MEETING

STATE OF CALIFORNIA

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

ENVIRONMENTAL CONTAMINANT BIOMONITORING PROGRAM

SCIENTIFIC GUIDANCE PANEL

ELIHU HARRIS STATE OFFICE BUILDING

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AUDITORIUM

OAKLAND, CALIFORNIA

WEDNESDAY, JULY 29, 2009

8:33 A.M.

JAMES F. PETERS, CSR, RPR
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APPEARANCES

PANEL MEMBERS

Dr. Edward Moreno, Chairperson

Dr. Asa Bradman

Dr. Dwight Culver

Dr. Marion Kavanaugh-Lynch

Dr. Ulricke Luderer

Dr. Thomas McKone

Dr. Julia Quint

Dr. Gina Solomon

Dr. Michael P. Wilson

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

Mr. Allan Hirsch, Chief Deputy Director

Dr. George Alexeeff, Deputy Director, Scientific Affairs

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

Ms. Fran Kammerer, Staff Counsel

Dr. Rachel Roisman, Public Health Medical Officer, Safer Alternatives Assessment and Biomonitoring Section

APPEARANCES CONTINUED

DEPARTMENT OF PUBLIC HEALTH

Ms. Lori Copan

Dr. Rupali Das, Chief, Exposure Assessment Section, Environmental Health Investigations Branch

Ms. Diana Lee, Research Scientist

Dr. Sandy McNeel

Dr. Jianwen She, Chief, Biochemistry Section

DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Dr. Myrto Petreas, Chief, Environmental Chemistry Branch

ALSO PRESENT

Mr. Davis Baltz, Commonweal

Ms. Holly Brown-Williams, University of California, Berkeley

Mr. Trudy Fisher

Mr. Tom Jacob, DuPont

Dr. Rachel Morello-Frosch, University of California, Berkeley

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1 PROCEEDINGS

2 CHAIRPERSON MORENO: Good morning. Welcome back
3 a second day of the Biomonitoring Guidance Panel meeting.
4 All right. Good morning. I'd like to call the
5 meeting back to order, and welcome the public back, and
6 all our Panel members.
7 Let's go through some meeting logistics. The
8 restrooms are, if you exit this side of the dais here and
9 ahead to your right the restrooms are there. As far as
10 emergency, there's exits in the rear of the auditorium and
11 again to the side of the dais. And if you need to find
12 your way to security and exit past security.
13 This meeting is being audiocast. So everyone who
14 is speaking Panel members, Program staff and general
15 public, please speak clearly, speak up into the
16 microphone. The recommendation is that for the panel
17 members, please speak about an inch away from the
18 microphone. And I think if you're speaking at the podium
19 about three or four inches away will be fine. So that
20 will help the transcription as well.
21 We've also been alerted that the cell phones, I
22 believe, when they're synchronizing, updating Emails, or
23 when calls are coming in, it interferes with the equipment
24 here. So if you can turn off your phones, please turn
25 them off, at least set them on silent or vibrate.

1 When you speak today, please state your name, so
2 our transcriber can record that. And so people -- and
3 also people listening on the audiocast will know who's
4 speaking. And that's it.
5 So for today, for our Panel meeting today, the
6 goals are to listen to several presentations by Program
7 staff and also some of our panel members on issues that
8 are related to results communication in biomonitoring
9 studies.
10 We will then provide feedback on Program
11 planning, in particular again, result communication. Each
12 presentation will be followed by a brief opportunity for
13 panel members to ask questions of the presenters.
14 And at the conclusion of all the presentations,
15 which will be about 11:50 today, the general public will
16 have an opportunity for comment.
17 Following that, the Panel will have further
18 discussion. And at that time, we will be -- there will be
19 opportunity for the Panel to make recommendations to
20 Program staff.
21 In terms of handling public comment, similar to
22 the yesterday, if anyone in the public would like to
23 provide comments today, we're requesting that you fill out
24 one of the pink requests sheets and bring it up to the
25 front. And during the public comment, if necessary, or as

1 necessary, we will take the allotted time and divide it by
2 the number of people who wish to speak.
3 And also for people if you're listening on the
4 audiocast, you can submit comments that we will read
5 allowed. And the Panel and the staff will address the
6 comments. If you send them to biomonitoring@oehha.ca.gov.
7 And you need to send those in during this meeting.
8 And as a reminder, please keep the comments
9 focused to the agenda items that are being presented
10 today. The materials for the meeting are provided in the
11 meeting binder and is on CD for Panel members. And
12 they're also available as handouts. And we also have them
13 in a binder. Again, they're at the entrance to the
14 auditorium, for anyone here in the auditorium who wishes
15 to look at the handouts.
16 We're going to take one break today, mid-morning
17 and that's it. So with that, I'd like to introduce Diana
18 Lee who will begin the presentations.
19 (Thereupon an overhead presentation was
20 Presented as follows.)
21 MS. LEE: Good morning. At the last Scientific
22 Guidance Panel meeting in March, we shared some
23 preliminary information about work we are carrying out
24 related to results communication. The Panel indicated, at
25 that time, support for the Program's efforts to report

1 results to individuals, to larger communities from which
2 these participants come and to the medical community.
3 Panel members also indicated an interest in
4 reviewing and providing input on draft materials that
5 would be used for results communications once they became
6 available.
7 The Program staff are taking definitive steps to
8 further our work in this area. And prior to actually
9 developing any materials, we welcome the opportunity to
10 have some overarching discussion about results
11 communication and related issues.
12 --o0o--
13 MS. LEE: Thus, just as a reminder, the enabling
14 legislation in Senate Bill 1379 provides this language,
15 "That participants shall be provided with information and
16 fact sheets about the Program's activities and its
17 findings. That individual participants may request and
18 receive their complete results. Any results provided to
19 participants shall be subject to institutional review for
20 protocols and guidelines. And when either physiological
21 or chemical data obtained from a participant indicates a
22 significant known health risk, the Program staff
23 experienced in communicating biomonitoring results shall
24 consult with the individual and recommend follow-up steps
25 as appropriate."

1 So these are the guiding issues in the
2 legislation that the staff are working to implement. We
3 are also guided, as indicated in the third slide --
4 --o0o--
5 MS. LEE: -- that the National Research Council
6 made some recommendations in their publication entitled
7 "Human Biomonitoring for Environmental Chemicals." And
8 this was published in 2006, copies of which were provided
9 to the Panel members. And the full NRC report is also
10 available on line as well.
11 In that publication, I believe it's Chapter 6,
12 they made -- or these statements actually come from the
13 exec summary, the ones here on this slide. The first one
14 being, "Communicating biomonitoring results may be the
15 most vexing challenge to the field of biomonitoring." And
16 we understand certainly and appreciate that there are
17 challenges to this task. However, we see this also as
18 great opportunities, given that both other states, as well
19 as the national biomonitoring programs are also looking to
20 California to help set some guidelines in this area.
21 Certainly, the second statement, "There is no one
22 recipe for good biomonitoring communication...", we all
23 fully support.
24 And the third bullet is most appropriate in that
25 we totally believe that, "To achieve proper communication

1 requires explicit funding, early planning, and empirical
2 evaluation of communication methods and messages." And
3 this is where our work is now focused.
4 --o0o--
5 MS. LEE: So our Program's desired outcome
6 ultimately is to develop a best practices framework. And
7 this most likely will consist of a spectrum or continuum
8 of recommended approaches, activities, and materials. The
9 considerations for this spectrum must take into account
10 the overarching goals of a particular study or question,
11 the population to be sampled, the biomarkers selected,
12 certainly the exposures of concern, and the available
13 resources.
14 --o0o--
15 MS. LEE: So this morning's presentation will
16 provide an overview of a background in issues related to
17 reporting of biomonitoring information to participants
18 and/or communities. We will describe what CECBP is doing
19 to develop a best practices framework through the
20 activities described by the speakers in this panel.
21 And we will also talk about some of the materials
22 being developed for these specific projects. We will be
23 bringing in the views of others involved and experienced
24 in these issues as exemplified by our speakers. And we
25 will solicit discussion and recommendations from the Panel

1 and ultimately the public.

2 We view this as the first of several sessions on

3 this topic. And we look forward to continuing the

4 dialogue at future panel meetings.

5 So without much further ado, as indicated in your

6 agenda, we will have five speakers.

7 --o0o--

8 MS. LEE: The format for this is that we will

9 have 20 minute presentations by the speakers, followed by

10 roughly five minutes allotted for clarifying questions

11 from the Panel.

12 We will take a short break after the fourth

13 presentation and then we will return for the final

14 presentation.

15 After that, there will be some questions

16 presented to the Panel and the public to help guide the

17 discussion. And forthcoming then will be the

18 opportunities for both Panel discussion, as well as public

19 comment.

20 At this time, I'd like to introduce all the

21 speakers at one time, so that we can move quickly through

22 the presentations.

23 Our first speaker will be Dr. Rachel

24 Morello-Frosch. She will be providing a background to the

25 overall topic of results communication and related issues.

1 Dr. Morello-Frosch is an Associate Professor at the
2 University of California, School of Public Health in the
3 Department of Environmental Science, Policy, and
4 Management.
5 Prior to coming to Berkeley, she was at Brown
6 University, and she continues research collaborations with
7 staff at Brown and also at Silent Spring Institute. Her
8 recent publications, one of which was provided to the
9 Panel in your binder, highlights the work that she is
10 doing with report-back issues for both biomonitoring and
11 environmental sampling studies with communities. Dr.
12 Morello-Frosch also serves on the Technical Advisory Group
13 for the California Environmental Health Tracking Program.
14 She will be followed by Holly Brown-Williams, who
15 will speak about integrating health literacy best
16 practices and biomonitoring results communication.
17 Holly is Director of Policy at Health Research
18 Action within the UC Berkeley School of Public Health.
19 She directs major center initiatives and oversees the
20 dissemination of policy recommendations within Health
21 Research Action's periodical, Perspectives, as well as
22 other publications. She's well known to many of us within
23 the California Department of Public Health. She currently
24 serves on the Advisory Board also for the California
25 Environmental Health Tracking Program. And prior to that,

1 when Holly was with UC's California Policy Research
2 Center, she also helped develop a report from a
3 Legislatively established expert working group - some of
4 the panel members were actually involved in that working
5 group - that was entitled Strategies for Establishing an
6 Environmental Health Surveillance System in California.
7 This report included a recommendation for a
8 statewide biomonitoring program. Holly has also
9 co-authored several issues of Perspectives, where she's
10 stressed the importance of engaging communities in
11 environmental health surveillance efforts. With support
12 from the California Department of Public Health,
13 Occupational Health Branch, she recently co-authored an
14 issue on reducing led exposures in the workplace. She's
15 also currently co-authoring an issue on the need to
16 involve public health professionals in chemical policy
17 reform efforts.
18 Holly will be followed by Lori Copan, who will be
19 providing a description of two biomonitoring projects
20 client under way as part of the California Environmental
21 Health Tracking Program. Lori is a research scientist
22 within the Environmental Health Investigations Branch,
23 currently working on chemical emergency preparedness
24 issues, environmental health tracking, and biomonitoring.
25 She coordinated the development of a statewide

1 biomonitoring program for the Department and the labs in
2 2003. And recently served as project coordinator for a
3 mercury biomonitoring project involving pregnant women in
4 2007, and for a children's asthma study conducted in
5 Imperial county in 2006.
6 Through these and other projects, Lori integrates
7 a participatory and capacity building approach to
8 involving communities in scientific research studies of
9 environmental health hazards.
10 Lori will then be followed by Dr. Asa Bradman,
11 aka. Dr. CHAMACOS.
12 (Laughter.)
13 MS. LEE: And Dr. Bradman, as you know, is a
14 Guidance Panel member. But in his other life, he is an
15 associate director for the Center for Children's
16 Environmental Health Research at the School of Public
17 Health, at UC Berkeley, and is a co-principal investigator
18 along with the other Dr. CHAMACOS, Dr. Brenda Eskenazi, of
19 the Center for Health Assessment of Mothers and Children
20 of Salinas, hence CHAMACOS.
21 We will take a very short break after Dr.
22 Bradman's presentation to be followed by the last
23 presentation by Dr. Julia Quint, also a Panel member, who
24 will be addressing biomonitoring issues within
25 occupational settings. Dr. Quint is retired from the

1 California Department of Public Health, where she was a
2 research scientist and served as the Chief of the Hazard
3 Evaluation System and Information Service, acronym HESIS,
4 and occupational health program for many years.
5 Dr. Quint has extensive experience in evaluating
6 the hazards of workplace chemicals and in communicating
7 health effects of chemicals to workers, employers, health
8 care providers, and others.
9 Post-retirement, in addition to serving on the
10 Scientific Guidance Panel, she's a member of the
11 Department of Toxic Substances Control Green Ribbon
12 Science Panel, and also CalOSHA's Health Expert Advisory
13 Committee that recommends protective exposure limits for
14 chemicals.
15 So I'd like to welcome our first speaker, Dr.
16 Rachel Morello-Frosch.
17 (Thereupon an overhead presentation was
18 Presented as follows.)
19 DR. MORELLO-FROSCH: Good morning, everyone.
20 Today, I want to give you some background information in
21 terms of things that we might want to be thinking about as
22 we deliberate strategies for reporting back results in the
23 aggregate and to individual study participants, based on
24 some of our experience in doing research in diverse
25 communities, both personal exposures assessment in homes

1 and biomonitoring.

2 --o0o--

3 DR. MORELLO-FROSCH: So I'm going to start out

4 talking about some of the scientific challenges that we're

5 faced with in results communication and then some

6 suggested frameworks for addressing those issues,

7 including clinical ethics and community-based

8 participatory research strategies, and draw a little bit

9 from our experience in household exposure studies in Cape

10 Cod, Massachusetts and northern California.

11 And in addition, interviews of scientists as well

12 as study participants who have been in biomonitoring and

13 household exposure studies, as well as members of

14 different IRB staff and some of our research, and then

15 talk about what the implications are more broadly for

16 future work in this area.

17 --o0o--

18 DR. MORELLO-FROSCH: So some of the scientific

19 challenges in a nutshell, and this is by no means an

20 exhaustive list, related to personal exposure assessment,

21 is that we're trying to move away from chemical by

22 chemical analysis. And so we have definitely made big

23 strides in that direction, in that we're assessing

24 pollution exposures from multiple pollutants, both ones

25 that we know fairly well, such as lead and mercury. And

1 then also what we tend to call emerging contaminants,
2 things that are appearing in people's intimate
3 environments and homes and in their bodies that are
4 appearing unexpectedly from sources that we're not quite
5 sure and pathways that we're not quite clear on
6 scientifically.
7 And yet we're addressing also issues related to
8 data gaps, in that until recently the assumption was that,
9 no data, there was probably no problem. And the emergence
10 of a lot of personal exposures assessment work over the
11 last decade or so is indicating that exposures are more
12 ubiquitous than we might think. And we're also -- the
13 technology is getting better and so we're able to detect
14 levels at lower and lower levels.
15 And so this suggests both a challenge and an
16 opportunity, in that we can perhaps move towards exposure
17 reduction, even when health implications may remain
18 unclear if the sources are known. And this is
19 particularly important for many of the communities that I
20 work with, that are both highly vulnerable and highly
21 impacted by multiple sources of pollutants, both from
22 stationary and mobile sources and also from within their
23 homes.
24 --o0o--
25 DR. MORELLO-FROSCH: So the history of

1 biomonitoring and household exposure studies, this has
2 been going on for quite some time. It's not necessarily
3 new. It's been critical to health surveillance, including
4 lead testing of workers, and programs to test children to
5 asses exposure from lead paint in homes, and also to
6 assess whether or not interventions are working. So a lot
7 of the work that's going on, the tracking of cotinine to
8 assess exposure to environmental tobacco smoke, mercury,
9 and lead has shown that many of the public health
10 interventions are, in fact, quite successful. So here is
11 an example.
12 --o0o--
13 DR. MORELLO-FROSCH: This chart on the Y axis
14 shows the proportion of women of child-bearing age. And
15 on the X axis it shows the concentration of mercury in
16 blood in parts per billion. And it compares it to EPA's
17 reference dose. And so it gives you a sense that about 12
18 percent of women that were tested have mercury levels that
19 exceed EPA's reference dose.
20 So it gives you a sense of how we're doing and
21 maybe where we are -- how much more we need to go.
22 --o0o--
23 DR. MORELLO-FROSCH: The other useful -- for
24 surveillance in terms of biomonitoring, is to assess who's
25 bearing the burden of different types of pollutants or

1 which exposure groups seem to be the most highly impacted.
2 So lead, this is a fairly common way to look at average
3 medium concentration of blood leads in kids. And this
4 chart indicates that some of the higher median
5 concentrations are in African-American children, who were
6 living below the poverty line.
7 So again, these types of benchmarks help us
8 assess who's impacted and also what progress we've made
9 and where we need to go.
10 --o0o--
11 DR. MORELLO-FROSCH: So these are the good things
12 about personal exposure assessment and biomonitoring. The
13 challenges are that the technology is getting better, the
14 analytics are getting quite fast, and can detect at lower
15 levels.
16 But the science and the analytical chemistry is
17 outpacing our knowledge about what these chemicals mean
18 for health, particularly for, again, the so-called
19 emerging pollutants. Things that we've been studying more
20 recently such as phthalates, brominated flame retardants
21 and other pollutants, that are increasingly showing up in
22 the environment and in our homes and in our bodies, and
23 trying to interpret what that means, both in the aggregate
24 and for individual study participants.
25 --o0o--

1 DR. MORELLO-FROSCH: The other issue is that very
2 often, not always, but very often we detect these
3 chemicals, but we're not quite sure where they're coming
4 from or what their main pathways of exposure are. And as
5 one study participant so insightfully pointed out when we
6 interviewed her, she wasn't necessarily worried about the
7 uncertainty in her results, but she stated quite candidly
8 that, you know, none of these chemicals that you found
9 comes with a return address, in terms of really knowing
10 where this stuff comes from.
11 So in short, our capacity to detect precedes our
12 capacity to interpret what it means. There are very few
13 regulatory benchmarks to compare with, as in the mercury
14 case that I just showed you. More often than not, we
15 don't have that kind of benchmark to help contextualize
16 results. And until recently, there have been few
17 comparison studies to be able to compare the distributions
18 of these chemical exposures in different populations.
19 --o0o--
20 DR. MORELLO-FROSCH: There's also some
21 implications for environmental justice that I just want to
22 put on the table here for future discussion, which is that
23 many communities - and Lori is going to be talking about
24 this as well - conduct biomonitoring for many reasons to
25 track exposures, to assess the extent of contamination

1 with particular chemicals of concern, and then in certain
2 cases, it's to leverage government action, of funding for
3 future research, industry action and legal remedies.
4 And yet, even in these situations, there are
5 significant EJ concerns about the implications of
6 biomonitoring in that. By following the molecule, there
7 is the potential to lose site about some of the social and
8 economic drivers that lead to the exposures that occur in
9 the first place. So it's important not to lose sight of
10 the forest as we're searching in the trees, so to speak.
11 Concerns about ways in which report back happens
12 to ensure that communities are not stigmatized and
13 discriminated against, viewed as quote unquote
14 contaminated communities, which can potentially have
15 impacts. This has been an issue that's been discussed
16 quite a bit in Canada, in terms of early biomonitoring
17 efforts of inuit communities in the circumpolar north, and
18 ways in which there was some missteps in how report back
19 happened.
20 And those issues, I think, have been worked out.
21 We learned some good lessons that can be learned from that
22 experience.
23 And then in the banking of biological samples,
24 you know, how do you give people consent to -- for future
25 testing of biological samples, as the science gets better

1 and we can test for other pollutants into the future
2 --o0o--
3 DR. MORELLO-FROSCH: So in terms of results
4 communication, I'm going to cover two frameworks that I
5 think represent this continuum that presenters today are
6 going to be discussing.
7 The first one is clinical ethics, and the second
8 one community-based participatory research or CBPR, as we
9 like to call it.
10 --o0o--
11 DR. MORELLO-FROSCH: So clinical ethics in a
12 nutshell is one in which health professionals or
13 scientists decide whether results are clinically relevant.
14 And clinical action levels of exposures generally are
15 determined prior to the initiation of the study. And so
16 if results are below a clinically actionable level, then
17 generally there's no report back to individual
18 participants. There may be aggregate report back, in
19 terms of looking at overall distributions and study
20 population. But individuals are not given necessarily
21 their results.
22 This is the way it's done for CDC's NHANES.
23 Although, there's some discussion about changing this
24 strategy a bit, so that individuals can get their results,
25 regardless of whether or not they're above clinically

1 actionable levels.

2 --o0o--

3 DR. MORELLO-FROSCH: So that's a fairly

4 straightforward one. There are some drawbacks. One of

5 which is that clinical ethics has evolved significantly.

6 In the medical setting now, patients are given a lot of

7 information that has a lot of uncertainty, in terms of

8 what it means for their health. And patients are being

9 asked to be more proactive in directing their health care.

10 So one could suggest that clinical ethics itself

11 has evolved, in that more information to individuals is

12 becoming more of the norm. And so just deciding whether

13 or not something is clinically actionable about whether or

14 not you report may not be appropriate anymore, even in a

15 clinical ethics context.

16 The other issue is that it could preclude

17 individual action to reduce exposures, even when the

18 health effects may not be well known, because science

19 later reveals that there may be potential health effects

20 below what were seemingly clinically actionable levels.

21 And then we learn that the levels of -- that adverse

22 impacts can happen at lower levels, as is the case of

23 lead, where the benchmark has been lowered over many, many

24 years, as the science indicates that adverse impacts

25 happen in levels below what was previously considered as a

1 safe benchmark.

2 The same could be said for other pollutants, such

3 as mercury and endocrine disrupting chemicals. So it

4 precludes individual action to do something to reduce

5 exposures, even when the health implications may be

6 unknown.

7 --o0o--

8 DR. MORELLO-FROSCH: So the community-based

9 participatory research model, which, again this is part of

10 a continuum, so there's no, sort of, strict, you know,

11 CBPR list here. But to give you broad brush strokes about

12 what we mean, is that in this situation exposure

13 assessment, when you're talking about testing air and dust

14 in people's homes or doing biomonitoring is viewed as a

15 joint venture, both between researchers and community

16 members and study participants.

17 And that there's shared decision making about how

18 aggregate and individual report-back protocols are

19 developed. In part, to addresses some of these issues of

20 stigma and concerns about discrimination and how to frame

21 results, and then how to use those results once they're

22 provided back to the community. And so there's an immense

23 amount of time spent reporting to communities and

24 individual study participants, as much as you're reporting

25 the results to your scientific peers at conference and in

1 peer-reviewed publications.

2 The other issue is that researchers spend a lot

3 of time working with community members to clarify what

4 information exposure methods, an exposures study can and

5 cannot provide. And so there's a lot of times spent

6 making clear that most of these studies exposure studies,

7 and implications about health will remain relatively

8 uncertain. Although information can be provided about

9 individual chemicals and what is known from toxicological

10 evidence and other human health studies.

11 --o0o--

12 DR. MORELLO-FROSCH: So developing those

13 materials is definitely a joint venture and is something

14 that we have done extensively, both in our work with

15 Silent Spring Institute and their Cape Cod Household

16 Exposure Study. This was a study that was initiated

17 several years ago, where they tested 170 homes air and

18 dust and took urinary samples.

19 I looked mostly at endocrine disruptors that were

20 potentially linked to breast cancer. But this was not a

21 health study, it was strictly an exposure study.

22 And this study got a fair amount of coverage when

23 it was first published in '03, because it was one of the

24 early studies that detected pollutants from consumer

25 products in homes.

1 So phthalates were found in all homes, as well as
2 several endocrine disrupting chemicals and flame
3 retardants were considered to be quite high compared to
4 Europe, for example. And it was also shown that many of
5 these chemicals had no health-based guidelines or
6 benchmarks.
7 --o0o--
8 DR. MORELLO-FROSCH: We worked with Silent Spring
9 to expand the household exposure study to northern
10 California. We looked at a community in Richmond as well
11 as in Marin County. A small number of homes. We had
12 fewer resources. We did not have resources to do
13 biomonitoring, but we did take indoor samples of air and
14 dust and did outdoor air sampling as well.
15 We were interested in analytes that could be
16 coming from industrial activities, transportation sources,
17 as well as consumer products in homes. And we wanted to
18 look at pollutant levels in communities with and without
19 major industry, which is why we were looking at Marin and
20 Richmond.
21 And, again, we spent a significant amount of time
22 with community members, in terms of not only doing the
23 data collection protocols, but also explaining the study,
24 recruiting, being really clear about what the study was
25 and was not going to achieve, and explain to people, you

1 know, what they could learn from the study, and then
2 asking them whether or not they wanted their results at
3 the individual level.
4 --o0o--
5 DR. MORELLO-FROSCH: This has been published in
6 the literature in Environmental Science and Technology.
7 But one of the big findings was that we found extremely
8 high household dust levels in both Marin and Richmond
9 homes. And some of the highest in the published
10 literature, possibly likely to California's furniture
11 flammability standard.
12 Since we didn't have blood levels in the homes
13 that we tested for, we used -- got access to NHANES data
14 to compare blood levels of brominated flame retardants in
15 California residents versus residents of other states, and
16 found that indeed the average blood levels of these flame
17 retardants are higher among California residents than in
18 residents from other states.
19 --o0o--
20 DR. MORELLO-FROSCH: And so we did provide this
21 information back to communities, because they wanted to
22 know, you know, what does this mean in terms of what
23 people might be exposed to. I know, we didn't take blood
24 from us, but is there a way that you could give us a sense
25 of what's blood levels might be among Californians more

1 broadly.

2 --o0o--

3 DR. MORELLO-FROSCH: So this was something that

4 was helpful to our communities, even though we didn't have

5 biomonitoring data directly from that.

6 So just to give you this notion of the continuum

7 of report back frameworks from clinical ethics, which is

8 on your left, and CBPR which is all the way on your right,

9 there are a lot of pieces of levels of community

10 engagement in the report-back strategy.

11 So on the far left, when you're closer to

12 clinical ethics, there is relatively little community

13 influence on the communication's strategy. Sometimes

14 community context helps shape the communications strategy.

15 But then as you move along the continuum closer to a CBPR

16 approach, you're drawing more on community engagement, in

17 terms of their soliciting their opinions, through pre- and

18 post-research meetings about how report back should work,

19 both in the aggregate and individually. To engaging them

20 in actually helping do the recommunication and

21 dissemination of results to actually helping them help do

22 protocol design. And how do you sort of settle along this

23 continuum will depend very much on what type of study

24 that's conducted in the context in which it is conducted.

25 --o0o--

1 DR. MORELLO-FROSCH: So the basic things that we
2 have found that study participants are interested in,
3 after we've interviewed them, are very basic, very
4 straightforward. They want to know what we found? How
5 much? Is it high? Is it safe? Where did it come from?
6 What should I do?
7 These are very straightforward questions.
8 Unfortunately, they're not always the easiest to answer.
9 --o0o--
10 DR. MORELLO-FROSCH: So we have employed
11 different kinds of strategies. And we have made these
12 materials available to the Biomonitoring Program. But we
13 tend to combine text as well as graphs to give people kind
14 of a take-home message about what we found, either in
15 their homes or in their bodies.
16 Generally, it's summarized in a page, because
17 you're sampling for a lot of analytes, and you want to
18 kind of try and give them a take-home message and help
19 them sift through the materials and what they might want
20 to focus on.
21 So this is an example of the kind of text that we
22 provide. In this case, we're indicating that we found
23 some weed killer in their urine. And that it's likely
24 that they could reduce their exposures by decreasing their
25 use of pesticides in the home.

1 --o0o--

2 DR. MORELLO-FROSCH: Then graphs. These are the
3 types of graphs we have used. And this is for dust
4 levels. But similar strategies can be employed for
5 biomonitoring results. So we tend to show people where
6 they are in the distribution of other people that were
7 included in the study, so they can see where they fell.
8 If there is a guideline available, we tried to
9 provide it. Very often there is not one and we make clear
10 in supplemental materials that there is not. And we try
11 and provide them information about what type of chemical
12 this is and how it's used and what types of things that we
13 find it in, and what is known about its health effects
14 from toxicological evidence, as well as human epi studies,
15 if those are available.

16 --o0o--

17 DR. MORELLO-FROSCH: So in terms of reactions of
18 study participants. Why do people do this, if, in fact,
19 there are capacity to distill this information and tell
20 them what it means is limited? Why do people still ask
21 for the results?
22 When we consented people to participate in the
23 studies, 98 percent of them said yes, I want my results,
24 despite all these uncertainties. And they participate in
25 these studies for a variety of reasons. One, they're

1 curious. They want to know where chemicals come from and
2 how they get exposed. A lot of them want to help support
3 the scientific enterprise, and so they feel that they have
4 an important role in that.
5 And then many of them just really want to
6 understand exposure routes and sources of chemicals, and
7 find out whether or not what they think is going on is, in
8 fact, through. Many people are actually very aware about
9 how they can come into contact with chemical exposures
10 through consumer products, and believe that they're doing
11 a good job in controlling the use of these chemicals in
12 their homes. And they later come to find out that their
13 capacity to control some of these exposures may be
14 somewhat limited.
15 And so very often they want to see whether or not
16 there's opportunities to take these results to take action
17 to reduce their exposures, either as individual consumers
18 or collectively, in terms of working with other community
19 members to reduce exposures, depending on the potential
20 source.
21 --o0o--
22 DR. MORELLO-FROSCH: And the key here is we want
23 to be trying to match messages to the strength of the
24 evidence. And the two issues I think that when we talk
25 about report-back protocols and how to categorize

1 pollutants, especially when you're sampling for a lot, is
2 thinking about where we are on the continuum about the
3 knowledge of the efficacy of exposure reduction methods.
4 So there's certain situations where we can tell people
5 where we think pollutants may be coming from, but the
6 exposure reduction methods that are applied in that have
7 not really been tested in terms of whether or not they're
8 effective. But you can still tell people, you know, where
9 these things might be coming from.
10 And then the other continuum that's important to
11 take into consideration is the knowledge of the exposure
12 effect relationship, what. Do we know about the potential
13 health impacts of the pollutants that we're looking for,
14 and to be clear on what the uncertainty is on that
15 continuum as well.
16 --o0o--
17 DR. MORELLO-FROSCH: So I show this slide,
18 because this is a situation -- this is a very interesting
19 study that was done that looked at a dietary intervention,
20 and basically showed that children that were initially on
21 a conventional diet and then put on an organic diet, their
22 urinary metabolites and malathion and chlorpyrifos
23 decreased quite a bit.
24 And so the health implications of this kind of
25 thing are not necessarily clear and scientifically

1 contested, but there's some pretty straightforward
2 information you can gave to someone about how they can
3 reduce their exposures if they want to, regardless of
4 whether there is health implications of these issues have
5 been clarified by the scientific community.
6 --o0o--
7 DR. MORELLO-FROSCH: So the key here, I'll leave
8 you with this framework, which is it's important to link
9 results with the capacity for individual and collective
10 action. And so one of the things that we've worked with
11 is how can you identify for people which pollutants are
12 likely to be coming from local sources nearby, either from
13 industrial facilities or mobile sources, or consumer
14 products. And then on the left-hand side, there are some
15 local sources and consumer products that are going to
16 require corrective action to reduce exposure levels,
17 whether we're talking about permitting or land-use
18 decision making from outside courses, or policy
19 interventions to get rid of certain pollutants in consumer
20 products.
21 And then there's on the far right, there are some
22 consumer products that individuals can act on immediately
23 to reduce their exposures, again, even if the implications
24 for health are not known.
25 --o0o--

1 DR. MORELLO-FROSCH: So implications that I want
2 to leave you with is that we want to set expectations for
3 what studies can and cannot tell study participants. And
4 when we're communicating results, where possible, we want
5 to show how people can use those results to take action
6 where possible, either individually or collectively what
7 needs to be done.
8 So if it's a matter of consumer action, then it
9 can be an issue of reading a label, and avoiding certain
10 products. But there may be situations where consumers
11 can't read labels, because there aren't labeling
12 requirements, and so that may require more policy
13 intervention and changes.
14 And the importance of trying to make these
15 results as meaningful as possible. Reporting in the
16 aggregate is key, and having that -- using that as the
17 context for understanding their individual level of
18 results, I think, is important.
19 And if there's regulatory benchmarks available to
20 apply them right now, there's a capacity of those
21 available. That may start changing. But at minimum, we
22 can try and compare the results to distributional
23 information, both the study population itself that was
24 studied, and then also NHANES provides an excellent source
25 of information. You can do some pretty sophisticated

1 demographic comparisons and hone in on demographics that
2 are similar to your study population to make those results
3 even more meaningful.
4 And the key is also I think categorizing these
5 results into meaningful use and source categories. If
6 we're sampling for a lot of pollutants, I think it's good
7 to kind of create chapters that are meaningful to
8 participants, in terms of what are their source
9 categories. Are these pollutants that are predominantly
10 pesticides, consumer products? These kinds of things, I
11 think, help make the results even more meaningful when we
12 can categorize them.
13 --o0o--
14 DR. MORELLO-FROSCH: And then also create another
15 category for those pollutants for which you have very
16 little information, in terms of source pathways, exposure
17 pathways sources, and health impacts. And those -- kind
18 of that uncertainty chapter is key to communicate to
19 people as well.
20 The other thing is cultural and community context
21 is key. And I think there has to be some flexibility to
22 modify communication protocols mid-stream and assess as
23 you're going along, because inevitably you have to make
24 some adjustments, based on literacy issues, which Holly is
25 going to talk about. And also helping people balance

1 their right to know about their results and making it
2 their sort of -- in the context of their capacity to act
3 to reduce exposures, and to clarify how much intervention
4 is really possible to reduce exposures due to cost as well
5 as scientific uncertainties.
6 --o0o--
7 DR. MORELLO-FROSCH: This is my Research
8 Collaborative that has helped do this sort of ethical side
9 of our exposure assessment research, Silent Spring, Brown,
10 UC Berkeley, of course, and Communities for a Better
11 Environment here in Oakland.
12 Thank you.
13 CHAIRPERSON MORENO: Thank you, Dr.
14 Morello-Frosch. At this time, we have to take a few
15 minutes for Panel members to ask questions.
16 Dr. Wilson.
17 PANEL MEMBER WILSON: Than you very much. That
18 was extremely interesting and helpful. And I'm wondering
19 if you could comment about your experience in working with
20 community-based organizations, including perhaps labor
21 unions whose purpose is to, you know, to organize
22 communities to bring people together and to help represent
23 them and to communicate information, how that has worked,
24 you know, as a vehicle for communication versus in the
25 absence of a community-based organization.

1 DR. MORELLO-FROSCH: I can talk a little bit
2 about our experience working with community-based
3 organizations. We've had less experience working with
4 unions.
5 But it's extremely helpful to engage
6 community-based organizations, in terms of designing
7 communication protocols, because they can help you flag
8 what strategies are likely to work and which ones could
9 potentially fall flat and not work, both in terms of
10 communicating the information in a way that people can
11 understand, but then also engendering trust in the program
12 and the research itself, and kind of overcoming
13 skepticism.
14 And it can be helpful on the front end, in terms
15 of as you're recruiting people and getting them to
16 participate in the study and recruit them and explain to
17 them what the study can and cannot do. And then it's
18 helpful on the communication side -- results communication
19 side as well.
20 Their expertise has been invaluable in testing
21 the literacy level of the text itself, in terms of
22 communication protocols, as well as the graphics. A lot
23 of back and forth on visuals and the combination of the
24 packets as well. And then figuring out strategies for
25 follow up for people. It's been invaluable when you're

1 doing those community focus studies.

2 CHAIRPERSON MORENO: I'd like to take one more

3 question. We're a little bit behind. So go ahead, Dr.

4 Culver.

5 PANEL MEMBER CULVER: Do you have any

6 difficulty -- Dwight Culver. Do you have any difficulty

7 in getting your IRB to accept your protocols?

8 DR. MORELLO-FROSCH: That's a great question. We

9 had a lot of back and forth with our IRBs. Initially,

10 they didn't say they couldn't do it. They just wanted to

11 have a very thorough discussion about what the

12 implications were about communicating these results when

13 they were uncertain.

14 And then in the end, the IRB felt pretty strongly

15 that people who wanted their results and who were taking

16 the time to participate in the study and who were well

17 informed at the beginning, about all of the uncertainties

18 that were going to be accompanying the communication, they

19 felt comfortable with that. So we were allowed to do it,

20 but we had a very thorough discussion about the

21 trade-offs, potential trade-offs, of do doing that. But

22 in the end they definitely supported it and felt it was a

23 good thing. And we didn't have any complaints ever from

24 study participants who were alarmed or concerned or upset

25 at getting their results back. We sometimes got calls for

1 clarification of results from ourselves, but no one
2 ever -- there were no registered complaints to the IRB
3 about participant concern or stress.
4 CHAIRPERSON MORENO: Dr. Morello-Frosch you'll be
5 with us for the rest of the morning, right?
6 DR. MORELLO-FROSCH: Yes.
7 CHAIRPERSON MORENO: So the Panel members will
8 have another opportunity to ask more questions later.
9 All right, we have our next speaker. Holly
10 Brown-Williams speaking on integrating health literacy
11 best practices in biomonitoring results communication.
12 (Thereupon an overhead presentation was
13 Presented as follows.)
14 CHAIRPERSON MORENO: Welcome.
15 MS. BROWN-WILLIAMS: Thank you very much for the
16 opportunity to speak today. It's hard to follow on the
17 heals of one of my heroes, but I'll give it my best shot.
18 While my work at Health Research for Action is
19 more focused on policy development, I have many colleagues
20 there with expertise in health communications, health
21 education, health literacy, as well as in sciences like
22 epidemiology.
23 And we have more than 20 years of experience in
24 developing health communications and testing the
25 communications resources. And those resources have

1 reached millions of people in the United States and
2 outside the U.S.
3 I'd like to start by giving you some background
4 on health literacy and its relevance to biomonitoring
5 results communication.
6 --o0o--
7 PANEL MEMBER WILSON: Holly, can you speak into
8 the mike a little more.
9 CHAIRPERSON MORENO: You can readjust the mike
10 there.
11 MS. BROWN-WILLIAMS: So how well do people read
12 and write in the United States? It's kind of a joke, but
13 it's not a joke really.
14 And just start, this is a general definition
15 about literacy, but the definition of health literacy is
16 the degree to which individuals have the capacity to
17 obtain, process, and understand basic health information
18 and services needed to make appropriate health decisions.
19 And limited literacy presents many challenges in
20 communicating complex health information. And when I
21 think about biomonitoring results communication, that
22 seems amplified to me many times over.
23 --o0o--
24 MS. BROWN-WILLIAMS: Just A few basic statistics
25 that more than half, 90 million of Americans have literacy

1 skills below high school level and difficulty
2 understanding and acting on health information.
3 A majority of Americans read below or between the
4 Seventh and Ninth grade levels. Twenty percent below the
5 Fifth grade level. But more importantly, most people read
6 several grade levels below their actual highest grade of
7 school that they completed.
8 And in contrast, most health information is
9 written at the 10th to 12th grade level. And a number of
10 studies I looked at recently around health literacy and
11 physical activity most of the materials were above the
12 14th grade level.
13 --o0o--
14 MS. BROWN-WILLIAMS: Most people wouldn't
15 understand a lot of the complex things that they're faced
16 with. I've given a couple of examples. I'll just read
17 the first one from a research consent form, which says, "A
18 comparison of the effectiveness of educational media in
19 combination with the counseling method on smoking habits
20 is being examined."
21 I'm pleased to report a couple of consent forms
22 I've seen more recently from Bay Area studies have been a
23 lot better than this, but I don't think this is uncommon.
24 --o0o--
25 MS. BROWN-WILLIAMS: And even more everyday

1 examples, like picking up your prescription, there are
2 many challenges that people face. I'll give you a couple
3 of examples running through the spectrum of health
4 literacy experience.
5 --o0o--
6 MS. BROWN-WILLIAMS: A very simple message that's
7 written at the first grade level. Take with food, most
8 people would understand, 84 percent of people.
9 --o0o--
10 MS. BROWN-WILLIAMS: A slightly more complex
11 message, you suddenly have more than -- or less than half
12 of the people really able to understand those directions
13 it's written at the 10th, 12th grade level that medication
14 should be taken with plenty of water.
15 --o0o--
16 MS. BROWN-WILLIAMS: I've seen this on many of my
17 own description. It's a very complex message written at
18 the 12th to 13th grade level. And only eight percent of
19 the people would understand these instructions.
20 --o0o--
21 MS. BROWN-WILLIAMS: Literacy levels are also
22 lower among the poor, among minority populations, the
23 elderly, people with less education, populations like
24 recent immigrants who have limited English proficiency to
25 begin with. And these populations are more vulnerable and

1 at higher risk for poor health because they have
2 challenges in accessing health. They are also, as Rachel
3 noted, have higher cumulative exposures to environmental
4 contaminants.
5 Another interesting developing aspect of the
6 health literacy movement is a focus on public health
7 literacy. And I think this is highly relevant for
8 biomonitoring. Some of the experts interested in this
9 emerging field believe that the current framing of health
10 literacy limits the problem to the capacity and
11 understanding of the individual.
12 I mean, in fact, working with a lot of health
13 literacy professionals most don't feel that way because
14 they understand the health system problems and don't place
15 the burden on individuals, but an emphasis on public
16 health literacy incorporates population health
17 perspectives, and is intended to really promote
18 understanding and advocacy on societal level factors that
19 influence health.
20 And the result of this is intended to be, you
21 know, more activism around policies that are health
22 protective. I think that's very relevant for
23 biomonitoring and chemicals policy change.
24 Beyond measuring health literacy, it's important
25 to build on the points that Rachel is making about

1 participatory approaches in developing health materials,
2 including for the Biomonitoring Program.
3 A couple of the key elements in using a
4 participatory approach for designing materials would be to
5 define what your objectives are with your audience; to
6 assess their knowledge, attitudes, and behaviors; to set
7 up a participatory design of materials process development
8 with your audiences; and then to use a sequence of
9 ongoing, developing, and testing of the communication
10 materials and engaging the recipients of the materials and
11 other stakeholders to plan how those materials will be
12 delivered. Of course, to evaluate the impact of the
13 health messages and revise them as appropriate and then
14 ultimately to adapt them for other audiences.
15 --o0o--
16 MS. BROWN-WILLIAMS: Some of the best practices
17 in health communication, in terms of general practices,
18 are to again very consistent with what Rachel has learned
19 in her studies, you really want to start by finding out
20 what people want and need to know, what they understand,
21 how they want to receive the information, and how the
22 information can be made relevant and useful to their
23 lives.
24 You need to keep the audience in mind. Consider
25 the attributes that define your target audience as a

1 group. You can draw on demographic research to find out
2 more about the audience, but more importantly engage the
3 audience in techniques, like focus group research, to gain
4 insight into their beliefs and values.
5 Of course, when it comes to actually developing
6 the materials, it's important to keep those statistics in
7 mind. Aim for a sixth to seventh grade leading level or
8 lower. Focus on just a few main messages. Make sure that
9 people understand, you know, what it is that they're
10 expected to understand, and break up the complex topics.
11 There's lots of simple techniques, like just using fewer
12 syllables in words, fewer words on a page, larger fonts,
13 using some simple pictures, and also avoiding more complex
14 graphics.
15 --o0o--
16 MS. BROWN-WILLIAMS: And it's important to
17 consider as well that health numeracy and quantitative
18 ability plays a really big role in people's understanding
19 of health information and is also relevant to
20 biomonitoring.
21 I mean, to understand most health information,
22 people need a working knowledge of numbers. But more than
23 half of U.S. adults have trouble with quantitative
24 literacy. And that includes the knowledge and skills
25 required to use numbers contained in printed materials.

1 People interpret numbers differently, and risk
2 data is almost always difficult to explain and understand.
3 While experts normally rerecommend using simple graphics
4 to highlight key points and messages, there's a lot of
5 disagreement in the literature about what type of visuals
6 work best. Because graphs are abstract, require matching
7 different kinds of information, and are not perceived as
8 well by a lot of the users, they're not well understood by
9 people with limited literacy skills.
10 Other ways to express numbers are often better
11 understood, such as comparing numbers to known quantities,
12 giving analogies, and showing pictures. Again, this is a
13 little bit more challenging in the domain of biomonitoring
14 results communication, but these are just some general
15 principles.
16 It's also just reinforcing, important to find out
17 what the person already knows and then to build on that
18 information.
19 --o0o--
20 MS. BROWN-WILLIAMS: When you're providing risk
21 information, it's really important to be clear about the
22 timeframes. Most of the points on this slide really
23 relate to more known risks, like in fields of, you know,
24 sort of, established epidemiological studies, but I think
25 some of the basic principles are still very relevant.

1 People need to know is it an immediate risk? Is
2 it something that's going to be a risk in five years? Is
3 it a lifetime risk?
4 Specify the nature of the risk. Is it a risk of
5 getting a disease, having a recurrence, dying from what
6 you have? Also, decide whether to talk about a risk in
7 positive or negative terms, and whether to present the
8 risk in relative or absolute terms. For example, you
9 know, some people say you're twice as likely to have
10 something occur versus one of four people will have that
11 occur. And studies have shown that people better
12 understand the information when the risk is framed and
13 positive in absolute terms.
14 When dealing with uncertainty, which we certainly
15 will be in this statewide program, it's important to
16 include in the risk information and acknowledgement that
17 scientists continue to study and learn and to provide the
18 recipients of information with other sources where they
19 can learn more about the information that they've
20 received.
21 --o0o--
22 MS. BROWN-WILLIAMS: I'd like to turn now to work
23 we're doing with a local study, the Cohort study of Young
24 Girls, Nutrition, Environment and Transitions, which has a
25 shorthand name of CYGNET. CYGNET is a project of the Bay

1 Area Breast Cancer and the Environment Research Center,
2 which is a multi-disciplinary center based at UCSF and Bob
3 Hiatt is the principal investigator of that study. It's
4 one of four studies nationally funded by the National
5 Institute for Environmental Health Sciences and National
6 Cancer Institute.
7 And CYGNET is funded through this Center and
8 these grants. Other studies -- excuse me, other centers
9 who are collaborating to study environmental and genetic
10 determinants of puberty in girls, using mostly the same
11 methods and pooling data along with Kaiser are Mount Sinai
12 School of Medicine in New York, and the University of
13 Cincinnati.
14 The principal investigator of the CYGNET study is
15 Larry Kushi. He is an Associate Director in the Division
16 of Research at Kaiser Permanente based here in Oakland.
17 He's got co-PIs from UCSF, UC Berkeley, California
18 Department of Public Health, University of Michigan, and
19 Roswell Park Cancer Institute in New York.
20 The Bay Area Breast Cancer and the Environment
21 Research Center as well as the CYGNET study also have a
22 community outreach and translation core that's lead by
23 Zero Breast Cancer based in San Rafael and Janice Barlow
24 is their executive director.
25 And I believe Janice and Gail Windham from the

1 California Department of Public Health are here in the
2 audience today. Can you -- I couldn't see you. Great.
3 Gail and Janice contributed to the background for
4 my presentation and would be the technical experts who can
5 answer any questions you might have about the CYGNET
6 study.
7 --o0o--
8 MS. BROWN-WILLIAMS: The goal of the study is to
9 better understand the role of environmental, genetic, and
10 other factors in the onset of female puberty as a
11 susceptible exposure period relating to later risks of
12 breast cancer.
13 440 girls were recruited when they were six to
14 eight years old from Kaiser clinics in Oakland, San
15 Francisco, and San Rafael. The team has now followed the
16 girls for five years. They're in the sixth year of the
17 study. And they've collected urine samples annually;
18 blood at baseline or year two for some of the girls;
19 saliva at baseline, if no blood and in year five. They've
20 done annual physical exams of the girls for anthropometric
21 measurements. And the parents or other care-givers of the
22 girls who were assented into the study have completed
23 questionnaires.
24 They're testing for more than 80 chemicals or
25 congeners found in personal care and household products,

1 in the diet, or persistent in the environment with a focus
2 on endocrine disruptors.
3 Classes of chemicals or congeners measured in
4 urine include phytoestrogens, phthalates, and phenols as
5 well as cotinine. Classes of chemicals measured in the
6 blood include PCBs, PBDEs organochlorine pesticides, such
7 as DDE and PFCs.
8 The study team did not originally include in the
9 consent that results from the biomonitoring portion of the
10 study would be reported back, but have subsequently
11 decided for ethical reasons to provide the individual
12 results to the study subjects
13 --o0o--
14 MS. BROWN-WILLIAMS: Some of the challenges in
15 communicating results to this population are that the
16 young girls really constitute a vulnerable population.
17 Their development is not complete. And they may be
18 affected by early chemical exposures or other
19 environmental risks.
20 Areas of concern include behavior, growth,
21 reproductive maturation, and other health problems.
22 However, the effects are not now known in many of these
23 areas. There's also little or no knowledge of the safe
24 levels for most of the chemicals tested, because the
25 effects of these chemicals on puberty are just now being

1 studied.

2 There are limited means for reducing personal

3 exposure to some of the chemicals. There are challenges

4 in selecting comparison values since few of the chemicals

5 have existing health-based guidelines, some of which are

6 based on outdated risk assessments anyway, or are not on

7 the health endpoints of concern.

8 There are also a vary large number of chemicals

9 that are tested to be reported. And just for context, CDC

10 NHANES most recently tested for 148 chemicals, but they

11 only reported the individual results for lead, mercury,

12 and cadmium, which have clinical action levels.

13 They plan, in the future, to offer some, you

14 know, more detailed -- individual level results on

15 request. But at present, they only report the aggregate

16 data for nationally for all of the chemicals.

17 --o0o--

18 MS. BROWN-WILLIAMS: I think some of the more

19 personal challenges are the anxiety that can be caused by

20 receiving information where the implications are

21 uncertain. The possibility of misinterpreting results to

22 signify increased risk when it might signify those risks

23 or conversely underestimating the potential risks and

24 failing to act on information about known risks.

25 The findings from the CYGNET study are also

1 intended to help clinicians in responding to patient's
2 questions. The CYGNET team won't provide the patient's
3 individual results to the physicians, but they will be
4 training physicians and informing them about chemicals
5 that were tested, what will be shared with the patients,
6 and other background information.
7 I know Gina Solomon and Mark Miller did a very
8 interesting piece in pediatrics about the need to educate
9 clinicians about environmental health risks. And this is
10 a very important dimension to the project.
11 --o0o--
12 MS. BROWN-WILLIAMS: Healthy Research for Action
13 is working with the CYGNET team to conduct some background
14 that will inform the development of their communication
15 materials. We've planned four focus groups that will take
16 place in August with parents or care-givers of the girls
17 in the study. Three of the focus groups will be in
18 English and one will be in monolingual Spanish.
19 The primary goal of the focus groups is to learn
20 the parent's preferences for content and format of
21 reporting their daughter's individual study results, as
22 well as the accompanying educational materials.
23 Additional goals of the groups are to better
24 understand the parent's knowledge about the study goals
25 and anticipated outcomes, about their expectations for

1 what they'll learn in the study; general understanding,
2 fears, and misconceptions they have about their daughter's
3 risk from environmental exposures.
4 --o0o--
5 MS. BROWN-WILLIAMS: The work that we've
6 completed so far is we've reviewed relevant literature,
7 both in biomonitoring and generally in risk communication.
8 We've identified a number of report-back materials that
9 have been used in other studies and conducted some
10 readability assessments of those materials and selected
11 three that we're going to test in the focus groups. We've
12 also done other background work, in terms of preparing for
13 both UC Berkeley and Kaiser's IRB process. And we've been
14 working with the CYGNET staff who will be responsible for
15 recruiting the participants and dealing with the consent.
16 The focus groups will be completed in late
17 August. They'll be recorded, transcribed, and the Spanish
18 transcripts will be translated. We'll be analyzing the
19 data in September and reporting the results to CYGNET no
20 later than the end of October.
21 --o0o--
22 MS. BROWN-WILLIAMS: Some possible next phases
23 for this work would be to build on the focus group results
24 to design, test, and refine a new reporting tool and
25 educational materials. The timelines have been uncertain

1 about whether it would be feasible to do that with the
2 CYGNET study, but we believe that a logical next step from
3 doing the focus groups is to design what you think is the
4 optimal material and sequentially test that material with
5 either people who are in a study or people who have
6 similar attributes.
7 A second possible next phase is an evaluation of
8 CYGNET's overall results communication process. And Julia
9 Brody, a long time colleague of Rachel's, has submitted a
10 proposal to do that evaluation, as well as evaluate one of
11 the other related studies in the Bay -- in the Breast
12 Cancer and the Environment Research Centers.
13 --o0o--
14 MS. BROWN-WILLIAMS: Some related work we're
15 doing on this topic, Rachel and I are collaborating with
16 support from the California Department of Public Health on
17 a perspectives issues. Diana mentioned that's a
18 periodical that HRA publishes. And we'll be focusing on a
19 number of issues in biomonitoring, the uses in
20 value -- the uses and the value of population
21 biomonitoring; special issues in the development of
22 California's program; implications of current experiences
23 with other biomonitoring efforts in the U.S.;
24 considerations for reporting results to participants and
25 the public; and recommendations for advancing

1 biomonitoring to promote policies that prevent health
2 problems associated with toxic exposures.
3 --o0o--
4 MS. BROWN-WILLIAMS: We are scheduled to publish
5 these issue by the end of December.
6 Another activity that is in the development
7 stages is a study called Maternal-Infant Environmental
8 Exposure Project. A letter of intent for this project has
9 been developed and is under consideration by the
10 California Wellness Foundation.
11 And this study is a collaboration with the
12 California Department of Public Health with UCSF, led by
13 Tracey Woodruff, who directs the Program on Reproductive
14 Health and the Environment there, and with Rachel and
15 colleagues of mine at Health Research For Action. We're
16 developing a proposal for a pilot study to measure and
17 compare levels of more than 100 chemicals in 50 pregnant
18 women by collecting their blood and urine, and their
19 newborn infants by collecting their umbilical cord blood,
20 which would represent in utero exposures. And these would
21 be collected at UCSF and San Francisco General Hospital.
22 --o0o--
23 MS. BROWN-WILLIAMS: The CDC has agreed to
24 analyze samples for up to 10 chemical classes, possibly
25 more than -- representing more than 100 different

1 chemicals. The labs at the California Department of
2 Public Health may also conduct analyses for some blood
3 metals, phthalates and organophosphates.
4 Another component of the study is to administer
5 questionnaires to study participants to try to understand
6 how they may be exposed through work, diet, use of
7 consumer and personal care products for a subset of
8 chemicals.
9 And the piece that Rachel and I have been working
10 on is to develop and test an approach to providing
11 participants with their test results. And another phase
12 of that would be to provide the individual results through
13 in-person interviews with all of the subject participants.
14 It's a very rich way to gain an understanding about what
15 they understand, the questions that they have, and to
16 inform, in particular, a process where in a statewide
17 program like California's, you probably would not have the
18 luxury of that kind of in-depth interaction with people.
19 We've received feedback on the letter of intent,
20 but the proposal wasn't invited in the recent phase. We
21 are hopeful that they will invite a proposal for their
22 next board docket. And it's possible too that the scale
23 of funding would be outside what they could support so we
24 might need to look for project partners. But it's a very
25 exciting opportunity to, you know, conduct another

1 biomonitoring study that includes a report-back component.
2 Thank you very much for the time and I'm happy to
3 answer questions.
4 CHAIRPERSON MORENO: Thank you for the
5 presentation. We'll take two questions from the Panel
6 members. There will be time again after the presentation
7 is over for public comment.
8 Dr. Culver.
9 PANEL MEMBER CULVER: I just wanted to say that I
10 enjoyed that presentation very much.
11 MS. BROWN-WILLIAMS: Thank you.
12 CHAIRPERSON MORENO: Any other questions from
13 Panel members?
14 MS. BROWN-WILLIAMS: And my contact information
15 is on the last slide as well as my colleague Carrie
16 Graham, who's organizing the focus groups and we'd be
17 happy to follow up individually with anyone.
18 CHAIRPERSON MORENO: Thank you very much.
19 MS. BROWN-WILLIAMS: Thank you.
20 CHAIRPERSON MORENO: All right. We're going to
21 move on to our next speaker, Lori Copan with the
22 California Department of Public Health will be speaking on
23 biomonitoring pilot projects within the Environmental
24 Health Tracking Program.
25 (Thereupon an overhead presentation was

1 Presented as follows.)

2 MS. COPAN: I guess this is how to move the

3 slides.

4 Well, thank you everyone for coming today -- this

5 morning. I would like to attempt to integrate some of the

6 literacy aspects that Holly brought up, as well as the

7 participatory aspects of community-based participatory

8 research into kind of the practical application of two

9 studies that are small community-based studies, within the

10 Tracking Program that I have had the privilege of being

11 involved with for the last year and a half.

12 And I'm pretty sure that most of the Panel and

13 probably most of the audience understands that the

14 Tracking Program provides data, information, and tools to

15 stakeholders about health outcomes -- chemical exposures

16 and health effects. And it's quite a unique program in

17 the fact that it really does integrate, as part of the

18 values and principles of the Program, participatory

19 procedures, collaboration, capacity building, when needed,

20 and principles of -- and a framework of Environmental

21 Justice.

22 So as we, in the Program -- I've actually for the

23 last year and a half kind of the liaison between the

24 Tracking Program and the Biomonitoring Program. And I've

25 taken very seriously, in terms of thinking about in these

1 two small tracking programs -- projects rather, the
2 directive in the legislation that indicates that as a
3 appropriate, the Program shall utilize the principles of
4 Environmental Justice strategy, so that activities of the
5 Panel, and the implementation of the Program provide
6 opportunities for public participation, community capacity
7 building, and meaningful stakeholder input.
8 So basically when fully funded, this Program can
9 do a statewide biomonitoring survey or it does small
10 community-based biomonitoring surveys. It's important
11 that obviously that aspects of participation and capacity
12 building are related to results communication and what
13 people can eventually do with the information that they've
14 garnered after the State program leaves.
15 --o0o--
16 MS. COPAN: I know that over the past few panel
17 meetings, you've had the opportunity to look at or to
18 learn a little bit about the Tracking Pilot Program --
19 Projects. And I really don't want to -- I did intend on
20 going over them in the next three slides. However, I
21 can't seem to get this presentation down to 20 minutes, so
22 I'm going to gloss through these.
23 I think the important point to note is that these
24 are two small projects, that they're in Tulare county and
25 Imperial county, two counties that are some of the poorest

1 counties in California. That the Tulare county has 34
2 participants, seven of whom are children. The Imperial
3 county 31 participants. We're looking at one analyte in
4 Tulare county. We're looking at multiple analytes in
5 Imperial county. We've already collected samples from
6 both of these.
7 --o0o--
8 MS. COPAN: It's important, on this slide, to
9 note that there are multiple partners involved in these
10 projects. They include governmental agencies, large
11 national and international nonprofits, non-governmental
12 agencies, very small community-based organizations,
13 that -- with leaders who come from the community, that --
14 and also that when we think about results communication,
15 we're integrating providers from the communities as
16 volunteers, so that they can help to build their capacity
17 and we can learn from them as well.
18 The laboratories -- it's been quite an
19 extraordinary laboratory collaboration as well. We have
20 national laboratories. We have the county laboratories.
21 We have university laboratories and federal laboratories
22 for CDC.
23 --o0o--
24 MS. COPAN: There's also environmental monitoring
25 that goes along with both of these projects: Air

1 monitoring in Tulare; drinking water in locally grown
2 produce for perchlorate exposure in Imperial county. Both
3 projects have a questionnaire -- an exposure
4 questionnaire. And where we're currently at is that we
5 have all of the data. We're currently analyzing it, and
6 we hope to be communicating results in the winter or --
7 fall or winter of this year.
8 --o0o--
9 MS. COPAN: So obviously there have been
10 tremendous numbers of opportunities for collaboration
11 between the Tracking Program and the Biomonitoring
12 Program. We've had opportunities to -- obviously, we
13 can't develop lab capacity without having samples. And
14 also in addition to getting the samples, the Tracking
15 Program has provided the Environmental Health Laboratory
16 Branch with $45,000 in monetary resources to help develop
17 that capacity, purchase reagents, et cetera.
18 This is a great opportunity to develop and test
19 methods for results communications with participants and
20 with providers as well, who would be the agents of
21 communicating results.
22 As we've just learned through the report that
23 Diana quoted, through what Rachel and through what Holly
24 have just gone through, that we need to evaluate our
25 communication models and how we do -- how we go about

1 recruiting, designing, implementing, and informing
2 participants in studies. It's really created important
3 partnerships between State programs, non-governmental
4 organizations, community organizations, and participants
5 as well in the program.
6 And it has been, and will continue to be, an
7 opportunity to evaluate and improve multiple approaches
8 for how to work with communities, how to transfer sample
9 something as simple as how do we get samples from places
10 like Imperial county and Tulare county and get them to the
11 lab. And then the lab taking those samples and processing
12 them in ways that it needs to to process and to learn
13 about its own methods. These small biomonitoring projects
14 provide those practical steps that we all need to build
15 this program.
16 Obviously, it's investigating community exposures
17 and it's an opportunity, as we go forward and as we've
18 looked at what we've done, to explore how community
19 capacity contributes to biomonitoring projects and to
20 biomonitoring, in general.
21 --o0o--
22 MS. COPAN: This is a little bit like the slide
23 that Rachel had presented, but it's actually not a
24 continuum. It's between the traditional clinic ethics --
25 clinical ethics and the community-based participatory

1 approach. From the Tracking Program's perspective, what
2 we really want to try to achieve is that when the Program
3 leads and when the -- and the community knows the results,
4 that there's actually something useful left behind, that
5 the community can then take the research findings and end
6 the partnerships that have been developed with State
7 programs, with local programs, with local providers among
8 themselves and try to promote desired change for those who
9 actually want to do that.
10 These are a bunch of things that Rachel alluded
11 to, but these are practical things that we've done in the
12 Program that help us to understand about capacity
13 building, communication, strategies, and biomonitoring
14 results communication.
15 Locals as research partners has been really
16 important. Also, helps to build capacity, not bringing
17 locals in just when it's time to talk about the results
18 and figure out how to do it, but to bring them in to
19 understand the scientific process from the beginning,
20 within the designed implementation, and the carrying out
21 and the results communication of the Program.
22 And, you know, ultimately what we've tried to do
23 throughout these different approaches is, you know, the
24 participant needs shape -- shape the communication and
25 help to shape the project.

1 --o0o--

2 MS. COPAN: Specifically related to results
3 communication. Their process for learning about results
4 communication has been to have formative focus groups with
5 participants that's pre-biomonitoring and pre-results
6 communication. We've just conducted at the end of June
7 one pre-biomonitoring, pre-consent, focus group in Tulare
8 county, which I'll talk specifically about the results.
9 And in Imperial county we'll also be discussing some of
10 the pre-results communications, focus groups. Those are
11 to be planned probably for September.
12 We want to have post-biomonitoring focus groups
13 as well, with participants to learn about, you know, the
14 impact of this, and to be able to evaluate our methods.
15 We've had community meetings before consent and after to
16 communicate aggregate results and to have people kind of
17 have a shared experience together.
18 We'll be performing evaluation strategies of
19 their meetings, of our study process, of procedures, of
20 the materials that we do. And an essential component of
21 that is that we really want to learn from the health care
22 providers who are being integrated into this process.
23 --o0o--
24 MS. COPAN: So in terms of the study
25 participants, pretty much the research questions are those

1 that both Holly and Rachel have done in theirs have
2 looked. But, you know, we want to know why do
3 participants want to be involved in biomonitoring studies,
4 what do they want to know, what concerns and needs do they
5 have in response to learning about contaminants in their
6 bodies, how do the results affect their lives, how do the
7 results affect their behaviors, how much written
8 information, what's appropriate, how much is -- what
9 quantity and at what literacy level, and related to the
10 grass, we want to know what visual tools best aid in the
11 understanding of personal results.
12 --o0o--
13 MS. COPAN: In the interests of time, I'll skip
14 through these, because I'm going to actually cover each
15 one specifically. But this is for the pre-biomonitoring
16 focus group that we just conducted in Tulare toward the
17 end of June, two weeks before the consenting process for
18 the study. And it was -- there were 28 adults in that
19 study. Seven of them participated in this focus group.
20 It was held in the living room -- a living room of a
21 participant in Lindsay. We had some pizza beforehand. It
22 was held in Spanish. And there was one -- six people were
23 monolingual Spanish speakers in the group, and one person
24 actually had Spanish as her second language. Her first
25 language was Mixteco. And she understood completely

1 the -- she was able to respond in Spanish, but her 14 year
2 old daughter who was also a participant in this study and
3 also a participant in the focus group helped to translate
4 some of what I was asking in the questions.
5 --o0o--
6 MS. COPAN: So in terms of the current knowledge
7 of this study, participants had really good current
8 knowledge of what this study was all about, in terms of
9 the procedures for the study that we were collecting
10 urine -- that we were going to collect urine for seven
11 days, that we were also conducting air monitoring, but
12 they had many, many misconceptions that the study would
13 actually help to answer their health concerns and form
14 causal relationships and links between pesticides. And
15 for this study, we're just looking at the chlorpyrifos
16 specific metabolite, TCPY.
17 And this was great, because what it actually
18 helped us to understand is that there's been really good
19 community organizing. However, before the consent process
20 took place, in doing this, we were able to really hone in
21 and help people to understand before they consented to the
22 project that these questions could not be answered by
23 participating in the study.
24 This was a quote from one of the -- the 14 year
25 old girl who participated. And it was in response to if

1 you were asked by a neighbor to describe this study, What
2 would you tell him or her. And she said that, "The
3 pesticides affect the health of many people like children
4 and, later they get asthma or cancer. And that pesticides
5 in the air affect the health of children, and that's why
6 it's important to do these tests," meaning to do
7 biomonitoring, to do the urine tests.
8 --o0o--
9 MS. COPAN: Reasons for participating, I think,
10 reflect some of what Rachel had spoken about. But there's
11 definitely an aspect of working with local people who are
12 respected. This is a photograph of the local organizer
13 Irma Arroyo. And, you know, she has a cultural folkloric
14 organization, as well as does some environmental work.
15 And people really respected her and trusted what she was
16 actually coming into the community and saying, you know,
17 let's do this. Let's participate in this study.
18 The people recognized that they had multiple
19 health issues, that they lived -- they felt vulnerable
20 from living near orange groves, because the chlorpyrifos
21 was used on orange groves. And to be recruited, people
22 had to live near the orange groves.
23 And this kept -- this theme of learning how to
24 protect themselves came up again and again. And
25 interestingly enough, it came up from the one very young

1 person in the study, the 14 year old. And this concept
2 of, you know, we want to help you all to help us to draw
3 attention to this problem, this spraying, came up again
4 and again in the focus groups.
5 --o0o--
6 MS. COPAN: People expected the air to be -- the
7 air to be very high, the air monitoring in chlorpyrifos.
8 And they expected that their urine levels would be very
9 high as well.
10 And everybody in actually both of these studies,
11 the 34 participants in Lindsay, and the 31 participants in
12 Imperial county everybody unanimously wanted their
13 results, and thought that it was obvious that they should
14 have their results. So the clinical ethics framework
15 really is a bit extraordinary in thinking that wow, we
16 wouldn't communicate results to people at this point in
17 time with biomonitoring.
18 --o0o--
19 MS. COPAN: As I said, that people expressed a
20 tremendous number of health concerns. And they wanted to
21 have those health concerns related to this study. And
22 they also -- a couple of them also blamed themselves for
23 exposures that their children had, because the children
24 worked in the fields with them at sometime during their
25 life, and asthma was a huge burden among people in this

1 focus group, as well as diabetes. Seven people were
2 participating, three of them had diabetes. And asthma was
3 pretty prevalent among the families as well.
4 In fact, one person really broke down and cried.
5 She just felt so helpless with her children's asthma, and
6 really wanted this study to be able to figure out why her
7 kid has asthma, and it's not. We stopped the focus group
8 and explained very explicitly that we wouldn't be able to
9 do that, because it just felt like something that had to
10 be talked about at that moment.
11 --o0o--
12 MS. COPAN: People wanted, you know,
13 interestingly enough wanted really to have a lot of policy
14 change as a result of this small biomonitoring study.
15 They wanted more control over pesticides. They wanted
16 this type of research to call attention to the issues
17 within the community. They wanted some policy changes for
18 the growers. And again, the mantra of I want to know how
19 to reduce my exposures by the 14 year old in the focus
20 group was quite interesting. And I think the study -- the
21 CYGNET study will be also very interesting in learning,
22 you know, what are the needs in young people versus what
23 is the impact and the needs in older adults or adults.
24 --o0o--
25 MS. COPAN: Again, just the health communications

1 reflects a lot of what Rachel had talked about. The first
2 three really would have to do with what we can do in our
3 results communication feedback with providers, you know,
4 strong -- we can't link the current illness or illness in
5 the family with this pesticide, but we can talk about the
6 consequences of pesticides, and we can -- pesticides and
7 we can talk about how to reduce levels.
8 And, you know, the other issues that involve
9 calling attention and changing laws are things that we
10 can't -- we probably won't be able to address in doing
11 personal results communication. But certainly through our
12 partnerships with community-based organizations and NGOs
13 that would be possible.
14 --o0o--
15 MS. COPAN: How to communicate results -- I'm
16 getting the two minute sign.
17 So, you know, people want what everybody wants
18 and what everybody intuitively knows about what they want
19 when they go to a medical appointment. They want to
20 be -- they want somebody to sit with them. They want to
21 be looked at when they're spoken to. They want someone to
22 demonstrate concerns. They want their information that
23 it's being explained to them to be something that the
24 doctor or the health care provider works with in that
25 moment. And not that they're given something completely

1 different and unrelated to what was reviewed during this
2 session to take home and to read later, that's multiple
3 pages.
4 They want doctors to be thorough. They want
5 their problems to be taken seriously. And they want to
6 reduce their levels. And this quote was -- it just
7 indicates that, you know, people understand that they and
8 people like them, and that everyone needs help in
9 understanding information. And pointed out that even
10 though they can read, some people need that extra help
11 with sitting down with the providers.
12 --o0o--
13 MS. COPAN: Health literacy issues. I think that
14 they were covered -- in terms of visual information was
15 covered very well by Holly. We did test out a couple of
16 graphs, one that just looked at basically one -- three
17 graphs that looked at one contaminant. And this
18 particular study, you know, we're going to have the
19 opportunity to look at best practices with a small scale
20 study for a single contaminant. And this is in Tulare.
21 In Imperial we'll be looking at multiple
22 contaminants, perchlorate and metals in urine. And we'll
23 be able to look at graphics for how to do that and test
24 those out as well.
25 But particularly more testing is needed in this

1 area. We can't give people reams of paper describing
2 different chemicals. We have to use graphic information.
3 And some information will be able to stand on its own.
4 And I'm sure that if the Program ever does become a
5 statewide program, people have to be able to understand
6 the information that's given to them without sitting down
7 for a health care provider. And that's an essential
8 component for us to figure out in these small studies.
9 --o0o--
10 MS. COPAN: We looked at these three graphs. The
11 one on the left was the one that was extraordinarily easy
12 to understand for folks. And it was just a simple bar
13 graph. And I was astounded by how much they could really
14 tell me about, you know, interpreting the overall what the
15 meaning of the graph, what the difference between men and
16 women were. I assigned to each person in the group that
17 they were a particular participant number. And each one
18 of them could tell me how they rated with respect to above
19 the CDC average, below the CDC average, and in comparison
20 with each other.
21 So I really needed to understand what -- you
22 know, do bar graphs really work, because we used them all
23 the time in our work. The other two really, I just got a
24 lot of -- to test out our methods of how we're going to
25 communicate graphically with the group that we're using,

1 because some graphs may be easier to understand with
2 different groups.
3 --o0o--
4 MS. COPAN: So the impact is that we were able
5 to -- of doing this work -- thank you, Sandy, one minute,
6 but I think that was three minutes ago you showed me two
7 minutes. Thank you.
8 So this led to a more explicit consent process.
9 We could make sure that people understood that they
10 weren't going to know about health outcomes by
11 participating in the study. We're able to emphasize that
12 this is an exposure assessment study. We know that in
13 our provider group, as we address results communication,
14 that we don't just -- we must not only talk about the risk
15 from chlorpyrifos, and the consequences, but we also have
16 to figure out a way to direct people to local resources to
17 address their needs around diabetes and address their
18 needs around asthma that they particularly feel impacted.
19 So it was very worthwhile information for us, as we think
20 about how to work with providers.
21 You know, we identified a good source of
22 information for how to organize personal results and
23 identify some graphic options to eliminate that have been
24 used in other studies. And again, in emphasizing the
25 importance of partnerships, when we leave people need to

1 be able to participate in other ways and to have outlets
2 for doing the policy types of actions that they want to
3 do. So those relationships are important.
4 I'm going to stop. I should just tell you that
5 we have a group of providers from both --
6 --o0o--
7 MS. COPAN: -- the Imperial county and Tulare
8 that are basically volunteer providers, who are
9 physician's assistants in Tulare county, who are a husband
10 and wife team, who are both physicians in Mexico and
11 physician's assistants in Tulare. In Imperial county we
12 have a physician and a nurse that we have within our State
13 program. Rachel and Rupa and Eric Roberts from the
14 Tracking Program and Michelle Wong and Galatea King and
15 myself will be participating in developing materials for
16 the results communication.
17 And so what we'll -- just briefly, we're going to
18 have to develop a results interpretation protocol, develop
19 an individually tailored report-back mechanism for that
20 person, and develop a letter that people can understand.
21 And the community teams will be, you know, engaging with
22 us in conversations and relevant reading. I'm hoping that
23 some of them are listening in this morning to this
24 framework for thinking about results communication,
25 provide feedback and guidance on the protocols to the

1 State steam as we develop these, and that ultimately
2 they'll be communicating results. And we want to learn
3 from them what their experience has been.
4 --o0o--
5 MS. COPAN: And just very -- honestly this is the
6 last slide. We've had the opportunity, Imperial county,
7 to really look at some of the aspects of literacy in our
8 consent form. And so the limitations need to be clearly
9 defined. The reading level needs to be -- we had a
10 consent form that was between a sixth and eighth grade
11 reading level. A long the consent process, which we did
12 in groups, people were able to make decisions along the
13 way, as to whether they wanted to donate their urine to
14 research after the tests were conducted, whether they
15 wanted their personal results back about perchlorate in
16 drinking water and perchlorate in locally groin
17 vegetables, and whether they wanted the results back for
18 urine. And across the Board, the 31 participants wanted
19 to do all three of those things.
20 And I've said quite sufficient amount of
21 information about community collaborations.
22 Sorry for going over. I guess we all have.
23 CHAIRPERSON MORENO: All right. Thank you very
24 much for that presentation. Let's take a couple of
25 questions from Panel members.

1 Dr. McKone.

2 PANEL MEMBER McKONE: Tom McKone. Thank you.

3 That was very interesting really again. I think all of

4 the presentations have been very effective in carrying

5 across the message that, you know, the quality of the

6 science really depends on knowing how to work with the

7 communities.

8 It's no longer a situation where we can stand at

9 a distance and collect information and call it objective.

10 We really have to know how to work with the communities or

11 else they won't, you know, trust what we're doing with the

12 information and then the quality will go down.

13 So I think you made clear, you know, the

14 significant the quality of the science is really related

15 to these sort of relationships. I had a comment was you

16 mentioned that actually the histograms are the ones that

17 people related best to, in terms of understanding -- I

18 raise this, because 10 years ago I was at a meeting with

19 EPA, where they did a study -- a different study trying to

20 look at how communities and policy makers understand

21 variability and uncertainty.

22 And in that case, I think it's about the same

23 finding, but they found out that a box -- an enhanced box

24 and whiskers, where there's a really big box showing like

25 the 50 percent range, and then smaller boxes on top of

1 that, and then tried to point arrows on where the people
2 are. But something that shows mass and volume and area is
3 easier for people to relate to than something that just
4 shows dots or a curve. Curves are very hard to
5 understand. A cumulative probability plot fails
6 miserably.
7 But something that shows area and mass, in terms
8 of where things are located seems to work. So I don't
9 know if that's consistent -- I don't know if we're in the
10 same track a decade later or --
11 MS. COPAN: Well, I don't know who the
12 participants were in the graphic that you described. So
13 it really depends on who the participants were and that
14 it's difficult to make generalizations for, you know --
15 California is such a diverse state, that I think it
16 behooves us to test out different types of information
17 with different populations within California.
18 But I have to confess my ignorance, I don't know
19 what a histogram is, but if it's a bar chart --
20 (Laughter.)
21 PANEL MEMBER McKONE: Yes.
22 MS. COPAN: -- then, yes, the answer is yes.
23 (Laughter.)
24 PANEL MEMBER McKONE: Bar chart, sorry.
25 CHAIRPERSON MORENO: Dr. Bradman.

1 PANEL MEMBER BRADMAN: I just have a brief
2 comment and then kind of a picky questions.
3 Can everyone hear me?
4 PANEL MEMBER BRADMAN: I have a brief comment and
5 then kind of a picky question.
6 Just the brief comment is that there's a lot of
7 rich Information here and I appreciate all the information
8 that's been presented. And at the end, your point to kind
9 of highlight the consent form. And I think it's important
10 to understand that the consent form is kind of -- consent
11 is a dynamic process that goes on between the researcher
12 and the staff and the participant, and that it's not
13 just -- it's kind of a living document that the consent
14 form is a basis for conversation with the participant.
15 And it's during that conversation that really the
16 parameters of the study are defined. And hopefully it's
17 the beginning of the relationship between the participant
18 and the study.
19 My picky questions, sorry to zero down. But in
20 the bar graph that you presented, which people found easy
21 to understand, we've been grappling with how do you take a
22 biological concentration and compare it to a standard. In
23 some of the worked that Rachel talked about, she made
24 comparisons to an EPA standard for environmental
25 concentrations.

1 And it's not so easy to take something like a
2 reference dose and convert that to a microgram per
3 litter -- the units in here are a little too small for me
4 to read right now.
5 But I'm curious what process went to define those
6 levels? And should --
7 MS. HOOVER: Can you repeat the question for the
8 audience.
9 MS. COPAN: Can you put that chart up? Would
10 that be possible.
11 PANEL MEMBER BRADMAN: Because it talks in here
12 about an EPA-acceptable level for TCPY in urine. And as
13 far as I know, I don't know of an EPA-defined acceptable
14 level.
15 MS. COPAN: For pregnant women?
16 PANEL MEMBER BRADMAN: Well, for pregnant women
17 and for men.
18 MS. COPAN: I have to tell you that these -- the
19 three of these are not -- these are three graphs that have
20 been used in biomonitoring studies that have been well
21 publicized. The one on the left is actually from a PANNA
22 study that is exactly like the one that we're doing. We
23 weren't involved with it. It was from four years ago.
24 And the way that they described it were through
25 these lines across the bar. And I don't know, because we

1 didn't develop this graph, we're looking toward these
2 graphs for -- you know, for hints about what we should
3 develop. And when we do develop graphs for communicating
4 results in these two projects, we'll be sure to focus
5 group test them before pilot test them with individuals to
6 have them learn about what the results are.
7 And really the provider team will be deciding,
8 you know, what are the reference levels that should be on
9 these graphs in order to make that comparison.
10 PANEL MEMBER BRADMAN: Okay. And just something
11 to think about, defining an acceptable level or reference
12 level for something like a biological concentration could
13 be controversial.
14 MS. COPAN: This is -- I think what this is, is
15 these are air -- these are air -- results in air.
16 PANEL MEMBER BRADMAN: It says urine right here.
17 And I understand now that this was an example.
18 MS. COPAN: Okay. Well, the bar graphs are the
19 participant's results in urine. The levels -- the lines
20 that are indicated here are the results in air.
21 That's what I understand anyway. My apologies,
22 if it's not really clear. Again, I'm taking information
23 from other sources and using it. And my apologies if they
24 have their own level of difficult in error.
25 MS. LEE: I think it's fair to say that the use

1 of comparison values is certainly an issue for anyone
2 involved in biomonitoring. And this is something that the
3 staff at the Office of Environmental Health Hazard
4 Assessment will be focusing on in future sessions of the
5 Scientific Guidance Panel meeting. So it will come up
6 over and over, I assure you.
7 PANEL MEMBER BRADMAN: Just to highlight here.
8 This is not just a comparison to something like NHANES.
9 It's actually taking the next step in estimating dose.
10 MS. LEE: Definitely. And this is, you know,
11 these procedures for deriving comparison values need to be
12 considered carefully. And that's why future sessions -- I
13 mean, we know that this is part of our work definitely.
14 MS. COPAN: Right. And just to comment that in
15 terms of -- because these studies collect environmental
16 data as well, such as air data, perchlorate levels in
17 drinking water, perchlorate levels in food, we will be
18 have to figure out ways of communicating all three of
19 those, the urine and in the monitoring.
20 CHAIRPERSON MORENO: Okay. Well, thank you.
21 PANEL MEMBER KAVANAUGH-LYNCH: That's okay.
22 CHAIRPERSON MORENO: If you maybe can ask the
23 Panel together after our presentation.
24 Thank you very much.
25 Okay. Our next speaker is Dr. Asa Bradman. Dr.

1 Bradman is speaking on returning results to participants
2 in the CHAMACOS, which is Center for Health Assessment of
3 Mothers and Children of Salinas growth cohort study.
4 (Thereupon an overhead presentation was
5 Presented as follows.)
6 PANEL MEMBER BRADMAN: Thank you for having me
7 speak today. I just want to say I'm not sure how much new
8 I can add today after the presentations we've had. So I'm
9 going to try to zip through pieces of this and hopefully
10 leave more time for discussion. I'll be talking about
11 returning results in -- can everyone hear me.
12 DR. McNEEL: No. Just project, that would be
13 great.
14 PANEL MEMBER BRADMAN: I don't have the strongest
15 voice. I'm thinking of taking an acting class actually to
16 project more.
17 (Laughter.)
18 PANEL MEMBER BRADMAN: Okay. So returning
19 results in the CHAMACOS study. CHAMACOS you've heard is
20 the Center for the Health Assessment of Mothers and
21 Children of Salinas. CHAMACOS also means small child in
22 Mexican Spanish, which was something that we came up with
23 in partnership with our community to kind of define this
24 project.
25 --o0o--

1 PANEL MEMBER BRADMAN: Just very quickly, I want
2 to highlight. There's a lot of people involved in this
3 project, both locally in Monterey county, where we're
4 centered and also here in Berkeley.
5 I want to particularly highlight Brenda Eskenazi
6 who's the Director and Kim Harley who's now working very
7 hard on this study, and also Tom McKone has been involved
8 for years in the exposure piece of this.
9 --o0o--
10 PANEL MEMBER BRADMAN: So an outline of what I'm
11 going to talk about today. I'm going to just describe
12 quickly what CHAMACOS is, and then really just provide our
13 experience as a case study for doing research, and
14 returning results. And some of the issues it might raise
15 for the Biomonitoring Program.
16 --o0o--
17 PANEL MEMBER BRADMAN: Briefly, CHAMACOS is a
18 community university partnership. We've defined community
19 broadly. We work with a number of national laboratories,
20 environmental agencies. We've also worked with State
21 agencies like the Department of Public Health. Locally,
22 we've worked with advocacy groups like CRLA, and grower
23 representatives, like the grower-shipper association.
24 We also have a number of individuals and
25 community members involved, and also locally based medical

1 providers and farmworker groups, like the South County
2 Outreach Effort. So we have a fairly broad coalition of
3 people who are involved in this project.
4 --o0o--
5 PANEL MEMBER BRADMAN: Again, we're located in
6 Monterey county. We're focusing on the Salinas valley of
7 California. Our primary focus started on organophosphate
8 pesticides, which are used heavily in the region, almost
9 year round, where there's quite intensive row crop
10 growing, lettuce, strawberries, and things like that.
11
12 --o0o--
13 PANEL MEMBER BRADMAN: So this study, in some
14 ways, has the characteristics of investigator-initiated
15 project. And also, in many ways, the characteristics of a
16 community-based research project. In fact, different
17 pieces of this fall into that spectrum.
18 When we started this project about 12 years ago,
19 13 years ago, actually before we began the project, we
20 went out and conducted a community assessment. We talked
21 with medical providers, and we began to define a study
22 with the local community.
23 Some of the comments we got back, I just want to
24 emphasize, and this may be a bit repetitive to what we've
25 heard. But one, some of the -- one, people really wanted

1 to know how they environment is affecting them.
2 They want to get access to the results. And they
3 want to make sure that we are going to stay in the
4 community and follow up, that we weren't going to do a
5 study, provide results and disappear. And those were some
6 of the key messages that we got back.
7 --o0o--
8 PANEL MEMBER BRADMAN: And we've tried to fulfill
9 those requests.
10 A last piece that was important was that we
11 should hire people who can work effectively with the
12 community, that were from the community. And in many
13 ways, our staff and our project is very representative of
14 the Monterey county, Salinas valley community.
15 --o0o--
16 PANEL MEMBER BRADMAN: So just very quickly about
17 the study. Our primary objectives have been to assess
18 exposures to pregnant women and children; determine the
19 relationship with a number of health outcomes; and then
20 we've done studies and programs to try to reduce
21 exposures.
22 --o0o--
23 PANEL MEMBER BRADMAN: It's a longitudinal birth
24 cohort study. We enrolled 600 pregnant women. The
25 children now are turning nine. We have a number of

1 contacts that have involved neurobehavioral assessments,
2 questionnaires. We've also collected many, many samples.
3 At this point we have about a hundred thousand samples or
4 more archived. And we've done a number of measurements in
5 those samples, looking at both exposure and health outcome
6 --o0o--
7 PANEL MEMBER BRADMAN: Briefly, and in this talk,
8 we'll be concentrating on the dialkyl phosphate
9 metabolites, which are a metabolite of nonspecific
10 metabolite for a class of organophosphates. And I'm going
11 to highlight some points related to these measurements
12 that present some challenges to us for results
13 communication and also will be more generally applied to
14 the Biomonitoring Program.
15 So just very quickly -- you don't need to
16 memorize this, there's a lot of OPs used in the valley,
17 organophosphates. There's also two classes, diethyls and
18 dimethyls. I'm not going to go into details like that,
19 but there are some issues in how these different
20 metabolites behave.
21 --o0o--
22 PANEL MEMBER BRADMAN: We've been using the
23 measurements to look at exposure over time. These are
24 measurements during pregnancy. And then in the children
25 up to five years of age, on reference -- it references the

1 NHANES results for women who participated in NHANES and
2 also children age six to eleven. You'll notice the NHANES
3 children ages don't actually overlap with participants in
4 our study. And you'll hear later about how the importance
5 of us being able to make comparisons to NHANES as a means
6 for us to communicate results.
7 --o0o--
8 PANEL MEMBER BRADMAN: We've also looked at
9 potential exposure factors, what explain the exposures,
10 diet seems to be important. We've actually replicated
11 that study on organic food that Rachel talked about.
12 --o0o--
13 PANEL MEMBER BRADMAN: We've also looked at a
14 number of health outcomes. In this case, we're looking at
15 Bayley's in two years old.
16 --o0o--
17 PANEL MEMBER BRADMAN: So we've generally used
18 this biomonitoring data in a number of contexts that are
19 likely to be the same uses that will go on for the State
20 biomonitoring Committee.
21 We've tried to characterize exposure, look at
22 trends, identify predictors, and estimate risks. We're
23 also looking at health risks. I'm sure the State program
24 may ultimately engage in looking at health risks in
25 relation to exposure, although I don't think that's

1 written into the legislation.

2 But basically, everything we're doing is likely

3 to overlap with the kinds of activities that the State

4 program will do.

5 --o0o--

6 PANEL MEMBER BRADMAN: So some case studies here.

7 Well, this is really one case study with different

8 components of the challenges we faced in returning results

9 --o0o--

10 PANEL MEMBER BRADMAN: Initially, and I guess

11 this is 12 years ago. And the IRB At Berkeley has --

12 certainly in our experience has changed a bit. But the

13 IRB initially was very unsupportive of us in returning

14 results. Among Brenda and myself, I think was kind of a

15 basic feeling that it's important to return results, that

16 people have a right to that information.

17 And our IRB didn't agree with us. In fact, this

18 is an example statement we got. "Test results for

19 individual subjects are not meaningful, likely to cause

20 unnecessary alarm. Members felt strongly that subjects

21 only be provided with a copy of the manuscript." And

22 that's a quote.

23 Today, that sounds like an unreasonable way of

24 approaching returning results. But it's not

25 uncharacteristic of what we faced. And I think it falls

1 into the spectrum of what was described earlier of what we
2 would call clinical ethics.
3 --o0o--
4 PANEL MEMBER BRADMAN: And at that point, the IRB
5 was thinking that way.
6 However, IRBs are dynamics. And they're very
7 engaged in their research community. The staff
8 particularly are very engaged with the research that
9 people are conducting. We had a number of meetings with
10 the IRB. And they agreed to reevaluate that decision,
11 dependent on us working with the community to develop a
12 strategy to return results.
13 So we can convened several meetings with a range
14 of both partners -- research partners in the study, also
15 general members of the community and those on our
16 community advisory board.
17 Just an example up her, we have the growers in
18 the upper left, grower organizations, medical providers,
19 farm worker groups, advocacy groups and also the ag
20 commissioner.
21 --o0o--
22 PANEL MEMBER BRADMAN: So, some of the results of
23 that experience. One, doctors strongly objected to
24 returning individual results. And that fits exactly
25 within the framework that Rachel talked about.

1 There was concern about doing harm to
2 individuals, i.e. causing unnecessary alarm. And also
3 they were very concerned about the burden of interpreted
4 non-clinical tests. All of them were in a period when
5 managed care was coming in in Monterey county, and they
6 did not want to spend responding to questions that they
7 couldn't answer, which we felt was very legitimate. I
8 mean, they are really up against the wall and
9 overburdened, particularly in these nonprofit community
10 based clinics.
11 Advocates, as you might, expecting, strongly
12 supported returning individual results. Basically, a
13 right to know issue. Industry also supported returning
14 individual results. They also saw it as an individual
15 rights thing. So really our biggest challenge was coming
16 up with a strategy that would assure the medical staff
17 that they wouldn't be overburdened by this, and then also
18 address some of the concerns of our IRB.
19 --o0o--
20 PANEL MEMBER BRADMAN: There were kind of three
21 things that changed the views of IRB and satisfied the
22 medical staff. One was that we would return the results
23 in person. And this had to be done verbally, and there
24 was not going to be any sort of -- there was an
25 opportunity to explain what we were doing, and therefore

1 address any concern or alarm.

2 We were also -- I shouldn't say required by the

3 IRB, but we also said that we would place the results in

4 context of research, i.e. these were not clinically

5 defined tests. Therefore, we cannot use it to make

6 statements about health risks or implications for

7 individuals. And that's probably a point of discussion

8 there, I think, in this group.

9 Another key point for our IRB and the medical

10 people was that there was an ability to compare the

11 results to national reference data. In fact, NHANES

12 hadn't come out yet, when we started this, but during this

13 community engagement process, the NHANES report started

14 coming out and that actually provided assurance to people

15 that we had some comparison to a group outside our study

16 area, that we could provide some meaningful comparison or

17 relationship. And that actually was a key point in

18 enabling us to go ahead, work with our IRB and come up

19 with a process to return results.

20 --o0o--

21 PANEL MEMBER BRADMAN: So the final approach,

22 which was accepted by IRB, was that we would return

23 results -- I should mention here that we had participants

24 opt in. During the consent process they were told about

25 this study, and they were asked whether they would or

1 would not like results. And if they asked for results,
2 then we planned to give to them.
3 The participants were informed in person -- these
4 were the criteria that were defined with us and the IRB --
5 that they would be informed in person -- we're actually
6 not allowed, at this point, to do it by phone, or by
7 letter. The result -- and again, we're talking about
8 individual results here -- that they were placed in
9 context of population and reference data, i.e. NHANES.
10 That we emphasized the research context. We also planned
11 to offer and agreed to offer follow-up testing for anyone
12 who requested it.
13 Our own priority, of course, was to make sure
14 that people understood the results, but they didn't feel
15 stigmatized, i.e. my exposures are higher. And if we were
16 testing for a substance with a known risk, i.e. lead,
17 which we worked on with the State Health Department, we
18 would follow clinical guidelines. And lead, of course, is
19 an easy one, because there's fairly standard guidelines at
20 this point. Although, we know that those guidelines may
21 change.
22 And again, I want to emphasize that the consent
23 process -- this whole effort really began in our exchanges
24 with the IRB. And it ended by coming up with a consent
25 form that involved a conversation with participants. And

1 I really want to emphasize the importance of that
2 conversation.
3 --o0o--
4 PANEL MEMBER BRADMAN: There's a number of
5 challenges with regard to return results, and some of
6 those have already been touched upon. One, you have to
7 budget staff for in-person -- time and staff for in-person
8 meetings. It's time consuming, and it needs a budget.
9 Research staff must be blinded to results. This
10 was a challenge for us, because we're doing health
11 assessments and we can't have our staff, who are doing
12 health assessments, also knowing what people's individual
13 results were.
14 We have a skeleton staff at this point. And
15 that's created some challenges, because we can only have
16 certain people who can actually give results. Initially,
17 very few people were requesting results, less than five
18 percent.
19 This is a longitudinal study, so we see people on
20 a repeat basis. And we also now have much of our data in
21 our field office in an accessible form. So now, as we
22 reconsent people, we ask them, do you want your results
23 now? And almost everyone says yes. So, at this point,
24 about 60 percent of our participants have received
25 individual results.

1 And as we go through the nine year assessment,
2 where we start catching up with people who we missed at
3 the seven year and earlier, I think probably this number
4 is going to go up to somewhere between 90 and a hundred
5 percent, that most will be getting their individual
6 results.
7 --o0o--
8 PANEL MEMBER BRADMAN: I want to highlight some
9 technical challenges about the meaning of exposure data.
10 And I should emphasize here that we haven't addressed
11 these in our relation -- in our talks with participants.
12 But they're in the background, and I'm not quite sure -- I
13 think somehow they do need to be dealt with.
14 This alludes to my comment earlier, for many of
15 these chemicals measured in biological samples, there's no
16 known standard to define high exposure for biomonitoring.
17 There's no clinical guidelines. You can take things like
18 RFD or a benchmark, you can make assumptions about
19 excretion, you can estimate dose, but all of those involve
20 modeling. They're controversial. And there's no -- at
21 least as far as I'm concerned right now, there's no easy
22 way to take many of these compounds and convert them to
23 what would be a quoted unquote, you know, hazard quotient
24 over one or under one or someone on a continuum. And
25 that, I think, is a real challenge.

1 Our emphasis has been this is for research. We
2 don't know what it means. We hope in the future that this
3 will help inform policy and public health practice.
4 Biomarkers may not actually rereflect exposure.
5 I talked about the dialkyl phosphates, the DAPs. And this
6 is true for many of the other things that will be measured
7 in this program, for example, TCPY and other metabolites.
8 Probably also true for pyrethroid metabolites.
9 The DAPs themselves are in the environment. In
10 other words pre-form DAPs may be in the environment. The
11 participants my be exposed to the pre-formed DAP. And
12 what you're measuring in your urine reflects exposure to
13 the DAP itself, and exposure to the parent pesticide
14 compound.
15 So intrinsically, there's a limitation there in
16 the quality of your biomarker, which raises a lot of
17 issues about risk assessment.
18 We've done some work on that with -- I
19 shouldn't -- that's a mistake here. This is was done in
20 Dana Barr's laboratory, but we've done some work showing
21 that these DAPs are in the environment. I shouldn't --
22 the lead author on that was a man name Guy Ourisson. I
23 have that paper, but anyway just to emphasize that point.
24 --o0o--
25 PANEL MEMBER BRADMAN: Some other issues. And

1 this particular applies to nonpersistent compounds, which
2 we've been focusing on. There is good correlation within
3 a day of someone's measurements. But there's not
4 necessarily good correlation over several days. Let me
5 give some concrete examples here. When we look at the
6 correlation of a spot and a 24 hour urine sample collected
7 on the same day, the correlation is about.7. Not bad.
8 When we look at the correlation of samples over several
9 days, a day apart the correlation is .3. Two days apart
10 it's .3. Three days apart, it basically attenuates to
11 zero
12 --o0o--
13 PANEL MEMBER BRADMAN: If we look at levels of
14 these particular DAPs in 24 hour urine sample collected
15 three days apart, the correlation was just .1.
16 --o0o--
17 PANEL MEMBER BRADMAN: So to put this
18 graphically. This graph can be a little hard to
19 understand. I don't know if I have a point -- I don't
20 have a Pointer here.
21 These are levels in an individual of 24 hour
22 samples of DAPs taken three days apart. This is on a log
23 scale. So if you look at some of those big lines, the
24 bottom is the low and the top is the high.
25 And on the left that's on a log scale. So for

1 some people three days apart, their metabolite levels
2 change by two orders of magnitude. Whereas, some people
3 they changed almost not at all. Most people changed
4 around half or, you know, a full order of magnitude so.
5 Just to underscore their there's a lot of variability.
6 In these and while we haven't addressed that and
7 how we're returning results, there some issues about
8 whether what you're -- the information you're giving to
9 people is meaningful
10 --o0o--
11 PANEL MEMBER BRADMAN: In fact, in some cases, it
12 may be meaningless in terms of their overall exposure.
13 --o0o--
14 PANEL MEMBER BRADMAN: I'm not going to go into
15 details here, but we feel strongly that recording results
16 to the individual is one part of reporting results to the
17 general community. And that means engaging, research
18 partners and advisory boards. It also means providing
19 participant forums and opportunities for groups of
20 participants to come to meetings and hear about the study
21 results.
22 And we often limit those just to participants.
23 So they're in a situation where they can ask about their
24 own participation in the study, and what this study has
25 found. And then, of course, we have a number of general

1 community presentations to different groups, churches,
2 migrant, things like that. But again I want to emphasize,
3 the general community efforts in communication, I think,
4 are part and parcel of the process of returning results.
5 --o0o--
6 PANEL MEMBER BRADMAN: So just a quick synopsis
7 here. And this reiterates some of the things that have
8 been talked about important. It is important to work
9 ahead of time with potential participants in communities,
10 to understand what people need and how they can best
11 receive the information. Address concerns of
12 constituents. Again you've got to budget resources and
13 time for people to return results.
14 The IRBs should be looked at as a dynamic
15 organization that you have to build a relationship with.
16 And there may need to be some interaction to educate them
17 on what you're doing and gain those approvals. And
18 hopefully use that to, you know, define -- I think
19 ultimately define best practices, which was a lot of what
20 was discussed earlier today.
21 And then again, it's important to understand the
22 limitations of biomonitoring data and challenges about
23 what they actually mean, both in terms of an individual
24 measurement, and then also in terms of referring to other
25 kinds of reference data or health benchmarks.

1 --o0o--

2 MR. BRADMAN: So just a quick thanks to your

3 funders. We've had a funding from NIEHS and EPA

4 primarily, also NIOSH and a number of foundations as well.

5 --o0o--

6 PANEL MEMBER BRADMAN: So I think I'm on time.

7 So I'm happy to take questions.

8 CHAIRPERSON MORENO: Thank you, Dr. Bradman.

9 A cup of questions from Panel members, before we

10 take a break?

11 Dr. Wilson.

12 PANEL MEMBER WILSON: Thank you, Asa. That was

13 really interesting as always. And I'm wondering if --

14 that maybe it's too early in the contemporary

15 biomonitoring arena that we've been in, in the last five

16 to ten years. But if there is anything that has been

17 written or published on the efficacy of differing

18 communication approaches in communication to communities

19 and community groups as to action that was taken or not

20 taken by those communities in response to that

21 information. And, you know, perhaps maybe this is

22 something that Julia will address, I don't know, but if

23 there's literature pointing to actions taken in work

24 places, for example, in response to information on lead

25 levels or so forth relative to other kinds of

1 communication. Do we have any knowledge about the
2 efficacy?
3 PANEL MEMBER BRADMAN: Well, anecdotal
4 information?
5 PANEL MEMBER WILSON: Say again?
6 PANEL MEMBER BRADMAN: I have some anecdotal
7 experiences.
8 PANEL MEMBER WILSON: Okay.
9 PANEL MEMBER BRADMAN: You know, I mean, one --
10 some of the growers actually after -- some of our studies
11 and presentations started providing chairs for people to
12 have lunch, sit on to have lunch, so they're not sitting
13 in the fields, and provided umbrellas for shade, pretty
14 basic. But the point was, was to keep them out of the
15 fields when they're eating.
16 There's some local groups that are developing
17 some housing initiatives, housing quality initiatives that
18 we're participating in that relate to some of the work we
19 did on housing quality. And that actually is a direct
20 outgrowth of -- we've gone into over 2,000 houses now and
21 done inspections.
22 Some of those strawberry growers that we've
23 worked with are using gloves for pickers to reduce
24 transferable residues, which we've shown it definitely
25 reduces exposure. The glove use is also related to their

1 concerns about biological contamination. In fact, I think
2 the dissemination of gloves and strawberry picking across
3 Monterey probably has more to do with concerns about
4 biological contamination than pesticides.
5 But there was some response to the work that we
6 did on pesticides that at least generated interest. I
7 think in response to our study, a lot of pickers were lot
8 interested in using gloves, but it wasn't until the
9 biological issues came up that the growers started
10 providing gloves.
11 So there have been some kind of anecdotal
12 responses. We haven't gone out and, you know, assessed it
13 formally. We've talked about doing that. Rachel and I
14 have talked about doing that. We haven't talked formally
15 with participants about their results. Our sense is, is
16 that people appreciate the opportunity to talk on a
17 one-on-one basis in a private setting about what we found
18 about them and about the study in general.
19 And we have not had any issues about people being
20 unduly alarmed or concerned. I think there is the
21 potential for that. You know, the physicians were
22 concerned about do not -- do no harm and that information
23 can hurt people. I actually agree that that's possible,
24 but I think that concern is, in some ways, trumped by the
25 individual right to know.

1 CHAIRPERSON MORENO: One more question from Panel
2 members.
3 Dr. Quint.
4 PANEL MEMBER QUINT: Julia Quint. I don't have a
5 question. I just wanted to respond in part to Michael.
6 I'll get into this more with my presentation, but the
7 workplace is different in the sense that actions or the
8 responsibility of the employer if the biomonitoring is a
9 part of the workplace assessment. You know, the employer,
10 even if the regulation isn't protective per se still has a
11 responsibility to prevent, you know, material impairment
12 of health to the worker, you know, over the working
13 lifetime.
14 So really it's -- there is, you know -- there is
15 somebody who has responsibility for making changes to
16 protect workers in those situations. Often, it doesn't
17 happen. You know, there are other things too, in terms
18 of, you know, workers have -- by law have to have their
19 exposure results when they're done in an investigation of,
20 you know, exposures in the workplace. So that's mandated.
21 And the exposure monitoring can be done in the
22 presence of a worker representatives. So the union can be
23 involved if there is a union, so there is an opportunity
24 for more than the individual to respond to the data if it
25 shows -- if the data showed that, you know, there is

1 over-exposure. All of these things are very complicated
2 though when you don't have protective standards. And I'll
3 talk about that.
4 CHAIRPERSON MORENO: Dr. Culver, and then we'll
5 break.
6 PANEL MEMBER CULVER: Just a short addendum to
7 what you said, Julia. The manager or the supervisor in
8 industry needs an awful lot of education. And the
9 communication to the management group is a very tough
10 thing to do in industry. The worker communication
11 requires more than just giving them an MSDS, the Material
12 safety data sheet and saying do this. It takes a great
13 deal of education of the worker to allow the worker to
14 comply with the information that's available about his
15 protection.
16 So the industry or occupational setting is a very
17 interesting setting for communication, health
18 communication.
19 CHAIRPERSON MORENO: All right. Thank you.
20 Thank you, Asa. We're going to go ahead and take
21 a break now. And it's -- on this clock, I've got 20 till
22 11, so if we could take a 10 minute break we'll be back
23 here and start again at 10 till 11.
24 Thanks.
25 (Thereupon a recess was taken.)

1 CHAIRPERSON MORENO: We're going to get started
2 in just about a minute here.
3 Okay, if people could please take their seats,
4 we'll get started.
5 All right, welcome black. We're going to move on
6 to our next presenter, Dr. Julia Quint, who will be
7 discussing biomonitoring within occupational settings.
8 (Thereupon an overhead presentation was
9 Presented as follows.)
10 PANEL MEMBER QUINT: Hi. Thanks a lot for
11 letting me talk to you about occupational biomonitoring.
12 And I am going to do two things, or maybe three things.
13 First of all, just to -- because occupation --
14 biomonitoring in occupational settings tends to be, for
15 many reasons, a bit different from, you know,
16 biomonitoring for general populations. So I'll try to
17 give you a background of what those differences are just a
18 brief overview of just biomonitoring, occupational
19 biomonitoring.
20 And then to give you three examples of how it's
21 used. It's used probably many other ways, but I've picked
22 out three examples. And then to talk about the different
23 ways that the results are interpreted and communicated for
24 those -- in those three different examples.
25 --o0o--

1 PANEL MEMBER QUINT: So lots of folks are
2 involved in occupational biomonitoring. This is a
3 definition that was taken from a report by the
4 International Union of Pure and Applied Chemistry. This
5 is an organization of many countries. The representative
6 from the U.S. is the National Academy of Sciences. In the
7 UK it's the Royal Society of Science. So, you know, these
8 are prestigious scientists who are also interested in
9 occupational biomonitoring.
10 And in 2000, they wrote a report on
11 recommendations for Volatile Organic Chemicals, looking at
12 how it was done in many different countries, the analytes
13 and things like that. And this definition is pretty close
14 to -- it's not that different from biomonitoring for
15 general populations, except that, you know, there is an
16 emphasis on evaluating exposure, and the health risk. And
17 I'll talk about occupational biomonitoring and its history
18 and why that is true.
19 So when you talk about occupational
20 biomonitoring, you're all -- you are talking about giving
21 information back on exposure and some information on
22 health risk.
23 --o0o--
24 PANEL MEMBER QUINT: So it's been conducted for a
25 long time. The action levels that I'll be describing in

1 more detail for the U.S. date back to the 1980s. And so
2 occupational biomonitoring is just one way to access
3 exposure and health risk. And as we know for other
4 biomonitoring, it's not a measure of an adverse health
5 effect.
6 And it does allow, as when you do it in general
7 populations, for integrated exposure. This is
8 particularly important for in occupational settings,
9 because for a number of the chemicals that we have
10 exposure limits for legal exposure limits for, there's
11 skin notations.
12 That means that the chemical can be absorbed
13 through the skin. And those are noted by -- there's a S
14 notation by those particular chemicals, not so much in
15 environmental health. But in occupational health, that
16 really highlights that you can be exposed by inhalation,
17 which is the normal route of exposure, but skin absorption
18 is a problem as well.
19 So when you do biological monitoring, unlike air
20 monitoring, you can really assess the amount of the
21 chemical that's going through the skin, as well as other
22 routes of exposure. So that's important.
23 And it tells you, not only about body burden,
24 which we also find out about in biomonitoring of general
25 populations. But in environmental health, you know, you

1 have protective equipment. Asa talked about gloves. For
2 many chemicals that have skin notations, the employer has
3 to provide, you know, protective gloves.
4 A lot of these gloves have break-through time, so
5 that the chemical can then break through. So
6 biomonitoring will give you an assessment of that.
7 It also assesses non-work exposure. And the way
8 in which the sampling is done, you can get at what the
9 body burden was before the work exposure began.
10 And during the 9/11 incident, there was a big
11 biomonitoring study done by NIOSH, and I think Mount
12 Sinai, that looked at first responder exposure after the
13 incident and the body burden of several chemicals. So
14 it's very, very useful.
15 --o0o--
16 PANEL MEMBER QUINT: What are some of the
17 underlying issues?
18 It's, in it's essence, an industry hygiene tool.
19 And industrial hygiene, you know, that whole discipline
20 has to do with keeping the workplace, you know, clean, in
21 its simplest terms, and to prevent harmful exposure. So
22 biomonitoring is rooted in industrial hygiene.
23 --o0o--
24 PANEL MEMBER QUINT: And there are guidance
25 values that are used as action levels for most of the, you

1 know, in occupational biomonitoring. I'll talk more about
2 those. And you have to look at those with caution. I
3 mean occupational biomonitoring is used as an example of
4 how you can really relate the internal exposure to the
5 external exposure, because they're very much correlated
6 with air monitoring.
7 But a lot of the, you know, limits, the air
8 limits, against which you measure -- or that are used to
9 compare the internal exposures are not protective against
10 chronic health hazards. So that has to be kept in mind
11 when you're looking at that.
12 --o0o--
13 PANEL MEMBER QUINT: Sampling is based on the
14 pharmacokinetics of the chemical or toxicokinetics, how
15 much is absorbed, that half-lives and things like that.
16 You want to sample the workers at time when you know
17 you're going to be getting at the metabolite or the parent
18 compound that's present.
19 --o0o--
20 PANEL MEMBER QUINT: And there's a lot of
21 variability, because the chemicals -- that's where the
22 pharmacokinetics comes in. You know, the chemical --
23 you're different individuals depending on age, disease,
24 state, pregnancy, all of those things can affect --
25 especially if it's a metabolite that you're measuring, how

1 much metabolite you're getting.

2 So when it comes to the workplace because are

3 these individual differences, you need to protect the

4 workers' rights, because, you know, even for -- because

5 they could be used to discriminate against individual

6 workers. So it's very, very important. And almost all of

7 the countries that use biological monitoring, this is a

8 component that people pay attention to. And I'll give you

9 an example of how that's done in the UK.

10 And the other thing that I talked about earlier

11 that's different from general population biomonitoring is

12 that the workers -- the employers are responsible for

13 keeping the workplace safe for workers. And that's true

14 even for substances that don't have exposure limits.

15 There is a regulation that puts responsibility on the

16 employer for dealing with chemicals, even if there is no

17 permissible exposure limit for that chemical. And they

18 must make monitoring results available to workers and

19 their representatives.

20 So there is no choice, as in the clinical

21 setting, of not sharing those results with workers.

22 They're entitled to those results.

23 --o0o--

24 PANEL MEMBER QUINT: And, you know, as I said,

25 another distinguishing feature is that we do have guidance

1 values or action levels for a lot of occupational -- so
2 that you can use those to take action once you get the
3 biological monitoring -- the biomonitoring results and
4 occupational settings.
5 Now, in the U.S. and the UK, very few of -- and
6 they're used in various countries. A lot of countries
7 have adopted these guidance values, they're called by
8 different names. And some are done by, as you'll see in
9 the U.S. most of those are by a private organization. And
10 in other countries, like in Germany or the UK, they're by,
11 you know, government agencies or regulatory agencies, so
12 it does vary.
13 The World Health Organization has a list of
14 values that are used by many people in terms of action
15 levels.
16 In the U.S. and the UK, although there are about
17 40 some, as you'll see, guidance values in the U.S., very
18 few of those are mandatory. So they're not tied, even
19 though they're linked to air exposure data, they're not
20 mandatory. They're only mandatory for a few vertical
21 standards, like lead and cadmium, arsenic maybe, but
22 they're not mandatory for a lot of chemicals.
23 So they exist. They are good tools. We have a
24 number of chemicals that can be absorbed through the skin,
25 but it's completely at the discretion of the hygienist or

1 whoever is doing the investigation, as to whether or not
2 biological monitoring -- whether or not that's conducted.
3 The German biological -- their guidance values
4 are called tolerance limits. They're called BATs. And
5 they are technical guidelines that the government actually
6 makes -- they're not -- they're regulatory, in the sense
7 that the employer has to abide by them. They don't have
8 to conduct -- they're encouraged to conduct biological
9 monitoring, but they only are mandatory for chemicals that
10 have dermal absorption.
11 So in Germany, it's a little bit -- they're
12 different. You know, they are a part of the regulatory
13 framework. But the employers need only, you know -- they
14 need only to conduct biological monitoring for chemicals
15 that have dermal absorption.
16 So it varies. And there are many other countries
17 that have them, probably as many different rules as to how
18 they're used.
19 --o0o--
20 PANEL MEMBER QUINT: Now, in the U.S., we have
21 what the most popular guidance values are called,
22 Biological Exposure Indices. BEIs, and they are developed
23 by the American Conference of Governmental Industrial
24 hygienists, ACGIH. And although it has governmental in
25 its name, it's a private organization. That has wreaked

1 havoc, because many people think that this group develops
2 underground regulations. But, you know, it's really not a
3 governmental organization. They just have government in
4 their name.
5 And they have these BEIs for 43 substances. And
6 31 of those -- I started at first to compare the BEIs with
7 the chemicals that are in our Program for, you know,
8 designated or priority chemicals, and quickly learned that
9 a lot of them have notations. So like there are 43
10 substances, but 31 have notations. And I'll talk a little
11 bit more about those.
12 For 21 of those -- and the notations can -- you
13 can have several notations for one substance. So they
14 don't all add up to 43. But for some of the BEIs, there's
15 a notation about that says it's non-specific, which means
16 that it -- whatever the determinant is or the analyte that
17 you're measuring, it's not specific for that chemical. It
18 can also, you know, be measured -- it also can be produced
19 by another substance.
20 A number of them, nine of them, have a notation
21 that says that they're semi-quantitative. So that means
22 that you can use it to identify these substances, but you
23 can't quantify. So that's limiting. And a lot of them
24 have -- 16 of them have a notation that says that they're
25 background. That means that they're non-occupational

1 exposures that contribute to that.

2 Now, these -- that is incorporated into the BEI,

3 so that's not as much of a problem.

4 Now, what do these BEIs represent?

5 It generally represents -- they generally

6 represent levels in healthy workers exposed at the

7 threshold limit values. Now the threshold limit values

8 are those air concentrations that are also developed by

9 ACGIH also non-regulatory.

10 But even more confusing, they're not regulatory,

11 but most OSHA's PELs are basically the same as 1968 TLVs,

12 because they were adopted when OSHA was formed in 1970,

13 and they pretty haven't been updated. Most of Cal OSHA's

14 PELs are the same as the TLVs, because that's usually the

15 starting point for the updating of the CalOSHA PELs.

16 So BEIs are correlated to the threshold limit

17 values. Both BEIs and threshold limit values are

18 developed by a non-governmental agency. But both the

19 threshold limit values and the BEIs are used worldwide in

20 many cases. So many, many countries' regulatory limits

21 are based on TLVs. They are highly -- I mean, they are

22 just used a lot.

23 And so, you know, that has become -- and because

24 OSHA has not updated their permissible exposure limits,

25 it's almost recommended that an ACGIH updates their

1 threshold limit values on a regular basis. And there are
2 transparent documents that, you know -- they have
3 documents that really transparently kind of identify what
4 the threshold limit value is based on. So they're very
5 useful and have become like surrogate standards.
6 Although, the ACGIH is very clear in saying that these
7 are -- these values are to be used -- and I'm talking
8 about the air levels for industrial hygienists. They're
9 not supposed to be the basis of standards.
10 But, in fact, that's how they've been used over
11 the years. And I say that because it's very important.
12 Because of lot of the TLVs are not based on chronic health
13 effects. And so when you compare biological levels to
14 TLVs and then say that that's protecting, because this
15 last statement is very important.
16 BEIs generally indicate concentrations below
17 which there will be no adverse health effects, because
18 it's based on the TLV. The TLV is base on prevention of a
19 certain health effect. You just have to be careful in
20 identifying what that health effect is. Because often
21 it's not cancer. It's not reproductive or developmental
22 effects. So it's a little complicated, but I think it's
23 important to clarify that, because when you interpret
24 results.
25 --o0o--

1 PANEL MEMBER QUINT: Now, unfortunately there's
2 so much light you can't see that. But this is the BEI
3 document for nitrobenzene, and I just cut off part of the
4 top. So this is a full document that explains how you
5 sample and all of that, but I did put the definitions for
6 the notations. And nonspecific -- I can't read it up
7 here -- pretty much says that, you know, it's not -- the
8 non-specific -- okay. I should go over the recommended
9 BEI. See you have the determinant. So for this
10 particular chemical, it's para-nitrophenol in the urine,
11 tells you when to sample, and of shift, and at the end of
12 the workweek. And it gives you the BEI value, five
13 milligrams per gram creatinine.
14 And the one notation there is Ns, so that's
15 non-specific. So it means that the para-nitrophenol in
16 the urine, which is the analyte that they recommend that
17 you measure, and they tell you when to measure it is not
18 specific necessarily for this chemical. I think parathion
19 also has para-nitrophenol.
20 And the BEI is based on methemoglobin. Whereas,
21 nitrobenzene is a carcinogen. It's on the Prop 65 list,
22 so it's not based on the health effect.
23 --o0o--
24 PANEL MEMBER QUINT: Here is lead. Lead is not
25 based on the TLV. It's based on actually health effects,

1 many of which experts now recommend. And the BEI is 30
2 micrograms per deciliter, but a lot of experts now
3 recommend 10. But the BEI is actually based on -- it's a
4 health based number. And it's based on a lot of the
5 endpoints that experts now are saying should -- the level
6 should be lowered to 10, and that's hypertension,
7 cognitive -- spontaneous abortions and a number of other
8 health effects.
9 --o0o--
10 PANEL MEMBER QUINT: So there are three ways that
11 its -- and I don't have much time left. So there's three
12 ways in which these BEIs are used. The three examples I
13 wanted to tell you about are the two standards. It's a
14 component of medical surveillance programs. And that's
15 very important, because it's a part of a medical
16 surveillance program, these biomonitoring values. And the
17 trigger for conducting medical surveillance for lead and
18 cadmium is usually an action level. You have to be over a
19 certain air concentration, and then it's triggered.
20 NIOSH health hazard evaluations are another way.
21 These are evaluations that NIOSH can conduct by law if
22 they get a written request from an employer or an employee
23 representative. And it's usually a request saying we
24 feel -- you know, we'd like to understand -- we are
25 experiencing health problems or we're concerned about

1 health problems and we are trying to -- and we would like
2 to know whether or not it's related to our exposure at
3 work.
4 And in one instance like in investigating
5 symptoms related to 1-bromopropane, NIOSH actually
6 identified 48-hour bromine in the urine as a new
7 biological monitor for 1-bromopropane. It correlated
8 well. So sometimes you can actually identify new
9 biomonitoring methods through that.
10 And then the last one is research studies. And
11 there's one --
12 --o0o--
13 PANEL MEMBER QUINT: -- i'll end talking to you
14 about.
15 And so with the cadmium standard, I mean, this is
16 probably the most comprehensive, in terms of how the
17 biomonitoring is conducted, how the results are used, and
18 communicated and that sort of thing. So I won't go over
19 all of this. But the results are really when the
20 biomonitoring is done, in this case, it's also you use
21 another marker of kidney damage, early kidney damage,
22 which is beta 2-microglobulin. You use those two things
23 in concert, it will tell you how frequently the worker has
24 to be examined. Again, it's triggered by the worker being
25 exposed over a certain air concentration.

1 But then once you get those results back, it will
2 dictate how frequently the worker needs to be examined,
3 and ultimately whether or not the worker needs to be
4 removed from exposure.
5 And certain medications, there are a whole list
6 of them, can confound the results, because they can
7 confuse the results.
8 --o0o--
9 PANEL MEMBER QUINT: Now, how are the results
10 communicated? The worker gets a copy of the biomonitoring
11 results from the employer within two weeks. And it says
12 with a sheet explaining the results. I looked in the
13 appendix to the standard at the sheet explaining the
14 results, it's like a paragraph. It says name of worker,
15 results, how it compares to normal, medical examine,
16 normal, abnormal. That's about it.
17 So I don't find that it really -- maybe in some
18 cases if the employer is inclined, they can supplement
19 that. And there's certainly a lot of, like in the
20 Occupational Lead Poisoning Prevention Program, there are
21 lots of people who have done great health education to
22 augment that.
23 And then they also get the physician's written
24 medical opinion from the employer within two weeks.
25 --o0o--

1 PANEL MEMBER QUINT: And the physician's medical
2 opinion includes the worker's diagnosis, medical
3 conditions that cadmium exposure may impact, the results
4 of any other tests, and recommendations regarding work
5 removal or limitations.
6 And this is very important, a statement that all
7 the information, medical exam, bio -- all test results,
8 biomonitoring and otherwise, have been clearly and
9 carefully explained to the worker. That can vary, I'm
10 sure, depending on the provider.
11 And also important, the employer's information is
12 limited to findings related to cadmium exposure. So the
13 worker is protected in that way as well.
14 --o0o--
15 PANEL MEMBER QUINT: Now, in the UK, on their
16 website, just to make sure that worker's rights are
17 protected, they have very clear and understandable
18 guidelines. They tell the worker, understand your test
19 results and the actions that are to be taken with those
20 results; decide who has access to the results, union,
21 whether you want -- they're anonymous or pooled -- or
22 anonymous and pooled probably are the same thing. But to
23 make sure that, you know, your individual results aren't
24 communicated; and that the sample analysis is limited to
25 chemical exposures at work, because a lot of workers are

1 frankly concerned about, you know, using their urine or
2 blood to look for other things like maybe, you know, drugs
3 or something like that.
4 And they say explicitly in the UK that the test
5 results will not affect employment conditions, which is an
6 understood right --
7 --o0o--
8 PANEL MEMBER QUINT: -- in the U.S. but not as
9 explicitly stated in most cases.
10 Okay. This was a NIOSH health hazard evaluation
11 of casino workers. And they did biological monitoring,
12 and they also used a marker for lung cancer.
13 Two minutes, okay.
14 And they made recommendations to the employers
15 and the workers. And I put this little notice up here, is
16 because one way of communicating those findings is to post
17 this report in the workplace. And it, you know, has to be
18 visible. You can't cover it up. And it can't be defaced
19 or altered, so that's one way. I didn't find anything in
20 the report.
21 Now, NIOSH conducts an open conference, so that
22 there is a way, you know, for workers to confidentially
23 discuss their concerns with medical staff. So there is an
24 opportunity for that, but I didn't see anything in the
25 report on a closing conference. I think there is also, in

1 their procedures, a closing conference.

2 --o0o--

3 PANEL MEMBER QUINT: So they found -- you know,

4 what they found here was they found levels of the marker

5 for lung cancer, NNAL. And it's specific for tobacco.

6 They found that within their work shift that these workers

7 had higher exposure. So, you know, their work was putting

8 them at risk for lung cancer. That was a clear finding.

9 And that correlated -- they were also exposed to

10 environmental tobacco smoke components, which they

11 measured in the air. And they made recommendations to the

12 employer and to the workers. So one of several

13 recommendations to the employer was to ban smoking in

14 casinos, because there's no way you can, through

15 ventilation or otherwise, you just have to ban it. And

16 that's consistent with the Surgeon General's report in

17 2006, and others. And form health and safety committees.

18 They did have -- and to have smoking cessation classes for

19 employees. So that was three of the recommendations.

20 The employee recommendations included stop

21 smoking, see doctor for health concerns or symptoms, and

22 they also recommended to the employer to form health and

23 safety committees, so that employees and management could

24 have a chance to discuss health concerns and exposures.

25 And they recommended to the employees that they join those

1 health and safety things.

2 --o0o--

3 PANEL MEMBER QUINT: So this is the part of the

4 report that would be, I guess, the communication report in

5 pretty -- I guess -- I don't know how simple the language

6 is. I'll have to ask Holly and Rachel about that.

7 But this is the only thing in the report. The

8 report is kind of dense. It has a lot of appendices, but

9 they do have this page, which for most of us, you know, it

10 looks simple; what they did, what they found. And then I

11 cut off the other part, but it's what managers should do

12 and what employees should do.

13 --o0o--

14 PANEL MEMBER QUINT: So the other thing is

15 this phthalate study that you have a copy of - it's

16 available in the binders and otherwise - that was just

17 published. It was a collaborative study between NIOSH and

18 CDC.

19 And anyway, I'll just -- just briefly. It was

20 156 workers from eight industries. They evaluated

21 phthalate metabolites, mid-shift and end-shift. And they

22 found data. And it was a pre- -- they did this as a

23 preliminary study, for an Epi study, because there is no

24 good Epi study of phthalate-exposed workers. And they

25 just wanted to identify industries where, you know, there

1 was likely to be exposure, and whether or not they could
2 use the metabolites to find levels -- to find exposures
3 over backgrounds. And they compared them with NHANES.
4 And what they saw were, you know, evidence of
5 exposures that exceeded NHANES results by, you know,
6 appreciable margins. And they knew it was -- and they did
7 this mid-shift remember and end-shift, so they were
8 comparing -- they didn't do pre-shift.
9 But anyway, in almost all cases, the exposures
10 exceeded the NHANES levels.
11 --o0o--
12 PANEL MEMBER QUINT: And so this is what they
13 concluded from that, that the within-shift increases
14 indicated that there was exposure to phthalates. And
15 since we don't have, you know, exposure limits or normal
16 levels for phthalate metabolites, you couldn't say
17 anything about the health significance of the results.
18 They sent letters. Those are in your binders.
19 And it had background information on phthalates. Nothing
20 about health effects. They compared group and individual
21 results and how they compared to NHANES. And they also
22 indicated for each worker whether or not the particular
23 phthalate was used at their workplace. That was
24 eliminated from what you have.
25 And they gained, they highlighted in a box, that

1 there was lack of knowledge about the health significance
2 of the results.
3 --o0o--
4 PANEL MEMBER QUINT: This is how the results were
5 communicated. I have since corresponded to the lead
6 author, and she has used graphs in some cases. Found it
7 difficult to use graphs in this case, because there were
8 so many different metabolites. She also prefers to talk
9 to workers. This was a study that was done all across the
10 country at different -- they had a really hard time
11 identifying work places where phthalates were used,
12 because there's no good use data for any of these
13 chemicals that we've shown in the past.
14 So, you know, this was the best that they could
15 do in terms of communicating results. And she did list
16 her phone number on the letter. She did also say to me
17 that in all cases, in studies that she's done, that
18 workers always want their results.
19 She was struck, in this study, by the work places
20 where there were Spanish-speaking workers that nobody
21 asked for their results, and that was troubling to her.
22 And we'll hope to inform, you know, studies in the future,
23 because they do plan to follow up on this. This was
24 considered a preliminary study.
25 And she doesn't know -- she could speculate about

1 what that means, but didn't -- you know, there may be
2 reasons for that.
3 --o0o--
4 PANEL MEMBER QUINT: So basically, you know, in
5 occupational biomonitoring, it's more focused in the sense
6 that, you know, you're doing it to say something about the
7 worker's exposure and to reduce that exposure, and to
8 reduce to the extent that the monitoring results reflects,
9 you know, a health effect, based on the air limit. You're
10 trying to reduce health risks. And, you know -- but you
11 have to keep in mind that most of those occupational
12 health limits don't protect against chronic toxicity. And
13 only required as a part of medical surveillance for a few
14 standards. So we have a lot of limits, but they're just,
15 you know, not required.
16 And it varies. You know, depending on the
17 communication, it varies. Depending on whether or not
18 it's a research study, health hazard evaluation, or a
19 standard. Much more comprehensive when it's mandated.
20 Thank you.
21 CHAIRPERSON MORENO: Thank you, Dr. Quint.
22 Why don't we go ahead and see if there's one or
23 two questions by Panel members for Dr. Quint.
24 Why don't we take one from Dr. Wilson.
25 PANEL MEMBER WILSON: Thank you, Julia.

1 And this sort of gets to Asa's question that the
2 correlation of the BEI with TLV, I guess that's the -- is
3 that the only place where we have -- we're talking
4 biomonitoring data and actually a dose measure and
5 assigning it to an air concentration measure, right?
6 PANEL MEMBER QUINT: Right. Yeah, much has been
7 made of that recently. There is a growing literature
8 in -- well, I don't know. I think it's -- Amy first made
9 me aware of it. But there are a number of papers now
10 about interpreting, you know, human biomonitoring results
11 and cautioning against comparing external exposures to
12 internal exposures without having -- using pharmacokinetic
13 data. And, you know, if you -- and they have various
14 ways, what they call, reverse and forward dosimetry
15 methods for converting the external to an internal dose.
16 And then you can compare it to a biomonitoring result.
17 But they point to occupational health, where the
18 biomonitoring, you know, action level with, the BEIs, are
19 correlated closely with the air levels. And so there you
20 can make a statement about health risks because you've
21 done that correlation up front.
22 So, you know, that's why it's important to
23 understand what the limitations of the standard -- the air
24 measurement is that you're comparing it to, because only
25 for led and mercury as they so well point out, do we have

1 the sort of -- here's the result, here's some clinical --
2 you know, epidemiological or clinical findings that
3 correlate those results to the internal dose.
4 So, yeah, I think it's -- you know, again, you
5 know, we don't have pharmacokinetic data. We're running
6 in to this with a lot of standard setting in occupational
7 health, where increasingly, you know, it does improve your
8 PEL or your RFD or your RFC or all of these guide -- you
9 know, these risk numbers.
10 But those data are lacking for a lot of
11 chemicals. So what do you do in the meantime. I think
12 that's going to be a big struggle for everybody as Dr.
13 Bradman pointed out.
14 PANEL MEMBER WILSON: I guess if I could just
15 follow that up. The thing that seems -- that's troubling
16 to me about that and I guess also referred to by Asa, was
17 just the enormous variability in the biomonitoring -- you
18 know, the actual -- the BEI that an individual, you know,
19 could receive, how different it could be over time and
20 probably activity and so forth.
21 You know, it's such a snapshot in time, you know,
22 and could very well not represent reality, I guess, you
23 know, for the worker.
24 PANEL MEMBER QUINT: Well, I think -- and you
25 have an opportunity within, you know, this kind of a study

1 with the phthalates, to look at, you know, a relationship
2 between exposure, because they only went -- they went into
3 plants that used these chemicals, and they picked out
4 operations where, you know, the phthalates were actually
5 used. And, you know, if you -- the limitations of the
6 study and why it's a pilot, is they didn't do pre-shift,
7 because they had a limited -- you know, there's all over
8 the country, you can imagine how difficult this was to set
9 up.
10 But they did mid-shift and they did end-shift.
11 And so those values represent increases over that time
12 period. So the worker could have come in with some burden
13 of phthalates, but unless they went and showered in
14 phthalate containing, you know, personal care products,
15 between the mid-shift and the end-shift, a lot of it does
16 represent their workplace exposure.
17 It did correlate with tasks too. Those tasks
18 that had the highest inhalation exposures had the highest
19 values. I just was saying that in the sense that -- and
20 they want to go back and do seasonal variation. They want
21 to do more sampling. They want to do end of shift,
22 post-shift, pre-shift and then you can -- you would have a
23 chance to see that variation, you know, to control that
24 variation, maybe a little bit.
25 I don't know if Asa -- I don't if that's

1 particular to the OPs or whether or not other people have
2 seen that with larger studies.
3 PANEL MEMBER BRADMAN: You know, I think it
4 varies. I mean, certainly we know there's a range of
5 half-lives and persistence of different compounds.
6 Can everyone hear me?
7 You know, DDT obviously is very persistent. Some
8 of the PBD congeners are very persistent. Some of the
9 higher brominated compounds are much less persistent. You
10 know I think the kinds of results we found for urinary
11 Metabolites may be characteristic for other, you know,
12 nonpersistent compounds. Also, it depends on whether the
13 exposure is intermittent or constant, you know, and
14 whether it's affected by diet or behavior.
15 If there's air concentrations in the home, maybe
16 it won't vary that much, even though these are relatively
17 non-persistent compounds.
18 Again, I think these raise challenges, and I'm
19 not sure how to sort them out. And I'd say again that we
20 have not really dealt with them in how we inform results.
21 CHAIRPERSON MORENO: All right. If I may, we
22 have -- Dr. Culver, I think had a question for Diana.
23 We're about 15 minutes over at this point, but we
24 still have all of our panelists here. And I know you have
25 a presentation to -- because you want to present some

1 questions to the Panel for some guidance. So would you
2 like to maybe give the presentation or should we ask the
3 Panel if they have a few more questions of all of our
4 panelists now that the presentations are finished?
5 MS. LEE: If it's okay with the Panel, I think
6 some of the questions and so on, the discussion that the
7 Panel members might have would be addressed also through
8 discussion of some of these questions that I'm about to
9 pose.
10 CHAIRPERSON MORENO: So we can move on to your
11 presentation.
12 MS. LEE: It's a very -- it's not even a
13 presentation.
14 CHAIRPERSON MORENO: Thank you.
15 MS. LEE: If it's okay, if I can just do it from
16 here instead of at the podium?
17 CHAIRPERSON MORENO: Certainly.
18 (Thereupon an overhead presentation was
19 Presented as follows.)
20 MS. LEE: So we've heard from a variety of
21 speakers and had many examples provided to us of
22 work-in-press and work completed that describes some of
23 the issues revolving around results communication. And
24 again, with the eye of developing a best practices for
25 results communication, I put forward some of these

1 questions to you to help guide the discussion, the
2 questions, and also from the public as we approach the
3 public comment period, so that we ask, for instance, from
4 your own experiences with reporting biomonitoring
5 information, either to specific individuals or to groups,
6 what lessons can you share to inform the development of
7 best practices for results communication that the
8 biomonitoring program is currently in the process of
9 developing.
10 Secondly, given that the Program is charged with
11 looking at essential -- eventually, a State
12 population-based kind of sample, we recognize the
13 challenges in a number of ways of having to do that.
14 A number of the studies we've heard from, for
15 instance, are looking at geographically placed samples.
16 So also we have the option of carrying out community
17 studies, as defined in the legislation that indicate the
18 may not be geographically placed, and they can include
19 occupational groups as well.
20 Given that, what strategies or actions for report
21 back or results communication do you recommend for
22 non-geographically placed population versus a
23 geographically placed sample or for occupationally defined
24 populations?
25 And we've already heard also from a number of the

1 speakers about the use of comparison values. And I've
2 indicated that we'll be working on developing those also.
3 But in terms of some of the currently used existing
4 biomonitoring studies and/or programs, what comparison
5 values from other biomonitoring perhaps or studies could
6 be used to provide context for communicating results?
7 And then always mindful of the caveat of adequate
8 resources. What would you define as a sufficiently
9 responsible approach for the California Environmental
10 Contaminant Biomonitoring Program to follow with respect
11 to reporting results to individuals.
12 --o0o--
13 MS. LEE: And kind of as a subcase for that last
14 question, that might be with respect to recruitment,
15 informed consent procedures for instance, addressing the
16 inability of the Program to link health effects with body
17 burden levels in particular, the considerations of
18 programs should be given to capacity building for
19 participants, community and specifically health care
20 providers, how can individual health care providers be
21 integrated in to the results communication report-back
22 efforts?
23 CHAIRPERSON MORENO: All right. So this
24 open -- I'm sorry these are open questions that -- there
25 are seven questions here. And I would just actually, if

1 it's okay, invite any Panel member to address anything --
2 any of these seven questions.
3 MS. LEE: And I can put it back to the first
4 slide, if that would help.
5 CHAIRPERSON MORENO: Dr. Quint.
6 PANEL MEMBER QUINT: This is Julia Quint. I
7 guess it's a question for those folks who have or are
8 conducting studies, how have you interacted with -- you've
9 described situations where you've had focus groups for the
10 community, you know, I think in various ways. And I was
11 wondering if you had also done the same for community
12 health care providers, you know, to let them know the
13 study is going on and to prepare them, you know, in some
14 way to try to educate them about -- to inform them about
15 what you're doing and to educate them about what questions
16 they may get? Because I think this is a big -- you know,
17 just to let you know that the program on reproductive
18 health in the environment is having -- there's a whole
19 focused effort on bridging the gap between, you know, how
20 clinicians think about evidence-based medicine versus, you
21 know, environmental health, and all of these animal-based,
22 you know, concerns that we have or concerns that we have
23 based on animal data really hasn't been integrated to a
24 whole extent.
25 And I guess Gina has written an article on this.

1 But I think it's huge the void that we're trying to -- you
2 know, we don't know what the results mean. And I think in
3 a lot of clinical medicine, there's no appreciation that
4 these are high on the radar when you're dealing with many
5 other -- you know, this evidence-based sort of paradigm.
6 So, you know, I guess one way to do it would be
7 to make sure from the beginning of the study where the
8 sampling is done, that if you can convene providers,
9 especially people who are delivering health care, to the
10 group that is being biomonitored to, at the minimum, make
11 sure that they are included, informed about, and have some
12 sort of dialogue regarding, you know, all of these issues
13 that, you know, Rachel and Lori and Holly raised about
14 what's important, you know, it's very resource intensive.
15 MS. LEE: And this is the opportunity for the
16 speakers to also comment on any of these.
17 CHAIRPERSON MORENO: Dr. Solomon.
18 PANEL MEMBER SOLOMON: Yeah. I'm having a tough
19 time actually reconciling the sort of -- or balancing some
20 of the factors that we need to consider here, because
21 obviously we, you know, care about and must adhere to the
22 public right to know and to individual's right to know in
23 this effort. But, you know, it's easy to sort of fall in
24 to something that becomes very resource intensive and
25 almost sort of boutiquey, where each patient or individual

1 has to get quite a bit of personal attention and time,
2 thereby pulling staff time and resources from other
3 aspects of the Program.
4 And that can work okay as long as it's a
5 small-scale effort, but could be very difficult to scale
6 up, I would imagine. And so I'm interested in whether
7 some of the people who have done more sort of
8 individualized or participatory approaches have some
9 thoughts about ways to scale it up in a cost-effective
10 manner, or whether we should maybe be sort of thinking
11 about whether we can really do that in this Program. And
12 it seems to me that there are ways to communicate results
13 without sort of ongoing and intensive community
14 involvement.
15 And for a statewide Biomonitoring Program, it
16 just would be hard to keep up our end of the bargain, in
17 terms of the sort of the touch factor with individual
18 communities over time. And if we start down that pathway,
19 I don't want it sort of, you know, start doing it with
20 some of our pilot projects, and then at a certain point
21 realize that it's not doable, and then have to pull back
22 from the community involvement. So I think it is a good
23 thing for us to be thinking about right now.
24 CHAIRPERSON MORENO: Dr. Kavanaugh-Lynch and then
25 we'll to our panelists. You look like you have some

1 thoughts.

2 So go ahead.

3 PANEL MEMBER KAVANAUGH-LYNCH: Mel

4 Kavanaugh-Lynch. I want to maybe play a little bit of

5 devil's advocate to what Gina just said. I was struck in

6 the presentations about actually the variation. Although,

7 there's community information gathering in each one of the

8 presentations we heard. There are varying flavors.

9 So from my view, focus groups are very much from

10 the traditional academic-centered approach to research,

11 and not a CBPR approach. That's, you know -- the

12 researchers decide what information they want to gather

13 from participants. They decide what groups to put

14 together. They decide what questions to ask. They create

15 focus group guides. They go in, they do these procedures

16 and then they leave, and they analyze the information.

17 That's not a CBPR approach.

18 In a more CBPR approach, you're developing

19 community capacity at the same time that you're partnering

20 on the project, which then leaves community capacity

21 behind, to be able to actually do some of the -- perhaps,

22 as an example, do some of the actual delivering of results

23 to communities, to help with interpretation, to help

24 developing action plans for changes to make to, you know,

25 creating actual action plans, which is part of CBPR.

1 So actually putting some effort in the initial
2 phases of partnering with community organizations around
3 the State might actually allow for very tailored and very
4 specific reporting without great expense.
5 CHAIRPERSON MORENO: Why don't we hear from panel
6 members?
7 MS. COPAN: I wanted to answer -- my name is Lori
8 Copan. And I wanted to reflect on the question of, you
9 know, how have we involved health care providers?
10 MS. LEE: You actually have to hold it like this.
11 MS. COPAN: Okay. I wanted to reflect a little
12 bit about some approaches we've used to involve health
13 care providers in the work that we're doing.
14 For the Tulare county study, one of the things
15 that we'd like to do is, first of all, we've met with the
16 health officer within the county, and involved her from
17 the beginning. She's come to the community meetings that
18 we've had, as well as some other staff in the County
19 Health Department. In fact, I think she and some folks at
20 some of the community clinics would be those who would be
21 communicating results, were it not for the fact that most
22 of the results need to be communicated in Spanish. And
23 they didn't feel that their Spanish was really developed
24 enough to be able to do that.
25 So one of the approaches that we want to use is

1 to go -- is probably in September or October to conduct a
2 workshop with all health care providers who might want to
3 come from the county, organized through the Health
4 Officer's office, to really kind of do an overview on what
5 we know about pesticide exposure and health effects. So
6 that kind of will, we hope, to address, you know, some
7 basic issues around raising levels of information within
8 the county among providers who can come.
9 We have -- as I pointed out, we made a tempts to
10 recruit local providers in the hopes that we could leave
11 something behind in terms of the local capacity and to
12 perhaps have champions for local groups, who could
13 actually join them in some of the activities that they may
14 be planning for the future. It certainly says a lot when
15 a locally respected physician gets up and talks about the
16 results of the study in parallel with members of the
17 community. It's harder to then discredit the findings
18 within the community, when there's a variety of folks who
19 are participating.
20 So that's been -- up until -- we're just starting
21 to work with those providers. And we hope to be able to
22 do constructive interviews with them to have them become
23 involved in, you know, the shaping of the communication
24 protocols. And then to -- afterward, to talk to them
25 about what kinds of burdens or what kinds of expectations

1 that doing this kind of work presents to them, in terms of
2 their general practice.
3 Diana and I were involved in a study on mercury
4 in fish in Sacramento with a GYN office. And it was, I
5 think, 181 women were in the study who were pregnant. And
6 we -- it was pretty astounding that though the majority of
7 women were from communities who did a lot of fishing in
8 the Sacramento River, where there are advisories on
9 warnings, they had never integrated into their practice
10 approaches to educating about mercury.
11 And we were able to find through that study a
12 couple of pretty easy ways to start talking about some
13 kind of biomonitoring within medical practice. One was
14 within the CPSP program, it's a -- I can't remember the
15 acronym, Childhood --
16 MS. LEE: Comprehensive Perinatal Services
17 Program
18 MS. COPAN: Yeah. So it's for low-income women
19 who are pregnant. Within that program, we were able to
20 pay for the counseling for biomonitoring consultation or
21 speaking about the results, and we were also able to bill
22 to Medi-Cal as well as to private insurers for, in this
23 case, for mercury. So, you know, a more commonly
24 available test in blood that costs something like $150 if
25 someone does it. So we're hoping to explore ways as well

1 through these projects to figure out, are there ways -- if
2 a person in the community comes to these providers, either
3 through research or outside of research and says I'm
4 concerned about these chemicals in my environment, can
5 they get reimbursed somewhat for that educational session?
6 So we'd like to explore ways of doing that as
7 well in this. We were able to do it with the mercury
8 study. Clearly, you know, that has more relationship, but
9 we would like to explore with this as well.
10 DR. MORELLO-FROSCH: So there were two big
11 questions. I want to address the one that Gina raised,
12 which is how do you take some of the experience from very
13 targeted and deep community-based studies, in terms of
14 report back and scale it up in a way that's practical for
15 a statewide program, which I think is a very significant
16 challenge?
17 And so for non-geographically focused
18 biomonitoring, I don't think you're going to be able to
19 have the same level of deep community and one-on-one
20 engagement with study participants, for a variety of
21 logistical and cost reasons.
22 However, I think that there are possibilities --
23 you know, what people really need is some assistance in
24 walking through the materials. And so there's ways to try
25 and do that, for example, structuring conference calls

1 that help people walk through the materials they've
2 received in kind of generic ways, organizing the
3 pollutants again in kind of source-specific intuitive
4 ways, so that people can figure out how to get the
5 take-home messages, how to read these graphs, what they
6 mean, and what they don't mean.
7 We're trying to get some resources to experiment
8 also with some on-line tutorials about how to walk through
9 text as well as graphic information materials that people
10 might receive in the mail. Again, to try and scale this
11 up in a way that's practical when you have a broad-based
12 geographic scope, in terms of how you would be doing this.
13 And then to some extent, there's going to have to
14 be probably something available for people who have deep
15 concerns about a particular issue to actually talk to
16 someone if that comes up. That, in our experience, has
17 been more rare, when we haven't had the resources to do
18 the deep one on one with people following up.
19 But I think to some extent, there will have to be
20 a little bit of that in order -- either via Email or phone
21 calls or having resources for people to address specific
22 concerns. CDC has a little bit of that for people who
23 want to call and get specific information on specific
24 results.
25 So I don't have a clear path to kind of lay out

1 for you, but I think there are ways to kind of take the
2 experience from the graphics and the communication and
3 text information from these deep community-based studies,
4 that can still be relevant to a broad-based, not
5 geographically specific focus.
6 And then think about how to engage with study
7 participants in a broader scale to help them walk through
8 and interpret their results.
9 The second issue was the health provider issue.
10 And I think, you know, as people well know, there's a long
11 way to go, in terms of educating health providers about
12 why we do this kind of work. And it's sort of contrasting
13 with their familiarity with evidence-based medicine, as
14 Julia had pointed out.
15 And I think that there are some opportunities, as
16 this program is rolled out, to provide sort of educational
17 opportunities for the health provider community on a
18 broader scale about, you know, why do we do this kind of
19 work; why these -- why we track this kind of information,
20 exposures, and don't necessarily link it to health
21 effects; why its useful from a public health point of
22 view?
23 And I think even starting there would be a very
24 significant boost, and reach a lot more people, and then
25 make it somewhat easier when health providers are

1 confronted potentially with questions from their patients
2 who have participated in this kind of work.
3 MS. BROWN-WILLIAMS: Holly Brown-Williams. I was
4 just going to add to Dr. Kavanaugh-Lynch. Yes, I mean,
5 yes to all of your points. I think those are all the
6 essential elements, and really ending up with materials in
7 a process that community members are interested in; are
8 relevant to their lives; that reflect information that
9 they can comprehend and put to some use.
10 I think all of the projects that we talked about
11 employ those techniques for varying degrees, in part
12 because we have described pieces of larger projects. For
13 example, I know in the work that is being done in Tulare
14 and Imperial counties preceding the focus groups were a
15 lot of other activities, working with the communities and
16 being engaged with the community providers.
17 In the CYGNET study, there have been wonderful
18 efforts through in-person informal meetings that they call
19 tea talks, as we'll as very accessibly written news
20 letters to reach the girls and the families and the study
21 regularly. And, you know, help them understand the nature
22 of the study, their participation, you know, kinds of
23 information that they'll get. So we sort of have that as
24 a background for going into -- you know, to use a focus
25 group to probe further with people about what their

1 expectations are, what they want to know.

2 What's always so interesting is that I think a

3 lot of people who have expertise and information, jump to

4 conclusions about what people want to know in certain

5 areas. And I know in my center, we developed a guide for

6 Californians on Medi-Cal to understand their choices

7 between different kinds of Medi-Cal. And we immediately

8 assumed people would want to know something about the

9 Medi-Cal program.

10 Well, after, you know, many, many community

11 meetings and focus groups, people did not want to know

12 anything about Medi-Cal. They wanted to know about their

13 benefits, how to access them. So, you know, I think that

14 it's all part of a larger process, and then engaging

15 community organizations in the dissemination of

16 information and things are all critical pieces that have

17 been used effectively in other studies as well.

18 CHAIRPERSON MORENO: Thank you. Okay. Thanks

19 for those thoughts from our speakers. So back to the

20 Panel members. Any thoughts, Dr. Bradman and then Dr.

21 Luderer.

22 PANEL MEMBER BRADMAN: I'm not sure what more can

23 be said. I think there's some principles that are coming

24 out today. One, it's important to dialogue ahead of time

25 with potential participants and also related groups,

1 community groups, perhaps industry groups, perhaps unions,
2 depending on the context. And that seems to be a basic
3 principle that's coming out today.
4 I think -- and this might be a personal bias. I
5 think in-person reporting is good, but alternatives should
6 be available and in-person may not be practical, you know,
7 for example with 2,000 people across the State.
8 It seems like another principle is that we should
9 make comparisons, if possible, to health-based reference
10 levels. And they may need to be caveated. If
11 health-based reference levels aren't available, the
12 exposure information needs to be compared -- ideally
13 should be compared to population reference data.
14 It's important to understand that the work may be
15 done solely for research, and that it might not provide
16 information about individual health risks or health
17 symptoms.
18 I think the medical community should be
19 considered one of the variety of communities that may need
20 some outreach. For a statewide project, it would be
21 important to, you know, send letters as the State Health
22 Department to health officers of the counties affected,
23 which may be all counties and/or other smaller
24 jurisdictions. For example, there's some cities that have
25 their own health departments. And it may be worth also

1 reaching out to slightly lower down. And that could
2 possibly be a venue for communicating with physicians in
3 an area.
4 I think it would be extremely difficult on a
5 statewide program to try to reach out to individual
6 physicians, other than some sort of, in a way, top down
7 communication approach, trying to put articles and things
8 like the -- you know, local medical societies or again
9 through the State -- through the County Health Officer.
10 It seems like the consent process is an essential
11 piece of this. And consent should be an opportunity to
12 enroll people but also explain people to the study. I
13 would say a basic principle would be that the consent
14 should be read allowed by the consentor, in that there
15 should be an opportunity for probing and a dialogue there.
16 And it shouldn't be just a written consent that's read by
17 a participant.
18 So I don't know if that's a distillation that
19 helps, but I think that's kind of the themes that have
20 been talked about today.
21 CHAIRPERSON MORENO: Dr. Luderer.
22 ACTING CHAIRPERSON LUDERER: Can everyone hear
23 me?
24 I really want to say that I really agree with all
25 the things that Dr. Bradman just said. I think he's

1 really done a good job of distilling the kind of key
2 points of all of these wonderful presentations that we
3 heard this morning. And I wanted to really focus on one,
4 which is the -- you know, how does one best communicate
5 results back to the participants. And one of the tensions
6 that I thought kind of came up in all of these
7 presentations this morning is this tension between
8 communicating the results in a way that's understandable
9 to everyone, to all the participants, so not making it too
10 complex, making it understandable to various different
11 levels of education, and maybe not providing enough
12 information or enough detail for some of the participants.
13 And so, you know, it seemed to me in hearing
14 about the different approaches that have been taken in
15 these different projects that were talked about this
16 morning, that obviously ideally -- and I think several of
17 the other Panel members have already said this -- if you
18 can provide individual tailored results that are based on
19 feedback from the participants about what kind of
20 information they needed and what format they would best
21 comprehend information, that would be the ideal, but then
22 we can't do that in a statewide program.
23 So one of the ideas that I just really liked was
24 this idea about maybe having some sort of a web-based
25 interface, you know, where maybe participants are provided

1 information that's, you know, one level of detail that
2 everyone is provided, but then having someway where they
3 can go to either, you know, via a website might be the
4 most practical type of approach on a statewide kind of a
5 study, to get additional detailed information.
6 And I also really think that this idea of
7 capacity building with the community organizations, that
8 that's an additional way that participants can, if they
9 really want to have more detailed information, could
10 access that.
11 CHAIRPERSON MORENO: This is Ed Moreno.
12 At least with regards to the provider -- engaging
13 providers, I think everything that's been said, I agree
14 with.
15 In terms of contacting the health officers, I
16 think that's a very good idea. But what the health
17 officers would most likely do would be turn to the
18 community and find those providers who have been providing
19 care to the targeted population or groups, and save
20 programs a considerable amount of time in identifying
21 those people who have participated in the past or have an
22 interest.
23 The other thing is if you're not where the
24 program is already, there are UC training programs
25 throughout California in some of the cities and some of

1 the communities they might be targeting in. And the
2 health officers and the health departments typically have
3 working relationships with those professors working in the
4 communities. And just like in the Fresno area, there's
5 programs in Merced and Fresno, and Bakersfield. So those
6 are some of the ways that we could engage providers.
7 Okay, other panel members?
8 Dr. Quint.
9 PANEL MEMBER QUINT: Julia Quint. I think
10 somebody -- I mentioned the - I think it was Lori - the
11 environmental justice aspect of our charge. And I think
12 particular sensitivity has to be paid to folks who work in
13 communities, which sometimes are the polluting source in
14 the community. And so to be prepared, people have to
15 balance, especially now, you know, economic concerns with
16 health concerns, and often are in difficult positions in
17 terms of not feeling empowered to really, you know, act on
18 the rights that I said are there in terms of the
19 employer's responsibility and all of that.
20 So I think it's sometimes a very sensitive issue.
21 And I don't know to what extent the questionnaires will
22 get at work contribution versus more environmental causes.
23 But I would hope that in this work that, you know, we do
24 find a way to incorporate attention to occupation, and the
25 sensitivities associated with that, in terms of the need

1 to earn a living, as we all appreciate, with, you know,
2 feeling responsible, as somebody said, about their
3 children being exposed, you know, and internalizing that
4 responsibility and find a venue for people to turn that
5 into policy or some kind of action, or to know that there
6 are other, you know, venues that we can use to address
7 some of these issues, that it's not an individual action
8 that's needed necessarily.
9 CHAIRPERSON MORENO: Dr. Kavanaugh-Lynch and then
10 Dr. Solomon.
11 PANEL MEMBER KAVANAUGH-LYNCH: I had two
12 questions for Rachel. One was, I'd love to see an example
13 of a message you provide for a chemical that is not under
14 individual control. And the other is you presented
15 comparison data to the California data for NHANES, I
16 believe.
17 DR. MORELLO-FROSCH: No.
18 PANEL MEMBER KAVANAUGH-LYNCH: No. Oh, it was
19 national.
20 DR. MORELLO-FROSCH: For the Richmond study, we
21 provided comparisons -- Oh, sorry.
22 We did not provide comparisons of biomonitoring
23 data to NHANES data, because at the time for most of those
24 pollutants, NHANES data was not available in the Cape
25 study. So when the reporting needed to happen, we didn't

1 have that information available. So just as they're being
2 compared to each other for biomonitoring. But for media,
3 for air and dust, we compared to values when they were
4 available.
5 PANEL MEMBER KAVANAUGH-LYNCH: Okay, thanks.
6 DR. MORELLO-FROSCH: And then in terms of your
7 question about an example for pollutant, you said,
8 overwhich an individual doesn't have control?
9 PANEL MEMBER KAVANAUGH-LYNCH: Yes.
10 DR. MORELLO-FROSCH: So we gave people
11 information, for example, if we thought that there was a
12 pollutant inside people's homes that, for example, was not
13 coming from an indoor -- not likely to be coming from an
14 indoor source, but coming from transportation emissions,
15 or, for example, oil combustion, in the case of Richmond
16 activities, either from the port or from refining
17 activities nearby, we indicated that.
18 Other situations we were pretty clear where the
19 pathway could have come from indoors or outdoors.
20 PANEL MEMBER KAVANAUGH-LYNCH: But then what
21 recommendation did you give for reducing exposure compared
22 to your weed killer example, you can stop using weed
23 killer in your backyard?
24 DR. MORELLO-FROSCH: Well, so in certain
25 situations when it was clear, you know, we could say that

1 we were telling people that it could be coming from oil
2 combustion, which would mean from port activities and from
3 refining activities, which links to interventions that are
4 based on land-use decision making and the need for
5 organizing.
6 So our community partner in helping us
7 disseminate those results at community meetings
8 highlighted those issues quite clearly, in terms of ways
9 that people could engage collectively. Similarly, in the
10 case of brominated flame retardants, when we were showing
11 those results, again we were telling people that you can't
12 necessarily go to the store and read the label and avoid
13 those things. It has to do with the fact that it's
14 formulated in a lot of products and it's hard to tell when
15 it's in there.
16 And so that requires policy interventions. These
17 are the things that are currently going on to address
18 brominated flame retardants and consumer products. So
19 those were the ways we were sort of linking collection and
20 individual action with our community partners.
21 The other issue I just wanted to address a point
22 that was made earlier about giving people different levels
23 of detail. And I think one --
24 MS. HOOVER: Can you bring the mike closer and
25 speak louder.

1 DR. MORELLO-FROSCH: Sorry, is this good? I'm
2 going to be like slobbering all over this.
3 (Laughter.)
4 DR. MORELLO-FROSCH: We provide kind of layered
5 report-back materials. So we provided people with a
6 one-page summary sheet that gave people kind of a
7 take-home message of these were the things that popped out
8 in your results. Really trying to stick to one page, for
9 people who just kind of want the take-home message and
10 they're not really interested in anything else.
11 And then people got graphic information on the
12 different analytes for air and dust. And they could --
13 those people had the opportunity to dig deeper and go
14 through. We tried to categorize the pollutants by
15 different categories, by source and the type of chemicals,
16 and then tried to highlight those chemicals for which
17 there's really not a lot of information about sources and
18 pathways.
19 And then we also provided a very detailed
20 background table for each of the analytes, so people could
21 know where these things are commonly used, what is known,
22 in terms of toxicological evidence or Epi evidence, and
23 then whether or not the chemical had been banned in other
24 places, like in Europe, due to concerns about health.
25 So we gave people the layers, depending on how

1 much they really wanted to consume, in terms of
2 information. There was some people that were just really
3 happy with the summary. And then there were people that
4 just really wanted to dig deep.
5 CHAIRPERSON MORENO: All right. Thank you.
6 Why don't hear from Dr. Solomon and then we'll
7 move in to public comment. And then after public comment
8 we'll continue the discussion and then finalize some
9 recommendations from the panel to the Program.
10 PANEL MEMBER SOLOMON: I just wanted to underline
11 what Asa mentioned before about the importance of consent,
12 and what's communicated up front, because I think that
13 that -- you know, instead of just thinking about how we're
14 going to communicate the results, I think communicating up
15 front is, if anything, even more important.
16 I guess I'm biased by my clinical experience
17 which is, you know, a fair number of the patients that I
18 see are people who have some kind of health concern and
19 have ended up in the hands of somebody who has done some
20 kind of biomonitoring of some type and something has
21 turned up high, and it can send people on to, you know,
22 quite a spiral of anxiety.
23 You know, once people get the idea that some
24 result is clearly tied to some health symptoms that
25 they're experiencing, it can be hard to get that out

1 of -- you know, persuade them otherwise. And so,
2 communicating up front is really important.
3 And I just -- you know, I think that there are a
4 lot of ways to communicate results effectively. I just,
5 again, want to sort of remind us that this study can't be
6 everything to everybody. This is a Biomonitoring Program,
7 we can't -- you know, efforts that may lead to community
8 empowerment may flow from this, but aren't necessarily
9 something that can be done as, you know, by the staff of
10 the Program.
11 And so, you know, we should try to stay realistic
12 about the trade-offs that we would be considering, if we
13 sort of try to turn it into a program with very deep
14 community engagement, and recognize that we would then be
15 trading off sample size and number of analytes in a, you
16 know, very concrete way. And whether -- you know and to
17 what degree we think that that makes sense versus allowing
18 other groups to use the information and, you know, if they
19 want to do community organizing, great. But perhaps
20 that's not something that can be done by the staff.
21 CHAIRPERSON MORENO: Thank you, Dr. Solomon.
22 All right, we have -- we're going to move in to
23 public comment and then we'll bring it back to the Panel
24 for discussion and final recommendations.
25 I'm going to start off. We have three speakers,

1 but I'm going to start off with reading an Email from
2 look -- it looks like Diana -- here it is, Diana Graham,
3 staff scientist, Keller and Heckman.
4 "I was particularly interested yesterday in the
5 Panel's discussion to prioritize biomonitoring of DDT,
6 apparently because there were results indicating that the
7 immigrant population had higher concentrations than native
8 born Californians. (Not and unexpected finding.) In the
9 context of Dr. Morello-Frosch's presentation, what
10 individual actions or policy changes would the panel
11 expect to happen, if it is confirmed that immigrants have
12 higher body burdens of DDT than native-born Californians.
13 That would justify using limited resources to monitor for
14 DDT, instead of something else?"
15 Was that clear?
16 Well, are there any responses to this? If not,
17 we'll just read it and enter it.
18 Okay, I want to thank Diana Graham for bringing
19 that to our attention.
20 And now we have three presenters. And I will --
21 given the amount of time we have left, we'll be keeping
22 track of time.
23 The first presenter is Trudy Fisher.
24 Well, Trudy, could you hold off for one second.
25 MS. FISHER: Sure.

1 CHAIRPERSON MORENO: Thanks.

2 So we have about 12 minutes. So keep your

3 comments limited to three or four minutes.

4 Thanks.

5 MS. FISHER: No this is very quick. I just

6 wanted to quickly address a suggestion that had been made

7 earlier concerning good practices in written

8 communication.

9 Can you hear okay?

10 As you may remember from yesterday, I'm somebody

11 who had worked in a building that had ventilation problems

12 and over seven years breathed a low level of autobody

13 paint chemicals.

14 Previous to that though, in college I'd been a

15 literature major and graduated summa cum laude. And so I

16 have a long history in reading and enjoying literature and

17 so on. And when I had to teach myself to read again, one

18 of the benefits is that I have a professional background

19 in graphic design and book design. So I've been able to

20 deconstruct the reading experience and have some practical

21 insights for some, you know, what can help as far as

22 written communication.

23 One of the suggestions that had been made earlier

24 was to use larger size fonts. And I just wanted to let

25 you know actually sometimes that can work against the

1 reading experience. It's more like speaking loud, but
2 continuing to use complicated sentence structure. What
3 you want to do is really help the reading brain by helping
4 the reading eye. So the more you can group phrases, even
5 if that means putting in a discretionary -- a soft return,
6 so that the article doesn't just end at the end of a long
7 sentence -- or a long line, you want to bring it around.
8 You want the eye to see as a group.
9 Really length of lines. Line lengths. The
10 margins that you use on the page really play a critical
11 role. Serif type faces for the most part, that's why for
12 so many centuries, serif-type faces were used in book
13 design. I wouldn't necessarily recommend Times. I
14 personally don't think that's a real legible face.
15 If you're going to have a series of bulleted
16 items, which I think are very useful just for somebody to
17 get an idea, make the comparisons and so on, really use
18 them as bullet points. No offense, Dr. Bradman, but you
19 might actually want to introduce a space or a tab every
20 time you've used a bullet, because otherwise it functions
21 as -- it becomes an odd first word in your paragraph.
22 It's a little black mark and then some letters. And it
23 takes a person out of the reading experience, not just for
24 somebody who's had a chemical injury, like I have, but
25 actually somebody just really, as I say, it's part of the

1 reading experience. You don't want to have -- you don't
2 want the fourth wall to be broken. You want somebody to
3 be able to get into that reading experience and just keep
4 reading.
5 So put a tab, put a space after your bullet.
6 Keep your bulleted items parallel. If you're going to use
7 a punctuation at the end of it, use it consistently. It's
8 like a bar graph. It really is, except form from text.
9 You want everything just to be parallel. You want words
10 to be shaped as groups, so the eye can look at it and read
11 it and so on.
12 Anyway how, thank you.
13 CHAIRPERSON MORENO: Thank you for your help.
14 Okay, next we have Davis Baltz, Commonweal.
15 MR. BALTZ: Davis Baltz with Commonweal.
16 I'd like to start out with the quote from the
17 National Academy, a report on biomonitoring, that spoke to
18 the technology of biomonitoring outpacing our knowledge of
19 health impacts.
20 And I really think that's -- while there's some
21 truth to that, it's sort of a downstream observation. And
22 it would actually be -- a better way to phrase it is, the
23 widespread introduction of chemicals into the marketplace
24 without adequate toxicological and health data has
25 outstripped our ability to assess chemical safety.

1 So in that regard, biomonitoring is actually
2 providing more information and more information is good.
3 I think we all can appreciate that, but we shouldn't let
4 the advances in the laboratory prevent us from moving
5 ahead as fast as we can in developing our communication
6 strategies.
7 So biomonitoring is not a new field. It's been
8 used, you know, for blood leads and breathalyzers and
9 other techniques for some time. But just as it's
10 advancing quite rapidly in the laboratory, the
11 communication methodologies are also advancing. We heard
12 a lot of very valuable examples today from the presenters.
13 So just to, you know, reflect back, look at Dr.
14 Bradman's comments in his presentation from his IRB board,
15 that not so many years ago they felt it would not be
16 meaningful and would cause alarm to provide results to
17 participants.
18 And I think I detected in the room when that was
19 said that people were sort of intake of breath and shaking
20 their heads like how could that be?
21 And I think, you know, there's an emerging
22 consensus now that it is the ethical thing to do, and we
23 really must provide individual results. And rather than
24 framing it that if you give results you're going to cause
25 harm, you actually make cause harm by not providing

1 results, if for no other reason that you would prevent the
2 opportunity for people to learn how they could take
3 individual actions to reduce some exposures.
4 And I think we also heard in the presentations,
5 whereas maybe some years ago a small number of people or a
6 smaller number of people were requesting their results
7 now, it's over 90 percent and maybe approaching close to
8 100 percent.
9 And certainly in the biomonitoring work that
10 Commonweal has done, that's been our experience also, is
11 that people -- they have questions about biomonitoring.
12 And we shouldn't fool ourselves that it's a panacea. It's
13 not going to answer all questions. Dr. Morello-Frosch
14 pointed out some of the potential drawbacks for
15 communities. You know, the danger of being stigmatized or
16 discriminated against. We still don't know that an
17 individual exposure can be tied to a specific source. The
18 time biomonitoring sample is taken is a snapshot of what
19 is detected at that time. And there may be other
20 chemicals that people are exposed to that don't show up in
21 a one-time snapshot, that could be important, especially
22 for the non-persistent ones.
23 So all of these things need to be sort of laid
24 out, as much as possible, before the studies get under
25 way. And our experience has been the more pre-work you

1 do, the better off you are. It enables you to do less
2 post-work, and maybe leave something in place that's
3 meaningful, as Lori mentioned is something that's
4 important.
5 And I think also, the more people understand
6 about biomonitoring, before they agree to join a study,
7 the more receptive they are to joining the study and the
8 more they'll ultimately get out of it.
9 So all that said, this legislation does require
10 this program to convey individual results. And that does
11 present some challenges.
12 Diana, your list of questions is, you know, deep
13 and hard to answer all of those. Maybe when we come back
14 to Panel discussion, one follow-up question I might have
15 for Dr. Bradman would be when you were conveying the
16 results in the CHAMACOS project, how long does it actually
17 take to have the interview with an individual study
18 contributor, and you also had in one of your slides that
19 if requested, follow-up testing would be offered or
20 something like that. And I'm wondering if you have very
21 many requests for that, and what exactly it entails,
22 because I could see that being something of a red flag for
23 a large effort that the State might undertake.
24 How to control the costs of delivering individual
25 results is going to be difficult. I think community-based

1 participatory research, for the reasons that we've been
2 talking about, would be very effective to have a better
3 relationship with the community that's being biomonitored,
4 and again leaving something meaningful in place
5 afterwards, so when there -- it makes sense for a
6 geographic study or a smaller community-based study for
7 that kind of more intensive pre-work to happen. I really
8 would encourage the Program to do that as resources are
9 available. It's going to be much more difficult for the
10 statewide studies that you'll ultimately do when resources
11 become available. And, you know, we feel that's also a
12 very important part of this program is to get some
13 statistically significant data that can then be used by
14 the legislature and others to make broader macro
15 decisions.
16 So, just to conclude, Commonweal has been, you
17 know, involved with biomonitoring for a number of years
18 now. We're going to continue to do so. We're going to
19 continue to follow this program. And as the State
20 develops its strategies for working with communities, and
21 you would like to partner with some NGOs, we are ready to
22 help you and make contributions as appropriate.
23 So thanks again for all the good discussion and
24 presentations today.
25 CHAIRPERSON MORENO: Thank you, Davis.

1 Our last presenter or speaker Tom Jacob with
2 DuPont.
3 MR. JACOB: Thank you. Tom Jacob from DuPont.
4 I just wanted to make a few observations about
5 this morning's discussion as an individual who's been
6 embedded in industry circles since -- well, for a number
7 of years.
8 And during that time, these notions of broad
9 systemic population biomonitoring programs have moved from
10 notions to the realities that we have with CDC and with
11 this emerging program. And it's out of that experience
12 that I just wanted to convey a few things.
13 Number one, I think it's important to realize in
14 the budget nightmare in which we're currently embedded,
15 that these community-based programs that have been the
16 object of discussion this morning seem to be likely to
17 occupy more of the space in this California Biomonitoring
18 Programming than we perhaps had envisioned at the time the
19 legislation was passed.
20 And from an industry standpoint, that gives rise
21 to more uncertainty, and I think perhaps a degree of
22 discomfort. Perhaps a sense whether naive or informed,
23 I'm not really sure, that the more narrow these studies
24 are, the more narrowly focused geographically, the smaller
25 they are, the more potential is there for, either

1 researcher or sponsor biases to distort results or the way
2 in which the information is utilized.
3 And I think part of the concern there is a
4 concern with the reality to which Davis was alluding and
5 which others have alluded that there is a frontier
6 character to all this. And part of that is that the
7 technology of detection and identification has gone well
8 ahead of our ability to really understand to our
9 satisfaction the implications of a lot of the results that
10 we're getting. And that poses a real challenge from the
11 standpoint of communication.
12 I think Dr. McKone noted that understanding the
13 community is essential to delivering science that's
14 meaningful to the community in the end. I think there's
15 another side to that. And that is that particularly in
16 the current atmosphere, without a broad population-wide
17 systemic biomonitoring effort, this Program is going to be
18 increasingly reliant to draw conclusions, to make
19 inferences from these community-based studies.
20 And I think with that, comes a need to assert
21 that there is some continuity and integrity to the science
22 and the results that are coming up, as well as those that
23 are going down to inform the community.
24 And I think that answering the questions that
25 have been presented here at the end is extremely crucial

1 to providing and delivering the guidance that will be
2 necessary, in order to provide some degree of competence
3 that, in fact, what we're getting from these
4 community-based studies is generalizable, is useful in the
5 context of drawing some statewide conclusions and some
6 policy inferences.
7 Thank you.
8 CHAIRPERSON MORENO: Thank you.
9 All right. So that concludes the comments
10 provided by people listening to the audiocast via Email
11 and our three public commenters. So I'm going to bring it
12 back now to the Panel.
13 We have sometime for further panel discussion,
14 and this would be the time to make additional
15 recommendations to Program staff.
16 Actually Dr. Bradman and then Dr. Wilson.
17 PANEL MEMBER BRADMAN: I'll just quickly answer
18 Mr. Baltz's questions. Our meetings with participants are
19 about 30 minutes to return results. These are done in the
20 context of an office visit, usually involving other
21 sampling or behavioral assessments or other interactions.
22 So there's no additional scheduling time or, you know,
23 back time on the front and end, in terms of reaching
24 someone and things like that.
25 And so far, no one has requested follow-up

1 testing. Although, that's a little -- it's almost built
2 in to our system. This is a longitudinal study, where we
3 repeat sampling. So we've never actually returned results
4 where we don't have results over a period of time often
5 with multiple tests. It's almost by definition the way we
6 do things. There's repeat testing. And no one has asked
7 for additional follow up. But that's partly, I think, in
8 the context of our study design and how we're returning
9 those results.
10 PANEL MEMBER WILSON: Mike Wilson. I wanted to
11 thank, you know, the members of the public for their
12 comments. And I was sort of struck by Tom Jacob's comment
13 that biasing on the side of community-based participatory
14 research could increase uncertainty and potentially
15 distort results.
16 And it seems that that's possible, but not
17 necessarily -- that that could be prevented with good
18 study design.
19 And so I guess when it comes to this question of
20 how do we define a sufficiently responsible approach, I
21 think my sense of this is that it's clear to me that the
22 medical ethics approach is insufficient, and I think
23 actually for ethical reasons and also given the
24 limitations of the science.
25 And at the same time, I think what we've heard

1 today is that a CBPR approach that has deep roots in a
2 community has the potential to -- just to be too
3 exhaustive for the Program and impractical. And so I
4 guess my suggestion is that the -- that we aspire to a
5 community-based approach, that that be the bias, if you
6 will, or the default, sort of, aspiration of the Program.
7 And that that -- to do that -- and I think as
8 we've heard from the presenters today and from the other
9 members of the Panel that that's going to require a
10 concerted effort to involve one or more community-based
11 organizations.
12 And to do that effectively, what we found in
13 working with labor has been that that has to happen early
14 on. And that where you get in trouble and where we've
15 gotten in trouble specifically has been in bringing in
16 those individuals late in the game, where they feel as an
17 add-on, if you will, and didn't have an opportunity to
18 make the questionnaires more effective and to improve
19 recruitment and so forth.
20 And also to lend some credibility to the project
21 among members, and reduce some amount of suspicion, and
22 then communicate findings.
23 And so I was also struck by Gina's comment that
24 doing that could detract from other aspects of the
25 program, or perhaps the number of analytes we are able to

1 assess. But my sense is that if we -- that in the end,
2 those relationships are going to -- that time dedicated,
3 staff time dedicated to building those relationships is
4 going to have long-term payoff in the effectiveness of the
5 program, and in the -- yeah, I guess, that's what I'm
6 saying -- in the long-term effectiveness of the Program.
7 And so it's worth doing and worth investing staff time
8 early on.
9 And I guess I'll just conclude. I was struck,
10 just one of our first meetings that we had there was a
11 member of the public who described the process that led to
12 the atmospheric test ban of nuclear weapons in 1963 by
13 President Kennedy. That that was a -- that was the result
14 of a biomonitoring study conducted by epidemiologists,
15 pediatricians, dentists and members of -- and community
16 based groups looking at radioactive isotopes in children's
17 teeth, baby teeth. And that they were able to identify --
18 they could actually track when these nuclear weapons were
19 detonated in the atmosphere, they could track the delay in
20 radioactive isotopes appearing in teeth around the world.
21 And so that to me was an example of taking a --
22 you know, biomonitoring findings without restricting the
23 findings based on the sort of medical ethical approach.
24 We had no idea what the health effects would be of
25 isotopes in children's teeth. But it was compelling

1 information and it led to an extraordinary change that's
2 in place today.
3 And so I guess that's where I see the, you know,
4 potential power of information and moving that information
5 as much as we can into the community that's affected.
6 CHAIRPERSON MORENO: Other comments?
7 PANEL MEMBER BRADMAN: I just wanted to say one
8 thing. Mike, I really appreciate what you said. If I
9 understand though, Mr. Jacob's comments, your concern was
10 not necessarily about community-based versus not
11 community-based. It was small studies versus statewide
12 representation? Am I correct there? And I think that
13 that's a concern probably we all share.
14 MR. JACOB: Yeah, it's both. I mean, there's a
15 concern that in the more -- the smaller More narrowly
16 focused issue targeted the study, that there's a potential
17 for the study design to end up being aimed in a particular
18 direction that may not be delivering sort of generalizable
19 results that can be meaningful in the context of a
20 statewide -- an effort to draw statewide conclusions, a
21 statewide program.
22 But also the fact that we're increasingly subject
23 to external resources to fund these studies to create
24 them, create the opportunities, and sometimes they come
25 with strings. Sometimes those, you know, funds are ours.

1 Sometimes they come from the public interest communities.
2 Sometimes from labor. And it takes discipline to make
3 sure that those don't embed themselves in the study design
4 in some way.
5 That was really the point. And the suggestion
6 was just that the more reliance we have on the
7 community-based studies, it just raises the question of
8 what are we delivering to the statewide level that's truly
9 generalizable and consistent.
10 PANEL MEMBER BRADMAN: Thank you. And, you know,
11 I think there are some issues there. I believe the
12 legislation does kind of call for or allow, you know,
13 focusing on specific communities. But I think there is --
14 there's a loss by the fact that the State does not have
15 the resources to do a statewide project. And I think
16 right now maybe we just need to mourn that, and then
17 figure out if there's anyway we can get these resources to
18 do it without, you know, depleting other State programs to
19 get it done. But I think your comments really underscore
20 the need to also emphasize that we need to somehow go out
21 and do a broader project.
22 CHAIRPERSON MORENO: Dr. Solomon.
23 PANEL MEMBER SOLOMON: A couple of things. The
24 strontium 90 in kids teeth study actually was never
25 communicated to individuals. That was, you know, public

1 health action based on, sort of, aggregate public health
2 data. And I think that -- I mean, I really do -- I think
3 I'm an outlier on this Panel maybe, but I really feel
4 like -- actually the whole continuum of medical ethics to
5 community-based participatory research didn't work for me.
6 Because to me, the sort of continuum is how public health
7 oriented versus individually tailored the studies are.
8 And if something is, sort of -- you know, where there's a
9 lot of direct contact and communication and focus on the
10 individual, that's actually much more of a medical model.
11 And a public health model is really looking at,
12 you know, people, populations, and the aggregate.
13 And so I actually think that some of the more
14 community-based participatory research things are actually
15 more of a medical model than what was portrayed maybe
16 as -- I don't know if I totally understood what the
17 medical ethics thing meant.
18 And I think that, you know, we should be thinking
19 on a public health model and not spent, you know, trying
20 to do one-on-one patient sort of contact as part of this
21 study. It doesn't make sense to me. But I understand
22 that other people feel differently.
23 And then I also think that the commenter who
24 asked about DDT does deserve a response, speaking of
25 individual models here.

1 And since I made that motion, I guess what I was
2 thinking at the time was, number one, that the laboratory
3 at DTSC already has the capability of monitoring for DDT
4 and so it is not a lot of additional work for the program
5 to add it.
6 Number two, there is -- you know, there is some
7 indications of population patterns that maybe have some
8 public health importance in the California population, but
9 that those have not been fully elucidated. So I actually
10 heard that the data that Mexican-Americans who have, you
11 know, immigrated to the U.S. have higher concentrations of
12 DDT and then wanted to know more. You know, is it certain
13 age groups? Is it, you know, men more than women? Does
14 this apply to, you know, kids as well, because of current
15 use or does this mostly reflect past use?
16 And so I thought gee, you know, we could begin to
17 get a handle on some of that, and it, you know, could be
18 important in terms of both -- well, who knows, maybe we
19 could spur public health action in Mexico.
20 Anyway, so that was what I was thinking. But I
21 also was thinking about the discussion that our Panel had
22 had about not all chemicals in the high-priority group --
23 or in the priority chemicals group are high priority. So
24 frankly I was thinking of DDT as maybe not a high, but as
25 in the priority group but not high priority. So I hope

1 that helps the commenter.

2 CHAIRPERSON MORENO: Dr. Quint. And, Diana,

3 could you switch to the next slide so we could be reminded

4 of what those other three questions were that you had.

5 That one, yeah.

6 Okay, Dr. Quint.

7 PANEL MEMBER QUINT: I am interested in the

8 question about -- I guess it's not up there anymore --

9 about being sufficiently responsible.

10 I guess of concern to me is this balance between,

11 for instance in the phthalates study, the occupational

12 study, part of the IRB -- you know, in getting approval by

13 IRB, they really honed in on the clinical significance of

14 the results. And I think there was emphasis in the report

15 back that, you know, there was no information about the

16 health significance of the studies.

17 What bothers me with how you walk that narrow

18 line and having answered a lot of questions through the

19 talking to people about, you know, these issues over the

20 public telephone response system that we had in the health

21 department, is, you know, how do you balance that with,

22 you know - we have phthalates - if there are women of

23 child-bearing age who are exposed at higher levels than

24 what we have -- know right now are the NHANES levels, do

25 you have some responsibility to say something about what

1 information we know?

2 Put it into context and not predict what's going

3 to happen an individual's health or to a group of women's

4 health, but what is the responsibility to be more

5 forthcoming about what you know about the health effects

6 of some of these chemicals, for which we don't have

7 standards?

8 And, you know, it's just a question that bothers

9 me. My sense is, it's not - and this is personal - not

10 being responsible, not to tell people what we know, even

11 if it's qualified information, about, you know, a

12 condition or -- and this would be, you know, something

13 that we know toxicologically about the chemical and the

14 ability to affect, you know, health outcomes.

15 So I'm not expecting an answer. It's just

16 something that I think we have to wrestle with, because on

17 the one hand you have to abide by whatever, you know,

18 rules the IRB places on you. And some of these things

19 don't have answers, but I think we do know certain things.

20 And how to best communicate those should be sort of paid

21 attention to.

22 CHAIRPERSON MORENO: Other comments?

23 Dr. Wilson.

24 PANEL MEMBER WILSON: I'm going to weigh in one

25 more time. And I think -- I was struck again by Gina's

1 point. And I think, in my mind, there's a -- that
2 community-based research, if you will, and community-based
3 data generation and communication of results is going to
4 be the basis on which we can make the program a public
5 health as broadly publicly health applicable, if you will
6 and effective for the population and I guess for the State
7 of California.
8 And so when I think about community-based
9 participatory research, it's delinked, in my mind, from
10 narrow highly localized and individually specific
11 strategies.
12 I think of it more as making as much as we can in
13 reaching populations, in being as effective as we can
14 possibly be in doing that. And that that is sort of
15 acts -- our communication with community-based groups and
16 with labor, if we're -- organized labor, if that's the
17 direction we're headed, is going to allow us the access to
18 populations and helping -- it will help -- the information
19 we can provide is going to help those organizations
20 support communities in taking steps.
21 And I guess the -- and I support that. And I
22 think it's important for public -- I think it's a basis
23 for public health action. And I guess the -- when I was
24 speaking about the medical/ethical approach or a clinical
25 ethics approach, I think the definition that Dr.

1 Morello-Frosch has in her paper is what I was referring
2 to. That it assumes that decisions about whether and how
3 to report individual biomonitoring results rests with
4 scientists and medical experts and should be based on
5 whether the risk relationship between exposure and health
6 effects is understood.
7 If results fall below this clinical action level,
8 individual data is generally not reported to participants.
9 And so that would be the -- I wouldn't support that
10 approach. I guess that's the point I was trying to make
11 to clarify that definition.
12 So thank you.
13 CHAIRPERSON MORENO: Well, I think our Program
14 staff are hearing some good opinions from professionals on
15 your Guidance Panel.
16 We actually have -- I can tell the Panel right
17 now, we have about 10 minutes left scheduled for
18 discussion. We can continue discussion.
19 But are there any specific recommendations that
20 anyone would like to suggest we make to Program staff at
21 this time?
22 Again we've shared a lot of -- professional
23 opinions have been shared with you. I think you've --
24 there's quite a bit of information that you've received.
25 I think that as you move forward and you'll keep this in

1 mind. You've taken notes. You'll keep this in mind. You
2 will be prepared to raise those issues, because you know
3 how certain panel members feel about issues discussed
4 today.
5 MS. LEE: Well, I'll take that as a specific
6 recommendation.
7 Also, as I indicated in my prefacing remarks to
8 this Panel this morning, this is only the first of
9 additional discussions that we hope to have with you. And
10 no specific timelines are set at this point for some of
11 that, but I think you heard from some of our speakers this
12 morning that there are activities in process, for
13 instance. And at some point when those activities are
14 completed, we would like the opportunity to come back and
15 share some of the results of some of those ongoing
16 activities now.
17 CHAIRPERSON MORENO: Okay. All right, well then
18 I'm going to close this portion of the -- or this agenda
19 item and we're going to move on to the next, which is to
20 introduce Dr. Rupali Das who will -- of the Exposure
21 Assessment Section of the Environmental Health
22 Investigations Branch with the California Department of
23 Public Health, who will be providing us a summary.
24 DR. DAS: Thank you, Dr. Moreno. And good
25 morning to the audience and Panel members.

1 Today, we discussed -- we had several great
2 presenters all talking about results communication issues.
3 We started with Diana Lee from the California Department
4 of Public Health Biomonitoring Program reminding us that
5 at the last meeting Panel members supported providing
6 feedback to participants, and that this was described in
7 the enabling legislation for the Biomonitoring Program as
8 well. And she also stated that communication may be the
9 most vexing challenge of the biomonitoring efforts. And
10 that the Program's desire is to develop best
11 practices -- a best practices framework.
12 We then heard from Dr. Rachel Morello-Frosch from
13 the UC Berkeley School of Public Health, who stated that
14 biomonitoring science has been outpacing the capacity to
15 interpret health effects. And that was a sentiment that
16 was echoed throughout this morning's presentations.
17 But that biomonitoring provides us an opportunity
18 to change behavior and to reduce exposures. She described
19 a continuum of community engagement from the clinical
20 model to the community-based participatory model, and then
21 described two specific studies that looked at results --
22 providing results to participants, the Cape Cod study and
23 the northern California study.
24 And she stated that, in terms of reporting back,
25 that they used a combination of text and graphics and

1 provided some examples of that feedback.

2 The studies recommended -- she recommended based

3 on her studies that it is important to set expectations in

4 advance of doing the study to indicate how participants

5 can use results to take action and to consider cultural

6 issues when doing the study and providing feedback.

7 Holly Brown-Williams of the UC Berkeley Health

8 Research For Action then spoke to us and said that most

9 health information is presented at a much higher level

10 than the average literacy, and gave us some examples of

11 complex message that would not be understandable by most

12 people.

13 She highlighted best practices in health

14 communication. That included keeping the specific

15 audience in mind, engaging the audience, for example, with

16 focus groups, but not limited to focus groups; to use

17 analogies and pictures rather than numbers, which are less

18 understandable. And she described CYGNET the Cohort of

19 Young Girls Nutrition Environment and Transitions - I hope

20 I got that right - in which girls were recruited at age

21 six to eight and have been tested for about 80 chemicals.

22 And the challenges in reporting results in this

23 study include that there's little knowledge of safe

24 levels, again a sentiment expressed by various presenters;

25 that there are limited means for decreasing personal

1 exposures; that there's a problem with selecting reference
2 values; that uncertainty of the meaning of -- the clinical
3 meaning of these results may cause anxiety; and that there
4 maybe both over interpretation and under interpretation of
5 these levels; and that Health Research for Action is
6 continuing to look at these groups to model outreach and
7 feedback -- report-back methods.
8 And then she described the Perspectives issue
9 that was mentioned yesterday as well, and the
10 maternal-infant pair study that was described yesterday as
11 well.
12 Lori Copan of the California Department of Public
13 Health spoke about -- who is the liaison between the
14 Environmental Health Tracking Program and the
15 Biomonitoring Program, described two pilot projects that
16 the Tracking Program is conducting in Tulare and Imperial
17 counties, and this involves biomonitoring of urine, as
18 well as measuring metabolites and compounds in air, water,
19 and produce.
20 Both of these projects have a results
21 communication piece, and she focused her comments there.
22 And she stated that this small biomonitoring project
23 should be looked at -- or could be looked at as a model
24 for building communication and results communication for
25 the overall Biomonitoring Program.

1 The goal of the biomonitoring -- of
2 community-based participatory research is that the
3 participant would shape results, and that the study
4 doesn't leave the community, but leaves capacity in the
5 community to shape results.
6 In terms of the results of her focus groups and
7 community meetings that they've conducted in tracking, it
8 was apparent that there's good general knowledge of the
9 studies, but there are misconceptions about what the
10 studies can answer. And specifically participants really
11 wanted to link study biomonitoring findings with
12 individual health conditions. And it's important to have
13 people realize that that is not possible in these kinds of
14 studies.
15 People wanted also to link results and their
16 children's health concerns. They wanted to learn how to
17 reduce levels on a personal basis, but also to change
18 practice on a larger level and to have laws that come out
19 of the findings of the biomonitoring studies.
20 Individuals who participated in these studies
21 wanted providers to sit down with them and go over the
22 results. And again, as with previous presenters, Lori
23 stated that it's best to use graphic information not just
24 text to communicate results.
25 She described that there's a provider team

1 composed of community and State members. And the goal is
2 to develop best practices and a model to conduct outreach
3 or feedback to participants.
4 Dr. Asa Bradman of the UC Berkeley CHAMACOS
5 Program spoke about his experience -- or their experience
6 resulting in -- returning results in the CHAMACOS birth
7 cohort.
8 CHAMACOS briefly is a community/university
9 partnership assessing exposure to pregnant women and
10 children. And there is -- the feedback portion of it
11 involves sitting down with individuals for 30 minutes
12 during a health -- normal health visit.
13 The focus has been on organophosphate and using
14 NHANES as a comparison.
15 Dr. Bradman described that initially the IRB was
16 not supportive of returning results, but through a
17 community engagement process, and also as a result of
18 NHANES coming out with results during the course of the
19 study, the IRB changed and now feels that results should
20 be returned with the following stipulations:
21 That results should be returned to individuals on
22 an individual visit; that the context of the study should
23 be specified that it's research not clinical; that the
24 results should not be used to stigmatize individuals, and
25 that when clinical guidelines are available and the

1 results indicate, those should be followed.
2 The challenges of the study are that in terms of
3 returning results, there really needs to be a dedicated
4 budget. It's difficult to schedule a time to return
5 results to working people particularly. There are no
6 standardized clinical guidelines for most of the
7 substances with the exception of lead. Biomarkers may not
8 always reflect exposure.
9 And that there's sometimes good correlation for
10 short-term exposures, but not such great correlation with
11 long-term exposures due to both inter- and
12 intra-individual variability.
13 The recommendations from this presentation,
14 including working with participants ahead of time to both
15 set expectations and to understand what results need to be
16 provided; to interact with and educate IRBs; to understand
17 the limitations of their results; and also to budget
18 resources that will support the kind of feedback that
19 you're promising in the study.
20 Dr. Julia Quint, the retired chief of a program
21 in the California Department of Public Health and the
22 Scientific Guidance Panel was Dr. Bradman spoke about
23 biomonitoring in occupational settings. And stated that
24 occupational biomonitoring really entails giving
25 information back on exposures and health risks. But that

1 the way in which the results are provided and maybe the
2 detail really varies according to individual providers,
3 it's essentially an industrial hygiene tool, which the
4 goal of keeping the workplace safe; that the limits are
5 not protective against chronic health effects. They're
6 really focused on acute health effects.
7 There's a need to protect workers rights, as the
8 results can be use to discriminate against workers and
9 that needs to be kept in mind.
10 And the unique future of occupational
11 biomonitoring, is that the employer is responsible for
12 protecting the worker, even in the absence of a reference
13 value.
14 Other countries, including Germany, the UK, and
15 the World Health Organization have guidance levels. The
16 most popular guidance level is the U.S. biological
17 exposure indices, which are available for 43 substances,
18 but very few of them are mandatory.
19 There are some other values as well, including
20 threshold limit values, that are developed by the American
21 Conference of Government Industry hygienists, which is not
22 a governmental organization in spite of their name.
23 And the OSHA permissible exposure levels.
24 And TLVs, although they're not regulatory or
25 mandatory, are often used because the OSHA PELs have been

1 revised, whereas the TLVs are revised and the process is a
2 little more transparent.
3 The biologic exposure indices may be based on
4 both either TLVs or health effects, and may be used for
5 one of three purposes, medical surveillance, health hazard
6 evaluations which are formed by the national for
7 occupational and safety and health, when they investigate
8 specific health concerns and research studies. And
9 depending on when -- where they're used, this affects the
10 way the results are communicated to the workers involved.
11 Biomonitoring results in the workplace can
12 indicate how often a worker has to be monitored for those
13 substances for which there is a standard for communication
14 and providing feedback.
15 Dr. Quint provided examples of communicating
16 results, based on a cadmium standard. And she also
17 described health hazard evaluation of environmental
18 tobacco smoke in casinos with a very dense complex report.
19 And a one page summary that the recommendations basically
20 were to ban smoking in casinos and to form health and
21 safety committees. And she also provided another example
22 of a phthalates study that was complex, because it took
23 place across the country.
24 This did result -- the study found that there was
25 a cross-shift or mid-shift increase in phthalate levels.

1 A letter was sent to workers. Workers always wanted their
2 results, and I believe their some ongoing work in that
3 regard.
4 We then had discussion, no specific
5 recommendations, but some of the themes that arose through
6 our discussion were that there needs to be a balance
7 between the resources needed for individualized feedback,
8 and the need to ramp up on a large statewide generalizable
9 study.
10 Dr. Bradman actually provide a set of
11 recommendation that weren't adopted by the whole
12 committee, but included that the dialogue needs to occur
13 ahead of time with groups. The in-person reporting is
14 good, but other options should also be explored. That
15 comparisons should be made when reference values are
16 available, that should be used as a standard for
17 comparison of individual -- or group results. That the
18 distinction should be made between a research study and a
19 clinical study. Health care providers should be
20 reached -- or attempts should be made to reach them
21 through local health officers, city health officers when
22 they exist, and the local medical societies. That consent
23 should be part of an information-providing process.
24 And there was some discussion about ways to
25 provide research -- I'm sorry, feedback and dissemination

1 in a web-based provision was discussed.

2 Dr. Moreno stated that local health officers

3 could help identify appropriate health care providers in

4 the community, and in that way save the Program resources,

5 in terms of finding the appropriate providers.

6 Again, there was a lot of discussion about the

7 individualized approach or the merits of providing

8 individual results versus the effort needed to provide

9 that and to focus instead on a larger statewide effort.

10 There was a feeling expressed that empowerment

11 may flow from this, but that community-based empowerment

12 should not be the focus of this program, because of

13 trading off with other goals, although not all Panel

14 members felt that way.

15 And the recommendation that the Program should

16 keep all this discussion in mind, and that we would

17 address it further in the next Scientific Guidance Panel

18 meeting.

19 Thank you.

20 CHAIRPERSON MORENO: Thank you, Dr. Das.

21 All right, I think that was a great summary of

22 today's events.

23 With that, I think we're about to adjourn. I

24 just want to let people know that the final meeting

25 presentations will be available on the website as soon as

1 possible. And there will be notice sent out to
2 individuals on the biomonitoring list serve when those
3 materials are available.
4 The next meeting is planned for October 6th and
5 7th this year in Sacramento at the California
6 Environmental Protection Agency Headquarters. And, Allan,
7 do you have any final comments?
8 CHIEF DEPUTY DIRECTOR HIRSCH: Just to say that
9 an 11 hour meeting requires a lot of meeting preparation,
10 more than you would think. And I'd just like to thank the
11 OEHHA, EPA, DPH, and DTSC staffs for all your work. We
12 had a lot of thoughtful presentations, between yesterday's
13 presentations on chemical selections, today's program on
14 data presentations, the panelists certainly for all of
15 their work too. And last, but not least, the
16 behind-the-scenes work by OEHHA's Information Technology
17 staff, so that we have the computer screens working, the
18 microphones. There's always a lot more work than it
19 seems.
20 And, you know, this building is only 11 years
21 old, but it doesn't appear to have been very well set up
22 for audiocasts, let alone webcasts. So with all of the
23 issues we've had, I know that the IT staff has just
24 doggedly been working on trouble shooting and getting the
25 audiocast to work properly.

1 So I really appreciate their hanging in there and
2 solving the various problems.
3 CHAIRPERSON MORENO: Thank you to everyone.
4 We're adjourned.
5 (Thereupon the California Environmental
6 Contaminant Biomonitoring Program Scientific
7 Guidance Panel meeting recessed at 1:00 p.m.)
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1 CERTIFICATE OF REPORTER

2 I, JAMES F. PETERS, a Certified Shorthand
3 Reporter of the State of California, and Registered
4 Professional Reporter, do hereby certify:
5 That I am a disinterested person herein; that the
6 foregoing California Environmental Contamination
7 Biomonitoring Program Scientific Guidance Panel meeting
8 was reported in shorthand by me, James F. Peters, a
9 Certified Shorthand Reporter of the State of California,
10 and thereafter transcribed under my direction, by
11 computer-assisted transcription.
12 I further certify that I am not of counsel or
13 attorney for any of the parties to said meeting nor in any
14 way interested in the outcome of said meeting.
15 IN WITNESS WHEREOF, I have hereunto set my hand
16 this 20th day of August, 2009.
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