3-16-1987

Proposition 65 Implementation

Senate Committee on Toxics and Public Safety Management

Senate Committee on Budget and Fiscal Review

CALIFORNIA LEGISLATURE

SENATE COMMITTEE ON TOXICS AND PUBLIC SAFETY MANAGEMENT

SENATOR ART TORRES, CHAIRMAN

AND

SENATE COMMITTEE ON BUDGET AND FISCAL REVIEW SUBCOMMITTEE NO. 3

(Health, Human Services and ALRB)

SENATOR BILL GREENE, CHAIRMAN

Interim Hearing on

PROPOSITION 65 IMPLEMENTATION

STATE CAPITOL
SACRAMENTO, CALIFORNIA

MARCH 16, 1987

JOINT HEARING

SENATE TOXICS AND PUBLIC SAFETY MANAGEMENT COMMITTEE

AND

SENATE BUDGET AND FISCAL REVIEW COMMITTEE NO. 3

STATE OF CALIFORNIA

PROPOSITION 65 IMPLEMENTATION

STATE CAPITOL

ROOM 2040

SACRAMENTO, CALIFORNIA

MONDAY, MARCH 16, 1987

10:00 A.M.

Reported by:

Evelyn Mizak
Shorthand Reporter

87-7-25

APPEARANCES

MEMBERS PRESENT

SENATOR ART TORRES, Chairman, Senate Committee on Toxics and Public Safety Management

SENATOR BILL GREENE, Chairman, Senate Budget and Fiscal Review Subcommittee #3

SENATOR HERSCHEL ROSENTHAL

SENATOR JOHN SEYMOUR

ASSEMBLYMAN LLOYD CONNELLY

ASSEMBLYMAN TOM HAYDEN

STAFF PRESENT

BOB FREDENBURG, Chief Consultant, Senate Toxics and Public Safety

DAVID GUSTAFSON, Counsel, Senate Toxics and Public Safety

JOLYNE BUDMARK, Secretary, Senate Toxics and Public Safety

PATRICK LENZ, Chief Consultant, Senate Budget Subcommittee #3

ALSO PRESENT

DR. ALEX KELTER, Acting Deputy Director, Public Health
Department of Health Services

THOMAS WARRINER, Under-Secretary
Health and Welfare Agency

DR. STEVE BOOK, Ph.D., Executive Secretary
Scientific Advisory Panel

ROBERT TOUSIGNANT, Assistant Chief Counsel
Department of Health Services

SARAH REUSSWIG, Program Analyst
Legislative Budget Committee

CAROL BINGHAM, Principal Program Analyst
Legislative Budget Committee

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P R O C E E D I N G S

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CHAIRMAN TORRES: We are going to open the hearing. I'd like to introduce Bob Fredenburg, Chief Consultant to the Toxics and Public Safety Committee; to his right is the counsel to the Committee, Mr. David Gustafson; and to his right is Patrick Lenz who is the Chief Consultant to the Subcommittee No. 3 of the Budget health and welfare area.

I want to thank everyone for joining us this morning, and I welcome you to this Joint Hearing of the Senate Budget and Fiscal Review Committee. Senator Greene will join us later as will other Members of the Legislature as they arrive in the Capitol.

We are having a Joint Committee meeting this morning because the problems associated with Proposition 65 implementation concern both policy and budget. This morning I hope we can begin to focus on both.

The hearing today has two parts. First, the Department of Health Services will discuss their policies on the identification of cancer causing chemicals. The Department released a set of guidelines in November of 1985. I hope we can learn what makes good science in evaluating cancer causing chemicals as a result of this testimony today.

The second issue area is the Proposition 65 implementation activities of this administration. The Committees are interested in the policies which the agencies are following as well as the cost associated with those policies.

The Health and Welfare Agency has been designated the lead agency for Proposition 65 implementation. At the beginning of this month, the Agency released: the Governor's list of carcinogens; an outline of an Advisory Committee; and an interpretation of some portions of the Initiative. We hope to hear from the Agency on all of these areas.

This Joint Hearing also is the first step of legislative action. Working with the budget and public policy together, I believe we can move Proposition 65 the fastest way possible.

We will be having further hearings, and our findings will be reflected in both budget action and legislation. We hope to work with the Administration, business interests, agriculture and environmental groups to make Proposition 65 work in California.

First of all, we need to know what we're doing and why we're doing it in this State.

The first witness this morning is Dr. Alex Kelter of the Department of Health Services. Dr. Kelter will be talking about the science of the Department's cancer guidelines. I believe Dr. Kizer is in Washington and cannot be with us this morning.

Dr. Kelter.

DR. KELTER: Good morning, Mr. Chairman. A pleasure to be here as always.

What I'll do for the purposes of the Committee and to be timely, we'll outline the Department's guidelines primarily as regards their purpose and their structure, and then if there are any questions that are more specific I'll be happy to entertain them.

The Department began developing these guidelines about five or six years ago in response to our perceived need to have some regular established scientific principles for determining whether or not a chemical should be regarded as a carcinogen.

In addition, we felt it was very important to have established a set of procedures by which to assess the potency of carcinogens; that is, are they a strong, powerful carcinogen or are they very weak, like saccharin, and to have a reliable, reproducible method for estimating this risk so as to avoid the potential for regulatory agencies determining what they wanted a risk assessment to look like before the science had been reviewed.

So in effect, we accomplished that purpose by adopting the guidelines in November of 1985, and they are largely based on those previously published by the International Agency for Research on Cancer, which is abbreviated IARC for short.

Risk assessment itself has four major scientific activities. The first is hazard identification, and it's this process that results in a list. The question being asked in that hazard identification stage is: What are the hazards associated with exposure to this chemical at any dose, if any? And if the answer to that question is: In animal studies or in human studies or in laboratory studies of various kinds, the substance has been shown by some accepted scientific principles to cause mutations or cancer, then the answer to that question is: Yes, there is a hazard associated with this chemical and it should be subjected to the following three stages in risk assessment.

The next stage is what's called dose response assessment, where some mathematical expression of how strong the chemical is for the causing of this effect is evaluated. And there are many different ways to do so. Again, the major purpose of our guidelines is to establish some baseline methods for estimating risk where there are many competing models available, and different experimenters and different observers may use different methods. We think it's important to have, if you will, a recipe which should be used unless there are other extenuating circumstances.

So, the dose response assessment takes a substance which has a hazard associated with it and tries to estimate how strong an effect this would be.

The third step is exposure assessment. This is not really part of our guidelines at the moment, and at the point when the guidelines may be revised, probably the most substantive revision would be the inclusion of some aspects of exposure assessment.

If a substance causes cancer and it is very potent but nobody's ever exposed to it, then it really doesn't matter. So exposure assessment is critical but it's not usually something the Department gets into in the risk assessment process.

CHAIRMAN TORRES: On that point, Dr. Kelter, in the forward to the DHS Cancer Guidelines document, it states that the document is not regulatory in nature but is intended to provide guidelines for assessing the risks of carcinogenic substances.

DR. KELTER: Right.

CHAIRMAN TORRES: Does this document then represent a cancer policy of the Department of Health Services?

DR. KELTER: No, it represents guidelines for performing risk assessment for carcinogens.

CHAIRMAN TORRES: So then we are not dealing with policy. We are dealing with guidelines?

DR. KELTER: We're dealing with what we called and what the National Academy of Sciences has called science policy.

If the answers to all of our questions about the causes of cancer and the effects of chemicals, if those answers were known, we wouldn't need science policy. But since they're not known, and there are numerous ways to interpret scientific information, we have, and other agencies have, agreed that written guidelines to help make the scientific judgements concerning the results of animal experiments and human studies were very important to the process of judging what estimates of risk should be like. And that's really the purpose of the guidelines -- to establish some a priori principles for the interpretation of scientific experiments.

Cancer policy -- the words "cancer policy" have been used over the years, and early on in the development of these guidelines, it was anticipated that some regulatory role might also be included in the document, but in our final version we elected not to do that.

So they do not have firm regulatory significance, but they do contain policy which we and the National Academy call science policy, differentiated from public policy. Public

policy, obviously, would be something along the lines of: Okay, so this stuff causes cancer; what are we going to do about it?

None of those "what are we going to do about it" kinds of issues are part of the guidelines. The guidelines simply say: Does this stuff create a hazard, and how should we assess that hazard; how should we estimate it. Not what should we do about it.

CHAIRMAN TORRES: Are you comfortable with that?

DR. KELTER: Sure. Having risk assessment guidelines is a great step forward. The California Department and California government were the first to adopt such guidelines as formal administrative policy. Subsequently other states and federal agencies have more or less done some of the same things.

Yes, it's a great step forward. I'm very comfortable with it. And the subsequent questions of what do we do about it continue to be parts of the regulatory programs of several areas in DHS.

CHAIRMAN TORRES: So the questions will be asked what we do about them?

DR. KELTER: Well, they always have been in the context of each individual program: in toxics, the Hazardous Waste Program specifically exists to deal with that question; food and drug and drinking water, the same.

CHAIRMAN TORRES: So, will these guidelines be applicable to other agencies as well, like Food and Ag, like the Governor's Scientific Panel?

DR. KELTER: Well, the guidelines are available for consideration by any agency and by the Science Advisory Panel for Prop. 65, as are the guidelines of other agencies and IARC and NTP and EPA.

CHAIRMAN TORRES: I realize that, but my question is more specific than that.

Will these guidelines be adhered to by other agencies?

DR. KELTER: That's up to them. The Department's guidelines are strictly those of the Department.

CHAIRMAN TORRES: I'd like to welcome Mr. Seymour and Mr. Rosenthal as well.

Assemblyman Connelly, you're welcome to join us as well.

DR. KELTER: The fourth and final step in risk assessment is what is called risk characterization, and it summarizes and amalgamates, if you will, the results of the first three steps.

So to review them, the first step is hazard identification -- does it or doesn't it cause cancer in animals or humans. Secondly, if it does, how potent is it. And thirdly, is anyone exposed to it.

So the risk characterization summary step makes a statement that under given exposure conditions, exposure to the substance would likely cause this number of this kind of effect in this kind of an exposed population.

I want to reemphasize the fact that a couple of issues that are prominent in Prop. 65 are not part of the guidelines and never have been. One of them, as I've mentioned, are the

concepts of risk management, the "what are we going to do about it" kinds of questions. As the guidelines are now framed, they involve science policy and not public policy. So, they don't include issues like "what are we going to do about it."

They also do not include issues of definition of significant risk. And again, the question of significant risk, what is acceptable and what is not acceptable, is not a scientific question. It's an issue of public policy, and the guidelines do not deal with that either.

That's all I can say, I think, with regard to an outline of the purposes and content of the guidelines. I'd be happy to try and answer any other questions.

CHAIRMAN TORRES: In light of assertions from what we consider scientifically reputable sources, such as the Federal Office of Science and Technology, the International Agency for Research on Cancer, and the Department of Health Services' own Cancer Guidelines regarding the validity of using animal data for determining human cancer, and with the Reagan Administration's Office of Science and Technology which recently stated that:

> "It is reasonable to treat an animal carcinogen as if it were a human carcinogen .... this principle has been accepted by all health and regulatory agencies and is regarded widely by scientists in industry and academia as a justifiable and necessary inference."

The International Agency for Research on Cancer also makes the same assertion.

Would you please comment on the use of the data for the purposes of identifying those chemicals that should have been placed on the list and perhaps were not?

DR. KELTER: Our guidelines by and large say exactly what you've just said, that animal data is useful and acceptable data for the purposes of identifying substances which may pose a cancer threat to humans. And we use animal data, as stated in the guidelines, to construct the dose response assessment. In other words, to say how strong or weak a chemical may be in causing cancer in the animal studies, and therefore perhaps in humans.

So, our guidelines say pretty much what you just quoted from the Office of Science and Technology policy.

CHAIRMAN TORRES: Do you believe that the science policy repeated in your own Department of Health Services' guidelines should be used as a basis for setting public policy?

DR. KELTER: It's an element of the basis of setting public policy, but public policy, going beyond science policy, includes the economic, political, and social considerations that our guidelines do not incorporate.

Public policy, the making of decisions, the exercising of options for what to do about it, is based on a number of contributions, and our science policy in the guidelines should make a contribution, I would think.

CHAIRMAN TORRES: Then I'm confronting a word salad here, and I'm trying to figure out just where the greens, and the tomatoes, and the onions are. Let's see if we can get that into it specifically.

DR. KELTER: Okay.

CHAIRMAN TORRES: We have a policy in California now, as articulated by our own Department of Health Services, which says that it is not a public policy but a science policy.

DR. KELTER: Science policy.

CHAIRMAN TORRES: And as a result of that, since it is a science policy, we are not going to be asked the questions of what to do about it; we're just going to be asking the question of whether it is a carcinogen or not.

DR. KELTER: Right.

CHAIRMAN TORRES: But also we are thereafter asking the question or stating that the guidelines which the Reagan Administration has put forward, the International Research Center for Cancer has put forward, and our own Department of Health Services has put forward in terms of guidelines, and that is that animal contact and experience ought to determine human risk factors --

DR. KELTER: Right.

CHAIRMAN TORRES: -- are not going to be utilized in the determination of potential chemicals for this list?

DR. KELTER: Well, I wasn't addressing myself to the Prop. 65 list.

My understanding is that the first minimum list for Prop. 65 was determined by the interpretation of the Act itself. And that subsequent revisions and considerations on additions or deletions from the list that are to be based on science will come from the recommendations of the Science Advisory Panel.

My understanding is, the first list was based on the Act itself, not on Department's guidelines or IARC's guidelines or anybody else's guidelines, but on the statute itself as passed.

CHAIRMAN TORRES: So you anticipate that the list may increase as a result of the Scientific Panel's review of all the other chemicals which may or were not included within the initial list?

DR. KELTER: I would anticipate that it may increase, yes.

CHAIRMAN TORRES: And it may increase as a result of following Department of Health Services' guidelines, or as a result of following political and economic considerations, as you mentioned earlier?

DR. KELTER: No, my understanding is that the Panel will be asked to consider the guidelines and will do so at its meetings. And once it has adopted criteria which will be science-based criteria, that they will then add to or delete from the list based on those criteria.

My understanding, and again you should hear this from the Agency rather than from me, but my understanding is that the Science Advisory Panel is strictly that -- science advisory. Not economics, feasibility, what have you. That they will simply be

asked to do the same kinds of things that DHS' guidelines were asked to do: separate the carcinogens from the noncarcinogens.

CHAIRMAN TORRES: So the Scientific Panel which the Governor has appointed will incorporate as its standards the Reagan Administration's Science and Technology Assessment, the International Research on Cancer, and our own Department of Health Services' guidelines with respect to animal experimentation?

DR. KELTER: I don't know if they will or not. They could, but whether they will or not, I would think, is going to be up to them.

CHAIRMAN TORRES: From your own perspective, what would prompt them not to adopt those well-grounded principles that seem to have a consensus in the scientific community?

DR. KELTER: I don't really want to speak for the Panel. Some of the elements included in our guidelines and the other guidelines you referenced remain controversial in some scientific circles. There are some scientists who don't believe that one can extrapolate from animal experiences to human. There are some scientists who don't believe that the models, for example, that are used in DHS guidelines are applicable. There are some scientists who believe that carcinogens have thresholds. There are some scientists who believe that laboratory tests, such as the Ames test, are not reliable predictors of human or animal experience.

So in some scientific circles, there is controversy about these areas. The Department feels, from its own

perspective, that it has made choices in its guidelines that have some semblance of consensus in the general scientific community, but in other circles there are still controversies.

So, I wouldn't try and speak for the Panel in deciding what they will do.

CHAIRMAN TORRES: No, but you are the spokesperson for the Department.

DR. KELTER: For the Department, and our guidelines speak for themselves. We accept animal evidence for carcinogenicity in the Department's guidelines, and we use them to do risk assessments.

CHAIRMAN TORRES: All right, and my question again is: Would you recommend then to the Scientific Panel that they ought to do the same?

DR. KELTER: I think they would be wise to consider our guidelines carefully and those that are based on, including IARC and NTP.

CHAIRMAN TORRES: Mr. Connelly.

ASSEMBLYMAN CONNELLY: Thank you very much. This is very prestigious to let an Assembly Member sit with a Senate Committee. It only happens once in a while, so I'm allocated to three questions, so answer them carefully.

(Laughter.)

DR. KELTER: Okay.

ASSEMBLYMAN CONNELLY: In light of the Department of Health Services' policy that animals are in fact good indicators for human carcinogens, IARC, NTP, EPA and so forth, did

individuals in the Department of Health Services, pursuant to Prop. 65, recommend to the Governor the full list of 250?

DR. KELTER: I believe so.

ASSEMBLYMAN CONNELLY: Could you tell me who they were?

DR. KELTER: Who who were?

ASSEMBLYMAN CONNELLY: Who they were. Was it you? Was it three or four different people? Who did it?

DR. KELTER: I actually don't recall. We did correspond with the Interagency Committee early, after the Proposition was passed. And I don't remember who signed the documents, but the Department did make its recommendations.

ASSEMBLYMAN CONNELLY: Just so I'm clear on this point, the Department of Health Services recommended to the Governor the full list of 250?

DR. KELTER: I believe what we said was: Were the list to be based on scientific criteria alone, we would recommend the scientific criteria that are in the Department's own guidelines.

ASSEMBLYMAN CONNELLY: Senator Torres, is it appropriate to ask that that correspondence be made available to this Committee and I think the Members of the Toxics Committee on the Assembly side would like to see it as well.

CHAIRMAN TORRES: Yes.

ASSEMBLYMAN CONNELLY: When I asked that, you understand the request is for all correspondence. It seems to me that it would be helpful to see the individual recommendations to the Department head, and then the Department head's recommendations to the task force so that we can understand how that recommendation was formed and why, in fact, it was made.

DR. KELTER: I'll certainly bring the request back to the Department. I can't imagine why, but if there are any potential problems with that, I'll certainly let you know.

ASSEMBLYMAN CONNELLY: Thank you, sir.

CHAIRMAN TORRES: Any other questions?

Would you consider the selection of the individuals to the Scientific Panel by the Governor to represent the various schools of scientific thought?

DR. KELTER: I'm not sure what you're asking.

What I would say is, the Panel certainly represents a cross -- a full spectrum representation of the various fields of expertise that were called for for the Panel.

If you're asking do the Panelists represent the parts of the scientific world that may have problems with the DHS guidelines, I'm not sure whether it really does or not.

CHAIRMAN TORRES: You're familiar with the abilities and resumes of all of the members of the Scientific Panel.

DR. KELTER: Most of them.

CHAIRMAN TORRES: Would you consider all of them to be free of direct and indirect economic conflicts of interest?

DR. KELTER: I'm not sure I'm qualified to answer that. I'm not personally familiar with a lot of the Panelists. I have seen summaries of their curriculum vitae.

My observation would be that the Panel represents a balanced view of the state of the science in the areas of carcinogenesis and reproductive toxicity.

CHAIRMAN TORRES: Were these individuals required to submit a Statement of Economic Interests?

DR. KELTER: I don't know that.

CHAIRMAN TORRES: What attempts were made, or do you know if any attempts were made to determine the income of members of the Panel?

DR. KELTER: I don't know that. The Department of Health Services, at least from my jurisdiction, was not responsible for doing that.

CHAIRMAN TORRES: Who was, do you know?

DR. KELTER: I would think it would have been done in the Health and Welfare Agency.

CHAIRMAN TORRES: The Health and Welfare Agency made those determinations?

DR. KELTER: The Health and Welfare Agency being the lead agency did the lion's share of the work in assembling recommendations for the Panel, yes.

CHAIRMAN TORRES: I'm trying to get a focus on definitions.

DR. KELTER: Okay.

CHAIRMAN TORRES: The term "reproductive toxin", how would you define that?

DR. KELTER: That's a good one, and I think it's going to be one of the first very important tasks that the Science Advisory Panel undertakes.

As you know, Prop. 65 did not define the term "reproductive toxicity" and left it open. And it could be rather

broad. Reproductive toxicity could include issues such as the malformation of a newborn in a species or human. It could include alterations in the fertility of the species, whether it's because of the effect on the male or on the female. It could include issues dealing with the size and state of health of offspring, whether it be a litter of animals or of humans. So, it could be a very broad term.

On the other hand, it could be interpreted more narrowly, depending upon the scientific context in which the definition was created.

CHAIRMAN TORRES: Let's talk about that.

Has your Department identified any reproductive toxins?

DR. KELTER: We are still pulling in the responses from our regulatory parts of the Department as to whether they have caused substances to be identified or labels as reproductive toxins.

The three parts of the Department which might do that would be the Sanitary Engineering Branch, the Food and Drug Branch for the Toxics Division. Those are the three parts of DHS that have the regulatory authority to make such determinations.

CHAIRMAN TORRES: Have you made a list of those?

DR. KELTER: We're in the process of doing that.

CHAIRMAN TORRES: And that's what this draft is about?

DR. KELTER: I'm not sure what draft you have.

CHAIRMAN TORRES: The Toxic Triage Priority Setting Document.

DR. KELTER: No. The Toxic Triage Priority Setting Document is intended for use of officials at the state or local level, or anyone else, trying to put uncharacterized hazardous waste sites in some priority order for characterization. Appended to that was a list of chemicals which have been put together and considered broadly reproductive toxicants.

The data for those chemicals has not been assembled, reviewed, quality assured, or in any way adjudged by the Department. And I believe there's a disclaimer on the list which says that.

We do not intend for that list to be judged as the Department's list of reproductive toxins.

CHAIRMAN TORRES: So how did one qualify to get on the list? How did a chemical qualify to get on this?

DR. KELTER: We had no criteria. We simply took the extensive lists of reproductive toxicants put together by other scientists based on some or other kind of published data and said: Until a further review can be conducted, one may assume that these chemicals have at least some animal evidence for some kind of reproductive toxicity, but we have no idea whether the evidence is any good or not. For arbitrary purposes of ranking hazardous waste sites, if something's on this list, consider it a reproductive toxicant, but we're not putting forth the Department's stamp of science that this really is a reproductive toxicant. We're taking somebody else's word for it.

CHAIRMAN TORRES: Now ethylene dibromide, EDB, is considered to be a known carcinogen. Are you in agreement with that?

DR. KELTER: It is on our list and IARC's list of substances for which there is sufficient evidence in animals that it causes cancer.

CHAIRMAN TORRES: Why wasn't that put on the Governor's list then?

DR. KELTER: My understanding is that the first list produced under Prop. 65 was produced according to the dictates of the statute, not according to scientific principles.

The Scientific Advisory Panel for Prop. 65 was not available to review the first list, and so the first list was intended to be one required by the Act, not scientifically generated, is my understanding.

CHAIRMAN TORRES: So you at no time participated in helping or recommend, put together, the list that initially emanated from the Governor's Office?

DR. KELTER: I was involved in some discussions about the list. And the Administration's issuance of that list is based on its desire and interpretation of the Act that the first minimum list is that required by the Act.

CHAIRMAN TORRES: Would you consider that EDB is a potent mutagen?

DR. KELTER: I believe there's plenty of evidence that EDB is a rather potent carcinogen and mutagen.

CHAIRMAN TORRES: What does that mean in your opinion?

DR. KELTER: It means that in experiments done on animals, a very high percentage of the animals administered EDB in the experiment developed tumors and they did so very soon after administration.

CHAIRMAN TORRES: So you would consider this a reproductive toxin as well?

DR. KELTER: I'm not as familiar with the reproductive data, but I believe -- no, I don't believe. I am not familiar with the reproductive data on EDB.

CHAIRMAN TORRES: If you were an employer and you were familiar with the EPA's report on EDB, would you warn your workers or potential employees to be careful around its use?

DR. KELTER: I would definitely, and my understanding is that current federal and state law already requires such a warning to be given.

CHAIRMAN TORRES: Yet it was not included on the list to be kept out of our drinking water.

DR. KELTER: My understanding is the first list was constructed according to the minimum requirements of the Act.

CHAIRMAN TORRES: And those minimum requirements excluded a chemical like EDB? Why do you think that is?

DR. KELTER: I don't know, Senator. I didn't write the Act.

CHAIRMAN TORRES: What standards led you to presume that EDB -- and I know you weren't in on the final decision making process -- but what interpretation do you think led people to believe that a chemical like EDB should not have been placed on the list?

DR. KELTER: I'm not aware of any attempt for the first list to follow strict scientific guidelines. As I've stated, the Scientific Advisory Panel was not available at that time;

therefore, the first list was constructed according to our interpretation of the statute itself.

CHAIRMAN TORRES: Which is what? What is that interpretation? That's what I'm having difficulty understanding.

DR. KELTER: Not being an attorney, I don't think I could probably give the justification the support that it deserves from the legal point of view. I think it would be better to have someone more familiar with that legal interpretation answer the question.

I would be able to interpret it, I think, if it were a scientific judgment, but my understanding is that it was not.

CHAIRMAN TORRES: So a scientist looking at Proposition 65 could not interpret what it meant because it could not interpret Proposition 65 from a scientific viewpoint?

DR. KELTER: The first list, the minimum requirements for the first list, as I understand them, were hard to interpret. And Counsel recommended and the Administration supported the interpretation of the Act which resulted in the list that the Governor issued.

As a scientist, I honestly do not understand all of the intricacies of the legal interpretation that resulted in the first list.

CHAIRMAN TORRES: But as a scientist today, you would have put EDB on this first list; wouldn't you?

DR. KELTER: If the list were to be constructed according to scientific guidelines, I think there's justification for putting EDB on the list.

CHAIRMAN TORRES: Mr. Connelly.

ASSEMBLYMAN CONNELLY: According to scientific guidelines being that it's known to cause cancer.

DR. KELTER: According to the Department's carcinogen guidelines, which include both human and animal evidence that a substance may increase the risk of cancer, yes.

ASSEMBLYMAN CONNELLY: This line of questioning is important because the issue as to minimum only follows the requirement that known carcinogenic substances be listed. After that it said at a minimum it shall include, and then we get into this argument about the listing.

So the thing that's frustrating to me, and I don't want to dump it on you because it sounds like you made the recommendation either individually, or at least the Department of Health Services did, but there's not a question of a minimum. The statute says known to cause cancer. And when you say based upon the State's policy, IARC's policy, NTP and the Environmental Protection Agency, EDB is known to cause cancer. It's one of the 250, and the Department of Health Services recommended that it be listed, and it wasn't listed, I get angry. Not at you, but I get angry because that's not in the language of the statute that talks about a minimum list. That's in the part of the statute that says known to cause cancer.

And you're saying that it is known to cause cancer based on all the State guidelines.

And I think that's the line of the Senator's questions, as I understand it, and you're getting a little bit of our

frustration there, but it's not a legal issue. It's just -- it is a scientific determination issue with those three words.

DR. KELTER: I understand your point, and at the point when the scientific criteria determine the list of substances, those scientific criteria will come out of the Scientific Advisory Panel.

Not to sound like a broken record, but my understanding is that the first list was constructed solely on grounds based on the wording of the statute, not upon scientific criteria.

CHAIRMAN TORRES: Senator Rosenthal.

SENATOR ROSENTHAL: I guess the frustration is, I guess they looked at it specifically from legalese, from the legal as they interpreted what the Initiative said.

CHAIRMAN TORRES: Well, let's see how you would interpret it, Senator.

SENATOR ROSENTHAL: Oh, I would have put 250 or 300 items on there if in fact the various departments had indicated that they were cancerous to animals, because I understand that if it's cancerous to animals, it's cancerous to humans.

I mean, I haven't run across any of them that were cancerous to animals and weren't cancerous to humans. So, I have no problem.

CHAIRMAN TORRES: Well, Proposition 65, just let me read it so we have a better idea of what we're dealing with. Proposition 65 states that a chemical is, quote:

> "known to the State to cause cancer or reproductive toxicity within the meaning

of this chapter if in the opinion of the State's experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity."

Now, what does that tell you, Senator?

SENATOR ROSENTHAL: As I say, I would have no problem, but he keeps referring to the next portion which calls for some sort of a minimum list based upon known carcinogens that have been known to cause cancer in humans. And some of those that have been known to cause cancer in animals may not have been yet sufficiently identified perhaps, except there's a relationship between animals and humans since we are an animal of some form.

CHAIRMAN TORRES: Is the issue before us, then, that there wasn't a legal body of experts by which these decisions could be made? Is that the legal problem that we're faced with?

I know you're not a lawyer, but I'm just asking. Is that what you've heard in the scuttlebutt around the Department?

DR. KELTER: Well, that's part of it.

Phrases in the part of Prop. 65 that you quoted were not defined in the Proposition. "Generally accepted scientific principles" in some cases are in the eyes of the beholder. We will ask the Scientific Advisory Panel what they think "generally accepted scientific principles" are.

CHAIRMAN TORRES: Any other questions of this witness?

Thank you.

DR. KELTER: A pleasure.

CHAIRMAN TORRES: Give our best to Dr. Kizer.

DR. KELTER: I will.

CHAIRMAN TORRES: Is Mr. Secretary Allenby here, Clifford Allenby?

MR. WARRINER: No, he isn't. I'm Tom Warriner. Mr. Allenby was unable to be here this morning.

CHAIRMAN TORRES: How do we know you're really Mr. Warriner?

(Laughter.)

MR. WARRINER: Well, I have my Driver's License.

CHAIRMAN TORRES: Under the new immigration law, that would not be sufficient.

(Laughter.)

MR. WARRINER: Actually, when I'm not doing Prop. 65, I'm trying to ensure that the State gets a good share of the money under the Immigration Reform Act, too. And actually a driving license is one of the pieces of paper which they will be allowed to --

CHAIRMAN TORRES: One.

MR. WARRINER: Yes, there's six others, of which none of us have with us.

CHAIRMAN TORRES: That's correct.

MR. WARRINER: But I have my driving license.

CHAIRMAN TORRES: Well, welcome to the Committee, Mr. Under- Secretary. I know you've been under a lot of pressure.

MR. WARRINER: I've lost ten pounds.

CHAIRMAN TORRES: Have you really? Probably from drinking some of the water that you should have included some of the chemicals --

(Laughter.)

MR. WARRINER: No, no. According to my wife, I'm probably not drinking enough water and drinking other things.

CHAIRMAN TORRES: Well nevertheless, welcome to the Committee.

MR. WARRINER: I'm pleased to be here.

ASSEMBLYMAN CONNELLY: Senator, I'm going to go over to the Assembly. I just got a note they've started to pray over there, and so I try to get there right when the prayer's going to start.

So thank you for letting me sit in.

CHAIRMAN TORRES: That's right, you are marrying a minister; aren't you?

ASSEMBLYMAN CONNELLY: That's correct.

(Laughter.)

MR. WARRINER: Shall I begin?

CHAIRMAN TORRES: Please.

MR. WARRINER: There were a lot of questions that I'm sure will find their way to me after we get started, but I thought I might do a quick overview in terms of what we've done to this point on Prop. 65 implementation.

Then, if it pleases the Chair, I will go through the questions that were asked in the letter, and then of course, any other questions that might still be unanswered.

CHAIRMAN TORRES: The Members, I think, have a letter in their packets.

MR. WARRINER: I was over the weekend planning what I should say by way of the opening statement.

You've already mentioned the Scientific Advisory Panel has been organized. The protocols under which the Panel is to operate have been published, and the Panel will hold its first meeting on the 31st of March.

The Safe Use Determination Process procedures have been issued. They will also be published as a part of Title 26 of the California Administrative Code.

The initial list of chemicals, which you've already discussed, and the candidate list of chemicals have also been published.

We're in the process of preparing a BCP that'll be done on a composite basis. That is, to reflect the staffing changes in all the effected departments. That process will be done in the next several weeks, reviewed by the Department of Finance, the Governor's Office, and then be sent here in the form of a finance letter.

Since there are staffing needs which are immediately relevant, such as caring for the Scientific Advisory Panel, we are administratively establishing positions in the Health and Welfare Agency to care for the Scientific Advisory Panel itself, and those positions will be in effect, hopefully, the first of April.

We're also beginning to confront the issue of warnings. One of the most, I think, significant parts of Proposition 65 is the provision for warnings which have to be given to people who are exposed to chemicals listed.

We've put together a group of people that includes government specialists, consumer specialists, and producers and the sellers of products in hopes of coming up with some good ideas that will give the consumer a good warning and also not burden more than is necessary to provide that warning the delivery system for goods and services in California.

If the Chair pleases, I could start to answer the questions.

CHAIRMAN TORRES: Please.

Mr. Olsen, would you please come forward. We didn't mean to exclude the minority consultant to the Budget Committee.

MR. WARRINER: This is on the letter dated March 11, 1987 to Secretary Allenby; Safe Drinking Water and Toxic Enforcement Act Scientific Advisory Panel:

> "What selection criteria were used in selecting members of the Scientific Advisory Panel?"

What we did, as you know, the Governor by Executive Order established a cabinet level working group, and involved Health Services and other department and agencies effected by Proposition 65.

We reviewed the Proposition and determined those areas, those disciplines that were important to have on the Panel for purposes of reviewing the chemicals for inclusion on the Panel.

When we identified the six disciplines that seemed to be relevant, we determined that we should have at least two of each. In some areas, reproductive toxicity, that was particularly important because there are male and female specialists from within the different disciplines.

We then had each of the departments or agencies named in the cabinet level working group nominate people for inclusion on the Scientific Advisory Panel: two for each discipline, plus two alternates. Those then were reviewed by all the other participants in the work group and ranked. And it's from that list that the Governor selected the Panel that now is acting or will soon be acting on the 31st.

> "Were appointees required to report on current or past sources of direct or indirect income prior to selection by the Governor of the members?"

What we did was, we put together a protocol that described how the Panel was going to operate. And a part of that protocol requires a full disclosure of all outside income. Since many of these people were academics, we also required disclosure of sources of funding that would go to the university and might in some way be to their benefit.

Now, I personally talked with each of the twelve people who were selected by the Panel, ten in person and two on the telephone, and provided them with written material dealing with the Panel's operation. And I discussed with them at that time the need for a full disclosure of all their assets and dealt also

with the funding requirement, and told them that they would be required to fill out a complete Conflict of Interest statement, and that that statement would have to be available at or before the first meeting of the Panel.

All of them agreed, of course, to do that. All of them under questioning felt there would be no conflict situation. They've all been provided with the Conflict statement, the same one that all of us fill out, which has been adjusted since it has the academic components if the money goes to the university, and then they don't necessarily get salary because of it, but it could effect their success in the academic community if they were people who brought in a lot of research money that would be to their benefit. So we wanted to identify that.

The statements are not in yet, but they will be in, and they will be made public as soon as we have them.

> "Will the panel apply a standard for the definition of 'known carcinogens and teratogens' different than that used by the Governor in establishing the list of 'chemicals known to cause cancer or reproductive toxicity'?"

My belief is that they will.

> "What legal authority will the advisory committee operate under?"

They operate under the authority granted them by the Proposition itself which talks about a panel of scientific experts and seems to provide sufficient authority for that body to be housed in the Health and Welfare Agency as the lead agency.

"How does the Administration plan to fund the activities of the Advisory Panel? If a budget change proposal will be made, what is the anticipated date of that request?"

They will be funded and a budget change proposal will be made, and it should be here in the next several weeks. That'll be in the form of a finance letter which will take into consideration not only the support for the Science Advisory Panel but the other staff that'll be necessary to implement Proposition 65.

Item Number Two:

"Governor's List of Chemicals Known to Cause Cancer or Reproductive Toxicity.

"What scientific standard did the Agency or the Governor apply when issuing the list of 29 carcinogens and reproductive toxicants."

That is the issue on which there are already some questions. Again, for purposes of the initial list, it was treated as a legal question to be determined based upon the Initiative itself, the language that talks about at a minimum, and also by reference to the arguments contained in the ballot proposition and the information contained in the IARC and NTP lists.

That exercise for the initial or primary list was completed when that list was exercised. From here on in, it'll

be up to the Panel itself, the Scientific Advisory Panel, to adopt criteria and add chemicals to the list.

CHAIRMAN TORRES: Welcome to the Chairman of the Subcommittee #3 of the Budget Committee, Senator Greene.

MR. WARRINER: Good morning, Senator.

> "What is the Administration's legal interpretation of the meaning of Health and Safety Code Section 25249.8(a), '... Such list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d)'?"

That is the question which I responded to under Point 2(a). That's the legal issue that's involved in a law suit and questions whether there is created a patent or latent ambiguity by those references that requires resort to the ballot Proposition argument itself and other interpretative guides such as the wordings of the IARC and NTP lists themselves.

> "3. Guidelines and Safe Use Determination Procedures.
>
> "Briefly describe the Health and Welfare Agency's proposed procedure for issuing interpretive guidelines and safe use determinations ...."

So-called SUDs.

Published in the Notice Registry and will be a part of Title 26 of the California Administrative Code is the safety determination process.

Basically it was the feeling that a danger posed by Proposition 65 was if people became anxious and concerned, that they had questions that they needed to have answers to, and if there wasn't a good way to answer those questions, that people would make decisions not based on what the law requires but based on some emotional reaction or fear anxiety. The campaign surrounding Proposition 65 was one that attracted a great deal of attention, and I think there were things possibly said in that campaign which might frighten people and force them to make decisions regarding plant location and whatnot which are not warranted under Prop. 65.

So the safe use determination process was intended to be a way to avoid any pernicious effect the Proposition would have by uncertainty and confusion in that it creates a process by which questions can be asked by people effected by the Proposition and by which they can receive, hopefully, prompt and helpful answers. It does have a PY implication and is part of the BCP put together to answer those needs because there will be staff requirements connected with the safe use determination process.

"What will be the standard upon which
the Agency will make a determination --"

CHAIRMAN TORRES: By "PY", you mean personnel years; right?

MR. WARRINER: Yes, sir.

CHAIRMAN TORRES: Because there's some people who don't understand what PY means.

MR. WARRINER: I didn't either until I got this job.

(Laughter.)

MR. WARRINER: But I'm learning very quickly, PYs are personnel years, yes.

I thought "people" before, but --

CHAIRMAN TORRES: I saw some of the correspondence in absolute disarray; they did not know what "PY" was. I just wanted to make sure they're aware of that.

MR. WARRINER: I'm pleased that there are still some people who use words instead of acronyms. My wife says I've lost the ability to talk in whole sentences or in other than initials.

(Laughter.)

MR. WARRINER: I thought your comment about the salad was sort of the way I feel sometimes when looking at these things.

SENATOR GREENE: In the legislative process, use the words.

MR. WARRINER: I'll do my best. It's being bred out of me by this assignment, though.

> "What will be the standard upon which the Agency will make a determination on a request for either an interpretive guideline or a SUD?"

The standard will basically -- if the SUD asks a question as to whether a particular use of the chemical is within or without 65 -- that is, is it a significant level of the chemical or not -- that's a scientific question and we would apply basic scientific principles by whatever operating agency had the most relevant experience in the area.

There's not a standard of evidence such as you might have in a civil trial.

CHAIRMAN TORRES: Are you familiar, Tom, with the standards that I articulated earlier to Dr. Kelter?

MR. WARRINER: Yes, sir.

CHAIRMAN TORRES: Are those the standards, those three types of standards? Will that be the standards that'll be used by the Scientific Panel?

MR. WARRINER: I should correct something that your question suggests maybe in your mind.

The SUD process does not involve the Scientific Advisory Panel. The SUD process involves a regulatory agency.

CHAIRMAN TORRES: Which is you.

MR. WARRINER: Which is the Health and Welfare Agency as the lead agency, and all the departments -- the Water Board if the SUD had to do with discharges into water; the Health Department if it had to do with areas of their traditional control.

So, that is a separate process, and the Panel itself would be concerned with adopting either the EPA standards, the Health Services standard, the IARC standard, the NTP standard, or some synthesis of all of those.

We're going to supply each of those to the Panel in anticipation of the March 31 meeting, hoping that they will at that time adopt one or more or all of those if that's appropriate, so that they will have the procedures to operate immediately.

> "What due process provisions are provided to allow for an appeal to a finding on a SUD or an interpretative guideline?"

None. A SUD is an advisory opinion only. It's like an Attorney General's opinion. If you request one and it comes out the way you don't want it, then that's too bad. It doesn't have any regulatory effect in and of itself.

If the State determines the way you're going to use that chemical will violate Proposition 65, and you go ahead and use the chemical that way, then there's a piece of evidence out there that's going to hurt your case. The SUDs are public documents available to everyone.

If you ask and you find that the advice of the regulatory agency is that your use is okay, then you would still have to face the fact that a district attorney, or a private litigant, or the Attorney General might disagree with that determination.

All you're getting from a SUD is the view of hopefully a responsible agency who has experience in the area. You're not getting a "Get Out of Jail Free" card. We don't have the capacity. That's not part of what's given to the lead agency under Proposition 65.

"What effect will SUDs or interpretive guidelines have on regulatory action by departments or agencies other than the Health and Welfare Agency?"

I answered that question.

"Given the potential complexity of determining whether a significant risk is present for each request of a SUD, will a $500 fee allow the Agency to recover its cost?"

The answer to that is two-fold. One, it's a $500 filing fee plus any cost in excess of $500 to the State incurred in responding to the SUD. There's also provision in the procedures to waive the fee.

My concern was that people like Chevron Oil Company don't really need the State. Chevron has lots of scientists and toxicologists who can make their individual decisions, and Chevron can decide what to do.

I'm not picking on Chevron. I'm using them as an example.

But there may be lots of people who employ 13 employees who have a question about the Proposition, and there needs to be a way to respond to them. And if their response requires a great deal of expense, then we need to have provisions to meet the needs of small business people as well, since in a sense the SUD process might help to even up the playing field in terms of available scientific expertise.

CHAIRMAN TORRES: Before we go on to Four, will the SUD be issued based on numeric standards of what constitutes a significant risk?

MR. WARRINER: That would depend. If there is a numeric standard available, of course for a lot of the chemicals the Health Department has already established a numeric standard, then it would be a question of extrapolating that standard to the particular use of the chemical.

In some instances for some chemicals, the SUD may be the first time that the issue of the use of that chemical might be confronted.

Many of the chemicals on the initial list and also on the candidate list are medical drugs and whatnot for which discharge, numerical discharge standards, are not now available.

CHAIRMAN TORRES: How do you anticipate the SUD process to work in respect to pesticides?

MR. WARRINER: Well, I think that the initial question would probably go to Food and Agriculture for their review. Food and Agriculture is traditionally involved in licensing pesticides.

However, since they have risk-benefit, risk analysis, and various other provisions that are now done by the Health Department, the Health Department will be involved in the process. That's existing law.

What we'd like to do is tie the two together. We think there needs to be a central focus, because you can't have Food and Ag saying one thing, some other State agency saying another

thing. We need to have at least a consistent standard when it comes to particular chemicals, and we hope the SUD process would allow for that development.

CHAIRMAN TORRES: Did I hear you correctly earlier to say that the SUDs could be used as a defense in terms of a discharge against penalties contained in Proposition 65?

MR. WARRINER: It would seem to me that if a company had applied and received a SUD that determined that their particular use of a listed chemical was not a significant, was not significant for purposes for Prop. 65, then that would be a piece of evidence which could be offered.

Likewise, if the application for a SUD turned out that the use was in Prop. 65, was a significant, then that would be evidence which a district attorney could use.

We're neutral. I mean, we issue them like an Attorney General's opinion, based upon our judgement, scientific judgement as to what the correct answer is.

CHAIRMAN TORRES: But you're in communication with the Attorney General's Office with respect to a number of those procedural issues?

MR. WARRINER: They are aware of the SUD process. I have not heard anything from them contrary on that.

CHAIRMAN TORRES: I see. Do you plan to communicate with them in terms of procedural guidelines from their perspective?

MR. WARRINER: I would expect that we will hear from the District Attorneys' Association and from the Attorney General and

other regulatory bodies, because we will be creating scientific determinations which will have significance in a regulatory context. That's true.

CHAIRMAN TORRES: All right.

Senator Greene.

SENATOR GREENE: How would you anticipate that a company would be able to determine that a substance did not come under the Proposition?

MR. WARRINER: That would be a scientific process. Initially the chemical --

SENATOR GREENE: Yes, but the firm, the company, would be able to make that determination, or would that be one that the State would have to step in and make?

MR. WARRINER: I'll have to answer the question two ways. One, of course, there's no obligation on anyone to apply for a SUD.

If you manufacture and use a chemical, and you talked to your own chemist and your own scientists, and you're sure that the way you're going to use that chemical will not produce a significant amount of that chemical, then you don't have to ask for anything. You make your own decision and act.

If you're not sure, or if you're a small company and don't have scientists, or for whatever reason you want the State's opinion, then you would apply for it, and the scientists in whatever State agency had most expertise will review how you are going to use that chemical, try to make a decision on the scientific principles as to whether the way you're going to use

that chemical is going to release a significant amount of that chemical or not and bring you within 65.

SENATOR GREENE: So in that instance, then, firms would be operating as they do now?

MR. WARRINER: Oh, yes. They're not obligated. You can go ahead and take your chance. We're only trying to offer services to people who might want to use them.

CHAIRMAN TORRES: Yes, I understand that, but that raises a very interesting question by Senator Greene's remark, and that is that if a specific company requested or did not seek to request a SUD, they could go on discharging certain elements without any review by the Agency.

MR. WARRINER: No, that's not true.

A SUD is a way for people to know in advance what the science of the particular use would be; what would be the outcome.

CHAIRMAN TORRES: Right. If their scientific experts do not want you to know what the scientific outcome is, how then would you proceed to do so?

MR. WARRINER: You would be -- they would be involved in the existing regulatory function. If they were discharging into the drinking water system, monitoring currently goes on. The monitoring would continue to go on as to chemicals listed in Prop. 65, so the Water Boards would be monitoring and would know if the people were improperly discharging.

CHAIRMAN TORRES: Is it your interpretation, then, that if that discharging is occurring, and if a company does not request a specific SUD, that a third party could do so?

MR. WARRINER: The SUD process allows for people who are effected to apply for it. Sure, you could be a neighbor, you could be somebody who would be effected by the use of the chemical.

CHAIRMAN TORRES: So you're arguing that standing will be the criteria in determining the accessibility to SUD.

MR. WARRINER: I think you would have to be effected, but you could be effected as a consumer could be, as all of us could be effected by a discharge of a chemical. So it's not limited to the users of the chemical.

CHAIRMAN TORRES: So you're saying that under this interpretation, a corporation or a company would not be able to maneuver out of the applicability of the law by not requesting a SUD. The mere discharge of their particular products by the monitoring by the State would take that into account?

MR. WARRINER: Oh, yes, sir.

And also the district attorney or prosecutors, anyone could ask for determinations.

CHAIRMAN TORRES: I understand they could ask for it. My concern is will they be aware of it?

MR. WARRINER: Yes, I hope so.

(Laughter.)

CHAIRMAN TORRES: You hope so. That's a large presumption.

MR. WARRINER: Our intention is, through the SUD process, is to provide public notice when a request for a SUD is made. That will be published.

CHAIRMAN TORRES: I understand that, but if the company doesn't request a SUD, then there is no record of a public notice because no request has been made.

MR. WARRINER: That's right, and that industry would be at its own peril if the discharger failed to warn.

CHAIRMAN TORRES: Well, they may decide that their discharge is much more important to them than the peril of the penalty under Proposition 65.

MR. WARRINER: That's a risk that exists.

CHAIRMAN TORRES: We've had that in the past in terms of discharges in other parts where certain companies feel that a $5,000 fine is worth the risk rather than dealing with the whole other issue of cleaning it up.

MR. WARRINER: What we had tried to do through the SUD process is not -- we can't grant exemptions under 65. Proposition 65 exists and is binding on everyone who uses chemicals that are listed. That's nothing we do.

All we did was try to make available to people who might be effected by the use of the chemical an opportunity to find out what the State's view of the science is.

So, we're neutral. I mean, it doesn't matter who asks; we issue what we believe to be the correct answer under the facts of that particular chemical.

CHAIRMAN TORRES: I understand your neutrality in terms of the procedural aspects of this Act, but you are not neutral when it comes to the advocacy and the enforcement of this Act.

MR. WARRINER: No, in fact, this does not effect our ability to enforce the Act. Hopefully it will help that, because we'll be making available the science.

CHAIRMAN TORRES: I understand that, but all I'm suggesting is be aware as the process continues that that may be a problem.

MR. WARRINER: Right. Well, we don't want to turn it into somebody who only helps people avoid it. I mean, the idea would be that we would help people avoid uncertainty and decide not to locate a plant or something because they don't know what Prop. 65 is.

We think Prop. 65 can be understood and is something that people will understand and will deal with.

CHAIRMAN TORRES: I'm not impugning anything upon you at this point.

MR. WARRINER: Later.

CHAIRMAN TORRES: As far as I'm concerned, the slate is clean. What happens thereafter, as long as we're aware of what the problem areas are that may or may not be out there, let's be aware of them at the outset.

MR. WARRINER: Right.

SENATOR GREENE: On this point, I can foresee a situation, and I believe many people when they say that they are not given the complete data or correct data, I can very well foresee. And I can very well accept the idea that a corporation has technical people to give them that identification of the substance that they're using, or whatever, and the people will

just give them a short, you know, quickie job. They don't do a good job.

They give it to the firm. The firm paid them under a contractural basis in good conscience and what have you, and the people who did the work gave them a half job, or maybe they did not check their data enough. I can very well see that happening. The people are not doing it intentionally or anything.

But then they get caught in the process. And everybody that does it maybe aren't necessarily doing it intentionally. They're getting bad technical information. If they do not have in-house technical expertise, they go outside to get it.

You know, it's a brand-new field. Very few people really know it. And it's very easy to give people a half job, three-quarters of a job.

MR. WARRINER: Senator, that was one of our concerns about the SUD process.

We do have scientists that do decent work. I mean, the Health Department, as you learned earlier today, is I think on the leading edge in a lot of these areas. So we want to make good use of those people.

We don't want people to make silly decisions based upon a misapprehension of the facts. And there is some anxiety that this is a new area, and that maybe there isn't out there all the resources, private resources, that the State would provide a useful service in doing this.

It is hoped to be a useful service.

Moving on:

"What is the legal status of the interpretive guidelines as issued by the Health and Welfare Agency?"

They are legal interpretations by the lead agency. Our intention is to issue them eventually as regulations along with the SUD process and the procedures under which the Panel itself operates.

CHAIRMAN TORRES: So they will be issued as regulations?

MR. WARRINER: Right. They'll be proceeded under -- they'll proceed under the Administrative Procedure Act. The Act does not apply to the chemical list, but it does -- you know, we would imagine it applies to all the rest of the provisions of processes that are adopted by the lead agency.

CHAIRMAN TORRES: Will the cancer guidelines adopted by the Scientific Panel also be issued as regulations applicable to all other agencies?

MR. WARRINER: That was not our current intention. I'm not sure that they have to be.

Again, the chemicals themselves are outside the Administrative Procedure Act. You could argue that the procedures under which the Panel operates to identify the chemicals wouldn't have to be issued as an administrative procedure regulation. That's not clear.

I think the Panel has authority to adopt its own procedures under which it can operate. They're going to have to decide that on the 31st.

CHAIRMAN TORRES: When they organize?

MR. WARRINER: Yes.

"Upon what basis did the Health and Welfare Agency make the determination to define employees to include both full and part time employees?"

I think I'm responsible for having made that decision. And it may not make me particularly popular with some people who have a lot of part-timers, but our feeling was there is no time reference in the Initiative itself. So, we figured that what was intended was that we look at the day when the discharge took place, and if you've got the right number of employees on that day, then that's the number of employees that you have for purposes of that application.

Otherwise, if you average the number of employees over a year or two years, you can't draw that language out of the Initiative. So we picked an interpretation that says count noses on the day you have the discharge, and if you come up with the right number, you're within the provisions of Prop. 65, even though other days during the year you might not be.

We felt that that was concerned with exposure to people, and if you were exposing that number of people on that day, then you should be effected by the Proposition.

"Please clarify your Agency's interpretation of the definition of 'knowingly'."

There is an Attorney General's opinion, a preliminary one, which is going to be issued as a permanent opinion.

CHAIRMAN TORRES: When will that be issued, Tom?

MR. WARRINER: We have the preliminary form. I can supply that with you.

CHAIRMAN TORRES: We'd appreciate that.

MR. WARRINER: I expect to see the final version in the next several weeks.

But "knowingly", we adopted there basically a criminal statute interpretation of "knowingly", and that seemed to be because of the type of penalties associated with the correct interpretation.

And I don't believe the Attorney General will be changing from the preliminary one, but we won't know that until they finally issue it.

> "Does your Agency's determination of significant risk require a finding by the Health and Welfare Agency based on an 'evaluation of scientific risk assessment of a chemical's inherent toxicity and potential human exposure'. How will that determination be made?"

It'll be made by the scientists based upon a scientific evaluation of the dangers the particular chemical poses on the list.

We'll have to adopt a standard. There's a standard already built into the Initiative about the reproductive toxins: a thousand times the anticipated exposure with zero effect.

If you look at the typical mid-range on the cancer side would be one additional cancer based upon a million exposures, but I think we'd like to ask the Scientific Advisory Panel's recommendation on that. The midline is what Health Services has typically been using.

"In addition to your testimony, the Committees would appreciate receiving the following documents and material."

I've already provided copies of the correspondence from the Agency and the Health Department regarding the Panel.

The financial disclosure forms, they'll be submitted as soon as we receive them. It should be within the next two weeks.

And so far, no one's asked for an interpretation or a SUD, but I think business will pick up. I have every reason to believe it will pick up.

CHAIRMAN TORRES: Did the Department of Health Services make any recommendations to the initial list?

MR. WARRINER: Yes, they did.

CHAIRMAN TORRES: Were those recommendations accepted or rejected?

MR. WARRINER: They were both.

CHAIRMAN TORRES: Which ones were rejected?

MR. WARRINER: They recommended -- I think you could call it a recommendation -- that on strict scientific grounds, the initial list should be the initial list we published, plus the candidate list.

The reason for not doing that was what I discussed earlier, and that was the line between known human carcinogens and suspect carcinogens, which is a line that IARC and NTP take.

They also -- the recommendation from Health Services --

CHAIRMAN TORRES: Who takes? Would you define that so people know?

MR. WARRINER: Yes, the World Health Organization and the National Toxics Program, which is part of the United States Public Health Service, divide their lists up into categories.

There's a category, in the case of IARC, the World Health Organization, Categories 1, 2, and 3. Category 1 is known human carcinogens. Category 2 is suspected, and Category 3 are chemicals for which additional information is required.

The NTP, the National Toxics Program, which is part of the United States Public Health Service, basically divides up into two groups: again, the first group being the known, and the second group being the suspected human carcinogens.

There is some difference between the two lists in terms of chemicals, one having some different chemicals than the other. But those two chemical lists are the output of the procedures that each of those organization has in place.

That goes back to your earlier question the Senator had about adopting a policy.

The other point in the Health Department recommendation was that the Health Department recommendation included a concern that the public be made aware as soon as possible of chemicals we were concerned about. So, that was the other reason for

identifying the candidate list in the same way that we identified the initials. Both lists are published.

CHAIRMAN TORRES: When you say "known" and "suspect" --

MR. WARRINER: Correct.

CHAIRMAN TORRES: -- where do you place EDB? As a suspect chemical then?

MR. WARRINER: For these purposes, it would be a suspect chemical.

CHAIRMAN TORRES: Even though it is known to cause cancer.

MR. WARRINER: One of the difficulties is, when you look at the IARC and NTP lists, they use "known" as chemicals for which there is human study information. The "suspect" chemicals for them are chemicals where there is limited human information but animal cancers. So the interpretation we used for the initial list, the primary list, is based upon the IARC and NTP and the references contained in the Initiative to have the first list contain only those that are, quote, "known", and the second, the candidate list, is the list which the Panel is charged with immediately reviewing, and the Panel's obligated to review it within a year and will be making quarterly updates to move chemicals off of the candidate onto the primary list as the Panel reviews them.

CHAIRMAN TORRES: But the International Agency for Research on Cancer, which is the one you quoted --

MR. WARRINER: Right, IARC.

CHAIRMAN TORRES: Right, says that:

"... where there is sufficient evidence of carcinogenicity in animals, for practical purposes it is reasonable to treat such chemicals as if they presented a carcinogenic risk in humans."

MR. WARRINER: Well --

CHAIRMAN TORRES: That's always in most of their documents that I've ever read, so I don't understand what language you used.

MR. WARRINER: Yeah, I'll read some more of the references to that if I can find it.

When they described their Category 2 -- all the Category 1 drugs are included chemicals. All of the Group 1, known human carcinogens, are included in the initial list.

The question that you're asking is as to the second list, saying does IARC make a distinction?

The IARC, when you read the entire monograph, where it describes it, it describes the evidence as to the second list as being at one end "almost sufficient", and at the other end "limited and requiring more information." So they're not -- IARC itself was not prepared to move the chemicals off of 2, which is really divided into 2(a) and 2(b), onto Group 1 without more information.

So we treated -- what we issued was basically our version of IARC, in that there's a Group 1, the knowns, and Group 2, our candidate list of suspect ones. And we'll be moving from the suspect onto the initial list as the Panel reviews the chemicals over the next twelve months.

CHAIRMAN TORRES: Who was counsel who advised you throughout this initial process?

MR. WARRINER: We received legal advise from the Department of Health Services.

CHAIRMAN TORRES: I understand that. Who was the counsel?

MR. WARRINER: Robert Tousignant. I can supply a copy of the legal opinion.

CHAIRMAN TORRES: We would like to see a copy.

MR. WARRINER: Surely.

CHAIRMAN TORRES: Any further questions? Senator Seymour, Senator Greene.

SENATOR SEYMOUR: As I listen to the discussion taking place and asking the question of: Is the initial list sufficient; does it comply with Proposition 65; was the intent for lengthening that list?

I want to make sure that what I'm hearing is in the Department's opinion accurate. What I am hearing is that it is the Department's opinion that at this particular stage, the Department and the Administration in publishing their list has kept with the total intent of the law of Proposition 65.

Is that true or false?

MR. WARRINER: Yes, Senator.

SENATOR SEYMOUR: And further, that we can expect, as the Scientific Panel progresses with its studies, that that list will get longer, not shorter?

MR. WARRINER: I have every reason to believe that's true.

SENATOR SEYMOUR: And thirdly, that the reason that the Administration and the Department have adopted the posture that they have is that perhaps they don't want to over react to a longer list and then have to backwater or retract?

MR. WARRINER: Well, two concerns. Initially --

SENATOR SEYMOUR: Why not come out with 250 on the list, and then as the studies develop and show that you were wrong, and that maybe it should be 240 or 120 or 80, then you'd back off. Why not?

MR. WARRINER: The difficulty with that interpretation was -- would be that that would mean there would be chemicals on that list which may not finally end up on the list over the next twelve months by the Scientific Advisory Panel. There is no assurance that the initial list will be identical with the candidate list after the Scientific Advisory Panel has gone through that.

When you look at IARC, NTP, EPA, and Health Services, all those lists are slightly different, so there are chemicals, particularly on the Group 2 chemicals, where there are differences between the different groups that are evaluating them. So it's reasonable to assume that the Scientific Advisory Panel will make its own independent judgement, and that you could not simply assume that the chemicals on the candidate list will automatically be on it. They have to be reviewed by the Panel, have to be reviewed by the Panel consistent with the scientific policy that they'll have to adopt on the 31st.

SENATOR SEYMOUR: My last question, Mr. Chairman.

Are there any known carcinogens that have been left off the initial list of those known and published by these agencies and scientific bodies you've been describing?

MR. WARRINER: The Governor's initial list includes every known human carcinogen identified by the World Health Organization or the United State Public Health Service National Toxics Program.

SENATOR SEYMOUR: Thank you.

CHAIRMAN TORRES: Senator Greene and then Senator Rosenthal.

SENATOR GREENE: I have two questions. One is a follow-up on the question that Senator Seymour was asking.

You say that there are some substances which are not on all the lists. Are there any which are only, say, two of the lists and not on the third?

MR. WARRINER: I can't answer that question.

SENATOR GREENE: Because I was going to say, if you had that situation --

MR. WARRINER: Two out of three.

SENATOR GREENE: -- it seems that in terms of complying with the law for the safety of human beings, that that would maybe be grounds, even though they might not be on the third list. You can't answer that.

You made reference in your testimony that you are developing your budget change proposals.

Now, last year the Administration submitted their toxics budget one week before the conference committee. The subcommittees had finished their works, the full committees; the Houses had acted on the budget as they viewed it.

Now the Chair of this Committee as a member of the Fiscal Subcommittee here, when will you have that developed? In fact, can we tie you down to make certain that you will have it so that the subcommittee, which has more time to go into more depth, which has staff which are more familiar with working with these specific budgets than, say, some of the other total fiscal committee staff persons, will you have that for us before the subcommittee finish their work, which will be in May? And then we would need to have it in our hands in time to look at it, which would mean April.

MR. WARRINER: What day in April?

(Laughter.)

SENATOR GREENE: Well, I'm not giving a day. I'm asking you. I'm giving you at least a frame of reference.

MR. WARRINER: All right. I'll do my best. I can't promise more than that.

SENATOR GREENE: Why couldn't you give me a date? Why couldn't you and your people just, if you have to work 20 hours a day, 7 days a week -- and I'm not saying that to be funny -- it seems to me that it should be that important to you.

MR. WARRINER: It is very important.

SENATOR GREENE: It certainly is that important to the citizenry.

MR. WARRINER: It is very important to me. And it's important to me that we get it to the Legislature soon enough so that there can be meaningful debate and review over --

SENATOR GREENE: Because you're going to be criticized if you don't, and it's going to make you look bad. You know, it's going to make you look like you're dodging.

I'm not accusing or anything; I'm just stating a fact. It's going to make you look bad; it's going to look like you're dodging. And if there's criticism now, this is just going to be another criticism.

MR. WARRINER: And I do not want to add to that.

SENATOR GREENE: Well, that would do that. You can see that that would do that; right?

MR. WARRINER: Yes, sir.

SENATOR GREENE: And particularly with my mentioning it now.

(Laughter.)

MR. WARRINER: Yes, sir. I have the very distinct impression you have a strong feeling about this.

SENATOR GREENE: Well, it's just in terms of being able to do our work. You know, I assure you, I'm not expert in this area. But we can fumble our way through if we have enough time to do it.

MR. WARRINER: I would only think it would be valuable to us to get a full legislative review of the proposals because this is a new area we're working on. This is not something where you can draw on necessary history to tell you what the correct

answer is in terms of staffing, so I will do my best to have the procedures to you as quickly as possible.

SENATOR GREENE: Thank you.

SENATOR ROSENTHAL: Just a follow-up.

There are a number of organizations that list what they consider to be carcinogens: the World Health Organization --

MR. WARRINER: Yes, sir.

SENATOR ROSENTHAL: Whatever. And there are differences between --

MR. WARRINER: Yes, Senator.

SENATOR ROSENTHAL: -- between them.

It seems to me that if I were looking at a list of all of the organizations that made a list, and maybe there's a half a dozen of them, and I just checked off the ones that were on all six lists, that if in fact the Administration had given us a list, let's say, of 60 or 70, we might not even be here today.

So my question is, why didn't we at least have what everybody considered to be a carcinogen, not just on two lists, and not on three, not on one list and not on three or four, or whatever number of lists there are, but those items which were on every single one of the lists? Why wasn't that just an automatic kind of a thing which said: Hey, if we do that, at least we'll not be suspect. Because I'm sure that the Administration understood from what was being said before they came out with their list of 29 that that sort of a list was not acceptable to us and the general public generally.

Why didn't somebody give some thought to doing that type of thing? Instead of 250 or whatever the number everybody thinks there is, but the 75 that everybody says is?

MR. WARRINER: I think -- what we did was, we put together the Scientific Advisory Panel; we put together the Panel with a charge to go through the chemicals, the entire suspect list, within twelve months. We've committed to a --

SENATOR ROSENTHAL: I'm not talking about within twelve months. I'm saying that had you done something, just somebody who is not a scientist, taken all the lists, and I'm not a scientist, it would have been simple for me to say: Hey, what does everybody consider to be a carcinogen.

MR. WARRINER: Right.

SENATOR ROSENTHAL: EDB, whatever. Was that left off of anybody's list?

MR. WARRINER: I understand what the Senator's saying.

Our feeling was that it was best to have the Panel up and operating, and have the Panel do that. We're going to do it every three months, we're going to update that list until we've gone through the entire candidate list. So, we may be further along on this road fairly soon.

CHAIRMAN TORRES: It's 90-day updates?

MR. WARRINER: That's our plan, at least in the first year. After the candidate list has been gone through, we're obligating the Panel to keep meeting at least twice a year. But the candidate list represents the initial commitment. After that, IARC and NTP produce chemicals on a regular basis that would have to be reviewed.

CHAIRMAN TORRES: All right.

Any further questions of Mr. Warriner?

Thank you very much, Mr. Warriner.

MR. WARRINER: My pleasure, sir.

CHAIRMAN TORRES: Would Mr. Steve Book come forward. We'll take a five-minute break for our court reporter here.

(Thereupon a brief recess was taken.)

CHAIRMAN TORRES: We're going to reconvene the Joint Committee. Our star assistant is back now and ready for action.

I'd like to welcome to the Committee Dr. Steve Book who is Executive Secretary for the Scientific Advisory Panel on Proposition 65, the Safe Drinking Water Initiative.

Welcome to the Committee, Doctor.

DR. BOOK: Thank you, Senator.

I really don't have any opening -- any comments.

CHAIRMAN TORRES: All right, I do.

I recently read in my hometown, small hometown newspaper that you disagreed with the nature of the list which was finally issued. You felt that there should have been other chemicals included on that list.

I'd like to know which ones and why?

DR. BOOK: When I was with the Department of Health Services, or I guess technically I still am with the Department of Health Services, I expressed an opinion to the Deputy Director that I thought -- that I thought was consistent with the Departmental guidelines, the cancer guidelines that we discussed, that those chemicals shown to have sufficient evidence of

carcinogenicity in animals should be included on the initial list for Proposition 65, because as has been stated before, we do routinely utilize animal data to protect people from exposure to carcinogens.

CHAIRMAN TORRES: As Executive Secretary to this new Scientific Panel, what are going to be your guidelines in determining inclusion or exclusion of chemicals within the list?

DR. BOOK: My function as Executive Secretary to the Panel is to really serve the Panel. The direction for the Panel will be dictated its Chairman, Dr. Kilgore, and by the Panel itself.

So, I'm primarily there to assist them in making their decision.

CHAIRMAN TORRES: I understand that, Dr. Book, but you and I both know that staff people, where ever they may exist or be, have recommendations. They are not there as mutants merely to serve the will of a particular committee or panel or organization.

You have your thoughts, and I'm sure you're going to prepare a briefing book; are you not?

DR. BOOK: Yes, Senator.

CHAIRMAN TORRES: And part of that briefing book, I'm sure, will be to outline the various parameters of the issues regarding Proposition 65. Isn't that the case?

DR. BOOK: Certainly.

CHAIRMAN TORRES: And one of those parameters is going to be the standard by which this Panel will be required, or at

least begin, to look at which chemicals shall be placed on a list. Won't that be a recommendation?

DR. BOOK: You mean the priorities by which they will address chemicals?

CHAIRMAN TORRES: Yes.

DR. BOOK: Probably so.

CHAIRMAN TORRES: And I'm sure that your recommendation will also include a review of those standards that have been used by other organizations, the World Health Organization, President Reagan's Science and Technology Committee, as well as our own Department of Health Services, of which you are still a part, in respect to what kinds of standards ought to be used in the inclusion and exclusion of certain chemicals on the list. Wouldn't that be correct?

DR. BOOK: Yes, Senator, and many of those materials have been distributed to the Panel already.

CHAIRMAN TORRES: They've been distributed already; haven't they?

DR. BOOK: Yes.

CHAIRMAN TORRES: And what have you distributed to the Panel?

DR. BOOK: The Panel received, or last week was sent out the Department of Health Services carcinogen guidelines.

CHAIRMAN TORRES: Those are the guidelines that I quoted earlier?

DR. BOOK: Yes, the Blue Book, as it's called.

CHAIRMAN TORRES: And that's this book here; right?

DR. BOOK: Yes, sir.

CHAIRMAN TORRES: And in this book, the guidelines state:

> "... most substances that are carcinogenic in one animal species are also found to be carcinogenic in other animal species when adequately tested."

Is that a correct statement?

DR. BOOK: Probably so, sir. I can't recall exactly.

CHAIRMAN TORRES: All right. And:

> "Further, almost all substances that are known to be carcinogenic in humans, for which animal data exists, are also carcinogenic in animals."

DR. BOOK: Yes.

CHAIRMAN TORRES: "Thus, there is substantial scientific support for the assumption that a substance carcinogenic in animals will, with high probability, be carcinogenic in humans."

DR. BOOK: Yes.

CHAIRMAN TORRES: And that's going to be part of your recommendation?

DR. BOOK: It'll be part of the information that's provided to the Panel. They will have the ultimate recommendation, but that will be part of the background material that is supplied to them.

CHAIRMAN TORRES: Given your familiarity with the members of the Panel, what do you think they'll do?

DR. BOOK: I can't tell, Senator. I suspect that among experimental biologists there is an appreciation for the universality of mammalian systems, and that they will take that into account. That is, if a substance is carcinogenic in several animal species, then it is likely that it is carcinogenic in other species. And I'm sure that they will take that into account.

CHAIRMAN TORRES: How many chemicals are on the present list now, the short list as it's known?

DR. BOOK: There's 26 carcinogens and 3 reproductive toxins.

CHAIRMAN TORRES: That's 26 carcinogens and 3 reproductive toxins?

DR. BOOK: Yes.

CHAIRMAN TORRES: Do you anticipate that EDB may be one of those reproductive toxins that will be placed on the list?

DR. BOOK: Perhaps not as a reproductive toxin, but as a carcinogen.

CHAIRMAN TORRES: As a carcinogen.

What other chemicals did the Department of Health Services recommend for inclusion within the first list which were excluded?

DR. BOOK: My initial -- the memo that I wrote to the Director's office included those chemicals designated by IARC and NTP as having sufficient evidence of carcinogenicity in animal species.

CHAIRMAN TORRES: And that's a standard which Mr. Warriner indicated to us earlier, the World Health standard?

DR. BOOK: Yes.

CHAIRMAN TORRES: Is it possible to obtain a copy of that memorandum?

MR. WARRINER: I think that's what you also asked Dr. Kelter. He has a copy of it, I'm sure. But we'll be sure that you get that as well.

CHAIRMAN TORRES: It would be very important to us to determine just how the decision making process actually takes place in the Department and the Agency. Help us in making a better judgement call.

Any questions? Senator Greene.

SENATOR GREENE: I have one question out of curiosity.

Do you have any knowledge as to why your suggestions were not followed through with? Were you given any information, or did you inquire, or was any offered as to why your initial recommendations were not followed through on?

DR. BOOK: Well, I think half of my recommendations were. I was --

SENATOR GREENE: Well, I meant in their entirety.

DR. BOOK: With regard to the public information and the public right to know about the chemicals that are carcinogenic in animal species, I believe that was distributed with the initial list.

I believe the reason my recommendations about the size of the list were not followed was because that initial list was

determined on a legal criteria rather than on scientific criteria.

SENATOR GREENE: What was the legal criteria?

DR. BOOK: Mr. Warriner can discuss that better than I can. I'm not a lawyer.

SENATOR GREENE: Yeah, but it was related to you; was it not?

DR. BOOK: I believe it had to do with some -- some difficulties interpreting -- in interpreting the Proposition from a legal perspective.

CHAIRMAN TORRES: Is your counsel here?

MR. WARRINER: Mr. Tousignant?

CHAIRMAN TORRES: Yes.

MR. WARRINER: Yes, he is.

CHAIRMAN TORRES: Would you please come forward.

SENATOR GREENE: I thought the citizens read it pretty clearly. I don't know why it would require any additional interpretation.

CHAIRMAN TORRES: Would you please identify yourself.

MR. TOUSIGNANT: Sure. My name is Bob Tousignant, and I'm an Assistant Chief Counsel with the Department of Health Services.

CHAIRMAN TORRES: Welcome to the Committee.

Senator Greene, would you like to ask your question again.

SENATOR GREENE: What was the legal question that surrounded the interpretation of the Initiative? Millions of

Californian seemed to interpret it pretty clearly. What was the difficulty you had?

MR. TOUSIGNANT: I think, as Under-Secretary Warriner identified earlier, I mean, the basic legal question relates to whether or not the references to the Labor Code sections that are included in the minimum list requirement of the Proposition are clear on their face, or whether there is some latent ambiguity in those references.

SENATOR GREENE: What does that mean? Explain that clearly. What ambiguities do you think that there might be, and what is it that is unclear?

I understand what you said, but you haven't been specific. Would you please be specific.

MR. TOUSIGNANT: The Proposition refers to Labor Code Section 6382(b)(1) and 6382(d).

SENATOR GREENE: All right.

MR. TOUSIGNANT: Those are two sections which relate to a list of chemicals that is published by the Department of Industrial Relations.

SENATOR GREENE: All right.

MR. TOUSIGNANT: The second of those --

SENATOR GREENE: Which relates to workers on job sites and employers.

MR. TOUSIGNANT: That's right. The second of those references includes -- again refers to federal regulations which relate to occupational health and safety, and those regulations, it's the federal Hazard Communications Standard, require

employers to identify risks of a wide variety of chemicals to their employees, not only carcinogens and reproductive toxicants, but also sensitizers, irritants, hepatotoxins. There's a wide variety of chemical substances that are required to be identified under the Hazard Communications Standard.

As to carcinogens, the Hazard Communications Standard differentiates between known and potential carcinogens, suggesting that known carcinogens and potential carcinogens risks should be communicated to employees.

The question that comes up from the Proposition is, in light of the wide variety of substances that are referred to, which of the substances are required or were required by the Governor to be included on the minimum list?

And we narrowed that list to include known substances in light of the repeated references in the arguments that were presented to the voters that it related to known and not suspected carcinogens.

I hope that was clear.

SENATOR GREENE: Well, yes, your reply was clear.

Potential indicates that there's some evidence; is that correct?

MR. TOUSIGNANT: That's correct.

SENATOR GREENE: And if you have some evidence, then in light of the amount of evidence which is available, that is known. I just means that you have not completed your studies, or that there are still additional studies to be conducted. But once something is potential, that's known, is it not, to a degree?

MR. TOUSIGNANT: To a degree, but again, it was -- I think it's the implementation process to ask the scientists to review what is known about the carcinogens which are listed by international organizations as potential carcinogens or suspect carcinogens to identify which of those in their view are known to the State to cause cancer.

SENATOR GREENE: On that point, what are these scientists going to do to go out and prove one way or the other? Are they going to do out and conduct some experiments on people or what? Because they're going to draw on the body of knowledge, the body of research, the --

CHAIRMAN TORRES: Just so they don't do it on my body.

SENATOR GREENE: Right.

(Laughter.)

SENATOR GREENE: So, they're going to review all the data and all the research and what have you, and if no one has conducted any additional research since the last research, what are they going to be able to do which goes beyond what they can do now?

MR. TOUSIGNANT: Presumably they'll decide based on the data that exists. We don't expect them to do additional research.

SENATOR GREENE: Yes, but that data exists now though, sir, that's my point.

MR. TOUSIGNANT: That's correct.

SENATOR GREENE: So if they can do it later, why can't they do it now?

MR. TOUSIGNANT: Well, they can do it now, but the Panel was just named March the first, or February 27th.

SENATOR GREENE: But they don't come to the Panel without any knowledge. They're supposed to be on the Panel because they already have that knowledge. So they knew this when they walked through the door. Before they even knew they were going to be appointed they knew this.

MR. TOUSIGNANT: This Panel has not yet met, Senator.

SENATOR GREENE: They don't have to meet.

MR. TOUSIGNANT: Their first meeting is March 31st.

SENATOR GREENE: All right. I think I've made my point.

CHAIRMAN TORRES: Nowhere in the Initiative is there a distinction between animal and human; is that correct?

MR. WARRINER: The Initiative does not mention animal, though it does mention humans.

CHAIRMAN TORRES: Right, but every scientific guideline that we've talked about had the parameters of that to be the case nonetheless; isn't that correct?

MR. WARRINER: When you talk about the IARC or the NTP, they divide it up into groups.

CHAIRMAN TORRES: Right.

MR. WARRINER: Group 1 is known, Group 2 is identified as suspect. For instance, on the IARC Group 2, it includes exposures for which at one extreme the evidence of human carcinogenicity is almost sufficient as well as exposures for which at the other extreme it is inadequate. IARC and NTP, which are the groups which are specifically referred in the argument

included in the ballot proposition, further focus on that distinction.

Again, the distinction is for purposes of the initial list, not for -- the distinction is not for purposes of what the Scientific Advisory Panel will do starting the 31st of this month.

CHAIRMAN TORRES: We understand that, but it's still very unclear as to why ambiguities which Counsel raised here had an impact as they did on known carcinogens, like EDB, which we know and is well-accepted in scientific circles to be a known carcinogen, yet that carcinogen was not included within the list.

MR. WARRINER: The Proposition --

CHAIRMAN TORRES: And the rationale is, the reason it was not is because there was some legal problem. Now we hear the legal ambiguities, and those legal ambiguities really do not seem to have relevance to the issue of known carcinogens.

MR. WARRINER: They do.

The Proposition arguments say "known" not "suspected". That's the terms that are used at least two times in the ballot arguments.

CHAIRMAN TORRES: Are you suggesting to this Committee that EDB is not a known carcinogen, it's merely suspected?

MR. WARRINER: The question is not what the Scientific Advisory Panel. The question is what the Governor was required to do under the Proposition for the initial list.

CHAIRMAN TORRES: I understand that, Mr. Warriner, and that required some mens re, some understanding of what was going on.

In that instance, it seems to me that that EDB, a carcinogen, was known to be a carcinogen. I don't want to belabor the point, I'm just trying to figure out what Counsel's thinking was in interpreting Proposition 65.

MR. WARRINER: Again, you focus on the fact that we're talking about humans, we're talking about "known", we're not talking about "suspected". And when you pull the IARC and NTP list out and physically look at it --

CHAIRMAN TORRES: It says to me, when I pull out that language, it says quite clearly to me that animals have a direct propensity to occur in the same way in human beings and other mammalian aspects.

MR. WARRINER: Come back to the term "known". The term "known" was used in the ballot arguments; not "suspected" but "known".

It didn't say "animal"; it only mentioned humans. It talks about "known", not "suspected".

So what we did for purposes of the first list only was identify all the, quote, "known" human carcinogens.

CHAIRMAN TORRES: But there was not distinction in the Initiative between and human.

MR. WARRINER: There was no mention of animals.

CHAIRMAN TORRES: That's my point.

MR. WARRINER: In fact, there was no argument anywhere that I was aware of that indicated that we were concerned with animal carcinogens. The focus was on "known" to humans.

CHAIRMAN TORRES: Good heavens! It would just assume common sense that that would have been the case because of the evidence that we have on most of the carcinogens.

Excuse me if I'm incorrect, but most of the evidence we have on most of the carcinogens that are well, quote, "known" to the scientific community to be mutagens, to be reproductive toxins, to be carcinogens, are based upon animal tests; are they not?

DR. BOOK: That's correct.

CHAIRMAN TORRES: And as a result of those animal tests, we have certain restrictions on their usage, if not restricted period. Isn't that correct, based upon those animal tests?

So I don't know who -- I'm trying to figure out who is talking to whom in this whole experience. It just boggles my mind as to trying to figure out how could an initiative even be more closely or better written in the future, because that's the other thing in the back on my mind as we begin initiatives and the process.

How do we write them more carefully so we don't have this burro-cratic interaction which results in confusion?

SENATOR GREENE: Mr. Chairman, on your point, which goes to the same thing.

The voters do not vote on the argument. They vote on the Initiative. You keep referring to the argument.

The argument is not a part of the question. The question is on the Initiative.

And that gets right back to the point that the Chair is making. The voters did not vote on the argument. You keep referring to the argument, what the argument said.

Well, the argument is to explain the issue to the voters. The argument is not what citizens vote on. They vote on the Initiative.

So in terms of what you implement, you don't implement the argument. You implement the Initiative.

MR. WARRINER: But for purposes of construing the Initiative --

CHAIRMAN TORRES: Understood, Tom Warriner. I understand exactly what your answer's going to be, and all I can say is, you should have talked to our Attorney General who obviously does not agree with your Counsel's interpretation because thereafter he refused to defend the Governor on any lawsuits based upon the short list because he didn't find any ambiguity in the Initiative.

MR. WARRINER: You probably should ask him about that.

CHAIRMAN TORRES: We have.

MR. WARRINER: I can't speak for him.

SENATOR GREENE: I'm sure you had to search long and wide to get a reason, because pointing to the argument is --

CHAIRMAN TORRES: No, I'm just trying to figure out how decisions are made.

So, what happens now? Let's say there's another initiative on the ballot that effects your department.

You will not communicate with the Attorney General as to his interpretation or her interpretation at some future date on the initiative? You will rely upon your own in-house counsel for that interpretation?

MR. WARRINER: We did in this case, yes. I can't speak for what future initiatives might bring to us.

CHAIRMAN TORRES: I understand that, and I'm not asking you to speculate. I'm just asking, given this particular instance, you relied on in-house counsel and no communication was made to the Attorney General for an Attorney General's opinion?

MR. WARRINER: We did not request an opinion on this subject.

CHAIRMAN TORRES: Pardon me?

MR. WARRINER: We did not request an opinion on this subject.

CHAIRMAN TORRES: On a subject of this magnitude, no request was made for an Attorney General's opinion to make sure that you covered --

MR. WARRINER: Well, there are undoubtedly lots of areas in which Attorney General opinions are not requested. I spent a lot of time in the Attorney General's office. We got a lot of opinion requests, but not every possible subject is explored by way of an opinion.

CHAIRMAN TORRES: I understand that, Tom, but this is not an Initiative to deal with, you know, signposts. It's an initiative which was probably one of the most controversial initiatives on the ballot in 1986. It was not an initiative that

no one knew about. It was not an initiative that most people didn't understand. They had very polarized opinion one way or the other.

And I'm just trying to figure out what goes on in the thinking processes in the Department in making sure to cover themselves.

I would not, for example, rely solely on Legislative Counsel to guide the actions of this Committee if it involved a substantially controversial issue. Nor would I think any other Member of this Legislature would. They would request the Attorney General for an opinion to make sure that we had it covered.

I mean, goodness gracious! I even requested an Attorney General's opinion for a baby shower gift to make sure that I was covered under the FPPC, and I did not rely on the FPPC or Legislative Counsel, and I certainly wouldn't put that issue as important as the issue of interpreting an initiative which garnered statewide and national attention.

Assemblyman Hayden.

ASSEMBLYMAN HAYDEN: Thank you, Mr. Chairman.

I wanted to go back to ask Dr. Book some questions. Perhaps I misunderstood your testimony.

When you recommended the IARC list as the scientifically appropriate list, were you doing that for the Department of Health Services or as an individual?

DR. BOOK: No, I was doing that as an Acting Chief of the Office of Environmental Health Hazard Assessment in a

memorandum to the Deputy Director of the California Department of Health Services.

ASSEMBLYMAN HAYDEN: Did it have any further authority than that?

DR. BOOK: Not that I know of.

ASSEMBLYMAN HAYDEN: Was that passed on to either Mr. Warriner or to the Scientific Advisory Panel?

DR. BOOK: It wasn't passed on to the Scientific Advisory Panel. It was passed on to Mr. Warriner and to the members of the interagency steering group.

ASSEMBLYMAN HAYDEN: Did you get a reply to that from any member of the interagency working group?

DR. BOOK: No, not officially. I mean, some people said that --

ASSEMBLYMAN HAYDEN: Did you have conversations with -- there were people who said: Nice memo?

DR. BOOK: Yes.

ASSEMBLYMAN HAYDEN: Who for instance from the interagency groups said that it was a good memo?

DR. BOOK: I think some staff of the Water Board, for example.

ASSEMBLYMAN HAYDEN: Did you get anything from Food and Ag?

DR. BOOK: No.

ASSEMBLYMAN HAYDEN: Anything from any of the other agencies?

DR. BOOK: No.

ASSEMBLYMAN HAYDEN: Anything back from Mr. Warriner?

DR. BOOK: No.

ASSEMBLYMAN HAYDEN: Verbal?

DR. BOOK: I think he referred to it as my "ethical" memo.

ASSEMBLYMAN HAYDEN: He referred to it as your "ethical" memo. Did that imply that -- what did that imply, at least as you heard the term?

DR. BOOK: I think because I thought that we were justified in -- at least it was my position as the author of that memorandum that I felt that we were justified to -- we were justified to include the animal data on the list for Proposition 65.

ASSEMBLYMAN HAYDEN: Did you know that in Proposition 65 in the codes that are referenced, that specific reference is made to animal or human, and that you were not simply on scientific grounds on some good grounds, but there is legally referenced, a reference to animal as well as human?

DR. BOOK: In one of the codes?

ASSEMBLYMAN HAYDEN: Yes, In the codes referenced by Prop. 65.

DR. BOOK: Yes.

ASSEMBLYMAN HAYDEN: You knew that at the time?

DR. BOOK: I don't recall exactly the citation. Oh, I don't know if I knew it at the time.

ASSEMBLYMAN HAYDEN: Would you say by calling it an "ethical" memo, well let me ask Mr. Warriner.

Did you call Dr. Book's memo the "ethical" memo?

MR. WARRINER: He has a phrase in there where he suggested it's important to give public notice, public information, and he felt that it was an ethical duty to let the public know of the concerns that we had.

That's one of the reasons why we chose the two-list approach so the public would have full knowledge of all the chemicals we were concerned with.

ASSEMBLYMAN HAYDEN: So you called it an "ethical" memo because --

MR. WARRINER: He used the term. He felt there was an ethical obligation to advise the public.

ASSEMBLYMAN HAYDEN: I thought that Dr. Book just said that you called it the "ethical" memo.

MR. WARRINER: I did, too.

ASSEMBLYMAN HAYDEN: And you called it the "ethical" memo because he was recommending that the process be open to the public?

MR. WARRINER: No, no, no, no.

What he said was that the public should be made aware of all the chemicals that we were concerned about. That was the reason for the primary and secondary, or candidate, list, was to let the public know all the chemicals that the Panel's focused on.

ASSEMBLYMAN HAYDEN: So in calling it an "ethical" memo, you didn't imply that it was ethical as opposed to your conclusions and recommendations?

MR. WARRINER: No, I wouldn't put it that way, sir.

ASSEMBLYMAN HAYDEN: It wasn't the right thing to do as opposed to what you were about to do?

MR. WARRINER: No, I wouldn't put it that way either.

(Laughter.)

ASSEMBLYMAN HAYDEN: I have no other questions.

CHAIRMAN TORRES: At any time did you or anyone associated with the recommendations, you Counsel, or you Mr. Warriner, request an informal or oral opinion from the Attorney General's office, or a telephone conversation with one of your friends in the AG's office regarding the interpretation of this Initiative?

MR. WARRINER: We did not request an opinion either informal or formal.

CHAIRMAN TORRES: You never picked up the phone and said, "Hey, Harry, or whoever you may be out there, what do you think about this issue? We're trying to compare notes."

MR. WARRINER: No, I did not ask for an opinion.

CHAIRMAN TORRES: Counsel, did you at any time?

MR. TOUSIGNANT: No, I didn't.

CHAIRMAN TORRES: You felt you were fully competent to analyze this Initiative?

MR. TOUSIGNANT: There were a variety of arguments presented from a variety of sources, and we saw those. And we prepared our own analysis, yes.

CHAIRMAN TORRES: At no time did you compare notes of your analysis or at any time have any telephone conversations

with any member of the Attorney General's staff regarding this issue?

MR. TOUSIGNANT: We discussed with the Attorney General's office matters of representation, of course, but --

CHAIRMAN TORRES: Matters of representation. This was after the list was issued or prior to its issuance?

MR. WARRINER: Might have been the day before.

CHAIRMAN TORRES: Might have been the day before when you told him that you were going to come out with a shorter list than you had anticipated or than others had anticipated?

MR. WARRINER: Well, actually, there were other people who argued the list should have been four chemicals, or no chemicals, and there were other people arguing we ought to have 267 chemicals. But when it became clear that we were going to issue a list that was going to get us into court, either the long or the short, depending on how you want to look at it, approach, we contacted the Attorney General's office and discussed that.

CHAIRMAN TORRES: This is speaking procedurally, are there times when you, Counsel, would deal with the Attorney General's office to compare notes on issues that come before you?

MR. TOUSIGNANT: Generally not unless we anticipate litigation, imminent litigation against the Agency or by the Agency.

CHAIRMAN TORRES: All right.

The reference, for your own information, the reference that Mr. Hayden was referring to which cites the Labor Code Section (b)(1) specifically cites the human or animal carcinogen,

which might have given some light to your analysis in terms of dealing with the list, especially as it related to those other areas that we discussed before.

Any other questions? Senator Greene.

SENATOR GREENE: On that point, I thought that Mr. Warriner and the Counsel stated that there was no reference to animals. Now it comes out that in the various sections of code, or in one or two sections of code, animals are mentioned.

MR. WARRINER: There is no --

SENATOR GREENE: Now, those sections of code are specifically referenced in the Initiative. And you just testified earlier that nowhere was there any reference to animals.

So now, which is it? It can't be both, sir.

MR. WARRINER: There is no mention of animals in the wording of the Initiative.

SENATOR GREENE: Yes, but it references a specific code which has animals. So, you know, it's understood, if it's referencing specific sections of code, you should, it seems to me, be reading those sections of code rather than be reading the argument.

Now, how do you square that, sir? I mean, I really don't understand it.

MR. WARRINER: For purposes of calculating what is the intent of the voters, what the voters had with them at the time they voted was the Initiative itself and the ballot arguments that were provided to the homes of every registered voter in

California. So the documents they had in front of them was the Initiative and the --

SENATOR GREENE: But legally, legally, if specific sections of code are included within the Initiative, that is included. Legally. You don't have to be a lawyer to know that. All you have to know is the structure of law.

MR. WARRINER: The question was, did it mention animals or humans, and it only refers to humans in the Initiative itself.

SENATOR GREENE: But the code mentions animals, sir.

MR. WARRINER: Right, the code also mentions the other references, and it's those references themselves that create the ambiguity.

SENATOR GREENE: I'll bet you in court your argument won't stand up.

CHAIRMAN TORRES: I guess we understand what voters have in their possession on election day, and sometimes we don't feel that's enough either, or maybe in some cases it may be too much.

However, you and I have a higher duty and a higher responsibility. And that higher duty requires us, mandates us by law and by moral obligation, to make sure that we examine an initiative in all of its aspects. And if a code section is referenced, then that reference ought to be incorporated within standards that we pursue.

And I think you know that, Mr. Warriner.

MR. WARRINER: It is.

CHAIRMAN TORRES: Well, it wasn't in this instance.

Mr. Hayden.

ASSEMBLYMAN HAYDEN: I should point out further that if he shifts the argument, Mr. Chairman, to the ballot argument as opposed to what the Initiative says, the ballot argument says that the IARC list and the NTP list will be included. So it's fairly clear what lists the proponents were speaking about.

I think that this is --

MR. WARRINER: The argument is, of course, over what part of the IARC and NTP lists are included.

ASSEMBLYMAN HAYDEN: I wanted to ask you a question, Mr. Chairman.

You asked earlier what now becomes of these Department of Health Service guidelines?

CHAIRMAN TORRES: Yes, we have.

ASSEMBLYMAN HAYDEN: They seem to be at odds now with the new State policy.

CHAIRMAN TORRES: Well, it's my understanding those guidelines will be recommended to the Scientific Panel to incorporate as part of their review process.

Isn't that correct?

DR. BOOK: I believe that's what Dr. Kelter indicated, and that's certainly our intent, to make this information available to the Science Advisory Panel.

MR. WARRINER: Also, in addition to the Health Services one, there's also the EPA, which is a similar document, the IARC document itself, and the NTP document. So all of those present policies that the Panel can choose.

ASSEMBLYMAN HAYDEN: Does that mean that you're recommending that these guidelines, these DHS guidelines, which are roughly equivalent to the IARC and NTP lists, be adopted as part of the minimal list by the Scientific Review Panel?

MR. WARRINER: You're asking two questions. First of all, the Panel has to select a procedure.

ASSEMBLYMAN HAYDEN: All right.

MR. WARRINER: It could select Health Services; it could select IARC itself which is very close; it could select the EPA which is slightly different, or the NTP program.

After they've selected the policy, then they have to decide whether all, some, what part of the chemicals that were reviewed by those procedures by the body that initiated the procedures should be included on the Panel's list of chemicals. It's a two-fold process.

ASSEMBLYMAN HAYDEN: Maybe I'm missing something, but if they're not going to do original research, this Panel --

MR. WARRINER: Correct.

ASSEMBLYMAN HAYDEN: If they adopt one of these long lists in the 250 range as valid policy, then what more do they have to do with respect to this debate over a short list versus long list?

MR. WARRINER: What they do is adopt a policy which says how they're going to view carcinogens. And then they look at what the group that originated that policy found to be the applicability of that policy to chemicals. And then they decide whether the policy was correctly applied or not, and that helps them decide which of those chemicals go on the primary list.

ASSEMBLYMAN HAYDEN: It sounds like they could come up with a list shorter than the best known federal authorities have come up with, a list shorter than the International Association for Research on Cancer, and a list shorter than the DHS's guidelines, not by doing new research, but by just arguing that all these established bodies are wrong.

How will they do that? Through a conversation? It would be an open hearing, I assume?

MR. WARRINER: Oh, yes.

ASSEMBLYMAN HAYDEN: With no new research, how are they going to argue that these rock-bottom lists are wrong?

MR. WARRINER: I don't know what the Panel's going to do, but I would expect them to adopt one of the known procedures as their basis for action.

ASSEMBLYMAN HAYDEN: Well then, if it shifts from your legal argument that the Initiative is flawed back to the scientific argument, do you have any disagreements with Dr. Book about --

MR. WARRINER: Again, we're not shifting. The initial list was a legal exercise by the Governor's Office in selecting.

ASSEMBLYMAN HAYDEN: Right.

MR. WARRINER: The second and subsequent additions to that list are by the Science Advisory Panel based upon the requirements of the Initiative itself.

ASSEMBLYMAN HAYDEN: But you'll have no recommendation?

MR. WARRINER: As to chemicals?

ASSEMBLYMAN HAYDEN: Right.

MR. WARRINER: No. That's up to them.

The Governor was quite clear that the Governor's Office is no longer involved. The Panel itself reviews the chemicals and makes a decision about moving them on to the list.

ASSEMBLYMAN HAYDEN: Are you calling the scientists to testify who are the authors of the aforementioned policies and protocols, IARC, NTP?

MR. WARRINER: I think what Dr. Book has done is provided copies of each of those to the Panel with the anticipation that they would, before the meeting, read them and become familiar with them, and then discuss among themselves which ones they think should be the policy under which this Panel operates.

The IARC arrangement's pretty much the same as the Health Services' guidelines in terms of the list.

CHAIRMAN TORRES: Thank you very much, gentlemen.

MR. WARRINER: Thank you.

CHAIRMAN TORRES: Sarah Reusswig who is the Program Analyst for the Legislative Budget Committee.

Welcome to the Committee.

MS. REUSSWIG: Thank you very much, Senator.

My name's Sarah Reusswig with the Legislative Analyst's Office. To my right is Carol Bingham, Principal Program Analyst for the Health Section.

Our statement's going to be very brief because basically, given the state of the Governor's budget and the fact that we haven't received any further BCPs, there's really not much to tell you at this point.

Our analysis of the Governor's proposal or of Proposition 65 included three sections. First of all, we evaluated what the Proposition requires the State to do. You've already talked about that: lead agency, setting up a list, revising that list annually, and reporting illegal discharges by certain employees.

And then we evaluated what the State could do. Going beyond that, we made some assumptions about, or looked at what the State has done in the past in other areas of environmental health concern, and came up with some conclusions about what the State ought to do at the very least.

The Scientific Advisory Panel seems to be going in the direction of addressing those concerns. What they ought to do at the very least is provide some statewide kind of guidelines as to what ought to be included, what shouldn't be included, so that the courts, as they implement the Proposition, if that is in fact where it's going to be left, will have some sort of statewide consistency.

Until we get some sort of budget proposal, however, we have no basis on which to tell you how much this is going to cost simply because there is so much discretion left up to the Administration.

We'd be happy to answer any questions you have.

CHAIRMAN TORRES: Any questions?

SENATOR GREENE: I have a question.

Well, it might not be fair to ask this of analysts, but Mr. Chair, let me point this out to you, and it's something I'm in the middle of, of course, with OSHA.

I wonder if there's any connection in the Governor's desire to phase out Cal OSHA and the action that they've taken in the compliance with this?

I mean, it might be reaching, but considering some of the other things going on, it might not be farfetched, because if you look at statements to comply an annual list, where it says chemicals that are regulated are carcinogens by the State Occupational Safety and Health Act, you do away with that, then you're left with federal. And federal's coverage in this area is minimal compared to the State's coverage in this area, even to notification of hazardous substance on the job, just advising workers that they're working with those kinds of substances.

So it might not be too farfetched to think that there's an interconnection in this separate and apart from any separate desire relating to OSHA.

I just throw that out because it seems like a strange coincidence.

CHAIRMAN TORRES: Good point.

Any other questions?

All right, this hearing is adjourned. Thank you very much.

(Thereupon this Joint Hearing on the Implementation of Proposition 65 was adjourned at approximately 12:15 P.M.)

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CERTIFICATE OF SHORTHAND REPORTER

I, EVELYN MIZAK, a Shorthand Reporter of the State of California, do hereby certify:

That I am a disinterested person herein; that the foregoing Joint Hearing of the Senate Committee on Toxics and Public Safety Management and the Senate Budget and Fiscal Review Subcommittee #3 regarding the Proposition 65 Implementation was reported in shorthand by me, Evelyn Mizak, and thereafter transcribed into typewriting.

I further certify that I am not of counsel or attorney for any of the parties to said hearing, nor in any way interested in the outcome of said hearing.

IN WITNESS WHEREOF, I have hereunto set my hand this 18th day of March, 1987.

Evelyn Mizak

EVELYN MIZAK
Shorthand Reporter