

NATIONAL INSTITUTE FOR OCCUPATIONAL
SAFETY AND HEALTH

PUBLIC HEARING ON UPDATING HAZARDOUS DRUG LIST

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ANDERSON COURT REPORTING

706 Duke Street, Suite 100

Alexandria, VA 22314

Phone (703) 519-7180 Fax (703) 519-7190

PROCEEDINGS

MR. REED: Good morning. So thank you for coming to our public meeting this morning. This is the first public meeting that we have had and the first update of the list of hazardous drugs for NIOSH.

My name is Larry Reed, and I, along with Tom Connor, will be facilitating this public meeting for NIOSH. Also in the back we have Barbara McKenzie, who is principally involved in helping to arrange the meeting in the ongoing effort to update the list of hazardous drugs.

Also at the table here, I'll introduce a little more formally in a moment is Anita Schill, who is a NIOSH Associate and Director for Science. And we'll have a few introductory remarks from John Howard, who is on leave through I believe Labor Day.

But mostly, I wanted to sort of set the stage for our discussion and introduce Anita to give those comments or remarks from Doctor Howard. But the purpose of the meeting, again, is to

update the list of hazardous drugs from the NIOSH Alert that was finalized three years ago.

We had prepared a list of hazardous drugs, and you'll hear more about that process from Tom later on this morning. And we also promised in the NIOSH Alert that we would update this in a periodic fashion. And this is the first update of that list from 2004. So, again, the purpose of the meeting today is to hear public comment in a very detailed and ongoing process for seeking public comment and helping us then to finalize the updated list of hazardous drugs. So with that, I would like to introduce Doctor Anita Schill, who, as I mentioned earlier, is the NIOSH Associate Director for Science, located here in Washington, D.C. And Anita has a few remarks from Doctor Howard.

DOCTOR SCHILL: Thank you, Larry. Good morning, everybody. On behalf of Doctor Howard and the Office of the Director at NIOSH, I would like to thank all of you for being here and to welcome you to this public meeting, which, as

Larry said, is the first meeting to update our list of hazardous drugs and the definition of hazardous drugs. And all of these were first published in the 2004 Alert that Larry mentioned, and so this is a very exciting milestone for us to actually be beyond publication of the Alert and now to be doing the first update.

I'd also like to thank you for your willingness to participate in this public forum. Your input is critical to producing the best possible information on hazardous drugs. NIOSH has a long history of soliciting public participation and feedback from workers, employers, and other interested stakeholders, as well as our scientific peers.

This public meeting comes from or continues our tradition of working closely with those who care about our science and the impact it has on workers, work places, and work settings.

Your comments will help us to achieve our aim of increasing awareness among health care workers and their employers about the health risks

posed by hazardous drugs and measures for protecting their health.

Additionally, your participation in this public meeting will help the scientists at NIOSH fulfill our commitment to one of our core values, and that's quality. NIOSH is committed to using only the best science, the highest level of data quality, and the most transparent and rigorous review processes for our scientific work.

In addition to this public meeting, the public comment period for this definition and list of hazardous drugs will extend to September 20th. We believe that the information shared in this public meeting and the public comments we receive in our docket will improve the quality of our work and we embrace your contributions. We whole heartedly embrace your contributions and thank you very much for being here.

MR. REED: Thanks, Anita. Just for those of you who don't know Anita, she, as well as Doctor Howard, were passionately and actively engaged in the creation of the Alert, finalization

1 of it, so for that I'm very thankful. We have a
 2 few moments. I'd like to -- and we're relatively
 3 small. Since this is was our first meeting, we
 4 didn't know how to gauge the size of the room, so
 5 for subsequent meetings, you know, we have like
 6 this, we will adjust accordingly. But we're small
 7 enough, most importantly, that we can introduce
 8 ourselves I think, and we'll pass along the
 9 microphone. And if you would do so, please, by
 10 stating your name and organization or affiliation.

11 And you don't need to -- as I mentioned,
 12 the court reporter will capture the names on a
 13 separate listing that Barb has in the back. So if
 14 you haven't already signed up on this list of
 15 attendees, please do so at the break. That's
 16 going to be the official capture of names.

17 I also want to mention to you, too, that
 18 we have a court reporter here who is transcribing
 19 the entire proceedings verbatim, so as part of
 20 this process, I would ask that, in general, that
 21 when you ask questions and have communications
 22 with us, that you either speak from this

1 microphone or from the portable one that we'll
 2 have that we'll take around to you, to identify
 3 you, as well as hear more specifically the
 4 comments that you have for the transcription. So
 5 with that, I'll go ahead and grab the microphone,
 6 and then, Barb, maybe you could help me with the
 7 movement.

8 MR. NAUMANN: Good morning. My name is
 9 Bruce Naumann and I'm with the American Company,
 10 and I'm also participating on the Advisory Panel
 11 for this update.

12 MR. JOHNSTON: Good morning. I'm Jim
 13 Johnston with WYETH.

14 MR. McGRATH: Bill McGrath,
 15 Bristol-Myers Squib.

16 MS. GOULD: Janet Gould, Bristol-Myers
 17 Squib.

18 MS. MATTHEW-BROWN: Dianne
 19 Matthew-Brown, AFSCME.

20 MS. McCONNELL-MEACHEN: Mary
 21 McConnell-Meachen, Boehringer Ingelheim
 22 Pharmaceuticals.

1 MS. McDIARMID: Hi, Melissa McDiarmid,
 2 I'm an occupational medicine physician at the
 3 University of Maryland and was a member, as many
 4 of our colleagues from Pharma who aren't saying,
 5 in the original hazardous drug work group. So a
 6 number of us have been joined at the hip for a
 7 long time and it's nice to see colleagues here
 8 together to go to the next level.

9 MR. O'CALLAGHAN: Hi, I'm Jim
 10 O'Callaghan, I'm with the NIOSH Health Effects
 11 Laboratory in Morgantown, and I'm a member of the
 12 hazardous drug group.

13 MS. REILLY: Good morning. Cindy
 14 Reilly, I'm with ASHP, American Society of Health
 15 System Pharmacist. I am a member of the work
 16 group. I'm joined by my colleague, who stepped
 17 out for a moment, Justin Coffy, who is the
 18 Director of Federal and Regulatory Affairs for
 19 ASHP.

20 MR. KASTANGO: John Kastango, Clinical
 21 IQ Consultant, member of the USP Steril
 22 Compounding Committee.

1 MR. STEELNACK: John Steelnack with
 2 OSHA's Office of Biological Hazards.

3 MS. MORGAN: Good morning. I'm Theresa
 4 Morgan, I'm a reporter with Inside OSHA.

5 MS. SLAVIN: Hi, I'm Katie Slavin with
 6 the American Nurse Association.

7 MR. SIGLER: Hi, I'm Joel Sigler with
 8 Kaiser Permanente.

9 MS. BULL: Good morning. Jonca Bull
 10 from Genetech.

11 MR. BARFNECHT: Good morning. Tom
 12 Barfnecht, Abbott Laboratories, Occupational
 13 Toxicology.

14 MR. SCHATZ: Tony Schatz,
 15 Shering-Plough.

16 MR. MARVIN: Good morning. Richard
 17 Marvin with American Society for Therapeutic
 18 Radiology and Oncology.

19 MR. ADER: Alan Ader with Safe Bridge
 20 Consultants. I'm an Occupational Toxicologist.

21 MR. RALE: Good morning. My name is
 22 Hank Rale, I'm with Containment Technologies

1 Group, retired Eli Lilly. I was a member of the
2 original working group on the Engineering Control
3 Section.

4 MR. SCHWARTZ: Chuck Schwartz, Pfizer,
5 Inc. I'm a member of the working group. I was
6 not part of the Pharma Group the first time
7 around, but I'm looking forward to working with
8 you guys.

9 MR. TROUT: Hi, Doug Trout with NIOSH,
10 and I'm a member of the NIOSH working group.

11 MR. BLOSSER: Fred Blosser, NIOSH Public
12 Affairs.

13 MR. PACENTINO: Good morning. John
14 Pacentino with NIOSH.

15 MS. REISSMAN: Good morning. Dori
16 Reissman, also NIOSH.

17 MS. BENSON: Kimberly Benson, FDA.

18 MR. HUNTLEY: Good morning. Carl
19 Huntley, Division of Drug Oncology Products, FDA.

20 MS. VERBOIS: Leigh Verbois,
21 Pharmacologist, Food and Drug Administration.

22 MR. REED: Okay, thank you. NIOSH is a

1 research organization. We are part of the Centers
2 for Disease Control; and as such, the work that we
3 do is science driven and is research. The
4 products that we develop are recommendations. So
5 the list that we have is not a regulatory product,
6 it is a non-binding product, it is meant as
7 guidance, so I just wanted to emphasize that point
8 in this process.

9 I also want to emphasize the point that
10 the purpose of the meeting here is to seek public
11 comment and input that will be transcribed and be
12 used as part of the process that you learn more
13 about in a few minutes about finalizing the list
14 that we hope to do so in the next few months.
15 Next slide, Tom, please.

16 The agenda is -- I share the slide only
17 just sort of to get the flow of the day today. We
18 are just a one day meeting and I think the size of
19 the group will allow us to interact as much as
20 possible.

21 I do have some logistics issues to
22 discuss. Again, if you are attending the meeting,

1 as you are here, I would ask that you please sign
2 your name to the list and affiliation. Barb has
3 it in the back, that's our official record of your
4 attendance and involvement, and also for the court
5 reporter's purposes of correlating what you say to
6 the transcription. Also, Barb has a second list,
7 an important list. If you want to provide comment
8 here, we ask that you sign a separate list. We're
9 aware of only one official presenter at this point
10 in time, and that's from ASHP.

11 But again, we have ample time throughout
12 the day, so we would just ask that you put your
13 name on the list and we'll go in that order for up
14 to ten minutes of presentation and discussion on
15 the list.

16 And then we have a third list I think
17 Barb created just a few minutes ago, and that is,
18 if you want to be engaged or want to see future
19 interactions of this nature on the definition and
20 list of hazardous drugs, we'll keep you on a
21 distribution list for future involvement, so
22 that's -- we'll get a third list.

1 And I guess also in terms of logistics,
2 Barb has asked me to remind you that the restrooms
3 are in this direction, to your right, my left.
4 Cell phones probably won't work in the basement,
5 with maybe one exception, but you probably know
6 that already if you've tried to phone out.

7 As I mentioned earlier, we have a
8 transcription that will be an important part of
9 this process as we finalize the list of drugs.
10 And since we have ample time, there will be
11 sufficient time I think for those people who have
12 questions, you know, of the presenters, if the
13 presenters don't mind being asked questions.
14 Again, we would just ask that you use the
15 microphone and that you identify who you are for
16 the official transcript. And the agenda that you
17 see in front of you is very flexible and will
18 identify the break times and the times to come
19 back from that, so it's a very sort of informal,
20 flexible process right now. I'm looking to Barb
21 now. Did I miss anything in terms of logistics?
22 She's much better at this than I.

1 MS. McKENZIE: No; at lunch time, if you
2 wish to leave your stuff here, I will stay in the
3 room, so you don't have to --

4 MR. REED: Okay. Next slide, please.
5 Just a brief overview of the Alert; as Melissa
6 actually mentioned when we were doing
7 introductions, Melissa McDiarmid, who was a part
8 of this effort from the very beginning and a big
9 creation of the Alert, many of you who are here in
10 this room were part of that effort, and it was a
11 fairly long effort, but it was a very good and
12 important effort that was scientifically -- that
13 created as its principal product the NIOSH Alert.

14 And that effort began actually in
15 September of 2000, in Washington, D.C., where we
16 had a meeting of effected partners and parties,
17 and we heard a passionate appeal to NIOSH to
18 develop an alert that would be the scientific
19 basis for one identifying or communicating concern
20 about the health effects from exposure to
21 antineoplastic agents and other medications, and
22 also to provide recommendations for preventing

1 these exposures. As an important part of that
2 effort, we recognize the importance of having a
3 list of drugs that would be a recommended list of
4 those drugs that we consider to be hazardous when
5 health care workers are exposed to them over a
6 long period of time in their work setting. So,
7 again, that's sort of the basis for this meeting
8 here. And it is an appendix in that we're
9 referred to throughout this meeting, an appendix
10 of the alert itself.

11 The Alert was -- again, I won't go into
12 the details of it, but it took about four years to
13 complete, and it was a very interesting process in
14 the sense that it was a very large group of
15 passionate people with one commonality, bright and
16 passionate people, I might add.

17 The one commonality was worker
18 protection. And we all I think had our
19 differences in this effort, and we had a very sort
20 of -- what I thought to be a very good mix of
21 participation across labor, industry, trade
22 organizations and associations, academia, and

1 government. And I think we began with 20, and at
2 the end of our effort, we had upwards of 50 to 60
3 people involved in this effort.

4 So I would say that from that
5 standpoint, it was unique in terms of the broad
6 engagement of effort, in terms of developing the
7 original draft of the Alert. Then NIOSH took this
8 draft, very early draft of product, the Alert,
9 finalized it through a very rigorous process --
10 was a very -- what we would call a highly
11 influential product, and through a very detailed
12 scientific effort of peer review, both scientific
13 peer review, as well as stakeholder peer review,
14 we finalized it through several iterations. And
15 Tom and I know that it was a very thorough
16 process, and others who were involved in that
17 effort. So from that was the product basis by
18 which we are now updating the list.

19 Next slide. I won't go into details of
20 this. It's a very detailed slide. But actually
21 this is Doctor Howard's suggestion that we -- and
22 it was a very engineer-like suggestion. So I was

1 surprised, but also I think it was -- turned out
2 to be I think a very good recommendation, that we
3 create a flow chart of the process to help us
4 think through and see, visualize the intricate
5 effort that would be needed to update both the
6 definition, as well as the list of hazardous
7 drugs.

8 Again, I won't focus on the details of
9 it. Could you go back to the first slide, please?
10 This would be the definition.

11 Again, we have two slides on the
12 process, one is the definition, and again, I won't
13 bore you with the details.

14 But basically, on the definition, we
15 assess the literature from the original definition
16 that Tom will talk about in a few moments from the
17 Alert itself that was based principally on the
18 ASHP definition with some minor modifications. We
19 went through this process over the last year or
20 two and we determined -- we assessed within NIOSH
21 that we didn't think there was enough reason, a
22 scientific basis for changing the definition. So

1 through this flow chart, we basically came down to
2 no changes in the definition, and we then would go
3 to step two. Going back to step -- we have two
4 fingers here. Had we determined that there would
5 be a change, a proposed change in the definition,
6 we would go through this very detailed process of
7 public comment, a public meeting, and then the
8 finalization of this definition through a very
9 detailed process. Next slide, please.

10 This slide shows the flow chart for the
11 updating of the list itself. Basically, it's a
12 carry-on, a continuation from the first slide,
13 where we decided that there was no change in the
14 definition necessary. Then we're going through
15 this sort of detailed process.

16 I'll just identify some key aspects of
17 it. Internally, you'll hear more about this in a
18 moment, internally, we reviewed information
19 relevant to new drugs that had been approved since
20 2004, the development of the Alert itself. In
21 that, information would be the FDA warnings and
22 approvals, an important part of that effort.

1 We now have a public comment meeting
2 here that's going to be an important part of this
3 collection of information effort.

4 We then also, you'll see in a moment, we
5 have a very large group of expert panel members
6 who will be helping NIOSH assess this information,
7 and the information that will be assessed will be
8 the information in the docket that will remain
9 open, as Anita said, until June, excuse me, until
10 September 20th, information that we gather here at
11 this public, as well as the information that
12 you'll hear about in a moment that was developed
13 by an internal group of NIOSH experts that did the
14 original assessment of information to develop this
15 proposed list of updated drugs.

16 So we will have a meeting of this peer
17 review group probably in the fall sometime. And
18 then we'll finalize -- NIOSH will finalize this --
19 the updated list based upon the collected
20 information. And if there's substantial reason to
21 change the definition, we would possibly do that,
22 as well, depending upon whatever information we

1 hear. But at this point, it's just the list of
2 drugs that we would propose updating.

3 So I think that's all, Tom, for this
4 slide. I have two more and then I'll pass it on
5 to Tom for more sort of detailed and substantive
6 discussion of the process itself. But I just
7 wanted to mention to you that we had -- as part of
8 this effort, you'll see a summary slide at the
9 end, we had a group of internal NIOSH experts; Tom
10 Connor, who is sitting here, who will be talking
11 in a few moments, is a toxicologist in the NIOSH,
12 Division of Applied Research and Technology in
13 Cincinnati; Barb McKenzie is a biologist, also in
14 the same division of Applied Research and
15 Technology; Jim O'Callaghan, Jim, if maybe you
16 could raise your hand here, is a pharmacologist
17 who is in the Health Effects and Laboratory
18 Division of NIOSH in Morgantown, West Virginia;
19 lastly, we have Doug Trout, raise your hand,
20 please, Doug, who is an occupational physician,
21 who is in the division that I represent, the
22 Division of Surveillance, Hazard Evaluations, and

1 Field Studies, he's an octoc.

2 So collectively, through a long effort
3 that lasted over a year, we gathered information
4 with this group and we developed this proposed
5 updated list of hazardous drugs based upon the
6 collective information that we were aware of.

7 I mentioned earlier that we have a panel
8 of experts. I think they are all here, with
9 perhaps one exception, correct, Tom?

10 Okay. And this panel of experts we put
11 together, we wanted to have -- make sure that it
12 was representative, that it was an unbiased
13 objective or representation in the balance
14 perspective, I should say, of the effected parties
15 here in terms of helping us then assess the
16 collective public comment from the docket from
17 this meeting and from the NIOSH initial work that
18 was done.

19 And then they will provide us this
20 expert response. We plan to meet sometime in the
21 fall, hopefully October/November range, after we
22 have the transcripts of information and when the

1 panel has had a chance to analyze and read and
2 digest all of that information.

3 And I'll just mention by name, Caroline
4 Freeman from Federal OSHA, Melissa McDiarmid, you
5 heard earlier, is from the University of Maryland,
6 Bruce Naumann from Merck, Marty Polovish, who is
7 not here I believe today, is representing ONS,
8 Cindy Reilly from ASHP, Chuck Schwartz from
9 Pfizer, Debora Van der Sluis from Genentech, also
10 representing BIO, a trade organization for the
11 bioengineer drugs, Leigh Verbois from FDA, Kristen
12 Welker-Hood from ANA, and last, Vernon Wilkes from
13 VHA.

14 So again, you'll hear a summary of this
15 process, again, at the end of the presentation.
16 But now I'd like to pass this on to Tom Connor,
17 who will talk more about the definition and how we
18 generated the updated list from the internal NIOSH
19 group. So, Tom.

20 MR. CONNOR: Thank you all for being
21 here today. It's good to see a lot of old faces
22 that were involved with this process. We've been

1 working on this since basically -- in 2000, we
2 started thinking about the Alert and how to do
3 this. And, as Larry mentioned, it's been quite a
4 bit of work to do this update.

5 We had -- first we said we were going to
6 do it on a yearly basis, and then we really had to
7 work out the process on how we were going to do
8 that, and that really took a quite a bit of time
9 once we developed the process, and then we had to
10 go through and actually do the review internally
11 in NIOSH so we could provide some information to
12 our panel of expert reviewers.

13 So basically, what we did, this is the
14 definition that we developed with the help of the
15 NIOSH working group. I know a number of you were
16 members of the NIOSH working group and you are
17 familiar with it. And, as Larry mentioned, we
18 were up to about 50 or 60 individuals at a time
19 when we completed the Alert, so we had quite a bit
20 of input. We basically took this definition from
21 the ASHP definition that had been used in the
22 technical assistance bulletin and we just modified

1 it a little bit, added basically the last -- the
2 structure activity relationship criteria to that
3 definition. Larry, if we could have the next
4 slide.

5 We also -- we have not done a
6 quantitative risk assessment on these drugs. It's
7 been kind of a qualitative assessment, hazard
8 assessment. We have not done a quantitative risk
9 assessment.

10 We recognize that there are occupational
11 exposure limits that are used by industry, and
12 there are some criteria that are applied with
13 developing definitions for hazardous drugs. We
14 have this as part of the definition, as a foot
15 note to the definition for further guidance in --
16 if individuals want to develop their own list of
17 drugs or just guidance how we may use this
18 information towards developing a list. Next one.

19 In the current NIOSH definition, we have
20 136. The majority, about two-thirds of these, are
21 antineoplastic drugs. This is the appendix A in
22 the NIOSH Alert that Larry mentioned. So, again,

1 about two-thirds of these are antineoplastics.
2 The others are some antivirals, some
3 immunosuppressant drugs, hormonal agents, and a
4 couple of monoclonal antibodies. What we did on
5 that list, and I think most of you are aware, this
6 is a similar approach that OSHA had used in their
7 guidelines for the safe handling of hazardous
8 drugs, where we went to a number of institutions
9 that had, for actually a number of years,
10 developed their own list of hazardous drugs.

11 So we went to those institutions, and
12 you can see the NIH Clinical Center, Johns
13 Hopkins, Northside Hospital in Atlanta, and
14 University of Michigan. And also with the help of
15 Bruce Naumann and others in Pharma, they developed
16 a list of hazardous drugs that we combined all of
17 these into the Alert, and from those, this is how
18 we generated our sample list of hazardous drugs.

19 We needed to find a more systematic
20 approach now that we were updating the list of
21 hazardous drugs. So what we did, we have been
22 collecting information on all new FDA drug

1 approvals since the publication of the Alert in
2 2004. We also have been collecting -- most of you
3 are familiar with Medwatch, I'm sure, warnings
4 from Medwatch. Most of these have been black box
5 warnings, you're familiar with the black box
6 warnings.

7 So we collected all of these since the
8 publication of the Alert in 2004. And we also
9 looked at the current list of hazardous drugs from
10 NIH. They had the most comprehensive list when we
11 did the first go around with the Alert. So we
12 wanted to take a look and see what new drugs they
13 may have included. And I think, in addition to
14 two in the first -- I mean the first two groups,
15 we had about 15 additional drugs from the NIH list
16 that we included. Out of this approximately 150
17 drugs that we gathered information for, we --
18 Larry mentioned the NIOSH internal group that Doug
19 and Jim and I, and who else, Barb, I'm sorry,
20 Barb. Actually, Barb has been very instrumental
21 in getting all this information together for us.
22 We haven't been able to do this work without her.

1 We reviewed these drugs, we did, again,
2 a qualitative hazard assessment on these and
3 categorized them as -- if we considered them to be
4 a hazardous drug or if they did not fit the
5 definition, the NIOSH definition of a hazardous
6 drug. We came up with 62 drugs on our initial
7 list that we considered to be hazardous drugs.
8 The next one.

9 So what we are looking for, we are
10 looking for today input from this group of
11 individuals and information from the NIOSH docket
12 to correlate all of this information and put it
13 together for this panel that Larry mentioned,
14 panel of experts, to evaluate what we did,
15 identifying those 62 potential hazardous drugs,
16 and have this external group review that and
17 provide feedback to NIOSH about how they would
18 rate or rank these drugs, whether they would be
19 hazardous or -- all drugs are hazardous,
20 obviously, to some extent, but whether they would
21 fit the definition of hazardous drugs.

22 As Larry mentioned, we'd like to have

1 the meeting of the reviewers sometime in
2 October/November and get the list finalized as
3 soon as possible. We had made a commitment to do
4 this every year. Obviously, we are three years
5 behind schedule. And we have a large number, we
6 have approximately 150 drugs on our list, on our
7 current list. We don't foresee having this, if we
8 do it next year, we'd have a much smaller list.
9 And we may be able to modify this procedure a
10 little bit if we just have a few drugs to look at.
11 Larry.

12 Here is the contact information for
13 Larry and myself. I'm sure you have that. But if
14 you want to -- if you need to get in touch with us
15 about anything. Larry, you wanted to say a few
16 words to wrap it up?

17 MR. REED: Yeah, thanks, Tom. Other
18 than just to reiterate, sort of this effort here
19 is an ongoing effort that we plan to do
20 periodically, and this public meeting is an
21 important part of that effort. So as I mentioned
22 earlier, I think we have one scheduled

1 presentation, is that right, Barb, ASHP. And so,
2 again, if you want to make a formal presentation,
3 we have ample time to do that today. So please
4 make sure that your name is on the list. And
5 we'll start with the first person from ASHP, and
6 I'm sorry, that would be you, Judy -- Cindy.

7 MS. REILLY: (off mike)

8 MR. REED: Yes, please.

9 MR. REILLY: Good morning. I'm Cynthia
10 Reilly, I'm with the American Society of Health
11 System Pharmacist. I don't really have an
12 official presentation, just a few comments that I
13 wanted to start out with. ASHP is a pharmacy
14 association that represents about 30,000 members
15 that practice in a variety of health systems, all
16 of which obviously are involved in handling the
17 medications that are proposed for the list, as
18 well as the existing list. ASHP has a long
19 history of being involved in this process.

20 As Doctor Connor had mentioned, the
21 original list was based on our technical
22 assistance bulletin, was one of the resources that

1 was used in developing that. I can't say it was
2 based on it, but it was one of the resources.

3 So, obviously this is an area that ASHP
4 is quite interested in and has a long history of
5 being involved in. So we're pleased to continue
6 to be involved in this process.

7 In a personal level, as I started to
8 look at this process, I thought back to the time
9 when I was a practicing pharmacist, and I admire
10 everyone who's been involved in this process.
11 This is new for me, I've just started with this.
12 And it's not an easy process, it's not an easy
13 decision, as you look at the drugs and try to
14 determine, because you obviously are dealing with
15 the safety of health professionals, which is
16 something that ASHP takes very seriously, that I
17 take very seriously.

18 So as I started this process, I sat down
19 and pulled many, many package inserts and did a
20 lot of research. But basically, ASHP would --
21 supports the designation of hazardous drug for
22 many of the drugs that are proposed for the

1 update, including those for which we have evidence
2 that they are known hazards, the ones that have
3 been previously designated by the National Tox
4 Program, et cetera. However, we do advise caution
5 with the classification for some of the
6 medications on the list. As you know, once drugs
7 receive that classification, there are strict
8 guidelines for receipt, storage, preparation,
9 transport, administration, and disposal of these
10 products.

11 And all of these factors will impact
12 health care practitioners, not just pharmacists,
13 not just nurses, but also other staff in the
14 facility that are involved in patient transport,
15 et cetera. So there are a lot of individuals
16 involved, and obviously there's cost involved, as
17 well, for training, for facility design, for
18 personal protective equipment.

19 One of the things is, we started to look
20 at this process and seek input from our members
21 who have been experts in this area for a while, is
22 that some individuals have questioned the extent

1 of what is an occupational exposure and then what
2 is the evidence for some of the individual agents
3 on the list, and in many cases, that evidence is
4 more consistent with internal dosing in the
5 patient rather than what might be deemed from an
6 occupational exposure.

7 We also had several members that have
8 urged us to present their view that the dosage
9 formulation is something that should be
10 considered. Many of these products are capsules,
11 tablets, et cetera, where the risk from
12 occupational exposure may be limited. One of the
13 things that we have found from our members, as
14 well, is that they are also -- in practice, they
15 look at this as a tiered approach. It's not an
16 all or nothing. The way that they look at it,
17 they will treat different agents differently. And
18 so ASHP knows that this occurs in practice, though
19 we also know that there's variation in how
20 individual will look at assigning the tiers.

21 And we would -- and we think in some
22 ways that adds to the confusion. When an

1 individual goes from one practice site to another
2 practice site, something that was treated as
3 hazardous somewhere may not be treated as
4 hazardous elsewhere.

5 And so we would actually prefer a
6 process where that tier was official assigned, as
7 far as what the risk level was from exposure. Our
8 members tell us that some institutions use a three
9 tiered approach, whereas others, ASHP would more
10 advocate for a two tier, simply because, for
11 educational reasons, and then just the science
12 base, how you determine what would be in that
13 second tier would be difficult.

14 But for medications that are intact
15 formulations, we would consider, and obviously
16 we'll talk about specific agents later, but some
17 of those we would consider low risk, whereas
18 manipulation of those agents, crushing tablets,
19 opening capsules, would be considered higher risk,
20 and we can talk a little bit more about the
21 particular agents when we get to that part of the
22 meeting. ASHP would encourage people to think

1 about some of the practical aspects of how this
 2 will be applied in the actual work place as we
 3 move forward. That's it. Any questions?
 4 MR. SCHWARTZ: Chuck Schwartz from
 5 Pfizer. In the toxicology world, we've been
 6 looking at controlled banding strategies based on
 7 different levels of hazard for quite some time.
 8 Am I hearing that what you're advocating is
 9 perhaps a similar type of structure be set up on
 10 the exposure, equivalent to the exposure side,
 11 where things like powders for reconstitution,
 12 liquids, things like that, might be in one band,
 13 coated tablets, capsules, other types of, you
 14 know, solid dosage forms, be in another band, and
 15 then the controlled strategy be built around the
 16 matrix of what type of exposure there is against
 17 the depth of, or not the depth, the level or
 18 degree of hazard?
 19 MS. REILLY: Well, I'm not a
 20 toxicologist, I'm a pharmacist, and I'm not
 21 exactly sure with the structure that you're
 22 looking at, but that is something that we're

1 looking at and proposing. However, I think our
 2 final -- and we have draft comments that are
 3 currently posted on our web site.
 4 Our final comments will deal a lot more
 5 with how these individual agents are handled. For
 6 instance, some of the sleep agents that are on the
 7 list, if they were to remain on the list, we would
 8 be more firm in advocating for this tiered
 9 approach, simply because, you know, when you're
 10 dealing with, and I'm blanking on the Rimalteon.
 11 The brand names are coming more to mind than the
 12 generic, which I don't want to use.
 13 MR. SCHWARTZ: Don't do that.
 14 MR. REILLY: I don't want to use the
 15 brand names here. But like, for instance, all the
 16 agents that are used for sleep, are used for
 17 depression, that are used widely throughout the
 18 facility, there's large training requirements that
 19 would be required for -- we're not just talking
 20 about the oncology nurses or the immunology nurses
 21 that are much more familiar with these
 22 precautions, we'd be dealing with every nurse on

1 every floor.
 2 And I think if some of those agents were
 3 to remain on the list, that would really have us
 4 encouraged looking at it as a tiered approach for
 5 risk.
 6 MR. SCHWARTZ: Okay. Thanks very much.
 7 MS. REILLY: Anything else?
 8 MR. CONNOR: We have struggled with this
 9 issue even when we were developing the first list
 10 of hazardous drugs. You know, we recognize -- we
 11 have a powder that needs to be reconstituting, you
 12 may have a capsule, so you have different physical
 13 forms of this. The toxicity of the drug does not
 14 change.
 15 And this is kind of the approach that
 16 NIOSH has taken, that the inherent toxicity of the
 17 drug remains the same. But there is a different
 18 occupational exposure scenario. If you're
 19 crushing a coated tablet, then it's another form.
 20 So you could have different forms of the same drug
 21 with the same toxicity, but different exposure
 22 potential. So this -- we struggled with this

1 early on, and it's something that we still
 2 struggle with here. So we're looking for feedback
 3 from this group on it.
 4 MS. REILLY: And ASHP would acknowledge
 5 that if you were to have this tiered approach, it
 6 increases the educational needs, and that is
 7 certainly a factor that should be part of the
 8 consideration, and ASHP is, of course, interested
 9 in participating in any education.
 10 But we also have a concern that with
 11 some of these agents on the list, we already know
 12 that health care practitioners are not necessarily
 13 always consistent with the recommendations for
 14 precautions, and we worry that some of the agents
 15 on the list will actually, in some ways, could
 16 make that worse, because they're like, oh, that's
 17 not toxic, and that cavalier attitude could extend
 18 to agents that we know are toxic.
 19 MR. CONNOR: I think the flip side of
 20 that is, if someone is handling a drug, do I have
 21 to go look up, do I need to wear gloves with this,
 22 do I don't need to wear gloves with this, and so I

1 think our approach has been -- we don't want to
 2 include everything as a hazardous drug, obviously,
 3 but to try to have somewhat of a realistic
 4 approach, too, because a busy nurse or a
 5 pharmacist, you know, they can't always run and
 6 look and see how should I handle this. So to
 7 handle them, we use the term like standard
 8 precautions universal cautions in the alert, so
 9 that if you're wearing gloves or protective
 10 equipment, for one, you could wear them for the
 11 other. And I know in the real world that doesn't
 12 always happen.

13 MS. REILLY: One of the things also that
 14 we would encourage and ASHP is very involved in
 15 this area is the use of technology. So, for
 16 instance, with CPOE and electronic medical records
 17 and medication administration records, there are
 18 mechanisms that can be useful to help in that
 19 education as far as notes on the packaging that
 20 goes up to the floor and notes on the medication
 21 administration records, so that there is -- in
 22 some ways that can help. But we recognize that

1 education is a huge component of this.

2 MR. REED: Thanks, Cindy. Barb, do we
 3 have any other presenters? Okay. Anyone who
 4 would like to present informally or ask questions
 5 about the process or -- feel free to do so.

6 MR. ADER: Alan Ader from Safe Bridge
 7 Consultants. I was wondering, in the development
 8 of the new list, the new, updated list, why NIOSH
 9 had not just used -- added those compounds for
 10 which FDA had required labeling in their package
 11 insert and their official labeling which required
 12 the warnings that are I would call common to
 13 hazardous drugs in the past, where they described
 14 -- referencing the various guidelines that had
 15 been previously established, like the CDC
 16 guidelines, I think they reference the Australian
 17 or New Zealand guidelines for handling cytotoxic
 18 drugs and so forth, and why they just had expanded
 19 it beyond that list.

20 MR. CONNOR: Well, it's my
 21 understanding, and the FDA people can correct me,
 22 but those warnings currently only apply to

1 chemotherapy antineoplastic agents. We have other
 2 drugs which fall outside that category which are
 3 hazardous. And the current warning that is in the
 4 package inserts, in most cases, those references
 5 are, some of them, 20 years old.

6 And we've had several meetings with the
 7 FDA. I failed to mention that we have been doing
 8 meetings and conference calls with the FDA group,
 9 and they can elaborate on this a bit more, to look
 10 at that warning and maybe have it extend to all
 11 hazardous drugs so it's more uniform for these
 12 types of drugs. Would someone from the FDA like
 13 to comment on that? Thank you.

14 MS. VERBOIS: So right now --

15 MR. REED: You may want to identify
 16 yourself, Leigh.

17 MS. VERBOIS: Oh, Leigh Verbois, Food
 18 and Drug Administration. The Food and Drug
 19 Administration is looking comprehensively at this
 20 issue. We are trying to develop guidance to lead
 21 investigators and reviewers in determining whether
 22 or not drug products need safe handling comments

1 within their label. We are in the process of
 2 trying to update this information. There's a
 3 guidance that we are currently working on, but
 4 that's not out for public comment yet, we hope it
 5 will be soon.

6 As Tom mentioned, we are -- the
 7 procedures for a proper handling comment is placed
 8 solely in chemotherapy agents at this point. And
 9 we are trying to develop criteria by which we
 10 would go forward to determine whether or not we
 11 need safe handling comments within labels. Like I
 12 said, at this point we're still in the draft
 13 stage, so -- and we are here to hear your comments
 14 so that we make sure we incorporate the
 15 information and your concerns into our guidance
 16 document.

17 MR. REED: Thanks, Leigh. Did that
 18 answer your question, Alan?

19 MR. ADER: (Nodding)

20 MR. REED: Okay. Any other questions?

21 MR. SCHATZ: Tony Schatz,
 22 Shering-Plough, occupational toxicology. I wasn't

1 part of the original group that put this together,
 2 but one of the questions I have reading the
 3 definition of a hazardous drug is, at what point
 4 do you look at weight of evidence and make a
 5 determination for a reproductive or tratigenicity
 6 (?) or any of the end points that are listed?
 7 What do you look at when defining
 8 whether it's a hazardous drug under one of those?
 9 Because as a person at a particular
 10 company, it may be my job to then assign whether a
 11 drug should be on the list or not on the list
 12 according to your criteria, and we always look at
 13 weight of evidence approach and look at the
 14 different data and different species, et cetera,
 15 and we make a decision based on that. I'd like
 16 you to comment on what that is from NIOSH's
 17 perspective, or do you just look for the word
 18 tratigene (?) and put it on the list?
 19 MR. CONNOR: Well, we did a little bit
 20 more than that. It is a very difficult process.
 21 This is why we organized this internal NIOSH
 22 group. We went through all of the package insert

1 information that was available. Obviously, if
 2 something has a fertility category DRX, I mean
 3 that's kind of a red flag, we look at that. No?
 4 Okay. But it's a red flag. It didn't
 5 automatically go on there, but that would be a red
 6 flag.
 7 Category C is somewhat difficult.
 8 Sometimes -- Category C, as I think you're aware,
 9 is very broad. You can have almost no effects,
 10 and then you can have some serious effects close
 11 to the therapeutic dose in there. So we tried to
 12 weigh that evidence.
 13 With the gentox data, we would look at
 14 the gentox data and try to evaluate all the gentox
 15 data that was available in the package insert. I
 16 know there are different pharmaceutical companies,
 17 I have seen schemes that they use, and these get
 18 fairly complicated.
 19 So we try to look at that data and
 20 evaluate it. The same with the carcinogenicity
 21 data, if it's a very rare tumor that you only see
 22 in a mouse, we would probably exclude that, we

1 would not consider the carcinogen. If there's
 2 evidence of tumors in humans, lymphomas and so
 3 forth, and then there's also evidence in mice and
 4 rats, then we would then probably include that.
 5 So we did try to weigh the evidence as much as
 6 possible.
 7 MR. SCHATZ: Okay. You mentioned the
 8 FDA categories, and I went to a meeting actually a
 9 couple of years ago on teratology society, where
 10 the FDA was represented and there was discussion
 11 about redefining those categories. I'm not sure
 12 where we are with that, and maybe the FDA can
 13 comment on what they're doing from that front.
 14 MS. VERBOIS: There's a specific group
 15 set up to work with reproductive categories and
 16 we're not directly involved with that. There is,
 17 as we have also heard, a move towards that, and
 18 that has been going on for quite some time, and
 19 there's substantial discussion, but we haven't
 20 heard it going any further than probably what you
 21 heard two years ago.
 22 MR. CONNOR: Chuck, did you want to --

1 please. We welcome any comments. Please --
 2 MR TROUT: My voice really carries. Do
 3 they need me at the microphone? I would caution,
 4 there are some unique circumstances sometimes
 5 around reproductive categories. I know that you
 6 can't say that, well, X perhaps, D, you can't --
 7 it's not black and white. The tetracycline
 8 antibiotics are a category D. They would not, I
 9 don't think, fall into the category of hazardous
 10 drugs. Boy, I better hope -- I think we all hope
 11 they don't. They cause a very specific type of
 12 development effect and it's just not in the scope
 13 of -- The other thing is that, I really like the
 14 idea that we said at the first meeting, through
 15 all of the package inserts and such, was a
 16 qualitative kind of reading. And I know for a
 17 fact that in more -- well, in at least one
 18 instance, that a very rare tumor type in one
 19 strain, one sex, was the sum and substance of the
 20 evidence that put something on the list of 62
 21 drugs that wanted to be added to the list.
 22 So knowing that that was just a first

1 read-through, that was actually one of the drugs
2 that I wanted to comment about when we get to the
3 discussion parts of this. So knowing that that
4 was just the first read-through of it is
5 encouraging.

6 MR. CONNOR: Yeah, so basically we
7 developed this list, and it's a proposed list. We
8 understand that some of these may not fit in a
9 category. We also understand some that are on the
10 list that we did not consider. Some of the
11 individuals on the panel may have additional
12 information where those would be moved to the list
13 of hazardous drugs, so I think it could go either
14 way.

15 Again, we went through the package
16 inserts, we had this committee, we reviewed it, we
17 discussed it and tried to look at the weight of
18 evidence and came up with a proposed list, and now
19 we're looking for guidance from all of you people
20 and other people in the public to comment on that
21 list.

22 And if you want to have a, you know,

1 we're open for discussion here now. This is what
2 we're going to do today until we run out of things
3 to discuss. So if you have a particular one that
4 you want to comment on, please do that, if you
5 feel comfortable doing that now. I don't mean to
6 put you on the spot.

7 MR. TROUT: Okay. The drug that I'm
8 thinking of is one of our drugs, and I'm in kind
9 of an awkward position here. So we have some
10 other people who are from our company who will be
11 providing comments on that, you know, the advocate
12 versus a member of the expert panel. I'm a little
13 uncomfortable commenting about a specific drug,
14 but I wanted to use that as an example.

15 Other things that I was thinking about,
16 though, as I read through all the package inserts
17 preparing for this were mechanism of -- genesis,
18 where the effects are clearly secondary to other
19 effects.

20 There were a couple of them that, boy,
21 when you read that, it sounds an awful lot like
22 these tumors and rodents are secondary to

1 metabolic activation, which is a mechanism that's
2 irrelevant in humans.

3 Any expert panel or whoever would tell
4 you that, that they've dismissed these. Certain
5 types of thyroid tumors, certain types of mammary
6 tumors that are seen in rodents, and it seemed
7 like many of them were on the list, and that was
8 what the evidence was all about.

9 Also, with the reproductive end points,
10 the way testing is done, you test to failure, to
11 use the euphemism that we work with. So you must
12 show FDA the level at which the effects are going
13 to occur, okay, because the dose makes the poison.
14 Well, the lack of dose, therefore, is an indicator
15 of safety. We have to worry about those respects.
16 And it seems like that needs to be brought into
17 the picture for many of these comments. Thank
18 you.

19 MS. GOULD: Janet Gould, Bristol-Myers
20 Squib. And I just want to follow up with what
21 Tony and Chuck just said about dose response,
22 because before coming here to prepare, I looked

1 through our drugs that are on the list to try to
2 understand why they were put on the list.

3 And so I was looking at, okay, if it has
4 a positive, then on the table, that meant, you
5 know, it was a carcinogen and animal studies or
6 repro studies or a category D, it was -- caused
7 developmental effects.

8 But then when I looked at the dose that
9 causes it, it could be, yes, it was -- caused
10 tumors in animals, but the dose was much higher
11 than the one mig per kilogram that was noted in
12 the note, or the ten mig dose, therapeutic dose.
13 So I would like comments on the dose, as well.

14 MR. CONNOR: Well, basically what I
15 said, we took a qualitative approach. We
16 developed a list that we would like you and others
17 to comment on, and these are the types of comments
18 that we want back. So, again, this list is not
19 set in stone. We developed something to work
20 with. The easiest way to do it was to put a
21 plus/minus because there were so many drugs, we
22 just couldn't list out all the information on a

1 single table. So this is a starting point for us
2 basically. So --

3 MS. GOULD: So then I guess I'm
4 wondering, for providing comments on our drugs,
5 would it be helpful, you know, for either arguing
6 for or against it being on the list, to provide
7 that. I mean the data based on the criteria and
8 you would take a look at that, that would be a
9 good way to go about it?

10 MR. CONNOR: Yes; and some of them --
11 obviously, some of them are very high doses, many
12 times the therapeutic dose, but if you look at
13 some -- we were looking at some of them yesterday,
14 and in fertility, sometimes it's only very close,
15 one or two times, three times the therapeutic
16 dose, so we have to take that into consideration
17 also.

18 MS. GOULD: And I guess if the
19 therapeutic dose is like way above ten migs and
20 it's at the therapeutic dose, that's a different
21 situation than if it's much lower.

22 MR. CONNOR: Yes.

1 MS. GOULD: Yeah.

2 MR. REED: Thanks. I would just add
3 while the next questioner comes up that if you
4 have comments on specific chemical, excuse me,
5 drugs, or comments on the process itself that you
6 don't -- you would like to expand on or provide
7 additional information, the docket is the best way
8 to do that. And, Barb, at the break, I think
9 we'll put that docket information on the web site
10 up on the flow chart or the chart here.

11 MR. O'KELLY: Hi, Jim O'Kelly from
12 Pharmacology Associates. A couple of points; we
13 look at hospital's operations and we're concerned
14 about the potential complexity of a hospital going
15 about implementing this. We're primarily looking
16 at RECRA on your published list already, and when
17 we look at hospitals, they just throw up their
18 hands because it's just too complex.

19 And I think one of the particular, I
20 talked to Cindy about this on the phone,
21 particularly to go to more and more of a tiered
22 approach or the different categories, it's hard

1 for us, when you actually see what's going on in
2 the hospital, it's hard for us to envision how
3 they can implement the finer points within your
4 current -- the direction you're moving.

5 So if there's anything you can do to
6 simplify it with an eye to how the hospitals are
7 actually going to implement the precautions and
8 the -- we deal with the recommended waste disposal
9 as one issue. So --

10 MR. REED: I'm sorry, just a question on
11 that. Are you looking for guidance more on the
12 issue of worker protection or the disposal?

13 MR. O'KELLY: Well, I'm trying to think
14 of the implications within the hospital
15 environment on how they have to respond to the
16 entire life cycle of your drug. And to the extent
17 that -- right now, when we look at how hospitals
18 are currently operating within the various RECRA
19 plus your initial list plus the other lists that
20 are out there, we don't see the level of
21 compliance that we would hope for, primarily
22 because they just can't keep up with it. So I

1 just think that -- I would strongly encourage you
2 to consider the operational implications within a
3 hospital, because, you know, we're concerned that
4 people will just say -- I can't even begin to
5 abide.

6 And we generally just -- we incorporate
7 your recommendations in our recommendations, and
8 we're having a -- running into a challenge. The
9 people go, you guys are being too conservative.
10 So that's one issue, and just a couple of others.

11 Along with that, to the extent that
12 there are any other lists that are out there, and
13 I can provide you our sources if you'd like, we
14 would encourage you to make sure that you're
15 integrated with those other lists because there's
16 frustration in the community with the differences
17 between the list of carcinogens in particular.

18 And one of the things as I came in, you
19 mentioned your goal was to update this list every
20 year, I don't think the community can absorb that.
21 I would encourage more of a three to five year
22 time table, because the thought that somebody

1 would have to revisit this process, revisit their
2 training every year, I think that would be just --
3 I don't know that you could do it, but I don't
4 know that anybody would be happy to do it.

5 MR. CONNOR: Well, as I mentioned, you
6 know, we haven't done this in three years, so that
7 we do have very large lists. We don't foresee
8 that unless you guys keep approving new drugs all
9 the time. Actually, the drug approvals the past
10 few years have been higher than they have in the
11 past, so we had a double whammy.

12 We got more drugs and we had more years
13 that we had to look at. But I think -- I
14 understand the question about -- you talked about
15 how you deal with this on a practical basis. We
16 get many calls every -- almost daily on specific
17 issues on how to handle this. A lot of them deal
18 with how do we dispose of the waste materials.

19 I'd be interested in any of the lists
20 that you have that we could look at. We have
21 tried to be conservative. As I mentioned, some of
22 these -- some of the drugs on this list may not

1 stay on the list.

2 We are not changing what we have done
3 since the Alert was first published, we're just
4 adding -- updating the list. And I really think
5 -- I personally think that's a good thing. A very
6 toxic drug comes out, should we wait three years
7 to tell people that they have to handle this on a
8 -- using proper precautions? So I know it's
9 difficult for you guys, and the whole issue of
10 RECRA lists versus, you know, hazardous drug list,
11 is a very complicated issue to deal with. Thank
12 you.

13 MR. REED: Thanks. I would just
14 reiterate a point that Tom said, that if you have
15 information on additional lists that we haven't
16 considered, please send those. It's best I think
17 to send it to the formal docket. Thanks. Any
18 other questions?

19 MR. SIGLER: Hi, I'm Joel Sigler with
20 Kaiser- Permanente. In my organization, one of
21 the drugs that we're struggling with trying to
22 figure out engineering controls based on your

1 list, it's created a lot of discussion in our
2 organization, is BCG, and there are those that are
3 in favor of significant engineering controls and
4 others that think that's too conservative. I'm
5 just wondering if you'd give any insight to the
6 discussion that may have occurred when BCG was
7 originally put on the list? That might give us
8 some guidance.

9 MR. CONNOR: Initially it was on the
10 list, and this is one we do get questions on. It
11 was on the list because it was on those lists that
12 we adopted for the first go around. Lucy Powell
13 was scheduled to be here, most of you know Lucy.

14 Her recommendation is that BCG should
15 not be on the list of hazardous drugs the way it
16 is, because it should be handled separately from
17 other drugs so you do not get cross contamination
18 of those drug products, which have been shown in
19 the past, there is evidence to document that, that
20 the BCG should be handled in a separate
21 containment isolator biological safety cabinet
22 from IV drugs. And she and I have had quite a few

1 discussions on this, about whether it should be on
2 that list, whether we should identify it
3 differently somehow with a footnote or something,
4 so that's something that we need to take into
5 consideration. Did I answer your question?

6 MR. SIGLER: Yeah; and I'm sorry, I
7 don't want to get too specific about this, but it
8 sounds like you're saying that it may or may not
9 end up on the list, but you would still recommend
10 some kind of barrier isolator or other engineering
11 controls?

12 MR. CONNOR: Yes; I think that's what
13 Lucy -- I think if you look in the package
14 inserts, the recommendations by the manufacturer,
15 I think that --

16 MR. SIGLER: Yeah; I'm just wondering,
17 any other insight to discussion of whether even
18 that was necessary? Because some of our people in
19 our organization think that it's not really an
20 airborne hazard and it's more of a, you know, a
21 needle stick hazard. I don't necessarily feel
22 that way, I'm just wondering if there was any

1 other discussion that you might be able to share.
 2 MR. CONNOR: I don't know if I've seen
 3 data on that, I'm sorry.
 4 MR. SIGLER: Okay, thank you.
 5 MR. CONNOR: Okay.
 6 MR. REED: Thanks, Joel. Any other
 7 questions or comments?
 8 MR. SCHATZ: Tony Schatz,
 9 Shering-Plough. Did I hear you correctly when you
 10 said that you were not going back to the original
 11 list to update that, you were just adding or
 12 subtracting from it? Because I mean they were
 13 based on different criteria than what you're
 14 basing the updates on.
 15 MR. CONNOR: That is correct. Right now
 16 we are not looking at the appendix A, that is in
 17 the Alert, we're not making any changes to that.
 18 BCG might be an exception because it does not
 19 really fit in the hazardous drug list, it should
 20 be a separate category.
 21 What we did, which I did not mention,
 22 we, at NIOSH, took that original list, appendix A,

1 and applied NIOSH criteria from the definition to
 2 that list in retrospect, and those drugs that we
 3 have on there fit that definition.
 4 MR. SCHATZ: So the current definition
 5 you're using the drugs on appendix A fit that?
 6 MR. CONNOR: I'm sorry, say that again.
 7 MR. SCHATZ: The definition you showed
 8 --
 9 MR. CONNOR: Yes.
 10 MR. SCHATZ: -- with the three source of
 11 information, they meet that?
 12 MR. CONNOR: Yes.
 13 MR. SCHATZ: The ones that are on the
 14 list?
 15 MR. CONNOR: So we went, again, in
 16 retrospect, after we had that list, and we applied
 17 those criteria to that list.
 18 MR. SCHATZ: Okay. And the discussion
 19 about dose response and exposure and clinical dose
 20 was mentioned, and whether that's relevant to
 21 occupational exposure, you know, is the question.
 22 But is there going to be, at maybe an outcome of

1 this, more guidance put in the Alert for risk
 2 assessments as opposed to you need to do a risk
 3 assessment? Will there be any kind of guidance
 4 put in there on dose response or physical form or
 5 certain things that people need to consider for
 6 risk assessment?
 7 MR. CONNOR: I think it would depend on
 8 the feedback that we get from you guys. If you
 9 feel strongly about those issues, please send that
 10 information to us by way of the docket.
 11 MR. REED: Yeah; Tony, I would agree
 12 with Tom, that we would certainly consider that
 13 information. And if we think there's a sufficient
 14 need for guidance in this area, dose response will
 15 certainly address it.
 16 MR. CONNOR: This is an ongoing process,
 17 we are developing it, we hope to keep refining it
 18 as much as possible.
 19 MR. McGRATH: Good morning. Bill
 20 McGrath, Bristol- Myers Squibb. Just a general
 21 comment about the two lists that we have here.
 22 I'm looking at the original appendix A, which only

1 has the generic name, the source, how it got on
 2 the list in the first place, and the therapeutic
 3 application of the drug, and the new list which
 4 has a lot more information, justifying whether or
 5 not it would be on the list. I would suggest, you
 6 said you don't intend to modify the appendix A
 7 right now, but I think in order to make it a more
 8 helpful document, since we do talk about dosage
 9 form earlier in the guidance, that we at least add
 10 the house applied column to the overall list when
 11 it gets updated. I think this kind of
 12 information, if I were a person that was working
 13 with the compound, I'd be -- and there were many
 14 dosage forms for a particular compound, there
 15 might be an injectable version, there might be a
 16 solid dosage tablet and capsule like cytoxin, for
 17 example.
 18 I think in helping make decisions about
 19 risk, it would be very helpful to know how the
 20 drug could be supplied in the health care
 21 facility. So I think any more information,
 22 creating more of a table with additional

1 information, I think that's going to improve the
2 value of the list itself rather than just whether
3 or not an individual compound is on the list or
4 not.

5 MR. REED: That makes sense, thank you.

6 MR. CONNOR: Come on, Alan.

7 MR. REED: Come on, bring it on.

8 MR. ADER: Okay. Alan Ader from Safe
9 Bridge Consultants. I wanted to reiterate a
10 couple of points made by some of the folks and
11 then add a few comments in general. We took a
12 look at the list and there are at least 15 to 20
13 compounds that should not be on the list because
14 they haven't had a quantitative risk assessment
15 done. As Chuck said, the dose makes the poison,
16 and I think it's critical to understand that in
17 the nature of this process. The second point I
18 wanted to make was, the nature of the testing
19 approaches for FDA approvals versus to deal with
20 these types of compounds, FDA follows OECD
21 guidelines and other guidelines, testing
22 guidelines, that requires for reproductive and

1 developmental tox, that a toxic dose be achieved
2 so that to cause maternal toxicity in some of
3 these tests. At some point there is a dose
4 limiting -- a dose, but many of these compounds
5 have maternal toxicity at very high doses, and I
6 think we're placed in that list because they did
7 show that, but they're not occupationally relevant
8 because they are at such high doses.

9 So the nature of the testing should be
10 evaluated as part of this overall quantitative
11 risk assessment. And significant scientific rigor
12 should be applied so that you can actually have
13 appropriate designations. If you have a compound
14 on your list that shouldn't be handled like
15 others, it may dilute the overall impact of the
16 listings.

17 Lastly, the point that has not been
18 made, which I think is important, is for a group
19 of these compounds that are not absorbed
20 occupationally, in other words, they're higher
21 molecular weight compounds that are not absorbed
22 by inhalation, which is the primary route, and by

1 dermal routes, because they're large molecular
2 weight materials, and that should be taken into
3 account.

4 There are probably five to ten of those
5 compounds on the list for which rigor, in
6 evaluating whether they should be on the list,
7 should be applied. They're only given by IV
8 injection because of that reason. And many
9 companies do not consider them to be hazardous
10 drugs, although they need to, like all
11 pharmaceuticals, need some rigor in their
12 handling. So those are my points. I guess -- I
13 had one question. In the current system that you
14 have for submitting comments, you don't really
15 have a section on general comments? You'll accept
16 those, I assume, but do we need to go to some
17 other page and submit general comments in addition
18 to the specific comments drug by drug?

19 MR. REED: No, I'd like to keep it
20 simple. Barb, if you're okay with it, just to go
21 to one -- to the one web site for both general and
22 specific comments, is that --

1 MS. McKENZIE: Yeah; there's an address
2 on the comment --

3 MR. ADER: Okay. Because right now I
4 just saw -- all I saw is yes, no, maybe, or --

5 MS. McKENZIE: Right; at the top of the
6 comment, on the right hand side, there's an email
7 -- send your comments to that address.

8 MR. ADER: Okay.

9 MS. McKENZIE: And I'll put those up on
10 the -- on the break.

11 MR. REED: Okay. Thanks, Alan. Just to
12 clarify in my mind, you said the 15 to 20 drugs
13 that were on the list you don't think should be on
14 the list, and that's the new list, correct?

15 MR. ADER: Yeah; not the past list, the
16 current list, the 62.

17 MR. REED: Okay.

18 MR. ADER: There's probably at least 15
19 to 20.

20 MR. REED: Okay.

21 MR. CONNOR: I just wanted to mention,
22 we are very concerned about diluting the list with

1 drugs that should not be on the list. We think
 2 that's certainly counter productive if we do that.
 3 But suppose you have, I'll throw out a question to
 4 you guys, a high molecular weight drug that's
 5 probably not going to be absorbed -- or inhaled,
 6 but it's super toxic, really toxic, very low
 7 doses; now, would you make an exception for that?
 8 Suppose it's therapeutic, you know.

9 MR. ADER: The general answer is, it
 10 depends.

11 MR. CONNOR: I think -- why don't we
 12 take -- how long are we scheduled for a break?

13 MR. REED: I would suggest that we take
 14 a break. I think we're going to finish early, but
 15 I want to make sure that there's ample time for
 16 comments and questions. So I would suggest that
 17 we take a break now. I have 10:30, if we could be
 18 back by 10:45, we can talk, you know, do whatever,
 19 and then come back with additional questions with
 20 a fresh mind. So 10:45, please.

21 (Recess)

22 MR. REED: Okay, thank you. We'll

1 regroup here. Barb is going to give us a primer
 2 on the web site addresses here for comment.

3 MS. McKENZIE: The hazardous drugs web
 4 site is www.cdc.gov/NIOSH/topics/hazardousdrugs.
 5 And another easy way to get to it is if you just
 6 go to the NIOSH web site, which is
 7 www.cdc.gov/NIOSH, click on H in the alphabet up
 8 at the top, and you'll get to the H list, and
 9 hazardous drugs is there under health care, you
 10 can just click on that.

11 At the very top of that page, there's a
 12 box about this public meeting, and there's a link
 13 to the Federal Register notice and a link to the
 14 page that has the fit list, the not fit list, and
 15 the comment grid. And the comment grid gets
 16 mailed back to the docket office, which is
 17 NIOCIN.docket@cdc.gov, and that is at the top of
 18 the right hand -- on the right hand side of the
 19 comment grid, mail to.

20 And if you just put hazardous drugs in
 21 the subject line, it will get to the right
 22 mailbox. And you can also send general comments

1 to that email address also, not just the comment
 2 grid, and questions or, you know, anything that
 3 you have. Tom and I both will view that mailbox
 4 on a regular basis to see what comes into it.

5 MR. REED: Thanks, Barb. Any questions
 6 on the docket information? Again, September 20th
 7 is the deadline for comments formally submitted.
 8 Tom and I had a short discussion at the break, and
 9 there was a question, I forget who it was who
 10 raised the question about the original list, and
 11 this particular meeting is principally for -- to
 12 comment on the updated list of hazardous drugs,
 13 the new proposed additions to the list. We would
 14 also consider comments on the original list
 15 itself. So, again, it would be best if you could
 16 send those to the docket with specific comments.

17 So we have a chance after the break now
 18 to get back into questions and comments. Again,
 19 we're looking for both comments on the actual
 20 definition itself, the process, and if you have
 21 comments on the specific drugs themselves, if
 22 there's sufficient time, we would be happy to hear

1 those, as well. So any additional questions from
 2 the public?

3 MR. NAUMANN: Bruce Naumann from Merck.
 4 I just had a question to help get us, you know,
 5 back on track and thinking about what we're really
 6 trying to accomplish here, because obviously we're
 7 all -- we all have the same goal, we're trying to
 8 protect health care workers.

9 And I wanted to ask Tom a question.
 10 He's done a lot of work over the years monitoring
 11 levels of hazardous drugs and various health care
 12 settings and published a review article I think
 13 earlier this year on the subject. I'm wondering
 14 if you can just help us understand in general what
 15 you've seen over the years in terms of levels
 16 outside of biological safety cabinets on the
 17 floor, et cetera, and try to relate it back to
 18 what the -- kind of the overall philosophy of the
 19 Alert is, trying to increase awareness, making
 20 sure people are using proper precautions. And if
 21 you have anymore recent data after the Alert has
 22 -- now that the Alert is out a few years, to see

1 if things are actually improving or ultimately,
2 you know, considering there are safe levels for
3 hazardous drugs, how much of a margin of safety
4 there might be and how much more work we have to
5 do to get to what our goal is in terms of -- I
6 mean obviously the best level would be zero, we'd
7 like to see no measurable -- and reality is, you
8 are measuring some, and I'm wondering, you know,
9 order of magnitude -- per square centimeter, et
10 cetera, and if you have a goal in mind as to what
11 you're really trying to accomplish.

12 MR. CONNOR: Thank you, Bruce.
13 Basically, I think -- starting off when we had our
14 initial discussion about the Alert was to make
15 people aware of the issue. Back in the 1980's,
16 there were studies done that showed the use of
17 biological safety cabinets had reduced exposure,
18 and the methods then were quite crude. They were
19 looking at chemical mutogens being excreted in the
20 urine and measuring those and the study that was
21 done by Roger Anderson, who was the Director of
22 Pharmacy at M.D. Anderson Cancer Center for many

1 years.
2 It showed that when you stopped using
3 the horizontal flow, which obviously blew all the
4 drugs towards the worker, that the amount of
5 mitogenic drugs being excreted in the urine went
6 down considerably. So, you know, at that time,
7 everyone said we'll get a class 2 biological
8 safety cabinet and we're okay, we don't have to
9 worry about technique, we don't have to worry
10 about anything else. And then studies started
11 coming out of Europe. Paul Sessinc in the
12 Netherlands and some other researchers in Italy
13 and Germany started doing environmental studies,
14 and people were using biological safety cabinets
15 and so forth, and they were still showing
16 contamination in the pharmacy, in the patient
17 treatment areas, basically doing wipe samples,
18 measuring the amount of drugs that were on work
19 surfaces and floors and so forth.

20 So a number of us realized that we
21 probably have the same problem in the United
22 States. So with Melissa's help and Larry's help,

1 we initiated the NIOSH working group. And we
2 developed the Alert, basically at that time just
3 to raise awareness.

4 And I think we have, we've gone, you
5 know, we have strong associations with Oncology
6 Nursing Society, ASHP, some -- also with ANA, and
7 pharmaceutical manufacturing groups, and I think
8 we've gotten the word out to a lot of people in
9 the United States and around the world.

10 We get questions on almost a daily basis
11 on specific handling issues, either by email, by
12 telephone, from U.S. -- all around the world, and
13 there's certainly an awareness of this issue, and
14 I think that was our major goal. As far as the
15 levels are found, you know, we usually measure
16 nanograms per square centimeter, two or three or
17 four of the more common drugs, and they're good
18 methods available for sampling, environmental
19 sampling and measurement of sycoflocimid, (?)
20 iflocimid, (?) fluorouracil, methotrexate, -- and
21 a few others. So they've typically been used as
22 markers.

1 But as I mentioned, there's about 100
2 antineoplastic drugs out there and 120 drugs that
3 we consider hazardous, so we don't know, you know,
4 some of the drugs could be much higher levels than
5 the ones that we're looking at, we really don't
6 know that. But we use these as markers, as some
7 indication of exposure.

8 And we have not really done longitudinal
9 studies. We're analyzing some data now that will
10 give us a feel for changes that have taken place
11 in the U.S. There's really not that many studies
12 that have come out of the U.S. looking at this.
13 There's been a few, the one published by WIK a few
14 years ago, but really not a whole lot.

15 We've seen levels from, you know, down
16 to our limited detection, which is a couple of
17 nanograms usually per square centimeter up to, you
18 know, several hundred, even up into thousands of
19 nanograms per square centimeter.

20 So, you know, that's not much, but when
21 you multiply that by, you know, 100 square
22 centimeters, which is sometimes used for

1 calculation for germal exposure, that could be a
 2 considerable amount of that one drug, and we don't
 3 know what's going on with the other drugs. So
 4 it's been about -- in that range. We would
 5 obviously -- we know we can't get it down to zero.
 6 We would like to, you know, reduce the exposure as
 7 much as possible using engineering controls and
 8 then backed up by proper use of technique and
 9 personal protective equipment. Melissa, do you
 10 want to add anything to that on an overall
 11 philosophy since you were so instrumental in a lot
 12 of this?

13 MS. McDIARMID: Well, in terms of
 14 whether there's the efficacy question, which I
 15 think maybe Bruce is wondering why -- was it worth
 16 it or what did we do, I guess even before we say
 17 was the effort regarding many of our people --
 18 activities regarding the Alert, I think it was,
 19 but there's only sort of semi- quantitative
 20 information kind of -- a nurse that had been in
 21 our group at Maryland did a -- I don't know if
 22 some of you remember, we were in San Antonio at

1 the Rollout, we were doing an onsite
 2 questionnaire, and it was to try to see -- we got
 3 permission for anybody who signed up for that to
 4 be able to call them back in six months to find
 5 out whether there was any change in handling or
 6 level of visibility in their hospitals.

7 We wanted to kind of see whether this
 8 was going to just be, you know, like a one shot
 9 wonder or whether they were going to actually do
 10 something. And I don't recall the detail, except
 11 that I think a majority of the folks did have a
 12 working group put together or something like that
 13 as a result of coming to the meeting. Of course,
 14 some places are more ready to hear the gospel than
 15 others, as we know, right, so -- and they may have
 16 already, you know, this maybe -- first of all, the
 17 fact they even came to the meeting in San Antonio
 18 meant that they were sort of thinking about this
 19 or we had, you know, so maybe they were the worry
 20 well, we might say.

21 But like Tom, I probably get at least
 22 two or three calls a month about it, and typically

1 they're in the area that a doc does, which is like
 2 surveillance, alternative duties, stuff like that.
 3 And unfortunately, I think we needed to remind
 4 people.

5 But as somebody who used to be at OSHA,
 6 and I was very instrumental in writing the 1995
 7 guidance, it kind of griped me that we even needed
 8 to do this again, because you would think people
 9 would get it, and I can't think of another
 10 industry that has, you know, such common use of
 11 just no holds barred toxicons.

12 And I know you guys in Pharma don't
 13 understand the way that -- what goes on in
 14 hospitals, but it would make you crazy. I mean
 15 you'd be taking aspirin every day if you were in
 16 charge of the safety and health, because it's just
 17 a totally different deal than what you're used to
 18 seeing in your places, which are, you know, very
 19 well controlled, and your companies invest in
 20 safety and health. That's not happening in health
 21 care, it is still not happening in health care,
 22 not just with these toxicons, but with anything.

1 I mean they're just now getting to blood borne, I
 2 did you not, and TB, and respirators don't make
 3 me, don't make me, and do we really have to fit
 4 test. I mean it's all this get out of jail free
 5 card stuff because we wear the white hats and we
 6 don't have enough money, and yet, as some of you
 7 have heard me say, nobody told paracelsus (?) to
 8 call off the rules of toxicology because they're
 9 entering a hospital, you know, that's not the
 10 deal.

11 And unfortunately we are just now
 12 getting them kicking and screaming to deal with
 13 not just this hazard, but all kinds of them. But
 14 I think that the hook we have, in a way, for
 15 hazardous drugs is, even me, who has practiced in
 16 health care my whole career would say, some of
 17 these agents are at the top of the hit parade in
 18 terms of hazard.

19 You know, a lot of our colleagues never
 20 work in an industry where group one carcinogens
 21 are still handled on a regular basis, let alone
 22 with complete disregard for safe handling.

1 complete. And explanations vary from I didn't
2 know to I'm in a hurry to don't make me or the
3 training or HAZCOM doesn't cover it, which, of
4 course, is not true.

5 You know, this pull down menu of excuses
6 would just make us crazy if we were in another
7 industry, but in health care, it's just ubiquitous
8 (?). But I think what's finally getting peoples
9 attention, and I'm getting back to the original
10 question that Tom said was, I think that the
11 resurgence of interest and concern that the Alert
12 generated did allow another generation, if you
13 will, of maybe younger health care workers or
14 younger safety and health people who had to sort
15 of do training or get religion or whatever, I do
16 think that it's ultimately helped.

17 But, you know, as I said to Tom
18 yesterday, you know, there is change at a glacial
19 speed, that's true in federal agencies and it's
20 way true in health care institutions.

21 And it's just a really tough issue
22 because they -- some of my colleagues in other

1 areas of occupational health have said that, you
2 know, to all the excuses, we hear probably some of
3 you from your own companies about doing the right
4 thing, to all those excuses, add this notion of,
5 in health care, you're sort of, you know, our
6 business, our mission is care of the sick, and so,
7 you know, we're supposed to sacrifice ourselves.

8 And a number of us have actually even
9 written papers on why health care doesn't get it,
10 and I think part of that sacrificing yourself is
11 the expectation, you know, that we inherit from
12 Florence Nightingale, who, you know, kept the hot
13 stovepipe from falling on a patient by exposing
14 her own arms to it, and we're still doing that
15 every day and accepting explanations for hurrying
16 to do the work, or cutting corners because a
17 patient needs the drug, or we can't afford the
18 right thing to do, so we'll muddle through.

19 But it's just these toxicons are so
20 unforgiving that, you know, the rules of risk
21 don't get called off because of our wholly
22 mission, and that's just been a really tough thing

1 to sell, especially in this time of, you know,
2 this huge financial crisis in health care. So all
3 by way of saying, yes, I think the intervention
4 has helped, and I think, you know, these updates
5 have helped.

6 But it's incredibly frustrating, from a
7 safety and health point of view, because this kind
8 of recalcitrance just wouldn't be accepted in
9 another industry, but it is in health care because
10 of this psychosocial notion of us, you know,
11 sacrificing ourselves and not spending the little
12 bit of money there is on health care protection.

13 But this will be the last thing I say.
14 For anybody that has to, you know, kind of sell
15 this, I remind folks, besides the paracelsus
16 comment that I made, that, you know, in the same
17 way that, when you get on an airplane and they
18 always tell you, if the oxygen mask appears and
19 you're with a child, they tell the adult to put
20 the mask on first, even though that might seem,
21 you know, momentarily inappropriate, you do that
22 so that you don't fall out and so that you can

1 still take care of your child, and I think that's
2 the same thing, and I've used that example giving
3 talks in health care, that we have to protect
4 health care workers, as well, because otherwise,
5 we're not going to be able to care for our
6 patients, or certainly in the example of -- or a
7 pandemic flu, if we, you know, if we're namby (?)
8 about wearing respiratory protection and having
9 those standard rules at our emergency room door,
10 we're going to have to close the institution,
11 because we're going to contaminate it from the
12 inside and the outside, and then where will the
13 mission be. And this is just really hard for our
14 community to get. But I think that they do get
15 the airline thing and that sort of makes sense to
16 people. So that's kind of, you know, one of the
17 things that I bring up when I'm talking to
18 leadership in health care, to help them kind of
19 get it. Anyway --

20 MR. CONNOR: Thank you.

21 MS. McDIARMID: You're welcome.

22 MR. CONNOR: Bruce, does that answer

1 your question?
 2 MR. NAUMANN: Well, actually --
 3 MR. CONNOR: Go ahead.
 4 MR. NAUMANN: -- now that we've got the
 5 discussion going, I hope I didn't, you know, send
 6 the message that I didn't think it was worth it.
 7 MR. CONNOR: Oh, no.
 8 MR. NAUMANN: I'm a busy guy and I
 9 wouldn't be spending my time doing this unless I
 10 thought it was worth it. What I was really trying
 11 to do was, focus -- because we were getting there
 12 with the earlier comments, more in the concept of
 13 how do we make the process as efficient and
 14 science-based as possible so that we will have
 15 greater, you know, compliance at the hospitals?
 16 How do you, you know, avoid the delusion effect?
 17 And so as we go through the, you know, the process
 18 of trying to evaluate each of the proposed new
 19 listings, and actually, some of the ones that are
 20 proposed not to be on the list are possible
 21 candidates, too, after looking through them, some
 22 are borderline, that's the question. Where do we

1 draw the line? What are we really trying to
 2 accomplish?
 3 Which subset of compounds do we want to
 4 single out to say, you know, hospitals or
 5 whatever, you really need to focus on these
 6 compounds, forget about these others ones that are
 7 just kind of borderline.
 8 If you look -- if you do any kind of a
 9 risk assessment, you realize you're, you know,
 10 orders are magnitude away from a problem. Which
 11 are the ones that we really -- do you really need
 12 to focus on to make sure that you're protecting
 13 your workers?
 14 MR. REED: Thanks, Bruce. As the next
 15 speaker comes up, I just want to mention as an --
 16 it's more of an anecdotal aside. From Melissa's
 17 presentation, you can see how passionate and
 18 intellectually, sort of the focus she's brought
 19 this topic to our attention. From where I sat
 20 seven years ago now almost, she single handedly
 21 sort of stimulated the NIOSH involvement that got
 22 this off the ground.

1 And one last sort of tangenuous side to
 2 what Tom mentioned earlier, we do have some
 3 additional documents that are being spun off from
 4 the Alert, to provide additional recommendations
 5 in the areas that we thought were important, that
 6 we didn't cover as thoroughly and deeply in the
 7 Alert as we would want to have done at the time,
 8 and also, the additional information has come to
 9 our -- that we want to expand upon. For example,
 10 medical surveillance, there's a work by solutions
 11 document that's been finalized.
 12 We had one in the draft stages as being
 13 peer reviewed on protective equipment, one in its
 14 very early stages on engineering controls, and
 15 lastly, we have a fourth topic that probably won't
 16 be a work by solutions, it'll be some other type
 17 of technical policy document on alternative duty.
 18 So we have additional work in this area that we
 19 hope to help in this transformation process.
 20 MS. BROWN: Can everyone hear me? I
 21 usually don't have any problem carrying my voice
 22 either. I'm actually the weird person in this

1 group.
 2 MS. REED: Excuse me, could you identify
 3 yourself, please?
 4 MS. BROWN: Oh, I'm Dianne Brown, I work
 5 for AFSCME, which is the American Federation State
 6 County Municiple Employees.
 7 I'm not a doctor, I'm not a nurse, I'm
 8 not a scientist, I am a health and safety rep for
 9 a union. And I am the voice of the housekeeper
 10 and the custodian and the pharmacy tech. And for
 11 the folks in this room, I want you to remember,
 12 especially public employees, public hospitals that
 13 really have no money, they are not using the
 14 engineering controls that you think they're using.
 15 The technique out there would make you cry, okay.
 16 I don't even do this stuff for a living and I can
 17 look at the technique and it makes me cry, okay.
 18 Just from working with this great group, I'm
 19 working with a lot of public hospitals now, and
 20 the reason I am is because of the Alert, because
 21 some of the pharmacists who I don't represent read
 22 the Alert and started raising some questions, and

1 then the pharmacy technicians got brave enough to
2 start asking the questions, too, who are, in some
3 cases, actually showing symptoms of over exposure.

4 I think that the medical surveillance
5 work place solution is very important because I
6 actually have a hospital who's actually
7 considering putting it in place for the pharmacy
8 techs because of that document.

9 So when we look into increasing the list
10 or adding to the list, I want you to remember that
11 all scientific studies that you do in your perfect
12 world, that gets all thrown out the window when
13 you talk about who's mixing this stuff, especially
14 in some of these public hospitals. Even the
15 teaching hospitals are not as pristine as we would
16 like to think they are.

17 I saw stuff being mixed in a basement,
18 in a -- I'm serious, it was a converted janitor's
19 closet that they were mixing these drugs in, and
20 there were shelves of all kinds of stuff all
21 around them, stuff that shouldn't have even been
22 there, and they're mixing in this tiny place and

1 practically running into each other. And they
2 wouldn't allow me to bring a camera in, but I wish
3 I could have taken pictures and shown them to you,
4 because that's the world that I'm living in. And
5 I do think that these updates are very important.
6 I'll be really interested to see the other
7 documents that come out, because I can use those
8 to start these conversations and to get with these
9 hospital administrators about, I know you have
10 this amount of money to work with, but we really
11 need to control these because you may be
12 contaminating your patients, you know, other
13 places in the hospital, you might be contaminating
14 visitors, not to mention your workers, and in
15 particular, the housekeeping staff who really get
16 no training at all.

17 And don't forget that, you know, over
18 half the states have no OSHA protections at all,
19 at least not currently, and so there's nobody
20 going to go in and smack them around, nobody is
21 going to get a fine, nobody is going to get
22 inspected.

1 So what our folks depend on are the type
2 of documents you have that NIOSH puts out, because
3 they don't even want to hear the word OSHA, they
4 don't even look at the standards, they could care
5 less -- technical documents as recommendations as
6 how I push these changes in these work places.
7 Thanks for the time.

8 MR. CONNOR: Thanks.

9 MR. REED: Thank you, Dianne. Any other
10 comments or questions?

11 MR. JOHNSTON: Jim Johnston from WYETH.
12 You mentioned engineering controls, and I
13 wondered, in terms of quantitative evaluation,
14 whether or not you had considered surrogate
15 testing, typical drug preparation steps to look at
16 exposure risk potentials?

17 MR. CONNOR: We haven't really discussed
18 that. I don't see -- I think it's the standard
19 practice that's used, I think it addresses a bit
20 more. But certainly using surrogates, I did one
21 study using fluorescein dye, you know, florosi (?)
22 dye they use for training for pharmacists and

1 nurses to look at the technique.

2 I think if you have a suitable
3 surrogate, if you're testing in engineering
4 control, it's a lot safer than using the agent.
5 There may be some drawbacks to that because of the
6 physical characteristics. I think maybe Alan
7 could address that a bit more.

8 MR. JOHNSTON: Yeah.

9 MR. CONNOR: Just a follow-on for Alan
10 is that, there are typical different types of drug
11 preparation steps, and typical ways they're
12 handling, depending on the form and so forth, and
13 to make evaluations on a particular way in which a
14 drug is formulated and so forth might be helpful
15 to evaluate this particular methodology versus
16 another one and do that in a quantitative way.

17 But perhaps Alan wants to talk to that.

18 MR. ADER: Alan Ader from Safe Bridge
19 Consultants. We do a lot of work for
20 pharmaceutical companies and we've done some work
21 in the drug delivery and hospital pharmacy type of
22 -- and compounding pharmacy to look at worker

1 exposure under different conditions, different
2 compounds, using both surrogates and the actual --
3 what we call the active pharmaceutical ingredient,
4 and we would always urge both -- and I think that
5 this is an important aspect, that the quantitative
6 exposure assessment needs to be performed for your
7 facility, for your particular use.

8 Whether you have the resources or not to
9 do that is another question, because certainly a
10 public hospital may not have the funds to do
11 quantitative industrial hygiene assessment. But
12 as you already have pointed out, you could
13 qualitatively assess that and say it doesn't look
14 right based on some criteria which has been
15 established by the NIOSH hazard alert.

16 So you could do both a qualitative risk
17 assessment and a quantitative. As an industrial
18 hygienist and toxicologist, I always learned to
19 take your pumps with you and try to do that. But
20 it doesn't seem to be the norm as it was 20 -- 25
21 years ago when I was an industrial hygienist to go
22 out and actually measure exposure, but you need to

1 do that.

2 And I think the hazard alert does say
3 you should consider that in addition to a
4 qualitative assessment. But I would urge NIOSH,
5 in their engineering aspect of, I think you called
6 it, Larry, you said something that there's going
7 to be an engineering document to support the
8 recommendations that you do quantitative
9 assessment of biological safety cabinets,
10 lamorative flow hoods, what do we call those
11 devices that are engineered solutions that go on
12 top of the, I'm not sure what you called it --

13 MR. CONNOR: Closed system transfer
14 device?

15 MR. ADER: Closed system transfer, and
16 any other devices that people have, ventilated
17 enclosures, and so forth, that there be
18 quantitative data to support, why are we using
19 this control. That's what's done in the
20 pharmaceutical industry.

21 We come up with quantitative data to
22 show, hey, this is why we're using this control

1 for this type of compound. And I would urge NIOSH
2 to consider developing some of the base data for
3 that for use in health care type of applications.

4 MR. CONNOR: Thank you, Alan. One quick
5 question, do you find that surrogates really
6 represent the drugs? I mean you've got --

7 MR. ADER: Yeah; as far as surrogates
8 go, the type of surrogates that are out there are
9 both, I would call them non- hazardous sugars,
10 like mannitol and lactose are used as indicators
11 of exposure. And then there are existing low
12 toxicity material such as naproxisodium and
13 acetaminophen are used.

14 I'm a favorite of using active
15 pharmaceutical ingredients, because I think they
16 behave a little bit more like the other types of
17 active pharmaceutical ingredients that you're
18 trying to mimic. But we tell our clients who do
19 surrogate tests to choose a surrogate which
20 behaves something like your active ingredients.
21 So the particle size and bulk density, these are
22 terminologies for pharmaceuticals, should be

1 similar. And if you're handling solutions, they
2 should have the same flowability characteristics
3 as your active pharmaceutical ingredient that
4 you're concerned about. If you have lyophilize
5 power, the lyophilize powder should be similar to
6 what you might handle with the active ingredient
7 that might be hazardous or toxic.

8 So we would recommend that you test
9 using a surrogate, but that you follow it up with
10 the actual compound that you might be interested
11 in evaluating. So test your unit or device or
12 control with naproxisodium or acetaminophen and
13 then follow that up with the active ingredient
14 that you're most concerned about, so that you show
15 a consistency between the results.

16 MR. CONNOR: Thank you. It's more than
17 I wanted, but that's all right.

18 MR. REED: Did that answer your
19 question, Jim?

20 MR. JOHNSTON: Yes.

21 MR. REED: Any other comments or
22 questions?

1 MR. RALE: Hank Rale, Containment
 2 Technologies Group, and kind of as a person with a
 3 foot in both camps, almost 30 years in
 4 pharmaceutical, and we build isolators for
 5 hospital pharmacy, as well. That was -- the idea
 6 of testing was primary before we ever released a
 7 product. We actually worked with Lucy Powell and
 8 developed procedures, techniques, and also worked
 9 with Safe Bridge Consultants to do significant
 10 testings so we understood what the exposure limits
 11 would be, handling 100 to 150 doses in an eight
 12 hour period, and doing air sampling and surface
 13 sampling. And we have all those protocols and
 14 would be happy to share them if you'd like to take
 15 a look at them.

16 MR. CONNOR: Okay, thank you.

17 MR. REED: Thanks, Hank.

18 MS. REILLY: Hi, Cindy Reilly again.
 19 Two comments, and the first was actually more of a
 20 question. Has any consideration been given to the
 21 characteristics of the worker? Like, for
 22 instance, we know the demographics of the work

1 force are changing, particularly in pharmacy, and
 2 I can't speak necessarily to other groups, but in
 3 pharmacy, it's increasingly becoming a female
 4 field, and so you're looking at different workers
 5 who are handling these agents at different lengths
 6 of exposure.

7 If you look at some of the agents that
 8 are proposed on the list, there are some that you
 9 might consider are toxic only to certain sub
 10 populations that are working with them, like a
 11 pregnant woman or someone of child bearing age
 12 versus a man with fertility, and then also some
 13 immunocompromised agent, so that if the worker was
 14 not immunocompromised, the toxicity might be less.

15 So has there been any discussion of that
 16 or -- work characteristics at all?

17 MR. CONNOR: No; I don't think we have
 18 taken that into consideration. We are aware that
 19 pharmacy is getting to be more and more women, and
 20 obviously, most of the nurses are women. We were
 21 talking in the break, one of the questions we get
 22 all of the time is about oxytocin, which is

1 obviously, in the third trimester, it could be a
 2 concern for occupation exposure. So, you know,
 3 that is one example where you would have a certain
 4 population that would be susceptible to that.

5 And I don't know if we should somehow in
 6 the Alert identify that it's only that population,
 7 because I get probably a call every week about
 8 oxytocin, why is it listed as a hazardous drug.
 9 So we really haven't looked to that issue. It's
 10 maybe something we need to consider.

11 MS. REILLY: Well, I think, just as --
 12 that the demographics of what is toxic and for how
 13 it will change, in fact, it will increase when you
 14 start to look at the changes in the work force.
 15 And your comment about oxytocin kind of leads to
 16 my next comment. We get calls about that, as
 17 well, and as we posted our comments, several
 18 members called us and said, are they going to look
 19 at the old list, you know, this is what we feel
 20 about this.

21 And then we also got some comments from
 22 individuals that felt that some of the drugs

1 should be on the old list that aren't. OKT3 (?)
 2 was suggested as something that should be
 3 considered. And then there was, you know, just
 4 some question as to why some drugs were
 5 considered, but not others. Protuximad is being
 6 considered, but not Implixomad, and I'm not sure
 7 -- I'm assuming that this was based on an
 8 assessment of the labeling. But there was -- I
 9 think the members were looking for some
 10 consistency, and I think that this is what makes
 11 it difficult for them to implement, because they
 12 see one agent on the list, whereas they see
 13 something with a similar mechanism and that's not
 14 included.

15 MR. CONNOR: Actually, this came up in
 16 the break, too. We did not include all
 17 monoclonalantibodies(?). We looked at each one
 18 individually and determined if it should be on the
 19 list. That's another question we get, you know,
 20 are monoclonalantibodies on the list of hazardous
 21 drugs, and we tell them certain ones based on the
 22 criteria. So we did it on a drug by drug basis

1 rather than on a class of drugs. And again, we
2 want consistency.
3 Like Bruce said, you know, we would like
4 to have a very concise list that people can look
5 at and not have questions about, but we still have
6 all these drugs that fall in that gray area around
7 that list, and those are the ones that really give
8 us the problem, and that's why we're trying to get
9 feedback on those that are in the gray area.

10 MS. REILLY: Okay. Thank you.

11 MR. CONNOR: Thank you. Excuse me, if
12 you have -- you said there were a number of drugs
13 on the list that you -- were not on the list; if
14 you could -- okay, let me know. And also, I think
15 Larry wanted to bring up the existing list.

16 MR. REED: Go ahead.

17 MR. CONNOR: This would be a good time.
18 We've mentioned BCG today, we mentioned oxytocin,
19 they're kind of a little bit of -- not really --
20 maybe -- and somehow we should handle them a
21 little bit differently than the list of hazardous
22 drugs. If there are other drugs on that list that

1 you feel strongly should not be on there, I think
2 we would like some feedback on that also.

3 Again, we took that list from four
4 institutions and one that Bruce developed for us
5 also, but there may be some that may not quite fit
6 on that list, and so if you have strong feelings
7 about that, we would appreciate feedback. And
8 also, again, the list that we -- the ones we
9 determined do not fit on this list, this time, if
10 you have -- think some of those should be on the
11 list, we would like feedback on that, too.

12 MR. NAUMANN: Bruce Naumann, Merck.
13 Just as a follow-up to Cindy's comment, you know,
14 the Alert itself is not, you know, a stand alone
15 document. Obviously, it drives a lot of
16 procedure, practices, and so forth, good handling
17 practices, hospitals, et cetera, but it's really
18 not the only resource.

19 And the Alert does a good job of
20 directing people toward the safety data sheets
21 that are generated by the manufacturers, and
22 that's a very good source of information on what

1 the hazards are and what, you know, the critical
2 effects are that ultimately led to the
3 occupational exposure limits, which are required
4 to be included in section A in the safety data
5 sheet by OSHA. So typically, when the
6 occupational exposure limits are established, you
7 know, you're looking at the entire range of data,
8 all of the potential susceptible sub populations,
9 including the unborn. So the limits that are
10 established are designed to protect all
11 individuals, males, females, pregnant females,
12 both sexes intending to have a family, and the
13 unborn.

14 And so, you know, typically we don't --
15 I mean the internal documents that we have
16 highlight what the critical end point was that we
17 were thinking about in the margin of safety that's
18 built in to protect that susceptible sub
19 population.

20 Safety data sheets don't get into that
21 kind of detail, like the OEL is based on this
22 particular effect and it's got a safety factor of

1 100 built into it, but it certainly discusses all
2 of the potential effects, and if they're written
3 very well, get into giving you some idea of where
4 the no effect levels were, et cetera, so you can
5 infer from that typically what the main concern
6 was with the compound.

7 Certainly some of the earlier sections
8 of the sheet, I guess section 3 is becoming
9 section 2 under the GHS system, and that's
10 designed to provide an opportunity for the reader
11 to see what the primary hazards, the most
12 important adverse health effects that are
13 associated with the compound, and I would assume
14 that any driver for an occupational exposure limit
15 would be reflected somehow in that label text that
16 appears up front.

17 MR. REED: Thank you, Bruce. Any
18 additional comments or questions?

19 MR. SCHATZ: Tony Schatz again, Shering.
20 This is to follow up on what Bruce said about the
21 MSDS and the Alert not being a stand alone
22 document. I guess the question I have would be,

1 and one of the concerns I have is, the Alert
2 allows for people to put things on the list at
3 their facility based on the definition in the
4 Alert, et cetera.

5 Obviously, that's going to lead to
6 inconsistencies of drugs being on different lists
7 and different facilities. And I know that you're
8 trying to come up with an expert list, so to
9 speak, and it's a recommendation, there's no
10 regulatory arm behind it, but it's -- are there
11 any plans or any text in the Alert moving forward
12 or anything that would kind of give people an idea
13 of the expertise that's involved and required to
14 put something on a list?

15 Because there are a lot of people out
16 there that are just aren't qualified, frankly, to
17 make that determination and put something on the
18 list. Is there anything going forward to, maybe
19 in the text portion, to explain what the expertise
20 is that's required and how the list has come
21 together from NIOSH so that maybe people would
22 refer to that more than doing their own thing, so

1 to speak, or just some comments on that.

2 MR. CONNOR: This is -- actually, we
3 addressed this early on, because we developed --
4 we took lists that had already been developed, and
5 we were aware that these were the drugs that were
6 used in that facility, and they may not use all
7 the drugs that were considered hazardous, so
8 that's why we -- we actually had a number of other
9 lists that we did not include when we developed
10 the first one, because some institutions would
11 just list the antineoplastics as hazardous drugs,
12 and I would say the majority of them were doing
13 that, the other list that we found.

14 These lists were fairly comprehensive.
15 The NIH list was the most comprehensive because
16 they do handle so many different drugs. The one
17 that Bruce developed for Pharma was quite
18 comprehensive. But we were afraid that we may be
19 missing some because they were not being used at
20 those institutions.

21 The other part of that is, people have
22 been and are doing -- generating their own lists.

1 And we developed the NIOSH Alert so they could
2 look to this list for guidance. We also have some
3 wording in the appendix A about how to generate
4 your own list, what type of information to put
5 together. There are some -- not a lot of detail.

6 But a number of institutions, like NIH
7 is obviously a good example. They have a small
8 committee that reviews the new drugs that they
9 start to use and whether it should be handled as a
10 hazardous drug. Other health and safety
11 committees in hospitals and other institutions
12 also do this to some extent, but they may not have
13 the expertise to do it, as you mentioned. So, I
14 don't know, we could include some more guidance
15 about how to do this, that's something we could
16 look into.

17 MR. REED: Tony, do you think that the
18 guidance that's in the Alert now needs to be
19 expanded?

20 MR. SCHATZ: I think it could be a
21 little bit, you know, I can't get into the details
22 at the moment -- but if you look at a definition

1 of what a carcinogen is or -- things that we
2 discussed about -- those kinds of decisions that
3 are very -- that someone -- trained to do that --

4 MR. REED: I'm sorry, could you speak
5 here?

6 MR. SCHATZ: My voice doesn't carry. As
7 far as the details right now, I can't, without
8 looking through the Alert again and looking at the
9 specific language, give you an idea of what should
10 be updated, if anything.

11 But some of the concern of what's come
12 up today about tumors in one species of mice, or
13 you know, in female mice, but not in rats, et
14 cetera, and some of the weight of evidence
15 determinations that we make as experts in the
16 field of toxicology or whatever, you know, maybe
17 we need to expand on some of that, I don't know.

18 But dose response certainly is
19 important, and we talked about that today, so I
20 guess when you look at a definition, if you don't
21 know this as a background, if you're not trained
22 in this, you look at carcinogen, you look at

1 repro, you look at developmental tratagen(?), and
2 you may not get all those nuances and all those
3 important weight of evidence and dose factors that
4 you need to put into making a decision, and maybe
5 we need to expand that, maybe we don't, I'd have
6 to look at the document a little closer.

7 MR. REED: Okay. Thank you.

8 MR. NAUMANN: Bruce Naumann, Merck
9 again. Just going back to the original activity
10 on the list, it's not my list, I was actually in
11 Chuck's role last time, you know, so I was
12 representing Pharma, and you know, one of the
13 things that we actually suggested the first time
14 around was, we were expressing concerns about
15 having a list, you know, all the things that you
16 have mentioned, you know, lists are outdated, you
17 know, the minute they're published and so forth,
18 what about all the old compounds that didn't quite
19 make the list the first time.

20 And I think our suggestion was that what
21 we ought to really do is, try to identify those
22 types of drugs that tend to, you know, find

1 themselves on the list. And we pointed to the
2 American Hospital Formulary Service therapeutic
3 classification criteria, which actually does --
4 was reflected in the list, and that, you know,
5 gives the users some additional information to
6 help them understand the types of compounds.

7 So I suspect we'll probably never --
8 we'll have to think about it I guess as we go
9 through it, and maybe next time, you know, is
10 having a list really the best approach or giving
11 more general guidance, telling them to look up the
12 classification, if it's in one of those
13 categories, it's in, if maybe it satisfies certain
14 dose criteria. I think the other Pharma comment
15 last time was to try to capture this concept of
16 dose response, not purely hazard, but hazard plus
17 potency in terms of the dose cut-off.

18 So the ten milligrams per day clinical
19 dose and the, you know, the animal dose of a
20 milligram per kilogram per day were recommended as
21 really being hard wired to the definition and not,
22 don't take this the wrong way, you know, buried in

1 the fine print in a footnote.

2 And I think, you know, the people that
3 are qualified -- there are people qualified, there
4 are people running pharmacies that have, you know,
5 Ph.D.'s in pharmacology and certainly capable of
6 evaluating dose response.

7 So if you have the right people
8 involved, it's very easy to apply some very
9 straight forward criteria, and that's the thing,
10 we have to keep it simple and direct at achieving,
11 you know, what it is we're trying to accomplish in
12 terms of the types of compounds, including the
13 potency of those compounds, so hopefully we'll get
14 there.

15 MR. CONNOR: Thanks. I'll tell you,
16 we've got a lot of feedback from individuals like
17 out in the middle of North Dakota somewhere, and
18 you know, I'm not -- I'm just using that as an
19 example, but they really appreciate having the
20 list with some guidance. I mean they really need
21 it. They don't have the expertise to do it. As I
22 mentioned, some facilities have put together a

1 committee, they may have a pharmacologist or a
2 toxicologist on their committee, and so they do
3 have some of the expertise. But a lot of places
4 don't do that, they have not been able to generate
5 their own list. So it has been helpful to them to
6 have some type of guidance.

7 MR. REED: And I would add to what Tom
8 said that we had this internal discussion
9 certainly within NIOSH about the need for a list,
10 and I think we felt that it was very important to
11 have such a list. Doctor Howard, the Director of
12 the Agency, was at least as adamantly supportive
13 of the list, if it were a living list, and, hence,
14 this meeting and the process for updating it on a
15 periodic basis. Are there any other questions or
16 comments?

17 Okay. Not seeing any questions, I think
18 we'll -- I'll just have some closing comments.
19 And I'm not sure, Anita, we don't want to put you
20 on the spot if you want to say anything, or Tom.
21 But on behalf of NIOSH, and I guess originally on
22 behalf of the entire working group that helped get

1 this all -- effort off the ground with the Alert,
2 and on behalf of NIOSH itself and the hazardous
3 drug group that will -- that has done so much work
4 so far, and then most importantly, I think
5 engaging the expert panel, thanking them in
6 advance for their hard work in helping assess this
7 information for the final NIOSH decision on the
8 update is very important, so I want to thank you
9 for that. Barb has something additional to say
10 here. Barb is reminding me, I guess I thought I
11 had done that, but just to be perfectly clear, if
12 there are comments on the specific drugs
13 themselves, you know, assuming that we have the
14 time, we can do that now.

15 There's also the mechanism for that
16 through the docket, as well, where you can provide
17 that information up until September 20th. So if
18 you have comments, thanks for that reminder, Barb,
19 if you have comments on the specific drugs
20 themselves, we have time to do that now if you're
21 ready to do so. So anything I think is fair game
22 basically is what we're saying, the process, the

1 definition, and the specific drugs themselves.

2 MR. SCHWARTZ: Chuck Schwartz from
3 Pfizer. Not wanting to go to specific comments,
4 but getting a little closer there, the -- one of
5 the things that I wonder about is, should we be
6 really concerned and calling out specific doses
7 that define -- specific doses in terms of a
8 clinical dose or animal toxicology studies or such
9 that appear to be black and white lines, or does
10 the whole thing boil down to it all depends.

11 And one of the things that I'm thinking
12 about here is that many times the therapeutic does
13 of the drugs are based on very, very specific and
14 fine detailed pharmacologic end points. Some of
15 them have no relevance in a healthy population,
16 and they only effect patients who have a disease.
17 So if we start to look at just the dose of less
18 than X milligrams per day, we start to get tangled
19 up in wasting resources, and very sensitive to
20 what was said before about focusing our resources
21 on the drugs that really are hazardous. And there
22 are some out there that really -- this is a great

1 tool to use.

2 There are some that really belong here,
3 and you know, the overall effort is tremendous.
4 But we've got to be careful that we don't use
5 bright lines of X milligrams per kilogram in a
6 toxicology study, an OEL of less than however many
7 micrograms per cubic meter, a dose of so many
8 milligrams per day. I mean serious organ
9 toxicity, carcinogenesis, developmental
10 reprotoxicology, that's what we're after, that's
11 what we've got to focus on, not fine pharmacology.

12 MR. CONNOR: I think Bruce mentioned
13 that we buried the footnote. We did not want to
14 be wedded to a specific number. And in that
15 footnote we say that it is used in some instances
16 to make these determinations. But we did not want
17 to have a really, you know, a black and white
18 cut-off line as you mentioned, realizing that
19 there are -- there will be exceptions. And that's
20 why we kept the footnote the way it was.

21 And the other part of that, there are
22 certainly some targeted therapies now that will

1 only bind to certain receptors. If you don't have
2 that -- it's not going to bind to those receptors.
3 So, you know, we're aware of that, we're trying to
4 take that into consideration. Again, it's the
5 gray area that's really difficult. The black and
6 white ones are fairly straight forward, but we're
7 asking your help on the ones in the gray area.

8 MR. REED: Are there any additional
9 comments or questions? And Barb's reminder, do
10 you have any comments, for example, on the
11 specific drugs themselves that we proposed adding,
12 or those that may be missing from the list that
13 you think should be added?

14 MR. CONNOR: If we do adjourn, it sounds
15 like we may be, do we want to keep the individuals
16 on the panel here for further discussion?

17 MR. REED: Yeah, I was just going to
18 mention that the panel of experts, for those who
19 are here, and John, I know that you may be filling
20 in for Caroline from Federal OSHA, we would like
21 to spend a few minutes just to talk about the
22 process from here, the fall meeting, in

1 preparation for the fall meeting, where we assess
2 all of the information that has been put into the
3 public domain. So I guess one last opportunity
4 for questions and comments. Okay.

5 MS. McCONNELL-MEACHEN: Mary
6 McConnell-Meachen from Boehringer Ingelheim. We
7 had a little discussion earlier about list versus
8 no list, and while my personal preference is a
9 process as opposed to a list, I think if we're
10 going to have a list and we really want it to be a
11 well defined list, then we need a process to go
12 back and look at the things that were left off and
13 not just wait for people to make suggestions, but
14 an organized approach to look at older drugs that
15 might have been missed.

16 MR. REED: From the original list?

17 MS. McCONNELL-MEACHEN: From the
18 original list, yes.

19 MR. REED: Okay, thanks.

20 MR. CONNOR: Bruce, was it you and Chuck
21 that helped develop the Pharma list?

22 MR. NAUMANN: Chuck is representing

1 Pharma this time --

2 MR. CONNOR: Okay.

3 MR. NAUMANN: -- as I was last time, and
4 basically there's like this network --

5 MR. CONNOR: Okay. So that was fairly
6 comprehensive, the evaluation that you guys did at
7 that time, was it not?

8 MR. SCHWARTZ: Just for the record, I
9 was not part of that process.

10 MR. CONNOR: Okay, all right.

11 MR. SCHWARTZ: That's Bruce's fault.

12 MR. NAUMANN: That's right. As I
13 mentioned before, we looked at the proposed list,
14 which came from the various institutions, NIH
15 being the most comprehensive, and we kind of got a
16 sense for the type of compounds that were included
17 on these existing lists and took a step back,
18 looking at the definition and tried to understand,
19 you know, what sorts of compounds were we really
20 concerned about outside of the antineoplastics,
21 and that's why we got into the ASHP AFHS, you
22 know, classifications scheme. And so we did, we

1 did a very comprehensive review of compounds. I
2 guess looking back, I think we extended it beyond
3 -- obviously we extended it beyond the compounds
4 that were already on the list, because -- actually
5 I think about -- I was tallying them up on the
6 airplane, and we actually proposed about 20
7 percent more compounds be listed, I guess.

8 So how many are on there, 132? I think
9 we had about 20 or 30 compounds that we added to
10 the list as part of that process based on looking
11 at other therapeutic classes that had mostly
12 reproductive and developmental toxicity concerns
13 that were not included in the original list. So,
14 yeah, I would say it was pretty comprehensive last
15 time.

16 And we had a dialogue about getting into
17 some of these gray areas and trying to incorporate
18 or factor in dose response to the extent we could,
19 and I think we were probably more inclusive than
20 less inclusive kind of on purpose because of the
21 goals of what we're trying, you know, I think what
22 you're trying to accomplish here, knowing that

1 maybe in some areas they're not paying attention.

2 So -- and then we get into this
3 philosophical problem of having too many compounds
4 and diluting it. So it's a tough line to walk,
5 but I think it was pretty comprehensive the first
6 time around. And that's why, as you indicated,
7 when you did your retrospective review, it came in
8 pretty close, right, relative to the definition
9 that --

10 MR. CONNOR: Yes.

11 MR. NAUMANN: -- we have working with
12 right now.

13 MR. CONNOR: So when you went back and
14 looked at it, you would look at like all
15 antineoplastic drugs on the -- list?

16 MR. NAUMANN: We looked --

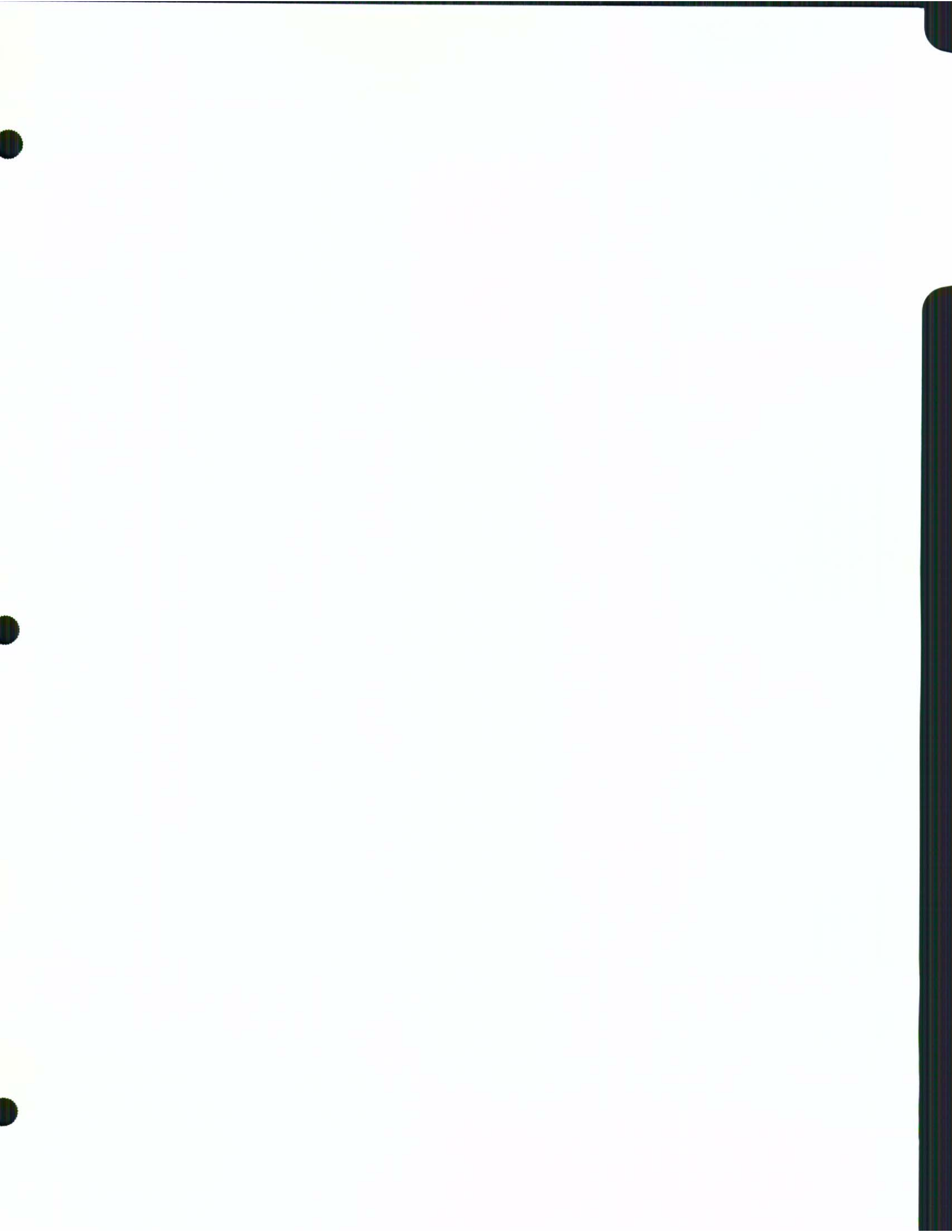
17 MR. CONNOR: You would look at all
18 neoplastics?

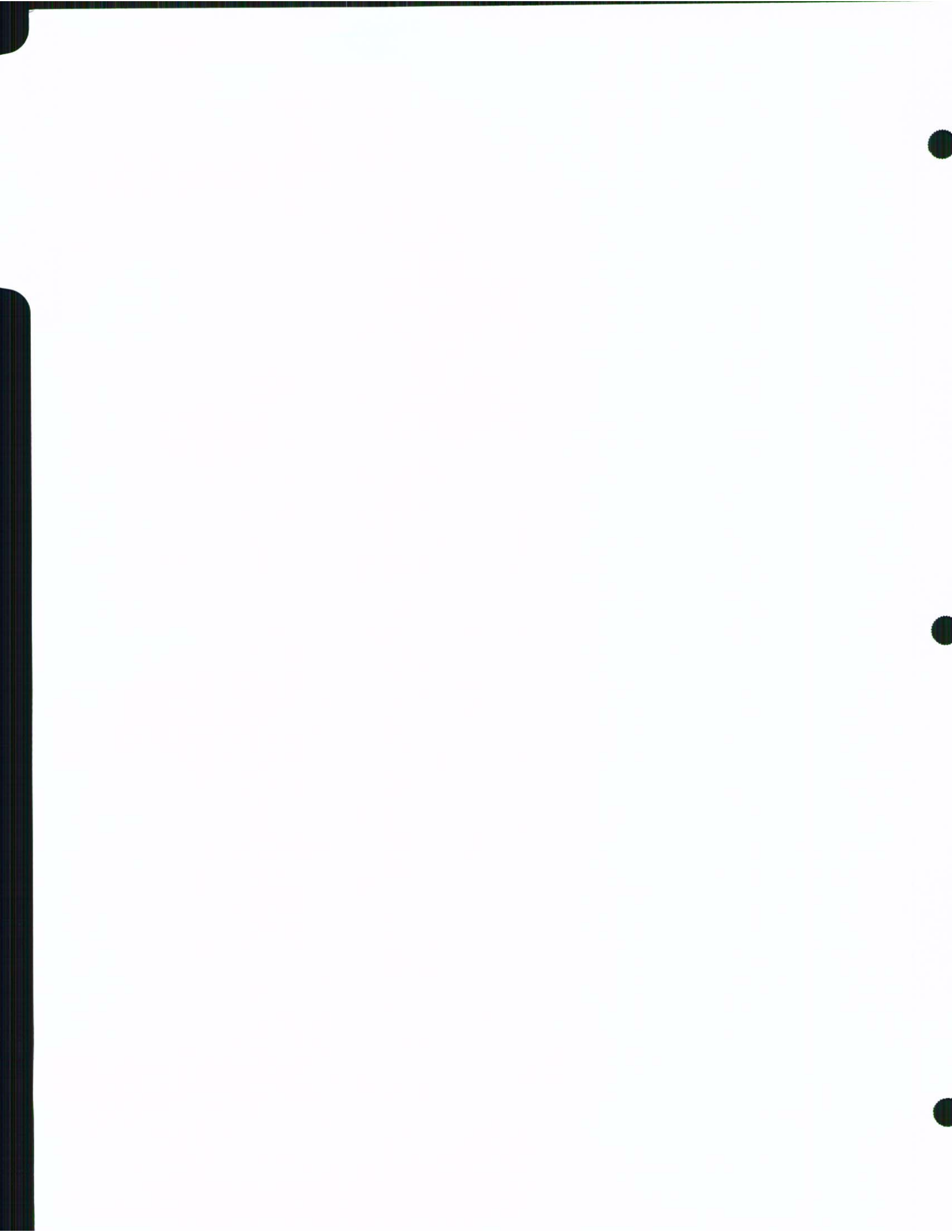
19 MR. NAUMANN: -- we looked at the
20 monographs in the specific categories that we had
21 identified that seemed to be consistent with the
22 NIOSH definition.

1 MR. CONNOR: Okay.
 2 MR. NAUMANN: And there were maybe about
 3 eight or nine different sub categories outside of
 4 the antineoplastic. It went through, you know,
 5 the compounds that were at least included in that
 6 -- the information monographs that were available
 7 at the time.
 8 MR. CONNOR: I'm just getting at, would
 9 we have missed drugs in those categories?
 10 MR. NAUMANN: That document doesn't
 11 include all drugs.
 12 MR. CONNOR: All right.
 13 MR. NAUMANN: So there may be some
 14 internationally. Even the PDR I think reflects
 15 mostly drugs that are sold in the United States
 16 primarily.
 17 MR. CONNOR: Okay. So that gets back to
 18 Mary's question, okay. Thank you.
 19 MR. NAUMANN: Yeah; so there may be some
 20 older drugs out there that should be listed and
 21 there probably should be some formal mechanism to
 22 go back and get caught up if, in deed, and it

1 (Whereupon, at 11:46 a.m., the
 2 PROCEEDINGS were adjourned.)
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1 sounds like we do want to stay with a, you know, a
 2 list of some sort even though we'll probably
 3 continue to call it an example list, but we don't
 4 want to leave obvious ones off the list and
 5 mislead people.
 6 MR. REED: Great; thanks, Bruce. Any
 7 other questions or comments? Okay. Again, I
 8 guess this -- Tom mentioned earlier, we would like
 9 the panel to stay on, all who are here. And also,
 10 the two members -- additional members of the NIOSH
 11 working group, if you can, that would be Jim
 12 O'Callaghan and Doug Trout, just to chat about the
 13 process from here on out.
 14 And so, again, I guess I want to thank
 15 you all. This is a great meeting for NIOSH in
 16 terms of assessing the public information about
 17 this list. And I guess I would just lastly say
 18 that it's -- as the working group effort was years
 19 ago, this effort is great because it focuses on
 20 sort of commonalities in a diverse group of
 21 people, the commonality being worker health. So
 22 with that, thank you very much for your comments.





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