

1 on individual chemicals for which the person had
2 concern. That got, everybody on the speakers list
3 has got ten minutes. I would suggest to you,
4 however, you best put that ten minutes into trying
5 to deal with questions of process, not with
6 questions of individual chemicals and whether or
7 not a certain rat study was correctly interpreted or
8 not correctly interpreted. That's really not part of
9 what we're here at, here for, but again, you've got
10 your time, you use it as you wish. We,
11 everybody's comments are going to be recorded.
12 For that reason, during the discussion period, we
13 specifically would like you to identify yourself again
14 and speak into the microphone. I hope we can
15 avoid as much as possible abbreviations and jargon.
16 That, that sort of helps everybody. We have with
17 us two members of the Board of Scientific
18 Counselors, Dr. Lynn Goldman, now with Johns
19 Hopkins, previously at EPA, Dr. Clay Frederick from
20 Rohm and Haas, and they're going to be very much
21 involved in trying to pick out themes for the
22 discussion period; the idea of a discussion period
23 rather than just presentation after presentation is a
24 bit of an experiment. We're trying to see if we can
25 help focus the discussion on ways to improve the

[REDACTED]

1 process. We hope to be able to get a little bit of
2 dialogue, not only in terms of among you, in terms
3 of ideas that may have come forward, and one of
4 the things you'll have to evaluate when this is over
5 is whether that really helped or not. Based on
6 what I heard yesterday, I think it has helped. The
7 information that you, that will be provided, either
8 through transcripts or through all the written
9 comments that we've received from presenters and
10 some written comments from those who could not
11 be here to present, all of this will be made
12 available, this material put together. George, I
13 forget, I forgot what time you said it would take,
14 you gave an estimate last, yesterday.

15 **DR. LUCIER:** For the written
16 material are ready very soon after the meeting.
17 The transcripts will probably take four to six weeks
18 before that's completed and available, and we'll
19 send it out to anyone who wants it at the time.

20 **DR. GOLDSTEIN:** You've no doubt
21 come across a very efficient staff at NIEHS and NTP
22 have made available help with this meeting. Any of
23 you want the written materials or want to be on the
24 mailing list for the others, please let me know.
25 Okay, so that's our information. We're going to,

1 this morning, basically go through a series of
2 presentations, and then take a break and have a
3 discussion of these presentations. There are some
4 people who haven't checked in yet. Perhaps they
5 will be here, I'm trying to see which list I've got
6 that describes who's here and who's not, but
7 anyhow, we can go through the list of the folks
8 who are planning to present. Let me first ask if
9 the NTP folks have anything they'd like to add from
10 what they said yesterday.

11 **SPEAKER:** No, thank you.

12 **DR. GOLDSTEIN:** So our first
13 presenter will be Ashley Coffield of the Center for
14 Children's Health and the Environment.

15 **MS. COFFIELD:** Good morning.

16 **DR. GOLDSTEIN:** If you'd like,
17 why don't you use the, you're really presenting to
18 the group out there. I'm sort of the moderator. If
19 you need help, if anybody needs help with
20 overheads or slides, let us know in advance. We
21 have very effective people here to help us with
22 that.

23 **MS. COFFIELD:** Hi, my name is
24 Ashley Coffield. I'm with the Center for Children's
25 Health and the Environment at Mount Sinai School

[Redacted]

1 of Medicine. I'm here this morning on behalf of
2 Dr. Philip Landrigan. I'm going to be reading his
3 testimony because he was unable to be here today.

4 Thank you very much for inviting me to
5 appear before you this morning to offer comments
6 before the National Toxicology Program concerning
7 the NTP Report on Carcinogens. My name is Philip
8 Landrigan. I'm a pediatrician and Professor and
9 Chair of the Department of Community and
10 Preventive Medicine at the Mount Sinai School of
11 Medicine in New York City. I direct the Center for
12 Children's Health and the Environment at Mount
13 Sinai, a children's environmental health policy
14 center supported by the Pew Charitable Trusts. I
15 am Co-Director of the Mount Sinai Center for
16 Children's Environmental Health and Disease
17 Prevention Research, a children's environmental
18 health center supported by the National Institute of
19 Environmental Health Sciences and the U.S.
20 Environmental Protection Agency. I have spent the
21 past 30 years studying the impact of environmental
22 toxins on human health, with particular emphasis on
23 the health of children. My purpose today is to
24 argue strongly for the preservation of the NTP
25 Report on Carcinogens. The Report on Carcinogens

1 is an extremely valuable document. It presents to
2 Congress and thus to the American public the
3 results of the testing and evaluation of chemicals
4 undertaken by the U.S. National Toxicology
5 Program, perhaps the most outstanding independent
6 toxicology testing program in the world. The
7 Report on Carcinogens fulfills the absolutely
8 fundamental purpose of biomedical research in a
9 democracy. It informs the public of the research
10 that they have supported. The public has a right to
11 know the results of research conducted by the U.S.
12 Public Health Service and the National Toxicology
13 Program because the results are directly relevant to
14 individual decisions about the preservation of health
15 and the prevention of illness. American citizens
16 need to be informed about which chemicals in the
17 environment cause cancer in order to protect
18 themselves and their families. The biannual
19 publication of the Report on Carcinogens is in the
20 best tradition of Jeffersonian democracy. It is a
21 document that must continue to be published, and
22 the process by which it is developed must remain
23 independent and uncorrupted by special interests.
24 Various special interests have introduced a series of
25 proposals that would dilute the quality and lessen

1 the independence of the process by which the
2 Annual Report on Carcinogens is produced, thus
3 fundamentally corrupting the Report. One adverse
4 proposal would require the scientists at NTP to
5 consider non-peer-reviewed materials as they
6 formulate their decisions concerning the
7 carcinogenicity of various chemicals. This is a very
8 dangerous proposal. One of the great safeguards in
9 the procedures that have been followed over the
10 years by NTP in preparing past reports is that
11 evaluations are restricted to consideration of
12 reports that have been published or accepted for
13 publication by the peer-reviewed literature or
14 developed by independent peer-review bodies, such
15 as federal agencies or the World Health
16 Organization. To allow non-peer-reviewed junk
17 science on the table would corrupt the review
18 process. It would introduce data that have not
19 been subjected to the scrutiny of peer-review. I
20 strongly urge the NTP to reject any proposals to
21 produce non-peer-reviewed data for consideration.

22 A second dangerous proposal is that the
23 decisions of the NTP carcinogen panel should be
24 subject to endless re-review. This proposal would
25 have the effect of delaying the publication of the

1 Report on Carcinogens. Moreover, it would rapidly
2 and inevitably degenerate into an exercise in jury-
3 shopping. Affected parties would continually demand
4 reexamination of data if they did not get the result
5 that they sought the first time around. I strongly
6 urge the NTP to reject this proposal in all its
7 versions.

8 Finally, a proposal has been put forward to
9 move the work of preparing the report from the
10 National Toxicology Program to the National
11 Academy of Sciences. I am a member of the
12 Institute of Medicine of the National Academy of
13 Sciences. I have great respect for the Academy.
14 Over the years, I have served on and chaired a
15 series of Academy meetings. That said, I think it
16 absolutely inappropriate that the work of preparing
17 the Report on Carcinogens be transferred to the
18 National Academy of Sciences. NAS committees are
19 staffed entirely by volunteers, people who give
20 unstintingly of their time to evaluate pressing
21 issues of national importance. Preparation of the
22 Report on Carcinogens is a tedious, repetitive task
23 that will require extensive staff resources. Those
24 resources exist and are in place at the NTP. They
25 do not exist at the National Academy of Sciences.

1 Moreover, the NIEHS has done an admirable job of
2 keeping the National Toxicology Program and the
3 Report on Carcinogens honest and credible. Why
4 tamper with this success? I would argue to keep the
5 responsibility for preparing the Report on
6 Carcinogens within NTP. I thank you again for
7 having allowed me this opportunity to speak before
8 you. I respectfully request that these remarks be
9 entered into the record. I urge you to preserve the
10 vigor and independence of the Report on
11 Carcinogens. Do not allow this national resource to
12 become corrupted by special interests and affected
13 parties. Thank you.

14 **DR. GOLDSTEIN:** Thank you, Ms.
15 Coffield. Our next speaker is Philip Leber of the
16 Goodyear Tire and Rubber Company.

17 **MR. LEBER:** Thank you, Mr.
18 Chairman. Today, my comments will definitely be
19 more along the lines of the process. The first
20 slide, please. Let's go to the second slide.

21 The three main areas I want to talk about
22 is what can we agree on. We certainly have a lot
23 of disparity of opinions on the situation, but what
24 can we agree on. Secondly, I'm going to very
25 quickly go over some of the concerns, and thirdly,

1 get into a proposal for a process enhancement.
2 Again, I want to say that these comments also
3 apply to the bioassay program. Some of the
4 reports on the NTP bioassays, I think, warrant also
5 significant review, peer-review.

6 Next slide, please. Okay, the, I am, I am
7 making the assumption today that NTP in this
8 process accepts the concept that good science is
9 absolutely fundamental and central to the task at
10 hand, and that is taking a chemical, looking at the
11 data surrounding, pertinent to that chemical, and
12 making a truly scientific decision on the
13 classifications which it belongs.

14 Secondly, in order, if this is a true
15 assumption, then it requires that it include the
16 qualified and informed personnel on how those data
17 on a particular chemical can be judged
18 appropriately within a scientific methodology to
19 come to an appropriate enhancement classification.

20 Next slide. Part of the components, as I
21 see it, of good science, are that all significant data
22 and issues are considered and certainly the
23 comments with regards to peer reviewed data,
24 nobody has any objections to, that is quite
25 appropriate, but there has to also be some debate

1 and discussion on the critical points within the
2 process. Secondly, the bases for decisions need to
3 be clearly articulated and documented in an open
4 manner and opposing views also need to be
5 addressed. I was a little distressed yesterday to
6 say, to hear that there were folks who felt that
7 dialogue was not needed, that it was superfluous,
8 and that's just not consistent with the scientific
9 process. Obviously there's a contention factor, how
10 do you resolve points where there is significant
11 disagreement. Perhaps that's when you call in an
12 expert group of consultants and so forth to work on
13 these, and final point there is bias, and you know,
14 there was a lot of concern about bias from various
15 parties, and I think that when you have, with large
16 committees such as the BSC, the Board of Scientific
17 Counselors, you have ten or twelve people there
18 and if bias enters into the discussion, it's going to
19 be eliminated. No one person who is biased is
20 going to carry the day. So I don't think that that's
21 really a concern. Next slide, please.

22 Okay, real quickly, these are some of,
23 many of these issues were discussed yesterday.
24 The first point though, again, I know that we've
25 heard that there's pretty strong feeling on the part

1 of NTP that stakeholder inputs is not being
2 excluded, but as I said yesterday, there's no
3 evidence, there's no significant evidence that it is
4 being taken into account, and the only thing we
5 have to go on is the feedback and the form that
6 these background documents take, and so if we, if
7 input is given, the comments are not, or the
8 documents are not changed, we have to assume that
9 there is no consideration.

10 I'll go to, number five is semantic
11 classifications is known. I think there's a very
12 significant point here, and I'll discuss it a little bit
13 further. Next slide, please. Okay, with regards to
14 the transparency issue, if you look at the process
15 that was outlined yesterday, the background
16 document, the review of data proceeds for about
17 nine, ten months and it's only at the point where
18 there's, it's time for a Board of Scientific
19 Counselors public meeting and a review of the
20 background document that it comes to light what is
21 the main issues, what has NTP nominated the
22 chemical to be, a known carcinogen, reasonably
23 anticipated, and so forth. We can provide input,
24 but we don't know which direction the debate is
25 going, and then finally, as I said too, there's just,



1 there's just not a, the back and forth, which is
2 really an intrinsic and important part of scientific
3 deliberations. Next slide.

4 Okay, this is, this is probably the guts of
5 my, my presentation. It appears to me that one,
6 many of the, the concerns would be addressed by
7 having a chemical specific workshop invited to any
8 and all parties who have, want to participate in a
9 toxicological workshop and discussion. Come
10 prepared to talk about bioassays, come with your
11 epidemiologist, and come prepared to talk
12 pathology, but this workshop should be held very
13 early in the process, and I, I don't attach any, I
14 don't want you to attach any significance to the
15 RG2 process. It could be at the RG1 process. It
16 even could be before that. But I think if we had a
17 direct document that came out of a workshop and
18 then that was passed on to RG1, RG2, we would at
19 least be able to get into the trenches and to
20 discuss the, the contentious issues if there are any,
21 but that's the way to work scientific issues out, not
22 where you are pressured with time and a large
23 number of chemicals to make quick decisions.
24 Again, the message is, let's, let's front load the
25 process and, for working out the fine points, and

1 then I think the rest of the process will go much
2 more smoothly. Next slide, please.

3 Okay, just real quickly, again I think for
4 enhancement of the process, I'd like to see a little
5 bit more opportunity, also for the BSC chairs or, to
6 solicit...certainly there's enough points left in the
7 written comments or oral comments, but there ought
8 to be some curiosity as regards the disparity that is
9 apparent between the panel's document and the
10 public comments and, but I'd like to see more of an
11 interactive type of situation, and then secondly, and
12 then again, I don't, none of, this proposal does not
13 want to make for further effort and time on the
14 part of NTP staff. I think in a sense it would ease
15 the burden both for the BSC as well as staff, which
16 just too many chemicals to review at one time.
17 The time factor has been discussed, and then
18 thirdly, I think that, you know, the makeup of the
19 BSC needs to be a little bit heavier in basic
20 toxicology and bioassay carcinogenesis
21 epidemiology. Next slide, please.

22 Secondly, I think with regards to...

23 DR. GOLDSTEIN: One minute.

24 MR. LEBER: Okay. The language
25 in the terms being used, known Human Carcinogen.

1 I understand that there was a new criteria for a
2 known human carcinogen, but we still have the
3 situation where your limited evidence in humans
4 progressing right to a known human carcinogen
5 category. Let's go to reasonably anticipated plus
6 or double A or something like that, but if it's not a
7 known human carcinogen, let's not confuse the
8 public by saying that it is.

9 Next slide, and finally, NTP is not a
10 regulatory agency, everybody acknowledges that, so
11 I think it's an excellent opportunity to practice
12 strictly science, and the suggestions of let's move
13 the process faster, let's involve less people, let's
14 not have dialogue, that's just not in the scientific
15 interest or the public interest. So I just don't think
16 that there's a compelling basis to say that,
17 you know, that certain parties should be excluded.
18 One final slide, please.

19 Here's a couple of quotations that came
20 from Carl Sagan's book and it's, science strides
21 indeed require free exchange of ideas and its
22 values are antithetical to secrecy. Okay, thank you
23 very much.

24 **DR. GOLDSTEIN:** Our next speaker
25 is James Hathaway, Rhodia Incorporated and also

1 the CMA Inorganic Acid Mists Panel.

2 **DR. HATHAWAY:** This first slide
3 basically shows who I am and who I'm representing.
4 You can go ahead to the next slide.

5 Here are our expectations of the process
6 for carcinogen classification. I think they are
7 things that everyone in the room here would agree
8 on and based upon our experience we feel there's
9 serious deficiencies in every one of these areas.
10 Next slide.

11 Our experience is based upon the sulfuric
12 acid mists deliberations, and from those
13 deliberations and what's gone on afterwards, we
14 have no ability to determine whether industry
15 positions were ever seriously considered. There are
16 no written reports available to understand how the
17 internal NTP committees made their decisions. Next
18 slide.

19 I do know that the materials prepared by
20 the NTP for the external peer review committee did
21 not include original articles. They were primarily
22 extracts from the International Agency for Research
23 on Cancer Monograph, and they did not discuss
24 criticisms of key studies provided by industry.
25 They did take one point out of context to try to



1 justify their position, and that was it. Next slide.

2 Neither of the two primary reviewers for
3 sulfuric acid mist were epidemiologists, even though
4 only epidemiology studies were being used for
5 classification. Given the number of substances
6 considered, it seems doubtful there was adequate
7 time for other members of the committee to
8 comprehensively evaluate the materials on sulfuric
9 acid mist. Next slide.

10 There was insufficient time for public
11 comment, limited to five minutes. Industry's
12 comments were never seriously discussed by the
13 review committee during their public meeting. It
14 seemed to me they were more interested in
15 finishing as quickly as possible so they could get
16 home early, and industry has never seen a
17 documented explanation for why their comments
18 were disregarded.

19 Now, some of you in the room may feel
20 that industry comments ought to be dismissed out
21 of hand and some people feel that they make
22 economic arguments and other things that try to
23 persuade people to alter their classification. Our
24 comments are strictly limited to the science and
25 curiously, another federal agency, the Agency for

1 Toxic Substances and Disease Registry has issued a
2 toxicology profile on sulfuric acid in December of
3 1998. As far as I know, industry did not provide
4 any comments on that document. Our group
5 certainly did not, and interestingly, the authors and
6 reviewers of that document independently arrived at
7 essentially the same conclusions as comments
8 provided to the NTP by industry. The ATSDR
9 document stated that the IARC based their
10 classification on very limited human data. It also
11 states there is no information that exposure to
12 sulfuric acid by itself is carcinogenic. Other
13 scientists, including those from another government
14 agency, have criticisms of the IARC classification of
15 sulfuric acid mists that are similar to those made
16 by industry. Clearly, industry's scientific comments
17 merited full consideration. However, industry's
18 comments were apparently dismissed, no explanation
19 was documented. If the NTP is going to act as a
20 rubber stamp basically endorsing IARC decisions
21 without really a critical independent review, then
22 they ought to state that's what they're going to do.
23 But if they really want to be an independent,
24 careful, rigorous process, then they have to change
25 a number of things. I think using summaries from

1 IARC as opposed to the original articles, limiting
2 the amount of time available for the external peer
3 review scientists to review this, not having people
4 with adequate training and background for many of
5 the items under consideration ends up with a
6 problem. If we have an inappropriate classification
7 based upon a flawed process, it does nobody any
8 good. Thank you.

9 **DR. GOLDSTEIN:** Thank you, Dr.
10 Hathaway. The next speaker is Michael Jacobson of
11 the Center for Science in the Public Interest.

12 **DR. JACOBSON:** Good morning.
13 Thank you very much for providing the opportunity
14 to speak here. I'm the executive director of the
15 Center for Science in the Public Interest. I
16 appreciate this opportunity. CSPI focuses mostly on
17 chemicals that occur in foods, but is also
18 concerned about human exposure to chemicals in
19 the air, water, workplace, and consumer products.
20 I've become familiar with the Report on Carcinogens
21 through my participation in the NTP's review of
22 saccharin, the artificial sweetener. Thus, while my
23 views might be somewhat colored by that one
24 experience, I hope they'll still be helpful.

25 First, I'd like to emphasize the great value of the

1 report. It is critically important that some
2 government agency review in a public way the
3 safety of a wide variety of chemicals and provide
4 its conclusions to the public. Decision-makers,
5 industry, labor unions, public interest groups,
6 journalists, and others have come to rely on the
7 report as an authoritative listing of chemicals that
8 may pose a cancer risk to humans. To stop
9 publishing that listing or to prepare it in a non-
10 public manner would be a serious loss to the
11 public. The need for an objective report on
12 carcinogens is all the greater considering that
13 another ostensibly objective source of information,
14 the International Agency for Research on Cancer,
15 holds its meetings overseas and in secret and has
16 numerous industry representatives serving on the
17 committee and as participating observers. Its
18 reviews now deserve much less credence than they
19 once did.

20 Judging from my experience with the
21 saccharin review, if the NTP is to continue
22 overseeing the production of the report, several
23 changes might be in order. The process of having
24 four votes is extraordinarily cumbersome and time
25 consuming. I suggest that the NTP devise a way to

[Redacted]

1 streamline the process, perhaps eliminating at least
2 one of the committees and two of the votes. For
3 instance, the RG1 committee's vote might be just
4 completely expendable. Furthermore, in practice,
5 RG2 and the Executive Committee are hardly
6 independent reviews, because the nominal members
7 of the Executive Committee appear to delegate their
8 vote to an underling, sometimes a person who sat
9 on the RG2 committee. Thus, it might make sense
10 to have only one government committee, either the
11 RG2 or the Executive Committee plus the outside
12 board of scientists.

13 Second, the scientific review document on
14 saccharin was not as objective as it might have
15 been. For instance, epidemiological evidence of
16 carcinogenicity was downplayed and little attention
17 was given to tumors in organs other than the
18 urinary bladder and to the phenomenon of co-
19 carcinogenicity. Thus the document was skewed
20 heavily towards delisting. The NTP should, the NTP
21 staff should consider producing these documents
22 itself rather than hiring a consulting firm. Third, I
23 am skeptical that members of the Board of
24 Scientific Counselors can review carefully all the
25 scientific data provided by the staff and consultants

1 and all the comments provided by the public on the
2 sizable groups of chemicals that are discussed at
3 individual meetings. My sense from the saccharin
4 meeting was that some of the members did not
5 review all the available information, had their minds
6 made up in advance, and ignored the input from the
7 public. The discussion of complex issues was, to
8 say the least, perfunctory. It might be more
9 appropriate to divide up the chemicals under review
10 among a much larger number of scientists.

11 A fourth concern is that holding the
12 meetings of the Board of Scientific Counselors in
13 North Carolina is a sure way to minimize public
14 input. Many people find it far less expensive, far
15 more convenient to go to Washington than North
16 Carolina, lovely a place as that is. Typically, the
17 attendees at the meetings, according to one
18 member, are almost exclusively industry
19 representatives. What with all the citizens groups
20 and trade associations in the Washington area, I
21 urge that the NTP hold future meetings of the Board
22 of Scientific Counselors in Washington.

23 My next point reflects the fact that any
24 given chemical being reviewed has numerous well-
25 funded and well-staffed corporate defenders. By

1 contrast, critics tend to be thinly funded and thinly
2 staffed unions or citizens groups. That's hardly a
3 level playing field. Twenty years ago, the Federal
4 Trade Commission and possibly other government
5 agencies provided public participation funding to
6 ensure that issues were carefully and fully, fairly
7 debated in the context of rule making proceedings.
8 I suggest that on controversial chemicals or issues,
9 the NTP provide modest funding to interested
10 citizens groups to enable them to hire consultants
11 or staff needed to conduct in-depth reviews and
12 report their conclusions to the NTP.

13 Finally, the NTP should stick to its rules.
14 In the case of saccharin, the Board of Scientific
15 Counselors voted four to three not to delist that
16 chemical. After that meeting, the director of the
17 NTP, Dr. Olden, sent a letter inviting seven other
18 scientists to provide their views on saccharin. In
19 effect, Dr. Olden took it upon himself to create a
20 new ad hoc committee. Worse, the NIEHS has kept
21 secret the replies from those scientists. The
22 agency has denied my request under the Freedom of
23 Information Act to obtain copies. Perhaps the
24 reason why is that, as I have learned, two of the
25 three scientists who responded recommended that

1 saccharin not be delisted. So that is not on any
2 official record. Frankly, it looked like Dr. Olden
3 was trying to stack the deck. That kind of monkey
4 business and the secrecy that followed has no place
5 in what is supposed to be a public review of
6 carcinogens.

7 To conclude, let me just reiterate my first
8 and most important point. The Report on
9 Carcinogens is a valuable document. The
10 government should continue to produce it. Thank
11 you.

12 **DR. GOLDSTEIN:** Thank you, Dr.
13 Jacobson. Our next speaker is Donald Smith. Mr.
14 Smith, we have no listing for your affiliation.
15 Perhaps you have none, and you're a citizen.

16 **MR. SMITH:** My name is Donald L.
17 Smith. I'm a private citizen from Tucson, Arizona,
18 acting on a concerned basis. Thank you for
19 allowing me to speak. The comments yesterday and
20 today are deeply disturbing to me because common
21 sense tells me if the background one uses to reach
22 a decision is shown to be faulty, one is obligated
23 to reconsider one's decision. That doesn't seem to
24 be the philosophy here, so perhaps a new truth in
25 dealing with NTP statement is in order, and it goes

[Redacted]

1 something like this; if you send us a written
2 comment regarding the background data we use, we
3 won't acknowledge that we received it, nor will we
4 let you know if it was considered, and if you
5 choose to spend your money to come twice to
6 testify, according to Dr. Frederick yesterday, as I
7 understood it, we won't pay much attention to your
8 verbal testimony. Now if that sounds a little
9 cynical, it's because outside of the beltway, we no
10 longer feel that the typical agencies are responsive
11 to the public. At the close of my remarks, I'll try
12 to suggest an alternative answer to Mr. Tozzi's
13 provocative question yesterday, why the rush, and I
14 am sorry, but it's impossible to talk about the
15 generality of the process without some specifics.

16 My commentary, that I sent in a written
17 format was to delist solar radiation exposure to
18 sunlamps and sunbeds from the 9th. Next slide,
19 please. The report, which was filed on March 1999,
20 NTP Report on Carcinogens background document,
21 on pages 18 and 19, place 3 and 4, please flip it.
22 Finding of the association of cutaneous malignant
23 melanoma with use of sunlamps and sunbeds
24 showed these nine references as proof. Back to 2,
25 please. However, 14 months before then in the

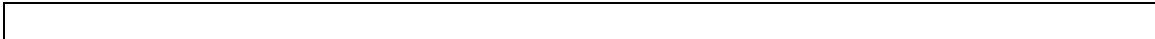
1 Journal of the American Academy of Dermatology,
2 an article by Swerdlow and Weinstock listed 19
3 articles purporting to show the link between CMM
4 and sunlamps, and they reviewed all of them,
5 including these 9 articles, and their conclusion was,
6 at this time, the published data were insufficient to
7 determine whether tanning lamps caused melanoma.
8 Furthermore, in the IARC document, in 1992, their
9 conclusion was there was no support for non-
10 melanoma. So therefore, there's no evidence to
11 link sunlamps and sunbeds with any form of skin
12 cancer.

13 The next slide, please. Regarding solar
14 radiation, an article was published recently by Allen
15 J. Christopher, a respectable physician, and his
16 conclusion was, the conclusion that can be drawn
17 from looking at these studies as a whole is that
18 melanoma is not due to sun exposure. The
19 conclusion is so clear that it is difficult to
20 understand why scientific consensus still clings to
21 the idea that sunlight causes melanoma. He
22 postulated that skin temperature is the primary
23 latitude dependent climactic factor operating in the
24 induction of melanoma. His article is a significant
25 package that may suggest that maybe this is a

1 wake-up call on global warming. So unless and
2 until NTP ascertains that temperature's involved,
3 then solar radiation cannot be. I have a question
4 to ask you, for Dr. Jacobson's people. Does NTP
5 not have a system whereby the appropriate
6 databases are automatically scanned to routinely
7 update your data on this? It's just a very common
8 practice to put it into the databases now, and it
9 will come right up and basically there we've got 14
10 or 15 months before this report was finalized and
11 obviously you're not aware of it.

12 Next slide, please. There's a concept out
13 that false, deceptive, misleading and
14 unsubstantiated statements in advertising, and I
15 submit when you are publishing documents to go to
16 public action, that falls under the definition of
17 advertising, and FDA and FDC have jurisdiction
18 regarding statements regarding ultraviolet radiation.
19 So if you look at the, at what is trying to be
20 published in the 9th, which in my opinion is the
21 FDMU statement, you have a faulty data linking
22 sunlamps and sunbeds, data to consider temperature
23 as an inducing factor for solar radiation, no
24 economic impact, which has some severe economic
25 consequence potentials, no paperwork impact, no

1 health impact, did not consider phototypes,
2 subtypes. It assumes in the IARC documents that
3 all phototypes, subtypes are equally as susceptible
4 to solar radiation as a type one, and that, as we
5 know, is definitely not true. You had no
6 consideration for tolerance of ultraviolet radiation
7 with the changes that built up in constitutive
8 pigmentation and facultative pigmentation. You had
9 no universal, biological efficacy rating scale, and
10 yet the EPA has long had the ultraviolet index,
11 which is an excellent tool for doing so. It failed to
12 consider co-carcinogenicity of ultraviolet radiation
13 among other substances, and yet we know that all
14 genetic backgrounds are not equally susceptible. If
15 it were so, then type fives, the brown skin, type
16 five, the black skin would have the same incidence
17 of skin cancer as do the more fair skinned, and
18 that's, we know that's not true. Didn't consider
19 smoking as a contributing factor, and yet we know
20 that squamous cell carcinoma is reduced by 50
21 percent in non-smokers. It didn't consider diet,
22 and yet a study by Black, et al and Baylor showed
23 that a low-fat diet, the incidence of squamous cell
24 carcinoma is reduced by 90 percent in a two-year
25 period. It didn't consider the beneficial effects of



1 ultra, of exposure. It failed to consider the risk
2 versus benefit analysis, and yet there's evidence to
3 show that there may be four or five hundred people
4 disadvantaged by lack of exposure to everyone
5 that's affected by overexposure. There was a lack
6 of consistency. It did not, it gave Tamoxifen the
7 same beneficial information listing, but solar
8 radiation exposure to sunlamps and sunbeds did
9 not. Equally true was that alcoholic beverages did
10 not have any beneficial statement. The Treasury
11 Department has allowed statements on wine bottles
12 showing the beneficial effects on the coronary heart
13 disease. So those of us out there in the
14 hinterlands, we might be reasonably expected to
15 ask, doesn't the right hand know what the left hand
16 is doing.

17 There's been some discussion about why
18 the legal process is used by those listed that are
19 not in agreement. Well, it's very simple. There's
20 transparency in the legal process and
21 accountability, so we can come in and reverse some
22 of these things that we, we disagree with.

23 Three slides quickly. I submitted a
24 Decision Tree, which I suggest that in business as
25 common practice, when you're getting ready to

1 make a serious decision, that you follow a Decision
2 Tree. It's the last three slides there you can show
3 quickly. That Decision Tree takes you through the
4 steps that I would submit this committee should
5 have looked at before reaching this decision.

6 Finally, why the rush? Looking back and
7 thinking about this last night and being deeply
8 disturbed at what I heard here, I thought back at
9 the mistakes that have been made in my 40-year
10 business career, and they inevitably came in a rush
11 to judgment, and in looking why did those happen.
12 It's because a group of people had their mind made
13 up, and when you have your mind made up, the
14 prevailing opinion is don't confuse me with the
15 facts. Thank you very much for your attention.

16 **DR. GOLDSTEIN:** Thank you, Mr.
17 Smith. Our next speaker is Joseph Levy of the
18 International Smart Tan Network.

19 **MR. LEVY:** Good morning, and
20 thank you for the opportunity to address this group.
21 My name is Joseph Levy, and I am executive
22 director of the International Smart Tan Network, and
23 I'm here to discuss the process of your group's
24 proposal to list ultraviolet light as a known
25 carcinogen. Smart Tan is a Michigan based

1 educational organization representing nearly 20,000
2 indoor tanning facilities in the United States,
3 Canada, Australia, and New Zealand. More than
4 3,000 of these facilities are full members of the
5 association, while an estimated 15,000 other
6 facilities use Smart Tan training materials and so
7 forth to train their employees and teach their
8 customers the concepts of what we call Smart
9 Tanning, which by definition, means teaching people
10 of all skin types how to make appropriate decisions
11 about their sun habits based on their individual
12 characteristics. We're teaching them to think and
13 be smart, based on their skin type, their heredity,
14 and their constitutive tolerance to ultraviolet light.

15 For the purposes of this brief time period I
16 have today, let us simply say that sunburn
17 prevention is the bottom line of our responsible
18 message, and our research within the tanning
19 industry suggests strongly that our message,
20 teaching prevention, is more effective at meeting
21 that goal than the blanket approach of teaching
22 abstinence from the sun. That's the essence to our
23 objection to the blanket listing of ultraviolet light
24 as a known human carcinogen in the 9th Report on
25 Carcinogens. Treating a life-giving commodity such

1 as ultraviolet light, and let us not lose that
2 perspective that we need ultraviolet light exposure
3 to live, as a carcinogen would be a great disservice
4 to the public. It would only serve to add to the
5 noise of misinformation and hyperbole on this topic.
6 It is our belief that the public needs to be
7 educated on how to balance the potential benefits
8 and the potential risks of ultraviolet light exposure,
9 and much of the science, not all of it, behind that
10 balance is discussed in my organization's 22 pages
11 of written comments filed to your group June 2nd.
12 Smart Tan would have prepared a more
13 comprehensive filing June 2nd and would have
14 participated in this entire process had we known
15 about it earlier. Our Federal Regulatory Review
16 Committee, which handles this type of matter, only
17 became aware of NTP's proposed listing two weeks
18 prior to filing that submission in June. We filed
19 that document without benefit of having read the
20 Background Document for Solar Radiation and
21 Exposure to Sunlamps and Sunbeds completed in
22 March, and we were not aware of any of the steps
23 leading up to that point. As we are here today to
24 discuss the procedures and the listing criteria used
25 in the preparation of the Report on Carcinogens, I

1 must point out that it is a great procedural error
2 for NTP to have ignored my organization and my
3 industry up to this point. According to your
4 Criteria for Listing Agents, Substances or Mixtures
5 in the Report on Carcinogens, there are three points
6 in the process where, quote, an agent, substance,
7 or mixture, or exposure circumstance petitioned for
8 listing or delisting will be announced in the Federal
9 Register, trade journals, and NTP publications to
10 solicit public comment. As executive director of
11 the International Smart Tan Network, I'm the
12 executive editor of Tanning Trends magazine, which
13 is Smart Tan's trade journal for the indoor tanning
14 industry, which is arguably the industry that would
15 be most affected by your committee's actions. At
16 no point in this process was my organization or our
17 trade journal contacted by NIH or NTP regarding the
18 potential listing of ultraviolet light as a known
19 human carcinogen. Your guidelines state that you
20 should have, and this breach of protocol served to
21 prevent my organization's full participation in this
22 process. That becomes a more serious
23 consideration when one considers that the review
24 process of this research did not include any
25 research about positive effects of ultraviolet light

1 on human health. I would remind you that the field
2 of photobiology was founded around the study of
3 positive effects of ultraviolet light and that there
4 are dozens of different positive effects being
5 studied today. It is ironic that this century began
6 with the realization that ultraviolet light and
7 sunlight were useful in treating disease and at the
8 end of the century, we're talking about classifying
9 ultraviolet light blanketly as a carcinogen.

10 I noticed in your proposed listing the
11 highly-publicized drug Tamoxifen on the list of
12 carcinogens, you have parenthetically stated that
13 Tamoxifen may also have positive effects.
14 Interesting that ultraviolet light is not treated in
15 the same fashion, considering the dozens of
16 positive effects of ultraviolet light, starting with the
17 undisputed fact that we would all die if we did not
18 have it. I suspect that fact makes UV a very
19 unique item on your list. Are there any other items
20 on the list that humans need to survive? Because
21 so much of the, because the research about
22 ultraviolet light contains so many confounding
23 variables and because there is so much research
24 about the positive effects of ultraviolet light, the
25 failure of NTP to contact my trade journal could be

[Redacted]

1 construed as negligent. It certainly kept my
2 organization from participating, and based on NTP's
3 background document on ultraviolet light, the scope
4 of your investigation appears to have been limited.
5 In addition to the failure to contact the tanning
6 industry's trade journal and the failure of NTP to
7 take into account any positive research about
8 ultraviolet light, I must take this opportunity to
9 mention that your background document on this
10 topic is flawed, fails to account for some fairly
11 significant research, and it would only be fair of
12 your group to allow my organization and my
13 industry time to prepare a report on exactly why
14 that is the case. Since we have not been included
15 in this process up to this point, I think that would
16 be a show of good faith on your part. Were you to
17 proceed at this point without pausing to consider
18 that case that my organization can present, you
19 would be failing to consider all the evidence.

20 Again, as Mr. Smith said, why the rush?

21 Additionally, I would ask you to consider
22 all the consequences of your actions. Here is a
23 very likely scenario: there are many diseases,
24 including breast cancer, colon cancer, ovarian
25 cancer, osteoporosis, rickets, and even heart

1 disease that research suggests may be prevented or
2 retarded by regular ultraviolet light exposure. The
3 biological mechanism for this phenomena has been
4 established and is understood. Yes, more research
5 needs to be done, but the roots are there. I want
6 you to consider this, should this proposal pass and
7 ultraviolet light is listed as a carcinogen, you may
8 be unnecessarily suggesting to people that they
9 avoid ultraviolet light exposure entirely. What
10 would the consequences of that be? In the not too
11 distant future, it is entirely plausible that a class-
12 action lawsuit of, let us say, osteoporosis patients
13 who avoided ultraviolet light because of this
14 group's suggestion could be organized. Their case
15 would be that your group's blanket listing of
16 ultraviolet light as a carcinogen misinformed them
17 of the full picture about UV light and that their
18 disease could have been prevented had they been
19 counseled on how to evaluate the benefits and risks
20 of ultraviolet light exposure. This group could just
21 as easily be breast cancer patients or colon cancer
22 sufferers. I make this point not to you as any type
23 of threat, my group has no intention of organizing
24 such a case, but as a plea that you stop and
25 consider the full set of ramifications that your

1 actions will have.

2 In closing, I'd like for you to, I'd like to
3 ask that you allow my organization and Mr. Smith
4 the time to officially make our case before
5 proceeding with your listing. Because we were not
6 included in this process from the beginning, I think
7 that that would be in the spirit of the procedures
8 you established to ensure fairness and accuracy in
9 your report. Thank you very much.

10 **DR. GOLDSTEIN:** Thank you, Mr.
11 Levy. We're actually running ahead of time, and we
12 have a speaker from this afternoon who's got some
13 changes that have to be made, and we were going
14 to put him in at the end of this morning, but
15 perhaps we ought to put you in now, Frank, since
16 they, this would allow us to get back on time and
17 if people were planning around what they thought
18 we'd be doing, we would be much more in sync
19 with the schedule. So, Franklin Mirer of the
20 International Union of the United Automobile
21 Workers. Dr. Mirer is also a member of the BSC.

22 **DR. MIRER:** Thank you very much,
23 and I appreciate the opportunity to get this in. I
24 do have to get back to Detroit this evening early,
25 and I will summarize, summarize my written

1 comments which are out on the table and have been
2 provided to the, provided by the NTP. I really can
3 sympathize with my colleagues from NTP, NIEHS.
4 We have a group of laboratory scientists dragged
5 into, into a straight-up standard regulatory
6 controversy. It's sort of like a group of civilians
7 transported to the middle of Kosovo without benefit
8 of training in this area and much of, much of what
9 we've encouraged here so far is just re-arguing, re-
10 arguing issues we've heard and considered before.

11 In my written testimony, I'll summarize it,
12 let me make two or three main points and then talk
13 about improvement of the process. First of all,
14 classification of a substance as known or reasonably
15 anticipated is a necessary hazard identification step
16 which triggers the rest of the risk assessment
17 process, and it's simply necessary to do this in a
18 concerted way and NTP has been picked as the
19 agency to do it. It needs to be done. It triggers,
20 it triggers the rest of the analysis that deals with
21 the more complex questions of exposure response
22 which have been raised here.

23 A second point is that the present criteria
24 for concluding that laboratory studies, from
25 laboratory studies that a substance is reasonably

1 anticipated to be a human carcinogen are both valid
2 and simple, generally recognized. This conclusion
3 can be done, reached fairly quickly. The fact is, to
4 try and put this in simple language, any chemical
5 which behaves in the laboratory system in the same
6 way as tobacco smoke or asbestos or soot or
7 benzidine dyes, all things well established to be
8 human carcinogens, some since the 18th century.
9 Any chemical that behaves in the way these do in
10 the laboratory system is reasonably anticipated to
11 be a human carcinogen, and what this means to me,
12 and the way I explain it to our members, is that
13 there is some dose of this chemical by some route
14 which will cause cancer in humans, and the other
15 steps of the risk assessment process follow by,
16 follow into what the actual risks of current
17 exposures are, and what we're arguing about here
18 regarding this thing is whether we're going to start
19 the process of public health evaluation or not.

20 Third point is that the Report on
21 Carcinogens has an important scientific function
22 which should not be distorted by the regulatory
23 controversy, that the correlation between laboratory
24 testing and the effects in humans is an active
25 subject of scientific investigation and it should be

1 done on purely scientific criteria, and just for an
2 example, the evolving discussion of particle
3 carcinogenesis, the effects of soot. You know,
4 when I was growing up in this field, we used to
5 speculate on how is it that asbestos is carcinogenic
6 and silica is not carcinogenic in people and many
7 careers were built around those two questions and
8 we now know that, in fact, the opposite is true.
9 Silica is carcinogenic.

10 So let me now address quickly questions of
11 process. First of all, I believe that the Scientific
12 Counselors' review, which seems to have drawn
13 most of the fire here is sufficiently elaborate and
14 extensive to meet, to meet the needs. You have to
15 remember that the Scientific Counselors' review is, I
16 believe, the third or fourth step along the process
17 and there are three or four steps after, after the
18 review by which the process goes. The documents
19 that we have, in my opinion, are sufficient to make
20 that review. We get the IARC, the full text of the
21 IARC review, if there has been one. We get the
22 additional information provided by NTP, and we get
23 the key scientific papers upon which those things
24 are based. We read them and take them into
25 account, and I certainly think it's sufficient.

1 DR. FREDERICK: Plus the external
2 comments.

3 DR. MIRER: Well, we get the
4 external comments at the point which they're
5 available to us, and they have been mailed fairly
6 early in the process in many cases, and for those
7 who've been at these meetings, what we are
8 attempting to do is have an on the record
9 discussion amongst the BSC members who have to
10 take the vote. We have to have an on the record
11 discussion amongst ourselves as to what our
12 opinions are, and sometimes those are spirited, and
13 sometimes they're straightforward, but that's what
14 we are trying to get to in the meeting.

15 Finally, some pieces that would improve it.
16 I think while the decision rules for including
17 reasonably anticipated from animal data alone are
18 fairly straightforward, I think that the process is
19 weak in the areas of epidemiology and human
20 health, human exposure assessment, and those two
21 are parts of each other. If we're going to be
22 reinterpreting epidemiology, we have to interpret
23 both the effect and the exposure as we're doing it,
24 and I think the process would be strengthened by
25 having more people involved in that. Others have

1 commented on that.

2 Unpublished health data are really not
3 appropriate to the, to the review. Actually there
4 hasn't been that much unpublished data. There's
5 been some re-analysis, but not that much
6 unpublished data.

7 The third point is that involvement of
8 potentially affected industry should remain as it is
9 now. There's plenty of input and plenty of papers
10 supplied to us. I believe it's adequate to make the
11 review. I think peer review has to encompass a
12 range of scientific views, not be encumbered by
13 conflict of interest and that stakeholder involvement
14 is a whole other process having to do with risk
15 management rather than risk assessment.

16 Just some other brief points, I believe that
17 the Levels of Evidence developed by NTP for
18 analyzing its own bioassay data should be carried
19 forward into these, into these background
20 documents. I think that they were very helpful in
21 the process of evaluating bioassay data and an NTP
22 staff or expert in this area should apply them
23 retroactively to non-NTP studies. I believe that
24 similar levels of evidence should be developed for
25 interpreting epidemiology data. That would give us



1 a much more consistent set of decision rules for
2 epidemiology, which is actually where we end up in
3 controversy most frequently. I think the role of
4 mechanism in the background document should be
5 more focused around what its relation is for listing
6 criteria, and I believe we need to focus better what
7 the role of genetic toxicology is in relation to the
8 listing criteria, rather than just simply deciding this
9 isn't on the documents. Thanks very much.

10 **DR. GOLDSTEIN:** Thank you,
11 Frank. We've got, the next speaker I'm not sure is
12 here, Rabbi Daniel Swartz. Is Rabbi Swartz here?
13 Okay, Bob Musil of the Physicians for Social
14 Responsibility.

15 **DR. MUSIL:** Thank you very much,
16 Dr. Goldstein. I'm Dr. Robert Musil. I'm executive
17 director and CEO of Physicians for Social
18 Responsibility, which has 15,000 members
19 nationwide. I want to thank you for the
20 opportunity, Dr. Olden, to present our views here
21 today and to the panelists who are here. We want
22 to comment briefly and I don't have slides and
23 overheads, so you can relax, on the procedures for
24 reviewing nominations for report listing and
25 delisting and the current listing criteria.

1 I want to make just a few brief main
2 points. The first is the Physicians for Social
3 Responsibility believes that the Report on
4 Carcinogens serves an essential function of
5 identifying substances, mixtures, and chemicals in
6 situations that might cause cancer, to which
7 significant numbers of persons in the U.S. are
8 exposed. We have found the reports to be
9 informational, scientific review documents that help
10 educate the public, help professionals and other
11 agencies. We consider them essential, and that's
12 because Physicians for Social Responsibility also
13 believes that there is a fundamental public right to
14 know which substances or exposure circumstances
15 are known to be or reasonably could be anticipated
16 to be carcinogenic. We believe that is why
17 Congress has mandated, and properly so, the NIEHS
18 to issue the RoC report under the Public Health
19 Service Act so that public and health professionals
20 will be informed and educated about the risk of
21 exposure to carcinogens, available cancer data, and
22 the regulations promulgated by federal agencies to
23 limit exposures.

24 It seems to us, and I should say directly,
25 that Physicians for Social Responsibility is

1 frequently engaged in legislative and regulatory
2 activity and quite familiar with the lobbying
3 process, but in this case, it seems to us it is not a
4 good idea to question the Congressional mandate
5 that has put this vital process under NIEHS and the
6 National Toxicology Program. We believe that the
7 current review process should be carried out mostly
8 as it has been occurring, with some improvements.
9 We believe that there is the expertise to staff the
10 work, that there is an excellent scientific support
11 staff, and that the process is generally insulated
12 from the political process and from the influence of
13 powerful corporate interests who understandably
14 have financial incentives to use scientific opinion in
15 support of individual chemicals. That, in our view,
16 is the problem to be avoided, and therefore,
17 Physicians for Social Responsibility also believes
18 that the RoC report process should not be moved to
19 the National Academy of Sciences or any other
20 agency that may prove to be slower, more costly,
21 or that would include direct corporate science and
22 review committees and consider non-peer reviewed
23 science. It would not serve the public interest to
24 remove the RoC report from the purview of NIEHS,
25 a respected agency. We also think as Physicians

1 for Social Responsibility that it's important to
2 remember that the public interest is best served by
3 the release of balanced and timely reports. For a
4 majority of agents and substances the scientific
5 conclusion as to carcinogenicity is clear and can be
6 reached fairly quickly, so long as outside financial
7 interests are not given the opportunity to endlessly
8 delay the process under the guise of full and fair
9 debate as appears to be happening with the current
10 report. This newest report should be released
11 immediately so that appropriate steps can be taken
12 to protect the public health. Therefore, we believe
13 that the scientific process and procedures currently
14 used in the National Toxicology Program, though
15 not perfect, generally result in good and balanced
16 outcomes. As long as the procedure remains fair
17 and all sides receive an equal chance to present
18 their data and views, the scientific deliberations
19 will be mainly trustworthy. The sort of decisions
20 to be made in the RoC report are scientific
21 decisions and thus they should be made only by a
22 panel of scientists who are shielded from strong
23 lobbying and special interest pressures. This is not
24 and should not be a political process. Dr. Olden
25 and members of the panel, it is your job to ensure

1 that the process used by the NTP remains fair and
2 based upon reliable science, including a good
3 balance of experts and an excellent review process.
4 PSR urges you to continue your efforts to improve
5 the process by making it more open, by looking at
6 all the science, and for holding meetings like this
7 today. Now that you have developed the process,
8 Physicians for Social Responsibility encourages you
9 to stick with it and to let it work to protect the
10 public health. Thank you very much.

11 **DR. GOLDSTEIN:** Thank you, Dr.
12 Musil. Our next speaker is Kerry Lane of the
13 Delray Medical Center, Dr. Lane.

14 **DR. LANE:** Good morning. My
15 name is Dr. Kerry Lane. I'm a medical doctor. I
16 have a long interest in cancer. I've seen a lot of
17 it over the years. I'm a practicing anesthesiologist
18 in Florida, and if you're asking yourself why I'm
19 here, generally I'm supposed to address the process
20 of NTP's evaluation of carcinogens, and historically
21 this has been geared towards industrial chemicals.
22 I had an interest in occupational medicine some
23 years ago, but apparently I took a wrong turn. The
24 reason I'm here mostly is because I feel that
25 aflatoxin is a major carcinogen associated with the

1 use of tobacco products. Aflatoxin is the most
2 potent carcinogen known, causes cancer in every
3 animal model studied and causes p53 mutations and
4 ras mutations which is found in the majority of
5 most human cancers. This is significant to the NTP
6 in an examination of primary and secondary smoke
7 as carcinogens, but I think that aflatoxin
8 contamination of our public spaces from tobacco
9 smoke is a confounding variable with respect to a
10 lot of these other carcinogens that NTP is trying to
11 regulate. Ultraviolet light is one carcinogen that
12 comes to light. Melanoma shows p53 mutations
13 which can be caused by aflatoxin, so I think that
14 aflatoxin is certainly a confounding variable here.
15 Another example would be asbestos, where asbestos
16 exposure alone without tobacco smoke shows a
17 fairly low incidence of cancer, but when you add
18 tobacco smoke to it, the cancer rate goes up
19 significantly. Something similar is also seen with
20 Hepatitis C. Aflatoxin combined with Hepatitis C,
21 the instance of hepatoma, liver cancer goes up 20
22 times. I suspect there's also a confounding
23 variable with aflatoxin and a very common
24 carcinogen which is probably also in tobacco called
25 xeroallonone (phonetic) which is an estrogenic

1 micro-toxin which likely causes breast cancer in
2 conjunction with aflatoxin in smokers and people
3 who are exposed to second-hand and primary
4 smoke. Much of this evidence is from p53
5 indications where p53 is a biomarker. Unfortunately
6 for we human beings, we have been the test
7 subjects. What I'm suggesting is NTP and other
8 federal governments, other federal organizations,
9 including CDC, FDA, NIOSH, NCI, and whoever else
10 feels up to the task should assess this concept and
11 provide a micro-toxins surveillance network on
12 tobacco products and provide a regulatory
13 framework to remediate this problem. It seems to
14 me that technological fixes are probably available
15 to even prevent this contamination. This is
16 significant because obviously the aflatoxin and
17 other p53 mutation chemicals that are involved in
18 tobacco smoke are involved in the majority of
19 cancers, human cancers. If we can remove these
20 chemicals, we'd go a long way towards preventing
21 human cancers. I've been instructed by the
22 attendees this morning, there were a lot of
23 corporations and particular chemicals feel that
24 they're being put upon by NTP, and I think that
25 the, this secondhand smoke and primary smoke

1 issue with aflatoxin should be seriously addressed
2 because I do think it's a confounding variable in
3 many of these cancer-causing agents. The p53
4 tumor-suppressor gene is the final arbiter whether
5 or not a cell dies or not once it becomes
6 carcinogenic, and if a p53 tumor-suppressor gene is
7 mutated by aflatoxin from cigarette smoke, you
8 know, you're pretty much done for. Thank you
9 much, thank you for your time.

10 **DR. GOLDSTEIN:** Thank you, and
11 again, I'd like to thank the speakers for keeping
12 within the time, giving us, actually an interesting
13 scheduling issue. We have, I hope Dennis Falgout's
14 here. Is he here, speaker for the Metal Finishing
15 Association of Southern California? Okay, well,
16 basically we're well ahead of ourselves. We've got
17 two, in a sense, competing issues here. One is
18 that we can keep to schedule, take our break now,
19 extend the break, and try to get ourselves back into
20 the schedule with the speakers later. That has the
21 advantage of allowing people who might have
22 wanted to come for a specific presentation to be
23 here or keeping it with the schedules. The other
24 approach is to allow the individual speakers who
25 might be scheduled for later this afternoon, who

1 would just as soon speak this morning and don't
2 care if they miss some of the audience, to speak
3 now. I'm tempted to allow the latter, and basically
4 to say, if there is anyone who was scheduled for
5 speaking this afternoon and who would like to
6 present now, the floor is yours. First come, first
7 serve, until we run out of time. Anybody like to
8 take me up on that offer? Well, hearing none,
9 let's, we'll, there is somebody, okay.

10 **MS. NABORS:** Thank you. I'm
11 Lyn Nabors, executive vice president of the Calorie
12 Control Council. Like many others before me and
13 yesterday, I'm going to use a specific substance to
14 illustrate my remarks. The Calorie Control Council
15 is an international association of manufacturers of
16 low-calorie and reduced fat foods and beverages;
17 companies that make or use saccharin in their
18 product are among the Council's members. The
19 Calorie Control Council petitioned the National
20 Toxicology Program to delist saccharin from its
21 Report on Carcinogens on the basis of NTP's new
22 criteria incorporating the use of mechanistic data.
23 This was NTP's first request, I believe, to delist on
24 this basis. The Council appreciates this opportunity
25 to comment on the process of delisting and listing

1 and recognizes the massive task that NTP
2 undertakes to compile accurate information on all
3 substances under review. Since consideration of
4 mechanistic data and possible delisting are
5 essentially new to the process, we would like to
6 share our experiences in hopes that they will help
7 in future reviews.

8 Our comments, like many others that you
9 have heard in the last couple of days, specifically
10 relate to the proceedings of the Board of Scientific
11 Counselors and as an aside, I have to say, I'm not
12 sure Michael Jacobson and I attended the same
13 meeting.

14 In petitioning for the delisting of
15 saccharin, the Council provided a wealth of
16 information, including results of numerous
17 mechanistic studies conducted over the past few
18 decades. These studies demonstrate clearly that
19 the bladder tumors observed in male rats that had
20 high doses of sodium saccharin are not hazardous
21 to man. There is overwhelming evidence from
22 animal studies, human epidemiology and basic
23 mechanistic research, that rat bladder tumors are a
24 high dose phenomenon with no relevance to
25 humans. This is the foundation of Calorie Control

1 Council's request that saccharin be delisted from
2 the Report on Carcinogens. Information provided by
3 the Council was evaluated by NTP internally and
4 two internal committees voted to delist. NTP then
5 prepared the saccharin report and submitted it with
6 the Board of Scientific Counselors prior to their
7 October 1997 consideration of saccharin. There
8 were a few inaccuracies in the NTP report which
9 the Calorie Control Council addressed in its October
10 1997 comments before the Board. The overall
11 conclusions of the NTP saccharin report, however,
12 appeared to support the conclusions of the two NTP
13 internal committees, which had clearly indicated
14 that saccharin should be delisted.

15 Based on the Board's proceedings, we'd
16 offer the following important points on how future
17 Board reviews might be improved. Point number
18 one, the Council believes that the Board of
19 Scientific Counselors should be provided with a
20 balanced presentation from NTP as one indicator of
21 their main decisions to date, with their vote and
22 the rationale for those decisions. Unfortunately,
23 the verbal NTP presentation on saccharin to the
24 Board of Counselors was not balanced and gave
25 little indication that two NTP committees had

1 already voted to delist. In point of fact, the
2 presentation gave misinformation and incorrect
3 calculations on saccharin consumption and differed
4 from NTP's written document on saccharin.
5 Mechanistic data, the basis of the Council's
6 proposed delisting of saccharin, was almost entirely
7 overlooked by the NTP presenter. Not surprisingly,
8 the majority of the Board of Scientific Counselors
9 largely ignored this mechanistic data as well.

10 Point number two, and this one has been
11 mentioned by a number of others. Sufficient time
12 should be allowed to discuss issues raised,
13 including time for petitioners to provide data to
14 place other presentations in perspective. For
15 example, questions arose at the Board's meeting
16 concerning private consumption of saccharin. It
17 was noted by one of the panels that there were
18 individuals in the audience who could probably
19 answer those questions, yet they were never
20 allowed to do so. Decisions should not be made on
21 incorrect assumptions.

22 Point number three, assigning a consultant
23 or group of consultants knowledgeable about the
24 substance under discussion should be available to
25 the Board of Scientific Counselors. Numerous

[Redacted]

1 substances are considered at a single meeting and
2 the Board members have a substantial amount of
3 information on each substance which is provided
4 about 30 days before that meeting. With the
5 volume of information provided, it is doubtful that
6 Board members can review adequately and digest all
7 the data. The scientific community of the
8 substance in question can easily facilitate
9 deliberations, provide insight, and answer questions.

10 Point four, members of the Board are
11 selected from a variety of disciplines and areas of
12 expertise. It is important, therefore, that all
13 members participate in the deliberations. The
14 Council suggests that procedure be set up for
15 perhaps audio and video conferencing in order that
16 all Board members might participate if they cannot
17 physically be there. I would have to say that at
18 the time of the review that we were involved in,
19 there were only seven members at that meeting,
20 and I realize that that number has doubled, so that
21 comes, I'm pleased in that context. We're able to
22 reach a sufficiently larger group of people.

23 In conclusion, it is important to note that
24 although NTP's Board of Scientific Counselors voted
25 four to three against delisting saccharin, a third

1 NTP committee, the Executive Committee,
2 subsequently also voted to delist. The fact that
3 three NTP committees voted to delist and that two
4 working groups of the International Agency for
5 Research on Cancer, after reviewing saccharin's
6 mechanistic data, unanimously agreed that there is
7 strong evidence that the mechanism of
8 carcinogenicity in experimental animals does not
9 operate in humans brings into question the process
10 by which the NTP Board reached its conclusion and
11 suggests the need to bolster the scientific
12 information made available to the Board. Thank you
13 very much.

14 **DR. GOLDSTEIN:** Thank you.
15 Again, let me make that offer for anyone else who
16 is scheduled to speak this afternoon. Dr. Waddell,
17 would you like to?

18 **DR. WADDELL:** If the slides work,
19 I'll be happy to do mine.

20 **DR. GOLDSTEIN:** Okay, slides
21 work, we have some, and I must take the time of
22 thanking the folks here who have been working with
23 us. It's been very effective. I'm usually accustomed
24 to having something break down, and so far, great
25 job.

1 **SPEAKER:** Maybe you ought to
2 knock on wood.

3 **DR. GOLDSTEIN:** Dr. Waddell.

4 **DR. WADDELL:** The first slide you
5 can see, can we dim the lights? Thank you for the
6 opportunity to express our opinion on the process
7 of preparation of the Report on Carcinogens from
8 NTP. For several years now, I have noted with
9 increasing concern that the reports have not kept
10 pace with the advancing knowledge of the nature of
11 these so-called carcinogens. In my opinion, it is
12 time for a drastic revision in the process of
13 preparing the reports. Next slide.

14 First of all, let me show you where it is
15 clearly stipulated in the statute that created the
16 RoC for the reports to provide a statement
17 identifying the extent to which standards decrease
18 the risk, and those are clearly expressed in the
19 statute, decrease the risk to public health from
20 exposure to such substances. The reports have
21 failed to provide this information.

22 The introduction section of the 8th Edition
23 of the Report acknowledges this deficit and offers
24 several paragraphs to explain the omission of this
25 risk reduction evaluation. This defense takes the

1 position that any reduction in exposure will result
2 in a reduction of risk. This mere extrapolation to
3 zero is reminiscent of the Delaney clause. It is not
4 congruent with the current thinking of many
5 toxicologists. The RoC has evolved into a
6 document that is no longer useful and actually is
7 confusing and contradictory to a reader depending
8 solely on it for carcinogenicity information. The
9 reason for this dilemma is essentially because the
10 reports do not contain any appropriate quantitative
11 information regarding dose or mechanism of action.

12 I should like to give a few examples
13 illustrating why this linear extrapolation creates a
14 problem. Arsenic, chromium, and nickel are listed
15 in the RoC currently as either known or reasonably
16 anticipated to be human carcinogens, but all are
17 essential nutrients in the human diet. Furthermore,
18 all three are ubiquitous in foods. Chromium and
19 nickel are even added to vitamin and mineral
20 supplements such as One-A-Day, Centrum, Centrum
21 Silver, and many others. Users of these
22 preparations must surely be confused by the listing
23 in the RoC that these minerals are carcinogens.
24 Estradiol-17 Man, Estrone, Progesterone, and
25 conjugated estrogens are listed in the 8th Edition as

1 either known or reasonably anticipated to be human
2 carcinogens, but as even most laymen know, these
3 substances are also naturally occurring hormones in
4 women and are prescribed by physicians for
5 treatment of menopause, osteoporosis, and other
6 purposes. What could be more confusing to a
7 woman who has been prescribed by her physician a
8 substance and then learns that it is listed by the
9 NTP as a carcinogen? If women were to accept the
10 proposal in the introduction to the reports that any
11 reduction in exposure reduces the risk, they would
12 then be confronted with the choice of having their
13 ovaries removed to reduce their exposure to this
14 carcinogen or to maintain their normal hormonal
15 status as a woman.

16 Benzene and vinyl chloride are, of course,
17 listed in the RoC as known human carcinogens. The
18 specific neoplasms these substances produce at high
19 concentrations are well known to the scientific
20 medical community. However, OSHA, another
21 federal agency, has evaluated exposures to these
22 substances and concluded that exposure to one part
23 per million of either of these chemicals is not a
24 risk to workers. The NTP RoC made no statement
25 evaluating how much these statements reduce risk.

1 Time does not permit a recitation of the
2 epidemiological data supporting the OSHA decision
3 for one ppm of benzene being safe for a worker's
4 lifetime; however, it should be noted that benzene
5 is ubiquitous in the atmosphere and that most of it
6 is naturally produced from decaying biomass and is
7 not produced by man's activities. The volatile
8 organic chemical, or VOC, data base contains levels
9 of benzene in the ambient air in the United States.
10 It may come as a surprise to some people that even
11 in the most remote pristine locations individuals are
12 breathing seven quadrillion molecules of benzene
13 per day. Certainly a quantitative evaluation on the
14 effect of dose is appropriate for benzene.

15 Vinyl chloride at high doses can cause
16 angiosarcoma of the liver, no question. However,
17 health surveillance databases of workers around the
18 world in industries using vinyl chloride reveal that
19 not a single case of angiosarcoma has appeared in
20 these workers hired since 1974 and exposed to one
21 ppm when this standard was set.

22 Finally, alcohol, a substance consumed by
23 more than a hundred million Americans is under
24 consideration for listing in the 9th RoC as a known
25 human carcinogen. Yet many reports have

1 consistently and convincingly shown that moderate
2 consumption is beneficial to the cardiovascular
3 system. Studies also reveal that moderate
4 consumption is associated with a reduced risk of
5 dying, regardless of other factors. A thorough
6 analysis of all this data concluding that there is an
7 association of alcohol drinking with cancer reveals
8 that all these studies are confounded by other
9 factors that may be causing it, such as an alcoholic
10 lifestyle, cigarette smoking, poor diet, poor oral
11 hygiene, potential viral infection and many others.

12 In conclusion, the current process does not
13 fill, fulfill the mandate from Congress to provide
14 quantitative statements concerning the reduction of
15 risk from reductions in exposure. Secondly, dose
16 response and mechanism of action data are
17 available and should be used, I would say, must be
18 used. We get into a dilemma if we do not use
19 quantitative data. Review panels that include
20 scientists with detailed knowledge of dose response
21 and mechanism of a specific substance should
22 allow, should allow for quantitative evaluations.
23 Other agencies provide at least as much qualitative
24 information as the RoC and some even provide
25 quantitative evaluations. The RoC should certainly

1 contain quantitative information to assist the reader
2 with evaluating any potential reduction of risk from
3 a reduction in exposure. Perhaps Congress...if this
4 cannot be done, the reports will continue to be
5 redundant and of little or no value. Perhaps
6 Congress in that case should even consider
7 termination of the reports. Thank you.

8 **DR. GOLDSTEIN:** Thank you, Dr.
9 Waddell. I understand that Mr. Falgout's here,
10 please, sir, from the Metal Finishing Association of
11 Southern California.

12 **MR. FALGOUT:** Here, I was two
13 hours earlier. I thought I had plenty of time. You
14 guys have been whistling through this.

15 My name is Dennis Falgout. I'm a
16 registered professional engineer. I work for a
17 consulting engineering firm, Pacific Environmental
18 Services, Inc. in Herndon, Virginia. PES has worked
19 with the Metal Finishing Association of Southern
20 California for the past twelve years to help its
21 member-companies reduce toxic emissions,
22 emissions of toxic compounds in the environment.
23 We've measured emissions to the atmosphere and
24 exposure to workers of toxic compounds. We've
25 also carried out some joint research projects with

[Redacted]

1 the California Air Resources Board and the South
2 Coast Air Quality Management District to evaluate
3 and develop Best Available Control Technology for
4 hexavalent chromium. The current Chairman of the
5 Board of Directors of Metal Finishing Association,
6 Ms. Carol McCracken and the Chairman of the Air
7 Quality Committee, Mr. Randy Solganik. Neither
8 could be here today, so I am appearing here to
9 speak for the Metal Finishing Association of
10 Southern California.

11 The Association believes that in addition,
12 that the addition of nickel and all nickel compounds
13 to the list of known human carcinogens was policy
14 driven and not scientifically supported. This action
15 will adversely affect our industry. Our comments
16 today are not based on the interpretation of the
17 toxicology or epidemiology data but instead on the
18 review procedures and listing criteria used in the
19 Report on Carcinogens.

20 NIEHS should base its positions on
21 carcinogenicity totally on its own independent
22 review of scientific literature. NIEHS should not,
23 as a reading of the RoC reveals, base its positions
24 on the conclusions of other committees or
25 regulatory agencies. Furthermore, it appears that

1 NIEHS cites IARC and other committee views only
2 when those views support the NIEHS position.

3 The Association joined with the USEPA and
4 Health Canada support a Toxicological Review of
5 Soluble Nickel Salts. The study was completed in
6 March of this year, of '99, by Toxicology Excellence
7 for Risk Assessment, TERA, in Cincinnati, Ohio.
8 This study included procedures for independent peer
9 review, records of comments and recommendations
10 from peer review meeting, and managing potential
11 conflicts of interest. TERA also employed an
12 effective process for resolution of differences in
13 viewpoint, which led to compromise and
14 development of consensus. NIEHS should emulate
15 the procedures used, followed by TERA during the
16 development of its RoC rather than the current
17 procedures.

18 In Section 34(b)(4) of the PHS Act,
19 Congress identified that, specified that NIEHS
20 should publish a list of carcinogens, known to be a
21 human carcinogen and two, to which a significant
22 number of persons are exposed. The law also
23 states that NIEHS should provide, should provide
24 information on the nature of exposures, the number
25 of persons exposed, and the extent to which

1 regulation will decrease public risk. The
2 Association sees no evidence that NIEHS has done
3 more than publish a list of carcinogens.

4 Your agency's position on the
5 carcinogenicity of compounds carries enormous
6 weight with the regulatory agencies at all levels of
7 government. Therefore, NIEHS should publish
8 information that would allow other agencies to
9 interpret the relative risks of various compounds.
10 Our specific suggestions regarding the NIEHS
11 criteria for listing compounds are as follows: The
12 criterion for designating a known human carcinogen
13 should require the highest level of scientific
14 certainty. Also, it should require that human and
15 animal studies be consistent and supportive. The
16 criterion for designating a compound reasonably
17 anticipated to be a human carcinogen should be
18 based on a secondary level of certainty. Animal
19 studies should exclude potential carcinogens if they
20 are inconsistent or not supportive. Three, NIEHS
21 should speciate compounds and recognize significant
22 differences between species as compared to
23 blanketing an entire class of compounds. And
24 number four, NIEHS should clarify the standard
25 required, standards required to achieve a listing of

1 a known human carcinogen. The current standards
2 are too subjective and seem to be based on policy
3 rather than science.

4 Our specific comments on the review
5 procedure for listing compounds in the RoC follow:
6 One, require more than a simple majority of the
7 panel members at each level to add a compound to
8 the list of known human carcinogens. Two, RoC
9 should identify the key facts, studies, that
10 supported each panel's decisions and
11 recommendations. Number three, broaden and
12 extend the time of the peer review process for
13 extra-agency opinions to agency proposals and
14 publish both comments and responses. Number
15 four, RoC review committees should not depend on
16 IARC or other agency conclusions alone but should
17 independently base its findings and designations on
18 the research reports published in the literature.
19 And number five, NIEHS should expand the RoC
20 report to include information on the nature and
21 prevalence of public exposures and the extent to
22 which Federal regulations could protect public
23 health. And that's the full extent. Any comments,
24 questions?

25 DR. GOLDSTEIN: Well, we'll have a

1 chance to discuss later. We have a different
2 format. Thank you. Actually we have one speaker
3 who I don't think is here, but just to be sure, is
4 Rabbi Daniel Swartz here from the, or anyone else
5 from the National Religious Partnership for the
6 Environment? Okay. If not, let me suggest that we
7 take a break. We will get back on schedule, return
8 at 11:15 and we'll have a discussion then from
9 11:15 to noon. 11:15 as it's scheduled.

10 (WHEREUPON, a brief break was taken.)

11 DR. GOLDSTEIN: I'd first ask the
12 National Toxicology Program folks if there's
13 anything they'd like to respond to specifically in
14 the way of clarification. Dr. Lucier...

15 DR. LUCIER: Let me, if you don't
16 mind, Bernie, just briefly go over the entire process
17 for the report on carcinogens, since some of the
18 people weren't here yesterday when Bill Jameson
19 presented that. I think it's been alluded to many
20 times that this is a multi step process that begins
21 when we do a Federal Register announcement
22 calling for information relevant to an agent that
23 we're considering or considering for listing. This
24 usually happens, you know, in the probably eight or
25 nine months before we have our Board of Scientific

1 Counselors meeting. Then using this information and
2 deliberations of the NIEHS we prepare an actual
3 document that's made available to everyone, it has
4 been in the past, 30 days prior to a Board of
5 Scientific Counselors meeting and prior to the
6 Board of Scientific Counselors meeting there's two
7 government meetings both with votes on whether or
8 not something should be listed or delisted, the RG1
9 and RG2. So the Board of Scientific Counselors is
10 the third step in the review process, one in which
11 rightfully so many of the discussion points were
12 directed at, because that's the open external peer
13 review part of the process.

14 After that there's another call for public
15 comments, a review by our, the Executive
16 Committee. All this information in its totality is
17 considered by Dr. Olden and the recommendation
18 that he makes to Dr. Shalala and ultimately the
19 report then is submitted to Congress.

20 **DR. GOLDSTEIN:** Thank you. Now
21 what we'll do is we'll turn this over to Lynn
22 Goldman and Clay Frederick to discuss themes,
23 make responses. For those who weren't here
24 before, these are two members of the Board of
25 Scientific Counselors. Lynn...

1 DR. GOLDMAN: Yeah, I'll go ahead
2 and lead off. I thought that there were some very
3 interesting and new ideas that came out from the
4 comments this morning. The idea that there might
5 be a workshop, a technical scientific workshop
6 earlier on in the process, say at the RG2 phase, I
7 thought was a very interesting idea, and I thought
8 it would be interesting to think in terms of whether
9 that might be an efficient way to bring in more
10 input versus more time for presentations between
11 the Board, in front of the Board of Scientific
12 Counselors, which has also been mentioned or even
13 both of those ought to be considered in terms of
14 improving the process and having more of an
15 opportunity for discussion and input on the
16 scientific issues.

17 The other thing that I thought was an
18 interesting point from Dr. Jacobson, the idea of
19 perhaps streamlining the RG2 in the Executive
20 Committee process and I wanted to say a little bit
21 about that, as somebody who did Chair the
22 Executive Committee for awhile when I was in the
23 government and I really think that that's a very
24 different process than the scientific process that
25 happens with the RG2. I think it's an important

1 process, even if the quote, unquote, votes don't
2 appear to change. What's happening there is that
3 the results of the deliberations are being brought to
4 the attention of the policy level in agencies in
5 government that are responsible for actually
6 regulating some of the substances that might be up
7 for listing. I think it's extremely important that the
8 policy level has to focus on this issue and that it's
9 an important role that the NTP process plays within
10 the government, and, you know, regardless of
11 whether the votes change or not, I don't think
12 that's where the focus ought to be. I think it's just
13 something different going on there and I think it's
14 pretty critical. I'll say from my personal experience
15 there were times when I wouldn't have known,
16 leadership in EPA wouldn't have known that some of
17 these issues were under consideration or not for
18 that process, simply because perhaps at the
19 scientific level there was less awareness of the
20 policy relevancy importance at the policy level of
21 some of those issues. So, I think it just needs to
22 be looked at in a slightly different light.

23 There were a number of comments about
24 the need to make sure that the trade organizations
25 and other organizations are aware, and I was glad

[Redacted]

1 that Dr. Lucier went through the process again,
2 because it seems to me that there are opportunities
3 for that. You know, what I'm concerned about
4 there is that how that is done is through the
5 Federal Register, by and large. I think that actually
6 trade organizations are pretty good at keeping track
7 of what's in the Federal Register, but that scientists
8 don't read that journal. You know, that perhaps
9 there could be more aggressive outreach to the
10 scientific community, to make sure that the
11 scientific community is aware of what's happening
12 and Dr. Lucier, you may be able to clarify. There
13 may be efforts along those lines that I'm not aware
14 of. But it seemed to me that in the discussion
15 section here, that what might make sense to talk
16 about would be have some further discussion about
17 again process issues around not only the peer
18 review itself, but also the RG1 and RG2 processes
19 and the ability to perhaps alter those processes so
20 that there is more opportunity for scientific
21 exchange and give and take. Also to somehow
22 increase the transparency of how people's scientific
23 comments are being taken into account in the
24 process and not necessarily would there have to be
25 something like notice and comment, which from my

1 comments yesterday people probably realized I
2 really would not like to see that happen to this
3 process. So that at least it's clearer to people who
4 put arguments forward that are rejected, that those
5 arguments have been heard and that the folks
6 rejecting them, they may not agree with the
7 reasons that they're rejecting them, but they're
8 consciously rejecting them or that perhaps as, Dr.
9 Goldstein, as you mentioned yesterday, that they
10 may agree with the argument, but still agree with
11 the definite call about the listing, because that's
12 what is at issue and that the argument simply
13 doesn't overturn a definite call. So, I would like to
14 see that because it seems to me that this issue of
15 transparency is the most consistent one that people
16 are raising today.

17 **DR. GOLDSTEIN:** Dr. Frederick.

18 **DR. FREDERICK:** Well, I like Lynn
19 was struck by Phil Leber's proposal with regard to
20 the possibility of a workshop early in the process.
21 You know, just thinking about it, I don't know how
22 feasible it would be logistically and this and that,
23 but I would look at that, if we were to do
24 something like that very early in the process. The
25 background documents are prepared by an external

1 contractor and they're continually modified in the
2 course of the process and are refined through RG1
3 and RG2 proceedings. But I can see where for
4 example that a background document could be
5 prepared by the contractor and made available to
6 interested parties and then a workshop could be
7 held very early on prior to or immediately following
8 the RG1 meeting with a focus on being sure that all
9 the technical issues are on the table for discussion.
10 I could see that as a possibility. I'm not sure how
11 practical that would be, but it at least conceptually
12 has some level of appeal for me. I'm not
13 particularly enthralled with the idea of having a
14 continual ongoing debate in the course of this
15 process. I think that would just bog everything
16 down forever. But I think a well-defined event
17 early on, to be sure that all of the relevant
18 information was on the table early in the process,
19 could be enriching for the process.

20 If I could now move forward with, I
21 appreciate the supportive comments from a variety
22 of groups here. I'd like to say that I'm an industry
23 guy and there's something of a mixed, this could be
24 viewed as kind of a mixed issue by some with
25 regard to my participation in the process.

1 However, I feel that the fundamental principles
2 endorsed by CMA with regard to the responsible
3 care program, good product stewardship, are
4 basically the same principles embodied by the NTP
5 evaluation process and I see no fundamental
6 conflict in the alignment of those principles. Now
7 when you get into specifics of how data is
8 evaluated on a specific case, inevitably given a
9 group of scientists, there will be some level of
10 disagreement on specific technical issues.
11 Philosophically I see very strong alignment between
12 those programs.

13 As we look through the various comments,
14 I mentioned Phil Leber's proposal on the workshop
15 and his concern for lack of dialogue in the process,
16 and he and another presenter later on, Donald Smith,
17 made me think that maybe I'd left the wrong
18 impression. I either misspoke or spoke and left the
19 wrong impression yesterday with regard to verbal
20 testimony. I'd like to be clear on this. It's very,
21 it's my opinion that the most effective way to be
22 involved in this process is to present a
23 comprehensive technical document early in the
24 process that fully presents all the technical issues
25 on the area of concern early in the process. Then

1 later on, at the actual public meeting, the verbal
2 testimony at that point just highlights the particular
3 issues of concern, with regard to the advocate on
4 the point, as well as might highlight any other
5 issues that may have developed in the course of
6 the intervening time. But I did, I have felt at
7 certain times in the past there's been an
8 inappropriate emphasis on the verbal testimony at
9 the meeting, relative to the early presentation of a
10 comprehensive technical document and that was
11 what I was trying to present yesterday and I may
12 not have expressed that very well.

13 DR. GOLDMAN: So, you liked those
14 presentations?

15 DR. FREDERICK: I actually have to
16 say, I love intellectual debate and I actually enjoy
17 the verbal presentations. My concern is that they
18 may have gotten inappropriate weighting with regard
19 to effectiveness. So, that's basically what I was
20 trying to point out. Jim Hathaway's comments, his
21 comments with regard to lack of feedback, with
22 regard to input in the process and lack of
23 discussion of key points is a matter of concern. I
24 acknowledge that, and I think I would encourage
25 NTP staff to find ways to acknowledge the receipt

1 of input and I think we as a board will look for
2 ways to more consciously highlight the fact that we
3 have evaluated external information. I said
4 yesterday I personally am very conscientious about
5 reading every word, every page of every submitted
6 comment, but I think there's some things we can do
7 to highlight the fact that this has been evaluated
8 and is a part of the discussion.

9 Michael Jacobson's comments with regard
10 to the saccharin experience, his interest in
11 providing funds for public interest groups to
12 explore some of the issues on the table, I have to
13 admit is interesting. I don't know if there's a
14 vehicle to actually make that happen, but I am very
15 well aware of the fact that public interest groups
16 are often sorely strapped for resources and I
17 acknowledge that as an interesting problem.

18 The issues about lack of consideration of
19 the most recent publications is a continuing
20 problem in the sciences, you know, as science
21 continues to develop. I don't, if there is a
22 substantive technical issue that has changed the
23 landscape in a substantive way, I would suggest
24 that a delisting petition be submitted at the earliest
25 opportunity, using cited technical information as a

1 basis for that proposal.

2 The issue of reaching out to various groups
3 that Joseph Levy brought up with regard to
4 notification is a problem. I realize not everybody
5 follows the Federal Register. These notices are up
6 on the NTP website, but not everybody checks the
7 website from time to time and I think it's worth
8 highlighting that maybe a little more aggressive
9 program, trying to reach out to interested parties,
10 both public interest groups as well as trade groups,
11 that sort of thing, using e-mail and cost effective
12 options would be something worth exploring.

13 Moving on to Kerry Lane's comments with
14 regard to aflatoxin and tobacco smoke, it sounds
15 like this is a worthwhile and a confounding variable
16 in various toxicity findings. This looks like it's
17 certainly something to be explored from the
18 research point of view and I know NTP has an
19 active exposure evaluation program. They just held
20 a recent workshop in that area and I think in the
21 course of NTP research this is something that could
22 be considered for further evaluation, in terms of its
23 effects.

24 Finally Dr. Waddell, there's a variety of
25 concerns to be raised. What I think I would like to

1 suggest for Dr. Waddell, during the discussion
2 period, that he provide a suggestion with regard to
3 the nature of the listing for alcoholic beverages.
4 As we discussed yesterday, Dr. Rubin's presentation,
5 it was the opinion of the Board that high levels of
6 exposure are associated with risk and that was
7 discussed somewhat yesterday in Dr. Rubin's
8 presentation. I particularly noted the increased risk
9 of esophageal cancer that had been noted in Dr.
10 Rubin's publications and in his verbal testimony.
11 There are other aspects that can be considered, but
12 that's one that has a reasonably strong association
13 from my perspective. But if Dr. Waddell would be
14 interested in suggesting some language for the
15 listing, I for one would be very interested in
16 hearing what those suggestions might be.

17 So, let me stop with that and I thought it
18 was a very fruitful discussion this morning, the
19 presentations I felt were very good and I commend
20 the speakers.

21 **DR. GOLDSTEIN:** Dr. Lucier.

22 **DR. LUCIER:** Let me react quickly
23 to a couple of things. One, we obviously receive a
24 lot of letters on the Report on Carcinogens,
25 hundreds and hundreds of them, and we do try to

1 respond to them all. I don't know if we respond to
2 each and every one, but clearly we try to respond
3 to all of them. We don't necessarily do a point by
4 point discussion of each of the issues that were
5 raised, but we respond to people and we indicate
6 that we're looking at this material, to see how it
7 may impact upon the listing or delisting for a
8 substance.

9 The second point is that all the background
10 document summarizes the literature up to that point
11 in time. We also look at any other substantive
12 publications that are important to the listing or
13 delisting of a substance, right up to the time that
14 Dr. Olden submits the report to Secretary Shalala.
15 So, even though the background document isn't
16 necessarily updated, each and every publication
17 that's important or pieces of information that we
18 receive through our public comment procedure after
19 the Board of Scientific Counselors' review is
20 considered in Dr. Olden's recommendation to
21 Secretary Shalala.

22 **DR. FREDERICK:** Yeah, I think
23 that's a good point. I said it several times
24 yesterday, but some of you are new here today.
25 I'm very well aware of the fact that all these inputs

1 are advisory with regard to Dr. Olden and his
2 responsibilities. Ultimately even if new breaking
3 scientific information were to become available
4 subsequent to all of the recommendations, RG1,
5 RG2, RG3, I would hope that NTP staff would
6 provide that information to Dr. Olden and he would
7 take the appropriate decision relative to providing
8 the information necessary for the public.

9 **DR. GOLDSTEIN:** We have, we'll
10 first hear from Dr. Mirer next and then Dr. Waddell
11 and...

12 **MR. TORSEN:** Mark Torsen from
13 NIOSH. I have four comments that I'd like to make.
14 Before I say that, I want to put my views in
15 perspective. I didn't know what the Report on
16 Carcinogens was three years ago. Now I'm serving
17 on the RG2. First of all, I want to second Lynn's
18 proposal or suggestion on the RG2 and the
19 Executive Committee. They really do serve two
20 different purposes and for NIOSH they make us look
21 at the issue from two perspectives and often those
22 perspectives collide, which in turn makes the whole
23 community more ripe for dialogue. I think it's a
24 very useful addition to the whole process.

25 First of all, I'd like to talk about the

1 quality of the documents. I think the documents
2 are of high quality generally and it's a package that
3 we're looking at, not just a single document. In
4 regard to quality, I think they are peer review
5 quality. In addition to that, the RG1 and the RG2
6 serve as sort of the peer review process and I know
7 people have called for transparency, but we all
8 know the peer review process is not transparent.
9 The final document gets published and we don't
10 know what that looked like initially. I'm not saying
11 that's the best, but we accept those documents and
12 there should be some acceptance for the documents
13 provided by NTP. I say this because I want to
14 make sure the process is expedited because I want
15 to avoid process, I mean analysis...the paralysis by
16 analysis. I say this because in working at NIOSH,
17 I've seen line by line review of documents, where a
18 whole page it takes a day just to go over it. Those
19 documents go out and then they're bombarded with
20 criticisms. My wife is a writer and an editor and
21 she said, show me a document and I'll show you
22 what's wrong with it.

23 Next I want to address the frustrations. I
24 empathize with all those people that are frustrated
25 with not being heard. But there's another

1 frustration that I think occurs in the process and
2 that's the frustration of having remarks heard again,
3 again and again, contrary remarks to the document.
4 Many of the things I've heard in the last few days,
5 I've heard before, and repeatedly, and I won't go
6 into that any further. But I do realize there's a
7 perception that people are not being heard, so
8 whether it's reality or just perception I think there's
9 a need that NTP address this view that people are
10 not being heard. So, something has to be done so
11 people are heard.

12 The last thing I want to talk about is the
13 expertise in the Board of Scientific Counselors.
14 There was one comment, I think it was yesterday,
15 that there should be chemical specific experts at,
16 participating in the meetings. I would say that the
17 experts have been heard from in the peer review
18 document. I think these experts often bring a bias.
19 They think I'm an expert in a certain area and I try
20 to state my expert opinion, and I don't think that's
21 an NTP issue. I think in terms of the expertise on
22 the Board of Scientific Counselors, one comment
23 was made regarding the lack of individuals
24 associated with the chronic bioassay. From my
25 experience at these meetings, there's more

1 knowledge in regard to chronic bioassay in this
2 room than you'll find in any room, at the Board of
3 Scientific Counselors meeting than you'll find
4 anywhere in the world. They may not be
5 specifically on the panel, but the expertise is in the
6 room. On the other hand, there has been a policy
7 of background in epidemiology and I think the NTP
8 has realized that and are addressing that and are
9 attempting to improve it.

10 **DR. GOLDSTEIN:** Good. Dr. Mirer's
11 next.

12 **DR. MIRER:** First, a small point
13 with regard to the comments on sulfuric acid.
14 Again, we did see the original papers and we did
15 read them and the response to the, it was taken
16 into account the comments of the CMA acid
17 boreate input panel. I will say that from the
18 perspective of being on the review committee, there
19 is a knee jerk negation of every nomination that has
20 a industry group behind it and nevertheless we
21 listen to them objectively and see whether issues
22 have been raised that are significant.

23 Second point, with regard to peer review
24 and transparency, in traditional peer review, if it's
25 a journal article, the peer reviewer is always

1 anonymous to the person who submits the article
2 and sometimes the author is anonymous to the peer
3 reviewer. So, traditionally there's zero transparency
4 for peer review and so in the study section, all the
5 notes are destroyed afterwards and nobody can find
6 out who said what. So needless to say, the
7 process we've got is quite alien from what
8 traditional peer review is, to some extent.

9 Third point, regarding transparency and any
10 kind of sitting expert committee. Dr. Frederick has
11 mentioned it, and it's certainly true, people bring a
12 lot to this committee that isn't, like the rule
13 breaker that's in their experiences and analytical
14 methods that inherently in this is a lack of
15 transparency in a sitting committee. This is sort of
16 contrary to the kind of Congressional legislation.
17 Nevertheless we have written comments, and there's
18 a written transcript of what we've said and all the
19 comments here, including silly things that I've said
20 and the record is there.

21 Finally on this question of responding to
22 submissions. One, the notion of the preparation of
23 the background document and the review is that
24 that is limited to reviewed information, from
25 reviews and original papers. By its nature, by the

1 very nature of those comments we've received are
2 unreviewed, unreviewed reviews of the information.
3 They're not peer reviewed, they're personal opinion,
4 unsupported by the peer review process and usually
5 by interested parties, so that there's a contradiction
6 clearly between using those comments as a
7 substantial basis for reaching their decision and
8 limiting their review to peer reviewed documents and
9 it creates a asymmetrical situation between the
10 background document and what goes on in
11 committee. I'm not actually prepared, I'm not
12 prepared to say that we, we're almost barred from
13 listening to those comments, but certainly they have
14 to be directed towards evidence that is in the peer
15 reviewed literature that we can respond to or work
16 from.

17 Finally we need more expertise in
18 epidemiology, because all the fine questions that
19 we've had have turned on epidemiologic
20 interpretations, including the saccharin question,
21 which turns on epidemiology.

22 **DR. GOLDSTEIN:** Dr. Waddell.

23 **DR. WADDELL:** Bill Waddell,
24 University of Louisville. I'm pleased to respond to
25 your request about how I would list alcohol; I

1 would not list it. The reason I would not list it is
2 that there's no clear evidence that it is a
3 carcinogen at all. All the evidence that's been
4 pointed to and that was pointed to in the
5 background document was based on epidemiological
6 evidence, all of which is confounded by one factor.
7 A lot of that was not known at the time of the
8 Allrach (phonetic) decision in 1987. I was there; I
9 know. Only information on viral hepatitis B and C;
10 there was no information on, about controls. The
11 information on smoking in the epidemiological
12 studies is not properly adjusted. When I say that, I
13 mean that the studies that were done, most of them
14 were done with concurrent smoking and other
15 things. They're done with multiple linear
16 regression, to just try to separate the two factors,
17 it's complementary. The only way to really separate
18 that is to take a non-smoking drinker and a non-
19 drinking smoker, and I summarized in the
20 information that I submitted early on those studies
21 in which there were non-smoking drinkers and
22 there's only...

23 **DR. GOLDSTEIN:** Well, Dr.
24 Waddell, that's very interesting and very
25 appropriate, but could we get to the process...to

1 point out the process is very important, and I don't
2 want you to lose that.

3 DR. WADDELL: Okay, the process,
4 well, you asked me to comment, I'm sorry. The
5 process does not involve proper evaluation of the
6 information. I was particularly distressed during
7 the five minutes that I had in the presentation,
8 when the committee kept talking about the studies
9 of control for cigarette smoking. There's no way to
10 control for it, and I wanted very much to clarify
11 that, that I had submitted the studies that had no
12 smokers, but I was not permitted to say anything
13 on it. So, the process is flawed.

14 Another point that I could make, you asked
15 yesterday about Dr. Rubin's comment about
16 esophageal, the explanation. There's no information
17 on that. That merely is a theory of Dr. Rubin's.
18 As a matter of fact, there is good epidemiological
19 information, so that is not true. What I would like
20 to do, I hope I've answered that, but the thing I
21 wanted to do while I'm here for just a minute, is to
22 emphasize what I see as the major flaw. The major
23 flaw is that a substance is taken at any dose, in
24 any condition and then labeled a carcinogen, and
25 chromium is a good example of that. It's only

1 hexavalent chromium that is a carcinogen, being
2 inhaled as such. As a matter of fact, if chromium
3 comes in contact with any organic matter, it's
4 immediately reduced to tri-metal. Tri-metal, and all
5 the information says that chromium metal and tri-
6 metal chromium is not a carcinogen. But your
7 listing says chromium and certain compounds of
8 chromium. If you read the profile, it does not
9 clarify that chromium itself is not a carcinogen, yet
10 it is listed as such. My plea is to when you
11 prepare these, be specific and then you will satisfy
12 everybody. In other words, if you say chromium
13 under these conditions is a carcinogen. We have
14 no other information or the information is
15 insufficient, lay it on the line, say it, and then you
16 don't hear anybody come and say, well, why did
17 you do this and why did you do that. Now that's
18 my feeling on the process.

19 **DR. GOLDSTEIN:** Okay. We have
20 somebody else who's speaking and then...Dr.
21 Goldman, do you have a specific...

22 **DR. GOLDMAN:** If I could, I want
23 to ask him just a follow up question on that and
24 using chromium as an example, which is actually
25 the place where I actually agree with most of what

1 you've said, which is not true for most of what you
2 said. But in the case of chromium, where, you
3 know, you clearly have hexavalent chromium that is
4 a great concern for carcinogenicity and you have
5 other forms of chromium that are nutrients,
6 micronutrients and you would want to enrich the
7 listing in terms of explaining that. But you also
8 want the listing to address that there were other
9 forms that are nutrients.

10 **DR. WADDELL:**What I would say is
11 that hexavalent chromium is a carcinogen, in the
12 human, because that's the argument that you have
13 and I don't think anybody can contest that. Then
14 you could list in there in your description in the
15 paragraph, you should say low doses of chromium
16 includes etc. and supplements are not carcinogenic.
17 Go ahead and say it, that's stuff the public wants
18 to know.

19 **DR. GOLDMAN:** But then what
20 you've specified, you're not talking about low levels
21 of hexavalent chromium in food as harmless,
22 hopefully you would then specify that those are
23 other forms. That's what I'm trying to elicit.

24 **DR. WADDELL:** I think the profile
25 should discuss this and clarify. They do not

1 clarify, they actually confuse it. By listing
2 chromium as a carcinogen in the listing and then to
3 say in the profile chromium is not a carcinogen is
4 contradictory.

5 DR. FREDERICK: Bernie, let me
6 just say something. I think the point is well taken,
7 that there be appropriate explanatory language on
8 the issues. I have to say, I have not read the
9 chromium listing...

10 DR. WADDELL: I have a copy here.

11 DR. FREDERICK: ...recently. I
12 thought it was appropriately directed toward the
13 dangers of hexavalent, but I haven't read recently,
14 so I can't say that. But I think if you feel that
15 there's an inappropriate listing in this regard, I
16 think you or anyone else, I think an appropriate
17 submission to NTP, with the appropriate
18 documentation would be the relevant thing to do.

19 DR. WADDELL: Most of them tend
20 to make contents or whatever of one specific
21 circumstance and extrapolate it into all dosages and
22 that's the problem.

23 DR. GOLDSTEIN: Let me just point
24 out that we've got three different kinds of
25 enrichment, I like that term, proposals that we've

1 heard. One is to, if you will, amplify and enrich
2 based upon public health benefit. So that there is
3 public health benefit to Tamoxifen, there may be
4 public health benefit to alcohol; that should be
5 stated. Another is that we should enrich this
6 description of listing by pointing out about the
7 differences in chromium, species, or nickel alloy. A
8 third proposal is that we take into account dose, in
9 essence the crystal and silica argument, the sulfuric
10 acid mist argument, that in fact at low doses there
11 may be no risk and therefore they should be
12 specified somehow. I just want to make that clear
13 that we've got, there's been a fair amount of
14 discussion of this, but they're coming from three
15 different directions, but all three seem to be aiming
16 at expanding what is said in a simple declaration of
17 carcinogenicity.

18 **DR. WADDELL:** Clarification of the
19 facts and not extrapolating from...

20 **DR. GOLDMAN:** Could you list
21 those three again and then there was the fourth one
22 that Dr. Waddell was...

23 **DR. GOLDSTEIN:** The three I have
24 are basically that there is some public health
25 benefit and that ought to be stated. The Tamoxifen

1 kind of situation, perhaps alcohol, that there are
2 different forms and therefore you just say chromium
3 where we're losing the fact that we do know that
4 trivalent chromium is not a carcinogen, it's a
5 nutrient, etc. Dose is a third, the argument has
6 been made that for certain of these chemicals,
7 certain of these species, the sand I have here, that
8 perhaps there is no risk at lower doses. The same
9 thing would be true, IARC I know specifies for
10 sulfuric acid mist, not to worry about low levels
11 less than mist levels. So, those are the three I've
12 got.

13 **DR. GOLDMAN:** And well, in Dr.
14 Waddell's fourth one...

15 **DR. WADDELL:** The fourth one...

16 **DR. GOLDMAN:** Which is a
17 completely different point.

18 **DR. WADDELL:**What you're saying
19 is be complete. In other words, if you have
20 information that hexavalent chromium is a
21 carcinogen, so say that, and the others are not. If
22 you say that you inject nickel into the muscle of a
23 rat and you get a sarcoma, that's the evidence.
24 There's no evidence that nickel is a carcinogen
25 orally. So, I mean, say these things and make it

1 clear to the public. I agree that the profiles are
2 very...

3 **DR. GOLDSTEIN:** So, you're going
4 to a different level, which is a level not just of
5 saying we know that such and such is carcinogenic,
6 that does not necessarily apply to its valence form,
7 you would like it to be specified that this has been
8 found in three rat species, done intramuscularly and
9 subcutaneously but not by mouth.

10 **DR. WADDELL:** Dose, mechanism of
11 action. Be specific, and then you won't get in any
12 trouble.

13 **DR. GOLDSTEIN:** Well, I've got to
14 apologize to Bill and give him a chance to take...

15 **DR. FREDERICK:** But Bernie, let
16 John, I think he's got some relevant information on
17 the issues raised by Dr. Waddell and then if you
18 could let Jim do his thing. Would that be okay,
19 please?

20 **MR. BUCHER:** John Bucher, NTP.
21 I'd just like to clarify what we attempt to put in the
22 summary statements. We put into the summary
23 statements a description of the specific studies, the
24 types of studies that form the basis for the call,
25 either known or reasonably anticipated. We try to

1 state that if it's a...the epidemiology findings
2 support a known level of evidence comes from
3 exposures is X,Y,Z occupational settings. So that
4 while we do not state specifically that we rule out
5 the possibility of carcinogenicity under exposures
6 under other circumstances, we do try to give a
7 sense of where the basis, the kinds of studies that
8 are used to provide the basis for this.

9 DR. FREDERICK: Thanks, Bernie. I
10 just...

11 DR. GOLDSTEIN: Okay. We are
12 running over and we've got a bunch of people
13 waiting. So, I'd like to get at least the folks
14 standing in line here.

15 MR. KELLY: Bill Kelly with Federal
16 Focus. I do have a comment on the second one. I
17 think it is possible to expand the listings
18 themselves to address really multiple aspects and
19 still keep them relatively brief. It think it's
20 important, particularly with regard to knowing,
21 saying that you know that something is a
22 carcinogen. One could actually go and look at the
23 literature , what you're really saying is we know for
24 sure this causes cancer, perhaps under certain
25 circumstances, at high occupational levels for

1 people that work in a certain industry for a certain
2 number of years and it causes it in a particular
3 site. So, the actual listing would say, this is
4 known to cause lung cancer in workers who have
5 been exposed to high occupational levels for at
6 least 20 years or something like that. It would still
7 be quite brief and then you would couple that, I
8 think it's important here and I think we're looking
9 for some concrete suggestions at this point in the
10 discussion. Couple that with really a strong
11 statement about some of the listings that people
12 need to go back to the profiles and look to see
13 what more, what the listings really mean, because
14 they can't just be taken as blanket statements. Then
15 be sure to put sufficient information in the profiles
16 themselves, that addresses these enrichment
17 issues that you talk about.

18 The other point I wanted to talk about
19 originally has to do with Dr. Goldman's point about
20 how to introduce more transparency, I guess at the
21 RG1 and RG2 levels and that Phil Leber raised
22 about front ending of the process. Because I think
23 one of the fundamental concerns that's come out
24 here in the last few days, is that industry feels,
25 well, not just industry, but a lot of people feel that

1 by the time a background document or an issue
2 gets to the RoC subcommittee, there are data flaws,
3 there are analytical flaws that become embedded in
4 the process and they don't, you don't know whether
5 they've been handled and then they get carried
6 before the Executive Committee and the directors
7 and secretaries level. What I'd like to suggest, and
8 I'm not sure how this interacts with the workshop
9 idea, I think it could though, is that if a petition is
10 sent in from the outside, there's a very specific
11 nomination process. There's a document that has
12 to be prepared. Actually don't know whether those
13 are made publicly available, but those get submitted
14 to the RG1. Now my impression about how RG1
15 works when there's an internal nomination is that
16 it's quite different. Perhaps this could be clarified
17 by NTP. My impression is simply that RG1 meets
18 and somewhere in the course of the meeting
19 somebody makes a nomination, says I think this
20 should be listed as no reasonably anticipated and
21 perhaps a few words on it, desire a closer look or
22 whatever, and then a vote is taken. What I would
23 like to see is that a nomination is made somewhere
24 along the line, whether internally or externally, an
25 initial nomination document is prepared, which has

1 a provisional, an initial rationale in that document,
2 in terms of primary data that's the basis for the
3 nomination. Then that is made available along with
4 the initial call for public comments. So people
5 actually have something to comment on at that
6 point. Then you take that document and it goes,
7 it's looked at by RG1, it's looked at by RG2 and
8 then before it goes to the RoC subcommittee,
9 you've got the comments, you've got the RG1 and
10 RG2 deliberations on it. You revise it at that point
11 as appropriate. You call it something different,
12 perhaps you call it the review document at that
13 point. Then you submit that to the RoC
14 subcommittee and further public scrutiny. I think
15 that could provide a lot of complexion from these
16 concerns about carrying forward data flaws and data
17 analysis flaws. I don't think it will require a lot
18 more work. I think that work is already done. It
19 was done at different points in the process. What
20 you'd be doing is moving it, it's called front
21 ending, but moving it farther forward in the process
22 and giving people a more focused opportunity to
23 comment, which in the end might save a lot of
24 effort. Because right now I think a lot of people
25 who comment on the first stage of the process have

1 to take a scattered gun approach to the issues,
2 rather than say okay, here's what we see the
3 thinking is on this and we can say, yes, we agree
4 with that or no, there's a real error here and we
5 need to focus on that and correct it.

6 **DR. GOLDSTEIN:** Thanks. Time is
7 running low. I'm going to restrict ourselves to the
8 folks who are standing now.

9 **MR. BAYARD:** Thank you, Dr.
10 Goldstein. I'm Steve Bayard from OSHA. I'll only
11 take about a minute and a half. I wanted to thank
12 you first, and the NTP and the Board of Scientific
13 Counselors for focusing on the process. Also in
14 the midst of defining U.S. Regulatory Agency
15 effectiveness in classifying carcinogens, especially
16 the NTP listing remains an oasis and it's vital in my
17 estimation that it not be slowed down to any extent
18 at all. In that vein, I would like to try to dismiss
19 the idea that the NTP should be doing a
20 quantitative assessment of dose and potency of
21 carcinogens. I think it's very difficult to do, even
22 under the best of circumstances and it's best left to
23 the regulatory agencies that have those provisions
24 required. Also, and Dr. Mirer's comments, we
25 wholly second his speech. I also think the NTP

1 should not be in the business of elucidating the
2 benefits of chemicals, whether it's an essential
3 element or whether it's good for vitamins. I just
4 don't think that should be the business of the
5 listing. On the other hand I do think that the NTP
6 in listing carcinogens should have a responsibility
7 to list by exposure, we have in the qualitative
8 differences in focusing by exposure. I think the
9 example that Dr. Waddell made of nickel is a prime
10 example that I could think of. It's a homeostasis
11 mechanism in the GI tract for nickel is not much if
12 it gets into the system. On the other hand, it's
13 quite good if it's a sterile nickel compound, then
14 it's a known carcinogen, and maybe even a nasal
15 carcinogen.

16 So, I think we have these obvious
17 differences that efforts should be made to list
18 chemicals by exposure. When I was with EPA I
19 made that recommendation and I didn't get far with
20 it.

21 Also with respect to exposure, there are
22 certain chemicals that I think the NTP should even
23 consider sensitive subgroups. For example, the
24 bioassay that causes lung tumors don't have the
25 benefit of having smokers with compromised

1 systems and affected lungs. So, to answer Dr.
2 Waddell's claim that there's a confounding of
3 alcohol by smoking and smoking by alcohol, well,
4 just consider that this is a human that we're trying
5 to predict on and to identify either of these
6 subpopulations is a difficult task.

7 Finally, I didn't mean to focus on Dr.
8 Waddell, but he had the same issues that I did.
9 But Dr. Waddell said that OSHA had called benzene
10 safe at one part per million, and I would like to
11 disavow him of that information. OSHA has other
12 provisions in its statutes which limit the levels that
13 states set. The benzene level was not set based on
14 the actual statement. Thank you.

15 **MR. LEBER:** Phil Leber from
16 Goodyear. First of all I hear that we're pretty
17 much in agreement and consensus that this should
18 be a scientific process and I was happy to hear the
19 words of encouragement from our Board of
20 Scientific Counselors representatives and perhaps
21 we do need a forum such as a workshop early on to
22 sort of bang out the differences and to try to reach
23 the consensus, the truth, the scientific truth with
24 regard to the data and the classifications. I just
25 want to make a couple comments to support that

1 concept.

2 One is that there are no shortcuts. If the
3 public is going to be served, there is no benefit in
4 calling a chemical a carcinogen, if the data don't
5 support that. There's no value in calling a
6 chemical a known human carcinogen if it is strictly
7 an animal carcinogen and the evidence is not there
8 for the human effects. I think that the scientific
9 process takes a lot of poring over data,
10 deliberation, scientific judgment to come to that,
11 quote, correct decision. I was, I don't think that
12 the comments that we ought to shorten the time,
13 we ought to use less input, expertise, to move the
14 process along, because if we come up with the
15 incorrect decisions, nobody is served.

16 Just a quick comment on the issue of bias.
17 I'm going to use a paraphrase here to say that
18 people are not biased, opinions are. So, if
19 somebody comes into the room and we're talking
20 about carcinogenesis, it doesn't matter whether
21 you're from an environmental group or industry,
22 government or what party, it's the ideas that have
23 bias or do not have bias. So, I would suggest that
24 if somebody comes in to a forum and says I have
25 information, I can talk about animal carcinogenesis,

1 or epidemiology, they should be heard.

2 Then finally the 9th report, I know that's
3 on the fence right now, perhaps that's not quite the
4 right word, but I think that if the comments and the
5 opinions expressed here the last couple of days
6 have validity, and I think they do, I think that Dr.
7 Olden and the NTP staff ought to give consideration
8 as to whether these 22, 24 chemicals should go
9 ahead, be listed in the 9th report, given some of
10 the concerns that have been expressed. Thank you.

11 **DR. GOLDSTEIN:** Just one quick
12 comment from the Chair, just to make it clear. I
13 quite agree with a lot of the things you said about
14 what people have been saying here, but this has
15 not been set up as a consensus gathering meeting,
16 this is a meeting to get opinions forward. I don't
17 think it would be fair to ever say that we've arrived
18 at some consensus here.

19 **DR. FREDERICK:** Absolutely, and I
20 want to say that I think where Lynn and I were with
21 regard to an early workshop, was not a consensus
22 building workshop, it was input with regard to the
23 technical issues on the table. I just want to be
24 clear about that.

25 **MR. LEBER:** I just meant that the

1 consensus was that science is important, that's all.

2 **DR. GOLDMAN:** I think that the
3 issue is that it's a very different thing to do, to
4 have a workshop where the science is brought
5 forward versus have a consensus conference, which
6 is a very formal kind of a workshop that is very
7 difficult to do. I think it would be more, I would
8 never even recommend thinking about that for every
9 single chemical for the RoC, because that would be
10 biting off something that just, I think is just not
11 digestible for the NIEHS. So, but you know, but
12 otherwise you did reflect it accurately and the
13 other thing that you said, I think that there really
14 are, I think you're right, there are two separate
15 issues here and one is, process improvements for
16 the future in the whole process of doing the RoC
17 and the second one is the 9th report, which
18 obviously many of the comments, and I haven't
19 responded to those as we've gone along, because I
20 felt that we're on the first thing, but it is clearly
21 something that's being brought forward by many of
22 you and that is asking the NIEHS to consider that
23 and it's just something that I don't think that Clay
24 and I have felt was really, you know, the subject of
25 why we were brought here.

1 **DR. GOLDSTEIN:** Jim Hathaway and
2 Jackie Warren...

3 **MR. HATHAWAY:** Jim Hathaway, I
4 represent CMA Inorganic Acid Mists Panel. I just
5 want to offer a contrary comment to what the
6 gentleman from NIOSH said on quality of
7 background documents. While I was going through
8 my presentation on sulfuric acid in North Carolina, I
9 read through about a half a dozen of other chemical
10 background documents. These were all ones where
11 epidemiology studies were a primary factor and I
12 felt that none of these were scholarly documents.
13 In fact I thought that every one of them was very
14 poorly written and I think that the NTP can and
15 should expect a much better work product from
16 their consultant.

17 **MS. WARREN:** Thank you. Jackie
18 Warren. I've worked in this field for 25 years and I
19 have to say that as a dissenting voice on the
20 proposal to move what is becoming increasingly an
21 adversarial exercise even further into the NTP's
22 process on this. I think it's something that could
23 potentially destroy the integrity of the process. I
24 don't think that the NTP really, I think they should
25 be thinking about ways to insulate their process

1 from further pressures of the kind that are being
2 brought now, demands to respond. The Agency has
3 no obligation to respond to every comment that
4 everybody makes. The right that they are extending
5 to people to be aware of the process going on and
6 have an opportunity to submit comments and to
7 testify, they have a right to ask that those things
8 be considered. They don't have the right to
9 demand a response to every single one. I think to
10 the extent that you put scientists on the spot on
11 these panels, making them realize that if they have
12 to write down every single justification, it's the
13 antithesis of the kind of peer review that Frank
14 Mirer described in an earlier comment and that it's
15 going to change and distort the nature of the
16 process in such a way that it won't really be peer
17 review anymore.

18 I wanted to read from the wonderful report,
19 as it was characterized yesterday, the President's
20 Commission On Regulatory Decision Making & Risk
21 Management. In Chapter Six there's a statement
22 that says, and I quote, potential peer reviewers
23 with financial conflicts should be disqualified from
24 service on peer review panels that could
25 specifically influence regulatory decisions related to

1 the products or interests of their organizations. We
2 can't emphasize that too much. To the extent that
3 you go with further workshops and you bring in
4 industry scientists and consultants and put them
5 effectively into the process of making the decisions
6 on characterization, I think you will so corrupt this
7 process that the NTP's annual report will not be the
8 last bastion of a place to look for government
9 scientists' best judgment on what substance is a
10 carcinogen. I mean for 25 years industry's initial
11 knee jerk reaction has been, this doesn't cause
12 cancer, nothing, nothing has ever been introduced
13 as a possible carcinogen that received an agreeable
14 response from industry, and they're entitled to their
15 opinion on that. But just in terms of protecting
16 public health and following the mandate of Congress
17 and what this report is supposed to do, I think you
18 should think about insulating a little bit. Because
19 no matter how many times you open the process
20 more, it will never be enough. I mean you can see
21 now, people have had an opportunity they never
22 had before and all they've done is come in with a
23 thousand different criticisms of why it's too short,
24 it doesn't give enough response, doesn't have a
25 written document, they want these other things that

1 they can have a further chance to throw rocks at
2 and possibly take to court. I think it's a very
3 slippery slope, with a very bad ending for the
4 whole process.

5 **DR. GOLDSTEIN:** We'll stop here.
6 We had a lively discussion. I thank everybody who
7 was involved in it. I'm not sure if Charlotte Brody
8 is here, so we will start again at 1:00 o'clock.
9 (WHEREUPON, a luncheon recess was taken.)

10 **DR. GOLDSTEIN:** First, let me ask
11 if there was anyone on the schedule this morning
12 who is here now? Okay. We actually have, let's
13 see, of the first five speakers, four canceled, and
14 one has spoken. So, we're already into the
15 speaker, the sixth speaker, and you have the
16 numbered listing, speaker #44 and even that
17 gentleman is not here.

18 **DR. GOLDMAN:** Who is that?

19 **DR. GOLDSTEIN:** It's listed as
20 David Weinberg, but Ed Ferguson will speak for
21 Dave Weinberg. But just to be sure, Charlotte
22 Brody, Joseph Suchecki, we've heard from Lyn
23 Nabors, Sylvia Johnson and Scott Schneider.
24 Well,...

25 **SPEAKER:** There's a couple of

1 people at lunch.

2 DR. GOLDMAN: Yeah.

3 DR. GOLDSTEIN: Well, if they do
4 come and they are speakers, I'll certainly let them
5 back onto the schedule. So, why don't we start
6 with Ed Ferguson?

7 MR. FERGUSON: Do we go right
8 here?

9 DR. GOLDSTEIN: Right up there.
10 You've got 10 minutes and if you need help with
11 slides or anything, we'll get it for you.

12 MR. FERGUSON: Good afternoon.
13 My name is Edward Ferguson. I'm testifying on
14 behalf of Chroma Corporation. We appreciate the
15 opportunity to appear here before you today to
16 offer our views on the RoC review process. As we
17 supplied the panel with a copy of our statement,
18 I'll be brief in my remarks this afternoon. Chroma
19 recommends that the NTP revise its RoC review and
20 evaluation process, to more accurately recognize
21 differences in the potential carcinogenicity of
22 various forms of compounds that incorporate the
23 same metallic element. We understand that this is
24 the current practice in the immediate system for
25 classification under the existing substantive

1 program.

2 Before proceeding further, let me briefly
3 explain who Chroma is and why we care about this.
4 Chroma is engaged in the custom formulation and
5 compounding of colorants used in plastic products.
6 It is located in McHenry, Illinois. The colorants
7 Chroma compounds are used in a wide variety of
8 plastic products, including packaging, appliances,
9 automobiles, durable goods and industrial products.
10 The cadmium pigments used in this process are
11 extremely insoluble compounds of cadmium sulfide
12 and salamite. They produce bright strong colors
13 and have excellent heat stability, light fastness and
14 chemical resistance. These pigments do not migrate
15 from the plastic in which they are incorporated,
16 this is because they are in a highly insoluble fire
17 hexagonal inter crystalline form, with very little
18 extractable cadmium. But encapsulated in plastic,
19 it's virtually impossible to extract the cadmium
20 ionic species, even after long periods of
21 environmental exposure.

22 As I stated earlier, Chroma believes the
23 NTP should amend it's RoC review and evaluation
24 procedures to assure that it consistently takes into
25 account differences in potential carcinogenicity

1 between compounds. This has been done in
2 numerous instances in the past by the NTP. For
3 example, lead acetate and lead phosphate have been
4 listed by the NTP with no other known compounds.
5 Likewise certain nickel compounds are listed by the
6 NTP as probable human carcinogens. Selenium
7 sulfite is listed, but not all selenium compounds.
8 As to cadmium, however, all compounds are listed
9 by the NTP as known human carcinogens, yet we're
10 aware of no rational scientific basis to assert that
11 all forms of cadmium should be listed as known
12 human carcinogens. To the contrary, there is no
13 human epidemiological study that would support the
14 designation of cadmium sulfide and selenide as known
15 human carcinogens. Despite this lack of evidence,
16 the NTP's designation of all cadmium compounds as
17 known human carcinogens includes both cadmium
18 sulfide and selenide. This over broad designation
19 poses severe consequences for Chroma and other
20 manufacturers using insoluble cadmium pigments,
21 whose products may now be targeted by regulatory
22 authorities for further control and possible
23 prohibition. Moreover, we know that currently
24 there's great uncertainty that even soluble forms of
25 cadmium should be listed as known human

1 carcinogens by the NTP. This is because all the
2 past epidemiological studies that reported an
3 increased incidence of lung cancer in workers
4 employed in cadmium production facilities had
5 failed to account for worker exposure to other
6 confounding variables, namely arsenic. While follow
7 up studies have attempted to compensate for
8 arsenic exposure, they were unable to fully discount
9 potential influence of exposure to arsenic. Given
10 the current state of science, we believe there is no
11 justification for NTP to continue to designate all
12 forms of cadmium as known human carcinogens. To
13 address this issue we believe the NTP should revise
14 its RoC review process to account for differences in
15 the potential carcinogenicity between forms of
16 compounds as is done under the EEU system for
17 classification under the existing chemicals program.
18 Under that program, for example, each cadmium
19 compound is considered and listed separately for a
20 thorough and complete evaluation of all of the
21 scientific evidence. The explicit recognition that
22 differences exist between the potential
23 carcinogenicity in different forms of compounds will
24 ensure that the NTP's evaluation review process is
25 scientifically fair and accurate. Since the

1 designation of a substance as a known human
2 carcinogen can have enormous impacts on consumer
3 and market perceptions, it should only be made
4 after NTP has conducted a complete study of all the
5 scientific evidence relating to each compound.
6 Only forms of compounds for which there is
7 unequivocal evidence from epidemiological studies
8 should receive the known human carcinogen
9 designation. Thank you.

10 **DR. GOLDSTEIN:** Thank you, Mr.
11 Ferguson. Our next speaker is Michael McCann of
12 The Center To Protect Worker Rights.

13 **DR. McCANN:** Thank you for this
14 opportunity to speak. My name is Dr. Michael
15 McCann. I'm Director of Ergonomics & Safety at
16 The Center To Protect Workers Rights, which is the
17 research arm of the Building & Construction Trades
18 Department of the AFL-CIO. I'm actually presenting,
19 these remarks were prepared by Dr. James Platner,
20 who's Director of Research & Pathology at CPWR,
21 but could not be here today.

22 The Center To Protect Workers Rights
23 strongly supports NIEHS's efforts in publishing a
24 Report on Carcinogens to the U.S. Congress by the
25 National Toxicology Program in response to Section

1 301B4 of the Public Health Services Act as
2 amended. Here are our comments from the
3 September 15 meeting, on sustaining and improving
4 NTP's process for updating this document's listing.

5 We support the listing of all agents subject
6 to exposure circumstances, which are either known
7 or reasonably anticipated to cause cancer in humans
8 and to which a significant number of children,
9 women and men in our country are exposed. We
10 believe NTP's listing process for the reporting of
11 carcinogens has been objective and fair and we
12 insist that it remain so for the public good. If
13 anything, the current process risks becoming so
14 complicated that listings may be unnecessarily
15 delayed over small details that are largely
16 independent of the scientific health data. While the
17 report is entirely informational and has no
18 regulatory role, it is the basis for informing the
19 public of carcinogens and suspected carcinogens in
20 the workplace and environment. Listing serves a
21 useful purpose of informing citizens about a
22 potential concern, so they may assess their own
23 situation, while hopefully stimulating additional
24 resolves to answer unresolved questions. The
25 Report on Carcinogens serves as an essential public

1 health tool for protecting children and workers and
2 communities, even as technical issues about a listed
3 carcinogen or suspected carcinogen are being
4 recalled. For example, this credible report is an
5 important source of information for OSHA's Hazard
6 Communications rule and for the Proposition 65 in
7 the State of California's Drinking Water Enforcement
8 Act of 1986. The credibility of the Report on
9 Carcinogens is based in large part on NTP's
10 unbiased assessment of peer reviewed data. This
11 process must be entirely open. A proposal appears
12 to be that NTP consider non-peer reviewed data
13 confidentially provided by parties with economic
14 interest in the carcinogenic data, substance or
15 exposure circumstance. We strongly disagree. The
16 very nature of this report is that it is conducted in
17 accordance with the highest standards of open
18 scientific scrutiny, which demands open access to
19 data sets for potential reevaluation and peer review
20 of data, methodology and analysis. There are other
21 opportunities to introduce such anecdotal data,
22 including data on economic impact and data on
23 feasibility of technological controls in appropriate
24 settings such as the regulatory process of OSHA
25 and EPA. We agree with the comment that reviews

[Redacted]

1 for the reporting carcinogens should be done in
2 Washington, D.C., to provide easier access to the
3 interested public. In summary, we support the
4 process for NTP's Report on Carcinogens. We urge
5 you to place public health first in timely publication
6 of important public health information. The long
7 term interest of workers and the public lies in the
8 performance of scientifically valid evaluations.
9 Proposals that restrict public access to
10 deliberations, delay the listing process, or introduce
11 into the debate confidential data sets which have
12 not been subject to peer review and cannot be
13 challenged, clearly do not improve the process and
14 are strongly opposed. Those are written comments,
15 and I have a couple personal comments.

16 Before I went to work at CPWR for about
17 20 years I was involved in writing, researching
18 hazards of art materials and ran the Center For
19 Safety In The Arts. This is much, artists, like much
20 of the public, are very concerned about cancer
21 causing chemicals and I constantly would get phone
22 calls about they saw this in the paper, that in the
23 paper, is it carcinogenic. There are many cancer
24 causing chemicals in art, but we don't need to say
25 they all are. One of the sources I did rely on is

1 the NTP Report On Carcinogens. In fact, we placed
2 that and updated it on our website, because people
3 were interested in a credible source. If we allow
4 the use of data that is not peer reviewed, then I
5 think that affects the credibility. I think a
6 comparable situation is what has happened in some
7 instances with the threshold limit values, where
8 you'll see in the documentation so and so from
9 such and such company says that this level has not
10 found any problem. That type of statement in
11 documentation really affected I think the credibility
12 of a lot of TLBs. I would not like to see that
13 happen here. Thank you.

14 **DR. GOLDSTEIN:** Thank you. We
15 have two more speakers on the schedule. I'd like
16 to just point out that I'm going to diverge a little
17 bit at the end of these two speakers, instead of
18 going directly into the kind of discussion thing, I
19 note that there's some people in the audience who
20 sat here attentively for two days now, without
21 saying a word. So, I'm going to, you know, just
22 think about it, if anyone would like to make a
23 presentation, who hasn't presented yet, at the end
24 of the next two speakers, the microphone is yours,
25 for whatever you'd like to say, within 10 minutes of

1 course. Al Collins...I'm sorry, we actually have
2 three speakers listed. Michael Sprinker of the
3 International Chemical Workers Union. Is Michael
4 here? Perhaps not back from lunch.

5 **MR. SPRINKER:** Since I can't write
6 on paper anymore it seems, I can't read my own
7 writing, I think I inherited that from my father, a
8 veterinarian.

9 Anyway, I'm Michael Sprinker, the Director
10 of Health & Safety for the International Chemical
11 Workers Union Council of the United Food
12 Commercial Workers International Union. I'm also a
13 certified industrial hygienist and have spent
14 somewhere in the range of about 10 years working
15 for the State OSHA program in Oregon on the
16 enforcement side as an industrial hygienist. I'd like
17 to thank you very much for the opportunity to
18 speak on this issue, which is of critical importance
19 to our members. I'm sorry I couldn't be here
20 earlier, I had originally planned on coming in either
21 yesterday or for all day today, but I was in Florida
22 investigating a fatal electrocution of one of our
23 members. It's sometimes, as we talk about
24 carcinogens and all, I know we all still consider
25 those other hazards out there too, which

1 unfortunately are a little bit quicker at taking lives.

2 The International Chemical Workers Union
3 Council represent workers in organic and inorganic
4 chemicals, pharmaceuticals, as far as the mining
5 industry, zinc, sulfur, phosphate mining and
6 processing, paints and coatings, additives, natural
7 gas, non-nuclear, nuclear weapons, manufacturing
8 and I guess demanufacturing too, waste processing,
9 as well as a few folks in nursing homes and other
10 industries. They've been exposed, many of our
11 members have been exposed and retired members
12 been exposed to previously controversial, if I can
13 use that term, carcinogens and processes, such as
14 asbestos, benzene, betadine, various
15 pharmaceuticals, formaldehyde, carbon disulfide,
16 beta methallamine, strong acid reduction and so on
17 and so on. At least they were told that was
18 controversial at the time, or years past. They
19 currently remain exposed through manufacturing,
20 processing or other activities, to a number of those
21 carcinogens and also to other so-called new
22 controversial carcinogens, such as methylene
23 chloride, ethylene oxide, chrysotile asbestos,
24 fiberglass, refractory surrounding fibers. When I
25 use the term controversial, it doesn't mean I'm

1 disagreeing with that. I mean I'm sorry, that I'm
2 agreeing that they're controversial. They are also
3 regularly exposed to the newest controversial
4 products, such as diesel exhaust particulates, silica
5 and a number of others. In fact oftentimes our
6 members are among the first who are exposed to
7 those new carcinogens, because they oftentimes
8 manufacture them.

9 From the first list I gave, you can see
10 ICWU members and their families, like workers and
11 their families throughout this country and
12 throughout the world are familiar with the
13 controversy over carcinogens. In fact if I could go
14 back in time, it was, I actually forget his name, one
15 of the first discussions in public at a general
16 meeting of non-scientists about the possible nature,
17 that workplace chemicals could be carcinogenic.
18 Dr. Huber, I believe, was at an ICWUC convention
19 back in the early '50s. Our members at sites which
20 processed the miracle fiber, asbestos, in Southern
21 California and elsewhere, were told for so long that
22 their lung problems and early deaths from cancer
23 were not due to that miracle fiber and certainly not
24 due to the safe form of that fiber. Those folks
25 went on strike for their health and safety and that

1 of their friends, families, and neighbors. When
2 they were told by the company that their actions
3 could cause the plant to close, they said, that was
4 better that it close, than they had people
5 continuing to die. That's a pretty hard stance to
6 take, even in the '60s and '70s, as some
7 deindustrialization was occurring in this country.
8 But they just watched too many people die.
9 Remember, too, that this was in the days before
10 OSHA's adoption of the Hazard Communications
11 Standard, a standard that requires the review of
12 NTP and other lists, preparing material safety data
13 sheets. Remember too, there are those who said
14 that workers could never understand the information
15 on MSDS sheets or the hazardous chemicals. The
16 past 15 years have shown that to be one of the
17 more inaccurate predictions. The rise in worker
18 knowledge in health and safety hazards, as well as
19 the reduction of exposures among our members,
20 among workers who have participated in real
21 training is a result of the openness required about
22 the identity of chemical products, their health and
23 safety hazards, exposure control measures and
24 precautions. The requirement that positive
25 carcinogenic tests and listings of IARC and NTP

1 status be specifically noted in MSDS's has greatly
2 increased the ability of workers, who have few
3 resources, certainly in comparison to those that
4 industry and others possess, to protect themselves
5 through taking action. The Report on Carcinogens,
6 as we've heard, is mandated by the Public Health
7 Services Act, now has to be biennial, and it's
8 supposed to be listing all substances known to be
9 carcinogens to humans or reasonably anticipated.
10 Also includes information about the nature of the
11 exposure, how many people, and a description...and
12 we do, we rely as labor, as workers, as do many
13 people in organizations, on a process which reviews
14 credible evidence and studies, and which has a
15 large degree of independence or influences which
16 may be seen as looking at issues not directly
17 related to public health. I know truthfully there are
18 times we wish there were some things listed that
19 aren't in labor. I have members that I don't want
20 to say wished, but when they find they have
21 cancer, wish it was from something, wish they knew
22 what it was from in the workplace, so then that's
23 knowing or not knowing. But at least we have a
24 place we can look to and see that someone has
25 independently made a determination based on what

1 knowledge is out there about a particular
2 compound, group of compounds or processes. We
3 believe NTP does that to a very large extent. One
4 only has to look at the perceptions of many towards
5 OSHA standards for the influences which delayed
6 standards for many years, as well as the
7 controversy over the ACJ TLP process, to see that
8 there needs to be an agency that can operate
9 independently of those influences, to the degree
10 possible. The independence of NTP in its ultimate
11 determination of listing a chemical process, mixture
12 or substance, is critical to the scientific value of
13 its work. It's also truthfully pretty critical to
14 whether or not people have faith in that work or in
15 the determination of whether or not something is or
16 is likely to be a human carcinogen. We've already
17 seen over time that there's unfortunately been a
18 shift from publishing a list every year to every two
19 years. Now probably, I think back in the old days,
20 when it was every year, it was being a little,
21 Congress was perhaps being a little, maybe didn't
22 quite understand some of the difficulties in trying
23 to put something like that together every year and
24 review all the data. But we don't need more
25 delays, where such delays are not scientifically

1 indicated. My training was as a scientist, and
2 unfortunately one of the things that we find in
3 science is that there's sometimes something we
4 believed for years may not be accurate and then,
5 you know, then you admit it's wrong, you found
6 more information and go on from there.
7 Unfortunately with chemical carcinogens, a lot of
8 times the wrong data was that oh, this stuff is
9 harmless, this stuff can't hurt you, there were these
10 studies and so on and it shows it in rats, but
11 you're not a rat.

12 **DR. GOLDSTEIN:** One minute.

13 **MR. SPRINKER:** Okay. So, let me
14 just finish up here then and you know, we do
15 support NTP. We do support the idea of, to some
16 degree of having, maybe having a public meeting
17 early on in the process, but again, not one to try
18 and come to consensus of all of us whether
19 something is a carcinogen or not. We're going to
20 continue to rely on NTP to be able to do that. We
21 do hope too that, and I do like this process now of
22 some of NTP being published on the web, that does
23 help us, does help our members. It clearly helps
24 us at being able to address some concerns of our
25 members.

1 One of the things I did hear earlier and
2 there was such a long line, I didn't have a chance
3 to mention, we did hear that the idea of dose
4 should be noted in discussions of NTP, when NTP
5 talks about why something is listed. But I believe
6 at this point, as a general belief, there may be
7 some specifics that are different, but given the
8 multitude of exposures which most studied workers
9 have had, and the latency period of cancers to
10 initial exposures, I really don't believe NTP could
11 accurately state or imply that exposure to low dose
12 levels, the levels that maybe workers have had in
13 the past, some of which were very high, are safe.
14 Certainly as a certified industrial hygienist, I've
15 monitored a lot of exposures and I've reviewed a
16 lot of monitoring data in workplaces. I'm
17 continually amazed at the very poor quality of much
18 exposure monitoring that's out there. Whether
19 airborne, dermal, which is almost nonexistent in
20 monitoring and other routes, and I think NTP would
21 need to look very carefully before putting too many
22 caveats on, too many qualifications on the
23 carcinogenicity of a given compound. Thank you.

24 **DR. GOLDSTEIN:** Thank you, Mr.
25 Sprinker. Our next speaker is Al Collins from The

1 National Association of Metal Finishers and Metal
2 Finishing Suppliers' Association and the Association
3 of Electroplating and Surface Finishing. Mr.
4 Collins.

5 **MR. COLLINS:** Thank you. My
6 comments are going to be brief. I'm pinch-hitting
7 for some colleagues that came down for the original
8 meeting in Southern California and couldn't make it
9 back. I'm also not very comfortable speaking this
10 way. I live in a little town in Virginia and my
11 experience has been being in front of our City
12 Council, and I'm part of a neighborhood association,
13 and listen to people scream about wanting to serve
14 beer at their outdoor restaurant or whatever.

15 **DR. GOLDSTEIN:** They won't raise
16 your taxes though.

17 **MR. COLLINS:** I can speak to
18 that. My name is Al Collins. I'm Vice President of
19 Regulatory Affairs for The National Association of
20 Metal Finishers. I'm here today to present the
21 comments on their behalf. I want to thank
22 everyone for the opportunity to be able to do that
23 in this forum. NAMF recognizes our responsibility
24 to the public to conduct our operations in a safe
25 and environmentally responsible manner. In fact for

1 the past six years we've been working with EPA
2 closely and created a partnership that's resulted in
3 a metal finishing goals program. Under this
4 program the metal finishing industry is committed
5 to reduce water use and energy use by 50 percent
6 and would cover 98 percent of the metals that we
7 use. We hope to reach this goal by the year 2002.
8 EPA has used the metal finishing goals program as
9 a model for other industries and we're very proud
10 of the accomplishments that we've made here,
11 because they demonstrate our commitment to the
12 environment and to worker health and safety.

13 So with that said, I would like to address
14 the addition of soluble nickel compounds to the
15 list. We believe that this action would adversely
16 affect our industry and would provide little or no
17 additional protection to human health and the
18 environment. The metal finishing industry, along
19 with EPA's Office of Water & Health Canada
20 sponsored a toxicological review of soluble nickel
21 compounds. The study was completed in March of
22 this year and it was submitted to NTP. It was
23 completed by Toxicology Excellence For Risk
24 Assessment or TERA in Cincinnati, Ohio. The study
25 included procedures for independent peer review,

1 records of comments, recommendations for the peer
2 review meetings and ways to manage potential
3 conflicts. TERA also employed an effective process
4 for resolution of differences, which led to
5 consensus. We believe this is a good model to
6 use. The process also provided an opportunity for
7 interested parties to observe the proceedings and
8 participate. We encourage you to consider the
9 findings in this report as you finalize the RoC.

10 As you know, the RoC carries enormous
11 weight with regulatory agencies like EPA, who use
12 these findings to develop standards and limitations.
13 Therefore, we believe that NIEHS should publish
14 complete background information on their decisions
15 and offer an opportunity to comment on the
16 development process. In fact we believe the
17 development of the RoC should be held to the same
18 standards as a regulation and we suggest the
19 Administrative Procedures Act as a good model to
20 follow, because it offers a formal comment period
21 and requires development of a formal response to
22 comment document as part of the record. We
23 believe this would go very far to improve this
24 process.

25 Our comments today are not based on the

1 interpretation of the toxic...toxicology or
2 epidemiology data, but instead on the review
3 procedures and listing criteria used in RoC. Our
4 specific suggestions regarding the criteria for
5 listing compounds in the RoC are as follows: 1.
6 The criteria for designating compound as a non-
7 human carcinogen, should require the highest level
8 of scientific certainty and also it should require
9 that human and animal studies be consistent and
10 supportive. 2. The criteria for designating a
11 compound as reasonably anticipated to be a human
12 carcinogen should be used as a secondary level of
13 certainty. Animal studies should be, should exclude
14 potential carcinogens, if they are inconsistent or
15 not supportive. 3. NIEHS should speciate
16 compounds and recognize the significant difference
17 between species. 4. NIEHS should clarify the
18 standards required to achieve a listing of a known
19 human carcinogen. Right now we believe that they
20 would be improved if they were more objective.

21 Specific compounds and the review
22 procedures for listing compounds in the RoC are as
23 follows: 1. Require more than a simple majority
24 of the panel members at each level to add a
25 compound to the list of known human carcinogens.

1 2. The RoC should identify the key studies that
2 support each of the panel's decisions. 3. NIEHS
3 should broaden and extend the time for peer review
4 and publish both comments and response to
5 comments. 4. RoC Review Committee should not
6 depend on IARC or other agency conclusions alone,
7 but should independently base its findings and
8 designations on published reports. Lastly, NIEHS
9 should expand the RoC report to include information
10 on the nature and prevalence of public exposure,
11 and to the extent that which regulations could
12 prevent that.

13 Again, I thank you very much for providing
14 this forum and for considering our comments.

15 **DR. GOLDSTEIN:** Thank you very
16 much. Is Michael Groger here? U.S. Environmental
17 Protection Agency?

18 **SPEAKER:** I haven't seen him
19 today.

20 **SPEAKER:** He was here yesterday.

21 **DR. GOLDSTEIN:** That's an official
22 part of the record now. Okay. Let me again,
23 anyone can speak any time during the discussion of
24 course, but I just thought that since sometimes our
25 discussions get moving in certain directions, that

1 we ought to give an opportunity for anyone who's
2 been here, who hasn't spoken yet, who'd like to
3 have the microphone, to come up here for 10
4 minutes, by all means do so. Any takers? Okay.

5 So, let me again ask our folks from NTP
6 and NIEHS whether there's any clarifying comments
7 you'd like to make or would like to summarize
8 anything from what we've heard? Let me turn this
9 over again to Drs. Goldman and Frederick.

10 **DR. GOLDMAN:** Clay and I always
11 ...let's get this going in the right direction. Clay
12 and I always have something to say. One of the
13 things that actually I wanted to bring up as a
14 possible point of discussion is a discussion that we
15 had at lunch actually, and it hasn't really been
16 brought up very much in this session, but again
17 going back toward that issue of attempting to find
18 ways to increase the transparency and opportunities
19 for input into this process. A suggestion was made
20 this morning that one possible way of doing this
21 would be to hold some kind of a working
22 conference early on in the process. But another
23 idea that we were discussing, and I think it would
24 be worth hearing some additional reactions to, is
25 that perhaps there could be some kind of a process

1 that the NTP would carry through, where rather than
2 simply announcing which compounds are scheduled
3 to go through the review, that perhaps at the time
4 of that announcement, that there might be some
5 specific questions that are asked that have to do
6 with the scientific issues that become apparent
7 fairly early in a process like this actually, for the
8 individual compounds. So for example, if it's
9 immediately apparent at the beginning of a process
10 that the basis for a listing decision might largely
11 have to do with say epidemiology studies, where
12 there are specific questions about exposure, that
13 that could be actually indicated in that initial
14 announcement that that's an area where the NTP
15 particularly is interested in getting information. Not
16 exclusively, because of course any information
17 might be relevant, but to kind of signal early on in
18 the process, not only both that the listing
19 consideration is going to occur, but also what at
20 the earliest stages the scientific issues are that are
21 likely to be the most difficult, the most
22 contentious, the most interesting, most important,
23 to try to get that information in writing at a very,
24 very early stage.

25 DR. FREDERICK: I agree that

1 could be quite useful. Inasmuch as what we've
2 done here has been kind of a healthy discussion of
3 issues at hand, I'd like for you to think of this as
4 kind of like being a Board of Scientific Counselors
5 meeting; the emphasis is on counselors, with regard
6 to providing advice, with regard to process and that
7 sort of thing. We discussed a wide range of issues
8 from a wide range of perspectives, but at the end
9 of the day it's all advice to the caretakers of this
10 program, who have been placed in that role by
11 Congress, and it's obviously something that I'm very
12 aware of, even as we meet as a panel with some
13 formalized structure, we're in this advisory role and
14 trying to bring, help provide the best information.

15 This morning we talked about a workshop
16 as one possibility to help get information on the
17 table. I don't know if that's a good idea or not.
18 It's something that is worth considering and would
19 go into the advice category for consideration. But
20 I think, I do sound like a broken record on this,
21 but I'd like to really kind of close my comments
22 here today by saying and emphasizing once again,
23 the most important thing a person can do, from any
24 group that wants to have input in this process, is
25 to prepare a good strong technical document and

1 submit that as early as possible in this process. I,
2 as a member of this group, will do everything I can
3 to acknowledge the points raised in the document.
4 That does not necessarily mean that I will agree
5 with every argument presented, but I will do what I
6 can to acknowledge the points that have been raised
7 from the outside. I'm very appreciative of
8 the input that's been provided here.

9 **DR. GOLDSTEIN:** Any comments
10 from anyone? I've got a couple of areas we could
11 go, but first let me just turn this open for
12 comment. Again, please identify yourself.

13 **MR. DUSTIN:** Dave Dustin,
14 Rutgers University. There have been a couple of
15 speakers who have mentioned the possibility of
16 requiring greater than a simple majority of the
17 panels or each of the panels to be the baseline for
18 recommending a listing. This is one area where
19 political science has something actually foundational
20 in political science to say about the role of
21 majorities. Among, there are two principles of
22 majority rule that are relevant here. Among people
23 who have a similar probability of being right, a
24 majority rule is actually the rule that best has the
25 opportunity of being right. So, if you believe that

1 everybody on the committee has an equal
2 probability of being right, then a majority rule on a
3 given vote is most likely to get the right answer
4 out of that group. The second thing is, majority
5 rule is roughly symmetrical compared to other
6 rules. That is, if you have an opportunity for
7 different kinds of decisions, majority rule is the
8 one that's most likely to be fair and most likely to
9 operate the same way, going in different directions.
10 We've already heard commentary from some
11 speakers who believe that delisting is a higher
12 burden than listing is. If you believe that that may
13 be the case, then you certainly don't want to raise
14 the burden for listing, because you're going to push
15 the burden for delisting even higher above that.
16 So, sort of based on these relatively foundational
17 principles of majority rule, I think suggesting that a
18 higher than majority, higher than majority be
19 required for listing is a bad idea.

20 **DR. FREDERICK:** Let me respond to
21 that, David, because I've actually felt that the
22 mixed opinions are the most interesting opinions we
23 deal with. I said this before here today, that it's
24 not so important exactly how the vote goes, so
25 much as the fact that when we have a mixed

1 opinion we provide that information. Because I
2 think it probably reflects, I would like to think that
3 sampling of the board is representative of sampling
4 of consensus in the broader arena of science.
5 Providing that input to him, that there's a mixed
6 opinion on the issue at hand, I think is very
7 valuable input. What he chooses to do with that,
8 is his burden to carry. In part I think informed by
9 the group that meets after us, the Executive Board,
10 which I feel carries a certain level of advice,
11 responsibility on advice, with regard to policy and
12 philosophical issues that kind of run a little higher
13 than science, but once again advisory, it is his
14 burden.

15 **MS. CLAASSEN:** Hi, I'm Ann
16 Claassen. I'm with Latham and Watkins, Counsel to
17 the CMA Elements Panel. Again, as many have
18 said, thank you very much for holding this meeting.
19 I wanted to respond to Dr. Goldman's question
20 about the idea of publishing questions right at the
21 start of the process. I think that indeed would be
22 very helpful and I thought Mr. Kelly had a very
23 good suggestion right at the start of the process,
24 function, what actually was the main issue of the
25 petition and those two could actually be combined,

1 before you even start writing the background
2 document. Put out the notice, these chemicals have
3 been nominated, these are the reasons they gave
4 for the nomination, and here are some additional
5 questions that have been asked about them. I think
6 that would be very helpful. I don't know that that
7 would be to the exclusion of also having a
8 workshop on chemicals for which you've had a
9 petition. I think with a process like that you would
10 find that people were indeed very interested in
11 getting this problem documented along the process,
12 if they know at the beginning of the process it was
13 started.

14 I also wanted to address a question that
15 was more from the last session, but it's come up a
16 lot during the last couple of days, and that is, the
17 idea that all peer review studies should be part of
18 the process. I haven't heard anyone say differently.
19 I haven't heard any people say that they shouldn't
20 be part of the document. But there's two things
21 that I think that you need to consider and grapple
22 with. One is the difficulty in publishing a negative
23 study. Journals like to publish positive studies,
24 because those are the ones that give us a handle
25 on understanding the mechanisms of toxicity and

1 carcinogenicity. So, a positive study gets
2 published. A negative study we have great
3 difficulty getting published. It doesn't mean that we
4 don't try to publish them and some of them do get,
5 but I think you need to grapple with what to do
6 with the knowledge that there are negative studies
7 out there, but there may be, you know, assume that
8 they are out there and couldn't make it into the
9 journal process. The other thing is that if you
10 know that there is a study in the pipeline that
11 would address important issues for, for whether or
12 not a chemical is carcinogenic, you know, if you
13 know that somebody is about to publish a study on
14 a potential confounder or about to publish a, yet
15 another epidemiology study or if there's about to be
16 some large symposium on a specific chemical, new
17 research in it, then that may be a reason to push
18 that chemical to the next meeting of the
19 subcommittee, rather than to do it right now.

20 Thank you.

21 **DR. GOLDSTEIN:** Thanks.

22 Comments.

23 **DR. GOLDMAN:** Just a point of
24 information, it is possible to have unpublished yet
25 peer reviewed studies. People can set up,

1 especially I've seen, and these two groups actually
2 do this, they can set up peer review processes and
3 I've seen those undergo the same kind of
4 consideration as published peer reviewed reports.
5 Of course it is also possible to publish something
6 in a peer reviewed journal that's completely garbage
7 science too. So, there are ways to do that and
8 take those unpublished studies and put them
9 through a peer review process.

10 **MS. CLAASSEN:** That's good, if
11 NTP was clear that that was something that was
12 happening.

13 **MS. TROXEN:** I'm Elizabeth S.
14 Troxen, I'm with the Manufacturer's Association. I
15 do want to thank Dr. Goldman and the rest of the
16 NTP staff for being very good listeners for the last
17 couple of days and giving us the opportunity to air
18 our views. I do want to pick up on this idea of
19 delisting. Some folks in particular have kept
20 reminding us that there is a delisting process and
21 procedure. I think I did take some, Dr. Dustin's
22 idea about the idea about quorum, if it's raised
23 higher for in fact the listing products than it is for
24 delisting. But I think the idea of in other scientific
25 assessments that I've worked with, and I've worked

1 with a number of them, one of the benefits of that
2 process was that there was a periodic opportunity
3 for review of the science. Since these reports
4 come out every year or two years, that in fact
5 there is a periodicity of this that if in fact the
6 delisting process works well, there should be, as
7 information developed, perhaps moving into,
8 facilitating that delisting process, so that in fact as
9 we get information, our knowledge can be included.
10 So, I just wanted to make that suggestion.

11 I did want to just make some general
12 comments, just that I think in my experience,
13 because even if I work for industry, I'm also a
14 citizen, I'm also interested in good public policy.
15 In the past I've worked with many people in this
16 room, including Jackie Warren and others on other
17 issues, where we have in fact met on common
18 ground, to I think improve process and to get on
19 with making government work and focusing on
20 priority issues. Just that good process to me is the
21 start of good science and good science is the
22 basis for understanding, and good understanding
23 should be the basis for good public policy and I
24 think we all benefit. Thank you.

25 MR. HATHAWAY: Jim Hathaway

1 with Rhodia. I think most people when they talk
2 about non-peer reviewed studies, they're thinking
3 that industry has some studies that they did that
4 they would like to, you know, put on the table.
5 But with sulfuric acid there's a very interesting
6 thing we came up against and there have been
7 three lifetime animal studies. One sponsored by
8 the EPA and two by the NIEHS, none of which even
9 had a formal report prepared. These studies were
10 very high dose, with a large number of animals,
11 three different species and there were no
12 respiratory tract tumors whatsoever found in any of
13 these. But according to the protocols, these could
14 not be used, because these were not published.
15 We're in the process of trying to see if we can't
16 get NYU that did the EPA study to go back to their
17 25 year old data and actually write a journal article
18 on it. We'd like to have them tell us something
19 that maybe the NIEHS could have done, drag out
20 their data on the two that they had sponsored and
21 actually finalize published reports, so that these
22 could be available for use. I think that if that
23 information on three negative lifetime animal
24 studies had been available to IARC or to maybe
25 even the NTP various review groups, they might've

1 used some of our criticisms of these epidemiology
2 studies that they're provided.

3 DR. GOLDSTEIN: Other questions,
4 comments?

5 DR. LUCIER: If I could make one
6 clarification regarding the issue on the height of
7 the bar for listing or delisting. It's the same
8 height for listing or delisting and we use the same
9 process for listing and delisting. So, we really don't
10 ask that different criteria be applied for delisting as
11 listing. It's the same criteria and the same
12 process.

13 DR. GOLDSTEIN: I'd like to make
14 a couple of quick points of things I want to be sure
15 people have a chance to react and not pass by.
16 One is a, early on there was a call for having the
17 known carcinogens based purely on epidemiology.
18 At other times there were discussions of
19 mechanistic information and its role; can
20 mechanistic information only raise things up, can it
21 only lower things down. Raising up makes it a
22 higher, more room to be carcinogenic level,
23 lowering it down can it take something out of the
24 known to reasonably anticipated or vice versa, or
25 should mechanistic information be available for both

1 decisions or for neither decision. Anybody want to
2 pursue this any further? We'll just leave it with
3 these little bit of indirect discussions as to what
4 we should be doing with mechanistic information.

5 DR. WADDELL: It ought to be
6 used for both.

7 DR. GOLDSTEIN: Okay, Dr.
8 Waddell...

9 DR. WADDELL: Why exclude it
10 from one or the other? I mean it's part of the
11 decision.

12 DR. FREDERICK: Let me say that I
13 firmly agree with Bill on that and I think that's
14 right in line with where NTP staff is and the
15 scientists who participated in the revision of the
16 process. That we know enough we feel about the
17 mechanisms of carcinogenicity to incorporate that
18 information in all of these decisions, all this
19 decision making. That said, immediately when you
20 get into a situation where epidemiology is not at
21 the 95th percentile of certainty and a relative risk
22 of two, three, four, these sorts of numbers, if that
23 value is lower, then immediately you get into some
24 problematic issues. But what I think it's fair to say
25 was we, as a group who revised the process, felt

1 that we wanted, we wanted to bring in the full
2 body of information and there's a certain issue here
3 of caution and protectiveness of society and please
4 don't quote me on that, but to a certain extent it
5 relates to how high you run the body count, before
6 you call it a done deal. We as a group of
7 scientists felt like we ought to take the full body of
8 information together and we didn't. We didn't want
9 too many people part of the remote question.

10 **DR. GOLDSTEIN:** Other comments?

11 Dr. Olden...

12 **DR. OLDEN:** Well, let me say that
13 I have only myself to thank that we've been here
14 for the past two days it seems, because when I
15 came on in '91 and went around and talked to you
16 for about a year, year and a half, I listened, and
17 one of the things you told me you wanted was peer
18 review. Now the first seven reports on carcinogens
19 were in fact prepared by government scientists, NTP
20 scientists, and they were published to the Secretary
21 and forwarded to the Congress, without the peer
22 review process that we ultimately put in place. So,
23 for the past two days, I think without exception, all
24 the comments have focused on the peer review
25 process, which we indeed put in place. But I guess

1 we were in hopes that most of the comments about
2 process would've come forward with the agency
3 report on carcinogens. I don't quite understand
4 why they did not. So, this is not indeed the first
5 report that we published, but we didn't hear
6 anything about process, I don't believe. But I need
7 to go back, but certainly not to the extent that
8 we've heard now. They are in relationship to
9 specific chemicals. So, we will go back and take a
10 look, because ultimately I've had a conversation
11 with my boss, the Secretary, and see if we did get
12 and certainly I'm pretty sure we did not, because
13 we would've responded. So, clearly the process
14 involves transparency, public input and peer review.
15 So, that's why we instituted so clearly, we value
16 public input, quality peer review and scientific
17 rigor. So, we will digest the comments that we've
18 heard here today and the NTP Executive Committee
19 and Board of Advisors, the first advisory boards,
20 will prepare a response and let you know what, if
21 any, changes in process, and I guess I started off
22 by, yesterday by saying, I know of no entity, no
23 organization, no company, no process that can't be
24 improved and certainly I've heard some things here
25 that I thought were quite good, good suggestions

1 and I hope others in the NTP and the NTP Executive
2 Committee and the Board of Scientific Advisors will
3 agree that they are good and we will respond and
4 institute those things. But when I reported to the
5 Secretary to get these changes, the peer review
6 incorporated, I pointed out to her something that I
7 think many of you don't probably think we
8 appreciate, that our first mission obviously is to
9 protect the health of the American public, period.
10 But above and beyond that, I said to the secretary,
11 I think it's important to have peer review, because
12 that clearly this report not only could have
13 significant impact on human health, but it could
14 also have significant impact on the economy. So,
15 we do appreciate that in the department. It is
16 something that we're obliged to consider in our
17 evaluations, human health. But clearly that is why
18 we want to have additional input, which means
19 we've brought in The Board of Scientific Counselors
20 to give us advice, because we, government
21 scientists are not empowered, but we could make a
22 mistake. So, before we publish a report that could
23 have either, in other words, sometimes maybe we've
24 made a mistake the other way; in other words, it is
25 a hazard to human health, but we've decided not to

1 list it, whereas certainly having a diverse group of
2 scientists who certainly represent not only the
3 public, but certainly give us advice. We are very
4 much concerned about making sure that the product
5 that we send forward to Congress and ultimately to
6 the American people is right, as much as it can be
7 based on the data that's available on that date.

8 But you understand that people call me up, I guess
9 to the last hour with something that they've just
10 submitted to press and at some point I have to
11 send the Secretary a report. As someone said
12 yesterday, it's the law. That in two years, and I'm
13 trying to get us to stick to the two years and in
14 fact it was I who petitioned to get it changed from
15 one year to two years, because that was more in
16 line with reality. These guys who worked very hard
17 over here who have to prepare a report and get it
18 ready in one year. So, I didn't want to always be
19 behind schedule.

20 I think we can and have an obligation to
21 prepare and submit a report every two years.
22 There are consequences in not doing that. So, I
23 want to be responsible to all American people, not
24 only mothers and dads and industry, but everybody
25 and so I think I have an obligation to get a report

[Redacted]

1 in that's timely and timely to me means roughly
2 every 24 months. So, I thank you for your input
3 and it's been very valuable and I think you will
4 hopefully most of you will be pleased with the
5 response of the National Toxicology Program.
6 Thank you.

7 (Round of applause.)

8 DR. GOLDSTEIN: It falls upon me
9 to very nicely be thanking Sadie Lange and her
10 staff for the superb job, despite hurricanes. We
11 really do appreciate how smoothly you've run this
12 conference and we thank the two members of the
13 Board of Scientific Counselors who've sat here for
14 two days and were so responsive to all the
15 comments.

16 (Round of applause.)

17 (WHEREUPON, the Public Meeting was concluded at
18 2:15 p.m.)

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1 C A P T I O N

2 The Public Meeting in the matter, on the
3 date, and at the time and place set out on the title
4 page hereof.

5 It was requested that the Meeting be taken
6 by the reporter and that same be reduced to
7 typewritten form.

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