

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  
CERTIFIED SHORTHAND REPORTER  
LICENSE NUMBER 10063

A P P E A R A N C E S

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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.

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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

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

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

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

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

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

20 ACTING DIRECTOR ZEISE: Thank you, Laurel.

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

1 your participation in this important meeting.

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

7           So we're starting this meeting with a tribute to  
8 Dr. Julia Quint, who served this Panel with distinction.  
9 We were very sorry to hear the news that Julia passed away  
10 this weekend. Julia served on the SGP I think since  
11 1980 -- sorry since 2008. And also it was exactly one  
12 year ago today that we received a note from Julia that she  
13 was resigning from this Panel.

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



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

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

6           Barbara.

7           DR. MATERNA: Thanks, Lauren.

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

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

20           She had the perfect combination of being both an  
21 exacting scientist and a passionate advocate. She would  
22 not be deterred when industry groups sent in their  
23 toxicologists to oppose her arguments for a health  
24 protective Cal/OSHA standard for chemicals like  
25 1-bromopropane or n-methylpyrrolidone. She had the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21           Thank you.

22           ACTING DIRECTOR ZEISE: Thanks, Barbara and Gina.

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

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

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

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

20           So more information on the July meeting is  
21 available on our Biomonitoring website at  
22 [www.biomonitoring.ca.gov](http://www.biomonitoring.ca.gov).

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

25           CHAIRPERSON BRADMAN: Thank you. Before we

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

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

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

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

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

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

9           Amy, identify yourself.

10           Members of the public who are not at the meeting  
11 can send an email to [biomonitoring@oehha.ca.gov](mailto:biomonitoring@oehha.ca.gov). Emailed  
12 comments relevant to the topic under discussion will be  
13 read allowed during the meeting. Public comments will be  
14 subject to time limits and the time allotted will be  
15 divided equally among all the individuals wishing to speak  
16 on that item.

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

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



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

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

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

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

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

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

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

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

15                           --o0o--

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

22                           --o0o--

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

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

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

14 --o0o--

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

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

25 --o0o--

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

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

12 --o0o--

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

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

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

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

10 And so as a part of the funding process, we had  
11 20 applicants that actually represented a total of 27  
12 states that provided applications for this funding, and  
13 they were evaluated by a review panel.

14 --o0o--

15 DR. MOWBRAY: We were grateful to select six  
16 awardees to receive funding for five years at a total of  
17 \$5 million, and you can see those states here. And we are  
18 very excited. We've been working with the states for over  
19 a year now on their projects, and I am going to turn it  
20 over to them to talk more specifically about what their  
21 goals are for their individual projects.

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

1 Biomonitoring California.

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

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

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

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

25 --o0o--

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

7 --o0o--

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

14 --o0o--

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

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

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

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

9 --o0o--

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

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



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

7 --o0o--

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

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

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

25 And we are concentrating on flame retardants.

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

3 --o0o--

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

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

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

22 --o0o--

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

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

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

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

19                               --o0o--

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

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

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

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

14                           --o0o--

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

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

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

11                           --o0o--

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

16                           (Laughter.)

17           DR. DiBARTOLOMEIS: So thank you very much.

18                           (Applause.)

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

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

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

5           So here's Marc.

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

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

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

18                           --o0o--

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

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

8 --o0o--

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

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

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

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

5 --o0o--

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

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

25 We've established and convened an advisory panel.



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

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

12 --o0o--

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

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

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

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

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

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

23                           --o0o--

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

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

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

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

21 --o0o--

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

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

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

12 --o0o--

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

21 (Applause.)

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

1 New Jersey Biomonitoring Program.

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

4 DR. PARSA: Thank you very much.

5 --o0o--

6 DR. PARSA: Good morning.

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

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

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

25 The goal five is the increased collaboration and

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

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

7 --o0o--

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

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

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

23 --o0o--

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

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

13 --o0o--

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

20 --o0o--

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

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

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

13                           --o0o--

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

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

20                           --o0o--

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



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

5                           --o0o--

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

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

18           Thank you very much.

19           (Applause.)

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

24           (Laughter.)

25           DR. MOWBRAY: Jason Mihalic is the Chemistry

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

3 So welcome.

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

6 MR. MIHALIC: Thank you.

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

12 --o0o--

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

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

1 and mining.

2 --o0o--

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

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

15 --o0o--

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

25 --o0o--

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

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

19 --o0o--

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

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

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

11 --o0o--

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

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

23 --o0o--

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

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

3 (Laughter.)

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

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

15 --o0o--

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

22 --o0o--

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

25 (Applause.)

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

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

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

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

15 Okay.

16 --o0o--

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

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

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

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

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

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



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

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

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

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

25                           --o0o--

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

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

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

20 --o0o--

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



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

12 --o0o--

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

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

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

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

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

14 --o0o--

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

17 Thank you.

18 (Applause.)

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

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

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

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

8                               --o0o--

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

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

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

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

6 --o0o--

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

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

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

23 --o0o--

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

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

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

13 --o0o--

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

25 A state employee complex. Our laboratory is





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

5 --o0o--

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

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

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

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

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

5 (Applause.)

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

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

18 CHAIRPERSON BRADMAN: Yeah. Okay. Thank you.

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

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

1 Tom.

2 PANEL MEMBER MCKONE: Tom McKone, University of  
3 California.

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

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

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

18 PANEL MEMBER MCKONE: I've got remember to be on  
19 the mic.

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

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

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

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

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

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

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

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

4           Go ahead. Jenny.

5           PANEL MEMBER QUINTANA: Is this on?

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

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

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

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

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

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

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

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

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

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

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

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



1 their analysis.

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

11           CHAIRPERSON BRADMAN: Right. Okay.

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

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

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

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

3 CHAIRPERSON BRADMAN: Thank you. I think given.

4 PANEL MEMBER BARTELL: Asa one more question.

5 CHAIRPERSON BRADMAN: I'm sorry one more comment.

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

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

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

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

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

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

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

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

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

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

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

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

6 Okay. Take it away.

7 CHAIRPERSON BRADMAN: All right. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

16 PANEL MEMBER BARTELL: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

25           PANEL MEMBER SCHWARZMAN: Thank you all for that

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

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

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

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

1 doing the targeted communities, you know, the PFC.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11           CHAIRPERSON BRADMAN: Thank you. That's great.

12           DR. NASCARELLA: You're welcome.

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

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

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

25           PANEL MEMBER SCHWARZMAN: Thank you. I had



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

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

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

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

22 CHAIRPERSON BRADMAN: Dr. Quintana.

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

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

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

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

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

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

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

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

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

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

1 interpret variability in the results to the participants.

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

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

13 CHAIRPERSON BRADMAN: Any other comments from the  
14 Panel?

15 Dr. Bartell.

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

23 PANEL MEMBER MCKONE: I have another topic.

24 CHAIRPERSON BRADMAN: Sure.

25 PANEL MEMBER MCKONE: Have we finished

1 confounding or smoking?

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

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

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

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

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

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

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

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

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

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

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

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

14 PANEL MEMBER QUINTANA: Oh, go ahead.

15 CHAIRPERSON BRADMAN: No, go ahead.

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

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

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

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

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

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



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

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

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

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

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

1 we've collected samples from children.

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

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

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

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

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

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

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

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

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

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

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

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

10 So anyway. Thank you.

11 (Off record: 12:00 PM)

12 (Thereupon a lunch break was taken.)

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

2                   (On record: 1:05 PM)

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

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

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

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

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

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



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

14 --o0o--

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

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

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

8 --o0o--

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

17 --o0o--

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



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

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

8                               --o0o--

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

16                               --o0o--

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



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

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

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

25 And we also know that benchmarks change, and that

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

5 --o0o--

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

10 --o0o--

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

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

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

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

7 --o0o--

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

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

25 --o0o--

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

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

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

23 --o0o--

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

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

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

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

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





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

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

9 --o0o--

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

17 --o0o--

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

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

1 what the heck should I do about it?

2 --o0o--

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

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

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

20 --o0o--

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

1 what is their experience.

2 --o0o--

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

11 So this was a project where we recruited around  
12 90 pregnant women who were getting prenatal care at San  
13 Francisco General. We measured chemicals in the mothers  
14 and their babies at delivery. And most of them are  
15 predominantly Spanish speaking. They were also English  
16 speaking.

17 --o0o--

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

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



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

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

15 --o0o--

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

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

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

3 --o0o--

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

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

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

19 --o0o--

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

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

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

8 --o0o--

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

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





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

11 --o0o--

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

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

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

1                   --o0o--

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

11                   --o0o--

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

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

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

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

3 --o0o--

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

12 --o0o--

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

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

24 --o0o--

25 DR. MORELLO-FROSCH: They also gave us feedback

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

9 --o0o--

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

20 --o0o--

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

1 lot on this topic.

2 --o0o--

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

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

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

25 --o0o--

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

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

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

22 --o0o--

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

1 and our funders.

2 --o0o--

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

5 And thanks so much.

6 (Applause.)

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

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

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

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





















































































































































































































































## 1 C E R T I F I C A T E O F R E P O R T E R

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

4 That I am a disinterested person herein; that the  
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6 Biomonitoring Program Scientific Guidance Panel meeting  
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11 I further certify that I am not of counsel or  
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13 way interested in the outcome of said meeting.

14 IN WITNESS WHEREOF, I have hereunto set my hand  
15 this 3rd day of December, 2015.

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