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Transcript of Meeting of
Pesticide Program Dialogue Committee
Georgetown University Conference Center
3800 Reservoir Road, N.W.
The Leavey Center, Main Floor, Salon H
Washington, D.C.
October 20-21, 2005
Day 1

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ATTENDANCE LIST

1
2 Jim Jones Director, Office of Pesticide
3 Programs, OPPTS, Chairperson
4 Margie Fehrenbach Designated Federal Officer, OPP
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6 Lori A. Berger Ph.D., Director of Technical
7 Affairs, California Minor Crops
8 Council
9 Robert Rosenberg Director, Government Affairs,
10 National Pest Management
11 Association, Inc.
12 Bill Tracy National Cotton Council of
13 America
14 Rebeckah Freedman Adcock Director, Congressional
15 Relations, American Farm Bureau
16 Federation
17 Dr. Steve Balling Director, Agricultural Services
18 Del Monte Foods

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1 Carolyn Brickey Executive Director, Protected
2 Harvest

3 Erik Olsen Senior Attorney, Natural
4 Resources Defense Council

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6 ATTENDANCE LIST (cont'd)

7 Michael Fry Director of Pesticides and Birds
8 Program, American Bird
9 Conservancy

10 Amy Liebman Environmental Health Consultant,
11 Migrant Clinician Network

12 Troy Seidle Director, Science Policy, People
13 for the Ethical Treatment of
14 Animals

15 N. Beth Carroll, Ph.D. Senior Stewardship Manager,
16 Syngenta Crop Protection

17 Allen James President, Responsible Industry
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1 Stephen Kellner Senior Vice President and
2 General Counsel, Consumer
3 Specialty Products Association
4 Dr. Hasmukh Shah Managing Director, American
5 (Day 2 only) Chemistry Council
6 Julie Spagnoli Executive Director, Regulatory
7 Affairs, Clorox Services Company
8 Jay Vroom President & CEO,
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10 **ATTENDANCE LIST (cont'd)**

11 Gary Libman Vice President, Regulatory
12 Affairs and Quality Assurance,
13 Emerald BioAgriculture
14 Corporation
15 Alan Lockwood, M.D. Chair, Environment Committee,
16 Physicians for Social
17 Responsibility
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1 Pediatrics, Medical University
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3 Dr. Nancy Lewis Associate Professor, Department
4 of Nutrition and Health Science,
5 University of Nebraska
6 Mary Ellen Setting Assistant Secretary, Office of
7 Plant Industries & Pest
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10 Dr. Jose Amador Director, Agricultural Research
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ATTENDANCE LIST (cont'd)

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Larry Elworth Executive Director, Center for
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1	Patrick Quinn	Principal, The Accord Group
2	John D. Schell, Ph.D.	Vice President/Toxicologist,
3		BBL Sciences
4	Dr. Terry Troxell	Director, Office of Plant and
5		Dairy Foods, CFSAN, FDA
6	Allen Jennings	Director, Office of Pest
7		Management, USDA
8	Dr. Melody Kawamoto	National Institute for
9		Occupational Safety and Health,
10		Centers for Disease Control &
11		Prevention
12	Jennifer Sass	(Portion of Day 1)
13	John Kepner	Beyond Pesticides
14	Frank Gasparini	(Day 2)
15	Maureen Serafine	New York
16	Nancy Golden	
17	Craig Thomson	EPA, Region VII
18		

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P R O C E E D I N G S

DAY ONE - OCTOBER 20, 2005

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Brief Opening Remarks were made by Jim Jones followed by a presentation on Registration Review. The transcript begins during the presentation by Susan Lewis and Jay Ellenberger.

MS. LEWIS: -- we can get valuable input during that comment period. We hope to have a final rule issued next summer, Summer of 2006, and then we'll begin implementation in the Fall of 2006.

Next. I also wanted to post our website. After the rule was issued, we developed a relatively extensive home page website for registration review and I'll leave you with the web address. There's a fair amount of information and there are links to the schedule and the rule -- proposed rule itself.

Thank you. Any questions?

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1 MR. JONES: Before going into the registration
2 and reregistration, I think it will be useful to have a
3 little bit of discussion here. I do want to thank all of
4 you who have participated on this workgroup. One of the
5 things I failed to mention in my opening remarks is we've
6 tried, in the last year, to have more workgroups and then
7 giving us more focused time and attention in between the
8 meetings. One of the frustrations I've had is that some
9 of the issues we deal with are so complicated, you really
10 can't give informed advice in a 30-minute or a 50-minute
11 session twice a year, and so, we've been relying more on
12 workgroups. This workgroup's been incredibly effective,
13 I believe, in both spending the time, the energy and the
14 effort to give informed advice and has given us very good
15 advice and that advice has, frankly, underlined the
16 proposed rule, and will continue to, I expect, help us
17 make choices about how we implement.

18 But I'd like to open it up on this topic before

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1 we move on to the registration and reregistration
2 presentations.

3 Julie?

4 MS. SPAGNOLI: Just one question, you know, with
5 the scheduling, and I know we had a lot of discussion and
6 debate, but if they're going to do it by classes, are you
7 still -- there's still going to be individual decision
8 documents issued. Are those -- so, they're not going to
9 all -- you're not going to wait to issue all the decision
10 documents for the whole class at one time or, I guess,
11 just looking at that scheduling, that was a question that
12 it kind of raised for me. If you're going to do it by
13 classes, then does a decision for the entire class get
14 made all at once or for each individual chemical?
15 Because we were going to be looking at all the individual
16 end use products as well.

17 MS. LEWIS: I think the initial concept is the
18 decision ultimately will have to be on an individual

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1 active ingredient basis, as we're doing it today. There
2 may be times when there is no issue and you may be able
3 to make independent decisions because there may be a two
4 or three-year window if the class is large enough. There
5 may be other times, depending on whatever the technical
6 issue is, that, to resolve it, it all gets done at one
7 time. So, I think it's really going to depend on the
8 class.

9 MS. SPAGNOLI: If an issue for a class is an
10 environment effect, then a product that only has indoor
11 uses --

12 MS. LEWIS: Yeah.

13 MS. SPAGNOLI: -- may be not -- it may just fall
14 out right away?

15 MS. LEWIS: Yes.

16 MR. JONES: Okay, thanks, Susan and Jay.

17 Okay, Debbie Edwards, the Director of the
18 Special Review and Reregistration Division is going to

1 give us a tolerance reassessment and reregistration
2 update now.

3 MS. EDWARDS: Thank you. This presentation is,
4 obviously, in your packet and it's got a lot of numbers
5 and chemical names and so forth, so I'll be going through
6 it relatively quickly. But it's for your reference.

7 First slide there, just to start out, what I
8 want to do today is tell you what we accomplished in FY
9 2005, which ended on September 30th, and what we intend
10 to do during FY 2006. In FY 2005, you can see here the
11 program -- this is for the entire program, not just the
12 Special Review and Reregistration Division, but it's
13 Office of Pesticide Programs, so this includes
14 biochemical, biological pesticides and antimicrobials.
15 We did 41 decisions, of which 28 were reregistration
16 eligibility decisions and 13 were tolerance reassessment
17 eligibility decisions.

18 We reassessed a total of 722 tolerances, of

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1 which 167 were inert ingredients and 555 were active
2 ingredients.

3 There are a couple slides here just showing the
4 REDs that were completed. Like I said, there were 28 of
5 them. You can see on this slide one that probably would
6 draw your attention. 2,4-D is obviously a very big
7 chemical to have completed this year.

8 Next slide. These are the rest of the REDs that
9 we completed this past year, and there you will see that
10 all of the EBDCs have been completed. So, that was a
11 pretty big accomplishment as well.

12 Next slide. This is the list of the 13, I
13 believe -- I think that's right -- TREDs, tolerance
14 reassessment eligibility decisions. Probably the biggest
15 ticket item there is Cyhexatin. That's an Organo-10
16 that's now been closed out and essentially all the
17 tolerances, except for one import, has been revoked.

18 Next slide. This is the slide that we show you

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1 each time. The pie chart on the left shows you that we
2 have completed 271 of the REDs. We have 110 REDs yet to
3 go, but that includes -- that's not just for FY '06, that
4 does include the '07 and '08 REDs that we will need to do
5 for non-food uses, as well as the IREDs that will convert
6 to REDs once we complete our cumulative assessments.

7 The bar graph there, you can see how we're
8 moving along in our progress. The Government Performance
9 and Results Act goal this year was 7,838 tolerances and
10 we completed 7,817. So, we were very close on that goal.
11 In terms of the overall goal, which is 9,721 tolerances,
12 we're currently at 7,817.

13 Next slide. This just shows -- this is just a
14 bar chart showing what we have done by year since 1996.
15 You can see that 2002 was a very big year at 2,600 and
16 some tolerances reassessed that year. That was the
17 second and third goal. The last bar on the right is
18 actually what we need to do this year. So, this year, we

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1 need to reassess 1,904 tolerances. That's actually the
2 2006 goal, and you see it's not as big as what we had to
3 do back in 2002.

4 The next slide just shows the progression over
5 the years. This is the same information presented a
6 variety of ways, but it shows us moving toward that goal
7 of 9,721 tolerances reassessed.

8 Next slide. This, again, we give you each time.
9 It's our progress toward completion of tolerance
10 reassessments for the organophosphate pesticides, the
11 carbamates, organochlorines, carcinogens and high hazard
12 inerts. You can see there that in FY 2006, we still need
13 to complete 544 organophosphates, 228 carbamates. These
14 include, though, tolerances that were nearly reassessed
15 when we did the IREDs. So, once we're done with the
16 cumulatives, those will be done.

17 And then carcinogens, 478 with other being 654.
18 So, that's kind of the breakdown for this year of what we

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1 need to get reassessed.

2 Moving into, again, the goals for FY 2006 or
3 actually the plan for 2006. As I said, we have 1,904 to
4 be reassessed. This is the breakdown of what those
5 tolerances are. 286 of those are inert ingredients, 52
6 are antimicrobial active ingredients, 5 are biopesticide
7 active ingredients, 38 will actually -- we've already
8 determined are simply revocations, and the remaining
9 1,523 are conventional active ingredient pesticides.
10 But, again, if you look down there at the bottom, 528 of
11 those -- of that 1,523 are associated with complete
12 IREDS.

13 Okay, next slide. The bottom part of this slide
14 we pretty much already covered, but there at the top it
15 says overview of our plan for this year. We will be
16 doing 66 decision, 49 REDs and 17 TREDs.

17 Next slide. These are some highlights. I'm not
18 going to give you every single chemical that we're going

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1 to be doing next year of those 66, but these are some
2 highlights that you might be interested in of the FY '06
3 plan. You can see there we're doing organic arsenicals,
4 copper compounds, ethylene oxide, methyl bromide,
5 permethrin, pyrethrins, piperonyl butoxide and MGK-264,
6 pentachloronitrobenzene, and the triazoles, triadimefon,
7 triadimenol and propiconazole. But this is actually
8 bigger than that because it will include the free
9 triazole assessment, which encompasses a number of other
10 chemicals that have been registered since 1984. So,
11 that's a very big and important assessment. We expect
12 that public comment period to open early in the calendar
13 year, probably late January, mid to late January.

14 Next slide. We have four remaining cumulatives
15 to complete this year. They are the organophosphates,
16 the N-Methyl carbamates, the chloroacetanilides and the
17 triazines. You can see here -- oh, go back -- the
18 remaining organophosphates we have to do are DDVP,

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1 dimethoate and malathion. The N-Methyl carbamates,
2 obviously, are aldicarb, carbofuran, formetanate HCl.

3 Next slide. The remaining chloroacetanilide is
4 acetochlor. The triazines are simazine and propazine.

5 For antimicrobial decisions that are -- I would
6 highlight here, these are the three wood preservatives,
7 CCA, coal tar/creosote, pentachlorophenol. They will
8 also be doing, by the way, all the quaternary ammonium
9 compounds and chlorine dioxide, which are also pretty
10 high profile antimicrobial chemicals.

11 Next slide. What we're going to do very shortly
12 is put up new schedules and the new schedule that we keep
13 up there for the revolving -- it's a revolving six-month
14 schedule around public comment periods opening. So, that
15 should come up in the next few weeks. So, be looking for
16 that. Thank you.

17 MR. JONES: Any questions for Debbie? Carolyn?

18 MS. BRICKEY: There's a lot of big ticket

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1 chemicals on that list. Are you going to be giving us,
2 in the future, more of a qualitative review of what
3 you're doing with all these chemicals? I mean, pick out
4 some that you think are important, because it all just
5 sort of spins in your head when you look at this.

6 MS. EDWARDS: Jim?

7 MR. JONES: We have not used in at least six
8 years the PPDC as the forum to get into chemical-specific
9 or cumulative-related issues associated with tolerance
10 reassessment. That had fallen under the purview of the
11 CARAT now. It's certainly something that we can have
12 some discussion around, the extent to which there may be
13 the desire for using -- the committee, itself, doesn't
14 seem like the logical place. Perhaps a subcommittee to
15 look at a few. I'm certainly open to what your needs are
16 around that.

17 We have -- the process that we, of course, have
18 been using is the CARAT-informed process, which is the

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1 six-phase public participation process. Many of the
2 chemicals that I think are making your head spin have a
3 six-step process where there are two specific
4 opportunities for public participation. But I'd be open
5 to getting some feedback from this group as to is there
6 anything above and beyond that that you, this committee,
7 would like to have, and then, of course, I've got to
8 think about it and talk to my management about the
9 intersection between this committee and the CARAT around
10 an issue that has historically been the purview of the
11 CARAT.

12 MS. BRICKEY: Right. Well, it's not so much
13 that I think there aren't adequate opportunities for
14 public comment on each one. It's just that there's so --
15 there's implications for so many of these as a group and
16 I just would like to get a better handle on understanding
17 that, I guess.

18 MR. JONES: Okay, okay. We'll do some thinking

1 around that and perhaps we can get some further insights
2 into how we might do that.

3 Larry?

4 MR. ELWORTH: Well, you raised the issue that
5 it's not something we need to discuss in this meeting,
6 but when was the last CARAT meeting? It was like --

7 MS. EDWARDS: Probably two years ago.

8 MR. ELWORTH: Was it two years ago? Several
9 years ago. It's fine with me if this is addressed in
10 CARAT. If it's not going to be -- if we're not actually
11 going to have a CARAT meeting, if there's a way to come
12 back to your management and say, there's significant
13 interest in stakeholders, this is an existing forum,
14 we've avoided doing this up to this point because there's
15 another advisory committee established.

16 MR. JONES: Right.

17 MR. ELWORTH: But I think that kind of
18 discussion is real helpful, and if it doesn't swamp the

1 entire agenda for this meeting, that would be really good
2 to do.

3 MR. JONES: Well, help me with the "it" there.
4 For example, the chemicals in '06, probably of the ones
5 we listed there -- help me out, Debbie, I'm going to
6 guess -- half of them already are -- the risk assessments
7 are in the public domain. Maybe even more.

8 MS. EDWARDS: Yeah.

9 MR. JONES: So, I need a little help with the
10 "it" about what exactly -- because, you know, having us
11 give you sort of the functional equivalent of technical
12 briefings for some subset, I'm not sure that's it. So,
13 think about that. I definitely want to understand what
14 would make it useful for all of you. I'm very open to
15 the idea. I just want to make sure we do something
16 that's useful.

17 MR. ELWORTH: Right, right, that's a good point.
18 I think from the point of view of this committee -- and

1 it kind of goes back to what Carolyn was saying -- what
2 would be interesting to me, and I won't speak for
3 everybody else, is for you to, perhaps, go through an
4 example that illustrates some of the issues you're
5 running into in evaluating these chemicals. And I don't
6 know which one it should be, but that's very instructive.
7 We have -- it's the kind of thing we went into in detail
8 in CARAT that I don't think we need to do in terms of
9 process here.

10 But having an opportunity to look at the kind of
11 issues you folks are running into, whether it's about the
12 bromide or the pyrethrins or some of the -- or the
13 triazoles, whichever it is, that would be very
14 interesting to us because it illustrates some of the
15 policies that you're dealing with. That's where it would
16 be interesting to me.

17 MR. JONES: Okay.

18 MR. ELWORTH: But that would be germane to this

1 committee.

2 MR. JONES: Okay, Jay?

3 MR. VROOM: I guess I would agree with Carolyn's
4 observation that looking at this can make your head spin,
5 but I would say that from an entirely different
6 perspective, in sort of a wow, what great progress. You
7 know, not that you're necessarily just going to be able
8 to fall down and cross the finish line and meet the
9 deadlines for August 3, 2006, but I think you've got
10 tremendous momentum. And absent, you know, great advice
11 from the CARAT for the last two years, apparently you've
12 been able to work without the interference of too much
13 advice. But I think it represents a lot of good
14 progress.

15 Jim, I'm curious. I remember one of the things
16 that was a concern about sort of the distance between
17 whenever and 2003 August -- 2006, August 3 deadline was
18 the potential for relocating the offices physically of

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1 OPP. Where are you at on that or is that something you
2 want to defer to Marty to tell us about?

3 MR. JONES: We fought mightily to not move
4 before August 3rd and we did not succeed in that respect.
5 We did succeed, however, in ensuring that the move will
6 occur in one fine week in May, as opposed to over a five-
7 month period, which was the original schedule.

8 UNIDENTIFIED FEMALE: (Inaudible) PPDC meeting.

9 MR. JONES: Okay. Well, maybe that's what it
10 will have to be because we don't want to be back moving
11 our -- so, for a week in May, right, Marty? May?

12 MS. MONELL: The first week of May.

13 MR. JONES: We will be moving about -- a little
14 less than three-quarters of a mile down by the old
15 Crystal Station I. It looks like it's going to be a
16 beautiful building.

17 UNIDENTIFIED MALE: Don't get FEMA to help.

18 UNIDENTIFIED MALE: I've got a couple extra

1 trailers for you.

2 (Laughter.)

3 UNIDENTIFIED FEMALE: I was just curious to a
4 comment you made. You said the CARAT six-step process.
5 Whatever happened to the abbreviated process that was
6 presented to us?

7 MR. JONES: We actually put out a Federal
8 Register notice that described not only the six-phase
9 public participation process, but when and under what
10 situations we would use an abbreviated one, which would
11 include a four-phase process or even for some low-risk
12 compounds, a one-phase process. All of the chemicals
13 that Debbie walked through on her website -- on our
14 website, it tells you which of these phases, whether
15 we're going with the low-risk one or the four-phase,
16 which is a one public participation, or the six-phase,
17 and it has the intended schedule for all of them. So, it
18 is being used for chemicals that we think warrant it.

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1 But that being said, if we're in a four-phase
2 process, and during the public participation process we
3 realize, oh, stakeholders think there's a really big
4 issue here, we'll amend it to a six-phase.

5 Allen? I'm sorry, is that Jose? I'm sorry.

6 DR. AMADOR: Jim, sometimes people ask me about
7 the PPDC and, you know, what goes on in the Office of
8 Pesticide Programs, and you can relate to some of this
9 reassessment, like we had 10,000 -- almost 10,000
10 reassessments, you know, since 1996. Do we have a sense
11 of how many products were voluntarily withdrew or
12 withdrawn from companies not wanting to go through the
13 process? You know, it seems to me that would be
14 something that people might want to know, how many
15 companies --

16 MR. JONES: Let me ask Debbie, but --

17 DR. AMADOR: -- voluntarily withdrew not having
18 a product?

1 MR. JONES: I'm not sure that we have that off
2 the top of our heads. One of the things, as a general
3 comment I'll make, is there is so much done associated
4 with all of these chemicals. We have always struggled
5 with how to efficiently communicate it, and that is as it
6 relates to the kind of risk mitigation all of them get,
7 from changes in PPE to changes in REIs to use deletions,
8 the range of it, it's just so vast. It's been very hard
9 for us, affecting so many chemicals, to succinctly
10 communicate that. But I'm going to let Debbie give a
11 sense as to how many products have been voluntarily
12 removed.

13 MS. EDWARDS: Not actual products, but back on
14 the pie chart, it does show that 231 cases were canceled.
15 So, that's a fairly significant percentage. People that
16 dropped out, I think, pretty early on.

17 MR. JONES: Yeah, those are the ones who tended
18 to drop out early on because they didn't want to support

1 the chemical with the data generation. One --

2 DR. AMADOR: Is that just the chemical or the
3 use of the chemicals (inaudible)?

4 MR. JONES: That's a chemical. That's a whole
5 chemical, which is a very crude --

6 MS. EDWARDS: That represents about 400 active
7 ingredients.

8 DR. AMADOR: Four hundred active ingredients.

9 MR. JONES: Gary?

10 MR. LIBMAN: This question, I guess, is for
11 Debbie. You say that you have 286 inerts left. I'm
12 curious about inerts. We didn't talk much about the
13 inerts. I assume that list is also on the website. How
14 would this change the so-called -- the old lists that we
15 had, List 3 and List 4A and B and so on on the inerts?

16 MR. JONES: Debbie's conferring with some of the
17 originators of that list, who happen to be at her left
18 right now.

1 **(Laughter.)**

2 MS. EDWARDS: I don't know that that list -- is
3 that list on the Internet, Lois?

4 MS. ROSSI: I'm not sure if it's on right now.

5 MR. LIBMAN: So, where did the 280 --

6 MS. EDWARDS: There shouldn't be any more list
7 one inerts, I wouldn't think after --

8 MS. ROSSI: No.

9 MS. EDWARDS: I'm not sure that there are now.

10 UNIDENTIFIED MALE: No, those should have been
11 those high -- those five high risk (inaudible).

12 MR. LIBMAN: Well, it's the List 3 ones I'm
13 concerned about.

14 MS. EDWARDS: Ideally, they all end up down in
15 List 4.

16 MR. LIBMAN: Well, there still are some on List
17 3 and those are the ones that have not been evaluated
18 yet.

1 MS. EDWARDS: Right.

2 MR. LIBMAN: So, how are we moving towards
3 getting those to List 4 or off the list?

4 UNIDENTIFIED FEMALE: Each reassessment decision
5 concludes with what list it should go on. If you look at
6 some of the reassessment decisions that we've done, it
7 will say, and this was formerly on or this was on List 4,
8 it stays on List 4 or this was formerly on whatever list
9 and that's the new classification.

10 MR. LIBMAN: I was under the impression that the
11 lists -- the so-called four lists would actually go away
12 at the end of 2006. Is that not true? Those lists will
13 still be there?

14 UNIDENTIFIED FEMALE: I don't think so.

15 MR. JONES: The inerts subject to tolerance
16 reassessment are only those with a tolerance. The Lists
17 1 through 4 includes all inerts, which would include
18 those without a tolerance. Once we have finished our

1 inerts -- total inerts review, you'll either be on List 1
2 or List 4. This will deal with it for those that have
3 food uses. The food use inerts, you'll either end up as
4 -- on List 4, meaning we've made the safety finding, or
5 we'll designate you as a List 1 inert and you'll have to
6 do a lot of data or some other kind of regulatory action.

7 But then there are a meaningful number of non-
8 food use inert ingredients that will not have been
9 addressed through the tolerance reassessment process.

10 Anyone -- Julie, you've asked your -- okay.

11 MS. SPAGNOLI: This is kind of further on
12 Larry's point about, I guess, what it might be, and I
13 think, you know, the CARAT and the TRAC really address a
14 lot of the big policy issues. I mean, that was really
15 what they were set up to do. But I think as these --
16 especially some of these bigger chemicals have come
17 through, you know, additional issues have been raised or
18 policy issues, and a lot of times it comes through that

1 public comment period that a particular issue is raised
2 about some water issue or something in particular. So,
3 that may be -- you know, if it doesn't go to the CARAT or
4 the TRAC.

5 But some of these issues that maybe have been
6 raised later as some of these chemicals have gone through
7 and through the public comment period, that may be
8 something that might be valuable to bring back to this
9 committee, some of those smaller policy issues that have
10 been raised.

11 MR. JONES: I understand. My experience in this
12 program is that you -- stakeholders representing all
13 parts of the stakeholder community are quite facile at
14 figuring out what it is about our assessments and our
15 regulatory -- but our assessments they have an issue
16 with, and they're not shy about doing that. And so, one
17 of the things that we rely on is as our assessments roll
18 out the door, which I mean over half of the ones that are

1 going to be decided next year -- and it may be as high as
2 75 percent -- the assessments are out there. What
3 happens then is people who have a stake in them look at
4 them, and then as they identify issues, generic or
5 specific, they raise them.

6 Partly, I think we're just implicitly relying on
7 that process to help us define issues that may require or
8 may benefit from deliberations from a larger body. If
9 there are some other aspects of that work that you'd like
10 to engage in dialogue around, it would be useful for us
11 to put our heads together and figure out what they may
12 be.

13 Bob?

14 BOB: Jim, I just wanted to comment from a
15 specialty crop perspective. I think we feel that there
16 have been a lot of inputs to the agency. I know we
17 participated through the EBDC Task Force, the Triazole
18 Task Force, and I think there are a lot of listening

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1 posts out there and I perceive that the agency has been
2 working with at least these bigger task forces in getting
3 input and particularly on specialty crops, which are
4 always concerned that we may lose products. I think
5 we're very positive that we've been listened to and our
6 concerns have been addressed.

7 MR. JONES: Okay. Well, over the course of --
8 Larry?

9 MR. ELWORTH: I guess it's not so much that I
10 have an issue with anything you're doing on this, but I
11 think there's something that you need greater oversight
12 for. I guess, in a sense, what I wanted to suggest is
13 that the level of policy discussion in CARAT was very
14 useful, and if we're not going to do that, it would be
15 nice to fill that in either through a CARAT meeting or
16 through this. That's all I'm saying. It's not a --

17 MR. JONES: Just an observation, and perhaps my
18 analysis is wrong on this, but my observation of the

1 CARAT process, which I think gave the agency excellent
2 advice, most importantly around the public participation
3 process. I thought that was a very valuable activity.

4 My observation about when CARAT meetings would
5 be held would be when the stakeholder said, we need a
6 meeting and we need to talk about this, and the agencies
7 would get together and go, okay, that seems like a
8 logical thing. I'm hearing all of this vibrating around
9 this issue. We need to get together with everybody and
10 figure it out. I think that one of the reasons we've
11 gone for two years, I'm not speaking for the
12 Administrator or the Deputy Administrator, just as an
13 observer and a participant of the process, is that that's
14 not occurred where people are saying, here's my issue, I
15 need to have a forum to talk about it. If that were to
16 happen -- now, being the good bureaucrat, I'd like to
17 suss it out, figure it out, and go to my management and
18 go, this is what people really want to talk about, as

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1 opposed to having you all run to the Deputy
2 Administrator.

3 But if we could do that, I would be happy to
4 facilitate that kind of dialogue either at this meeting
5 or at a CARAT meeting. Yes?

6 UNIDENTIFIED MALE: On behalf of USDA, I mean,
7 I'd like to echo the same thing. If there are specific
8 items that you feel are worthy of tabling right now, I
9 certainly would like to hear it and be happy to pass it
10 up in order to do that. But, personally, I mean, if it's
11 a matter of, well, we'd like to just put together a
12 meeting, I don't know what to put on the agenda. So, I
13 mean, if there's specific policy areas or, you know, even
14 some general areas that you can flush out for me, I'd be
15 happy to listen.

16 MR. JONES: Let me just ask all of us, us at the
17 government and you and the committee members, to think
18 about over the next day-and-a-half, a little bit more --

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1 in a little bit more flushed out way, what is it that
2 would be useful for you and if you think it's useful for
3 you, we're going to find it useful for us. I will tell
4 you that.

5 All right, why don't we -- Lori?

6 DR. BERGER: Just one quick question, especially
7 in regard to what you mentioned there, Burleson, and
8 CARAT. It was my understanding, and I'd have to go back
9 and look at the minutes or record, that there were some
10 items that the group is going to be following up on, a
11 to-do list or comment on or there were some specific
12 things that the group did want to reconvene on and
13 discuss. So, that's my recollection, and from a
14 stakeholder's standpoint that represents several
15 specialty crops, we really find that that's an excellent
16 forum and we'd like to see it continued. So, any
17 recollection of that? I know that there were a lot of
18 transition issues and cooperative extension concerns and

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1 that type of thing.

2 UNIDENTIFIED MALE: I think that there are --
3 you're correct. There were specifically related to some
4 of the utilization of farm bill type programs for some
5 interaction with specialty crops, but some of the other
6 pesticide uses. I will be candid with you right now.
7 That's an area that is still -- we're still working on
8 and don't feel that I have something to report back to
9 you at this point. I'll try to see if we can find a
10 little bit more. But that is a work in progress.

11 MR. JONES: Okay, thanks very much. I
12 appreciate all that.

13 Lois Rossi, the Director of the Registration
14 Division, is going to give us an update on our
15 registration activities broadly in OPP. Thanks.

16 MS. ROSSI: With the conclusion of the Fiscal
17 Year 2005, we completed our first full year in
18 implementing the Pesticide Registration Improvement Act,

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1 better known as PRIA. It was certainly a year of
2 developing comprehensive work plans, process
3 improvements, and efficiency measures.

4 Next slide. What you have presented there,
5 during the Fiscal Year, we approved 24 new active
6 ingredients. As you can see there, we had 12
7 biopesticides which are listed for your information
8 there.

9 Next slide. We had two antimicrobials and, next
10 slide, and we had 10 conventional pesticides, two of
11 which were for import tolerances only. So, that was our
12 new chemical activity list. On that list, you can also
13 see that there were two reduced risk pesticides, both of
14 which were NAFTA joint reviews, and I am pleased to
15 report that these two active ingredients were approved
16 within 14 months and 16 months of the day they came in
17 the door, which certainly validates the efficiencies that
18 you experience when you do a joint review.

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1 Next slide. New uses. 164 new uses associated
2 with 702 crops associated with 32 previously registered
3 active ingredients or conventional active ingredients
4 were approved in the Registration Division. Twenty-seven
5 of those were reduced risk new uses, 45 were OP
6 alternative new uses. And then we also had eight new
7 uses in the antimicrobial area.

8 Next slide. This slide presents our Section 18
9 activity for this year, and a lot of which was associated
10 with approving exemptions in anticipation of soybean
11 rest. But that gives you a look at the number we
12 received and approved and the crises that were declared,
13 which I understand is a lower number than usual, and with
14 still our average turn-around time of around 42 days.

15 Next slide. This slide presents a description
16 of all the PRIA actions that we've encountered this year,
17 except for, obviously, the first one which is Fast-Track
18 amendments, which were not approved -- which were not

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1 covered under PRIA, and you can see there's a fairly
2 large number of those that we still have. I know there
3 was a lot of talk throughout the year in various
4 discussion groups about focusing our attention on PRIA
5 paid actions and not focusing any resources or attention
6 on Fast-Track amendments. But, as you can see, there's a
7 fairly large number across all the divisions, and in the
8 conventional area, we were able to eliminate our backlog
9 with Fast-Track amendments this year, and we intend to
10 almost treat them like PRIA in trying to meet the 90-day.
11 I know antimicrobials has been doing that for a long
12 time, and the Registration Division, that's our goal this
13 year. And you can see the numbers for other PRIA
14 actions, non-Fast Track amendments, Fast Track new
15 products, non-Fast Track new products. Quite a lot of
16 work and accomplishments this year.

17 Next slide. With regard to the inerts, we are
18 pleased to have a new branch in the Registration

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1 Division, the Inerts Ingredients Assessment Branch. The
2 Branch Chief is Pauline Wagner, formerly of the Health
3 Effects Division. And we have nine people working,
4 including Pauline, working in that branch right now. It
5 was set up to handle the approvals of food use petitions,
6 new clearances of inerts, as well as the reassessment
7 that Debbie was mentioning in her overview.

8 This year, we were able to complete 17 new food
9 use approvals. Last year, I think we did 16. So, we did
10 one more than we did last year. We currently have 32
11 pending, including those we received in this fiscal year.
12 I think for those of you who are concerned about the
13 inerts and the approval of new food use inerts, it
14 represents a backlog from the beginning of PRIA of
15 probably about 12 pending old ones that have been pending
16 since 2004 or prior to March of 2004. We intend to
17 eliminate that next year by trying to complete 22 to 25
18 new approvals.

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1 And our reassessment program, I think, Debbie,
2 our numbers differ by one, but we'll -- I think there
3 might have been one of those ones that was signed very
4 late on September 30th. We have 168 completed this year
5 and we've got 285 remaining to be reassessed to meet the
6 August 3rd deadline of next year.

7 Next slide. This just gives you some statistics
8 on what the workload has been like since the enactment of
9 PRIA. We've had 2,850 total submissions, of which we've
10 completed a little more than half. Over 99 percent have
11 been completed by the PRIA goal. We did issue 18 "not
12 grant" decisions, which is less than 1 percent of the
13 total submissions and we had 144 actions, which is
14 approximately 5 percent of the total submissions that we
15 had to renegotiate the due date.

16 And the next two slides just give you a little
17 more breakdown of where those "not grant" decisions, as
18 well as the -- next slide -- the negotiated due dates

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1 data.

2 UNIDENTIFIED MALE: Could you tell us what AD,
3 BPPD and RD mean?

4 MS. ROSSI: Oh, sure. Antimicrobials Division
5 is AD, Biological and Pollution Prevention Division is
6 BPPD, and RD is Registration Division. Those are the
7 three regulatory divisions in the Office of Pesticide
8 Programs.

9 Okay, just a look ahead of what's on our plate.
10 As I said, we have comprehensive work plans now which
11 basically are work plans that list all the work. For
12 conventional pesticides pending in the Registration
13 Division, we have 21 new active ingredients on our work
14 plan. They roughly break down into 13 active ingredients
15 that will have domestic registration and eight active
16 ingredients requesting import tolerance only. It may
17 appear to be a very high proportion of import tolerance
18 only actions, but many of those were pending many years

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1 and they never were on the work plan in previous years
2 and now they came in and paid the PRIA fee and
3 consequently are on the work plan. Many of those are on
4 schedule to be completed within Fiscal Year 2006.

5 There's 22 biopesticide new active ingredients
6 pending and 10 antimicrobial new active ingredients.
7 And, again, the goal, obviously, is to meet the PRIA
8 deadline, and in most cases, we beat the PRIA deadline.

9 Next slide. I'll just call to your attention
10 the website for the conventional pesticides. We do have
11 the new chemical work plan posted and it gives the
12 information on the PRIA due date, as well as the
13 anticipated quarter that the agency intends to make the
14 decision on the pesticide. We shortly will have -- in
15 the month of November, we'll shortly have a very
16 comprehensive work plan of the new uses for conventional
17 pesticides, as well as the inerts. The new use work
18 plan, just to give you an idea of the size of it, when

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1 you put it in tables on this size paper, it's over 40
2 pages, and so, consequently, it takes a lot of review
3 before we put this up on the web. That's what we're
4 going through the final stages of now.

5 So, that, in a very brief overview, is the
6 status of what the Registration Divisions have been up to
7 this last fiscal year. Thanks.

8 MR. JONES: Questions? Steve?

9 STEVE: Lois, what is the PRIA deadline? What's
10 the time frame?

11 MS. ROSSI: Well, it depends what kind of an
12 action it is, like, for example, a new chemical that
13 comes in the door today would have a 24-month time frame.

14 STEVE: Um-hum.

15 MS. ROSSI: If it was reduced risk, it has a 21-
16 month time frame. If it's a me-too product, it has a 90-
17 day time frame. It depends on the category. There are
18 90 categories, and those are on the web. They're all

1 associated with a different time frame. There is a
2 different time frame and there is a different fee
3 associated with all those 90 categories.

4 STEVE: So, presumably, there has been an
5 improvement, it sounds like there has. So, what
6 percentage more? How many more new registrations are you
7 running through this system now?

8 MS. ROSSI: Well, for new active ingredients, I
9 think we're pretty much at the same -- this year, we were
10 at the same capacity that we were at in previous years,
11 between the 10 and 12 or 10 and 14 range. But I think
12 you're going to see that the workload then starts
13 dictating the outputs, and so, like, if you have -- like
14 right now we have 21 actions pending. I think all but
15 about seven of those will come out in the next year. So,
16 we'll have that.

17 As far as new uses go, this year we had --
18 generally we have sort of in the range, typically, of 200

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1 to 230. This year, we had 164 for conventional
2 pesticides. And -- but it was over a large number of
3 active ingredients. In other words, you didn't get a lot
4 of new uses for one active ingredient.

5 Next year, what's on the plan of all the work
6 that we're trying to accomplish in 2006, I think the new
7 uses come out to be 268. So, I don't think we've had
8 enough experience to start seeing how the outputs are
9 going to be directly related to the inputs yet, but
10 that's what you're going to start seeing.

11 STEVE: I'm trying to get a sense of what the
12 end of the pipeline's going to start looking like in the
13 next several years.

14 MS. ROSSI: Right. And you'll be able to tell
15 that --

16 STEVE: When do you expect to see a whole lot
17 more available --

18 MS. ROSSI: And it will depend. Like, for

1 example, this year the conventional -- RD, Registration
2 Division, only received one new non-food use chemical
3 application and one import tolerance. That's all the new
4 stuff we received in the whole fiscal year.

5 STEVE: Wow.

6 MS. ROSSI: I already know in 2006 we're
7 expecting to get at least four new active ingredients
8 within the first six months. So, it really is going to
9 depend on what comes in the door.

10 STEVE: And so, from a workload perspective, do
11 you have to go to outside consultants to do a lot of
12 this? Can you handle it all internally?

13 MS. ROSSI: Well, we do have contracts -- we
14 have contracts in our Health Effects Division and in our
15 Environmental Fate and Effects Division. So, we have
16 contracts for the review of the -- for the initial review
17 of the data.

18 STEVE: So, they can expand and contract --

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1 MS. ROSSI: Right. And for new chemicals,
2 pretty much the new data comes in -- the application
3 comes in the door and the data is shipped to the
4 contractors for those various disciplines.

5 MR. JONES: But I think, Steve, the biggest
6 change is the predictability completely turns around,
7 whereas you submitted five years ago and --

8 STEVE: It's still there.

9 MR. JONES: Well, that -- that was the case five
10 years ago, and what was going to come out and when it was
11 going to come out was difficult for anyone to have
12 predicted. Now, you submit and 99 percent of the time,
13 99 percent plus, you'll get a decision from the agency in
14 the time frame that's set in the statute.

15 STEVE: That's fine.

16 MR. JONES: I think that's the real change in
17 the system, which we've been hearing for years and years
18 and years was the most important part if you're trying to

1 run a company, is the predictability of the timing of
2 your decision.

3 Larry?

4 MR. ELWORTH: A couple of things that I actually
5 would modify based on Lois' comments. I'd be interested
6 in -- not necessarily today -- in looking at the -- what
7 the revenue stream is from PRIA.

8 MS. ROSSI: What?

9 MR. JONES: I'm sorry, Larry, the what history?

10 MR. ELWORTH: The revenue stream.

11 MR. JONES: Revenue stream, okay.

12 MR. ELWORTH: I don't need to see that now, but
13 it would be interesting to see that. Based on what you
14 just said and what Lois said, actually looking it over --
15 looking at it over more than a one-year period would
16 probably be more instructive than looking at it in an
17 individual year.

18 MR. JONES: Right.

1 MR. ELWORTH: But I'd, also, at some point,
2 again, and maybe not right now, be interested in some
3 feedback from registrants about how PRIA's worked for
4 them, both registrants that are taking advantage of PRIA
5 opportunities and registrants who aren't. I just want to
6 flag that.

7 MR. JONES: Okay.

8 MR. ELWORTH: Because I think it would be a real
9 interesting discussion.

10 MR. JONES: Okay. Sure, we can do that in a
11 subcommittee. I can tell you in FY '05, we collected \$10
12 million in PRIA.

13 MR. ELWORTH: Yeah.

14 UNIDENTIFIED MALE: Was that on target or was
15 that (inaudible)?

16 MR. JONES: You know, when we were giving
17 technical advice on the bill when it was being developed,
18 we thought we'd collect around \$15 million. But what

1 isn't so important is what you think you're going to
2 collect because you collect what's submitted. So, you're
3 always in balance. So, it really doesn't matter so much
4 how much you collect, it's how much -- that you collect
5 enough to do the work that you get, which it's designed
6 to give you that equilibrium.

7 UNIDENTIFIED MALE: Yeah. One suggestion and
8 one question. I think it might be useful to go back and
9 I think you've got the data to take a look at average
10 time frames for completion of various actions pre-PRIA
11 and what you're doing now, because I think it's -- when
12 you talk about performance measures and efficiency, I
13 think that's a great way to quantify some of the
14 improvement that we're seeing. And I think it is -- I
15 mean, it's an exceptional, you know, first year. I think
16 you guys all ought to be proud of it.

17 Lois, I've got a question for you, though. What
18 keeps you up at night? What do you worry about most when

1 you look ahead about ensuring compliance with these time
2 frames and what categories do you worry about the most?

3 MS. ROSSI: What categories -- I didn't hear the
4 last part.

5 UNIDENTIFIED MALE: What actions? I'm thinking
6 particularly about the short-term actions, and as you
7 look ahead and you see obstacles to full compliance or,
8 you know, time -- timeliness, uncertainty concerns, what
9 are you seeing or are you not worried at all?

10 MS. ROSSI: Well, yeah, first of all, nothing
11 related to PRIA keeps me up at night.

12 **(Laughter.)**

13 MS. ROSSI: Well, I think the single-most
14 important factor for successfully meeting deadlines,
15 internally and externally, externally is the quality of
16 the package. The renegotiated dates, the "not grants"
17 are all related to quality of package, data and that it
18 was -- that should have come in with the package and

1 didn't, or data wasn't up to speed. So, I think from an
2 external point of view, that's probably the single factor
3 that assures success.

4 Internally, I think it's just -- I think having
5 a work plan and having the work laid out for down to the
6 reviewer level, so that if you're a reviewer in the
7 registration division, for example, you can print out
8 your workload for the week, for the month, for the year,
9 for the next quarter. You can print that out. The
10 Branch Chief can do the same, the Product Manager can do
11 the same, across all different categories, new chemicals,
12 new uses, all the PRIA codes, the me-toos, the non-Fast
13 Tracks, all the different ones, including product re-
14 registration and Fast Track amendments.

15 So, they can see their workload and I think it's
16 just -- it's really truly managing the workload rather
17 than having this vision of this over-burdened -- this
18 huge burden of stuff that you don't even know sometimes

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1 where it is. I think that's been the challenge for the
2 managers in the Registration Division. I think that's
3 where we've really concentrated our efforts this year.
4 So, I mean, I think that's the challenge, to just stay on
5 top of and manage the workload.

6 MR. JONES: Bob?

7 BOB: Yes. I just wanted to thank Lois and the
8 Registration Team and Tina and the HED Team on behalf of
9 IR-4 and specialty crop growers for the spectacular job
10 this year. We count on a calendar year rather than a
11 fiscal year and we have 655 clearances that have been
12 granted so far. Our long-term goal is 500 to 600 a year
13 and we expect to have over 800 by the end of the year.
14 So, it's been a great partnership. We just had another
15 technical working group meeting this week with the
16 agency. I can say our relationship with the EPA couldn't
17 be better. We have very open cooperation. We're working
18 on some new initiatives like international harmonization

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1 through crop grouping, which Lois has taken the lead in,
2 so we're thankful.

3 I also wanted to thank industry because part of
4 -- you know, we submit a petition, but also with PRIA, it
5 requires the notice of filing, the labels and so on. In
6 the past, those could come in independently, and now,
7 we're charged with putting that all in together as an
8 initial submission package. Crop Protection Industry has
9 been very cooperative in working with us to put all that
10 information together in initial submissions. So, again,
11 thanks to the agency for a fine job.

12 MR. JONES: Thanks, Bob. Allen? I'm sorry,
13 Gary?

14 MR. LIBMAN: Hi. My questions are regarding the
15 negotiated due dates. Someone more skeptical than myself
16 would say, are these negotiations because the --

17 **(End of Tape 1, Side A)**

18 MR. LIBMAN: -- due dates.

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1 MS. ROSSI: The usual reason is is that, at
2 least in RD, that the -- there's some piece of data that
3 needs to be either clarified or redone or some data
4 that's just not acceptable at the point after it's been
5 reviewed. That is, by far, the most reason.

6 I think in -- and I think it's probably more of
7 a piece of data in RD whereas in maybe, for example, the
8 Biological and Pollution Prevention Division, it's the
9 whole package of completeness of the package. So, that's
10 what -- that's really what most of these have been
11 related. And just to -- just to let you all know what
12 the process is for a negotiated due date, it's not an
13 easy thing to do internally. It -- what has to happen is
14 -- in other words, a reviewer just can't go out on their
15 own and renegotiate a due date. It has to be brought up
16 to the division level, and then actually Jim or Marty
17 actually sign a form in which it's articulated, the whole
18 history of this application and why, at this point in

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1 time, do we feel we need to renegotiate the due date.
2 And it's approved at the Office Director level.

3 MR. LIBMAN: But are they renegotiated back to
4 zero again or is it just like a month or --

5 MS. ROSSI: No, no, no, no, not at all, not at
6 all. They're -- the rule of thumb we use in RD is if it
7 takes six weeks, for example, for the registrant to get
8 that piece of data in, we extend it for six weeks and
9 then we allow ourselves whatever time we think it would
10 take to review that piece of data. So, let's say it
11 takes four weeks, we would ask for a 10-week renegotiated
12 date. And we actually speak to the registrant about that
13 before we even do the proposal that then goes up the
14 management chain. So, it's not just like, okay, this is
15 PRIA action that has a one-year PRIA time frame,
16 renegotiated date, we tack on another year. It's very
17 specific to what needs to be completed and the time frame
18 it will take to review that piece of information.

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1 UNIDENTIFIED FEMALE: Just to further clarify
2 what Lois raised, we do have management controls over the
3 renegotiation of due dates and we have a regular process
4 for that. It's also less than 5 percent of the total
5 number, which you -- if you noticed, one of Lois' slides,
6 there's a huge number of actions that were submitted over
7 this past year and less than 5 percent had to have
8 negotiated due dates.

9 The statute also puts the restriction on us that
10 we have to have this agreed upon in writing. So, this
11 isn't something that the agency can arbitrarily impose
12 upon the registrant. We have to actually negotiate it,
13 and what we do is rely upon email in this day and age,
14 and we have copies of those email exchanges, along with
15 the form that Lois was describing. So, it's a pretty
16 thorough examination and a rigorous review of any
17 requests to renegotiate a due date.

18 MR. JONES: Okay, Allen, Jose, Jay and Julie.

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1 Let's try to wrap this up.

2 ALLEN: Thank you, Lois. On your third slide,
3 if we could go back to -- I just have an easy question
4 that would clarify something for me. The one that is
5 titled '05 Registration Activity New Uses. That's not
6 it. Back up one. It must be the other one.

7 MR. JONES: Allen, could you speak into the mic
8 a little more clearly so we can get the --

9 ALLEN: Go back the other way. One more. It's
10 near the front, the third one. We don't need the slide
11 necessarily.

12 (Laughter.)

13 ALLEN: The line indicates that you approved 164
14 new uses associated with 702 crops. I work in the non-ag
15 area, so I'm a little confused. I thought every crop
16 that you had a use on counted as a use. What's the
17 difference between the new use and associated with
18 multiple crops?

1 MS. ROSSI: It's the crop grouping. For example
2 -- and, Bob, you probably can give a detailed example of
3 a crop grouping, but like, for example, there's a crop
4 grouping called the bulb vegetables, and that would
5 include like onions, garlic. shallots.

6 ALLEN: But you lump those all into that use?

7 MR. JONES: That's one new use.

8 MS. ROSSI: Yes. Yeah, that's one new use.

9 MR. JONES: So, sort of give some representation
10 of how much work you have to do. One use could have 15
11 crops.

12 MS. ROSSI: Right.

13 ALLEN: But the companies submit data, I
14 suppose, for each crop?

15 MS. ROSSI: They submit it for the crop grouping
16 and there's representative crops that you have to submit
17 the data on to get that crop grouping.

18 ALLEN: Got it, thank you.

1 MR. JONES: Thanks. Jose?

2 DR. AMADOR: I wish you had left the previous
3 slide on, that's the one that I needed, but we don't need
4 it either. I notice on the section --

5 MR. JONES: Can you speak into the mic? You
6 need to really speak into the mic, folks. It's hard to
7 hear.

8 DR. AMADOR: I notice that you have on the
9 Section 18, you know, it's an outstanding record there,
10 no request denied, zero. But there were 66 that were
11 withdrawn. Were they withdrawn because they were going
12 to be denied anyway or by an objection that was raised by
13 your group? That one there, that's, you know --

14 MS. ROSSI: In some cases, that's true. That's
15 definitely true in some cases. In other cases, they were
16 withdrawn because we were able to register a new use.
17 So, there is a variety of reasons. But the reason you
18 gave definitely is in there.

1 DR. AMADOR: And does the state still play a
2 very important role when submitting a Section 18 petition
3 to EPA?

4 MS. ROSSI: The state submits the application,
5 yeah.

6 DR. AMADOR: Yeah, I know. But still how well
7 they do the package and the whole thing has a lot to do
8 with whether it's going to be approved or not.

9 MS. ROSSI: Definitely, especially in justifying
10 the emergency.

11 DR. AMADOR: I think this is outstanding then,
12 because Section 18, particularly in our area, we get new
13 pests or diseases or something loses the (inaudible) and
14 we need a Section 18 and I think this is an outstanding
15 record. Congratulations.

16 MR. JONES: Thank you. Jay?

17 MR. VROOM: A factor that's going to cut across
18 all three of these areas is the impact of the -- whatever

1 the new part 158 requirements will end up being, and I
2 wondered if each of the three groups could comment on
3 what they would anticipate that might mean given what we
4 think we know about where Part 158 will resolve. Most
5 particularly, I think from our perspective, opposite
6 the registration review process, looking more
7 prospectively -- I don't know if Susan can come back up
8 or Jay can speak to that. But in particular, we feel,
9 you know, as we've expressed previously, that we really
10 prefer, from the agricultural registrant perspective, a
11 more solid commitment to a chronological approach because
12 we think we've been through enough of the kind of so-
13 called high risk or worst first process steps with FQPA
14 tolerance reassessment and reregistration that we ought
15 to get back to a more orderly kind of chronological
16 predictable kind of process for that.

17 And as an example, we think it would be not
18 logical to force the OPs and the carbamates through a

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1 registration review process right away. But, once again,
2 I think Park 158 is a factor that -- I know we're going
3 to talk about that on the afternoon agenda with Bill, but
4 in the context of these three presentations, I'd be
5 curious to know what sort of your gut sense is.

6 MR. JONES: Well, for -- and Lois and I have
7 spent some time talking about this. For registration of
8 conventional pesticides, the chemicals that are submitted
9 and have been submitted for the last three years or so
10 are already in compliance with the proposed 158. That's
11 what companies are submitting right now. So, to me,
12 that's no impact.

13 We were going to follow 158 for conventionals
14 with a proposal for the microbials, which should be --
15 you'll hear about later this afternoon, and then a little
16 further down the line will be one for antimicrobials,
17 which is -- I just can't really speak to in so much
18 detail because it's not developed enough to really -- to

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1 speak to it. So, I don't think that it would be much
2 impact in the finalization of 158 on our registration
3 program, our reregistration program. I think it will
4 provide greater clarity to registration review.

5 And the issue of the scheduling, again, we're
6 trying to balance kind of a -- in registration review, a
7 -- our preference going in was chronological. It's the
8 only way you -- we felt we could manage it in an
9 effective manner. As we got more into it, we began to
10 realize that you can have even more efficiencies when you
11 group things, because when you use the same kind of
12 science, you use the same kind of economics, you use the
13 same kind of biological information. So, we're trying to
14 balance the let's try to move this through
15 chronologically with the need to be more efficient in how
16 we do things by grouping. I expect that that workgroup
17 is going to continue to talk about that issue in the
18 months to come.

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1 Julie?

2 MS. SPAGNOLI: I guess somebody had asked sort
3 of what the registrant's perspective was about PRIA, and
4 I think from a business planning perspective,
5 predictability is just -- you can't -- I mean, that is so
6 valuable because when you're trying to, you know, plan
7 for a business, an introduction of a product, obviously,
8 having some idea of predictability is just invaluable.

9 I think, also, just to speak to what Lois said
10 about, you know, for the reviewers, too, to have a work
11 plan, to know what they're -- you know, kind of what the
12 order of their work is, I think that has got to increase
13 efficiency, because I -- you know, speaking as someone
14 who was in -- did registration work for a number of
15 years, it used to be kind of the squeaky wheel tactic.
16 You know, you were at that product manager constantly,
17 especially if you were getting pressured from the
18 business and --

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1 UNIDENTIFIED MALE: You have a friend who was.

2 MS. SPAGNOLI: What?

3 UNIDENTIFIED MALE: You have a friend who was.

4 MS. SPAGNOLI: Yeah. No, I mean, you know, I
5 just -- I believe that this -- having that predictability
6 takes that aspect -- you know, where you don't have to --
7 you can know when you can, you know, expect to hear
8 something, so you're not, gee, I got to call the product
9 manager every day to keep bugging him because, you know,
10 if I don't do it, my competitor is. So, I just think
11 it's got to have increased the efficiency within the
12 reviews, too.

13 MR. JONES: Okay, Michael and Larry and then
14 we're going to wrap this session up. Michael?

15 MICHAEL: You said for the carbamates that have
16 already started the process that all of the 158
17 requirements have been complied with. (Inaudible) days
18 of FIFRA and never had an avian reproductive study done.

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1 Is that going to be required for (inaudible)?

2 MR. JONES: I think I said conventional
3 pesticides. I was talking about --

4 MICHAEL: (Inaudible) carbamates, isn't it?

5 MR. JONES: I was talking about new submissions
6 to the agency. If you're submitting to the EPA in the
7 last three years a new chemical, I said those chemicals
8 already have the data that's in the proposed rule for
9 158. Sorry.

10 Larry?

11 MICHAEL: But you didn't answer my question.
12 Will it be required for reregistration (inaudible) avian
13 reproduction studies?

14 MR. JONES: I -- Debbie, do you know if there's
15 an avian reproduction study required for -- or in-house
16 for --

17 MS. EDWARDS: I don't believe there's one in-
18 house. I think we will be requiring one.

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1 MR. JONES: The decisions on Aldicarb have not
2 been made, but will be in the spring of this year -- next
3 year.

4 Okay, Larry?

5 MR. ELWORTH: Just a quick question, and this
6 may be a typo. What's the difference between the number
7 of requests received and 340 and 66 and even 27 doesn't
8 add up to 517.

9 MS. ROSSI: They can't add up because they're
10 over the course of different years.

11 MR. ELWORTH: Okay. I just wondered if there
12 was like another mystery category.

13 MS. ROSSI: No, no.

14 UNIDENTIFIED MALE: Ignored category.

15 MR. ELWORTH: Right.

16 UNIDENTIFIED MALE: Maybe it will go away.

17 **(Laughter.)**

18 MR. JONES: All right. Well, thank you for

1 that. I think I may have misjudged how much interest
2 there was in talking about some of these issues from past
3 meetings where there wasn't as much interest. But I,
4 frankly, appreciate the engagement on these issues
5 amongst all of you.

6 Before we move on to the next session, I think
7 there are four people who came in since we originally did
8 introductions. Michael, I believe you -- if you could
9 introduce yourself and who you're representing to the
10 rest of the group.

11 MR. FRY: Sure. I'm Michael Fry. I represent
12 American Bird Conservancy. I'm their Director of
13 Pesticides and Bird Program.

14 MR. JONES: And I think Steve Kellner and Bob
15 Rosenberg and Erik may also have joined us, and anyone
16 else who I just haven't -- Steve? Where is Steve? Oh,
17 there you are. They're all next to each other, too.

18 MR. KELLNER: We represent the --

1 UNIDENTIFIED FEMALE: Wait for a minute.

2 MR. KELLNER: -- (inaudible) portion of the
3 industry and -- thanks -- I guess we're involved in a lot
4 of different things, regulatory things, in particular,
5 and we're headquartered here in D.C.

6 MR. ROSENBERG: I'm Bob Rosenberg. I appreciate
7 you drawing attention to my tardiness.

8 (Laughter.)

9 MR. ROSENBERG: I'm the Senior Vice President
10 for the National Pest Management Association which is a
11 reference to my age, not my responsibilities.

12 MR. JONES: Erik? Someone pass Erik a mic.

13 MR. OLSEN: I'm Erik Olsen with Natural
14 Resources Defense Council.

15 MR. JONES: Okay. We're running a little behind
16 schedule, which makes me very anxious, but I'm going to
17 try to just chill out and I'm certainly not going to
18 shortchange this next session, which I think is something

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1 that many, not all of you, are very interested in, and
2 that is the proposed rule and a few other issues
3 associated with human studies. Anne Lindsay is going to
4 moderate this session.

5 MS. LINDSAY: Okay. A lot of you know that in
6 my job I do a fair amount of travel, including
7 international travel, so I always have the experience
8 when I'm on the plane of looking at the landing card, and
9 it seems to be a universal requirement, both in the U.S.,
10 but all the other countries I go to, that you have to
11 identify your occupation. This always provokes some kind
12 of identity crisis for me. I don't know whether it's
13 just because I'm now very tired having traveled long
14 miles and I'm befuddled, but I think what should I call
15 myself?

16 Government official, federal official, nameless,
17 faceless bureaucrat? Sometimes that probably would be
18 the right choice. But I always end up choosing civil

1 servant. I do that not because I always feel that I live
2 up to that job description, but because I think that is
3 the best job description for anyone who is public
4 service. We are here to be your servants, the servants
5 of the citizens and public in our country. I go off on
6 this little tangent as the introduction to this
7 discussion because I know that the topic of human studies
8 is one that's fraught with all kinds of controversies,
9 with very strong feelings, very decided views. It's one
10 of those topics where I actually think it can be hard,
11 even within yourself at times, to find agreement.

12 I know, just speaking for myself, I'll look at a
13 particular issue associated with this topic and find
14 myself of many minds and find that I actually need to
15 consult and talk with a lot of other very thoughtful
16 people, many of whom have very different views than I do,
17 in order for me to come to a resting place on an issue
18 that I'm comfortable with, that I feel good about, that I

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1 feel responsible. It's not very often, certainly in my
2 work experience, that you get to directly confront and
3 try to grapple with ethical issues.

4 I will not describe that as a fun experience
5 because it's actually a very hard experience. You have
6 to actually ask yourself what your values are. You have
7 to ask yourselves, I think, a series of hard questions
8 about the values that are held by the society within
9 which you live, and sometimes some of those values may
10 not be ones that you personally share or that you share
11 easily, but you also have to understand them so that you
12 can respect them and do them honor.

13 So, this is a topic where, since I've been
14 engaged in this, I've been very proud to think not only
15 of myself as a civil servant, but what I really want you
16 to know are I believe that those people at EPA who have
17 been shouldering the largest part of the burden on our
18 human studies work over the past -- now it's many years

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1 actually -- I was going to say few, but it's actually
2 many years, are some of the people that I most respect in
3 our organization and that have consistently taught me
4 what it actually means to be a civil servant. So, I can
5 assure you that in your interactions with this -- on this
6 topic, you are dealing with sort of the very best and the
7 finest of this country's civil service, and that's the
8 resource that our agency's bringing to bear to handle the
9 issue and a sign of the seriousness with which we treat
10 it and the import.

11 The session itself, as opposed to the topic, is
12 organized along some very simple lines. Bill Jordan and
13 John Carly, who are two of those finest civil servants
14 that I was talking about, are going to do a short recap
15 of the rule that we proposed about a month ago. And
16 although I know many of you have probably actually read
17 the rule, are reading the rule, are studying the rule
18 because you want to give us comment, we thought it would

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1 be good just to give you this sort of summary. So, if
2 you already know it, bear with us. If you don't know it,
3 it will actually maybe help your study of the proposal,
4 and then we would save as much time as possible, having
5 gone through that recap for all of you who care to either
6 ask questions that would help clarify portions of the
7 rule and help inform your comments on the rule, or if you
8 just have observations and perspectives that you want to
9 share with us and with each other at this point in time,
10 opportunity to do that.

11 I do want to do the specific caution that Jim
12 gave generically earlier. Comments that you make here
13 are important to us and will, I think, really enrich our
14 understanding of your perspectives and your concerns.
15 But they don't substitute for the official comment in the
16 notice and comment process. So, don't neglect to do that
17 if this is a topic that you want to weigh in on.

18 Another caution, which, again, I'm assuming is

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1 probably not necessary, but you all know that in our
2 Appropriations Act this year, there were certain
3 prohibitions that were put into place in terms of what
4 EPA can consider acceptable to rely on with regard to
5 human studies that involve intentional dosing toxicity
6 types of issues. Those are things that because we are
7 under that prohibition until the rule -- the proposed
8 rule becomes a final rule, we can't talk about
9 specifically today. The focus is on the rule itself, the
10 proposal, not on the specific chemicals. I doubt that
11 you would want to bring any of that up, but if you were
12 thinking about it, it would be helpful if you didn't
13 because you'll find us saying we're sorry, we can't
14 actually respond to something.

15 And with that, I would really like to turn it
16 over to Bill and John to do the recap.

17 MR. JORDAN: Thank you very much, Anne, for the
18 useful introduction. We are going to go through a

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1 presentation that we have used in various places. Jim
2 Jones, Anne Lindsay, John Carly and I have participated
3 in meetings with particular stakeholder groups and
4 conference calls and the like, and so, if you've been in
5 any one of those previous sessions, we hope this material
6 will sound familiar and that -- but I, nonetheless, want
7 to say that it's become clear, as John and I have gone
8 forward in conversations with people, that there are
9 still aspects of the proposed rule that we -- that folks
10 don't understand completely. I put that at our feet as
11 the responsibility for not having made it as clear as we
12 should, and so, I hope you'll listen carefully and try to
13 follow through and follow our presentation.

14 I'll say that if you do start talking about one
15 of those human studies that we're not permitted to
16 accept, consider or rely on. We had thought about doing
17 one of the see-no, hear-no, say-no -- speak-no evil kind
18 of things with Anne and John and me, but we'll have some

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1 sort of signal to let you know that's out of bounds.

2 I want to give credit to John Carly and Keith
3 Matthews who, along with me, were the three principal
4 drafters of the rule. For whatever flaws, I think I take
5 responsibility. But they've done -- Keith and John, in
6 particular, have done a good job in making it more
7 intelligible. And, today, we're going to go through and
8 talk about the rule. It was published on September 12th
9 in the Federal Register. It contains some of the
10 strongest protections for human subjects ever proposed by
11 the Federal Government, including a categorical ban,
12 without exception, on any new testing of pesticides,
13 which involves intentional dosing of pregnant women or
14 children.

15 The public comment period is open, as required
16 by the Appropriations Act, for 90 days, and it ends on
17 December 12th. You can find the Federal Register notice
18 announcing the rule, together with background materials

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1 on EPA's website at the location listed on our slide.

2 I think it's important in this conversation for
3 everybody to be on the same page with respect to the
4 terms that we're using. So, we're going to start with an
5 explanation of key terms and then summarize the context
6 of the proposal, laying out some elements relating to the
7 background of pesticide regulation and human studies, and
8 then I'll summarize the key provisions of the proposed
9 rule and talk about the agency's plans for the next
10 several months. That should take maybe 15, 20 minutes,
11 and then we'll open it up for questions and discussion.

12 The first term to talk about is human research.
13 Research is defined in the Common Rule or regulation that
14 already exists as a systematic investigation intended to
15 develop new, generalizable knowledge. It involves
16 intervention or interaction with living human beings
17 and/or with identifiable information about them. These
18 definitions are very broad and embrace many different

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1 kinds of studies. To make sure that we understand and
2 appreciate the breadth of these definitions, I'm going to
3 illustrate that by describing some of the many kinds of
4 human research that we received with regard to
5 pesticides.

6 Many human studies involved collecting data on
7 people who, in the course of their daily activities, are
8 exposed to pesticides. For example, somebody who's
9 mixing, loading or applying a pesticide. These studies
10 do not involve intentional exposure. Other examples of
11 human studies which don't involve intentional exposure
12 include epidemiological studies, analyses of accidents or
13 incidents and monitoring or observational studies.

14 Now, there are other types of studies that do
15 involve intentional exposure, that is to say, exposure to
16 the subjects which they would not otherwise have been
17 exposed had they not been participating in this study.
18 There are many kinds of intentional dosing studies. For

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1 example, studies to test the effectiveness of a mosquito
2 repellant. In this study, a human volunteer will apply
3 the repellant to his or her forearm and then insert the
4 arm into a chamber filled with hungry mosquitos, and then
5 we monitor to see whether or not the mosquitos like and
6 bite.

7 Another example is a dermal absorption study.
8 In this kind of study, a small amount of the chemical is
9 placed on the skin of a volunteer. The researchers then
10 determine how much of the chemical is absorbed through
11 the skin and how quickly by measuring levels of the
12 chemical in blood, urine, or other excreta. This kind of
13 information can be very important in assessing a
14 pesticide's risk in occupational settings.

15 As a final example, there are the intentional
16 dosing studies to identify or measure toxic effects,
17 which have been the subject of most of the public
18 controversy. In these studies, volunteers typically

1 receive small, but increasing doses of a chemical to
2 ascertain the dose which causes a threshold adverse
3 reaction. The great majority of human studies on
4 pesticides received by OPP come from observational
5 studies. That is ones which don't involve intentional
6 dosing.

7 And by the way, we use the term "intentional
8 dosing" or "intentional exposure" interchangeably.
9 They involve collecting information on people who, as
10 research subjects, are simply engaging in their normal
11 daily activities.

12 The next term I want to talk about is the Common
13 Rule. The Common Rule was promulgated in 1991 and it
14 defines the ethical and procedural standards applying to
15 all human research conducted or supported by the 17
16 participating federal departments or agencies that also
17 adopted it at the same time as EPA. In very broad
18 summary, the Common Rule requires that proposed research

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1 be reviewed and approved by an independent oversight
2 group, known as an Institutional Review Board. In the
3 human studies area, that's reduced to an acronym, IRB.

4 It also requires that participants be selected
5 fairly and that they give their fully informed and fully
6 voluntary written consent to participate in the research.
7 EPA was an original signer of the Common Rule and our
8 version of the Common Rule or our codification of the
9 Common Rule appears in Title 40 of the Code of Federal
10 Regulations Part 26.

11 Finally, I want to define the terms first party,
12 second party and third party research. Human research
13 conducted by a federal Common Rule agency is referred to
14 as first party research. Research conducted by others
15 with support from a federal Common Rule agency is
16 referred to as second party research. This would include
17 academic researchers who are working on grants, for
18 example, from EPA. Research conducted by others with no

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1 support from any federal Common Rule agency is referred
2 to as third party research.

3 EPA's Common Rule, as it now exists, applies to
4 all of EPA's first and second party research. It does
5 not, however, cover third party research. This proposal
6 that we have put out would extend EPA's Common Rule to
7 certain regulated third party research as well.

8 Okay, you all have, I'm sure, a better
9 appreciation, the vast majority of people, about the
10 complexity of assessing the risks of pesticides. You
11 understand, I hope, that we look at animal toxicity
12 studies to develop an assessment of the pesticide's
13 potential toxic effects, at fate and exposure studies to
14 estimate how and at what levels people may be exposed.
15 Sometimes, however, we have other information, including
16 data from human research, to help us in assessing the
17 potential human risk from pesticide use.

18 We think that the record shows that human

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1 research can help inform regulatory decisions and we know
2 that the use of human research has also raised profound
3 ethical and scientific issues. We have struggled for a
4 number of years to find the most appropriate approach to
5 regulating intentional dosing pesticide studies.

6 Although it started earlier in 2001, we asked the
7 National Academy of Sciences for advice on whether and
8 under what conditions such studies should be allowed and
9 considered by EPA. The current proposal that we put
10 forward relies very heavily on the NAS's advice.

11 Our goal in developing the proposed regulation
12 has been to protect the welfare of human research
13 participants in two ways, by setting rigorous standards
14 to guide how new human research is performed and by
15 defining criteria by which EPA will judge the
16 acceptability of research once such research has been
17 completed. All people who participate as human subjects
18 in research must be treated ethically and must be fully

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1 informed of the potential risks that their participation
2 would raise. Every effort must be made to minimize their
3 risks from participation in research, and we strongly
4 discourage and hope to do everything we can to prevent
5 the conduct of research that do not meet rigorous ethical
6 and scientific standards.

7 As you'll hear in these next set of slides, the
8 principal focus of our proposed new regulation is
9 intentional dosing human studies for pesticides conducted
10 by private researchers without Federal Government
11 support; in other words, by third parties.

12 So, let's turn now to the rule. This regulation
13 will establish stringent enforceable standards for the
14 ethical conduct of research involving intentional dosing
15 of humans with pesticides. Our proposal is based on and
16 generally consistent with the recommendations of the 2004
17 report from the National Academy of Sciences, which they
18 developed after a distinguished panel spent over a year

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1 studying this controversial subject. In some respects,
2 our proposed rule goes farther. It contains even more
3 protective provisions than the NAS recommended and goes
4 beyond the specific requirements of the FY 2006
5 Appropriation Act.

6 The provisions of the proposal affect a variety
7 of players and activities, and it's important to keep in
8 mind and be clear about these distinctions. For purposes
9 of the discussion, it can be divided into the following
10 categories. There are requirements applying to third
11 party investigators regarding the conduct of new human
12 studies. There are requirements applying to first and
13 second party investigators, EPA and EPA's grantees
14 regarding the conduct of new human studies. And finally,
15 there are requirements applying to EPA in our role as
16 regulators regarding how we will review completed human
17 studies.

18 In one of the most important provisions, the

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1 proposed rule would prohibit any new third party
2 intentional dosing studies with children or pregnant
3 women intended to submission to EPA under the pesticide
4 laws. This prohibition is consistent with the
5 requirements of the Appropriations Act, that the rule not
6 permit the use of pregnant women, infants or children as
7 subjects, but it is broader in that it would apply to all
8 intentional dosing studies, not just toxicity studies,
9 which is how we understand the Appropriation Act to
10 require us to act.

11 We think these special populations deserve
12 additional protection and we can see now justifiable
13 reason for testing pesticides on either of these groups.
14 These prohibitions against conducting new intentional
15 dosing studies with pregnant women or kids do not allow
16 any exceptions, either for EPA or regulated third
17 parties. We want to send the message to everyone clearly
18 that certain kinds of human research can never be

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1 acceptable and should not be conducted.

2 In addition, these same prohibitions also apply
3 to EPA. The proposed rules would prohibit EPA or our
4 grantees, first and second parties, from either
5 conducting or supporting any intentional dosing studies
6 with pregnant women or children. Now, here it differs
7 from what I just was talking about for third party
8 because it applies not just with respect to a pesticide,
9 but with respect to any other environmental substance.
10 This prohibition is also consistent with, but broader
11 than the requirements of the Appropriations Act and it
12 would apply to all intentional dosing studies, not just
13 toxicity studies, and it applies to all substances, not
14 only pesticides throughout EPA.

15 The next prohibition that I want to talk about
16 is one that prohibits -- not only prohibits the conduct
17 of the new intentional dosing studies, but it also
18 forbids EPA from relying, in its pesticide decision-

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1 making, on the results from these studies, whether
2 they're new studies or old studies. There is one very
3 narrowly crafted exception that I'll be talking about in
4 a few minutes.

5 In addition to these basic prohibitions, EPA's
6 new regulations would extend the requirements of EPA's
7 Common Rule to all third parties who conduct intentional
8 dosing studies intended for submission to EPA under the
9 pesticide laws. Now, remember that the Common Rule
10 defines the ethical standards that apply to human
11 research conducted or supported by EPA and other federal
12 departments and agencies, and remember, too, that because
13 there are no exceptions to the prohibitions that I've
14 been discussing, this extension of the Common Rule would
15 apply only to third party intentional dosing studies with
16 adult subjects, not including pregnant women.

17 Extending the Common Rule will help ensure that
18 people who volunteer for third party intentional dosing

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1 studies are treated ethically, that potential risks are
2 fully disclosed to them and that every effort is made to
3 minimize the risks that they bear on behalf of society.

4 Third party intentional dosing studies, human
5 research with pesticides, is not now required to undergo
6 any kind of external review, although I will point out
7 that many studies do undergo at least some external
8 review. We think the absence of such a requirement is
9 not wise. And so, the NAS recommended that each proposed
10 new study should be carefully examined on a case-by-case
11 basis before it is conducted to evaluate the soundness of
12 the study design, the potential risk to subjects and the
13 potential benefits to be gained from the study.

14 Consistent with that recommendation and with the
15 related requirement of the Appropriations Act, EPA is
16 proposing to establish a Human Studies Review Board.
17 Now, we're going to create a new acronym, HSRB. The HSRB
18 will review study protocols before the research is

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1 conducted and also review the reports of research after
2 it is completed.

3 We received a lot of questions about how the
4 HSRB would operate. The rule provides that no EPA
5 employees would serve on the HSRB and that the members
6 would have to meet the conflict of interest requirements
7 for special government employees. That means that they
8 could not work for or have a financial interest in any
9 stakeholder such as an environmental advocacy group or a
10 pesticide company if that stakeholder had an interest in
11 the issues that they were addressing.

12 Every new intentional dosing study for a
13 pesticide would undergo ethical review by a local
14 institutional review board, IRB, and then also be
15 reviewed by EPA staff and then the HSRB. The
16 recommendations of all three groups, the IRB, the EPA
17 staff, the HSRB concerning both science and ethical
18 issues, would be provided to the investigators before a

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1 study begins. Under the Common Rule, the IRB is required
2 to monitor the research while it is in progress and both
3 EPA staff and the HSRB will review the report of the
4 research when it is completed.

5 We've gotten a lot of questions about other
6 aspects of the operating details, the frequency of the
7 meetings, the opportunities for public participation, the
8 organizational location of the HSRB, and those details
9 are still under discussion within the agency and remain
10 to be decided.

11 The proposal breaks new ground in putting
12 forward, for the first time by any federal agency,
13 ethical standards for the agency's decision to accept or
14 reject completed human research. There are three
15 elements in this part of the proposal. First, for
16 studies initiated after the proposed rule is turned into
17 a final rule and becomes effective, those studies would
18 be accepted only if information is available to the

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1 agency to demonstrate that the research complies with the
2 Common Rule. So, scientifically valid and --
3 scientifically valid and relevant research conducted
4 before the final rule becomes effective would generally
5 be accepted if there's no clear evidence that they were
6 fundamentally unethical or significantly deficient with
7 respect to the standards prevailing when those studies
8 were conducted. Both criteria track very closely with
9 the advice of the National Academy

10 The proposed rule allows an exception to these
11 criteria under very restrictive conditions. Under the
12 proposed exception, EPA could consider and rely on a
13 scientifically sound and relevant study which does not
14 meet the ethical standards only if to do so would be
15 crucial to the protection of public health; that is to
16 say, it would lead to a more protective regulatory
17 position on EPA's part. And then we would do so only
18 after seeking public comment and consulting with the HSRB

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1 about our determination.

2 I want to underscore that this exception applies
3 only to EPA's consideration of completed research and it
4 does not provide an exception to the prohibitions against
5 conducting new intentional dosing studies with pregnant
6 women or children. If such studies were conducted, they
7 would be subject to the administrative actions detailed
8 in the rule for non-compliance, except that we might
9 consider it if it led us to put a more restrictive
10 program in place for that particular pesticide.

11 UNIDENTIFIED FEMALE: Bill, could you repeat
12 that, please?

13 MR. JORDAN: Okay. I want to point out that the
14 exception that we're talking about here applies only to
15 EPA's consideration of completed research. It does not
16 provide an exception to the prohibition against
17 conducting new intentional dosing studies with pregnant
18 women or children. If such a study were conducted, it

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1 would violate our regulations and would be subject to the
2 administrative actions detailed in the regulation and we
3 would not consider it unless we concluded that the
4 consideration of that study and reliance on it was
5 necessary to support a more protective public health
6 outcome in terms of, for example, reducing the amount of
7 pesticide that would be allowed into the environment.

8 On August 2nd, the President signed our FY 2006
9 Appropriations Act. That law includes a provision
10 specific to human studies with pesticides. The provision
11 prohibits EPA from using any of its resources to accept,
12 consider or rely on third party intentional dosing human
13 toxicity studies for pesticides or to conduct any
14 intentional dosing human toxicity studies for pesticides
15 until the agency publishes a final rule or issues a final
16 rule setting specific standards in this area. We've
17 taken pains, we think, to ensure that the proposed rule
18 is consistent with that legislation.

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1 As required by the Appropriations Act, we've
2 allowed for a 90-day public comment period on the
3 proposal. That ends December 12th. The Appropriations
4 Act also requires that a final rule be issued within 180
5 days of enactment or by the end of January, January 29th.
6 We expect to meet that target.

7 Rather than waiting for the beginning of the new
8 fiscal year last October, we began discontinuing our
9 reliance on third party intentional dosing human toxicity
10 studies in our decision-making under FIFRA and FFDCA. We
11 have developed guidance that we've given our staff to
12 make sure that they understand the scope of the
13 prohibitions in the Appropriations Act and that is being
14 implemented as well.

15 So, I want to review the six elements of the
16 rulemaking that are sort of the key highlights, although
17 there are certainly a lot of other details in it. EPA's
18 proposal prohibits third parties from conducting

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1 intentional dosing human studies for pesticides with
2 children or pregnant women. It prohibits EPA from
3 conducting intentional dosing human studies for any
4 substance, pesticide or something else, with children or
5 pregnant women. It prohibits EPA from relying in its
6 pesticide decision-making on intentional dosing studies
7 with children or pregnant women, subject to the exception
8 that I just described.

9 EPA's proposal also extends the ethical
10 standards of the Common Rule to all third party
11 intentional dosing human studies for pesticides intended
12 for submission to EPA. It established a Human Studies
13 Review Board to conduct a rigorous review of all
14 intentional dosing studies for pesticides, both before
15 they are conducted and after they are complete, and it's
16 consistent with the principles of the Nuremberg Code and
17 the 2004 NAS report.

18 So, at this point, I'll turn it back to Anne to

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1 moderate the discussion.

2 MS. LINDSAY: So, you've had a recap and a recap
3 of the recap at the end. Now's the time to open the
4 floor to questions, observations, comments.

5 Carolyn, you're up.

6 MS. BRICKEY: I just want to highlight two
7 aspects of this rule that I want to comment on. First of
8 all, and this may be a silly question, but I don't think
9 it is, what are kids? What age?

10 MR. JORDAN: The proposed rule defines a child
11 as any person who is younger than 18 years old.

12 MS. BRICKEY: So, college students would
13 presumably fit the bill for giving informed consent?

14 MR. JORDAN: If the college student is 18 or
15 older, then they would be treated as an adult.

16 MS. BRICKEY: I have some of those and --

17 MR. JORDAN: So do I.

18 MS. BRICKEY: -- I shudder to think about their

1 ability to evaluate the risks of being exposed to a
2 pesticide, much less the other risks they're exposed to.

3 UNIDENTIFIED MALE: I shudder to think about the
4 stuff they're testing already.

5 (Laughter.)

6 MS. BRICKEY: So -- I can't regulate that,
7 Larry.

8 (Laughter.)

9 MS. BRICKEY: So, my question to you is, how
10 much thought have you gone into or how much can you talk
11 about the aspects of written -- full informed written
12 consent and how that will be evaluated? What
13 requirements will be in place to make sure that that
14 happens?

15 MR. JORDAN: The proposed rule, by extending the
16 provisions of the Common Rule to third party research,
17 captures a long history of thinking about informed
18 consent. Informed consent is required by the Common

1 Rule. The IRB looks at the materials developed by the
2 investigator to make sure that once consent is given, it
3 is informed. The IRB is responsible for examining the
4 design of the research and comparing that with the
5 informed consent materials to make certain that they are,
6 in fact, appropriate in terms of conveying content in a
7 way that people can understand and appropriate in terms
8 of conveying all of the kinds of content that the
9 volunteers who participate in the research should
10 receive.

11 In addition to that, the materials developed for
12 informed consent will go to EPA staff who will do the
13 same kind of review, and finally, will go through a
14 review by a Human Studies Review Board. So, with those
15 three layers of review, we're hoping that -- and from
16 very different perspectives, the perspective of the local
17 IRB, as well as EPA, who deals with pesticides and has a
18 full understanding of -- as best a -- as good an

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1 understanding of the potential risks involved as
2 possible, as well as the expertise brought by the HSRB
3 members, we hope that we've got a good shot at getting it
4 right.

5 MS. BRICKEY: Will the designers of the studies
6 be required to submit anything other than just the form
7 that they're going to use to get people to sign? Will
8 there be other materials involved? What other evidence
9 would be required?

10 UNIDENTIFIED MALE: In the proposed rule,
11 somebody proposing to conduct a new study would submit
12 the complete protocol. All of the informed consent
13 materials, both the information materials and the consent
14 materials, which are often done in different documents,
15 recruiting materials, advertising materials. The Common
16 Rule, itself, has one section which --

17 (End of Tape 1, Side B)

18 UNIDENTIFIED MALE: -- certain of those specific

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1 questions, such as exactly how has the risk been
2 minimized. IRBs are charged by the Common Rule with
3 finding that risks to subjects have been minimized. We
4 want an explicit discussion of risk minimization and so
5 forth. There's several other of the specific points. In
6 short, we expect to ask for a considerable amount of
7 information, certainly far more than a form, and we also
8 expect to require submission of evidence after the study
9 is completed that these design aspects were properly
10 carried out. Bill didn't mention it, but the staff and
11 the HSRB will be looking on the backside of the process
12 to make sure that what we reviewed and approved on the
13 front side is what actually happened and that the design
14 was properly carried out.

15 MS. BRICKEY: Second thing, quickly, because
16 this is important.

17 MS. LINDSAY: Okay, because now we've got lots
18 of -- you opened it up very well because now we've got

1 lots of cards.

2 MS. BRICKEY: So I get my say since I opened it
3 up.

4 (Laughter.)

5 MS. LINDSAY: That's good, but just remember
6 your neighbors.

7 MS. BRICKEY: In regard to your nearly drafted
8 exception, it appears to me that what you've done is
9 create a rebuttable presumption, but it goes the wrong
10 way. The people who have to show that these things
11 weren't done would be people that weren't involved in the
12 studies, and I don't see how that's ever going to happen.
13 The people who are bringing the study forward to get the
14 study accepted would not have to show anything. I mean,
15 do you see what I mean?

16 UNIDENTIFIED MALE: I understand exactly --

17 MS. BRICKEY: The burden of proof is reversed.

18 UNIDENTIFIED MALE: -- what you mean, but I

1 don't --

2 MS. BRICKEY: Thank you. You don't agree? Why
3 not?

4 UNIDENTIFIED MALE: With respect to new
5 studies --

6 MS. BRICKEY: No, we're talking about your
7 exception here for old studies.

8 UNIDENTIFIED MALE: All right, okay. Now we've
9 just shifted gears substantially because the earlier
10 discussion had to do with new studies, the proposal of
11 new studies and the review of the materials.

12 MS. BRICKEY: Right.

13 UNIDENTIFIED MALE: Now, if we're talking about
14 acceptance of old studies, it's a completely different
15 focus. The starting point is the realization that when a
16 study has been completed, there's not a whole lot we can
17 do one way or another to affect the conduct of the study.
18 It's been conducted. So, we have to decide what to do

1 with it.

2 Yes, there is a different burden of proof
3 between the two standards. This was discussed at
4 considerable length by the Academy in their report. It's
5 important, also, to recognize that there's a wide range
6 of old data. There is data germane to pesticide risk
7 assessment that goes back to the twenties that's on some
8 of the World War I war gases that is relevant to some
9 fumigants, for example. And this is the -- in many
10 cases, this is the only or the best available data about
11 the relevant assessment of the toxicity of those
12 materials. And those assessments are important today,
13 but it is irrational to expect people in the twenties to
14 have followed standards that were developed generations
15 later. It's also unreasonable to expect to be able to
16 track down those investigators.

17 So, we have to -- we tried to find a way to
18 accommodate the very, very wide range. In the case of

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1 more recent studies, our conduct has been when there
2 wasn't enough information to support a finding, we asked
3 for more good data and we've gotten it. But, you know,
4 we have the authority to do that. We can ask for
5 information.

6 MS. LINDSAY: Okay, Carolyn --

7 MS. BRICKEY: Okay --

8 MS. LINDSAY: -- I would like to let some other
9 people -- I'll come back to you. Would that be all
10 right?

11 MS. BRICKEY: Very well.

12 MS. LINDSAY: I'm also worried -- I see some
13 cards going down, and so, I'm --

14 MS. BRICKEY: They'll keep going down as long as
15 I talk probably.

16 MS. LINDSAY: Well, if you don't mind, I'd
17 actually like to let a few other people ask their
18 questions and then I'll come back to you. I'm going to

1 try to do it in the order that I think they appeared. If
2 I don't get it quite right, forgive me. But I think,
3 Erik, you would be next, then Amy Liebman, Jay Vroom, Bob
4 Rosenberg, Alan Lockwood and John Schell. So, Erik --
5 and remember which order I just said -- oh, and I skipped
6 Melody. So, it will be Jay Vroom -- I don't know, you're
7 going to come after John Schell, Melody, if that's okay.
8 Erik?

9 MR. OLSEN: Yeah, I guess I wanted to first
10 acknowledge that I think EPA has sort of jumped into an
11 anaconda pit on this issue. I mean, it's not an easy
12 issue, and recognizing that, there are going to be a lot
13 of difficult questions here. I wanted to just explore a
14 couple of questions. One is the rule appears to be
15 limited to studies that were intended to be submitted to
16 the agency. If I, for example, did a test on children or
17 pregnant women in Europe and submitted it to a foreign
18 regulator or submitted it to California DPR and that

1 foreign regulator or California DPR submitted it to EPA
2 for consideration under harmonization or some other
3 reason, would that be prohibited? Would that be covered
4 by this?

5 I guess what I'm going to is it seems to us, at
6 least, that the requirement that a study be intended to
7 be submitted to EPA -- and that's just one example, there
8 are plenty of others -- is problematic, and perhaps
9 creates a hurdle for the agency that you don't need to
10 create for yourselves. That the agency has plenary
11 authority under FIFRA and other laws to regulate any use
12 of a pesticide, including in research, and it would seem
13 to us, at least, that that requirement of intent is
14 difficult to impossible to determine in some cases and
15 unnecessary. So, I guess that's sort of a two-part
16 question on the intent issue, and I wanted to come back
17 to another question if I can.

18 UNIDENTIFIED MALE: I'll take the first shot,

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1 and Jim and Anne, feel free to add. Requirements as it
2 relates to new research apply to third party intentional
3 dosing studies for pesticides. That's the phrase that
4 we've been using and I've been using in the presentation
5 here. It's actually spelled out in some detail in the
6 Section 26-101(J), and there it says that research
7 conducted by any person who conducted such research,
8 intended to submit the results to EPA are actually the
9 people who are covered.

10 I think it is that particular provision that
11 Erik is zeroing in on and saying, does it have to be
12 limited only to people who intended to submit the data to
13 EPA or can it be -- why didn't EPA propose something
14 that's broader than that? And the answer is that we
15 understand our authority under FIFRA to be limited to the
16 regulation of certain people who are engaged in the
17 business of selling and distributing pesticides in the
18 United States, or developing data, and we think that we

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1 can regulate their development of data in connection with
2 that, and so, our authority defines the limits where we
3 can regulate the behavior of companies, individuals
4 engaged in research.

5 MS. LINDSAY: Jim?

6 MR. JONES: A little bit further on that. We've
7 had a number of discussions with some people who have
8 raised this issue. As Bill said, our understanding, our
9 belief about our statutory reach here is what drove us to
10 that conclusion. We've done a couple of things in the
11 rule to help make it clear that it's presumptive if
12 you're a pesticide manufacturer, no matter what you say,
13 we're going to infer your intent is to submit to the
14 Environmental Protection Agency. But we are open to and
15 have committed to actually having some dialogue around
16 does the statute constrain us in this way because that --
17 we are not intending to create any kind of a loophole
18 around this. We're just trying to put our -- put a reg

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1 out that is compliant with what we understand to be our
2 statutory reach.

3 MS. LINDSAY: There's actually something else
4 that I want to add, but I want to check with Bill to make
5 sure, though, that I'm also right as I'm doing it. So,
6 Bill, you can say, no, you're wrong, Anne, if I'm wrong.
7 But I also believe another piece of the proposal, Erik,
8 is if there were a study conducted that was not intended
9 to be submitted but nevertheless came to us for whatever
10 reason, we would be looking at that and considering it
11 using the same ethical standards that we would for
12 something that was clearly intended for submission to
13 EPA, so that if it comes to us, it gets judged -- if this
14 is newly conducted after the rule becomes final, we are
15 using what are the current standards, and this final rule
16 would, for us, be the current standards.

17 Am I right, Bill?

18 MR. JORDAN: Right. The provisions that I

1 talked about regarding the conduct of new research is
2 just that. It is the conduct of new research by
3 investigators who are third parties. Anne's talking
4 about the behavior of EPA in our capacity in the review
5 of data and there is no limitation whatsoever about the
6 applicability of the ethical standards. Those ethical
7 standards apply whether the study was generated with the
8 intent to support a registration or whether it was done
9 by an academic researcher in Japan and simply came to our
10 attention, and there was no reason -- no earthly reason
11 to think that that researcher had an intent to submit it
12 to EPA. We would still apply the same set of ethical
13 standards in judging whether or not it was acceptable.

14 MR. OLSEN: I think I understand what you're
15 saying, but what the rule says is there needs to be
16 substantial compliance with the standards and the
17 requirements of the rule. And that sort of brings me to
18 my second question. The preamble talks about substantial

1 compliance being sort of -- that if there's a trivial
2 administrative oversight, that that's not a problem. But
3 the rule, itself, doesn't speak to that, and I'm
4 wondering if the agency is considering being clearer
5 about what substantial compliance really means. That it
6 really means pretty much compliance with all the
7 requirements except if you initialed on the wrong page or
8 signed in the wrong place or something like that. Is
9 that what you're thinking?

10 MR. JORDAN: The proposal contains a discussion
11 of that particular phrase and refers to minor
12 administrative non-compliance. It cites a report by the
13 Food and Drug Administration. We've had conversations
14 with people who serve on IRBs and they say that almost no
15 study that comes through their review process meets every
16 single aspect of the Common Rule, that some problem is
17 identified for virtually every study. So, what we are
18 trying to get at is the notion that we want to make sure

1 that the people who are participating in the research are
2 treated ethically so that there will be substantive
3 compliance.

4 We've asked for public comment on it and we did
5 that because we recognize that the terms or the phrase
6 "substantial compliance" was not very exact. We hope the
7 public comments will give us a way to do something that's
8 a little more precise.

9 MR. OLSEN: Your public health exception
10 specifically allows consideration of studies on children
11 if there is a -- you described it as a narrow exception.
12 Would increasing crop yield be a public health exception?

13 MR. JORDAN: That certainly was not what we had
14 in mind when we wrote it.

15 MR. OLSEN: My last issue is on past studies. I
16 think it was John who mentioned some of the old phosgene
17 experiments, for example, from years ago or maybe some
18 other studies. My question is, what would you look to

1 for evaluating what the past standards were? Would you
2 be looking to the Nuremberg Code and Helsinki Declaration
3 and Common Rule or what are you evaluating in that
4 circumstance?

5 UNIDENTIFIED MALE: As the standard is stated in
6 proposed Section 602, we would be looking at standards
7 prevailing at the time the studies were conducted. None
8 of the standards that you just mentioned were developed.
9 The earliest was 1947. These war gas studies were done
10 in the twenties, some were done in the thirties.

11 MR. OLSEN: I'm only referring to, say, John,
12 past the 1940s.

13 UNIDENTIFIED MALE: We would, as the criterion
14 says, look to see what standards were prevailing at the
15 time of the study. Between 1947 and 1964, Nuremberg was
16 pretty much the only thing out there. 1964 was the first
17 edition of the Declaration of Helsinki. There were
18 significant revisions to the Declaration of Helsinki in

1 1975 and in 1983 and in 2000. The HHS Rules came out in
2 1971 as guidelines; in '74 as rules and so on. I mean,
3 there's a whole history of a gradual accretion and
4 refinement and maturation of prevailing standards.

5 MR. OLSEN: So, that's what you're talking
6 about? You're talking about --

7 UNIDENTIFIED MALE: That's what I'm talking
8 about.

9 MR. OLSEN: -- the gradual accretion of the
10 Helsinki Amendments that came in over time and the
11 Common Rule, once that was accepted, the HHS Rules that
12 came in and so on.

13 UNIDENTIFIED MALE: Also, I want to make it
14 clear that we're also talking about, in addition to the
15 Declaration of Helsinki, we're talking about other
16 international standards, the SIAM (phonetic) Standard,
17 the National Standards in the U.K. or various other
18 places where studies have been conducted.

1 MR. OLSEN: Thank you.

2 UNIDENTIFIED MALE: Prevailing studies when the
3 standards were done is what we're talking about.

4 MS. LINDSAY: Okay, Amy, thank you for your
5 patience.

6 MS. LIEBMAN: Thank you. You spend a lot of
7 time talking about pregnant women and children and
8 Carolyn brought up, you know, college students in terms
9 of, you know, a population that she was concerned about.
10 But there's a lot more vulnerable populations out there
11 than children and pregnant women. There's a lot of low
12 literate, non-English-speaking poor people who might be
13 very interested in getting some money, and I'm just
14 curious about what kinds of protections that we're
15 looking at and how we deal with other vulnerable
16 populations.

17 UNIDENTIFIED MALE: The core Common Rule,
18 Subpart A, directs IRBs to take particular care to ensure

1 that a proposed study provides adequately for the
2 protection of people in vulnerable populations. It
3 lists, among others, pregnant women and kids, but it also
4 mentions prisoners, it mentions people with reduced
5 mental capacity. I think it may be broader than prisons,
6 it may be institutionalized people. I've forgotten
7 exactly. But certainly there are a lot -- and it
8 specifically mentions people in reduced economic
9 circumstances.

10 There's a large body of literature and
11 interpretation in the guidance to IRBs that HHS has put
12 out about how to interpret the level of payment, for
13 example, whether that becomes an undue influence in
14 encouraging people to agree to participate in studies
15 which they might not otherwise participate in.

16 The Common Rule approach starts from the premise
17 that the subject populations are all potentially
18 vulnerable, and it's the responsibility of the

1 investigators to design something that incorporates risk
2 minimization, fair selection and those sorts of things,
3 and it's the further responsibility of the IRB to confirm
4 that those things have been done. And in the case of the
5 subparts applying to pregnant women and kids or the HHS
6 subpart for prisoners, that there's additional specific
7 guidance there that says IRBs are supposed to also think
8 about this and this and this and this and this specific
9 point. That's kind of the general approach.

10 MS. LIEBMAN: You guys just take an extra step
11 and you specifically mention women -- or pregnant women
12 and children in your proposed rule, correct, even though
13 there's all these other populations out there -- but you
14 don't mention them in your rule.

15 UNIDENTIFIED MALE: Well, we do. We mention one
16 other one, which is prisoners, and we said that because
17 the provisions are unsettled, generally, in the rest of
18 the Common Rule community, we're going to defer decision

1 on that.

2 UNIDENTIFIED MALE: But we're prohibiting
3 testing on those two sub-populations, we're not
4 prohibiting testing of people of reduced economic means
5 or people who don't speak English. John then talked
6 about the things that you need to do to ensure that they
7 can be properly informed and consent in a way that's
8 properly informed.

9 UNIDENTIFIED MALE: I just want to say something
10 that I hope most of you appreciate, but it bears
11 repeating and it bears pointing to, and that is that
12 there is an enormous body of work already in existence in
13 the area of human research ethics. It is not EPA's place
14 to step forward and unilaterally change that. We work
15 within a long history of development of understandings
16 about what it means to treat research participants
17 ethically.

18 So, when it comes to questions of vulnerable

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1 populations, there are, in fact, as John mentioned,
2 specific provisions in the Common Rule which we are
3 extending to third party research. There are specific
4 understandings about what people ought to do, what
5 investigators ought to do when dealing with members of
6 those populations, which we are adopting and embracing by
7 virtue of having extended the Common Rule there, and
8 which we will try to bring to bear through our role in
9 EPA and through the Human Studies Review Board, who will
10 all be people familiar with that long history.

11 So, rather than try to commit that material to
12 regulation, we are trying to align ourselves with that
13 existing body of understanding and ethical practice.

14 MS. LINDSAY: I want to underscore Bill's last
15 point here. I know for me one of the -- it's a learning
16 lesson that I've not completed yet. The phrase "Common
17 Rule" stands for an extraordinary amount of work in this
18 arena. And so, when we say the word it's very short, but

1 it's referring to a very large body of information and
2 every opportunity I have to interact with someone who
3 either has been involved in the design and conduct of a
4 study involving people or who have been on an IRB, my
5 eyes are opened as to what goes on when the process works
6 right. I know there are times when the process probably
7 doesn't work right.

8 But for those of you who may be like me with a
9 lesser experience of the Common Rule, it may sound like
10 there are lots of issues that are not being thought of.
11 But I actually think the Common Rule covers a very large
12 gamut of issues that aren't individually articulated.

13 Let me move on. I think, Jay, you got the
14 honors next, and I know there are two new cards that are
15 up. So, you'll come after Melody.

16 MR. VROOM: Thank you, Anne. I wanted to
17 commend the presentations that all of you have made,
18 beginning with your remarks about the grasp of ethics and

1 I'd argue that even before this issue started to take
2 shape in the FQPA process, now quite a few years ago,
3 that there's been an overlay of ethical considerations
4 that civil servants in the agency and elsewhere in the
5 Federal Government that have something to do with
6 pesticide regulation and pesticide registrants and the
7 user community have always applied. It is a cumulative
8 process and we're adding a lot to the body of knowledge
9 and I think, you know, the points that Bill made about
10 getting a common understanding about key terminology is
11 really important so that we're all, more and more,
12 speaking the same language represents a lot of very
13 important cumulative steps around getting final
14 resolution to a place that we've needed to be
15 collectively for a long time.

16 Specific to the concept of things that are
17 already on the books, not only at EPA but also in other
18 agencies, the NAS report did refer to the existence of

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1 the Office of Human Research Protections at FDA and I
2 wonder if Dr. Troxell could comment on this. Was there a
3 consideration, though, Bill and John, to -- actually in
4 the new EPA rule, contracting by way of a memorandum of
5 agreement, this responsibility to this group that already
6 has momentum and experience and operational processes in
7 place at FDA? And if that was considered and rejected
8 for certain reasons, is it possible to take some of the
9 operational processes that the Office of Human Research
10 Protections at FDA had in place that would -- so you
11 don't have to reinvent those wheels and, in particular,
12 since the vast majority of the studies that pesticide
13 registrants would do going forward, as they have in the
14 past, will be done by contract research firms that are
15 also doing pharmaceutical tests submitted to FDA? It
16 seems like there would be a lot of sense around having
17 the same kind of process design within whatever EPA is
18 doing in the Office of Human Studies and Review Board

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1 that FDA applies.

2 MR. JORDAN: The Office of Human Research
3 Protections is located in the Secretary's Office at the
4 Department of Health and Human Services, and it's
5 responsible for overseeing all of the issues relating to
6 ethical treatment of participants in human research
7 across HHS, including FDA and NIH and NI -- CEC and on
8 and on. But they also serve as a place where, across the
9 government, they are the leaders and we have turned to
10 them repeatedly and worked with them in the development
11 of this proposal and expect to continue to work with them
12 as we move forward in the final rule and as we try to
13 implement it.

14 I think your question focused primarily on could
15 we somehow hand off to OHRP or somebody at HHS the review
16 functions related to Human Studies Review Board? That's
17 one of the details regarding the functioning of the Human
18 Studies Review Board that we're still discussing. I

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1 don't think that we have either decided that's a good
2 idea or a bad idea. But it's -- it's a possibility that
3 we're -- we would look at.

4 MR. CARLY: Let me just add that an awful lot of
5 what OHRP does is compile and disseminate the guidance
6 material for IRBs and that kind of stuff. They are the
7 clearinghouse for this huge body of information and law
8 that's secreted over the years that Anne and Bill were
9 talking about. That is not a function that overlaps with
10 what we've been talking about in this rule.

11 Among the things that OHRP also does not do is
12 they do not make study-specific acceptability judgments
13 in behalf of any of the HHS agencies, including FDA. So,
14 that kind of decision remains a responsibility internal
15 to all the participating agencies and we would have to do
16 that ourselves.

17 MS. LINDSAY: Okay, thanks, John. Bob, I think
18 you're up next if I'm remembering correct.

1 MR. ROSENBERG: Yeah. And you know what, my
2 educational experience is in political science, which is,
3 of course, not really science at all. So, I have like a
4 -- I mean, a dumb question but one that would help me
5 kind of understand the issue better. Why is this data
6 valuable? Does anyone understand the relative -- or can
7 they explain the relative value of human versus non-human
8 data? I mean, is it more reliable, more valuable? I
9 mean, what's -- you know, how do you even think of it?

10 MR. JORDAN: Okay.

11 UNIDENTIFIED MALE: There's not a clamor of
12 people trying to reach the microphone.

13 **(Laughter.)**

14 MR. JORDAN: I'll take a shot at it. The
15 National Academy of Sciences report discusses why human
16 data might -- I underline the word "might" -- provide
17 information that's not available from research with
18 animal models or other kinds of research. And it has to

1 do with a couple of different things.

2 One is that sometimes humans and animals do not
3 respond in the same way to exposure to a substance. And
4 when there is a difference, that difference may matter in
5 terms of what kind of regulatory decision is made. There
6 are some notable examples where humans are more sensitive
7 to the toxic effects of substances than animals are. So,
8 that could lead to a more stringent regulatory position
9 with regard to what's acceptable.

10 Secondly, there are kinds of effects that animal
11 models simply aren't capable of picking up, even though
12 the animal might be experiencing those effects. A
13 headache, for example, is hard to diagnose in a
14 laboratory animal, and there are other kinds of things
15 that somebody who knows more about animal testing could
16 probably list off a dozen or so types of effects. So,
17 those are a couple of reasons.

18 I think, to be fair, there are folks who want to

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1 do testing with humans in order to demonstrate that
2 humans are less sensitive than animals, and therefore,
3 exposure to the material at a given level would be safer
4 than you would think otherwise from an animal study.

5 MS. LINDSAY: Okay. Alan, thank you for
6 patiently waiting.

7 DR. LOCKWOOD: Thank you. I think if I were to
8 extend the metaphor that Erik Olsen made, I wouldn't have
9 said jumping into a pit of anacondas. I think maybe
10 cobras or some other highly poisonous snake might be a
11 more appropriate analogy.

12 First a comment and then two specific questions.
13 I think that if the proposed rule actually did what was
14 indicated in the presentation, there would not have been
15 the intense scrutiny and exceptions taken to the proposed
16 rule by people in the media, letters to the editor and
17 various conversations. I think it's fair to say that --
18 and I think that this was one of the things that you said

1 was sort of off-limits for specific questions, but the
2 number of exceptions that would appear to allow inclusion
3 of pregnant women and children into various testing
4 regimens.

5 The two specific questions that I would have,
6 one centers on the prevailing standard, noting that
7 Nuremberg came in the forties and the other standards
8 that were mentioned came thereafter. But the Hippocratic
9 Oath and the first Do No Harm principle of the
10 Hippocratic Oath is substantially older than any of
11 those. Is that one of the standards that will be taken
12 into account by the agency?

13 And then a more specific question about the
14 provision in the proposed rule that would allow the
15 administrator to waive all or parts of the rule, if you
16 could comment on that. Thank you.

17 MS. LINDSAY: Can I just say one thing before we
18 actually let the experts answer your questions? First of

1 all, I may have been confusing you. The only things we
2 don't want to talk about are the specific chemical
3 studies that might fall within the prohibition defined in
4 the Appropriations Act. So, anything about the rule,
5 itself, is a legitimate field for discussion at this
6 session. So, you don't need to feel like you can't talk
7 about some of those other parts.

8 The other thing I wanted to say, I actually --
9 my family, many members -- I'm the outlier. Many members
10 of my family are physicians, and so, I actually am very
11 pleased to hear you refer to the Hippocratic Oath. It is
12 actually what I say to myself when I'm engaged in these
13 discussions and looking at the issues, whether they might
14 be around individual chemicals or the rule itself. I
15 think it perfectly and very succinctly captures what we
16 all need to keep in mind when we're trying to sort our
17 way through or step through the cobra pit, if that's how
18 you'd like to characterize it.

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1 So, Bill?

2 MR. JORDAN: Why don't you do it? I'll let John
3 Carly answer the question about the Hippocratic Oath.
4 Dr. Lockwood's question about authority to waive
5 requirements is one where perhaps the regulation is not
6 as clear as it should be, but I will take a second or two
7 and explain what I think he is referring to.

8 In the proposed rule in Section 26-401(A)(2), it
9 says that the administrator may waive applicability of
10 some or all of the requirements of these regulations for
11 research of this type, which refers back to research
12 conducted or supported by EPA outside the United States.
13 It contains an erroneous cross reference. The
14 appropriate cross reference should be to part of the
15 Common Rule which says 26-101(H) and -- okay. So, now
16 that I've done all of the kind of legalistic connect the
17 dots part, let me tell you what that's all about.

18 The Common Rule, which has been in place for

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1 nearly 15 years, says, in effect, sometimes research by
2 the government will be conducted outside of the United
3 States, and when that happens, it will need to comply
4 with the ethical standards of the country in which that
5 research is taking place. And in recognition of the fact
6 that other countries have different schemes that may not
7 align completely with the scheme that is set up by the
8 United States in the Common Rule, it is permissible for
9 the head of the agency to allow a waiver of the Common
10 Rule so long as the provisions of the host country for
11 the research are -- provide at least as much protection,
12 are at least as protective. So, that's the reference
13 back to 26-101(H).

14 And 401(A)(2) says you can do that for studies
15 involving children as well. Now, that has nothing to do
16 -- nothing to do with the prohibition against doing
17 intentional dosing studies with children. It does not
18 authorize any exception to that prohibition.

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1 The last thing to say is that the language that
2 we have here is verbatim the language that appears in the
3 Health and Human Services regulation providing additional
4 protection of children for subjects in research and it
5 has been in force for over 20 years. And I have not
6 heard that that provision -- I've asked folks. I've
7 asked whether that provision has led to some sort of
8 creation for loopholes for HHS to somehow vitiate the
9 protections for children and I've heard no one say that
10 they've ever heard the slightest suggestion that that
11 would be abused in that manner, and we certainly don't
12 intend it that way.

13 Now, the -- one more thing. Dr. Lockwood
14 referred to reports in the press that dispute the
15 assertions made in our presentation today. I won't go
16 into the details other than to say I do not agree that
17 EPA has put forward a proposal that contains the kinds of
18 loopholes that have been reported in the press, and I

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1 find those mischaracterizations very troubling and ones
2 that, frankly, have gotten in the way of the quality of
3 the debate about things that I think are important to
4 talk about, and I'd be happy to continue that
5 conversation with anyone at another time.

6 MR. CARLY: Thank you, Bill. Tough act to
7 follow. With respect to the Hippocratic Oath and the
8 more general question of what sorts of standards might be
9 deemed to have been prevailing at sometime before the
10 Nuremberg Code was developed. The criterion in which the
11 reference to prevailing standards occurs begins by saying
12 that -- by referring to the possibility that something
13 might be fundamentally unethical. And then there's a
14 parenthetical defining what that might mean. For
15 example, intended to inflict harm. That's the flip side
16 of the Hippocratic Principle of doing no harm.

17 If there's any evidence that a study was
18 intended to harm the participants, that would tip it into

1 the fundamentally unethical bucket, which is one --
2 that's the first of the pair of criteria there that says
3 if it's fundamentally unethical or significantly
4 deficient with respect to prevailing standards. So, in
5 my sense, the Hippocratic Oath is embedded in that first
6 part, the fundamentally unethical. So, it would -- it
7 doesn't quite enter the prevailing standard argument, but
8 it is problematic to figure out what standards people
9 thought they were complying with.

10 There are some documents from the early 20th
11 Century, in fact, from the late 19th Century, addressing
12 research ethics. They are few and far between, and the
13 extent to which they prevailed is a matter for academic
14 argument. It's tough to deal with those really old
15 studies. But we also have to first find them to be
16 scientifically meritorious in today's terms and directly
17 relevant to the issues that we're addressing. So, the
18 issue doesn't arise very often.

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1 MS. LINDSAY: Okay. Just a matter of timing and
2 sequence. I'm remembering my original -- and by my
3 count, there's five new cards up after my original
4 sequence. It's quarter of 12:00 and you've all been
5 extraordinarily patient sitting here all morning long.
6 I'd like to finish it out by noontime if we can, but I
7 also don't want to cut anybody short who needs to raise
8 an issue or question. I'm mindful of the promise I made
9 Carolyn Brickey, that she gets the closure comment. So,
10 just to reassure folks that I'm noticing the cards, but
11 I'm also trying to keep an eye on the time because I
12 don't know that you can all sit here a whole lot longer
13 without being given an opportunity for a break.

14 So, with that, John, I think you are next in my
15 order.

16 MR. SCHELL: Thanks, Anne. This is just real
17 quick and Jay brought it up previously. The FDA has a
18 lot of history with dealing with working with humans in

1 clinical trials. Bill, you made a statement earlier that
2 with this rule, you're sort of blazing new ground. Are
3 these provisions substantively different than what the
4 FDA uses in its Phase II clinical trials? And if so,
5 why?

6 MR. JORDAN: The vast majority of the proposed
7 regulation is taken from existing regulations that have
8 been promulgated by either HHS or the Food and Drug
9 Administration. The new material, the place where we are
10 blazing new ground is the last subpart, which contains
11 the ethical standards for judging whether or not to rely
12 on the results of human research in our decision-making
13 at EPA. And we have worked with FDA as well, I should
14 add, not only OHRP.

15 MR. SCHELL: And one more quick question and it
16 has to do with -- and Erik talked about this earlier, too
17 -- the submission of data that's collected elsewhere.
18 There's likely to be a real swell of information being

1 generated by the Reach program over in the EU. Are you
2 familiar with how close their standards are to the Common
3 Rule? We're doing a pharmaco-kinetic study and we're
4 being held to some very high standards, just how
5 applicable would those data be if we wanted to submit
6 them over here?

7 MR. CARLY: There have been several studies done
8 that took the contemporary versions of the Declaration of
9 Helsinki and the Common Rule and the SIAM's guidance and
10 various other standards and kind of stacked them up in a
11 table and concluded that in -- if you look at what they
12 try to do in substance, they're very close. They differ
13 in procedural detail and in the level of detail. The
14 Declaration of Helsinki, for example, is more on the side
15 of a declaration of principles than it is an operational
16 guidebook, whereas the SIAM's guidance goes into a whole
17 lot of procedural detail.

18 So, if you look at these documents and try to

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1 find differences, there are lots of small points of
2 incongruency. If you look at these documents and compare
3 them in terms of the substance of what they're trying to
4 do, they rest on the same fundamental principles. They
5 may take a somewhat different approach, but they're
6 basically trying to do the same thing.

7 As a matter of practice, EPA and other agencies
8 have, in the past, generally concluded that a study that
9 meets a contemporary ethical standard in the EU is -- you
10 know, it's not an automatic thing, it's not a free pass.
11 But the presumption is that something that is highly
12 ethical in Western Europe is going to be considered
13 highly ethical in the U.S. I mean, there's a lot of
14 interchange and sharing of data. It's not going to be a
15 problem.

16 MR. SCHELL: So, the term -- when you say
17 complies with the CR, you'll know it when you see it, you
18 can't --

1 MR. CARLY: Yeah. But remember that the Common
2 Rule incorporates this 101(H) Section that says here's
3 what you do with data that's actually run in other
4 countries. So, the provision for assessing the
5 comparability of international standards to the Common
6 Rule is built into the Common Rule itself. You don't
7 need to do a separate thing that allows for that
8 crosswalk.

9 MS. LINDSAY: Okay, Melody, you end sequence
10 number one.

11 DR. KAWAMOTO: Okay, thanks. I'm asking about
12 the HSRB members would be free of any conflicts of
13 interest. I realize that conflicts of interest has a
14 pretty specific definition, so I'd like you to clarify it
15 and to give examples of who would be eligible, because
16 you did mention two groups that wouldn't be eligible.
17 And then after that, the second question is, what would
18 be the scope of their authority? Would they have the

1 final say, especially with regard to exceptions?

2 MR. JORDAN: The Human Studies Review Board
3 members would advise EPA. They would not make the
4 decisions. EPA, under the statutory authorities that we
5 administer, is the final place where decisions are made.
6 With regard to the conflict of interest, there is a
7 federal law that prescribes conflict of interest
8 requirements for special government employees. If you're
9 familiar at all with the FIFRA Scientific Advisory Panel
10 operations, that would be the simplest way to illustrate
11 how this set of requirements would apply because that's
12 what they follow in selecting members to perform peer
13 review of scientific research and guidelines and risk
14 assessments that we've developed here at EPA. Generally,
15 we tend to get people who are in government or academia
16 as members of the Scientific Advisory Panel, and I would
17 expect those two places to be sources that we would turn
18 to again.

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1 DR. KAWAMOTO: Okay. I was also wondering if,
2 since some of this isn't scientific, other types of
3 experts would be involved? For example, maybe religious
4 or ethical, people who are dealing with it in academia or
5 in the public.

6 MR. JORDAN: Right. The National Academy of
7 Sciences' recommendation regarding the Human Studies
8 Review Board identified three disciplines that they
9 thought should be represented as part of the Human
10 Studies Review Board, expertise in research ethics being
11 one of them, biostatistics being a second and --

12 UNIDENTIFIED MALE: Human toxicology.

13 MR. JORDAN: -- human toxicology. We would
14 expect those disciplines to be among the ones, although
15 not necessarily the only ones. The question of whether
16 to bring in people who are sort of representative of
17 community values, for example, from a religious group or
18 some other patient representative group, for example, the

1 patient advocacy group, is something that's a detail we
2 haven't discussed. But, you know, I think it has a lot
3 of merit.

4 MS. LINDSAY: Okay, my second sequence, which I
5 think is roughly in the correct order that the cards came
6 up, would start with John Kepner down at the end of the
7 table, Amy Brown, Steve Kellner, Michael Fry, Dr.
8 Roberts, and if no new cards come up after Dr. Roberts,
9 we would end with Carolyn.

10 MR. KEPNER: Yeah, just two parts. One's just a
11 clarification from the answer from Amy Liebman's
12 question. Would there be -- you mentioned that, you
13 know, for ensuring that folks that are low income, low
14 mental capacity, you know, prisoners, et cetera, that
15 they would -- you know, they have to be properly
16 informed. But is there any protocol to avoid or prohibit
17 like a study that would be just made up of folks from
18 those communities or is it just that they have to be

1 properly informed?

2 MR. CARLY: I think this -- first off, this
3 certainly isn't covered by the proposed rule
4 specifically. Secondly, part of this -- one of the two
5 parallel towers of this edifice of accumulated
6 information and the history of oversight of ethics is the
7 whole business of informed consent. There's an immense
8 amount of information. There's guidance all over the
9 OHRP website to IRBs, about how to deal with informed
10 consent in special circumstances, including some of the
11 ones that you alluded to, but a much longer list of cases
12 that have turned up where there were kind of special
13 concerns or issues. People started thinking about it and
14 oh, goodness, and a case like that, how do you really
15 make sense out of the principle of respect for persons
16 and autonomous consent?

17 Rather than address the specifics, I'd encourage
18 you to look at that body of stuff that applies to any

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1 Common Rule work, and it's available routinely to all
2 IRBs. And by the way, OHRP requires training of IRBs in
3 these and related matters in order to maintain their
4 registration and certification as approved IRBs.

5 MR. KEPNER: Okay. And just one --

6 MR. JORDAN: Before you ask your next question,
7 I want to disagree slightly with John in that I think the
8 regulation that we proposed does address the question in
9 that it extends the Common Rule to third party research,
10 and the Common Rule specifically provides, in 26-111,
11 Paragraph A(3), that selection of subjects is equitable.
12 And then there's a discussion of what equitable means,
13 and it would, in my view, under this language, not be
14 equitable to target a population that was low income or
15 exclusively mentally limited in terms of their ability to
16 understand something.

17 MR. KEPNER: Okay, thanks. The other thing
18 is, you mentioned that folks would have to submit

1 recruiting --

2 (End of Tape 2, Side A)

3 MR. KEPNER: -- ag study or something like that.
4 So, are they required to say it's a pesticide dosing
5 study or could they just say you're going to -- you know,
6 they'll do this chemical, here's the scientific name, you
7 know, that's about it?

8 MR. CARLY: It has long been -- I'm not sure if
9 it's quite correct to say required. It has long been
10 common practice in a great many areas for IRBs to review
11 recruiting materials, and in a lot of cases, particularly
12 in university settings, these IRBs are -- they have books
13 of policy guidance and things, and they probably specify,
14 in at least some cases, what those things are. But
15 there's no regulation that says here's what you're
16 permitted to do or what size type you're permitted to use
17 in recruiting.

18 I've got to say, as far as I can tell, there are

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1 a fair number of cases where recruiting materials are not
2 addressed by the IRB, they're not submitted to the IRBs.
3 That would change under this rule for the covered studies
4 where we would specify that that stuff and the IRB's
5 comments on it would have to be submitted to us. Then
6 the after the fact stuff, we would expect to see the
7 actual recruiting posters that were used, make sure they
8 reflected any comments that came from the HSRB or the IRB
9 or whatever.

10 MS. LINDSAY: Okay, Amy? Amy Brown?

11 MS. BROWN: Well, I'm not sure I want to open my
12 mouth anymore because I am one of those who actually does
13 do observational studies with my students, not
14 intentional dosing studies, but have done a number of
15 them over the years. I've been thinking about the IRBs
16 that I work with and they all, very rigorously, review my
17 protocol and my informational materials, my -- what I'm
18 going to say to the people, all of the recruiting

1 materials. But I don't believe I've ever been asked if
2 all of my subjects can read and understand the language
3 that the materials are printed in.

4 Now, because I've known my subjects and I know
5 that they can do that, that's never been an issue, except
6 in one case when I had a subject who spoke primarily
7 Spanish and I just opted him out of the study. But I
8 suppose it would be better -- it would be easy if you're
9 running, say, a farmworker study. The IRB is going to
10 think about it and say, gee, we need to make sure that
11 they can read and understand the materials. But they
12 don't typically ask me if my people in a campground or my
13 pesticide applicators all are literate and all actually
14 read English.

15 So, I wonder if there can -- there are certainly
16 -- for my IRB, there are definite pieces of information
17 that I must provide and certain wordings and certain
18 things -- a whole huge list of things they require. I

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1 wonder if it could be a question that could be part of
2 the Human Subjects Review Board. You know, I'll take it
3 back to my IRB and suggest that they do this routinely,
4 but ask if people who speak other languages can actually
5 understand these materials, that you have to somehow
6 certify that.

7 MR. CARLY: It's already part of the Common
8 Rule, that IRBs are supposed to satisfy themselves that
9 the informed consent material is likely to be understood.
10 It has to be written in -- I've forgotten the precise
11 language -- understandable language. And there's a whole
12 body of literature about whether that means a sixth grade
13 level or an eighth grade level or, you know, a graduate
14 level. And in criticisms of things, some people say, oh,
15 this is too sketchy, it's not complete, and then they
16 look at another one and they say, oh, this is too
17 complete and confusing, it's not brief enough. There's
18 somewhere in there that the IRB picks on any given study.

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1 But they're supposed to be thinking about that. It would
2 not be new.

3 MS. BROWN: Absolutely. They think about the
4 level of the language.

5 MR. CARLY: Yeah.

6 MS. BROWN: And the technical level of the
7 language. They don't want hype.

8 MR. CARLY: There's also --

9 MS. BROWN: Whether they've -- they've never
10 asked me if my people can (inaudible).

11 MR. CARLY: There's a lot of recent (inaudible)
12 coming out of OHRP and elsewhere that asks investigators
13 to explore ways to confirm understanding. I was reading
14 a couple of articles just recently about ways to do that,
15 different ways of getting people like to say back in
16 their own words what you've just told them kind of thing.

17 MS. BROWN: There are good ways. I'm just
18 suggesting that since EPA is going to establish an HRSB

1 -- HSRB?

2 MS. LINDSAY: Yes, HSRB.

3 MS. BROWN: That that be really specifically
4 included -- for any study.

5 MS. LINDSAY: And, you know, Amy, I was going to
6 say, I think you're offering some good practical
7 experience and insight where there are opportunities for
8 improvement. When the HSRB gets up and running, we
9 actually expect that one of the things that will happen
10 is that there's this kind of practical experience that
11 will get more broadly --

12 MR. CARLY: Best practices guidance.

13 MS. LINDSAY: -- disseminated. So, it's a good
14 -- I really like your suggestion.

15 Steve?

16 MR. KELLNER: A real quick one. With respect to
17 the HSRE, is there a turn-around time by which the review
18 must be given back to the agency?

1 MR. JORDAN: The proposed regulation does not
2 have a turn-around time. We did ask for public comment
3 on it, recognizing, as somebody said earlier today, that
4 predictability is an important benefit for people who are
5 dealing with the agency.

6 MR. KELLNER: Thank you.

7 MS. LINDSAY: Okay. Michael, you're next.

8 MR. FRY: Thank you very much for your
9 explanation this morning. I think the final rule is
10 going to reflect a lot of the questions here. But you
11 did bring up just the appearance to me of a possible
12 loophole when you were giving your definitions of first,
13 second and third parties and then, in your description of
14 the prohibitions on intentional dosing studies with third
15 parties. When you mentioned that the prohibition applies
16 to regulated third parties and that not all third parties
17 are going to be regulated in this, what classes of third
18 parties are not going to be regulated and how does this

1 regulation or non-regulation of third parties apply to
2 your acceptance of data from, say, oversees?

3 MR. JORDAN: Okay. This is -- your question is
4 a replay of the question that Erik Olsen asked and it's
5 been one of the challenges for us to try to communicate
6 clearly about. The prohibition applies to persons who
7 are conducting new studies that they intend to submit to
8 EPA under FIFRA, the pesticide law or the Food, Drug and
9 Cosmetic Act, the provisions that relate to tolerance
10 setting. The reason that we voted that way is because we
11 think that's the extent of our legal authority. We're
12 happy to have people send us comments saying, no, you may
13 actually have a broader legal authority. But we can't
14 prohibit things. We can't reach out and effect people
15 who are beyond our legal authority.

16 So, that's -- to the extent you call that a
17 loophole, it's not a loophole of our choosing. We
18 believe it's a loophole of Congress' choosing.

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1 Now, that has to do with what investigators are
2 allowed to do with regard to research, according to EPA.
3 We're telling the investigators, don't do this kind of
4 study. Wholly apart from that is what we are telling
5 ourselves we will do when we get the results of completed
6 studies. There is no limitation whatsoever. We apply
7 these ethical standards to all studies that we will be
8 reviewing. That standard is the Common Rule for studies
9 initiated after the effective date of the rule. Does
10 that answer your question?

11 MR. FRY: Yeah.

12 MS. LINDSAY: Okay, Dr. Roberts?

13 DR. ROBERTS: I think I'd like to preface by
14 saying, as a pediatrician, I certainly agree with not
15 intentionally dosing children. But my question deals
16 really with the fact that, in some situations, we have
17 more of an absence of data on children's exposures. And
18 so, my question would be if there's -- in the event of

1 data -- lack of data on children, but there was a study
2 done on adults, how would EPA then determine exposure
3 limits in children? Would it be the same exposure levels
4 as an adults or would there be some type of additional
5 protective factor since children are physiologically
6 different?

7 MR. JORDAN: The short answer is that in
8 preparing a risk assessment for the effects of a
9 pesticide on human health, we have a very large database,
10 primarily from animal toxicology studies, that informs
11 our understanding of the potential risks to humans. That
12 database includes testing of animals at different life
13 stages so that we can evaluate whether or not there are
14 differences in susceptibility between the young and the
15 old, or mature adult animals. We also take into account
16 whatever information we might have from accidents and
17 incident reports, but that, I would say, is a less
18 significant factor in understanding and appreciating the

1 differences and hazards for adults and children. That
2 deals with the hazards side of the risk assessment.

3 The other piece of the risk assessment has to do
4 with exposure, and there, we have a huge amount of
5 information about sources of exposure that children could
6 have, and the databases that we use captures the
7 differences in exposure attributable to the fact that
8 children have a different surface area to body weight
9 ratio, have a different food consumption to body weight
10 ratio, have different activity patterns that cause them
11 to be in places where pesticides might be used more often
12 or with greater frequency. They engage in behaviors like
13 sucking their fingers that would -- you don't see me
14 doing except toward the end of the day.

15 (Laughter.)

16 MS. LINDSAY: Okay. And I guess, Larry, you
17 just couldn't resist the opportunity.

18 MR. ELWORTH: A quick procedural question. When

1 comments are made in the PPDC, in order for you to be
2 able to consider them in the rulemaking, they still need
3 to be made in formal comment, is that correct?

4 MS. LINDSAY: Yes, they need to be submitted to
5 the docket.

6 MR. ELWORTH: Okay, good, good. Because there
7 were a couple comments made. I'm glad you're considering
8 this rulemaking because I want to make sure people --

9 MS. LINDSAY: I mean, I -- just to say,
10 obviously, for me, everything that people have said, I
11 hope to incorporate in my thinking and to use as wisely
12 as I'm capable of. But the specific consideration, you
13 have to have it in the docket.

14 So, Larry's going to put his card down now that
15 he's asked his procedural question. Carolyn, did you
16 have something you wanted to close this out with?

17 MS. BRICKEY: Yeah, I have a couple of things.
18 First of all, with regard to the exceptions for old

1 studies, what I was trying to point out is that given the
2 fact that we had a moratorium on the use of old studies
3 for several years, it would be logical and reasonable to
4 have a presumption that those studies would not be used.
5 Yet, the language incorporated in the rule reverses the
6 presumption and there's no one out there who's going to
7 step forward with clear evidence that these studies were
8 fundamentally unethical because there's, in most cases,
9 not enough information to do that. You might look at the
10 surface value or the facts about the study and conclude
11 they were unethical, but they probably wouldn't be
12 fundamentally unethical. I think that probably falls
13 under the shock the court kind of standard.

14 As to significant deficiencies, a number of
15 these studies were conducted at a time when there was
16 very little substantive rule requirements out there. So,
17 the ones I know about, I can't think of any of them that
18 are going to be rejected under this standard, and that is

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1 a concern that I have.

2 Secondly, as to the comment that Bill made about
3 the fact that vulnerable populations can be taken into
4 account, I thought that was incredibly important, and I
5 would urge you to incorporate that into the rule, because
6 I think the more those fundamental significant points can
7 be incorporated, the better the standard is going to be
8 and the better the rule is going to be. I realize you
9 can't incorporate everything and I realize that this new
10 board you're creating will probably have a lot of those
11 issues to be addressed at that level. But I believe this
12 is fundamentally important and ought to be part of the
13 rule.

14 With all due respect to the folks who are
15 experts on the history of these rules, they may have a
16 long and glorious history, but we have some equally bad
17 history in the way human testing has been conducted in
18 the past. So, we have to look at that very carefully and

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1 make sure that what we're doing on the ground is done
2 right.

3 MS. LINDSAY: Okay, thank you. I think that was
4 a worthy close-out statement and I appreciate you doing
5 that for us.

6 I want to take just one more minute because I
7 know you're anxious, and I think Jim needs to talk just a
8 little bit about a revised schedule for the rest of the
9 day, but speaking, first of all, just on behalf of
10 myself, I do really want to thank each and every one of
11 you for the questions, the observations, the suggestions
12 that you've made. I know that it will have a very
13 significant impact on my participation in the agency
14 process to develop a final rule. I'm very impressed with
15 the seriousness with which all of you take the topic. It
16 makes me feel good about being a civil servant.

17 I hope we have been able to do the same sort of
18 service for you in our presentations and our answers as I

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1 think you've done for us. With that, let me turn it over
2 to Jim.

3 MR. JONES: Thanks, Anne. Thanks, John.
4 Thanks, Bill. I would just like to add I'm not someone
5 who's afraid or shies away from controversy. It's
6 something I do in my job every day. I would like to say
7 that I think that was the most useful dialogue I've seen
8 around this controversial topic in the six years or so
9 that I've been a participant in such a conversation. I
10 want to thank you all for that.

11 We've had to make some adjustments to the
12 schedule. As I say to my team in both old and new
13 chemicals, it's important to be on time, it's more
14 important to get it right. So, we extended both of the
15 topics this morning because I think it was important to
16 hear what you all had to say and advice to us. So, we
17 did make that adjustment.

18 What we're going to do is take lunch right now.

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1 If folks could be back at 1:10, and we have shortened the
2 -- to the strategic plan update to just 15 minutes. So,
3 when we get back, Marty Monell is going to give us a 15-
4 minute update on where the agency is on that. And then I
5 understand we may be able to pick up a little time in one
6 of the topics in the afternoon. If not, we will just go
7 over a little bit to make sure we have enough opportunity
8 for all of you to give us some more good advice.

9 So, I will see you all back here in one hour.

10 Thanks very much.

11 **(Whereupon, a luncheon recess was taken.)**

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AFTERNOON SESSION

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MR. JONES: As I mentioned before, we broke for lunch. We've had to make a couple of adjustments to the agenda. I do very much appreciate the robustness of the dialogue this morning, actually in both of the sessions. We very appreciate it. We really don't mind so much having to maneuver the agenda around to accommodate that.

So, what we're going to do this afternoon is

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1 we're going to start with an abbreviated version of the
2 preview of the EPA strategic plan, which Marty's going to
3 do right now. And then we'll move into the pesticide
4 performance measures discussion. Let me just preface
5 Marty's presentation, the agency's strategic plan is what
6 Marty's going to be talking about, and the agency does
7 create -- it's a revision to an existing strategic plan
8 that's been in place for a number of years. We're
9 getting into the public participation process in the not
10 too distant future, and it just is important for -- what
11 may appear to many to be a bureaucratic exercise, though,
12 for people to be heard.

13 So, one of our messages around this is simply
14 that it's something worth paying attention to. It isn't
15 just a bureaucratic exercise. It actually is used by the
16 agency in evaluating performance. There is a trickle
17 down effect that's very meaningful to us in the pesticide
18 program and for all the other programs at EPA. So,

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1 realizing that not everybody is here yet, but time's
2 short. We need to get started.

3 Marty?

4 MS. MONELL: Okay. As Jim said, this session is
5 going to focus on EPA's strategic plan revisions, which
6 we have just begun to become engaged upon. I thought I
7 would start by laying out what the National Pesticide
8 Program's goal is. This is not a specific goal within
9 the EPA strategic plan. This is our programmatic goal.
10 It's to protect public health and the environment by
11 ensuring pesticides and alternatives are safe and
12 available for a healthy America. Pretty good to capture
13 all of the various kinds of issues and concerns that we
14 have in our program.

15 GPRA, the Government Performance and Results
16 Act, basically mandated that agencies update their
17 strategic plans every three years. EPA's last revision
18 was in 2003. We are now starting in 2006 on our next

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1 endeavor. Although it's a five-year plan, we do have to
2 revise it and look at it, at least, every three years for
3 possible revisions.

4 It's very, very fast-paced. By the way, this
5 presentation will be available on our website, so
6 although I'm going to rapidly go through it, if you want
7 to focus in on any particular items, it will be available
8 on the PPDC website.

9 The important changes of this process and across
10 EPA is the focus on stakeholder involvement. I think the
11 agency learned from its experience in 2003 that it
12 engaged in a limited amount of stakeholder involvement,
13 really reaching out to every possible concerned party to
14 provide us feedback and input into the strategic planning
15 process. We here in the Pesticide Program, I think in
16 particular, we're a little short-changed because our
17 stakeholders in the states and regions aren't necessarily
18 those which were engaged by the rest of the agency in

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1 terms of getting feedback from states and other
2 stakeholders.

3 There have been goal teams formed and they are
4 led by two co-national program managers, Susie Hazen, our
5 Acting AA, is one of them, and Al McFarland from ORD, the
6 Office of Research and Development, is the other co-lead
7 -- excuse me, it's Jim McFarland, I'm confusing names.
8 Then we have several other offices that are involved,
9 including a regional office as a co-lead, Region VII,
10 who's represented at the PPDC today, is one of the co-
11 leads for this goal.

12 What you see on your screen now are the five
13 goals for EPA basically laid out by media. Although our
14 goal, Goal 4, has a lot of cross-cutting issues and
15 cross-media involvement. So, for instance, we have the
16 Brownfields Program from OSWER (phonetic) in Goal 4 and
17 the rest of OSWER is in Goal 3. We have a tiny little
18 piece of water activity in Goal 4, as well as OECA and

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1 international activity. So, we're sort of the potpourri
2 of the goals, if you will.

3 These are the milestones. Again, they'll be on
4 the website if you want to see it, but if you do take a
5 look at it, it is a very aggressive schedule for arriving
6 at these changes and agreeing upon them.

7 For OPP, we're going to take one objective and
8 we want to focus it on protecting human health in the
9 environment by ensuring that pesticides and alternatives
10 are safe and available for a healthy America. And then
11 we have two sub-objectives under that. One is focused on
12 pre-market or sort of the gateway activities of
13 registration, and then one focused on registered
14 pesticides already in use, and we have several strategic
15 targets under that.

16 This desire of ours to restructure our piece of
17 the strategic plan really is part of a larger effort to
18 make an alignment -- a better alignment from the agency's

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1 strategic plan to our piece of the agency's strategic
2 plan to our annual planning processes and right down to,
3 as Lois was talking about this morning, to the divisional
4 work plans and the individual employee's work plans. So,
5 we want them all to eventually line up so that they are
6 in accordance with one another.

7 Along with that, of course, we're attempting to
8 get our budget structure lined up in this format, also,
9 so that we have a -- we have a couple of budget program
10 areas, if you will, that match up with the gateway, the
11 entry to the marketplace types of activities, and then
12 dealing with existing chemicals in another arena.

13 The field programs, for those of you that don't
14 know, are right now separated out as a separate program,
15 if you will, within OPP's budget, and we really think
16 that this has done a disservice to the entire program.
17 Field programs don't exist in and of themselves. They
18 basically support -- for the most part, they support the

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1 existing old chemicals program, but in many ways, they
2 also support the registration, the gateway activities
3 that we're engaged in.

4 So, we felt that it was more appropriate to
5 incorporate the field program activities, as appropriate,
6 into the gateway and then the stewardship components
7 under this restructured architecture. We would also, as
8 you see there, we would incorporate all these examples of
9 particular programs within the field programs into those
10 two areas.

11 This is Goal 4 as it currently is written. My
12 understanding is that the goal teams want to keep the
13 current five-goal structure, so that this Goal 4 will, in
14 fact, stay the same. That's fine. It's general enough
15 that it will -- that it certainly covers all of our
16 activities and it also recognizes the fact that we are
17 unique -- this goal is unique because of all of the
18 cross-media and cross-agency approaches to the work that

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1 we must do.

2 This breaks it down a little bit more. Now,
3 we're getting down to the objective level. This is the
4 current architecture. We are basically combined with the
5 regulation of toxic chemicals. So, you've got TOSCO and
6 FIFRA combined under this one objective by addressing
7 both chemical organism and pesticide risk. What we
8 propose to do is to pull out the pesticide piece, to have
9 a single objective of, again, protecting the public
10 health in the environment by ensuring pesticides and
11 alternatives are safe and available for a healthy America
12 by being the effective gateway to the market and an
13 effective steward for those already on the market.

14 We think this really is appropriate to capture
15 what we do that is somewhat different from what the
16 Toxics Program does.

17 Under that objective, that proposed objective of
18 addressing our Pesticide Program distinctly, we will have

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1 two sub-objectives. The first sub-objective currently
2 talks about through 2008 -- again, this was a five-year
3 plan -- we would be protecting human health and the
4 environment from pesticide use by reducing exposure to
5 the pesticides posing the greatest risk. Now, we're
6 considering the sub-objective to read that -- to
7 acknowledge that we're dealing with registered pesticides
8 already in use and then talk about ensuring their safety
9 and including in that sound science/risk assessment,
10 acknowledging that very significant part of our work in
11 this area, and then also the risk management issues and
12 the field infrastructure that affords the safe use, the
13 international activities of harmonization and so forth
14 and all of the communications and outreach that we're
15 engaged in in the region states and with the tribes.

16 Under those current sub-objectives, there are --
17 they call them strategic targets right now where we've
18 labeled it areas emphasized, because I didn't want to

1 list out all of the strategic targets because, quite
2 frankly, they're not as meaningful as we thought they
3 might be back in 2003. So, basically, we recognized the
4 reregistration, protection of endangered species and
5 threatened species, reassessment of tolerances, reduction
6 in the decision times, reduction of mortality to
7 wildlife, and then address tribal pesticide exposure.

8 What most of these targets consist of are
9 (inaudible), are outputs, they're the number of decisions
10 you make, they're the number of endangered species that
11 are threatened on -- one of the services lists that we
12 have not endangered them any more than they already were,
13 those kind of targets. That, while meaningful, really
14 didn't do justice to the way our program runs.

15 So, what we're doing now and what you're going
16 to hear in the next presentation is we've zeroed in on
17 three areas for which we're developing measures and for
18 which the measures will include indicators of whether or

1 not we're meeting our measures and to arrive at the
2 desired result, which is an outcome, as human health
3 performance, ecological effects performance and then, of
4 course, benefits, the benefits of use and registration of
5 pesticides.

6 The second sub-objective that I referred to is,
7 again, currently talks basically about ensuring the
8 availability of pesticides, including public health
9 pesticides and antimicrobial products that meet the
10 latest safety standards, sort of a general registration
11 type of sub-objective. What we want to do is, and are
12 proposing, is to change that a bit, change the emphasis a
13 bit to include the sound science risk assessment and risk
14 management activities that are included in the
15 registration activities, which is all part of the pre-
16 market registration work that we do in OPP.

17 Again, under the registration component, if you
18 will, the current targets include promoting the use of

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1 reduced risk pesticides. That's basically how many acres
2 are being treated with reduced risk pesticides. Well,
3 again, that tends to be output-oriented. It's numbers
4 without telling what the outcome of doing that might be.
5 So, we're doing a lot of work towards addressing outcomes
6 again rather than outputs. Then registration numbers,
7 reduction in registration decision times, number of
8 tolerances again, and then maintaining timeliness of
9 Section 18 decisions, again numbers, numbers of days it
10 takes us to do the Section 18s. Not that that is not
11 important to measure, but what you also need to be
12 covering or caring about is the outcome of reducing those
13 Section 18 times.

14 So, again, these are the three areas that you're
15 going to be hearing about shortly that we are proposing
16 to focus upon for the strategic targets as indicators of
17 the measures that we're in the process of developing.

18 Now, the next steps is we have a Coordinating

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1 Committee and we have a Senior Management Steering
2 Committee and we have involved the states and the tribes
3 in the measures development process. As far as the
4 strategic plan is concerned, I'll just back up a little
5 bit and say that while you're being given this very
6 brief, fast, quick overview, there will be opportunities
7 coming up over the winter for public comment, for further
8 discussion of where we're going with the agency's
9 strategic plan, and certainly, we encourage you to become
10 engaged at the appropriate time if you have a strong
11 feeling about where we're headed with the new
12 architecture that we're developing for OPP.

13 That was really fast, I know, sorry about that.
14 But any questions?

15 UNIDENTIFIED FEMALE: Are we going to get copies
16 of your --

17 MS. MONELL: Yeah. I mentioned earlier I'm
18 going to put it up on the PPDC website.

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1 Yes?

2 UNIDENTIFIED MALE: Marty, I may not have seen
3 it because Rosenberg's head was in the way most of the
4 time, but what did --

5 UNIDENTIFIED MALE: Is there a reflection?

6 (Laughter.)

7 UNIDENTIFIED MALE: Yeah, keep Bob away from the
8 projector, please.

9 (Laughter.)

10 UNIDENTIFIED MALE: Pesticide effectiveness. I
11 mean, you can register lots of pesticides. Is that one
12 of the outcomes is does this stuff actually work?

13 MR. JONES: Well, it's implicitly caught in
14 the benefits, what benefits does it provide? If it
15 doesn't -- if it's not effective, chances are it's not
16 providing many benefits to society or to the user.

17 UNIDENTIFIED MALE: The benefits you were
18 speaking of were mostly health benefits, weren't they?

1 MS MONELL: No.

2 MR. JONES: No, we're thinking of them very
3 broadly.

4 UNIDENTIFIED MALE: Okay.

5 MS. MONELL: Actually, the benefits were
6 separated out from health and ecological and the benefits
7 we were contemplating were more of the economic side.

8 UNIDENTIFIED MALE: Okay. That was the
9 Rosenberg's head portion.

10 (Laughter.)

11 MR. JONES: Jennifer?

12 MS. SASS: Yeah, thank you. I, obviously, came
13 in late -- a couple of us have. But I'm concerned about
14 some of the wording in the objectives because it's very
15 important -- obviously, you understand how important it
16 is, to get the objectives right because that's how you're
17 going to measure the success of your program. So, I'm
18 curious about how you're going to use sound science to

1 measure the objective of ensuring safe pesticides.
2 There's other things that I just think need a little
3 qualification or detail or thought out. If that's your
4 objective statement, I'm concerned. You can't make
5 pesticides safe. You can use them safely, you can use
6 them safer. You can encourage a safer development, but
7 you can't make something that kills pests safe, and if
8 that's an objective, I'm concerned about the measuring
9 standards. It's important.

10 MR. JONES: Sure.

11 MS. MONELL: Um-hum, um-hum.

12 MR. JONES: I mean, one of the things, I think,
13 we've got to figure out is independent of the agency's
14 participation, getting individuals and groups like you to
15 participate with comments like that, do we want to have
16 some other forum to get your feedback that we can make
17 sure it gets fed into? Because I'm a little bit nervous,
18 based on past practice, that people aren't necessarily

1 going to avail themselves of the agency's strategic plan
2 public participation process, whereas I do know you will
3 be coming to these meetings and if we did have some kind
4 of focused time, whether it was in a conference call or
5 something, that we probably would get some meaningful
6 feedback. So, I think that's one of the things we've got
7 to struggle with.

8 MS. MONELL: Well, what the --

9 MR. JONES: So we can get very specific comments
10 like that, Jennifer, in our --

11 MS. SASS: Well, one of the reasons why it
12 struck me specifically is because I'm on this NIPTAC
13 (phonetic) interim ad hoc working group on nano
14 materials, which means we exist for a very short time in
15 cyberspace. But one of the things is that the -- it's a
16 multi-stakeholder group. We work really well together
17 and I'm impressed, but one of the things I've learned is
18 that the industry people on the group are not willing or

1 not particularly amenable to having an objective
2 statement that says our objective is to develop nano
3 materials safely. They've expressed concern that that's
4 a standard that's too difficult to meet.

5 So, I'm curious about how you guys are going to
6 meet that.

7 MS. MONELL: I would just note one of the slides
8 that I rapidly proceeded through has the time table and
9 the agency's document is going to be put out for public
10 comment in April, and so, we may be able to pull our
11 piece together and present it at the next PPDC meeting
12 for full discussion before it's too far in cement.

13 MR. JONES: Or maybe even before then in kind of
14 a conference call. Because I'm not sure, Jennifer, if
15 that's actually going to be the objective statement.

16 MS. SASS: This is like a draft early thing?

17 MR. JONES: Um-hum.

18 MS. MONELL: Oh, yes.

1 MS. SASS: I was just thinking about it then.

2 MR. JONES: No, you raise a good point.

3 MS. SASS: A number of the objective statements
4 go toward facilitating pesticides into the marketplaces.
5 That seems, to me, to be an objective you can obviously
6 achieve. The objectives on the protection side seem to
7 be more difficult to achieve, let's say. And what
8 concerns me overall is that only the objectives that
9 involve facilitating market availability are going to be
10 achievable.

11 MR. JONES: Okay.

12 MS. MONELL: Well, we will certainly work on
13 figuring out an appropriate forum to incorporate those
14 kinds of comments. That was very helpful, thank you.

15 UNIDENTIFIED MALE: I don't want to get into it
16 and I --

17 MR. JONES: Yeah. (Inaudible).

18 UNIDENTIFIED MALE: I don't want to get into a

1 debate over that issue right here. We'll comment on it
2 later. But actually the Food Quality Protection Act does
3 provide that if the EPA requires the testing and the
4 testing has been reviewed by EPA that it is a finding of
5 safety of our products. It is different from the past
6 laws. The Amendments of 1996, in fact, do provide a
7 finding of safety for our products. So, it's not just
8 any more safe use, applicator protection and the others.
9 The products, themselves, after going through the
10 comprehensive review of the Environmental Protection
11 Agency today, under FQPA, when the agency makes its
12 finding, it is making a finding of safety.

13 MR. JONES: Right. I think what I'm hearing
14 from Jennifer -- and it's one of the -- it's a good segue
15 to this next topic, it's -- as you've heard our vision
16 involves ensuring safe pesticides and available
17 pesticides. How do you measure? How do you measure
18 safe? And if you don't lay out the correct objective for

1 measuring it, then your ability to evaluate it becomes --
2 that's largely what this next group, which is going to be
3 talking about indicators and results, is what they're
4 struggling with. How do you create appropriate measures?
5 But I agree with your statement that that is the standard
6 that we're trying to meet and that's the standard that we
7 have in our vision statement, where we want to be.

8 UNIDENTIFIED MALE: The slide you just showed us
9 gave us a time line for commenting and development, but
10 it indicates a public comment period in the April or so
11 time frame next year.

12 MS. MONELL: Well, that's for the entire agency
13 strategic plan, correct?

14 UNIDENTIFIED MALE: Are you planning on a public
15 comment process before we get to that stage for --
16 specifically for the OPP?

17 MR. JONES: Well, that's what I'm thinking of.
18 It will sort of somewhat be dependent on when we schedule

1 this next meeting. We may have to do something in
2 advance of that so that we can accommodate that. But I
3 really -- I think that if we're going to get meaningful
4 feedback out of the stakeholder community, if we don't
5 host some kind of forum, I'm just not sure we're going to
6 get -- the agency is going to get the kind of feedback
7 that it's looking for.

8 Okay, more to come on that. It's a good segue
9 to the next topic, which is pesticide performance
10 measures, which we, after our last PPDC meeting, began a
11 workgroup which I understand a number of you have
12 participated on. I can't emphasize enough just how
13 important it is for EPA and the Pesticides Program to get
14 this issue right. The increased attention by Congress
15 and by the Office of Management and Budget on federal
16 programs being able to demonstrate results is not seeming
17 to lessen. I think it's just going to continue on.

18 I, frankly, think it's an appropriate attention,

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1 that we ought to be demonstrating results. I think that
2 we have demonstrated, in this program, high capacity for
3 measuring output, and for many years, that is what the
4 system expected and just when we think we get our arms
5 around outputs, they say, well, that's not good enough, I
6 want outcomes. But actually outcomes is why we're here
7 in the first place. We're here to protect public health,
8 to protect the environment, to ensure that pest control
9 techniques and technologies are available. Now, the
10 people who we report to are saying, well, you need to be
11 able to measure that and it can't just be number of
12 Section 18s, it can't just be number of reregistrations
13 and registrations and tolerance reassessments. You got
14 to get to the outcome. So, we have engaged, in the
15 Pesticides Program, with our colleagues in the regions
16 and with the states, and now, more recently, with our
17 stakeholder community, as captured by the PPDC, in
18 attempting to develop outcome measures, and it is very

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1 difficult.

2 For those of you who haven't participated in
3 this exercise with us in any of the sub-workgroups,
4 you'll probably come out of this session today
5 understanding just how difficult that can be. So, with
6 that, I'm going to turn it over to Sherry Sterling, who
7 joined the Pesticides Program a number of months ago,
8 expressly with the responsibility of leading our efforts
9 in this effort. Sherry?

10 MS. STERLING: Good afternoon. I am here on
11 behalf of the workgroup that this group commissioned at
12 the last PPDC meeting. They've asked me to go over and
13 get -- have an overview of this, and also David Widowski
14 (phonetic), who's the Chief of our Economic Analysis
15 Branch will also, at the workgroup's request, will be
16 going through an example of the other benefits.

17 So, with that, what we're going to talk about
18 today, just very briefly we're going to go through some

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1 information that the workgroup felt is important for you
2 to understand so that you understand how the PPDC's
3 advice will be used. The PPDC workgroup members will
4 talk about their goals for that workgroup. We will give
5 you the overview of the other benefits piece. David will
6 do that. And then, finally, we'll end with some next
7 steps that the workgroup has talked about.

8 The first thing I want to kind of walk through,
9 and Marty mentioned this just briefly, but I want to go
10 into a little bit more detail about this. The workgroup
11 found it very helpful to understand this in a little bit
12 of depth, so please bear with me with the bureaucracy and
13 the red tape for just a moment.

14 We have a three-level process here, a three-
15 tiered process. At the bottom, we have the task groups.
16 Those task groups are looking at and trying to develop
17 the measures that Jim was just speaking of, we're trying
18 to develop those measures in very specific task areas,

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1 and they're down at the bottom. ESA being endangered
2 species; of course, water quality; worker safety includes
3 the CNT elements as well as worker protection; food
4 safety, actually this kind of got merged into just a
5 basic human health as we worked through the issues; and
6 also, the last one there, the code -- I'll break the code
7 for you, Strategic Ag Initiative and Pesticide
8 Environmental Stewardship Program is the last grouping
9 and those are voluntary programs.

10 So, task groups are working on those. The staff
11 are developing output measures and then outcome measures,
12 actually looking towards the things that we do, how do
13 they really matter out in the world. That information is
14 going to the middle tier, which is the Coordinating
15 Committee. David and I are on that Coordinating
16 Committee. I'm the Chair of that with a regional person,
17 and our focus is to come up with mission areas, three
18 mission areas, and we'll go into this -- I'll go through

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1 this one more time, but the three mission areas are
2 protect human health, protect the environment and these
3 other benefits from pesticide use. We're doing those
4 overarching, big picture, mission area measures and we're
5 also taking the task -- the very individualized task
6 measures and we're forming a quilt, if you will, that
7 will show the picture of what the agency -- what OPP is
8 doing and how what we do matters in the world.

9 These measures aren't just measures to tell a
10 story. That would be great. We do have some -- we've
11 identified some measures that will tell a story. We call
12 those indicators, environmental indicators or health
13 indicators, but indicators. What we're trying to do with
14 this is focus more on management, what can we effect, how
15 effective are we in our program? So, that's why we're
16 calling them performance measures. Make that
17 distinction. They need to work together to tell the full
18 story, but we're focused, in this group, on performance

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1 measures.

2 What we do, the Coordinating Committee, is
3 they'll send it to our executive level that Marty is the
4 Chair with a Region VII Division Director and numerous
5 Division Directors in the program, so that's our
6 executive level. We'll look at the recommendations, at
7 this quilt that the Coordinating Committee has developed,
8 and they will eventually make recommendations to Jim.
9 That will then go up our chain of command to the system
10 administrator and to the Office of Chief Financial
11 Officer and all that kind of good stuff before it makes
12 its way finally to OMB.

13 We'll hope that it goes -- we just do a one-shot
14 deal and it goes straight through, it's very linear,
15 boom, boom, boom. But, in fact, we expect that at all
16 stages, there will be lots of -- there will be iterative
17 loops in there, people will come back and ask us, can you
18 develop this better, what does this mean? So, we expect

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1 that this will be iterative.

2 We're really pressing to keep things moving in
3 this, as far as we have control of it, up to the point
4 where we -- it goes out of OPP, we don't have as much
5 control over it. So, the -- when we talk through the
6 time frame, it gets a little bit sketchy once it goes out
7 beyond OPP.

8 On the next slide, I just wanted to emphasize
9 again the mission areas. These are the big -- these are
10 really the three areas that we're working on based on our
11 program goal. So, protect human health, protect the
12 environment, and this last category is a little bit hard
13 to understand, so let me spend a moment on that. By
14 other benefits, we put other in there because we think
15 protecting human health and protecting the environment
16 are, indeed, benefits from the program. These are the
17 additional benefits, and this is something that's
18 important to understand.

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1 When David gives his example of benefits, you'll
2 be thinking, but what about the human health elements?
3 Those benefits are captured in another mission area. So,
4 this will be just those in-between sorts of things and
5 the -- and more -- and some of the economic benefits.
6 So, I want you to keep that in mind as we go through this
7 with -- as David goes through that.

8 So, we go to the task areas. These relate in
9 most of our part to the field programs that we have now.
10 But they really support the program as a whole. So, I
11 would say that as we're looking at this -- at the three
12 mission areas, the first two, water quality and
13 endangered species, while they will have some impact on
14 protecting human health and the other benefits, those
15 primarily are focused on protect the environment mission
16 area.

17 The last two, worker safety and this food
18 safety/aggregate risk, while they will have -- those,

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1 too, can have impacts on other benefits and protecting
2 the environment; in fact, those two really are strongly
3 in support of the human health area. So, that -- when we
4 come together and pull everything together, that's pretty
5 much how things will sort out, working together.

6 So, we go to the schedule, just -- we are -- and
7 we really have a need to be moving forward. So, our goal
8 is to have measures that the Steering Committee has
9 reviewed during November and we turn over to the Office
10 Director to -- for his final recommendations/decision
11 process.

12 Does that mean that you have lost your chance?
13 Absolutely not, because what's very important is the very
14 last bullet on this page and that is that we are going to
15 continue -- the year of -- throughout 2006 -- I have 2005
16 there -- but 2006, if we do it this way, is the year of
17 tweaking. We'll be tweaking our performance measures
18 throughout this time. We have some other -- we really

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1 do, though, have to kick that off, though, in 2006, in
2 January, we need to begin implementation of those
3 measures that are ready and not all the measures that
4 you'll see today will be ready in January 2006. I
5 apologize for the errors on here -- on the date there. I
6 was brain dead last night when I did this.

7

8 Anyway, there -- those that are ready to go, we
9 want to implement them. Those that aren't quite ready to
10 go, we want to keep working on them because sometimes it
11 takes more than just a couple of months to develop a
12 measure and, you know, all the supporting information and
13 the baseline information that you need.

14 What the group will be getting, I do --

15 **(End of Tape 2, Side B)**

16 MS. STERLING: -- so that it's not completely --
17 it's still draft. So, it's not completely finished up.
18 We're doing that because we would value having input

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1 early on and you'll see today by the example that we
2 think that we can be partners in this. So, with that,
3 Steve, or workgroup members, if there's anything else you
4 want to add?

5 STEVE: Yeah, I'll add a few things. The first
6 thing I'll add is, never be late for a meeting. You got
7 to sign things. Although, actually, this time, I was an
8 hour-and-a-half late, I missed half the meeting
9 yesterday. So, I thought, hey, I'm going to be able to
10 avoid it.

11 UNIDENTIFIED FEMALE: You thought you were safe.

12 STEVE: Yeah, I thought I was safe. I don't
13 know anything, right? But, of course, Larry volunteered
14 and then conveniently had to be gone this afternoon. So,
15 I will stand in.

16 One thing I ought to do quickly is go through
17 the members, Sherry, does that make sense, so you have a
18 clue who's on this committee, which will give you a sense

1 of why Sherry probably felt brain dead last night. I'm
2 on the committee. Dan Botts, I think, is on the
3 committee. I think he was on one phone call, but I don't
4 remember him actually saying anything. Carolyn Brickey
5 is sort of a virtual member, in absentia. Amy Brown,
6 Larry Elworth, Caroline Kennedy, Jimmy Roberts, Bob
7 Rosenberg, John Schell, Julie Spagnoli, Michael Fry, Jim
8 Burdette from North Carolina. What's Jim's background?
9 I'm not sure what his role is.

10 MS. STERLING: Jim is a state representative.

11 STEVE: Okay. Izzy Sidiqi (phonetic)
12 representing Ray McAllister, representing Jay Vroom, who
13 sometimes represents himself.

14 **(Laughter.)**

15 STEVE: And Nancy Golden. Did I miss anybody?

16 MS. STERLING: Is Tom Byden --

17 STEVE: Oh, Tom Byden, that's right.

18 MS. STERLING: And Caroline Kennedy.

1 STEVE: I said her.

2 MS. STERLING: I'm sorry.

3 STEVE: So, you can imagine that it's a rather
4 difficult group to work with and Sherry certainly has her
5 challenges.

6 We believe our primary objective is to review
7 and comment on the process for developing the performance
8 measures and the substance of the performance measures as
9 well. This is a really big, big elephant to get your
10 arms around. We've all been touching various parts of
11 it, and so, we're not quite sure how we're going to
12 proceed, particularly --

13 UNIDENTIFIED FEMALE: The back part of the
14 elephant?

15 STEVE: Yeah, that would be Larry. The time
16 frame is very tight and I -- you know, obviously, they're
17 going to be presenting to the Steering Committee next
18 month. So, we're trying to get rolling fairly quickly to

1 get into substance, which David will give you some sense
2 of in the upcoming discussion. Our point of contact then
3 is that Coordinating Committee, as Sherry said, but we do
4 think that we're going to have to probably, at various
5 points, reach down to the workgroups, the individual
6 workgroups, to get more detail, to get better
7 understanding on specific issues.

8 We're looking at a number of things. The
9 validity of the measure, does it make sense? The
10 meaningfulness of the measure, are you actually going to
11 accomplish anything with this? The value of the measure
12 to EPA, to OMB, to stakeholders, to whomever; the
13 sufficiency of the data; and any additional measures that
14 may be necessary. Sort of to discuss the issue of
15 sufficiency of data, one of the things that I think we
16 are very concerned about is the issue of cost, that there
17 is a direct correlation between the value of the data,
18 the accuracy of the data, the depth of the data and the

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1 cost of getting that data. Relatively little of the data
2 that EPA needs on outcomes is readily available.

3 So, those are the kinds of things that we really
4 need to think through and whether it makes a lot of sense
5 -- now, it's not our choice, it's OMB's choice in many
6 cases, but whether it makes a lot of sense to be spending
7 tremendous amounts of dollars on seeking out data
8 measurements that take away from the job at hand. That
9 was a little editorial, though. I'm not sure the rest of
10 the group agrees with that.

11 I mentioned that we feel our role is to look at
12 substance, but in that process, we will also be looking
13 at the process part. You know, as we go through, we
14 think we might have some thoughts about process. An
15 additional point is that we very much appreciate the
16 issues that Jim and his staff face in this whole process.
17 It is a bit overwhelming, but there is a lot of great
18 information out there. If we can get OMB to understand

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1 sort of the dynamics of what we're trying to accomplish,
2 I think it will go a long way. But we'll have to see how
3 that process continues.

4 I think that's it. Are there any questions?
5 Beth?

6 DR. CARROLL: Yeah, Tom and I passed in the air,
7 so I haven't had an opportunity to talk to him. But who
8 makes up the task groups? Is that EPA individuals?

9 MS. STERLING: Yes, it's EPA staff, plus each of
10 the task groups has a state representative, at least one
11 state representative on that group, and also a tribal
12 representative. So, it's pretty much just folks within
13 our internal circle, if you will.

14 STEVE: Yes. Julie?

15 MS. SPAGNOLI: I think another point that was
16 brought up in the discussion, too, is to make sure that
17 we're looking broadly at the whole program, at all of
18 OPP, that we don't focus purely on measures that are

1 measuring conventional chemicals for crop uses. Because
2 it seemed that when we got into the discussions, that
3 there was sort of a very focused and that we want to make
4 sure we're looking at measures in other areas to kind of
5 cover the program as well.

6 STEVE: Would that be antimicrobials as well?

7 MS. SPAGNOLI: Antimicrobials.

8 STEVE: Okay, changing focus.

9 **(Laughter.)**

10 STEVE: Bob?

11 BOB: And other non-ag uses.

12 **(Laughter.)**

13 STEVE: See Sherry's challenge.

14 BOB: Exactly. And I think, Steve, you sort of
15 covered it. One of the things that struck me was we
16 looked at a bunch of possible measures that David
17 presented to us, and some of them lent themselves to some
18 fairly easy measurement and some of them didn't, and the

1 concern I have is that if you only measure those outcomes
2 for which there is readily available data and ignore the
3 ones for which there isn't data, then you get a very
4 distorted picture and it's, I mean, I think, worth asking
5 whether or not there are funds available or ways
6 available to collect the data for which those easily, you
7 know, or readily available data sets are not currently
8 available, or else maybe the whole exercise is somewhat
9 distorted.

10 MR. JONES: One of the things that I keep
11 reinforcing with our team is that it isn't necessary
12 that for every measure you can actually measure it. You
13 may -- there may be -- the best ways to evaluate the
14 program may be in areas where you can't right now measure
15 it. But maybe in five years or in ten years you can.
16 But that being said, it's also important to have a number
17 of measures that can be evaluated. We can't just sort of
18 wrestle -- well, here's the 10 measures that would

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1 optimally evaluate our program, none of which can be --
2 we have data to evaluate us against. At the same time, I
3 really don't want to just have, as you were describing,
4 well, here are 10 things we can do that we know we can
5 do, but they give you an incomplete picture of the
6 effectiveness or lack thereof of this program.

7 So, I'm comfortable with having a mix of the
8 two, and that being said, even the ones that we're not --
9 you can't measure, we're not necessarily going to be
10 asking for funds to be able to measure them, the theory
11 being that if you have out there in the public domain,
12 here's how we'd like to evaluate this program. Over
13 time, people who are into measurement begin to measure
14 those things.

15 STEVE: Jennifer?

16 MS. SASS: I don't know, but are we going to
17 discuss some examples of the measurements at this point?

18 STEVE: Yes.

1 MS. SASS: Okay.

2 STEVE: Okay. David, good lead-in.

3 MR. WIDOWSKI: Thank you and thank you very much
4 for those introductory comments from the working group.
5 Although, Steve, you said that your group can be
6 difficult to work with, and I'm not going to comment on
7 that, I will say that I am very appreciative of the
8 insights, the comments and sometimes the appropriate
9 criticisms that were raised yesterday on the presentation
10 that we made to the group. So, I think however you're
11 working together, you represent a wide range of expertise
12 and it's been very helpful so far, and I'm sure as we
13 present other measures on human health and the
14 environment, that same expertise will prove very
15 valuable.

16 As Sherry said, I'm going to talk today about
17 eight specific measures that we'll give you a chance to
18 kick around and chew on. I'm going to point back to the

1 objective that Marty mentioned or pointed out in the
2 strategic plan with respect to our mandate, to ensure
3 that pesticides and the alternatives are safe and
4 available for a health America. I'm going to focus --
5 and this area of measures focuses on availability and
6 we've decided to take a fairly economic approach to the
7 benefits or the importance of availability of pesticides.

8 So, in order to take this -- what is a pretty
9 broad portion of our mission landscape, the other
10 benefits, and connect that to a set of performance
11 measures, as task group, as part of our process,
12 identified six goals that would allow us then to
13 translate our strategic mission statement into a set of
14 potential measures that have some concrete validity and
15 the other aspects of performance measures, as Steve
16 mentioned.

17 I'd like just to run through them very quickly.
18 We identified improving and maintaining user

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1 profitability as an important goal. The second was
2 maintaining or improving trade opportunities. The third
3 is lowering expenditures of remediating -- for
4 remediating pesticides in the environment. The fourth is
5 enhancing and/or stabilizing the food supply. The fifth
6 is protecting property and the last one is protecting
7 public health. And the challenge for the group then is
8 to translate these goals into performance measures, that
9 as Sherry said, reflect not -- aren't just an indicator
10 of the environment, but reflect what we can do and things
11 that we can change as a regulatory or as a government
12 program and satisfy the importance of being measurable,
13 being replicable and are based on data that we can
14 collect periodically that allow us to assess our progress
15 or our performance over time.

16 So, that said, I'm going to jump into these
17 eight measures and these eight measures are on three
18 different slides, and each one of those slides represent

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1 a different tier of the data availability, the cost
2 question, how much data are out there right now that we
3 could measure, what are going to be harder for us to get
4 and what kind of measures really would depend on a new
5 set of data collection, either by the government or by
6 the public in order to support our evaluation of our
7 performance.

8 So, the first measures are kind of in the low-
9 hanging fruit category, and these are two measures that
10 are both associated with improving or maintaining user
11 profitability. The first one is a measure that's
12 proposed to cover a portion of our registration program.
13 It doesn't cover the entire registration program, and one
14 of the reasons we focused on the Section 18 program is
15 that it is something that we evaluate on an annual basis
16 in the Biological and Economic Analysis Division where
17 I'm the Chief of the Economic Analysis Branch. On an
18 annual basis, we evaluate a number of Section 18s with

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1 respect to the potential economic loss that's avoided
2 through the potential granting of a Section 18.

3 So, one of the attractions of this measure and
4 each one of these measures, I've listed some attractions
5 or some pros and some challenges or limitations. One of
6 the advantages of this is that we have a well-developed
7 methodology for measuring loss. We do it on a regular
8 basis and a Section 18 program does require that states
9 submit data that allow us to make this evaluation
10 whenever a Section 18 is submitted to the agency. So, we
11 have data that will allow us to make that measure, and
12 generally, people find the measure to be the avoided loss
13 or the value of the avoided loss as a concrete and
14 understandable measure.

15 One of the challenges or limitations of this
16 kind of measure is that it doesn't fully measure the
17 benefits of registration. So, that raises the question,
18 how much of our program and how much of the benefits of

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1 availability are we actually describing with this kind of
2 a measure? And that's one of the things that we would
3 need to consider as we contemplate moving forward with
4 potentially adopting this measure.

5 One of the other factors, just in kind of a
6 process or internal issue is that the Biological and
7 Economic Analysis Division sees a portion of the Section
8 18s that are submitted annually. So, we would need to do
9 some additional work to develop mechanisms and models for
10 estimating the overall value of the avoided crop loss
11 from all the Section 18s that are submitted to the
12 agency.

13 The second measure is what was described as the
14 benefits of our generic registration or me-too program.
15 This is intended to measure the benefits to pesticide
16 users of having generic pesticide products available for
17 use and the potential savings and expenditures that would
18 result from the registration of me-toos or generic

1 products.

2 The advantage -- and what we did is we focused
3 actually, and that's one of the points that Julie raised,
4 is we had originally focused on looking at agricultural
5 uses, and one of the reasons is listed in the first
6 advantage or the first pro, and that's that we have data
7 readily available for expenditures on different kinds of
8 products among agricultural uses. We don't have at our
9 disposal a huge amount of data for the antimicrobial
10 uses, but that's obviously something that's a point of
11 discussion that we can talk more about.

12 The other thing is that the advantage of this
13 measure, it's really intuitive. It's how much does a
14 user spend on pesticides or pesticide products? The
15 limitation -- one of the limitations of this measure is
16 that pesticide expenditures tend to be a fairly small
17 proportion of agricultural product expenditures, and it
18 does, again, focus on a limited aspect of our program.

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1 The question that we'd have to evaluate is to what degree
2 this captures an important part of our program in
3 deciding whether or not we want to move forward with that
4 measure?

5 So, those are the first two measures for which
6 we've got data kind of at hand that we could easily
7 access.

8 As we move into the next tier, I call this a
9 group of measures that potentially require substantial
10 data collection. These are -- they're a set of three --
11 these address two of our goals. One is maintaining or
12 improving trade opportunities and the last two have to do
13 with lowering expenditures for remediating pesticides in
14 the environment.

15 The first measure, looking at measures for the
16 trade opportunities that arise from our regulatory
17 program kind of covers two different parts of that
18 landscape. One has to do with phyto-sanitary assurance

1 and minimizing the adulterated commodity that could
2 potentially be rejected for export across state or
3 international boundaries, and the other area has to do
4 with the value of our harmonization system for tolerances
5 that allow us to export commodities internationally.

6 One is we might be measuring our work with
7 registering or maintaining availability of pesticides
8 that limit or prevent adulteration of commodities and,
9 therefore, could be facilitated in international trade in
10 the various commodities and the important economic value
11 of that trade. And the other one is kind of the flip
12 side of that, it's listed as a harmonization.

13 The advantage of this is, obviously, that trade
14 is a very important economic activity. One of the
15 challenges, with looking at this measure, is the sometime
16 difficulty in linking our program activities to
17 international trade and to what degree the volume of
18 trade is related to pesticide registration or the

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1 registration activities and to what degree the volume of
2 trade is subject to other economic factors. And so, that
3 presents a methodological and data challenge for us in
4 potentially contemplating implementing this measure, and
5 collecting those data could be tough as well. So, those
6 are a couple of challenges of that potentially important
7 measure.

8 The next two measures, as I said, have to do
9 with our goal of expenditures for remediating pesticides
10 in the environment. The first one is a description of
11 solid waste remediation. In this case, we're thinking
12 primarily about pesticide containers and the programs
13 that we have, they're voluntary programs that exist for
14 recycling pesticide containers and the grant program that
15 we provide for clean sweep activities for eliminating
16 pesticides and pesticide containers in local programs.

17 One of the pros of this measure or advantages is
18 that there are some data out there that track the amount

1 of solid waste that's collected through these voluntary
2 programs, and it's -- and the -- and I list it as an
3 advantage, but it's actually something that you could
4 look at both ways. It's an important -- some folks will
5 say it's an important part of our waste stream monitoring
6 and some folks would say, when you look at the total
7 volume of solid waste in the United States, pesticide
8 containers represent a pretty small proportion of that.
9 And so, the questions that are -- that's a point of
10 discussion and debate as we consider or contemplate going
11 forward with this particular performance measure.

12 One of the limitations on this measure is the
13 expense for collecting data and how those expenses are
14 borne that would allow us to continually collect
15 information on pesticide container recycling.
16 Particularly for some of our clean sweep activities,
17 there's been one or two studies on looking at the volume
18 of waste that was collected, but those were pretty

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1 intensive and expensive studies, and it comes back to
2 that question that Steve raised, how much are you willing
3 -- do you want to spend on performance measures and what
4 is it telling you?

5 As I said, both a pro and a con would be,
6 depending on where you sit, is the importance of
7 pesticide containers in solid waste and to what degree it
8 represents an important proportion of solid waste.

9 The third measure in this tier of requiring
10 substantial data collection is also associated with
11 remediating pesticides in the environment and that
12 focuses on the -- I wrote down cost changes, but the
13 working group has very kindly suggested that we have cost
14 because we're talking about economics and in a fairly
15 narrow sense, in this particular set of measures, we're
16 going to substitute expenditures. So, I'm going to
17 rename this expenditure Changes for Remediating
18 Pesticides in Drinking Water.

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1 The advantage of this potential measure -- and
2 in this case, we would be looking at or possibly looking
3 at what it costs community water systems to implement or
4 develop mechanisms and tools for removing and/or
5 remediating pesticides in drinking water and how those
6 potential expenditures change over time, both for capital
7 expenditure and ongoing variable costs.

8 The advantage of this measure is that it
9 addresses an important part of our program which is
10 drinking water. The challenge for this is that
11 collecting systematic data from a large number of
12 community water systems can be a challenge in and of
13 itself, but then that raises one of the questions that we
14 -- the working group raised yesterday, which was how do
15 you know when you're looking at expenditure for a
16 particular remediation system in a particular system is
17 designed to be used when the water is turbid, when there
18 are suspended particulate matters, and this same kind of

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1 system may be also useful for removing a pesticide? How
2 do you portion those expenditures to that portion which
3 is attributable to pesticides? So, there's potentially
4 some methodological and data collection issues associated
5 with that measure.

6 Now, that's the second tier of measures, as I
7 mentioned. Then we go into -- we occasionally call these
8 the pie-in-the-sky measures, but I think I'll be a little
9 more concrete and those are the ones that maybe require
10 new methods and new data and could be potentially costly.
11 Yesterday, in our discussion, we had some very good --
12 oh, I should say I appreciate the insights that the
13 working group members provided in trying to help us
14 conceptualize what kind of data really are necessary
15 where we may not have data readily available, but it's
16 important to measure a particular aspect of our program.
17 So, this gets into that area where -- and I should say
18 across all these, we appreciate and we value the input of

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1 the PPDC and this is an area where we can really use some
2 of your expertise in helping guide us how we might move
3 forward with these measures.

4 The first measure has to do with maintaining --
5 our goal of enhancing or stabilizing the food supply and
6 that's the characteristic of resistance management,
7 because the pests do -- or the spectrum and the
8 distribution of pests do change over time, resistance
9 management is an important part of our program, both in
10 the kind of products that are available through the
11 registration and the reregistration activities.

12 The obvious advantage of this is it's important
13 for our program, but one of the big challenges, how do
14 you define or measure resistance? One can look at it as
15 defining a specific set of pests on a pest/use/site
16 combination and then trying to track the biology of that
17 particular pest over time. But that becomes a very
18 expensive proposition. One can also look at kind of the

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1 macro level, how many different products or how often do
2 you have to change products for managing a particular
3 pest? But that has its own limitations, too, and
4 interpretation.

5 So, we see some big challenges in implementing
6 this measure. At the same time, we recognize that it's
7 potentially capturing important benefit from one of our
8 key mission areas. The second measure on this list is --
9 has to do with our goal of protecting property and this
10 is one that's described as expenditures on structural
11 best control and damage. I had initially been thinking
12 about this in terms of termite control, but I was
13 reminded yesterday that toxic mold remediation is also an
14 important part of our structural pest control and
15 structural damage environment that we have to be
16 concerned about.

17 The advantage of this measure is it's another
18 important economic activity, an important part of our

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1 mission area. The challenge associated with this measure
2 is where do you get data on this measure? There's a
3 couple of ways that we -- and Bob mentioned a couple
4 yesterday, that there were a couple of ways to look at
5 this. One, you could look at the value of the wood
6 that's been destroyed on an annual basis and looking at
7 the kind of expenditure on replacing that. You can also
8 look at the changing expenditures associated with your
9 structural protection activities. In both of those cases
10 we were challenged, in our task group, in trying to
11 identify sources of these data that meet the requirements
12 for developing an appropriate, valid, replicable
13 performance measure. But it's an area where we would
14 welcome input from the PPDC.

15 And then the last measure is associated with our
16 goal of protecting public health. This is probably one
17 of our most challenging measures that we thought was
18 important to include in our set of potential measures,

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1 but we really kind of hit a wall in what kind of sources
2 we would have for collecting data to help us evaluate
3 this particular measure.

4 The advantage of this measure, obviously, is
5 that protecting public health is an important part of our
6 mission. The challenge is, how do you define the
7 pesticide contribution for disease and disease
8 transmission across vectors, across human beings and
9 different kinds of environments, and how do you portion
10 that to the things that we can do, getting back to what
11 Sherry mentioned, as a performance measure. And then how
12 would you go collect data on a systematic basis that
13 would allow us to have kind of a level or a baseline from
14 year to year or whatever period you're measuring across,
15 whether it's year to year or every three years, every
16 four years, or every decade?

17 So, in a quick nutshell, those are the kind of
18 measures that we've developed for contemplation and

1 consideration. These are the ones that we presented
2 yesterday to the working group and now I guess I will
3 open up to the entire committee to start kicking around
4 and providing some insights into helping us understand
5 our measures. Thank you.

6 UNIDENTIFIED MALE: Well, if I can add, one of
7 the frustrating parts of this, as you can probably tell
8 from looking at what David presented, is we're sort of
9 back to an elephant analogy. We're ignoring the elephant
10 in the room, which is the giant bulk of registrations of
11 compounds that actually mitigate pests. So, we're
12 looking at Section 18s and we're looking at me-toos and,
13 you know, all the little extra stuff because those things
14 have measures.

15 But the real effect of benefits is actually
16 having effective compounds available in a safe manner,
17 you know, to be managed in a safe manner. That's what
18 EPA does at least from a benefit standpoint. So, that's

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1 a little frustrating.

2 I think it's particularly important the fact
3 that, legislatively, EPA is required to get rid of the
4 bad actors. That's what FQPA was all about. And so,
5 what they're doing is replacing the bad actors with
6 newer, better compounds in -- of course, with their
7 industry partners.

8 But it -- this is a real value that I -- you
9 know, I'm not quite sure how to get a handle on the fact
10 that we actually have good replacement compounds
11 available to us that are safer and better and that sort
12 of thing. So, that's a frustration that I think when we
13 look for readily available measures, we don't get the
14 real effect of what EPA does.

15 MR. WIDOWSKI: I'm just going to go right around
16 the horn here. So, Julie?

17 MS. SPAGNOLI: You know, again, looking at it
18 from a public health standpoint, I think we don't need to

1 try to limit the program's contribution and just would
2 say how much do we reduce illness? I think when you're
3 looking at -- I mean, getting away a little bit from
4 vector borne illnesses into emerging pathogens. I don't
5 think anyone would deny there's a benefit -- whether you
6 even have to measure that benefit if you have something
7 to kill the, you know, avian flu virus.

8 So, I think -- but how do we -- the performance
9 measures, how do we get to that product? How do we
10 assure that that's -- we have a safe and effective
11 product for that use? So, I think there may be a
12 different way at looking at what is the program's
13 performance measure and getting from Point A to Point B
14 instead of saying what's the benefit once we get to the
15 Point B, because the benefit, once we get to Point B, is
16 fairly evident. So, I think it may be just another way
17 of looking at what performance are we trying to measure?

18 MR. WIDOWSKI: Carolyn.

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1 MS. BRICKEY: Yeah, it strikes me from what
2 Steve was saying and what I was thinking already is that
3 we are kind of nibbling around the edges a little bit and
4 maybe we're looking at it backwards, I'm not sure. But
5 it sort of seems to me like we need a Jimmy Stewart
6 model, you know. Remember that movie where he imagined
7 the world if he weren't there. I think probably just
8 about every agency in government has that same issue.
9 You know, what would the world be like if you didn't
10 exist?

11 So, I'm not a modeler, I don't know how to do
12 that. But, you know, it seems to me that's what you
13 really need. You need to make some reasonable
14 description of what would happen if you didn't have a
15 program that did what you do. I mean, there's no more --
16 in just looking at these individual measures, you know,
17 for example, cost related to remediating pesticides in
18 water. Well, you're remediating pesticides in food to

1 the same extent or more. So, you know, nothing strikes
2 me particularly singular about these individual items.
3 They're not invalid, but they're not singular. There's
4 others that are just as important and you could spend a
5 lot of time spinning your wheels coming up with 14 more
6 of those, but I'm not sure you'd be any closer to
7 figuring out how to collect data to show what they are.

8 So, Jimmy Stewart.

9 **(Laughter.)**

10 UNIDENTIFIED MALE: I just heard a bell, another
11 angel got its wings.

12 UNIDENTIFIED MALE: That would certainly be a
13 full employment act for all the economists that I
14 (inaudible).

15 UNIDENTIFIED MALE: Just one thing for the
16 working group, even the virtual working group member here
17 to my left, to keep in mind is that not all pesticides,
18 obviously, mitigate pests. You know, we have -- there's

1 a large group of pesticides which are plant growth
2 regulators, for example, and actually they're easier to
3 measure because you can measure yield increases or
4 quality -- quality is hard sometimes, but you can
5 certainly measure yield increases and get a better
6 understanding. So, I'd like to remind everyone to put
7 that into the equation, too. That it's not just killing
8 things.

9 MR. WIDOWSKI: Beth?

10 DR. CARROLL: Well, I kind of -- I agree with
11 Carolyn. It does look like it's nibbling around the
12 edges. But the other thing that strikes me about it --
13 and I'll pass all this along to Tom who is serving on
14 your committee. It strikes me that a lot of these
15 overlap and I think getting at the overlap is going to be
16 a little bit difficult. For example, if you're looking
17 at incidence and cost of vector borne illnesses, are you
18 going to look at that from the standpoint of water

1 quality as well? You know, there's just a lot of things
2 that look like they do overlap.

3 I'll just mention, too, as far as trade
4 opportunities, industry has data, you know, on what goes
5 where. I mean, we kind of know where -- if we have a
6 product that goes on an orange, for example, we kind of
7 know where that orange is going if it's in a certain
8 state. We kind of know what's coming in from other
9 countries. So, there is data out there that could be
10 helpful to you. If you ask us for it, I'm sure we'd be
11 able to figure out some way to make it available to you.

12 Then I would also suggest from the trade
13 opportunities portion and also resistance management, the
14 scientific societies have some of that information and I
15 think we may want to take a step back and see if Leonard
16 Geonesi (phonetic) couldn't participate in some of these
17 activities because he has an awful lot of this data
18 already collected.

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1 MR. WIDOWSKI: Thanks. Allen?

2 ALLEN: I think one outcome measure that the
3 agency could consider would be a measurement of
4 concentration of pesticide residues or metabolites of
5 pesticides such as is being done in the National Exposure
6 report. So, partnering with the Centers for Disease
7 Control and expressing support for that program and
8 expansion of it, I think you can consider if a
9 concentration of a residue goes down in the average
10 American, that that would be likely to be a health
11 benefit. I think --

12 UNIDENTIFIED MALE: Allen, if I could just
13 quickly comment on that over here?

14 ALLEN: Sure.

15 UNIDENTIFIED MALE: That's actually sort of the
16 next thing we're going to look at. This other benefits
17 part was really like --

18 UNIDENTIFIED FEMALE: Besides human health and

1 the environment. What (inaudible).

2 UNIDENTIFIED MALE: Right. What do pesticides
3 do? Well, they kill insects and grow plants. There's a
4 whole section -- the much larger section is the human
5 health benefits portion that presumably we're going to go
6 over next. That's the next burden.

7 UNIDENTIFIED FEMALE: So, basically, this
8 benefit --

9 UNIDENTIFIED FEMALE: Other benefits is other
10 things besides protect human health and protect the
11 environment.

12 UNIDENTIFIED MALE: Right. This is --

13 UNIDENTIFIED FEMALE: This is other benefits.

14 UNIDENTIFIED MALE: There are three goals or
15 three issues.

16 UNIDENTIFIED FEMALE: Right, protecting human
17 health, protecting the environment.

18 UNIDENTIFIED MALE: This is the easy one.

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1 **(Laughter.)**

2 UNIDENTIFIED MALE: Can I just add a little bit
3 to that? That was one of the things I was going to say
4 because we talked a lot about nibbling around the edges
5 and overlapping, and we felt the same way yesterday. So,
6 when we decided we were going to do human health next,
7 one of the issues behind that is that when you look at
8 the last one, vector born illness, well, that also
9 relates. So, we were trying to make the point that when
10 we do the human health, we really need to try to wrap all
11 these things together.

12 UNIDENTIFIED MALE: Just one final quick point
13 on that. There's also a need for support for the
14 National Children's Study, which is envisioned as being a
15 longitudinal study starting with preconception or
16 conception to age 21 or so. That's a program that's
17 struggling to get off the ground and could possibly be
18 integrated into the agency's mission as well.

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1 MR. JONES: Thanks. And when we do get to the
2 workgroup on the human health side, you'll see that both
3 of those are being explored by the task group. Thanks.

4 Jennifer? All right, thanks.

5 MS. SASS: Well, the advantage of going last is
6 I have a lot less to say.

7 UNIDENTIFIED MALE: You're not last.

8 **(Laughter.)**

9 MS. SASS: Oh, right, we're going around again.
10 So, it's possible that what I'm going to say is in the
11 next section, in which case, I'd like to say that I think
12 there might be some tactical communication problem with
13 your designations of your titles. That actually -- my
14 concern goes back to my statement about setting your
15 goals very carefully, because these goals were defined by
16 you as meeting the benefits of pesticides on -- and human
17 health issues. But I don't see these as the human health
18 issues, I see them as important and I think they've been

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1 identified well, but I see them as covering the -- you
2 know, the pesticides are good for your part of the
3 equation and that's important and that's legitimate.

4 But there's another part and I want to second
5 what Steve said because it was exactly what I wanted to
6 say, which is and there's a whole initiative by EPA to
7 encourage reduced risk alternatives and there's no way of
8 asking -- the questions here are all, you know, how --
9 what would life look like with or without Chemical A on
10 tomatoes or something or whatever? I want to ask the
11 question, what would life look like -- what's the cost
12 and benefit of Chemical A and how could you get the same
13 benefit to your tomato, but get an increased benefit to
14 your health or water or avian species if you move from
15 Chemical A to Chemical A minus one? That question isn't
16 in here. Does that make sense?

17 UNIDENTIFIED MALE: That's right. Again, today
18 we're just looking at the benefits piece of it. We're

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1 not going to be doing anything --

2 MS. SASS: Well, that would be a really
3 important benefit. We might have a communication --

4 UNIDENTIFIED MALE: (Inaudible).

5 UNIDENTIFIED MALE: We would --

6 UNIDENTIFIED MALE: Because there's also protect
7 the environment as the third mission.

8 UNIDENTIFIED MALE: We would capture that,
9 Jennifer, in the environment or the human health side,
10 and in theory, you would have good outcome measures for
11 all three and then every five years when you looked at
12 how you were doing, you would always show, if you were
13 doing your job right, that benefits stayed high and got
14 higher, human health got better, the environment got
15 better.

16 MS. SASS: Right.

17 UNIDENTIFIED MALE: If you saw benefits going up
18 but the environment going down, you'd go, whoa, whoa,

1 whoa, we can't be doing this right if that's what we're
2 doing, or in converse, you saw human health increasing or
3 -- human health decreasing, there was more sickness
4 associated with this, you'd stand back and you'd go,
5 we're obviously not implementing this program very well.
6 So, we do syntactically. It is a syntactic --

7 MS. SASS: So, what are you calling this section
8 that we've just seen?

9 UNIDENTIFIED MALE: The benefits.

10 UNIDENTIFIED MALE: Other benefits.

11 UNIDENTIFIED FEMALE: Other benefits.

12 MS. SASS: These eight points are called other
13 benefits?

14 MS. STERLING: Other benefits because if you'll
15 remember, I said, we see that protect human health and
16 protect the environment are benefits, too. We have
17 benefits wrapped into those. These are the benefits
18 other than those that are direct to -- directly related

1 to those other two areas.

2 MS. SASS: Okay, I think these are important,
3 but one-sided then. I think it needs to capture the
4 other side. So, I'll wait for the whole discussion, but
5 I also think when presenting this to people, we need to
6 be very careful about how we all -- we all conceive
7 benefits differently.

8 UNIDENTIFIED MALE: Sure, absolutely.

9 MS. SASS: And I think we just need clear
10 communication and titles.

11 UNIDENTIFIED FEMALE: These are the benefits.

12 UNIDENTIFIED MALE: I was worried yesterday in
13 the presentation that the costs -- the environmental
14 costs, the human health costs are all in different
15 sections than the benefits. And to derive a real
16 meaningful cost benefit analysis, you have to address
17 them together. So, you know, the cost of protecting a
18 crop, you have to factor in spray drift, the effects on

1 asthma of children. You have to look at run-off, water
2 quality, the expense of the municipalities in having to
3 monitor their water and getting rid of pesticides in
4 their water. All of these things are in the
5 environmental section and I'm sure there are going to be
6 some benefits in the environmental section, as well as
7 costs. But I think you really have to address the costs
8 along with the benefits in each of these performance
9 measures.

10 UNIDENTIFIED FEMALE: I second that. It's
11 difficult to think about it in this way.

12 UNIDENTIFIED MALE: Well, can I respond to that?
13 I had sort of the same question, but maybe from a
14 different angle, and that is, if we were all still using
15 DDT because it's a wonderful life and EPA isn't here, the
16 costs would be tremendous.

17 UNIDENTIFIED FEMALE: What do you call the
18 costs?

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1 UNIDENTIFIED MALE: The health and environmental
2 costs. But it would be a great product, the benefits --
3 you know, the resistance problems might be a bit of a
4 problem, but, you know, it was a good product.

5 (Laughter.)

6 UNIDENTIFIED MALE: But the point is, what we do
7 is we remove those from the system and we try to maintain
8 the benefits approximately the same and then we keep
9 ratcheting up the health and environmental values, and
10 that's what Jim was trying to get to. So, we can't say
11 that every compound is perfectly clean. We don't have
12 that compound yet that has absolutely no environmental or
13 health effects. Hopefully, we will someday. But what we
14 do is keep mitigating those effects.

15 UNIDENTIFIED MALE: Just a few points. It's a
16 wonderful life because EPA is here.

17 (Laughter.)

18 UNIDENTIFIED MALE: I want to make that point.

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1 I can't imagine it not being here. It's a wonderful life
2 because we're here. But the -- analytically, every
3 individual action has every one of these elements and
4 they're all integrated. Every individual action that we
5 take, of the 2,000 we took last year, has some element of
6 economic benefits, human health and environmental. What
7 we're trying to get at is how you look at the entire
8 program, not any specific action, but the entire program,
9 what are the results as it relates to the environment,
10 what are the results as it relates to human health? Are
11 they getting better or are they getting worse? And what
12 are the results to aggregate societal benefits other than
13 human health and the environment?

14 So, I can understand how you can, on an
15 individual basis, look at them all together, and that's
16 actually the appropriate way to do it and the statute
17 makes you do it that way. But when you're looking at the
18 program in an aggregate, I think it actually makes a

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1 great deal of analytical sense to look at them
2 separately. Is the environment getting better over time,
3 is it getting worse? Is human health getting better over
4 time, is it getting worse? Are societal benefits getting
5 higher over time or are they getting lower? So, I think
6 that that -- I hear what you're saying, but I think the
7 analytical framework that we are bringing to that
8 separation makes sense in an aggregate.

9 UNIDENTIFIED FEMALE: And to think, you know,
10 something like resistance management, why that has to be
11 part of the -- you know, we struggled with it trying to
12 figure out a way to measure it. But you can have -- you
13 know, if you find this chemical -- Chemical A is the
14 safest chemical of all and we don't really need anything
15 else from a safety standpoint, let's only use Chemical A
16 and really soon Chemical A doesn't work any more. So, I
17 think that's why -- you know, you're saying, we really
18 need, not only for food issues, but even for public

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1 health and for other, you know, that resistance
2 management needs to be something we somehow have to get
3 our hands around as a way to measure, because if we don't
4 factor that into the whole picture, we're going to end
5 up, in the long run, not being as successful.

6 UNIDENTIFIED MALE: Ray?

7 RAY: Well, most of the points I've thought of
8 have been covered. Understanding what other means and
9 the fact that these -- the two preceding mission areas
10 are going to be discussed subsequent to this meeting is
11 helpful. It's important to -- that the users of
12 pesticides go through this kind of cost benefit analysis
13 every time they purchase a product and decide to use it.
14 And they get very quantitative in their measurements and
15 maybe we can learn something from the way they make their
16 decisions in analyzing these costs and benefits. We also
17 need to keep in mind the non-essential clause in
18 tempering our discussion of when a benefit means you do

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1 use a product or are unable to use a product.

2 UNIDENTIFIED MALE: Bob?

3 BOB: Yeah, I was going to give Ray a plug here
4 and then he didn't take advantage of it, but I know that
5 somebody mentioned Leonard Geonesi and I know Croplife
6 Foundation just came out with a report on fungicides and
7 the benefits, and I think that's a pretty important
8 database.

9 I wanted to mention about the Section 18
10 economic loss avoidance because IR-4 is like any other
11 government program, we're always looking for measurement
12 performance standards, and we always do and have done
13 like the agency, the number of clearances and
14 registrations. But what we started to do, in cooperation
15 with the agency, is looking at the Section 18 economic
16 loss avoidance data of petitions or Section 18s that were
17 supported by IR-4 data, and we've got a database now from
18 1998 through 2004 and we're going to continue it. It

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1 basically shows a \$10 billion economic loss avoidance.
2 We have this database by state crop and active ingredient
3 and so on. So -- and certainly, Jim, you know, that's
4 available.

5 So, I would say, you know, that's one measure,
6 but then we keep -- one of the other things we keep
7 asking is, well, what is the adoption rate? I think
8 California captures most of any state, you know, the
9 products that are being used. Unfortunately, other
10 states don't capture that. They're also economic data
11 services that you have to buy the data and I think the
12 agency has some access to that information.

13 I wanted to comment one thing on the trade
14 harmonization, as an opportunity, I would tend to argue
15 that that could be a barrier. In the NAFTA context, it
16 may be true, but a lot of the commodity groups we're
17 working with are saying that because IR-4 and the EPA
18 have been so up front in the global market of registering

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1 a lot of new products, these products are not registered
2 in other countries and there are no MRLs or tolerances in
3 those countries. So, we're running into a number of
4 issues where growers that grow products here and export
5 to countries where MRLs are not established cannot use
6 these products if they're going to export their crops.
7 So, I'd be very -- there's a downside to this
8 international harmonization and I would say it's very
9 serious right now.

10 UNIDENTIFIED MALE: Bob, I would just possibly
11 tweak your last statement. There's a downside to
12 registering so many things so quickly. The upside would
13 be international harmonization, so that everybody else is
14 moving so fast.

15 UNIDENTIFIED MALE: That's right. It's
16 certainly not a downside.

17 UNIDENTIFIED MALE: Okay.

18 UNIDENTIFIED MALE: We're just so good at doing

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1 this.

2 UNIDENTIFIED MALE: Bob Rosenberg and Gary?

3 MR. ROSENBERG: Well, I mean, just a few quick
4 comments. I'm not even sure what the point of them is,
5 but one of them is I'm just like --

6 UNIDENTIFIED FEMALE: He's going to say it
7 anyway.

8 MR. ROSENBERG: You knew I would. It's just the
9 difficulty of measuring the OPP contribution to a
10 particular outcome seems to me like something that's very
11 difficult to do. If, for instance, you just took a very
12 simple measure, for instance the outcome was a reduction
13 in the incidence of West Nile Virus, the question then
14 would be if we could count that, and I think we can count
15 that, then is how much of that reduction in the incidence
16 of West Nile Virus was attributable to the availability
17 of effective pesticides? And if you could measure that,
18 then how much of the fact that effective pesticides were

1 available is attributable to OPP actions? I mean, I just
2 don't even know where you begin to think about some of
3 these things. I'm only saying that just to highlight the
4 complexity of thinking through some of these issues.

5 The second point I wanted to make, and one that
6 I'm sure some people will disagree with, was in addition
7 to the eight that were up there and one that -- if there
8 was a fourth category of like beyond pie in the sky, just
9 like not even worth talking about, but there's kind of a
10 quality of life issue of the six-and-a-half billion
11 dollars of structural -- commercial structural pest
12 control done. Almost none of it is done -- I shouldn't
13 say almost none of it. A --

14 **(End of Tape 3, Side A)**

15 MR. ROSENBERG: I think it's one that actually
16 drives most consumers in their pest management, lawn care
17 and other practices, and it's probably a fairly important
18 factor.

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1 UNIDENTIFIED MALE: Okay.

2 UNIDENTIFIED MALE: Okay.

3 UNIDENTIFIED MALE: Well, I appreciate all of
4 the -- I'm sure you guys are ready to -- oh, sorry,
5 Terry.

6 DR. TROXELL: Well, I just want to echo what
7 Carolyn said and indicate that the FDA, I'm sure USDA,
8 also, has great difficulty with developing appropriate
9 performance measures for part. Exactly what you're
10 saying, Bob, is we do things at one stage and the measure
11 is -- you know, if we put out a guidance, well, how do we
12 relate that to fewer people getting sick, whether it be
13 EPA or FDA? So, there's many steps in the process.

14 I really do think what Carolyn says is critical.
15 I mean, how do you model if there were no EPA? You can
16 model for a corporation. If they come out with a new
17 product, they can measure how many units they sell, you
18 know, how many -- people are walking around with iPods

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1 and smiling or whatever. But you cannot -- but what it
2 seems we're being asked to do so often is how -- how can
3 we enhance rather than -- so, what's the incremental
4 change rather than what is the total impact, and it's
5 very, very difficult to get a handle on quantitative, to
6 get a handle on the results.

7 Just to point out that this is, I think, pretty
8 generally a problem in government agencies, at least,
9 that are involved in public health and so on.

10 UNIDENTIFIED MALE: Okay, Sherry?

11 MS. STERLING: Just that the workgroup asked me
12 to tell you something that you've already heard, that the
13 next thing that they will tackle is the human health
14 mission areas, and included in that will include the safe
15 -- the worker safety, as well as the food aggregate risk
16 piece. Once we've gone through that, we'll then tackle
17 the environment mission area with the water quality
18 areas, as well as the endangered species. And I'm sure

1 that after that, we'll want to take a -- they'll want to
2 take a step back and look at everything together and --

3 UNIDENTIFIED MALE: After that, we'll retire.

4 **(Laughter.)**

5 MS. STERLING: Not before I do.

6 MR. JONES: I want to thank, in particular, the
7 members of this committee for working on this issue.
8 Even though some judgments have to be made in the January
9 time frame, I can assure you they will be interim in
10 their very nature because I'm quite certain that we will
11 not have nailed it and that it's going to take some time
12 to nail it, and I expect that we're going to work at this
13 both in EPA and with this committee until we get it to
14 the point where we can stand back and go, you know what,
15 I think that those are meaningful and appropriate
16 measures for this program. So, thanks very much for what
17 you have done and we look forward to future advice from
18 all of you in the not too distant future.

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1 Now, Bill Diamond is going to give us just a few
2 updates here on some of the other rulemakings that we
3 have going on. We heard this morning about the
4 registration review rulemaking. Bill, the Director of
5 Field and External Affairs Division, is going to just
6 give us quick updates on three of the rulemakings that we
7 have in the active stage in our program right now.

8 MR. DIAMOND: Good afternoon. This is one of
9 those sessions where we're going to be able to make up a
10 little time on the agenda, not only because I talk
11 quickly, but because this session, by design, is supposed
12 to be an update on the status of activities as opposed to
13 issue engagement like the previous two.

14 What we're going to try and walk through fairly
15 quickly is just to give you a quick sense of where we are
16 on a couple of the rulemakings that are pending that will
17 be out in the not too distant future, we hope, a sense of
18 how this rulemaking fits into our broader activities

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1 overall programmatically and then just give you a quick
2 heads-up for some of the ones that are a little bit
3 further down the rulemaking pipe and that you ought to be
4 paying attention to in the not too distant future again.

5 In terms of the role of rulemaking overall, just
6 to set a little context, we think it's just another one
7 of the components we've talked about that carries out the
8 overall mission that you've heard a number of times, and
9 the intent of what we try to do with the rulemaking is to
10 make sure that it advances that mission in terms of the
11 contribution it can make, but also in a high quality
12 fashion under the time desired.

13 The role of rulemaking overall is fairly clear
14 to most people, but just to reiterate a couple of things
15 we see as the most valuable contributions, is that
16 it's -- you don't need rules to do everything in the
17 program, but for a couple of things, it's essential and
18 for this it makes a valuable contribution here, and I

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1 think that's reflected in the rules that we're focusing
2 on right now from a number of perspectives here.

3 Here's some of the benefits that we try to
4 achieve overall in terms of the rulemaking part of our
5 program, the real regulation rules as opposed to our
6 registration rulemaking activities here. Clearly, it's
7 essential for establishing some of the base requirements
8 and things like worker protection and other areas to
9 achieve the overall objective of public health and
10 environmental protection, but also, additionally, it
11 gives some secondary benefits that are reflected in a
12 couple of rules as well, clarity of understanding of what
13 the rules are, transparency in terms of what's applicable
14 to everyone, consistency of application. It's in the
15 rules, people understand it better, people can utilize it
16 better, and there's less redundancy on case-by-case
17 determinations there.

18 Overall, in terms of just the structure, when

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1 we're trying to make some changes in the program and how
2 we do overall, the rulemaking process is very valuable,
3 we think, to try and achieve that objective.

4 When we move to our rules, there's a big demand
5 for a number of different rules, some small, some large.
6 These are the types of areas we try and group them into
7 in terms of helping us to organize our efforts, but also
8 in terms of trying to decide priorities when we have to
9 choose between them with a limited number of resources.

10 Clearly, the health and environmental
11 improvements are at the top of our list. Some of those
12 rules that fall into those bins would be the container
13 integrity rules, containment rules, certainly the worker
14 protection rules, applicator certification rules in terms
15 of their competence and their safety, protect themselves.
16 A second large category would be program modification.
17 Registration review that was talked about this morning
18 falls into that bin.

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1 Sound science through sound data to help us make
2 the decisions. The complete suite of the 158 rules that
3 we're working on would advance those objectives. And
4 then, finally, efficiency process improvements, some
5 things like the Section 18 emergency exemption process
6 would fall into those things. These aren't the only ones
7 we're working on in those areas, but these are some of
8 the key ones that would advance on all four fronts how we
9 do our business.

10 In terms of just a quick update on a couple of
11 the rules that are the most pressing ones here, these are
12 updates, we're not going to get into the issues. These
13 three sets of rules are all post public comment period.
14 We're going to talk to process and timing and what the
15 issues are in terms of how do we get it out as opposed to
16 the content issues here.

17 Section 18, emergency exemption process is
18 intended to streamline that process, make it more

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1 understandable to people and try and move things more
2 quickly through that process. It was proposed about a
3 year ago. We got a relatively finite number of comments
4 on that, some fairly detailed, but a fairly small number.
5 We've basically got the final rule drafted in response to
6 those comments and it's going through the final inter-
7 agency review process internally and then, obviously,
8 through OMB and coordinating with our other partners who
9 have a review role in that rulemaking process.

10 As people are aware, while this is going on,
11 we've got a pilot program that continues until the final
12 rule. That basically is test driving and taking
13 advantage of some of those improvements while the rule's
14 under development. Promulgation of the final rule looks
15 like it's going to be probably early in 2006 as we wrap
16 up that process. We think it's on the right track. We
17 don't see any major barriers holding that up yet.

18 And then we're already planning the

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1 implementation of the roll-out workshops to educate
2 people in terms of what will be different, how do you do
3 things, and for the people that haven't been involved and
4 knowledgeable on the pilot, what it means for the changes
5 in this rule here.

6 The container and containment rule, we've got an
7 effort underway to try and upgrade or improve the
8 requirements for the specific structural integrity of
9 containers, so we can minimize the exposure during
10 handling, facilitate container disposal and recycling,
11 cleaning them up and making sure that they're the right
12 and proper and safe level, and then through the
13 containment aspects, try and prevent exposure through
14 spills and releases is the underlying attempt at that.

15 This rule has been under development for a
16 number of years now. We've had several rounds of public
17 comment period. The most recent one was in June of 2004.
18 We had a significantly larger set of comments on this

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1 than we did for the last Section 18 we were just
2 describing. We're in the process of revising that
3 comment -- that final rule package now and then we'll
4 move into final agency review. We're right on that cusp
5 now in terms of trying to get it into that process of
6 closure internally through the external review.

7 Right now, it looks like we're on the same track
8 for early 2006 for the final promulgation of that rule
9 and we'll also be getting the rule out in terms of how do
10 we implement that through whatever changes are necessary
11 at the state level, education and training and other
12 activities.

13 As an aside here, I'll just mention that in
14 terms of this package, one of the issues that has come up
15 recently is the agency's endorsement and support for
16 recycling as part of this, separate from rulemaking. The
17 agency's been strongly supportive of recycling activities
18 now. Recently, we've been actively involved with a

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1 number of the other partners in terms of developing a
2 voluntary standard for recycling of pesticide containers,
3 and just recently, the Assistant Administrator has
4 committed us to try to explore regulatory options to
5 enhance the container recycling that's already out there
6 on a voluntary basis. We expect that that's going to be
7 an increasing activity for us in the coming months. It
8 won't be something that will be contained in terms of the
9 final container rule, it's on a different time frame. We
10 do feel a certain sense of urgency to try and make sure
11 that that happens and we'll be working with some of our
12 partners to try and develop that.

13 The last big rule that I'll be talking about in
14 terms of specifics here is the conventional pesticides
15 data requirements rule, Part 158, big 158. That's to
16 update the requirements, basically, to reflect current
17 practice overall. And the benefits of this is primarily
18 some of the objectives we talked about earlier; clarify,

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1 transparency, consistency, but also to give us an updated
2 foundation in the rulemaking for the next generation of
3 data requirements that we'll be looking at.

4 This rule was proposed in March 2005. It was
5 based upon a lot of the case-by-case lessons and
6 practices that have gone on over the last decade. So,
7 there's a lot of involvement on this, contains a lot of
8 specific issues that went to the Science Advisory Panel
9 throughout, again, the last decade, and it's kind of
10 capturing it all. It also is a means to clarify and
11 reorganize the rule structure itself so it's more user-
12 friendly and understandable.

13 We proposed a 90-day comment period. We had
14 requests for an extension of that comment period, so we
15 went to a full six-month comment period to enable people
16 to get their thoughts together and give us informed
17 comments. That comment period closed in September. We
18 had over 150 different comments, again, some fairly

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1 extensive, some more focused, some technical, some
2 programmatic. We're in the process now of reviewing that
3 -- those comments, trying to break them out in terms of
4 different activity areas and then we'll move, obviously,
5 to finalization and modification of that package as
6 appropriate.

7 Right now, that package is targeted for final
8 issuance in early 2007. That time frame is going to be
9 flexible in terms of the extent of the difficulty of
10 dealing with some of those issues. It could advance a
11 little bit, it could slide a little bit as we get our
12 hands on it in terms of the work that's involved to look
13 at, modify and debate some of those issues that the
14 comments will raise.

15 The last area that I'll look at here is just
16 some of the other upcoming rules that are in the
17 pipeline. We've got one in terms of data requirements
18 for plant incorporated pesticides. Again, the entire

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1 suite of 158 that's in the early planning stages, this is
2 kind of an early warning. The next one we have is the
3 158L&M rules. That's data requirements for biochemical
4 and microbial pesticides. It fits into the same
5 structure of the large 158. These are sequenced so that
6 they can be all -- we've got the structure in place when
7 these things are ready. It also is reflective of the
8 amount of work and where we are in the developmental
9 process.

10 That proposed rule is now currently undergoing
11 inter-agency review and we plan to issue that early in
12 2006 as a proposal.

13 One of the things that was referred earlier, I
14 think, in one of the sessions is the crop grouping
15 expansion. We see this as more of a technical fix.
16 We're planning to expand the crop grouping for tolerance
17 setting. We're working closely with the IR-4 people who
18 have done some of the scientific legwork of what's the

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1 documentation and what's appropriate. Benefits there,
2 obviously, are some less testing, some increased speed.
3 This is a scoping type of thing determined in part in
4 terms of the contents and the timing in terms of when
5 that documentation is ready.

6 One of the things that's not mentioned up here,
7 I'll just say in passing, is the 158W data requirement
8 rule that has the same scope for the antimicrobials, the
9 data requirements, what testing requirements are there.
10 That's in the queue. It's a little bit further behind
11 the 158L&M. We expect to have that one moving along in
12 the next calendar year as well.

13 That's the quick tour of what it is in terms of
14 timing and what's in the pipeline. Any questions, I'll
15 be glad to address them.

16 MR. JONES: Carolyn?

17 MS. BRICKEY: Well, I just -- it just strikes me
18 that there's an awful lot of good verbiage about the

1 whole rationale for your rulemaking program that might be
2 applicable to the performance measures group.

3 MR. DIAMOND: Well, we've obviously been
4 involved, in terms of working with them and in terms of
5 the performance group people. In terms of rulemaking
6 itself, it's just one of the contributions under that
7 large protective umbrella. We're looking for measures
8 internally in terms of how effective we are, what would
9 be a good kind of programmatic measure. Timing would
10 certainly be one. You can't get the benefits of these
11 rules if they're not on the streets. We've done a good
12 effort over the last couple of years to try and
13 accelerate those types of things.

14 The contribution in terms of the quality of
15 those rules is a little bit harder to get our hands on,
16 and since it contributes -- ultimately, if we have better
17 data -- to better human health and environmental
18 protection. Breaking that out in terms of a separate

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1 measure is kind of difficult, but it's something that
2 we're at least exploring.

3 MR. JONES: (Inaudible).

4 UNIDENTIFIED MALE: First of all, I wanted to
5 commend you. This was an excellent presentation. And,
6 also, commend your group because you got -- a lot of
7 people who are not heavily involved in this thing may not
8 know this, but there is a lot of discussions internally
9 and externally. You had part of our industry come in and
10 talk to you about this 158L&M and we do appreciate that.
11 I think our points are in there, too, as you'll see.

12 MR. DIAMOND: Yeah, we appreciate that in terms
13 of -- particularly in the early planning stages. The
14 earlier that we can engage people and get their input, as
15 opposed to just waiting until the public comment period,
16 the quicker it is for all of us, the better for us, so we
17 make a large effort. And that's not just my group, but
18 all of the client organizations, the other divisions play

1 a large role in that, and I think that's contributing to
2 our means to accelerate some of these processes.

3 MR. JONES: Beth?

4 DR. CARROLL: I'm just curious and maybe I
5 missed this along the way, but why would you not be able
6 to go ahead and put recycling into the container and
7 containment rule? It seems like a perfect place for it.
8 And we spend a lot of money, our company does, at least,
9 and we'd kind of like to see a level playing field.

10 MR. DIAMOND: We explored that extensively in
11 terms of trying to determine if that was a vehicle and
12 there's a couple of reasons for that. One is that, just
13 legally, there was no mention in terms of a recycling
14 proposal or a recycling aspect in the proposal. So, we
15 would need a re-proposal, we would need a re-notification
16 process, et al.

17 The second part of that is we've done none of
18 the -- we've had some discussions in terms of what that

1 recycling type of approach would be, but there's a range
2 in terms of scope and coverage that is not defined here.
3 We also haven't done any of the economic analysis that
4 would have to be done to support those things. Once you
5 get that, which goes to the substance and contents of
6 what the rule would be, even if it's kind of a narrow and
7 defined thing, you've got to run through the whole
8 gauntlet, again, of not just the public comment period,
9 but the internal review process.

10 The container rule, which I say has been under
11 development, is kind of at the eleventh-and-a-half hour
12 out there now. We don't think it's appropriate to lose
13 the benefits of having that one out there by holding it
14 up for a year, a year-and-a-half, if that was the case,
15 for this narrow one that can proceed on a separate trail,
16 and the decision we've got is to explore those. We
17 haven't got a decision yet that the agency will go ahead
18 on that. Senior management and others still have to be

1 engaged on that decision.

2 MR. JONES: Bob, then Jose.

3 BOB: Yeah, Bill, I just wanted to personally
4 thank you and your division for working with IR-4 and the
5 crop grouping expansion and also the Registration
6 Division and Health and Effects Division. I don't know
7 whether people really -- I know Lois mentioned it this
8 morning -- really realize the importance of crop
9 groupings. There are currently 508 crops that you can
10 register on in the U.S. right now, and if we had to do
11 residue studies on each individual crop, we would get
12 nowhere. So, by having the current 19-crop groupings and
13 representative crops, we can get a lot of mileage out of
14 doing GLP residue studies.

15 We're proposing to probably double or triple
16 that number. It's amazing about the number of crops that
17 are being grown in the United States now with our diverse
18 ethnic populations. I think people will be surprised to

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1 know how many there are that currently there are no pest
2 control tools for.

3 The other benefit of this, and I think we're
4 just seeing it more recently, is in the international
5 arena. This may be a mechanism by which we can work with
6 the Europeans and the Asians in harmonizing MRLs, because
7 some countries have crop groupings but without
8 representative crops and others are looking to adopt a
9 uniform system. I think we have an opportunity to
10 provide a global leadership role with this project. I
11 want to thank the agency for taking this as a strategic
12 initiative.

13 MR. JONES: Thanks, Bob. Jose and then Troy?

14 DR. AMADOR: Bill, it looks like you're going to
15 have that workshop on Section 18 early in 2006. Is that
16 more or less the target date?

17 MR. DIAMOND: Yeah. Well, we hope -- what we're
18 hoping to do is once we roll these rules out is that not

1 too far after that, we move into the implementation mode.
2 The first thing is communication and training. So, we
3 haven't got a date set yet. Once we get closer to a firm
4 thing that we know when it's going to pop out of the
5 final process, then we'll get to scheduling, but we
6 expect that to be not too far after when it's actually
7 published, which would be at least in the first half of
8 calendar 2006 is our hope.

9 DR. AMADOR: What audience are you going to
10 target for that workshop?

11 MR. DIAMOND: Well, we'd have to look at that,
12 too. Part of it is the interest of that, but the Section
13 18s could have a wide variety. I think part of it -- the
14 thing that we would be talking to is state counterparts
15 and also the people who have been engaged in the pilot to
16 inform us where it would be -- where the training and the
17 outreach would be most valuable.

18 DR. AMADOR: It would be nice if you let some of

1 the universities know, as well, because these states are
2 the ones that submit the 18, but a lot of the data that
3 the states need is collected by the universities in
4 experimentation like mine. So, it would be nice to know
5 ahead of time when it's going to happen. I'm pretty sure
6 there would be a lot of people in my group that would
7 like to know about it.

8 MR. DIAMOND: Right.

9 MR. JONES: Troy?

10 MR. SEIDLE: Thanks. I appreciate the heads-up
11 about the plant incorporated protectants rulemaking. Can
12 you give a little more background on the time frame?
13 Which division, is it BPPD or OSCP that's --

14 MR. DIAMOND: It's BPPD -- I've got too many Ps
15 in there probably. Yeah, it's Janet Anderson's division
16 that we're working closely with. As you probably know, a
17 lot of these rulemakings require a lot of legwork up
18 front. Her division on the L&M and on this one is being

1 very aggressive in doing that so we can get to that
2 point. I'd say we're just now starting to tier it up,
3 which is the internal agency process to identify that
4 it's going to be there, have the other parts of the
5 agency, have the workgroup. That's usually at least a
6 year in advance. The reason we're doing that now is so
7 there's no surprises and the process can start becoming
8 aware while we're still preparing the substance.

9 So, it's a little ways off. I'm sure Janet
10 would be glad to talk to you in terms of more details of
11 the direction we're headed on that.

12 MR. JONES: All right, well, very good. We're
13 30 seconds ahead of schedule.

14 **(Laughter.)**

15 MR. JONES: So, we now get a 15-minute and 30-
16 second break. See you all back at 3:15.

17 **(Whereupon, a brief recess was taken.)**

18 MR. JONES: We need to get started here. We've

1 squandered our 30 seconds of being ahead of schedule.

2 UNIDENTIFIED FEMALE: Shhh. Shhh.

3 MR. JONES: Thank you. Okay. The next session,
4 which will be led by Drs. Bradbury and Levine, the
5 Directors of the Health Effects Division and the
6 Environmental Fate and Effects Division in OPP, not in
7 that order, is to be a little bit of a tickler for all of
8 you about where we see the future of toxicity testing for
9 pesticides, and frankly, for other chemicals, how we see
10 it evolving in the coming years, and I think in terms of
11 five to 15 years.

12 Not necessarily is this session designed to
13 engender a lot of dialogue around it, but as much to sort
14 of begin to inform you about the long-term strategy that
15 we're engaging in as are several others within the
16 Environmental Protection Agency and outside the EPA as it
17 relates to toxicity testing. So, with that, I'll turn it
18 over to Steve Bradbury and Tina Levine.

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1 DR. LEVINE: Thank you, Jim. What we're going
2 to do here is give you a bit of an update on where our
3 thinking is about the future of toxicity testing. A few
4 years ago when we were in the midst of TQM and the
5 government, we used to talk about continuous improvement,
6 and that's where this sort of fits in. Even as we are
7 codifying changes into Part 158, we're thinking about
8 where are we going from here and what are the next
9 improvements that we need to make to the testing scheme?

10 We face challenges at EPA, as the regulated
11 community does, too, as well as the regulated community
12 and regulating authorities abroad, but given that we have
13 finite resources and time to generate and to evaluate
14 data, how are we going to cope with this? When
15 confronted with large numbers of chemicals to assess,
16 which ones do we look at first? When confronted with a
17 wide range of possible toxicity endpoints, which outcomes
18 are more likely?

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1 We like to sort of visualize this, as do many
2 people, I think, as a funnel with filters selectively
3 screening out to be able to hone in on the most important
4 endpoints of concern. We're going to talk about a couple
5 of areas, both in terms of more efficient use of animal
6 testing, as well as using non-animal methods to screen
7 this afternoon.

8 There are a number of current projects going on
9 to consider the best way to do toxicity testing in the
10 future. There's a project that NAS/NRC is working on.
11 We have a couple of programs at EPA, computational tox
12 programs, as does the FDA. There are a number of
13 projects with ILSI/HESI and the OECD has also been
14 considering these challenges.

15 Among the principles and goals we have for the
16 next generation of toxicity testing, we want to have a
17 sufficient and credible amount of data for assessing and
18 managing our decisions. We don't want an overwhelming

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1 amount of data, but we want to have enough and of good
2 quality. We want to be able to reduce cost and time to
3 develop data, as well as reducing the cost and time for
4 us to review the data. We want to reduce the use of
5 animals. We want to take advantage of advances in
6 science and technology, but we want to have peer-reviewed
7 credible sound science decisions.

8 We want our data requirements to be clear to the
9 interested stakeholders and consistent in the way we
10 apply them, and we want our -- the process that we use to
11 transition to these new paradigms to be transparent.

12 With that, I would like to turn the discussion
13 over to Vicki DeLarco (phonetic), who is a Senior
14 Scientist in the Health Effects Division, who has been
15 very involved with the ILSI/HESI project on tier testing
16 -- whole animal tier testing.

17 DR. DeLARCO: Yeah, I'm going to tell you a
18 little bit about this project. But let me tell you who

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1 is HESI, the Health Environmental Science Institute.
2 It's a global organization under ILSI that supports
3 scientific projects that address important issues in the
4 area of health and environmental risk assessment by
5 bringing together scientists from academic, government
6 and industry to work together to seek balanced approaches
7 to addressing these problems.

8 Designing an improved toxicity scheme to provide
9 a better basis for human health risk assessment is a high
10 priority topic among a number of organizations.

11 Therefore, there's multi-sector interests in this area.

12 So, towards that end, HESI pulled together a group of
13 scientists from all over the world, about 50 or so
14 scientists that represented nine different countries from
15 Academic and government, in addition to EPA. It also
16 involved some of our international regulatory
17 authorities, in addition to the industry.

18 In the first meeting that they had, they wanted

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1 to reach consensus on a scientifically credible and
2 viable approach for evaluating the safety of pesticides
3 more efficiently, with fewer animal, with fewer
4 artifacts, and more accurately. So, when we first got
5 together in 2001, there was unanimous agreement that we
6 wanted a science-based approach. We wanted a more
7 hypothesis-driven paradigm and that we should take a tier
8 testing scheme and that this scheme needed to provide
9 assurance that pesticide -- that the pesticide can be
10 used without damaging human health, and that it starts
11 with existing knowledge, what you understand about the
12 toxicological properties of that class or that class of
13 chemicals, and also, the use patterns.

14 To develop this new paradigm, they broke out the
15 group into three task forces. There was a group that
16 looked at how to improve the metabolic information that
17 we get, how to improve the systemic tox and how to
18 improve the life stage information. Two of our senior

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1 laboratory investigators were the co-chairs on two of
2 these task groups. Dr. Hugh Barton from our National
3 Human Effects Research Laboratory at RTP chaired the --
4 what we call the ADME, absorption, distribution,
5 metabolism and elimination task group, and Dr. Ralph
6 Cooper co-chaired the life stage group.

7 The charge to each of these task groups was to,
8 as you designed this tiered approach, to introduce
9 greater flexibility, so it could accommodate the existing
10 science, and also keep up with new science that might
11 emerge and to emphasize the three Rs, reducing and
12 refining animal usage and to ensure that it included
13 evaluation, at least in the base set of studies that they
14 start with, for all relevant toxicity parameters.

15 We wanted a more integrative approach where you
16 just don't do the systemic tox test and then you do the
17 life stage test and do the metabolism test, but these
18 different tests would interact and inform each other.

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1 And then incorporate and improve understanding of
2 exposure. In other words, how would this be used? Were
3 we concerned with intermittent, episodic situations and
4 therefore we wanted to focus on getting better hazard
5 data, short-term hazard data, what were the routes that
6 people would be exposed by?

7 If you look at the papers, these papers are now
8 available on the HESI website. We asked them, even
9 though they're not in publication right now, to make them
10 available, so people can start reading them, because we
11 do think that this is an important milestone. When you
12 think about it, you bring 50 scientists together from all
13 over the world to reach consensus, that, in itself, is a
14 milestone, and we think this proposal has some merit.
15 But it's just rolling out. It's undergone journal
16 review. It will show up in critical reviews in
17 toxicology. It will probably be published, if not the
18 end of this year, the very beginning of next year.

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1 But we need to -- we want to engage an extensive
2 dialogue not only with the scientific community, but our
3 stakeholder groups.

4 Although there are a lot of improvements in this
5 proposal, there still needs to be some foundation
6 building, in our opinion, and -- for example, the
7 proposal drops the mouse cancer bioassay. For years, we
8 have been asking for two species, and this will be an
9 issue that will not only need more discussion and
10 documentation, we realize there will be different views
11 on it. Another area is that because it is science-based
12 and you start with this base set, what are the triggers
13 that may take you to an upper level of testing, in other
14 words, a toxicity that you might see that you want to
15 chase down, not that you want to chase down, that you
16 need to chase down and characterize further. Although
17 there's some discussion about those triggers, there will
18 be a need for more dialogue and discussion thinking

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1 around them.

2 The scheme is based on exposure considerations,
3 depending on a margin of exposure, you may not need to go
4 to more upper tiers of testing. But what is that margin
5 of exposure? We have considered exposure in other
6 situations, like for our biopesticides and our
7 antimicrobials, that we haven't done in this situation.
8 So, more dialogue is needed there.

9 The other thing is -- for example, the one
10 generation enhanced study that they've proposed to look
11 at life stage effects has a lot of things built into it.
12 It will be important to do a prospective analysis to take
13 this new approach and get some laboratories, government
14 laboratories, maybe in collaboration with the industry
15 laboratories, and run some new chemicals through it to
16 see if it's going to do what we think it's going to do.
17 As we engage in further dialogue with the scientific
18 community and with our stakeholder community, other

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1 issues might arise, technical issues, maybe policy
2 issues. So, again, this is just beginning to roll out.

3 Now, in any new proposal that you look at, it's
4 important to document that. We've started the scientific
5 documentation process. In other words, if you design
6 something new, you want to go back to look at what have
7 you been doing for the last 30 years and what have you
8 learned from that. And so, we have this large database
9 and we've been examining it to look to see what studies
10 or measures have been very valuable in the risk
11 assessment process and what measures have contributed
12 very little.

13 One analysis that we did recently that we
14 released publicly is looking at the dog studies; in other
15 words, what benefit is there to do a one-year dog study
16 beyond the 90-day dog study? From our look at the
17 database, it appeared that there was very little
18 information that we were getting from that one-year

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1 study. So, we took that to the SAP to get their opinion
2 on it and to review that and they were generally
3 supportive, but they had several major recommendations.
4 Our original analysis was based on about 77 pesticides,
5 and they wanted us to go back and look at more
6 pesticides, particularly those where the dog was not
7 necessarily the sensitive species to set the RFD. And
8 they wanted a larger analysis to ensure that we had more
9 classes of pesticides represented. So, we've already
10 begun work on that based on those recommendations.

11 The other thing that's important is sort of
12 international harmonization and they felt that we needed
13 to engage with our international colleagues on this
14 issue. In Germany, they have done similar work in
15 looking at the database on dog studies, and we are in
16 communication with them now seeing how we can bring our
17 two analyses together and continue that international
18 work.

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1 There's other analyses of our database that we
2 have ongoing and we're looking at our rodent cancer
3 bioassays. Right now, there's four studies that are done
4 and -- to see if somehow we can reduce that protocol and
5 not lose information. We're also looking at our two
6 generation reproductive studies and seeing how often do
7 we detect effects in the second generation that you
8 wouldn't pick up in the first generation or get a lower
9 (inaudible) in the second generation. And then the last
10 thing that -- one of the other things that we're looking
11 at is rat developmental neurotoxicity study. As some of
12 you might know, we put out retrospective analysis of that
13 study a couple of years ago, but last year, we received a
14 number of new rat DNTs, and so, we've been evaluating and
15 looking at them. So, that analysis is ongoing.

16 Another important step as you move towards the
17 next generation of toxicology data requirements is to
18 work in several venues to gain international

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1 harmonization, and that's really critical. It's unlikely
2 that the regulated community are going to want to meet
3 different data requirements. So, we have a commitment to
4 international harmonization and we began that dialogue
5 with -- earlier this year at an OECD meeting and we'll
6 continue that dialogue.

7 The other thing is this is new and it hasn't
8 been widely available. So, an education process is going
9 to be very important. We've been working internally with
10 our own staff, going in detail over these proposals just
11 to bring everybody up on the same page. That included
12 some of our other counterparts, CAL EPA and Health
13 Canada.

14 We started outreach with our stakeholder
15 community with our May 158 workshop and we're continuing
16 it with this meeting.

17 So, we think that the ILSI proposal is an
18 important springboard. One consideration that we should

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1 be looking at as we move forward to the next generation
2 of requirements, but it's just one activity, we're
3 looking at a number of activities, and Steve's going to
4 talk to you a little bit about our computational program
5 and how this proposal intersects nicely with that.

6 DR. BRADBURY: Before I start, I just wanted to
7 take a couple of minutes and reflect back on Tina's
8 introductory comments and sort of touch base again and
9 make sure we're all in the same context. One of the
10 challenges that was, I think, reflected in our discussion
11 on performance measures and our goals is how to ensure
12 that we're protecting public health and the environment
13 and ensuring the benefits of the products, but how do we
14 do that as efficiently as we can so we focus limited
15 valuable resources as effectively as we can, so we
16 maximize the use of all of society's resources in moving
17 ahead and making these decisions.

18 So, we're sort of faced with a challenge of how

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1 to ensure that we have sufficient credible information to
2 make informed and proper decisions and use those limited
3 resources wisely. The integrative testing, integrative
4 assessment concept gets at how do we ensure that we're
5 using all sorts of available information to help drive
6 that decision-making and to help focus limited resources
7 where they need to be focused?

8 So, in other words, in addition to just using in
9 vivo testing in sort of today's world of toxicity testing
10 in today's world of doing risk assessments, how do we
11 start advancing the incorporation of other technologies
12 -- it could be technologies that are coming out of the
13 computer, it could be technologies that are coming out of
14 cell lines or in vitro assays, to help inform us as to
15 what questions are really critical for a given decision
16 we need to make and how do we then focus resources,
17 resources for the regulated community, resources for the
18 government agencies and the regulatory agencies to ensure

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1 that everyone's focusing those resources as fine tunely
2 as we can?

3 One piece of the building blocks to advance this
4 integrative testing and assessment paradigm relies on
5 many of the principles that Vicki just talked about, how
6 to maximize the information content for every animal
7 that's used in a toxicity study, how can we take
8 advantage of information that's learned in a classic, if
9 you will, study to help support human health risk
10 assessment, how can that same information inform our
11 ecological risk assessment and improve our ability to
12 extrapolate across species?

13 So, getting that more efficient, more
14 diagnostic, more hypothesis driven in vivo testing
15 protocol is a very important part of the evolution of
16 this integrative assessment and testing paradigm.

17 But this funnel on the -- the funnel concept on
18 this slide is trying to address the challenge of how do

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1 we decide when, what and how are we going to do in vivo
2 testing? How do we deal -- if we think about the agency
3 as a whole and its challenge with a variety of chemical
4 inventories, how do you take a look at those large
5 chemical inventories and decide how to focus in on
6 specific chemicals when you need to and what do you need
7 to really learn about a given chemical, given your
8 regulatory decision-making process? How do you move
9 towards the use of the computer in silico-predictive
10 models, as well as in vitro testing and other kinds of
11 emerging technologies to help zero in on that question so
12 that when you are doing your in vivo testing, it's
13 focused on the likely drivers for that overall risk
14 assessment? Or for a given chemical, how do we start
15 thinking about, as Jim said, five, 10, 15 years down the
16 road and zeroing in on what's the most likely adverse
17 outcome for the chemical and can we use emerging
18 technologies to help zero in on what the most likely

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1 adverse outcome is for a chemical and move away from --
2 over time with the right science and the right public
3 participation to a paradigm that instead of requiring
4 testing for all possible in vivo tests and every possible
5 outcome, how do we start to zero in on the efficiencies
6 of doing that kind of testing?

7 So, one of the aspects that we're looking at
8 with partners, not only in EPA, but across the Federal
9 Government and internationally, is the use of a variety
10 of in vitro techniques and computer techniques,
11 quantitative structure activity relationships, for
12 example, which take a look at a structure and try to
13 predict biological potency, but also the development of
14 omics (phonetic) technology, the emerging molecular
15 biology technologies that are being used in drug
16 discovery and in vivo chemical discovery, but also
17 starting to be used in helping to understand what
18 potential adverse outcomes may be associated with a

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1 chemical structure.

2 So, the computational toxicology program in the
3 EPA is a program that's trying to more aggressively and
4 systematically take a look at those emerging technologies
5 and see how that information and those techniques can
6 start to be used in a risk assessment venue just as they
7 are starting to be used in a drug discovery and an eco-
8 chemical discovery concept. Again, the evolution of the
9 process is, first, probably just how to help one better
10 define your question and define information needs and how
11 to better use information that we can be gathering in a
12 number of contexts.

13 One of the reasons we're also taking a look at
14 this is the realization that these kinds of technologies,
15 computational toxicology, omics technology, genomics,
16 proteonomics (phonetic), they're happening now in the
17 industry and one can imagine over the coming years that
18 information will be part of the information to help

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1 interpret the potential risk of a compound. So, we want
2 to be at the front end of that process with partners in
3 the regulator community, academia and our international
4 partners to be at the front end of that so that we're
5 prepared to take advantage of that information as it
6 starts to emerge.

7 So, I think it's a foregone conclusion that
8 those technologies are happening and that information
9 will emerge. How do we understand how to use that
10 information in the risk assessment process?

11 And, again, as I was saying before, there's a
12 number of different activities going on globally in terms
13 of this whole matrix of tools and techniques that are
14 coming into play. Vicki talked about the ILSI/HESI
15 efforts. There's not only the efficient in vivo testing
16 concept, but also efforts in the omics and how are those
17 technologies going to start to play into the risk
18 assessment process?

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1 I mentioned EPA's computational toxicology
2 program. Tina mentioned the National Academy of Science,
3 the National Research Council addressing these issues as
4 well. FDA, of course, is looking at toxico-genomics and
5 how does that play into the risk assessment of drugs and
6 understanding efficacy of drugs, and the OECD is also
7 taking a look at this issue of how does one think about
8 the information needs to make different kinds of
9 decisions and how do we integrate these concepts of in
10 silico, in vitro, and in vivo information to maximize
11 information content, maximize efficiencies, but still
12 make credible sound decisions?

13 Bill Diamond was talking just before the break,
14 in part, about Part 158, and sort of the evolution of
15 that testing requirement. If we use Part 158 as just an
16 example of the evolution of the techniques that we're
17 talking about, we're sort of at the stage now where we've
18 gone over the last 15, 20 years the evolution of in vivo

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1 assays and increasingly diagnostic information in in vivo
2 assays and how those inform, in this case, pesticide risk
3 assessments and pesticide decision-making. There's
4 similar parallels in drug discovery, drug evaluations in
5 other parts of our society.

6 What we're trying to do now is taking a look
7 ahead and thinking about the test requirements, the risk
8 assessment technologies of five years out, ten years out,
9 and thinking about those kinds of technologies and being
10 part of that research community science evolution and
11 being aware of what's going on and being part of what's
12 happening so that those technologies can be focused and
13 efficient and helpful, say, in the realm of pesticide
14 risk assessment and pesticide decision-making.

15 But it's clearly more than just a science
16 activity. While science is part of it, it's just a part
17 of it. The reason to have the visit today and some
18 visits we've had in the past on computational toxicology

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1 and related issues is to just keep you informed of the
2 evolution right now, especially of the science and the
3 science foundation for aspects of a potential paradigm
4 shift in the way risk assessments are done, realizing,
5 again, science is only part of it. As we go through the
6 science development and the transition from different
7 paradigms at the appropriate stages of the evolution of
8 science, there's really important aspects of public
9 participation and dialogue in terms of how is this
10 information going to be used. How will these paradigms
11 play out as we move from today to five years from now, 10
12 years from now, 20 years from now?

13 So, if we think about the Part 158 process and
14 sort of our existing in vivo test methodology and how
15 they're applied in cumulative risk assessments or other
16 techniques, the very many and different types of public
17 participation processes that were a very important part
18 of that whole process, science was part of it, but there

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1 was a lot else -- a lot of other activities that had to
2 happen to make sure that we all understood how to use
3 that science appropriately.

4 Obviously, those same kinds of discussions and
5 dialogue and public participation will be playing out
6 over the coming years as these technologies start to move
7 their way from the research labs and the conceptual
8 models into the peer review process and the scientific
9 foundation and vetting process and this slide here, this
10 figure here, is just trying to get across the point that
11 as these technologies start to mature and the science
12 becomes a bit more focused, having dialogue with
13 stakeholders and the public in terms of thinking about
14 these technologies as they evolve and how they can be
15 appropriately used and interpreted in regulatory
16 decision-making.

17 With that, I'll stop and we can field some
18 questions.

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1 MR. JONES: Carolyn?

2 MS. BRICKEY: I guess I support the concept
3 behind this topic and I certainly support the notion of
4 abbreviating studies if they don't work well or adding in
5 new types of data and information that we don't look at
6 now. The only cautionary thing --

7 (End of Tape 3, Side B)

8 UNIDENTIFIED MALE: We use the kinds of things
9 that you have at the top of that chart to validate what
10 we were seeing in animal testing and being able to apply
11 it to humans, and the kinds of things that we were seeing
12 animals, can it really happen in a human population? We
13 use these in vitro -- these mechanistic studies to draw
14 that link.

15 There's a real emphasis to sort of take away
16 those two components, the animal testing and the human
17 testing. We heard earlier today that we want to minimize
18 human testing. We're talking about animal reduction, and

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1 we're seeing a lot more emphasis on it. Vincent Cogliano
2 (phonetic) at IARC (phonetic), just last year, wrote a
3 paper where he proposed that you don't even need
4 epidemiological studies or animal testing, the two-year
5 chronic animal bioassay to declare something a human
6 carcinogen just based on these kind of in vitro testing.
7 Is that where you think that this is headed? It probably
8 is okay for compounds that are truly contaminants and
9 hazards like PCBs where if we invoke the precautionary
10 principle, it's probably not a big deal. But when you're
11 talking about evaluating a pesticide that has a positive
12 aspect to it as well, eliminating something based
13 strictly on some of these early testing, I just think
14 there might be some real problems with that.

15 UNIDENTIFIED MALE: I think as Vicki was looking
16 at the figure and circling efficient animal testing, I
17 think thinking about how can some of these techniques --
18 like you were saying, understanding the mechanism of

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1 action that are understanding some aspects of how there
2 may be variability across species in a mechanism, that
3 can inform the in vivo testing to ensure that that in
4 vivo testing is designed in such a way that it's
5 informing the overall understanding of the dose response
6 curve, for example.

7 So, there's a lot of different possibilities to
8 be thinking about in this kind of technology and as it
9 evolves. I think most folks are thinking about how does
10 this kind of information, in an integrated sense, help
11 improve our understanding of the toxicological processes,
12 help us improve dose-to-dose extrapolation, help us
13 improve our understanding of species-to-species
14 extrapolation or age class-to-age class extrapolation.

15 I think there are some concepts that are
16 certainly playing out with this technology. If you're in
17 the drug discovery or the agro-chemical discovery mode,
18 where using some omics technology may help you as you're

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1 sorting through 10,000, 15,000, 20,000 structures, how
2 you may want to start even in the computer or in the cell
3 study on your bench top, how you want to start to
4 continue to streamline your discovery process. Over the
5 next 15, 20, 25, 50 years, it will be sort of fascinating
6 to talk again in 50 years and see where this is all
7 going.

8 UNIDENTIFIED MALE: I guess my point is what's
9 the decision here? Carolyn brought it up, but probably
10 from a different perspective. We do a whole animal repro
11 test and we're looking at neuro development and then
12 you're going -- you're doing in vitro testing and you're
13 looking at (inaudible) cells or whatever, and the whole
14 animal study may not be telling us something, but the in
15 vitro may be telling us something, but the in vitro may
16 be telling us something because it doesn't happen in a
17 whole animal. So, where is your decision point? We've
18 got a lot of redundancy in a whole organism that you guys

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1 are stripping away in the in vitro testing. So, it just
2 -- from our perspective, being in this business for the
3 last 20 years, it just seems like the decision point, the
4 data that are going to be used for the decision point
5 seem to be moving up higher on that chart that you have.

6 MR. JONES: Let me say from my perspective and
7 what I've asked our team to do in this exercise is that
8 any change in the system along these lines needs to
9 increase our knowledge and not decrease our knowledge.
10 So, if we -- in our research and the evolution of this --
11 if we get to a point where, you know what, Jim, we may be
12 ready to move out with this approach versus this one, the
13 first question is, are we gaining knowledge or are we
14 losing knowledge? And the whole objective for us in it
15 is about we think that there are ways to harness newer --
16 the newer science, new technologies in a way that we gain
17 knowledge. That's what we're trying to do in our
18 engagement and investment in this.

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1 Jennifer?

2 MS. SASS: One of my points was actually that
3 joint point there. I have three points and that was my
4 second, which was how are you going to -- I mean, not how
5 are you going to, just that we need to start all thinking
6 about knowing that we need to begin to define thresholds
7 or some way of knowing when we're going to make a
8 regulatory decision on the data so that we're not
9 generating data forever, saying, well, this test only
10 shows us so much, we need to do the next. I think that
11 -- I hope that what EPA is doing is not trying to
12 revolutionize toxicology, but trying to streamline and
13 enhance a registration process, which is different.

14 And IARC doesn't actually use almost all of --
15 IARC doesn't use this data to make its decisions because
16 IARC doesn't use unpublished data. Almost all of this is
17 unpublished data and mostly historically it has been
18 crude and not that useful. No offense to the people that

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1 have to do it. I know it's also expensive and time-
2 consuming. So, I think the idea of streamlining this
3 process is a good one and that will entail defining when
4 to make a decision and -- that's number one -- that's
5 number two, so back to number one.

6 I think that the ILSI/HESI/EPA report --
7 ILSI/HESI report -- I mean, I've skimmed through it, I
8 haven't looked through it. It's fat, it's in three big
9 white papers. But I have a question which is, where did
10 the funding come from? And the reason why I'm concerned
11 about that is because it wasn't really a stakeholder
12 process. ILSI and HESI defines themselves as an
13 academia/industry/government tripartite process. I've
14 looked at the authors and almost all of the academic
15 authors are also industry consultants, some of them
16 substantially.

17 Many of them are the best in the field and they
18 are the experts in that area, including the government

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1 people, and I recognize that, but it wasn't a stakeholder
2 process. So, that means that certain questions and
3 certain concerns may not have been introduced early in
4 the process, and late in the process, only tweaking
5 usually gets done. For instance, in the Part 158
6 revisions, I handed in substantial comments and those
7 concerns may have been germane had they gotten in early
8 in the process, but I was not one of the people that was
9 called by EPA to come and talk with them before that
10 proposal was released. So, who foots the bills for
11 number one?

12 Number two, the threshold issue, it's not a
13 question, it's just something we need to keep on the
14 table.

15 And number three, I think maybe this fits here,
16 maybe in the computational toxicology section, but I'm
17 concerned about whether there's also, in your
18 conversations, concern about the nano materials and the

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1 nano pesticides that are coming around the corner, and
2 not quite around the corner, some of them have gone
3 around the corner. So, I wonder if you have an inventory
4 developed of the nano pesticides that have been
5 registered or are applying for registration or whether
6 you even distinguish them as that versus in their bolt
7 component?

8 So, whether you've made a decision about whether
9 these are new or existing chemicals, whether there's
10 information that could be gathered for these nano
11 pesticides that are -- is already available, very basic
12 chemistry information that would be available without new
13 testing because they would have to be available to
14 develop a pesticide, and whether that's submitted, and
15 also whether there's FIFRA 6(A)(2) requirements on any of
16 that or whether it's just -- there's just no category
17 yet, in which case, I want to suggest that one be made so
18 that somebody can actually look at that.

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1 And then, finally, to encourage you -- and I'm
2 sure you're doing this -- to integrate that thought into
3 these testing strategies, because it's not too early to
4 begin to think about that.

5 MR. JONES: Steve, do you want to take the first
6 couple and I'll --

7 STEVE: Sure. Which is first and which is
8 second?

9 **(Laughter.)**

10 STEVE: The threshold -- I really appreciate
11 Jennifer's comments about the threshold and she's exactly
12 -- I appreciate those comments. Understanding how this
13 information may or may not be used in different kinds of
14 decision-making is part of the evolutionary process.

15 The nano technology, I can handle part of that.
16 As many of you know, from Society of Toxicology to other
17 venues, sort of the whole issue of how to assess the
18 exposure and effects of nano materials is rapidly

1 expanding, and certainly, the Pesticide Program, as well
2 as our colleagues in OPPT, the Toxic Substances part, are
3 involved in those activities. The agency is -- I think
4 it's about ready to finish up a white paper on starting
5 to think about how to do risk assessments for nano
6 technology. So, at least in that part of the question
7 that you asked, we're certainly engaged in a number of
8 activities to be -- with the science as it evolves --

9 UNIDENTIFIED FEMALE: Steve, some of us don't
10 know what nano pesticides are.

11 STEVE: Well, nano technology would be -- and
12 there's probably others around the table that can do
13 better than I, but the use of -- the development, the
14 chemistry development of very, very small particles, nano
15 particles, that may have a variety of beneficial uses
16 that we've never used that technology before, delivery of
17 materials being looked at in the pharmaceutical area,
18 being looked at in a number of different areas. But

1 micro-particles, nano particles.

2 MR. JONES: And we're not aware of any companies
3 who have come to us with nano pesticides. We have heard,
4 in the antimicrobial industry, some companies talking
5 about some concepts that they've got, and it is an area
6 that, I think, we need to do some thinking around. So,
7 there are no nano pesticides that I'm aware of right now.

8 UNIDENTIFIED FEMALE: Thank you.

9 MR. JONES: And then the ILSI/HESI questions.

10 UNIDENTIFIED MALE: Go ahead, you can do that.

11 UNIDENTIFIED FEMALE: Well, HESI is funded by
12 member companies. They pay dues.

13 MS. SASS: This project, I mean, sorry.

14 UNIDENTIFIED FEMALE: Are you talking about the
15 (inaudible), is that what you asked?

16 MS. SASS: Yes.

17 UNIDENTIFIED FEMALE: Yeah, that's what I'm
18 speaking to right now. But the way that you have to look

1 at this, that was a scientific project. It had a start,
2 it has an end and then scientific publications will come
3 out of it. Our process is separate from that. We have a
4 different process and that's what we've been describing
5 to you, where we'll look at all the relevant science
6 that's out there as we move forward to improve how we
7 assess human health risks. That's one that we'll look at
8 it because it's a piece of science that was developed by
9 this international group of experts and it's going to be
10 published, and you can't turn a blind eye to any science.
11 But as we mentioned, we realize there's some issues in
12 those papers, some unresolved issues, but at least what's
13 important about that is the thinking's beginning. People
14 are starting to think about it and the dialogue's
15 starting. It has provided a good foundation to get the
16 dialogue started.

17 MR. JONES: The funding issue where --

18 UNIDENTIFIED FEMALE: I just mentioned that

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1 they're funded by member companies. They pay dues.

2 MS. SASS: So, this product didn't get -- I
3 mean, EPA Pesticide Office has hired ILSI --

4 MR. JONES: Yes.

5 MS. SASS: -- has contracted out to ILSI to do
6 certain projects. So, my question was --

7 UNIDENTIFIED FEMALE: That's a different part of
8 ILSI. That's the Risk Sciences Institute, and this is
9 the Health Environmental --

10 MR. JONES: We didn't fund this project.

11 MS. SASS: Okay, that's what I was getting at.
12 Thanks.

13 UNIDENTIFIED FEMALE: But there was sweat equity
14 if you include that.

15 MR. JONES: Right. Although we didn't encourage
16 them to make invitations to the public interest
17 community, which they did, and the response back they got
18 was that we don't have the capacity to participate in

1 this level of an activity --

2 MS. SASS: That's where cloning comes in. We're
3 working on that.

4 MR. JONES: I won't comment on that, but we
5 recognize that just -- we need to have some way to deal
6 with that and it can't be just to say, well, you missed
7 your chance. The fact that people can't participate
8 because of resource issues doesn't mean that, therefore,
9 they shouldn't be given consideration. We've got to
10 figure out how to deal with that reality. So, we're
11 aware of that reality. We've tried to do things about it
12 and there are other things we still have to do because
13 it's not an outcome that -- that's one of the reasons
14 we're doing this.

15 Any test that we were going to ultimately rely
16 on would, of course, go through things like our Science
17 Advisory Panel which would be an opportunity for further
18 participation.

1 Okay, I think I saw Pat and Troy.

2 MR. QUINN: I just -- I wanted to make a related
3 comment. You know, I think to the extent I understand
4 it, computational toxicology sounds like it holds
5 enormous promise, and I want to get smarter about it, but
6 people who work with it more closely than I do tell me
7 its promise for regulatory institutions may be 10 years
8 away. I guess alongside that, I want to make sure that
9 the agency stays focused on low-hanging fruit, on things
10 like acute toxicology where there are in vitro methods
11 that have been developed, where there are other
12 approaches that are available to us.

13 Now, one has come out of this group, it's this
14 antimicrobial cleaning product alternative testing
15 initiative that Tina has been working on with us and Jim
16 has been working with ICFAM on, but it takes far too
17 long, frankly, to get those approaches examined in a
18 responsible manner so that they can be used for a narrow

1 regulatory purpose, and that's what I think we need to
2 keep in mind is, identifying test methods of approaches
3 that allows EPA to do its work in a responsible and
4 scientifically sound manner, and not be beholden to broad
5 validation exercises for every active ingredient in every
6 product. So, I just wanted to offer that.

7 MR. JONES: Thanks. Troy?

8 MR. SEIDLE: Thank you. I would support what
9 Pat said, of course, and with respect to low-hanging
10 fruit, we are very supportive of the content of the
11 ILSI/HESI ACSA and proposals. We do recognize, as do
12 many people around the table, that the current testing
13 and data requirements are anything but lean or efficient.
14 There's a lot of redundancy and a lot of waste. I think
15 those white papers go a long way to addressing those
16 concerns.

17 With respect to the time table for Part 158, I
18 guess a question/comment, is EPA, is OPP committed to

1 incorporating, to the greatest extent possible, some of
2 the recommendations, the innovations that ILSI/HESI are
3 recommending? Because if it's taken 20 years to get to
4 this point with a proposed rule, it would be a shame to
5 waste another 20 years and miss the boat to incorporate
6 some of these things into Part 158.

7 MR. JONES: As it relates to Part 158, they
8 won't be because they're not ready to be incorporated
9 into 158. The commitment on our part is to pursue them
10 along the lines that we've been talking about here, is
11 that they need to get -- there are a number of issues
12 that need to be sorted out, some pretty serious issues
13 that need to be sorted out, to take them through
14 additional peer review including, for example, the
15 Scientific Advisory Panel. We see 158 as not a once-in-
16 20-year exercise, but something that we should be doing
17 on a routine basis and are committed to doing it on a
18 routine basis, and hopefully, if we're to come back here

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1 in 20 years, we will note that the 20-year lapse between
2 the first one and the second one was the exception and
3 not the rule, and the rule became that EPA was routinely
4 updating its data requirements.

5 Okay, let's wrap this session up. Thank you to
6 -- oops, do we have one more? Oh, sorry. Terry, I keep
7 missing my peripheral vision.

8 DR. TROXELL: I have a, maybe, different
9 perspective. I think your point about 10 years plus out
10 for the omics is right on because -- and -- well, anyway,
11 what I think we have with the omics is we're going to
12 have tons of information. We're going to have thousands
13 of genetic changes, thousands of protein changes,
14 thousands of metabolic changes that you're going to be
15 able to measure and that's going to lead us to
16 information overload, and as a risk manager, you know,
17 it's kind of frightening to think we're going to have all
18 this information and how are we going to really relate

1 that to real concrete endpoints that are adverse?

2 We know that human beings, you know, every day,
3 their systems are varying and changing, adapting and so
4 on, and there are a lot of things that are happening that
5 are going to be just simply adaptive effects to whatever
6 you eat, breathe, drink, whether it be food component or
7 residue of a pesticide or contaminant. But what we
8 really want to know is what's -- which of those changes
9 are concretely linked to adverse effects? That is the
10 bridge that has to be made over the years so we can link
11 things. In fact, in the end, of course, we're going to
12 know so much more about human health, more about human
13 health that doesn't even relate to contaminants, but also
14 we'll understand so much more about individual variations
15 and there are going to be things that we never imagined
16 that we're going to discover and it's going to present
17 many new challenges, but also -- but the key in the end
18 is going to be to link those individual points in the

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1 micro array lighting up to real effects that might be
2 adverse for humans and that we have to be concerned
3 about.

4 MR. JONES: That's a good point. Okay, let's
5 wrap this session up. Thank you, Tina, Steve and Vicki.
6 Thank all of you.

7 We're going to now move into sort of our last
8 session associated with some of the worker issues that
9 many of which, not all of them -- actually all of them,
10 we have talked to this committee about before, and Bill
11 Diamond is going to take us through a number of updates,
12 basically, around our PRIA worker protection efforts, the
13 Pesticide Safety Education Program and the National
14 Assessment of Pesticide Worker Safety, and then my
15 colleague from OECA, Jack Neylan, is going to give us a
16 brief presentation about something hot off the press from
17 that program, which is the Worker Protection Standard
18 Program Review Final Report.

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1 All right, Bill?

2 MR. DIAMOND: The three sessions that I'll be
3 covering are the three topics. There will be two quick
4 updates and one kind of more in-depth project overview.
5 So, we'll move through those fairly quickly and spend
6 most of the time on the third one here.

7 The first one that we've got here is the update
8 on the Pesticide Safety Education Program. We've talked
9 about those at the last couple of meetings in terms of
10 issues for funding and improvements and some of those
11 things.

12 What we were trying to do in terms of background
13 here is we did conduct an overall review with a bunch of
14 different stakeholders. That was primarily last year.
15 We got some perspectives on different critical questions
16 that needed to be addressed to have improvements in the
17 program to maintain the value, but also to try and
18 improve efficiencies, cost effectiveness and value in

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1 terms of the outcomes there.

2 In the May meeting, we presented that in a
3 report that was kind of a summary of here's areas you
4 should focus on some more and we've been, over the last
5 six months or so or five months, trying to follow up on
6 that to get some of those things started here.

7 Broadly, the follow-up actions came in about
8 five different areas. The first one that got a lot of
9 attention was to try and improve the funding mechanism.
10 There was an issue in terms of how effective and timely
11 the distribution process was and also the issue of
12 accountability that we've been talking about in a number
13 of areas. What we're doing is we're establishing a
14 stakeholder workgroup to explore some alternative funding
15 mechanisms that will also consider some accountability
16 needs, and I'll mention a little bit more on that in just
17 a minute.

18 The second area was to try and set some training

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1 priorities, recognizing the evolution of needs over time
2 and that with the demands exceeding the ability to
3 perform those -- all that training, that we have to work
4 with certain people to try and identify what the top
5 priorities were out of all those competing demands. At
6 this past summer's National Certification and Training
7 Workshop that we held, we worked with a number of
8 different partners to try to identify that as a follow-up
9 in terms of what are the most pressing areas, who might
10 be able to provide those things, and what are the
11 specific actions that would come out of that? So, we
12 think we're in the process to move ahead in that area.

13 In terms of program efficiencies, the notion of,
14 again, trying to get more bang for the buck out of that
15 and also try to encourage regional and national
16 collaboration on the material development, eliminate
17 redundancies, maybe get some regional centers of
18 expertise were some of the ideas that were tossed around.

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1 In terms of following up on that and in terms of
2 practice, we've already started doing some of those
3 things. Development collectively of valid exams and
4 manuals for both fumigation and aerial application are
5 being initiated so that we can have standardized
6 materials that everybody can use for those areas, for
7 training and individual states and localities do not have
8 to reinvent the wheel on that.

9 And a similar one in terms of trying to take
10 advantage of work that's already been done out there, our
11 EPA Region 5 had worked to develop a valid exam for
12 structural applicators, and we're looking to see whether
13 or not that has benefit to take nationally and transfer
14 that information to other people.

15 In terms of the next area, expanding the scope
16 and coverage of the certification regulations. I'm going
17 to talk a little bit more about that later in this
18 session here, but it was basically the notion that there

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1 are some gaps in terms of people who are handling
2 pesticides, that may be bringing them under the umbrella
3 of certification and training requirements would make
4 sense, and we've started to initiate some regulatory
5 planning on that front.

6 The last one, the accountability measures, this
7 goes to kind of like accountability in the small sense,
8 not the mega sense of mission areas, but project-specific
9 areas that would flow from those types of things, and how
10 do we develop those measures specifically to demonstrate
11 the results of these targeted or niche activities? How
12 much benefit do you get from a certain investment in
13 training or certification? So, at about a second or
14 third tier level, we'll be looking with our partners in
15 terms of how to demonstrate the value and contribution of
16 this part of the program to achieving our overall
17 objectives.

18 If you go to the next slide, this just gives you

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1 an update in terms of where we are in terms of funds
2 available and distributed for the Safety Education
3 Training Program. In FY 05, we had \$1.2 million, the
4 same as the previous year, that were distributed through
5 an IAG with USDA, the traditional mechanism that we've
6 had over a period of time. That letter of credit was
7 sent out in September for people to start funding them
8 and notifying them of the availability of funding. So,
9 that money is out and in the pipeline.

10 We expect that for Fiscal Year 06, we're going
11 to be using the same distribution mechanism. We
12 anticipate that we would have the same level of funding,
13 barring some additional Congressional action that would
14 affect our entire program. We're not targeting this one
15 particularly, but the FY 06 process is clearly not closed
16 yet, as Congress still has to reconsider that.

17 The critical actions here in terms of where do
18 we move in the future is -- FY 06 would be the last year

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1 for this cycle of the IAG. We've been talking to USDA
2 and they've agreed that we ought to explore different
3 alternatives for the funding mechanism to try and address
4 some of those fundamental concerns. What we're doing is
5 we're going to be working with a number of the
6 stakeholders that were involved in that process of coming
7 up with the action areas to try and determine what are
8 the criteria and the mechanisms that we ought to consider
9 in planning to follow up that new mechanism for the
10 future.

11 Some of the criteria for us would be, obviously,
12 we're not going to have a disruption in the mechanism
13 availability to get that money out into the field, but
14 also to try and anticipate what those needs are going to
15 be to make it effective and give us the flexibility to
16 plan for the future training needs, as well as
17 maintaining the base that we've got in the past.

18 Before I move to the next topic, any questions

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1 on that one?

2 MR. JONES: Amy?

3 AMY: Bill, who is on the stakeholder groups
4 that will be working with you to -- beyond USDA, who's
5 identified -- to establish the alternate funding
6 mechanism?

7 MR. DIAMOND: This will be the same cast of
8 characters that we had for the program review, basically
9 the involved parties who were in training, and what you
10 can expect is that over the next couple weeks and months,
11 very near term, we'd be contacting people to explore
12 their interest in doing that.

13 AMY: I would just encourage you to -- for those
14 groups that you're expecting representation from, like
15 APCO and AAPSE and APSCRO (phonetic), to actually contact
16 the president of that organization to ask for who might
17 be a good representative from their organization to be on
18 that rather than hand-picking.

1 MR. DIAMOND: I think that's our plan. That's
2 our plan.

3 AMY: That would be great.

4 MR. DIAMOND: I think, also, one of the things
5 we'll explore with them is people who maybe were involved
6 in some of the previous process. So, we've got the
7 learning curve that's up there, but we're obviously going
8 to consult with who they think is the most appropriate
9 people to engage.

10 AMY: Okay, that would be good. Will there be
11 more discussion of PSEP in your presentation to come?
12 Because if so, I'll hold off on my other comment.

13 MR. DIAMOND: Only to the extent that some of
14 the concerns that we heard were some of the same concerns
15 that people are saying we ought to look at regulatory
16 changes in terms of future coverage, for example, in
17 terms of people who may need training and certification.
18 So, it will be there, but it's not going to be

1 specifically broken out for the PSEP activities which is
2 just, here's what we're doing to try and change and
3 address that funding mechanism and programmatically,
4 things as how we do specific manuals, for example.

5 AMY: Okay. Then I'm not sure if this comment
6 is germane now or later, but I'll make it now and you can
7 decide. The American Association of Pesticides Safety
8 Educators or AAPSE did -- recently compiled a summary of
9 data on the 2004 Pesticide Safety Education Programs, and
10 we have that summary -- I have that summary with me
11 today, so I'll just pass it out. I just want to bring
12 your attention to one section where it talks about
13 program efficiency because that has come up before and
14 you were talking about sharing manuals and trying to
15 decrease the number of materials that states actually
16 have to develop for themselves. We do appreciate that.

17 The report confirms that most states do share
18 multiple training resources that were developed outside

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1 their state or they share between states, and that
2 includes manuals, CDs, presentations, many, many more
3 things. We share resources as far as people and
4 presenters as well. So, there's a lot of information
5 there on both quantity and quality of program.

6 MR. DIAMOND: I think that's very helpful. We
7 recognize that there's some potential for efficiencies
8 there in terms of collective development of materials.
9 But, also, given the nature of the industry, that there's
10 some that are going to have to be more targeted and it's
11 appropriate for the people maybe locally who were
12 informed about those to develop those. So, it's going to
13 have to be a mix and we'd certainly like to see that so
14 we can take advantage of that information.

15 AMY: Great.

16 MR. DIAMOND: Anything else on that?

17 (No response.)

18 MR. DIAMOND: Okay. Not seeing any, we'll move

1 along to the next one, which is the PRIA Worker
2 Protection Resources. Again, this is kind of an update
3 on that. Let me remind you of the background on this,
4 that PRIA authorized funding to enhance worker protection
5 activities, emphasis on enhance.

6 And the activities that are identified at the
7 bottom of that page in terms of the objectives are, to
8 try and look at existing activities and address and
9 reduce the risks, but also to better characterize the
10 risks because, again, information can inform your
11 decisions on that, and then generate improved data that's
12 useful not only for the communication aspects, but also
13 in terms of the risk management aspects.

14 When we look at the program for worker
15 protection, as we told you before, we kind of structure
16 it in terms of four critical components: Effective
17 prevention, improved ability to respond to incidents that
18 do occur, the improved quality and usefulness of

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1 information that's available on incidents and occurrences
2 and to then utilize that information effectively on two
3 tracks, one internally to make improved risk management
4 decisions if we see some patterns or trends of levels of
5 activities that helps us make better judgments in terms
6 of our risk assessment and risk management processes, but
7 almost as importantly, to make sure that that
8 information's available in a usable fashion for all of
9 the other interested stakeholders because the educational
10 component is something that's very valuable, but also in
11 terms of just program status, accountability and
12 measurement as well.

13 So, those are the four major areas we try and
14 bin things into when we look at our program management.

15 In terms of the strategic approach to how we
16 move on these activities, some of the principles of using
17 that additional fund was, again, to build on existing
18 foundation and activities, to start new things that may

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1 be enhancements, but not to start brand new areas.
2 Obviously, to maximize risk reduction when we target the
3 use of the funds, but also to advance all four of those
4 different components because we think the combination of
5 them is what achieves the protective safety net that we
6 want out there in the field. Then, also, since it's kind
7 of a short-term cycle of funding, to try and get some
8 near term results out of that investment of money there.

9 What we've done -- this one is difficult to
10 read. You've got the handout there, but this is just to
11 try and give you a sense of two things. One, that we're
12 trying to do some life cycle planning over the five-year
13 window of the PRIA funding here and to distribute it over
14 those range of different activities. You've got the --
15 at least on this page, you've got two of the large
16 headings. On the next page of the matrix, you'll see the
17 other ones.

18 What you've got here is that you've got, for

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1 example, in terms of prevention and safety training, the
2 notion in terms of the training element, but also the
3 hazard communication elements as critical functions that
4 are necessary to improve the prevention aspect of it,
5 recognizing that you're not going to be able to prevent
6 everything. Then you've got the response aspect so
7 people can, once there is a potential incident or a real
8 incident, they can have better treatment in a more
9 effective manner. In that type of area, some of the
10 emphasis that we've got on enhancements is in terms of
11 the health care providers, making sure that they've got
12 the materials necessary to do the appropriate things, but
13 also that they can be aware of the potential incidents
14 and those things, and we've got a couple of different
15 activities that are involved there that would provide,
16 again, strengthening those types of things.

17 You'll note that in some of these cases, it's
18 kind of like a fixed funding over that five-year cycle.

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1 In others, it's spot funding. That, again, goes to the
2 notion of what the type of output is that we're trying to
3 achieve as a result of this funding.

4 This one would be the sound data and the
5 information/dissemination type of aspect of that. The
6 credible reliable information on occupational incidents.
7 We're trying to strengthen the database using the sensor
8 database of information through the NIOSH project to
9 expand the coverage of that to get a representative
10 sample of potentially impacted agricultural workers, and
11 then to utilize that information in terms of some of the
12 -- the bottom one of better information on what the
13 agricultural workers are. We've used that for a long
14 period of time. That's to try to expand and enhance our
15 information on those particular areas there.

16 I guess the point I would make on this type of
17 stuff is now that we're in the second year or going into
18 the third year of this funding, we think we've got a good

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1 handle on it in terms of the funding mechanisms that
2 we're going to be using, which is why we did some life
3 cycle planning, so we didn't have to have downtime with
4 getting that money out in the field. We expect to,
5 hopefully, start seeing some of the results of that in
6 terms of tangible products, but also in terms of improved
7 understanding and education.

8 For example, the work in terms of hazard
9 communication in terms of the Spanish Language Radio
10 Network would be something that we think would be
11 something that would be valuable in the real term. The
12 HAZCOM communication area, we're putting pilots out there
13 that this year will be in the field to test what's an
14 effective means to reach the target audience and then
15 what are some of the downsides, what are some of the
16 benefits that we can use that may potentially be rolled
17 into a regulation or may potentially be rolled into the
18 field practices in the not too distant future?

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1 Any questions on that update?

2 UNIDENTIFIED FEMALE: I have a clarification.
3 What are the units in these charts, these tables, these
4 money tables again?

5 MR. JONES: Hundreds of thousands of dollars.

6 MR. DIAMOND: Right, those are hundreds of
7 thousands of dollars.

8 UNIDENTIFIED FEMALE: Times everything times
9 1,000, okay.

10 MR. JONES: Thousands, thousands.

11 MR. DIAMOND: Thousands of dollars. So, it's
12 400,000, for example, under that first one.

13 **(Laughter.)**

14 MR. DIAMOND: Our budget's going the other
15 direction, so you're right. If it is, I've got some more
16 expenditures I can make under these things.

17 Anything else?

18 DR. AMADOR: Bill, can you expand on the

1 training for farmworkers? The AFOP and AmeriCorps, are
2 those the only ones that are doing the training? Is that
3 where the money's going for or --

4 MR. DIAMOND: Back it up one. In terms of the
5 first one, AFOP and AmeriCorps, those are the ones for --
6 it's one of our primary mechanisms to train farmworkers,
7 train the trainer type of things, out in the field in
8 terms of materials development, but also training
9 delivery, and we've had a long-standing relationship with
10 these parties in terms of their effectiveness to reach
11 these people, and what we're doing under here would fall
12 under the real category in terms of enhancement as was
13 intended under the PRIA investments of quicker
14 development of needed materials, expanded use in terms of
15 targeting certain audiences.

16 DR. AMADOR: Well, where do the universities
17 come in on this part here, training?

18 MR. DIAMOND: Excuse me?

1 DR. AMADOR: The universities, where do they
2 come in?

3 MR. JONES: Jose, could you use the mic?

4 MR. DIAMOND: Under the first one there?

5 DR. AMADOR: Yeah, under the first one, where do
6 the universities come in? Do they work with AmeriCorps
7 or --

8 MR. DIAMOND: No, I don't think -- that's a
9 direct grant to those organizations.

10 DR. AMADOR: Just to only?

11 MR. DIAMOND: Yes. That's not just a
12 representative, so that's different.

13 Amy?

14 AMY: If you look at the summary sheet that
15 AAPSE prepared in our report, there were 614,000
16 farmworkers who received training from PSEPs. Many of
17 the states don't target farmworkers as one of their
18 primary groups, but we do -- most states do train them

1 along with the other members -- the other groups that we
2 train. So, we're not in that up there. Any training
3 that we do of farmworkers comes outside of the EPA funds
4 and is supported by state funds or registration fees or
5 other fees that we bring in, grant funds or other fees
6 that we bring in. But we do do farmworker training.

7 DR. AMADOR: But do you work with these two
8 groups? You don't work at all with them?

9 AMY: Sometimes we do, but in a limited -- I
10 mean, in our state we have -- both Mary Ellen Setting
11 and I have worked with the AmeriCorps folks, but in, I
12 would say, a limited setting. In other states, they may
13 not.

14 MR. DIAMOND: This is clearly just a piece of
15 the puzzle. What we're representing here is just the
16 PRIA dollars that are invested for clarity. We've had
17 other charts that try and mesh how it meshes with the
18 rest of the program, but it's a little too busy to put up

1 here.

2 We've got base investments in all of these four
3 areas, so this is truly an enhancement on top of that,
4 and as Amy legitimately said, we've spent a lot of time
5 with the group that came up with these recommendations
6 trying to explore the practice and the reality that
7 you've got a whole network of a lot of different
8 providers for training for the certified applicators, but
9 also to reach this group and we're trying to make sure
10 that that meshes smoothly so we're not, one, being
11 redundant, but we get the best efficiency out of the
12 total contribution of everybody.

13 MR. JONES: All right, thanks, Bill.

14 MR. DIAMOND: We'll get into the third area of
15 the -- National Assessment and Regulations, and we've got
16 this on a separate file here, but let me just get started
17 given the late time here.

18 Basically, to shift gears and spend a little bit

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1 more time in terms of the worker safety activities,
2 worker safety defined broadly as both the certified
3 applicators and the agricultural worker protection
4 programs. Last spring, we issued a report about our
5 recent efforts to identify progress and gaps in those
6 programs that had been developed over a number of years,
7 and targeted areas for further exploration -- exploration
8 in terms of both activities, training, education, but
9 also rulemaking.

10 I wanted to focus in terms of here of what we're
11 thinking about in terms of the potential scope and time
12 frame for rulemakings, but I wanted to run quickly
13 through a couple of slides that sets it in the context so
14 people don't think of it as it's outside of our program.
15 Just like the previous ones, we've got a -- this is one
16 component or one plank in terms of the entire program
17 that we're doing here.

18 This chart basically describes the breadth of

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1 the program, activities when we're talking about worker
2 safety. I think we don't have to spend much time on it,
3 it does cover a bunch of things from our containment
4 activities and storage and disposal to our traditional
5 competency of applicators and minimizing exposure of
6 occupational workers.

7 When you look at the activities, what we try and
8 look at is all of the available tools, not just the tail
9 end of it, the field component, which is what a lot of
10 people think about in terms of how do we appropriately
11 mix this blend of tools to try and address the different
12 forms of risk, everything from adequate risk assessment,
13 risk management, labeling activities, risk mitigation,
14 what we think of as the field component, training, front
15 line flexibility and some feedback, and then what we
16 think is an important component as well is the individual
17 activities, the citizen protecting themselves through
18 understanding and making informed judgments, the citizen

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1 being anybody that's the end exposed population there.

2 If you look at this, this is just a brief
3 graphic or shorthand. What we have here is we've got a
4 whole range of potential risks pathways that we've got to
5 deal with and address and we've got that range of tools
6 that we try and look at that from risk mitigation,
7 individual actions, rulemaking and other activities that
8 try to collectively protect a different range of
9 populations. When we're talking about worker safety,
10 we're clearly talking about the agricultural workers and
11 handlers, we're talking about the pesticide applicators,
12 to protect themselves, but as a vehicle, also, as a
13 secondary benefit to protect the general public and
14 vulnerable populations.

15 What we're trying to do with this program and
16 our activities collectively is -- if you'd go to the next
17 slide -- this is the rest of the components. Okay, we
18 can move on to that one. Is to try to appropriately

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1 expand that range of protection utilizing all of those
2 different tools so that we have the right balance for all
3 of those populations and get them the right protections
4 that are part of our mandate, but part of the program
5 already.

6 The background in terms of when we're shifting
7 more to just the adequacy of the rules, start with what's
8 on the books now, the Agricultural Worker Protection Rule
9 was promulgated more than 12 years ago now. So, it's
10 been out there for a period of time and it's time to try
11 and take another look at it.

12 The Applicator Certification Rule is part of
13 that protective web. It's been on the books for more
14 than 30 years without an update. So, that's the base
15 there and it's been a long time for both of those.

16 We think it's timely to review the adequacy of
17 those rules in the light of both today's condition, but
18 also today's information that's available in terms of the

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1 effectiveness of those activities, but also in terms of
2 the changing circumstances and what -- the process that's
3 been in there for a number of years is that we've been
4 looking at some of those activities and that we produced
5 a couple of reports last spring that kind of summarized
6 the complete suite of what people looked at and some of
7 the recommendations that were potential there.

8 If you look at the next slide, those reports
9 identified a number of things that were going well with
10 both of those programs, but a number of potential
11 deficiencies that needed to be addressed, and regulatory
12 changes was one area that we were charged with exploring
13 for filing some of those gaps. I'd note that in terms of
14 some of those areas, that we're now plowing new areas,
15 that some of the states, particularly, have taken extra
16 steps already to fill some of those perceived gaps, and
17 we think that that can provide us information, lessons
18 and models for our consideration as we move into the

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1 regulatory arena.

2 In terms of the next slide, some of the
3 principles that we'll be looking at, it's the same we do
4 for any regulatory development. We'll be following our
5 standard goals and principles. In terms of openness,
6 transparency, trying to move quickly through the
7 regulatory process, but also to allow enough time for
8 meaningful input from all the interested stakeholders.

9 I want to hit now in terms of just the specific
10 areas that we're going to try to be looking at as we
11 initiate the rulemaking consideration here. I'm not
12 going to hit everything. If you've read the report that
13 we issued last year, you've already got a flavor for
14 what's on the table, and what we're doing now is deciding
15 what's realistic to be on the table and then how do we
16 translate that into specific regulatory provisions to
17 meet the goals I discussed earlier.

18 Here's just one example in terms of the

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1 applicator certification of competency that was
2 identified as part of these things, the thought in terms
3 of under the supervision provision that we've got in the
4 rules there. The original intent of that was to provide
5 adequate supervision for the safe application of
6 pesticides by people who are not certified at this time.
7 What you've got in terms of practice out there is that
8 it's probably not fulfilling the goal about how it's
9 being practiced in the field.

10 You've got some potential there for employees
11 using restricted use pesticides, for example, that under
12 the current regulation, a company with maybe 500
13 employees can all apply that pesticide under the
14 supervision of a single certified applicator. That ratio
15 probably is behind the scope in terms of guaranteeing
16 that that protective part of the program is fully in
17 effect.

18 Another one is the notion in terms of what does

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1 under the supervision mean. A lot of is, in practical
2 common sense, means somebody is there in real-time to be
3 able to do something. It varies. We've got one state
4 that's been identified that the under the supervision can
5 work if the person's up to five hours -- within five
6 hours of the site of application, 150 miles away. That
7 probably stretches the definition of what effective
8 supervision is, and that's a gap that we probably ought
9 to address. I'm not targeting this as just the only one
10 we've got there, but we think there probably can be
11 improvements in terms of that type of thing, just as an
12 example.

13 Another type of example in terms of the
14 competency that we're trying to get at is do we have the
15 right scope and coverage in terms of the people who are
16 handling potentially harmful materials here, should they
17 have certification and training requirements here? For
18 example, in terms of -- there's pesticides that are used

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1 in schools, for example, here and that right now there's
2 no nationally required certification of competence,
3 whether it's training requirements, testing requirements,
4 to ensure that that particular avenue of risk is assured
5 that you've got the right people handling those materials
6 in the right way.

7 Dealers are another area that people raised on
8 the table for us in terms of they utilize, they handle a
9 lot of these potentially high-risk pesticides. Half the
10 states now have some requirements in terms of them being
11 certified as competent. That's an area that we ought to
12 be looking at and exploring in this exercise here.

13 When we look at applicator certification, the
14 types of broad areas that we're looking at for potential
15 exploration for regulatory changes here are basically to
16 ensure that those who have -- present a potential risk in
17 terms of -- to the public, have basically a standard set
18 of training, competence, materials, whatever, to ensure

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1 the adequate level of competency, and in other areas,
2 it's basically just raise the competency standard
3 appropriate to the level of risk. Those are kind of the
4 principles we'd be looking at in those areas.

5 The other area would be to try and look at
6 national consistency and improved program administration
7 for efficient, cost-effective use of government
8 resources. This would be the types of things in terms of
9 accountability and standardizing some of the categories
10 that people are certified in to, again, get some of the
11 benefits that are out there.

12 Shifting to the worker protection side, we're
13 going to be trying to develop two parallel sets of
14 rulemakings, and at the same time, they would be two
15 things that are moving through the pipeline, but distinct
16 regulations, distinct Code of Federal Regulations
17 processes. We think there's enough overlap there and
18 commonality of interest to move them through the process.

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1 Just procedurally, it helps us somewhat in terms of
2 moving them in tandem as well. If we have to break them
3 apart because of the nature of the issues, we will, but
4 right now, that's what our thinking is to start ahead of
5 this type of thing.

6 Shifting to the agricultural worker side here,
7 similar examples of some of the potential deficiencies
8 that were identified that might be addressed through
9 regulatory activities, some of the ones we've got
10 identified up here. The nature of the risk information
11 that's available to agricultural field workers is not
12 specified now. This would mesh with some of the type of
13 stuff we talked to a little bit earlier about the use of
14 some of those PRIA dollars to identify what is effective,
15 hazard communication, what's information that's valuable
16 and meaningful and then what's the delivery mechanism to
17 do that. That would feed into this process as we move
18 ahead here.

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1 Also, and then meaningful training. What is
2 meaningful training? Right now, there's a requirement
3 every five years to have a retraining. We think that
4 that's -- given the turnover in terms of the worker
5 population, in terms of the types of information
6 that's --

7 **(End of Tape 4, Side A)**

8 MR. DIAMOND: -- of training to be effective to
9 achieve the public health protective goal. And then just
10 the bottom line administrative type of improvement there
11 is if you're reading through that worker protection
12 regulation itself, it's very complex. It doesn't
13 communicate well. That may not be important in terms of
14 the people in the field who are not going to be out there
15 reading the regulation, but certainly the people who have
16 to try to implement it, understand it, and then carry out
17 its protections. So, one of the areas we're going to be
18 looking at is to try and simplify and make it clearer and

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1 make it more user-friendly to the people out there to,
2 again, enhance the level of protection through better
3 understanding.

4 Some of the areas that we've be looking at are
5 regulatory changes and, again, some of the other areas
6 are increased training, better materials, this would be
7 the regulatory component of it, is to identify what would
8 be the parameters of effective information that are
9 needed to allow self-protection there. Simply some of
10 the complex regulatory language so it's better to
11 understand, and then, again, improve the administrative
12 aspects of the worker protection program to ensure cost
13 effective things in terms of -- there's some potential
14 savings there that we can take advantage of, state plans
15 for worker protection that are already on the books out
16 there.

17 That's the scope. You get a sense for what
18 we're talking about here is parameters because we haven't

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1 decided, here's the specific provisions of how we're
2 going to be doing this forward. I'll get to it in a
3 minute in terms of how you might get involved in this
4 process.

5 The current process to kick off the rulemaking
6 schedule was started earlier this year. When we finished
7 up those reports, we moved quickly to start getting the
8 -- it in the queue for regulatory development. You've
9 got a lot of overhead and paperwork to just tee it up.

10 In June, we did our first draft of the
11 regulatory blueprint, which defines the scope so people
12 inside the agency can understand the potential reach of
13 what you're looking at. In September, we went through a
14 tiering process which says, what level of scrutiny does
15 it have to have inside the agency? There's three tiers.
16 This has been tiered, both of them, as a tier two, a lot
17 of important issues, large potential impacts, but not the
18 highest or the lowest type of tier. It basically is how

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1 many people inside the agency are interested and want to
2 play in this rulemaking?

3 Now that we've been tiered up, in November,
4 we'll identify who else in the agency would be
5 participating, specifically representatives from the
6 usual cast of the characters, research and development,
7 our enforcement colleagues, our general counsel. Regions
8 and states would be probably participating along with
9 tribes on that workgroup to develop our internal drafts
10 and considerations.

11 We'll be publishing in the November reg agenda
12 the Federal Register Notice in terms of the projected
13 time frame for what we'd be moving ahead on this, and the
14 first critical step would be we're looking to have a
15 proposal in the spring 2007 time frame for both of these
16 rules.

17 The last thing here is that what level of
18 engagement the PPDC would like to have in these rules.

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1 There's been a high level of interest in terms of both of
2 these areas over the last couple of years. We think that
3 it's probably appropriate, similar to some of our other
4 rulemaking activities that we have a PPDC subgroup on
5 worker safety, on these rules that's self-selected, and
6 the process would be the same that we've worked through
7 some of these other things.

8 Unlike -- we don't think this is kind of like a
9 registration review example where we had people from the
10 git-go involved with that rule package because there was
11 truly a rule package that came out of the need to develop
12 a program. All of the work that's been done over the
13 last number of years with broad stakeholder engagement
14 and a lot of public participation and outreach, we think
15 we're already beyond that. So, we think that the model
16 is more in terms of we've got some concepts now, what
17 does the rule, itself, have to do? So, it's not
18 brainstorming, it's more with these issues, how do we

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1 move forward?

2 That would be information exchange at critical
3 points and then input at critical points when we have
4 particular early drafts of rules, for example, and then,
5 obviously, the standard notice and comment under the
6 Administrative Procedures Act. And then even if we --
7 whether or not we have a subgroup on these rules, we
8 would have something where we'd have regular updates if
9 people are interested to the full PPDC. And I guess
10 that's what we'd like to throw out for you. Does that
11 process make sense? Is there any interest? What the
12 level of interest is? And if so, then we'd be inviting
13 interest expressed over the next couple of weeks to us
14 because we are going to be starting to get started on
15 this.

16 If we go to just the last slide, for people to
17 get back to Kevin Keaney, who will be running this out of
18 his organization, or myself, in the next month or so to

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1 express interest in doing that. So, I guess we'd throw
2 it open now to either questions on the scope issues or
3 the process type of issues. Bob, I'll start with you.

4 BOB: You know what, I apologize, I think
5 there's probably not any organization that probably
6 supports what the agency has done to enhance
7 certification and training more than NPMA. I think we've
8 twice successfully lobbied the U.S. Senate to pass
9 legislation to require training for anybody who applies a
10 pesticide in a school, have actually sort of succeeded in
11 getting language in FQPA that later got watered down that
12 defines maintenance applicators and service technicians,
13 with the goal of having the requirement that those people
14 be trained.

15 So, I say all that as a prelude to say that I
16 slightly object to the use or the citation of the study
17 about the 25 children over a five-year period. I think
18 that was -- I think anybody that looked at that study

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1 closely would arrive at the same conclusion, more or
2 less. Trying to use that statistic as a basis for
3 further regulation is, in my opinion, well, not a good
4 thing for the agency to do. It was 2,500 children that
5 had reported -- there were reports to poison control
6 centers over a five-year period of which 90 percent plus
7 were asymptomatic. I mean, the numbers weren't
8 especially compelling out of 66 million school kids.

9 My only point is I just -- we don't think that's
10 a particularly credible study and wish the agency
11 wouldn't use that as the basis for justifying expansion
12 of training requirements for people to make application
13 of pesticides in schools. We think that's a good idea to
14 expand those and we support it fully, we just wish you
15 wouldn't use that study.

16 Secondly, we'd love to participate, and I think
17 most applicator groups would love the opportunity to
18 participate and continue to participate in what you're

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1 doing.

2 MR. DIAMOND: Okay, Becky?

3 MS. FREEMAN ADCOCK: I guess on your structure
4 for the evolution of the rule or the process, I was just
5 wondering if you could describe where USDA is involved
6 and at what point, and also, I think, yes, I know my
7 organization would be interested in participating,
8 obviously, in a subgroup through PPDC or whatever venue
9 you think appropriate.

10 MR. DIAMOND: All right. We worked closely,
11 obviously, with USDA on this and we plan to work closely
12 with them in terms of throughout this process. That's
13 both in terms of our developmental work -- we anticipate
14 that USDA would be part of the initial workgroup and
15 then, obviously, as part of our rulemaking process, as
16 you know, they get formal reviews at critical junctures
17 of proposal and final. So, it was an oversight if we
18 didn't list them up there. We don't -- we plan to have

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1 them there.

2 MS. FREEMAN ADCOCK: I was assuming that they'd
3 probably be in the November meetings because it would
4 probably help you head off a lot of things that, you
5 know --

6 MR. DIAMOND: No, we think that's a valuable
7 thing and we anticipate that, yeah.

8 MR. JONES: Julie and then Allen and then Amy.

9 MS. SPAGNOLI: I guess just a clarification on
10 scope and I remember working with Bob on that school
11 legislation. I think one of the things that clearly came
12 out of it in looking at scope was, you know, how are you
13 defining a pesticide that's subject to this? I think --
14 you know, they, clearly, in that legislation, did not
15 include disinfectants as being subject to that. I guess
16 looking, also, at the definition of a pesticide, dealers,
17 are they looking at, you know, every 7-Eleven just
18 because they might, you know, have some toilet bowl

1 cleaner or something in the store? So, you know, I guess
2 -- I'm not saying that there's not some efforts that
3 should be underway here, but I think you, obviously, have
4 to very clearly define the scope.

5 MR. DIAMOND: Yeah, we appreciate that. Some of
6 the issues that were discussed, obviously, over the
7 number of years in terms of we're not trying to have a
8 blanket, everybody, everything, and we're not going to
9 try and start from scratch some of those discussions that
10 we've had over time that have informed our judgment.
11 And, also, maybe I moved through it too quickly, we're
12 looking at knowledge as the scope of potential coverage
13 of users and what makes sense to require versus how
14 broadly you go, but also that you wouldn't require the
15 same levels of certification or training of whatever
16 would come out of there to try and tailor something
17 that's appropriate to the potential risks. Not all of
18 these things would require the same things as restricted

1 use pesticides, but on the other hand, maybe some minimal
2 improvement. So, those scope issues are critical to
3 defining not just the rules, but the outcomes of what we
4 try to do.

5 MS. SPAGNOLI: And I think that's good. I mean,
6 just for janitorial workers, I think there's good basic
7 training that should be -- that, obviously, is different
8 than for restricted use pesticides.

9 MR. JONES: Thanks. Allen?

10 ALLEN: Thank you. I think our industry -- I
11 think you'll find the supplier industry, especially on
12 the non-agricultural side, extremely supportive of what
13 you're trying to do. I would like to reemphasize what
14 Bob said about the study that was cited. We will
15 actually be taking some more direct action relative to
16 communicating with the agency on the inadequacy of that
17 study and its many, many shortcomings. We were
18 disappointed to see that the agency has even given it the

1 light of day so far. So, it was just a bad study that
2 shouldn't be used for any purpose in our view. And so,
3 we'll be sending some further information to the agency
4 on our viewpoints about that study.

5 MR. JONES: Okay, Amy Brown and then Amy Liebman
6 and then Melody.

7 MS. BROWN: How will the certification and
8 training advisory group process fit into this stakeholder
9 -- the new PPDC workgroup and what will be the
10 connections and how will things we --

11 MR. DIAMOND: Well, we've obviously worked
12 closely with that group in terms of getting to this
13 point. We expect to continue to use that as a venue,
14 just as we would this, as we try and develop and refine
15 ideas.

16 MS. BROWN: Well, I'll certainly be happy to
17 volunteer to be on the PPDC subgroup.

18 MR. JONES: Amy Liebman?

1 MS. LIEBMAN: I would like to volunteer, too, to
2 work on any subgroup. I also just wanted to -- you're
3 doing a lot of work on this, so thank you. But I wanted
4 to just mention some things that I think are missing from
5 here, and I do -- I'm an educator, I'm a trainer, I do
6 believe that training is the cornerstone to effective
7 worker protections. But I would like to see a lot more
8 language about enforcement and reporting in here. That
9 is also as critical as training. So, the reporting needs
10 to be happening on a number of levels, and I say this at
11 every meeting, but it needs to be said again. We need a
12 national reporting system for pesticide exposure
13 problems. Then the enforcement part about that is just
14 as critical as any training's going to be. So, please
15 get that back in there.

16 MR. JONES: Thank you. Melody?

17 DR. KAWAMOTO: I'd like to volunteer for the
18 subgroup, also. I think what Amy said about the

1 reporting is really important because, at this point, you
2 know, as Bob's concerned about the accuracy of the data,
3 I think without such a reporting system and I think
4 there's a lot of under-reporting, that we won't really
5 know what's out there. So, it's really important to
6 consider that.

7 MR. JONES: Okay. Mary Ellen? Thanks, Melody.

8 MS. SETTING: As a state lead agency for
9 pesticide regulations, I agree that a PPDC workgroup on
10 this issue would be appropriate and I would certainly
11 like to be a part of that. I think you can use a lot of
12 the models already provided in state regulations for
13 enhancing some of the federal programs. We're looking
14 forward to have the federal regs be brought up to the
15 standard that many of the states have had in place for a
16 number of years.

17 MR. JONES: Thank you. Jose?

18 DR. AMADOR: I'd just like to second what a lot

1 of people have said. I think this is very appropriate
2 that we look at where we are on the farmworker training
3 part of the program. In my own state, it's being done,
4 but I don't think it's being done with the intensity that
5 it was done in the past, and I'd like to volunteer, too,
6 for the subgroup.

7 MR. JONES: Thank you. All right, John, you'll
8 have the last word on this topic.

9 JOHN: I just wanted to -- I'd repeat what some
10 folks have said and just sort of add our support for the
11 JAMA studies, just to put it on the record that the PPDC
12 was not universally opposed to the agencies in that
13 study, and until we have a sufficient reporting
14 mechanism, I think that's one of the better things we
15 have. So, we need to reinstate an incident reporting
16 system.

17 MR. JONES: Okay. We are now going to move on
18 to a very related topic. A number of you have, over the

1 years, frankly, asked me, asked us at the EPA to please
2 invite our colleagues from the Enforcement Office. OECA
3 is the acronym we use in the EPA. So, we did and they
4 have been gracious enough to agree to participate in this
5 meeting. We are quite fortunate that just a few days
6 before this meeting, a report that many of you have been
7 waiting for for some time was released by that office.
8 So, not only are they here, they're on the agenda.

9 So, Jack Neylan from our Office of Assurance and
10 Compliance -- Enforcement and Compliance Assurance is
11 here.

12 MR. NEYLAN: Yeah, that's a mouthful. When
13 Steve Johnson suggests you come to these meetings, I
14 guess it's a strong incentive as well.

15 MR. JONES: Who?

16 **(Laughter.)**

17 MR. NEYLAN: In your package, you should have
18 the full program review report. I don't have a

1 PowerPoint because of the late signing of this and coming
2 to this. This was a review of the Worker Protection
3 Standard Compliance and Enforcement Program, which was
4 basically spurred by kind of two events, I guess, to some
5 degree.

6 In 1998, the Children's Health Protection
7 Advisory Committee issued a report that suggested that it
8 was time for a review of the Worker Protection Standard,
9 and then in 2000, what are they called now, the
10 Government Accountability Office also issued a report
11 that suggested that, among other things, that there
12 should be improved oversight of the implementation of the
13 Worker Protection Program.

14 So, I guess coincidentally, around the same
15 time, the agency was looking at reviewing various
16 programs, and because of these two things, it sort of
17 popped up high on the radar screen for a review. So, we
18 started one. The review was done by a person in OECA

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1 that was not connected, in any respect, with any of the
2 Worker Protection Program, a fellow by the name of Dan
3 Palmer.

4 They basically set a couple of goals, I guess,
5 early on. One was to assess the effectiveness of
6 headquarters, regional, state and tribal efforts to
7 ensure compliance with the Worker Protection Standard,
8 and also to assess our efforts at implementing the Worker
9 Protection Standard.

10 The review began in 2000. It continued through
11 2001. The review process, itself, was fairly
12 complicated. In the appendices, there's some information
13 about how the review process was supposed to be
14 conducted. It's got information about when different
15 regions and some states were reviewed and so forth.

16 There were various review teams. They were
17 composed of headquarters, regional, state or tribal
18 people, and all that's in here.

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1 The review, itself, when you read it, suggests
2 that -- came out with basically seven general findings
3 and recommendations. I'll just read very carefully. One
4 was we needed a clear strategic vision for this program.
5 I'm talking again about the compliance and enforcement
6 program. Accountability at all levels should be
7 improved. Communication between EPA and states and with
8 workers and growers should be enhanced. More training
9 for co-regulators was needed to enhance implementation.
10 Better information for measuring the success of the
11 program was needed. The level of and the utilization of
12 resources are issues that are hampering implementation.
13 And last, implementational levels should be strengthened,
14 from headquarters all down through the states and tribes.

15 If you -- when you read the report, you'll see
16 that some of this is echoed in the National Assessment
17 that the Program Office did as well, so you'll see some
18 commonality between the two.

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1 Now, as you can see, there's been some time
2 lapse between when this review was done and when this
3 report was signed, and one of the other things we've
4 decided to include in there is something we're calling
5 progress since the review. So, you will see, following a
6 lot of the findings and recommendations, some things that
7 have happened in the program that we've done to try and
8 address the findings and recommendations, because we were
9 relatively well-aware at some point along the time, where
10 this report was sort of showing the need for some program
11 improvement. So, you'll see that.

12 Now, we're looking at this, along with the
13 worker safety thing, to kind of go and start improving
14 the program, and one of the first things we've done since
15 -- or most recently, was we met with a number of the
16 state pesticide regulatory managers the week of September
17 12th and we're starting to begin kind of looking at this
18 report and developing a strategy and an action plan to

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1 implement these review recommendations. So, we're kind
2 of looking to the future and seeing what more needs to be
3 done to move along.

4 I think a lot has -- as you'll see when you look
5 at some of this, a lot has happened to -- in terms of
6 improving things. But, obviously, I think that probably
7 still more needs to be done. One of the things is
8 probably getting some better measures of success in this
9 program, which is one of the things we're lacking.

10 MR. JONES: I appreciate it, Jack. I know the
11 report just came out, and although we made efforts to get
12 it to you, you may not have had an opportunity to digest
13 all of it. But if you have any questions for Jack, this
14 would be a good place to start. I expect that this is an
15 area that we'll probably come back to at this meeting as
16 the agency and its co-regulators have some opportunity to
17 do the kinds of things that Jack just described. This
18 certainly won't be the last opportunity.

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1 MR. NEYLAN: And I'm sure some of this will feed
2 into the efforts at rulemaking.

3 MR. JONES: Right. So far, although I didn't
4 make an announcement, so I'm going to do it now, no one
5 has signed up for making public comments, but since I
6 didn't make an announcement to that effect, you wouldn't
7 have known what to do. So, if there is anyone the
8 general public, outside of the committee, who would like
9 to make a comment, you just make yourself known and we'll
10 -- okay.

11 All right, well, very good. It's been quite a
12 day here. I know I need some time to digest the many
13 things that I heard over the course of this day and I'm
14 going to start my evening by spending an hour on a soccer
15 field with a bunch of eight-year-olds coaching.

16 **(Laughter.)**

17 UNIDENTIFIED FEMALE: Jim, may I make a
18 suggestion on the process?

1 MR. JONES: Yes, please.

2 UNIDENTIFIED FEMALE: I wonder if, instead of
3 leaving the public comments to the very end of the day,
4 especially when we go late and maybe people can't stay, I
5 don't know, if maybe just maybe three times, maybe like
6 before each break, before lunch and maybe after. So, we
7 could just do like a five-minute option (inaudible).

8 MR. JONES: Okay.

9 UNIDENTIFIED FEMALE: And just make them
10 shorter, but more often.

11 MR. JONES: I think that's a good idea. All
12 right, we'll try that.

13 Amy?

14 AMY: If we're making general comments for the
15 future, could I make a plea for a list of acronyms? You
16 know, I actually do know most of them, but sometimes I
17 get confused. I think there are some people who don't.

18 MR. JONES: Sure. We should, on our part, try

1 very hard to avoid acronyms and when we use them, to
2 follow them right away with what they mean. And then if,
3 on your part, you could help enforce that and call us on
4 it when we use it, it's -- they're pervasive in this
5 town. It's very hard for people to understand.

6 So, with that, I think we are wrapped up for
7 today. We're going to return tomorrow, I think 9:00,
8 Margie, is that right? Is that our starting time? 9:00
9 tomorrow.

10 It is important to take any valuables with you,
11 but you can leave the papers here. They're very
12 valuable, but they can be replaced, and we will have
13 replacements. But anything that you don't want taken
14 that we can't replace, which would be anything other than
15 these papers, please take them with you. I hope you all
16 have a good evening and we'll see you tomorrow morning.

17 **(Whereupon, the meeting was adjourned.)**

18

1

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Transcript of Meeting of
Pesticide Program Dialogue Committee
Georgetown University Conference Center
3800 Reservoir Road, N.W.
The Leavey Center, Main Floor, Salon H
Washington, D.C.
October 20-21, 2003
Day 2

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6 Lori A. Berger Ph.D., Director of Technical
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12 Bill Tracy National Cotton Council of
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14 Rebeckah Freedman Adcock Director, Congressional
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16 Specialty Products Association
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18 (Day 2 only) Chemistry Council
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11 Management, USDA

12 Dr. Melody Kawamoto National Institute for

13 Occupational Safety and Health,

14 Centers for Disease Control &

15 Prevention

16 Jennifer Sass (Portion of Day 1)

17 John Kepner Beyond Pesticides

18 Frank Gasparini (Day 2)

19 Maureen Serafine New York

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P R O C E E D I N G S

DAY TWO - OCTOBER 21, 2005

MR. JONES: Just a quick review of the morning agenda, which I'm going to do simply to buy a little time so you can get yourselves situated.

Okay, so we will start this morning with a half-hour update from the work group -- the PPDC workgroup on PRIA process improvements. Then we're going to spend an hour on an issue that, as I mentioned yesterday, over the last, at least, two years, maybe longer, numerous amongst you have asked that we spend some substantive time on, and that is spray drift.

Right before the break, I'll take Jennifer Sass' idea of having public comment for five minutes. So, there's a little bit closer alignment between when we're talking about an issue and people having an opportunity in the general public to give us some comment if they so choose.

We'll take a short break and then we'll come back and wrap up the morning with a little bit of administrative work associated with the renewal of our charter and membership of the PPDC and then our usual

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1 planning for the next meeting. I've already identified a
2 number of follow-up items from yesterday and I expect
3 I'll be adding at least one from today that we can review
4 at the end of the morning. And then, again, we'll have a
5 short public comment process and we'll wrap the meeting
6 up.

7 Just as a brief introduction around the PRIA
8 Process Improvement Workgroup, this committee advised us
9 soon after PRIA passed, probably in the spring meeting
10 after PRIA passed, that there wasn't broad interest in
11 participation in the PRIA Process Improvement Workgroup.
12 However, you suggested that we have such a workgroup for
13 interested parties, but again, as I mentioned yesterday,
14 before the Agency got too far down the road with
15 implementing these process improvements, that we would
16 seek the advice of the PPDC, which we've been doing at
17 each of these meetings. It tends to be a relatively
18 short part of the presentation.

19 So, this morning, Marty Monell and, I believe,
20 Greg Watson and Elizabeth Leovey are going to give us an
21 update on where that workgroup is. All right, Marty?

22 MS. MONELL: Thanks, Jim. I'm just going to

1 briefly give you the background. This is the statutory
2 provision in PRIA, the Pesticide Registration Improvement
3 Act, fondly known as PRIA, that provides for the Agency
4 to take a look at its processes in its registration
5 activities, and to the greatest extent possible, to come
6 up with some improvements that basically will enable us
7 to make certain that we meet the time frames without
8 harming, in any way, our risk assessment, risk management
9 process.

10 So, that's sort of the purpose of this statute,
11 to make sure that we have processes that are effective to
12 bring home the registration actions.

13 What we have done and what we did do for the
14 last PPDC meeting was to really look at each registering
15 division and the science divisions and go through some
16 streamlining efforts, and you heard at this meeting last
17 spring, some of those efforts from each of the
18 registering divisions. At the last PPDC Workgroup
19 Meeting, we -- the members heard from the science
20 divisions, as well as updating from the registering
21 divisions. They heard from the science divisions on some
22 of their efforts to better engage and more efficiently

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1 engage in their scientific reviews. We will be bringing
2 that information back to the next PPDC meeting. We
3 thought that, for this PPDC meeting, we would focus on a
4 couple of items that were -- on which we've done a lot of
5 work and which were of major importance to everyone.

6 So, I'll turn it over now to Greg Watson, who
7 has graciously agreed, on behalf of the workgroup, to do
8 a little presentation, and I want to also reintroduce --
9 for those of you that don't know Elizabeth Leovey.

10 Elizabeth Leovey is the Senior Advisor to the Office
11 Director for PRIA implementation, and she's been doing
12 this since Rick Keigwin left about nine months ago. So,
13 I want to thank her very much.

14 MR. WATSON: Thank you, Marty. I also want to
15 thank Marty and Elizabeth for their contributions to the
16 slide set. So, I appreciate all the help in getting that
17 set up.

18 The first priority that the workgroup decided to
19 work on that was an issue statement or problem statement
20 that came both from EPA, as well as the Industry FEE
21 Coalition was the labeling. I guess that shouldn't be a
22 surprise given that labeling has been an issue under

1 discussion for quite a few years. In fact, there's some
2 people in this room that have been involved in the
3 Consumer Labeling Initiative to try to make labeling of
4 consumer-oriented products more simple and
5 understandable, and there have been PR notices over time.
6 PR Notice 83-3 was actually a label improvement program.
7 There were follow-ons from that in 84 and 87. So, again,
8 it wasn't really a surprise that this was an area of
9 interest.

10 After a lot of discussion within the group, OPP
11 moved to establish a Labeling Committee. That will be a
12 standing committee that represents or have
13 representatives from the registering divisions, which
14 are, of course, the registration division, the anti-
15 microbial division and BPPD. SRRD is also represented,
16 as well as FEAD. Again, that makes perfect sense given
17 FEAD's alliance to the states. And the enforcement and
18 compliance is also a needed component of that group
19 because, again, labeling obviously has strong linkages to
20 enforcement questions, as well as compliance with FIFRA
21 and, again, hence the involvement of OGC.

22 I think it's important to recognize within this

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1 labeling team that it's not the intention to concentrate
2 on product-specific items. As is pointed out here, the
3 purpose is to look at labeling policy and not specific
4 examples within products.

5 And I think that the other part of that is also
6 the intention for internal as well as external
7 communication and we'll mention that again as we go
8 through -- particularly as we talk about the Label Review
9 Manual.

10 One of the charges, the first component, again,
11 as I just mentioned, was the Label Review Manual. That
12 actually is posted on EPA's website. This is really the
13 most comprehensive document that's available both to
14 those within OPP that are responsible for working in the
15 registering divisions, as well as for the registrant
16 community. So, it was seen to be, not only by the label
17 team and the FEE Coalition and the PRIA WorkGroup, as a
18 very important document and one that needed to become
19 living or evergreen. So, it's, again, an important part
20 of the effort.

21 As you can see, a website also will be
22 established within the plan and that will be, also,

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1 again, a way of communicating decisions to the
2 registrants, as well as general public. There actually
3 is already a database that is a conversation point
4 between the state regulatory authorities and the EPA
5 called the Slits (phonetic) Database, and that actually
6 has been recommended by the FEED Coalition as a place
7 where we could look for further items for the OPP
8 Labeling Committee to look for for other things that need
9 to be worked on.

10 Just to give some more concrete examples of what
11 the Labeling Committee has been working on, you can see
12 the list there, and again, the underlying theme is an
13 emphasis on non-product-specific questions.

14 And, again, to do the list the converse way,
15 there's also a list of things that are -- the Committee
16 is not going to be working on. I think, again, the key
17 emphasis here is if there is a product-specific issue
18 that has arisen through a registration decision, that the
19 intent is that that would still remain within the
20 appropriate registering division, and I think that's an
21 important component. However, I think it's also
22 important that the labeling team provide a framework in

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1 the guidance that they're working to provide so that
2 there will be a consistent approach on -- when there's,
3 again, these general issues that -- so they can be --
4 again, set the frame. And, again, that's mainly
5 consistency and a fairness issue that's trying to be
6 managed.

7 Some logistical information about the work the
8 group is doing. These are really some of the operational
9 things. To set an internal procedure document, the
10 establishment of an email box where questions can be
11 posed to the Committee, and the website for the, as we
12 mentioned, the two-way communication. The website name
13 even is actually named after a website that exists within
14 BPPD and, again, that is -- seemed to be the best working
15 model. And, again, the approach on the Labeling
16 Committee has been not -- in terms of the Label Review
17 Manual, has, again, to create a separate subgroup that
18 will work on, again, keeping that -- the Label Review
19 Manual up to date.

20 Again, some examples of the specific label
21 language. Part of the important questions as a point of
22 sometimes controversy is mandatory versus advisory label

1 language. To give you an example, a mandatory statement
2 within -- as it's defined within PR Notice 2005 it uses
3 words like "must" or "shall" in its recommendations or
4 its statements on labeling.

5 Advisory statements seem to be recommendations.
6 So, for example, if a product label says, you must apply
7 this product using nozzle XYZ, that's a mandatory
8 statement. If the label statement is we recommend that
9 you apply this product using nozzle XYZ, then that's an
10 advisory statement.

11 However, it's always not that simple. If you
12 have -- there are several statements on labels that say
13 "do not" versus the word "avoid." And, again, I think
14 that's part of the issue that the Label Committee is
15 trying to work through, is to get a little more clarity
16 there.

17 One of the components within that topic that is
18 of interest particularly to industry is we've asked for
19 consideration of a creation of labeling statements that
20 will allow stewardship of products toward intended
21 audiences or customers bases without going to a
22 restricted use classification. Now, we recognize that's

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1 a potentially difficult topic, but, again, it's important
2 to industry to provide, again, a stewardship tool to make
3 sure the intended uses of products are there.

4 The second area that is of -- that's, again,
5 more of an issue is warranty statements, and these are
6 placed on labels by the registrant and their real
7 intention is to outline and state as clearly as they can,
8 the liability limits that are intended for that specific
9 product by industry. One of the reasons that's been an
10 issue for us is that when you're doing product
11 development work on a new product, you cannot do research
12 that will cover all the agronomic and all these
13 conditions regarding advocacy and expected performance of
14 product. So, that's another area that's being worked on
15 within the Committee.

16 Regarding next steps, again, the intention is
17 that the next PRIA FACA meeting that will be held in
18 January of 2006, or planned to be held, is to present the
19 work that the group has made so far on the topics we've
20 mentioned, and to come forward with the recommendations
21 or -- that we have given from the industry side to the
22 Committee, as well as the ones they've developed for the

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1 Labeling Review Manual. And, again, the for sale
2 statement there is, again, the aforementioned, we're
3 trying to create this category that allows the use of
4 stewardship for intended customer use.

5 Switching gears completely, that was a pretty
6 quick overview of the work the Labeling Committee is
7 doing, to another initiative that is being taken up
8 within the framework of the Committee, and certainly, the
9 cornerstone of PRIA is that there must be a complete
10 application when it is submitted to EPA. Without that
11 foundation, all the time lines and all the work and the
12 registrant expectations cannot be met.

13 So, there have been some initiatives within
14 particularly AD, or Antimicrobial Division, with industry
15 that works on registering products in that area, and
16 there also has been some work within BPPD.

17 There have been some discussions regarding the
18 registration division. Our feeling is that within RD,
19 the spectrum of registrants within that area is very
20 diverse and that may require more dedicated thought and
21 effort on the best way to provide guidance. For example,
22 there are several companies that have registrations

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1 within the registration division that have only one
2 product in registration, as compared to R&D-based
3 companies who have several hundred.

4 Another initiative that's being worked on within
5 OPP, within the group or within the committee is the Blue
6 Book, and you can see the title on that document. I have
7 to sort of smile about this one because my version of the
8 Blue Book -- I've been working in Regulatory Affairs for
9 over 14 years and my copy is more gray than blue on the
10 cover because of the many times it's been copied and
11 xeroxed. So, I think that's a welcome initiative to try
12 to look at the guidance and, again, it will be focused
13 toward providing a complete application.

14 As far as topics for the next meeting workgroup,
15 again that's planned for January of 2006, a key thing, as
16 I think I've mentioned in previous presentations to this
17 group, is to look at the next topic that the group needs
18 to take up in earnest. Hopefully, you can see from the
19 presentation that there's been a lot of work and effort
20 and progress made on the labeling issue and we need to
21 look at that now being more in an implementation phase,
22 the next issues that we want to move forward on.

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1 With that, I will close, and if there's any
2 questions or comments from the floor, I will let
3 Elizabeth or Marty answer them.

4 **(Laughter.)**

5 MR. JONES: Go ahead, Steve.

6 STEVE BALLING: In the discussion about labels
7 and warranties, I'm wondering if the issue of liability
8 waivers ever came up and whether that's appropriate to
9 that particular discussion. And if it's not appropriate,
10 then I would suggest to Jim and Anne that maybe we ought
11 to have that discussion at some point.

12 MR. WATSON: It actually has been put as sort of
13 a parking lot issue. For minor crops, and particularly
14 within the IR-4 program, there frankly has been a lot
15 more concentration on residue information as compared to
16 product use. But it was felt because, frankly, some of
17 the legal precedents that are now being established, that
18 probably this should be parked there, okay, until we get
19 --

20 STEVE: Well, it's being more than parked right
21 now.

22 MR. WATSON: But, again, to have an OPP Labeling

1 Team pick that up as a topic until --

2 STEVE: True.

3 MR. WATSON: -- it proceeds further and there's
4 more clarity --

5 STEVE: I see.

6 MR. WATSON: -- is probably something we said we
7 need to know -- keep track of where it's going and what's
8 happening, but to put it as a topic that we're going to
9 put front and center, it's been the decision not to or
10 recommendation.

11 MR. JONES: Sort of a related procedural issue
12 is that the process improvements this group has been
13 working on that are, to me, very clearly process
14 improvements, I think you need a labeling committee, good
15 idea, you should do it, you should help us improve
16 applications, good idea, we should do it. The Blue Book
17 needs to be updated, process improvement, ITIM,
18 information technology, good. Getting into the policy
19 resolution of some of the labeling issues I don't think
20 is necessarily appropriate for the process improvement
21 workgroup. I think we need to find a different forum for
22 dialogue around the --

1 STEVE: No, that makes more sense.

2 MR. JONES: -- substance of any of the issues
3 that then get identified by the Labeling Committee.

4 STEVE: But maybe we could add that to an agenda
5 item for the next PPDC meeting.

6 MR. JONES: Erik?

7 MR. OLSEN: Yeah. I just wanted to raise a
8 cautionary flag about that issue. It sounds like you're
9 already raising it. But my question is, for warranty
10 statements, I'm just curious, what does EPA do now for
11 warranty statements that are placed on a label? Do you
12 approve the warranty statement basically as part of the
13 label?

14 MR. JONES: Where's our registering master?

15 MR. WATSON: I can answer for the registering.
16 There actually is a portion of the Label Review Manual
17 that provides direction.

18 MR. JONES: Greg, give us an example of a
19 warranty statement.

20 MR. WATSON: Oh, gee, you don't have that much
21 time.

22 MR. JONES: They're that long?

1 (Laughter.)

2 MR. WATSON: That's the Syngenta one in small
3 print, okay? It takes up a full printed page almost and,
4 yes, it is written by lawyers here. So, it's --

5 ANNE LINDSAY: Elizabeth could supplement this
6 or update this, but I believe that, at least
7 traditionally, the warranty statement is something that
8 is typically drafted by the company who's seeking the
9 registration and by their attorneys. I think when we're
10 reviewing the label for purposes of assuring that it
11 reflects the registration that we're likely to grant,
12 we'll look at that warranty statement to make sure that
13 there's not something in the warranty statement itself
14 that would conflict with or undermine other portions of
15 the label that have to do with use instructions,
16 necessary precautions, that would cause a user to go
17 astray in following the label.

18 If we're satisfied that the warranty statement
19 is not going to cause those kinds of problems, I think we
20 generally treat it as a statement that the company wants
21 to make with regard to their product. So --

22 MR. OLSEN: I mean, in terms of liability, I

1 would think it's important for EPA to be somewhat hands
2 off on that. I presume you are, but I was surprised to
3 hear this was --

4 MS. LINDSAY: Well, that's why I'm trying to
5 describe --

6 MR. OLSEN: -- raised as --

7 MS. LINDSA6Y: We're just looking at it to see
8 that it's not accidentally conflicting.

9 MR. OLSEN: But you're not -- there's no implied
10 endorsement of the labels by EPA --

11 MS. LINDSAY: No, no.

12 MR. OLSEN: -- when you review the warranty?

13 MR. WATSON: I think that's clear. And, again,
14 the comments, if you look at -- as Anne has just
15 described, that's exactly what the guidance that the
16 Label Review Manual provides, and frankly, our comment,
17 Erik, if you recall in the last meeting you attended from
18 industry's side is this was clearly an issue that was in
19 the hands of OGC, the folks that are on the Labeling Team
20 that are doing that.

21 MR. OLSEN: Okay. I would just want to make
22 sure that that was clear. One other question is this

1 idea of for commercial use only, not for residential use,
2 for professional use only. Would that be enforceable if
3 it's on a label?

4 MR. JONES: I think that that's why that's such
5 a challenging issue. Some of those may be enforceable
6 and there are other aspects of it that may not be, and
7 that's what we struggle with in making sure that if we're
8 going to do something like that, we do it in a way that
9 is enforceable.

10 MR. OLSEN: Yeah. So, the question is, is this
11 a substitute for restricted use or not? I guess I have
12 an issue with it if EPA is going to assume that there's
13 full compliance with, say, for restricted -- I mean, for
14 professional use -- I don't even know what that means,
15 for professional use -- but for professional use only.
16 If EPA then says, well, okay, we're going to assume that
17 it's only used by registered -- you know, by somebody
18 that's actually trained, blah, blah, blah, and therefore,
19 it's safe and allows a fairly risky product on the market
20 or to continue being marketed, there is a statutory
21 process for that, which is restricted use, and if the
22 product is dangerous enough to require some kind of

1 training before you use it, et cetera, it would seem that
2 you have an approach to doing that, which is the law, and
3 that ought to be pursued.

4 I'm not discouraging companies from trying to be
5 responsible in saying, you know, this product should have
6 additional precautions. But once it's on the label, in
7 our view at least, it ought to be enforceable.

8 MR. JONES: And I think we would agree with that
9 last statement. If it's on the label, it needs to be
10 enforceable.

11 MR. COLBERT: And from the enforcement --
12 primarily the states' perspective -- many of these aren't
13 enforceable. They don't know who the class is that is
14 supposed to be -- that sales are supposed to be limited
15 to. So, that's one of the issues, is it enforceable? In
16 terms of what the purpose of it is, from our perspective,
17 I don't have the answer. I mean, there are restrictions
18 on restricted use, but from the enforcement side is, is
19 it enforceable, and some of these classes are not well-
20 defined. Like you said, who is professional only.

21 MR. JONES: I will give you one example that
22 we've been struggling with right now and it has to do

1 with the remediation of bio-contaminated facilities, as
2 in the anthrax context. It's pretty clear that the kind
3 of training that you would get as restricted use as a
4 certified applicator is totally irrelevant. It's not
5 totally irrelevant. It doesn't help you do that
6 application effectively, and yet, you want people to be
7 trained specifically in that kind of -- you know, how we
8 decontaminated the Hart Building or how you
9 decontaminated the building in Florida or the other post
10 offices.

11 So, one of the things that we struggle with is,
12 is there a way in which you can make sure people receive
13 appropriate training for a VERY specific application that
14 they're not going to get just by being a certified
15 applicator, and that's something we're right in the midst
16 of right now struggling with in the context of how would
17 you potentially label something for that kind of a use?
18 I mean, that was one example of what we're struggling
19 with now.

20 MR. OLSEN: I think that's a really good
21 question. It doesn't seem like that's a procedural sort
22 of improvement issue.

1 MR. JONES: I would agree with that. Right.

2 MR. OLSEN: So, if we start getting into those,
3 I think we need a broader discussion about that.

4 MR. JONES: No, I would agree that those are the
5 kinds of things we need to sort of bring back into a
6 broader policy kind of forum, like the full committee.
7 Bob, I think you wanted to respond to something as part
8 of that discussion and then I'll pick up.

9 MR. ROSENBERG: Well, we're not going to draw
10 attention to the late arrivers again, are we?

11 **(Laughter.)**

12 UNIDENTIFIED MALE: You already did yourself.

13 BOB: I just want to respond to Erik and say
14 that I have some experience with two examples of that
15 kind of restrictive label language. The first, I think,
16 time it was attempted was when the agency wrote its PR
17 Notice 96-7 relating to termiticides, and then, again,
18 with aduicide for area-wide application labeling. The
19 issue was the toxicity characteristics of the products
20 did not match the criteria for them being deemed
21 restricted use products, but there were compelling
22 reasons why they ought not to be sold to persons who were

1 not commercial applicators.

2 And in the case of termiticides, it was simply
3 the difficulty of application, having to drill into holes
4 and trench down four feet around the perimeter of a
5 house.

6 I'd also say that there's been some mixed
7 success with enforcement. In the case of termiticides,
8 there were some pretty high visibility examples of, I
9 think, Lowe's and Home Depot both retailing PCO Only
10 products back in the nineties, and about maybe a third of
11 the states felt as if they had sufficient leverage to
12 enforce the label. And, actually, did --

13 UNIDENTIFIED MALE: Did they say PCO Only?

14 BOB: They say, I think, certified applicator.
15 But, I mean, the intent was PCO. I would agree when we
16 grappled with the issue the first time in '96, we
17 probably didn't come up with the right set of words to
18 create enforceable label language and think that it's
19 worth taking another look and seeing if there isn't a
20 better set of words that would give the states more
21 unambiguous authority to do that kind of enforcement.

22 BETH: This is not necessarily specific to just

1 this, but it would be really nice -- I know you go up to
2 the deadline on these overlays, but it would be really
3 nice to have them in our packets prior to the meeting or
4 available outside. There's a lot of information here,
5 and I know you'll post it at some point, likely, but it
6 just would be really nice to have them ahead of time.

7 MR. JONES: I agree with that. This example
8 that -- it was the workgroup who was responsible for
9 pulling these together, so yes, I think as a general
10 matter, it's useful to have these things in advance.

11 Julie?

12 MS. SPAGNOLI: You know, Greg's saying about the
13 Blue Book, and I think I really dated myself when we had
14 that meeting and I brought up the mission statement from
15 the original labeling unit and everyone -- how many
16 people remembered that?

17 One of the questions that's come up with the
18 group that's working on consumer labeling, we had a
19 conference call earlier this week, is the real -- I think
20 where we're at on the consumer labeling is we've come up
21 against a lot of policy questions, especially with
22 changing labels for environmental stewardship information

1 or safe use information. And so, we've sort of run up
2 against some policy issues and I guess the question is,
3 is now, how do we coordinate or where does this consumer
4 labeling workgroup then go to the labeling committee, you
5 know, with some of these policy questions, and that was
6 something that came up just this week as to what that
7 relationship -- again, because the -- we're not looking
8 at the labeling committee as part of the PRIA Process
9 Group. It's really a separate entity that's now been
10 established to deal with labeling policy issues.

11 MR. JONES: Those are good questions and we need
12 to think about how to integrate all of that.

13 MS. SPAGNOLI: Just as these things have
14 developed.

15 MR. JONES: Yes.

16 MR. WATSON: Just to quickly follow up on that
17 comment. That was exactly the original intention because
18 the intended use pattern that's being requested in the
19 application is exactly what you're trying to define on
20 the label, hence the question. Again, I agree with the
21 statements that it probably needs to move out of arena,
22 but that's where it's started.

1 MS. SPAGNOLI: You know, just to add to Bob's
2 comments. When I was with Bayer, with the termiticide
3 product, one of our concerns was these products were
4 showing up on these do-it-yourself websites and, again,
5 the products really were never intended for just home
6 application because of the special equipment that's
7 required.

8 MR. JONES: Ray?

9 RAY MCALLISTER: I have a couple of points for
10 clarification. As I've followed, kind of at a distance,
11 this discussion about the professional application only,
12 I think I understand that while we want to restrict the
13 use to a certain class of applicators, that the
14 definition -- the legal definition of restricted use --
15 doesn't quite fit the reasons why a registrant wants to
16 sell only to a particular market. Is that correct? Is
17 it a matter of the legal definition of restricted use and
18 the class of --

19 MS. LINDSAY: I don't have perfect recall, and if
20 Bill Jordan's actually around, he might do better with
21 this. I think the statute gives us latitude to restrict
22 products for a number of reasons, one of which is the set

1 of reasons that Bob articulated around toxicity. But I
2 think, also, if we look at a particular product that's
3 proposed for us and we look at it and say, this requires
4 highly specialized knowledge, it requires access to
5 equipment that you would never expect the homeowner on
6 the weekend to be able to purchase, you know, because of
7 cost, because of -- you don't even know where to go to
8 get it. If you got it, you wouldn't know what to do with
9 it.

10 So, if it's just a highly complex, very
11 specialized use pattern that requires really significant
12 training or if we have evidence of widespread misuse
13 under current conditions of registration, and after
14 examining that, we realize that the misuse might be
15 related back again to the level of sophistication that
16 the user needs to have and the level of equipment
17 sophistication necessary, and that these misuses are
18 causing significant either environmental or human health
19 problems. We have the ability to restrict.

20 So, it's not a -- it's not totally driven by
21 toxicity, although I think classically and historically
22 we've looked at toxicity as sort of driving or leading

1 characteristics, so that if you've got something really
2 highly toxic, even if it actually might be simple to
3 apply, you just don't want people like me to have access
4 to it for -- because of the possible consequences of
5 misuse. So, there's a range of reasons you can restrict.

6 The other piece, though, that the Agency always
7 has to think about in doing that is the point that Jim
8 made earlier, which is if you restrict something but
9 there are no training categories out there in the states
10 and, you know, APSEE, for instance, may not have done
11 training manuals for it or other kinds of training
12 material, you can restrict it, but the applicators that
13 then are eligible to use it are no more better educated
14 or trained than I might be or -- I don't know if you're a
15 certified applicator -- you might be. And so, you
16 haven't actually achieved much.

17 So, when you're actually talking about
18 restricting something for whatever set of reasons, you
19 also need to be thinking about the sort of implementation
20 in the field and do you have the wherewithal to achieve
21 what you want. It's actually kind of an illustration of
22 the issue Bill Diamond was raising yesterday and Marty

1 with our strategic planning, that the field program has
2 to be integrated into the registration decision in order
3 to be able to make it work.

4 MR. JONES: Ray?

5 MR. MCALLISTER: In a situation like this where
6 this workgroup has discovered a concern which requires a
7 policy decision at a different level than they're working
8 at, and it probably requires some significant technical
9 input that this group may not be immediately prepared to
10 provide, but does need some stakeholder input, how would
11 you go about resolving it?

12 MR. JONES: Well, I think we need to think about
13 what would be the appropriate process for bringing
14 resolution to it. Having watched this committee struggle
15 with labeling issues before, I'm not sure this is the
16 right forum, but whatever we do, it's not going to be
17 divorced from having public participation. Like any kind
18 of labeling issue that we've struggled with over the last
19 10 years, we're going to bring some public process to it.

20 So, in the back of my mind, I am thinking about
21 the PPDC as the place, but I'd like to see this committee
22 have a little more success around issues like that. We

1 do have the consumer labeling workgroup that I was about
2 to pull the plug on at this meeting, but they were
3 resuscitated just before the meeting, and so, we're going
4 to give them a shot to show their stuff at the next
5 meeting, and maybe you'll all convince me that actually
6 these are the kinds of issues, labeling issues, that this
7 committee would be effective at.

8 But we need to think of a forum to tee them up.
9 It needs to have broad stakeholder participation and
10 there needs to be broader public participation as well.
11 So, I've noted that issue.

12 Michael, unless you want to talk about the
13 process issues, which is what this ostensibly is about, I
14 think we've clearly identified that there the process
15 workgroup got a lot of good process moving forward, and
16 stumbled into a policy area. We're going to make sure
17 that we do not have the process implementation workgroup
18 starting to resolve some of these policy issues. I
19 think, once again, this showed the interest in this
20 committee around substantive issues, although I really
21 don't want to diminish the importance of this process
22 improvement workgroup. I think they've identified a

1 number of very important issues that are strictly process
2 that are going to make the process better and I'd like to
3 see them continue down that vein. I think it's been
4 pretty effective and would like to keep them plugging
5 away at those kind of things.

6 Speaking of a substantive issue, as I've said a
7 number of times over the last day -- thank you to the
8 team who presented the PRIA process improvements, Greg,
9 Elizabeth and Marty.

10 Spray drift is an issue that we've struggled
11 with for a number of years in the pesticide program,
12 probably since we've been a program. We've had a number
13 of efforts in the last five years, which have been highly
14 controversial. This committee has, as I've stated,
15 repeatedly asked that we, as a group, focus on some of
16 them. Now, I have the combination of the committee
17 asking for some focus on it and my boss. That's a very
18 powerful combination when the two of you line up
19 together. And so, we are going to do some focus on spray
20 drift and Anne is going to tee the issue up for us.

21 MS. LINDSAY: Okay. And I don't feel at all
22 squeezed between a rock and a hard place. Before I

1 actually launch into drift, I'd like to make an
2 introduction. This is Allison Wiedeman. She is a Branch
3 Chief in our Office of Water and has significant
4 responsibilities with the NPDES Permit Program here at
5 headquarters, and we've gotten to know each other quite
6 well over the last year or two since OPP and the Office
7 of Water have been spending a lot of time on the
8 intersection between the Clean Water Act and FIFRA.

9 There are a couple of topics I want to cover in
10 this session quickly, and Allison is actually going to
11 help me with some of the FIFRA-NPDES portion. So, before
12 we got started, I wanted to make sure you knew who she
13 was, and she's been listening to you in the last session.
14 I assured her that you were the world's best FACA
15 Committee. So, you need to live up to that billing or
16 she's going to doubt my every word. I said you don't
17 pull your punches, you ask hard questions, but you are
18 really constructive and helpful. So, make me a truth
19 teller today.

20 There are a couple of topics that I want to
21 cover quickly, but we've only got, I think, an hour
22 allotted for this and we've started a little bit late.

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1 But I do want to save some time at the end to see if you
2 can start sharing with us some specific issues that you
3 would like us -- as we've set up this workgroup, we've
4 talked about -- that you'd like this workgroup to be
5 focusing on.

6 Before we get there, I want to talk a little bit
7 with you about our progress on the drift reducing
8 technologies project, that's the overhead here. I want
9 then to move to -- describe to you one of our current
10 efforts to integrate and coordinate FIFRA and Clean Water
11 Act activities, and then finally to talk more
12 specifically about the formation of this subgroup and
13 what issues it might actually take on board, which will
14 probably also lead then back to the kind of labeling
15 questions that we were just talking about at some point.

16 So, if you focus for the moment on this
17 flowchart, we, that is OPP and ORD, recently won an
18 innovation grant from the Agency, from EPA, to develop
19 this drift reducing technologies process, and the idea,
20 if you remember back from May, is fairly simple. Can we
21 identify specific application technologies and then test
22 them and measure and verify that, in fact, when you use

1 these application technologies, you reliably achieve
2 drift reduction and you actually have a sense of what is
3 the magnitude of the drift reduction when you use this
4 specific kind of technology, so that it's not just
5 anecdotal or best professional judgment. You actually
6 have scientific data that underlies that and you know
7 with confidence that you're achieving a real degree of
8 risk reduction?

9 This process that we're launching on with ORD is
10 a process that's actually been developed by a specific
11 branch within our Office of Research and Development. I
12 think it's called the Environmental Technology
13 Verification Branch. And they've used this model process
14 on a whole array of different technologies. I don't
15 think any of them have been associated with pesticide use
16 in the past. This is sort of the first pesticide trial
17 application. An example, I've been told, is they've used
18 this on some diesel engine technology improvements, but
19 I'm not an expert in diesel engines, so I can't actually
20 tell you more about that.

21 But it starts out with the funds that we got
22 from the innovation grant, we've been able to hire a

1 contractor who, at this point in time, is going out and
2 gathering information from -- frankly, globally, about
3 existing application technologies and, also,
4 methodologies that may exist, measure the reduction
5 associated with those technologies, data and information
6 about how much they reduce drift, all kinds of relevant
7 information. I think of this almost as a survey of the
8 field paper. So, it will pull together in one place
9 pretty much everything that has been published or is
10 known about drift reduction technologies and ways of
11 measuring that, and I think the expectation is that this
12 paper would be done probably by the end of this calendar
13 year.

14 If you go then to the next box where it says
15 develop verification programs, this is envisioned as a
16 stakeholder process, and so, all kinds of people would be
17 engaged at this point, folks who actually use this
18 application technology currently, real users, I think
19 manufacturers of application technology, pesticide
20 manufacturers, public interest groups, anybody who
21 actually has a care and concern for this issue. In
22 working with the White Paper, the expectation is that

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1 this group and the Agency team would ultimately identify
2 one or two specific technologies that ought to be piloted
3 through the rest of the process, and not only the actual
4 specific technology, but if there are (inaudible)
5 methodologies for measuring the drift reduction, sort of
6 what those are and whether they can be used as is for
7 conducting the pilot test, which takes place in the third
8 box, or whether there's additional work with those
9 methodologies that need to be done.

10 And one of the other important kind of implicit
11 reasons for the stakeholder process is that you actually
12 hope that you're beginning to create incentives and ideas
13 in people's minds about, okay, if I were actually going
14 to adopt and use such technology, what are the other
15 sorts of barriers that I would have to overcome. There's
16 always, I think, a cost issue for farmers and other
17 users. Can they afford to purchase new equipment if
18 they've already got an investment? But there may be all
19 kinds of other barriers and obstacles in addition to the
20 cost one. I don't know how to use it, I haven't been
21 trained to use it, education issues.

22 So, you start identifying, even in box two, what

1 some of those other barriers are and you start getting
2 people interested in addressing those barriers and
3 figuring out how to get around them. In box three,
4 you're actually going to do the measurement process and
5 verify the performance of these one or two technologies.

6 Assuming that they actually come out of that
7 verification process with, yeah, they really do reliably
8 achieve risk reduction, in the fourth box, EPA would take
9 that information and actually incorporate into our drift
10 models the use of these pilot drift reduction
11 technologies and validate and peer review that.

12 And then you would go to the nominate
13 pesticides/use box, and ideally, at this point, you might
14 have a specific use or set of uses and pesticides in mind
15 where you would then -- let's do sort of a strawman risk
16 assessment to see if all the users of this particular
17 pesticide for this particular use, use this new
18 technology, what kind of risk reduction would you
19 achieve? And, ultimately, then you might get to the
20 stage of looking at label options where it says give
21 credit or maybe reduce use restrictions. If you had a
22 buffer zone in place that was large, maybe you could

1 reduce the buffer zone if it was tied to that specific
2 technology.

3 You could also then look at cost savings
4 analyses. If people were able to use this technology and
5 had a reduction -- a lessening of a restriction because
6 you knew it was no longer necessary in order to mitigate
7 risk -- would that lead to cost savings ultimately for
8 the grower, user and others, and then you would also be
9 looking at grower education. So, this is a draft process
10 with the basic high level steps laid out.

11 Jay Ellenberger, who's sitting behind me, and
12 Norm Birchfield are the two principal people within the
13 Office of Pesticide Programs who are in charge of this
14 project. They are, as I'm talking, thinking about how to
15 set up the stakeholder process that's in box two, and I
16 think those of you around the table who may have an
17 interest in this process, think you might want to be
18 engaged or think you know people who would want to be
19 engaged, it would be very valuable if you would get in
20 touch with Jay and let him know your level of interest,
21 because we would hope that a year from now, we'd be able
22 to, for instance, come back here or be in other venues

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1 where we could report what I hope will be the success of
2 this project, or certainly, where we are with it and what
3 we think we're learning from it.

4 If this works, it obviously has broader
5 application than just for the selected pilot technology,
6 and you'd have to figure out how to do this more broadly.

7 So, let me pause here and see if there are any
8 brief questions about this project, because I think it's
9 quite different than the next set of issues that I want
10 to talk about.

11 Carolyn?

12 MS. BRICKEY: Yeah, describe real quickly what
13 the pilot technology is and then give me some idea what
14 others are. Is this closed system application that we're
15 talking about?

16 MS. LINDSAY: The pilot technologies haven't
17 been selected, but, for example, I know that there's a
18 certain kind of air blast, what is it --

19 UNIDENTIFIED MALE: Aerosys (phonetic) sprayer.

20 MS. LINDSAY: An Aerosys sprayer that some
21 people think might really reduce drift. So, we'll be
22 looking at some very particular application equipment and

1 technologies. This is a fairly technical stakeholder
2 process, as I understand it. It's not the kind of policy
3 group that this group is. I don't know if that helps you
4 any. You're looking at me puzzled still.

5 MS. BRICKEY: Yeah. I'm just wondering, is this
6 closed system application or what is -- I mean, what's a
7 sprayer to do? I mean, I don't understand.

8 MS. LINDSAY: Closed systems, I think, are
9 actually designed to try to protect the applicator as
10 they're applying.

11 MS. BRICKEY: Right, right.

12 MS. LINDSAY: This is about when you've got the
13 pesticide coming out of the nozzle into the world.

14 MS. BRICKEY: Yeah.

15 MS. LINDSAY: Depending, for instance, if you've
16 got an airplane, the way you set the nozzles on the
17 airplane --

18 MS. BRICKEY: I know about airplanes.

19 MS. LINDSAY: Okay, okay. Well, but that's a
20 type of technology, and depending on how you do it, you
21 can cause drift to occur over large areas or you can
22 reduce the amount of drift that occurs, both the amount

1 and the distance over which drift can occur. And the
2 same is true for different kinds of land application
3 technologies. This is about what comes out of the
4 application equipment and how can you reduce -- make sure
5 that more of it goes on target.

6 MS. BRICKEY: Okay.

7 UNIDENTIFIED MALE: A closed system would be a
8 greenhouse. Is that what you're talking about?

9 MS. LINDSAY: So, Larry, I think you're next.
10 You're holding your head.

11 UNIDENTIFIED MALE: Well, Larry's been here all
12 of three minutes. (Inaudible).

13 **(Laughter.)**

14 MR. ELWORTH: Which will not prevent me from
15 asking an insightful and probing question, and maybe
16 you've already said this. What is the cross connection
17 between USDA on at least two different areas, one is with
18 conservation programs --

19 **(End of Tape 1, Side A)**

20 MS. LINDSAY: -- all of that would actually be
21 incorporated through this stakeholder process. I
22 understand, from talking with Pat Cimino and others, that

1 some of the NRCS programs actually might be used in
2 conjunction with --

3 MR. ELWORTH: Are currently being used.

4 MS. LINDSAY: Okay. And so, the effort would be
5 to get that incorporated into this pilot, so we're not
6 doing something separate, but we're taking advantage of
7 what's going on.

8 MR. ELWORTH: It would also be really useful to
9 talk to somebody fairly senior at ARS to make sure
10 there's kind of a regular connection back with them,
11 because, you know, they're spread all over the country.
12 They could be doing exactly what you want to be doing
13 in --

14 MS. LINDSAY: Right.

15 MR. ELWORTH: -- you know, Missouri or
16 somewhere.

17 MS. LINDSAY: Right. So, this is not meant to
18 actually duplicate other activities; it's meant to
19 incorporate it effectively.

20 Ray?

21 RAY: What time frame are you working on with
22 this grant and what's the end part of the grant?

1 MS. LINDSAY: My understanding is we'd like, by
2 a year from now, to have worked our way pretty much
3 through this process with one or two pilot technologies.
4 I don't know whether we'll succeed, but that's the
5 expectation.

6 John?

7 JOHN SCHELL: Anne, you may not have the answer
8 to this yet, but in one of the earlier boxes, you talk
9 about verifying performance, do they achieve risk
10 reduction. Do you have any sense of sort of a threshold
11 risk reduction for a technology to be a candidate? Is it
12 a two-fold risk reduction, an order of magnitude or --

13 MS. LINDSAY: I don't think we've gotten to that
14 point.

15 JOHN: You haven't gotten to that far? And will
16 you do a cost benefit once you do that?

17 MS. LINDSAY: Yeah.

18 JOHN: Okay.

19 MS. LINDSAY: That's how we make these kinds of
20 decisions. So, Jose?

21 DR. AMADOR: First, I'd like to thank you
22 because I guess I was one that brought up the issue of

1 drift a lot of times to the PPDC and wanted to have
2 something done on it. This is a problem in my area, I
3 know. There's a lot of people being sued and being
4 contested because of drift, so I'm glad to see that we're
5 doing it.

6 One question that I have, on this environmental
7 technology verification, is that a very involved thing?
8 Are we going to look at the impact that the drift
9 pesticide is going to have on the environment all the way
10 to water and soil and animals, wildlife? I mean, who's
11 going to do that? Are you going to have the contract --
12 I mean, I'm not familiar with the terminology, I'm not
13 familiar with the technology.

14 MS. LINDSAY: This project is focusing on
15 application technology. the project, itself, is not
16 doing the kind of broad brush work that I think you're
17 describing. We, ourselves, when we do risk assessments
18 are, and we continue to be, looking at the whole range of
19 potential exposures that might occur in the environment
20 as the result of drift and doing appropriate risk
21 assessment analyses to make a call as to whether there's
22 a level of risk there that merits when you factor in the

1 benefits, risk mitigation, risk management decisions on
2 our part.

3 But this is just narrowly focused on
4 technologies that might be capable of reducing drift and
5 developing information about how much -- when you use the
6 application technology the right way, how much does it
7 actually reduce drift? Which is something right now I
8 don't think we, at least in a regulatory sense, actually
9 know. So, it's getting scientific and getting data about
10 another piece of that whole process of pesticide use and
11 application that I think has largely been absent.

12 DR. AMADOR: Well, I commend you for bringing
13 this to the forefront because I had a feeling that maybe
14 we didn't want to tackle the drift issue because it was
15 too complicated, we didn't know what we had and all that.
16 So, I assume this is going to be an ongoing part of the
17 Office of Pesticide Programs from now on, right?

18 MS. LINDSAY: Yes. Rebeckah, I think you're
19 hiding in the corner, but next.

20 MS. FREEMAN ADCOCK: Only because we're having a
21 little group meeting probably and this subject will come
22 up later today. I just want to sort of seek some

1 clarification based on the questions that have been
2 asked. Am I understanding this process basically to be
3 an identification process for technologies that reduce
4 risk and that you really haven't put any other boxes
5 around it other than that yet and you're going to draw
6 from existing information --

7 MS. LINDSAY: Yes.

8 MS. FREEMAN ADCOCK: -- and existing
9 technologies and try to figure out and sort out, in the
10 end, is there anything out there that really we can tell
11 people on the label or otherwise, or give them an option
12 to say, if you use this, then your risk will go down this
13 much and you might even be able to use the product
14 differently perhaps.

15 MS. LINDSAY: Yes.

16 MS. FREEMAN ADCOCK: That that will be factored
17 in.

18 MS. LINDSAY: You've captured it, I think, quite
19 well. I would also emphasize it's not just the
20 identification of these types of existing technologies,
21 but then assuming that they pan out, what can be done to
22 create incentives --

1 MS. FREEMAN ADCOCK: Are they reasonable?

2 MS. LINDSAY: -- for broader adoption and use.

3 MS. FREEMAN ADCOCK: Right.

4 MS. LINDSAY: And forming that --

5 MS. FREEMAN ADCOCK: That would be for
6 agricultural and non-agricultural use? I would assume
7 that there would be a --

8 MS. LINDSAY: I think right now, in my mind,
9 we're focused on ag, but it obviously would be relevant
10 to any kind of pesticide use.

11 MS. FREEMAN ADCOCK: It could be broadened, I'm
12 assuming.

13 MS. LINDSAY: Yeah.

14 MS. FREEMAN ADCOCK: Okay. And you're saying
15 this is a stakeholder group or eventually that you're
16 going to want some --

17 MS. LINDSAY: By the time we get to box two --
18 and Jay is telling me he needs to get to box two soon --
19 we need to have some kind of a stakeholder process that
20 adequately brings people with the right technical
21 expertise into it and gets us the sort of balanced array
22 of people.

1 MS. FREEMAN ADCOCK: Would it help to have an
2 actual user? I don't mean like me representing a user,
3 but an actual user around.

4 MS. LINDSAY: I believe it would very much help
5 to have real users because if real users aren't engaged
6 from the get-go, I don't know you develop the -- so,
7 that's why I know I'm the wrong kind of person to be
8 there. And I think Bob Rosenberg, the political
9 scientist, he's not necessary either. But he'd be
10 welcome.

11 (Laughter.)

12 MR. ROSENBERG: I've met real users.

13 (Laughter.)

14 MS. LINDSAY: Lori?

15 DR. BERGER: What types of crops do you
16 anticipate looking at?

17 MS. LINDSAY: I think this would have to depend
18 on the selection of the technology first that you're
19 going to run through the pilot. But I don't think we're
20 at the point where we're talking about crops. The first
21 part of it is looking at the technologies.

22 DR. BERGER: Well, that's going to drive some if

1 it.

2 MS. LINDSAY: Um-hum.

3 DR. BERGER: So, I think that's something that
4 really needs to be considered up front.

5 MS. LINDSAY: Okay.

6 DR. BERGER: You know, orchard crops, row crops,
7 field crops.

8 MS. LINDSAY: Right.

9 DR. BERGER: That's just going to really
10 confound things, and I think it's definitely a very
11 worthwhile project and our group is very willing to help
12 out and provide people and resources. I do think a year
13 is a very aggressive schedule for this series of projects
14 here.

15 MS. LINDSAY: You know, Jim is a real task
16 master, and just like he drives you to get back here and
17 sit down at the table, he asked us to set ourselves stiff
18 goals, but he also -- the emphasis is on doing it right.
19 So, if we get into this process and we feel like we've
20 got a good process going, but it's clear that it's got to
21 go longer than a year, I'm confident that we'll adjust
22 the schedule accordingly.

1 Gary?

2 MR. LIBMAN: Lori sort of took my thunder on the
3 year thing, too. I agree with that, too.

4 One other thing, you're talking about
5 agricultural, but I'm not sure how you can do this, but
6 you might want to incorporate some of the forestry
7 applications into this as well, not to -- maybe even
8 public health on rivers and things, but certainly
9 forestry where there's a major problem with this. I'm
10 not sure how you can get that into the matrix, but I
11 think it would be very useful.

12 MS. LINDSAY: Okay, that's a good suggestion.
13 Let me, if it's okay, move on to the rest of our
14 presentation because I do want to save some time for some
15 further discussion.

16 My second topic which I wanted to bring to your
17 attention, an activity that started within the Pesticide
18 Program, that we believe will help really much better
19 integrate activities under the Clean Water Act and
20 activities under FIFRA. I think you've heard Jim talk
21 about one of his personal goals that he's made actually a
22 programmatic goal for all of us in the Pesticide Program

1 is essentially to make decisions under FIFRA in such a
2 way that we're not, however inadvertently, setting, say,
3 a user up for possible Clean Water Act problems. In
4 other words, we want to make our two statutes work
5 together to achieve the goals.

6 We believe the goals are very complementary and
7 consistent between these two statutes, but we need to
8 actually make sure that our individual decision-making,
9 as we grant registrations or reevaluate registrations --
10 and in the future that will be through registration
11 review -- lead to appropriate outcomes under both
12 statutes. And users, for sure, need to have the
13 guarantee that when they're using pesticides correctly,
14 that they're going to be in compliance both with FIFRA
15 and the Clean Water Act, that they're not inadvertently
16 being put in the position of possibly violating one or
17 the other statutes.

18 So, as part of our planning for the coming
19 registration review program, we've been working primarily
20 with our EPA regional colleagues, at this point, to
21 develop an internal standard operating procedure for
22 addressing water bodies that may be impaired by

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1 pesticides in the registration review process. Now,
2 there are other reasons water bodies can be impaired, but
3 sometimes pesticides are identified as being one of the
4 causes of impairment. And our goal in this internal
5 project is really that we have a process that would allow
6 for the systematic inclusion of impaired water body
7 information into our risk assessment processes and our
8 risk management process for registration review.

9 If you're talking about the new use of a
10 pesticide, it doesn't seem to make sense because you
11 haven't actually authorized the use yet.

12 As we've been having some of the discussions
13 that I've referred to in introducing Allison between OPP
14 and the Office of Water, this is actually one of the
15 issues that I think, quite logically, has come up, which
16 is, well, if you're trying to figure out the appropriate
17 relationship between those two statutes, are we, in fact,
18 taking a look at what's going on in the real world, the
19 information we have there from the 303D program and
20 incorporating it back into our FIFRA process, or has that
21 perhaps not been done systematically.

22 Drift would not be the only factor that might

1 lead to impairment, obviously, but drift could be one of
2 the contributing factors. As we're envisioning the
3 process, we would start with the identification of 303D
4 listed water bodies where pesticides were actually
5 identified as the cause of the impairment. So, the first
6 thing would just be systematic identification of that.
7 We would hope that largely our regional staffs could be
8 working with state officials, tribal officials, local
9 officials, to actually gather for us the data that was
10 the basis for the 303D listing, because that data right
11 now does not systematically come into the pesticide
12 program and I think it's because, frankly, there hasn't
13 been a clear, obvious process for doing that either
14 within the agency or externally. So, if you don't have a
15 process, you're not going to be able to sort of
16 systematically get it.

17 Such data that we got through this process would
18 go into the docket for public comment at the initiation
19 of a registration review for an individual pesticide.
20 Now, remember, from all of our registration review
21 discussions that sort of the start is the creation of a
22 docket where we put all relevant information associated

1 with that pesticide. So, this would become a piece of
2 relevant information where there is a 303D listing and
3 would go in there from the beginning, and be available
4 for everyone to look at and provide the agency comment
5 on, according to the procedures that we've outlined for
6 registration review.

7 During the risk management process in
8 registration review, we would expect that the pesticide
9 program, in collaboration with our regional colleagues in
10 the Office of Water, would be looking at this
11 information. Where it was appropriate we would be
12 thinking about should there be monitoring plan options
13 developed as a condition of continuing registration that
14 would allow us to establish the extent to which
15 additional water bodies, beyond the ones that are listed,
16 might actually be impaired, because I think one of the
17 underlying issues is monitoring can be spotty.

18 You can have data from one place and it shows
19 you have a problem, but you may not have data from a lot
20 of other similar circumstances and you simply don't know
21 whether the impairment is also occurring there or it's
22 not occurring because there are other factors at work.

1 And so, some of the risk management options that we might
2 look at, if these concerns are substantiated, would be
3 appropriate monitoring options.

4 And then, finally, we would issue our
5 registration review decision, and if we had judged that
6 risk mitigation was appropriate, whether it was
7 monitoring plans or other risk mitigation measures, that
8 would be part of the decision. Once the decision was
9 made, then we would, obviously, follow up with the
10 implementation of the decision appropriately.

11 So, all of this is a plan for the future. The
12 SOP is actually still under development, but that's kind
13 of the process that we're envisioning for ourselves, and
14 we'll be taking this SOP probably to the November SFIREG
15 Water Quality Committee Meeting so we can discuss it with
16 our state officials. So, those are public meetings.
17 There's an opportunity for other people who are
18 interested to come -- State FIFRA Issues Research and
19 Evaluation Group. Thank you for the help. November 1 is
20 the actual date and it will be in D.C. But don't think
21 that that's the only opportunity to talk to us and
22 interact with us. Steve Bradbury, Debbie Edwards and

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1 Bill Diamond are the Division Managers who are sort of
2 working on this process. So, you should feel very free
3 to talk with them about this, ask your questions, get
4 clarification, add in your good ideas.

5 Let me go on now to talk more specifically about
6 the formation of a PPDC subgroup that would focus on what
7 I will call drift policy issues. We're not envisioning
8 this group to look at the kind of very technical issues
9 that I talked about in the drift reduction technology
10 project. In May, we solicited interest from this group
11 and Margie actually got the names of several PPDC
12 members, and let me just remind you who they are.
13 Because you named yourself doesn't mean that you continue
14 to have to name yourself. You're always able to take
15 your name out of consideration. You're also able to add
16 your name if you didn't do it.

17 But the people who expressed interest to Margie
18 were Carolyn Brickey, Michael Fry, Ray McAllister, Lori
19 Berger, Dan Botts, and then we've got three other people
20 who are not PPDC members but have held up their hand.
21 Dave Scott -- and for those of you who don't know Dave,
22 he is actually from Indiana, a state official there.

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1 He's very knowledgeable and very experienced on drift
2 issues and actually chairs AAPCO's, which is the state's
3 professional organization, Off-Target Pesticide Movement
4 Committee. So, he has been identified by AAPCO as their
5 representative to the subgroup. And George Wichterman.

6 So, from the world of kind of pesticides and
7 PPDC, that's what we've got right now, and as I say,
8 those of you who held up your hand can change your mind,
9 although I hope you don't, and those of you that didn't,
10 but think you might be interested, you can add your name.
11 Just let Margie know. You can let me know, too, but I
12 forget things and Margie doesn't.

13 MR. ELWORTH: Anne, a quick question, going back
14 to Gary's comment.

15 MS. LINDSAY: Yes.

16 MR. ELWORTH: I bet the Forest Service people
17 haven't thought about this, maybe a little outreach to
18 people on the forestry side would be helpful.

19 MS. LINDSAY: Okay.

20 MR. ELWORTH: Because they wouldn't even know
21 about that. If you all want to do that -- Burleson or
22 Al?

1 MS. LINDSAY: Yes. I actually think of forestry
2 as an agricultural activity and that's --

3 MR. ELWORTH: We do, too. Forest Service
4 doesn't always.

5 MS. LINDSAY: Anyway, we'll work with Al to get
6 -- because, obviously, I think on this -- even though I
7 don't think at our last meeting USDA held up their hand,
8 I would hope --

9 UNIDENTIFIED FEMALE: We'll raise it for them.

10 UNIDENTIFIED MALE: I can hold up somebody
11 else's hand.

12 MS. LINDSAY: We know that we need them.

13 UNIDENTIFIED MALE: And mosquito abatement
14 districts, also, should be brought in.

15 MS. LINDSAY: Well, that's where we'll have
16 George. Anyway, in addition, we've been having some
17 internal discussions with the Office of Water about
18 whether they would actually like to be very active
19 participants with the pesticide program in this subgroup,
20 and I'm very happy to say that they're very interested in
21 doing this, which is why I'm asking you all to impress
22 Allison today.

1 The Office of Water is actually, right now,
2 going through some internal thinking and cogitating about
3 how to get some appropriate, I'll call them, people from
4 the world of water, because right now, these are people
5 that are from the world of pesticides and really know the
6 pesticides, which doesn't mean you don't know anything
7 about water.

8 But we'd like to have, for instance, at least
9 one state official who has, at the state level, more
10 direct responsibilities for Clean Water Act
11 implementation. We think that would be appropriate.
12 From public interest groups who work that end of things,
13 from other folks that I actually don't know who would
14 bring relevant experience, expertise and
15 responsibilities, so that we end up having a workgroup
16 that both knows pesticides and who actually knows water
17 quality issues very broadly.

18 So, Allison and other folks within the Office of
19 Water are working on that right now. I think we're
20 hoping to end up with a group that I would say would be
21 in the range of 10 to 15. It doesn't mean it can't be a
22 little bigger or a little smaller, but we want to try to

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1 keep it to a size where it can really work because we
2 would expect this to be a working workgroup.

3 Our current plans are that we would like to
4 actually start this up and have an initial kick-off
5 session, I'll call it, early in the new calendar year.
6 We know that drift is actually -- and the policy issues,
7 in particular, are very controversial. There is, no
8 matter how you look at it, no matter where you stand,
9 there is a lot of implications to where you come out on
10 the policy issues, and so, I think neither OPP nor OW is
11 expecting that this group would come to consensus
12 recommendations. Obviously, if the group did, we'd be
13 likely to be very happy. I always have to reserve
14 judgment.

15 **(Laughter.)**

16 MS. LINDSAY: You could come to consensus on
17 something and we'd go, oh, no, although I think we'd be
18 hard-put if the group came to consensus not to figure out
19 a way to deal with recommendations. But we do expect
20 that what we could have is what I would call just a very
21 serious constructive dialogue, frankly, kind of like the
22 dialogue we had yesterday morning on that other very

1 controversial policy issue, human studies. So that,
2 first and foremost, those of us who work at the agency
3 could be sure, both in the pesticide program and in the
4 water program, that we really understood key issues, and
5 not just what the key issues are, but where the various
6 stakeholders really stood on those issues and sort of why
7 you stand where you do. We can think we know that, but
8 that doesn't mean that we necessarily do know that, and I
9 think the subgroup could help us ensure that kind of
10 confidence in our knowledge.

11 We do also expect to get, what I would call,
12 good, constructive ideas about ways to effectively
13 address the key issues that the group identifies and
14 maybe at least what I would call some cleaning out of the
15 underbrush, so that where there are issues, that the
16 group at least comes into kind of a common perspective,
17 if not full consensus, we would know that and some issues
18 might become less challenging to deal with and we would
19 know more clearly what were the big ticket issues.

20 Possible topics that I've thought about for this
21 group and kind of starting places are, first of all, and
22 this is a question -- this begins the kind of questions

1 for you to give us some reaction to -- education.

2 Because we would have this blended group that we've not
3 put together, do we need to plan on education both around
4 drift, around pesticide issues, around water issues to
5 make sure that there's some kind of common level playing
6 field within the group members? And, actually, we may
7 discover that the agency learns something from it, too.
8 So, should there be education at the beginning and kind
9 of what might those broad educational topics be?

10 Are there policy issues associated with label
11 enforcement around drift that ought to be considered?
12 Particularly since we're looking at the sort of
13 intersection of NPDES, Clean Water Act and FIFRA, do we
14 need to have some certainty around enforcement and what
15 are those policy issues?

16 Would this group think it important to look at
17 label incentives that would serve to reduce drift, for
18 example? Picking up some of the stuff from the project,
19 not the technical piece, but possible policy labeling
20 issues that you might see. And then, of course, the
21 whole NPDES/FIFRA intersection, we're engaged -- and
22 Allison will tell you a little bit more about that in a

1 moment -- in a rule-making, but it doesn't apply -- the
2 rule-making underway does not apply broadly to
3 agricultural operations, although we've made very clear
4 that our practice -- our historical practice and current
5 practice is not to require permanence for agricultural
6 operations.

7 I'd like to let Allison have a few minutes to
8 talk with you and then open it up for some discussion,
9 specifically around what issues you think the subgroup
10 should really be dealing with.

11 MS. WIEDEMAN: Thank you, Anne. I'm very
12 grateful to be in front of such a distinguished group of
13 people and very happy to be able to talk about this issue
14 and try to move it forward, which has been a challenge,
15 because we don't know the answers. So, the purpose of
16 forming this group is to find those answers.

17 A little bit about me so you know where I'm
18 coming from. I'm in the Office of Water at EPA and I'm
19 specifically in the Water Permits Division. Our mission
20 in the Water Permits Division is to look at situations
21 and develop policies for situations that would require a
22 national pollutant discharge elimination system permit,

1 NPDES permit.

2 And to do that, we ask ourselves the following
3 questions: If a situation needs to have a permit, there
4 must be a discharge of a pollutant to navigable waters of
5 the United States and from a point source. So, those are
6 four of the criteria that need to happen, one or all,
7 it's not inclusive, before we determine whether or not
8 something needs an NPDES permit.

9 I think you're probably aware that the recent
10 rule-making -- well, the rule-making that we are involved
11 in finalizing that was proposed earlier this year when we
12 were finalizing a rule-making and working with the Office
13 of Pesticides is the two situations where we have
14 determined that pesticide applications do not need an
15 NPDES permit, and that is where they are applied over
16 water, such as on canopies, to eradicate forest pests,
17 and also on water to eradicate waterborne pests. So,
18 either over or on water as long as these applications are
19 applied in accordance with FIFRA, a NPDES permit is not
20 necessary, the programs are complimentary, the FIFRA
21 program takes care of any environmental concerns that we
22 have. But more importantly, we made the legal

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1 determination that an application of pesticides in these
2 cases is not a pollutant. So, it doesn't trigger one of
3 the requirements for an NPDES permit.

4 And during this process, we have been working
5 very closely with the Office of Pesticides. It's been a
6 great process to integrate our programs and to learn
7 about each other's programs and know that we need to
8 continue to do this and we plan on doing that in very
9 specific and intentional ways. That rule-making will be
10 coming out as final sometime in January, I hope.

11 But there is one situation where we have said in
12 that rule-making we will not address and that is the one
13 of drift. And the reason we are not addressing whether
14 or not drift needs a permit is because -- while we don't
15 say it this way in the preamble -- we don't know enough
16 about the situation to make that determination and we are
17 going on to say that we are going to be forming a FACA
18 process to look into that situation. And in a nutshell,
19 the question is, does drift require an NPDES permit? And
20 this could be drift generally over land applications or
21 it could be associated with water applications as well.

22 A couple of things I wanted to talk about in

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1 terms of questions that I would like this group to
2 consider, and again, let me stress that we're very
3 grateful that we could say in the preamble that this
4 situation is going to be dealt with through this
5 committee. It gives us a perfect and logical next step
6 that I think the public will accept, and I know that
7 going through this process, we will be able to
8 objectively look at all sides.

9 Some of the questions that I see we need to look
10 at are obviously within the realm of does pesticide drift
11 need an NPDES permit or is drift -- it's both a technical
12 and a legal analysis and that would involve asking
13 ourselves the questions, is drift a pollutant? Pollutant
14 and discharge and point source are all defined in our
15 permit regulations. So, we have clear definitions for
16 what those are. And does the situation for drift fall
17 under any of those categories? Is drift a pollutant? Is
18 drift a discharge? Is drift a point source?

19 And if not, then what are the other mechanisms
20 by which we can control drift is the next question. Do
21 we use labeling and additional verbiage on labels? Are
22 the current labels okay? Do we need to talk about

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1 requiring additional best management practices? These
2 kinds of things we need to look into.

3 You all wouldn't be starting from scratch.
4 There's a lot of information that we have put together on
5 this issue already. We've done considerable legal
6 analysis of court cases across the country on this.
7 There are a handful of court cases that have dealt with
8 the subject of drift and they span the spectrum of yes,
9 they do need a permit and, no, they don't need a permit.
10 And we can provide that type of legal analysis to you.
11 We can provide the technical information on drift that we
12 have been able to gather so far. We can provide
13 information on situations where drift occurs so that you
14 all have a launching pad on which to be able to gear up
15 and move forward with this issue.

16 I basically covered the points I wanted to say,
17 but I did want to also add one thing and reiterate what
18 Anne was saying about the environmental technology
19 verification program. I was working with that program
20 when it started in 1997 and, at that time, we were
21 looking at septic systems and verifying different septic
22 systems. Basically, a niche like this has been necessary

1 for a very long time. There are entrepreneurs out there
2 that are developing technologies, but they don't have the
3 resources to verify them, and this program -- you know,
4 to verify the performance of a technology can cost
5 upwards of \$100,000 with all the sampling and the
6 reporting that's required. This type of program can
7 subsidize that for the developer and allows us then to
8 promote innovation and to find those technologies that we
9 may not otherwise have access to.

10 So, I think it is an extremely beneficial
11 program and has grown by leaps and bounds over the years
12 and I'm glad to see they're going into the pesticides
13 arena as well.

14 MS. LINDSAY: Okay. One comment before I turn
15 the floor over to you. It could be tempting to folks, or
16 at least some of you, to actually want to talk with us
17 about the rule that Allison gave you a status report on.
18 I'd like to encourage you, though, not to go down that
19 path. We're actually at that point in the rule-making
20 where it's not really appropriate for us to be having
21 large discussions. The comment period is closed and it's
22 also not the purpose of this session. So, Allison's

1 given you some good background, but I will try to be very
2 firm in keeping us from going in that direction and you
3 actually will do the best job of helping me do that if
4 you do it yourselves.

5 MS. WEIDEMAN: Yeah, because I'm supposed to be
6 impressed with this group, right?

7 MS. LINDSAY: That's right. And you don't want
8 to cause Allison more problems.

9 The other piece is, I think, with regard to some
10 of Allison's suggestions for possible topics or issues,
11 I am not thinking of this group as a group to do
12 extensive legal analysis. It may be that there is some
13 legal analysis or understanding of the operation either
14 of the Clean Water Act or of FIFRA that the group will
15 need to get started right, but I'm viewing that more as
16 background operation. So, those of you who have
17 expressed an interest in it, but who may not be attorneys
18 or who may be attorneys but occasionally like to do
19 something other than legal analysis, we're not going to
20 be asking you to actually do legal analysis in the group.

21 And with that, I'll stop and ask for some
22 reaction. Beth, is your -- your card's been up for a

1 long time.

2 DR. CARROLL: Yeah.

3 MS. LINDSAY: Are you number one?

4 DR. CARROLL: I think so.

5 MS. LINDSAY: Okay.

6 DR. CARROLL: I have two questions.

7 MS. LINDSAY: Sure.

8 DR. CARROLL: One is, what's your time frame for
9 this subcommittee or subgroup?

10 MS. LINDSAY: I think that -- well, I told you
11 we'd like to get it started early in the new year.
12 Although the issues are hard and complicated, I would
13 really like to have the group be able to -- because, of
14 course, it has to report back to this full committee. I
15 would like it to be able to have a substantive report
16 back to what would be the next PPDC meeting, and although
17 Margie hasn't scheduled that yet, that would be in the
18 springtime, I would expect. I don't know whether it will
19 be the week we actually move to our new building, but,
20 you know, it could be the May/June time frame. That
21 doesn't mean it would necessarily declare itself
22 finished. But I would like to see it work in a fairly

1 intensive fashion.

2 DR. CARROLL: And is the intent to develop
3 additional rule-making?

4 MS. LINDSAY: That's something the Agency's not
5 decided upon.

6 DR. CARROLL: Okay. And then, finally, just for
7 clarification, if I could go back to the collection of
8 data for registration review, where is that coming from?
9 Is there -- and I'm just not familiar necessarily with
10 how they report 303D. How far back are you going? Is it
11 anecdotal? Is it recorded somewhere?

12 MS. LINDSAY: No, there is -- this probably
13 illustrates that you're telling me there's a need for
14 some --

15 DR. CARROLL: Education.

16 MS. LINDSAY: -- basic education. But there is,
17 under the Clean Water Act, a whole 303D listing process
18 and states list water bodies that are impaired for a
19 variety of reasons. But one of the reasons could be for
20 pesticides and there's a whole reporting system that goes
21 with that and they base their decisions on data and other
22 relevant information, and we want to get that data and

1 information into our system so it's not merely an
2 anecdotal process.

3 DR. CARROLL: So, it resides in the state, it
4 doesn't reside in Office of Water?

5 MS. WIEDEMAN: Well, in terms of impairments?

6 DR. CARROLL: Right.

7 MS. WIEDEMAN: No, we have all that -- we have
8 that information as headquarters as well in EPA.

9 DR. CARROLL: So, would that not be the logical
10 place to go for it as opposed to collecting it from --

11 MS. WIEDEMAN: Are you speaking with respect to
12 the drift issue?

13 DR. CARROLL: No, the 303D listing and re-
14 registration or registration review.

15 MS. WIEDEMAN: Okay. Well, any information that
16 you all need on impairments from -- that are on the 303D
17 list --

18 DR. CARROLL: I mean, I understood you to say
19 you were going to get it from the regions, and if it
20 already sits here --

21 MS. LINDSAY: I think --

22 MS. WIEDEMAN: It's readily available.

1 MS. LINDSAY: But we need to actually, Beth --
2 you know like the previous discussion on PRIA process
3 improvements, we need to make the process of getting that
4 information into OPP's registration review really
5 operational and streamlined, and to be very candid with
6 you, historically, it's not been. So, if it's already at
7 headquarters, we would use it. We also, though, believe
8 that there is information that our regions can help us
9 access. But we will be taking it from the most efficient
10 available way.

11 Let's see, Bob, I think you were next.

12 MR. ROSENBERG: Yeah, and I just had two
13 questions. Allison, you had mentioned the initiation of
14 a FACA process. Is that something different from the
15 PPDC workgroup?

16 MS. WIEDEMAN: No, I'm sorry, that's the same
17 thing.

18 BOB: And the second question, this is probably
19 just a reflection of my naivety about all this. You had
20 said something about the Water Office needing to make a
21 determination as to whether drift constituted a point
22 source discharge of a pollutant.

1 MS. WIEDEMAN: Yes, right.

2 BOB: Isn't it correct -- maybe it isn't -- that
3 drift is not permissible, in some broad sense, on a label
4 and would be an enforceable FIFRA violation and is it
5 necessary to go beyond that?

6 MS. WIEDEMAN: Well, that's the question we want
7 you to answer.

8 MS. LINDSAY: But, Bob, you'd have to look, and
9 I know that our state official at the table would back me
10 up on this, you would have to look, in any particular
11 case, at what the label actually said. So, in some cases
12 --

13 BOB: So, it's a labeling problem --

14 MS. LINDSAY: -- I think we've got labels where
15 we've made it fairly clear what's enforceable and a state
16 official like Maureen would be able to take action. If
17 it were violated, I am afraid, unfortunately, that there
18 may be other labels where it's less clear and our state
19 officials may have challenges when they think that harm
20 has occurred in making their case.

21 BOB: Don't you feel that you've made some
22 headway on that issue, at least in a narrow sense, with

1 the revised language that was contained in the adulticide
2 PR notice?

3 MS. LINDSAY: You're right. For the mosquito
4 adulticides, when that labeling gets in place on labels,
5 I believe that will be a substantial improvement in the
6 quality of labeling. But that's one specific use pattern
7 and our country is a wide and varied place.

8 I'm not sure who literally is next, so Erik --
9 I'm going to kind of go this way because I'm not doing a
10 good job of keeping track of which one. . .

11 MR. OLSEN: Yeah, I just want to follow up on
12 the whole enforceability and enforcement issue. I'm
13 assuming that the Enforcement Office will be part of this
14 negotiation also, is that right?

15 MR. WIEDEMAN: We work very closely with our
16 enforcement folks.

17 MR. OLSEN: Would they be part of this group?

18 MS. WIEDEMAN: Good question. I think that the
19 formation of the group is something that we still have
20 yet to decide.

21 MR. OLSEN: I would strongly encourage that just
22 because they're the ones that are going to be stuck with

1 whatever ends up coming out of that.

2 MS. LINDSAY: Can I clarify something, though?
3 It's not a negotiation.

4 MR. OLSEN: I understand that.

5 MS. WEIDEMAN: Right.

6 UNIDENTIFIED MALE: Okay, sorry.

7 **(Laughter.)**

8 MS. LINDSAY: Some people may want it be --

9 MR. OLSEN: None of these are negotiations,
10 whatever.

11 MS. LINDSAY: -- a negotiation, but we -- OPP
12 and OW are asking the PPDC if they would be willing to
13 have a subgroup to give us advice on these issues, and I
14 think that there are a set of enforcement policy
15 questions and I have confidence that whether they're
16 direct members on the group or they're actually --
17 usually we have what I would call kind of a shadow group,
18 just like we did with registration review. There was a
19 team within OPP in that case who provided the support and
20 interacted with the subgroup of the PPDC. I would expect
21 we would have that kind of internal team that supports
22 our interaction with the PPDC subgroup and it would have

1 appropriate enforcement involvement, and I think our
2 Pesticide Enforcement Division Director wants to say
3 something on this point.

4 MR. COLBERT: I think the question would be --
5 and it's a little early maybe to know -- is the scope and
6 the goals of exactly what questions you want to answer
7 and in what order. Enforcement will come up, it always
8 does. For us, the question is, is it too early? We
9 don't want to get in necessarily too early, but, of
10 course, we don't want to get in too late. But I think
11 that's one of the things that will have to go into it.
12 It may be that right off the bat you'll say, enforcement
13 is going to be a key player in this. I can't tell.

14 MR. OLSEN: Well, this is just part of a broader
15 issue which is, to us, one of the big issues with drift
16 is problems with the label specificity and enforcement of
17 the label. You know, that really seems to be a crucial
18 central issue. I'm not sure a negotiation over label
19 enforcement is a good idea. But, you know, I think
20 that's important. For example, on the soil fumigants
21 that are injected into soil, is that drift if it gets
22 out? You know, there are issues like this where there

1 have been incidents where there was no enforcement taken
2 apparently because of some questions. I'm not sure
3 that's a good example, but that would be something I'd
4 hope.

5 The last point I wanted to make is on the 303D
6 listings, that's extremely spotty. I mean, some states
7 are pretty good about collecting data on pesticides and
8 doing 303D listings and a lot of states are not. They
9 just don't have the resources to go out and do
10 comprehensive pesticide testing, as we found out with
11 plenty of examples. I won't name any chemicals, but
12 there are a lot of chemicals where we know -- you know,
13 intensive monitoring shows up significant water quality
14 issues, but a lot of states have just never done the
15 monitoring. Therefore, they've never listened and,
16 therefore, if you're building a whole house of cards on
17 303D listing based on lack of monitoring, you know, just
18 flagging that issue I think is important.

19 MS. WIEDEMAN: Yeah, I think that's a good
20 point, and you also don't know the source of the
21 pesticides as well. So, it's one tool in the toolbox,
22 one source of information.

1 MS. LINDSAY: Another thing just on your first
2 part of sort of what's inclusive in the term drift, I'm
3 not going to use the right technical language, but we're
4 trying to focus on the movement -- the off-target
5 movement of the pesticide that occurs at the time of
6 application. So, volatilization, after it's applied, for
7 instance, or other terms that you might use, are not, as
8 we're looking at it, part of what we would ask this group
9 to look at, which is not to say that --

10 MR. OLSEN: Why would that be? Because that's
11 one of the big problems that we've had repeatedly.

12 MS. LINDSAY: Well, I was getting ready to say,
13 it's not to say that there aren't issues there and that
14 there wouldn't be opportunities to discuss them, but we
15 see this as sufficiently different that we want to keep
16 them separate.

17 Jose, I think you had some stuff you wanted to
18 say.

19 DR. AMADOR: Yeah, my name is not Sue, but I
20 cannot find my card. I don't know what happened to it.

21 **(Laughter.)**

22 UNIDENTIFIED FEMALE: A boy named Sue.

1 MS. LINDSAY: Well, you know what, Jose, I
2 actually can't see what it said at all, it was just your
3 face I recognized.

4 DR. AMADOR: That's why I highlighted this so
5 you could see it, but it says Sue. I can't find mine.

6 **(Laughter.)**

7 DR. AMADOR: I got a question and a comment and
8 a suggestion. The question, Allison, could you repeat
9 again what NPDES stands for? I'm not too good at
10 acronyms.

11 MS. WEIDEMAN: Sure. National Pollutant
12 Elimination -- sorry, National Pollutant Discharge
13 Elimination System, NPDES permits.

14 DR. AMADOR: Thank you. The comment, I'm glad
15 you put education at the top of the list because there's
16 a lot of education that is needed on this issue. There's
17 a lot of questions. And the suggestion that I have,
18 Anne, yesterday, there was a subgroup that was formed on
19 farmworker safety. I think there should be somebody from
20 that group on this committee. Some of the issues that I
21 deal with are application of chemicals when there's
22 people working out in the field either by air, that is

1 sprayed directly on the people, or sometimes just by
2 drift, people who are working in an adjacent field. I
3 think that the farm safety factor should be included in
4 this subgroup. Whoever Kevin or Bill Diamond think is
5 the best person maybe ought to be in this group, too.

6 MS. LINDSAY: That's a good suggestion, and
7 actually, I hope that maybe we get some folks that
8 represent that community to --

9 MS. WIEDEMAN: What community is that?

10 MS. LINDSAY: Farmworker.

11 MS. WIEDEMAN: Okay.

12 MS. LINDSAY: And we actually have some folks on
13 our committee here who, unfortunately, this turned out to
14 be a bad time for them and they weren't able to actually
15 be here. But if not them, I think we can look in other
16 quarters.

17 DR. AMADOR: That's some of the complaints that
18 I often here from people, that they put chemicals on
19 while they are in the field working.

20 MS. LINDSAY: Pat?

21 MR. QUINN: So, as I understand it, the
22 questions you'll be trying to deal with, in part, will be

1 is drift a pollutant, is it a point source and is it a
2 discharge. So, for those -- and if it's one of those,
3 then it might require an NPDES permit. So, can you kind
4 of give the group a feel for what one goes through in
5 obtaining an NPDES permit and how that would apply to a
6 pesticide application?

7 MS. WIEDEMAN: And, you know, it has been --
8 there are folks across the country -- applicators across
9 the country that actually want to be able to get a permit
10 so that it gives them clear authority to apply and gives
11 them protection against citizen litigation. But to get a
12 permit, one supplies a permit application to the state
13 permitting authority. That application generally goes
14 through a public review process, and after that process
15 and after any changes are made, then the permit is
16 granted.

17 MR. QUINN: How long does that take?

18 MS. WEIDEMAN: Well, that varies between state.
19 That's a very good question and a very good concern, and
20 it could take, you know, a matter of weeks and it could
21 take a matter of several months. So, that is an issue
22 that we need to look at.

1 MS. LINDSAY: Pat, this may actually be what I
2 would call a --

3 MS. WIEDEMAN: One more thing.

4 MS. LINDSAY: Sure.

5 MS. WIEDEMAN: Sorry. One of the things that
6 EPA has -- a program that EPA has instituted years and
7 years ago to --

8 **(End of Tape 1, Side B)**

9 MS. WIEDEMAN: -- under that general permit, and
10 depending on the way the states operate, a notice of
11 intent is often enough to go ahead and have coverage.

12 MR. QUINN: And that kind of standardization may
13 make sense in these kinds of circumstances. I just
14 wanted to have you illustrate that it can be a fairly
15 lengthy, cumbersome process which can take quite a bit of
16 time to resolve public concern.

17 MS. LINDSAY: That may actually -- your question
18 may actually be a topic that it would profit the group
19 early on to get some -- Allison only has a minute or two
20 to give you a very thumbnail sketch to actually provide
21 more information about what it's really like.

22 Maureen?

1 MS. SERAFINE: Anne, simply to provide a state's
2 perspective on applying for a SPEEDIES (phonetic) permit,
3 I am told in New York State it will take about six years,
4 and you can verify that. Although I don't work in the
5 Office of Water, our SPEEDIES people and permitting
6 process is extremely cumbersome.

7 MR. ELWORTH: That's really a misnomer.

8 MS. LINDSAY: Well, I think we're not going to
9 ask New York to come to this group.

10 (Laughter.)

11 MS. LINDSAY: But, no --

12 MS. SERAFINE: You need to really evaluate in
13 deciding that drift, although it is unintentional, is
14 actually a pollutant because that would negate the rule-
15 making that you have just made or are in the process of
16 making and require all aquatic applicators then to just
17 move ahead and ask for a SPEEDIES permit because they
18 never know if drift will occur.

19 MS. WIEDEMAN: Well, I guess I don't see it
20 quite that way. We're clear on the policy that the
21 application of pesticides, in accordance with FIFRA, does
22 not need a permit, that it is it not a pollutant, that it

1 is a product used for a beneficial purpose. So, the
2 situation with drift and there's other situations like,
3 well, what happens if there's residuals left, with the
4 breakdown products. Those are all issues that we have to
5 look at to make the determination if those are pollutants
6 or not.

7 But I think there are two different situations.
8 Even though I know that drift can occur, when the
9 application occurs, we just have to draw the line and say
10 that, at this point, the application of pesticides is not
11 -- proper application is not a pollutant.

12 MS. SERAFINE: Okay. I would honestly say that
13 would be dependent upon the definition that you come up
14 with for drift. If you're talking about causing harm,
15 then you have to relate it to what detection limit of
16 that pesticide would be determined to cause harm.

17 UNIDENTIFIED FEMALE: Good point.

18 MS. LINDSAY: Larry?

19 MR. ELWORTH: I realize I'm still a little bit
20 confused. How are you using the 303D list?

21 MS. LINDSAY: I'll try again, but I may not
22 succeed. If a state has listed a water body as impaired

1 because of pesticide use, then what we would like our
2 standard operating procedure to be is that we have a
3 process working with our regional colleagues, with our
4 Office of Water, to get the underlying information upon
5 which that impairment decision was based and any other
6 relevant information.

7 MR. ELWORTH: Then you would use that
8 information to --

9 MS. LINDSAY: Yeah, the same way we would use
10 any other information from the real world in our risk
11 assessment process.

12 MR. ELWORTH: Why wouldn't you use the TMDL
13 list?

14 MS. LINDSAY: Why would we?

15 MR. ELWORTH: Why wouldn't we?

16 MR. JONES: Basically, Larry, if the state has
17 identified a water body as impaired by a pesticide, I
18 think we need to know that.

19 MR. ELWORTH: Sure, sure.

20 MR. JONES: And I think we need to consider it
21 in our characterization the way we consider all kinds of
22 data. Now, my understanding is that a TMDL is done only

1 if you have impairments. So, the impairment is going to
2 be the broader universe. I want to know if there are
3 impairments and I want to make sure that we're dealing
4 with that knowledge appropriately. As Erik said, I
5 recognize that that doesn't define the entire universe,
6 although I do think it's sort of a missing piece to the
7 puzzle if we don't even know it and, therefore, are in no
8 position to evaluate what it tells us.

9 What we do about it depends on what we've
10 learned. If you look at that data and you realize the
11 underlying basis of it was very weak, you may not do
12 anything. If you look at that data and you realize that,
13 you know what, it's only the tip of the iceberg, it may
14 lead you down a different track. I think it's very
15 dependent on what you've learned from. To me, it's just
16 adding one more piece to the puzzle to get a clear
17 picture of what's going on as it relates to a pesticide
18 in the environment.

19 MR. ELWORTH: The reason I ask --

20 MR. JONES: It's pretty straightforward.

21 MR. ELWORTH: -- is kind of going back to Erik's
22 question, because the TMDL information is very, very

1 specific. You can really figure out this stretch of
2 water for this chemical.

3 MS. LINDSAY: Okay. Michael?

4 DR. FRY: I understand the need for having the
5 FIFRA permit for the aquatic applications of pesticides,
6 but I have a question, and that is, how far downstream
7 does the pesticide in the water remain beneficial and
8 where does it become a pollutant? Methoprene used for --
9 as a larvicide when it goes downstream and starts killing
10 lobster larvae, it's obviously a pollutant at that point.

11 UNIDENTIFIED FEMALE: That's a residual issue.

12 MS. LINDSAY: That actually is kind of a
13 concrete example of one of the issues that the Agency has
14 been focused on. I don't actually think we have a
15 specific bright line answer for you here nor time to go
16 through it today. But it is one of the sub-issues that
17 we've been talking about, and that this subgroup, when it
18 gets up and running, may want to examine. So, thanks for
19 the example.

20 Rebeckah?

21 MS. FREEMAN ADCOCK: I think I would like to
22 build a bit on Maureen's response to defining what would

1 be considered off-target application. I think, you know,
2 from my mind, the notion of drift has already achieved
3 such negative status that that's automatically the
4 assumption that drift is bad. Off-target or non-target,
5 perhaps, application of a pesticide, I think, is
6 something, by the Agency's own, at least verbal
7 admission, is unavoidable. You can't say I'm going to
8 spray something here and that it wouldn't get on a blade
9 of grass here.

10 The unfortunate consequence that the user
11 community, whether ag or non-ag, is experiencing is that
12 there is a campaign, according at least to Internet
13 sources, of folks going around the country with cotton
14 swabs looking for that sort of defining detail on whether
15 somebody's doing something appropriately or not and
16 putting -- at least my folks believe -- unfair pressure
17 on people who are doing things and following the label,
18 and those are some very fundamental threshold questions
19 that are going to be very challenging for the group, but
20 that we are going to have to determine, within some
21 flexible bounds, I would assume, because the labels are
22 different and the chemicals are different, what is the

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1 policy at the Agency on non-target drift or whatever
2 we're going to call it, you know, maybe making one a more
3 negative term and one a more positive term, but realizing
4 that the more positive term is going to occur. That's
5 what the label is considering as included in the use of
6 the product.

7 The other thing, if these discussions are
8 going to lead to a larger OPP policy or some sort of
9 guidance -- I don't mean that necessarily in the formal
10 term -- but in some way giving instruction to the label
11 and registration process for non-target applications,
12 spray drift, whatever we're going to call it, we have so
13 many other challenges. The users are seeing so many
14 other challenges and so much pressure on other issues,
15 water included, species issues included, which hopefully
16 will be addressed somewhat through the counterpart rule,
17 but they still remain, and then the worker issues as
18 well. If we're going to knock out the beast, we're going
19 to have to knock out the beast because the people with
20 their tails hanging out are the people who are using the
21 products and think that they're doing what they need to
22 do to cover their tails. Right now, they're finding that

1 that's not the case.

2 MS. LINDSAY: That is actually one of the things
3 that I hope, ultimately, with the advice that we get from
4 the PPDC, that we'll be able to improve --

5 MS. FREEMAN ADCOCK: So, we can discuss those
6 other issues as well. Would that be appropriate?

7 MS. LINDSAY: I don't want to have this be an
8 endangered species group.

9 MS. FREEMAN ADCOCK: Right, right, no, I
10 understand that.

11 MS. LINDSAY: But it's got to stay focused on
12 drift.

13 MS. FREEMAN ADCOCK: So, we are focusing on
14 water and drift and not the other issues and drift or do
15 we know yet?

16 MS. LINDSAY: I see this as focused on water and
17 drift. If I hear from enough different quarters that
18 there's some other pieces that should be fitted in there
19 or if it's very obvious that you need to take something
20 else up, then we can consider if that's appropriate to
21 do. We may also learn something from this process that
22 then would be applicable in other situations. But if we

1 take on the whole universe of drift-related issues, I
2 think it's a very -- it's very big.

3 MS. FREEMAN ADCOCK: Right. I guess my only
4 concern is we've seen situations from at least farm user
5 perspective where we've done something within the purview
6 of the water issue that may have exasperated something on
7 -- and this is by example, not necessarily exclusive to
8 pesticides, but we've seen a situation where we gave
9 people guidance on how to improve their practices
10 relating to water protection and we exacerbated their
11 practices relating to air protection or air improvement.

12 And I would hope that as we're moving, if we are
13 just going to deal with water, that at least in the back
14 of our minds, we're not making it worse for the other
15 ones.

16 MS. LINDSAY: Yeah, and I would say if in the
17 course of this group's working it comes up with, well,
18 this would improve this situation, but we have a concern
19 that it's going to exacerbate, then this subgroup can
20 certainly advise the full group before you go down that
21 road or before the Agency goes down that road, that other
22 set of issues needs to be examined because we're just

1 pushing the problems from one media to another, we have
2 not done what we ought to be doing.

3 Terry:

4 DR. TROXELL: Do I get the last word?

5 MS. LINDSAY: It looks like it.

6 DR. TROXELL: A dimension of this, it doesn't
7 relate to water, but a possible dimension on this is
8 FDA's enforcement on tolerances. It provides somewhat of
9 a bound, possibly.

10 UNIDENTIFIED MALE: Oh, don't go there.

11 **(Laughter.)**

12 UNIDENTIFIED FEMALE: Is that advice?

13 UNIDENTIFIED MALE: It's advice Anne has given
14 to me many a time.

15 UNIDENTIFIED MALE: Phone call for you, Terry.

16 DR. TROXELL: No, it's never been our intention
17 to take enforcement action against a no-tolerance
18 pesticide being on a commodity due to drift from what's
19 applied using, what shall I say, good application
20 practices. As a matter of fact, I don't know what the
21 levels are likely to be on some of the crops when they're
22 harvested when we might see them and if -- if we're

1 actually catching in the FDA snare lots of products
2 because of this kind of situation. Also, what kinds of
3 non-good application practice situations might ultimately
4 be caught in that FDA snare if there's excessive drift?

5 I think we'd like to know a lot more about that
6 and how that affects, including by the way, the situation
7 you don't want to deal with, where the pesticide is
8 lifted off of one field and moves over to another.

9 Because we look to pretty low levels and, you know, while
10 a pesticide may be applied weeks prior to harvest, which
11 helps a lot, it's still possible that if there's
12 excessive drift, we may ultimately catch some situations
13 and farmers may be unnecessarily impacted even if the
14 pesticides are being applied appropriately.

15 MS. LINDSAY: Okay, thanks. As I said to
16 Rebeckah, I think we want to keep it, at this point,
17 focused on drift as I described it and the water -- the
18 Clean Water Act/FIFRA intersection, but I also believe
19 that as the group goes through, if we come up with -- if
20 we get good advice that helps us resolve some of those
21 issues constructively, I think it will have broader
22 application and we will also, I think the group, itself,

1 and the Agency, be mindful that if we make changes to
2 deal with one problem and we haven't thought about inter-
3 related issues, we will need to do that, because our goal
4 is not just to push environmental problems around, but
5 actually to improve them in a way that will also improve
6 the ability of farmers and other pesticides users to do
7 their business.

8 So, I think we've overrun our time. I feel my
9 boss' anxiety on my left quarter.

10 MR. JONES: All right, well, that was a very
11 good session. Actually, we're going to take a break
12 right now and we're going to start with public comments
13 if there are any public commenters. Right now, no one
14 has signed up, but if you want to, we're going to, when
15 we get back at quarter after, start with that and I will
16 have an abbreviated committee status session.

17 All right, 15 minutes.

18 **(A brief break was taken.)**

19 MR. JONES: As I mentioned yesterday, the
20 Federal Register Notice appeared yesterday requesting
21 nominations of qualified candidates who wish to be
22 considered for one or two-year terms. This is required

1 under FACA. It's not meant to be some signal to any or
2 all of you. Also, required under FACA is if you are
3 interested in serving for another term, you need to apply
4 and the FR Notice describes what it is you need to do.
5 It's pretty straightforward. Send an email to Margie,
6 name, address, telephone number, and actually, a brief
7 description as to what you bring to this exercise.

8 We do get a lot of applications for appointment
9 to the PPDC every other year when we go through this
10 exercise. So, it's something that people do take notice
11 of, which isn't that surprising. I think it's viewed as
12 an important way to get advice to the Agency. So, I
13 particularly just want to raise that to your attention
14 that it is important if you want to continue to serve --
15 to be appointed again, that you would need to submit an
16 application. Again, it would go to Margie. The FR
17 Notice tells you exactly how to do that and it's pretty
18 straightforward.

19 As has been the case, I believe, the entire 10
20 years of this committee's existence, our goal is to have
21 a broad representation with a balanced committee and hold
22 two to three meetings a year, which I think is what we

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1 have been doing and plan on continuing to do.

2 Nominations are due by November 7th, so three
3 weeks or so, email, fax, regular mail. I would
4 discourage regular mail myself because it takes us so
5 long to actually process it.

6 UNIDENTIFIED FEMALE: And it comes fried.

7 MR. JONES: Our next PPDC we're tentatively
8 scheduling for March, actually, before our move and we'll
9 get some details around that shortly. So, those are just
10 some things I wanted to make sure I spent a little bit of
11 time on so that you weren't caught unaware. I'm sure the
12 charter is less interesting to you than is the process
13 for applying to serve.

14 Burleson just submitted his application. I have
15 to say, Burleson, you, like me --

16 **(Laughter.)**

17 MR. JONES: -- are -- I will bring a -- oops, I
18 don't really want to tell you what he thinks he's going
19 to bring to the -- no.

20 **(Laughter.)**

21 UNIDENTIFIED MALE: So, technically, you could
22 deny the application.

1 MR. JONES: No, the government representation
2 here is what it is.

3 DR. AMADOR: Are you asking for an up or down
4 vote on that?

5 (Laughter.)

6 MR. JONES: No, there's a different process for
7 our participation that isn't so transparent.

8 (Laughter.)

9 MR. JONES: That goes also for our colleagues
10 from the services and from FDA and our colleagues from
11 OECA and NIOSH and EPA regions.

12 UNIDENTIFIED MALE: I think Steve wants a
13 different FDA regulation.

14 (Laughter.)

15 MR. JONES: So, to spend a little bit of time on
16 a couple of things that I've noted, which I would not
17 claim to be all-inclusive in terms of follow-up, but some
18 of the highlights. Actually, the transcript of this
19 entire meeting -- it's not if you're Anne Lindsay who
20 speaks in clear, articulate sentences all the time. So,
21 when she reads the transcript, I'm sure she feels very
22 good about it. When I see the transcript, I'm like,

1 where did I get my education, this is remarkable.

2 But the point being that we capture what the
3 advice is that we're getting here and we go through that
4 and we make sure that we are following up with the kinds
5 of things that are important to follow up on. I've
6 captured a handful -- a little more than a handful of
7 things that I just wanted to relate to you that I'm
8 committing now to have some follow-up around.

9 The first was an issue that came up very early
10 yesterday morning. We've already had some discussions
11 with our senior team, even though it seemed like we were
12 here all day yesterday, which we were, but we're, you
13 know, figuring out other ways to work with our management
14 around the edges. That is sort of a feeling amongst a
15 number of you that there needed to be some dialogue as it
16 related to the 40-odd chemicals that we're going to be
17 doing tolerance reassessment and re-registration on
18 between now and August 3rd. We will internally spend
19 some time thinking about what would be useful, but it
20 would also be very helpful to get your thoughts, not
21 necessarily now, I think we did a little bit of that
22 yesterday, but off-line about what you think would be

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1 useful around that.

2 I would, again, repeat one of the things I said
3 yesterday, which is that you'll find out what's useful by
4 spending some time with those risk assessments. That's
5 where you're going to see issues that you think may
6 deserve either a CARAT or discussion at the PPDC. We'll
7 spend some time internally thinking about what would be
8 valuable, both from the Agency's perspective in getting
9 advice and also to stakeholders for some dialogue or
10 discussion around those issues.

11 So, again, as you think of things, please let us
12 know and that will certainly help inform the thinking at
13 the Agency.

14 On our second point, on the strategic plan,
15 we're going to come up with some mechanism to get to this
16 committee some more specificity with respect to how the
17 goal four is going to be characterized as it relates to
18 our work before it's so far down the line that it gets
19 very hard to make any meaningful change. The Agency is
20 looking for, as Marty described yesterday, a way to get
21 more stakeholder input and they actually think that the
22 PPDC is a very effective way to do that.

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1 I'm not sure if our next meeting may be a little
2 too late, so we may actually have a conference call
3 sometime between now and March if it turns out that March
4 is a little too late to really have meaningful feedback
5 around that, and you'll have much more specific language
6 to react to. We should be able to get it to you several
7 days in advance, have either a conference call or a
8 discussion here at the PPDC. Again, it depends on the
9 Agency schedule whether we need to have a conference call
10 around that or we can actually use this forum when we get
11 back together again. So, we will be definitely doing
12 that.

13 We heard from the performance measures workgroup
14 that the workgroup is going to next look at human health
15 measures that we have identified and ecological and
16 environmental measures, and I'm really just saying that
17 as a reminder, that that commitment has been made by that
18 workgroup and that's next on their agenda.

19 Around the worker and certification and training
20 issues, a number of you expressed interest in the
21 formation of a workgroup as we begin to think through how
22 to take some of the recommendations that came out of

1 pretty meaningful stakeholder processes into potential
2 regulatory changes and Bill Diamond has taken that as a
3 task he needs to put together, a PPDC group to provide
4 advice around some of those issues.

5 A number of you have already identified an
6 interest. Margie will follow up with another email note
7 to you all saying, you know, we're about to get this
8 going, if you're interested and you did not express
9 interest, let me know and we'll move out on that.

10 I mentioned earlier today that we were about to
11 pull the plug on the Consumer Labeling Committee. I've
12 said it a number of times over the last two years. This
13 works -- this advice works when people are willing to
14 invest in the time necessary to really vet an issue, and
15 many of the issues that we struggle with are not amenable
16 to an hour-long meeting to get that advice. And the
17 consumer labeling, we had some interest in further
18 evaluating and framing some issues and then coming back
19 to the full committee with some advice. It seemed to be
20 languishing there for a while. I was ready to pull the
21 plug, but I got word from Lin Moos, who's been leading it
22 on our end, that that committee has gotten resuscitated

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1 in the last month or so, and so, they've had a meeting a
2 couple of weeks ago, they're going to be having another
3 one before our next meeting and will be on the agenda at
4 our next meeting in March, if that's when we're having
5 it.

6 So, that activity is still ongoing. If there
7 are people who are interested in participating who have
8 not been heretofore, Lin Moos is the appropriate contact.
9 Of course, you can let Margie know and she'll hook you up
10 with Lin.

11 Let's see. Spray drift, sort of being the last
12 concrete specific issue. We have a list of those of you
13 who are interested in participating in this sort of joint
14 water-pesticides activity. It is going to be
15 bureaucratically, in the world of FACA land, that this is
16 going to be the FACA that it's going to report back to,
17 but we are going to supplement our membership with people
18 who are water stakeholders. We'll look to the Office of
19 Water, as well as you to help identify who those groups
20 are to make sure we have appropriate balance. Many of
21 you have already expressed interest. Again, have that
22 open for a while.

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1 Anne had mentioned that we'd like to have a
2 kick-off meeting around that at the beginning of the new
3 year, the new calendar year as opposed to the fiscal
4 year, and we will keep you posted. Again, if you haven't
5 expressed interest and you think you would be, let Margie
6 know.

7 Those are some of the highlights of the things
8 that I know, without even having to talk with anybody, we
9 are going to be following up on. As we get back to the
10 office and slog through our notes and transcript, we'll
11 likely identify additional things.

12 The final item is to just throw out a few ideas
13 and I have more ideas than we will have time. So, I both
14 want to hear your feedback about the ideas for the next
15 meeting agenda as well as any additional ideas that you
16 have. Some of these came up as we went through the day-
17 and-a-half. Some of them, I think, may have been
18 identified just by myself as we went through the meeting,
19 either way.

20 The first one is something -- we thought about
21 talking about it at our last meeting, but we decided not
22 to because there is another FACA that EPA has that is

1 working on it, and that's nanotechnology. But I do think
2 that there is some need for us to begin to -- at least
3 begin educating ourselves about what it is and what is
4 the potential interface with pesticides, and perhaps, we
5 could have a representative from that other FACCA, which
6 is actually managed out of the toxics office -- our
7 sister office -- come and talk with us.

8 That's an area where I think it we would all be,
9 I think, informed. I'm not sure we necessarily need to
10 task ourselves with anything, but I think some education
11 around that may be useful for us. So, that's something
12 we may want to do.

13 I heard yesterday, and I think it makes some
14 sense, that some analysis around PRIA would be something
15 the group is interested in. I said yesterday, we're
16 going to continue to work performance measures and we
17 want to do it with the advice of this committee, and so,
18 we're committed to continuing to work it and committed to
19 getting advice from all of you. So, that is something
20 that I'm very interested in having on the next agenda.

21 Spray drift, I expect that there will be some
22 report out. I doubt by March we'll have any consensus or

1 solution, but there will be an expectation that after the
2 initial meeting or maybe a couple of meetings, there will
3 be a report as to, this is so far what we've done, even
4 if it's a status report, there will be some desire, on my
5 part, to have a report out from that.

6 Again, the Consumer Labeling Workgroup, I expect
7 we'll have a report out from that. Depending on how much
8 has occurred, there may or may not be some report out
9 from this Worker Protection C&T Workgroup that I
10 mentioned.

11 I certainly will keep at the forefront of my
12 mind that there is an interest in having more dialogue
13 around the old chemical issues for '06. Again, I think
14 we need to figure out how to have that dialogue and if
15 this is the right forum or if it should be something like
16 the CARAT. So we'll keep it on the agenda until we
17 figure out which way to go on that.

18 I think it may be useful, I'm not sure, I'm
19 going to put it out there though, as we get close to
20 finalizing this SOP that Anne talked about as it relates
21 to working with the Office of Water as it relates to
22 impaired water bodies, of actually bringing that here to

1 have a more robust discussion around that.

2 So, those are some things that I think may be
3 populating the next agenda. Again, I'll open it up now
4 for thoughts about those things or other topics that you
5 think are important for us to give consideration to as a
6 committee.

7 Bob?

8 MR. ROSENBERG: This isn't a topic suggestion,
9 you know, this is more of a format discussion. I'm
10 trying to think of how to say this. Well, two things.
11 One, Jim, you had said yesterday that the Agency was
12 growing increasingly reliant on or was valuing the work
13 that was being done by workgroups of this committee, and
14 kind of unrelated, but related, is the fact that I
15 probably suffer from a fairly severe case of attention
16 deficit disorder and I find eight-hour meetings really
17 challenging, even ones at which I don't actually have to
18 do anything and it must be even that much worse for you.

19 I'm kind of wondering if it might be kind of a
20 good idea to think about whether maybe we could look at
21 changing the format to where maybe we meet from sometime,
22 9:00 to 1:00 or 2:00 on the first day and then actually

1 break out into workgroups for the afternoon and then
2 resume on the second day, which would sort of break it up
3 a little bit, provide some opportunity for the workgroups
4 to work and, you know, just have some virtue to it.

5 MR. JONES: I think we've got a number of
6 workgroups now. I know that some met -- I think two of
7 them may have met Wednesday. That is something, I think,
8 worth giving consideration to. So, you'd sort of make it
9 a two-day meeting with at least one half day, maybe two
10 half days where you're in the workgroups. That's
11 something we should give thought to.

12 UNIDENTIFIED FEMALE: Jim, for those that may be
13 on more than one workgroup, maybe dividing --

14 MR. JONES: Right.

15 UNIDENTIFIED FEMALE: You know, doing some
16 staggering (inaudible).

17 MR. JONES: The logistics of sort of if you're
18 participating on more than one workgroup, which I really
19 do want to do things that encourage workgroup
20 participation and not discourage it. So, that's
21 something we'd need to give thought to.

22 Gary?

1 MR. LIBMAN: First of all, I second that idea.
2 I think it's a great idea, especially for those of us who
3 have to come from outside the Beltway. In my case, I'm
4 considerably outside the Beltway. It would be nice,
5 instead of having the workgroup the day before, which
6 most of us can't get to, then it would be nice to have it
7 the same day. So, I recommend that, too.

8 One other topic for your thoughts is something
9 we talked about a little bit yesterday and it's something
10 that just keeps on rearing its head all the time. I
11 won't say its ugly head, but at least its head, and
12 that's inerts. I know we're getting closer to the FQPA
13 deadline of 2006 on the inerts, but there's still so much
14 confusion about what they're doing and what's not being
15 done. I would love to see some more of a clarification
16 on this thing, because it's very important for those of
17 us as a registrant.

18 MR. JONES: Okay.

19 UNIDENTIFIED MALE: I'd like to second that
20 because some of the inerts are actually industrial
21 products as well and it makes it a very confusing thing
22 in terms of TMDLs and 303D.

1 MR. JONES: Okay. Julie?

2 MS. SPAGNOLI: I guess this is a request for the
3 Consumer Labeling Workgroup, that if perhaps the Agency
4 could look to see if we could get somebody from OGC to
5 help us because I think where we keep coming to kind of a
6 standstill is a lot of ideas have been developed or a lot
7 of ideas have been put forward in suggestions, but then
8 it's, well, how could we do this? Is it going to take
9 rulemaking -- is it going to be no way, we can't do it
10 without changing the law? Is it well we can maybe do it,
11 but it's going to take rule-making? Is it a PR notice?
12 Is it a policy change?

13 We really need some guidance, I think, to find
14 out what recommendations can we come forward with and how
15 -- not only what are the recommendations, but how do we
16 recommend it be implemented and I think that would be
17 real helpful.

18 MR. JONES: Okay, all right, I'll take that
19 back. Melody?

20 DR. KAWAMOTO: NIOSH has been working on nano-
21 technology. We have a group that's working on it and I
22 think they've been working on it for over a year now.

1 MR. JONES: Okay, thanks. Erik?

2 MR. OLSEN: I'd like to support the concept
3 since Bob and I always agree on everything --

4 **(Laughter.)**

5 MR. OLSEN: I wanted to support the concept of
6 maybe trying to squeeze in some of the workgroup meetings
7 right afterwards. I think it would be useful for
8 everybody.

9 I also apologize for not being here yesterday
10 afternoon, but one issue is these potential performance
11 measures, and it sounded like, from the report back I
12 got, that you guys didn't totally resolve everything in
13 that conversation yesterday.

14 **(Laughter.)**

15 MR. OLSEN: I'm being diplomatic. You know, one
16 thing that, to us, would be important to raise is most
17 people, I think, in the public would think that if you
18 said what's EPA's potential performance measure for
19 success in the pesticide program, probably at the top of
20 the list would be are they protecting public health and
21 the environment, which doesn't really leap out at me from
22 this.

1 So, I think some way to figure out how to
2 discuss risk reduction in a way that EPA can actually try
3 to measure it might be a worthwhile discussion for us to
4 have or maybe you just want to think about that between
5 now and then.

6 MR. JONES: A little clarification around that,
7 because this is something that we've struggled with quite
8 a bit, not exactly that point, but there are three areas
9 that we're attempting to develop performance measures,
10 protecting human health, protecting the environment and
11 then this group that we're calling other benefits. Now,
12 when we started doing this three years ago, I consciously
13 kept our team away from other benefits and on human
14 health and the environment because I knew, analytically,
15 the latter is the easiest to do, and that the harder --
16 way much more difficult analytically is trying to do the
17 first two. So, I'm like, let's keep this in abeyance
18 because we're going to need less time because it's more
19 straightforward and there's more data. And we struggled
20 along, struggled along, struggled along on those other
21 two and then, finally, I'm like, well, we've got to start
22 working on this because we need to have -- there are

1 three important parts of this and we have to start
2 working.

3 Well, even though they started a year-and-a-half
4 later, of course they got farther ahead because
5 analytically it is more straightforward. Strategically,
6 I would have preferred to have put forward the human
7 health one first, but as I said, analytically, it's so
8 much more difficult. It's easy to do my part of it,
9 which is to articulate the goal. Actually coming up with
10 the measure is incredibly difficult for both human health
11 and the environment.

12 So, I would recognize that strategically that
13 wasn't the most masterful move, but that was the group
14 that was the furthest ahead, even though we had tried to
15 set it up so that the human health and the environment
16 would have been further along. I think that confused
17 people. You know, why are you talking in your
18 performance measures about benefits? I think people who
19 participated in the meeting -- in the workgroup became
20 clear because they spent, you know, five hours on it and
21 it became -- and they could understand it. But people
22 who were then just at the PPDC got very sort of why are

1 you leading with this.

2 So, that's the story behind the story there. It
3 really does get to the analytics behind human health
4 measurements in our work and environmental measurements
5 are just so much more difficult because the data sources
6 are just not as available, so --

7 MR. ELWORTH: And what we've done is queue up
8 protecting human health for the next meeting.

9 MR. JONES: Those are the next two that are
10 being done.

11 MR. OLSEN: That was exactly my point was that I
12 think that we need to have that discussion on what the --
13 how you're going to measure that because you're not going
14 to be able to measure dead bodies necessarily, you're
15 going to look at something else.

16 MR. JONES: It is very, very hard. Well, I
17 expect we're going to have some very meaningful pet
18 measures the next time we measure pet health from some of
19 our actions last year, which some of you may not have
20 focused on, but -- okay, appreciate it.

21 Pat?

22 MR. QUINN: I think given the level of interest

1 in the human studies issue yesterday and the fact that
2 you will have issued a final rule four or six weeks in
3 advance of the next meeting and you'll probably be doing
4 things like selecting and announcing the members of the
5 HSRB and everybody will be scrambling to try to
6 understand what their role is on both the front end and
7 the back end of the review process, it might not be a bad
8 idea to have another session on human studies.

9 MR. JONES: I don't know how that slipped my
10 list.

11 **(Laughter.)**

12 MR. JONES: I can't even imagine how that didn't
13 -- you're probably right, that's very good advice, Pat.

14 Okay, well, in closing, I just want to relate
15 one of my stories from talking to my kids, who give me
16 some of the greatest insights about my work. This
17 morning, my daughter -- I'm home a little later because
18 these meetings start remarkably late for my schedule and
19 so I'm hanging out with the family in the morning.
20 Usually, I'm not around to talk too much and to wake them
21 up. So, my daughter said, so, what are you doing today,
22 Dad? Why are you here, basically is her question.

1 I said, well, I'm -- this is a stupid answer,
2 but I said it anyway. I said, well, I'm meeting with
3 some stakeholders today.

4 (Laughter.)

5 MR. JONES: And she's like, what are you talking
6 about? So, I tried to describe it to her and as I'm
7 walking out the door, she says, well, have fun with your
8 work friends today.

9 (Laughter.)

10 MR. JONES: I said, these are not my friends --
11 no, I'm just kidding.

12 (Laughter.)

13 MR. JONES: And like, oh, what she's saying is
14 not have fun so much, but you're going to be with a
15 community today and you need to sort of take advantage of
16 being with the community and that, I think, is something
17 important for all of us to remember, is that we are part
18 of a community and it's the broad community of this
19 nation. It's not that we are a pesticide community, but
20 we are a community and it's important for us to remember
21 that. I think, actually, the way in which we have
22 engaged each other as a community in the last day-and-a-

1 half, I think, has been very positive in a way that
2 allows issues to evolve and move on. Whether you think
3 it's forward or backward, it allows issues to move on.

4 I really do want to thank everyone for the
5 professionalism with which you've all brought your
6 perspective to this meeting so that the Agency is able to
7 avail itself of your advice. So, I very much appreciate
8 the degree to which we have operated as a community over
9 the last day-and-a-half, and frankly, over the last 10
10 years. So, I thank you very much for that. And I hope
11 you all have safe travels wherever you're going and a
12 good weekend. Thanks.

13 **(The meeting was concluded.)**
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CERTIFICATE OF TRANSCRIPTIONIST

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ELIZABETH M. FARRELL

Transcriptionist