

Work plan excerpt

AFTERNOON SESSION

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EXCERPT OF THE CIC DISCUSSION ABOUT THE ACRYLAMIDE
WORK PLAN AT THE OCTOBER 17, 2003 MEETING

1 to ten months before heading off to -- before proceeding
2 with the work plan and defining a new NSRL.

3 CHAIRMAN MACK: And how would you answer the
4 coalition of pregnant women who have read the Swedish
5 studies and say, should I or should I not continue
6 eating potato chips?

7 MS. CORASH: Well, I wouldn't substitute my
8 judgment on that for that of FDA; and what I hear FDA
9 saying is, on the science we have now, it's not changing
10 its recommendations, which is eat a healthy diet, but
11 it's not --

12 CHAIRMAN MACK: Whatever that --

13 MS. CORASH: -- issuing changes --

14 DR. MACK: -- that may be.

15 MS. CORASH: -- based on acrylamide.

16 CHAIRMAN MACK: The difficulty is, what is a
17 healthy diet?

18 Thanks a lot.

19 MS. CORASH: Yeah, sure.

20 DR. MACK: I'm sure as hell glad I don't drive
21 with her in the back seat.

22 Okay, we're going to take a five-minute bladder
23 break, and then we're going to start the deliberations.

24 (Recess taken.)

25 DR. HERTZ-PICCIOTTO: Well, I just want it to
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1 be recorded that I'm impressed with -- that this topic
2 is so boring we couldn't get input, and I'm happy to try
3 to lead off this discussion.

4 I think that we're in a sort of watershed place
5 right now, or time, in chemical carcinogenesis and that
6 it may well be that the findings on acrylamide might be
7 part of the key to understanding something about the
8 background rates of cancer in the human population
9 which, up until now, has really remained a puzzle with
10 many, many years of effort on the part of scientists in
11 industry, government and academia mostly leading to
12 identification of chemicals that don't explain a lot of
13 the background risk, with the one exception being
14 smoking and potentially PAHs and possibly some of the
15 other constituents of cigarette smoke.

16 So I take this as being really an important
17 point and a place where it's impressive that
18 internationally and nationally the organizations
19 involved in regulation and monitoring are taking this
20 very seriously, and it is exciting the amount of
21 research that is about to take place, and I think all of
22 us are -- will be very eager to see what the results of
23 this research leads to.

24 So, on the one hand, there's a question
25 regarding what is the state of knowledge right now; and,

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1 on the other hand, where might we expect to be in a year
2 or two years from now. And I think that it's important
3 to think about that second question in particular with
4 regard to consideration of whether we should wait or
5 not.

6 And I do want to point out that a decision to
7 wait is, in fact, an endorsement of the current NSRL.
8 That to not re-evaluate the NSRL is essentially to say
9 that we are endorsing what exists currently on the
10 books, and I think that we need to take that into
11 account.

12 It seems probable to me that in two years from
13 now or even in eight to ten months from now there will
14 be some more studies and we will still be saying there's
15 a tremendous amount that we don't know, that the gaps
16 are -- may even increase. Of course, a little bit of
17 knowledge always opens up other questions.

18 So to really sort of face where we are, we do
19 have to think in terms of what answers are we going to
20 get in the next few years that would enlighten us so
21 much that it would justify not acting at this point.

22 I just want to make one comment in regard to
23 the question of people's behavior changing in ways that
24 could be harmful, and this is one of those arguments
25 that one hears often, and, you know, I have a hard time

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1 with that. It's hard enough to get people to change
2 their behavior when we do have really solid answers.

3 We know that -- or we think we know that the
4 diet with more fruits and vegetables and less of certain
5 kinds of fats would be a lot better for the population,
6 and we can't get people to do -- to move in that
7 direction.

8 So, you know, I'm not really worried a lot that
9 people are going to say, you know, the french fries out
10 at you-name-your-fast-food-restaurant are so full of
11 carcinogens, I'm going to go home and start cooking my
12 own french fries.

13 My observation is that we've raised a
14 generation of people who actually don't know how to cook
15 at home anyway and -- speaking of my own kids, but --
16 probably some of them -- one of them. So I'm not -- I
17 think that's not really the kind of concern that should
18 dominate our recommendations.

19 Now, I'd like to suggest -- we don't have a
20 huge amount of time and we have a lot of important
21 questions to try to address, and I would like to propose
22 that we divide the discussion into about four parts, I
23 think.

24 The first thing I'd like to see us do is have a
25 discussion about the scientific issues and -- separate

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1 from the action, regulatory, and the particular work
2 plan that's before us.

3 In particular, I'd like to address the
4 carcinogenicity data and what are the relevant tumors
5 here. Clearly, several authoritative bodies have
6 evaluated this evidence and considered acrylamide to be
7 a probable human carcinogen depending on the language,
8 which body will give you slightly different wording
9 there, but that, I think, is the basic idea.

10 Were we to accept some of the arguments that
11 these are essentially all benign tumors, I think that
12 would -- we would have to understand a little bit how it
13 could be that those authoritative bodies have come to
14 their conclusions, which doesn't mean that we might not
15 want to disagree. We could. So I would actually like
16 to settle that question with a little bit of discussion
17 in a few minutes.

18 Then, if there's anything to say about the
19 mechanisms with regard to either the metabolite
20 question, glycidamide versus acrylamide, it appears to
21 me that there's disagreement based on what's in the
22 literature, and I think Tom did a very nice presentation
23 about -- Tom McDonald -- about the state of the science
24 on this -- on that point.

25 We might also want to discuss a little bit the

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1 human data that are -- that have been published, the
2 studies that are out there, and maybe the
3 epidemiologists can at least clarify for the
4 nonepidemiologists on the committee what we think about
5 those studies.

6 Now, I understand we're not -- our committee is
7 not directly responsible in any way for evaluating
8 reproductive effects and that there isn't a committee
9 under Proposition 65 dealing with neurotoxicity, and
10 that does seem to be at this point possibly the most
11 sensitive endpoint in human studies. At least that's
12 the endpoint that's been observed very clearly in
13 occupational -- occupationally-exposed cohorts.

14 And I think it's important to note that,
15 although I think we don't have much legally we can say
16 about that. That's my understanding, and I'm getting a
17 nod here of the affirmative from the legal department.

18 So I'd like to discuss some of these scientific
19 issues initially and see if we can come to, if not
20 closure, some degree of higher understanding.

21 The second area I'd like to outline for
22 discussion would be a discussion of the exposure
23 information and a little bit of clarity here on average
24 consumers. Maybe we'd like to have some discussion
25 about the -- what we might like to see OEHHA produce in

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1 regard to exposure assessment.

2 And I would like to suggest that we not limit
3 that to food, but I would love to see the comparative
4 data relating to water and personal care products, which
5 also seem to be another source, and then that relates
6 back to the question of absorption, dermal versus oral
7 absorption.

8 Then, from there, I think we could then proceed
9 into a discussion of the specific work plan issues, and
10 the first one being the NSRL, and I'd like to -- maybe
11 at that point I'll make some comments to lead off that
12 discussion.

13 The item three in the work plan, which had to
14 do with alternative exposure levels -- and I think
15 that's related to the NSRL, although they're not the
16 same question -- and so I think we should start at that
17 point, the NSRL, and then discuss this issue of
18 alternatives.

19 And the warning label question then would be --
20 and the detection method would then be the last two
21 items I think we should discuss.

22 So that's the order I would suggest we proceed
23 under. So, Mr. Chairman --

24 CHAIRMAN MACK: I think you set out a perfectly
25 appropriate order, so why don't you start discussing

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1 them, and you may stop for further comments from the
2 rest of us at your leisure.

3 DR. HERTZ-PICCIOTTO: Okay. Well, I think the
4 first question, actually, I would like to have
5 clarification on and hear from the toxicologists is the
6 relevance of the tumors that have been seen in the major
7 carcinogenicity bioassays, and we've read comments and
8 heard comments about the benign nature of the tumors.

9 There are the thyroid adenomas, there are the
10 mammary tumors, there are some -- I have them here in
11 front of me -- benign tumors, there are the adeno
12 tumors, there are some mesotheliomas of the testis and a
13 few others.

14 So maybe Joe or Jim or -- would like to make
15 some comments on that issue.

16 DR. FELTON: I'd defer to --

17 DR. HERTZ-PICCIOTTO: You defer to Joe, okay.

18 DR. LANDOLPH: Well, it's already listed. You
19 know, the EPA has listed it as a Group 2-B probable
20 human carcinogen, so I wouldn't presume to think past
21 that. That's already been an expert body that's done
22 it. IARC calls it Group 2-B, which is possibly
23 carcinogenic. That probable/possible is a continuum and
24 many chemicals fall into that.

25 I was impressed, I would have to say, with the

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1 study by Johnson, which was the Fischer 344 rat study,

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2 because they did it by relevant mode of administration,
3 which is in drinking water for two years, and they got a
4 number of different tumors:

5 Tumors of the adrenals, the mesotheliomas, the
6 follicular adenomas, thyroid tumors, and central nervous
7 system tumors in the males, pituitary adenomas, thyroid
8 follicular tumors, mammary adenomas and adenocarcinomas,
9 oral papillomas and uterine adenocarcinomas in the
10 females. So that's a lot of different tumors at
11 different tumor sites, both benign and malignant.

12 So that seems like a nice model to start from,
13 particularly because it uses the mode of administration
14 through the oral route, which is as relevant to humans
15 as you can get, although it's drinking water rather than
16 a feeding study, but it's still an oral route.

17 So it -- this looks like it has a reasonable
18 database behind it. Some of the tumors certainly are
19 benign, that's true, but this practice of adding benign
20 and malignant tumors together is common in that -- in
21 the regulatory literature.

22 DR. FELTON: I think what it's really going to
23 come down to as we -- you know, as we get into this is,
24 what do the shapes of these dose response curves look
25 like?

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1 And, you know, is this the type of thing where
2 we're going to have the data that we need to start to

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3 look at the no effect levels very carefully and
4 mechanistically.

5 And if we have the kind of tumors that we could
6 suggest that they aren't linear, that there is a
7 threshold, then that's important. If we decide that the
8 tumors really don't, that these are -- that we're going
9 to get a linear response in carcinogenicity, then I
10 think we don't need to discuss it any further.

11 Now, obviously, Dr. Friedman brings up the
12 point that some of these tumors may have some different
13 mechanisms of formation and may not be linear, and to me
14 that's important, although those aren't the only tumors
15 that have been seen.

16 So I think what our discussion should really be
17 is focused around how do we get at this risk assessment
18 the best way we can, and I don't think anybody here
19 would disagree, Joe, that, yeah, there's a lot of tumors
20 and that's why it's listed.

21 DR. HERTZ-PICCIOTTO: Okay. It sounds like
22 that's not particularly controversial.

23 How about if we have a little discussion about
24 the exposure issues and what are the -- what is it --
25 what information about exposure is going to be relevant

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1 that OEHHA should be considering in develop -- in its
2 next steps. Not a clear question, I guess.

3 Jim.

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4 DR. FELTON: Well, I mean, we can do a lot of
5 analytical chemistry, and it's been done very well, and
6 I'm sure we're going to get numbers that are going to
7 vary over mean, but we're going to come up with some
8 numbers that we can be pretty confident that we're going
9 to see in the different types of foods.

10 The next question, of course, for risk
11 assessment is, you know, who's eating those foods at
12 what age -- we've already gotten into all this
13 discussion -- but what we really need is exposure
14 information which, even though everybody talked about
15 all the stuff that's coming out, I don't think if we
16 wait a year from now we're going to have good exposure
17 information at different ages and different types of
18 diets. That's hard to get, as you know. So that's
19 where I think the emphasis has got to be.

20 CHAIRMAN MACK: It seems to me that the most
21 important piece of information about exposure that we
22 have currently is that it's highly variable. That
23 with -- going from one McDonald's to another or two
24 doses of the same brand of potato chips, there are big
25 differences.

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1 We know that there are differences in the
2 consumption of what are generally recognized to be
3 relatively high dose foods in the population by
4 ethnicity, by social class, by lots of different such

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5 things, and certainly by age.

6 So that the typical person, from the standpoint
7 of the past regulation issues, is a much different
8 kettle of fish or a much more difficult thing to deal
9 with than they have been in the past because there are
10 big differences within families and between families.

11 So I think the very fact of this variability is
12 something that's really important. Now, I'm first to
13 recognize that we don't know exactly how variable it
14 really is.

15 We don't have good assessments. We don't have
16 good sampling methods. It will take time to work all
17 those things out. But as of right now, we know that
18 there are things which are carcinogens which are highly
19 variable from food to food and highly variable in the
20 population as well.

21 DR. HERTZ-PICCIOTTO: Well, let me pose this.
22 Food is something we eat every day, several days --
23 several times a day --

24 CHAIRMAN MACK: Some of us more than others.

25 DR. HERTZ-PICCIOTTO: -- and -- you said it.

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1 So the variability in -- in the food products would seem
2 to me to average itself out if we have good estimates of
3 what people's intake of the foods are.

4 That, you know, today's french fries and
5 tomorrow's french fries might differ, but -- the

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6 likelihood that one person is going to get the highest
7 batch of french fries day after day after day is low
8 relative to the variability -- the potential variability
9 in -- you know, some people eat french fries 15 servings
10 a week, you know, some college students versus maybe
11 hopefully other people may be eating it somewhat less.

12 So the variability within the food supply for a
13 given food item would strike me as being less important
14 than characterizing what the variation is in human food
15 consumption.

16 CHAIRMAN MACK: I really don't think you can
17 assume that. I think certain people like their french
18 fries crisper, some people like their meat more
19 caramelized and well done, other people like it -- like
20 it rare.

21 And there may well be taste differences
22 which proceed over the lifetime, and so not only will
23 there be variability by food, in my opinion, there's
24 very likely to be variability in preference. So I don't
25 think we know. What you say is -- may be reasonable,

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1 but it may not be.

2 DR. FELTON: My question is: Can you take all
3 that variability -- and this is for you guys -- and put
4 that all into your risk bounds that you work on? I
5 mean, is that useable?

6 DR. HERTZ-PICCIOTTO: If you have the

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7 information and you can characterize what that variance
8 is in human consumption, then, yes, you could.

9 I mean, if you can characterize here's the
10 bottom 2.5 percent, here's the top 2.5 percent, here's
11 the median, then, yes, you would be able to plug that
12 into your formulas and determine what the variation is
13 then in risk level.

14 And it -- I mean, it's also important to know
15 what that variation is in order to determine how well
16 epidemiologic studies will be able to detect and define
17 any carcinogenic effects or other health outcomes, for
18 that matter, in relation to acrylamide.

19 Because if there's not sufficient variability,
20 then epidemiology isn't going to go anywhere with
21 telling you anything about the health effects from
22 acrylamide. You have to have variation; and if the
23 variation is insufficient, you won't be able to see an
24 effect.

25 CHAIRMAN MACK: But I think you were asking

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1 about the modeling for purposes of regulation, and there
2 we used a convention of one case per 100,000 people, and
3 here we have a situation where one has to ask 1,000 of
4 what -- 100,000 of what kind of people? 100,000
5 children from 0 to 5? 1,000 -- 100,000 pregnant women?
6 Are you -- are you going to simply take the average and
7 leave it go at that?

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8 And I really think we're in a situation here
9 where the usual kind of regulation guideline is not very
10 useful because neither do we know the distribution of
11 exposure in the population nor do we -- can we specify
12 with any degree of accuracy what the number of cases per
13 hundred thousand of the average population is. It will,
14 of course, depend on the age distribution, et cetera, et
15 cetera, et cetera.

16 But the answer to your question is, you have to
17 do -- you have to put it in if you're going to use that
18 methodology.

19 DR. HERTZ-PICCIOTTO: Actually, I think this is
20 a perfect lead-in to a discussion of the revision of the
21 NSRL, and we heard several presentations this morning
22 relevant to that; in particular, the one from Dr. Hattis
23 about what sorts of things could go into the -- given
24 current day information as of today -- into a revised
25 NSRL.

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1 I think it's important to recognize that
2 there -- we're all in a situation of shifting sands and
3 that what's -- what information we have today, it's
4 going to be somewhat different, you know, next month.
5 There may be even more papers out on pharmacokinetics by
6 early 2004, we may have further data, and so on.

7 Nevertheless, the question before us is whether
8 we want to recommend that OEHHA go ahead with a revision

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9 of its NSRL; and as I said earlier, I think to not ask
10 them to do that is actually to endorse the current NSRL,
11 and I think that would be remiss because we do have a
12 considerable amount of new information from the time
13 that that one was derived.

14 Comments from the other committee members?

15 CHAIRMAN MACK: I certainly agree. I don't
16 think there's any option but to try and revise it
17 because, just as you say, not to do so is the -- is an
18 acceptance of the current one.

19 Where I have comments is about the third part
20 of the work scope, which is an alternative NSRL, but I
21 don't know if you want to do that yet.

22 DR. HERTZ-PICCIOTTO: No, I think we should
23 stick with these questions, take them distinctly as they
24 are.

25 CHAIRMAN MACK: Let's force everybody else to

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1 express an opinion on altering the NSRL.

2 DR. FELTON: I agree.

3 DR. GOLD: I think we all agree that -- or
4 maybe I shouldn't speak for the group -- that we need to
5 take a look at revising it, but I think we want that
6 informed by additional information, and we heard a lot
7 about studies that are underway and how we should wait
8 for them.

9 I noticed kind of a minimal amount of human

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10 studies mentioned. There are a lot of laboratory and
11 mechanistic studies and so forth, which are very
12 important, but if we want to have some information on
13 what happens in humans and six months or a year from now
14 not being in the position of saying we still have this
15 problem of extrapolation from animal studies to humans,
16 then we have to, I think, encourage a collection of data
17 in humans.

18 And I saw a reference to the NHANES, which
19 certainly will be helpful as long as it is not
20 restricted to just adults, for example. There is a
21 component of the NHANES that looks at young folks, and
22 that would be a good thing to include.

23 And that we not try and ask OEHHA to come up
24 with this sort of a summary measure, but to examine
25 intakes across a wide spectrum and give sort of ranges

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1 and so forth in various subgroups of the populations to
2 the extent that it's possible. I'm not sure how much is
3 possible.

4 DR. FELTON: I'd like to reiterate what you
5 said, Dr. Gold. I think what we're missing here -- I
6 mean, you looked at all the gene tox data and the animal
7 data, and we can refine all that, but we're just so
8 short on good human data it's really hard.

9 I'd love to know before I go home why the 8,000
10 people in the acrylamide plant didn't come down with any

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11 significant tumors. Maybe you guys can tell me that
12 before we go.

13 But the main thing I want to say about the
14 NHANES -- and that's what I'm getting at -- is we tried
15 to use this for years for our heterocyclic amine data,
16 and the most unfortunate thing is it doesn't really tell
17 you about cooking parameters.

18 And here, for these compounds, cooking
19 parameters are going to be important. You know, was it
20 cooked in fat? Was it cooked in the frying pan? Was it
21 cooked burnt brown? Was it lightly cooked? And those
22 are going to be huge when we try to get exposure
23 assessment, and that data, to my knowledge, is not -- at
24 least the last time I looked at NHANES wasn't there.

25 DR. LANDOLPH: I guess I would certainly

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1 recommend going ahead slowly, carefully, prudently. It
2 will take quite a while to make a new document anyway,
3 and I think you certainly should get the results of the
4 JIFSAN meeting in April of '04 and incorporate as much
5 of that data into any new NSRL as you possibly can.

6 And I appreciate Jim's comment. Again, I would
7 consult your expert epidemiologists and see if you can
8 at least use that data to get some upper bounds to the
9 data and try and incorporate that into the document
10 wherever possible.

11 And I certainly laud Dr. Denton's letter to the

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12 FDA where it indicates you're going to partner and work
13 with them because I think it's very important.

14 This seems like such a big issue, it's good to
15 have a consortium working on it, although you may
16 diverge in your opinions later, but I certainly would
17 take advantage of all their expertise and their ongoing
18 effort in this area because it's just too big a job to
19 do on your own.

20 So I certainly would recommend partnering with
21 them and getting all the help you can. Not only from
22 them, but also perhaps from WHO or other agencies
23 involved in this.

24 DR. GOLD: This sort of -- the next point --
25 kind of goes back to your issue about exposure

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1 assessment, but maybe the colleagues on the committee
2 could comment on the contention that the adduct
3 information is a good surrogate measure of exposure.

4 And the reason I bring it up is to again exhort
5 the agencies and the powers that be that we need human
6 data, and there are repositories around that could be
7 exploited for looking at adducts potentially if there
8 was some sort of initiative from the appropriate
9 agencies.

10 So if, in fact, that's a good measure, which
11 I'd like to hear about, then what's the possibility of
12 using some of these repositories to again inform the

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13 decision making.

14 DR. FELTON: I could comment on that as far as
15 the adducts go. I mean, the darn trouble is they're the
16 best measurement we've got, but they're not good enough,
17 and that's what we always run into with adducts.

18 We'd love them to be totally related to risk
19 and just many times they aren't, but we don't have
20 anything better as far as exposure or risk, so we use
21 them. And we do everything, P32 post labeling,
22 accelerator mass spectrometry measurements, other types
23 of measurements, to get at these levels in humans that
24 have been exposed.

25 I think with acrylamide we're going to have

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1 levels that are going to make adduct work fairly doable,
2 but we've got to be careful what it means.

3 DR. GOLD: I wasn't commenting really on a
4 sense of getting an estimate of risk, more using it as
5 an assessment of exposure. And I think it ought to be
6 explored for that purpose.

7 Given that all these other -- every data set is
8 going to have its limitations so -- the NHANES is not
9 going to tell you how the food was prepared, but maybe
10 the composite of putting these different sources of data
11 together would round out the picture so it would be more
12 informed than it currently is.

13 DR. HERTZ-PICCIOTTO: I would guess that if the

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14 NHANES database could be used to evaluate the hemoglobin
15 adducts and look to see whether it correlates at all
16 with self-reported intake, if it does, then that's
17 important information. If it doesn't, that's also
18 important information.

19 If it can be a surrogate dose telling us that
20 self-reported exposure isn't the way to go, then that
21 would be useful for designing future studies to evaluate
22 risk in relation to acrylamide internal dose.

23 So I don't know exactly what -- whether that's
24 possible with NHANES, but that would be one -- you know,
25 one database. And, of course, there's many others.

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1 CHAIRMAN MACK: I was just going to say that
2 even before the self-reported dose issue is the feeding
3 studies of people who are given chips ad libitum to see
4 whether or not that, in fact, changes the adducts, and I
5 gather from Dr. Troxell that that's the sort of thing
6 that is going on now and that would be the first piece
7 of information that is pertinent.

8 DR. DENTON: Regarding the timing on the NSRL,
9 there was some discussion about -- as you know, that our
10 current NSRL was based upon the US EPA IRIS number. As
11 I understand it, the US EPA is going to be revising that
12 IRIS number.

13 George, do you or Tom know anything about the
14 timing of that or whether the recommendation of the

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15 committee -- I guess the relative importance of that
16 revision, should it or -- should it be happening as the
17 basis of the NSRL.

18 DR. ALEXEEFF: Just as a comment, there's
19 really no way to predict when US EPA will come out with
20 an assessment. I mean, there are some assessments we've
21 been waiting for several years that were supposed to be
22 done several years ago. So it could be soon. It could
23 be a long time.

24 DR. HERTZ-PICCIO: Another comment in regard
25 to the NSRL would be to investigate the possibility of

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1 using the human studies that exist to calculate upper
2 bounds, and I think this was mentioned by a couple of
3 people earlier today. The Marsh study, I think, might
4 be useful in that regard.

5 The problem with the Mucci study is the
6 particular endpoints they used, it's unclear whether
7 those are of relevance. They're not endpoints that were
8 observed in any of the animal studies, although I
9 suppose the same thing could be said in regard to the
10 pancreatic tumors that were seen in the Marsh study.

11 So -- in any case, I think this is worth
12 investigating, the fact that there is some human data
13 out there, and you might also look at the Schultz
14 re-analysis, which I happen to be a co-author on, of the
15 Marsh data in regard to the pancreatic cancer to see if

Work plan excerpt

16 those data would be useful.

17 Jim, you asked the question about the Marsh
18 data and why a cohort of 8,000 people didn't show any
19 excess. You know, the study is interesting. I had some
20 questions about some of the methodologic issues in that
21 study, although one of them may not be a particularly
22 big deal.

23 It is notable in that study, interestingly,
24 that there was no excess of non-malignant respiratory
25 disease, which suggests that -- in fact, there seemed to

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1 be a little bit of a deficit, which suggests that there
2 were fewer smokers than is typical in the general
3 population in that cohort, and that's somewhat unusual
4 for occupational studies, but it does suggest that the
5 pancreatic tumor excess could not be -- is probably not
6 explained by smoking.

7 And the other reason why I wouldn't expect that
8 that was explained by smoking is that the dose response
9 was internal to the cohort as well, which it's generally
10 been seen, and this has been studied in many, many
11 occupational cohorts that smoking doesn't differ a whole
12 lot from one exposure group to another within a cohort.

13 An adjustment for smoking, when it is
14 collected, has -- makes very little difference in
15 occupational carcinogenesis studies, is not big enough
16 to account for what's seen here, which was over twofold

Work plan excerpt

17 in the highest dose group.

18 Just a few days ago I was at a meeting of the
19 Board of Scientific Counselors for NTP and we were
20 evaluating lead, and the literature on lead is quite the
21 opposite, where all of the risks are in the order of
22 about 1.3-fold relative risks, and that's a case
23 where -- and there were no internal comparisons that
24 were done.

25 In that situation, it's easy to speculate and

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1 it's quite plausible that smoking could account for the
2 excess that's observed, but in this case it does not
3 appear that that would be -- that would be the case.

4 DR. FELTON: Can I ask you just a little
5 quantitative part of the whole thing, which I tried to
6 do but it's not my expertise, so -- the dose that the
7 people in the work place environment got, although it
8 was presumably pulmonary rather than oral versus what we
9 might think somebody ate for that same period of time
10 that they worked there in french fries, is there any way
11 we can use that kind of data to look at human risk?

12 DR. HERTZ-PICCIOTTO: Yeah, you could. And I
13 actually want to retract my back-of-the-envelope
14 calculation that I reported a little while ago because I
15 think I may have done that wrong. That's the -- one
16 should never report back-of-the-envelope calculations.

17 I think the best information we have on that

Work plan excerpt

18 right now is what Dr. Hattis presented earlier in which
19 he did the calculations to suggest that the power of
20 that study would have been adequate to see a 40 to 70
21 percent excess, if that's -- if I'm remembering
22 correctly what you said.

23 DR. HATTIS: That was the Mucci study.

24 DR. HERTZ-PICCIOTTO: In the -- oh, that was in
25 the Mucci study; not in the Marsh study.

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1 DR. HATTIS: I think that they're -- I have
2 done calculations from the Marsh study. I don't
3 remember them precisely enough to report.

4 I think our very highest group might have some
5 excess over the dietary, but the dietary background
6 would be expected to obscure some of the differences in
7 the lower dose groups.

8 DR. HERTZ-PICCIOTTO: But this is definitely
9 something that we can ask OEHHA to clarify in developing
10 their new NSRL, to take into account what really -- and
11 that sort of falls under the category of what I said
12 earlier, which is to use the epi data to construct an
13 upper bound and really determine what -- is the upper
14 bound based on what the exposures were in that study,
15 and that might include also determining what we know
16 about inhalation versus ingestion, where inhalation did
17 seem to be the main exposure route, although potentially
18 there was dermal exposure as well.

Work plan excerpt

19 And I did see some studies on pharmacokinetics
20 related to absorption by the dermal route, but I don't
21 remember seeing anything in this pile about inhalation,
22 so I don't know if those studies have been done, and I
23 don't know if anything is planned on looking at
24 inhalation since the main concern here is food, but it
25 certainly would help in the interpretation of the

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1 occupational studies.

2 DR. GOLD: Can I just say one thing, though,
3 about the human studies. I think it's good to use them
4 but not to restrict the investigation to the ones that
5 are published so far in this question.

6 I think the Marsh study has limitations of
7 size. I mean, there are less than five testis tumors
8 and thyroid gland tumors, which suggests the original
9 sample size was just too small to look at some of the
10 relevant tumors.

11 Some of the other studies that we were given to
12 examine, I -- as you alluded to, weren't necessarily
13 looking at the appropriate sites.

14 There are other human studies out there that
15 have -- there's a large international brain tumor study,
16 for example, that might be accessed for a purpose like
17 this and whether -- I don't recall whether the dietary
18 data would be sufficient, but I know they were very
19 interested in diet.

Work plan excerpt

20 So that there are other data sets out there
21 that should be explored and not restricted to the few
22 here that have admitted limitations -- severe
23 limitations.

24 DR. HERTZ-PICCIOTTO: I think it would be very
25 useful to have some epidemiologic data on some of the

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1 female cancers since both mammary and uterine tumors
2 were observed in animal studies.

3 DR. SPANGLER: Well, you know, there was one
4 uterine tumor seen in the rat study.

5 DR. HERTZ-PICCIOTTO: There were seven in the
6 high dose groups.

7 DR. SPANGLER: In Johnson?

8 DR. HERTZ-PICCIOTTO: There were five in the
9 high dose group, total, rats with an adenocarcinoma,
10 metastatic or nonmetastatic, of the uterus. Five in
11 high dose group, and then the other dose groups were 1,
12 2, 1 and 0 for those four. On page 160 of Johnson.

13 DR. SPANGLER: Okay. I see that.

14 DR. HERTZ-PICCIOTTO: Okay. Anything else we
15 want to say about the revision of the NSRL?

16 CHAIRMAN MACK: I guess I just have a lot less
17 confidence in the Marsh study than you do. The relative
18 risk for pancreas cancer is 1.25 and for deaths it's
19 1.36, and they looked at all tumors without an -- a
20 prior hypothesis.

Work plan excerpt

21 DR. HERTZ-PICCIOTTO: The dose response
22 analysis goes 0.8, 1.7, 1.5, 2.3. 2.3 in the highest
23 dose group. And then in the next analysis by cumulative
24 exposure it's 1. -- I'm sorry, my eyesight is going --
25 but the top one is 2.6. And I won't quote from our

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1 re-analysis.

2 Okay. Why don't we move on then from the NSRL
3 to the question of -- and these are sort of -- there are
4 sort of two issues, I think, that are somewhat linked.

5 One is this issue of developing an alternative
6 NSRL as outlined in point No. 3 of the work plan, which
7 says: Identify acrylamide levels in foods below the
8 limit of detection (regulation) -- I'm sorry. Wait a
9 minute. I'm sorry. I'm reading No. 2.

10 No. 3: Identify alternative acrylamide
11 exposure levels for certain foods based on public health
12 considerations.

13 So OEHHA proposes to develop alternative
14 regulatory levels and develop a regulation listing
15 acrylamide concentrations in such foods deemed to meet
16 the exemption requirements of Proposition 65.

17 And I think we heard a couple of comments about
18 some of the quagmires that that kind of plan might lead
19 to, so I think maybe this is worth a bit of thought.

20 Okay. So from -- my understanding of this is
21 that the proposal is to take foods that are clearly

Work plan excerpt

22 beneficial, if I'm understanding the intent here, and
23 that have particularly low levels, but that may not --
24 may still be above the NSRL, but are low relative to
25 other foods, and put them into a category -- a separate

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1 category. And that's my understanding of what the
2 proposed -- the proposal is.

3 And, Lauren, maybe you want to clarify that.

4 DR. ZEISE: That's one part of what we
5 potentially could do. Another part would be to take
6 foods for which there was quite a variability in
7 concentration and set a concentration level at a
8 relatively low level and that would turn into an
9 allowable concentration for that specific food type.
10 Things below that concentration level would be exempt.

11 DR. HERTZ-PICCIOTTO: So the thinking here is
12 that within a type of food, if there is a lot of
13 variability, then it should be possible for those
14 products that are often above -- at the high end to be
15 able to lower those exposures down to the low end.

16 And I think that certainly the premise of that
17 argument and that proposal is reasonable, and I think
18 there's a lot of information in our packets suggesting
19 that already a number of the European countries have
20 been putting their heads together to try to figure out
21 how to lower exposure levels and have some proposals and
22 ideas for how to do that in their food products.

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23 So this would sort of be an incentive for the
24 industry to look at their processes and use the best
25 available information to move their product down into

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1 that low end.

2 CHAIRMAN MACK: I have a couple of comments.
3 One of them is that presumably the level of risk, level
4 of exposure is going to depend on the temperature of the
5 cooking process, and I guess some of the logic that's
6 been expressed by some of the conclusions is that this
7 is inversely related to the likelihood of protection
8 against micro -- microbiological contamination. In
9 other words, they're afraid that maybe people will lower
10 temperatures so they all suddenly have contamination.

11 And I think the two thresholds are so likely to
12 be different that this is just not a rational thing to
13 consider. In other words, one need not be concerned
14 about that. I don't see -- I can't imagine the
15 circumstance in which there would truly be a likelihood
16 of microbial proliferation because somebody tried to
17 avoid the Maillard process.

18 And then with respect to general nutritional
19 content, that is so food-specific that I think you just
20 get yourself into a complete quagmire.

21 And in relation to the degree of variation in
22 quantitation and concentration in trying to come up with
23 a concentration level, you're going to have so many

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24 different individual circumstances that you have to
25 address that it seems to me that it would be a terribly

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1 person-hour intensive process trying to come up with
2 even -- keep up with the methods of measurement, much
3 less deciding what to do once you got the measures.

4 So I think -- and I guess they're all tied to
5 the issue of warning in the first place. And I guess
6 when we get to that, I think we've got to keep in mind
7 what the whole Proposition 65 is all about. It's about
8 trying to inform the public to lower their risk.

9 And we're thinking now that the way to do that
10 is regulating industry by putting out a guideline for
11 them to look after, but that's really not going to make
12 much difference in this particular instance because
13 there's so much variation in home cooking and in
14 cooking -- and in the temperature used by one McDonald's
15 compared to another McDonald's. There's going to be a
16 huge variation.

17 And it's much more important if we could try
18 and get the message to the public that there was a
19 potential risk here as opposed trying to regulate
20 industry. But more about that maybe later.

21 DR. SPANGLER: I just have a question, and
22 there's something that's been bothering me that I don't
23 really understand and maybe somebody can explain it to
24 me, but -- and this may not be the time -- but it has to

25 do with a conflict in the way the samples are analyzed.

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1 Apparently, there's some -- there's some
2 divergence of opinion because that's one of the things
3 that the fellow from the CLEEN organization mentioned,
4 and it's something that I didn't understand and it's
5 something, obviously, that there's a divergence of
6 opinion between that organization and the way the State
7 might have proposed doing it or -- it's just something
8 that I don't understand, and maybe I'm reading into this
9 something that's not there, but there appears to be a
10 conflict, and is --

11 DR. ZEISE: Yes, maybe I could again ask Ed
12 Weil to explain this. It has to do with the initial way
13 in which we discussed it in the work plan as something
14 being detected versus detectable, and it is "detectable"
15 in the regulation.

16 But the issue goes beyond just a difference
17 between the work plan and it was -- and the way it was
18 explained, so Ed.

19 MR. WEIL: Thank you.

20 I don't want to get too much in detail into
21 that. I think, in answer to your question, we have a
22 regulation that's pretty complicated, that lawyers argue
23 about all the time in front of judges, and the issue
24 that was brought up by Mr. Schmitz is that the
25 regulation basically talks about saying that, if a

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1 chemical is not detectable, it's treated under the law
2 as if it's not there, which is not necessarily the same
3 thing as saying that the chemical has not actually been
4 detected, because it may be possible to detect it.

5 But then you get into complicated legal issues
6 about what that means in court and whether you have to
7 have an actual test result in hand in which it was, in
8 fact, detected or you simply need the declaration of a
9 scientist who says, no question, if you run this test,
10 it will be there.

11 But I -- you know, these are issues that will
12 be addressed as the work plan proceeds and that OEHHA
13 will have to be cognizant of and that will be worked
14 out, and we're very aware of the comments made by CLEEN
15 and we'll try to get that issue resolved and hashed
16 out.

17 But I think, for purposes of the sentiment of
18 the committee, if there are ideas that the members want
19 to express about what methods ought to be looked at as
20 the most reliable, important, replicable methods to be
21 used, then that would probably be of more guidance to
22 OEHHA staff.

23 DR. FELTON: Just to comment on that from being
24 in this mess for years, I mean, what you heard from Dr.
25 Shibamoto is exactly where the problem is. It's not in

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1 the GCMS or the LCMS measurements. It's in how you
2 prepare the sample in these real complex foods. So the
3 amount of oils you have and how much starch is present
4 is going to affect your yields in how you do these
5 measurements.

6 And that's where -- whoever decides is the best
7 method -- is where the real standardization is. The
8 actual analytical tools you use are much more
9 standardized.

10 DR. HERTZ-PICCIOTTO: Well, it seems to me that
11 this sort of spills over into the other item, No. 2, on
12 the -- and it also, obviously, overlaps No. 4.

13 So I think maybe we should broaden this out
14 because -- I mean, I think the proposal number -- item
15 No. 3 in the work plan really lends itself to a lot of
16 problems that we can't even fathom at this point, but I
17 think they were sort of hinted at in some of the
18 comments about the -- what may end up being sort of
19 endless debate about what constitutes a bread, what
20 constitutes, you know, a chip.

21 And I'm not sure that OEHHA really wants to get
22 into that business of classification of foods, although
23 it does seem like a somewhat attractive idea to set up a
24 system that provides for incentives to sort of
25 self-regulate.

1 On the other hand, I want to go back to the
2 point that Dr. Mack made, and it was also made by one of
3 the -- I think it was the Center for Science in the
4 Public Interest -- that the spirit of Proposition 65
5 isn't regulation as much as public right to know.

6 And I think that, with that in mind, that
7 that's really the central question that we should be
8 keeping at the forefront of the advice that we give to
9 OEHHA: How best can the agency keep the public informed
10 in a manner that is useful and not alarming, but at the
11 same time informative and keeps the public as up-to-date
12 as the scientific and regulatory community is.

13 And I think that's -- that's really the heart
14 of what we should be doing. And I -- in that spirit,
15 I'd actually like to move us to a discussion of No. 4,
16 which certainly has bearing on No. 3, and No. 4 is: What
17 would be the content of any warnings that might go out?

18 And I would assume that within that we might
19 also want to discuss, you know, what kind of warnings
20 those would be, not just in content but in scope.

21 Is there going to be a little sign at the
22 fast-food restaurant as you walk in the door? You know,
23 is it going to be up on the menu and so on? But what
24 really is the point that the scientific and public
25 health community would like the public to know?

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1 We have this substance that formerly wasn't
2 known to be present and now we know it's present and we
3 know it is a harmful chemical and it's at levels that
4 are higher than a lot of other things that we have
5 little warning labels out there.

6 We have little warnings at the gas station when
7 you fill your pump, for those of you not from
8 California, that's been there for 10, 15 years now, and
9 is there a reason not to do that here, and what kind of
10 warning would we want to have?

11 Could it be a warning that is a little less
12 definitive than the warning labels that are out there
13 because the data itself are less definitive?

14 CHAIRMAN MACK: Let me address this for a
15 minute and just point out some of the complexities.

16 If you -- if we do develop methods of
17 measurement which are very precise and if we find that
18 that doesn't turn out to be a problem from -- after a
19 while, there still is going to be incredible variation
20 from food to food and from method of cooking to
21 method of cooking.

22 So what we're dealing with, as far as I'm
23 concerned, is a global problem. It's not a
24 food-specific problem. It's not a restaurant-specific
25 problem. It's not a method-of-cooking-specific problem

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1 even. It's a general problem.

2 And informing the public about 4500 different
3 kinds of foods and 350 different kinds of restaurants
4 and cooking methodologies does not seem to be a
5 particularly effective way of informing the public about
6 the danger.

7 And this, of course, is presuming that there is
8 truly a danger, and I'm accepting the animal studies,
9 I'm accepting the consistency of the thyroid carcinomas
10 and the additional noncarcinogenic problems to suggest
11 there is.

12 And when I see the estimates that Dale
13 provides, which suggests that there may be -- it might
14 be reasonable to think of molecular analogy between this
15 and other carcinogens and the difference between
16 exposure to very young people and older people and, of
17 course, we know that that's true not just for molecular
18 carcinogens but it's true for radiation and it's true
19 for -- for endocrine exposures as well, I think it's
20 quite reasonable to presume that that's going to be the
21 case.

22 So there are a few things that we are coming to
23 know about this stuff. We must presume that it's
24 dangerous, we do know that it's probably more dangerous
25 for some people than others, and we know it's all the

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1 hell over the place. And those are the things that I
2 think we've got to try and communicate to the public.

3 Now, this organization is not the most
4 efficient way to get that kind of a message out because
5 that's not the way you've traditionally tried to handle
6 things.

7 And maybe you can't do it any other way, but it
8 seems to me that trying to educate the public in a more
9 generic fashion about the global problem is what you
10 want to try and aim for, and whether or not you can do
11 that I don't know.

12 Maybe the poster like the one on the gas
13 station is not going to be the way to go. Maybe trying
14 to hit the media and trying to put up posters of a much
15 more detailed kind that say -- first of all, recognizes
16 our state of ignorance and, second of all, says the
17 facts that we do have concerns about and the few things
18 that we do know and that people have to pay attention to
19 these things, although there's no particular
20 organization or company or product that specifically can
21 be stated to be the risky one.

22 I don't know. But I just think that this is a
23 novel problem and we've got to have a novel solution for
24 it, and maybe it isn't even in OEHHA's camp.

25 DR. HERTZ-PICCIOTTO: Well, that's an

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1 interesting perspective.

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2 Okay. The very last statement you made,
3 though, I think is a little bit counter to the
4 information we saw that suggested that 83 percent of the
5 acrylamide seems to come from eight products, and that
6 would seem to me to be useful information rather than
7 this stuff is all over the place and it's in everything
8 and, you know, that -- which just seems to say, throw up
9 your hands, you can't doing anything about it, you have
10 to eat to live unless, you know, you want to go on some
11 starvation diet so -- and that really is --

12 CHAIRMAN MACK: Just to be clear, I would
13 certainly include that kind of information that we have
14 as part of the information. I'm not really saying,
15 ladies, it's all over the place.

16 DR. HERTZ-PICCIOTTO: Right. Okay.

17 DR. GOLD: Irva, can I just say one thing?

18 There are people -- limited number of people
19 who are expert in risk communication, and I would
20 suggest that maybe OEHHA, rather than listening to us
21 guess about how to do this, would solicit the input of
22 folks who know how to do it better for such purposes.

23 CHAIRMAN MACK: I think the only -- I'm not
24 saying what the thing should say. I'm just saying that
25 we're faced with the global problem, not a specific

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1 problem, and I think we've got to recognize that.

2 Does anybody else want to address that issue?

Work plan excerpt

3 DR. GOLD: I'm just want to say it's a
4 complicated message, and there are people who are more
5 expert at communicating complex messages to the public
6 than perhaps those of us sitting here.

7 CHAIRMAN MACK: Joe.

8 DR. LANDOLPH: Yeah. Based on the -- you know,
9 the animal data, the cancer potency factor of the
10 acrylamide is on the order of that for
11 n-nitrosodiethanolamine -- and there was another
12 compound in there as well -- so it's healthy as a
13 carcinogen based on the animal data, but I share your
14 misgivings.

15 I'm a little bit worried that the public is
16 getting burn out over stickering everything. I mean,
17 I've gone into grocery stores and seen heads of lettuce
18 stickered, and people will walk by and say, well, what
19 the hell is this? And they don't pay any attention to
20 it.

21 So I think this requires a lot of thought, and
22 I agree with your comments about using skilled risk
23 assessment communication people because otherwise people
24 are going to lose respect for the stickering and the
25 whole process is going to lose respect, which is the

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1 opposite of what we intended to have.

2 CHAIRMAN MACK: Any more wisdom from the people
3 up here?

Work plan excerpt

4 Mr. Roe, would you like to make a comment?

5 MR. ROE: Thanks. I'm David Roe. I don't
6 represent any group today. I was here as an observer. I
7 suppose I represent one of the original sponsors of Prop
8 65, meaning myself.

9 But what I thought I might do is provide just a
10 little general background. It's been long enough that I
11 don't think the last time I addressed this body it had
12 any of its current membership, so at least I represent
13 ancient history.

14 The most important thing to keep in mind is the
15 difference between the state law that you're operating
16 under and the federal system that Dr. Troxell
17 represents.

18 What happened in 1986, when the voters passed
19 Proposition 65, was to say that federal system is fine,
20 but it has a weakness, which is that complicated issues
21 of toxics exposure to people can be debated forever, the
22 25 years that was referred to earlier.

23 We want one change in California, which is that
24 when the facts get to a certain level, something changes
25 so that the momentum is no longer in favor of endless

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1 debate but in favor of doing something. Not something
2 drastic or definitive but something.

3 The threshold that was set was the finding that
4 this body makes, which is to a clear scientific

Work plan excerpt

5 threshold something is determined to be known to cause
6 cancer or reproductive toxicity. That was the threshold
7 in the law.

8 What happens at that point is not that anything
9 is restricted or banned, but that people who are exposed
10 to that chemical get some information to allow them to
11 make choices about whether they want to continue to be
12 exposed or change their behavior. They're fully
13 entitled to go ahead and keep doing exactly what they
14 were doing but they get some more information.

15 Now, that's not an ultimate solution to any
16 particular problem of toxic chemical exposure. It's a
17 weigh station.

18 The reason that it has been important and the
19 reason it was intended to be this is that it changes the
20 momentum. It creates momentum in favor of getting to
21 the ultimate solution, of getting more information, of
22 accelerating the process, of filling out the data cards,
23 filling in the data gaps, learning what it is that you
24 don't already know.

25 So my strongest piece of advice to this group

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1 is, make out your wish list, because you're operating
2 under a law where no longer is it your burden or FDA's
3 burden or the state government's burden to have to come
4 up with all of the science.

5 You've now engaged the constituency that's

Work plan excerpt

6 economically involved, that is involved in
7 manufacturing, selling and profiting from particular
8 products in private commerce. Now it's in their
9 interests to fill you in.

10 And the highest service you can perform for
11 OEHHA at this juncture is to be as clear as possible of
12 what it is you would want to know or what it is that
13 OEHHA ought to want to know in order to take any of the
14 proposed actions that are in the work plan, all of which
15 seem to me to be appropriate to explore. Perhaps not
16 all appropriate to take, depending upon the scientific
17 outcome, but certainly all appropriate to explore.

18 So all I really wanted to suggest was there was
19 a sea change when this law passed, but the sea change
20 was simply to change the momentum, once you got to a
21 threshold about where the science was going to come
22 from, where the momentum was going to come from to get
23 to a satisfactory ultimate solution about any particular
24 chemical and set of exposures. That's where you sit
25 now.

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1 There's nothing new about the situation that
2 you face with acrylamide. There's nothing new about a
3 chemical that's been long listed that turns out to have
4 odd manifestations or unexpected manifestations.

5 Lead was listed in the original list of only 29
6 chemicals. People at the time didn't expect that it

Work plan excerpt

7 would show up in dishes or tea cups or calcium
8 supplements or faucets.

9 And, indeed, when it did, people said, do you
10 know what the public health consequences will be if
11 people can't have running water or will eat off of
12 paper -- dirty paper plates? None of those, of course,
13 came to pass.

14 What makes this, of course, interesting and
15 complicated and worth all this attention is there are so
16 many new places and so many different food products, and
17 the weigh station solution of a warning is one which the
18 industries involved view with great alarm. They
19 certainly don't want to provide that weigh station on
20 the way to figuring out the ultimate solution.

21 But that is, indeed, what creates the incentive
22 to bring forward information. And, again, I suggest if
23 you can provide with -- OEHHA with the clearest possible
24 sense of what it ought to know scientifically, that's a
25 major service.

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1 One other comment on Dr. Mack's suggestion of
2 risk communication -- I'm sorry -- Dr. Gold's suggestion
3 of risk communication.

4 This, too, is a very old theme; and when the
5 law was originally passed, there was a good deal of
6 discussion about how warnings should go on at great
7 length and be hand-tailored to each individual situation

Work plan excerpt

8 and essentially recapitulate the full complexities of
9 the science in each context.

10 And the decision very sensibly was made, no,
11 that's not what this law is about. It's an on-off
12 switch. It may not be a perfect on-off switch, but it
13 has a purpose, and that purpose is best served by a
14 fairly simple, clear, unadorned communication.

15 There were a number of risk communication
16 experts that testified to a room with 600 people in it
17 and your predecessors sitting up at the table making the
18 opposite point. I just provide that to you as a piece
19 of historical perspective.

20 Obviously, this will come up again as the
21 regulatory process goes on, but I just wanted to give
22 you a little flavor for where we've already been.

23 And I'm happy to answer questions, but I'm also
24 grateful for the opportunity to relive old history.

25 CHAIRMAN MACK: I think you should probably

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1 present yourself every couple of years at a very minimum
2 because I think it's a very useful story for us to
3 hear.

4 Does anybody have any questions for Mr. Roe?

5 I would say that this situation may be
6 different than almost every other one that we've passed,
7 and it may be that we have to get into more complexity,
8 although if we could think of a way to avoid it, I'm

Work plan excerpt

9 sure we would all jump at it and maybe we can.
10 MR. ROE: I think this will play out, but I'm
11 suggesting there is something to be learned from the
12 successful history so far. Many crises have been
13 predicted that have not come to pass.
14 Thank you.
15 DR. HERTZ-PICCIOTTO: Well, I'm going to sort
16 of --
17 MR. WEIL: Excuse me. I'm sorry to interrupt,
18 but we really need to take a 15-minute break for the
19 court reporter. It's necessary at this point.
20 CHAIRMAN MACK: We'll take a break for how many
21 minutes?
22 MR. WEIL: Fifteen.
23 CHAIRMAN MACK: Fifteen.
24 (Recess taken.)
25 CHAIRMAN MACK: Can we get started again and

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1 catch up with this.
2 DR. HERTZ-PICCIOTTO: We're running late here
3 and not quite at the closure point, so let me make a
4 proposal here in regard to this general problem and give
5 a broad view of what I think maybe the committee
6 might -- and you can modify -- other members of the
7 committee can modify this -- but I think what we'd like
8 to advise is that OEHHA take responsibility for a public
9 health education effort and that the emphasis here is on

Work plan excerpt

10 education, which includes educating the public about
11 uncertainty and incompleteness of data, but at the same
12 time emphasizes what we do know.

13 And without spelling out all the details of
14 what we do know, we do know that acrylamide is a
15 carcinogen and we do know that it is present in certain
16 foods at levels that we can give some ballpark estimates
17 of and that there are certain food groups -- maybe
18 they're the eight we saw on a slide earlier today or
19 maybe it's a slightly modified version of that -- but
20 there are certain food groups or types of food or food
21 prepared in certain ways that are the bad actors, and
22 that based on the recognizably incomplete information,
23 this -- these levels of acrylamide may pose a risk -- a
24 significant carcinogenic risk.

25 I think part of the message also needs to state

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1 that the State of California is working with national
2 and international agencies to gather more information
3 and that that scientific information will be used to
4 update on a regular basis the information that goes into
5 these public health messages and that this is a dynamic
6 situation, which is a good thing.

7 And I think we shouldn't fear the fact that we
8 will put out a message today that will have to be
9 modified. That's the state of science and it's the
10 state of the world. Things are always changing and

Work plan excerpt

11 things -- and our knowledge is changing.

12 But I think that this would be a wise way to
13 proceed, and the specifics, you know, of how to carry
14 out that education campaign, I think, I'd leave up to
15 OEHHA.

16 And there's been some very creative ways in
17 which Californians have been informed about risks, and
18 I'm thinking of the -- our smoking education campaign.
19 So I think we can use the creativity that we have here
20 to devise that kind of a public education campaign.

21 So that would address, I think, the issue of
22 the work plan -- some of the work plan questions that
23 are out there.

24 And, again, I would emphasize that this would
25 be a dynamic campaign with changing -- with message --

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1 the message updated on a regular and not too infrequent
2 basis, and I think the agency can think about how
3 frequently that could be done in a realistic way without
4 falling behind the science.

5 CHAIRMAN MACK: Okay. Does anybody else have
6 any comments?

7 This is, obviously, a very broad piece of
8 advice. I would also mention the age, but I think you
9 will probably do that without me mentioning it, the fact
10 that children and pregnant women may be more pertinent.

11 Jim.

Work plan excerpt

12 DR. FELTON: So what's the alternative to that?
13 Would it be to say, yes, we feel the agency should be
14 giving advice to the public, but let's wait until the
15 FDA NTP study is in for more confirmation of the animal
16 data? Or do we say we go with what we have -- I guess
17 we go with what we have now and then we update it? I
18 mean, that's sort of the two alternatives.

19 CHAIRMAN MACK: I think the big difference
20 between what she's outlined and what we normally would
21 expect OEHHA to do is that there's less emphasis on the
22 regulation of the regulated community and demands that
23 they meet a specific level because we don't know quite
24 how to make that work easily and we don't know how to be
25 equitable in that kind of a mandate.

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1 So the global warning is a different issue than
2 having a small label on every loaf of bread that goes
3 into the grocery store.

4 DR. HERTZ-PICCIOTTO: Well, I -- on the one
5 hand, you're posing it as it's so global it's -- the
6 emphasis is not on regulation.

7 On the other hand, I would think that we would
8 expect the acrylamide levels to be reduced using the
9 information that is coming in, and quite clearly there
10 are a large number of studies and many of them are
11 examining ways to reduce acrylamide formation in the
12 production of the food supply, so it would seem to me

Work plan excerpt

13 that there is some incentive here in general for that
14 reduction.

15 And that -- I would hope that the message that
16 the food industry would take home would not be that, oh,
17 they needn't worry and -- in fact, you know, if it turns
18 out that certain foodstuffs are staying way up at the
19 high levels when methods are out there to lower them,
20 then that could end up going into the messages that
21 would come out in two or three years from now.

22 And in other words -- that's how I would
23 picture this. That this -- at this point, there's a lot
24 of uncertainty, and at the same time I think there is a
25 lot of hope that levels can be brought down based on the

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1 research that's going on, and I would expect that that
2 would be taken to heart.

3 CHAIRMAN MACK: Obviously, that policy would be
4 re-assessed from period to period, and one would expect
5 that the marketplace and the litigation environment
6 would both be motivators for food industry to bring down
7 the levels to the extent that they can.

8 And the marketplace, however, is a function not
9 only of risk but of the desirability of taste, and in
10 this particular case that's a very complex issue and
11 that's one of the things that makes it so difficult to
12 regulate.

13 But if it turns out that after a year or two

Work plan excerpt

14 the levels that are being measured, and more accurately
15 by then, are even higher or as high as they are now,
16 then maybe every assessment by OEHHA will take place.
17 So one -- one just doesn't know.

18 DR. GOLD: Just one comment. I wonder if we
19 might ask that periodically, I don't know, once a year
20 or something, that OEHHA would sort of update the
21 committee on the progress on their work plan so that if
22 we run into this situation ever again we might be
23 informed by how it progressed.

24 CHAIRMAN MACK: Yeah, I think that's like --
25 something we really would like to have.

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1 Are we finished? We have no mandate to
2 structure a formal recommendation with voting, so I
3 gather the information that was suggested is duly
4 recorded.

5 DR. DENTON: I would like to summarize your
6 recommendations and see if this is, in fact, what the
7 consensus is of the committee so that we're clear.

8 You are recommending, first of all, that we go
9 ahead and revise the current NSRL, and in that -- in
10 that revision, you had a -- you were recommending
11 appropriate caveats, for example, using the human data
12 to set an upper bound estimate, that sort of thing.

13 The second thing is that you -- you did endorse
14 the idea at least of the second part of the work

Work plan excerpt

15 plan, and that is -- second step, and that is defining
16 the methods of detection, but with the caveat that
17 there's a lot of sampling and measurement variability.

18 On the third part of the plan, which was
19 setting alternative risk levels for categories of foods,
20 you are recommending that we don't do that, but instead
21 craft a global generic warning in the spirit of the
22 right to know intention of Prop 65.

23 You are also recommending that we undertake a
24 public education -- health education effort in which we
25 would be devising public health messages with the

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1 intention that it would be an education campaign and
2 that it would be a dynamic education campaign in that,
3 as more information was available, that these public
4 health messages would be updated.

5 And then, finally, you are recommending that we
6 periodically update you on the progress of this effort.

7 CHAIRMAN MACK: I'm not sure I get the
8 distinction between the warning and the public health
9 message. I'm not sure where the warning is going to go.
10 If you had in mind that we wanted you to have a warning
11 in every shop and every grocery store, I don't know if
12 that was true.

13 I think that it might be one form that the
14 public health messages could take, but I don't really
15 think we have any wisdom to provide about that.

Work plan excerpt

16 And I would just make one statement -- I think
17 everybody would agree with it -- when we say that the --
18 that the message -- the public health message goes out,
19 it isn't something as bland as, have a good balanced
20 diet, as the FDA would propose. It's a little more
21 specific than that, mentioning specific foodstuffs in
22 the context of this particular chemical.

23 DR. DENTON: So if I could revise that then,
24 it's -- actually, you are recommending a public health
25 education effort which would be devoted to this whatever

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1 kind of global or generic language that we come up with?
2 Is that essentially it?

3 CHAIRMAN MACK: That's kind of what I had in
4 mind. I don't like to use the word "global." I don't
5 really think that's a good word. A warning with respect
6 to the dangers of this particular chemical which is --
7 goes out to the population in general. And while it
8 mentions certain foods, it isn't tied to -- necessarily
9 to any company or --

10 DR. HERTZ-PICCIOTTO: I would -- yes, I would
11 want to see the foods -- the particular kinds of
12 foods -- you know, chip, fries, we know those are among
13 the high ones, coffee -- brewed coffee, and as that list
14 becomes more -- clearer as more data come in, then that
15 would be fine.

16 And I would also include in this message that

Work plan excerpt

17 we are talking about a cancer risk very specifically,
18 and I -- it's not for us to say about reproductive harm,
19 but I would strongly suggest that that question be put
20 before the DART Committee, if it's not already part
21 of -- if that's not already in the works.

22 And I don't know if there's a mechanism for
23 addressing neurotoxicity through the state at all, but I
24 would think that that should also be considered,
25 although it's a -- it's got its own complications, and

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1 I'm not proposing that as part of this message.

2 DR. DENTON: Just regarding the DART Committee,
3 actually, the listing -- potential listing is actually
4 an administrative thing which wouldn't go to the DART
5 Committee, which actually is an OEHHA function, but we
6 also are aware of the neurological endpoint that appears
7 to be the one of concern which could be crafted as part
8 of this message.

9 CHAIRMAN MACK: I don't think she was -- I
10 guess what she was asking was whether or not they had
11 specifically looked at reproductive problems from this
12 chemical.

13 DR. DENTON: Has the DART Committee?

14 CHAIRMAN MACK: Yeah.

15 DR. DENTON: No. No. It --

16 CHAIRMAN MACK: Is there any plan to do that?

17 DR. DENTON: It's -- the listing -- the listing

Work plan excerpt

18 for acrylamide for cancer was through an authoritative
19 bodies mechanism, and that would be the same potential
20 mechanism for the DART Committee.

21 So your committee didn't see the -- your
22 committee didn't opine on the listing for cancer and,
23 similarly, you know, it would be another mechanism --
24 another mechanism is employed is the --

25 CHAIRMAN MACK: I understand that, but you came

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1 to us for a discussion of the process of the work plan,
2 and so we're asking, should there not be consideration
3 given to the involvement of the DART Committee in the
4 work plan for the same reason?

5 DR. DENTON: Well, it's not on the -- on the
6 DART Committee's -- it's not on the reproductive list.
7 And, also, it seems to be a neurological endpoint,
8 again, as the sensitive endpoint and not a
9 developmental.

10 Isn't that correct? No?

11 DR. FELTON: The researchers at our lab use
12 acrylamide as their positive control in their male
13 toxicity studies, so it's a great male teratogen.

14 CHAIRMAN MACK: They might mention that to the
15 DART Committee.

16 DR. HERTZ-PICCIOTTO: Well, I would wonder if
17 that also should in some way enter into the public
18 education campaign.

Work plan excerpt

19 DR. SPANGLER: And the message that is in this
20 public education campaign will necessarily have to
21 include -- mention that the largest exposure that one is
22 apt to see of acrylamide is going to occur in their own
23 kitchens.

24 DR. GOLD: So are we saying then in the
25 message, therefore, there might be something particular

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1 for children and/or pregnant women potentially? It's
2 something that OEHHA ought to consider in their message?
3 They've done it for other things. They might consider
4 it for this.

5 CHAIRMAN MACK: I specifically would suggest
6 that.

7 DR. HERTZ-PICCIOTTO: And just going back to
8 the medium, as opposed to the message, I would like to
9 see television used in this effort to educate people
10 since probably the overwhelming --

11 DR. DENTON: Lauren's budget. Lauren, can
12 you -- poor Lauren and her budget.

13 DR. ZEISE: Yeah, I just wonder if the new
14 governor could help us out with some of this.

15 DR. HERTZ-PICCIOTTO: Well, isn't there --
16 aren't there legal requirements for public service
17 announcements of some sort?

18 CHAIRMAN MACK: Okay, I think we've
19 completed -- we certainly haven't provided any wisdom

Work plan excerpt

20 but we've provided a forum. It's been educational to me
21 at least.

22 Thank you for your participation.

23 DR. DENTON: Wait. We have some updates.

24 Cindy, I think you're up.

25 MS. OSHITA: As has been my usual role, I've

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