

This verbatim transcript of the WTC Health Program Scientific/Technical Advisory Committee, Committee Meeting held telephonically on March 28, 2012, has been reviewed for concerns under the Privacy Act (5 U.S.C. § 552a), and personally identifiable information has been redacted as necessary.

**THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH**

convenes

MEETING THREE

WORLD TRADE CENTER HEALTH PROGRAM

SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE

WEDNESDAY, MARCH 28, 2012

TELECONFERENCE

The verbatim transcript of the
Meeting of the Scientific/Technical Advisory
Committee held telephonically on March 28, 2012.

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March 28, 2012

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TRANSCRIPT LEGEND

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In the following transcript: a dash (--) indicates an unintentional or purposeful interruption of a sentence. An ellipsis (. . .) indicates halting speech or an unfinished sentence in dialogue or omission(s) of word(s) when reading written material.

-- (sic) denotes an incorrect usage or pronunciation of a word which is transcribed in its original form as reported.

-- (phonetically) indicates a phonetic spelling of the word if no confirmation of the correct spelling is available.

-- "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

-- "*" denotes a spelling based on phonetics, without reference available.

-- (inaudible)/ (unintelligible) signifies speaker failure, usually failure to use a microphone.

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PARTICIPANTS

1 Committee Members

2

3 Occupational Physicians with Experience in Treating WTC Rescue and
4 Recovery Workers:

5 Steven Markowitz, M.D.

6 Professor of Environmental Sciences and Director of The Center for The
7 Biology of Natural Systems at Queens College, City University of New York,
8 New York City.

9 William Rom, M.D., M.P.H.

10 Professor of Medicine and Environmental Medicine, New York University
11 School of Medicine

12 Director, Division of Pulmonary and Critical Care Medicine, School of
13 Medicine, New York University, New York City.

14 Occupational Physicians:

15 Robert Harrison, M.D., M.P.H.

16 Clinical Professor of Medicine, University of California, San Francisco;
17 Chief, Occupational Health Surveillance and Evaluation Program, California
18 Department of Public Health, San Francisco.

19 Virginia Weaver, M.D., M.P.H.

20 Director, Occupational and Environmental Medicine Residency, Bloomberg
21 School of Public Health, Johns Hopkins University, Baltimore.

22 Physician with Pulmonary Medicine Expertise:

23 Thomas K. Aldrich, M.D.

24 Professor of Medicine and Director of The Pulmonary Training Program,
25 Albert Einstein College of Medicine, Yeshiva University, New York City.

26

27

28 Representatives of WTC Responders:

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1 Stephen Cassidy
2 President, Uniformed Firefighters Association of Greater New York, Local 94
3 I.A.F.F. AFL-CIO

4 Valerie Dabas
5 Human Resources Analyst, Patrolmen's Benevolent Association of the City of
6 New York, Inc., New York City.

7 Guillermina Mejia, M.P.H
8 Certified Health Education Specialist, Principal Program Coordinator, Safety
9 and Health Department, American Federation of State, County, and
10 Municipal Employees, District Council 37, New York City.

11 Representative of Certified-Eligible WTC Survivors:
12 Kimberly Flynn,
13 Co-Founder, Director, 9/11 Environmental Action

14 Catherine McVay Hughes
15 Vice Chairman, Community Board 1 World Trade Center Redevelopment
16 Committee, Lower Manhattan World Trade Center Redevelopment, New
17 York City.

18 Susan Sidel, J.D.
19 Resident of New York City and volunteer WTC responder.

20 Industrial Hygienist:
21 John Dement, Ph.D.
22 Professor, Community and Family Medicine, Duke University Medical School,
23 Durham, N.C.

24

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Toxicologist:

Julia Quint, Ph.D.
Research Scientist Supervisor II and Chief, Hazard Evaluation System and Information Service (HESIS), Occupational Health Branch, California Department of Public Health (retired), Oakland.

Epidemiologist:

Elizabeth Ward, Ph.D.
National Vice-President for Intramural Research, American Cancer Society, Atlanta. (Advisory Committee Chair-Person)

Mental Health Professional:

Carol S. North, M.D. M.P.E.
Professor, Department of Psychiatry, University of Texas Southwestern Medical Center, Dallas.

Environmental Health Specialists:

Glenn Talaska, Ph.D.
Certified Industrial Hygienist, Professor, Department of Environmental Health, University of Cincinnati, Cincinnati.

Leonardo Trasande, M.D., M.P.P.
Associate Professor in Pediatrics, Environmental Medicine and Health Policy, New York University; Associate Attending in Pediatrics, Bellevue Hospital Center, New York City.

Designated Federal Official:

Paul J. Middendorf, Ph.D., CIH
Senior Scientist
CDC/NIOSH/Office of the Director
Cincinnati, Ohio

PROCEEDINGS

(1:00 p.m.)

WELCOME AND INTRODUCTION

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DR. MIDDENDORF: Okay, let's go ahead and start. Good afternoon, everybody, this is Paul Middendorf. I want to extend a warm welcome to the Committee members and --

THE OPERATOR: Mr. Middendorf?

DR. MIDDENDORF: -- the members of the public who are on the phone with us.

THE OPERATOR: Mr. Middendorf?

DR. MIDDENDORF: We appreciate your interest in these proceedings. For those of you who have signed up to provide public comments, they are scheduled to begin at one --

THE OPERATOR: Paul?

DR. MIDDENDORF: Yes?

THE OPERATOR: This is the operator. You have to let me know -- are you ready to start that recording?

DR. MIDDENDORF: Yes, we're ready to start the recording.

THE OPERATOR: Okay. Give me just one second for you. Okay?

DR. MIDDENDORF: Yes.

(Pause)

THE OPERATOR: Thank you, sir. Your call is being recorded.

DR. MIDDENDORF: All right. Thank you. For those of you who have signed up to provide public comments, they're scheduled to begin at 1:10 this afternoon so we'll start those in just a few minutes. I have a few administrative details I need to go over. For our public commenters who are on the phone, I just want to review some telephone conference etiquette. We do want to provide as much public access to these Committee meetings as possible, but it's very important that the Committee members be able to hear, and every member of the public who wants to hear the proceedings be able to hear also. So just to remind you that your phone should be muted until I call your name. If you don't have a mute button on your phone, theoretically you can dial star-6

1 to mute your phone electronically. And to unmute it you can just
2 repeat that, dial star-6 again. So for the public commenters, when
3 you've finished with your comments we'll ask you to mute your
4 phone when you're finished.

5 It's very important for us to remember why we're here and why
6 we're meeting and set the appropriate tone for the meeting, so
7 let's spend just a few moments in silence to remember those who
8 were killed in the attacks on 9/11, and also those responders and
9 survivors who have since died because of this.

10 (Pause)

11 **UNIDENTIFIED:** Paul, can you hear me?

12 **DR. MIDDENDORF:** Yes.

13 **UNIDENTIFIED:** I have two of your public speakers here in the
14 room with me, T.J. and Jacques.

15 **DR. MIDDENDORF:** Okay. Please keep your phone on mute until
16 we ask for them to speak.

17 (Pause)

18 **DR. MIDDENDORF:** Okay. Thank you. We do -- just to remind folks
19 that copies of the agenda for this half-day telephone meeting can
20 be found on the Committee's website. If you're logged into the live
21 meeting or my meetings, it's the web conference part. You should
22 also be able to see it there as well.

23 Copies of the public comments that were received as of March 27th
24 around noon have been provided to the Committee before this
25 meeting so they'd have a chance to see those. They will also be
26 posted on NIOSH's docket 248, which is also available through the
27 Committee's website.

28 I'd like to do a roll call for the committee members now. So for the
29 roll call I'll call out the name of each member and ask you to let me
30 know that you're on the line. I'll also ask you to state whether or
31 not there have been any changes in your employment or interests
32 that would affect your conflict of interest. Also remind you that if
33 you need to leave the call, please let me know when you leave and
34 also when you return, to be certain that we continue to have a

1 quorum. Okay.
2 So Tom Aldrich?
3 **DR. ALDRICH:** Here, and there have been no changes in my conflict
4 of interest statement.
5 **DR. MIDDENDORF:** Okay. Steve Cassidy?
6 **MR. CASSIDY:** (No response)
7 **DR. MIDDENDORF:** Steve?
8 **MR. CASSIDY:** (No response)
9 **DR. MIDDENDORF:** And not hearing, he's not present.
10 Valerie Dabas?
11 **MS. DABAS:** I'm here. No changes to my employment.
12 **DR. MIDDENDORF:** John Dement?
13 **DR. DEMENT:** I'm here, no changes.
14 **DR. MIDDENDORF:** Kimberly Flynn?
15 **MS. FLYNN:** Here, and no changes.
16 **DR. MIDDENDORF:** Bob Harrison?
17 **DR. HARRISON:** Here, and no changes.
18 **DR. MIDDENDORF:** Catherine Hughes?
19 **MS. HUGHES:** Here, and no changes.
20 **DR. MIDDENDORF:** Steve Markowitz I don't believe is going to be
21 on but I'll check -- Steve?
22 **DR. MARKOWITZ:** (No response)
23 **DR. MIDDENDORF:** Guille Mejia?
24 **MS. MEJIA:** I'm here and no changes.
25 **DR. MIDDENDORF:** Carol North?
26 **DR. NORTH:** (No response)
27 **DR. MIDDENDORF:** I don't believe she's going to be on. Okay.
28 Julia Quint?
29 **DR. QUINT:** Here, and no changes.
30 **DR. MIDDENDORF:** Bill Rom?
31 **DR. ROM:** Here, and no changes.
32 **DR. MIDDENDORF:** Susan Sidel?
33 **MS. SIDEL:** Here and no changes.
34 **DR. MIDDENDORF:** Glenn Talaska?

1 **DR. TALASKA:** Here and no changes.
2 **DR. MIDDENDORF:** Leo Trasande?
3 **DR. TRASANDE:** (No response)
4 **DR. MIDDENDORF:** He said he would probably be on around 2:00,
5 so he's not here yet.
6 And Liz Ward?
7 **DR. WARD:** Here and no changes.
8 **DR. MIDDENDORF:** Okay. Virginia Weaver?
9 **DR. WEAVER:** (No response)
10 **DR. MIDDENDORF:** Okay. Virginia?
11 **DR. WEAVER:** (No response)
12 **DR. MIDDENDORF:** We have 12 present. That gives us a quorum.
13 Okay.
14 I also want to remind --
15 **THE OPERATOR:** Hello, I'm going to put Steve Cassidy on, please.
16 **DR. MIDDENDORF:** Okay.
17 **THE OPERATOR:** Thank you.
18 **DR. MIDDENDORF:** Steve, we just did the roll call. Are you there?
19 **MR. CASSIDY:** (No response)
20 **DR. MIDDENDORF:** Steve?
21 **MR. CASSIDY:** (No response)
22 **DR. MIDDENDORF:** Is Steve Cassidy there yet?
23 **MR. CASSIDY:** (No response)
24 **DR. MIDDENDORF:** Okay. Hopefully he'll let us know when he
25 comes on.
26 Okay, we do have 12 now. The amount we have is a quorum.
27 For voting -- I just want to go over the motions and voting
28 procedures. When a member of the Committee is developing a
29 motion what I'll do is I'll type it here on the computer so that it's
30 visible on the screens for those who are logged in to the web
31 conference, and each of you should be able to see it that way.
32 When the Chair calls for a vote I will have to do a roll call vote and
33 I'll ask each of you in turn to say yes, meaning you are voting for
34 the motion that had been put to the Committee; or no, meaning

1 you are voting against the motion that had been put to the
2 Committee; or abstain, meaning you are not voting on that
3 particular motion. If they recuse for a specific motion, I'll note that
4 also.
5 I just want to remind everyone that, according to our bylaws, the
6 majority of those voting determines the outcome.
7 So with that, I'll turn it over to Liz.
8 **DR. WARD:** Hi, and I'd like to add my welcome to Paul's. I think we
9 should probably proceed directly to John Howard's comments
10 because of the 1:10 deadline for beginning the public comment.
11 **DR. HOWARD:** Great, thanks, Liz. I appreciate that. And good
12 afternoon and good morning to every Advisory Committee member
13 and to all the members of the public, responders and survivors,
14 other attendees at the meeting. I just want to first of all thank
15 each Committee member again for your service. Your time and
16 your advice are greatly appreciated.
17 As I mentioned at your inaugural meeting in November 2011, the
18 Committee has an important role to play in the World Trade Center
19 Program. The James Zadroga Act specifies three general areas of
20 contributions from the Committee, and only three.
21 The first is providing input on eligibility criteria for Pentagon and
22 Shanksville responders, and modified eligibility criteria for
23 responders or survivors. The Act requires that, before making a
24 determination establishing eligibility for Pentagon and Shanksville
25 responders, the Administrator must consult with the Committee.
26 As you'll recall, we did this at the last meeting, February 15th, and I
27 want to thank the Committee for its consultation on the eligibility
28 criteria for Pentagon and Shanksville responders. At the present
29 time the regulatory language to add that eligibility criteria is being
30 prepared and will appear in a future Federal Register notice, as
31 well as on the World Trade Center website.
32 If the Administrator decides to consider modifying current
33 statutory eligibility criteria for New York City responders, then -- as
34 the Act requires -- the Administrator is required to consult with the

1 Committee for input.
2 In the case of changes in the survivor eligibility the Act requires the
3 Administrator consult not only with the Scientific Technical
4 Advisory Committee but also with the steering committees and the
5 data centers. At this time the Administrator is not planning to do
6 any modification to the current statutory eligibility criteria.
7 The second major area is identifying research needs. As I
8 mentioned before, Section 3341(c), pertaining to research, requires
9 the Administrator seek advice from the Committee. I want to
10 thank the Committee for its consultation provided at the February
11 meeting. On March 23rd, 2012, a funding announcement was
12 published for cooperative research agreements related to the
13 program. The receipt date for applications is May 21st, and a link
14 to the announcement can be found at grants dot NIH dot gov.
15 And thirdly, the third function of the Committee is providing a
16 recommendation regarding addition of conditions to the list that is
17 in the statute. As you are aware, we received a petition to add
18 cancer to the list of statutory conditions on September the 8th,
19 2011 and, pursuant to the Act, the Administrator requested the
20 advice of the Advisory Committee and provided a due date for the
21 recommendation of April 2nd, 2012, which is 180 days from the
22 date that the Administrator's request, which is in fact the
23 maximum amount of time permitted by the Act for the Committee
24 to submit its recommendation.
25 The Act provides that not later than 60 days after receipt of the
26 Committee's recommendation -- which, according to the calendar,
27 counting calendar days, would be June 1st, 2012 -- the
28 Administrator must publish in the Federal Register a proposed rule
29 with respect to the Committee's recommendation, or a
30 determination not to propose a rule and the basis for such
31 determination. As I said at your November meeting, it's important
32 to keep in mind as you deliberate today that the Committee was
33 established by the Act to provide advice of a scientific or technical
34 nature. Articulating the strongest possible scientific basis for the

1 Committee's recommendation on Petition 001, including an
2 evaluation of available information about the level of exposure to
3 carcinogenic agents, will be of the greatest value to the program.
4 And certainly I look forward to receiving your recommendation on
5 Petition 001 by April 2nd, 2012, and will give it the fullest and most
6 serious consideration.

7 Finally, some Committees -- Committee members have asked what
8 does the Committee do after April 2nd, 2012. And as I just stated,
9 the Act provides only consultative actions for the Committee in
10 relation to the Administrator's determining or modifying eligibility
11 criteria, preparing input for research solicitations, or determining
12 whether to add health conditions. So the Committee has a limited
13 role and meets only at the request of the Administrator based on
14 these three program needs. If there's no business to conduct with
15 regard to the Committee's consultative duties, then the
16 Administrator will not request the Designated Federal Official to
17 call a meeting.

18 So again, on behalf of the entire program, thank you very much for
19 your service on the Committee and I wish you a very successful
20 meeting today. Thank you, Liz.

21 **DR. WARD:** Thank you, John.

22 **PUBLIC COMMENTS**

23 Paul, I'll turn it over to you for public comments.

24 **DR. MIDDENDORF:** Okay, let me check real quick -- Steve Cassidy,
25 are you on the line?

26 **MR. CASSIDY:** (No response)

27 **DR. MIDDENDORF:** Steve, are you there? You need to -- Steve, if
28 you called in to the general line, you need to call back, you know,
29 on the --

30 **MR. CASSIDY:** I am -- I am here.

31 **DR. MIDDENDORF:** Oh, okay, I just couldn't hear you. Okay, great.
32 Just wanted to check and make sure you were here.

33 **MR. CASSIDY:** I'm here, thank you.

34 **DR. MIDDENDORF:** All right. Okay, moving on to public comments.

1 Each of the public commenters have signed up on a first come, first
2 served basis and each of them will have up to five minutes to
3 present. I'd like to remind folks that five minutes can go by fairly
4 quickly, so in four minutes I will let the commenter know that they
5 have one minute remaining so they can be sure to make the point
6 they need to. If they haven't finished in five minutes, I have to
7 rudely interrupt them and thank them for their comments. I
8 apologize up front to everyone to whom that happens, but we have
9 to do that to be fair to all our presenters and to stay on time. So I
10 want to point out that you do have the option of submitting
11 written comments to the docket for this Committee. The docket
12 number is 248, and the information on how to submit that is both
13 on the NIOSH docket web page and on the Committee website.
14 The last thing I need to do before beginning the comments is to
15 make sure the commenters are aware of the redaction policy for
16 public comments. The policy is in the Federal Register notice for
17 this meeting, and it's also on the Committee's web page. The
18 policy outlines what information will be kept and what information
19 will be redacted before it's posted to the docket.
20 So with that, let's go to our public commenters, and our first
21 commenter is Jim Melius.
22 **DR. MELIUS:** Okay. Thank you, Paul, thank the Committee. I'm Jim
23 Melius. I'm from the New York State Laborers Union. I'm also chair
24 of the steering committee for the responders' medical program.
25 First of all I'd like to thank the Committee for all of your efforts in
26 working on this issue, responding to the petition, drafting your
27 recommendations and -- I think very importantly -- drafting the --
28 really developing and drafting the scientific rationale for these
29 recommendations. I realize the amount of effort involved. You
30 didn't have a pattern or template to follow, and I really think that
31 you've done an excellent job of developing this draft document in a
32 very short time. So I appreciate it and I know others do also.
33 I have a few brief comments I'd like to make. One issue that came
34 up, at least in the development of the document, was some

1 concerns were raised about the cost and administrative burdens of
2 adding some number of cancer sites to the list of covered
3 conditions, and I really think -- feel very strongly that that's --
4 really shouldn't be a consideration for this Committee. You're only
5 asked to review the scientific evidence involved, and I think that
6 the implementation of your recommendation and issues related to
7 that are something that really is up to NIOSH and to the World
8 Trade Center Administrator to address going forward. So I really
9 don't think that should be a consideration, nor should the cost of
10 treatment or -- or issues like that are not something that should be
11 part of your review process.
12 That I -- again reminding that there's also a second step to this
13 process, that once a condition is added there's still a diagnosis and
14 attribution of a particular -- in a particular patient of whether or
15 not that cancer is World Trade Center-related and a certification of
16 that attribution by the World Trade Center Administrator. So I
17 think the administrative issues can be dealt with through that. And
18 again, it's not everybody with the conditions that are included in
19 the program. There -- there is a second step to this.
20 Secondly, I'd like to raise an issue of -- you already have it partially
21 covered, but I recognize that you're not in a position to review data
22 that's not been published yet, but you do acknowledge that there
23 are studies that I believe both have been submitted for publication
24 and for public -- that's both the Registry and the Mount Sinai
25 Program, and -- and I -- you have a general recommendation that
26 the Administrator should take those into account. If there's a
27 particular cancer site that you're discussing and whatever, you
28 think there's a particular issue that they should address based on
29 those, I think this may come up for prostate and thyroid cancer, I
30 would make -- do that as a specific recommendation 'cause it's well
31 possible that both of those studies will be published by the time
32 that the Administrator is in the process of developing his
33 recommendation and his Federal Register notice. And so those
34 may be very well available by that time and could well be

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considered in that process.

Finally, I would just point out particularly two cancers that are left off your list as we -- as I understand your report. One is breast cancer, which -- I realize there's not a great deal of literature linking breast cancer to occupational exposures, but I think we all have to recognize that that is a result of the fact that there were very few women working in most of the industries, at least in the past, where cancer was studied and where there were exposures to many of these carcinogenic agents, and --

DR. MIDDENDORF: One minute, please.

DR. MELIUS: -- I'm not sure that there's been a, you know, sort of a fair assessment of that. And I would ask you to sort of reconsider that. I believe you have a -- sort of set aside the -- an issue of female cancers, and I think that is -- probably falls under -- under that particular subject.

The second cancer I'd ask you to reconsider is brain cancer. Again, the literature may not be as strong as it is for some of the other cancer sites, but certainly it's something that's repeatedly showing up in studies of firefighters, as well as in petrochemical workers in the past and ongoing studies and it is something that -- I think there's a fair amount of evidence that it's related to chemical exposures, though again maybe not as strong as some of the other cancers you've listed and I think that deserves some reconsideration. So --

DR. MIDDENDORF: That's five minutes.

DR. MELIUS: -- thank you for your efforts and good luck going forward this afternoon.

DR. MIDDENDORF: Thank you, Jim. Our next public commenter is Lila Nordstrom.

MS. NORDSTROM: Hi, I'm here. Should I begin? I was a student at Stuyvesant High School on 9/11 and I'm the head of Stuy Health, which is an advocacy group for Stuy alumni who were there on that day. We were just three blocks from the World Trade Center and we were inside of our building until about 10:30 on the day. A lot

1 of us left the building after the dust cloud had already reached
2 Stuyvesant, and then later the school was used as a command
3 center for the rescue effort and not adequately cleaned ever
4 before we reoccupied it on October 9th in 2001. It was only three
5 weeks after the attacks. There was smoke and ash blown into our
6 school daily, and the barge -- the garbage barge for the debris was
7 right next to our school. It was right next to our air intake system,
8 and environmental testing showed that levels of particulate matter
9 outside Stuyvesant were often higher than they were at Ground
10 Zero.

11 I wanted to talk a little bit about some of the health conditions that
12 members of Stuyvesant are experiencing -- sorry, I'm on the street
13 and there's cars coming all of a sudden. Acid reflux and coughs and
14 respiratory problems were already pretty widespread among the
15 Stuyvesant population, but we have anecdotal reports of cancers
16 that are growing, as well as some autoimmune disorders. In the
17 last five years at least six cancers have been reported to me by
18 former classmates.

19 [identifying information redacted] from the class of 2002, I'm sure
20 you've heard from before, was diagnosed with Hodgkin's lymphoma
21 in 2006. He'd had severe flu and cold-like symptoms for years, and
22 he believes that environmental factors played a part in his
23 diagnosis.

24 [identifying information redacted] from the class of 2002 was
25 diagnosed with non-Hodgkin's lymphoma last summer, in August.
26 She went through six rounds of chemotherapy over the course of
27 four months. She's a teacher. She was unable to attend work at all
28 during that time and she's in remission right now, but her
29 treatment caused her to develop blood clots in her heart and a
30 clogged vein near her heart, so she's on blood thinners and she's
31 getting monitored every few days by giving blood.

32 [identifying information redacted] from the class of 2002 has had
33 two major surgeries in the last six years to remove multiple
34 synthroidonomas (sic), which are benign tumors. She had them on

1 both of her ovaries. These types of benign tumors are really rare in
2 younger women. She had no family history of this. And in some
3 cases these cysts actually turn out to be cancerous. She's been
4 told that they'll likely keep growing back and require further
5 surgeries, and the last surgery that she had she almost had to have
6 while she was pregnant. She ended up going under the knife three
7 months after giving birth, and she also believes that environmental
8 factors played some role.

9 There's also a thyroid cancer in the graduates of class of 2002, and
10 then for the class of 2003 the Columbia Spectator in 2007 reported
11 [identifying information redacted] was diagnosed with acute
12 myelogenic leukemia, which is a really rapidly-growing cancer in
13 the blood and bone marrow. It's normally found in much older
14 adults than he was at the time. He was in college at the time, and
15 he had to have a bone marrow transplant.

16 And then we also have reports of a melanoma from the class of
17 2003. It was removed, it hadn't spread and it was removed in
18 2009.

19 But these are just the cases that we know about anecdotally.
20 There are surely more than this, especially in the younger classes
21 who -- who, you know, are younger than the class of 2002 and
22 2003, and will probably develop similar conditions in the future.
23 There's already four cancers from my class alone, and that's in
24 addition to the numerous other 9/11-related health conditions that
25 people are reporting from these classes.

26 None of these cases have visited the 9/11 Health Center because
27 they spend their whole lives at the doctor's and they, you know,
28 don't necessarily have the ability to spend a full day getting
29 treatment for something that is not their main health problem. But
30 --

31 **DR. MIDDENDORF:** Four minutes.

32 **MS. NORDSTROM:** -- it's really important -- it's really important
33 that they be able to be treated at these centers. You know, we're -
34 - we're at an age where we're -- you know, high numbers of us are

1 uninsured. We're spread out all over the nation. A lot of us are
2 already being excluded from health coverage based on 9/11-related
3 preexisting conditions. I personally have had that experience in
4 California and I know other classmates of mine have as well. So it's
5 -- these cases are certainly going to keep appearing and there are
6 certainly already an alarming number, so it's really important that
7 we have somewhere to go where we can get treated for these
8 conditions, and also so that we know what to expect, you know, so
9 that we know what the rest of the students at Stuyvesant should be
10 looking out for and how -- how these conditions are, you know,
11 going to affect us in the future.
12 I think that's it for me. Thanks so much --
13 **DR. MIDDENDORF:** Thank you very much.
14 **MS. NORDSTROM:** -- for your time. Okay, bye.
15 **DR. MIDDENDORF:** Our next presenter is Micki Siegel de
16 Hernandez.
17 **MS. SIEGEL DE HERNANDEZ:** Hi, thank you, Paul. My name is Micki
18 Siegel de Hernandez. I'm the Health and Safety Director for the
19 Communications Workers of America in District One. Our union
20 represents different groups of 9/11 responders, as well as area
21 workers affected by the events of 9/11 and subsequent exposures.
22 The Committee should be commended for the work that went into
23 the draft recommendations. There was clearly an enormous
24 amount of thought and effort put into the draft. And the body of
25 scientific evidence that was compiled in such a short amount of
26 time is impressive. The STAC should also be commended for
27 recognizing in this draft that the lack of quantitative exposure data
28 is not evidence of a lack of exposure.
29 Our union advocates the inclusion of all cancers in the list of World
30 Trade Center covered conditions, and believes there is ample
31 rationale for that recommendation.
32 On page two of the draft -- the STAC draft -- it says, quote, 'Many
33 substances present in World Trade Center dust and smoke have
34 been classified by IARC as known, probable, or possible carcinogens

1 based on animal studies and mechanistic data, and the Committee
2 believes that such evidence is highly predictive for human
3 carcinogenicity. However, because there is limited concordance
4 between specific cancer sites affected in humans and animals, only
5 those substances classified based on human data are informative
6 regarding organ sites of carcinogenicity in humans' end quote.
7 Therefore, many World Trade Center contaminants for which the
8 evidence as recognized by the STAC as highly predictive for human
9 carcinogenicity were removed from consideration in the STAC's
10 deliberations because specific cancer sites in humans could not be
11 determined.
12 Instead, I would urge the STAC to reconsider this and recognize
13 that the presence of multiple carcinogenic substances supported by
14 IARC documentation, scientific documentation, and known to have
15 been present in World Trade Center contamination but for which
16 human cancer sites cannot be predicted, as lending scientific
17 credence to the inclusion of all cancers. If instead the Committee
18 decides to include only certain cancers and exclude others, it is
19 then incumbent upon the Committee to provide stronger support
20 than is in the current draft as to why those cancers not
21 recommended for inclusion could not be considered potentially
22 World Trade Center related.
23 And lastly, I want to echo what Dr. Melius said earlier and to
24 remind the STAC that the list of World Trade Center covered
25 conditions is not presumptive for any of the diseases currently on
26 the list, and similarly will not be presumptive for cancer. It will still
27 be up to a treating physician to determine World Trade Center
28 relatedness and attribution for any given individual based upon
29 many, many factors, including an individual's personal and medical
30 history, World Trade Center exposures, temporality of disease
31 onset or exacerbation, medical exams, test results, co-morbidities,
32 et cetera.
33 Thank you.
34 **DR. MIDDENDORF:** Thanks, Micki. Next commenter is Frank

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Tramontano.

MR. TRAMONTANO: Hi, good afternoon, this is Frank Tramontano from -- from the Patrolmen's Benevolent Association. This Committee has heard testimony about how the sampling data for the various carcinogens at the World Trade Center site were limited and how no samples were collected until four days after 9/11. Testimony also revealed how the samples were collected not to capture the highest exposures and not in a manner to estimate exposures for workers on the Pile. The Committee still only has one cancer study published to date to use in making this decision on the inclusion of cancers. Despite these shortcomings, this Committee in its March 18th draft has determined there is sufficient evidence to confirm that those who were exposed to carcinogens at the World Trade Center site have an elevated risk of developing cancer. However, the draft document arguments (sic) against recommending all cancers be covered. Some of those arguments presented against recommending all cancers are based on resources required to implement such a recommendation, while other arguments project how cancer patients and health providers would react. We feel these arguments should be considered outside the scope of the Committee's charge.

We support and strongly agree with the arguments presented in favor of adding all cancers. Some of these arguments include the large volume of toxic materials present in the World Trade Center, the presence of multiple exposures and mixtures with the potential to act together to produce unexpected health effects, the major gap in the data with respect to the range and level of carcinogens and the limitations of testing for the carcinogenic nature of the many chemicals and agents identified at the World Trade Center. These arguments, along with some of the key findings in the FDNY study, are more than sufficient to support all cancer recommendation to the program Administrator.

After ten and a half years, the only cancer study completed is the FDNY study. This study does not include data beyond 2008, and

1 the surveillance bias included in that study reduces the data back
2 to 2006. The fact that the cancer cases identified in the
3 surveillance bias were not early stage tumors and that Dr. Prezant
4 has testified before this Committee that the non-exposed group
5 have a good rate of participation in the FDNY monthly program
6 should suggest -- should question the relevance of the surveillance
7 bias.
8 Additionally, both the Mount Sinai and the New York City
9 Department of Health cancer studies, which have been promised to
10 this Committee but have yet to come out, appear to support the
11 findings of the FDNY study, despite those studies having some
12 serious limitations, not the least of which is failing to include 70
13 police officer responders that we know were diagnosed with cancer
14 within the time frame covered in these studies.
15 Yet despite having only one study with the new qualifications, we
16 believe there is sufficient scientific and medical evidence that
17 exists to support adding all cancers. We base this belief on the fact
18 that the FDNY study showed that the increased growth in cancers
19 of exposed firefighters versus non-exposed firefighters was
20 significantly higher in the later period of the study, from 2005 to
21 2008, than it was in the earlier period. Furthermore, it is logical
22 and acceptable for this Committee to accept that difference to
23 grow, thus establishing an even greater support for all the cancer
24 recommendation -- for an all-cancer recommendation. It would be
25 helpful if this Committee had an updated analysis through 2011
26 from the FDNY, using the same standard as in the original cancer
27 study of self-reported cases that have pathological confirmation.
28 The Committee's recommendation -- recommended approach is to
29 vote on individual cancers. This approach appears to leave out at
30 least two cancers that we believe there is evidence of being WTC-
31 related. The PBA has eight brain cancers -- cancer cases reported
32 to us with an average age of diagnosis of 36. The annual national
33 average is 6.5 per 100,000 with an average age of 56. Clearly the
34 average age for diagnosis that we have suggests something

1 unusual. We are asking that an immediate review be done on all
2 the brain cancer cases compiled by all the brain -- by all the cancer
3 study groups to determine the real rate of brain cancer among the
4 responder population.

5 Pancreatic cancer is another cancer we believe warrants a more
6 comprehensive review before it's left off the list. The PBA has six
7 pancreatic cancer cases reported to us with an average age of 48,
8 and the FDNY cancer study lists five pancreatic cancers. The same
9 issues can be raised with the cancer -- with this cancer, with our
10 average age of diagnosis being 48, when it is 72 among the general
11 population --

12 **DR. MIDDENDORF:** One minute.

13 **MR. TRAMONTANO:** -- suggesting that this, too, is a cancer that
14 demands immediate review.

15 Additionally, we do not -- we do not understand why pancreatic
16 cancer isn't being recommended for approval since it appears to
17 meet the Committee's specific criteria of arising in regions other
18 than the digestive tract. This Committee has a responsibility to at
19 least recommend that a further review be done on these two
20 cancers and the results be reported to the program Administrator.
21 We must remember there are real lives that hang in the balance,
22 making it worthy of a more comprehensive review.

23 Finally, we must remember that while the information before this
24 Committee hasn't changed in the last six weeks, there have been
25 changes in the lives of responders who have -- who are being
26 diagnosed with cancer. It is exactly for this reason Congress has
27 mandated that cancer -- that this cancer issue be reviewed. The
28 men and women who responded that day who are sick with cancer
29 today and need treatment are relying on this Committee to leave
30 no stone unturned in their review of the medical and scientific
31 evidence establishing the exposure between responders and
32 cancer. It is for these reasons we request the Committee to
33 require an additional review for brain and pancreatic cancer if they
34 choose today not to approve those cancers for treatment.

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Thank you.

DR. MIDDENDORF: Thank you very much. Our next presenter is Mary Perillo.

MS. PERILLO: Hello? Can you hear me?

DR. MIDDENDORF: Yes.

MS. PERILLO: Okay. Do you have my pictures?

DR. MIDDENDORF: Yes. When you tell me to put them up I will try to bring them up on the web conference.

MS. PERILLO: Okay, let's start with number one.

DR. MIDDENDORF: It doesn't look like it's going to work. There appears to be something wrong with the photograph. Let me try the second one -- no, there seems to be a problem with them.

MS. PERILLO: Okay. Is there a way that they can be entered into testimony with my --

DR. MIDDENDORF: We can attach them at the end of the docket, yes.

MS. PERILLO: Yeah, okay, great. Then I'll just --

DR. MIDDENDORF: I'll ask you to send me a new copy of them.

MS. PERILLO: Okay, that's fine. On September 11th my building, which is on the south border of the World Trade Center site, was very much involved. A number -- it remained standing, but a number of the windows -- all the windows on the west side and the north side and a couple of other windows in the building were blown in. And along with the windows blowing in, a tidal wave of World Trade Center debris also blew in the broken windows that included things from the sizes of 11-foot window flashings and computers, corners of desks, rugs, phones, to things in particle size so small as under -- what was it, what was our old number size? It's been such a long time since I've done the numbers. We needed to be clean below -- Kimberly, help me -- so many microns. But whatever it was, we were way -- we were way off the charts in terms of what was safe to breathe, even though at the time we were being told that it was okay to go back in. And we went back in with police escort to try to dig through the say three-foot deep

1 in the corner piles of dust and debris and find, I don't know,
2 personal photographs, my mom's engagement ring -- we went
3 through to find things at first.
4 And then we went through and worked for weeks and weeks and
5 weeks shoveling because our landlord said that he wouldn't clean
6 the building unless it was empty -- and empty of everything but
7 solid wood or metal. So we started doing that, all the while
8 pleading to the EPA and the DEP and the DEC and anybody who
9 would listen. I called the USGS and UC California Davis to see if we
10 could get numbers, tests and help with the cleanup. When we
11 finally found out that we had pretty much everything that Deutsche
12 Bank had in our apartment -- the pile was basically in our
13 apartments -- I called an old geology professor and he sent
14 someone to estimate a proper cleaning of my space, which was
15 \$26,000 so that was pretty impossible.
16 And then finally the EPA was convinced by the community to assist
17 with the cleanup, and we were one of the test buildings for the
18 cleanup. September 15th, 2002 was the day our cleanup began, so
19 in the year before that we spent a lot of time not living in the
20 building but clearing out the building ourselves. And without
21 electricity and water, we weren't doing a very good job of it and we
22 were taking it all to wherever it was we were living at the time.
23 So when our cleaning began it was a year and three days later,
24 something like that, and it was three shifts a day, seven days a
25 week for a month to clean one 12-story building with about 20
26 apartments. And mine failed three times in a row. It didn't clear
27 three times in a row and had to re-clean it, re-clean it, just
28 basically hosed it down till there was nothing left but water on the
29 walls, and I even tore some walls down to make sure that walls that
30 were perfectly flush to the floor were not harboring stuff I'd have
31 to breathe for the rest of my life in the building where I still live.
32 The best -- the best I can remember about the chemicals in our
33 dust is that it exceeded pretty much every exceedence (sic) that
34 was found in all the other places that were tested. I still own some

1 of the dust in a baggie. If anybody would like to test it now you
2 can have new samples. I don't know what happens to it after more
3 than ten years, but I know that there are two people in a lab who
4 know the numbers on what we had, and I know that we were
5 exposed to way too much, way too small particles for way too long,
6 and I really hope that you do add the cancers to the list, and also
7 that you add the community that was exposed. We really are very
8 grateful to the first responders who were there, and we were
9 there, too. We were next to them.
10 Okay? Thank you.
11 **DR. MIDDENDORF:** Thank you very much, Mary.
12 **MS. PERILLO:** Okay.
13 **DR. MIDDENDORF:** Our next presenter is Jo Polett.
14 **MS. POLETT:** My name is Jo Polett and I live seven blocks north of
15 the World Trade Center site. I'm impressed by the Committee's
16 grasp of the complexity and variety of toxic exposures within and
17 across the populations with which the master draft is concerned. I
18 do, though, have a couple of edits that I hope you'll accept.
19 On page 11, lines 18 and 19, the document states 'Dust entered
20 buildings through broken windows, open windows and air intakes.'
21 The fact is dust also entered buildings through closed windows.
22 Given the mass and force of the collapse cloud, buildings in its path
23 acted as sieves for the dust. So while a lot less dust entered a
24 building through a closed window than through a broken or open
25 window, the dust that made it through closed windows had
26 proportionately higher amounts of very small, highly respirable
27 particles. I ask that you amend the statement to read 'Dust
28 entered buildings through broken windows, open windows, closed
29 windows and air intakes.' An additional advantage of the proposed
30 correction is that it broadens the statement to cover the smoke-
31 borne particles referenced earlier in the draft that permeated the
32 closed windows of lower Manhattan buildings for months following
33 the attacks.
34 For the second edit please go to page 18, line 16 of the draft.

1 Quote, 'The US EPA did not find elevated levels of TCDD and house
2 dust,' end of quote. I understand that the aim of the paragraph is
3 to lay out the various conflicting findings regarding the quantities
4 of dioxins, furans and PCBs released by the attack in its aftermath.
5 Indeed, the sentence in question is immediately countered by a
6 sentence referencing the window film analyses that found high
7 levels of TCDD adhering to the outside of windows in buildings
8 within one kilometer of the site. However, the implication is that
9 the US EPA findings and the window film analyses deserve equal
10 weight. They do not. EPA scientists were constrained by EPA's
11 liability concerns. The Canadian team that conducted the window
12 sampling had no such constraints. Further, the EPA finding is not
13 sourced, though I expect it will be in the discussion that follows. In
14 any case, before an EPA finding can be accepted as credible, the
15 sampling method must be reviewed and the conduct of the method
16 must be assessed. In cases where it's not possible to charter a time
17 machine and watch EPA collecting the samples, negative findings
18 must be considered suspect.
19 I know this because I was present when EPA sampled my apartment
20 for heavy metals and dioxins during the first test and clean
21 program that launched in May of 2002. When I saw that the EPA
22 sampling technicians were setting up to collect the samples from
23 my kitchen counter, I insisted that they collect the samples from a
24 surface more likely to harbor contaminants. After a lengthy
25 argument, the technicians agreed to collect the samples from the
26 wood floor of my bedroom instead of the kitchen counter.
27 As reported at the first meeting of this Committee, the wide
28 sample results from my bedroom floor was 127 micrograms per
29 square foot. The results for antimony was 1090 micrograms per
30 square foot. Had I not been present during the sampling and
31 fought with EPA's technicians, the presence of WTC-derived heavy
32 metals in my apartment would have gone undetected.
33 For support of my contention that EPA's WTC findings were
34 constrained and corrupted by EPA's liability and policy concerns, I

1 refer you to the summary report of the US EPA technical peer
2 review meeting on the draft document entitled 'Exposure and
3 Human Health Evaluation of the Airborne Pollution from the World
4 Trade Center Disaster.' The peer review committee met in July of
5 2003 and published its report the following December.

6 **DR. MIDDENDORF:** One minute, please.

7 **MS. POLETT:** A major purpose of the EPA's document was to
8 obfuscate the difference between conditions indoors and
9 conditions outdoors and state, quote, 'Except for exposures on
10 September 11th and possibly during the next few days, persons in
11 the surrounding community were unlikely to suffer short term or
12 long term adverse health effects.' Peer reviewers unanimously
13 rejected this ploy, insisting that EPA make a clear distinction
14 between exposures to ambient air and indoor and occupations
15 exposures. They took the additional step of suggesting that EPA
16 convene an independent group such as the National Academy of
17 Sciences to analyze the indoor air data because they were so
18 discouraged by EPA's use of suspect data to support its analysis of
19 indoor air conditions.

20 **DR. MIDDENDORF:** Five minutes, Ms. Polett.

21 **MS. POLETT:** I ask that the Committee appropriately qualify the
22 EPA finding in question or delete it from the paragraph entirely.
23 Thank you.

24 **DR. MIDDENDORF:** Thank you very much. Our next presenter is
25 T.J. Gilmartin.

26 **MR. GILMARTIN:** Yes, T.J. Gilmartin here. I'm 31 years as a shop
27 steward with United Cement Masons Union in New York building
28 high-rises. I've already spoken once before at the federal plaza.
29 Now I just want to reiterate that in the 31 years that I was on a
30 construction site, everything that was at the Trade Center
31 according to the OSHA standards, I just can't see how they can't
32 put some of these OSHA standards to everything that was down
33 there -- the silicas, the dust -- the concrete dust, the asbestos. I
34 mean this is all stuff that, when I was on a construction site, I

1 would have got locked up or fined very high if I didn't have
2 respirators on and all. I mean just common sense tells me if you're
3 putting up these buildings and they have such high standards for us
4 putting up the buildings, what happens when two of them come
5 crashing down all at one time? And these buildings -- I mean it's
6 just common sense.
7 And you know, I just want to thank you for all the intent,
8 everything you've done, and I just want to add one other quick
9 point, that as much as you're doing this, I really appreciate it.
10 Don't let -- there's a lot of people coming out of the woodwork.
11 Even if you add this cancer and these cancers get added, you're
12 going to have everybody and their mother, pardon my French,
13 coming out of the woodwork, swearing that it was from the World
14 Trade Center. There are some real heroes that deserve -- deserve
15 to be taken care of, but there's als-- don't let the frauds discourage
16 you from what you're doing. You guys do a great job.
17 And now when -- I've got a few minutes. I have somebody else to
18 speak in my -- the rest of my time spot.
19 **UNIDENTIFIED:** Here is Chris Kraft, giving up T.J.'s time.
20 **MS. KRAFT:** My name is Christine Kraft. I am a retired clinical
21 social worker. On 9/11 I was already retired from my job and I was
22 a member of the Red Cross Disaster Mental Health Team. And as
23 such, on 9/11 we were dispatched down to Ground Zero, I had full
24 Ground Zero clearance. My job was to go down to Ground Zero to
25 take care of all of the first responders who were there, to make
26 sure everybody was okay. I will tell you right now that I have
27 several medical conditions. I have nodules in my lungs. I have
28 Hashimoto's thyroiditis. I have GERD's. I have a blown sinus, and I
29 have strange neuromuscular disorders. I was breathing that stuff
30 for quite some time.
31 My sister-in-law, who was down there for four days, has thyroid
32 cancer and she recently had half of her thyroid removed. I also
33 personally know many other people who have Hashimoto's
34 thyroiditis, as well as nodules of the thyroid -- which I also have --

1 which have so far not been diagnosed as cancer but there is a
2 chance that it will. They told my sister-in-law there was nothing --
3 even after a biopsy was done, they said it was probably not -- not
4 cancer, but it turned out that -- she chose to have the surgery and
5 it turned out to be cancer as well.
6 I know a friend of mine who was 12 years old and a student in the
7 area at the time, she now has thyroiditis as well, Hashimoto's. This
8 is a common disorder of middle-aged women. She is 20 years old.
9 I also know someone else who lived in the building that was near
10 the World Trade Center. She is a guide down there as well, and she
11 now has Hashimoto's as well. She is under the age of 40.
12 Nobody in my family or any of my friends' families ever had any
13 problems with the thyroid. Before that I was a runner. I was very
14 healthy, and I never thought in a million years that this would
15 happen to me. But at the same time, what we were breathing
16 there, and I'd like to follow the gentleman that was recently up, I
17 can stand in a room with second-hand smoke and that exposes me
18 to lung cancer. But I was in the pit of hell with every -- every
19 substance known to man and breathing that outright for days and
20 days on end and that doesn't cause cancer at all.
21 **DR. MIDDENDORF:** One minute, please.
22 **MS. KRAFT:** It's the logic that -- that it would be. Thank you very
23 much for your time.
24 **UNIDENTIFIED:** Thank you. Joe Morrone, a downtown resident, is
25 going to use the remaining minute.
26 **MR. MORRONE:** Hi, my name is Joe Morrone. I'm a resident of
27 Southbridge Towers. At the time of the attacks on the Trade
28 Center I worked on the New York Stock Exchange floor, and I was
29 President of the Board of Directors of Southbridge Towers. So --
30 and that was right in the line of all that smoke and everything. I
31 was just recently -- I remember the CDC coming down with Nadler
32 to talk to the Board of Directors at the time, to talk to our co-op in
33 February of 2002, telling us that the air was clear. And just so you
34 know, I asked him to leave and not insult my intelligence because

1 we didn't know about what bomb we were breathing because it
2 was just asbestos or just PCB or just lead, I could understand it, but
3 with all the particles that we were breathing with the Trade Center
4 being vaporized the way it was, I knew that eventually something
5 would happen. And ten years -- almost ten years to the day I was
6 diagnosed with a mass -- a real -- a mass on my kidney and --
7 **DR. MIDDENDORF:** Your five minutes is up, please.
8 **MR. MORRONE:** I'm sorry?
9 **DR. MIDDENDORF:** The five minutes is up. Thank you very much.
10 **MR. MORRONE:** Thank you.
11 **DR. MIDDENDORF:** Could I get the last gentleman's name, please?
12 **MR. MORRONE:** Sure, my name is Joe Morrone, M-o-r-r-o-n-e.
13 **UNIDENTIFIED:** And he lived and worked downtown.
14 **MR. MORRONE:** I worked on Wall Street, New York Stock
15 Exchange, and I lived there also with my children.
16 **DR. MIDDENDORF:** Okay, the name is Joe Morrone, M-o-r-o-n-e
17 (sic)?
18 **MR. MORRONE:** M-o-r-r -- double-r -- o-n-e.
19 **DR. MIDDENDORF:** Okay, thank you very much. Our next
20 presenter is Jacques Capsouto.
21 **UNIDENTIFIED:** Jacques Capsouto's right here as well.
22 **DR. MIDDENDORF:** Okay.
23 **MR. CAPSOUTO:** Hi, my name is Jacques Capsouto. I'm a resident
24 and business in Tribeca. I'm here to talk about Albert Capsouto,
25 my younger brother, who died of brain cancer -- I'm repeating,
26 brain cancer, which you have not included. He was diagnosed
27 November 16th, 2009 and died January 19th, 2010, nine weeks
28 after he got diagnosed. Albert was involved in the community, part
29 of community board one, for 19 years. After 9/11 it became a full-
30 time job to reconstruct downtown, so if I get emotional... He was
31 involved in four or five committees and he used to spend all his
32 time going by bicycle downtown to the -- to the Ground Zero. He --
33 sorry. He got diagnosed with glioblastoma (sic) number four,
34 which is a brain cancer, a mark of brain cancer. He died very

1 quickly. The cancer really disabled him so fast that -- he
2 deteriorate so fast that we didn't even have time to communicate.
3 We -- we opened a restaurant in Tribeca and we stayed open and
4 we fed people and we became a center for people to have -- for the
5 community to be able to have a place to gather together, so we
6 gave food away for 17 days. The name of the restaurant is
7 Capsouto Freres and is at 451 Washington Street, and we reside at
8 457 Washington Street, which is in Tribeca.
9 And I hope that you take my statement as a testimony to include
10 brain cancer. Please include it. He was very young and died very
11 quickly, and I think...
12 **UNIDENTIFIED:** And he never moved out of the area, either.
13 **MR. CAPSOUTO:** We -- we live in the area and then my mother --
14 we all of -- the whole family lives downtown and he's the only one
15 that came out so quick, so fast. My mom also lived in the area,
16 also died of liver cancer. They say there was -- they say there was
17 health -- that it was no problem being downtown. We had the
18 people from Con Edison bringing the dust to the restaurant. We
19 had to feed the firemen coming in the first two, three days, coming
20 in with the dust all over their clothes, coming into the restaurant.
21 We had -- but Albert was really involved. He must have spent
22 maybe three or four days going downtown on his bicycle to help
23 the small businesses, to help reconstruct downtown. As a matter
24 of fact, on October 28th of last year a park was dedicated to his
25 name on the -- on Canal and Valley and Lake Streets. If you -- the
26 park was the property of the Port Authority and he negotiated for
27 the Port Authority to give the land to the Park Department and
28 that's --
29 **DR. MIDDENDORF:** One minute, please.
30 **MR. CAPSOUTO:** -- the reason that the park was named after him.
31 I think I've said enough, and I think -- I think you should consider
32 brain cancer as another cancer to add to your list. I thank you.
33 Have a nice afternoon and I hope you all do a good job on the -- on
34 this Committee. Thank you.

This verbatim transcript of the WTC Health Program Scientific/Technical Advisory Committee, Committee Meeting held telephonically on March 28, 2012, has been reviewed for concerns under the Privacy Act (5 U.S.C. § 552a), and personally identifiable information has been redacted as necessary.

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DR. MIDDENDORF: Thank you very much, Jacques. I want to thank each of our public commenters for providing their perspective and their insight to the Committee, and it's always very helpful to hear from the people who live and work in that area. So on behalf of the Committee I want to thank each of you for coming and providing your information.

1 **DISCUSSION OF CANCER PETITION**

2 Before I turn this over to Liz, I just -- and as the Committee dives
3 into the decision-making part of the meeting, I want to just take a
4 minute to remind the Committee members what Dr. Howard
5 mentioned in his statement about the need to articulate the
6 scientific basis for their arguments. Looking out from the
7 administrative perspective to add conditions to the list, he needs
8 to know why a specific health condition or, in this case for this
9 petition, cancer or a specific type of cancer should be added to the
10 list of covered conditions. To accomplish this requires careful
11 building of arguments based on scientific evidence to make the
12 case for adding a specific health condition or cancer. That
13 evidence -- it will come from the available information on
14 exposure, epidemiology, toxicology, and it's important to
15 understand that this approach is based on an examination of the
16 best available evidence. It is not an approach based on merely
17 presuming the cancer is a likely health effect that may result from
18 the World Trade Center exposures. It won't be helpful to
19 recommend to the Administrator that he presume that a condition
20 should be added to the list unless the scientific evidence
21 demonstrates that it shouldn't be on the list.

22 In moving forward, the Administrator will have to make the case
23 for adding conditions, so the Committee will be most helpful if it
24 presents the scientific arguments for adding conditions. If you
25 want to say that another way, what the Administrator needs is for
26 the Committee to answer the question 'Should this condition be
27 added to the list?' for each of the conditions it decides to
28 recommend for addition.

29 So I'll turn it back over to Liz.

30 **DR. TRASANDE:** Paul, may -- this is Leo Trasande. I apologize for
31 interrupting but I realized I wasn't in at the earliest part of the call
32 and I just wanted to document that I was here.

33 **DR. MIDDENDORF:** Okay. Thank you very much. So Liz?

34 **DR. WARD:** Yes. So Paul and I talked a bit about how to best run

1 this meeting, given the challenges of having this meeting be a
2 teleconference, and also the need to really have a more formal
3 style of meeting using Robert's Rules of Order, and my sugges-- or
4 our suggestion is that we really look at the cover letter to Dr.
5 Howard and go through -- go through it kind of in sequence and
6 that -- so for example if it should talk about the first option of
7 recommendations to include all cancers as World Trade Center-
8 related conditions, the floor would be open for a motion to
9 approve that recommendation, then a second, then there would be
10 discussion, and then we would call for a vote.
11 With regard to the second option, there's a couple of ways that we
12 can proceed on that. We can have a motion to accept the second
13 op-- assuming that the first -- I mean if the first option -- the first
14 option is approved by the Committee, then obviously we don't
15 proceed to the second option, although we may talk about some
16 ways that the information that was compiled for the -- in the
17 second option might be used in the report. But -- but if the
18 Committee does not vote to go with option one, then we'll move
19 on to option two. And we can either consider option two as just
20 accepting all of the cancers listed in option two, or we can have a
21 motion to vote on each of the individual sites and site groupings
22 that were broken out.
23 I assume it's also in order that we could entertain motions to add
24 sites or organ systems that were not included in the draft cover
25 letter. But one thing we have to keep in mind is that if we add a
26 site or organ group, at this point we need to draft text that would
27 support that recommendation because, as I understand this from
28 Paul, essentially all of the writing on major points needs to be done
29 at the meeting and not later.
30 I should also make you aware that I know that the draft that was
31 posted had some minor typographical errors and the references
32 were not completely compiled. I've been working on that in the
33 interim and, you know, we'll make every effort to make sure that
34 the final document is properly formatted and doesn't include any

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errors.

So the way we're going to work this meeting is that Paul will actually be making the changes to the draft document that was circulated, or that was posted. And what I will try to do -- I want to be sure -- I know it's very difficult on these conference calls where, you know, a lot of people are trying to speak at the same time and if you're quiet like me sometimes you don't get heard. So what I'll try to do is, you know, if a number of people want to speak, I'll ask -- I'll take a minute and try to get a list of names so that I can be sure that everyone gets the opportunity to speak that wants to speak on an issue.

So at this point are there any questions before we open the floor for a motion to get started on discussing our recommendation -- any questions or overall comments?

MS. HUGHES: This is Catherine Hughes. I have a question of logistics. At what point in this conversation are we going to actually be voting for option one or option two?

DR. WARD: Well, when Paul and I talked about it, it was our thought that we would vote on option -- we would have discussion on option one and then vote on option one, because essentially if we vote in favor of option one, then option two is moot because we're not going to be voting on -- we're not going to be talking about a listing of specific sites.

MS. HUGHES: Okay, so if we're talking about option one, I wanted to draw everyone's attention to a *New Science* news article that came out at February 25th, 2012 which refers to the proceedings of the National Academy of Sciences that says bad stress is tied to inflammation, and that negative interactions may have biological effects. And it referred to two proteins that cause inflammation, that inflammatory triggers have been linked to increased risk of heart disease, high blood pressure, cancer -- which we're talking about today -- and depression. And the new results add to a growing body of research that links social stress to biological risk. So if -- 'cause I realized, when I was going through the testimony,

1 we had not talked much about the mental impact on physical
2 health. If one of our mental health experts could weigh in it would
3 be much appreciated.

4 **DR. WARD:** Okay. But let's -- I mean it -- you know, maybe it's
5 time to get a motion on the table regarding option one so then we
6 can -- we can start the substantive discussion on that option?
7 Anybody like to make a motion on option one?

8 **MS. SIDEL:** Well, actually I have a question. This is Susan Sidel.

9 **DR. WARD:** Okay.

10 **MS. SIDEL:** You know, it's kind of hard to start talking about option
11 one until I have an idea of what's going to be included on option
12 two. Do you know what I mean? Like if -- if certain cancers that
13 we -- that aren't there, if they're added, if there's a discussion
14 about them and that if they're added it may change -- it could
15 possibly change how people looked over at option one. I'm just
16 throwing that out there.

17 **DR. WARD:** Yeah, I think -- I mean does anyone else have a similar
18 concern?

19 (No response)

20 **DR. WARD:** I guess what -- you know, what we have to try to do,
21 since we have kind of a limited time for the meeting and we really
22 have only today to get this done, is to -- you know, to proceed as
23 efficiently as possible. Now I guess -- and Paul, you could help me
24 with this because I'm not really that used to running committees
25 with Robert's Rules of Order. I mean I guess if we are in the course
26 of discussing option one, a number of people feel that they can't
27 make a decision on option one before they have an opportunity to
28 discuss option two and see what the final list of cancers would be,
29 then we -- I guess we could -- you know, we can entertain a motion
30 that we not vote on option one before we --

31 **DR. MIDDENDORF:** Yes, you can table the motion.

32 **DR. WARD:** We can table the motion.

33 **MS. HUGHES:** Catherine Hughes here again. Can we have
34 clarification why brain cancer, pancreatic cancer and breast

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cancer's not, you know, being included?

DR. WARD: Well, I think at the end of the last meeting we -- the Committee recommended that we derive a list of cancers that should be included by reviewing three sources of information. One was the IARC list of cancer sites associated with cancer in humans for those sites -- for those exposures that were present at the World Trade Center, and that -- in our table, that is column one -- in our table four, that's column one.

And then the second -- second source was to review the areas of the body where there had been evidence of World Trade Center-related conditions that -- where chronic inflammation was part of the etiology or the cause for the -- for the biological process. And then the third was to look at the first epidemiologic study that was published, that's the firefighters, and look at sites that had any positive (indiscernible) at all in that study.

So we compiled the list from those three sources as accurately as -- I mean I did it and I assume other Committee members reviewed it. And then if it was -- if we got a positive signal from any of the three sources, then we included it in the list and we also discussed, you know, what -- we also in the cover letter we discussed what the level of -- what types of evidence were there and what the level of evidence was. So if it's not there, it means that -- so if brain and pancreas are not -- and breast are not there it's because we didn't pick them up from any of the three sources that we agreed on a priori.

Now that doesn't say that we can't now make a motion to include one of those. What we were trying to do with this draft is simply to follow the guidance that the Committee had with respect to how to generate the list.

MS. MEJIA: This is Guille.

DR. WARD: Hi, Guille.

MS. MEJIA: Sorry. Listen, I would like to make a motion that we include all cancers, make a recommendation to the Administrator that all cancers be included. And the rationale for including all

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cancers that we use the option two rationale to justify our option of including all cancers. So that's my motion.

DR. MIDDENDORF: I need specific wording to be able to put it up.

MS. MEJIA: Okay. That the STAC Committee -- the motion is is that we recommend to the Administrator that all cancers are covered, and that the rationale for covering all these cancers is the basis for option two. You know, we used that information to justify the coverage.

Sorry, I'm not very good at forming these motions.

DR. WARD: Yeah, we could say that we incorporate some of the -- we incorporate some of the rationales from option two to develop the rationale for option one. Would that capture what you're recommending?

MS. MEJIA: Yes, Liz. Thank you very much.

MS. DABAS: Hi, Liz, it's Valerie. I second Guille's motion.

DR. WARD: Great. So now the floor is open for discussion and, like I say, if it works out -- if it works out well that we're all speaking and everything's working out smoothly, I'll just -- we'll go like that. But if we need to start making a list, then we'll go that way. So the floor is open for discussion.

MS. MEJIA: Well, if I could start -- this is Guille again --

DR. WARD: Okay.

MS. MEJIA: -- I would just like to just state that, you know, we have in these meetings acknowledged the magnitude of the exposures that have been experienced by the responders and area workers and the survivors to this toxic mixture. And you know, the lack of information -- as Micki has stated earlier, the lack of information in the literature is -- is really not enough to say that certain cancers should be excluded. And there are -- there are procedures in place to deal with whether this -- whether an individual's cancer will be covered by the treatment program. So you know, we shouldn't be worried about that, so -- I'll just leave it at that.

DR. WARD: Thank you. Anyone else?

1 **MS. FLYNN:** Yes, Liz, this is Kimberly and, first of all, you know, I
2 want to thank you for taking the lead on this document. It's a
3 remarkable document and it represents an extraordinary effort,
4 primarily by yourself but also by the other experts.
5 Nonetheless, I want to speak in favor of option one, in favor of
6 Guille's motion to incorporate option two, and I think that the
7 additional rationale that we can use for every cancer that is not
8 currently listed in option two is quite simply the precautionary
9 principle, which is sound science and recognizes that as our
10 knowledge evolves it's going to lead us in a direction of
11 understanding all the ways that aggregate exposures, cumulative
12 exposures, synergistic exposures raise the risk of developing
13 cancers. As scientific knowledge grows, so inevitably does the list
14 of carcinogens. And almost without exception we will continue to
15 see a steady lowering of the threshold at which exposures to
16 carcinogens are known to have the potential to cause cancer.
17 I just, you know -- I mean you've heard a number of people giving
18 public comment today testifying in detailed ways about their
19 exposure scenarios. You know, we heard about a restaurant where
20 food was being served to returning members of the community and
21 responders. You know, we will never know -- we will never have
22 the kind of narrative that we would need to come to some kind of
23 detailed judgment about all of the substances to which people
24 were potentially exposed and all of the levels to which they're
25 exposed. So you know, if as a child, unbeknownst to my parents
26 who had to wait more than a year for an EPA cleanup, I was
27 crawling on a carpet that was a reservoir for WTC lead, silica,
28 fibrous glass, there was also highly alkaline concrete dust, carpet
29 fibers, along with some of the dust may have been coated with
30 something like TCDD that's a carcinogen and a potentiator for
31 other carcinogens. I may also have breathed PAHs in
32 (indiscernible) fumes for weeks at my day care on Church Street.
33 Exposures to PCP-172 which causes DNA hypermethyla--
34 hypomethylation, even at low levels, might have come in my

1 apartment windows in the first weeks following 9/11 and left an
2 invisible film on the beanbag chair.
3 I just -- I think that, you know, the question of what would my post-
4 9/11 cancer risk be is not something that we can nail down. And I
5 do not think we should resolve uncertainties in favor of no effect.
6 That's clearly what happened with respect to the government's
7 judgments, and the result of that was that protections were not
8 put in place and many, many people were unconscionably and
9 unnecessarily exposed and are now sick. So I would say that, you
10 know -- I mean actually I'm wondering if option one shouldn't be
11 framed a little differently. I'm wondering if the truer path here
12 wouldn't be to presume that all cancers are linked unless there is
13 some definitive evidence demonstrating that a given cancer should
14 not be linked.
15 **DR. ROM:** This is Bill Rom. Could I speak up?
16 **DR. WARD:** Yes, please. Thank you.
17 **DR. ROM:** So looking at all cancer, about five percent of all cancer
18 is related to occupational exposures. That's probably occupational
19 and environmental exposures, and I think we should try everything
20 that we can to try to get to that five percent. But thinking of the
21 other 95 percent, there's a lack of scientific evidence for those.
22 We're supposed to be a scientific advisory committee, as well as
23 technical, so I think we should really try to focus on those five
24 percent and get some agreement on that. If we say all cancer is
25 caused, then we should say acute myocardial infarctions, stroke,
26 dementia, Alzheimer's and every other disease potentially should
27 be causal. So I think we're overreaching, and I think we should
28 really try to focus on those that IARC has demonstrated data and
29 we have exposure data to match IARC, and try to make this
30 scientifically rational so that we engender the respect that we
31 need.
32 So I would vote -- I would recommend voting against the motion.
33 **MS. SIDEL:** I see that they don't -- is it okay to speak?
34 **DR. WARD:** Yes, thank you.

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MS. SIDEL: You know, this is a really -- this is just such a tough issue --

DR. HARRISON: Susan, this is Bob Harrison. Would you talk up a little bit? I'm having trouble hearing you.

MS. SIDEL: Sure -- sure, sorry. Is this better?

DR. HARRISON: Yeah, that's a little better.

MS. SIDEL: Okay. I was just saying that this has just been tough because I feel -- I feel option one and option two, but the problem that I have with option two is that so much of the information is dependent on things like occupational studies or exposure data. And you know, occupational studies don't discuss women. Most of them are all about men so there's like a gender bias in there. And then a lot of the other problem I have is that the exposure data is so faulty that the chemicals that were there, that we could say this chemical causes X, we don't have that necessarily. We also don't know what the synergistic effect is of everything all together. So it's so hard to just choose option two and say -- because I just -- I feel as though there's so much potential for so many other kinds of cancers that we just don't have -- we just don't have access to the data that we need to support -- to support it. You know, for example, like breast cancer. You know, maybe the chemicals down there could cause breast cancer, but we didn't find that on the IARC chart. But does that not mean that combinations of the chemicals there could have caused it or just the whole -- you know. Then the other issue also is that what happens when your body is already so compromised, you know, by -- by the toxins? And even just following the other paths of inflammation and the diseases that have already been covered under the health -- the World Trade Center health bill, not everything is covered because not everything has been explored. I mean there has never been the money or the time available to explore all the problems that people have. And you know, people get diagnosed, you know, outside of the program with things that should be included in the program, but it's just been impossible to do that. I mean the drug

1 is new but we've been -- you know, we started under the Bush
2 administration who were fighting tooth and nail for all health
3 consequences, which is a lot of the reason why we don't have the
4 exposure data that we need. So I don't know if that's scientific, but
5 the science is that -- that it should be there, but it's not there and
6 it's difficult to exclude something when you know that it's data that
7 should be there although it isn't because it just happens to be the
8 way things are at this point. Thank you.

9 **DR. WARD:** Thank you. Next speaker, please?

10 **MS. FLYNN:** This is Kimberly. I just want to speak up again in
11 response to the idea that we should solely rely on the occupational
12 literature. The occupational literature is extremely limited.
13 Studies often look at -- chemical by chemical or in clusters of
14 chemicals instead of taking account of the full breadth
15 combinations and concentrations of chemicals to which residents,
16 responders and survivors were exposed on and after 9/11.
17 Occupational studies, as has already been pointed out, the
18 occupational literature for the most part has not included women.
19 It was developed at a time when women had not yet entered those
20 types of jobs. Often occupational studies utilized OSHA standards,
21 which occupational safety and health experts will tell you have a
22 political component and are not as protective as they should be.
23 And occupational exposures do not take into account sensitive
24 populations or issues of genetic polymorphism.

25 I guess I -- after I talked about the limits of occupational studies,
26 there actually is a 2010 study called 'Occupation and Cancer' in
27 Britain that talks about shift work as an important risk in
28 developing female breast cancer. So I don't know whether or not
29 that made it into the IARC monograph, but we might consider it.
30 At any rate, I think that using occupational literature, as I have said
31 in the past, as the sole basis or as even the main foundation of our
32 decision means that we will be incorporating many of its flaws and
33 limitations.

34 **DR. HARRISON:** Liz, this is Bob Harrison. May I speak?

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DR. WARD: Yes, please.

DR. HARRISON: Okay. It's really a question, in consideration of the motion to approve all cancers, whether our advisory committee should take into consideration any statutory language or guidance from the Zadroga Act itself? In other words, what -- what criteria or scientific evaluation criteria should we be applying, if any, to consider these two options? Is there any standard by which we should consider this? Am I -- am I clear in my question?

DR. WARD: Yes, and I'll defer to Paul for the answer. I think we've talked about this before and the answer is really that the Committee is really being requested to develop the criteria as well as apply it. But Paul, would you like to respond?

DR. MIDDENDORF: Yeah, and if you're looking at the Zadroga Act for guidance in terms of how to make the decision, it gives very little. It basically says that the Administrator will need to review the scientific evidence to make his decision. So the Administrator has come to the science -- to the STAC and essentially has said 'I need you to help provide that scientific evidence so that I can move forward to essentially add covered conditions to the list.'

DR. HARRISON: Thank you, Paul. I would like to then speak in opposition to the motion to accept option one to cover all cancers, largely based on the concept that cancer is multifactorial. I think as suggested earlier by Dr. Rom, there are cancers for which there is substantial or other, more limited, scientific evidence for a relationship between occupational and environmental exposures than that cancer end point, and that departing from that principle by covering all cancers I think would be -- in my view, I think inconsistent or contrary to the -- you know, the best scientific principles, and I think would establish a -- represent -- that would - - that would really not -- not be consistent with other authoritative findings for a decision. I think, as Dr. Rom pointed out, would be a -- sort of a leap, a departure. So I would -- I would argue against option one.

MS. DABAS: Hi, this is Valerie. I just had a question for the two

1 people that are against option one. Could they name two cancers
2 with absolute certainty that they would believe that have no
3 environmental cause for those cancers?

4 **DR. HARRISON:** I would not. In fact, I think that's a -- this is --
5 that's a very good question. This is Bob Harrison again. I wouldn't
6 be able to name cancers for which, with absolute certainty, there's
7 no association or possible linkage between an occupational or
8 environmental cause and that cancer. That being said, I think there
9 are certain cancers for which, at this point in time, there's
10 insufficient evidence to conclude that there is such a link. And I
11 think that there's a difference between those two statements.

12 **MS. DABAS:** Well, my question in fact --

13 **DR. HARRISON:** For example, I would -- you know, if we get to the
14 -- you know, if -- if we move on from option one, depending on the
15 vote, to where we talk about specific cancers, I think we would
16 have a discussion and debate about prostate cancer, for example,
17 where I personally think that, although the evidence is suggestive,
18 it doesn't yet reach the level of significance that I believe that we
19 could link occupational/environmental exposures in many cases to
20 prostate cancer. That's just an example -- which is not to say that
21 there's not a linkage, but unless we were to have additional
22 scientific evidence, perhaps from studies that are going to be
23 forthcoming, I would suggest that there's probably -- the evidence
24 for prostate cancer does not equal the evidence for lymphopietic
25 cancers or for aerodigestive cancers.

26 **DR. ROM:** This is Bill Rom. That's a complicated question that
27 would take a whole course to answer, but there's limited evidence
28 for prostate, for example. Breast has been a struggle for years to
29 try to find some linkages and we're working really hard on that.
30 Uterine cancer is another one that's a challenge. There's some rare
31 uterine cancers like clear cell carcinoma are related to drugs and
32 previous generations. Small intestine and skin -- we have one of
33 the more common cancers and, you know, beyond UV light and --
34 Percivall Pott's scrotal observations we have very limited evidence,

1 so you have to go by site by site and histology by histology and
2 review all that. And we spend our lives trying to find the
3 associations and some of these are very difficult. Brain cancer, for
4 example, has been a challenge and we've been trying for years to
5 try to find environmental and occupational exposures for brain
6 cancer. And then there's a whole host of genetically-linked
7 cancers, and then some that are linked to viruses, and then diet is a
8 huge topic related to cancer. So it's a complicated question that
9 would take a long time to fully answer.

10 **MS. DABAS:** Thanks, Dr. Rom. I think Dr. Harrison answered it in
11 that there's nothing we can say for sure with 100 percent certainty
12 has no environmental links with cancer. So there's not one site
13 that we can say with 100 percent certainty that there's no way that
14 this person could have gotten it based on their environmental
15 exposures.

16 **DR. TALASKA:** Hi, this is Glenn Talaska. I'd like to speak against
17 the motion. I do believe that we need to provide the Administrator
18 with scientific arguments in favor of adding diseases, as he
19 requested. And I don't believe that the data are there that indicate
20 that all cancers should be covered by -- with our recommendation.

21 **DR. DEMENT:** Hi, this is John Dement. Could I speak as well?

22 **DR. WARD:** Yes.

23 **DR. DEMENT:** I'd like to also voice my opposition to the all cancers
24 issue. I think we've been charged with providing a rational
25 scientific basis for the selection of cancers to be included, if at all.
26 And I think we've approached it from a perspective of the best
27 evidence possible. I really think if we go the all cancer route --
28 although I'm very sensitive to the issue of rare cancers and there
29 not being sufficient data because of their rarity -- I think we have
30 the obligation to provide a sound scientific basis to the
31 Administrator, one that can be incorporated without a lot of
32 challenge.

33 I think we also need to be -- acknowledge when we do this that
34 there's a lot of uncertainty and there's a lot of area where, in the

1 future, we should be continuously vigilant about sites that pop up,
2 based on either studies of World Trade Center populations or
3 studies elsewhere in the scientific literature.

4 **MR. CASSIDY:** Hello, this is Steve Cassidy. Hello?

5 **DR. WARD:** Yes, Steve, we hear you. Thanks.

6 **MR. CASSIDY:** I'd like to speak on the topic. Reluctantly I have to
7 say that I don't agree with all cancers either. I'd like to be there. I
8 recognize that those who suffered the most severe exposures are
9 more likely to come down with cancers that are not yet defined in
10 Dr. Prezant's study. I want to remind everybody, and I think they
11 all know it, that the study goes back to really just 2008. And when
12 you look at that study you have to recognize that there were a lot
13 of people probably had cancer in 2007, 2008, didn't know it at the
14 time. I know for a fact that there are a lot of firefighters have
15 come down with serious cancers -- some are dying, some have died
16 -- since Dr. Prezant's study that were not included in his study. So
17 you know, I would love for it to be all cancers, but I don't think that
18 we can do it based on what we've been tasked.

19 I do think that when we get to the second round of this, if that's
20 where we end up, and we have to look at biologic plausibility
21 versus strongest evidence, I think biologic plausibility is the key.
22 And I think, you know, there are cancers that need to be included
23 when we get there -- brain cancer and pancreatic cancer, for sure.
24 And maybe we can move on to that, but reluctantly I have to say
25 no.

26 **MS. FLYNN:** This is Kimberly, and I'd like to just raise I guess a
27 point of clarification, refer to the testimony of Dr. Melius. Yes,
28 cancer -- we accept that cancer is a multifactorial disease. But
29 there are many checks and balances. Once the STAC makes the
30 recommendation, the implementation of that recommendation is
31 going to mean that the physician of each patient has to attribute
32 the cancer to World Trade Center -- well, first of all there's the
33 diagnosis of the cancer, and then there is the attribution of the
34 cancer. And that physician will of course be taking into account the

1 whole history of exposure to World Trade Center in detail. So I --
2 you know, it's not the case that we should be kind of making that
3 decision out in advance by saying 'Well, you know, certain cancers
4 there's some evidence for but it's just not quite enough for us to
5 add those cancers to the list.' And there are steps of scientific and
6 medical evaluation down the line before anyone is accepted for
7 treatment or anyone's treatment is covered.

8 **DR. WARD:** This is Liz. I did want to make a comment about that
9 and I'm hoping that some of the Committee members who have
10 occupational medicine and clinical experience will comment on it
11 as well, 'cause from my point of view as an epidemiologist for
12 those cancers that don't have, you know, a substantial body of
13 evidence supporting their potential association I would be hard-
14 pressed -- I mean I'm not sure how a physician would make that
15 determination about those cancers. I mean it's not in our
16 immediate, you know -- I mean we're not -- that's not exactly what
17 we're talking about here but I think it's relevant because it -- you
18 know, if there's no -- if there's very little evidence associating that
19 cancer potentially with the exposures, then there's very little
20 rationale or criteria to determine that one person's -- one person's
21 cancer is World Trade Center-related and the other's isn't.
22 So would any of the occupational physicians or practicing
23 physicians like to comment on that?

24 (No response)

25 **DR. WARD:** All right. Well, with no further comments on that,
26 we'll open the floor for the next speaker.

27 (No response)

28 **DR. WARD:** Is everyone still there?

29 **UNIDENTIFIED:** Yes, we're all still here.

30 **MS. SIDEL:** Well, I actually have a question. Maybe Paul can help.

31 **DR. WARD:** Sure, go ahead.

32 **MS. SIDEL:** Okay. Is there a safeguard with -- in place, going
33 forward so if Dr. Howard -- when he was speaking, we meet at his
34 pleasure and we answer this question for him, and so until he has

1 another big question, we're sort of, you know, on call. Well, how
2 would we raise these issues if -- say new evidence becomes
3 available if everything is -- I'm just remembering that there's only
4 four years for this, or five years, for this whole Committee, how
5 could these -- how could issues for things that we don't have the
6 kind of evidence that we want to have -- when that evidence
7 becomes available, or is there some way that we can do research to
8 get the evidence?
9 **DR. MIDDENDORF:** Well, what would happen is if someone were to
10 petition the Administrator again to add cancer or a specific type of
11 cancer or another health condition, he then could come back to the
12 Committee and ask for the Committee's advice on it.
13 **MS. SIDEL:** I see. Okay. Thank you.
14 **DR. WARD:** What I'd like to do then is make sure -- see if there's
15 anyone else who'd like to speak either in favor of the motion or
16 against the motion. And if not, call for a vote.
17 **DR. MIDDENDORF:** Okay. I'd like to make sure that the motion is
18 stated as the Committee wants it.
19 **MS. FLYNN:** So right now it's possible -- I'm sorry, this is Kimberly.
20 Is it possible for me to -- and I don't know my Robert's Rules all
21 that well, but to make a friendly amendment, citing a
22 precautionary principle as a scientific basis to include cancers that
23 are not listed under option two? The point being, you know, that --
24 **DR. MIDDENDORF:** What I would need is wording here. How
25 would --
26 **MS. FLYNN:** You would need wording.
27 **DR. MIDDENDORF:** Well, how would you word your proposed
28 amendment?
29 **MS. FLYNN:** What is the original -- could I ask you please to repeat
30 the original --
31 **DR. MIDDENDORF:** The motion on the table is 'The Committee
32 recommends that all cancers be covered.'
33 **MS. MEJIA:** Hi, this is Guille. Just want to remind everyone that as
34 the maker of the motion I think I'm the one that has to accept the

1 amendment --
2 **MS. FLYNN:** Yes, you are.
3 **MS. MEJIA:** -- to the motion.
4 **MS. FLYNN:** Yes.
5 **DR. MIDDENDORF:** So what would the amendment be?
6 **MS. FLYNN:** I moved that any cancers not covered under option
7 two would be covered under option one, under the precautionary
8 principle.
9 **MS. DABAS:** Hi, this is Valerie. Kimberly, is it possible that we get
10 a clean vote on this, just, you know, the first one, which was what
11 Guille said?
12 **MS. FLYNN:** Yes, I'll withdraw -- I'll withdraw the amendment.
13 **MS. MEJIA:** Thank you.
14 **DR. WARD:** Okay, so it's -- the motion has been called for a vote.
15 Paul, do you want to do the --
16 **DR. MIDDENDORF:** Sure, I'll do an alphabetical voting.
17 Tom Aldrich?
18 **DR. ALDRICH:** I vote against this motion.
19 **DR. MIDDENDORF:** Okay, vote no. Steve Cassidy?
20 (No response)
21 **DR. MIDDENDORF:** Steve? You're not coming through if you're
22 speaking.
23 (No response)
24 **DR. MIDDENDORF:** Steve?
25 (No response)
26 **DR. MIDDENDORF:** I can't hear Steve so I'm going to go on to
27 Valerie Dabas?
28 **MS. DABAS:** I vote for.
29 **DR. MIDDENDORF:** Vote yes. John Dement?
30 **DR. DEMENT:** No.
31 **DR. MIDDENDORF:** Kimberly Flynn?
32 **MS. FLYNN:** Yes.
33 **DR. MIDDENDORF:** Bob Harrison?
34 **DR. HARRISON:** No.

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in on the line where I was not able to speak.

DR. MIDDENDORF: Okay.

DR. WEAVER: So we're now voting for or against option one. Is that correct?

DR. MIDDENDORF: That is correct, and motion one is 'The Committee recommends that all cancers be covered.'

DR. WEAVER: Okay. So just so -- for the record, I've been on the call the entire time --

DR. MIDDENDORF: Okay.

DR. WEAVER: -- and have not heard the vote so far, but I would vote against that motion.

DR. MIDDENDORF: Okay. I'm going to go back to Steve Cassidy. Steve, are you on?

(No response)

DR. MIDDENDORF: I can't hear anything from Steve. And Leo Trasande?

(No response)

DR. MIDDENDORF: And make sure you're not on mute.

(No response)

DR. MIDDENDORF: Okay. Liz Ward?

DR. WARD: I would vote no.

DR. MIDDENDORF: Okay. Of those voting I have ten nos and one, two, three -- three yes.

So it's back to you, Liz.

DR. WARD: All right. So for the next option -- we need a motion -- there's a couple of motions that could be made. One would be to discuss each organ site or grouping of sites individually. The other could be to accept all of the sites that are currently listed, and I guess in either case we can also make separate motions to add addi-- for additional sites. But I guess probably the most efficient way to do it would be to talk about -- for someone to make a motion -- well, I guess -- why doesn't someone make a motion as to how to proceed on option two?

MR. FLANIGAN: Can I speak?

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DR. WARD: Yeah.

MR. FLANIGAN: Hi, my name is Shawn Flanigan. Something that wasn't mentioned, the sarcomas or bone cancers -- okay? And I know that there was a lot of speaker earlier on scientific data --

DR. WARD: Excuse me, Mr. Flanigan, are you a member of the Scientific and Technical Advisory Committee?

MR. FLANIGAN: No.

DR. MIDDENDORF: Okay, this part of the meeting is not open to you, sir.

MR. FLANIGAN: All right.

DR. MIDDENDORF: Please go to mute.

MR. FLANIGAN: Thank you.

DR. WARD: Okay. Is there anyone on the Committee who would like to make a motion?

MS. DABAS: Hi, it's Valerie. I make a motion for the second option, but to include breast, pancreatic and brain cancer.

DR. TALASKA: Glenn Talaska. Are you going to entertain multiple options or just one at a time?

DR. WARD: Paul, what's your recommendation on that?

DR. MIDDENDORF: Why don't you -- I think what might be helpful is if the Committee discussed how it really wants to proceed, whether or not it wants to go down the road of looking at everything all combined or if it would rather try to split this up.

DR. TALASKA: Could we do it in this fashion? Could we -- if there are -- anyone has any objections to any of the specific cancers that are cited in the -- in option two thus far, why don't we bring them up and then we could have a section where we add cancers?

MS. DABAS: Hi, this is Valerie again. I think there is a motion on the floor currently.

UNIDENTIFIED: I agree with you, Val.

DR. WARD: Okay, so the motion as I understand it that's on the floor is to include all of the -- all of the cancers and organ groups currently listed in option two, and in addition to include breast cancer, pancreatic cancer and brain cancer. Is there a second for

1 that motion?

2 **MS. FLYNN:** Kimberly, I second.

3 **DR. WARD:** Okay. So I think we'll have discussion on that motion
4 and then a vote. If it does not carry, then we can see if we want to
5 adopt Glenn's suggestion. Let's have discussion on that -- on that
6 motion.

7 **DR. ALDRICH:** This is Tom Aldrich. Can I say a word?

8 **DR. WARD:** Sure.

9 **DR. ALDRICH:** I think the discussion we had on option one pretty
10 much informs the result of this motion. I think the big part of the
11 reason option one did not carry was that a number of people felt
12 that there was -- there were some cancers, some of which were
13 included in option two, that -- for which there is insufficient
14 evidence. It seems almost a foregone conclusion what the results
15 of this vote is and I think we should just get right to the vote.

16 **DR. WARD:** Is anyone opposed to that?

17 **UNIDENTIFIED:** I think it's good.

18 **DR. WARD:** Okay, so let's proceed with the vote, Paul.

19 **DR. MIDDENDORF:** Okay. So what I've done is to copy all of the
20 bullets from motion two that are from the draft report. And then
21 also at the bottom here is 'and include breast, brain and pancreatic
22 cancer.' The question for the Committee is how would we -- is that
23 sufficiently clear to what the Committee is voting on, because you
24 have a lot of ICD codes and things like that listed for the other
25 types of cancer. Does that information need to be included here?
26 Do you know specifically what you're voting on?

27 **DR. WARD:** My thought would be, Paul, that probably the
28 Committee has a common understanding of what we mean and
29 that if -- if we were to adopt this motion that we would then have
30 time during the remainder of the meeting to add that additional
31 information to it -- the text and the draft.

32 **DR. MIDDENDORF:** Okay.

33 **DR. HARRISON:** Liz, this is Bob Harrison.

34 **DR. WARD:** Yes.

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MR. CASSIDY: I must have -- I gave a nice speech, you must have missed it. I must have been muted.

DR. MIDDENDORF: No, it's just when we went to the roll call vote, you didn't come in on it, so...

DR. WARD: Yeah, I'm hoping we're not having -- you know, missing people on votes because of technical difficulties, so I guess we'll -- we will go back and check on those who were missing from the second voting -- voting round, just to make sure we didn't -- we didn't miss their vote because we couldn't hear them.

Okay. So then I think the next logical step might be to proceed the way Glenn suggested, just to have a -- you know, an initial discussion and ask for people to speak on those cancer sites that they're opposed to including on that original list, or cancer sites that they would like to see added. Why don't we do the ones that people are opposed to including from the original list first, just to keep everything organized -- so the floor is open.

DR. ALDRICH: This is Tom Aldrich. I oppose the inclusion of prostate cancer for the reasons that are discussed in -- I think it's the second paragraph about prostate cancer.

DR. WARD: Okay, thank you. Now Paul, I think I just might have made a procedural error. Do we need a formal motion to open the floor for a discussion on the --

DR. MIDDENDORF: I think we need a motion that people will be discussing; something very specific.

UNIDENTIFIED: Yeah, I think at some point we can just move that certain -- whether we agree, so -- or we could have -- Tom could make a motion, and if no one seconded it, then it would die, for example. And then if not, then we could have -- so if someone suggests that one cancer be removed, we could have a second on that motion to remove it, and then if not, then that motion to remove it would die and then we could go on to a discussion and vote on whether that specific cancer should be removed. We could go one by one if we wanted.

DR. MIDDENDORF: Yeah, another potential for the Committee to

1 consider is whether or not it wants to go through the bullets that
2 were in -- individual bullets and just do those. So at some point
3 you will come up with something you don't want to include and you
4 can make a motion to -- to pull them out.
5 **UNIDENTIFIED:** Bullets where? I'm sorry.
6 **DR. MIDDENDORF:** From the report, the draft report.
7 **UNIDENTIFIED:** Okay, but I was just looking for where we had it.
8 **DR. MIDDENDORF:** In option two.
9 **UNIDENTIFIED:** Okay, hold on.
10 **DR. WARD:** I mean one way to do that might be to find out -- like if
11 we go to the first bullet we might say 'Is anyone opposed to
12 including -- including (indiscernible) neoplasms of the respiratory
13 system' or wish to propose that specific cancers within that
14 grouping be excluded. And then if not, we can just go -- we don't
15 really need discussion. We can go for the vote.
16 **DR. ALDRICH:** That makes really good sense. We could group the
17 vote.
18 **MS. DABAS:** Do we sort of know that there are going to be a
19 couple of problems, and maybe we could just go to those?
20 **DR. WARD:** Well, I think that was what Glenn was proposing, and I
21 guess either way is fine. It seems that we probably will want --
22 since we're including these -- since we're considering these
23 individually, I think we'll probably want a vote on the record
24 anyway, so it might be just as efficient to go through them one by
25 one, have the vote, if they're -- I mean find out if there's anyone
26 who wants to speak against it or modify it and then let's go to the
27 vote.
28 **DR. HARRISON:** Yeah, I think particular cancers -- I mean most of
29 us are going to agree with most of the ones on the list, perhaps. At
30 least that would be my surmise. To go over each one and to vote
31 to include each one is not -- you know, our report includes them
32 already. We just -- I think it would be more efficient if we just
33 voted to remove particular ones.
34 **DR. MIDDENDORF:** This is (indiscernible). I think you need to

1 move -- or make motions to include and/or exclude. It needs to be
2 on the record in both directions.

3 **MS. HUGHES:** Catherine Hughes here. On prostate cancer I
4 understand the Veterans Affairs for Agent Orange does include
5 prostate cancer, and some of the chemicals that were in Agent
6 Orange were down at the World Trade Center as well -- point of
7 clarification.

8 **MR. CASSIDY:** Liz, Steve Cassidy.

9 **DR. WARD:** Yes, Steve.

10 **MR. CASSIDY:** My thought was -- I mean that was a very close
11 vote, eight no, six yes. I mean maybe -- maybe there's a consensus
12 or maybe there's a theme emerging among the eight nos that -- to
13 be fleshed out, which would make this an easier process to have a
14 second vote. I don't know if there's --

15 **DR. WARD:** That's fine. I mean what we can do is I guess we can
16 talk about -- we can make a motion to proceed that way, and then
17 if we need the formality of a vote on each and every one, we can
18 do that.

19 **DR. ROM:** Liz, this is Bill Rom. I would like to second Tom Aldrich's
20 motion that the entire second list be accepted, with the exception
21 of prostate cancer, and have a vote.

22 **DR. WARD:** Shall we -- so that's the formal motion, Paul, so we
23 take a vote on -- shall we proceed on that motion?

24 **DR. MIDDENDORF:** This motion does not include breast, brain or
25 pancreatic. Is that correct?

26 **DR. ROM:** That's correct.

27 **DR. MIDDENDORF:** Let me pull all this down and I will find...

28 **DR. WARD:** But it doesn't close the -- it doesn't close the option of
29 discussing brain, breast --

30 **DR. MIDDENDORF:** No, it's just that they aren't included in this
31 particular one.

32 **DR. WARD:** Right.

33 **DR. MIDDENDORF:** I'm looking for the bullet on prostate.

34 **DR. ALDRICH:** It's page six, starts on line 26, I think.

1 **DR. MIDDENDORF:** Okay, here it is, 'Committee recommends
2 prostate' so it comes down to here. Is it -- Liz, do you want to look
3 or -- who made the motion?
4 **DR. ALDRICH:** That was me, Tom.
5 **DR. MIDDENDORF:** Tom, do you want to check and make sure that
6 I've highlighted the part you want me to remove?
7 **DR. ALDRICH:** Yes.
8 **DR. MIDDENDORF:** It is the correct section?
9 **DR. ALDRICH:** Yes, it is.
10 **DR. MIDDENDORF:** (Unintelligible)
11 **DR. ALDRICH:** I had another change that I'd like to recommend. Is
12 this the time to do it or not?
13 **DR. MIDDENDORF:** Yeah, I think you can amend your own motion,
14 yes.
15 **DR. ALDRICH:** Well, regarding the cancers of the eye -- let me find
16 out where that is again -- oh, it's page seven, line 16, cancers of the
17 eye and the orbit be listed for individuals engaged in welding. You
18 know, World Trade Center exposure was notable for a tremendous
19 volume of eye irritation, such that emergency treatment of --
20 washing out the eyes was the most common emergency treatment
21 that was provided acutely, and it was far more than welders. So I
22 think it would be a reasonable extrapolation to say that, with the
23 amount of foreign bodies present in the eyes of World Trade
24 Center responders, and probably residents, it ought not to be
25 limited to welders.
26 **DR. WARD:** So we could just drag the language -- end at 'World
27 Trade Center-related condition' and strike the --
28 **DR. ALDRICH:** That's what I would recommend.
29 **MS. HUGHES:** Catherine, Catherine seconds it.
30 **MR. CASSIDY:** Did -- did -- was that a formal motion, that we --
31 **MS. HUGHES:** It's a formal motion.
32 **MR. CASSIDY:** -- that we take that -- no, he has to make that as a
33 formal motion.
34 **DR. ALDRICH:** Yes, well, I would if I'm allowed to.

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MR. CASSIDY: Okay. And would you add it to your other one is what I'm asking.

DR. ALDRICH: If I'm allowed to.

MR. CASSIDY: Okay. So both those changes. I second it, too.

DR. MIDDENDORF: The motion on the table is for this 'engaged in welding.'

DR. ALDRICH: You can get rid of everything after 'condition.'

DR. WARD: Right.

DR. MIDDENDORF: After 'condition', okay. Okay, you want the next sentence struck as well?

DR. ALDRICH: Yes.

DR. MIDDENDORF: So is that the way you want it to read, 'The Committee recommends that cancer of the eye and orbit be listed as a WTC-related condition'?

DR. ALDRICH: Yes, but the next -- then there should be a carriage return.

DR. MIDDENDORF: Got it, okay.

DR. WARD: So if the Committee votes in favor of this motion, we may need to add a sentence there regarding the rationale, but we can go ahead and vote because -- I mean I think -- the rationale was stated, but I don't think it was captured, so we'll have to capture it.

MS. HUGHES: Liz, Catherine Hughes here. As a former -- I used to do construction way back when. Typically you're supposed to have shields around to protect where welding is, so even if you're not actually doing the welding you can also be exposed, and there was intense dust and smoke in the air for months.

DR. WARD: All right.

DR. HARRISON: So Liz, this is Bob. Just so I understand, the proposal on the table is to eliminate the connection to welding and list it just as cancer of the eye and orbit.

DR. WARD: Right, and the rationale would be that the eye was of - - you know, the irritation of the eye was a frequent event among

1 people who were working at the site, so the rationale is that -- you
2 know, that the direct contact with the materials was causing
3 irritation. The original ration--
4 **UNIDENTIFIED:** Would somebody on the call be able to speak to
5 the scientific or epidemiological evidence regarding cancer of the
6 eye and orbit relative to irritants, as opposed to welding? I don't
7 know this literature.
8 **DR. WARD:** Yeah, and the welding really came from the IARC
9 determination, so the -- so in the IARC compilation of cancer
10 science related to specific exposures, eye was specifically called
11 out for welding and not for anything else. I mean -- but I think the
12 rationale could be along the lines -- I think somewhere in here
13 where we talked about lip cancer -- I -- yeah, I think the lip on pa--
14 on my updated draft is bottom of page five, but we basically --
15 since lip, oral cavity and pharynx have not been specifically
16 designated in any of the sources, but because it's connected to all
17 the other -- you know, upper respiratory tract and the digestive
18 tract -- the rationale was that the lip, oral cavity and pharynx have
19 a high potential for direct exposure to toxic materials through
20 hand-to-mouth contact. And we've already included skin cancer, so
21 the eye is another, you know, surface on the body where you
22 would expect that there would be direct contact with toxins.
23 **DR. ALDRICH:** Where we know there was direct contact, because
24 there is literature about numbers of people who required eye
25 irrigation.
26 **DR. WARD:** Right.
27 **DR. HARRISON:** This is Bob. Just a follow-up question. Is there
28 anything in the rationale -- and this would probably mean going
29 back to the IARC document to understand why they listed welding,
30 that's specific to welding fumes as opposed to other irritants that
31 would have been present at -- or were present at Ground Zero?
32 **DR. WARD:** Not to -- I mean I -- yeah, I did not look at that source
33 document from IARC for that specific exposure.
34 **DR. DEMENT:** Hi, Liz, this is John Dement. I think the issue with

1 IARC is simply they were reviewing welding as an exposure
2 generally, and looking at sites where cancers were increased. So in
3 addition to eye, the document talks about lung and some other
4 sites.
5 **DR. HARRISON:** John, this is Bob. So there were no other -- so it
6 was a epidemiological observation, not specifically linked to some
7 exposure?
8 **DR. DEMENT:** No, it's --
9 **DR. HARRISON:** In the IARC review.
10 **DR. DEMENT:** Yeah, yeah, you know, IARC reviews typically --
11 exposures that they review some --
12 **DR. MIDDENDORF:** Hang on for just a second. For the purposes of
13 the transcript and the record, it would be helpful if people would
14 identify themselves before just jumping in.
15 **DR. HARRISON:** That was Bob Harrison making a comment and that
16 -- I think that was John Dement responding.
17 **DR. WARD:** I also think that I -- I mean I am in favor of keeping it in
18 with the rationale, but I also think that eye and orbit is such a rare
19 site, so we're going to -- I mean it will -- it would -- if we vote to
20 include the rare cancers, I think it will probably -- would be
21 included for that reason as well.
22 **DR. ALDRICH:** Well, I think that -- this is Tom Aldrich. I think
23 there's more specific, admittedly indirect extrapolative evidence
24 for eye cancers to be expected than for other rare cancers --
25 **DR. WARD:** Yeah, yeah.
26 **DR. ALDRICH:** -- but it's fully speculative.
27 **DR. WARD:** Yeah, yeah. So I guess the ques-- so -- so to the folks
28 who are questioning whether -- what the specific mechanism or the
29 specific agent would be, do you feel like you have enough
30 information to vote on the motion, or do -- or -- how should we
31 proceed?
32 **DR. HARRISON:** Yeah, this is Bob Harrison. I -- Liz, I confess I
33 simply don't have enough information. Eye cancers are extremely
34 rare. I don't think I've ever encountered a case in my 30 years of

1 occupational medicine practice, and there's certainly biological
2 plausibility to think that if IARC was to (indiscernible) for welding --
3 for welders, that a mechanism would be irritation. But I just don't
4 know beyond welding whether there's any other toxicologic or
5 scientific literature that would support eliminating the clause. I
6 just simply confess I -- I have insufficient information.

7 **DR. WARD:** Okay.

8 **MR. CASSIDY:** This is Steve Cassidy. Can I just say something?

9 **DR. HARRISON:** Yeah.

10 **MR. CASSIDY:** Somebody -- somebody earlier, I don't know who,
11 talked about the -- I think it was Tom -- talked about the number of
12 people who are -- who are recorded as having their eyes cleaned
13 and washed. And having been there, I can tell you that the Red
14 Cross and other volunteers were there every day washing the eyes
15 of first responders. I would say that virtually every first responder
16 who was there needed to have his eyes irrigated day after day after
17 day. So I don't know if there's any data out there that talks about
18 people having dust in their eyes for 30 or 60 days, over a 90 or 120-
19 day period, so maybe there is no study that we can compare this
20 event to, but -- but I know that irritants cause cancer, and that
21 people's eyes were irritated at a level probably never before seen,
22 on an ongoing basis -- not a one-time, not one day, ongoing.

23 **DR. MIDDENDORF:** This is Paul. Just something that you may want
24 to think about is that welding -- many forms of welding can
25 generate ultraviolet light, which is an ionizing form of radiation.

26 **UNIDENTIFIED:** May I say something also as a point of what Steve
27 just said? I just want to say that our supply tent went through
28 boxes full of cases of saline solution and we didn't -- I mean I think
29 we were just using the kind of saline solution that you use for
30 contact lenses, and we were just constantly running out. It was --
31 people just -- we just went through it, like tons of it. I know that's
32 not very scientific, but it was just always used every day for as long
33 as I was down there, which was three months. Thanks.

34 **MS. HUGHES:** Catherine Hughes here. I also just learned that

1 there were wash basins at the edge of the Pile that were used
2 regularly to clean the eyes, as well.

3 **DR. HARRISON:** Liz, may -- this is Bob Harrison. May I be
4 recognized?

5 **DR. WARD:** Sure.

6 **DR. HARRISON:** Thank you. Do we have a mechanism, as part of
7 the Committee process today, to -- you know, to place issues like
8 this on a -- in a so-called parking lot, or issues that we recognize, as
9 a Committee, are a potential concern or a possible -- possibly for
10 listing, but that need further information or research or data? This
11 is -- I don't know where this will come up in additional discussions.

12 **DR. WARD:** Well, I think that where we are now is that we have a
13 motion on the floor and we have a second to the motion, and we
14 have an amendment that was proposed and was accepted by the
15 person who made the original motion. So I think what we would
16 need to do is call for a vote, see what the vote is and then -- you
17 know, it's not -- you know, again, we can put anything in the
18 parking lot, but -- unless John Howard chooses to take it out of the
19 parking lot, it's -- you know, I -- but I do think we should go ahead
20 and have a vote on the motion that was proposed, as amended --
21 as Paul has captured it. Paul?

22 **DR. MIDDENDORF:** Yes. So the motion on the table now includes
23 all of option two, except for prostate, and removes welding from
24 the discussion of the eye. It does not include breast, brain or
25 pancreas -- pancreatic cancer. Is that correct? Is that the motion
26 that you have, Tom?

27 **DR. ALDRICH:** Yes, it is.

28 **DR. MIDDENDORF:** Let's go ahead and take the vote then.

29 **UNIDENTIFIED:** I have a question.

30 **DR. MIDDENDORF:** Tom Aldrich?

31 **MR. CASSIDY:** I have one question -- Steve Cassidy. Can I ask a
32 question before the vote?

33 **DR. MIDDENDORF:** Yes.

34 **MR. CASSIDY:** Okay. If we vote yes, does that mean this is the

1 final, or are there other people able to make motions to add things
2 to this particular motion? I mean is this the final?
3 **DR. WARD:** No. Well, I think the idea was we vote on this, and
4 then we have the opportunity to make motions to add additional
5 things.
6 **MR. CASSIDY:** Okay. Thank you.
7 **DR. MIDDENDORF:** So voting on motion three, which is all of
8 option two except prostate, and amending the discussion of the
9 eye to remove welding, and does not include breast, brain or
10 pancreas -- pancreatic cancer. So Tom Aldrich?
11 **DR. ALDRICH:** I vote yes.
12 **DR. MIDDENDORF:** Steve Cassidy?
13 **MR. CASSIDY:** Yes.
14 **DR. MIDDENDORF:** Valerie Dabas?
15 **MS. DABAS:** Yes.
16 **DR. MIDDENDORF:** John Dement?
17 **DR. DEMENT:** Yes.
18 **DR. MIDDENDORF:** Kimberly Flynn?
19 **MS. FLYNN:** Yes.
20 **DR. MIDDENDORF:** Bob Harrison?
21 **DR. HARRISON:** Yes.
22 **DR. MIDDENDORF:** Catherine Hughes?
23 **MS. HUGHES:** Yes.
24 **DR. MIDDENDORF:** Steve Markowitz is not here. Guille?
25 **MS. MEJIA:** Yes.
26 **DR. MIDDENDORF:** Carol is not here. Julia?
27 **DR. QUINT:** Yes.
28 **DR. MIDDENDORF:** Bill?
29 **DR. ROM:** Yes.
30 **DR. MIDDENDORF:** I'd better start using last names again. Susan
31 Sidel?
32 **MS. SIDEL:** Yes.
33 **DR. MIDDENDORF:** Glenn Talaska?
34 **DR. TALASKA:** Yes.

1 distinguish that, but there are some things that -- for which --
2 they're incorrect, so...

3 **DR. WARD:** Okay. Well, why don't we get -- why don't we talk
4 about them then. You know, hopefully we can -- you know, maybe
5 the order of business should be let's finish, you know, the major
6 recommendations, then we'll discu-- then we'll note any factual
7 errors, and then we'll go to any more minor editing.

8 **DR. QUINT:** Okay, thanks.

9 **DR. MIDDENDORF:** So let's take a ten-minute break. We'll be back
10 here in ten minutes sharp.

11 (Recess taken from 3:14 p.m. to 3:24 p.m.)

12 **DR. MIDDENDORF:** This is Paul again. We need to get started up,
13 so if everybody will come back to the phone.

14 **DR. TALASKA:** Okay, Paul, Glenn's on.

15 **DR. MIDDENDORF:** I'll do a roll call here in just a second.

16 **DR. ALDRICH:** Paul, this is Tom Aldrich. Can I send you some
17 suggested wording for that eye injury thing?

18 **DR. MIDDENDORF:** You mean for the body of the report?

19 **DR. ALDRICH:** Yeah.

20 **DR. MIDDENDORF:** Yeah, you can send it.

21 **DR. ALDRICH:** Thanks.

22 **DR. MIDDENDORF:** Okay, let's do a roll call just to make sure
23 everybody's here. Tom Aldrich?

24 **DR. ALDRICH:** Here.

25 **DR. MIDDENDORF:** Steve Cassidy?

26 **MR. CASSIDY:** Here.

27 **DR. MIDDENDORF:** Valerie Dabas?

28 **MS. DABAS:** Here.

29 **DR. MIDDENDORF:** John Dement?

30 **DR. DEMENT:** Here.

31 **DR. MIDDENDORF:** Kimberly Flynn?

32 **MS. FLYNN:** Here.

33 **DR. MIDDENDORF:** Bob Harrison?

34 **DR. HARRISON:** Here.

1 the non-Hodgkin's lymphomas?

2 **DR. WARD:** At this point they include Hodgkin's lymphomas, and
3 they also include CLL, which I think Bill -- Bill has some concerns
4 about also. So that is something that we can discuss. Maybe --
5 Paul, do we need a motion or can we just discuss it first?

6 **DR. MIDDENDORF:** You can have a little discussion, but if
7 somebody wants to change anything there'll have to be a motion.

8 **DR. WARD:** Right, right.

9 **DR. HARRISON:** Yeah, I'm not -- I wasn't quite ready to make a
10 motion, and I may -- I apologize if I'm out of Robert's Rules of
11 Order here. I just had some concerns about whether we intend to
12 include all lymphomas, both Hodgkin's and non-Hodgkin's
13 lymphomas. I think that the level of scientific evidence for
14 Hodgkin's disease or Hodgkin's lymphomas is less certain than for
15 the non-Hodgkin's lymphoma.

16 **DR. WARD:** Yeah, and I can tell you why it was done this way, is
17 that in the -- the IARC monograph program has basically lumped all
18 of these -- the leukemias and lymphomas together. And in part it's
19 based on the rationale that when you're looking at the
20 epidemiologic studies, especially the historical studies of that
21 whole group, there have been so many -- I mean some of them
22 were based on death certificates where the classification of the
23 leukemia and lymphoma was -- was, you know, very broad. And in
24 some cases the groupings have changed over time, so IARC kind of
25 decided to lump all of them together because when you try to list
26 them there's so much potential for inaccuracy. So that's -- so I kind
27 of followed the lead of the most recent work by IARC where they
28 were kind of tabulating cancer sites associated with IARC
29 carcinogens and they basically put all of them together. But you
30 know, I agree with you from what I understand, and I did double-
31 check when, you know, you made the comment that -- you know, if
32 -- there is very little occupational/environmental exposure that's
33 been associated with Hodgkin's lymphoma and quite a -- you know,
34 much more associated with NHL.

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DR. HARRISON: Thank you, Liz. And with that explanation in terms of how this is listed, I agree with the current listing and the phrase then on page seven regarding the LACs. But I don't -- I don't have a specific motion to make to amend that.

DR. WARD: Okay.

MS. DABAS: Hi, Liz, this is Valerie. I wanted to make not a motion for a vote but a motion to discuss the inclusion of brain, pancreas and breast cancer. I really would kind of like to get some feedback as to why they were excluded, where are we on trying to get those included. These are three cancers that we at the PBA have seen very high amounts of.

MR. CASSIDY: This is Steve Cassidy. I'm interested in that discussion, too, and I'm not sure that when that vote was taken, and was lost eight to six, whether everybody voted no -- of the eight -- simply because all three were added, any one particular of the three, or if in fact it was the prostate cancer that was removed from option two. So I'd like to know where people stand on that also.

DR. WARD: Okay. Well, I'm comfortable with just opening the floor for discussion on these three cancers without yet having a formal motion, so anyone can begin.

MS. DABAS: This is Valerie again. I guess I would start with pancreas cancer. I think that we've included the digestive system, and the pancreas is considered part of the digestive system as well as the endocrine system, and excluding that I think is very -- it doesn't make sense on the idea of biological plausibility where I read in some studies that they say that the inflammation also causes pancreas cancer, that certain carcinogens can interfere with the normal functions of cell growth, which is directly part of the endocrine system. So I'm a little confused about why pancreas was removed from the list -- was not on the list.

DR. WARD: Okay. Anyone else?

UNIDENTIFIED: Well, what are the grounds for adding it? What are the scientific grounds for adding it, other than that -- you

1 know, we looked at the chemicals that were involved and we
2 couldn't see chemicals where we had any sort of documentation of
3 the exposure that were causing brain or pancreatic cancer, so I'm
4 just wondering why -- how we would justify their inclusion and who
5 should work on that.

6 **DR. WARD:** Who said that, you know -- I think -- I just double-
7 checked, and you know, in the kind of groupings that I used, which
8 were the SEER groupings, it is correct that pancreas is listed as a
9 digestive system cancer. I can read a -- answer it better -- I didn't -
10 - I actually didn't include all in this list of cancers, only those that
11 were specifically indicated by the other three sources, so -- so
12 among the digestive (inaudible) cancers there's esophagus,
13 stomach, small intestine -- which I didn't include; colon and
14 rectum, anus, anal canal and anorectum -- which I didn't include;
15 liver and intrahepatic bile duct -- which I did include. Then there's
16 gall bladder and other biliary -- I believe I didn't include; pancreas -
17 - which I didn't include. So it was really within the digestive tract I
18 included those that had been specifically implicated by any of the
19 (inaudible) sources. I also included retroperitoneum, peritoneum,
20 omentum and mesentery because I had a feeling that those kind of
21 overlapped with the mesothelioma, but they were kind of sites
22 where you might find mesotheliomas so I wanted to include them
23 with central mesotheliomas. So I guess that's the rationale that
24 was the -- you know, within the digestive tract, only those sites
25 that have been implicated by any one of the three (indiscernible)
26 were included.

27 **UNIDENTIFIED:** So can I make a motion to consider adding
28 pancreatic to the digestive system of organs?

29 **UNIDENTIFIED:** I second.

30 **DR. WARD:** Any discussion?

31 **DR. MIDDENDORF:** I need specific wording on the motion first.

32 **UNIDENTIFIED:** On page five, line 14, the Committee recommends
33 certain cancers of the digestive system. So under the long list of
34 esophagus, stomach, colon, rectum, liver, bile duct, da, da, da, da,

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da, include pancreatic 'cause it's related in there.

DR. ALDRICH: This is Tom Aldrich. An important reason why all those digestive tract cancers were included is because of exposure. I mean direct exposure to high volume of dust because of all the aspirated and swallowed material. And that doesn't get into contact with the pancreas in the same sense that it does with esophagus and stomach and small bowel and large bowel. And I think that's a really important difference, and so the quality of the evidence is different for the two types of digestive cancers.

UNIDENTIFIED: I guess then I look again at, you know, the inclusion of -- we can look at digestive, but we could also look at the endocrine system where we've included thyroid, we've included kidney, we've included stomach, and then again we're excluding pancreas. You know, that's two systems where we have ample amount of organs that have been included but are including -- choosing to exclude an organ that is there twice, essentially. And then, you know, from speaking to some -- just looking at the literature it says then the pancreatic cancer is one of the cancers that is very difficult to diagnose, and that might be one of the reasons why it hasn't made it on the list and the liver has.

DR. MIDDENDORF: I'm going to butt in for just a second and remind people you need to identify who is speaking so that it's on the record. So this motion was made by Tom Aldrich and the motion was the Committee recommends adding pancreatic cancer to the list of digestive tract cancers.

Is that the motion that's on the table?

DR. ALDRICH: Yeah, but it wasn't made by me.

DR. MIDDENDORF: Okay. Who was that made by?

UNIDENTIFIED: Catherine.

MS. HUGHES: Catherine Hughes.

DR. MIDDENDORF: Catherine, okay.

DR. WARD: And it was seconded by Valerie?

UNIDENTIFIED: I'll take a friendly amendment to Valerie's ideas, too. Either one is fine.

1 **MS. DABAS:** Yes, I would second Catherine's motion to add
2 pancreatic cancer.

3 **DR. MIDDENDORF:** That was Valerie speaking.

4 **DR. WARD:** Right. And then it was Tom speaking --

5 **DR. ALDRICH:** Yeah, I said I think that the rationale for including
6 the tubular organs in the digestive tract makes a lot more sense
7 because it -- because there's rationale for heavy exposure. If
8 there's rationale for environmental causes of pancreatic cancer, I'm
9 open to it. I don't know that literature. And so I wonder if one of
10 the people who's more familiar with that literature would like to
11 comment on whether there's evidence of occupational or
12 environmental triggers for pancreatic cancer.

13 **MS. HUGHES:** Catherine Hughes here. I understand that
14 pancreatic cancer's on the fast track to be included under Agent
15 Orange for the Veterans Association, the VA.

16 (interference)

17 **DR. WARD:** We're getting some interference from somebody, so if
18 everybody would be sure they're on mute when they're not
19 speaking.

20 **MS. FLYNN:** This is Kimberly Flynn. As I understand it, there are --
21 there is an increase in risk for pancreatic cancer from occupational
22 exposure to diesel and other fossil fuel combustion products.
23 Anybody know anything about that?

24 **DR. TALASKA:** Glenn Talaska. I couldn't see anything like that from
25 any of the PAH studies so that -- when I looked through the PAHs.

26 **DR. WARD:** There are two diesel studies that just came out and I'm
27 trying to locate them, but it's -- I think -- you know, the evidence
28 we were using was the evidence that was available from the IARC
29 monograph, and diesel is scheduled for re-review, but it was --
30 their review was not available right now.

31 **DR. WEAVER:** This is Virginia Weaver. Could I just ask a question
32 of clarification?

33 **DR. WARD:** Sure.

34 **DR. WEAVER:** For the new cancers that we haven't discussed and

1 we haven't included in the document with a rationale for inclusion,
2 I guess that in the document to date we really approached it with a
3 eye to documenting exactly why we were including various cancers
4 and, since we have to finish this document in a timely fashion, it
5 would be difficult to take the additional three cancers and be able
6 to give them the same attention that the cancers that are in the
7 document to date have had. So could we revisit the parking lot
8 issue in terms of what our opportunities would be going forward if
9 we were not to include these cancers today?

10 **DR. WARD:** Well, as I understand it, it's quite likely that we may be
11 asked to address petitions -- in other words, if there are future
12 petitions to add other cancers to the list, Dr. Howard has the
13 option of asking our advice on those petitions. And at that point --
14 you know, if he does ask for our advice, that we would have the
15 opportunity to review the new evidence and consider whether to
16 add those cancers. But it's also my understanding that there's -- I
17 mean it -- we basically do have to reach agreement today, and if --
18 let's say the sense of us on the Committee -- if the majority of the
19 people felt that one of these three or two of these three cancers
20 should be included, then I think we would just have to write the
21 draft to indicate that, you know, this is the recommendation, this is
22 what the Committee was basing the recommendation on, and you
23 know, the time frame did not permit as full a rationale as what the
24 -- you know, as was provided by the other sites.

25 **MS. HUGHES:** Catherine Hughes here. On the breast cancer
26 there's recently an article in 2010 by Dr. Liu that PCBs enhance
27 metastatic (sic) properties of breast cancer cells by activating the
28 ROCK, R-O-C-K, the Rho-associated kinase. It says the conclusions
29 of the summary article I have, it's PCBs enhanced the metastatic (sic)
30 propensity of breast cancer cells by activating the ROCK signaling,
31 which is dependent on the R-O-S induced by the PCBs. So that
32 would be possibly one article to consider under breast.

33 **DR. HARRISON:** Liz, this is Bob Harrison.

34 **DR. WARD:** Yes.

1 **DR. HARRISON:** I don't believe that we have, or at least I have,
2 sufficient information on -- to vote to add additional cancers
3 beyond those that are listed in the current proposal under option
4 two without considering more scientific and epidemiological and
5 toxicological data. And in the preface to the -- to our current draft
6 we're using three criteria. We're using the IARC monographs for
7 limited or sufficient evidence, respiratory and digestive tract
8 cancers where inflammatory conditions have been documented,
9 and then answers for which epi studies have found evidence of
10 increased risk in World Trade Center responder and survivor
11 populations as referenced in Table 4. And if we were going to add
12 other cancers outside of those three criterias (sic) -- which I'm, you
13 know, perfectly comfortable doing -- then we would, I think, need
14 to more carefully review the scientific evidence presented for full
15 consideration by the Committee, and then a vote. But I don't
16 believe that I could vote without having done that first.
17 So process-wise, I guess I'm suggesting that if this Committee
18 needs to reconvene at a future date to review that evidence, then I
19 would, you know, certainly be -- I think that would be the route to
20 go.
21 **DR. WARD:** Yeah, and as I understand it -- Paul can comment as
22 well -- basically we don't really have the option of saying we need
23 to reconvene at a later date. I think we need to, you know, have
24 both people -- have -- if anyone is making a motion to add any of
25 these three cancers, we need to hear the rationale for that
26 addition, and then we need to have discussion as -- you know, by
27 the Committee, and then we need to take a vote. And as to
28 whether in the future we'll look at those cancer sites again, that's
29 really up to Dr. Howard.
30 **UNIDENTIFIED:** One point of clarification also is I just want to --
31 **DR. MIDDENDORF:** Who's speaking?
32 **UNIDENTIFIED:** -- is on the future list under VA to be added under
33 Agent Orange as well.
34 **DR. MIDDENDORF:** Was that Catherine Hughes?

1 **MS. HUGHES:** Yes, it was.

2 **DR. MIDDENDORF:** Thank you.

3 **MS. DABAS:** Hi, this is Valerie. I have a question. On page 41, the
4 Table 2, select agent that IARC has classified as carcinogenic to
5 humans and related cancer sites with sufficient or limited evidence,
6 2378 tetrochlorobenzoparadoxin (ph), says all cancers combined.
7 And I'm wondering why we haven't used that as our -- as the
8 rationale to at least get pancreas, breast and brain in.

9 **DR. WARD:** Well, it was -- that was -- that evidence was discussed
10 under the -- under option one. It was specifically cited under
11 option one. I don't -- I don't see it as a direct rationale for getting
12 pancreas, brain and breast in.

13 **MS. DABAS:** Right, but if we're saying that we would include using
14 the rationale that we'd use for digestive system, for identifying the
15 digestive system, adding that particular carcinogen agent to that
16 case, to say that we believe that because the digestive system has
17 been identified as one of the systems that we think has been
18 compromised, to include the other organs, that we also believe
19 that that plus this would get us there.

20 **DR. WARD:** I'm not sure I follow the logic. I mean I think -- you
21 know, we already discussed including pancreatic as part of the
22 digestive system and the rationale for why -- didn't think it should
23 be included because it wasn't an organ that had direct contact with
24 substances that were passing through the digestive tract or the
25 upper respiratory tract.

26 So Paul, can you help me remember exactly where we are in terms
27 of motions? We did have a motion and a second with regard to --

28 **DR. MIDDENDORF:** We have a motion on the table -- up on the
29 screen. The motion is that the Committee recommends adding
30 pancreatic cancer to the list of digestive tract cancers.

31 **DR. WARD:** Okay.

32 **DR. MIDDENDORF:** Below that I just put the digestive tract cancers
33 that were in the motion which passed.

34 **DR. WARD:** So maybe, Valerie -- I think maybe we can't really -- we

1 should probably stick to discussing the pancreatic cancer right now,
2 and then address the other cancers separately when there's a
3 motion to do so. So is there any further discussion on the
4 pancreatic cancer?

5 (No response)

6 **DR. WARD:** I would think it's time for a vote on the pancreatic
7 cancer.

8 **DR. MIDDENDORF:** So motion four, which was put forward by
9 Catherine Hughes and was -- if I remember correctly, an
10 amendment by whom?

11 **UNIDENTIFIED:** Valerie.

12 **DR. MIDDENDORF:** Or was it just seconded?

13 **DR. WARD:** Seconded, I think.

14 **DR. MIDDENDORF:** Seconded by Valerie, is that correct?

15 **MS. DABAS:** Yes.

16 **DR. MIDDENDORF:** Okay. So the motion on the table is
17 'Committee recommends adding pancreatic cancer to the list of
18 digestive tract cancers.'

19 And going to the vote, we'll do it again alphabetically. Tom
20 Aldrich?

21 **DR. ALDRICH:** No.

22 **DR. MIDDENDORF:** Steve Cassidy?

23 **MR. CASSIDY:** Yes.

24 **DR. MIDDENDORF:** Valerie Dabas?

25 **MS. DABAS:** Yes.

26 **DR. MIDDENDORF:** John Dement?

27 **DR. DEMENT:** No.

28 **DR. MIDDENDORF:** Kimberly Flynn?

29 **MS. FLYNN:** Yes.

30 **DR. MIDDENDORF:** Bob Harrison?

31 **DR. HARRISON:** No.

32 **DR. MIDDENDORF:** Catherine Hughes?

33 **MS. HUGHES:** Yes.

34 **DR. MIDDENDORF:** Steve Markowitz is not here. Guille?

1 **MS. MEJIA:** Yes.
2 **DR. MIDDENDORF:** Carol North is not here. Julia Quint?
3 **DR. QUINT:** No.
4 **DR. MIDDENDORF:** Bill Rom?
5 **DR. ROM:** No.
6 **DR. MIDDENDORF:** Susan Sidel?
7 **MS. SIDEL:** Yes.
8 **DR. MIDDENDORF:** Glenn Talaska?
9 **DR. TALASKA:** No.
10 **DR. MIDDENDORF:** Leo Trasande?
11 **DR. TRASANDE:** No.
12 **DR. MIDDENDORF:** Liz Ward? No, excuse me, Virginia Weaver?
13 **DR. WEAVER:** No.
14 **DR. MIDDENDORF:** Liz Ward?
15 **DR. WARD:** No.
16 **DR. MIDDENDORF:** Okay, the count I get is nine no and six yes.
17 The motion does not carry.
18 **DR. WARD:** Okay, so the floor is open for additional motions. Or
19 topics for discussion, if not motions.
20 **MS. SIDEL:** I'd like to make a motion to add brain cancer. I'm --
21 sorry, Susan Sidel.
22 **DR. WARD:** Is there a second?
23 **MS. HUGHES:** Catherine Hughes, yes.
24 **DR. WARD:** Okay. So can we have some discussion on the
25 rationale for adding brain cancer?
26 **UNIDENTIFIED:** Isn't the brain the largest part of the nervous
27 system, and the nervous system interfaces with the circulatory
28 system and the lymphatic system, and the pulmonary as well.
29 **DR. MIDDENDORF:** I just want to make sure who -- excuse me for
30 just a second, I -- who made the motion? Was that Susan Sidel?
31 **MS. SIDEL:** Yes, and Catherine seconded.
32 **DR. MIDDENDORF:** Catherine seconded, thank you. And is this the
33 correct motion, 'The Committee recommends adding brain cancer
34 to the list of covered conditions'?

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MS. SIDEL: Correct.

DR. MIDDENDORF: Okay.

MS. SIDEL: Thank you.

DR. WARD: Is there anyone else who wants to speak to the point of the rationale for adding brain cancer?

DR. HARRISON: This is Bob Harrison. I would just like to point out I believe that there's some evidence that exposure to solvents, in some studies, increases the risk of brain cancers. I don't know whether solvents, or solvent exposure, was among the World Trade Center. I know that we have identified benzene.

UNIDENTIFIED: Yeah, I just understand that some of the main floor of the World Trade Centers that was full of solvents -- oh, in the sub-basement, yeah.

MS. SIDEL: Even in another -- I'm sorry, Susan Sidel. May I speak?

DR. WARD: Yes.

MS. SIDEL: Catherine, maybe you can help me out with this, but didn't we talk about there were several doctors' offices in the towers that had X-ray machines? So that would be radiation.

MS. HUGHES: Okay, what I understand is there's a large cooling system which had a lot of the solvents in it, it was in the basement and the seventh and eighth floor.

UNIDENTIFIED: That was (indiscernible).

DR. WEAVER: Virginia Weaver. So it would be great to be able to flesh some of this out in more detail. There's data suggesting that formaldehyde increases brain cancer, although apparently it's somewhat population-dependent. We do know that formaldehyde is present in combustion products. There is an increased risk of brain cancer in firefighters, again suggesting that it may be reflecting combustion exposures. However, it's kind of hard to do this on the fly without being able to think through the lines of evidence and the fact that brain cancer did not fall out using our a priori criteria.

DR. DEMENT: This is John Dement. May I speak?

DR. WARD: Yes, John.

1 **DR. DEMENT:** I think this is one that's actually harder to come to
2 consensus about than the pancreatic cancer because I think, as
3 Virginia's pointed out, there are some exposures and actually a
4 number of case control studies, too, that point to firefighting and
5 solvents as brain cancer risks. But unfortunately, I don't think it -- I
6 don't think the level of evidence has risen to a level that would be
7 sufficient for IARC to classify it as such. There probably hasn't
8 been a review done in a while either, but nonetheless, that sort of
9 dates those data.
10 Also didn't vinyl chloride have some question about brain cancer, a
11 relationship, at one time as well?
12 **DR. WEAVER:** Virginia -- yes, I think it did.
13 **MS. HUGHES:** And also there was lots of plastics. Think of all the
14 computer terminals that were -- you know, imbedded in plastic
15 boxes, PVC --
16 **UNIDENTIFIED:** Carpet.
17 **MS. HUGHES:** -- and everything like that, carpeting.
18 **DR. WARD:** And so the one thing I can speak to is that in the most
19 recent IARC review brain cancer was not identified as one of the
20 sites. I think there were some early findings, but then the later,
21 larger studies did not see excess risk for brain cancer.
22 **MS. DABAS:** Hi, this is Valerie. I just wanted to know -- Dr. Rom
23 spoke earlier saying that he was doing some work on brain -- if he
24 had any thoughts on this. I might regret it, but...
25 **DR. ROM:** This is Bill Rom. Beyond what Bob Harrison said with
26 the solvent exposure, I really have nothing to add. And I think this
27 is a type of cancer that's under investigation, but there's no real
28 hard evidence for occupational/environmental exposures yet.
29 **DR. WARD:** I think unfortunately there's been a lot of studies that,
30 you know, were motivated by brain cancer clusters in various
31 industries. And frequently it turns out that there really isn't either
32 an excess risk or there isn't anything in particular that the brain
33 cancers are associated with. So it's been one of the very difficult
34 cancers in occupational health because it's -- you know, there's

1 been actually a lot of studies and they haven't really led to any
2 clear conclusions about the causes -- whether there's an excess and
3 what the causes might be.
4 So I -- I mean if no one has any further comment, we can just call
5 this motion to a vote.
6 **UNIDENTIFIED:** I just have a quick question here.
7 **DR. MIDDENDORF:** Who is that?
8 **MS. HUGHES:** This is Hughes -- Catherine Hughes. I understand
9 someone has -- if we vote to exclude a particular site, if -- a
10 lymphoma is still -- is lymphoma still covered in a non-covered site?
11 For example, someone has a lymphoma cancer in the brain?
12 **DR. WARD:** To the best of my knowledge, yes. I mean lymphomas
13 are classified as a group, regardless of what site they arise in, so --
14 and I will -- I didn't include the appendix of sites and histologies,
15 but I will. And I assume that the program -- you know, if the
16 program chooses to accept our recommendations, obviously they
17 will look in detail and make sure that all the relevant sites and
18 codes are included, but I made my best attempt using the SEER
19 database to specify that, and I think basically when -- you know, for
20 certain cancers like lymphomas, regardless of what site in the body
21 they arise in, they're classified as a lymphoma because most
22 cancers do arise in lymphatic tissue all over the body.
23 So Paul, shall we go ahead and have a vote?
24 **DR. MIDDENDORF:** Okay. So the motion on the table is 'The
25 Committee recommends adding brain cancer to the list of covered
26 conditions.'
27 With the vote here -- Tom Aldrich?
28 **DR. ALDRICH:** No.
29 **DR. MIDDENDORF:** Steve Cassidy?
30 **MR. CASSIDY:** Yes.
31 **DR. MIDDENDORF:** Valerie Dabas?
32 **MS. DABAS:** Yes.
33 **DR. MIDDENDORF:** John Dement?
34 **DR. DEMENT:** No.

1 **DR. MIDDENDORF:** Kimberly Flynn?
2 **MS. FLYNN:** Yes.
3 **DR. MIDDENDORF:** Bob Harrison?
4 **DR. HARRISON:** Yes.
5 **DR. MIDDENDORF:** Catherine Hughes?
6 **MS. HUGHES:** Yes.
7 **DR. MIDDENDORF:** Steve Markowitz is not here. Guille?
8 **MS. MEJIA:** Yes.
9 **DR. MIDDENDORF:** Carol North is not here. Julia Quint?
10 **DR. QUINT:** No.
11 **DR. MIDDENDORF:** Bill Rom?
12 **DR. ROM:** No.
13 **DR. MIDDENDORF:** Susan Sidel?
14 **MS. SIDEL:** Yes.
15 **DR. MIDDENDORF:** Glenn Talaska?
16 **DR. TALASKA:** No.
17 **DR. MIDDENDORF:** Leo Trasande?
18 **DR. TRASANDE:** No.
19 **DR. MIDDENDORF:** Virginia Weaver?
20 **DR. WEAVER:** No.
21 **DR. MIDDENDORF:** And Liz Ward?
22 **DR. WARD:** No.
23 **DR. MIDDENDORF:** Eight nos, seven yes. Eight no, seven yes.
24 **DR. WARD:** Thank you, Paul. So additional motions?
25 **MS. FLYNN:** The Committee recommends -- this is Kimberly. The
26 Committee recommends the addition of breast cancer to the list of
27 covered conditions.
28 **MS. SIDEL:** I second it. I'm Susan Sidel. I second her mo--
29 Kimberly's motion.
30 **DR. WARD:** Thank you. So shall we have a dis-- have people who
31 want to speak to the rationale for adding breast cancer?
32 **DR. MIDDENDORF:** Just one quick thing, was that Kimberly who
33 made the motion?
34 **MS. FLYNN:** Yes, it was.

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DR. MIDDENDORF: Okay. And Susan seconded?

MS. SIDEL: I did -- seconded it.

DR. MIDDENDORF: Okay. And is this the correct motion, 'The Committee recommends adding breast cancer to the list of covered conditions'?

MS. FLYNN: Yes.

DR. WARD: So I know people have -- several people have spoken on the rationale for breast cancer before, but it probably would be useful at this point, even if -- if you've said something before, say it again, because we really need to lay out the rationale as strongly and clearly as possible so that the Committee can consider whether they think that there's sufficient rationale for adding it.

MS. HUGHES: Hughes, one, there were many -- there was endocrine disrupters there; two, stress can attribute to increased cancer; three, Agent Orange -- breast cancer's on the fast track for that.

DR. WARD: Anyone else?

MS. HUGHES: I'm sorry, and four, there have been limited studies of women in occupational health.

MS. DABAS: Hi, this is Valerie. I think one of the things that I read in Environmental Health Perspective was the estrogen effect and BPAs, and that exposure to BPAs can cause the body to produce estrogen and then lead to breast cancer. So I think when we looked at plastics that were at the World Trade Center, some of the things that they talked about were cleaning products, plastic from computers, linoleum from the floors, the vinyls, synthetic fragrances and fabrics such as carpet that were burning. So I think there is some indication that, you know -- that this could have caused increased estrogen in women that's causing the breast cancer.

DR. WARD: So does anyone who's not in favor of adding breast cancer want to speak to their rationale?

DR. QUINT: Well, before you do that -- this is Julia.

DR. WARD: Okay.

1 **DR. QUINT:** I haven't decided one way or the other yet, but I just
2 want to say that there are lots -- there are data, studies, both in
3 vivo and epidem-- animal studies and human studies,
4 epidemiological studies indicating an association between PCBs and
5 breast cancer. And also there is a new -- and they're not
6 consistent, I should say that, so that gives me some pause. But
7 there is a new -- fairly new study showing increase in breast cancer
8 metastasis with PCBs and a specific mechanism that's been
9 proposed, and that was shown both in vivo and in cell cultures. So
10 I think we have a specific WTC exposure of PCBs linked to breast
11 cancer and, as I said, the data are not consistent in terms of the
12 association. But the new study showing an increase in breast
13 cancer metastasis, that is just one study, but it's pretty solid,
14 seemingly, evidence. I think it adds some weight.

15 **DR. WARD:** Glenn, you were -- I think you were the person who did
16 most of the work on exposure levels to PCBs. Do you want to
17 comment?

18 **DR. TALASKA:** Well, you know, the data -- there weren't data that
19 indicated that those -- at least biological. But again, subject to the
20 limitations of all the data that were collected, a relatively small
21 number of people that were collected after the fact, but fairly
22 persistent compounds, PCBs and -- so they should have been
23 increased in the people that were measured by the CDC. And I'm
24 just checking the wording that we did -- no, and I don't believe that
25 they were.

26 The dioxin is a similar thing. We had the window films that showed
27 that there were relatively high levels on the -- in the windows, but
28 there weren't elevated levels of any of the dioxins in the people
29 that were studied by -- again, by the CDC.

30 Then there were increases -- let's see, on one congener was
31 increased in exposed firefighters. Only one of the congeners in the
32 mean values were 27.8 parts per trillion for all site firefighters; 30
33 parts per trillion for those present at the collapse; 26.2 for those
34 arriving day one or day two, and 30.6 for those in special

1 operations. The firefighters not at the site had a lower average for
2 that one congener, so that was elevated. In retrospect, the
3 average was -- for the Agent Orange, the average, measured ten
4 years after their exposure, was -- in the ranch hand study was 49
5 parts per trillion and ranged to 313. So you know, they had -- they
6 had ten years for the stuff to go away. It has about a seven-year
7 half-life, if I remember correctly, and they were -- and their levels
8 were several times higher than what were seen in any of the
9 people that were measured in the early -- as far as we know, since
10 we didn't get the range -- in the -- at the World Trade Center. And
11 that was only one congener, and it wasn't for TCDD itself, which --
12 that's the biggest one in terms of exposure for dioxin and/or for
13 PCBs.
14 I'm re-looking at what we wrote. They certainly were at the site,
15 but the lev-- the air levels were said to reduce -- be reduced fairly
16 quickly. And again that's to be expected because PCBs are -- have a
17 really low vapor pressure. But you know, there still could be
18 dermal absorption from them, so that's the other side of the coin.
19 Again, Edelman did not see a difference between any of the mean
20 values of the firefighters or people -- or the firefighters who never
21 entered the Ground Zero site.
22 Dahlgren did see levels in -- I think he studied seven first
23 responders and that three were above the 75th percentile, two
24 above the 90th and one above the 95th percentile, which would
25 probably be unusual. But again, they -- that report was limited
26 because they didn't say how these people -- the seven people were
27 selected, although they did see some elevation in PCBs, too.
28 So the data are mixed -- there is no other way to put it -- in terms
29 of the exposure for PCBs and dioxin. It seems like there was an
30 enormous amount of dioxin in the air to begin with, but at least it
31 seems from the data that either it didn't get into people readily,
32 which is a very good thing -- and with the PCBs there's some
33 indication of exposure to some people to elevated levels of PCBs,
34 but those data are limited.

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DR. WARD: Good. And this is Liz. I think, you know, from my point of view, you know, one of the things that we didn't look at and we -- there probably isn't enough data to look at, but probably should be on the agenda for future research, is kind of the effects of the stress related to the World Trade Center exposures and how that might have affected the endocrine system, and that might have some direct bearing on breast cancer. But at this point, the studies just aren't -- I mean the studies haven't been done to show that.

I guess the other exposure that has been related to breast cancer is shift work. But again, you know, IARC did an evaluation of that and I think it -- based on limited evidence in humans, but then subsequent studies have not been confirmed at the early association. So -- and I do agree with the comments and I just don't know how to deal with it that, you know, there have been very few -- because so few women were involved in the industrial occupations that form a large part of the base of our knowledge about occupational carcinogens, we really don't have good information about the effect of many carcinogens on causing cancer of the female breast. Even the male breast is such a rare cancer that it wouldn't be picked up in occupational studies.

MS. FLYNN: This is Kimberly, excuse me, but I think this is actually a perfect instance where we really do need to lean on the precautionary principle. We are not going to have this information, number one. Number two, we are not just talking about shift work. We're talking about shift work on steroids. I mean we're talking about extreme shift work that was being done by female responders who were simultaneously being exposed to, you know, plastics fumes, who were simultaneously being exposed to 2378 PCBs, who were simultaneously being exposed to probably a range of xenoestrogens in World Trade Center dust and smoke. I guess I'm asking whether or not there's some possibility of pulling together a rationale here when we have a population that is -- you know, whose health impacts are simply not ever going to be

1 addressed by occupational studies, you know, in the next 15 to 20
2 years. And I guess I want to throw in that Edelman -- you know, I
3 don't want to repeat my comments, but Edelman is extremely
4 limited. And Glenn, you actually raised at least three important
5 criticisms with respect to the inadequacy of the Edelman -- of the
6 information provided in Edelman. I'd also like to say that we're
7 talking about, you know, exposures that are bio-- are cumulative
8 and we're talking about one stint on the Pile, one stint in
9 downtown where, you know, had Edelman come back and retested,
10 he might have gotten much higher blood lipid levels.

11 **DR. TALASKA:** This is Glenn. My major concern with Edelman, at
12 least to the PAHs, was the fact that those things have a fairly short
13 half-life, and yet he didn't sample until 21 days after the peak.
14 With dioxin compounds, as I was trying to point out in the -- by
15 bringing up the ranch hand study, you know, when they sampled
16 those people ten years after their exposure, they were still half-
17 again higher than the highest ones that were reported at the -- at
18 Ground Zero. And so that was a ten-year lag, where it would have
19 shown up relatively quickly after the exposure and it should have
20 been maintained for 21 days if you can see it ten years later.
21 That's my concern with, you know, making the inclusion.
22 You know, philosophically and personally, it's something that --
23 yeah, you'd like to see everyone -- this particular disease covered
24 because there's a possibility that perhaps there was some
25 exposures in some individuals, and that a few individuals whose
26 disease may be related to those exposures. You know, there's a
27 possibility that that would be happening, based upon the data,
28 because we don't have the ranges. We don't know what -- what --
29 the peak that Edelman saw for most of the markers that he
30 measured. But it's -- it would -- at least from -- the types of
31 exposures relative to what was seen in other places, it seems like
32 that would -- seem to me the probability would be that there
33 would be very few of those.

34 So on -- you know, at one hand I would support the notion, but the

1 science just isn't there to say that this is a condition where
2 everybody would -- or you would expect that people would have
3 this in an elevated probability. But I'm sure on an individual basis
4 there probably is somebody -- I can't say I'm sure. There may be
5 on an individual basis somebody who had a high level that just
6 wasn't documented because they weren't with some of those --
7 directly with some of the transformers or in the smoke from a
8 particular transformer fire that had some in it. You know, that's
9 where the chance is, as far as I can see.

10 Does that make sense?

11 **DR. WARD:** That makes sense to me -- this is Liz. But even so,
12 though, there's not a strong established association between PCBs
13 and breast cancer.

14 **DR. TALASKA:** Correct.

15 **DR. WARD:** So it's not -- I mean so it's not like we're saying there is
16 a strong epidemiologic association and if someone happened to be
17 in the plume when -- you know, near a transformer fire, then that
18 would have been a reasonable assumption that they would have
19 gotten a high exposure that would result in breast cancer. So the
20 problem is we don't have strong evidence for an association
21 between PCBs or TCDD and breast cancer, and we don't have
22 evidence -- we don't have much evidence that there was elevated
23 exposure in the population as a whole.

24 **MS. FLYNN:** This is Kimberly. I think, again -- I mean, and I won't
25 rehearse this, but the idea that we don't have that kind of exposure
26 data doesn't mean that those exposures didn't happen, number
27 one. And number two, I guess I'm wondering if there isn't any way
28 for us to craft a similar rationale to the rationale for coverage of
29 pediatric cancers, to cover female breast cancer, because we have
30 a small group of women in the monitoring program and we have a
31 very small group of women being seen at the World Trade Center
32 Environmental Health Center. We don't really have the possibility
33 of getting, you know, large enough numbers to be able to see an
34 up-tick.

1 **MS. SIDEL:** Hi, this is Susan. Could I speak, please?

2 **DR. WARD:** Sure.

3 **MS. SIDEL:** You know, I have such a tough time with basing
4 anything on exposure data because it is so faulty, and it's almost as
5 though the people that really needed the exposure data to be
6 accurate are the ones that are sort of being penalized because it
7 isn't, and so that's what sort of makes it really tough for me on a
8 moral basis.

9 The other thing is that women have just not had any kind of special
10 consideration whatsoever in the program -- well, maybe a little bit
11 over at Bellevue, but I know that in the responder programs there's
12 no special studies that deal with women's health and I know that a
13 lot of women have been impacted in very specific ways. It's just a
14 fault of the program because it's -- you know, you're not seeing
15 large numbers of women so there's a bias generally. And it's
16 difficult because, you know, we're recognizing that there's a
17 problem, but we're not in a position to do anything about it
18 because that would be prol-- you know, that's not the policy. So I
19 just sort of feel as though there has to be some other way that we
20 can get this in because I just don't think that you'll ever get the
21 kind of research that you need because no one is going to -- no one
22 is going to really do that research based on the numbers of people
23 that we have in the program, the number of women. It seems --
24 you know, ten years out it doesn't seem like anybody's really
25 interested in studying women's health.

26 **MR. CASSIDY:** Steve Cassidy, can I say something?

27 **DR. WARD:** Sure, go ahead, Steve.

28 **MR. CASSIDY:** I mean I know that the fire department is doing an
29 EMS study. I know there are a lot of women included in it. It's
30 frustrating that the results are not available at this time. It's just
31 frustrating that we don't have more data, but I know there is an
32 extensive study being done of EMS and they have a significant
33 population of women involved, to my knowledge.

34 **DR. WARD:** Thanks. And I also think it's -- it's not exactly

1 analogous to childhood cancer because the expected incidence of
2 breast cancer in the population is much greater than the expected
3 incidence of childhood cancer. So I think that even if you have
4 relatively small numbers of women in studies, you have more
5 opportunity to actually see an increased risk, if there is one.

6 **MS. HUGHES:** Catherine here. What if the age onset happens at an
7 earlier age than normal?

8 **DR. WARD:** Well, in the write-up of the rare cancer sites we did -- I
9 mean and this is just a proposal and, you know, it's kind of
10 something that the program would have to work on
11 implementation of, but the con-- at least conceptually the idea was
12 one would look at cancer sites by at least decade of age. So for
13 example, if someone got breast cancer and they were 25 years old,
14 that would likely qualify as a rare cancer. So if -- because it is, you
15 know, reasonable that some cancers -- you know, what you would
16 see is a shift towards earlier age at diagnosis if there was an
17 increased risk.

18 **DR. QUINT:** This is Julia. One of the issues, as I understand it, with
19 PCBs -- and this is based on just one study -- is metas-- you know,
20 the metastasis issue, so that not so much causation with PCB but
21 this new -- this study I mentioned, and I can send you the reference
22 -- show that PCBs actually, you know, cause the breast cancer to
23 metastasize to other sites, which would end up, you know, going
24 from treatable possibly to fatal cancer in women if this is really
25 true -- I mean if this bears out down the line. I know the specific
26 mechanism -- you know, reactive oxygen species generated by the
27 PCBs that activated a specific site mechanism that caused it. So I
28 guess my question is whether or not, in making recommendations
29 to the Director, that we should consider, you know, a cancer that --
30 you know, an exposure that could cause a cancer to metastasize,
31 whether or not that would be considered an exacerbation of an
32 existing condition or something like that, it if turns out -- the
33 exposure data side, I know there are issues with that and I'm not
34 sure how many women were actually included in Edelman's study,

1 but -- so the question is whether or not, if it turns out that PCBs
2 could, you know, influence metastasis of breast cancer, whether or
3 not that would qualify in terms of the -- what we're asked to
4 recommend here, you know, 'cause I'm not talking about causation
5 'cause those data are inconsistent. But if it turns -- I mean would
6 that be a legitimate area to comment on -- to make a
7 recommendation on, or to base a recommendation on?

8 **DR. WARD:** Well, I can -- I think I can give you an off-the-cuff
9 opinion. I mean I think if there was, you know, a body of evidence
10 that had been -- you know, where there was -- you know, it wasn't
11 just this was the first study and it didn't -- that -- if there was a
12 consistent body of evidence that showed an association between
13 PCB levels and likelihood of metastasis, then I don't think -- I don't
14 necessarily know that it would -- how it -- how the final decision
15 would be made at this point in time given the criteria that we --
16 that started with. I can say, as someone in the cancer field, this is
17 not something that -- you know, the effect of environmental
18 exposures on likelihood of metastasis or likelihood -- you know, or
19 on -- or even on survival after diagnosis is not an area that's been
20 really well-researched, so it's not something where I think one
21 would readily find a body of literature or a lot of precedents about
22 how that type of data was handled in, you know, regulatory or
23 advisory bodies. But -- but certainly -- you know, I think if there
24 was a solid body of evidence showing that a particular exposure
25 that was present at the World Trade Center, you know, was
26 associated with an increased likelihood of metastasis, then maybe
27 one could -- one could even think about including, you know, more
28 advanced cases of particular diseases in the category as World
29 Trade Center-related conditions.

30 So are there any further comments before we bring this motion to
31 a vote?

32 **UNIDENTIFIED:** Just wanted to answer the question, I don't believe
33 there were any women studied by Edelman. I could be wrong --

34 **UNIDENTIFIED:** Yes.

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UNIDENTIFIED: -- it wasn't indicated.

UNIDENTIFIED: I think you're right. I'm looking at it right now.

UNIDENTIFIED: Yeah, I am, too, and they don't mention anything at all about gender.

UNIDENTIFIED: Gender, yeah.

UNIDENTIFIED: So, just to clarify.

DR. WARD: Okay. So any further comments or questions before we call for a vote?

(No response)

DR. WARD: Okay. Paul?

DR. MIDDENDORF: Okay. The motion before the Committee is 'The Committee recommends adding breast cancer to the list of covered conditions.'

Okay, Tom Aldrich?

DR. ALDRICH: Yes.

DR. MIDDENDORF: Steve Cassidy?

MR. CASSIDY: Yes.

DR. MIDDENDORF: Valerie Dabas?

MS. DABAS: Yes.

DR. MIDDENDORF: John Dement?

DR. DEMENT: No.

DR. MIDDENDORF: Kimberly Flynn?

MS. FLYNN: Yes.

DR. MIDDENDORF: Bob Harrison?

DR. HARRISON: No.

DR. MIDDENDORF: Catherine Hughes?

MS. HUGHES: Yes.

DR. MIDDENDORF: Guille?

MS. MEJIA: Yes.

DR. MIDDENDORF: Julia Quint?

DR. QUINT: Yes.

DR. MIDDENDORF: Bill Rom?

DR. ROM: No.

DR. MIDDENDORF: Susan Sidel?

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MS. SIDEL: Yes.

DR. MIDDENDORF: Glenn Talaska?

DR. TALASKA: No.

DR. MIDDENDORF: Leo Trasande?

DR. TRASANDE: Yes.

DR. MIDDENDORF: Virginia Weaver?

DR. WEAVER: No.

DR. MIDDENDORF: Liz Ward?

DR. WARD: No.

DR. MIDDENDORF: Okay. Okay, I have nine yes and six no. The motion would carry.

DR. WARD: Okay, so now what we --

DR. MIDDENDORF: Liz, before moving on, I need to clarify one thing. A question for Bob Harrison, your vote on motion number five, 'The Committee recommends adding brain cancer to the list of covered conditions' -- could you restate your vote? I mean it doesn't make a difference in terms of the outcome, but it does make a difference in terms of being sure that we're accurate.

DR. HARRISON: Yes, that was yes.

DR. MIDDENDORF: It was yes. Okay, thank you. Back to you, Liz.

DR. WARD: Okay. So as I understand it, what we need to do now is really draft the text providing the rationale for recommending that breast cancer be listed as a World Trade Center-related condition. And maybe some of the Committee members that voted yes could try to give Paul some language that he could incorporate into the document, hopefully modeled along -- you know, I mean similar to the kind of information that we provided for the sites that were initially included.

(Pause)

DR. WARD: So I guess one rationale was that several of the -- well, I guess one big part of the rationale is that the li-- you know, that much less is known about occupational/environmental causes of breast cancer than other cancers because very few studies have been done in women. That was one -- in women in industrial

1 occupations. That's one point. I don't know if it would be the first
2 point.
3 Paul, are you trying to get this?
4 **DR. MIDDENDORF:** Yeah, I'm trying to find out where you are at
5 the moment.
6 **DR. WARD:** Well, we're nowhere because we're adding a new
7 cancer site -- I mean --
8 **DR. MIDDENDORF:** So do you want this at the bottom of the list?
9 **DR. WARD:** Right.
10 **DR. MIDDENDORF:** Okay, for option two.
11 **DR. WARD:** Well, yeah. I mean I guess we want to put it before --
12 **DR. MIDDENDORF:** Do you want to draft that now or do you want
13 to work on the other two possible motions?
14 **DR. WARD:** What other two possible motions?
15 **DR. MIDDENDORF:** One on...
16 **DR. WARD:** I mean, as I recall, there were -- I mean, at least with
17 regard to cancer sites, there were three possible motions, two of
18 which we voted no and one of which we voted yes, which is breast.
19 So --
20 **DR. MIDDENDORF:** I guess I was thinking of the rare cancer and
21 childhood cancer.
22 **DR. WARD:** I was assuming that that was included in the --
23 **DR. MIDDENDORF:** Included in the larger list?
24 **DR. WARD:** I thought so. Was everyone else --
25 **DR. MIDDENDORF:** Okay, rare cancers is there, childhood cancers
26 is there, yes. They are there. Okay.
27 **MS. DABAS:** Yes, but -- this is Valerie -- I don't think we -- I think
28 there was some questions about the definition of rare cancers that
29 was brought up on email.
30 **DR. WARD:** There were -- well, I don't recall. I mean does anybody
31 have a problem with the way it -- it's not specifically defined here.
32 If you look at -- in the cover letter, and then if you -- I mean in the
33 cover letter it's not -- a specific cutoff isn't given. But if you go
34 back and look at the supporting document -- I'm trying to find it, I

1 think on page 27. So basically what it -- what it's saying on page 27
2 is that it's acknowledging that there's lots of different ways that
3 cancers are classified. Most commonly in epidemiologic studies
4 they're classified by organ site of origin, but they're -- all cancers
5 that are diagnosed are -- have essentially two major classifications.
6 One is with regard to the organ site and the other is with regard to
7 the histology. So for exam-- and the two examples we cited here
8 are -- so for vinyl chloride (indiscernible) exposure, the cancer site
9 that was most strongly associated with it was angiosarcoma of the
10 liver, which is a specific histological site, distinct from the more
11 common type of liver cancers, although ultimately it turned out
12 that vinyl chloride was associated with the common type as well,
13 but similarly for bis(chloromethyl) ether, it was really a cluster of
14 small cell carcinoma or oat cell carcinoma that was associated with
15 that specific chemical. So what we're saying here is that we would
16 really want the classification of rarity to be based either on site or
17 site plus histology to allow for that. We're also saying that we
18 would want the classification of rare cancers to be based -- you
19 know, based for -- based on a patient's age, gender. For example,
20 breast cancer in men would be rare; it wouldn't be rare in most age
21 groups in women. So I think the idea here was to give the program
22 general guidance, but not to specify -- I mean there were some
23 email conversations that, you know, 15 per-- you know, you
24 wouldn't want to classify 25 percent of cancers that happen in the
25 United States as rare. But I think we were trying to give the
26 program some general guidance, and then they would
27 operationalize the guidance. But the idea would be to be really
28 inclusive of various options by which a cancer could be called rare.
29 **MS. DABAS:** Okay, thank you. Sorry, I didn't see that part --
30 portion of the -- that included the age. Sorry.
31 **DR. WARD:** So -- but -- so before we go into the rationale for
32 adding breast, are there any other motions that people want to
33 bring to the floor before we work on the language for the breast
34 rationale, and then we work on -- we ask for any factual errors that

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were found in the documents, any editorial suggestions?

MS. DABAS: Hi, it's Valerie again, I'm sorry. I just -- I wanted to get a vote on the prostate cancer and the rationale behind why we chose to exclude the prostate cancer. The three rationales that we used was IARC was -- which I believe prostate is on there in the second section of that. Also we used epidemiological studies and it appeared in the fire department studies, and we all are aware that it will appear in the other two studies that are coming shortly. And then when it goes to biological plausibility as far as inflammation and so forth, I think that -- you know, it fit two -- at least two of the three criteria that we put -- fit at least in two categories and for others all it needed to do was fit in one, so I think that -- I'd like to see a vote on the prostate cancer as well as some discussion on the rationalization for removing it.

DR. MIDDENDORF: I think the vote has already taken place.

DR. ALDRICH: This is Tom Aldrich. It's not right that the fire department say is positive for prostate. Actually it was -- did not show increased prostate when compared to the high-exposed firefighters.

DR. WARD: Yeah, and I picked it up initially because I was really using -- I didn't want to -- I wanted to put things on the table and not screen them out so, you know, there was one positive signal for prostate cancer which was the comparison of exposed to the general population, but then when you went deeper the evidence really was not -- evidence was really not in favor of the prostate cancer association. So I think, you know, that the -- that what Paul is saying is that the motion to exclude prostate cancer has already carried and there was discussion around that motion, so that this motion is not really in order at this point in time.

MS. DABAS: I'm not sure that's the case. I believe that the motion that was put was to include everything else but prostate, but it wasn't to specifically exclude prostate. And I think I would like to see a vote on the record as to the exclusion of prostate as well as some justification on the record for that.

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DR. WARD: Okay, Paul, what is your recommendation?

DR. MIDDENDORF: Well, we've -- to revisit prostate we'd need a motion to reconsider that vote.

MS. DABAS: It's Valerie, and I would like to put a motion to reconsider the prostate -- inclusion of prostate.

MS. HUGHES: Second -- Catherine Hughes.

DR. WARD: So I think, though, what Paul is saying is that -- and I'm not saying we should do this, but I think Paul was saying to reconsider the prostate we would have to reconsider the entire vote on including the entire list and the modification of eye. Is that what you're saying, Paul?

DR. MIDDENDORF: I think we can just reconsider -- basically I was -- an amendment to that that removed prostate, so I think we can go ahead and -- hold on just a second.

Motion would be to reconsider the entire previous vote because prostate was specifically excluded.

MS. DABAS: Paul, what I'm asking is that we vote to consider prostate; not to reconsider the motion, but to -- to vote for the inclusion of prostate cancer.

MS. HUGHES: Catherine, second it, just prostate only, though.

DR. WARD: So Paul, are you comfortable with just taking that vote for the record?

DR. MIDDENDORF: Yeah, I -- I think we can do that. So let's -- restate that motion. What is the motion?

MS. DABAS: The motion is to approve prostate cancer as part of this recommendation.

DR. MIDDENDORF: Being the -- 'The Committee recommends adding prostate cancer to the list of covered conditions'?

MS. DABAS: Yes.

DR. WARD: And we have a second?

MR. CASSIDY: Steve Cassidy, second.

DR. WARD: So is there any further discussion on the motion?

DR. DEMENT: Yeah, this is John Dement. Can I speak, please?

DR. WARD: Yes.

1 **DR. DEMENT:** You know, I think we do have some inconsistency in
2 the approach with regard to prostate cancer, and I think the prior
3 vote tied it in with the all -- approving the entire list, and also we
4 had the eye cancers in there. And I personally was torn with that
5 decision, and I think if we apply our rationale -- and the rationale
6 has to do with exposures to arsenic and cadmium, among other
7 things -- then I think prostate is legitimately one that ought to be
8 considered.

9 **DR. WARD:** Okay. Anyone else who would like to have discussion
10 before we vote?

11 **DR. WEAVER:** Virginia Weaver, and I have some concerns about
12 prostate because we could do more harm than good. In this
13 current environment where there's so much concern about the
14 appropriate technique to screen for prostate, and we know that we
15 pick up cancers that may never actually become metastatic and
16 cause significant disease but the surgery can be quite disabling, I
17 have concerns about including a cancer when there's less certain
18 evidence and concerns about the screening approach.

19 **DR. TALASKA:** Glenn Talaska, I have to chime in here, too. I think
20 my reservations with prostate cancer have to do with the one
21 carcinogen that we -- that is known to be a prostatic carcinogen
22 and that's cadmium. And again, going back to the Edelman data
23 with all their flaws, the levels of cadmium -- which has a very long
24 half-life -- in the firefighters at the site was lower than the
25 firefighters who never entered the site, and they were both
26 relatively low levels of cadmium. So that exposure -- you know,
27 they weren't anywhere near elevated, compared even to
28 population levels. And they were lower in the firefighters who
29 entered the World Trade Center than those who were -- who never
30 entered it and were used as the control group for that study. So it
31 would take away that one exposure that we have any exposure
32 data on.

33 **DR. WARD:** This is Liz -- no, go ahead.

34 **MS. FLYNN:** I'm sorry, this is Kimberly. I do want to point out,

1 however, that arsenic is also linked with prostate cancer and that,
2 again, the absence of data does not indicate the absence of
3 exposure. So Edelman didn't capture arsenic.

4 And the second thing I want to say is, while I understand Virginia's
5 hesitations, I think that those fall outside of the purview of the
6 STAC. I think those issues of screening and whether or not, you
7 know, there would be too many surgeries, all come under the
8 purview of implementation of those implementing STAC
9 recommendations.

10 **MR. CASSIDY:** Steve Cassidy.

11 **DR. WARD:** Go ahead.

12 **MR. CASSIDY:** I agree with that last comment about being
13 concerned about surgeries. I mean I don't think that has anything
14 to do with our decision. It may be a legitimate concern, but has
15 nothing to do, in my view, with whether or not we consider
16 prostate cancer being included.

17 And the other comment is that I'm certain not being at the World
18 Trade Center was better than being at the World Trade Center,
19 whatever those reports indicate about cadmium. That doesn't
20 make any sense whatsoever.

21 **DR. WARD:** Yeah, this is Liz, and I guess, you know, the things that
22 are weighing on my vote is the fact that the -- you know, the
23 epidemiological data for cadmium and arsenic in prostate is
24 relatively weak, and essentially the study of firefighters was
25 essentially a negative study, not showing an association with
26 prostate cancer and the fact that we really have very little previous
27 evidence of prostate cancer being associated with
28 occupational/environmental exposure, so I guess -- you know, in
29 my mind the -- that the ration-- you know, the rationale for
30 expecting that there will be an association is relatively weak
31 compared to many of the others. And -- yeah, that's basically
32 where I'm coming from.

33 **MS. SIDEL:** Hi, it's Susan Sidel. May I ask a question?

34 **DR. WARD:** Sure.

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MS. SIDEL: What is the average age for prostate cancer, because for some reason in my mind I thought it was like older men and we were seeing it in younger men, that that was one issue. And that the other issue was that -- I remember someone coming in to testify about how seclusive (sic) it was in her father's case and that usually it's -- it doesn't -- it's not quite as rapid of a progression as what happened with her dad. And I was wondering if that -- you know, if there's somehow we can carve out like exceptions to general rules, or is that getting into policy?

DR. WARD: Well, that's why -- you know, that's why we talked about age in the rare cancer thing, so -- so if some -- you know, rates of prostate cancers start going up once you hit about age 45, you start getting an increase in incidence of prostate cancer. So our recommendation was that the program really take age into account, and so if someone is diagnosed with prostate cancer at age 30, then they're -- you know, you would look at the expected incidence of prostate cancer at let's say age 20 to 30 or 30 to 40 as your definition of a rare cancer. So that was specifically -- I mean so that -- so someone diagnosed with prostate cancer at a really early age would be picked up by the rare cancer.

MS. SIDEL: Right.

DR. WARD: But the other thing is, you know, comparing the average age at which cancer is diagnosed is a really tricky business. So for example in the firefighters' study they excluded everyone over age 60 from the study, and the vast majority of people in the population were much younger than 60, so it almost -- it almost has to be true that the average age of diagnosis of prostate cancer would be much lower than in the general population 'cause you didn't have anybody over the age of 60 in that study.

MS. SIDEL: Yeah, so it gets skewed, yeah.

DR. QUINT: This is Julia. In addition to the LeMasters' meta-analysis of firefighters and showing -- I think it was, you know, 1.28 increase of prostate cancer, the IARC also did a meta-analysis after the LeMasters study which included two new epidemiological

1 studies and also found, again, an increase in prostate cancer.
2 That's in Volume 98 of the monograph.
3 So it seems that, you know, you keep finding prostate cancers
4 among workers -- firefighters in this case -- who have, you know,
5 the exposure to some of the same things that were -- just but more
6 so at the World Trade Center. So I know this has been used to sort
7 of indicate that firefighters have, you know, a propensity for
8 prostate cancer, and it wasn't increased based on the World Trade
9 Center exposures, and I would say that possibly we didn't see any
10 increase because, you know, these -- they're having these
11 exposures all the time and it's increased their -- the rate of
12 prostate cancer. So I'm going on the basis of like -- typical -- you
13 know, all of these mixtures of exposures literally being related to
14 an increase in prostate cancer based on lots of studies now, two
15 meta-analyses and lots of epidemiological studies and you -- it just
16 won't go away. So it seems to me there is something there.
17 **MS. HUGHES:** Catherine Hughes here. Is brain cancer considered a
18 rare cancer?
19 **DR. WARD:** Well, I mean the -- well, the -- you know -- well, it's a
20 lot rarer than lung and prostate and colorectal and breast. Again,
21 where you draw the line -- you know, I'm not sure where it will fall
22 when you draw the line, but it -- like I say, it is a fairly uncommon
23 cancer compared -- in most age groups compared to many of the
24 others we're talking about.
25 **MS. MEJIA:** This is Guille. I really do have a concern about voting
26 for prostate cancer when in a prior motion we had already voted to
27 exclude it, so I just wanted to chime in.
28 But the other thing is that we have to also consider a lot of
29 surveillance that has taken place with prostate cancer and all the
30 initiatives that have been undertaken by many public health
31 departments and organizations to increase awareness of prostate
32 among the male population, so -- you know, so there's -- there's
33 going to be a lot more people -- a lot more men identify with
34 prostate as a result of some of these screenings.

1 **DR. WEAVER:** This is Virginia, and I think that's a very good point.
2 Bob Harrison had made that, that surveillance bias for prostate
3 cancer is probably a big contributing factor to the increased rates
4 that are observed in men. And once again it just makes me
5 anxious, if we're not sure exactly how we should be screening and
6 when we should be doing surgery, that we could do more harm
7 than good.

8 **DR. WARD:** Yeah, I think that the surveillance bias makes it really
9 very hard to interpret epidemiologic studies for prostate. It --
10 because even if you look at the long-term incidence rates for
11 prostate over time in the U.S., there's this huge peak in incidence
12 when the PSA screening was introduced. And what's even stranger,
13 there's also a little peak in mortality, and I -- we think it's just --
14 that peak in mortality is not really due to more men dying of
15 prostate cancer, it's just that when physicians were filling out the
16 death certificates, you know, their awareness of prostate cancer
17 and -- was increased and they -- and more cases were getting
18 diagnosed so they were being included on the death certificate, but
19 they weren't really -- it wasn't that more men were dying of
20 prostate cancer. So when you have one of these cancers that is so
21 influenced by -- you know, there's such a large reservoir of
22 prostate cancers in men that are not systematic and would not be
23 diagnosed, except for the PSA test, that it just makes it incredibly
24 hard to do, you know, good epidemiologic studies.

25 **MS. DABAS:** Hi, this is Valerie. I mean I think that we -- my
26 understanding is FDNY takes the PSA test, regardless, anyway. So if
27 you're looking at the World Trade Center group, this was
28 something that they were doing ordinarily prior to, so I'm not sure
29 how surveillance bias falls into a group that was already getting
30 monitored, especially when they're looking at another group in a
31 similar circumstance.

32 **DR. WEAVER:** This is Virginia. And that's why there's an increased
33 rate in both the exposed and unexposed firefighters 'cause both of
34 them have been screened for prostate cancer.

1 **MS. DABAS:** But I assume that there's a difference in the rate
2 between the exposed and the non-exposed, and that's what we're
3 looking at.
4 **DR. WEAVER:** The rates are pretty similar. They're both elevated.
5 **MS. DABAS:** But to a different degree.
6 **DR. WARD:** No. Well, does anybody have the study in front --
7 **DR. ALDRICH:** (Unintelligible), I mean the rates are statistically
8 identical. The SIR ratio, which is the ratio of the SIR for the
9 exposed to the SIR for the unexposed, was 1.11 with a confidence
10 interval in the range of some .77 to 1.59. You can't get closer to
11 one than that. There's no dif-- there's no statistical difference,
12 there's no meaningful difference, in those rates.
13 **DR. MIDDENDORF:** And that's Tom Aldrich speaking.
14 **DR. ALDRICH:** I'm sorry, I should have identified myself.
15 **MR. CASSIDY:** Does anybody have any information on studies that
16 would outline how long after an exposure that people would
17 expect to get prostate cancer?
18 **DR. MIDDENDORF:** And that's Steve Cassidy.
19 **MR. CASSIDY:** That's Steve Cassidy, yes.
20 **DR. ROM:** This is Bill Rom, and I'm just signing off and turning my
21 vote over to Tom Aldrich 'cause I have a grand rounds speaker to
22 introduce, but I think that prostate is the problem of over-
23 diagnosis, with no occupational association.
24 **DR. MIDDENDORF:** Unfortunately, Bill, if you leave you cannot
25 have someone vote as a proxy for you.
26 **DR. WARD:** That does bring up the issue. It is now five minutes to
27 5:00 and, you know, we are in danger about those people who have
28 other commitments have to leave. So I -- with regard to Steve's
29 question, though, I think -- I mean I haven't done a literature
30 search on that specific point, but there are so few studies
31 documenting what the causes -- you know, documenting clear
32 causal factors for prostate cancer that it would -- you know, I don't
33 think you'd find studies that were able to define what the length of
34 time was between the exposure and the outcome. 'Cause for that,

1 you really need a pretty strong effect, so I don't think that data is
2 going to be available.
3 So I guess the que-- are there any other points on the prostate
4 cancer question that haven't, you know, been covered in one way
5 or another that anyone would like to see, and if not, I think we
6 should call this for a vote because we do want to make sure that
7 we have time to, as a Committee, draft the rationale for the breast
8 cancer inclusions before people have to leave, because every -- you
9 know, essentially everything -- you know, everything that's in this --
10 we have to draft, as a Committee, everything that's going in this --
11 in this letter to Dr. Howard. So are there any pressing issues
12 related to prostate cancer that have not already been covered?
13 **DR. TRASANDE:** This is Leo Trasande. I move to vote.
14 **DR. WARD:** Okay. Paul, go ahead with the vote.
15 **DR. MIDDENDORF:** Okay. Tom Aldrich? Oh, I need to restate the
16 motion. The motion is 'The Committee recommends adding
17 prostate to the list of covered conditions.'
18 **DR. ALDRICH:** I vote no.
19 **DR. MIDDENDORF:** Tom Aldrich, no. Steve Cassidy?
20 **MR. CASSIDY:** Yes.
21 **DR. MIDDENDORF:** Valerie Dabas?
22 **MS. DABAS:** Yes.
23 **DR. MIDDENDORF:** John Dement?
24 **DR. DEMENT:** No.
25 **DR. MIDDENDORF:** Kimberly Flynn?
26 **MS. FLYNN:** Yes.
27 **DR. MIDDENDORF:** Bob Harrison?
28 **DR. HARRISON:** No.
29 **DR. MIDDENDORF:** Catherine Hughes?
30 **MS. HUGHES:** Yes.
31 **DR. MIDDENDORF:** Guille Mejia?
32 **MS. MEJIA:** Yes.
33 **DR. MIDDENDORF:** Julia Quint?
34 **DR. QUINT:** Yes.

1 **DR. MIDDENDORF:** Bill Rom?
2 **DR. ROM:** No.
3 **DR. MIDDENDORF:** Susan Sidel?
4 **MS. SIDEL:** Yes.
5 **DR. MIDDENDORF:** Glenn Talaska?
6 **DR. TALASKA:** No.
7 **DR. MIDDENDORF:** Leo Trasande?
8 **DR. TRASANDE:** No.
9 **DR. MIDDENDORF:** Liz -- Virginia Weaver?
10 **DR. WEAVER:** No.
11 **DR. MIDDENDORF:** Liz Ward?
12 **DR. WARD:** No.
13 **DR. MIDDENDORF:** Okay, I have eight no and seven yes. The
14 motion does not carry.
15 Liz, I was wondering if we might want to take a very short break to
16 let people do whatever they need to for five minutes and then
17 come back?
18 **DR. WARD:** That's fine with me.
19 **UNIDENTIFIED:** I actually object. I actually am going to have to get
20 off this call fairly soon, and I'm actually concerned about quorum --
21 **UNIDENTIFIED:** And I'm --
22 **UNIDENTIFIED:** -- (unintelligible) fifteen.
23 **UNIDENTIFIED:** -- going to be kicked out of my space at 5:00
24 o'clock.
25 **DR. WARD:** Okay, so let's --
26 **DR. MIDDENDORF:** Let's proceed on then.
27 **UNIDENTIFIED:** Thank you very much.
28 **DR. WARD:** So we need a -- at least let's get the bullet points down
29 for what the main reasons for which the Committee is
30 recommending that breast cancer be included are.
31 **DR. QUINT:** Well, I think one reason is the -- there are some
32 studies showing a positive relationship between levels of PCBs in
33 both sera and tissue, mammary tissue, and increased risk of breast
34 cancer. I can quote -- I mean I have -- I can get some -- you know,

1 it's not -- the studies are not consistent, but there are some
2 positive studies showing that relationship.
3 **DR. WARD:** Okay. And I think we should include, since I know that
4 there's a large volume of literature, I think it would be appropriate
5 to cite --
6 **DR. MIDDENDORF:** Okay, I need to get that last thought down.
7 What is it, some studies correlating PCBs and what?
8 **DR. QUINT:** Breast cancer.
9 **DR. MIDDENDORF:** Breast cancer, okay.
10 **DR. QUINT:** Liz might be able to -- you're more familiar with the
11 data, but I do have -- I mean would you state that differently?
12 **DR. WARD:** I would guess I'd have to say: However, evidence is
13 conflicting. Because --
14 **DR. QUINT:** (Indiscernible)
15 **DR. WARD:** -- (Indiscernible) some studies that don't find an
16 association.
17 **DR. TALASKA:** This is Glenn. There is some evidence of exposure
18 to PCBs in the World -- at Ground Zero and in the World Trade
19 Center. There was -- the window film showed it and there was also
20 -- some people were posi-- had higher -- there was PCBs in some
21 samples.
22 **DR. QUINT:** And then I think the lack of --
23 **DR. MIDDENDORF:** What kinds of samples, Glenn?
24 **DR. TALASKA:** Biological samples. I don't remember what the --
25 there were air samples -- window films, and there were some --
26 one or two congeners that were elevated in blood samples.
27 **DR. MIDDENDORF:** Do I have this correct? 'Evidence of exposure
28 to PCBs in air samples --
29 **DR. TALASKA:** Window films.
30 **DR. MIDDENDORF:** -- films --
31 **DR. TALASKA:** And in some blood samples, and that would be -- let
32 me try to find the --
33 **DR. WARD:** I think it maybe is the Dahlgren study.
34 **DR. TALASKA:** That's right, Dahlgren, thank you.

1 **DR. WARD:** And that's on page 17.
2 **DR. TALASKA:** Yeah.
3 **DR. MIDDENDORF:** Okay.
4 **DR. QUINT:** Then I think we should also add the 2010 study
5 showing that PCBs enhance the metastatic properties of breast
6 cancer cells, activating the Rho-associated kinase, the ROCK, that
7 was shown both in vivo and in vitro.
8 **DR. MIDDENDORF:** Can you say that again for me, Julia?
9 **DR. QUINT:** A recent -- a 2010 study showing that PCBs enhance
10 the metastatic properties of breast cancer cells by activating the
11 Rho-associated kinase, or R-O-C-K.
12 **DR. MIDDENDORF:** You're going way too fast for me.
13 **DR. QUINT:** Oh, I'm sorry.
14 **DR. MIDDENDORF:** Metastatic properties of breast --
15 **DR. QUINT:** Cancer cells.
16 **DR. MIDDENDORF:** Yes?
17 **DR. QUINT:** By activating R-h-o associated kinase.
18 **DR. MIDDENDORF:** R-h-o?
19 **DR. QUINT:** Uh-huh.
20 **DR. MIDDENDORF:** Okay.
21 **DR. QUINT:** Dash, associated kinase, R-O-C-K. And that was shown
22 in that study in vitro -- human breast cancer cells in vitro and also
23 in vivo. And I don't know if you need this, but the cells were
24 metastasized to bone, liver -- to bone, lung and liver.
25 **DR. WARD:** And Julia, if any of these studies is not available on the
26 site, will you send them to Paul?
27 **DR. QUINT:** Yeah, I have this -- this study was a free download so I
28 can send the study, the one I just mentioned, and I will send -- I
29 will try -- I probably can get the one positive study, and I'll look for
30 the others showing the association between PCBs and breast
31 cancer risks. The one I'm looking at now is Cancer:
32 Epidemiological Biomarkers, 2000, by a Canadian group, Harrison,
33 et al.
34 **DR. WARD:** Now -- I mean I think there's at least 20 studies that

1 have been done.
2 **DR. QUINT:** That's right, and about 20 negative ones, as well. I
3 don't know, I'm just saying, I know it's inconsistent.
4 **DR. WARD:** Yeah.
5 **DR. QUINT:** I think it's the endocrine-disrupting properties of PCBs
6 as well.
7 **DR. WARD:** I was really --
8 **DR. MIDDENDORF:** If you want something more, you need to give
9 me the words 'cause I don't want to put words in the Committee's
10 mouth.
11 **DR. QUINT:** Yeah, I -- let me find...
12 **DR. WARD:** Then we could probably say something like PCBs and
13 some other substances present at the WTC site --
14 **DR. MIDDENDORF:** I'm sorry, say that again.
15 **DR. WARD:** And some other substances --
16 **DR. MIDDENDORF:** Yes.
17 **DR. WARD:** -- at the WTC site are --
18 **DR. MIDDENDORF:** At the WTC site.
19 **DR. WARD:** -- are endocrine disrupters, therefore potentially could
20 (indiscernible).
21 **DR. QUINT:** And I think we should -- I don't know if you --
22 **DR. TALASKA:** Liz, it's Glenn. I have to ring off.
23 **DR. WARD:** Okay. Thanks, Glenn.
24 **DR. TALASKA:** Sure thing, bye-bye.
25 **DR. WARD:** And Julia, I think it probably should say some -- well, I
26 don't know if all PCB congeners are endocrine disrupters. I --
27 **DR. QUINT:** Right.
28 **DR. WARD:** -- think that some of them are estrogenic and some of
29 them are anti-estrogenic.
30 **DR. QUINT:** That's exactly right, so we'd have to -- I don't have
31 that in front of me, unfortunately. So maybe just saying -- the ones
32 that were linked to the breast cancer risk in this one study were
33 congeners 105 and 108 -- I'm sorry, 105 and 118, and 170 and 180.
34 **DR. WARD:** My suggestion would be not to include -- get to that

1 level of specificity --
2 **DR. QUINT:** Yes, right.
3 **DR. WARD:** -- because we're not going to have time to look at
4 other studies and --
5 **DR. QUINT:** Okay.
6 **DR. WARD:** -- (indiscernible) same thing.
7 **DR. QUINT:** Exactly.
8 **DR. WARD:** So with the sentence that you're typing, Paul, it could
9 be -- you could just -- '...endocrine disrupters, which potentially
10 could influence breast cancer risk.' And we could -- somewhere get
11 in there, 'Breast cancers are highly dependent on hormonal factors
12 and therefore endo...
13 **DR. MIDDENDORF:** On hormonal --
14 **DR. WARD:** Factors, or are highly related to hormonal factors,
15 therefore -- yeah. Therefore could be impacted by endocrine --
16 further to endocrine disrupters.
17 Then I think our next point could be that there's varying -- you
18 know, that the opportunities to identify (indiscernible) related to
19 occupational exposures --
20 **DR. MIDDENDORF:** To identify what related to occupational
21 exposures?
22 **DR. QUINT:** Increased breast cancer risks.
23 **DR. WARD:** Yeah.
24 **UNIDENTIFIED:** It's not showing up on the screen -- on the
25 computer screen.
26 **DR. MIDDENDORF:** Can you see it now?
27 **DR. QUINT:** Yes.
28 **DR. MIDDENDORF:** Okay.
29 **DR. QUINT:** To identify breast cancer risks, right?
30 **DR. WARD:** Right, related to occupational exposures have been
31 extremely limited due to small numbers of women in industrial
32 occupations.
33 **DR. MIDDENDORF:** Small numbers of women...
34 **DR. WARD:** In industrial occupations and/or -- yeah, in

1 epidemiologic studies of industrial populations.
2 **DR. MIDDENDORF:** You'll have to restate that -- small numbers of
3 women in --
4 **DR. QUINT:** Included.
5 **DR. WARD:** It's due to small numbers of women in industrial
6 population studies.
7 **DR. MIDDENDORF:** Industrial population studies?
8 **DR. WARD:** Yeah, that's good.
9 **DR. MIDDENDORF:** Okay.
10 **DR. WARD:** Okay. Are there any other points in the rationale that
11 we should include?
12 **MS. SIDEL:** Hi, it's Susan Sidel. Do we want to say anything about
13 the lack of studies on women in this program generally?
14 **DR. WARD:** Not sure that's a part of the scientific rationale for
15 recommending --
16 **MS. SIDEL:** Okay, you're right.
17 **DR. WARD:** -- be included.
18 **MS. SIDEL:** Okay.
19 **DR. WARD:** Okay, are there any more points on that, or Paul can
20 take -- I think Paul can take the language that he's got and -- and
21 references sent by Julia and finalize the rationale for --
22 **MS. FLYNN:** This is Kimberly. Are you interested in the citation on
23 shift work, or is that not useful?
24 **DR. WARD:** I think we could add that as an additional bullet --
25 **MS. FLYNN:** Okay.
26 **DR. WARD:** -- included in the COPC list of potentially -- of potential
27 -- contamin-- while not included in the list of potential
28 contaminants of concern, it is known that, you know, shift work
29 was done at the World Trade Center site and IARC has found -- I
30 can't remember if it's 'limited' or 'sufficient' evidence for increased
31 risk of breast cancers associated with shift work involving -- I think
32 it's involving -- I forget, but I'll see if I can find it, but I think that
33 would probably be enough for the Committee to agree on. So Paul,
34 are you getting that?

1 **DR. MIDDENDORF:** No, my mind was elsewhere, I'm sorry. Do you
2 have another bullet, and what is the bullet?
3 **DR. WARD:** IARC has found -- then leave a blank for 'limited' or
4 'sufficient' 'cause I can't remember which, whichever one is correct
5 -- evidence for an association between breast cancer and shift
6 work. There was a little modifier of the shift work, but I think --
7 **DR. MIDDENDORF:** Wait a minute, you're getting too far ahead of
8 me.
9 **DR. WARD:** Between breast --
10 **DR. MIDDENDORF:** Between breast cancer and shift work -- okay.
11 **DR. WARD:** Then, period. It -- you know, both -- both -- I'm trying
12 to think -- both shift work and shifts of long duration were common
13 at the World Trade Center site. Yeah, were common at the World
14 Trade -- among personnel at the World Trade Center.
15 **DR. MIDDENDORF:** I'm sorry, what?
16 **DR. WARD:** Were -- among personnel involved in World Trade
17 Center rescue, recovery -- the list of -- list of categories of people
18 that were involved in the cleanup, the recovery, the rescue, the -- I
19 think Guille gave me that language for the first part. Right, Guille,
20 do you remember? Still here? Okay.
21 **DR. ALDRICH:** Do you want to know about a typo on the previous
22 page? Line 31, metastatic.
23 **DR. MIDDENDORF:** Such things are going to be able to be handled
24 by Liz. She can do copy editing after this. It's just that the content
25 has to be finished here in this meeting.
26 **UNIDENTIFIED:** Okay, I have what I think are pretty...
27 **DR. MIDDENDORF:** This is not finished -- both shift work and shifts
28 of long duration were common --
29 **DR. WARD:** Okay, so I'm looking for the --
30 **DR. ALDRICH:** -- at the World Trade Center.
31 **DR. WARD:** At the -- yeah, that's good enough, I think, for this. I
32 mean I just found the list of -- you know, the language that Guille
33 Mejia suggested was 'engaged in rescue, recovery, demolition
34 debris cleanup, and other related services.'

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DR. ALDRICH: Well, why be so specific?

DR. WARD: Yeah, we don't have to be that -- yeah.

UNIDENTIFIED: (Unintelligible) volunteers.

DR. WARD: Is everybody comfortable with the language as Paul has it typed now?

UNIDENTIFIED: Will you also be sending the Committee members a revision of this draft with the changes? What's the time frame for that?

DR. MIDDENDORF: When this meeting is over I'm going to save it. I will send it to the entire Committee. The Committee needs to commission Liz to make typographical and copy editing changes to whatever is here, but nothing more.

UNIDENTIFIED: Thank you very much.

DR. MIDDENDORF: Okay. There are some things here in the report that I think need to be edited out.

DR. QUINT: Not to mention the things that are not factually correct.

DR. MIDDENDORF: Well, on that problem we've got this note on, the text highlighted below does not reflect, and we don't want that.

DR. QUINT: I'm sorry?

DR. ALDRICH: (Unintelligible)

DR. MIDDENDORF: I'm sorry, on page three at the very top it says (reading) Please note that the text highlighted below does not reflect the final recommendation of the STAC. The text is for review by the Committee. We still take discussion of options for the recommendation and will be used as appropriate in the final draft to support the recommendations. So I'm assuming that you want that out.

DR. ALDRICH: Yes.

DR. MIDDENDORF: Is that correct?

DR. WARD: Yes.

DR. QUINT: Right.

DR. MIDDENDORF: All right. Option one was voted down. Do you

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want that out?

DR. WARD: Yes.

DR. QUINT: Yes.

DR. MIDDENDORF: So all of option one goes away.

DR. ALDRICH: Although at some point later on there was some reference to some members of the Committee supported more and -- no reason not to leave that in. Right?

UNIDENTIFIED: Yeah, I have to -- you know what, I wanted to comment on the option one because it raised like limitations of data and stuff like that, which is relevant. Like if you do a scientific experiment you talk -- have a limitations section, so some of it is relevant to the discussion, particularly when you talk about, you know, some of the evidence and -- you know, by -- you look at -- you can't delete all of option one.

DR. MIDDENDORF: Then you're going to need to go line by line and tell me what to delete and what not to delete, or what to change.

DR. WARD: So Paul --

DR. MIDDENDORF: Yes.

DR. WARD: -- I think for sure you want to keep the last paragraph in option one. Maybe we'll want to move it to the end.

UNIDENTIFIED: Perfect.

UNIDENTIFIED: I agree, that's really good.

UNIDENTIFIED: And what about the second to last paragraph about the findings of the FDNY study? So that's on page four, lines 4, 5 and 6. That should also be included.

DR. ALDRICH: I think that's discussed elsewhere and it doesn't advance this argument.

UNIDENTIFIED: Okay.

DR. WARD: Yeah.

DR. MIDDENDORF: Okay, I'm -- I need you to tell me exactly what to do.

DR. WARD: Okay, take that paragraph and then scroll to the --

DR. MIDDENDORF: This paragraph, 'In addition to the evidence...'?

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DR. WARD: Yes. Scroll on down to the end of the letter to Dr. Howard.

DR. MIDDENDORF: Go ahead. Scroll down?

DR. WARD: Yeah.

DR. ALDRICH: Page 28, more or less.

DR. WARD: Okay. So go back -- okay. So the question -- so maybe we move it right before the 'We appreciate the opportunity...' paragraph, and we need to figure out some way to make the transition.

DR. MIDDENDORF: So you want this paragraph removed from here.

DR. WARD: Yes.

DR. MIDDENDORF: You want it at this insertion point.

DR. WARD: I think so. So we just need to modify that first sentence so it's a more appropriate transition. Maybe something like: The Committee recognizes the limitations of existing evidence and the possibility that the presence of multiple exposures and mixtures could produce unexpected results. Something like that.

DR. ALDRICH: Well, it has to be something specifically related to the non-covered cancers.

DR. WARD: I think it's really the issue of acknowledging that they're -- we're making this recommendation in the light of considerable data limitations and uncertainties because --

DR. ALDRICH: The previous paragraph exactly leads into this. If this was -- rather than a new paragraph, part of the previous paragraph.

DR. WARD: What are you seeing as the previous paragraph?

DR. ALDRICH: (Reading) The Committee also recommends that, in addition to treatment of the listed cancers -- for the listed cancer sites, the health program provides funding and guidelines for medical screening and early detection based on a review of evidence regarding risks and benefits to the --

Oh, no, you're right, it doesn't -- it doesn't (unintelligible).

DR. WARD: And actually at the end of the paragraph we make

1 reference to the lack of epidemiologic data on female breast
2 cancer, so we probably need to take that sentence out now that
3 we've included breast.
4 **UNIDENTIFIED:** Right.
5 **DR. WARD:** So we need to take the last two sentences here out.
6 **DR. MIDDENDORF:** These two sentences?
7 **DR. WARD:** Yes.
8 **DR. MIDDENDORF:** Additional concern -- starting with 'An
9 additional concern' on line 14 and ending with 'reproductive organs
10 is limited' on line 18?
11 **DR. WARD:** Right.
12 **DR. ALDRICH:** You can leave that second to last sentence there.
13 That's not -- contradicts anything we've said before, and it's
14 relevant.
15 **DR. WARD:** Okay, so it's just the last one on breast.
16 **DR. ALDRICH:** Yeah.
17 **DR. MIDDENDORF:** So starting on line 16 with '(indiscernible)
18 availability' and going through 'is limited.'
19 **DR. WARD:** Right.
20 **DR. MIDDENDORF:** On line 18. Okay.
21 **DR. ALDRICH:** How about instead of -- at the beginning of that, the
22 second line of that paragraph, instead of saying 'arguments in favor
23 of listing all cancers', 'arguments in favor of listing additional
24 cancers'?
25 **DR. WARD:** Okay. But then we need to have a final sentence that
26 explains why we didn't, I guess. We could at the end say:
27 However, the majority of the Committee felt that --
28 **DR. ALDRICH:** Yeah, you're right.
29 **DR. WARD:** -- you know, the recommendations that were made
30 reflected the best available -- or kind of sound scientific rationale
31 and reflected the best available evidence at this time.
32 **DR. ALDRICH:** I like it.
33 **DR. MIDDENDORF:** What is it -- where and what?
34 **DR. WARD:** At the end of that paragraph --

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DR. MIDDENDORF: Yes.

DR. WARD: -- However, the majority of Committee members agreed that the recommendations made above have -- are based on a sensible scientific rationale and reflect the best --

DR. MIDDENDORF: Sorry, say that again.

DR. WARD: A sensible scien-- are based on a sound scientific rationale and the best -- and the best evidence available today.

DR. ALDRICH: That's good.

DR. WARD: Okay. Looks good to me.

DR. ALDRICH: Like it a lot.

DR. WARD: Good. So shall we move on to the --

DR. MIDDENDORF: How about if we go back up and look at option one. Does the rest of this go away?

DR. WARD: I think so.

DR. ALDRICH: Yep.

DR. MIDDENDORF: And with highlighted. You want this header, option two?

DR. WARD: No, that can go away, I think.

DR. MIDDENDORF: (Indiscernible) trying to do.

DR. WARD: Endnotes is horrible. Endnotes will hijack your document.

DR. MIDDENDORF: And she hung up.

DR. WARD: All right. Do you have a hard copy that you can write notes on?

(Pause)

DR. MIDDENDORF: Okay, back to doing business. Okay, so this -- at least I thought I was.

(Pause)

DR. MIDDENDORF: It'll pull up other documents but this one is hung up.

DR. WARD: Yeah, I mean and I do think you're at the point where maybe a hard copy would suffice 'cause I think all we're going to -- I mean I think all we need to do here is cross out the bold header and then --

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DR. MIDDENDORF: If you want to do that -- I mean you can work on that yourself.

DR. WARD: Well, I can't do it and share it with the Committee, so what I'm saying is we cross out the bold header, then instead of saying -- I would suggest amending -- the next sentence is 'The Committee recommends listing of the following site groupings and sites' -- and then we take out 'each to be discussed and voted on separately' -- 'be listed as World Trade Center-related conditions, based on the strength of the evidence summarized in Table 4 and additional evidence discussed below.'

And that's, I think, all you need to do.

DR. MIDDENDORF: Okay. Is that what the Committee wants?

DR. ALDRICH: I'm for it.

DR. WARD: That's fine.

UNIDENTIFIED: Sounds good to me.

DR. MIDDENDORF: I obviously can't do anything more with this document, so --

DR. ALDRICH: Well, I think the Commit-- this is Tom Aldrich. I think the Committee -- the sense of the Committee is -- we know what needs to be accomplished and we trust Liz to do it.

DR. WEAVER: This is Virginia. I agree.

MS. MEJIA: I agree, too. This is Guille.

DR. TRASANDE: This is Leo Trasande. I agree, and I also have to sign off at this point.

DR. DEMENT: This is John Dement, and I agree as well.

DR. QUINT: I agree -- Julia.

DR. HARRISON: This is Bob, I agree.

UNIDENTIFIED: (Unintelligible), I agree.

MS. FLYNN: This is Kimberly. I agree, but I have one question, which is any -- any small wording changes, are they still possible or not? I'm thinking of, for instance, adding the word 'survivors' to line 28. Possible?

MR. CASSIDY: This is -- in the interim -- this is Steve Cassidy. I agree.

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UNIDENTIFIED: I'm here right now, but they're kicking us out. It's almost 5:30, so you need me to vote on something?

DR. WARD: Well, I guess at this point -- Paul, I don't know that we have any choice but to --

DR. MIDDENDORF: I think we're likely below quorum at this point.

DR. WARD: Yeah, so we'll -- so Julia, if you're still on, can you send me a list of the factual changes -- or send it to the entire Committee, and I will go ahead and do fact-checking and incorporate them?

DR. MIDDENDORF: And whatever that is, we'll probably need to post that so that everyone can see, it's part of the open record.

DR. WARD: Okay, Paul, it may be down to just you and I.

DR. DEMENT: No, I'm -- this is John. I'm here, but I don't think we have enough to do anything.

DR. WARD: Yeah.

DR. ALDRICH: Tom Aldrich, I'm also here, but you know, it's -- we're pretty much done and I think you can handle the additional facts and changes and what-not.

DR. QUINT: Liz?

DR. WARD: Yes.

DR. QUINT: I'm sorry, my phone gave out so I was off for a minute.

DR. WARD: Oh, okay.

DR. MIDDENDORF: I think we're below the quorum.

DR. QUINT: Okay, 'cause I had some er-- there's some -- a couple of errors on page 15 --

DR. WARD: Okay.

DR. QUINT: -- that I wanted to call to your attention, but I guess it's too late now.

DR. WARD: Well, not necessarily. I think the Committee basically agreed that -- you know, that we can make those corrections --

DR. QUINT: Okay.

DR. WARD: -- so we would like you to put them in a list so that they can be shared --

DR. QUINT: Okay, that's fine.

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MS. HUGHES: I second it. Catherine Hughes seconds it.

DR. MIDDENDORF: I don't know that we have a quorum that could even vote on it, so...

DR. WARD: (Unintelligible) I don't know.

DR. QUINT: Yeah, my phone just completely went off. All right, I'll send you those.

DR. WARD: Thank you.

DR. MIDDENDORF: Send it to everyone, please.

DR. QUINT: I'm sorry?

DR. MIDDENDORF: Send it to everyone.

DR. QUINT: Oh.

UNIDENTIFIED: Liz, I have to check off also. I want to thank you and Paul for doing this, and we'll be in touch. Thank you.

DR. WARD: Great, thank you.

UNIDENTIFIED: I have to sign off, too. Thank you so much, Paul and Liz and everybody else on the Committee. Thank you very much.

DR. WARD: Thank you.

DR. MIDDENDORF: Yeah, we need to cut this off then. Thanks to everyone on the Committee. On behalf of the program I want to express a lot of appreciation for all the hard work under very strenuous conditions and think you've done an excellent job. Thank you very much.

UNIDENTIFIED: Thank you, Paul. Thank you, Liz.

UNIDENTIFIED: And thank you, Liz. Thank you so much. See you later, bye.

(Teleconference concluded at 5:32 p.m.)

This verbatim transcript of the WTC Health Program Scientific/Technical Advisory Committee, Committee Meeting held telephonically on March 28, 2012, has been reviewed for concerns under the Privacy Act (5 U.S.C. § 552a), and personally identifiable information has been redacted as necessary.

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I further certify that I am neither related to nor counsel to any of the parties herein, nor have any interest in the cause named herein.

WITNESS my hand and official seal this the 26th day of April, 2012.

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