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
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A P P E A R A N C E S

PANEL MEMBERS:

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

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

Carl Cranor, Ph.D., M.S.L.

Oliver Fiehn, Ph.D.

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

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

Megan Schwarzman, M.D., M.P.H.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT:

Dr. Lauren Zeise, Acting Director

Mr. Alan Hirsch, Chief Deputy Director

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

Mr. Mario Fernandez, Staff Counsel

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

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

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

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

DEPARTMENT OF PUBLIC HEALTH:

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

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

I N D E X

P R O C E E D I N G S

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

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

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

And with that, I would like to introduce Dr.

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

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

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

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

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

(Phone interference.)

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

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

(Laughter.)

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

(Laughter.)

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

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

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

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

(Laughter.)

DR. DiBARTOLOMEIS: -- is going to be sorely

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

Thank you.

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

So welcome, Dr. Calafat.

(Thereupon an overhead presentation was presented as follows.)

(Applause.)

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

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

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

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

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

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

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

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

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

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

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

medications.

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

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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DR. CALAFAT: In terms of biomonitoring methods,

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

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

So you really want a method that uses minimum

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

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

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

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

every single chemical.

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

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

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

You need to have well-maintained instrumentation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

because the methods are different.

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

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

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

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

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

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

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

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

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

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

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

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

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

On the other hand, about 82 percent of people had

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

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

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

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DR. CALAFAT: Okay. I should be done.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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DR. CALAFAT: Thank you, all.

(Applause.)

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

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

Dr. Cranor.

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

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

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

DR. CALAFAT: Um-hmm.

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

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

So could you talk about those two things?

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

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

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

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

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

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

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

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

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

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

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

don't know if I did answer your question.

PANEL MEMBER CRANOR: Thank you.

CHAIRPERSON LUDERER: Dr. Quintana.

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

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

DR. CALAFAT: Um-hmm.

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

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

PANEL MEMBER QUINTANA: Oh, oh. Sixty.

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

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

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

PANEL MEMBER QUINTANA: So they're not --

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

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

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

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

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

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

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

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

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

The story is very different when you're thinking

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

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

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

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

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

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

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

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

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

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

PANEL MEMBER QUINTANA: Yes.

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

(Laughter.)

CHAIRPERSON LUDERER: Dr. Schwarzman.

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

So here, we have a bunch of phthalates that are

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

For example, BPA is a plasticizer. We could

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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

DR. CALAFAT: Turn around now.

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

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

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

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

(Laughter.)

DR. CALAFAT: That's very nice.

(Laughter.)

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

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

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

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

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

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

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

Thanks.

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

I feel much better.

(Laughter.)

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

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

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

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

MS. HOOVER: Can you talk into the mic?

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

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

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

MS. BUERMEYER: Okay.

CHAIRPERSON LUDERER: We have quick question.

Dr. Bartell.

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

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

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

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

throughout that period of time.

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

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

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

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

(Laughter.)

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

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

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

Thank you.

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

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

(Laughter.)

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

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

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

Thanks.

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

(Laughter.)

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

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

method.

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

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

DR. DiBARTOLOMEIS: Thank you.

CHAIRPERSON LUDERER: Dr. She.

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

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

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

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

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

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

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

DR. CALAFAT: The standard reference materials.

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

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

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

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

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

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

Thank you.

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

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

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

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

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

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

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

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

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

DR. SHE: Thank you very much.

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

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

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

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

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

analytes.

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

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

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

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

CHAIRPERSON LUDERER: Dr. Cranor.

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

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

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

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

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

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

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

PANEL MEMBER CRANOR: Thank you.

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

I have one more question, which is regarding the

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

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

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

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

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

CHAIRPERSON LUDERER: Mr. Fiehn.

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

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

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

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

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

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

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

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

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

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

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

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

(Applause.)

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

(Laughter.)

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

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

(Thereupon an overhead presentation was presented as follows.)

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

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

So, Dr. Wu.

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

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

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

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

--o0o--

DR. WU: And there are actually no other

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

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

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

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

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

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

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

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

So this is really exciting to be able to look at

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

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

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

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

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

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

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

children's diseases.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

be interested in.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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MR. VOSS: So that's -- woops. I don't -- that's what I'll end on right there.

(Laughter.)

MR. VOSS: So thanks, and I'd love to take any questions.

(Applause.)

CHAIRPERSON LUDERER: Thank you very much. It looks like we have questions from Dr. Fiehn and then Dr. Schwarzman or the other way around.

PANEL MEMBER FIEHN: I'd like to repeat the question that I had before. Even if that's just a small population of pregnancies, obviously there are very interesting phenotypes associated with pregnancies. For example, preeclampsia, early child birth, but also, for example, following up with genital features that have been associated with phthalates.

So will any of this such kind of phenotypic data be collected and be available, because that would be informative?

MR. VOSS: I don't know the answer to that question. We're not going to be collecting it, right?

Nerissa Wu.

DR. WU: Hi. In the MAMAS study, we do not have plans to get that kind of information, but we can partner

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

CHAIRPERSON LUDERER: Dr. Schwarzman.

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

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

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

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

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

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

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

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

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

CHAIRPERSON LUDERER: Dr. Cranor.

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

MR. VOSS: Yes. The environmental breakdown product.

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

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

PANEL MEMBER CRANOR: Is that right?

MS. BUERMEYER: Normal and yet still shocking.

(Laughter.)

PANEL MEMBER CRANOR: That's right.

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

PANEL MEMBER CRANOR: Okay. Thank you.

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

MR. VOSS: Very true.

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

MR. VOSS: Oh, well, thank you.

(Laughter.)

MR. VOSS: We'll take that.

DR. DiBARTOLOMEIS: Take it back, Rob.

(Laughter.)

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

PANEL MEMBER CRANOR: Right.

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

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

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

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

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

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

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

MR. VOSS: Certainly. Thank you.

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

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

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

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

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

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

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

CHAIRPERSON LUDERER: Dr. Quintana.

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

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

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

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

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

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

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

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

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

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

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

All right. Do we have any public comments?

MS. BUERMEYER: I'll say something.

(Laughter.)

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

MS. BUERMEYER: Okay. Thank you.

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

(Laughter.)

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

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

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

CHAIRPERSON LUDERER: A comment or response?

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

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

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

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

CHAIRPERSON LUDERER: Thank you very much.

Dr. She.

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

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

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

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

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

DR. WU: It's high.

DR. SHE: Huh?

DR. WU: Asian is high.

DR. SHE: Oh, Asian is high.

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

(Laughter.)

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

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

(Laughter.)

MR. VOSS: Sorry to confuse you.

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

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

(Laughter.)

CHAIRPERSON LUDERER: Yeah. Myrto Petreas.

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

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

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

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

MS. HOOVER: Mic, Rob.

MR. VOSS: What's that?

MS. HOOVER: Mic.

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

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

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

DR. WU: Yes.

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

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

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

Myrto.

DR. PETREAS: Myrto Petreas.

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

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

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

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

Dr. Kavanaugh-Lynch.

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

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

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

CHAIRPERSON LUDERER: Just a follow up on that

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

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

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

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

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

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

Thank you.

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

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

All right. Thank you.

(Applause.)

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

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

Thank you.

CHAIRPERSON LUDERER: Thank you very much.

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

(Laughter.)

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

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

CHAIRPERSON LUDERER: 1:45.

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

(Laughter.)

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

(Off record: 12:32 PM)

(Thereupon a lunch break was taken.)

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

(On record: 2:01 PM)

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

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

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

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

Welcome, Karl.

(Thereupon an overhead presentation was presented as follows.)

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

here.

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

ACTING DIRECTOR ZEISE: Thank you.

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

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

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MR. PALMER: So what's our mission?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

alternatives.

So that's where we are with those products.

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

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

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

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

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

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

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

(Laughter.)

MR. PALMER: Or sinks to the bottom.

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Applause.)

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

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

Dr. Cranor.

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

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

PANEL MEMBER CRANOR: Pardon?

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

PANEL MEMBER CRANOR: Too loud?

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

PANEL MEMBER CRANOR: Sorry. All right.

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

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

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

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

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

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

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

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

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

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

CHAIRPERSON LUDERER: Dr. Quintana.

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

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

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

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

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

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

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

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

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

MS. BUERMEYER: You should just recycle.

(Laughter.)

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

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

I get this data?

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

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

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

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

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

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

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

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

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

information be publicly available, especially thinking about IP issues?

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

Thank you.

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

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

(Laughter.)

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

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

CHAIRPERSON LUDERER: Dr. Cranor.

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

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

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

(Laughter.)

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

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

PANEL MEMBER CRANOR: Thank you.

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

DR. DiBARTOLOMEIS: Michael DiBartolomeis, CDPH.

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

(Laughter.)

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

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

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

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

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

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

(Laughter.)

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

(Laughter.)

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

CHAIRPERSON LUDERER: Dr. She.

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

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

And then monitor parent compound for this

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

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

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

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

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

to our regulations, you might enjoy reading that.

(Laughter.)

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

DR. SHE: Thank you.

CHAIRPERSON LUDERER: Dr. Schwarzman.

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

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

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

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

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

CHAIRPERSON LUDERER: Other questions or comments from Panel members?

Dr. Kavanaugh-Lynch.

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

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

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

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

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

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

priority product workplan categories.

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

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

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

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

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

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

CHAIRPERSON LUDERER: Sara.

MS. HOOVER: Hi. Sara Hoover, OEHHA.

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

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

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

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

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

Dr. Quintana.

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

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

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

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

(Laughter.)

CHAIRPERSON LUDERER: Another questions, comments from Panel members?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Off record: 3:00 PM)

(Thereupon a recess was taken.)

(On record: 3:18 PM)

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

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

(Laughter.)

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

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

MS. HOOVER: He's on the phone.

CHAIRPERSON LUDERER: Oh, he is. Okay.

(Thereupon an overhead presentation was presented as follows.)

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

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

So, Dr. Plummer

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

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

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

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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.

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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.

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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

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

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

And these criteria are not joined by and.

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

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DR. PLUMMER: So why o-phthalates as a class?

There are a number of reasons that it's to consider these -- the o-phthalates as a class of chemicals. Many o-phthalates including some that are not

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The method currently includes 10 urinary

phthalate metabolites and can be expanded to include additional compounds with minor incremental costs of supplies and standards. And it would also require additional optimization and validation to add anything. And we discussed a lot of that with Antonia this morning as well.

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DR. PLUMMER: So the last criterion addresses how biomonitoring the class o-phthalates would help assess the efficacy of public health actions to reduce exposure to this class of chemicals. First, we expect continued use and exposure -- continued use of and exposure to o-phthalates, and for many we have very little exposure data as I've highlighted in this presentation.

By adding the class as designated chemicals, the Program can choose the most important phthalates to track over time, and can -- and can generate the necessary biomonitoring data to help evaluate regulatory actions on this class of chemicals.

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DR. PLUMMER: And so finally, the options for the Panel today are to recommend -- recommend adding ortho-phthalates as a class to the list of designated chemicals, to defer pending more information, or to recommend against adding ortho-phthalates as a class to

the list of designated chemicals.

And with that, I will take any questions.

(Applause.)

CHAIRPERSON LUDERER: Thank you, Laurel, and also for putting together that great background document, which I know huge amounts of work went into.

DR. PLUMMER: Definitely a team effort, yes.

CHAIRPERSON LUDERER: Yes, Dr. Cranor.

PANEL MEMBER CRANOR: A couple of questions, Laurel. One is just a clarificatory question. Right at the outset you put the criteria. Are those joint criteria that have to be satisfied or just many of them?

DR. PLUMMER: They are not. They're not joined by and, so not every criteria has to be met in order to --

PANEL MEMBER CRANOR: I had training in logic, and that's why I was wondering.

(Laughter.)

DR. PLUMMER: I would expect that question from you.

(Laughter.)

PANEL MEMBER CRANOR: Secondly, would you remind me, at any rate, what's the pragmatic difference between designated substances and prioritized substances under this Program? I think I'm not real clear about that.

DR. PLUMMER: Sure. Yeah, I can address that.

So the difference in designated. Well, a designated chemical is basically the first step. So if the Panel chooses to recommend adding something to the designated list, it can be measured in any biomonitoring study. A chemical doesn't have to be a priority chemical to be measured in any projects, but if we -- you know, it's -- elevating something to a priority chemical is, you know, also an important way to raise awareness and raise the importance of the chemical in the Program. So as far as actually what the Program can measure, there isn't a specific difference there, according to the legislation.

PANEL MEMBER CRANOR: What do you gain by making it a priority chemical?

MS. HOOVER: This is Sara Hoover. Basically, Laurel just answered the question in terms of our legislation. It's an opportunity for the Panel to say what the Panel thinks and recommends the Program priorities should be. And then what the Program does is we take Panel recommendations and we take other considerations like lab efficiency, resources, particular study populations, interest of study investigators, and that's what forms the choices of what we actually measure.

But, yeah, what Laurel said was correct in terms of our legislation. In terms of what we're going to measure, it doesn't have to be a priority chemical.

PANEL MEMBER CRANOR: Okay. But a reason for pressing that point seems to be that for other agencies being on the priority list may be very important.

DR. PLUMMER: Yes, that is true. And at this point, at a future date, if the Panel does recommend adding this class to the designated list, that is something that we could discuss.

PANEL MEMBER CRANOR: To the prior -- oh, today.

DR. PLUMMER: In the future.

PANEL MEMBER CRANOR: Today designated, in the future maybe prioritize.

DR. PLUMMER: Exactly. It's kind of like a step-wise multi-meeting process for that. So thank you.

CHAIRPERSON LUDERER: Dr. Bartell.

PANEL MEMBER BARTELL: Yes, thanks for that presentation. I'm just curious if you could clarify. If I'm reading this correctly, on slide 15, you cite that a CHAP report from 2014 about the relative anti-androgenic potential of, you know, some of these phthalates. If I'm reading this correctly, the one that's the most problematic on this list, DPenP, is not currently on the list of priority chemicals --

DR. PLUMMER: Yes, that's correct.

PANEL MEMBER BARTELL: -- for biomonitoring?

DR. PLUMMER: It's not on the list of designated

chemicals, yeah, or priority. That's more correct.

PANEL MEMBER BARTELL: Right. I noticed it's not on the list of usage information in the report that you all provided on page four too, which I -- you know, I don't know if you even know why that's not there. I mean, is it --

DR. PLUMMER: Yeah, I can answer that.

PANEL MEMBER BARTELL: Yeah, that would be great.

DR. PLUMMER: So like I mentioned earlier, the information provided currently by U.S. EPA is outdated. There actually wasn't a result that came back when I searched the database for that particular chemical, which is -- you know, phthalates in general are used as mixtures increasingly is what I've noticed from my research, similar to other chemicals, flame retardants and things like that.

So increasingly, they're reporting chemicals as a mixture of, for example, hexyl, octyl, and decyl. And you'll see -- so the -- or -- so that's just one example. And di-n-hexyl phthalate is also on this list from the CHAP Report. So that's one example of where maybe they're not using the pure chemical, but it's included in a mixture. And, you know, we don't know the ratio of what's in there, but we didn't include mixtures in the table. It was kind of a little too complicated, but that's another

little bit of information that -- but thank you for that question to highlight.

PANEL MEMBER BARTELL: Thank you. And I guess just a follow-up on that. As a comment, I think what we're hearing here is quite a similar story as the same one we discussed at our last meeting for PFASs, where, you know, there's sort of been rapid evolution. Now, as some of the initial problematic actors in this class of chemicals kind of get attention and start getting monitored and industry shifts to other ones, we know just less about the extent to which those are used and their toxicity.

But again here, we have some indication that we should be concerned about the toxic potential of some of this class of chemicals that apparently is, you know, not on the priority list for being measured right now. And one advantage potentially of us recommending that those be added as a class is that that would, you know, stimulate more interest and ability to sort of capture information, not just on biomonitoring for those chemicals, but as we heard on the consumer products side, and also in relation to other State agencies, may stimulate some interest in understanding better how they're used in products.

CHAIRPERSON LUDERER: Dr. Cranor.

PANEL MEMBER CRANOR: Just a quick follow up to

that. I had flagged DEHP. I'm not on top of the research, but I have read a fair amount, especially Shanna Swan's work. I think she studied DEHP and found the problems. And you're saying that there's a whole bunch of things that have greater potency to pose the same issues at least for little boys?

DR. PLUMMER: Yeah.

PANEL MEMBER CRANOR: Feminize them.

DR. PLUMMER: Well, and the other thing that these comments are making me think of is, you know, because they have all these -- all these phthalates have similar health effects in terms anti-androgenic effects, a lot of groups, the National Academy of Sciences and other groups, have -- and even the CHAP Report have proposed in support looking at these as a -- in terms of cumulative effects. So that's sort of another consideration to throw out there.

CHAIRPERSON LUDERER: Dr. Fiehn.

PANEL MEMBER FIEHN: Yeah, thank you. I think we should today stick to the task at hand that is the designation, not like prioritization, because for that I would need significantly more discussion, I guess, on the health effects of different compounds or so.

But I think what we -- what we can see here is the response of the industry, you know, to make new

compounds and phase them in and phase others out. And the problems that are associated with those in terms of designating any specific compound and rather going to a more broader net saying we need class-wise decisions -- product class-wise decisions, like here, the ortho-phthalates.

And for the chemistry, it gives us the reasoning to go from, you know, a set of just a few compounds, like four, to a widely targeted approach towards a non-targeted approach because we can't know really what kind of products people use, how old those products are, to which phthalates they will be -- you know, will be phased in, so -- or exposed to. So that means, you know, this could be a good compound class to look at this new idea of widely targeted, you know, instead of, you know, just having five compounds and then maybe we look at the compounds as we have seen this morning.

That then, of course, includes the metabolites of those compounds, right? And, you know, that means it is an actual analytical challenge. It's not that quite easy to do, even, you know, to see them. So maybe what could also then encourage the analytical labs to say on the one hand we would have quantitative data, and on the other hand we would have qualitative data of presence/absence for the time being.

You know, just to take out the concerns that we have discussed this morning of saying, you know, quantitatively, you know, it's so hard. And if you really want hard data, we can only do five or whatever number. You know, but qualitatively, it's also interesting to see, you know, what are we actually exposed to, and, you know, to get us data. Okay. So that's my five cents here.

DR. PLUMMER: Thank you.

PANEL MEMBER SCHWARZMAN: Question or suggestion.

CHAIRPERSON LUDERER: Kind of both.

PANEL MEMBER SCHWARZMAN: It kind of blends together.

CHAIRPERSON LUDERER: Dr. Schwarzman.

PANEL MEMBER SCHWARZMAN: Thank you. Thank you, Laurel, and whoever else helped you assemble this information, because I think it was -- you highlighted a lot of key points. And I would just choose a couple of those to mention, as I think very much supporting this class approach that you're putting forward potentially.

One point is obviously the dynamic nature of the industry that you've highlighted with your use chart. And you said you didn't even discuss the use of mixtures, but that's obviously a very relevant piece. And that from the industry side, that it is such a dynamic process of

substitution of one chemical for another. And the idea that from an analytical perspective, we would just be looking at a few substances doesn't reflect the reality of what's in use.

The other things that I would -- that I found very striking from the summary that you put together include that the test data that showed the presence of regulated ortho-phthalates in some 700 chemical products, so that simply regulating them doesn't mean that they're necessarily not used anymore, and is another argument for sort of keeping the suite of chemicals that are biomonitored for fairly broad and keeping the flexibility within the Program to keep monitoring for substances, whether they're regulated or not.

Another was the evidence about the presence of some currently non-designated o-phthalates in house dust samples, and also the German biomonitoring findings. So those are substances that we know are in use and are in people and are in the environment, and yet they're not on the designated list.

So I'm not saying anything new here, just to sort of highlight some pieces of the summary and the data that you put together that I found very striking. And the point that was already raised about one of the undesignated chemicals is among the most toxic or

potentially most bioactive anyway of the o-phthalates.

And the final point that I wanted to raise is one that you just hinted at about the National Academy's study on cumulative risk assessment that looked at phthalates as an example and -- of considering that -- those chemicals as a class. And I think they use two categories -- two criteria for whether you should do a cumulative risk assessment for a class of chemicals. And one is, you know, is there -- well, let me make sure that I get this right. That there are multiple similar chemicals within a class, and the other is that they contribute to a common health effect.

And I think that, you know, that report very much made that case. And I think it further sort of bolsters the point -- the validity in looking at ortho-phthalates as a class and giving the Program the flexibility to biomonitor whichever ortho-phthalates seem most relevant currently.

So I just wanted to highlight those pieces of information that I found very useful in your summary in consideration of this topic. So thank you for putting that together.

DR. PLUMMER: Yeah, thank you.

CHAIRPERSON LUDERER: Thank you for that great summary, too. We have some -- do we have any public

comments, because this would be a good time to take those?

Nancy Buermeyer from the Breast Cancer Fund.

MS. BUERMEYER: Thank you. Nancy Buermeyer, the Breast Cancer Fund. I promise my last comment for the day.

(Laughter.)

MS. BUERMEYER: As always, I want to start by thanking the staff and Laurel for that great presentation. I was reading the memo on the plane on the ride home last night. And it was both really great and really upsetting to see all of this information in one place. And the production value stuff is particularly helpful. So thanks for checking that, tracking that down. Although it does raise the issue of the fact that even within a range, companies can withhold how much they produce of these chemicals. And that use of quote unquote confidential business information is an ongoing concern for us, because we think it's the public's right to know how much of these chemicals are at least being brought into the market.

I just wanted to comment really quickly on the CHAP process. I think what was really special about the CHAP process is it showed that the cumulative analysis could be done, that it really did look at all of those different chemicals and looked specifically at the ones that had anti-androgenic effects. And those were the ones

they recommended for -- to be permanently banned, the two that they recommended lifting the ban on were the ones that did not have anti-androgenic problems. Although, they did have other health problems, so we kind of wanted them all to stay banned.

And I think the other piece around that is we talked a little bit about mixtures. And my understanding from some of the science indicates that mixtures are not just additive, but sometimes end up with effects even worse than the effect of the two -- you know, that they are synergistic as opposed to additive. So those mixtures are really important. And I think the more we can be flexible about what we look for and what we test for, the better.

We have for a while been encouraging the Program to look at these chemicals as a class for all of the reasons that people have talked about. Just one update on some of the changes in the market. There have been a number of market campaigns out there. And recently, Home Depot, Lowe's, and Menards have agreed to stop carrying vinyl flooring that includes phthalates. So that's a big political win for us and a big market win, but there's a lot of other products out there obviously with these chemicals in them.

But it -- and it also -- I mean, they said all

phthalates, which is good, but a lot of other products are going to be moving from the ones that have been regulated and highlighted to these newer phthalates, which we may or may not know much about it. So we would definitely encourage the Panel to designate this as a class.

And then the final note I want to make is once you've designated as a -- once these are designated chemicals, there is advantage to making them priority chemicals, which I know is a conversation down the road. But by virtue of it being a priority chemical in this Program, it automatically adds it to the Safer Consumer Products program list, which is important, because, for instance, in some of the legislation I mentioned earlier on the cleaning products, we actually referenced the Safer Consumer Products candidate chemical list, so that if those chemicals were in cleaning products, they had to appear on the label. So we used that as sort of a proxy for hazard. So it's really helpful to have a broad list of these chemicals that may have or do have health concerns, because it will have a ripple effect beyond just the Biomonitoring Program to some other policy issues.

So thank you very much. And I hope you will vote to designate these as a class.

Thanks.

CHAIRPERSON LUDERER: Thank you, Nancy.

Our next commenter is Veena Singla, Natural Resources Defense Council.

DR. SINGLA: Hello. Veena Singla with the Natural Resources Defense Counsel. I will keep my comments brief. Just to say that for many of the reasons already mentioned, we do strongly support the listing of ortho-phthalates as a class as designated chemicals.

CHAIRPERSON LUDERER: Thank you.

And our last commenter is Alexander Hoepker, Berkeley Center for Green Chemistry.

MR. HOEPKER: Alexander Hoepker, Center for Green Chemistry.

I had a question about the designation of chemical classes either by use and application or by toxicology. We've talked about ortho-phthalates in this context. But obviously, DINCH has been -- has also come up, which currently is not classified as an ortho-phthalate. And then there's this pie chart on slide 12. There's many alternatives epoxies, aliphatics and so forth.

My question was, could all of those be classified -- is there an argument to be made for those to be classified as a larger category? And are there health concerns with many of those -- many of those categories, particularly DINCH? I'm wondering if DINCH really should

be part of the phthalate category.

Thank you.

DR. PLUMMER: So, as we heard earlier, I think Sara highlighted, DINCH is actually already a designated chemical. And that's by virtue of inclusion by CDC. So it is already on our list.

And also, kind of as we alluded to earlier, we chose the class of ortho-phthalates, largely because it was a doable chunk to delve into from a research perspective to really understand the class. If the Panel expresses interest in the future in looking into some of these other classes of plasticizers, that's something we could, you know, potentially look into in more detail.

I anticipate that likely that there will be interest in that. And so that's something that we'll explore in the future potentially.

MR. HOEPKER: The health effects of DINCH.

DR. PLUMMER: Oh, the health effects. So the rest of the question was the health effects of DINCH.

I can't specifically comment on that. I haven't looked into it in detail. I don't know if -- Gail, if you had any comments on the health effects of DINCH or --

DR. KROWECH: I don't.

DR. PLUMMER: Okay. So that might be something we could, you know, get back to you about in the future

or -- we probably won't do a specific document on that chemical, but largely because it is designated already.

DR. KROWECH: Gail Krowech from OEHHA.

Several years ago, we did a survey of plasticizers looking at many of them. And from that, the Panel was very interested in aromatic -- or phosphate flame retardants and plasticizers, and we pursued that. So many of the phosphate flame retardants are also plasticizers. So we did look at that. And from that whole survey, the Panel basically picked one to look at, but we could definitely look at more in the future.

CHAIRPERSON LUDERER: Thank you very much.

Do we have any additional discussion or comments or motions from Panel members?

Dr. Cranor.

PANEL MEMBER CRANOR: I would move that we list --

MS. HOOVER: Talk into the mic.

PANEL MEMBER CRANOR: Sorry. I would move that we list the ortho-phthalates as designated substances.

CHAIRPERSON LUDERER: Okay. So Dr. Cranor has moved that the chemical class ortho-phthalates be included as designated chemicals in the California Environmental Contaminant Biomonitoring Program.

Is there anyone who would like to second that?

PANEL MEMBER SCHWARZMAN: I would second that motion.

CHAIRPERSON LUDERER: All right. So that has been seconded by Dr. Schwarzman.

So now, I'll go ahead and poll the Panel. So start on that end. Dr. Cranor?

PANEL MEMBER CRANOR: Yes, list.

PANEL MEMBER QUINTANA: Yes.

PANEL MEMBER BARTELL: Yes.

CHAIRPERSON LUDERER: Yes.

PANEL MEMBER FIEHN: Yes.

PANEL MEMBER KAVANAUGH-LYNCH: Yes.

PANEL MEMBER SCHWARZMAN: Yes.

CHAIRPERSON LUDERER: Okay. Unanimously yes. The Scientific Guidance Panel recommends designation of ortho-phthalates as a class in the CECBP.

So now we move to our open public comment period. Do we have any requests for time in that open public comment period?

MS. BUERMEYER: You want me?

(Laughter.)

CHAIRPERSON LUDERER: We've exhausted our commenters.

(Laughter.)

CHAIRPERSON LUDERER: None?

All right then. Well, then I'll just -- we will wrap-up. And it looks like we're actually going to be finishing a little bit early today.

So I wanted to make an announcement, which is an announcement -- a change in the Chair of the Scientific Guidance Panel. I've been the Chair now for a number of years. And I'd like to announce that I'm going to be stepping down as the SGP Chair after this meeting. I will continue on as a Panel member.

And I'm very pleased to be able to pass the reins to Dr. Asa Bradman, who unfortunately is not here today, but he has graciously accepted the Program's request to act as Chair. And he's done that a few times when -- or at least one or twice when I haven't been here, and I know he's done a great job.

And then I also wanted to announce that a transcript of this meeting will be posted on the Biomonitoring California website when it's available as always. And I wanted to also announce that our next meeting will be on November 18th. And the location is yet to be determined. So there will be updates about that, of course, on the website once that's determined.

And then finally, I wanted to remind everyone in the audience that the conference facility closes today at 5:00, which I don't think should be a problem, since we

have an hour to get down to the ground floor. And we recommend, yeah, heading down to the lobby before then.

All right. And with that, I'll adjourn the meeting and thank everyone for coming and for your participation.

(Applause.)

(Thereupon the California Environmental Contaminant Biomonitoring Program, Scientific Guidance Panel meeting adjourned at 4:00 p.m.)

C E R T I F I C A T E O F R E P O R T E R

I, JAMES F. PETERS, a Certified Shorthand Reporter of the State of California, do hereby certify:

That I am a disinterested person herein; that the foregoing California Environmental Contamination Biomonitoring Program Scientific Guidance Panel meeting was reported in shorthand by me, James F. Peters, a Certified Shorthand Reporter of the State of California, and thereafter transcribed under my direction, by computer-assisted transcription.

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

IN WITNESS WHEREOF, I have hereunto set my hand this 30th day of July, 2015.

JAMES F. PETERS, CSR
Certified Shorthand Reporter
License No. 10063