that are on your
22 priority product workplan, and that is for some -- for
23 food packaging, as well as for the -- I think the clothing
24 category and household furnishings, I mean, there are
25 definitely chemicals that would cut across multiple

1 priority product workplan categories.

2 You know, I think of like the polyfluorinated
3 alkyl substances, for example. And is that -- is there a
4 way for you to, you know, take that kind of thing into
5 account that might create, you know, kind of getting to
6 what Dr. Cranor was talking about, make -- you know,
7 rather than -- enable you to address multiple products
8 kind of at once, rather than having to do them all
9 separately?

10 MR. PALMER: Yes. Good question. I think
11 it's -- we have -- it's wide open in terms of our latitude
12 within the constraints of the regulations on what we pick.
13 You highlight a good point. We might, for example, choose
14 one class of chemicals because of their functional use and
15 their hazard traits across a number of these categories.
16 And we might pick multiple products. That poses some
17 logistical and pragmatic issues. But depending on how you
18 define those products and who you're capturing, it might
19 be very efficient, because what we find is that functional
20 use is an important thing.

21 So, for example, when we first said we were
22 looking at isocyanates and SPF in our public workshops, we
23 had folks coming from the adhesive industry, from other
24 people who, because they use isocyanates for the same
25 essential -- chemistry-wise for similar uses, and with

1 similar hazard profiles, and potential exposures. They
2 legitimately are saying, wow, you know, are you going to
3 look at us or not hopefully, from their perspective?

4 But we don't -- we're not constrained by that.
5 We might pick a chemical or some chemicals in a functional
6 use and think that in this round it maybe is -- the best
7 way to go is to focus on and across sectors and work with
8 the functional needs, because, you know, manufacturers are
9 looking, most of the time, for something that performs
10 something. And that is intrinsically -- some of those
11 issues then spur a lot of innovation across products and
12 by function.

13 So that's something we're certainly looking at.
14 We're not there yet. And in our limited bandwidth, those
15 kind of questions are really significant, in terms of how
16 meaningful -- in fact are meaningful criteria and
17 pragmatic can we be and practical, so -- but it's a
18 good -- we're very aware of that challenge.

19 CHAIRPERSON LUDERER: Sara.

20 MS. HOOVER: Hi. Sara Hoover, OEHHA.

21 I wanted to speak to some of what Meg brought up.
22 So I wanted to really assure you that functional
23 categories are always open to us, and we look at that
24 closely. So, in particular, plasticizers, we had an
25 effort a few years ago, I guess, where Gail did a lot of

1 investigating into plasticizers. And we've -- so every
2 time we bring a group of chemicals, we vetted it with the
3 Panel. So that's actually how we came to the conclusion
4 of looking at ortho-phthalates as opposed to a broader
5 category.

6 So I just wanted to put that out there and just
7 let you know that each time we look at a class, we always
8 consider the possibility of a functional group. We
9 understand the importance of that.

10 I also wanted to point out - you probably already
11 know this - but DINCH is already designated. So today
12 what we're looking at is designating -- this is a preview
13 for the next item -- you'll be looking at designating the
14 entire class of ortho-phthalates. So we always have to
15 bite off kind of a reasonable piece to consider. You kind
16 of probably had the -- looking at the document and the
17 amount of effort that went into just ortho-phthalates, you
18 can imagine if we broadened it. So just an explanation,
19 but we're always interested and aware of those other
20 possibilities.

21 CHAIRPERSON LUDERER: Any other comments or
22 thoughts from Panel members? I mean, do Panel members
23 have other specific suggestions possibly about how the two
24 programs could work together?

25 Dr. Quintana.

1 PANEL MEMBER QUINTANA: Hi. I had a specific
2 question about the role of non-targeted analysis, in terms
3 of how it would feed into your program, because I
4 understand that the Biomonitoring Program is very
5 interested in non-targeted analysis, which might turn up
6 just a bunch of stuff. We don't know what it is
7 sometimes, and sometimes there's no abstract number.
8 There's not even any databases, but it's really abundant,
9 and how that might feed into your program.

10 MR. PALMER: Well, you know, we're happy to get
11 data. You know, as long as it's good data, you know,
12 we're happy to get it. We're not -- I mean, I'm excited
13 about our collaboration, because we're looking and talking
14 to lab folks about the different abilities that we have,
15 and the different processes.

16 And, you know, my experience, and this speaks a
17 little bit to Meg's thoughts too, is that it's really
18 important that we have these conversations with the people
19 who are experts in their field, and how that might be a --
20 sorry -- might be applied for someone who has a different
21 criteria or a different look.

22 So we're open to whatever we can get, and we have
23 great latitude to use good data and sound science to
24 inform us on our decision making for policy. So bring it
25 on.

1 (Laughter.)

2 CHAIRPERSON LUDERER: Another questions, comments
3 from Panel members?

4 You know, I do have a question about the personal
5 care products priority category. Is that -- in terms of
6 picking the priority products, how specific will that get?
7 Would it be one particular, you know, I don't know
8 lipstick or something, but --

9 MR. PALMER: Yes. Well, that's a very good
10 question. I mean, from a regulatory standpoint when we
11 identify, what we call, a priority product, it has to be
12 very clear who we're capturing from a regulatory
13 standpoint, which means that, for example, a personal care
14 product toothpaste, for example. If you look at oral
15 care, there are a lot of different products. There's
16 toothpaste. There's tooth whiteners. There's
17 mouthwashes. There are a variety of things. We would
18 make it really clear that the specific type of product
19 that we're capturing and the specific chemicals that we're
20 capturing.

21 And so we found that it's very important -- one
22 of the lessons we learned, when we came out looking at
23 spray polyurethane foam, our initial, you know -- when we
24 put out information that we wanted to look at this, we
25 said we wanted to look at isocyanates in roofing and -- I

1 forget how we called it, but we included roofing systems
2 and insulation systems for walls.

3 When we looked at the data, we'd seen that for
4 roofs, they put -- apply a coating -- a UV protection
5 coating that many of them still use TDI. So we had said,
6 oh, well, that's a concern, and so we'd included that.
7 And then we got all kinds of feedback saying that's a
8 different product. You don't purchase a roofing system
9 that focus -- that makes foam with TDI in it. You buy a
10 separate product that is a coating that might have TDI in
11 it.

12 It's very important to the people that make those
13 things that they know that we're looking at. So it is a
14 challenge, and that's I think the other thing we're
15 learning in dealing with manufacturing. Most of the folks
16 on my team came from hazardous waste and Superfund
17 clean-up perspectives, risk-assessment driven, fairly
18 linear things. In the product world, there's a lot of
19 other factors that we're learning a lot about. So it's
20 important.

21 CHAIRPERSON LUDERER: Jianwen. You're behind the
22 thing, so it's hard for me to see you.

23 DR. SHE: Actually, I think Dr. Quintana's
24 questions and part to Karl and part to the laboratory.
25 How the unknowns method the laboratory try to develop can

1 work for both part? I think everyone remember what Dr.
2 Antonia Calafat said, she even view unknown start with
3 environmental sample is a good idea.

4 This also something I agree. For example,
5 biomonitoring, at least from urine part, we look for
6 metabolite. So now it's -- to find some unknown may be
7 more direct look for the parents. So environmental
8 samples tended to have a low metabolism capability. You
9 may either find it. So other part, for example, you can
10 identify chemical in the top food tree, and then which
11 serve better you avoid a lot of the issues like IRB
12 issues.

13 To start with that, that work with environmental
14 program much better, even some product that have
15 commercial secret you do not know. And then but the level
16 is so high enough to establish the -- to at least test the
17 paradigm of your biomonitor and unknown program to make
18 sure it's working.

19 I'll give you an example. For example, when we
20 do the PBDEs, we first use seal, seal is on top of food
21 tree, you know that by accumulations there, so you tend to
22 easily find it. If you go to very low level and then you
23 think they're already metabolite, so maybe start with
24 persistent chemicals, and then with some high species on
25 the top of food tree some product we may suspect that have

1 other things, since this maybe at least additional
2 compilation of the two programs.

3 CHAIRPERSON LUDERER: All right. Thank you. I
4 think it's time to move on to our next topic. So thank
5 you. For that good discussion.

6 It's actually time for a break. So we have a
7 15-minute break. So we'll reconvene at 3:15

8 (Off record: 3:00 PM)

9 (Thereupon a recess was taken.)

10 (On record: 3:18 PM)

11 CHAIRPERSON LUDERER: All right, everyone, I
12 think it's time to call the Panel back to order here.

13 Let's -- Panel members, please sit down.

14 (Laughter.)

15 CHAIRPERSON LUDERER: All right. Let's see. It
16 looks like we are missing one Panel member still and
17 Laurel. There's Laurel.

18 Is there somebody out in the lobby. Scott, is he
19 out there?

20 MS. HOOVER: He's on the phone.

21 CHAIRPERSON LUDERER: Oh, he is. Okay.

22 (Thereupon an overhead presentation was
23 presented as follows.)

24 CHAIRPERSON LUDERER: Well, I can just maybe call
25 everyone back to order slowly. So just welcome you all

1 back from the break. So our next agenda item, as has
2 already been mentioned, is consideration of the chemical
3 class ortho-phthalates as potential designated chemicals.
4 And Dr. Laurel Plummer, Staff Toxicologist, in the Safer
5 Alternatives Assessment and Biomonitoring Section of OEHHA
6 is going to be presenting a brief summary of information
7 from the document that the Panel received and that was
8 posted on the website for us now.

9 So, Dr. Plummer

10 DR. PLUMMER: Thank you very much. So good
11 afternoon, everyone. Today, I'll be presenting
12 information relevant to the consideration of the class of
13 chemicals known as ortho-phthalates, or o-phthalates I'll
14 use as abbreviation for this presentation, consideration
15 as potential designated chemicals.

16 And before I begin, I just would like to
17 acknowledge other OEHHA staff who were instrumental in
18 finalizing the document and the presentation. Dr. Shoba
19 Iyer, Gail Krowech -- Dr. Gail Krowech and Sara Hoover,
20 our Chief of the Safer Alternatives Assessment and
21 Biomonitoring Section.

22 So the first slide here shows the general
23 structure of o-phthalates. They're
24 1,2-benzenedicarboxylic acid esters with R and R prime
25 groups that are commonly alkyl groups.

--o0o--

DR. PLUMMER: Okay. So just a reminder for everyone, designated chemicals are those that can be considered for biomonitoring by the Program. Chemicals are designated in two ways, via inclusion in CDC's National Reports on Human Exposure to Environmental Chemicals Program, which we heard about earlier this morning, and also through recommendations from the SGP during these meetings.

--o0o--

DR. PLUMMER: All right. So here's a list of o-phthalates that are currently on the list of designated chemicals. There's quite a few. This is just a subset -- or this slide shows a subset of the entire class of o-phthalates. So the class is obviously much bigger than the ones that are listed here, and these are listed just in approximate order of alkyl chain length.

--o0o--

DR. PLUMMER: All right. So the SGP has taken a few actions on o-phthalates in the past. In March 2009, the SGP recommended that all designated o-phthalates be added to the list of priority chemicals. And as I mentioned earlier, since these were added via inclusion in CDC, that was the first action was to make them all priority. And then in November 2010, there was a

1 discussion in the SG -- about o-phthalates as well. And
2 the SGP recommended at that meeting that if new phthalates
3 are added to CDC's list, that those automatically be added
4 to the list of priority chemicals for Biomonitoring
5 California.

6 --o0o--

7 DR. PLUMMER: So because today we're presenting
8 this group of chemicals, I just wanted to review the
9 criteria for recommending additional chemicals. It's
10 outlined in the legislation. Pretty straightforward, but
11 basically exposure or potential exposure known or
12 suspected health effects, the need to assess the efficacy
13 of public health actions to reduce exposure to a chemical,
14 and then several analytical considerations as you can see
15 on the slide.

16 And these criteria are not joined by and.

17 --o0o--

18 DR. PLUMMER: So shown here are a few example
19 o-phthalates, the structures of them, just to illustrate
20 some that are not currently designated.

21 --o0o--

22 DR. PLUMMER: So why o-phthalates as a class?
23 There are a number of reasons that it's to
24 consider these -- the o-phthalates as a class of
25 chemicals. Many o-phthalates including some that are not

1 yet on the list of designated chemicals are high
2 production volume chemicals that are used worldwide as
3 plasticizers, and so widespread exposure is expected.

4 Restrictions in the U.S. and worldwide on certain
5 phthalates has already resulted in increasing use of other
6 o-phthalates as we heard in Dr. Calafat's presentation
7 this morning, some examples.

8 And data on the use and human exposure to
9 chemicals in this class is very limited. Including the
10 entire class of o-phthalates as designated chemicals would
11 be a resource-efficient approach for Biomonitoring
12 California, would facilitate broad laboratory screening
13 for o-phthalates, and also allow the Program flexibility
14 in response to market shifts, and give the Program the
15 ability to measure the most appropriate members of the
16 class.

17 --o0o--

18 DR. PLUMMER: Okay. So just a little -- some
19 highlights of restrictions on o-phthalates. In
20 California, effective in January 2009, six o-phthalates
21 were banned for use in children's toys and certain
22 childcare articles at concentrations above 0.1 percent.
23 Federally, similar restrictions are in place. And a new
24 federal proposal would expand the permanent federal ban on
25 DEHP, di-n-butyl phthalate and benzyl butyl phthalate to

1 include four additional phthalates. Diisononyl,
2 diisobutyl phthalate, dipentyl phthalate, and di-n-hexyl
3 phthalate.

4 And it would actually lift the interim ban on
5 diisodecyl phthalate and di-n-octyl phthalate. So that's
6 a 2014 proposed rule-making from the Consumer Products
7 Safety Commission.

8 And in California, manufacturers are directed to
9 use the least toxic alternative in replacing the
10 restricted o-phthalates. And this would prohibit
11 manufacturers from replacing these phthalates with
12 carcinogens or reproductive toxicants. So trying to avoid
13 the regrettable substitutions with that law.

14 --o0o--

15 DR. PLUMMER: Several o-phthalates are listed
16 under Proposition 65. You can see these listed here. And
17 this is the chemicals known to the State of California to
18 cause cancer and/or reproductive toxicity. Of these
19 listed here, di-n-hexyl phthalate is not included on the
20 list of designated chemicals.

21 --o0o--

22 DR. PLUMMER: So the next few slides are going to
23 cover information relevant to the criterion exposure or
24 potential exposure to the public or to specific subgroups.

25 --o0o--

1 DR. PLUMMER: So you heard a bit about the uses
2 of o-phthalates this morning from Dr. Calafat. And I just
3 wanted to highlight again some uses here that phthalates
4 are used to impart flexibility and durability to a number
5 of products from consumer products, building supplies, and
6 others listed there.

7 They're also used for a number of purposes in
8 personal care products and cosmetics, including as
9 fragrance carriers, in perfumes and scented products, and
10 to prevent brittleness and cracking in nail polish. So,
11 you know, some of those uses are going to pose particular
12 exposures for certain groups like workers.

13 --o0o--

14 DR. PLUMMER: The production volume -- production
15 and import volume is one indicator we often look at to
16 assess use in the U.S. In addition to some information
17 from that, which I'll highlight in a little bit, there
18 were some recent articles in Chemical and Engineering News
19 that discussed phthalate use, and there was an estimation
20 from one of those articles, Tullo 2015 - there's a link to
21 that article at the bottom of the slide - that indicated
22 that although alternatives to phthalates are beginning to
23 emerge in the marketplace -- you can see the yellow part
24 of the pie chart there indicates phthalates, and the other
25 smaller ones are alternatives -- worldwide consumption of

1 all plasticizers is about 18 billion pounds. As you can
2 see on the chart, phthalates still is estimated at about
3 70 percent of that total, according to the article by
4 Tullo.

5 And based on the most recent available U.S.
6 production import data from the U.S. EPA, which was the
7 reporting year 2012, numerous o-phthalates have production
8 volume that's considered high production volume, so
9 greater than a million pounds. And those are listed
10 there, DEHP, DEP, and several others.

11 Interestingly, and this contributes to the lack
12 of data that we know about use, is that several chemicals
13 that had high production volume in reporting year 20 -- or
14 2006 actually had data withheld in 2012, which is sort of,
15 I think, partly the new system of reporting that
16 manufacturers are actually allowed to claim confidential
17 business information. So that contributes to another
18 layer of our difficulty of knowing what's actually used.
19 And there is -- they are doing another collection of that
20 data for 2016 as well. So at some point in the next two
21 years, we'll have information about that.

22 --o0o--

23 DR. PLUMMER: So Biomonitoring California has
24 measured o-phthalates in several studies. I've
25 highlighted three of them here, the Firefighter

1 Occupational Exposures Project, the Maternal and Infant
2 Environmental Exposure Project and the Pilot Biomonitoring
3 Exposure Study.

4 And you can see that data from these three
5 projects shows detection frequency of 100 percent, or
6 close to that, for many of the o-phthalate metabolites in
7 urine.

8 --o0o--

9 DR. PLUMMER: So we talked a lot earlier with Dr.
10 Calafat about changing exposure trends. She highlighted a
11 few examples of phthalate -- o-phthalates that had either
12 increased or decreased during the last decade or so from
13 2001 to 2010. This is the U.S. NHANES biomonitoring data.
14 Zota et al., published a paper in 2014 that showed
15 decreases in urinary concentrations of diethyl phthalate,
16 di-n-butyl phthalate, benzyl butyl phthalate and di -- or
17 and DEHP, and also noted increases in urinary
18 concentrations of diisobutyl phthalate, di-n-octyl
19 phthalate, diisononyl phthalate, and diisodecyl phthalate
20 metabolites.

21 Dr. Calafat also highlighted the German
22 Environmental Specimen Bank earlier. She talked about the
23 data for DINCH, but there was also a recent study by
24 Schütze published in 2015 that looked at time trends in
25 DPHP metabolites in urine from the specimen bank. And

1 DPHP is a C-10 isomer, as Antonia mentioned earlier, that
2 is actually pretty high production volume. I think it was
3 like 50 -- like about 50 million pounds. You can refer to
4 page four in the document for the detailed information on
5 that production volume.

6 This -- these metabolites were detected in 2009
7 and 2012, but not in samples from earlier collection
8 years. And, in fact, the detection frequency for one
9 metabolite increased from about 3.3 percent in 2009 to
10 over 20 percent in 2012. And these were done using the
11 approach that we discussed earlier, where all of the
12 analytes were performed you know with the same method. We
13 talked about that a bit earlier.

14 And these two studies had reached a common
15 proposal that the change in exposure patterns were likely
16 associated with changing use patterns of o-phthalates in
17 consumer and other products.

18 --o0o--

19 DR. PLUMMER: So just briefly on known or
20 suspected health effects, there is evidence from studies
21 in laboratory animals that in utero exposure to
22 o-phthalates induces abnormalities in male reproductive
23 tract development, the entire spectrum of which is termed
24 phthalate syndrome. The Chronic Hazard Advisory Panel on
25 Phthalates and Phthalate Alternatives, which is convened

1 by the Consumer Products Safety Commission to assess
2 several phthalates, identified several phthalates as
3 anti-androgenic and capable of producing phthalate
4 syndrome in the rat with di-n-pentyl phthalate being the
5 most active. That was one of the compounds that Dr.
6 Calafat discussed this morning. And diisononyl phthalate
7 being the least active. So there's a list there of the
8 ones that they highlighted in the report.

9 In humans, there's some epidemiological evidence
10 that decreased anogenital distance in baby boys was
11 associated with maternal o-phthalate exposure. Some other
12 potential effects of o-phthalates were found in the
13 literature as well. And this includes effects on ovary,
14 disruption of thyroid hormone homeostasis,
15 neurodevelopmental effects, and then possible
16 contributions to allergic disease, and obesity.

17 --o0o--

18 DR. PLUMMER: Okay. So the analytical
19 considerations with regard to the class of chemicals
20 o-phthalates, Biomonitoring California's Environmental
21 Health Laboratory at CDPH currently measures urinary
22 phthalate metabolites using solid phase extraction high
23 performance liquid chromatography tandem mass
24 spectrometry.

25 The method currently includes 10 urinary

1 phthalate metabolites and can be expanded to include
2 additional compounds with minor incremental costs of
3 supplies and standards. And it would also require
4 additional optimization and validation to add anything.
5 And we discussed a lot of that with Antonia this morning
6 as well.

7 --o0o--

8 DR. PLUMMER: So the last criterion addresses how
9 biomonitoring the class o-phthalates would help assess the
10 efficacy of public health actions to reduce exposure to
11 this class of chemicals. First, we expect continued use
12 and exposure -- continued use of and exposure to
13 o-phthalates, and for many we have very little exposure
14 data as I've highlighted in this presentation.

15 By adding the class as designated chemicals, the
16 Program can choose the most important phthalates to track
17 over time, and can -- and can generate the necessary
18 biomonitoring data to help evaluate regulatory actions on
19 this class of chemicals.

20 --o0o--

21 DR. PLUMMER: And so finally, the options for the
22 Panel today are to recommend -- recommend adding
23 ortho-phthalates as a class to the list of designated
24 chemicals, to defer pending more information, or to
25 recommend against adding ortho-phthalates as a class to

1 the list of designated chemicals.

2 And with that, I will take any questions.

3 (Applause.)

4 CHAIRPERSON LUDERER: Thank you, Laurel, and also
5 for putting together that great background document, which
6 I know huge amounts of work went into.

7 DR. PLUMMER: Definitely a team effort, yes.

8 CHAIRPERSON LUDERER: Yes, Dr. Cranor.

9 PANEL MEMBER CRANOR: A couple of questions,
10 Laurel. One is just a clarificatory question. Right at
11 the outset you put the criteria. Are those joint criteria
12 that have to be satisfied or just many of them?

13 DR. PLUMMER: They are not. They're not joined
14 by and, so not every criteria has to be met in order to --

15 PANEL MEMBER CRANOR: I had training in logic,
16 and that's why I was wondering.

17 (Laughter.)

18 DR. PLUMMER: I would expect that question from
19 you.

20 (Laughter.)

21 PANEL MEMBER CRANOR: Secondly, would you remind
22 me, at any rate, what's the pragmatic difference between
23 designated substances and prioritized substances under
24 this Program? I think I'm not real clear about that.

25 DR. PLUMMER: Sure. Yeah, I can address that.

1 So the difference in designated. Well, a
2 designated chemical is basically the first step. So if
3 the Panel chooses to recommend adding something to the
4 designated list, it can be measured in any biomonitoring
5 study. A chemical doesn't have to be a priority chemical
6 to be measured in any projects, but if we -- you know,
7 it's -- elevating something to a priority chemical is, you
8 know, also an important way to raise awareness and raise
9 the importance of the chemical in the Program. So as far
10 as actually what the Program can measure, there isn't a
11 specific difference there, according to the legislation.

12 PANEL MEMBER CRANOR: What do you gain by making
13 it a priority chemical?

14 MS. HOOVER: This is Sara Hoover. Basically,
15 Laurel just answered the question in terms of our
16 legislation. It's an opportunity for the Panel to say
17 what the Panel thinks and recommends the Program
18 priorities should be. And then what the Program does is
19 we take Panel recommendations and we take other
20 considerations like lab efficiency, resources, particular
21 study populations, interest of study investigators, and
22 that's what forms the choices of what we actually measure.

23 But, yeah, what Laurel said was correct in terms
24 of our legislation. In terms of what we're going to
25 measure, it doesn't have to be a priority chemical.

1 PANEL MEMBER CRANOR: Okay. But a reason for
2 pressing that point seems to be that for other agencies
3 being on the priority list may be very important.

4 DR. PLUMMER: Yes, that is true. And at this
5 point, at a future date, if the Panel does recommend
6 adding this class to the designated list, that is
7 something that we could discuss.

8 PANEL MEMBER CRANOR: To the prior -- oh, today.

9 DR. PLUMMER: In the future.

10 PANEL MEMBER CRANOR: Today designated, in the
11 future maybe prioritize.

12 DR. PLUMMER: Exactly. It's kind of like a
13 step-wise multi-meeting process for that. So thank you.

14 CHAIRPERSON LUDERER: Dr. Bartell.

15 PANEL MEMBER BARTELL: Yes, thanks for that
16 presentation. I'm just curious if you could clarify. If
17 I'm reading this correctly, on slide 15, you cite that a
18 CHAP report from 2014 about the relative anti-androgenic
19 potential of, you know, some of these phthalates. If I'm
20 reading this correctly, the one that's the most
21 problematic on this list, DPenP, is not currently on the
22 list of priority chemicals --

23 DR. PLUMMER: Yes, that's correct.

24 PANEL MEMBER BARTELL: -- for biomonitoring?

25 DR. PLUMMER: It's not on the list of designated

1 chemicals, yeah, or priority. That's more correct.

2 PANEL MEMBER BARTELL: Right. I noticed it's not
3 on the list of usage information in the report that you
4 all provided on page four too, which I -- you know, I
5 don't know if you even know why that's not there. I mean,
6 is it --

7 DR. PLUMMER: Yeah, I can answer that.

8 PANEL MEMBER BARTELL: Yeah, that would be great.

9 DR. PLUMMER: So like I mentioned earlier, the
10 information provided currently by U.S. EPA is outdated.
11 There actually wasn't a result that came back when I
12 searched the database for that particular chemical, which
13 is -- you know, phthalates in general are used as mixtures
14 increasingly is what I've noticed from my research,
15 similar to other chemicals, flame retardants and things
16 like that.

17 So increasingly, they're reporting chemicals as a
18 mixture of, for example, hexyl, octyl, and decyl. And
19 you'll see -- so the -- or -- so that's just one example.
20 And di-n-hexyl phthalate is also on this list from the
21 CHAP Report. So that's one example of where maybe they're
22 not using the pure chemical, but it's included in a
23 mixture. And, you know, we don't know the ratio of what's
24 in there, but we didn't include mixtures in the table. It
25 was kind of a little too complicated, but that's another

1 little bit of information that -- but thank you for that
2 question to highlight.

3 PANEL MEMBER BARTELL: Thank you. And I guess
4 just a follow-up on that. As a comment, I think what
5 we're hearing here is quite a similar story as the same
6 one we discussed at our last meeting for PFASs, where, you
7 know, there's sort of been rapid evolution. Now, as some
8 of the initial problematic actors in this class of
9 chemicals kind of get attention and start getting
10 monitored and industry shifts to other ones, we know just
11 less about the extent to which those are used and their
12 toxicity.

13 But again here, we have some indication that we
14 should be concerned about the toxic potential of some of
15 this class of chemicals that apparently is, you know, not
16 on the priority list for being measured right now. And
17 one advantage potentially of us recommending that those be
18 added as a class is that that would, you know, stimulate
19 more interest and ability to sort of capture information,
20 not just on biomonitoring for those chemicals, but as we
21 heard on the consumer products side, and also in relation
22 to other State agencies, may stimulate some interest in
23 understanding better how they're used in products.

24 CHAIRPERSON LUDERER: Dr. Cranor.

25 PANEL MEMBER CRANOR: Just a quick follow up to

1 that. I had flagged DEHP. I'm not on top of the
2 research, but I have read a fair amount, especially Shanna
3 Swan's work. I think she studied DEHP and found the
4 problems. And you're saying that there's a whole bunch of
5 things that have greater potency to pose the same issues
6 at least for little boys?

7 DR. PLUMMER: Yeah.

8 PANEL MEMBER CRANOR: Feminize them.

9 DR. PLUMMER: Well, and the other thing that
10 these comments are making me think of is, you know,
11 because they have all these -- all these phthalates have
12 similar health effects in terms anti-androgenic effects, a
13 lot of groups, the National Academy of Sciences and other
14 groups, have -- and even the CHAP Report have proposed in
15 support looking at these as a -- in terms of cumulative
16 effects. So that's sort of another consideration to throw
17 out there.

18 CHAIRPERSON LUDERER: Dr. Fiehn.

19 PANEL MEMBER FIEHN: Yeah, thank you. I think we
20 should today stick to the task at hand that is the
21 designation, not like prioritization, because for that I
22 would need significantly more discussion, I guess, on the
23 health effects of different compounds or so.

24 But I think what we -- what we can see here is
25 the response of the industry, you know, to make new

1 compounds and phase them in and phase others out. And the
2 problems that are associated with those in terms of
3 designating any specific compound and rather going to a
4 more broader net saying we need class-wise decisions --
5 product class-wise decisions, like here, the
6 ortho-phthalates.

7 And for the chemistry, it gives us the reasoning
8 to go from, you know, a set of just a few compounds, like
9 four, to a widely targeted approach towards a non-targeted
10 approach because we can't know really what kind of
11 products people use, how old those products are, to which
12 phthalates they will be -- you know, will be phased in,
13 so -- or exposed to. So that means, you know, this could
14 be a good compound class to look at this new idea of
15 widely targeted, you know, instead of, you know, just
16 having five compounds and then maybe we look at the
17 compounds as we have seen this morning.

18 That then, of course, includes the metabolites of
19 those compounds, right? And, you know, that means it is
20 an actual analytical challenge. It's not that quite easy
21 to do, even, you know, to see them. So maybe what could
22 also then encourage the analytical labs to say on the one
23 hand we would have quantitative data, and on the other
24 hand we would have qualitative data of presence/absence
25 for the time being.

1 You know, just to take out the concerns that we
2 have discussed this morning of saying, you know,
3 quantitatively, you know, it's so hard. And if you really
4 want hard data, we can only do five or whatever number.
5 You know, but qualitatively, it's also interesting to see,
6 you know, what are we actually exposed to, and, you know,
7 to get us data. Okay. So that's my five cents here.

8 DR. PLUMMER: Thank you.

9
10 PANEL MEMBER SCHWARZMAN: Question or suggestion.

11 CHAIRPERSON LUDERER: Kind of both.

12 PANEL MEMBER SCHWARZMAN: It kind of blends
13 together.

14 CHAIRPERSON LUDERER: Dr. Schwarzman.

15 PANEL MEMBER SCHWARZMAN: Thank you. Thank you,
16 Laurel, and whoever else helped you assemble this
17 information, because I think it was -- you highlighted a
18 lot of key points. And I would just choose a couple of
19 those to mention, as I think very much supporting this
20 class approach that you're putting forward potentially.

21 One point is obviously the dynamic nature of the
22 industry that you've highlighted with your use chart. And
23 you said you didn't even discuss the use of mixtures, but
24 that's obviously a very relevant piece. And that from the
25 industry side, that it is such a dynamic process of

1 substitution of one chemical for another. And the idea
2 that from an analytical perspective, we would just be
3 looking at a few substances doesn't reflect the reality of
4 what's in use.

5 The other things that I would -- that I found
6 very striking from the summary that you put together
7 include that the test data that showed the presence of
8 regulated ortho-phthalates in some 700 chemical products,
9 so that simply regulating them doesn't mean that they're
10 necessarily not used anymore, and is another argument for
11 sort of keeping the suite of chemicals that are
12 biomonitored for fairly broad and keeping the flexibility
13 within the Program to keep monitoring for substances,
14 whether they're regulated or not.

15 Another was the evidence about the presence of
16 some currently non-designated o-phthalates in house dust
17 samples, and also the German biomonitoring findings. So
18 those are substances that we know are in use and are in
19 people and are in the environment, and yet they're not on
20 the designated list.

21 So I'm not saying anything new here, just to sort
22 of highlight some pieces of the summary and the data that
23 you put together that I found very striking. And the
24 point that was already raised about one of the
25 undesignated chemicals is among the most toxic or

1 potentially most bioactive anyway of the o-phthalates.

2 And the final point that I wanted to raise is one
3 that you just hinted at about the National Academy's study
4 on cumulative risk assessment that looked at phthalates as
5 an example and -- of considering that -- those chemicals
6 as a class. And I think they use two categories -- two
7 criteria for whether you should do a cumulative risk
8 assessment for a class of chemicals. And one is, you
9 know, is there -- well, let me make sure that I get this
10 right. That there are multiple similar chemicals within a
11 class, and the other is that they contribute to a common
12 health effect.

13 And I think that, you know, that report very much
14 made that case. And I think it further sort of bolsters
15 the point -- the validity in looking at ortho-phthalates
16 as a class and giving the Program the flexibility to
17 biomonitor whichever ortho-phthalates seem most relevant
18 currently.

19 So I just wanted to highlight those pieces of
20 information that I found very useful in your summary in
21 consideration of this topic. So thank you for putting
22 that together.

23 DR. PLUMMER: Yeah, thank you.

24 CHAIRPERSON LUDERER: Thank you for that great
25 summary, too. We have some -- do we have any public

1 comments, because this would be a good time to take those?

2 Nancy Buermeyer from the Breast Cancer Fund.

3 MS. BUERMEYER: Thank you. Nancy Buermeyer, the
4 Breast Cancer Fund. I promise my last comment for the
5 day.

6 (Laughter.)

7 MS. BUERMEYER: As always, I want to start by
8 thanking the staff and Laurel for that great presentation.
9 I was reading the memo on the plane on the ride home last
10 night. And it was both really great and really upsetting
11 to see all of this information in one place. And the
12 production value stuff is particularly helpful. So thanks
13 for checking that, tracking that down. Although it does
14 raise the issue of the fact that even within a range,
15 companies can withhold how much they produce of these
16 chemicals. And that use of quote unquote confidential
17 business information is an ongoing concern for us, because
18 we think it's the public's right to know how much of these
19 chemicals are at least being brought into the market.

20 I just wanted to comment really quickly on the
21 CHAP process. I think what was really special about the
22 CHAP process is it showed that the cumulative analysis
23 could be done, that it really did look at all of those
24 different chemicals and looked specifically at the ones
25 that had anti-androgenic effects. And those were the ones

1 they recommended for -- to be permanently banned, the two
2 that they recommended lifting the ban on were the ones
3 that did not have anti-androgenic problems. Although,
4 they did have other health problems, so we kind of wanted
5 them all to stay banned.

6 And I think the other piece around that is we
7 talked a little bit about mixtures. And my understanding
8 from some of the science indicates that mixtures are not
9 just additive, but sometimes end up with effects even
10 worse than the effect of the two -- you know, that they
11 are synergistic as opposed to additive. So those mixtures
12 are really important. And I think the more we can be
13 flexible about what we look for and what we test for, the
14 better.

15 We have for a while been encouraging the Program
16 to look at these chemicals as a class for all of the
17 reasons that people have talked about. Just one update on
18 some of the changes in the market. There have been a
19 number of market campaigns out there. And recently, Home
20 Depot, Lowe's, and Menards have agreed to stop carrying
21 vinyl flooring that includes phthalates. So that's a big
22 political win for us and a big market win, but there's a
23 lot of other products out there obviously with these
24 chemicals in them.

25 But it -- and it also -- I mean, they said all

1 phthalates, which is good, but a lot of other products are
2 going to be moving from the ones that have been regulated
3 and highlighted to these newer phthalates, which we may or
4 may not know much about it. So we would definitely
5 encourage the Panel to designate this as a class.

6 And then the final note I want to make is once
7 you've designated as a -- once these are designated
8 chemicals, there is advantage to making them priority
9 chemicals, which I know is a conversation down the road.
10 But by virtue of it being a priority chemical in this
11 Program, it automatically adds it to the Safer Consumer
12 Products program list, which is important, because, for
13 instance, in some of the legislation I mentioned earlier
14 on the cleaning products, we actually referenced the Safer
15 Consumer Products candidate chemical list, so that if
16 those chemicals were in cleaning products, they had to
17 appear on the label. So we used that as sort of a proxy
18 for hazard. So it's really helpful to have a broad list
19 of these chemicals that may have or do have health
20 concerns, because it will have a ripple effect beyond just
21 the Biomonitoring Program to some other policy issues.

22 So thank you very much. And I hope you will vote
23 to designate these as a class.

24 Thanks.

25 CHAIRPERSON LUDERER: Thank you, Nancy.

1 Our next commenter is Veena Singla, Natural
2 Resources Defense Council.

3 DR. SINGLA: Hello. Veena Singla with the
4 Natural Resources Defense Counsel. I will keep my
5 comments brief. Just to say that for many of the reasons
6 already mentioned, we do strongly support the listing of
7 ortho-phthalates as a class as designated chemicals.

8 CHAIRPERSON LUDERER: Thank you.

9 And our last commenter is Alexander Hoepker,
10 Berkeley Center for Green Chemistry.

11 MR. HOEPKER: Alexander Hoepker, Center for Green
12 Chemistry.

13 I had a question about the designation of
14 chemical classes either by use and application or by
15 toxicology. We've talked about ortho-phthalates in this
16 context. But obviously, DINCH has been -- has also come
17 up, which currently is not classified as an
18 ortho-phthalate. And then there's this pie chart on slide
19 12. There's many alternatives epoxies, aliphatics and so
20 forth.

21 My question was, could all of those be
22 classified -- is there an argument to be made for those to
23 be classified as a larger category? And are there health
24 concerns with many of those -- many of those categories,
25 particularly DINCH? I'm wondering if DINCH really should

1 be part of the phthalate category.

2 Thank you.

3 DR. PLUMMER: So, as we heard earlier, I think
4 Sara highlighted, DINCH is actually already a designated
5 chemical. And that's by virtue of inclusion by CDC. So
6 it is already on our list.

7 And also, kind of as we alluded to earlier, we
8 chose the class of ortho-phthalates, largely because it
9 was a doable chunk to delve into from a research
10 perspective to really understand the class. If the Panel
11 expresses interest in the future in looking into some of
12 these other classes of plasticizers, that's something we
13 could, you know, potentially look into in more detail.

14 I anticipate that likely that there will be
15 interest in that. And so that's something that we'll
16 explore in the future potentially.

17 MR. HOEPKER: The health effects of DINCH.

18 DR. PLUMMER: Oh, the health effects. So the
19 rest of the question was the health effects of DINCH.

20 I can't specifically comment on that. I haven't
21 looked into it in detail. I don't know if -- Gail, if you
22 had any comments on the health effects of DINCH or --

23 DR. KROWECH: I don't.

24 DR. PLUMMER: Okay. So that might be something
25 we could, you know, get back to you about in the future

1 or -- we probably won't do a specific document on that
2 chemical, but largely because it is designated already.

3 DR. KROWECH: Gail Krowech from OEHHA.

4 Several years ago, we did a survey of
5 plasticizers looking at many of them. And from that, the
6 Panel was very interested in aromatic -- or phosphate
7 flame retardants and plasticizers, and we pursued that.
8 So many of the phosphate flame retardants are also
9 plasticizers. So we did look at that. And from that
10 whole survey, the Panel basically picked one to look at,
11 but we could definitely look at more in the future.

12 CHAIRPERSON LUDERER: Thank you very much.

13 Do we have any additional discussion or comments
14 or motions from Panel members?

15 Dr. Cranor.

16 PANEL MEMBER CRANOR: I would move that we
17 list --

18 MS. HOOVER: Talk into the mic.

19 PANEL MEMBER CRANOR: Sorry. I would move that
20 we list the ortho-phthalates as designated substances.

21 CHAIRPERSON LUDERER: Okay. So Dr. Cranor has
22 moved that the chemical class ortho-phthalates be included
23 as designated chemicals in the California Environmental
24 Contaminant Biomonitoring Program.

25 Is there anyone who would like to second that?

1 PANEL MEMBER SCHWARZMAN: I would second that
2 motion.

3 CHAIRPERSON LUDERER: All right. So that has
4 been seconded by Dr. Schwarzman.

5 So now, I'll go ahead and poll the Panel. So
6 start on that end. Dr. Cranor?

7 PANEL MEMBER CRANOR: Yes, list.

8 PANEL MEMBER QUINTANA: Yes.

9 PANEL MEMBER BARTELL: Yes.

10 CHAIRPERSON LUDERER: Yes.

11 PANEL MEMBER FIEHN: Yes.

12 PANEL MEMBER KAVANAUGH-LYNCH: Yes.

13 PANEL MEMBER SCHWARZMAN: Yes.

14 CHAIRPERSON LUDERER: Okay. Unanimously yes.
15 The Scientific Guidance Panel recommends designation of
16 ortho-phthalates as a class in the CECBP.

17 So now we move to our open public comment period.
18 Do we have any requests for time in that open public
19 comment period?

20 MS. BUERMEYER: You want me?

21 (Laughter.)

22 CHAIRPERSON LUDERER: We've exhausted our
23 commenters.

24 (Laughter.)

25 CHAIRPERSON LUDERER: None?

1 All right then. Well, then I'll just -- we will
2 wrap-up. And it looks like we're actually going to be
3 finishing a little bit early today.

4 So I wanted to make an announcement, which is an
5 announcement -- a change in the Chair of the Scientific
6 Guidance Panel. I've been the Chair now for a number of
7 years. And I'd like to announce that I'm going to be
8 stepping down as the SGP Chair after this meeting. I will
9 continue on as a Panel member.

10 And I'm very pleased to be able to pass the reins
11 to Dr. Asa Bradman, who unfortunately is not here today,
12 but he has graciously accepted the Program's request to
13 act as Chair. And he's done that a few times when -- or
14 at least one or twice when I haven't been here, and I know
15 he's done a great job.

16 And then I also wanted to announce that a
17 transcript of this meeting will be posted on the
18 Biomonitoring California website when it's available as
19 always. And I wanted to also announce that our next
20 meeting will be on November 18th. And the location is yet
21 to be determined. So there will be updates about that, of
22 course, on the website once that's determined.

23 And then finally, I wanted to remind everyone in
24 the audience that the conference facility closes today at
25 5:00, which I don't think should be a problem, since we

1 have an hour to get down to the ground floor. And we
2 recommend, yeah, heading down to the lobby before then.

3 All right. And with that, I'll adjourn the
4 meeting and thank everyone for coming and for your
5 participation.

6 (Applause.)

7 (Thereupon the California Environmental
8 Contaminant Biomonitoring Program, Scientific
9 Guidance Panel meeting adjourned at 4:00 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 30th day of July, 2015.

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Certified Shorthand Reporter
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