SENATE COMMITTEE on FOOD and AGRICULTURE
Senator Dean Florez, Chair

Follow-up Methyl Iodide Hearing: Evaluating the Report of the Scientific Review Committee on Methyl Iodide to the Department of Pesticide Regulation

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SENATOR FLOREZ: I'd like to call the Committee on Food and Agriculture together. I do know we will have members coming in and out. Today's topic is "Evaluating the Report of the Scientific Review Committee on Methyl Iodide to the Department of Pesticide Regulation." I'd like to first start and tell everyone thank you for coming. I have a little rearrangement of the agenda so if you can listen in somewhat closely. Obviously, we're very happy everyone came and we're very thankful to the folks that have traveled from throughout the country here. We'd particularly like to also thank DPR Director Mary-Ann Warmerdam; thank you for being here. We'd also like to thank the members of the Scientific Review Panel who, again, have traveled great distance to be here with us today. On behalf of the Senate, we want to thank you for coming.

As I've mentioned, the hearing topic today is the evaluation of the report from the Scientific Review Committee. And in light of DPR's recent decision to move forward, to register what I believe, at least from the information I've reviewed, is a very dangerous cancer causing neurotoxic chemical. We want to make sure you understand my point of view right at the beginning of this, because we had a hearing on this, as you know, on February 8th. This is a follow-up to that particular hearing, where we had an opportunity to evaluate the health and environmental impacts of methyl iodide and explored, at that time, available alternatives.

I want to make sure, as I see many of my friends in the agriculture community here, as well, that we no doubt recognize there's some importance to the agricultural industry in terms of the economy and the United States as a whole, in terms of this particular approach. The food we grow throughout the state, obviously, is the backbone of our agricultural economy, and, of course, that makes us the fifth largest supplier of food and agricultural commodities in the world. But we also recognize that there are environmental and health impacts in terms of the surrounding communities and its workers. This committee has always been very clear in terms of trying to figure out how chemicals like methyl iodide will have an impact on the lives of the many workers, families, and those exposed to the chemical. It's for this reason what we're here for; to try to better understand the department's decision despite, at least from my view, the many concerns raised in the Scientific Review Committee in terms of the risk assessment used by DPR.

We're going to begin testimony today and listen to the director of the Department of Pesticide Regulation, as I mentioned, and her staff. From there, we're going to then move on and try to understand the regulatory path that got us here. And then, we'd like to get a better understanding of the proposed mitigations that have been put forward by the department.

Although the committee agenda points to hearing from the Scientific Review Committee first, we're going to, in essence, hear from them second, if that's possible. And we do recognize that the scientists that DPR contracted with to provide an external review of the risk associated with methyl iodide is an important topic. It is the topic for today. And we would specifically like to focus in on the specific health concerns that are present with the registration of methyl iodide.

Furthermore, we'd like to have some discussion and input, thoughts if you will, on the conclusions that were published, ultimately, in the risk assessment document. There's no doubt that we believe the government has an obligation to protect those who work in our farms and those surrounding communities around agricultural land and we want to make sure, obviously,

we have the safest working and living environment conditions possible. And at the same time, we're going to try to figure out how we balance that, if you will, with what we would see as a chemical that is on the horizon. We're going to try to go through some of that as we move forward.

I would like to say that it is a lengthy agenda. We have a lot of questions for the director. We also have a lot of questions for—a few more questions for the Scientific Review Panel.

I would ask if there is public comment today, that we, if possible, email that public comment to the committee. We'd like to make it part of the record and we would like to make sure that it is in written form as much as possible. Not to say we're not going to have a lot of public testimony at the end of this, but the goal of this hearing is to try to get on the record the responses from the Department of Pesticide Regulation and also the Scientific Review Panel's discussion and some questions we have for the scientists that put forward this particular report. So I want to make sure at the beginning of that that we take care of that.

And let me also thank Assemblymember Monning for being here. We very much appreciate you being part of this process. And as I mentioned, we may have other members periodically come into the hearing.

So let's go ahead and begin. If we could, can we have Mary-Ann Warmerdam, the director of the Department of Pesticide Regulation please come up? Thank you for being here. We very appreciate it. I think you've seen my hearings over the years. And so, I have a series of questions I'd like to go through, and if there is something I did not cover, we'd like to have you, then, cover that at the end. And, indeed, if you have a written statement we'd like you to submit that to the record as well. But I do have some questions I'd like to go over. First and foremost, the regulatory approval process that was mentioned earlier: We want to kind of try to understand the regulatory journey that this particular chemical, methyl iodide, has followed. And then, we want to have, of course, some questions regarding the external Scientific Review Committee's report.

So let's go ahead and begin. Thank you for being here.

MARY-ANN WARMERDAM: Thank you, Mr. Chairman, Mr. Monning, thank you for being here. My name is Mary-Ann Warmerdam. I currently serve as the director of the Department of Pesticide Regulation. I have with me our chief deputy, Chris Reardon, and also our associate assistant director, Dr. Marylou Verder-Carlos, who serves us as our science advisor. And I thought her ability to answer some of the more scientifically driven questions would be helpful to your deliberations today.

SENATOR FLOREZ: Wonderful. And as you see fit, feel free to jump in as we go through these questions. I only would ask if there is someone other than the Director making a comment, just state your name so we can make sure we have that on the transcript prior to an answer.

Let's start, obviously, for our purposes, with your characterization of the current regulatory state of methyl iodide. In other words, currently in California can it be used, are we at the beginning of the process, the middle of the process, or at the end of the process? How would you characterize the current state affairs for methyl iodide?

MS. WARMERDAM: First of all, we have a statement. I'll be happy to provide it to your staff for the record. And with respect to the process, this material was submitted for review by California in the early 2000s; however, it was not registered by USEPA until 2008. And as you know, Mr. Chairman, I expect Mr. Monning also knows this, in California we are prohibited from registering a material until such time as it has been approved by our federal colleagues. Once the material was approved by our federal colleagues we did a very extensive review. In fact, the review associated with this material is arguably the most extensive, robust, comprehensive in the history of the department.

I would characterize where we are as the latter third or so of the process. We did announce our proposed decision to register on April 30th of this year. We have allowed for an extended comment period until the end of this month. We will take into account, and we're hopeful that there may be helpful

information submitted as part of that process so that we can assure ourselves that we've not missed anything, because that is part of what our obligation is. To assure ourselves that as risk managers, we have not missed an important component.

Assuming that there is nothing new that comes forward—I'm not going to preclude that; I'm just, for the purpose of this conversation, assuming nothing new comes forward—then it is up to the registrant to take essentially the mitigation that we have put forward, that has been laid out for discussion in the comment period, and work with the USEPA to get what we call a "California only" label. We will be very careful in our review of that, to assure ourselves that everything that we have required will be included in that label. I expect that it will take USEPA at least until the fall of this year, perhaps towards the end of this calendar year, depending on their own priorities, to get the label back to us. We will also be working with the agricultural commissioners to work through the enforcement aspect of this, particularly the availability of this particular material, including the potential for a local permit conditions. It will be a restricted use material subject to permit.

SENATOR FLOREZ: Okay. Let's go through that latter part, getting us to at least this portion a little more slowly.

In order for this particular chemical to be finally approved, then applied, the steps you've mentioned begin after the one-third of the field left. So in other words, we've gone two-thirds; we're in the latter …

MS. WARMERDAM: Roughly.

SENATOR FLOREZ: Roughly. We're in the latter one-third of this particular approval process. And then you mentioned the label issue, which is as you mentioned, a California only label. And then you've also mentioned the USEPA making an approval, I believe, of that label. That, you assume will be some time within the period of fall and winter of this year, correct?

MS. WARMERDAM: Yes.

SENATOR FLOREZ: Take me, so we can get it on the record, a slower through what occurs between the California only label, the EPA putting its

stamp of approval on that and then add in the layer of public participation. So are there any more opportunities for public participation in the regulatory process at this point? Or is this it? Are there any more process issues for the public itself, or those who are opposed to this particular fumigant to participate?

MS. WARMERDAM: Well, let me just acknowledge that we've had an unprecedented number of both public opportunities as well as private meetings with the different stakeholders who've all been very exuberant in sharing with us their concerns and other observations.

And I also want to, at this point, if I might, Mr. Chair, compliment the Scientific Review Committee. Not only did they do a very robust review, but they also included a public comment period as part of their peer-review process, and that's quite unusual. And it was another task that this particular committee took upon itself; they gave us another opportunity to hear from the public. Moving forward, we have, of course, the public comment period. We will evaluate all those comments and will be responsive to those comments as well. It is possible, although we're not expecting it to be likely, but it is possible, that we would potentially make some changes based on those comments that would require us to go out of another round of comment. But we believe we've captured the field pretty broadly. If we do determine that it is appropriate to adopt our proposed decision and register the material for use, we will also have to adopt some regulations with respect to how this particular material can be used. And as part of that process there will also be some limited opportunity for public comment as well.

SENATOR FLOREZ: Okay.

CHRIS REARDON: Mr. Chair, if I could.

SENATOR FLOREZ: Yes.

MR. REARDON: Chris Reardon. DPR. I just wanted to add on to what the Director said. We're going to have to make this a California restricted use material, and so that will be a regulation that will be also available for comment as well.

SENATOR FLOREZ: At that point in time, once it—that additional comment you just mentioned, after that point, what would change in terms of its use even at that late stage? What would need to occur, if you will? What could you foresee? Or is it just kind of a …

MS. WARMERDAM: It is not a fait accompli, if that's the question.

SENATOR FLOREZ: Yes, that's the question.

MS. WARMERDAM: Much like EPA has communicated that they are looking at the information coming forth from the Scientific Review Committee's peer review, as well as our own risk assessment, and frankly, the mitigation that we have put forward as part of our risk management process, EPA is evaluating that for new scientific information, new data that is markedly different from what we already know. In the scientific realm we're always—well, to coin—to paraphrase Secretary of State Madeleine Albright, much as in the political world you try to be confident but never get over certain. In the scientific world we try to be confident but not over certain as well. So with respect to new data, should new data be developed by any interested party and communicated to us, that could, and would, cause us pause and, if you will, stop the clock for further evaluation.

SENATOR FLOREZ: Okay. And let me ask a—since we entered into the realm of politics for a moment, let me ask a political question. If you can answer it, feel—if you can't, that's fine. But what would be the rationale, from your perspective, of getting this done this year? In other words, what is the rush to—I would call it a rush—to move to a chemical that at least the Scientific Review Committee has some questions on? And we will go over your mitigation efforts in a moment. But why would we, if this were a bill; it's not a bill; this is your decision. I think in the Legislature, at least, and Mr. Monning may agree or disagree, but it seems to me that we would be allowing an outgoing administration a chance to prove something that an incoming administration of maybe different persuasion might take a pause and really go through further. Why would we need to do this now? One. And, two, we also have an incoming administration at the federal level, an EPA layer, that might

indeed want to look at this, or have suggested at least in some testimony that I've read, that they may want to take a second look at this. I mean, so then we're ahead of the feds who might say they want to take one more look at it, and the feds might then say, Well, California has already gone the California label. They're in the last one-third of the game. Why was this all coming to a head, from your perspective, now? Why couldn't this take place next February, for example?

MS. WARMERDAM: There are many layers to that question and I'll try to parse it out without missing some of the details.

First of all, the U.S. is under incredible international pressure from our partners under the Montreal Protocol, to eliminate methyl bromide from our suite of fumigants because methyl bromide is an ozone depletor. And we as a country are under international pressure to find an alternative for that particular material that is not an ozone depletor. So that's the lager backdrop.

Methyl iodide is not an ozone depletor. It has some other interesting characteristics, but it is not an ozone depletor and that certainly is an important backdrop for us.

We have talked to our federal colleagues as recently as 24 hours ago. They assure us that while they are looking at the documents that I just referred to, that they are not in a position to reconsider their registration decision. That may mean—this is their prerogative—that they look at the mitigation or constraints that they require under their label, as it were, which is the permit to use. But they have assured us that they are not going to—they're not looking at reevaluating the fundamental registration decision in large measure because they are looking to eliminate methyl bromide by 2015. That's the federal administration's goal. So that's part of that.

With respect …

SENATOR FLOREZ: And let me interrupt at that point and then we'll go right back to that.

MS. WARMERDAM: Yes.

SENATOR FLOREZ: So the layer that you're having discussions with at the federal level is one in which these are new appointments?

MS. WARMERDAM: Correct. This would be my colleague and their senior staff, our federal counterparts.

SENATOR FLOREZ: And are they new appointments or are they holdovers from the last administration?

MS. WARMERDAM: It is a new appointment. The assistant administrator is a new appointment and he is served by career appointees who serve at his pleasure.

SENATOR FLOREZ: Okay. Let's go onto your second point as we're going through this.

MS. WARMERDAM: Yes.

SENATOR FLOREZ: So that's one layer at the fed level.

MS. WARMERDAM: That's one layer. And I might add that because California is a large fumigant using state, EPA is desirous to see us eliminate methyl bromide from our portfolio of use. That's the federal layer.

With respect to the state layer, and I'm sure members of the audience would have different perspectives, but there is a perspective that we have had as long as eight years to review the properties of methyl iodide. I prefer to start the clock ticking when we received the original application and EPA registered the material for use. Between the two, we've been looking at this material in the predecisional mode for two years and that is viewed in our world as a deliberative comprehensive time period.

We've also taken an unusual step for us in doing a risk assessment prior to making a registration decision because we recognize that this is a material that is highly toxic that we need to respect. And in order to assure ourselves as risk managers that our staff had uncovered the entirety of the scientific data we did take the unprecedented step, well within our authority, but unprecedented, to commission a scientific review committee to assure ourselves and validate that the protocols that we used as we developed our risk assessment indeed were comporting with the standards of the scientific world.

SENATOR FLOREZ: So is it safe to say from your perspective that as a director you've actually, then, approved methyl iodide? Is that where we're at today? To cut to the chase.

MS. WARMERDAM: We have proposed a decision that we will have to wait comment on before we make a final assessment on whether or not to register.

SENATOR FLOREZ: Okay.

MS. WARMERDAM: And, Mr. Chair, if I might. I also want to assure you and Mr. Monning that if we did not believe that the constraints that we've identified were health protective—certainly they're much more health protective than our federal colleagues have put forward—we would not be in a position today to have made a proposed decision to register. We had to assure ourselves of the ability to use this material safely in California.

SENATOR FLOREZ: Okay. And given that, is it then safe to say that you are satisfied with methyl iodide as a fumigant actually being used safely in California?

MS. WARMERDAM: We believe, based on the available data that we have today and—this is the important component—the addition of the constraints that we've identified, that it can be used safely. Having said that, if you assume we register it by the end of the this year, plus or minus, the department has an ongoing environmental monitoring aspect to our program and that involves ongoing data development as well as data collection, and that is the way we assure ourselves that if we have misjudged, that we will find that out quickly and can correct appropriately. That is unique among the states, and we are the only state that not only has that level of, if you will, more local review, but we also have the additional level of the country agricultural commissioners that provide us with boots-on-the-ground, if you will, eyes and ears to assure ourselves that the permit conditions can and will be enforced.

SENATOR FLOREZ: Okay. Have we ever done that though? Have we ever actually reversed a decision? You mentioned an extra process.

MS. WARMERDAM: Yes.

SENATOR FLOREZ: I've been here twelve years; I'm not sure I've seen that.

MS. WARMERDAM: You point to a reality that it is uncommon for us to either cancel a product for use in California or reverse. And typically, that's the result of the registrant's decision to pull the registration from California as opposed to having it cancelled. That's been our experience. That prior to getting to that point they're informed of our thinking. Registrants, the manufacturers, tend to pull the registration as opposed to having us cancel it. And/or based upon our work with our federal partners—we work very closely with EPA—and there are a couple of materials that because of our collective work in evaluating the materials, EPA has made the decision to prohibit the material either its availability on the consumer end or agricultural market. So those things have occurred, yes.

SENATOR FLOREZ: Given all of that, is there an appeals process to your decision at this point? I know you've mentioned a lot of stops and gaps in this process, but once, let's say, you decide to do this in the fall, is there some sort of opportunity to challenge your particular decision in order to move this forward?

MR. REARDON: Mr. Chairman, no, there's not.

SENATOR FLOREZ: Okay. So this lies in your decision and it is a final decision and unless there are other factors that come to light, that would, then, allow for a change of heart, or change of process, or a change of fumigant?

MS. WARMERDAM: It's final in the sense that we have made a decision to move forward based on what we know but it is always open. Every material that we regulate, from the softest garlic oil that's used in organic production to fumigants, is constantly subjected to reevaluation more or less rigorously depending upon the threat. And each year, we put out a listing of all the materials that have been proposed for registration in California and make that available for public comment. And assuming that there's no new information, we may move forward with reregistering it. But it is an ongoing dynamic process. Our process is not static by any means.

SENATOR FLOREZ: Okay. So, in essence, if there is information that becomes available that methyl iodide is somewhat more hazardous than we thought, the regulatory process itself is equipped to deal with that question?

MS. WARMERDAM: Correct.

SENATOR FLOREZ: And then how would one access that regulatory process? If indeed this new information becomes available, how would one begin that process?

MS. WARMERDAM: We often receive unsolicited information both from stakeholders and interested parties, as well as from the registrants themselves. Maybe a good example is the information we received: A bit off topic, but neonicotinoids which is not a kind environment. The use of that does not enhance the environment for pollinators, particularly bees. And we received both unsolicited information as well as data that we developed ourselves that required us, based on that information, to put that material into what we call reevaluation, which is a formal process to revisit, whether or not we have the proper controls in place.

SENATOR FLOREZ: So reevaluation, revisit, reopening of the regulatory process whenever one …

MS. WARMERDAM: The registration process, yes. Correct.

SENATOR FLOREZ: That is at whose discretion at that point, to reopen, reevaluate, or to—whose discretion is that?

MS. WARMERDAM: It's a response to the information that is reviewed at first level scientists within our organization, and depending on the level of threat or concern, it is taken up and our sciences advisor is in a position to make a formal recommendation to us, as you will, risk managers, to take a different course of action or to use our authority to put a material into reevaluation.

SENATOR FLOREZ: Okay. So I guess the question—before we move onto the scientific panel's discussion or some of their comments—that I have to ask, obviously; so for you as director there is no outstanding question as to the safety of this product given your mitigation efforts?

MS. WARMERDAM: As a risk manager we're always aware that we have to make decisions based on the best available data. We do this, as does every other organization, whether it's Air Board or the Department of Public Health. We're risk managers. And the requirement for us is to look at the whole comprehensive level of data, taking into account our legal obligations, social requirements, and other information and make the best decision based on that information. So, yes, in answer to your question, I believe we have made the best decision based on currently available data.

SENATOR FLOREZ: Okay. And let me …

MS. WARMERDAM: And with the mitigation what we've put forward. Without the mitigation—let me be very clear here; if we were looking at California acting only on EPA's label without any ability to provide further constraints for California's needs, we would not register this material for use in California. We can only do so because as risk managers we have put into place, or we are proposing mitigation constraints that we believe are sufficiently health protective to allow this material to be used safely.

SENATOR FLOREZ: Okay. Assemblymember Monning.

ASSEMBLYMEMBER WILLIAM MONNING: Thank you, Senator Florez. First, I want to thank the Senator for convening this session this afternoon, and members of the department for joining us, and others who will be testifying this afternoon. I want to start also just by thanking the department for your cooperation and transparency through this process. You've been very responsive to our offices' inquiries and requests and I want to thank you for that.

Madam Director, you did cite the background of this related to methyl bromide. In my recollection it was 1996 that the Montreal Protocols identified methyl bromide as an ozone depletor. And as a signatory to that international treaty, the U.S. government agreed to phase out methyl bromide and there's been a series of—there have been multiple extensions through the federal government for lack of an alternative to methyl bromide. Is that accurate?

MS. WARMERDAM: That's correct.

ASSEMBLYMEMBER MONNING: What is your current understanding of the deadline? You said 2015?

MS. WARMERDAM: Correct.

ASSEMBLYMEMBER MONNING: And that means no methyl bromide available for use in agriculture?

MS. WARMERDAM: That's our understanding based on our conversations with our federal partners. They are extraordinarily desirous to get the United States into compliance with its international obligations.

ASSEMBLYMEMBER MONNING: And it seems—correct me if I'm wrong—but the main emphasis of that international treaty, as you cited, is methyl bromide is an ozone depletor and that by comparison the benefit of methyl iodide is that it's not an ozone depletor.

MS. WARMERDAM: That is one of its favorable characteristics, correct.

ASSEMBLYMEMBER MONNING: Favorable characteristics. Is it fair to say that methyl iodide for use on the ground and in agriculture presents some even greater potential risks than methyl bromide?

MS. WARMERDAM: With respect to air quality concerns, the USEPA has classified methyl iodide as a VOC, and so in that regard there has been some concerns expressed. We have also been assured by EPA, that they are reconsidering that classification. That's a federal conversation that we don't have control over, to be blunt. Having said that; we do have an affirmative obligation under the Federal Clean Air Act to manage VOCs coming from pesticides. As a matter of fact, I think we've had a couple of conversations with you and other members about our VOC regulatory package and now, program. Under our current regulatory requirements as it relates to VOC emitting pesticides, including fumigants, there is a robust constraint and reporting requirement to reduce VOC emissions from pesticides. And in the San Joaquin Valley, we've had some significant success. We have successfully reduced pesticide VOCs by 30 percent from the 1990 levels. Methyl iodide, should it be finalized for use in California, will also come under those constraints in those non-attainment areas, to address that question exactly.

ASSEMBLYMEMBER MONNING: Thank you. And by VOC, volatile organic compounds.

MS. WARMERDAM: Correct. Sorry.

ASSEMBLYMEMBER MONNING: That's fine. That's the nomenclature is for the record, to be clear.

MS. WARMERDAM: Yes, correct.

ASSEMBLYMEMBER MONNING: You stated very clearly that methyl iodide can be used safely. My real concern is will it be used safely? And I think your "can be used safely" contemplates compliance with the mitigation proposals that your department has put forward; as you said, would be subject to EPA review. Do you build in any risk factor of the likelihood in the workplace of those mitigation factors not being fully or 100 percent complied with?

MS. WARMERDAM: We do not take into account those who disregard the law and do not comply. That is a violation and subject to enforcement.

ASSEMBLYMEMBER MONNING: And would you agree that violations have been reported, not with methyl iodide but with other restricted chemical but with other restricted chemicals?

MS. WARMERDAM: Yes, there have been violations that have been prosecuted under the county agricultural commissioner authorities. And sometimes they do come to us for review and appeal. And we use our authorities to either affirm or deny the agricultural commissioner's action. But on these types of violations, it is unusual—not unprecedented, but highly unusual for us to overturn a county agricultural commissioner's boots-on-the-ground decision.

ASSEMBLYMEMBER MONNING: They're the frontline enforcement people.

MS. WARMERDAM: They're the frontline, correct.

ASSEMBLYMEMBER MONNING: But it is fair to say that with other restricted chemicals there is a history of reported violations and violations that

have been upheld and that some of those violations have created health risk to workforce or rural residents?

MS. WARMERDAM: It is difficult for us to regulate to either stupidity, ignorance, or ignoring the law.

ASSEMBLYMEMBER MONNING: But you would agree all of those factors permeate our society at the different levels?

MS. WARMERDAM: From time to time. My cousin is a CHP officer and he reminds me of that often.

ASSEMBLYMEMBER MONNING: Thank you. And just a couple of more questions, Mr. Chair.

One goes to the studies you have conducted and maybe studies you haven't conducted. My understanding is that as applied, it's contemplated that methyl iodide would be mixed in some combination with a chemical called chloropicrin that's currently used often with methyl bromide applications. Have your studies looked at the synergistic effects of chloropicrin mixed with methyl iodide in terms of cancer risk, other health, air quality risks?

MS. WARMERDAM: That is part of our obligation. If you'd like us to—Dr. Verder-Carlos can go into some detail about how we do that.

MARYLOU VERDER-CARLOS: Marylou Verder-Carlos. When we conduct risk assessments, we do them by active ingredients. So when we did the risk assessment on methyl iodide, we concentrated on the risk assessment on that chemical. However, when we do continuous evaluations, we do them by product, and so the interaction between methyl iodide and chloropicrin will then be picked up at that time. However, chloropicrin, as you probably already know, is also under reevaluation right now at the Department of Pesticide Regulation, and so we are also evaluating the effects of chloropicrin as a chemical on its own. So both chemicals are being looked at upon in evaluation as we speak.

ASSEMBLYMEMBER MONNING: Am I hearing you correctly that it would only be prospectively that you might look at the combined effect or risks posed by the combined use of methyl iodide with chloropicrin?

MS. VERDER-CARLOS: That has been how we've conducted our risk assessment, is by active ingredient.

ASSEMBLYMEMBER MONNING: And contemplating the chloropicrin being used with the methyl iodide?

MS. VERDER-CARLOS: Yes.

ASSEMBLYMEMBER MONNING: What's the timetable for the chloropicrin evaluation?

MS. VERDER-CARLOS: Right now, it is under evaluation now as a toxic air contaminant. We are proposing regulation for chloropicrin as a toxic air contaminant as we speak. And the full risk assessment will be finalized probably within the year or early next year. But the ambient air part as a toxic air contaminant has been completed.

ASSEMBLYMEMBER MONNING: Thank you. And just a final question for anyone on the panel.

Combined with your efforts on the evaluation of methyl iodide, what is your department doing in the exploration of safer alternatives to methyl iodide for use as a soil fumigant, say, with strawberry production?

MS. WARMERDAM: We do have an obligation, it's part of our mission actually, to look for reduced risk alternatives as it relates to pest management. And we do do that. We have made investments in various strategies. Ultimately, it is a market driven decision. We are obligated to review and assess the appropriateness of materials that are put forward to us in an application, and that is what you see—that is the work product that we are discussing today. It is not within our authority to refuse to register a material, assuming we can ask and answer all the questions appropriately.

We do believe that the mitigation requirements that we have put forward, we've been told by different stakeholders that those mitigation requirements are quite robust and may in fact lead to greater investment in alternatives. It is my understanding having said that, that with respect to certain commodities, particularly strawberries, the alternatives have yet to prove to be as cost-effective as the industry would hope them to be. But I would defer to those in

the industry to talk more directly to what the details of that alternative research is putting forward.

ASSEMBLYMEMBER MONNING: Thank you. I want to thank the Chair again for the opportunity. And I'll turn it back to you, Mr. Chair.

MS. WARMERDAM: Thank you for your interest.

SENATOR FLOREZ: No problem. And, Mr. Monning knows we only allow nine questions from the Assembly so he stayed within the limit. (Laughter)

Let's go over the Scientific Review Committee so we can get it on the record. The decision to contract with the external group of scientists—you mentioned earlier in your opening, or at least it answers one of my questions—it actually went an extra effort to do this. Whose decision was it to, in essence, contract with this external group of scientists and why did we make that decision?

MS. WARMERDAM: It was my decision to have an external peer review prior to a registration decision. I did not do that in a vacuum; I did that in consultation with not only the chief deputy director and Dr. Verder-Carlos, but also with another one of our associate directors who oversees our programs. So it was not done in a vacuum. I did it deliberately. Again, to assure myself that the risk assessment protocols that our staff had incorporated were complete and robust, so to validate what our staff had done. Not to second guess, but to validate.

We asked Dr. Froines—and maybe if I could, Mr. Chair, take a moment to thank Dr. Froines and the panel members for doing a very robust, comprehensive job in the risk assessment. And they provided us not only with their professional opinions, but some additional guidance that we took into account as we made our risk management decision.

But I believe that Dr. Froines, because of his work on our behalf—with us. I shouldn't say "on our behalf," but with us, as a member of the Toxic Air Contaminant Panel, has reviewed many of our materials and has a degree of familiarity with both our program and our obligations, as well as with what we

were trying to do. He graciously, although maybe a little reluctantly, I should defer to him, but he did graciously agree to chair and put together a panel of his peers who are subject matter experts and bring the best thinking as a peer review panel to our risk assessment.

But I want to make the distinction: The risk assessment is to look at the science and assure ourselves of that level of review and as a distinct and separate exercise from risk management.

SENATOR FLOREZ: We had already submitted something to OEHA anyway, correct?

MS. WARMERDAM: Yeah. We did an internal peer review with our colleagues at the Office of Environmental Hazard Assessment. We also worked with USEPA in doing a peer review. So this was, depending on how you want to measure it, a third level of peer review.

SENATOR FLOREZ: So why would we go to that third level? It just seems—and not that I don't applaud the level, but it also makes me a bit—you can't win here, right? You go another level and now I'm suspect.

MS. WARMERDAM: Thank you for recognizing that. (Laughter)

SENATOR FLOREZ: So I have to ask the question on that flip side. And if we recognize and we need to go to another level in order to contract with scientific review folks, one more step, if you will, one more layer, what were the instructions given to the actual committee? Because that, then, becomes the issue; is that you hire someone but you kind of give them instructions. Some instructions are peer review or were the instructions something different? I mean, how are we to know exactly what they were to determine, if you will?

MS. WARMERDAM: Let me answer that, again, in a couple of layers. Why did we determine to take the extra step? In large measure because methyl iodide is a new compound and it has only been registered for use in the United States for a couple of years. It's been used in limited acreage, primarily in the state of Florida. And because of the newness, we did not have as much data as we might have with some of the other chemistries that we routinely look at. So that argued for another level of discretion being exercised.

We contracted with the peer review panel. We can make that contract available to you. It articulates what we asked the peer review panel to look at and consider. We were pleased, if I can be so candid, to say that we appreciated not only that they viewed our scientists' work as having met a high degree of rigor, but they also did provide us with some of their observations that we took into account as it related to risk management.

The panel was not convened. In some of its communications, they acknowledged that their work was not to be risk managers. That was our job. That their work was to help us make the right risk management decision based on a complete risk assessment.

SENATOR FLOREZ: Okay. All right, well that worries me, so let me tell you why. Because if indeed the philosophy is you're the Scientific Review Panel and your job is not to be risk managers, to me that says no matter how dangerous you tell me this material is, we, on the other side, DPR is going to mitigate for that because you're the risk managers.

MS. WARMERDAM: No.

SENATOR FLOREZ: So in other words, if indeed the panel had said in every sentence or in a one sentence response to you, "This stuff kills, please do not use," then I would hope that you would be telling me today "We're not using it," versus, "We can mitigate against that." Does that make sense?

MS. WARMERDAM: We have a legal threshold that we are required, we are obligated to meet, and so it is not merely, *merely,* the risk assessment and the informed thinking of all the risk assessors that we are required to look at. Our legal obligation requires us to be more comprehensive than that. We do have an obligation to take social concerns, economic concerns, other data into account as risk managers. But we also have an obligation as risk managers to deny a registration if we do not believe that the mitigation is available to address the concerns that were raised by the various peer reviewers that we have consulted with.

So no, Mr. Chair. It is not, you tell me it's bad, and that's the end of the conversation. My obligation goes a step beyond that. My obligation is to say,

Yes. Thank you. I understand it's bad. There's no question. This is a highly toxic material. We completely agree. My obligation is, then, to take the next step and ask the question can this be mitigated and can it be mitigated to point where it assures us that it is sufficiently health protective?

SENATOR FLOREZ: And so, what you were expecting from the Scientific Review Panel was not necessarily for them to determine how best to use methyl iodide but rather …

MS. WARMERDAM: Correct.

MR. REARDON: Mr. Chair, I think, too …

SENATOR FLOREZ: That worries me.

MR. REARDON: Yeah. Well, I think the process, there's some confusion because I think what's—the scientific peer review that Dr. Froines has conducted for us, once that was completed, then we reviewed all the peer review …

SENATOR FLOREZ: Everything, including that.

MS. WARMERDAM: Yes, correct.

MR. REARDON: Including that. And so, we looked at all of it. And then the risk management process is entirely different. We factor in all the—by the way, not only do we factor in OEHA's in the peer, but also USEPA's peer review as well.

SENATOR FLOREZ: So you add OEHA, USEPA.

MS. WARMERDAM: The external peer review and our own risk assessment work. We also consulted with USEPA, and took guidance from both USEPA and the World Health Organization, in looking up the appropriate protocols that we as risk managers had available to us to ensure ourselves, again, that we made the appropriate decision given the available data.

SENATOR FLOREZ: What if the analysis had come back and said, No. This is bad stuff. Don't use it?

MS. WARMERDAM: The analysis being the external peer review?

SENATOR FLOREZ: What were we prepared to do?

MS. WARMERDAM: The External Peer Review Committee affirmed that, yes, this is very difficult material to manage. And, yes, it has extraordinary characteristics that we need to be aware of. We don't disagree with that characterization.

We do have an obligation, as Mr. Reardon just noted, to look at that body of work, the body of work that USEPA made available to us, the work that was done by our colleagues at OEHA, and take that collective body of work to inform our risk management decision.

SENATOR FLOREZ: So before we close, at least in your view of it, before we go through some of the comments in the report, was it, from your vantage point, a meaningful report?

MS. WARMERDAM: Absolutely.

SENATOR FLOREZ: Okay.

MS. WARMERDAM: It was meaningful in at least two ways: One, it validated the work that our internal scientists had done and that's always important to scientists. And as a science-based organization, you don't want to get so arrogant that you think you understand all the nuances. So the benefit of the external peer review panel was to validate the work that had been done. And the other benefit that they provided to us was some of their observations with respect to concerns, health concerns that we needed to take into account as we thought through what if any mitigation was appropriate. And so, yes, it was helpful on two levels.

SENATOR FLOREZ: Okay. Let's go, if we could, through at least some of their observations. And I'd like to get your reactions to some of them and how they may have weighed out in some of the other studies in totality that you've mentioned. And I'm not trying to reargue the science here, I'm just trying to state some factors, that when I read through the report kind of stood out and I'd like to get your reaction to them.

First, let's talk a little bit about worker safety. Obviously, we'll talk about worker safety in greater detail. And you made mentioned, made reference to what the fed standards were and what you actually did, which I think looked

on paper much better than the federal standards themselves in probably every facet. I want to go through those in a moment. But generally, there was a comment here in this particular report; I'd like to read it to you. It says: "It was abundantly clear that respiratory protection, despite strict regulations on paper, is commonly inappropriate, inadequate, or inaccessible." And these comments were at least in the report in respect to farmworkers' experience with methyl bromide. And I'm just wondering, given that their comment with methyl bromide seemed to be saying that respiratory protections were, in essence, uncommon in the fields themselves. They were inappropriate, inadequate, and inaccessible. Is this your experience, and will it be your experience with methyl iodide? Why is there a statement there about methyl bromide which has been in use for a bit? Now we're switching to a much more dangerous, lower to the ground type of application, what does that mean for the application for methyl iodide?

MS. WARMERDAM: Again, let me break it out into a couple and I'll ask Mr. Reardon to talk to some of the detail. With respect to worker protection: First of all, the applicators will be required to have specific training. They are highly skilled and trained with respect to the use of this particular material. So the average farm employee is not going to be the individual that is applying this material. That's expressly provided for.

With respect to the respirators themselves, we have worked off of standards developed by USOSHA. The types of respirators that we are requiring under our constraints have been ascertained by USOSHA to have a 90 percent level of protection for the chemistries of concern. These are respirators that are commonly used by employees in the chemical manufacturing industry.

That's the backdrop.

We have also, at DPR, taken, and this is separate and apart from these mitigations, we have regulatory requirements that affect who and how a respirator can be used. A respirator can only be used by an employee who's been fitted for a respirator; who has training in its use. And an employee is not

allowed to take that respirator off during the application. If he or she needs to remove their respirator, they are required to leave the application site in order to do so. The respirators themselves are prohibited from use by those employees who have facial hair that compromise the seal or the valve on the respirator. And the respirators are designed to account for perspiration or sweating occurring in the field. And the respirators themselves have been designed with that in mind.

SENATOR FLOREZ: And where do I find what you've just mentioned in any of the mitigation efforts? I mean, I didn't see some of the strategies mentioned.

MR. REARDON: And in fact, Mr. Chair, if you would, I have list for that. I'd be happy to hand it to you.

SENATOR FLOREZ: Yes, please. I guess I may have missed the specifics that have been mentioned.

And in terms of the 90 percent, how is the 90 percent reached as mentioned? The scientists seem to say 50 percent or something of that sort?

MS. WARMERDAM: We are working off USOSHA's evaluation of the respirators. That is not something that we create or make up or otherwise craft. We deferred to our colleagues at USOSHA to make a valid assessment and we work off of their validation, which is the industry standard.

MR. REARDON: I think it's important to note also, that before you are even fitted you go through a fairly extensive medical evaluation before you use a respirator. So you're just not going to go into a particular area and say, Oh, by the way, I'm going to put on a respirator. It's got to be fitted; you've got an evaluation; and you've got to have the training in order to do it.

SENATOR FLOREZ: Okay. And on what you've just given me, where is it? Even though you've handed it to me, I'm still trying to figure out what Ms. Warmerdam mentioned. What box is it on, counting from one to two?

MS. VERDER-CARLOS: The respirator is already required right now by the label—by the USEPA label. And so, the proposed use in California already—these are the only changes from the USEPA list.

MS. WARMERDAM: These are added to the USEPA label.

MR. REARDON: So in order to use a fumigant now, you'd be required to do that under existing regulations.

SENATOR FLOREZ: I understand. This chart is giving me the impression that our standards in every aspect are stronger than EPA, but what's not on this chart is the fact that we are only matching EPA on this standard and that's why it's not on this chart.

MS. WARMERDAM: For the respirator. That is correct.

SENATOR FLOREZ: Okay. So this isn't …

MS. WARMERDAM: This articulates the more health protective criteria that we've identified.

SENATOR FLOREZ: Where are you stronger than the EPA? And I get this, and these are all positives, as mentioned. But would it be possible for you to get us a list of every aspect of this process, including those where we not only exceed EPA, but where we are equal to, matched to EPA?

MS. WARMERDAM: Okay.

SENATOR FLOREZ: And also, areas in which we are weaker than EPA?

MS. WARMERDAM: We are not weaker, Mr. Chairman.

SENATOR FLOREZ: Okay. I just want to make sure. Because that other box …

MS. WARMERDAM: Just clarify that for the record; we are at least as health protective as USEPA. In fact, we'd be prohibited from being less health protective under EPA's own label. But we are at least as health protective as USEPA. And this summarizes where we have taken an extra level of precaution.

SENATOR FLOREZ: Okay.

ASSEMBLYMEMBER MONNING: Mr. Chair, can I just ask a question on the respirator issue? Just to follow-up on one of your questions.

SENATOR FLOREZ: Mr. Monning, of course.

ASSEMBLYMEMBER MONNING: While the respirator protection applies to those handling methyl iodide, applying methyl iodide, is there a requirement

for workers in adjacent fields who may come in after that application to wear respirators, working on another crop?

MS. WARMERDAM: The buffer zones that we've articulated require no individuals to be present both during the application and for 48 hours thereafter.

ASSEMBLYMEMBER MONNING: Based on that buffer zone. But there is still—in the real world a crew will be brought into an adjacent field. Even if that buffer is observed, those workers are not provided with respirators, is that correct?

MS. WARMERDAM: They would only be allowed into the adjacent field, assuming it's within the buffer zone, after 48 hours had elapsed.

ASSEMBLYMEMBER MONNING: The treatment interval.

MS. WARMERDAM: Correct.

ASSEMBLYMEMBER MONNING: And what about contemplating tarps that tear with wind conditions, particularly in the central coast? How do you factor in ambient air contamination when the tarps tear?

MS. WARMERDAM: With respect to the tarps, we are requiring a tarp that's referred to as a virtually impermeable tarp—film. It is much more restrictive, if you will, than EPA requires. We also do require the applicator to ensure the integrity of that film. That is the applicator's affirmative obligation under what would be the law if this is adopted.

ASSEMBLYMEMBER MONNING: Just a final question. That applicator does not have a 24-hour observation duty of those tarps. They have a monitoring duty, is that correct?

MS. WARMERDAM: They have a 24-hour obligation to ensure the integrity of the tarps.

ASSEMBLYMEMBER MONNING: But that does not require them to be present at the field for the 24-hour period or the period of reentry interval.

MS. WARMERDAM: How they assure themselves that they have met their obligation under the law, we expect that they may do some healthy

monitoring, particularly in early applications. But it is not a requirement under the proposed regs, if that's the question.

ASSEMBLYMEMBER MONNING: That's the question. Thank you. Thank you, Mr. Chair.

SENATOR FLOREZ: You got it, Mr. Monning. Sergeant, can you count Mr. Monning's questions for us?

MS. WARMERDAM: The Assembly is always precocious. (Laughter)

SENATOR FLOREZ: I'm kidding. Let me ask a question about the respirators before move onto some other issues. But I guess, because I live in the area and I see what workers really do and how they operate, and I also see workers working next to workers. So if you're methyl iodide applicators are, in essence, trained and they're putting the mask on and they're fitted and only that employee can use it if they're fitted, what does that mean for the person working in the field with the next contracting crew that has nothing on? Because they're not even, maybe in many cases not even aware of what's being applied across the street. So on Fresno Avenue, where I live, across the street is another field of, maybe, say, almond folks doing some cleanup and they're doing what they do, and yet they're not fitted with the applicator mask, and yet, we know that even with your 100-foot buffer zone, how does it all work together?

MS. WARMERDAM: That's a minimum. And I think it's important to nuance this a little bit. That is a minimum buffer zone. And depending on the particulars, which we can go into, to some degree it may go up to 2,500 feet. And that is designed to be health protective for not only the applicator, which we are significantly more health protective than EPA, but under our proposed buffers we are five times more health protective for those that are in our parlance, bystanders or located within the community. So those buffer zones are designed to take into account exactly that scenario, Mr. Florez, that we do not expose bystanders, workers, those who live in the area, to that risk.

SENATOR FLOREZ: Okay. What happens to the farmer because of the buffer zone—I mean, two different farms, two different contracting crews?

When the farmer needs to do something on the other side of the street that is within the buffer zone because it's across the street, how does one tell the other farmer You can't do what you're doing today because we are doing something different on the other side? I mean, is that a common occurrence in agriculture? Do our commissioners handle that?

MS. WARMERDAM: Yes.

SENATOR FLOREZ: How is that handled, from you perspective with this particular application?

MS. WARMERDAM: And let me just thank you for your leadership because it is because of your leadership that we have incorporated into the culture of agriculture the aspects of spray safe that you were so desirous of seeing. That kind of communication is what will be required to assure ourselves that we do not have those situations develop because of lack of communication. And on that point, if a farmer refuses to keep a crew out, an adjacent farmer, or a resident refuses to leave and they're within that buffer zone, then the fumigation cannot move forward under our criteria.

MR. REARDON: And that would be managed by the ag commissioners.

SENATOR FLOREZ: The ag commissioners …

MR. REARDON: Yeah.

SENATOR FLOREZ: Okay. Let me digress for a moment on the respirators, because that's something I just wanted to understand. Mr. Monning made mention to it. What's the penalty for someone being caught without one of these respirators, in your mind? Is this an individual ag commissioner/ag commissioner thing? Is it punishable? Does someone get to lose their farm? Are contractors put out of business? Is there a license that's revoked? What's the stick here?

MR. REARDON: I think the stick is if it's part of the application team, assuming this is all going to be done by professional applicators, professional licensing people, and if for some reason someone doesn't apply a mask or takes off a mask or does something not consistent with our regulations, then that ag commissioner is going to most likely issue a notice of violation. And we have

criteria in terms of what that violation is going to look like. So depending on the criteria, depending on the severity, depending on …

SENATOR FLOREZ: So the violation is to—I know the worker gets fired and then he has health problems after that, so that's kind of a double whammy.

MS. WARMERDAM: Probably a bad personal decision on his or her part.

SENATOR FLOREZ: Right. But what makes the worker know that, in essence, they're risking their job—not only their health, but their job if they are indeed trying to shortcut through a particular respirator?

MS. WARMERDAM: The applicatoring entity has an affirmative obligation to require and assure and, as you noted, reassign an employee who is breaking the law.

MR. REARDON: Ultimately, he might not be able to apply. He's got to follow the law.

SENATOR FLOREZ: And if he doesn't follow the law?

MS. WARMERDAM: Then depending on the severity of the violation it would be prosecuted by the county agricultural commissioner with the full powers available to them under our authorities.

SENATOR FLOREZ: Has anyone ever been prosecuted with methyl bromide ever? Pretend I had the answer right here.

MS. WARMERDAM: Yes.

SENATOR FLOREZ: They have? Are you sure about that?

MS. WARMERDAM: But if you're asking for specific citations, I would have to get back to you on that.

SENATOR FLOREZ: All right.

MS. WARMERDAM: We have many, many years of prosecution that cover a wide variety of chemistries.

SENATOR FLOREZ: Got it. Definitely get us that statistic. Because if indeed we're using methyl bromide as a, if you will, guidepost to this and the Scientific Review Committee kind of uses that particular guidepost as saying "inappropriate", "inaccurate," "inaccessible" protocols for methyl bromide, I

have no reason to think that this would be any different for methyl iodide and that concerns me. Even though we may on paper have the procedures, the penalties, the policies, it still is only very paperish if indeed our past experience with methyl bromide, as our scientific panel is pointing out, again, inappropriate, inadequate, inaccessible. So I'm just trying to figure out how to make those all work.

ASSEMBLYMEMBER MONNING: Mr. Chairman, if I might just interrupt.

SENATOR FLOREZ: Yes.

ASSEMBLYMEMBER MONNING: Because something that would be collateral to that question: Any data showing workers terminated from a job for complaining about the employer not following safety regulations, I've represented those workers in the past and it creates a deterrent for people standing up and calling OSHA, calling the ag commissioner, because of fear of losing the job. So I'd be curious to see any data of a worker who complained about these conditions who was terminated and through your process was restored to their job.

MS. WARMERDAM: We understand and we will get you whatever data we have available along those lines.

One of the distinctions I want to point out that relates to this question is that with respect to not only the Scientific Review Committee but all the peer reviewers, we're looking at the material based off of USEPA's label. And as I mentioned earlier, we agree we would not be in a position to register the material for use if our only option was USEPA's label. Now they're most unhappy with that conclusion on our part, but that is a significant distinction. We would agree with the observations made by the committee that under USEPA's label this material is not appropriate for California. And then it's additive to that, as risk managers we identified the constraints that you see before you.

With respect to the history of fumigants, I'd have to—please don't quote me on this, although I know you will, I believe …

SENATOR FLOREZ: Ms. Warmerdam, we're not quoting you; you're just on the record forever, so go ahead. (Laughter)

MS. WARMERDAM: Yes. Thank you, Mr. Chair, for that. We have in the high 90s in terms of the safe application of fumigants. Our performance rate is quite high. It's in the high 90s. I want to say it's a 98, 99 percent level and the data supports us in that. Is there the risk of human error? I'm afraid we are all burdened by the human condition.

SENATOR FLOREZ: Let me ask a couple of more questions. Now let's move past the respirators for a moment. And I appreciate the discussion.

I think you see our issue with methyl bromide. So from our vantage point you are telling us—from my vantage point—that you're taking stronger precautions; we have all of these extra protections; we have all of these extra additives, if you will, to USEPA law for methyl iodide. But the flip question is why didn't we ever do that for methyl bromide? Why didn't we take the same precautions, the same efforts, the same types of issues?

MS. WARMERDAM: We do have, as an industry standard for all fumigants but particularly methyl bromide; we have a higher burden of compliance, or regulation depending on your perspective, in California than I dare say any other state in the Union. We are the lead standard for pesticide management in the United States and I'm very proud of the work that we have done along those lines. So that affects what we have done over the years with respect to materials like methyl bromide. We do have a complete and certainly a higher level of protection in California relating to that material than other states do.

SENATOR FLOREZ: And I don't want to say—for the record, and this is on the record, that it is a very unfortunate, from my vantage point, a very unfortunate situation to be put in. I wish we could wait ten years for this. I really do. And the reason for that is we're put in a very interesting position where I think—as you mentioned, methyl bromide at this point in time is being phased out due to it being an ozone depletor. So if you look at the entire world and you look at all the stuff that's depleting the ozone in all parts of the world

and then you center down into, with a Google search, the Central Valley or the agricultural areas of California, and you hope for within the ten years the industry itself doing the research, doing integrated tests, other types of approaches, even to methyl bromide, so you kind of look at that and go, if we had a ten-year window we would at least move in that direction. But I think what we found is that we are worried about ozone depletion, and now I'm worried about farmworker lung depletion. I mean, I'm worried about a completely different thing, which is the stuff that used to go up into the air now lies lower to the ground and in my view has a possibility of being inhaled by real people immediately in their lungs and having anything from birth defects to all of the other cancer causing agents and I just think that's a really unfortunate position to be put in. I mean, if I were to be able to choose I would say that we would stay with methyl bromide, if we had to, until we had some answer to—because now I think we're being forced to a position where we're using more dangerous stuff—much more dangerous stuff. And I wish we could just, you know—and I guess the question that I just have to ask, because it's kind of a layman's question, but why couldn't we just put this off and continue to use methyl bromide? And I never thought I'd hear myself say that, so for all the activists out there going, "Oh, my gosh, Dean, where are you going with this?"

MS. WARMERDAM: He's gone over the bend.

SENATOR FLOREZ: Right. But if I have to weigh methyl iodide versus methyl bromide, it gives me a position of save the earth and the environment or save a lot of farmworkers lungs and birth defects. So I mean, I just feel like we're in this very awful situation. And my thought was why couldn't we continue to put it off? And you're telling me we can't?

MS. WARMERDAM: You always ask such complex questions.

SENATOR FLOREZ: It's common more than anything.

MS. WARMERDAM: No, I'm happy to respond. I've had a similar conversation with my counterparts at USEPA. We have used methyl bromide to reasonable effect, not without its problems and its own characteristics. But

we've used it, and we understand it, and we can appreciate how to best manage it. When I asked that same question, Mr. Chair, I was told, unequivocally—it was a verbal conversation, but nonetheless it was pretty unequivocal—that this administration is not interested in retaining methyl bromide as part of the suite of fumigants. Now if that changes, Mr. Chair, Mr. Monning, we would be delighted because again, we understand methyl bromide, we understand how it works. And I suppose if you're comfortable managing toxic materials, we have a high degree of comfort. So we would not discourage that from occurring. But absent that, we are still presented with an application for registration that has been provided to us legally. We have an affirmative obligation to evaluate that application, go through our processes that we've talked about today, and come to some sort of conclusion with respect to the application and that's where we are.

We also share your concerns with all the materials that we regulate that health, public safety, and environmental safety have got to be accounted for appropriately. We share that concern of yours.

SENATOR FLOREZ: Well, I think it's an unfortunate position that we're put in. And the reason I say that, obviously, I'm looking at all sorts of data but the thing that stands out to me, 53 members of the United States National Academy of Sciences, including three Nobel laureates, all urging that we not approve methyl iodide. I mean, I don't know what more I need to read. And yet, we are put in the position where we have to make this change. And I would say that I would rather stick with something—I'd rather stick to methyl bromide with the new protections that you've just mentioned that we didn't have maybe before on that, to at least give us a running shot, as Mr. Monning said, in some other approaches that are less chemical related. And I think that I'll also shout out to the industry—more research. And I know you're doing a lot of research, but more needs to be done and this is why the University of California funding is important here, because you look at UC Davis and some of the research that needs to be done and these are the kinds of things that we need to fund if we're going to ever—in terms of a solution.

Mr. Monning.

ASSEMBLYMEMBER MONNING: Thank you, Senator Florez. Just on this issue; it seems this registration process historically, it's all or nothing with the mitigations. But one day it's not registered for use; at some point it's registered for use with whatever restrictions. Have you ever considered, since methyl bromide is targeted for phase-out in 2015, a pilot registration of methyl iodide? As opposed to going from nothing to just open to the market, a more focused pilot program where you could do the observation, do the air testing, have closer observation and monitoring as opposed to just putting it out on the market?

MS. WARMERDAM: We do have the authority to authorize essentially research plots and that has been done over the course of the last two years. We can get you the information in terms of how many acres were utilized under that research authority that we have. And it did give us an opportunity to do exactly as you suggest.

ASSEMBLYMEMBER MONNING: Well, I appreciate that historical, but my question, is there a precedent for a pilot prospectively at the time of registration?

MR. REARDON: Well, and I would say, Assemblymember, that's part of our continuing evaluation. We're going to continue to evaluate all those sort of environmental factors. So that will be considered. We're going to look at everything. It's consistent with what we do now.

MS. WARMERDAM: But if the question is do we have the authority to pilot; that's not within our authority. We have, what I would argue, is a more robust approach, and that's this continuous evaluation with real field conditions under what we believe, particularly initially, will be carefully controlled application environments.

MR. REARDON: In that pilot, if I would, Senator, you and I had a talk about this before, if you recall. It was exactly the experimental(?) use. That for us, is the venue for us to look at all those factors.

MS. WARMERDAM: The pilot _____, yes.

MR. REARDON: The pilot zones.

ASSEMBLYMEMBER MONNING: And I appreciate that. So maybe it's terminology, because there has been a pilot program. But I would just ask if in your consideration for your authority, to condition registration as you proposed with certain mitigating factors—buffer zones, etc., etc.

My question for you to consider: Does it have to be all or nothing? Could there be an expanded pilot? Or a continued—because we have until 2015 where growers still have access to methyl bromide, which they may prefer because it's my understanding is it's less costly to them per acre. And so, I'm not advocating for registration, as you know my concerns, but I would encourage calibrating the introduction if that is the ultimate decision.

MS. WARMERDAM: We'll certainly take that under advisement. I also want to clarify; we're not advocates for a material or, frankly, against a material. Our obligation is to make a reasoned, scientifically-based decision on if it is used, how can it be used safely if at all?

SENATOR FLOREZ: Let's move onto one other part of the report. It has to do with the quality of risk management. And I just want to, again, read it. It says: "The lack of sufficient data raises serious doubts about the adequacy of any risk assessment to fully estimate the risk that would be associated with the introduction of methyl iodide into the general environment." And I guess, they're here. I'd just like to get DPR's thought process on this. Do you agree with that statement? because it seems to be saying any risk assessment doesn't allow for …

MS. WARMERDAM: Again, if I were sitting in the shoes of the Science Review Panel and was looking at the USEPA label, I would undoubtedly come to a similar conclusion. But we are looking at proposed mitigation that moves us beyond that particular question, as it were.

MR. REARDON: I think too, Mr. Chair, if I could just add to the Director. The risk assessment in and of itself isn't a decision, so when you look at that risk assessment—and we look at all the risk assessments—that's a component of our decision. So we look at, as I think the Director mentioned

last time, a whole bunch of factors isn't just based on one risk assessment. The risk assessment alone doesn't determine how we're going to make a risk management decision.

SENATOR FLOREZ: Okay. But I guess the way I've read that is that there is either sufficient or insufficient data to understand the risk factors. And I guess I'm just wondering …

MS. WARMERDAM: Yes. As part of that concern we did work with the registrant. I think we would say "work," they would argue "require," the registrant to develop additional data to help address the posity of data in certain areas. We also looked at the data that was made available to EPA and took that into account as well.

As I mentioned early on, this is a new material so the Scientific Review Panel and others are correct; the amount of data that is available for this material reflects that it is a relatively new material as opposed to a material let's say, like methyl bromide, which has been around for years and we know much more about it.

So I think the observation is accurate. We believe that given what I've just mentioned, we've addressed those concerns, or backfilled for those concerns.

SENATOR FLOREZ: And is there any, from your perspective, threat in terms of environmental contamination, not just worker, given this statement?

MS. WARMERDAM: We have looked at concerns. We talked a little bit about air quality and capturing it under our VOC criteria. The other area of environmental concern is ground and surface water; that has been raised. We looked at and did modeling with USEPA using the most worse case scenario modeling components and also consulted with our colleagues at the Water Board, and we believe with the addition of our buffer protections, well head protections in the mitigations, we have addressed and accounted for those concerns. We can give you additional information with respect to how we got to that.

We are also committed to, as part of our ongoing environmental monitoring program, looking at collecting additional data. And I expect we'll have, as part of that data collection, a monitoring component.

SENATOR FLOREZ: Okay. You just mentioned to me that the Water Board actually has sent some concerns in terms of this particular fumigant.

MS. WARMERDAM: We have consulted with our colleagues at the Water Board, and it is our understanding, based on the last communications we received, that they've agreed with our approach, or acknowledged the appropriateness of our approach.

SENATOR FLOREZ: Okay. Let's ask a few more questions. You mentioned some of the simulated field exposures. It's kind of what we're talking about—the testing, correct? So in other words, the report mentions, and I'll quote from it, "Data derived from simulated field exposure was limited because it was carried out under cooler winter conditions rather than the heat of summer on a windless day, and the data on the actual environmental fate of methyl iodide was fragmentary at best." What would you say to that in terms of their assessment?

MS. WARMERDAM: We account for, as we look at developing—and I can defer to Dr. Verder-Carlos for the details—but we account for those uncertainties as we look at how do we craft appropriate constraints or mitigation? Because we are considerate to the real world factors that influence how materials are used and we try to, one, identify that universe and then identify appropriate mitigation to address that universe.

SENATOR FLOREZ: So are you saying, then, for the record, that with confidence you've looked at weather, wind, heat, the environmental conditions even though the Scientific Review Panel seems to be saying that this was maybe looked at as in a vacuum, but you're saying that the totality of what you've looked at includes those other factors, particularly heat and the environmental conditions.

MS. WARMERDAM: Correct. And I would go on to say that because of the concerns that they raised and those observations that were put forward, it

was part of the consideration that we took into account as risk managers. So it was helpful to get the benefit of that thinking as we took it into account.

SENATOR FLOREZ: Okay. So was the Scientific Review Panel team wrong because they somehow didn't know that you had taken all those into account?

MS. WARMERDAM: What the Scientific Review Committee was is at a disadvantage, if you will, because they did not have the benefit, I suppose, of being a risk manager; they were tasked with being risk assessors. We are tasked with being risk managers and there's a very clear distinction between what our obligations are.

SENATOR FLOREZ: I get it. Let's talk about some risk exposure issues, if you will. Again, the Scientific Review Committee, and I'll quote them, "Methyl iodide is a highly toxic chemical which could result in exposures to a large number of the public and thus would have a significant adverse impact on public health." Do you agree with that particular conclusion? And again, they are giving you the facts you're now mitigating.

MS. WARMERDAM: They are giving me the facts as it relates to the scenario put forward by USEPA's label and under that set of facts, I would agree with their conclusions. I have no reason to disbelieve their conclusions based upon the USEPA label. We, however, have moved beyond USEPA's label.

SENATOR FLOREZ: The reports even go so far as to say, and I'll quote, "Adequate control of human exposure would be difficult." And again, what your agency's responsibility at this point in time is to find the appropriate steps to minimize?

MS. WARMERDAM: Correct.

SENATOR FLOREZ: So even though you may read a statement like that, your view is, is it a level that we can mitigate, is that correct?

MS. WARMERDAM: Correct. And so, looking at that, we then have an affirmative obligation to say, What if anything can we do to address that appropriate concern?

SENATOR FLOREZ: And given that, do you believe from your perspective that DPR had enough information to conduct a, again, the most thorough risk assessment available, given this study, given some other things you looked at? Enough data?

MS. WARMERDAM: One can always hope for more data.

SENATOR FLOREZ: And data on the health effects—the material.

MS. WARMERDAM: But I would go so far as to say that we are confident that we have captured all the available data as it relates to this particular material, and based on capturing that data and the peer review addressed toward that data, specifically in some cases, that, yes, we have a sound decision.

SENATOR FLOREZ: And the reason I asked that is that in the Scientific Review Committee's report it says that there was a major lack of critical health effects data which had a significant impact on all of the risk calculations. That was their comment. So I'm just wondering how you view their thought process, that there was just a major lack of critical health effect data to even get us to a reasonable conclusion.

MS. WARMERDAM: I'm not in a position where I would want to second guess their thought process in terms of how they came to that conclusion.

SENATOR FLOREZ: I guess the issue is would you agree with their conclusion even though you may not second guess? I guess I'm asking you to second guess, so let me just keep pushing you.

MS. WARMERDAM: Well, not second guessing them. Again, I go back to what were they working off of? They were working off of USEPA's label. Second guessing them, I believe that the conclusions that they reached are valid, ergo as risk managers we took that into account and developed the more health protective constraints that you see before you.

SENATOR FLOREZ: And even though—you've mentioned that they were at a disadvantage, but this is peer review data, correct? So in other words, they're reviewing peer-to-peer and you would still think that at least in their

questioning of the risk assessment, that it would be something—they were at a disadvantage even though they may have been looking at research?

MS. WARMERDAM: I would view it a little differently. That they view the data, and I'm not a scientist nor am I a peer reviewer so I will speak to it more as a layperson. I would view it as they were looking at the data, and if you'd allow me, in a raw fashion, an unmitigated fashion and I believe, and certainly our own scientists have put that forward, that those conclusions are accurate based in a raw, unmitigated fashion.

SENATOR FLOREZ: And I guess what I'm not understanding—we'll wait to hear from the Scientific Review Panel. But I get, I keep pushing you to second guess and I think you are telling us that they did the best with the data that they had?

MS. WARMERDAM: Yes. I am confident that they did the best they could with the data they had.

SENATOR FLOREZ: And even though they may have said that there isn't enough data here to perform a thorough risk assessment, your risk assessment is, from your vantage point, correct?

MS. WARMERDAM: We had the benefit of looking at not only their work, but EPA's work and other information that was made available to us as risk managers.

SENATOR FLOREZ: Okay. Let's go over two more subjects. And I've kept you're here for almost an hour and almost 15 minutes—an hour and a half plus. Let's go over mitigation. You did go over it pretty thoroughly and I'm not going to go over some of the questions. You've answered some of them. But in terms of the strategies that DPR, yourselves, have imposed or talked about, your sheet seems to say that you have stronger guidelines than the EPA in terms of the application. How would you portray your mitigation factors at this point in time? I mean, you went further.

I want to welcome our Pro tem. Thank you, Senator Steinberg

MS. WARMERDAM: Yes. So they're additive to what USEPA has put forward. I would characterize our mitigation as being the most health

protective, assuming we move forward as they're articulated. They are unquestionably the most health protective in the United States if not in the world as it relates to the use of this material.

SENATOR FLOREZ: Okay. And if indeed that—and I'll take that comment at face value. But why wouldn't the Scientific Review Committee somehow, then, review your review or your proposal for mitigation strategies? I mean, they've given you base—you've now made a judgment on mitigation of the base—if you will, the risk—and the Scientific Review Panel seems to be saying there isn't enough for you to make that assessment, but what do you think they would say given your particular—I'll ask them but I just want to get your take on it.

MS. WARMERDAM: And I would say that we have an affirmative obligation as risk managers, much as all our colleagues do in government, to look at the whole body of information available to us. That includes the science and the risk assessment itself; it includes economic factors; it includes social factors; it includes other data that is made available to us as part of our consideration. We, as risk managers, do not have the luxury of making these decisions in a vacuum. We have an affirmative requirement to be universal in our review.

SENATOR FLOREZ: And I guess the question I would have is how do we know—and let's end it here and let's hear from the Scientific Panel—but how do we know that your mitigations are going to be effective? Who is evaluating your decision if not the scientists and others? I mean, how do we know whether the buffer zones are going to be effective? How do we know that some of the sense of protections and some of the things you've outlined that go further than the EPA are going to be effective?

MS. WARMERDAM: Through our continuous monitoring and reevaluation process we have a protocol in place that give us a high level of confidence that, one, we will get the information we need to assure ourselves that the mitigation is appropriate. And secondly, if the information suggests otherwise, that we have an affirmative obligation to respond to what that

information is telling us and make appropriate adjustments. So we do our own self-evaluation. We are the pesticide managers that are authorized statutorily by *you* to do this work.

MR. REARDON: I was just going to say I might also mention, Mr. Chairman and Assemblymember Monning, that we require the ag commissioners to have an operational plan. As part of that operational planning process, we ask those questions. Particularly, we'll ask those questions anywhere this is going to be applied; sort of the metrics of what is going on in this areas. So they're required as well. It's part of our discussions with the California ag commissioner community.

SENATOR FLOREZ: Okay. Ms. Warmerdam, anything else you'd like to add in closing?

MS. WARMERDAM: I want to thank you, Mr. Monning, and Mr. Steinberg, for your interest in this. We're happy to provide you with information. I do have another commitment that I need to attend to. But I appreciate your interest. We are happy to share with you what we have. And I want to also assure you that we take our responsibilities as pesticide managers very, very seriously. And we do appreciate that everything that we touch has both very real human effects, as well as environmental effects. So thank you.

SENATOR FLOREZ: Thank you for your testimony. Appreciate it.

Let's move on to the Scientific Review Committee. We have the chairman here with us. Thank you, Dr. Froines. Thank you for joining us. And as the chair of the Scientific Review Committee that was convened, as mentioned by DPR, we'd like to get your take on some of the testimony you've heard today. And, obviously, we would like to hear from some of the other members as well, if they could please join us at the table. We'd sure love to have all of you here if possible.

JOHN FROINES, Ph.D.: We had been told that we would be the first to present. We weren't. We've been here sitting coolly in our heels for two hours. I consider that being sandbagged.

SENATOR FLOREZ: Sandbagged?

DR. FROINES: Yes. I don't think it's appropriate under the terms that were negotiated for us to participate in this.

SENATOR FLOREZ: Let me ask you a question.

DR. FROINES: Yeah, sure.

SENATOR FLOREZ: Why would you think that if your chair is still here listening, that we have a running transcript, and you're going to have an opportunity to respond to the department on any inaccuracies they may have made, that would be sandbagging?

DR. FROINES: Because we should have been able to present—we have five people here who are prepared. We were told that we would have fifteen minutes each.

SENATOR FLOREZ: You may have your fifteen minutes each.

DR. FROINES: And that we would be able to present our science, and that hasn't happened. So I don't want to pursue it any further, but it's frustrating.

SENATOR FLOREZ: Well, it shouldn't be frustrating because you have your fifteen minutes. We are going to sit here and listen to the testimony. It is going to be on the record. And, in fact, you have the advantage of now having heard DPR, to somehow tell us what wasn't correct. So I would actually completely disagree with you.

I'm sorry that you had to wait. But no one is leaving this committee. So I would just begin the testimony.

DR. FROINES: Well, we seem to have a problem insofar as the director of DPR is no longer here, so we're not responding to her, which we would have liked to have done.

SENATOR FLOREZ: You are responding to her, because you have now heard her testimony. If you had gone first, you would not have heard her testimony. That's called a response.

DR. FROINES: That's not true.

SENATOR FLOREZ: Go ahead.

DR. FROINES: Okay. The first thing I want to say is in terms of all this, I just want to mention that I was at one point director of the Vermont OSHA Program, so I'm very familiar with these kinds of issues. This isn't a new world for me. So that being said, I wanted to make a few points from her comments.

And the first thing I want to say is it seems to me, and I think everybody here would agree, that if you do not have enough information, if you don't know that a chemical is neurotoxic, if you don't know that it's neurodevelopmental, but all the evidence that you have indicates that it is, then you don't register a chemical when you don't have the necessary information that you need. It's registering a chemical with an enormous vacuum (and all our speakers will talk to that issue), so that the question that came up about "how can you register something when you don't have enough information," and then we repeatedly hear about how the mitigation factors are going to cover everything, that is just simply—it's simply not the case that you should that one should move ahead on a chemical that is so toxic that there's evidence of fatalities, disease, and illness, without knowing the scientific and health information that you need.

I want to say a good news/bad news story. And I don't mean to start off on a tense note because of what I said earlier, and I apologize for that. But I want to say one thing that seems to me to be extremely important; is that this committee does not believe that the mitigation strategies that we've spent two hours talking about are adequate and are going to protect the public. We do not believe the public health is going to be protected by mitigation strategies that were discussed here.

Now let me just tell you one thing. There's this issue that keeps getting brought up about the differences between risk assessment and risk management, and that DPR does risk management and our committee was doing risk assessment. Well, let me tell you something. If you have a farmworker who's not given a respirator, or who has an inadequate respirator, or that respirator is not going to work, or has a higher respiratory rate, or

works a longer day, all those factors are under Mary-Ann Warmerdam's mitigation factors.

The fact of the matter is—but what does that have to do with the risk assessment? Well, what it has to do with the risk assessment is that these workers who have all these so-called risk management characteristics, are going to be breathing higher exposures to the chemical. It's ridiculous to separate the risk assessment and risk management and say that they don't interact with each other. If you aren't being given a respirator, your exposure is going to be a lot higher than these EPA estimates, or the DPR estimates. And that we have to come to terms with the fact that the respirator issue is a risk assessment and a risk management issue and that it needs to be seen within that context. And there's nobody at this table who won't agree with the notion that respirators are inadequate, inappropriate, and inaccessible.

And we were very moved to tears when we heard from farmworkers at our hearing and they told us what the real world is like. The real world is not like what you hear in some labels that somebody promises they're going to adhere to when we're all grownups and we all know whether or not people adhere to those kinds of rules. So I think the fact of the matter is there are hundreds, if not thousands, of farmworkers who are going to be at significant risk from so-called risk management issues when they're not risk management, they're risk assessment and risk management.

And I will promise you that if you want, this group of people will write you a document on mitigation. I'll write you a document on mitigation—assessing their mitigation and assessing their targets and it won't sound like you heard here today.

SENATOR FLOREZ: Let me ask you a question. And we would love that document if you could produce that, because I think it would help us figure out if indeed, whether or not the Legislature wants to—I mean this is a decision from an outgoing administration. I think you heard me say that earlier. But if indeed the Legislature wanted to opine in a different way on the mitigation

strategies, I would not discount legislation *this year* that would actually do this, as you just mentioned.

Let me ask the threshold question. Can it be mitigated? So would you—I know you would take the time to look at their mitigation measures to improve it, but the issue is simply can it be improved? Is this something that can be mitigated at all?

DR. FROINES: Well, let me first say one thing. There are five people of an 8-person committee sitting here and I just promised you that we'll do it. So I'll promise you that I'll do it, and I can promise you that Kathy will do it, but the other guys will have to …

SENATOR FLOREZ: Well, let me put it to you this way: We would appreciate any correspondence, given what you've heard from the Administration, their mitigation measures, and we would certainly take that correspondence and try to figure out a legislative solution to this, in this session, if indeed we can—if we're moving in the direction if the decision is to do this, we would rather have the science folks really give us a much better way, if that's possible, to deal with this (period).

DR. FROINES: Well, let me just say that if nobody else will do it, I'll find some people and we'll do it. And I believe that if you go out into the real world, and I think everybody in this room knows what the real world in the valleys are about, that the mitigation strategies that are promised so articulately by Mary-Ann, are not going to be adequate, because this is without question one of the most toxic chemicals on earth. And that we're dealing with something that a chairman of a department of chemistry would say, You're taking up methyl iodide; are you out of your mind? And so, you've got to keep in mind who's looking at the problem.

So, I'll leave it at that. And if I can go and introduce—go back to where I was. But I really want to emphasize that the mitigation issue is really very, very important and it is fundamentally connected with the exposure assessment, and that's risk assessment.

SENATOR FLOREZ: Before you do that, let me get you on the record if I could. Number one, can this be mitigated? Before you would even venture to see if you would write something like that—maybe from the panel—can it be mitigated is the issue? And then I'd like to get all of your opinions as Dr. Froines introduces you at some point, maybe your introductory sentence to the committee is the following: And that is, is the process that you heard from DPR a moment ago logical? In other words, here's what I heard from a layman's perspective. That scientific panel was supposed to tell us what the risk of this chemical was. My job is to now take your report and mitigate the risk. Do you agree, fundamentally, that that is indeed what is occurring here or there should be one more round of you looking at now their risk assessments and saying whether or not—I mean is this more of a circular deal or do you just pass it over?

DR. FROINES: Let me just say it's her job to do the risk assessment. And given what we have found in terms of the lack of data, in terms of the data itself, she's not ready—*she's not ready* to go to risk mitigation. She doesn't have the information on health and public health risk to go to risk mitigation. She's got to do some science. She's got to find out if neurodevelopmental effects exist, and of course they exist. Nobody in this room, at this table, would doubt that statement. And we could bring in 100 more people who would say that. And so, the notion that we're going to make everything healthy and happy with mitigation—I've been through it at OSHA where you give citations and then you want to see compliance afterwards and it never seems to happen. And so, the reality is, I'm not sure that mitigation is what is necessary in here. And please …

SENATOR FLOREZ: Okay. Why don't we go ahead and introduce each other.

DALE HATTIS, Ph.D.: I just wanted to respond. I'm Dale Hattis. I'm a risk assessor, and I do risk assessment methodology as well. I'll talk to you a little bit later about the potential to do better risk assessment than is conventionally done.

But to your question about "can it be mitigated?" The exposures can be reduced by technical measures. The issue is that the target levels that have been proposed in DPR's latest risk management statement of 8 pages, were over 100-fold less than the target levels that were proposed by their own staff. So that's one of the things that has …

UNIDENTIFIED: Greater.

DR. HATTIS: Yeah. They're less protective. They're higher. So that maybe they have a better chance of reaching those target levels. But the efficacy of reaching the originally proposed target levels that we reviewed, more or less, you know, approved of, although with some serious reservations, that remains to be demonstrated. And one could be quite dubious about reaching those levels on a regular basis. One could also be dubious about how, on the basis of our understanding of what was done with methyl bromide on the efficacy of the—the practical implementation of the mitigation measures, but we'll talk about that in greater detail later.

THEODORE SLOTKIN, Ph.D.: Let me just add one comment on that. Ted Slotkin.

Ms. Warmerdam's characterization that our numbers were somehow not correct because we were using different labeling guidelines is completely incorrect. That had nothing to do with our determinations of what the safety levels would be. That has nothing to do with labeling.

SENATOR FLOREZ: Okay.

DR. FROINES: I've gone through my introduction. I think we've covered that. So I'm going to turn it over to Ed Loechler, from Boston University. And Ed will introduce himself.

ED LOECHLER, Ph.D.: Well, I'd like to begin by thanking the Committee for allowing me to testify today. And I just want to say that I am actually grateful that we got to go after Ms. Warmerdam for the very reason that you said, because I think there are some things that she said that are important to address.

SENATOR FLOREZ: And may I interrupt you for a moment. As you're going through your statement, it would be very helpful, it's just been in the first five minutes, pointing out the inaccuracies for us? because this is our second committee hearing on this. I would not discount a third. So as you kind of move through this, it's okay for you to point out, as you have quite pointedly, errors in discussion points prior to.

DR. FROINES: Let me just say before he starts that I apologize for being grouchy and it won't happen again.

SENATOR FLOREZ: That's okay. We'll keep you here until 9:00 tonight.

DR. LOECHLER: I've saved up a number of my comments in that regard for the end of my statement.

SENATOR FLOREZ: Thank you. Perfect.

DR. LOECHLER: My name is Edward Loechler. And I'm a professor of biology at Boston University. I am the person who provided these PowerPoint slides and I'm going to be referring to them as I move through my testimony.

I teach genetics in molecular biology. For over 25 years my laboratory has studied how chemicals cause mutations in cancer. And during that time, I've been continuously funded by the National Institutes of Health and/or the American Cancer Society. I've been on the editorial boards of scientific journals, chemical research and toxicology, mutation research, and carcinogenesis.

Methyl Iodide is a dangerous compound. It notably causes neurotoxicity and cancer. And I'm amazed that for such a simple compound, methyl iodide is toxic by a surprisingly diverse set of mechanisms, some of which I'll mention, and some of my colleagues will mention others.

In slide number 1, one way that methyl iodide is toxic involves its ability to put a methyl group on almost anything indiscriminately. And a methyl group is just a carbon with three hydrogens—quite simple—but it causes havoc. There's a whole class of compounds that do this. They include methyl nitrosourea, methyl methane sulfonate. And inside cells, these compounds put methyl groups on proteins, RNA, DNA, everything. But putting methyl groups

onto DNA is particularly unfortunate (slide 2) because it causes mutations in cancer. And the mechanism is not a mystery; it's well understood. The crucial site is this oxygen on the base quanine, and I've got a little circle around that methyl group. This modification leads to mutations in cancer because the methyl group causes mistakes when DNA is copied as cells are dividing.

Now the other two compounds I mentioned, methyl nitrosourea, methyl methane sulfonate, are the best studied compounds in this class. They're the easiest to work with. They're both ranked as probable human carcinogens by the International Agency for Research on Cancer.

And though less research has been done on methyl iodide, the work that has been done shows that methyl iodide behaves as expected. It methylates indiscriminately and it puts a methyl group on that same oxygen.

So in slide number 3, is a list of relevant studies and they show the methyl iodide reacts with DNA, causes cells to induce responses that indicate that the cell's DNA are sensing DNA damage. Methyl iodide causes mutations. It causes eukaryotic cells in culture to have properties, like cancer cells, and it causes cancer in experimental animals. Twenty-two of 25 published studies say that methyl iodide was positive in this regard.

The company proposing to market methyl iodide shows that methyl iodide causes thyroid tumors. And this information was the basis for estimating methyl iodide's likely human cancer risk.

Now is there any direct evidence that methyl iodide causes cancer in humans? Well, the answer is no. But of all of this evidence, my best guess is yes. I think undoubtedly methyl iodide will cause cancer in humans.

But how potent is it? Is there some value below which we don't have to worry very much?

So I'm going to leave the cancer question behind for a minute and I'm going to address instead, what DPR has proposed, and they have a target value, which is 96 parts per billion for workers.

I think this value is much too high. And I want to say that I believe those in DPR suggesting this value is good enough. They're acting honorably.

And I think this is merely an honest disagreement. But I want to tell you why I disagree with 96 parts per billion.

Now before I go through this, we've talked about these different groups within DPR and I just want to make it clear on what the arrangement is. So in slide number 4, over to the left here, there's DPR's risk assessment group. That's the medical toxicology branch. And they're the group that we interacted with, indicated by the vertical arrow. And they produced a report. They passed it on to DPR's risk management group who made the decision. So that's the structure.

And I'm going to contrast DPR's risk assessment evaluation, this is slide number 5, there on the left here, with DPR's risk management decision and that's on the right here.

And the risk assessment document, this is part of it. It's 500 pages long. The document on the right is 8 pages long—the risk management decision is 8 pages long. Now these risk assessments are based on—the primary one that's discussed; is fetal death caused by methyl iodide treatment of pregnant rabbits? And so, no rabbit fetuses died when pregnant rabbits were exposed to 2 parts per million methyl iodide. But fetuses did die at higher levels of methyl iodide. And later on I'm going to tell you it's more complicated than that but let's keep it simple for now, okay. So 2 parts per million is called the "no observed effect level," or "NOEL," like the Christmas song.

So I want to move on to the sixth slide which mentions this 2 part per million at the top. And again, I want to contrast risk assessment on the left with risk management on the right. Risk management started with 2 parts per million and ended up with a human worker exposure of 96 parts per billion. That's on the right. Risk assessment within DPR started off with the same 2 parts per million and ended up with 0.8 parts per billion. So it's 120 times smaller.

Now, I understand risk assessments evaluation, and so, I want to go through it as quickly as I can here.

So the first transformation is in slide number 7, and it has to do with differences between rabbits and humans. They breed at different rates, different exposure times, and there is a safety factor that is built in. And that gets us down to 230 parts per billion. That gets us from 2 parts per million to 230 parts per billion.

Now in slide number 8, I want to start off by telling a short story. So certain molds grow on improperly stored peanuts and other food stuffs. These molds make a compound called aflatoxin which causes liver cancer. And this is a problem, as I say in my testimony, and in many parts of the world.

So toxicologists wanted to study how does aflatoxin cause liver cancer? So they gave mice aflatoxin and they got no cancer. So then they gave aflatoxin to rats, and rats get lots of cancer. And the difference in susceptibility of rats and mice is huge. It's greater than 100-fold. And this is called an interspecies difference in susceptibility and it's often observed.

So by analogy, humans might be more susceptible than rabbits to methyl iodide fetal death. So DPR's risk assessment group added what's called an interspecies uncertainty factor of 3-fold just in case, to be prudent. And this is universally done. And this standard is described in the USEPA's integrated risk information system, so there's no mystery here about doing this. It's always done.

So here's another story. Many toxic substances inside our bodies are inactivated by a number of proteins, including one called glutathione S-transferase, a big name. It doesn't matter. About 25 percent of humans don't have glutathione S-transferase theta, which is the version of the enzyme that works on methyl iodide. Some humans don't even have it. Will they be more susceptible to methyl iodide toxicity? I don't know. It hasn't been studied. But they might be. Plus there are a myriad of other ways that subsets of humans can be more sensitive to methyl iodide. So to be prudent, another safety factor of 10-fold is added. And so, that is what I described in slide number 9.

Now I want to go to the actual data on fetal death in rabbits. It's in table 34A, a portion of which I have in slide number 10 here.

So this is the data for either death or late resorption of fetuses. With no methyl iodide, 2 percent of the fetuses are lost. That's right here. With 2 parts per million, 5 percent of fetuses are lost; 10 parts per million is 17 percent; and 20 parts per million is 31 percent. They're the numbers that I have boxed there.

Now I have taken that data and I plotted it down here. Here's a plot of parts per million. Here's a plot percent fetuses lost. Remember we said that 2 parts per million is the NOEL, the no observed effect level. And you'll notice that it's actually above the point with no methyl iodide. How could you call that a NOEL? And the answer is that 5 percent is bigger than 2 percent but it's not statistically significant. You can't prove that it's really different statistically. But the data looked very suspicious.

Now let's keep another thing in mind here. We're talking about fetal death, which is a gross indicator of toxicity. We don't know what's causing fetal death in rabbits. Let's just imagine that it's causing disruption of the endocrine system, the system that makes hormones. The endocrine system is undoubtedly really fouled up if it's causing fetal death. It's very likely that rabbits exposed to a level just below that level are not probably perfectly okay. The endocrine system is still being disrupted and this disruption is still probably causing subtler effects; it's just not killing the fetus. So because of these kinds of factors, the uncertainty in the NOEL, plus the gross indicator of fetal death, it's important to add another uncertainty factor of 10-fold and that's how we ultimately get to the value of .8 parts per billion, is through those four steps.

Now I want to add that some of my colleagues are going to tell you why this value is even too high.

Now I've discussed fetal death because it's what's mentioned by DPR in their decision to register. But there are a myriad of other adverse health effects

that methyl iodide causes and they are shown in table 14. And I've put boxes around all those that are significantly below the level proposed by DPR now.

There's one in particular that I want to mention, which is the general public hazard from cancer risk which is .04 parts per billion. Now having just one toxic endpoint I think is a reason for concern. But having so many toxic endpoints all in the same range of concentration represents a big red flag to me as far as I'm concerned. One of them is going to turn out to be a huge hazard to these people who are working or living in the vicinity of methyl iodide.

Now I've read through the decision to register document and there's no explanation offered for why these uncertainty factors can be ignored, why a value 120 times higher is offered. Why is that unnecessary? I have no idea. I can't evaluate it. There's no information there.

But I want to go through another puzzle which starts with a sentence which I won't read all of. It's here in slide 15. But it talks about principles used by the USEPA and this puzzles me. So for fetal death the USEPA used 10 parts per million as their NOEL—that's off to the left here—and DPR used 2 parts per million, a difference of 5-fold. So the USEPA ended up with a value of a standard of 193 parts per billion. Well if they used the same principles as the USEPA, you would expect that the value that they proposed would be fives times less, or about 40 parts per billion—which is down here in slide 17—but they don't. They're proposing 96—2.5-fold higher. How come? I don't know. But their verbiage—and if you read through the verbiage on page 5 in their document, it sounds like they're being very protective and they're doing all the things that I just went through. But the actual number that they end up with doesn't match the verbiage.

Now I just want to step out of my role as a scientific advisor and just make a personal statement. At one of the hearings, we heard from 100 farmworkers (about 40 testified). I couldn't help but think that if I were a worker walking into the field what principles would I hope would be applied. I would want a level of methyl iodide I'd be comfortable with, and that is not 96 parts per billion.

I think I've talked long enough. I do have some specific responses to some of the comments made earlier, but I think in the interest of my colleagues, I'll defer those comments until possibly a later time.

SENATOR FLOREZ: Okay. I'd like to hear your responses—a few of them now, and then we'll go around. You might save some folks some responses at the end, is what I'm saying.

DR. LOECHLER: Well, to begin with, I heard the comment that we didn't have the benefit of being risk managers, and then I heard the statement that, "of course, I'm just a layperson here." And I wonder in a scientific matter having to do with health hazards, what possible advantage is it to be a layperson in evaluating these health risks? What is the benefit of being a layperson as a risk manager in trying to evaluate the scientific basis of health hazards? I'm totally baffled by that particular statement.

We heard about the need to include economic and social issues, something like that. And I don't know. This is just my feeling, you know. It seemed like we were being offered two alternatives; use methyl iodide and jeopardize the health of workers and their families; use methyl bromide and deplete the ozone. The third possibility is you don't use methyl iodide or methyl bromide and you make strawberries a little more expensive. And I don't know, but when you're left with these kinds of serious issues, *serious issues* depleting the ozone, hurting workers and people who live in the fields nearby by adopting a standard that makes no sense whatsoever, that third option begins to sound like not unreasonable. Let's just charge a little bit more for strawberries. If people understood, I think they might consider that.

Well, I do think I've gone on too long, so let me defer.

SENATOR FLOREZ: Well, thank you. Thank you for traveling here. Okay.

DR. LOECHLER: I want to thank Senator Florez and the other Members of the Committee for enabling me to fly across country and take the "red-eye" back.

SENATOR FLOREZ: Thank you, Dr. Loechler, for coming.

THEODORE SLOTKIN, Ph.D.: My name is Theodore Slotkin. I have a Ph.D. degree in Pharmacology and Toxicology from the University of Rochester School of Medicine. And I've been on the faculty at Duke University Medical Center for over 40 years. I hold full professorships in the Department of Pharmacology and Cancer Biology, in the Department of Psychiatry and Behavioral Sciences and the Department of Neurobiology. And I'm the director of Graduate Studies for the Integrated Toxicology and Environmental Health Program. I sit on the editorial boards of four scholarly journals, including *Environmental Health Perspectives*, which is published by the National Institutes of Health, and is the topped ranked environmental health journal in the world. I've authored over 500 peer reviewed scientific articles. I'm among the top 5 percent of NIH grant recipients over the past 25 years. I'm ranked as one of the top one percent cited scientists in pharmacology and toxicology.

On this review panel I was asked to review the effects of methyl iodide as they relate to three specific areas in which I have expertise. And it's going to be easier because I don't have to give you numbers because I'm going to point out that the data is just lacking for these important areas.

- Neurotoxicity, which is toxicity directed towards the structure and function of the brain.
- Developmental toxicity, which means the enhanced sensitivity of the fetus and young child to toxic chemicals.
- And the combination of those two; developmental neurotoxicity, which is the special vulnerability of the developing brain to toxic insult. The sorts of things that lead, ultimately, to neurobehavioral deficits, attention deficit, autism spectrum disorders, lowered IQ, all of the things that I'm sure you're aware of.

Because the details of my conclusions are in the report, I'm just going to focus on the essential meaning of those conclusions and skip the details. And I'll deal with them in sequence.

First, there's absolutely no question that methyl iodide is neurotoxic. If you look at the material safety data sheets that are provided by companies that manufacture methyl iodide, or the HAZMAT listing provided by the National Library of Medicine, it says, "Central nervous system is the target organ." It points out the emergence of, quote, "Chronic neurologic symptoms that do not become manifest until days or weeks after exposure."

The case studies of people after methyl iodide poisoning all indicate lasting neurological damage, including severe psychiatric symptoms and movement disorders that resemble Parkinson's disease.

Laboratory studies similarly show clear cut neurotoxicity and they've identified the specific parts of the brain, types of cells that are targeted. And on top of that, methyl iodide concentrates in the brain. So if you do safety assessments that are based on blood levels, or inhalation levels, the brain is actually experiencing a much higher exposure than you would expect from any of the standard kinds of measurements.

So what I'd like to do is to address the issue of the fact of the "neurotoxicity" studies that were used by DPR and provided by Arysta were nothing of the sort. They were not neurotoxicity studies and they were totally inadequate to provide a launching pad for even beginning to calculate safety factors.

The exposure paradigm that was reported to DPR by Arysta and used in their assessment was limited to a single episode of exposure. And the behavioral tests were conducted during and immediately after exposure with a single assessment, very crude assessment, to structural changes two weeks later.

Let me give you an analogy. Suppose I wanted to study whether chronic alcoholism damages your brain and your behavior, and I think that we all know that it does, and I'm going to do that by getting you drunk once, measuring how long it takes you to sleep it off, and asking you two weeks later if you feel okay. I think I would conclude that, "Hey, alcohol, no problem." That's the kind of study that this was. That is not a neurotoxicity study.

Beyond that, this basic design defect, the techniques that they used came out of a paper that's 25 years out of date. No one in developmental neurotoxicity or neurotoxicity would use these techniques. They're insensitive. They're inadequate. The company they hired to do this provided background data of supposedly positive control studies that they did and they used a vicious neurotoxin—trimethyl 10. Most of the animals they couldn't detect anything. They had a higher rate of false negatives than ones where they could actually detect anything. To give you an idea of the inadequacy of the launching pad for even beginning to use a number and calculating a mitigation factor based on it.

Based on these kinds of studies and this approach, you would also conclude that lead, mercury, organophosphate insecticides and alcohol are not neurotoxic.

In the absence of a chronic exposure model and a properly conducted neurotoxicity study, there is no way to establish a no adverse effect level for the neurotoxicity of methyl iodide. And it's certainly going to be much, much lower than that which was postulated from the study that was provided.

Number 2, developmental toxicity: Well, here the most sensitive endpoint was fetal death. And, you know, it's already been pointed out, fetal death is the crudest endpoint you can imagine. So short of fetal death there's going to be all kinds of other stuff happening.

I'm not going to go into more detail as to what was wrong with the studies that were provided; they were based on the supposition that fetal death had to do with effects of methyl iodide on thyroid function.

You have my written comments. That's just wrong. Arysta's own studies showed that that was the wrong assumption. I had to point that out to them during the hearings. They seemed confused by it. They made an excuse that methyl iodide was more thyroid toxic than sodium iodide, the supposed negative control, and I pulled the data out during the hearings and showed them that they were identical. They were supposed to get back to me about it and never did.

The conclusion is, it's fetal toxic at levels much lower than that that are toxic to the adult. We don't know why. It's clear that using fetal death as an endpoint is ridiculously overestimating where the levels should be. And we have no way of knowing where the levels should be because we don't know the physiological changes that are contributing to the death and that are undoubtedly happening at much, much lower levels.

So now I'm going to combine the two—neurotoxicity and developmental toxicity. We have developmental neurotoxicity for which no studies have been done whatsoever. Federal regulations do not mandate a developmental neurotoxicity test or DNT, as it's called, unless there is a compelling reason for one. I don't understand the reasoning that would lead to a conclusion that methyl iodide does not require a DNT. It's neurotoxic, certainly. It's developmentally toxic, certainly. And let's add the third thing in, it's an endocrine disrupter. I mean, everybody's data, Arysta's data, it disrupts thyroid function. I think you know all about endocrine disruption and development than environmental concerns for the human population. But you know, there's a special relationship between thyroid function during development and development of the brain. If you're severely hypothyroid, you wind up with mental retardation; that's cretinism. But we now know that that's not an all or none phenomena. It's not like severe hypothyroid—cretinism/normal thyroid you're okay. So there's a spectrum.

And there's a lot of studies now. It's a hot issue, the developmental neurotoxin. That cryptic hypothyroidism, where there are no symptoms, but it's still not quite normal is sufficient to cause damage that culminates in lowered IQ, affective disorders, learning disorders and the like.

So if you were to go up to the thousands of scientists who study developmental neurotoxicity and tell them, "I've got a new compound that I want to expose people to. It's neurotoxic. It's developmentally toxic. And it's an endocrine disrupter. Do you think that we should do a developmental neurotoxicity study?" I'll give you really long odds, better than the odds to win the basketball championship, that every one of those scientists would tell you

this compound is going to be a developmental neurotoxin and they would be right. And no data on it. So how do you mitigate? How do you set a calculation?

And finally, I also want to express a personal opinion and that's separate from the scientific things I've said. I'm not an environmental activist and I've never before participated in a governmental review of pesticide safety. I'm not in blanket opposition to the use of pesticides. But methyl iodide alarms me and it does so for a specific reason. That everything that I see recapitulates the history of the organophosphate insecticides.

The organophosphates came into use in the 1960s to replace the persistent organochlorines, like DDT, because of environmental concerns. They were originally considered safe. They could be mitigated safely. And, because the symptoms of poisoning were unmistakable and could be monitored easily by measuring blood levels of an enzyme, cholinesterase, everyone was very comfortable about using them.

Beginning in the 1980s, about 20 years later, it started to become evident that the immature organism, the fetus and the newborn, was far more sensitive to organophosphates with a difference in the threshold for lethality of a factor of 10 to 100. Sound familiar?

In the subsequent decade, it was shown that this difference did not reflect cholinesterase inhibition, the mechanism that everyone was supposing was responsible for the toxicity—these compounds. And, in fact, my own research group was involved in showing that the developing brain got screwed up by levels of exposure 100 to 1,000-fold lower than what anyone thought based on what we knew about organophosphate insecticides.

Based on almost entirely on laboratory studies, not human epidemiology or poisoning incidents, this led the USEPA to ban the use of some of the most common organophosphates from use in the home starting in 2000—40 years later. But the damage had already been done, especially because human exposure to organophosphates was virtually ubiquitous; it represented more than half of the insecticide use in the world.

A number of research groups, then, began examining populations with higher than average exposures; inner city tenement dwellers in New York (where I grew up), agricultural workers and their families in California, and children living in agricultural communities also largely in California. What they found was exactly what was predicted from the laboratory work; impaired IQ directly related to the measured organophosphate exposure of the mother during pregnancy, increased rates of depression and suicide correlated with organophosphate use by farmers, and finally, in a report from just a few weeks ago, a 60 percent increase in the risk of ADHD (attention deficit hyperactivity disorder) from exposure of the general population to organophosphates, not the high exposure of—that's everybody. So the information about organophosphates was actually there much earlier—neurotoxic, developmentally toxic, developmentally neurotoxic. And yet, we failed to protect the general public from the consequence of their household use up until 2000, and we continue to use them in agriculture.

I think we're all aware that there is an unprecedented rise in the incidence of neurodevelopmental disorders, including learning disabilities, conduct disorders, autism spectrum disorders, and ADHD. It is increasingly clear to many scientists and other people in the regulatory sphere that exposures to neurotoxic chemicals in our environment contribute in a major way to this silent pandemic which costs us hundreds of billions of dollars each year and which compromises the quality of life of millions of children.

The USEPA estimates that one of every four production chemicals is likely to be neurotoxic, most of which never undergo testing for that effect, let alone for developmental neurotoxicity. So when we come across a compound that is known to be neurotoxic as well as developmentally toxic, an endocrine disrupter, it would seem prudent to err on the side of caution, demanding that the appropriate scientific testing be done in animals instead of going ahead and putting it into use, in which case the test animals will be the children of the state of California. For a volatile agent like methyl iodide, there is no blowout preventer that will protect workers or people living in adjacent communities

from the consequences of an accident, a shift in the wind, misapplication, or even simply repeated standard applications with inappropriate mitigation factors that don't mitigate anything.

I do not want to see the story of organophosphates repeated with methyl iodide, where 20 or 30 years from now we'll see a further deterioration and even higher incidences of neurodevelopmental disorders. I would not want you to be in the situation where you say to yourself, "I could have prevented that." Prevent it.

Thank you.

SENATOR FLOREZ: Thank you very much. Thank you for traveling out here.

May I ask you what you may have heard in the prior testimony that stuck out in your mind as egregious and worthy of correction as we …

DR. SLOTKIN: Well, I noticed that the whole idea of developmental neurotoxicity never came up. And there's a flaw in logic here. If developmental toxicity is the most sensitive endpoint, if neurotoxicity is the most commonly observed phenomenon from human poisonings and is supported by laboratory studies, if the USEPA failed to ask for a DNT, for a developmental neurotoxicity test, why should we propagate that error?

And it seems specious to me to even begin to try to calculate something that will mitigate and make something safe when you have no idea whether no adverse effect level is, except the certainty that it's much lower than anything that we've already looked at.

SENATOR FLOREZ: Thank you very much.

DR. FROINES: Question for you. Dr. Ronald Melnick sent you a letter and I was going to read it for this hearing, but I just wanted to ask you is you're having it and reading it sufficient or would you like me to read his letter here? I'm just worried about—concerned about time. It's whatever you would prefer.

SENATOR FLOREZ: Why don't we introduce it into the record and make it part of the transcript. And just so you know what I'm going to do, in all

fairness, is I'm going to ask the sergeant to bifurcate the hearing at the end of this and I would like this particular testimony to go to the transcriber. And I'm going to ask our trusty staff to, then, take exactly what you found egregious—we'll find exactly where the endpoints are and then we're going to draft a letter from us, our office, and Mr. Monning is welcome to join in on that, and we're going to ask for a specific formal response in writing to everything that you've just mentioned. But we're going to have to get the transcript, at least of this section, earlier. Sergeant, if we could make sure that we get that to transcript and back so we can get something out by the end of the week. So this will be part of this. So we'll have to …

DR. FROINES: The letter is very powerful. It has the same kind of flavor and power that the previous two speakers have had. So I'd recommend that you give it close attention because Ron Melnick was with the International Agency for Research on Cancer for many years and is probably one of the most knowledgeable people when it comes to carcinogenesis that there is in the world. And so, it would be a shame not to have his testimony.

SENATOR FLOREZ: We absolutely will include it.

DR. FROINES: So I believe that our next speaker is Katherine Hammond from UC Berkeley.

KATHERINE HAMMOND, Ph.D.: Thank you, Senator, for giving me the opportunity to present a scientific perspective on this debate.

I am Katherine Hammond, a professor of Environmental Health Sciences at the School of Public Health, University of California, Berkeley. I've served as chair of the Environmental Health Sciences Division and led the Industrial Hygiene Program. I hold a Bachelor's and a Ph.D. in chemistry from Overland College and Brandeis University, and a Master of Science from Harvard in Environmental Health Sciences where I learned industrial hygiene, a broad field which focuses on the recognition, evaluation, and control of chemical and physical agents which may harm workers' health.

My research over the past 30 years has focused on the assessment of people's exposure to potentially toxic chemicals, both in the workplace and the

in the environment. I've published over 130 articles in the peer-reviewed scientific literature, a dozen book chapters, and dozens of publications. I have served on numerous committees for the National Research Council and the Institute of Medicine, both part of the National Academy of Sciences, the National Cancer Institute, the World Health Organization, and both the U.S. and California Environmental Protection Agencies.

First, I'd like to say a few words about risk assessment, of course, which I teach at UC Berkeley. Risk assessment integrates several scientific fields but has two major strands. The first includes both toxicology and epidemiology and evaluates what adverse health effects a chemical might cause and the potency of that chemical in causing those adverse health effects. So how much of that chemical is needed to cause those effects? These data are used to set a target concentration to stay below. We could call that a risk assessment speed limit, right? That's what you've heard from my previous colleagues about that piece of it.

The second strand evaluates how much of this chemical are people exposed to; whether they're workers or community members, including children and pregnant women. Although I work with both strands, my expertise particularize in the second strand—evaluating the factors that might affect people's exposures and estimating the exposures that diverse people under different scenarios have when they use the chemical.

The California Department of Pesticide Regulation, DPR, published several documents in their risk assessment: Volume 1, Human Health Risk Assessment, corresponds to the first strand of risk assessment, adverse health effects caused in people and animals, and has already been discussed by my colleagues; Volume 2, Exposure Assessment, addressed the second strand, and I will focus my remarks on that part.

There are several problems with the risk assessment. DPR presented its estimates of people's exposure to methyl iodide in the Volume 2. In this document, DPR seriously underestimates the exposures of people in the various scenarios. I will discuss three aspects of this underestimate; there are

others. The three I will discuss are breathing rate, the length of the workday, and protection from respirators.

A major factor in the amount of a chemical that a person takes into his or her body is the breathing rate—how much air one breathes in each hour. The more air you breathe in, the more chemical comes along for the ride and enters your body. You may have noticed that when you walk fast or run, you breathe more deeply and rapidly. In fact, the amount of air you breathe in can increase ten times from resting to running. DPR used the 24-hour average breathing rate. That is the average, including sleeping time, and so estimated that workers breathe in 0.8 cubic meters of air in an hour. However, the occupational health community typically uses a higher value—1.2 cubic meters in an hour at work unless heavy work is performed, in which case even higher rates are used. In this risk assessment, OSHA has used 1.2 cubic meters an hour. In its dose reconstruction, the National Institute for Occupational Safety and Health, NIOSH, assume that a workgroup performs light work—light work—breathes 1.2 cubic meters in an hour while an adult who performs heavy work breathes 1.7 cubic meters in an hour, and heavy work is really saying just one-eighth of the time they're doing heavy work. This is more than twice the amount of air that DPR estimates.

The International Commission on Radiological Protection, ICRP, an expert group for estimating human doses to radiation, uses what they term "the currently accepted breathing rate of 1.2 cubic meters per hour." I don't mean to confuse you with throwing a lot of numbers out—and there are a lot—however, the bottom line is that occupational health scientists, whether they're at OSHA, NIOSH, ICRP, academic community, all of these use breathing rates that are 1.5 to 2 times higher than the rates that were used by DPR in estimating how much of the chemical is going to come into people's bodies, so this leads to an error…

SENATOR FLOREZ: We're pondering why DPR used the lower breathing rate.

DR. HAMMOND: Well …

SENATOR FLOREZ: I don't want to interrupt your …

DR. HAMMOND: Well, let me just say, I brought this to their attention.

SENATOR FLOREZ: Okay.

DR. HAMMOND: I thought that they might have seen the light and was disappointed that they didn't.

SENATOR FLOREZ: All right.

DR. HAMMOND: But it's not that it wasn't brought to their attention.

SENATOR FLOREZ: It's not that it wasn't brought to their attention.

DR. HAMMOND: Correct. I saw that as my duty as a member of the Science Review Committee. That was our job.

SENATOR FLOREZ: Okay.

DR. HAMMOND: So this factor alone leads to an underestimate by a factor of 1.5 to 2, so the true exposure is 1.5 to 2 times higher just for that one factor. The underestimate for the breathing rates for children is similarly problematic, and the California Air Resources Board, a sister agency, both under Cal/EPA to DPR, sponsored a study of breathing rates in the community. They actually measured the breathing rates of children and adults as they performed various activities. Compared to when standing, the breathing rate for children more than doubled when they walked and increased more than fourfold when they ran. However, when calculating the exposure of children near fields while methyl iodide was being used, DPR assumes the breathing rate equal to the rate found for standing. If they do walk around or play, they will be exposed to several times more methyl iodide than DPR assumes in its calculations. I guess we can't have children be inspired by the World Cup and start playing soccer.

A second major area where DPR underestimates worker exposure is the evaluation of the workday. DPR assumes that agricultural workers work eight hours a day, but we all know that agricultural workers often work longer. The Science Review Committee raised this issue, and DPR revised the final document to acknowledge the issue but did not change this assumption.

I'm going to quote from the document:

"DPR also believes that under specific conditions and situations, single-day durations for worker activities can and do exceed eight hours. For example, a survey of crop advisors indicated that an average workday could be as high as 9.16, plus or minus, one hour per day. DPR is currently examining the appropriateness of basing exposure estimates on an eight-hour workday. Should the department determine that a longer workday is warranted for certain activities, that will be taken into account when considering potential mitigation measures if methyl iodide is registered in California. It was assumed that all workers would be exposed to a full eight-hour workday." (End of quote ??)

It is not clear to me that DPR in fact took the longer workday into account when considering mitigation measures. I do not see where that appears in the notice of proposed decisions to register the pesticide products containing methyl iodide. If a workday is ten hours long, the workers may be exposed to 25 percent more toxic material than an eight-hour workday. A 12-hour workday would lead to a 50 percent increase in exposure. Neglecting these facts of field life can lead to an underestimation of the true exposure of these workers.

Next, I'd like to turn to respirators. The respirators were used—I'd like to say the respirators were incorporated into the exposure document. The exposures were estimated with the assumption of respirator use. So to that degree, they're not mitigation strategy. They're inherent in the exposure estimates.

Respirators should be used as a last resort to protect workers from toxic chemicals because there are so many things to go wrong with them. Murphy's Law and its many corollaries could have been inspired by respirators. There are problems even with a very good respirator protection program, which is quite complex and involves daily cleaning, proper storage, replacement of air purifying cartridges, daily or, more often, medical evaluation of employees prior to wearing respirators, fit testing, etc. It goes on and on. They're pages and

pages long. The medical evaluation's required because the use of respirators, these half-face respirators, puts additional strain on the heart and lungs.

Fit testing is critical. Individual factors that can prevent a good seal—the seal is the source of it. It's the critical piece. Anything that can affect that good seal and therefore prevent the respirator from working properly will mean that you don't have the protection, and these factors include facial hair, as was mentioned earlier, pimples, dimples, bug bites, a variety of things; sweat will degrade the seal.

One of the best ways to understand the challenges respirators pose to workers is to wear one for 15 minutes while walking around and trying to perform some tasks. I did consider bringing some for you to try this experiment. They're uncomfortable, and you can't talk while wearing them, a real problem for us academics and politicians, right? You can't eat; you can't drink; you can't smoke while you're wearing your respirator. They're uncomfortable and it gets worse the longer you wear it. And every minute you take the respirator off to talk, to drink, whatever, adds additional exposure. If one removes the respirator for 53 minutes in an eight-hour day and it otherwise worked perfectly, the protection factor is cut in half.

The American Thoracic Society reviewed respirators in a 13-page document from which I quote:

"Worker compliance with wearing required respirators has been studied on the basis of direct observation of the amount of time of appropriate use. These studies show that acceptability to workers is a significant factor limiting the ability of respirators to provide protection against inhalation hazards. In the workplace, the discomfort of the device is probably the factor most frequently limiting effective respirator use. Respirators fitting tightly over the face, cause a buildup of moist, warm air inside the mask. In a warm environment, such as we have in the fields, this enclosure also slows convection of heat away from the face, the normal cooling process of evaporation from the skin. The wearer's sensory discomfort rises in proportion to the temperature within the mask—the discomfort of respirator's elastic head

straps in obtaining a sufficiently tight facial seal, pressure on the face, the perception of aspiratory resistance, the feeling of being enclosed, and the effects on vision may all contribute to functional inability to keep the respirator on for more than brief periods of time in some persons. This inability at times is associated with panic attacks and claustrophobia." (End of quote ??)

All of these factors—the discomfort of wearing respirators, the detrimental effect of sweat on the seal, the inability to talk, eat, or drink or smoke while wearing a respirator—contribute to the frequent nonuse of respirators for portions of the workday. As described above, less than one hour of nonuse cuts in half the protection factor of the respirator, reducing it from, for this respirator, from ten to five. That's for just less than one hour.

Published papers in the scientific literature urged the use of protection factors of five or less for half-faced respirators. Industrial hygienists from both industry and academia are rightfully skeptical of higher protection factors, given their observations of usage in the field.

So I've outlined here three aspects of methyl iodide exposure to workers and children which lead to serious underestimates of the exposure. These effects are multiplicative. Thus the inhalation rate for children should be at least two to four times higher if they're playing outdoors; the inhalation rate for workers should be increased by at least a factor of 1.5; the length of the workday should be increased by an appropriate amount, perhaps 25 percent to account for ten-hour workdays; and the protection factor for respirators should be decreased to five or less.

Implementation of these aspects would increase the estimated dose in the DPR documents of methyl iodide to children and to workers by factors of 2:4. This is a very serious increase and exposure to a very toxic chemical.

Returning to the two strands of risk assessment, which I opened with, the first determining how potent a chemical is, how much it takes to cause cancer or neurological harm or affect a fetus, and the second, estimating how much people are exposed, the decision of DPR to regulate methyl iodide rests on flawed science in both of these areas, and I'm talking flawed science. The

exposures are higher than DPR estimates, in my opinion. The potency is underestimated. So the value of the target concentration which we aim to stay below is too high. My colleagues have described how, for some health effects—for example, developmental neurotoxicity—the studies are either poorly designed or even nonexistent, so the potency cannot be evaluated. Furthermore, the accepted rules for accounting for uncertainty in developing animal to data to humans or estimating effects in the fetus were followed on the risk assessment documents by DPR in February in 2009 and February 2010 but were not followed in the notice to register.

In the end, the scientists at DPR made estimates of target levels of methyl iodide available to the public and to the Science Review Committee for comment in 2009 and incorporated many, if not all, of these comments in the final February 2010 Human Health Risk document. Many scientists felt these values still underestimated the health risks posed by methyl iodide. However, these peer reviewed speed-limit values, not to be exceeded, were ignored by the risk managers who developed their own numbers without review by either the public or the Science Review Committee. These target maximum values are over a hundred times higher than those developed by DPR's own scientists and that have undergone extensive peer review. Such presumption is not merely an insult to the scientist who contributed to the risk assessment documents but also represents a threat to the health of the men, women, children, and children to be of California. Thank you.

May I make a couple of personal statements back to your comments? So in the question of mitigation—see, I actually do see there is a difference between the risk assessment and mitigation. In a risk assessment world, we do our best to understand what are the exposures, how potent is this chemical, and we set a target level. In many cases, if we have enough data, we might set what think is the safe level. You'll notice that no one really calls this a safe level. Even the numbers that are here, they're target concentrations to stay below. We don't know the safe level.

That's scientific decision. I understand there are economic decisions and other things that need to enter, and I'm not an economist. I wouldn't pretend to be one or present that information, but I would like to have the science respected for what it is. I think that when they take all these considerations together, they need to use the science as the scientists have come up with it. Distorting the science is not a way, is not a mitigation method, is basically what I would say.

DR. FROINES: I think, just to go back to what I said in the beginning, that the committee is very skeptical about the mitigation issue, and I think Kathy clearly demonstrated that, to be quite so candid, about this is all going to work perfectly is just really not accurate. Again, I would say, that if we can help further on mitigation, we'll be happy to …

DR. HAMMOND: And may I say on that line—sorry—but I agree. But one can evaluate the proposed mitigation strategies scientifically. That can be done and that can be the science piece that we contribute, so there is a role for science within that. So we can say this works or doesn't work or they've demonstrated this will cut it by 10 percent or 50 percent or 100 percent or whatever. So I think that's the role that I would see that we could do. In the end, deciding what's economically the best thing for the state is not my decision.

DR. FROINES: Well, I think that you just did something I didn't know I would get out of you, which is, you said you would help on this. And so, if she helps, we can do it. (Laughter)

Dale?

DR. HATTIS: Yeah. In the interest of time, I'm going to cut my remarks short. I've already prepared, had a prepared statement—I think you probably have it—and I'm going to start sort of in the middle and I'm going to focus—lots of my colleagues have focused on technical issues primarily, and I'm going to focus a little bit more on the interface between science and the risk management determinations because I think that's kind of a partly missing piece here.

There are two basic perversions in our field, and one is that technical folks in our arrogance want to make the decisions and the decision makers want to change the facts and/or, even more commonly, say that, avoid responsibility for their choices by saying "the scientists made me do it."

One of the things I think you need to consider is whether, in fact, the legal framework that you legislators have established helps keep the functions, as appropriately separate as they are. Now there has to be some juncture because the scientists have to know from the policymakers what's important, okay? What kind of numbers to produce, what kind of numbers are relevant to the decision, and then they have to do their level best to produce the numbers in as fair and thorough a way as possible, okay? So I think that's what the system, you know, needs working on.

One of the things that I did in preparing for this discussion is to look a little bit into the official legislative mandates at both FIFRA and those that have been modified somewhat for California decision making. I must be saying this as I am speaking, this is my legal understanding, imperfect as it is, speaking as a geneticist and should be accorded all the gravitas that that designation carries with it, the official—the national level, the applicable law calls for a balancing of health risks and economic benefits and a judgment that the risks of registration of a particular pesticide will not be unreasonable, all things considered. According to materials on the EPA website, the Federal Insecticide Fungicide (and Rodenticide) Act, provides for federal registration and pesticide distribution, sale and use—all pesticide distributed or sold have to be licensed. And if used according to label specifications, they will not generally cause unreasonable, adverse effects on the environment.

Now that's got, as you will recognize, a couple of little weasel words that means that it doesn't necessarily guarantee absolute safety, at least in this official standard, and it defines unreasonable effects on the environment to mean any unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of any pesticide or, two, a human dietary risk that results.

I'm not, as I said, an expert in California law either, even though I have some experience with the legislation. But in a letter to—I did find a letter to the California legislature from Paul Hellicker who's director of DPR on January 13, 2003, where he says: California law does not require consideration of economic benefits, and DPR does not register products with unmitigated, significant, adverse effects, no matter the benefit. California law provides a clear mandate to assure that pesticide use the state posted as little risk as possible to the public, farmworkers, and the state's environment. The basic decision rule is simple. DPR may approve a pesticide registration application and, if already registered, allow continued use. If it is convinced that the pesticide can be used safely, assuming the product is applied according to label directions and in accordance with any additional permitting requirements DPR might implement under given circumstances. Now some of that language is unfortunate, in my view, and this is now, again, my view as a citizen and does not represent the views of the committee necessarily.

One of the sources of difficulty in that language that cause concern in our technical analyses, in our review of the exposure analyses in particular—as has already been alluded to by Kathy—is the phrase, "assuming the product is applied according to label directions and in accordance with any additional permitting requirements."

We were consistently trying to push back and say, you ought to be assessing risks as to actually likely to be used with, no, rather than, you know, assuming that this tenfold safety factor, protection factor is going to happen because in fact, even in industrial settings, this is not routinely achieved. We know, you know, that by measurements of things like lead, which we've studied, you know, that you get a couple of fold factor from the use of registration of these respirators, but you don't get tenfold, even though the equipment is theoretically capable of producing the tenfold as measured in laboratory settings. But if you are a risk assessor, it seems to me you ought to be bound to register, to estimate the exposures and the risks according to what's actually likely to happen, not what the theoretical label requirements

say, okay? Because I think you ought to have—you know, policymakers should be making judgments based upon what the actual benefits and harms are likely to happen rather than have this stricture. And the exposure folks within DPR—this is distinguished from the health effects. The health effects folks were very responsive to what we asked them to do. They've changed several things. But the exposure assessors felt boxed in by this language, so that's something you should think about, either in law or in policy, as to whether that ought to be maintained. So I'm going to close by saying that there's a couple of other avenues for improvement that I think would improve the policymaker's information.

Another is the practice of only expressing the expected cancer risk in terms of conservatively calculated individual risks of harm at the maximal exposure levels. People get an unrealistic sense of what the likely total—basically by saying that the DPR folks said, you know, you're going to get something like eight times, ten to the minus fifth for these most exposed individuals in a neighborhood community or something like that and the official Prop. 65 standard is one time, so that's too much, according to that. But by only expressing things in this individual risk format, you miss the larger effect on the community as a whole. And the fact of the matter is, that as the material drifts downwind, you expose more people to less on average and get less risk. But the aggregate amount of, population aggregate tends to still go up as the wind carries it downwind.

It's, I think, at least some interest to calculate, Okay, how much is the total amount of exposure and total amount of expected cancer cases that I should anticipate, given not conservative assumptions, but central estimate assumptions, for the mean risks, taking into account all the individual differences that cause some people to be more susceptible, etc? So any of this kind of calculation would, I think, provide additional, potentially helpful information about what the total cost in health terms of the use of the material might be, and that could be juxtaposed in some sense with the other

consequences, the benefits as well as the other, what other adverse consequences there might be.

Now you might well ask, you know, Doesn't that set a precedent? You know, every time we build a highway, we increase particles, emissions. So it may not be just confined to carcinogenic pesticides, but maybe we should be asking our assessors, when they do their environmental impact statement, to try to focus not just on individual risk numbers, which can be judged either immediately tolerable or immediately not tolerable, but what is the overall community burden that's being imposed by this measure?

Finally what I want to suggest is that, in considering the array of mitigation measures that are rightly part of the risk management choice, we still need to have some kind of analysis. How practically would they change the exposures? Why do I stop at these measures or, you know, can they be usefully expanded or are they just too burdensome in their current framework? What we need in fact is not necessarily a risk analysis but a comparison of the effects of policy options, which might be called a policy analysis, and this is equally subject to technical analysis. It's a proper for the managers to frame the options, okay? What are the range of options that is really feasible for me to implement? And I think that they should have factors in there that represent the likely practical implementation of the options, given some plan for enforcement resources, you know, that are realistic and that they provide for because, otherwise there's no incentive for the policymaker. They could write whatever they want in the federal register or the official label. And then, if there's no penalty to proposing regulations that can't be enforced or won't be enforced in practice, then they get off scot-free for promising the world and still satisfying all the constituencies that they want to satisfy.

I think that it's better to have a system whereby they analyze the policy in an open way and disclose the burdens and the benefits and costs or other measures of pain essentially for alternative policies.

DR. FROINES: Do you think that this is an issue that is relevant to the legislature insofar as they can help improve on this problem?

DR. HATTIS: I think so, because in fact, if you have a statute that, on its face, calls for balancing, then I think you ought to really do a balancing and you should enable the decision makers to face the choices in which there's going to be some bad effects, right? Because you in fact won't prevent—I think this is part of the process of maturing in a society—that we face bad consequences. I think that we want to do the very best we can with our available resources to achieve good health outcomes and we want to, when we can't achieve, you know, zero risk—and that's the case often—we want to be able to acknowledge that it's part of consent of the govern to…

DR. FROINES: Could you write a short, one- or two-page document for Senator Florez that sort of outlines the …

SENATOR FLOREZ: Yeah, on the legal—I think what you're saying, that we ought to create some boundaries in which decisions are made, and the best way to do that is so that they're not caught, as you said, already with some conclusion that there's no way out. I think that's what I heard you say.

DR. HATTIS: Right. I think you want to make it feasible for them to acknowledge that their choices are not perfect and yet to have the benefit of some technical analysis. I basically had served on the National Academy Sciences Committee that has articulated ways of assessing the costs and benefits of new air pollution regulations. So many of the issues, in terms of framing the range of options that you consider, came up in that context, and I'll try to make a suitable extraction of rules from that …

SENATOR FLOREZ: That would be wonderful.

DR. HATTIS: In addition to a shorter …

DR. FROINES: That would be very helpful because clearly the question—a question—that deserves clear attention is, How do we look at policy issues within the context of everything going on as opposed to a kind of rigid regulatory framework which really doesn't work in the long run in some respects?

DR. HATTIS: The Hellicker statement says that we're going to be safe and we're not going to register it if it's not safe. Well, the ability to follow that

is questionable, and so the possibility exists that people do their own little back-of-the-envelope calculation out of everybody's sight and try to make a choice on that basis.

SENATOR FLOREZ: Assemblymember Monning.

ASSEMBLYMEMBER MONNING: Thank you, Senator.

I know the hour is late. I first want to start by just thanking all members of this panel for your presence, your work on this, your patience before your testimony today. The aggregate of your testimony, without exception, is that the risk in management or mitigation assessments that have now been provided to us fall short of drilling down to the level of the risk assessment in that there's a gap in the science applied to the mitigation versus the science applied to the so-called risk assessment in this bifurcation.

What I've heard from all of you is that we can't ultimately bifurcate when we're concerned about human health and environmental integrity. I'm glad that Dr. Slotkin raised the issue of the history with organophosphates. And just a short story—I'll keep it short—but in my past life as an attorney working, representing hundreds, literally, hundreds of farmworkers who were the victims of pesticide exposure, predominantly organophosphates, mostly fieldworkers, but also applicators, some fired for not using protocols of respirators, of closed systems that failed, being told to dump excess chemicals in the Salinas riverbed—the stories go on and on.

But the one that I recall is that of Mariana Florez. Her mother was taken into a field with a crew of about 35 workers, and it was an error. A mistake was made, and they were exposed to metasistox-R and some other chemicals. Metasistox-R went through this registration process, registered by the federal EPA, registered by the State of California. And after this expectant mother, who did not know she was pregnant at the time of the exposure, went through the full gestation, Mariana Florez was born with heart malformation and anencephaly, hip displacement, cleft palate, and died ten days after birth. And when her father came to my office the day of her birth with tears running down his face and asked what they could do—the wife and child had been flown to

San Francisco from Salinas. They'd never been in an airplane. What we did was arrange a car ride for him to be with his wife and the daughter before she died ten days later. Since that exposure, metasistox-R was taken off the market as unsafe at any speed.

So my concern when I look at this is to prevent the next Mariana Florez, not after the fact but before another family or families face that tragedy. And so what I appreciate about this panel's testimony is acknowledging the gap between preferred protocols and respirators that work perfectly in parts per million that never go above that safety threshold that sounds like it's imprecise at best in its calculation and the gap between that science and what happens in the fields in the state of California and in rural communities.

And so what I would appreciate and what I've heard offered in your continued commitment to this issue, beyond the commissioning of the peer review report that you prepared, would be some commentary supplementing or just reinforcing what you shared today in analyzing the proposed mitigations and how would you buttress those with science or what is the science lacking. I mean, that's what I've heard you say today.

So I think, as we move forward, one of our challengers as legislators is that we ultimately don't have—this is an oversight hearing; it's not a legislative hearing. We're not reviewing proposed legislation. We're looking at the work of a body that works independently of they don't have to put their findings before the legislature for approval. We have the right for oversight. We can't tell them to pull back that provisional approval. We can speak out on it. We can look at prospective tightening of regulations.

This isn't the first time pesticides have come before these bodies. We've worked to get field posting. We've worked to get material data safety sheets. We've passed the Birth Defect Prevention Act. But these are also laws on paper, just as label warnings are prescribed practices that anticipate no wind, no torn tarps, no respirators that get taken off. And so what we need to do is provide a reality check. How in the practice of the application of these

chemicals informed by the past and informed by past tragedies do we protect the health and safety of not just farmworkers but of rural residents?

So, again, Mr. Chair, thank you for affording me the opportunity. I really appreciate what I hear as a commitment to our shared interest, which is the health and safety of Californians, and that you're here today because you're willing to work with us going these next steps, so thank you very much.

DR. FROINES: Can I just say one thing about that, what you said? I never in my life thought that I would be hearing the testimony of perhaps 20, 30, 40 farmworkers. And as they testified, I burst into tears. I had never felt what I was feeling at that moment and you realize the severity of the conditions that they operate under. And so that, you know, we haven't thought about the issues of mitigation, and what we need to do, I think, is stay in contact with Senator Florez. We should work among ourselves and see what we think we can do, not promising that we are necessarily perfect, but to do the best we can to help you on the mitigation issue.

I think that it really needs to be done because, what's being said is somewhat too optimistic. Let me just be euphemistic about that. I was going to summarize the findings and I'm quite willing to do that, unless you think the time is growing late, because what I'm going to say is what's been said already, so whatever you prefer.

SENATOR FLOREZ: We'd always prefer that what's been said already be stated on the record. But let me ask you for a moment to hear a little bit of what Assemblymember Monning just mentioned and what I'm going to say, and then I'd like to get your reaction as we close, and then we'd like to then take this hearing and I would call it a recess until we have another opportunity to get back with DPR based on the transcript's comments.

DR. FROINES: Senator …

SENATOR FLOREZ: Yes.

DR. FROINES: Can I read one part?

SENATOR FLOREZ: You absolutely can. No, absolutely. Go ahead.

DR. FROINES: What I want to read is what was in the record and represents case examples of methyl iodide poisoning:

"One worker exposed to methyl iodide resumed work after three months. He vomited, was drowsy after his first day. In the hospital he manifested drowsiness, inability to walk, slurred and incoherent speech, abnormal eye movement, twitching upper limbs, and spastic lower limbs. Two weeks later, he continued vomiting, restlessness, and incontinence were reported. The patient became comatose and died several days later.

"Another individual working with methyl iodide experienced blurred vision, manifested unsteady gait after inhalation exposure to methyl iodide. Follow-up examination performed five months later showed normal gross neurological function but cognitively residual paranoia and confusion.

"Another worker complained of drowsiness and vertigo and was found to lack coordination. Four years after the last episode of exposure, clinical tests showed a slight deficit of short-term visual memory and increased left conduction time in lower-limb evoke response testing.

"Additionally, Hermit summarized the results of several reports of overexposure by two chemists and three workers. The symptoms were vertigo, drowsiness, headache, lack of coordination, double vision, and/or weakness."

So those are examples of real people, but I think it reinforces what Ted Slotkin testified to, because there is no question about the neurotoxicity when you hear stories like this.

DR. SLOTKIN: And there are laboratory studies that back that up too. But let me just add again, that the neurotoxicities were provided to DPR by the manufacturer found no evidence of neurotoxicity, which leads me to believe that they were simply incompetent.

DR. FROINES: And this shows—the thing that's important about this is this shows chronic, irreversible changes over long periods of time. This isn't a one-shot deal. And so one needs to think about what's going to happen over—exposure over 10, 20, 30, 40 years of exposure.

SENATOR FLOREZ: Okay. Well, look, I, number one, appreciate all of the comments. We'd like you to do a little more work for us, if possible, and I think, as Assemblymember Monning just mentioned, let's go over through kind of the work product of today's hearing, if we could.

The first big picture, it's pretty clear to us that the science behind this proposed methyl iodide approval is in question, if not seriously flawed. So to just summarize all of the comments made here, that in my mind is very clear.

Secondly, this is an oversight hearing, as Assemblymember Monning said. But the oversight hearing, at least from the Senate side—and I hope Assemblymember Monning will take this on the Assembly side—leads to a conclusion that the Budget Committee should be very wary of continued funding of departments that aren't forthcoming and don't have the requisite wherewithal to bring us a solution that will actually work for workers. And so let me say that we look forward to having one more discussion in Budget Committee with our colleagues over at CDPR to go through one more round of discussion on this, because let me just put it to you very frankly. If we were to just take what DPR said on its face, that it can be mitigated, that this absolutely, the protections in this particular case are there, here's a question we should all have, and that is, Where's the money? Where's the money for increased enforcement? Where's the money for OSHA and others to be out in the fields? Who is going to take the sticks that were mentioned earlier and make them effective? Who's going to make sure, even if it is possible to do this, that it's actually being enforced? And I think the best comment today, obviously, was the fact that, at some point, people need to talk to each other out in the field. So I imagine they will take a mask off to communicate something and that doubling of exposure over eight hours or, as we get past eight hours and into other hours is very troubling to us.

So we're going to really ask the governor to take the extra, extra step here, and I hope the Governor's Office is listening because we would like to the governor to reconvene this panel of experts to once again review the current proposal by DPR to give us exactly what you've given us today, and that will

take, you know—although Mary-Ann Warmerdam has laid out a plan, I think it is still—she still works for the governor of the state of California. And ultimately, when an administration makes a decision, it is the governor of the state of California that is making that decision. So we will ask by letter to the governor to allow a full airing of this particular proposal, out for experts, out for peer review, because it is that important decision. It's that important that we just cannot, in essence, implement and try to figure out whether our mitigation measures are going to work. We have to first integrate, as you've mentioned, the science with now the mitigation measures as proposed to see if they actually are workable.

It's also pretty clear to us that we need a more transparent review. A lot of stuff has surfaced here. In this latter portion, I do appreciate you pointing out some things that DPR failed to mentioned, which is about 90 percent of your testimony, and so we will now take the latter part of the transcript. I think you'll see that we will completely take your comments and questions and thought-provoking science and try to formulate a letter that actually gets to the point, and we will ask for a formal, written response back from the department—written—as though they were sitting right across from you at a hearing—in other words, sitting with you, not after you, not before you, but sitting with you. So we would ask you then to review that response.

So let's see if we can continue to move forward on this.

Very wary of implementation of this particular program. There's no doubt. And I doubt that the legislature—and I really think the legislature should intervene in this type of a decision that is so life changing for many of the farmworkers and communities out there because, at the end of the day—and it's no slight to Mary-Ann Warmerdam or others in the department, but we are the elected officials who are elected by our constituents to make these type of decisions, and we put our offices on the line when we make wrong decisions. Outgoing administrations don't have that type of, if you will, pressure point. And so we need that type of pressure point to make sure people understand the

decision that we are making and that we're held accountable to that. So we're a very big believer in doing that, but we've got to now formulate the letter.

We need you to look at their recommendations and we'll correspond with you on this.

I very much appreciate the legal suggestion that we work on the bans of decision making so that there's some sort of balance in this, and we will definitely want to work on that as well.

So I think this has been a very productive eye-opening, sobering presentation by the panel. And I just want you to know that we will now take this dynamic testimony and now try to make something of it in terms of action, because I think that's the name of the game is to not just say the hearing is adjourned. You know, you'll all call each other three weeks from now and say Whatever happened to the hearing? So just know we have some work product that we, the committee, will produce and we will get to you for comment. And we have some work to do. I know Assemblymember Monning has probably ten more ideas than I do here, at least in his house, than I do here in the Senate. But let us now get to work.

And I do appreciate your testimony. I do appreciate your flying all the way out here. And, you know, if the Red Eye is too late, stay the night. You know, at least you have a fresh start in the morning.

I would like to thank the Chair very much for convening everyone and giving us a very cogent, you know, response. So we will recess this committee and then we will come back and we will try to figure out the rest of the pieces on this. So thank you very much.

DR. FROINES: May I say one thing?

SENATOR FLOREZ: Of course, absolutely.

DR. FROINES: I just want to thank you because we wrote an 87-page report and we put enormous effort into it, and at one point it seemed like everything we had done had come to nothing. And so your support and willingness to continue is just inspiring for me and for everybody else, I think. So you don't know how terrific this is for this committee.

SENATOR FLOREZ: Well, I appreciate that. And I can tell you we very much know how you feel when we send legislation to the governor and he doesn't sign it. (Laughter) So we very much feel, you know, within that process you work so hard on an issue and you do your absolute best to make some very positive changes. Sometimes you see that fall-on-the-wayside due to, in many cases, politics other issues. You've mentioned it all earlier today. There is a—I think the key word that says what's lacking here is a policy analysis, as well another layer of whether or not this is just good policy, after all is said and done, and I think that's something that we have to work on at the next level for us.

I appreciate your coming out here. And we will recess this committee.

I want to thank Assemblymember Monning for being here. We look forward to having him here again.

And, obviously, we just appreciate everyone out there coming as well.

Written comments will be taken on the record to our email address for the committee, and I'm going to—who wants to volunteer to—John? Okay. So you want to state for the record where they can email any written comments at the end of this?

DR. FROINES: You should realize that Dale's getting a lot of credit. He's a biochemist geneticist and he's getting credit for policy. (Laughter)

SENATOR FLOREZ: Well, thank you. That's a good thing.

John, you want to …

MR. JOHN CHANDLER: You can send it to the committee at John Chandler, John.Chandler@sen.ca.gov, and that's John, J-o-h-n.

SENATOR FLOREZ: Okay. Thank you, John. And then we will make sure that's part of the record and we'll include that. Any emails that we get, we'll include them as part of the record.

DR. FROINES: Thank you very much.

SENATOR FLOREZ: Thank you all. We very much appreciate it. Thank you.

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