MEETING

STATE OF CALIFORNIA

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

RICHMOND CAMPUS

AUDITORIUM

850 MARINA BAY PARKWAY

RICHMOND, CALIFORNIA

WEDNESDAY, NOVEMBER 18, 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:

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

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

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

Thomas McKone, Ph.D.

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

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

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

Ms. Carol Monahan-Cummings, Chief Counsel

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

Dr. Martha Sandy, Chief, Reproductive and Cancer Hazard Assessment Branch

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY:

Dr. Gina Solomon, Deputy Secretary for Science and Health

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

DEPARTMENT OF PUBLIC HEALTH:

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

Ms. Duyen Kauffman, Health Program Specialist, Environmental Health Investigations Branch

Dr. Barbara Materna, Chief, Occupational Health Branch

Dr. Nerissa Wu, Chief, Chemical Exposure Investigations Unit, Environmental Health Investigations Branch

DEPARTMENT OF TOXIC SUBSTANCES CONTROL:

Dr. Erika Houtz, Research Scientist, Environmental Chemistry Laboratory

Dr. June-Soo Park, Chief, Biomonitoring Branch, Environmental Chemistry Laboratory

GUEST SPEAKERS:

Rachel Morello-Frosch, Ph.D., M.P.H., Professor, Department of Environmental Science, Policy and Management and School of Public Health, University of California, Berkeley

Mr. Jason Mihalic, Arizona Department of Health Services

Dr. Amy Mowbray, Associate Director for Policy, Division of Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention

Dr. Marc Nascarella, Massachusetts Department of Public Health

Ms. Julie Nassif, New Hampshire Division of Public Health Services

Dr. Bahman Parsa, New Jersey Department of Health

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

GUEST SPEAKERS:

Lovisa Romanoff, M.S., M.P.H., Deputy Director, Division of Laboratory Sciences, National Center for Environmental Health, Centers for Disease Control and Prevention

Mr. Shane Wyatt, Virginia Public Health Laboratory Emergency Response & Radiochemistry Groups

ALSO PRESENT:

Dr. Jamshid Eshraghi, Massachusetts Department of Public Health

Dr. Tina Fan, New Jersey Public Health Laboratories

Mr. Alex Hoepker, University of California, Berkeley

Dr. Veena Singla, Natural Resources Defense Council

Ms. Barbara Toth, New Mexico Department of Health

I N D E X

I N D E X C O N T I N U E D

P R O C E E D I N G S

DR. PLUMMER: Hello, everyone. Thank you for coming today. We're going to get going with the meeting.

Today our meeting is available via webinar. And I just want to remind you please speak directly into microphone, and introduce yourself every time you speak. And this is for the benefit of the people that are participating via the webinar and also our transcriber.

So the materials for the meeting were provided to SGP members and posted on the Biomonitoring California website. There are some meeting folders including the agenda at the table near the entrance where you came in. Today, we'll take two breaks, one around noon for lunch, and another at around 3:30. And you probably saw the restrooms and emergency exits are just out the back of the auditorium where you came in.

And with that, I'd like to introduce Dr. Lauren Zeise, Acting Director of the Office of Environmental Health Hazard Assessment.

ACTING DIRECTOR ZEISE: Thank you, Laurel.

Good morning, everyone. I'd like to welcome the Panel and the audience to this meeting of the Scientific Guidance Panel for the California Environmental Biomonitoring Program, also known as Biomonitoring California. And thank you all at this early stage for

your participation in this important meeting.

And I'm very pleased to acknowledge and welcome the representatives from the State biomonitoring programs and the National Biomonitoring Program who are attending and presenting at today's meeting, and other invited guests.

So we're starting this meeting with a tribute to Dr. Julia Quint, who served this Panel with distinction. We were very sorry to hear the news that Julia passed away this weekend. Julia served on the SGP I think since 1980 -- sorry since 2008. And also it was exactly one year ago today that we received a note from Julia that she was resigning from this Panel.

Julia was always an engaged and active participant in the Panel and she provided such thoughtful advice and guidance to the Program. And she also held a spotlight on issues for workers. And saw this as an important group for Biomonitoring California to study. And she inspired the FOX study of firefighters. And many of us who knew and had the pleasure of working with Julia -- actually many of us since the 1980s. Working with Julia was really a delight. And we all knew her as a relentless advocate for public health and worker protection. So we've asked two friends of Julia's who, again over many years, worked closely with her on public

health and occupational issues to say a few words about her, and her legacy.

So first, I'd like to introduce Dr. Barbara Materna who's Chief of the Occupational Health Branch in the California Department of Public Health.

Barbara.

DR. MATERNA: Thanks, Lauren.

I had the honor and the pleasure of working closely with Julia in the Occupational Health Branch, where she led our Hazard Evaluation System and Information Service, HESIS, until she retired and began her next career outside the confines of State bureaucracy, which I think was a lot more fun.

HESIS -- understanding the science about the health effects of toxic chemicals and sharing practical information to protect workers and the public was a mission that fit Julia to a T. She had the perfect -- oops -- She had the perfect -- what's the best way to aim at this? Okay.

She had the perfect combination of being both an exacting scientist and a passionate advocate. She would not be deterred when industry groups sent in their toxicologists to oppose her arguments for a health protective Cal/OSHA standard for chemicals like 1-bromopropane or n-methylpyrrolidone. She had the

scientific basis to support her positions and the tireless energy to do whatever it took to move forward on so many fronts of public health.

As I look around me and what CDPH, Cal/OSHA, CalEPA, and others are doing now, I can see Julia's influence everywhere, and realize how much we all learned from her.

She spearheaded the drive for safer alternatives to toxic chemicals many years ago with her work on things like n-hexane and auto repair products. She had the courage to convince CDPH lawyers that putting the names of products containing this harmful solvent on our HESIS fact sheet was the right thing to do. A step that drove these companies to reformulate their products.

When we got reports of California workers with severely lung disease from exposure to the butter flavor chemical diacetyl, she put out the first fact sheet in the country that clearly identified that hazard associated with this chemical.

But she was very frustrated that our ability to get out this information was limited, because we had no way to know where the chemical was being used in California. So she had an idea about what needed to be done next. It took incredible persistence and hard work and many more years, but one of her most recent successes

was a new California law that effective January, 2016 gives HESIS the authority to ask a chemical company for a list of who they sell a specific product to in California.

Julia's work on pollution prevention and upstream solutions started long before we all heard about green chemistry and safer consumer product regulations. I cannot imagine these efforts would be where they are at now without her influence.

Julia was also a master collaborator, reaching across all kinds of dividing lines, finding people to talk to and work with in environmental agencies, local health departments, trade associations, unions, and community groups. She was amazing, brilliant, kind, a fighter against injustice of any kind and will be sorely missed by all of us who loved and admired her.

I could go on, but Julia would remind us there is so much more work to be done in public health, so let's just get on with it. And I'm going to pass the baton to Gina.

CAL/EPA DEPUTY SECRETARY SOLOMON: So many of us who've worked with Biomonitoring California and, of course, on the Scientific Guidance Panel have had the privilege of working with Julia for many years. Many of us had -- you know, were her close colleagues and friends. And it's a horrible blow to lose her from our midst.

She was always so active and focused and engaged on the Panel. She would ask the best questions, and she also always was so gracious and supportive to the staff. And I think part of it was because she recognized, having worked in government, so many of the challenges that the program faced in terms of resources and other challenges. And so she would recognize those, but would never lower her standards of science for one minute or lower her hopes for what we could accomplish for one minute.

And for Julia, as such a great, brilliant toxicologist, science was for a purpose. It wasn't just for science sake. Science, for her, was really for two main things, one was to protect workers, especially low wage and most exposed workers; second, to protect communities and the public especially the most vulnerable and disadvantaged communities.

And for Julia there was no conceptual gap between occupational health, environmental health, environmental justice. Many of us, you know, have sometimes seen those areas as being fractured and separate. For her, it was all part of the same thing. And I think that that has been really important for me and for many of us to see.

And she showed -- I think one other thing about the biomonitoring -- about Biomonitoring California is that it's not a pure science program, even though it's

very solidly based on science. And it's also not a regulatory program. And in those ways it's very similar to HESIS. And she showed us how, through this sort of three step iterative possess, you can make a huge difference using science in a non-regulatory context by first identifying the problems, the emerging hazards, and then notifying people and sounding the alert about what the concerns and the issues are, and then becoming, you know, alert again to the problem of regrettable substitutes. And she was on top of the issue of regrettable substitutions way before that term became fashionable. She really was the first to focus on that ongoing problem.

So as we continue Julia's work, we need -- I think, you know, from my perspective, we need to remember always remember the workers, always be nimble to evaluate new issues as they emerge, and to call attention to those new issues as they emerge. And then to always remember that we're here to use our science to help others. And there's no time to waste, so let's get going.

Thank you.

ACTING DIRECTOR ZEISE: Thanks, Barbara and Gina.

So we've set up a tribute table for Julia in the back of the room. And I invite you to go to the table during lunch and at the break. So now, in the spirit of

Julia, we'll move on to today's important business.

So first of all, just an overview of the last Scientific Guidance Panel meeting. This was held in Oakland, July 16th of this year. And at this meeting, the Panel unanimously recommended that the class of chemicals known as ortho-phthalates be added to the list of designated chemicals for Biomonitoring California. The Panel received an in-depth review from Dr. Antonia Calafat of CDC's work on biomonitoring phthalates and phthalate alternatives, and discussed these important classes of chemicals with her.

And the Panel heard a detailed update on the new Biomonitoring California's program study, MAMAS, Measuring Analytes in Maternal Archived Samples, and heard other program updates, and also discussed with Dr. Karl Palmer, the Chief of the Safer Consumer Products Program within the California Department of Toxic Substances Control, how our Program can inform -- how our programs can inform each other.

So more information on the July meeting is available on our Biomonitoring website at www.biomonitoring.ca.gov.

So now, I'll turn meeting over to our Chair, Dr. Asa Bradman.

CHAIRPERSON BRADMAN: Thank you. Before we

start, I also want to acknowledge Julia's passing and really I guess say one thing. When my father died, a rabbi said to me, no one really dies until everyone whoever knew them also leaves this world. So I think all of us probably can feel that Julia, in many ways, is still present in this room and will be here present for many, many years.

We have a very full agenda today. First, I want to also thank OEHHA for considering me as the Chair of the Panel. And I look forward to continuing to serve the Program in this capacity.

I'm just going to quickly review now our goals for today. And just a reminder, we have a very full agenda today, so we're going to be pretty tight on the time schedule.

But the goals for the meeting today are to hear from representatives of State biomonitoring programs across the United States and discuss issues of common interests, participate in a session on best practices for returning biomonitoring results. And we'll hear from Dr. Rachel Morello-Frosch and Duyen Kauffman from CDPH, and also have a discussion about that content and also engage with the audience. We'll consider the classes of ortho-phthalates and PFOS compounds as potential priority chemicals. And then, as usual for each agenda topic,

we'll have time for both Panel questions and discussion and public comment.

In terms of just a reminder on how we'll be handling public comments for those in the room and also listening on-line, if a member of the public would like to make a comment, he or she should fill out a comment card which can be obtained from the table near the entrance of the auditorium. You can turn the cards into to Amy Dunn.

Amy, identify yourself.

Members of the public who are not at the meeting can send an email to biomonitoring@oehha.ca.gov. Emailed comments relevant to the topic under discussion will be read allowed during the meeting. Public comments will be subject to time limits and the time allotted will be divided equally among all the individuals wishing to speak on that item.

Please keep comments focused on the agenda topics being presented. There will be an open public comment period as the last item -- as the last item of the day, and you're free to comment on anything related to the Program at that time.

So at this point, I want to introduce Ms. Lovisa Romanoff from CDC who will be introducing the first agenda item, which includes a number of highlights from program -- biomonitoring programs across the country.

MS. ROMANOFF: Good morning. Unfortunately, for obvious reasons, I'm going to be brief. And I'm not going to present today because I have laryngitis. And this is -- we just have concluded yesterday a meeting -- a two-day meeting with state partners and national partners that are involved in biomonitoring all across the country.

And the downside of that is that I lost my voice. So I just wanted to say thank you again for having us out here. And then I'm going to turn it over to my co-worker Dr. Amy Mowbray who is our policy lead and has graciously taken on presenting today to you instead of me, so I can spare you from having to listen to this voice.

So Dr. Amy Mowbray who is our policy lead for the Division of Laboratory Sciences at the National Center for Environmental health.

(Thereupon an overhead presentation was presented as follows.)

DR. MOWBRAY: So let me see if this is -- is this -- can everyone hear me?

Okay. Great. So as Lovisa mentioned. My name is Amy Mowbray. I'm the policy lead for the Division of Laboratory Sciences at the Centers for Disease Control and Prevention. I work very closely with Lovisa who is the Acting Project Officer for the State Biomonitoring Cooperative Agreement.

So I'm going to go ahead and jump in. Our CDC's National Biomonitoring Program is one of six programs within our division at CDC that focuses on analytical chemistry. It's sort of seeded in our capability do that. And what we've done over the years is set up a national program where we conduct ongoing assessment of the U.S. populations exposure to more than 300 environmental chemicals by looking at participants in the ongoing NHANES survey.

We publish our findings in a summary report, which is the National Report on Human Exposure to Environmental Chemicals, and these are meant to provide national reference ranges for folks to use on the priority environmental chemicals that we're looking for.

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DR. MOWBRAY: Unfortunately, one of the challenges that we realized early on when conducting our own program is that the NHANES survey and the data then that we get from the NHANES survey are nationally representative, but do not provide exposure information by a specific state or locality.

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DR. MOWBRAY: So in 2001, we started the State Biomonitoring Program in an effort to help states use biomonitoring to assess chemical exposures of concerns in

their own communities. And the first part of that strategy was to try to get some funding out to as many states as possible in the form of creating planning grants. So actually creating plans to do biomonitoring in the states, not actually to execute those with a large amount of infrastructure that it requires to do biomonitoring. And we distributed about $10 million to 25 state and regional programs and ended up supporting a total of 33 states to do that.

At that time, we were hoping that funding would materialize, appropriated funding, from Congress to do a full scale National Biomonitoring Program. Unfortunately, that didn't happen during that time period.

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DR. MOWBRAY: But we managed to find some intramural funding to support an implementation grant. And we funded eight states, two individual states and the Rocky Mountain Consortium of six states to put those biomonitoring plans into action.

Luckily, at the end of that cooperative agreement, funding didn't materialize for a full-scale state biomonitoring program and we were actually able to put together a five-year cooperative agreement with three states.

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DR. MOWBRAY: And we used this dedicated funding to expand state laboratory capacity for biomonitoring awarding it to California, as you know, and the State of New York and the State of Washington.

At the end of the most recent five-year cooperative agreement here, the 2009 and 2014 agreement, we, at CDC, stepped back and looked at sort of the process that we had been taking to help support states in doing biomonitoring, and what sort of successes we had seen from the full five-year cooperative agreement and to think about --

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DR. MOWBRAY: -- how we wanted our next round of funding to best benefit and broaden biomonitoring -- the availability to do biomonitoring at the state level. And so the key outcome of our next funding opportunity announcement which was released in 2014 was we wanted to expand the amount of high quality, substantial, and previously unavailable state-specific exposure information. And in doing that, we wanted to be able to get more of the money to more states. So tried to stretch as far as possible.

And one of the ways that we strategized to do that was to really force states to try to leverage existing collaborations and strategic partnerships, which

I think you'll hear a lot about here when the states speak in a few minutes.

We also wanted to build on existing infrastructure. We were aware that a lot of states had instrumentation and expertise that came as a result of the Public Health Emergency Preparedness Grant for the Laboratory Response Network. And we wanted to try to get a little bit away from providing laboratory infrastructure and to really support actual biomonitoring studies.

And so as a part of the funding process, we had 20 applicants that actually represented a total of 27 states that provided applications for this funding, and they were evaluated by a review panel.

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DR. MOWBRAY: We were grateful to select six awardees to receive funding for five years at a total of $5 million, and you can see those states here. And we are very excited. We've been working with the states for over a year now on their projects, and I am going to turn it over to them to talk more specifically about what their goals are for their individual projects.

So to kick that off, I'd like to introduce Dr. Michael DiBartolomeis. I'm sure you all know who he is. He is the Chief of the Exposure Assessment Section at the California Department of Public Health and the lead of

Biomonitoring California.

DR. DiBARTOLOMEIS: Thank you, Amy. And good morning, Panel, and everybody in the room. It's been a tough year. First, we lose George Alexeeff and now Julia Quint. I hope you all memorize that photograph of Julia that was so nicely done by Mary Deems in the Occupational Health Branch, because it's the smile that is so Julia.

It didn't matter whether we were at a birthday party, or she was fighting industry for something, or our own administrative people up through the Department of Public Health, she always had that smile. And I've known her for 27 years, and I never remember her ever not having that smile. So as others have said this morning, I think the best way to honor her memory is to keep fighting on, and so we shall do that.

(Thereupon an overhead presentation was presented as follows.)

DR. DiBARTOLOMEIS: I also wanted to -- we had a great meeting the past two days. And I just want to say, that was -- it was fantastic and thank you for those who participated. I failed to mention one person who helped put this together, Dennis Tavares, our IT person. All these microphones and everything, it's because of him. So thank you.

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DR. DiBARTOLOMEIS: So this is going to be really quick in terms of the usual stuff we do I just have a quick personnel announcement, just some highlights of some ongoing studies, and then I'm going to introduce a new study that we haven't really talked much about over the past few meetings.

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DR. DiBARTOLOMEIS: So basically, I just want to welcome two new staff. They're actually in the Environmental Health Laboratory as visiting scholars. Su Zhang from Shanghai who is working on non-targeted screening, and Heng Wang who is working on environmental phenol analyses.

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DR. DiBARTOLOMEIS: And I'm not going through this slide in any detail. There's going to be more information about this in the next meeting about our regular study updates.

I just do want to highlight a couple of things. With regard to Pilot BEST, we have an analysis of the results return evaluation. And Duyen Kauffman will be presenting that this afternoon. So I wanted to call that to your attention. With respect to the Expanded BEST, we had a couple of major milestones. We returned many, many packets with the second round of chemicals in August. It

was a big process. And again, Duyen deserves a lot of credit, as well as the other folks in OEHHA and EHIB and the labs.

And also, we are following up with participants in the Expanded BEST with regard to those who had elevated arsenic levels. And we're going to be asking if they're interested in a retest as a clinical follow-up. So more on that some time in the future.

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DR. DiBARTOLOMEIS: I have brought this up before in various different ways, but we have, as you know, over the past -- starting with the end of -- actually, it was about a year ago, we presented some initiatives that the Program -- after it evaluated itself, some initiatives that we wanted to push forward in the next five years. You know, again, here they are in a nutshell. We've talked about statewide monitoring surveillance. We talked about targeted community and targeted populations, including workers. And we're -- of course, the principle of environmental justice, we want to incorporate into our work, not just in name but in principle and in action.

The one I want to concentrate on for the next -- for the rest of the talk is this consumer product chemical exposure concept. We've talked about this before. We've talked about policy over the past two days and how -- what

pushes policy and how biomonitoring can affect policy. It's my personal belief that working with consumer products and use -- doing shorter term exposure analyses and informing policymakers about chemicals in consumer products is one of the better ways we can push public health policy.

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DR. DiBARTOLOMEIS: So with that highlighted, I want to introduce a new study, which we are calling FREES or Foam Replacement and Environmental Exposure Study. And this is a collaboration -- let me catch up to my notes here.

This is a collaboration with UC Davis, with the Green Science Policy Institute, the Environmental Working Group and Silent Spring with money from UC Davis being the EPA STAR grant, which I think many of you are aware of. And with Biomonitoring California, it is the CDC funds, as well as the State donate -- you know, State funding.

And we're asking the question, is there a benefit to replacing foam furniture? And I think by benefit, we mean is there a reduction in exposure to certain chemicals, and ultimately, the implication is a reduction or an improvement in health outcome over long-term exposures.

And we are concentrating on flame retardants.

There are, of course, other chemicals in furniture, but these are the chemicals we're biomonitoring.

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DR. DiBARTOLOMEIS: So the study goals are displayed there. And I want to emphasize this is a pilot study. This is not meant to be the kind of beginning and end of all furniture replacement studies. We want to see if this is something that biomonitoring can participate in in terms of informing consumer product safety of regulations and those sort of things.

So ultimately, we're looking to assess, as a cooperative collaboration, changes in levels of flame retardants when furniture is removed -- or the foam is replaced, and that includes dust, as well as biomonitoring, you know, levels of chemicals in the blood and urine of people.

So it's -- we ultimately are after looking -- evaluating whether this type of methodology of replacement, coupled with biomonitoring and environmental assessment, is an effective way to assess exposure and also to, I guess, inform reduction strategies.

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DR. DiBARTOLOMEIS: Our analysis plan is actually also fairly simple in terms of just, you know, breaking it down. The UC Davis portion of this would be to model and

measures -- changes in the dust levels of flame retardants over time both, you know, at the time -- at the baseline and then over time as the foam has been replaced.

And the Biomonitoring California part of this is, of course, to biomonitor for PBDEs in serum, for organophosphate-containing flame retardants metabolites in urine. And I want to stop for just a second to say this study, along with -- we're moving ahead with reanalyzing some of the FOX urine samples for OPFRs. These are the first times we're implementing these new -- this methodology. So this is a big break-through for the Biomonitoring Program, and for biomonitoring in general. So just keep that in mind, you know, as you're thinking for your own state or at the federal level. This is groundbreaking in many different ways.

And we're also going to be looking at PBDEs and OPFRs in hand wipe samples from actual people's contact with the foam and the dust.

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DR. DiBARTOLOMEIS: So the timeline on this study is about a year and a half, and we're into it now. So we're -- time zero has already started clicking. And so zero is the baseline. We're looking for dust levels of PBDEs, and I presume OPFRs -- actually, I'm pretty sure of that. And serum, urine levels in people, so we're going

to get the baselines, the hand wipes, and then we'll have a baseline questionnaire to administer. And I think we're at various stages. I have -- let's see. Hold on. That's the next slide.

And then in six months, we will be doing a follow up with the dust in urine and exposure questionnaire. That is after the foams have been -- the foam has been replaced. And then after a year, we do the whole spectrum again. And then finally after a year and a half, we finish off with the three again.

So this is again a pilot, but the study design looks like it's -- it could be something that could be extended to a much larger kind of study design.

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DR. DiBARTOLOMEIS: So where are we with this? We're calling phase one the actual dust and biomonitoring part of the pilot for the initial population that we want to study. It's a convenience sample of residents in San Francisco and the East Bay that are knowledgeable about chemical pollutants. So it's a fairly not random -- could be any sample, because these are very knowledgeable people. It's about two-thirds complete, the actual baseline biomonitoring, the collection of specimens, et cetera. The next collection for these would be due in June of 2016, if you looked at our schedule.

Phase two, I didn't mention yet, but phase two is where we want to bring the EJ concept in. We've learned that there is a proposed partnership with First Community Housing in San Jose for finding households that are of lower income and more vulnerable, you know, in terms of where they're -- in terms of other socioeconomic, you know, factors. And the recruitment for that study would begin in January 2016.

Overall, we're hoping to have 20 to 30 households with about -- you know, up to 50 participants.

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DR. DiBARTOLOMEIS: And with that, I'm just going to show you, you know, our ever-changing acknowledgments slide. I'm never on there. I don't know when I -- I guess when I'm on there, that means I'm not here anymore.

(Laughter.)

DR. DiBARTOLOMEIS: So thank you very much.

(Applause.)

CHAIRPERSON BRADMAN: I just want to comment that we're going to hold questions and Panel discussion until after the States presentations are complete.

DR. MOWBRAY: Okay. Just as a heads-up, the order of the states that -- it will be Massachusetts, followed by New Jersey, then the Four Corner State Biomonitoring Consortium, Virginia and New Hampshire.

So our next speaker is Dr. Marc Nascarella. He's the Chief Toxicologist at the Massachusetts Department of Public Health, and the Director of the MDPH Environmental Toxicology Program.

So here's Marc.

(Thereupon an overhead presentation was presented as follows.)

DR. NASCARELLA: Good morning, and thanks for hosting Massachusetts here. I'd like to take a minute to say that the State based biomonitoring program in Massachusetts are the efforts of two bureaus within the Department of Public Health, the Bureau of Laboratory Sciences, and the Bureau of Environmental Health.

So this presentation represents work by myself and my team, as well as the team that's led by Dr. Jamshid Eshraghi in the Division of Analytical Chemistry in the Bureau of Laboratory Sciences.

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DR. NASCARELLA: So the goals of our cooperative agreement with CDC are to enhance the capability, capacity, and readiness of the State Public Health Laboratory and the Bureau of Environmental Health to evaluate vulnerable populations in targeted high-risk communities - and in those communities, we're looking at metals - and to conduct a statewide surveillance and

collect samples from a representative portion of the population to determine baseline levels of both metals and PCBs and to also document our emergency response capability by providing biomonitoring for acute chemical exposures and that will be provided for the suite of metals that we're looking at, as well as acute exposure to PCBs.

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DR. NASCARELLA: So a little more texture to those three goals. Within the vulnerable population, we'll be looking at children between the ages of five and 12. And why five?

Well, that's where the Childhood Lead Poisoning Prevention Program leaves off, and that's where we're hoping to pick up. We'll be looking at blood and urine analyses for lead, mercury, cadmium, and manganese. From the statewide population, we'll be looking at adult residents, looking at both serum and blood analyses for PCBs and manganese, as well as a suite of metals for urine analyses.

And as part of acute and episodic events in Massachusetts, we'll be responding with our Hazmat and other State partners to conduct biomonitoring as part of accidental or intentional chemical releases. And we're also using it to augment existing, kind of risk assessment

approaches. Those of you familiar with the APPLETREE style health assessments through ATSDR, we'll be providing biomonitoring as a service to individuals that are concerned about exposures at National Priority List sites.

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DR. NASCARELLA: So some highlights and accomplishments of what we've been able to do in this first approximately year and a half of funding. We've purchased and installed new instrumentation, a new ICP-MS in our laboratories, bringing that on-line through a completion of method development plans and experiments. Our metals will be analyzed via ICP-MS, and our PCBs via GC mass spec, mass spec. And we have an existing capability with PCBs. And we've been doing that for some time.

We've been able to hire five new staff. And I'm glad we put that up there in contrast to Michael's slide, where we see all of the Biomonitoring California staff. Hopefully, we're able to show you what we're able to do with these five FTEs. We have two staff that we've hired as junior toxicologists and two laboratorians and kind of a pivot person in the middle who has a background in both environmental health and laboratory sciences that serves as our coordinator.

We've established and convened an advisory panel.

And we've also partnered with our health survey team to implement a statewide sampling program that takes advantage of the behavioral risk factor surveillance survey, that's a CDC instrument in each state.

We've also developed outreach material for participants and collaborators, I'll go through that a little bit at the end. And we've developed technical resources for health based interpreting of biomonitoring results. And mainly, we've done that through responding to some episodic and acute chemical exposures in Massachusetts.

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DR. NASCARELLA: Some of the challenges we face, and I think this is universal across all biomonitoring programs, is the recruitment and enrollment of participants. I think we know how to do it, but with five FTEs that are dedicated to biomonitoring and the programmatic responsibility to health department staff to do everything else, it becomes a real burden, the enrollment of participants. It's an iterative process, and it takes a lot of time to build these relationships with community organizations as well as contact the individual participants.

There are challenges with establishing health-based thresholds for these analytes of interest.

As part of the National Exposure Report, those of you that have become familiar with it, you'll see it's stated there implicitly many times that these are exposure levels and these are not health-based thresholds.

Unfortunately, that doesn't address the concerns of the individuals at the Massachusetts Department of Public Health that want information on is this a level of health concern, or participants that approach us and say should we be concerned, or interactions we have with clinicians that are looking for guidance from us on the health impacts of exposure to this level. So that continues to occupy a great deal of our time as well.

Developing results communication to participants is also a challenge. Absent of good health-based thresholds, it's difficult to interpret that and explain it in a manner that's coherent to someone that is not involved in the background of why these levels don't exist.

PCB congener analysis is a technical challenge for our laboratorians. Finding a serum matrix that's free of PCBs continues to be a challenge. And complete removal of PCBs during the clean-up is a challenge.

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DR. NASCARELLA: With respect to participant recruitment and enrollment and how we're accomplishing

that through our vulnerable populations sampling, where we're really hoping to leverage our community health networks and go into some of these communities with trusted partners and leverage those relationships to collect samples and address community needs.

As I mentioned previously, we're also leveraging existing health survey resources within Massachusetts, using random digit dial surveys, where we ask an individual question. Are you interested in having a call-back from a member of our biomonitoring team? And then we'll seek to enroll them.

And we're also leveraging our relationships with local health departments, as well as the hazardous materials response teams. We're leveraging relationships with our Massachusetts Emergency Management Agency, as well as the federally funded State Emergency Response Commission. And we're also leveraging our relationships through the Human Health Risk Assessment Network that's in our state, working with both ATSDR and EPA Region 1, as well as our local risk assessors.

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DR. NASCARELLA: So a quick example of year one activity is we've been be able to respond to a number of mercury exposure events. Through this, we've been able to really streamline our coordination with local board of

health and state agencies. We've kind of greased the skids for our urine collection sample, collection analysis and interpretation, and our interaction between the Bureau of Environmental Health and the Bureau of Laboratory Sciences.

We've used it as an opportunity to develop outreach material and get feedback on that, and respond to some drinking water concerns, both respect -- with respect to developing reference levels for measurement of manganese and serum, as well as look at dermal exposures to arsenic.

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DR. NASCARELLA: And with that, I'll wrap-up by saying a true thank you to CDC. This is a true cooperative agreement where CDC is able to provide us to the funding, but almost more importantly, we have almost unfettered access to expertise at CDC. And that has been invaluable in implementing this program, and kind of establishing best practices in the state that are consistent with some of the federal approaches.

(Applause.)

DR. MOWBRAY: Our next speaker is from New Jersey is Dr. Bahman Parsa. He is the director of the Environmental and Chemical Laboratory Services at the New Jersey Department of Health, and he is also the PI for the

New Jersey Biomonitoring Program.

(Thereupon an overhead presentation was presented as follows.)

DR. PARSA: Thank you very much.

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DR. PARSA: Good morning.

Here at New Jersey our experience with the clinical sampling is limited just working as LRN-C laboratory. But once we got the grant, we established ourself with six goals.

The goal number one, which is the first and the most important goal in this program, is to have the laboratory capability and capacity in place, and specifically for analysis of PFC, PCB, metals and metals speciation. In that respect, we have developed three projects, which will encompass the goal two, three and four.

The goal number two is the PFC exposure in communities with contaminated drinking water. Goal three and four, the projects -- is the biomonitoring study using blood banks and clinical laboratory samples to determine the baseline levels for a number of analytes in blood and serum. And the third project is the expectant mother biomonitoring study.

The goal five is the increased collaboration and

communication within the Department, outside the Department agencies, as well as the scientific communities.

And goal six is the permanence and sustainability, once the -- this grant has been terminated.

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DR. PARSA: The project one is the environmental contaminant levels in blood and urine specimens from New Jersey clinical laboratories and blood banks. The objective is to determine metals, PFCs, PCBs in blood and urine among the New Jersey residents 20 to 74 years old, using remnant clinical laboratory and blood bank specimens.

Establishing the biomonitoring data for target analytes based on the gender, age, geographic location, and race to screen for disparities across the study population in New Jersey.

And then third is demonstrate laboratory capability to capacity to conduct biomonitoring in New Jersey for environmental pollutants and to develop infrastructure to respond to actual exposure incidents.

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DR. PARSA: Project two is assessing PFNA body burdens following drinking water intervention. The

objective is to determine if individual residents residing in communities with PFNA-contaminated drinking water have higher PFNA serum levels than the general population based on our baseline study in project one; evaluate the effectiveness of the interventions implemented to reduce exposure to PFNA in drinking water by monitoring serum concentrations of PFNA over time; estimate the half-life of PFNA in the body; estimate serum -- serum to drinking water ratios for PFNA and assess how they may inform the risk assessment of PFNA in drinking water; and, finally the PFOA -- we do analysis of other PFC compounds, PFOA, PFOS and the other things.

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DR. PARSA: The project, three which is under development, we haven't done much about it, is the -- to do the analysis for the expectant mothers and target analytes, or metals and PCBs; and sample collection is recruitment from hospitals, OB/GYN offices, and insurance providers.

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DR. PARSA: The progress that we have done for goal one, laboratory capability and capacity building in the PFC side, we have been fortunate to be able to get staff on board and also purchase an LC-MS/MS equipment. Method validation is under development. And also the

training of the individual at the CDC has been completed. For PCB, we have completed the purchase of the high resolution GC-MS/MS equipment. Unfortunately, not been able to recruit the person that we have, due to the procedure of problems that we have at New Jersey for getting new hires. Metals speciation, we are going to be purchasing the equipment and also the same issue of hiring person.

And the goal 2, investigational support, we have done the IRB application. Approval pending. Outreach for subject recruitment, sample collection is in progress, and the questionnaire we have also developed.

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DR. PARSA: The project one study plan has been completed. Partnership with clinical labs and banks have been developed. Planning for sample collection is underway. IRB application has been approved.

Project three, assessment environmental exposure of pregnant women to toxic metals is under development.

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DR. PARSA: The goal five we have already formed the state biomonitoring program, established a New Jersey State Biomonitoring Commission, and outreach and partnership with a different organization in New Jersey has been established.

Goal six, the permanence and sustainability is the -- first of all, the capabilities in goal one we have been in progress; foundation built, which is in goal five; and pursuing additional state funding as early as 2017.

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DR. PARSA: The challenges that we have is -- currently is the hiring the staff, as I mentioned, obtaining IRB approvals for the remaining projects, managing large number of samples in the LIMS and the storage of the samples, and reporting the data are the issues that was discussed yesterday as well.

Under general challenges for us is building a coherent biomonitoring program, harmonizing the efforts of our laboratory with the priorities, which is of the other department, environmental or epidemiological sector; and also the transition from grant funding to state funding, which is going to be a challenge for us.

Thank you very much.

(Applause.)

DR. MOWBRAY: Our next speaker is representing the Four Corner States Biomonitoring Consortium, which consists of Utah, Arizona, Colorado, and -- did I say Arizona already? -- New Mexico. Okay. Sorry.

(Laughter.)

DR. MOWBRAY: Jason Mihalic is the Chemistry

Office Chief at the Arizona Department of Health Services and he is representing the four corner states.

So welcome.

(Thereupon an overhead presentation was Presented as follows.)

MR. MIHALIC: Thank you.

Hello. My name is Jason Mihalic again. And I'd like to also acknowledge that here are -- represent Arizona, but there's also -- oh, thanks -- New Mexico -- representation from New Mexico, Colorado, and Utah in the room.

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MR. MIHALIC: Our group has a history of biomonitoring, in that, as Amy mentioned, we are one of the grantees at the Rocky Mountain Biomonitoring Consortium, back in 2001 to 2010 -- or actually more 2005.

And so in addition, many of our states are Environmental Public Health Tracking Network grantees. Collectively our four states encompass an area of roughly two and a half times that of California, but with only 40 percent of the population. In practical terms, that means that we're a land of notable population centers, such as Denver, Albuquerque, Salt Lake City, and Phoenix, but we're also combined with a lot of small communities, whose base economic structures are based on farming, ranching,

and mining.

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MR. MIHALIC: Because of a similar geography, we share many of the same public health concerns, and these became the backbone of our work, and include metals exposure through private drinking water wells, phthalates from common household products, 2,4-D herbicides, para-dichlorobenzene again from common household products, and pyrethroids, which are used for mosquito and tick abatement efforts within our community.

On the laboratory end, the chemical and/or their metabolite shows we've adopted CDC methods to analyze all of these analytes of interest, and we've begun with metals and pyrethroid -- actually metals and phthalates.

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MR. MIHALIC: We've incorporated these concerns into five projects to complete within the five-year grant period. And while this does come out to one project per year, we don't really look at it that way. Some of the projects are ongoing, such as the well water study, while other of the projects will be encompassed over a one-year period. And we really take in regional interest, geology, population risks, mining and agricultural exposures into account.

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MR. MIHALIC: In terms of participant recruitment, there's really no one-size-fits-all approach when you have four states involved. So what we have instead is a tailored approach unique to each state. Colorado, for example, has a leg up on all of us, because they have merged this project into an ongoing assessment in the San Luis Valley, which is a predominantly low income agricultural area and already has a participant base to work with. And the rest of us have started from scratch.

In that end, we've used various techniques, including direct mailing, using well water registry databases for the well water study, working with school boards to get the word out, local health departments, health fairs, community liaisons, sign-up sheets in government buildings, health clinics, and doctors' offices. So it varies state to state, but so far they've been fairly successful.

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MR. MIHALIC: One year in and we have experienced some successes. Each state has had their IRB approved. Assessment tools have been developed for the first two projects metas and phthalates. Sample collection protocols, which be uniform throughout the consortium, have been established, and communication, which is no

small feat when you're dealing with four states over a large area, we've tackled by having monthly phone calls for lab and epi, periodic phone calls for both, and then two face-to-face meetings during the year.

In addition on the laboratory side, method development for the metals in urine, creatinine, which, of course, in urine as well, and then the phthalate metabolite, which is also in urine are complete. And we currently have completed or are undergoing our validations.

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MR. MIHALIC: Both New Mexico and Utah have developed -- have already begun their sample collection. Colorado and Arizona are -- will be collecting soon, hopefully by the end of this year. Of course, there's only one month left in this year.

One of the advantages collaboration is that we're able to use each state's experiences for the benefit of the consortium. For example, New Mexico took the lead on an exposure assessment, Colorado in providing results back to participants, Utah in analyzing data, and Arizona with the method development.

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MR. MIHALIC: Lessons learned in terms of contracting complexities. You know, it's one thing to

have a CDC grant and it's another thing to work with State lawyers.

(Laughter.)

MR. MIHALIC: So while it just didn't go as smoothly as we had assumed it would - and it's just the nature of contracts. Issues such as a venue of dispute, indemnity, insurance all came to the fore, which are really boilerplate, and had to be dealt with. Using student interns it seemed like a great idea at first. But the reality is we train them and they leave. So that begs the question of whether or not that's worth it.

And in addition, also with student interns, some states have issues with non-state employees riding in state vehicles, which is another tactical issue.

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MR. MIHALIC: The big takeaway I'm hoping to be able to impart is that the collaboration is achievable, as we've shown over the last year. As resources dwindle, affordable biomonitoring, that perhaps collaboration is inevitable, especially if regionalization becomes an economically viable alternative to single-state funding.

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MR. MIHALIC: And lastly, I'd like to thank the Consortium and then also the CDC.

(Applause.)

DR. MOWBRAY: Okay. The next speaker is Shane Wyatt from Virginia. He is the lead scientist for the Virginia Public Health Lab Emergency Response and Radiochemistry groups, and is the co-project lead for the biomonitoring program.

(Thereupon an overhead presentation was presented as follows.)

MR. WYATT: Thank you. Good morning. Can everybody hear me?

Hi. I'm Shane Wyatt. I'm one of the co-lead investigators for this grant in Virginia. My partner, the co-lead, Chris Retarides, was unable to make it this week, so hopefully we'll move forward, and then you're the timekeeper.

Okay.

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MR. WYATT: I think before I get started real quick, it's important for me to point out that the Virginia Public Health Laboratory is structured a little bit differently from most other public health labs. We are part of a cabinet level department that is not associated with the Department of Forensics or the Public Health Department. So we are completely separate from the Virginia Public Health group.

And as part of that, for us to operate with them

and perform biomonitoring studies with them, we actually have to have a memorandum of understanding or an agreement -- operations agreement between us and them, so that we know who's responsible for what and how we move forward.

I'm not going to give a real in-depth overview of the program initially, due to time constraints. I'm hoping that that will come out as we go through and talk about some of the successes and challenges.

One of the biggest successes we've had so far has been with the other State agencies that we have targeted to work with. And probably they're not listed first, but probably the most important one out of that group is the Department of Health.

As I said, we're not part of that laboratory, so we do have to meet with them on a regular basis. They are providing access to -- for us to the local health departments. They are also helping us with access to toxicologists, as well as activities on the biomonitoring advisory committee that we have proposed. The Department of Environmental Quality, the Agricultural and Consumer Services and the Department of Fire Protections have also extended their willingness to help us with these different projects that we've proposed, and they're all involved in one way or another.

And they will all be involved in the advisory committee at least partially, depending on the projects that are going on. We had an opportunity earlier this year to present the biomonitoring grant.

And biomonitoring in Virginia is really a brand new project. It's a brand new activity for us. We did partake in the planning committee -- the planning grant initially. However, we never -- no real actual biomonitoring studies were conducted or have been conducted for -- essentially on an ongoing basis.

And so last fall, we were given the opportunity to present to the local health departments this grant that we've been awarded and discuss what we're -- you know, the projects that we have ongoing and some of the initial -- and some of the future plans. We propose three propose three projects initially that -- our intent is not to maintain those projects or those would be the only projects that we approach through the advisory committee and/or through the health districts. We plan that other projects will come up as they're brought to our attention.

And they -- we received a lot of very positive responses from the local health districts. They're very, very excited about having this resource and being able to come forward and use it.

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MR. WYATT: Like I said, we propose three projects, two of them have been combined down into one project, so we had two IRB applications. We did the IRB application through our health department. It went fairly smoothly for us for toxic combustion to firefighters, which was one of the projects we proposed.

The other one we had initially proposed a detection of uranium in urine and perchlorates in urine, and the general population within Virginia. We expanded that out to toxic metals. And the toxic metals and the perchlorate were two separate proposals and we combined them down to one IRB application, because we're both -- we're going to be analyzing urine for both of them and we just wanted to do one collection.

I'm not sure what happened. We had a delay on getting this one approved, mostly because the IRB board couldn't find the application, after we had submitted it. So we resubmitted it, and it went through relatively quickly.

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MR. WYATT: And I think -- since this is a brand new program for us, and I think some of the other states have run into this as well, our biggest challenge for our opinion has been establishing the infrastructure. We are the public health laboratory. We are very good at the

analytical methods. We're very good at analytical method development. We're very good at handling samples and reporting out results.

What we're not good at is going out and getting them. Samples just -- generally come to us. If people want to give us samples, they're beating down our door saying we have stuff for you. Very few people are aware of the biomonitoring program since it's a new one. And us going out is a new function as a laboratory. Us going out and collecting samples and doing recruitment and informing the public of the ability and the things that we can do.

So establishing this infrastructure has been one of the bigger challenges we have. But to try to make that a little bit easier, one of the things we focused on were analytes we had experience with, and analytes we had methods for.

So we are leveraging some of our LRN-C capabilities. We are a Level 1 LRN-C laboratory, and we are using the cyanide method as well as the toxic elements green method from that program to do the analysis for the firefighters.

The perchlorate method is one that we developed in-house at the request of the LRN-C, so we had one ready to go for that as well.

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MR. WYATT: We're working with the fire protection services to collect samples at this time. The big issue is is that we're having issues scheduling times to go out and collect the samples. The fire protection programs is they do controlled burns to train firefighters on a regular basis throughout the year. It's a facility that's relatively close to our laboratory, but we're having some discussions on how to best get the samples, who to do the draws, because it's going to include a blood draw, and whether or not they can do that themselves or we have to provide somebody to do that.

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MR. WYATT: This one I wanted to spend just a second. I want to hit this real quick.

The toxic metals and perchlorates study is intended to be a statewide general population study. However, we wanted to narrow the focus of our recruitment activities to something that would seem to be a little bit more manageable initially. And so what we decided to focus on were community colleges.

There are a lot of community colleges in Virginia. And because -- they're part of the Virginia university system. All of the credits that you take at one college are completely transferable to another. So a lot of people take advantage of that, and a lot --

especially local community individuals. So we have a broad range of ages. We have a broad range of communities that participate in the community colleges, and we have several staff at DCLS that are adjunct professors at the different community colleges.

We have access to these campuses. We have ways to contact the administrations and ways to work with them. We can get in contact with them. We are fairly well along with one of the local community colleges, and we're in the final approval stages to be able to go in and start collecting samples. And this will strictly be a urine collection. And we'll be doing the toxic metal and the perchlorate study.

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MR. WYATT: And perfect timing. As I said, Chris Retarides is the other principal investigator for this.

Thank you.

(Applause.)

DR. MOWBRAY: Okay. Our final speaker is Julie Nassif. She is the Chemistry Program Manager in the Division of Public Health Services, Public Health Laboratories for the State of New Hampshire.

MS. NASSIF: Thank you. I appreciate being here and giving you an overview of what we're doing in New Hampshire.

(Thereupon an overhead presentation was presented as follows.)

MS. NASSIF: We have -- when we put together our proposal, we really thought it would be an opportunity to build on our existing biomonitoring capabilities, as well as an opportunity to leverage our emergency response capabilities through the LRN-C.

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MS. NASSIF: So this is New Hampshire. And what we've proposed as part of our efforts are really two studies. The first is a targeted effort that -- I don't have a pointer, but is located in the southern part of New Hampshire. It's our population center. And the geology in that area is such that there's a lot of granite. And the opportunity for leaching of toxic -- of elements to leach into the groundwater there.

So our first project is to look at total arsenic, uranium, and speciated arsenic in elevated individuals in the southern part of the state, and then in 2017, to launch a statewide surveillance study that would look at a much broader range of chemicals.

And in preparation for our proposal, we reached out to a lot of partners within the State, both our public health partners in the asthma control program, climate change, environmental public health tracking, our local

health officer -- some of the major cities have health departments. We spoke with them. We spoke with some community advocates, and we put together what we think is an interesting list of analytes that are relevant to our jurisdiction.

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MS. NASSIF: So a little background on the arsenic and uranium study. A very high proportion of the population of New Hampshire is reliant on private bedrock wells for their drinking water. It's actually gone up, since about 50 percent of the population is reliant. The geologic formations coupled with past land-use practices related to apple farming provides a lot of opportunity for arsenic exposure and contamination of the groundwater.

Our previous data have shown that there is definitely groundwater contamination. And our data also show that there is a significant correlation between those that drink that water and having elevated arsenic.

I viewed this, and many others do, as the most significant environmental health problem in New Hampshire. We have the second highest rate of bladder cancer in the country, second only to our neighbor to the east in Maine.

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MS. NASSIF: So recruitment from this high-risk area will be broad. We'll try to reach all age

populations with a special emphasis on reaching underserved and sensitive populations. There is a major city right in that area that's -- that has public water, and we hope to recruit participants from there as a control population.

We'll be collecting a significant amount of data from people regarding their recreational, residential, and occupational histories. Because of the association between organic arsenic, we'll be asking them to refrain from eating seafood, and we'll ask them to do a food diary. As an incentive for them to participate, we'll ask them -- we'll offer them free well water testing as well.

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MS. NASSIF: The surveillance project is broader and potentially significantly more challenging to implement. We'll be looking at establishing some baseline ranges for New Hampshire. Much like our partners in Massachusetts, we'll be looking at BRFSS data to try and get a representative population. If that doesn't provide sufficient numbers, we will look towards this opportunistic recruitment. And these are some of the places that we'll be looking to that. Recruitment at blood donation centers, college campuses to reach a demographic that we might not otherwise be able to tap.

A state employee complex. Our laboratory is

located with a number of other state agencies. And we may be able to recruit some participants there. We've had discussions with some local hospitals and clinical partners that are interested in perhaps having us recruit participants from their offices and practices.

And we're working with both -- we hope to leverage the NP students at the University of New Hampshire to helps us -- they'll be doing their capstone project, and we hope to work with them, perhaps in some discrete projects around survey development and other projects like that.

And we're in discussion with Dartmouth College, where they house an NIEHS superfund toxic metals core and about some specimen exchange with them.

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MS. NASSIF: These are the analytes that we'll be looking at in our surveillance project, a whole suite of metals. Our city health officials were particularly concerned in pesticide application and misuse in indoor environments. So we'll be looking at metabolites of organophosphate and pesticide -- organophosphate and pyrethroid pesticides, cotinine, the marker for environmental tobacco smoke, perfluorinated chemicals, which I know you're going to be talking more about this afternoon. And we're hoping to get some good statewide

numbers for the perfluorinated chemicals as we have known sources of contamination in the state. And there's some interest in nutritional biomarkers, specifically iron and folate as well.

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MS. NASSIF: Now, we have had successes. I didn't put the successes up. We've been able to hire one individual. My colleague, Amanda Cosser, is here today. And she's serving as our project manager. And we have purchased analytical equipment. We have an ICP-MS/MS which is the same instrument that Massachusetts has.

We have had a number of administrative challenges related to acceptance of the funding. Some policies that are apparently unique to New Hampshire and lack of a state budget that forced us into a continuing resolution for several months, which really exacerbated our ability to hire staff. So we are really at the inception of the program now. We're in the process of hiring. We have -- we have three analytical chemists that we'll be hiring, as well as a project specialist.

Some challenges that are not unique to us, participant recruitment and developing an advisory committee that has a balance between technical expertise and community engagement. And I'd be happy to talk more about community engagement and what we've done initially,

which is reaching out through our Health Officers Association as well as our Healthy Homes group.

And thank you very much. That's what we're going to be doing in New Hampshire.

(Applause.)

MS. HOOVER: Thank you so much. That was a lot of information an a short time, so great job. And what I'd like to do is ask all of the people who just spoke to come and sit in the front row, and be available for questions, and then we'll pass mics around.

I also wanted to let Panel members know that a lot of that information that was just presented is available on the program profile forms. You have those in your packet and they're alphabetical. So if you have questions about some aspects of the program, take a look at those program profile forms. So we'll start with -- Asa will be facilitating from now on.

CHAIRPERSON BRADMAN: Yeah. Okay. Thank you.

So just to clarify the next period of time, we have about 10 minutes for Panel discussion and questions, and then we'll have some time for public comment and then more opportunity for discussion.

So I guess to start right now is to ask are there any clarifying questions from the Panel to any of the speakers or related topics?

Tom.

PANEL MEMBER McKONE: Tom McKone, University of California.

I guess it's probably a point for discussion later. But first of all, these are all really great programs. I mean, a lot is going on. It's fascinating to see it.

The one thing that didn't come through is how much integration and communication and sharing and whether there's ways to link the different state studies together. I know that goes on. Again, each talk was about what's going on in the state. And I think the next step is to figure out -- I'm assuming this goes on, but it would be nice to make sure we learn a little bit more about analytical methods.

CHAIRPERSON BRADMAN: Tom, a little closer to the mic.

PANEL MEMBER McKONE: I've got remember to be on the mic.

Just more information about coordination and even some meta-studies maybe taking different data sets for the same agents and then combining them across states.

DR. MOWBRAY: So I'm going to take a starting stab. This is Amy Mowbray from CDC.

Part of CDC's role as a -- for the cooperative

agreement is substantial programmatic, you know, involvement in what the programs are doing. And one of our goals is to help keep communication between the funded states open. So what we've done historically, and are continuing to do, is provide opportunities for state conference calls, and then at least one in-person meeting of all the funded states each year, where we talk about analytical issues, programmatic issues, and we allow information sharing.

We are also -- and I would say this is a collaboration between CDC and the Association of Public Health Laboratories, as well as our state programs, we are working on the development of a National Biomonitoring Network that will really help us allow the laboratories to set -- to sort of harmonize approaches for lab and for sample design an sample collection and help us to really integrate across the state programs.

And if anyone else at the states wants to say more about that?

MS. HOOVER: This is Sara Hoover of OEHHA. I'll just add too that, you know, we also had two days of discussions with programs. And we actually made a lot of good connections and mentioning the network. So that's definitely a big thing we were working on over the last couple of days.

CHAIRPERSON BRADMAN: Are there any other questions from Panel members about this recent presentation?

Go ahead. Jenny.

PANEL MEMBER QUINTANA: Is this on?

Okay. Hi. I'm Jenny Quintana from San Diego State University. I had a question to do with how your consent forms ask the participants for their permission because I noticed that sometimes your list of chemicals is maybe shorter than you'd like to expand to in the future. And I'm wondering if there is a general approach of asking for permission to do further analyses than you're currently planning to do or even beyond environmental contaminants looking at other factors such as genetics or other markers and how you approached that by the different states?

MS. NASSIF: Our approach to the informed consent has been to consent individuals to this testing, but to have an optional consent for further environmental testing. Genetic testing would probably not be well received in New Hampshire.

MR. MIHALIC: From the Four Corners point of view, we initially thought that we would have one approach for all four states, but the IRB process pretty much eliminated that, because in some states it's more thorough

than others, some states -- for example, from Arizona, we were only able to be -- to involve people in one project that we were working on right now, whereas other states are able to sign up participants for all five projects. So it just varies state to state in our case.

MR. WYATT: Virginia has taken an approach very similar to New Hampshire. We are looking for permission to participate in the study that they're being recruited for, and then they have the option of allowing us to test their samples at a future date for environmental chemicals. We -- as she said, genetic testing probably would not go over very well, but we do intend to store our samples for future testing.

DR. DiBARTOLOMEIS: And I think, you know, that that's similar to what we do in California. I think the only thing that I haven't heard, when we do go in for -- to do additional testing, I do believe we still have to go back to the IRB for -- we don't for an amendment?

I'm getting a shake of the head back there from my IRB.

MS. WU: We do tend to write our consent forms and the IRB protocol to be fairly expansive to include the option of coming back and doing other relevant environmental chemicals. We use language where we can expand on other panels. We do have the requirement of

returning results, which brings in an added complication if we are years down the road, and we want to -- we want to alert people that they might be getting that information long after their participation seems like it has ended.

CHAIRPERSON BRADMAN: Okay. I just wanted to mention this particular time period was budgeted for clarifying questions, and then we'll have the public comment period, and they'll we have time for more discussion. It's kind of hard to distinguish between those sometimes, but -- okay. Well, I have a clarifying question, and then a few discussion things I'll cover in a moment.

But in terms of the -- I think this is for New Jersey. There was talk about use of the remnant samples and from clinical labs and blood banks. And I'd be interested to hear more about that and, you know, what are the mechanics and how the material was collected. And I assume those are -- that's done anonymously, but I'd be interested in hearing more about that.

DR. PARSA: Yes, the subjects are de-identified, so we really do not have any idea what the names and so on. We just know the age. We know their, you know, gender, and so on. So what we have done is contacted the blood banks and to ask them to give us what is left from

their analysis.

Now, in the blood banks they have consent from the individuals to provide their samples for research and so on, so there is that part is covered. But for the clinical labs, we really do not have that consent and -- but since it is the identified, we are not obliged to give anybody any results. We may -- we are considering -- actually, it's not approved in our biomonitoring commission, to give the results to these participating labs just as a recognition of their collaboration with us.

CHAIRPERSON BRADMAN: Right. Okay.

MS. HOOVER: Another collaborator from New Jersey wants to add something.

DR. FAN: Tina Fan from New Jersey Public Health Laboratory. I'm the CT and the biomonitoring program manager.

I want to just answer -- add some information regarding your question. Yes, these are the remaining samples, but we are really talking very closely with the providers as was the clinical laboratory or the blood banks regarding the sample collection. And, for example, exact know what the tubes we want. And also many of them actually they have enough samples, we should be able to even know about when the sample collected. So we're going to document all those information regarding the sample

conditions. So we tried to try our best to get what integrity of the samples.

CHAIRPERSON BRADMAN: Thank you. I think given.

PANEL MEMBER BARTELL: Asa one more question.

CHAIRPERSON BRADMAN: I'm sorry one more comment.

PANEL MEMBER BARTELL: I don't think we have time.

MS. HOOVER: Actually, we're going to pause and just call for public comment now. Then we'll go to the full Panel discussion, so there will be plenty of time for questions and comment.

CHAIRPERSON BRADMAN: Okay. So just to reiterate, we do have time for public comment right now. I don't know if there are any questions that have been submitted, either on line or by email?

MS. DUNN: This is Amy Dunn. I just want to remind people before I read the public comment that we are not only broadcasting this, but also recording it, so I'd very much appreciate it if people can try to make sure to speak into the microphones, so that we can capture what you say.

We have a comment that came in from Courtney Carignan. And this is a question for the speaker from New Hampshire. "Why not measure arsenobetaine in urine rather than ask to avoid seafood"?

MS. NASSIF: This is Julie Nassif from the New Hampshire Public Health Laboratory. Thank you for that question, Courtney. We will be measuring arsenobetaine in the speciated arsenic method.

MS. HOOVER: And were there any public comments or questions from the audience now?

DR. PARK: June-Soo Park, Toxic Substances Control, CalEPA. My question for Shane from Virginia -- I believe Virginia biomonitoring group. I was just curious why perchlorate was chosen for monitoring? I wonder if there was any -- there has been any concern on exposure from drinking water or groundwater?

MR. WYATT: The perchlorate method was one we were actually asked to develop by the LRN-C program, so we had it. And we had done some initial screening of some basically the lab workers. And we found that everybody had some in their system. Virginia itself is very heavily involved in the aerospace industry, and there's a lot of rocket launches. It's also a very heavily agricultural state, and perchlorates are a natural part of certain fertilizers that are used.

And there was no concern, there has been no concern expressed about it in the environment or being in -- you know people being exposed to it. However, it was something that we'd some discussions with the CDC

about. And we decided to pursue this one just to see if we could establish a background or a baseline for what was in the population.

MS. HOOVER: Other questions from the audience, or comments?

Okay. Take it away.

CHAIRPERSON BRADMAN: All right. Thank you.

So now we can move into a more standard period for questions and also more discussion. And I'll have you take the lead. Thank you. Sorry for the interruption earlier.

PANEL MEMBER BARTELL: Thank you. Oh, that's all right. Scott Bartell, University of California.

I think it's very interesting what's going on in a variety of states. And you see I think though a tension sometimes between the designs in terms of where you're getting sample, either targeting high-risk populations or, you know, trying to work towards -- I don't think anybody is quite there yet, but trying to work towards a statewide representative sample.

And I guess one thing we've talked about a little bit in this Panel earlier this year is, you know, given the great expense and difficulty, although it's a laudable goal to do the statewide sampling in a representative sample, it's, I think, a lot more logistically complicated

and expensive than, you know, trying to actually go after high-risk populations.

And I think one can ask, you know, to what extent you actually gain information if you end up, you know, with contaminate levels that are similar to NHANES, which, you know, is a possibility once -- but you wouldn't learn that, of course, until you implement the statewide sampling.

So I guess the question I kind of have for CDC and/or the states is to what extent your cooperative agreements lock you into this goal of working towards statewide sampling? And if indeed you decide that your resources are better spent perhaps going after high risk populations, would you be able to shift those resources under the current cooperative agreements?

DR. MOWBRAY: This is Amy Mowbray from CDC again.

We have built in a pretty good amount of flexibility within the cooperative agreement through the funding opportunity announcement to let states decide what are their priorities when doing biomonitoring. So we -- I think early on in the first five-year cooperative agreement, we put a heavier focus on a statewide surveillance study. In this new cooperative agreement, we've really left it a little bit more open for states to determine what are the exposures they're most concerned

about. And in the presentation I sort of hit on this. We really want to just get more high quality data that is not available that can help states make decisions in their own communities.

MR. MIHALIC: Well, we've talked about this a lot with the four corners, and we're using the well water study for our statewide outreach, because mostly in the rural communities are where you find people whose primary source of drinking water is well water. However, in terms of the phthalate, we can do that in our larger cities, as well as the pesticides. We may end up going to agricultural centers for some of the pesticides, but you're absolutely correct it is very expensive.

So of the five projects, we're really looking at the one for statewide and then the others, if we can.

PANEL MEMBER BARTELL: Thank you.

CHAIRPERSON BRADMAN: Dr. Schwarzman, I think you had a comment earlier that you were --

PANEL MEMBER SCHWARZMAN: I did. It mostly got answered.

CHAIRPERSON BRADMAN: Okay. Did you want to ask anything else?

PANEL MEMBER SCHWARZMAN: Maybe I will spend just another moment on this, because this partially addressed my question. I was just mulling a little bit this notion

of establishing a baseline. A couple states mentioned this work to establish baseline levels for the State. And mine was sort of less a thought about resources, although very -- that's very relevant, and more about what we're doing with that information.

How much you might expect that it would differ from national levels obtained by the CDC, and also what -- how we're interpreting that kind of baseline information, because I think there's this human tendency to treat baseline as acceptable, and then to be looking for variations from that. And yet, if your entire population is actually exposed to a significant level of something, we wouldn't want to interpret, you know, that baseline measurement of time zero as equal to, like, well, this is just background levels or something like that.

So that's what I was mulling on, and I guess I would just be interested if any of you had reflections on why you're seeking that information or how you would like to use it?

MR. WYATT: This is Shane Wyatt from Virginia. Originally, the reason why we proposed the uranium study was Virginia has some very large uranium deposits. Most of the central and southwestern portion of the state is basically one big uranium mine. And a lot of the groundwater out there is contaminated with uranium. And

so what we specifically wanted to do was to move into those areas and target those populations, so that we could try and evaluate, like we said, a baseline.

However, our expectation is, is that we're probably going to see areas that are above the NHANES level. And we have intentions or our plans are to areas that we feel are elevated or of areas of concern to continue to do monitoring and/or do more focused monitoring in those areas. If we find areas that we're not seeing elevated levels, we may move on and go to another section of the state.

We have had this show up in the past with other communities, and we've been able to work with the health department to implement -- help the communities implement water filtration processes to help remove it from their drinking water systems. And then we've come back a year or so later and remonitored the community, and found that the levels have all decreased. So that's kind of where we're going with this, but we -- like I said, it's a very resource intensive sort of project to collect that many samples that recruit people.

DR. DiBARTOLOMEIS. I have a philosophical response as well as a more applied response.

Philosophically, you're right on target. There should be no chemicals that have no benefit or no

physiological purpose in your bodies if they're coming from a contaminated environment. I mean, you just basically have pollution in your body, and they don't belong there.

So if you can detect it, you probably want to get it even lower or completely eliminate it. So that's the philosophical sort of precautionary approach. It's certainly not a risk based approach, and we still have that tension between risk and precaution.

From an applied point of view, having a baseline established for the population will allow you to look at trends over time. So obviously, if we are doing the right things in terms of environmental protection and, you know, all the other types of regulations, we should see that baseline drop. If we see it go up, we're not doing the right thing. So there still is a reason to collect that baseline. We just have to frame it in probably a different way, in my opinion.

DR. NASCARELLA: Marc Nascarella, from the Massachusetts Department of Public Health. I think another aspect to look at is the high-risk communities that we're sampling are kind of a priori identified as these communities are ones that we'd like to sample, because we suspect that their levels are higher than other levels in the state, but I think there's also the

obligation of the health department to look at the entire community across the state, to the extent that you're not entirely sure what the vulnerabilities in that community may be. And they may not entirely fall into pre-established criterion, namely an environmental justice criteria or be inside of an inner-city area where most metrics would identify them at high risk.

To some extent, we don't know all the risks and -- of exposure to some of these analytes. And I think for that reason, it's important to establish a baseline level of exposure. And to some extent, if your levels do differ from national levels, then perhaps your entire state has had some level of increased risk. And that's an important piece of information to inform policy in your state.

MS. NASSIF: This is Julie Nassif from New Hampshire. The only thing I would add -- I was going to say much of what Marc said, but the only thing I would add to that is it's a very useful point of comparison when you're looking at a community with a known contamination issue to have a point of comparison to the state and not just the national averages, because at this point, we don't know if our individual states look very different than the national averages.

PANEL MEMBER SCHWARZMAN: Thank you all for that

reflection. That's exactly the kind of thinking I was hoping was going on. And I'll be curious to see the results of -- and whether there are these differences from the national data.

DR. PARSA: As far as New Jersey is concerned, we considered that this study that we are starting is going to be a pilot study. Definitely, we're not going to be covering all the state with this. Our sampling is limited, but we try to be as extensive as we can.

But really because New Jersey is well known for its Superfund -- it's the highest in the country, and maybe to fix the problem as well, we would like to get a catch on that and find out if there is indeed reality to a one to one ratio. And if it is, then this would beg to have a much more extensive study throughout. And then we will have to really control what samples we're getting and all that.

DR. FAN: I want to just add a little bit of comments about the New Jersey -- we talk baseline study. Using PFC as an example, you know, it's -- in New Jersey, there's a source of PFC. So from that -- you know, that's why we're doing both from the, you know, blood banks and the clinical laboratory. Give us some general ideas about the, I wouldn't say truly general population, but still can give us some ideas about the levels are, and then are

doing the targeted communities, you know, the PFC.

On the other hand, I think it's about PFC has the source, not just only from the water, it's in some other as well. So actually that would tell us, you know, if you really do an intervention in our targeted community, if that really -- if the PFC is going to reduce when you compare it to the -- like our project one, which we call general population exposure. So we think that's another thoughts we have there.

CHAIRPERSON BRADMAN: I have a question, a kind of derivative of the last discussion. I think of all the presentations, it was Massachusetts that talked about establishing health-based thresholds for analytes of interest. And I'm curious to hear more about that process, especially for things that don't have an established, you know, reference dose.

And then perhaps a larger discussion of how the states are dealing with issues of risk assessment and risk interpretation of the measurements. And if that's programmatic or -- programmatic within the biomonitoring programs or if that's handled in a different arena?

DR. NASCARELLA: Marc Nascarella from the Department of Public Health in Massachusetts again. Thanks for the question. That is a -- I think that's a problem that every state faces, and to some extent it also

exists with the -- at the federal level, certainly with interpreting the National Exposure Report data.

I think for some analytes, there's established levels at both clinical levels of concern, as well as levels of concern that indicate elevations in the general population. Much of our effort is mining the literature and mining different resources and pulling them together to understand where those levels -- what those levels might be and what the most appropriate level is for the given scenario, whether it be an acute exposure or a chronic exposure. So that's one approach.

The other approach is to begin to kind of -- I know years past, there was a discussion at this forum on BEI levels. And the approach we're taking is somewhat a hybrid of the two, where if we have an analyte, and there is no established clinical reference level, but there is an environmental exposure level that has been developed based on a critical effect in an organ system, whether it be in an epidemiological or an animal study, begin to really mine those toxicological data and understand what the critical effects are.

And then couple that qualitative or semi-quantitative information with the information that's quantitatively based on the biological monitoring to establish the level of exposure, and then begin to ask the

participants about once these levels are above an exposure level of concern, do they have health concerns, comorbidities that are consistent with the toxicological literature to prioritize? If you are above a median level, a 90th percentile, 95th percentile - and these are details we're working through now - what level of concern is a concern that's perhaps not a concern for the general population, but given your comorbidities, it might be a concern for you?

And these kind of considerations are really important at the participant level and become very important in the acute response. And when conducting statewide surveillance, perhaps less necessary, if it's from a normal healthy population, but information learned through the statewide sampling also informs that kind of approach.

Generally, that's kind of what we're working through. We're about a year and a half into our funding, so --

CHAIRPERSON BRADMAN: And it sounds like that investment of toxicological analysis and communication with the individual is really within the program. And I'm curious is that -- within Biomonitoring California, our Panel has generally suggested that the Program stay away from tox interpretation just because of the potential, you

know, gnashing of teeth between different stakeholders on how to interpret it. And incorporating that potentially -- those potentially fraught issues within the Program, you know, can create challenges that should be handled more in regulatory arena. And so I'm curious, does that come up in Massachusetts or in other settings?

DR. NASCARELLA: Well, I think, you know, one of the benefits of a Biomonitoring Program in the health department in Massachusetts was we are not the environmental regulator, and it's not a regulatory action. We are really focused on providing information to the participant that either informs a public health intervention or provides them with meaningful information to seek treatment, if necessary.

So it doesn't have to be a regulatorily -- a regulatory enforcement level. It doesn't have to go through that level of scrutiny. It simply has to provide meaningful information to the individual on this is information that we recommend you talk to your physician, or usually we recommend you take this information to your physician and call this number. And we'll refer them to the PEHSU or we'll refer them to a medical toxicologist, but it's really providing them with information.

And in the background, we use the research I mentioned to really underscore how hard we sell that

message. In other words, we recognize that you have impaired biliary excretion. You've been exposed to a chemical that this is a concern for you. We strongly recommend you speak with your physician about this, if you have any of these health effects that you see on this participant outreach information.

So we're not establishing levels that have to be technically right. We're establishing levels that are informed by the toxicological information to enable the participant to have a conversation with their physician.

CHAIRPERSON BRADMAN: Thank you. That's great.

DR. NASCARELLA: You're welcome.

CHAIRPERSON BRADMAN: I'm curious, do any other states or any comments from the Panel on this issue?

MR. MIHALIC: Just real quick. In our -- this is Jason Mihalic with the Four Corners. Our states take a very different look. Utah, for example, will use the information for policy purposes. Whereas, Arizona will use the information for recommendation -- public health recommendations. So it really depends on the politics of the state as to how this information will be used.

CHAIRPERSON BRADMAN: Dr. Schwarzman, was there another comment down here too or -- okay well, I guess you're up first.

PANEL MEMBER SCHWARZMAN: Thank you. I had

follow-on question to Dr. Bradman's line of inquiry, and hearing what Massachusetts is doing with the health effects level. It sounds like you're doing an amazing amount with very -- what can be very spotty data, and difficult to sort of draw conclusions from. And I wonder how you deal with exposures to pregnant women?

DR. NASCARELLA: So thank you for the question. Marc Nascarella, Department of Public Health in Massachusetts.

The exposures pregnant women we handle them, I guess, much in the same way. Many of these -- many of these chemicals, if they have toxicological information that indicates that they are a developmental toxicant, we convey this information to them as well. We provide them with information on our participant outreach material that indicates the risk to both the mother and the developing fetus, if the data from the toxic -- the review of the toxicological database indicates that it's warranted.

And, you know, for many of these chemicals, you're right, the critical effect is -- has been developed based on an understanding of an in utero exposure.

CHAIRPERSON BRADMAN: Dr. Quintana.

PANEL MEMBER QUINTANA: Hi. This is Jenny Quintana from San Diego State University. I was -- on a different topic, I was very pleased to see New

Hampshire -- representative from New Hampshire talk about measuring cotinine in the biological fluids, because of course exposure to secondhand smoke is truly a source of metals and PAHs, and some of the many contaminants that you mentioned measuring.

So I guess I'm curious as to people who are not measuring measures of tobacco smoke, how you approach this issue? And for New Hampshire, given the rising popularity of e-cigarettes, and the fact that cotinine may also reflect exposure to nicotine in e-cigarettes have you thought about moving to NNAL or other markers as well?

MS. NASSIF: That's -- that is the question, isn't it? So, at this point, we have not thought about moving to those others simply because of a capacity issue. I think we'll start with cotinine, and as we move forward, if it appears, and the data coming out of CDC, and other states that are looking at e-cigarette information, if it appears that we should move in that direction, then maybe in subsequent years we will.

PANEL MEMBER QUINTANA: So for other states, are you considering -- how do you handle exposure to secondhand smoke, which is truly a big population source of, and can help interpret, levels of these markers in biological fluids. For metals and PAHs how do you handle that exposure?

DR. NASCARELLA: In Massachusetts, we do administer an exposure questionnaire where individuals will identify if they are a cigarette smoker above a certain level. We quantify that level.

And I agree with you that cigarette smoke is a contributor to many of the analytes we're measuring. And that's essentially how we ascertain if they are a smoker or not a smoker.

MR. MIHALIC: From the Four Corners, we did consider cotinine in our application process, but opted for the actually six analytes of interest that we felt had a bit more bearing on the Four Corner states. Not to say that secondhand smoke is unimportant. It's just that we're really looking more from the sample collection and methods utilizing urine, rather than sputum. So when we sent in our application, we opted not to include cotinine.

MR. WYATT: Shane Wyatt with Virginia. We're taking the approach, as like Massachusetts, we're discriminating between smokers and non-smokers in the exposure questionnaire.

PANEL MEMBER QUINTANA: This is just an issue where I feel that it's helpful to measure secondhand smoke exposure, as well as firsthand smoke exposure - and I'm also speaking to the State of California here - not so much to measure that exposure per se, but to help

interpret variability in the results to the participants.

MS. TOTH: Barbara Toth, New Mexico Department of Health.

I would like to add to what Jason said about our attempt to measure cotinine, but what we are doing in -- at the Four Corners Consortium states, we -- similar to Massachusetts, we are using exposure survey, which has several questions about past and current smoking exposure, and smoking habits as well as -- if the participant does not smoke or has never smoked before, if there is any other member of the family who smokes? So it would capture also second-hand smoke exposure.

CHAIRPERSON BRADMAN: Any other comments from the Panel?

Dr. Bartell.

PANEL MEMBER BARTELL: Just a brief comment. And I think you all are probably aware of this. But, you know, one concern about relying solely on the questionnaire data is particularly if you're going after high-risk populations like pregnant women, they're sort of notorious for underreporting smoking, and other things during pregnancy.

PANEL MEMBER McKONE: I have another topic.

CHAIRPERSON BRADMAN: Sure.

PANEL MEMBER McKONE: Have we finished

confounding or smoking?

CHAIRPERSON BRADMAN: I think we have. So, please.

PANEL MEMBER McKONE: Okay. So I'd like to raise another issue, which is I sort of raise this wearing a hat of like a research -- what researchers can expect, particularly researchers working on research that supports regulation the decision-making on exposures.

And, you know, the NHANES data has, over the years, been remarkable for doing a lot. But the one thing that you can't do with it -- you can do a lot of population variability, but you can't do geographical variability. And there's a very good reason for that. It's not like CDC is being unfair. I mean, CDC had a choice, and you can't include the kind of representation and probabilistic sample needed. By trying to capture that other element, it would destroy the value of the data. So I understand why it's not done. I think we all do up here.

But the question is, as we move forward and the states start doing more of their owen biomonitoring, there may be an opportunity -- and again, I'm looking at this for the future of our research -- to see more geographical variability and how that might play out.

I mean, it's a bit of a dream in some ways, but

maybe it's coming closer to something we can have, because there's been a lot of regulatory decision-making at places like EPA, but even CalEPA that require and understanding of hot spots or hot regions and you can't -- you can't use NHANES. It's a national sample. You really need something much more specific. So my question is like is that under consideration. And if so, what are the opportunities and maybe some of the timelines for bringing about the opportunity for geographical variability?

DR. MOWBRAY: So this is Amy Mowbray from CDC. I can't give you a timeline. I would say that, you know, over the course of the last several years, we've been very focused on building infrastructure for biomonitoring and the states to just establish capability.

And I mentioned earlier that we're working with the Association of Public Health Laboratories on a National Biomonitoring Network. And we had a meeting in June of stakeholders from various, you know, obviously the states, but EPA and our sister divisions within the National Center for Environmental Health that are involved in the Public Health Tracking Network as well.

And I think a lot of the discussion is focused on starting small and starting to look at harmonization at a very sort of small level, where we're talking about the laboratory functions. I think, you know, everyone sort of

felt that the comparability of laboratory data across states was going to be a very big bite for us, but we are trying to engage other partners. And I mentioned the Public Health Tracking Network about how we might be able to look at data comparability across studies that would eventually get us to that point.

So again, this is sort of a very non-committal answer, but I think we are exploring those relationships and exploring how we might be able to house some data in the future and get data that would be comparable across states, but it's very early for us in that regard.

CHAIRPERSON BRADMAN: Okay. Dr. Quintana. And when you're done, I have a question too on a new topic.

PANEL MEMBER QUINTANA: Oh, go ahead.

CHAIRPERSON BRADMAN: No, go ahead.

PANEL MEMBER QUINTANA: Actually this question is for the Four Corners representative. In your paper, you mention tribal involvement, but I don't remember you talking about that today. And, of course, when I think of the Four Corners, I think of a very large tribal population with interesting exposures to uranium and other things.

MR. MIHALIC: Absolutely. And pardon me for not mentioning that in the talk. It was rather time limited, and I beg your pardon. Tribal, it's -- we are very

interested in working with the tribes, not just the Navajo Nation, which is -- goes into three of the four states, but in Arizona there are 28 tribes. So we've actually begun outreach to that end. It's a bit more complicated, just because each tribe will have their own IRB process. And this may be a process that lasts beyond the five-year grant, quite frankly.

But one of the -- the pyrethroid project actually came about from a tribal exposure question. Indian Health Services was using -- or actually it might BIA, pardon me, is using a pyrethroid pesticide for tick abatement. And there have been complaints to our health department in Arizona with regards to the safety of that particular pesticide.

And so it's projects like that that originate in a community that we've then wrapped up into the grant, that will then allow us to go back into that community and work. And in addition, the well water study is also of huge interest with our tribes. And in addition, one of the advantages really of being a consortium in this case is to work with the Navajo Nation.

Since they do cross state borders, they tend to -- obviously, they see themselves as a whole, but the three states see the entities within their state, but we are approaching the Navajo Nation as a whole, because we

are all part of the same. And it's little factors like that that really allow us to at least gain entry. And so that's very much on our radar, absolutely.

CHAIRPERSON BRADMAN: I have a last question - we have a few more minutes - about children and sampling from children. I've noticed that both in Utah and in Colorado, there was talk about sampling down to kids as young as age three. I had a question for Michael of the FREES study. Is there any plan to look at exposures in young kids, in any of these, I think, households? It wasn't clear to me.

And then I'm curious across the board, have -- has there been attention paid to getting samples from very young children and just curious about the success or challenges with that?

DR. DiBARTOLOMEIS: So this is Michael DiBartolomeis. Let me just get the specific question out of the way. The pilot study does not involve children. If this works we may, you know, in the future expand. We're actually going to talk about that a little this afternoon about what's on the 2016 kind of agenda items. And I think children is going to come up. So with that, I'll pass it on to whoever else wants to respond.

DR. NASCARELLA: I'll say that our study design does include obtaining samples from children. We have this year responded to several acute exposure events where

we've collected samples from children.

We do have IRB approval for surveillance of -- public health surveillance. So our work is not research, so we kind of have IRB authorization to do this, clearly focused on a public health intervention or to inform our programmatic responsibilities to the state. When collecting the samples from the children, we have both a consent and an ascent procedure for children that are of a certain age. We have them go through an ascent booklet, which describes the process and what's going to happen, so they understand in an appropriate manner. It's a coloring book style what's about to happen. And we get their ascent as well as the parent's consent.

MS. NASSIF: In New Hampshire, we will collect urine specimens from children. We've decided not to collect blood specimens from children, unless it's a medically indicated test.

DR. PARSA: Currently, New Jersey don't have any plan for children's studies.

CHAIRPERSON BRADMAN: It's about 12:00 o'clock. We have two minutes. If there's any -- anyone dying to ask one more question?

Otherwise, we have statement now on the Bagley-Keene and the upcoming break.

MS. HOOVER: Yeah. Let me just -- I'm going to

hand you this little note. Two things before you do that. One is so I mentioned these program profiles, which some in the audience might not have. Those will all be posted on our website, so those will be available. And it's really fascinating to learn about what's going on across the states.

Asa is going to make a quick announcement about lunches, and then Carol will give the Bagley-Keene reminder before we break for one hour.

CHAIRPERSON BRADMAN: Thanks. So for those of you who purchased lunch boxes ahead of time, those will and be available shortly, and they're set up in Room C160. And for those of you who did not purchase lunch ahead of time, which is probably most of us, there's a cafeteria you probably saw right around the corner, and there's food available there.

We're going to take a break at 12:05. We're going to have a statement about the Bagley-Keene rules in terms of discussions while we're not in session. And importantly, we're going to start promptly at 1:05, at the end of the lunch hour. And we ask that people return here by 1:00 PM, so we can get settled in and really get started at 1:05.

CHIEF COUNSEL MONAHAN-CUMMINGS: Hi. This is Carol Monahan-Cummings. I'm sitting behind you. I'm the

Chief Counsel for the Office of Environmental Health Hazard Assessment. And I'm just here to remind you that the Panel does have some discussion items this afternoon, where you're going to be taking a vote. And so please don't discuss those with members of the public or among yourselves, unless you come back and explain what you talked about here on the record. So probably best to talk about something else. Sounds like there's plenty this morning to talk about.

So anyway. Thank you.

(Off record: 12:00 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: 1:05 PM)

CHAIRPERSON BRADMAN: We're going to get started now. I want to -- are we missing -- just one, okay.

I want to welcome everyone back from lunch and officially call the meeting back to order. And I want to introduce Sara Hoover, who is the Chief of the Safer Alternatives Assessment and Biomonitoring Section and the OEHHA lead for Biomonitoring California.

And she'll be introducing the afternoon session and the speakers, so take the floor.

MS. HOOVER: Thank you, Asa. Yeah, welcome everyone back to our afternoon session. We're really pleased to have two speakers today. Dr. Rachel Morello-Frosch and Duyen Kauffman at CDPH. And Rachel is going to talk to us about the topic you see on the screen, educating biomonitoring participants about their exposure to environmental chemicals, what does the science say?

And we've had a long-time collaboration with Rachel in these topics. We've worked for years together on this, so we're thrilled to have her come to talk to us about it.

Rachel is a professor in the Department of Environmental Science, Policy Management, and the School of Public health at UC Berkeley. Her research examines

race and class determinants of environmental health among diverse communities, with a focus on social inequity, psychosocial stress, and how these factors interact with environmental chemical exposures, and she's looked at these kinds of questions in a variety of contexts, including, for example, her work on prenatal exposures to environmental chemicals.

She's also looking at applications of non-targeted approaches for biomonitoring, and she's also analyzing the bioethical challenges of exposure assessment and chemical biomonitoring in marginalized communities and how to communicate results in ways that inform study participants about exposure sources and potential health implications. Rachel.

(Thereupon an overhead presentation was presented as follows.)

DR. MORELLO-FROSCH: Hi, everyone. It's a pleasure to be here today. As Sara said, it's been great working with the California Biomonitoring Program both on a project, which I'm going to talk about today, the MIEEP project, and then also figuring out the ethics of results communication in studies, and the best way to sort of test our materials, which I want to talk about today as well.

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DR. MORELLO-FROSCH: Okay. So today I want to

give you just a quick and dirty overview of some of the things that this Panel has talked about before in terms of scientific challenges and ethical frameworks for results communication, and then touch a little bit on some research that we've done in terms of lessons that we can learn from other fields, such as genetics research and brain neuroimaging research, and then segue into some work we have done where we have interviewed study participants in a variety of studies. I'm not going to talk about all the results here today, but just give you highlights of how participants reflect on getting their results back, and then what are some of the implications for ethical decision-making and results communication.

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DR. MORELLO-FROSCH: So, you know, we're very lucky, in that technologies for biomonitoring just keep getting better and better. We can analyze more chemicals at lower and lower levels, and -- which is great, but our technology is definitely outpacing what we know about the implications of the exposures that we find for the communities that participate in our studies.

And so this is particularly true for emerging pollutants, novel chemicals that we discover. And sometimes we often can't say anything about what it means for health. And sometimes, we can't say very much even

about how people are getting exposed. And so as one of our study participants who we interviewed who participated in a biomonitoring study has eloquently said, you know, none of these chemicals that you've told me about, you know come with a return address. In other words, that sometimes it's difficult to figure out where this stuff is coming from and what I can do about it.

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DR. MORELLO-FROSCH: But we have ethical issues in terms of reporting back. And for some chemicals it's a no-brainer for something like lead. We have guidelines and levels of concern that trigger reporting requirements. Most health departments have protocols for how to do that. And we do it because we want people to be able to take action to reduce their exposures, and so lead is a good example of that.

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DR. MORELLO-FROSCH: But a harder example are some of the emerging contaminants for which we don't have benchmarks or levels of concern, or for compounds that have been banned, okay, and yet are still very persistent in the environment and which still show up in our bodies, and/or compounds where maybe at an individual level you can do something in terms of consumption behaviors, eating organic. But other participants, for example, farmworkers

who are exposed to pesticides, you tell them about their exposures, but their ability to control conditions in their workplace to reduce those exposures is quite limited.

So the tension between right to know, your information in terms of what you're exposed to and the realities of your ability to act upon that information.

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DR. MORELLO-FROSCH: The other issue I think that emerges is scientific uncertainty when you encounter incidental findings, which often happens in biomonitoring studies. And sometimes tensions that we have in terms of individual versus community right to know, individual participation in studies which can have implications for entire communities.

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DR. MORELLO-FROSCH: So probably the poster child for that kind of individual community tension was the first study that was done on the Inuit in the circumpolar north in Canada. And the idea was to test breast milk for certain industrial compounds. And originally people thought that this community would be an ideal quote unquote control community, and that levels would be -- expected to be quite low, because they were not living in places near industrial production.

When those results came back, the levels in breast milk for things like PCBs were unbelievably high. And so initially what happened was when it came out that, you know, these surprising results, the impact on the community was problematic, because the initial community that was tested faced a fair amount of stigma. Because they were known as the PCB people, other Inuit communities didn't want to trade with them.

Eventually, it was revealed that this is -- was a ubiquitous problem within communities across the circumpolar north. But this is sort of a -- sort of cautionary tale in terms of really understanding those tensions and the broader community impacts when we're doing results communication.

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DR. MORELLO-FROSCH: So given some of the scientific challenges, as well as some of the ethical issues, our perennial challenge is what do we tell study participants about chemical exposures, both in terms of personal exposures in their homes, if we're not just biomonitoring. I know the focus here is on biomonitoring, but this can also be about personal exposure assessment, air and dust sampling in homes, for example, as well as biomonitoring.

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DR. MORELLO-FROSCH: So until recently, most people followed what we like to call a clinical ethics model, where individual level report back to participants was based on whether or not we had a clear sort of benchmark, and clear implications for health were -- could be conveyed. So this is very kind of biomedically focused, very expert driven, health professionals and scientists decide when and how to report back.

And so for -- that means that for a lot of chemicals for which we don't know the health implications, there wouldn't be any report back. And now I think more people are realizing that there are some drawbacks to this kind of clinical ethical framework for results communication.

One is that it somewhat contradicts the current trend in medicine where patients are increasingly being encouraged to be empowered and proactive in directing their health care, patients are getting the results of lots of tests in health care settings. Sometimes the implications are not always clear. The other thing is it -- by not reporting back, we're limiting participant's ability to learn from their participation in studies and also maybe depriving them of opportunities to reduce or prevent exposures.

And we also know that benchmarks change, and that

there are -- now we know that there are potential health effects below action levels. In the case of lead and mercury, we know that's definitely the case. Here's just sort of the evolving --

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DR. MORELLO-FROSCH: -- benchmarks over time. Okay. So if we sort of use that as our strict threshold opportunities for prevention are far gone, which is ethically problematic.

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DR. MORELLO-FROSCH: The other sort of project that we have written about in our work is -- and this aligns with this current trend in medicine to provide more information to patients is known as the Open Notes Project.

And this was developed by Delbanco and colleagues to really see whether or not patients could get access to doctor's notes during regular appointments and see them and what is their reaction to getting that kind of information, does it improve their understanding of those meetings, indicators of their health status, does it enhance decision-making -- shared decision-making, and empower them in terms of understanding what's going on?

There was some concern that maybe patients would be worried at seeing that kind of -- those notes. And, in

fact, the results have been that in terms of testing, that patients who had access to their doctor's notes were more likely to adhere to medical regimens. They reported feeling more informed, in control of their health care, and they didn't have a lot of privacy concerns or worry or confusion in terms of access to the notes.

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DR. MORELLO-FROSCH: Other fields are the fields of genetic research. Genetics is kind of -- is someways similar in terms of trends, technological innovations, that's going on in chemical biomonitoring. We have a lot of technological change in genomics. It's catalyzed a lot of large scale projects, and increasingly people are wanting access to their genetic information when they enter these studies.

Similarly, neuroimaging research has expanded and has crossed a lot of fields. It's not just neuroscience anymore. It's economics, psychology. There's even a field called neurolaw. So a lot of these neuroimaging studies come across incidental findings. And again, this field has struggled with the extent to which they should be reporting back this type of information to study participants when the clinical significance may not be clear.

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DR. MORELLO-FROSCH: So there's been some work done in the field of genetics research in particular, but also neuroimaging research, where they have interviewed patients who are participating in genomic studies. And there is lot of support among participants for wanting to get this information back, even if there is a pretty high level of uncertainty about the health implications.

In fact, learning their results in participating in these genetic studies is a huge motivator for them to participate in these studies in the first place and to keep them in. They want this information. It's something that keeps them connected.

The other thing is that the reporting of genetic results, contrary to what people initially thought, does not necessarily cause undue worry. So there's -- in one particular study they did a randomized psychological assessment on disclosure of a genetic allele associated with increased risks of Alzheimer's disease, and it did not increase reporting of -- that result to participants did not increase in terms -- did not lead to more anxiety and depression and worry among participants who got that information.

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DR. MORELLO-FROSCH: So there has been a consensus workshop among genetics researchers as well as

neuroimaging researchers to kind of address this question. And how do we think about this a priori before we -- when we're developing our study protocols about when and how we're going to report incidental findings or genetic information whose clinical implications are not particularly clear.

And this schematic seeks to kind of put this in sort of -- create a visual. So here we look at sort of the potential health risk of the information from low to high. Is there a clinical utility of the information, so that a condition can't be treated, or what it means is really not known to very high -- has high clinical utility.

And then looking at sort of the net benefit to the participant from low to high. And so they tried to come to some kind of consensus about when they might report in terms of participant preference at when they are enrolled in studies.

So they have decided that when all of these things are low little clinical utility net benefit and health risks are low, they would not disclose. But as you go up this chain, you would disclose even in situations where you have participants when the health risk and net benefit and clinical utility are high, even where a participant has indicated at the beginning of the study

that they are not -- they want to support science, but they don't necessarily want this information that you might actually break that.

So this effort of them to kind of struggle with this question I think is interesting for those of us who are in the field of biomonitoring. I also -- I don't have time to talk about this today, but I also -- this is also becoming, I think, increasingly relevant, because genetics is also becoming more privatized. There's a lot of direct consumer marketing for genetics. Biomonitoring less so, but there could be a situation where there is more sort of privatization and direct marketing to people who are interested in being biomonitored and getting that information.

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DR. MORELLO-FROSCH: So in terms of our work, we have been interested in whether or not, you know, people who get their results experience undue worry and harm. And in our studies, and in studies that we have looked at that were not carried out by us, in general, people overwhelmingly want their biomonitoring results, if given an opportunity to get them.

And the other thing is knowledge of chemical exposures does not necessarily lead to counterproductive behavior. So a good example of that is breast milk

studies, does telling people that there are chemicals in their breast milk change breast feeding behavior?

So I think a lot of people have assumed that it very well could. There has been one study that has looked at this, and that found that, in fact, it did not appear to change the duration of breast feeding in that population. So I think that, right now, it doesn't appear to change these kinds of behaviors that we care about.

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DR. MORELLO-FROSCH: So we are definitely in new a kind of era where before we had sort of been constrained by clinical ethics framework, and now I think a lot of biomonitoring programs and even academic studies that entail biomonitoring have moved towards right to know. California -- Biomonitoring California is clearly one of them as this is codified in the law itself.

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DR. MORELLO-FROSCH: And so now our challenge is we have to tell participants what we find, and what do they want to know?

Our experience is these are sort of the basic questions that they are interested in having us answer. Very straightforward, and as we know not necessarily always the easiest to answer. What did you find, how much, is it high, is it safe, where does it come from, and

what the heck should I do about it?

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DR. MORELLO-FROSCH: So we embarked on a study called the Personal Exposure Report-Back Ethics Study. We have been interviewing study participants from a variety of biomonitoring studies across the country. So these include more traditional academic studies, as well as, quote unquote, advocacy biomonitoring studies led by NGOs, where participants are more public about their participation in these studies.

We've also been interviewing, in addition to study participants, IRB members, and as well as researchers themselves to get their opinions on these. We've held workshops. We've done a lot of user testing of biomonitoring reports, and we're also in the process of developing a digital report-back interface known as DERBI.

And collaborators on this include Silent Spring Institute, Berkeley, Northeastern, Harvard, Commonweal, and we've gotten NIH funding to support this.

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DR. MORELLO-FROSCH: So our interviews with study participants are about an hour to an hour and a half. We analyze them for different kinds of themes in an iterative process. And we're basically just trying to get a sense of what kind of meaning they find in their results and

what is their experience.

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DR. MORELLO-FROSCH: So one of the studies where we have followed up is a collaborative biomonitoring project known as Maternal and Infant Environmental Exposure Project, which we undertook with the Biomonitoring Program as well as UCSF. It was also known as Chemicals in Our Bodies. It's a little more clearer for the study participants. We sort of changed the name when we were consenting them in the study.

So this was a project where we recruited around 90 pregnant women who were getting prenatal care at San Francisco General. We measured chemicals in the mothers and their babies at delivery. And most of them are predominantly Spanish speaking. They were also English speaking.

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DR. MORELLO-FROSCH: And we analyzed them for chemicals in maternal and cord blood. And we also -- we -- they -- the participants got their results back. And I'll tell you the process by which we did that, but I want to give you a sense of sort of what they -- what their reactions were to getting the results.

We went back after participants got their results, and interviewed them. And these are the kinds of

things that people learned, and both in Chemicals in Our Bodies but also in the other studies in which we interviewed study participants.

People learned that there are a lot of chemicals in their bodies. And many of them -- actually, people, for example, who are very self-aware sometimes go into these studies assuming that you're not going to find much, and they're kind of shocked when you do, so people who eat organically, these kinds of things.

The other thing that's surprising to them is that we find chemicals that have been banned for decades that are still in their bodies. That the stuff comes from a variety of sources, and they're very -- they want to know where they stand. They want some kind of point of reference, like where did I come out compared to other study participants, where am I compared to the average, and even better, if there were a health guideline, but usually there isn't.

And the other thing that's a huge eye-opener for many participants is for them chemicals are something that you are exposed to from out there, a large facility, a roadway. And many of them realize that a lot of their exposures come from household products, things that they use every day, which is a huge eye-opener for them.

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DR. MORELLO-FROSCH: Participants go into these studies, in part because they are motivated to help the science, to advance scientific knowledge. That is a huge, huge motivator for them to get involved in these kinds of things in the first place, what we call research altruism. The other thing is upon getting these results, you know, pollution becomes personal. It makes them think, how am I getting exposed, how does this affect my health, how might this affect my family, what are the health implications?

And the other thing is how come there isn't more regulation and health information on these chemicals? That sparks that kind of conversation, and a sense of what we start to call toxic trespass. Despite some of their best efforts, you know, they're still exposed.

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DR. MORELLO-FROSCH: So some of the reflections are frustration at information gaps, really trying to understand how they might reduce exposures. So here's a quote from a study participant. This is not in Chemicals in our Bodies, but in terms of what they want. And so what -- what I would want from this study is give me something I can do about it. Don't just give me information that tells me I have problems, because that's frustrating.

But I'm proactive enough to say, okay, I have

this information, and now it's up to me to do something. So a lot of motivation to try and reduce exposures.

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DR. MORELLO-FROSCH: Different reactions to receiving results. Some people are really surprised, okay? So people say I don't have any strong chemicals in my home, I don't have anything out of the ordinary that some other person wouldn't have. So what did I do to get such harmful things in my body, and more than anything what can I do to eliminate them?

But then you have other participants, this one -- these are from Chemicals in Our Bodies, who say, "I know the world we live in". In other words, they're not surprised. They fully expected us to find something.

And then others who expected it because of the nature of the work that they do, and they assume that they're probably going to have high levels or levels of something.

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DR. MORELLO-FROSCH: The other issue is definitely trying to understand and distinguish between individual and community action, and sort of realizing that maybe government isn't doing as much for them as they could. So one participant says, "I'd like to see an increase in a factor of about 100 in the governance

interference in the manufacturing process. We are at an absolute low point in governmental regulation. We are so far from what the government should be doing".

"Well, it was useful that it doesn't matter how cautious you are, because you are always exposed to all kinds of chemicals, also, one is more aware of what one can do and the precautions one should take".

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DR. MORELLO-FROSCH: So we interviewed researchers as well. And researchers are finding that this report-back process is useful to them. It's an opportunity to just -- for discovery. When you talk to participants about what you find, you start having conversations about potential sources. Some participants even say that you can actually learn a lot from an N of 1, when you have, for example, anomalous results. And you go back and you talk to that participant about what's going on, you might discover new sources of chemical exposure.

The other thing is there's always a temptation among researchers to reassure participants, you know, when you're reporting that you find chemicals in their bodies. So a lot of statements of, "...there's no evidence that...", outdated EPA guidelines. Sometimes they realize that when they say, "...there's no evidence that...", it doesn't mean that studies found negative results. It's

just that there isn't any data.

So -- and still some people struggle. It's like is reporting this information really helpful? Are we causing people undue worry? On the other hand, people have a right to know. That sort of tension, I think, researchers still struggle with that.

And then just help them rethink this -- the ideas about health literacy and giving participants agency, and sort of democratizing and helping them understand the scientific process and all of its challenges.

So one researcher participant said to us, "When science is uncertain, the goal is not a public health message to tell people what to do, but stimulate a conversation having. Heaven knows, we need to find a way to talk about health policy above the first grade level".

So sort of getting beyond sort of traditional public health messages and really just helping people understand the nature of environmental health and chemicals and what are some of the broader implications of these exposures.

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DR. MORELLO-FROSCH: So in terms of recommendations, in materials just really thinking about the cultural context in which you're doing report back, and really understanding the difference between cultural

competency versus literacy. We really promote engaging different learning styles and visual styles. Some people are text people, some people are graph people. And some of the challenges are just, you know, we don't have benchmarks, so how do we do our best job in terms of contextualizing these results. And then the challenge of, you know, the time gap between when we take samples and when we return results to participants is -- still can be really long. So when you come back to participants, they've almost forgotten about you --

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DR. MORELLO-FROSCH: -- or sometimes they wondered where the heck you'd been for all that time.

And I think the other strong issue I want to emphasize is that we want to address opportunities for individual versus collective action. I think often we focus on individual action. And I think we want to lift up opportunities for participants to engage in collective action.

So, you know, participants says, "At first, I was thinking, 'God, I wish I didn't know all this', but the more I think about it, the more I understand it, the more I feel like it helps me to do whatever I can...if you know the information then you can't not participate in trying to make change".

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DR. MORELLO-FROSCH: So really thinking about when we're reporting back helping participants distinguish between exposures which might be more conducive to individual action, like eating organic, or changing your purchasing behaviors. And then there's just some exposures that individuals can't -- don't have any control over. And I think it's important for us to be transparent about that. And that requires more fundamental policy change

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DR. MORELLO-FROSCH: So here's an example. You know, pesticides -- you know, individual action can really go a long way. Organic, you know, the research really is pretty compelling on that, at least in terms on the consumer exposure side.

Flame retardants, less so, okay. People's ability to control their exposures to those things are much more limited.

So the last thing I want to cover here is that participants can really help us think about results communication protocols and how we can develop these in ways that are helpful to them. And so where -- you know, it was great when we did the MIEEP study with Biomonitoring California, because we had the opportunity

to actually trial run materials before we actually did report back, which was just phenomenal.

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DR. MORELLO-FROSCH: So we did what's called usability testing in our Chemicals in Our Bodies participants, where we showed them prototype materials and before -- you know, before report back happened and asked them, you know, what do you think? We want you to pretend that these materials are your data go through this and tell us what you think, and what's good about it, and what's terrible, and how can we make it better?

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DR. MORELLO-FROSCH: So just to give you an example of how participants can really help you make things better, this is the prototype that we started out with in terms of summary materials. And this is what we showed participants. So lots of texts going in all kinds of directions. And after usability testing, several iterations of usability testing, this is what the text ended up looking like, okay?

So it became -- it was initially crammed on -- all on one page, and then we ended up with a lot more space and spread out over two pages.

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DR. MORELLO-FROSCH: They also gave us feedback

on our graphs, and graphs are an interesting issue. Some people love them, some people don't. And here, it worked pretty well with this population, but they gave us some nice feedback on changing the legend. This blank, they didn't quite know what it mean. So other sort of tweaks to make that more understandable, helped us improve the legend, and make clear when levels were below the detection limit.

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DR. MORELLO-FROSCH: So again, I think usability testing when you engage study participants before you report back, you can really sort of have a great opportunity to make sure your protocols are resonating with them. These are some of their reactions when we -- when they were reviewing the prototypes, which I think was really helpful and made us feel like, okay, this -- we're doing the right thing here in terms of which messages are resonating. And then also getting feedback on which ones maybe not so much.

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DR. MORELLO-FROSCH: So I just wanted to leave you with some materials. We -- as a result of a lot of our work, we have created a report-back handbook called, "When Pollution is Personal". It's available for free on Silent Spring Institute's website. We've also published a

lot on this topic.

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DR. MORELLO-FROSCH: And we are developing a digital exposure report-back interface, which hopefully will make report back less cumbersome and more nimble depending on the study population that you're working with. The beauty of this is that it's geared towards people who are more digitally inclined, but you can also still continue to give people paper for those participants who are not, you know, computer savvy.

And this is now being used in several different studies currently. We're currently in the process of doing focus groups and testing it for a study that we're doing on -- with firefighters in the City of San Francisco.

And it has also a lot of really nice features for researchers themselves in terms of understanding what the data says in different kinds of groupings. And the other beauty of this is that you can collect analytics when people are opening up their results. You can get -- you can see what the mouse clicks are, where people -- which pages people are hanging out on, all kinds of things. So it can give you information that you might not otherwise be getting by just using paper.

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DR. MORELLO-FROSCH: So I just want to conclude here by saying that -- make a real plug for, you know, these biomonitoring projects and engaging study participants in results communication itself in the development of protocols. I think it's a huge opportunity to promote the program, to enhance environmental health literacy and to make sure that results communication and report back is useful to participants and to help them distinguish between the things that they have control over as individuals and the things that they may not.

And when you can engage them in that process, you can take into account what their expectations are from studies before you, you know, report back to them.

And I think the other thing that I have learned in my work doing biomonitoring studies is that results communication protocols are always in beta mode. You're just always making them better. You're always tweaking them. And you're always going to be changing them, depending on the community or the types of participants that you are collaborating with or engaging and enrolling in your studies.

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DR. MORELLO-FROSCH: So I just want to thank colleagues both here at Biomonitoring California that has enabled a lot of this work, as well as my other colleagues

and our funders.

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DR. MORELLO-FROSCH: And we have a lot of papers. I'm happy to make them available to you electronically.

And thanks so much.

(Applause.)

CHAIRPERSON BRADMAN: Thank you. We have about -- a few minutes scheduled right -- yeah, 10 minutes scheduled right now for just clarifying questions and then we'll go into our next topic. I want to emphasize that we have after the next talk, we have a lot of time scheduled to discuss this issue in depth. So let's just limit questions right now to clarifying questions, but we'll have a lot more time for discussion.

Any questions -- and that includes the audience, not just the Panel?

It looks like we have one question. Dr. Quintana.

PANEL MEMBER QUINTANA: Hi. Jenny Quintana, San Diego State University. One of your slides you had divided environmental exposures into things that were under their personal control and things that weren't, such as flame retardants versus consumer products, but I was curious how you -- if you had thought about including diet more explicitly, not just organic versus non-organic, but

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 3rd day of December, 2015.

JAMES F. PETERS, CSR
Certified Shorthand Reporter
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