

The series of emails below was exchanged between all members of the WTCHP Scientific/Technical Advisory Committee (except as noted) in preparation for the Committee's March 28, 2012 meeting. The Committee exchanged emails to develop a draft of the Committee's Report supporting the Committee's eventual recommendations to the WTC Program Administrator on the petition to add cancer or a type of cancer to the list of covered WTC-related health conditions. The Committee's Report will be discussed and deliberated upon, along with the Committee's final recommendations, during the March 28<sup>th</sup> meeting. The sender of the email is identified by bold and underlining. The date/time of the email is indicated below the sender's name. Any attachments, including draft report language, have been inserted with the emails they accompanied.

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**Elizabeth Ward (Committee Chair)**

Friday, February 24, 2012 6:02 PM

Dear WTC STAC Committee members:



Draft to Stac  
Committee Feb 24 20

As promised, attached please find a first draft of our response to Dr. Howard regarding the cancer petition and supporting documentation. The references are incomplete as my reference manager program has not been working remotely so I will have to add them when I'm back in the office next week.

Specific writing requests are highlighted in yellow for John, Glenn, Virginia, Bill, Tom, Steve M and Leo.

Requests for additional input from the committee on several topics are highlighted in yellow as well.

I hope everyone will provide comments on what is written so far and on any additional topics that should be covered.

Please return new text and comments to me as soon as possible, but no later than March 12. Please feel free to share comments with all members of the STAC Committee when you send them to me.

I will revise the document and get a draft back to you by noon on March 23.

If there are significant disagreements or issues related to the March 23 draft, I will highlight them in an email message so everyone will have the opportunity to think them over before the call.

**Guille Mejia**

Mon 2/27/2012 2:26 PM



Draft to Stac  
Committee Feb 24 20

Attached, please find the draft with my initial comments. I may have additional comments later on...

**Tom Aldrich**

02/27/2012 06:10 PM



Draft to Stac  
Committee Feb 24 20

Attached are my edits. I made extensive suggested revisions to the section on completed incidence studies (pages 10-12) and made a couple of edits to table 4, correcting an error in stomach cancer SIR ratio and adding melanoma SIR data.

**Bob Harrison**

Tue 2/28/2012 12:04 AM



BobHDraft to Stac  
Committee Feb 24 20

Nice work Liz. I made some minor edits in tracking mode (on top of Tom's).

My main comment is that we ought to add a table that shows the WTC exposures that are putative carcinogens. I think it's implicit in the text, but I think it would be helpful to actually have a list or table with references to the data that suggests these carcinogens were indeed present. As the rationale for recommending cancer treatment is based on the likelihood that these exposures occurred, I think this would strengthen the letter.

Another point - we don't mention the issue of latency or dose in terms of risk or stratifying groups. I believe we probably would not want to have a cutoff for duration or intensity of exposure, but the issue of latency might need to be discussed somehow. Right now the letter is silent on these 2 issues, and we could conceivably leave it that way if we don't want to tackle this head on.

**Julia Quint**

Tue 2/28/2012 9:56 AM



Cancer Recomm  
Draft EW 2 24 2012 J

Thanks for a great first draft and for getting it to us so quickly.

My edits on the letter are attached. I am still working on the remainder of the document. I will send the rest of my edits/comments as soon as possible.

**John Dement**

Tue 2/28/2012 10:58 AM

Thank you for all your efforts on behalf of our committee. I have attached an edited version with my suggestions. I added my edits to those provided by Tom and Bob. I have included the references which were discussed during our meeting.

**William Rom**

Wednesday, February 29, 2012 11:46 AM

Dear Elizabeth:

Really excellent first draft. I still have problems with the organ site list of cancers but think the justification exists for the sites in the letter and Tables—except for prostate which I favor deleting because of biological implausibility and any causative environmental or occupational exposures. I think that this is a surveillance effect. I added several lines on lung cancer and PM<2.5 microns.

**Bob Harrison**

Wed, 29 Feb 2012 19:46:17

>> I lean towards Bill's suggestion about prostate cancer. In my medical consultation on cases of firefighters who are covered under our California workers comp presumption law, I have not found evidence for occupational/environmental exposure and increased risk for prostate cancer.

**Valerie Dabas**

Wed 2/29/2012 3:18 PM

I would have to disagree, I do not believe we can compare the fire's in California with the toxic exposures at ground zero. From the meeting with the City Health Department last week regarding their

cancer study they reported an excess for prostate cancer of 43% among responder with a SIR 1.43, Mount Sinai has also reported an increase and the Fire study sufficiently reduced their initial finding of 32% to 14% for surveillance bias.

**Tom Aldrich**

Wed 2/29/2012 4:06 PM

Regarding prostate cancer, I think the jury is still out.

We can't use word of mouth re Mt Sinai and registry results----without seeing the full peer-reviewed results, we can't know how severe the problems were with selection bias and surveillance bias.

Regarding FDNY prostate cancer results, they seem to suggest that firefighting poses a risk of prostate cancer even in the absence of WTC exposure---SIR 1.35 with CIs that don't cross zero in the unexposed firefighters. That fits with prior studies that suggest a "probable" link between firefighting and prostate cancer with SIR estimated at 1.28, from metaanalysis of 13 studies (see LeMasters et al, JOEM 48:1189-1202, 2006).

The WTC-exposed FDNY group did not show an increased risk over unexposed, with estimated SIR ratio 0.90 (using correction for possible surveillance bias). The CI was predictably wide (0.62 to 1.30), so an increased risk from WTC exposure on top of firefighting occupation is not ruled out (nor is a decreased risk).

Given the uncertainty, I think we should not expect an answer from epidemiology, but rely on what's known in the toxicology realm regarding potential risk of prostate cancer relative to the toxins known to be present.

**Kimberly Flynn**

Wednesday, February 29, 2012 4:42 PM

I agree with Valerie. An expert present at the DOH briefing that Valerie referred to in her message said that we are seeing the signal of excess thyroid, prostate and blood cancers across 3 studies, with different methodologies and somewhat different, though not entirely distinct, cohorts. (This statement is not verbatim but very close.)

At the last STAC meeting, there was much discussion about the importance in our deliberations of what was unique in the WTC disaster as a polluting event, including its sheer scale. The collapse of massive skyscrapers and the resulting pulverization of their substance and contents, the uncontrolled combustion for many months (that among other toxics, emitted the largest ever recorded releases of dioxins), the range and intensity of exposures that occurred in the morning of 9/11, and also those that occurred for weeks, months and in the case of indoor environments, for years.

We know that responders and survivors were exposed simultaneously to complex mixtures, including multiple carcinogens, which have the potential to act synergistically. And most people were not wearing PPE when they were exposed. These exposures would seem to be different in nature and scope from the most firefighters' occupational exposures, as they appear to have involved higher concentrations and greater combinations of toxic substances and had much longer duration.

In its 2002 report on the WTC disaster, the Natural Resources Defense Council describes the WTC environmental disaster as 'an unprecedented environmental assault':

"The terror attacks on the World Trade Center, in addition to their heart-wrenching toll on human life and wide-ranging economic impacts, constituted an unprecedented environmental assault for Lower Manhattan. On that tragic morning, more than 1.2 million tons of building materials collapsed in the midst of one of the nation's most densely populated neighborhoods. An intense fire, fueled by thousands of gallons of jet fuel, spewed toxic gases into the air. Asbestos, used in the construction of one of the towers, rained down over the streets. Burning computers and other electrical equipment sent dioxins, mercury and other hazardous substances into the drifting plume. Vast quantities of dust, glass and pulverized cement were blown throughout the surrounding neighborhood. For more than three months after the event, acrid smoke continued to waft into the air. Dust particles continued to be dispersed throughout the neighborhood from the site's cleanup operations.

[...]

Exposure to pollutants from the World Trade Center attacks has come primarily in three phases. First, the collapse of the two 110-story towers and adjacent structures generated high-intensity, peak pollution discharges on September 11th. Second, fires from the crash of two fuel-filled airliners into the Trade Center towers and fires and the resulting smoke plume at Ground Zero following the towers' collapse created significant additional pollution discharges, which continued to some degree for at least three months.

Finally, the resuspension of asbestos, dust, pulverized cement, fiberglass etc., during the cleanup and transport of wastes at Ground Zero and in cleanups of residences and office buildings in the immediately surrounding area produced localized pollution hot spots. While addressed to some degree as of February 2002, such hot spots still pose problems in isolated locations (for example, improperly cleaned apartments and poorly cleaned building rooftops and ventilation systems in Lower Manhattan).

A major reason for concern is the large volume of toxic materials that was apparently

present in the World Trade Center towers. For example, by some accounts the north tower had as much as 300 to 400 tons of asbestos.<sup>5</sup> Also in the two towers were as many as 50,000 personal computers, each of which contained a wide variety of harmful constituents including four pounds of lead, as well as much lesser but still troubling amounts of mercury. The towers also contained 300 mainframe computers, and powering all these devices were hundreds of miles of wires and cables containing polyvinyl chloride and copper. The thousands of fluorescent lights used in the towers also contained mercury, a toxic metal. In addition, large amounts of fiberglass, used in insulation, were contained in the towers. To this must be added the unknown tons of plastics, which when burned produce harmful dioxins and furans; an unknown amount of painted or stained products and materials, which were one of many sources of volatile organic compounds within the destroyed buildings; and thousands of chairs and other office furniture containing such chemicals as polybrominated diphenyl ethers, which are persistent organic pollutants believed to pose dangers similar to PCBs. Additionally, several storage tanks containing petroleum products and a number of small hazardous waste-generating entities at the World Trade Center complex, which were destroyed on September 11th, added to the toxic mix.<sup>6</sup> And two Con Edison substations below 7 World Trade Center contained approximately 130,000 gallons of transformer oil contaminated with PCBs.<sup>7</sup> This listing is only illustrative and does not capture the full breadth of the toxic constituents that were dispersed into the environment on September 11th."

**Glenn Talaska**

Wed 2/29/2012 4:59 PM

Perhaps we need a discussion of the issue of increased surveillance and how it might impact the reported rate of prostate cancer. I believe there is a literature on the issue.

**Elizabeth Ward**

Wed 2/29/2012 5:49 PM



djp001.pdf



6604973a.pdf

As I think you all know, I wrote the draft document to reflect as best I could what I thought were the views of the committee, including the list of cancer sites generated from the general guidelines discussed at the meeting. I was intending to follow-up by sharing my views and/or background material on a few topics, so will start with prostate (and thyroid),

I too have qualms about including prostate cancer, for which the main usable evidence is the FDNY firefighter study results (I don't think we can consider the other studies until they're published or at least made available to us in a form that can be part of the public record, as some of the sampling reports were). (Note that in the draft that Tom edited, which was distributed last week, he fleshed out the description of the firefighter study and results).

The main reason I am concerned about including prostate based on the firefighter study results is that it is known to be a cancer that a lot of men have for a long time without any symptoms. This was originally learned from autopsy studies of men who died from other causes and were found to have cancers in their prostate. Many studies have found, and many doctors believe, that many of the men diagnosed with prostate cancer as a result of a positive Prostate Specific Antigen (PSA) screening test, which represent a significant proportion of all men diagnosed with this cancer, would have lived for a long time with the cancer before without developing any symptoms, including some who would have died of other causes before the cancer would be diagnosed. Thus, the surveillance bias issue is far more serious than it is for other cancers. The FDNY study did attempt to control for surveillance bias by setting a two year lag time for screenable cancer and also stated that the stage distribution was no different from the general population. I don't think 2 years is a long enough lag time for prostate cancer given what we know. The fairly technical articles I've attached would suggest to correct for surveillance bias would require lagging more like 5 - 10 years. The other issue is that the stage distribution will probably not be too informative with respect to surveillance bias, since 80% of men in the population are diagnosed at localized stage.

I also agree with Bill that (unlike lung cancer for example) there has not been much evidence for associations between occupational and environmental exposures and prostate cancer.

The decision of whether to include prostate is significant for a number of reasons:

- It is the most commonly diagnosed cancer, estimated to account for 241,000 of the 848,000 newly diagnosed cases among men in the US in 2012. Therefore coverage will have a significant impact on program resources.
- There is enormous controversy about the benefits of screening, early detection and treatment. Of two completed clinical trials of PSA screening, one showed a mortality benefit and one didn't. Pretty much all treatment options, except watchful waiting, are associated with significant short-and long-term side effects.
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Similar concerns could be raised about thyroid cancer. Although there is no screening test recommended, it is likely to be detected by a physician noticing a nodule on a clinical exam or be noticed in an ultrasound or CAT scan taken for other reasons. Like prostate, there is a fairly high prevalence of occult cancers at autopsy. It is a less common cancer than prostate, and less well studied,

so less direct evidence about what the lag time for surveillance bias should be. Similar to prostate, almost all are diagnosed at early stage, so comparison of the stage distribution would be unlikely to reveal an impact of surveillance bias.

Unlike prostate cancer, thyroid cancer has a well known environmental risk factor (ionizing radiation) which has been demonstrated both with respect to therapeutic radiation and I-131 contamination from nuclear fallout. The morbidity from treatment is significantly less than for prostate cancer but it's unclear at this point what proportion of cases really need treatment to avert death or progression to a more clinically significant cancer.

Although it is less common than prostate, the incidence of thyroid cancer is rising, it is estimated to account for 56,460 of the approximately 1.6 million cancers to be diagnosed in men and women in the US in 2012.

Look forward to hearing other opinions.

**Bob Harrison**

Wed 2/29/2012 5:51 PM

agree with Glenn - this topic has raised more discussion - maybe on our next call this should be an agenda item?

**Glenn Talaska**

Wed 2/29/2012 6:07 PM

I agree Liz. There are 2 compounds, arsenic and cadmium, which are associated with an increase in prostate cancer. Biological monitoring was done on 365 Firefighters both those who worked at the site and those who didn't for urinary cadmium. However, there was no bio measurement of arsenic. As I noted in my talk, but didn't embellish, unlike PAH, cadmium has a very long half life and if there was a significant exposure to it immediately after 9/11, the urinary levels would have remained elevated for some time. That was NOT the case and the firefighters who worked after 9/11 had urinary cadmium levels that were statistically significantly lower than FF who never entered the site. This is pretty good evidence that most workers at the site probably did not experience an exposure to cadmium right after. This reduces the biological plausibility for prostate cancer.

Two caveats:

Edelman did not show if there were any outliers in the cadmium data which would represent individuals who would have had a high exposure; if those persons exist and they developed prostate cancer I would

be in support of including them. In addition, less than 10% of all those who worked on the pile were sampled so we don't know anything about the range in the total population

Also, I can't say anything about arsenic since no samples were collected.

I hope this helps.

**Susan Sidel**

Wed 2/29/2012 6:54 PM

Initially, I was uncomfortable including prostate cancer because it is such a common cancer among men. But as I got more information, I realized it was a common cancer for *older* men, not for men in their 30's and 40's as was the case(s) in our population(s).

For me a compelling argument for including prostate cancer is twofold:

1. The average for age prostate cancer is 63 to 65. The FDNY and I believe the PBS/NYPD are seeing prostate cancer in WTC Responders that are in they're 30's and 40's. That is highly unusual, particularly in large numbers. And,
2. Ask yourself: Is it biologically plausible for to prematurely develop prostate cancer after being exposed to 72 different carcinogens, perhaps even all 72 carcinogens simultaneously; in the form of particles measured in micrometers or in aerosol form ... Heated by 25,000 liters of jet fuel and 200,000 gallons of oil and insulating fluid (stored underneath 7 WTC by Con Edison and Mayor Giuliani. Gonzalez, Juan. *Fallout*. The New Times Press. NYC. 2002

Cahill found petroleum burning in October 2001 one mile NW of Ground Zero where he was testing from a rooftop at 201 Varick Street.

**Guille Mejia**

Wed 2/29/2012 6:58 PM

Yes, we need to have this conversation on the 28th

**Elizabeth Ward**

Wed 2/29/2012 7:46 PM

Here is a table that shows the %'s of cancers diagnosed in each 10-year age for the major cancer sites. To see it, copy it into your browser.

[http://seer.cancer.gov/csr/1975\\_2008/browse\\_csr.php?section=1&page=sect\\_01\\_table.10.html](http://seer.cancer.gov/csr/1975_2008/browse_csr.php?section=1&page=sect_01_table.10.html)

(This is just one of the ways to look at cancers by age - and many more Tables in the SEER Cancer Statistics Review where it came from).

As you can see in this Table, although prostate cancer is most commonly diagnosed in older men, about 10% of patients are diagnosed under age 55. It is also important to remember that the average age of cancer diagnosis in any group will depend on the age group being studied. For example, the FDNY study was restricted to person-years under age 60 (i.e. once a person turned 60 their cancers and years of observation were no longer included in the study). For most adult cancers whose risk increases substantially with age, the average age in the FDNY study would have to be much lower than the average age in the general population. (If they had not restricted to age < 60 but 95% of their population was < 60 at the end of the study, you would still see a shift to younger average age among cancers diagnosed but it would perhaps be a little older).

Epidemiologic studies (including the FDNY study) look at the look at the number of cases observed in the study compared to the number expected based on age, sex and other characteristics. It's not possible to draw any conclusions about excess risks of cancer without that information. It is very important that all the populations that can be clearly identified (such as police ofdicers) be studied in this way.

**Guille Mejia**

Wed 2/29/2012 7:55 PM

Paul: I am just wondering if the email exchange

Presents a problem since the public is not being afforded

An opportunity to listen and provide comment. Regardless the coverage of

Prostate cancers has to take place

**Elizabeth Ward**

Wed 2/29/2012 8:01 PM

1. For the childhood cancers, we will need to agree on a definition. This link will bring you to a table of childhood cancers in the way they're usually grouped:

[http://seer.cancer.gov/csr/1975\\_2008/browse\\_csr.php?section=29&page=sect\\_29\\_table.01.html](http://seer.cancer.gov/csr/1975_2008/browse_csr.php?section=29&page=sect_29_table.01.html)

Sometimes they are defined as cancers occurring at age 0-14, other times 0-19 - we probably should specify.

2. I tried to find some definitions of rare cancers. I don't think there's one uniform definition. Part of

the problem is that there's lots of different ways to classify cancer. Here is one paper that looked at the issue.

**Bob Harrison**

Wed 2/29/2012 11:27 PM

According to the paper that Liz attached, about 1/4 of all cancers are "rare," as defined by fewer than 150 incident cases per million/year. I don't think that is what we meant by "rare" cancers - but maybe someone recalls the gist of our discussion around this issue.

**Paul Middendorf (Designated Federal Official) [sent to Guille Mejia]**

Thu 3/1/2012 7:18 AM

I think we're ok because the whole committee is acting as a working group in developing the document (which is how the committee decided to act during the first meeting in November), and working groups do not have to do their work in an open meeting. The whole document under consideration will be posted on the website several days ahead of time and will be presented and discussed in an open meeting. A synopsis of the discussions that will have taken place within the working group will need to be presented in the open meeting. The public will have their opportunity to make comments on the document, and at the meeting each member will have their opportunity to further discuss the document. What the working group cannot do is take a vote and decide the document is the "final version" until it is discussed in the open meeting. During the open meeting changes can be made to the document and then a vote can be taken.

I'm going to send something out to the whole group on this because if you're concerned, then likely others are, too.

**Susan Sidel**

Mar 1, 2012, at 8:13 AM

I second Valerie's concerns even though we are a "working group".

That said, I'm wondering if we are going to need another phone meeting (for just a few extra hours) to review our letter and continue our robust discussion and if so, we should set that up now.

Our thinking doesn't have to be "all or nothing" on prostate. If someone is young and sick with other WTC conditions, that particular early onset prostate cancer may be related to WTC exposure. We could have criteria. Also...we need to merge the document b/c several edits are not in later versions.

**Elizabeth Ward**

Thu 3/1/2012 8:19 AM

Bear in mind that we need to post a draft of our recommendations on March 23 so it is available to the public before the meeting on the 28th, and we will have only a few days after that meeting to produce the final document for Dr. Howard. If we are divided on the topic of whether to list prostate and thyroid, or other major issues, we may have to ask everyone where they stand and rewrite the draft with majority and minority opinions.

**Kimberly Flynn**

Thu 3/1/2012 9:36 AM

Thank you for your message, Liz, and for your very fine first draft. Only after seeing the draft along with recent emails from STAC members have the implications of the approach we discussed at the meetings become clearer for me.

Valerie said at our February meeting that she was not sure she agreed with the majority approach to including cancers until she saw the list of cancers recommended for WTC coverage. I feel the same way.

From our emails yesterday, you can see that a number of stakeholder reps, including myself, read the draft as recommending inclusion of prostate cancer (and, I'm assuming, thyroid cancer), based on the FDNY study. We know that the Sinai and DOH studies cannot be cited in the STAC's recommendation until those are published. But because we have all heard Dr. Landrigan's Feb 15 testimony and in addition, some of us were briefed by the DOH, I think we assumed that the data were trending in the direction of an excess of prostate, thyroid and blood/lymph cancers. (Sinai and DOH have controlled for surveillance bias in similar ways to the FDNY investigators, though I cannot tell you how many years delay each used in counting cases. Selection bias is different for each of these cohorts, as you know.)

With the STAC emails and the clarifying information you provided last night, it appears that there is a strong opinion among some of the STAC scientists that the FDNY epi findings for prostate cancer with or without Dr. Landrigan's statements on the Sinai findings cannot be the basis for including it on the list, even using the standard of a 51% 'more likely than not' determination.

Tom stated yesterday in his email that we should "rely on what's known in the toxicology realm regarding potential risk of prostate cancer relative to the toxins known to be present." Does the draft recommend inclusion of prostate cancer based on the presence of Arsenic and inorganic arsenic compounds or Cadmium and cadmium compounds in WTC dust/smoke, and IARC's determination that there is limited evidence that exposure can cause prostate cancer in humans?

I may have further questions/comments, but first I need to better understand the draft's current rationale for inclusion/exclusion of cancer sites.

**Valerie Dabas**

Thu 3/1/2012 10:12 AM

Should we be having these these discussions via e-mail in light of the FACA requirements? Will the correspondence be available to the public on the NIOSH website?

**Paul Middendorf [sent to Valerie Dabas]**

Thu 3/1/2012 10:18 AM

I think we're ok because the whole committee is acting as a working group in developing the document (which is how the committee decided to act during the first meeting in November), and working groups do not have to do their work in an open meeting. The whole document under consideration will be posted on the website several days ahead of time and will be presented and discussed in an open meeting. A synopsis of the discussions that will have taken place within the work group will need to be presented in the open meeting. The public will have their opportunity to make comments on the document, and at the meeting each member will have their opportunity to further discuss the document. What the working group cannot do is take a vote and decide the document is the "final version" until it is discussed in the open meeting. During the open meeting changes can be made to the document and then a vote can be taken.

I have a discussion scheduled with the attorney this afternoon and will add this issue to the list, and then I'll send something out to the whole group on this because if you're concerned, then likely others are, too.

**Susan Sidel**

Thu 3/1/2012 11:13 AM

I second Valerie's concerns even though we are a "working group".

That said, I'm wondering if we are going to need another phone meeting (for just a few extra hours) to review our letter and continue our robust discussion and if so, we should set that up now.

Our thinking doesn't have to be "all or nothing" on prostate. If someone is young and sick with other WTC conditions, that particular early onset prostate cancer may be related to WTC exposure. We could have criteria

Also...we need to merge the document b/c several edits are not in later versions.

**Julia Quint**

Thu 3/1/2012 11:34 AM

I am still editing the document. When I am done, I will incorporate all of my edits into the latest edited version. Thanks.

**Guille Mejia [sent to Paul Middendorf]**

Thu 3/1/2012 1:44 PM

Thanks for the clarification.

**Elizabeth Ward**

Thu 3/1/2012 3:00 PM

Thanks for your question. I think it will help clarify the process for all of us.

Prostate was listed in the original draft based on two criteria; the results of the FDNY study and the IARC listing of "limited evidence" in humans for cadmium and arsenic. One of the reasons I thought it was useful to compile Table 3 with evidence from all 3 sources was to get a picture of how strong the evidence is for different sites. When I compiled the draft and the table, I tried to use a very wide screen, for example, I included sites where there positive data in the FDNY study, even is some were not statistically significant. We didn't really have the opportunity to discuss the evidence on many sites in detail at the meeting, so in essence I think the "discussion" is being carried out through the email exchanges.

Although perhaps we didn't say it as clearly as you and Valerie did, I think we were all agreeing on the approach of using the 3 sources of evidence to compile the list but not necessarily the final list. Now we're looking at the results that came out of using the approach and sharing views about whether we agree that all of the cancers identified should be recommended to be listed as WTC-related conditions. We also have the opportunity to point out if any cancers were missed in error or to make a compelling case to add others that were not identified by these methods.

Based on looking more carefully at the prostate data as well as looking at other's comments I think there are a number of factors that weaken the argument including prostate cancer:

- As Tom pointed out yesterday, the prostate findings from the FDNY study, while showing a positive signal, really are giving a mixed message, because the risk is elevated in both WTC-

exposed and unexposed and is higher in the unexposed than the exposed when the lag time correction was made.

- As I pointed out yesterday, prostate is a cancer where medical surveillance bias is going to be huge concern because of PSA testing. The positive signal observed in the FDNY study in WTC-exposed and unexposed could very well just be a result of being in a medical surveillance program where PSA screening is offered (Tom - do you know if PSA screening is offered?). The same problem will apply to other studies.
- With respect to what we know about potential exposures to cadmium and arsenic, the only two IARC Group 1 carcinogens for which prostate is listed as a site with limited evidence, Glenn pointed out that in the firefighter biomonitoring study, urinary cadmium levels were lower among WTC-exposed compared to unexposed individuals (arsenic was not measured). In the Paul Liroy samples from Cortland, Cherry and Market Street, cadmium and arsenic levels were relatively low compared to levels of many other metals (for example, around 2500 ng/g for arsenic, 5700-8500 ng/g for Cadmium vs. 142,000 ng/g for lead for example).
- Finally, there were some cancer sites included in the Table that IARC classified as having sufficient evidence in humans and others as having limited evidence. Prostate was based on limited evidence for both arsenic and cadmium. When you look at the IARC monographs, the evidence is really pretty weak and inconsistent for both (see: <http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-8.pdf> and <http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-6.pdf>).

I hope this clarifies my thinking and how I see the process. I am really striving to develop a draft that captures the recommendations of the committee, and if there is a difference of opinion on some points the next draft should reflect that.

**Elizabeth Ward**

Thu 3/1/2012 3:36 PM

I know that at this point multiple versions of the document are being worked on. If everyone sends me their comments on the draft they worked on I will sort it out with the help of a science editor. I will also need to get all of the scientific references entered etc. once we're close to a final on the March 23 draft.

**Susan Sidel**

Thu 3/1/2012 3:39 PM

I really appreciate all your patience in explaining all of this and sending extra info along.

We can never forget that the WTC was an extraordinary experience. We LIVED in that dust... I say that as a Volunteer at GZ and a Resident.

287 chemicals and chemical groups are cited in the First Periodic Review on page 39

Out of 72 IARC carcinogen present at the WTC, we chose to include only 18 carcinogens and their associated cancer sites b/c they have human data (I think I have that right?).

I do not think we can choose among those results. I really do believe that we could create a criteria such as:

1. Prior to prostate diagnosis, there was diagnosis and treatment of other WTC related conditions.
2. Person is under the age of 55.
3. The WTCHP Administrator will have to certify their prostate cancer is WTC related.

This will never be linear. Biological plausibility is just standard

**Paul Middendorf**

Thu 3/1/2012 4:10 PM

HI, All

I have to put on my DFO hat at this point and make sure that the committee is not moving too far into discussion of the issues. Because the committee is working on this as a whole group rather than as a work group which is smaller than the quorum size, it complicates things. Some of the email conversation today may be crossing the line between accumulating information for discussion at the meeting and holding a discussion by email. The back and forth editing on the document could be problematic.

This process needs to be like the process used for the research recommendations. The information should be one way to the Chair who will compile the information and put it together into a document. The Chair can go back to individuals to ask for clarification or insight, but not hold a discussion with the entire group. That document will be the one that is put up on the web for the public and the committee to view and react to. Obviously with the limited time to meet, it will be a burden to thoroughly address each issue at the upcoming meeting.

**Tom Aldrich**

Fri 3/2/2012 8:55 AM

Regarding PSA screening, it was part of FDNY's regular wellness exams (every 18 mo or so) ever since 1996. Compliance was not as good pre-9/11 as post-9/11

**Glenn Talaska [sent to Paul Middendorf only]**

Fri 3/2/2012 3:59 PM



Draft\_to\_Stac\_Com  
mittee\_Feb\_24\_2012

Paul, here is a copy of my additions to Liz's first draft. I sent a copy to her, but have not heard that she received it. Could you reply when you get it? Thanks.

**Catherine Hughes**

Sat 3/3/2012 8:25 PM

Thank you very much, Liz, for your all your work on this draft document -- and everyone's contributions at the meeting and on this document.

Please find below a few suggested edits:

1. Bioaccumulative properties - There should be at least some discussion addressing the bioaccumulative characteristics/impact of some WTC compounds. For example, dioxins (characterized by the EPA as a likely human carcinogens) were present, are persistent, and bioaccumulate in human tissue.
2. Synergistic effects - There should also be a discussion addressing the synergistic impact (known and unknown) of so many toxins at elevated temperatures.
3. Where ionization smoke detectors present at the WTC? They use a small radioactive source as a key component in detecting smoke particles. The Radionuclide used in ionization smoke detectors is an oxide of americium-241. If so, the thin foil surrounding the americium could have been punctured and destroyed in the fire. If so, radioactivity could have leaked into the environment. If so, could this have had an impact on the thyroid.
4. Lip Cancer - If we are including skin cancer, then why are we also not including lip cancer when lips were equally exposed to the WTC smoke and dust?
5. Dates that should be included in document include:
  - o May 30, 2002 -flatbed trailer carried out the last steel beam from the WTC
  - o February 2010 - demolition of 130 Liberty (aka Deutsche Bank) completed

6. Limitations of Cancer Sites, Sensitivity of Carcinogenic Potential and List of Carcinogens - should be included; there were chemical found in the WTC smoke and dust that may never have been tested for their carcinogenic potential. From Cogliano's article:
- o p. 1834 -- "Further research often finds additional cancer sites....These new findings provide a compelling reason to regard every list of cancer sites as a work in progress, which may be amended if subsequent research provides strong evidence of additional cancer sites."
  - o p. 1837 -- "Further research has confirmed carcinogenic potential under conditions of lower exposure...."
  - o p. 1837 -- "A Growing List of New Carcinogens ... new research continues to find additional human carcinogens...."

**Virginia Weaver [sent to Liz Ward and cc'd to Paul Middendorf]**

Tue 3/6/2012 2:59 PM



Draft to Stac  
Committee Feb 24 20



LeMasters JOEM  
2006 Table 5.pdf

Based on my understanding of Paul's emails from 3/1, I am sending directly to you (rather than the group) my inserted text on metals and VOCs (in attached) and two concerns on the rest of the document below. If Paul thinks it is appropriate to send to the whole group, I am fine with that as well.

I was not on the phone for the afternoon of the last meeting in NYC so I missed the discussion. However, I have two main concerns:

1. Reliance on Zeig-Owens to select cancer sites in Table 4. This is an important article and it has been reviewed in at least two journal clubs at Johns Hopkins so far. The concern raised in those conferences is that latency is very short and the data to date on cancer in fire fighters without WTC exposures support an increased risk of cancer from their occupational exposures. There is substantial overlap between cancer sites in Table 5 in the LeMasters meta-analysis of fire fighters (who did not have WTC exposures) (attached) and Zeig-Owens. Tom Aldrich has already pointed this out for prostate, which is the cancer that has resulted in the most discussion among the group to date. Thus, the concern with Zeig-Owens et al. is that excluding a role for past fire fighter exposures in cancers diagnosed soon after 9/11 is difficult. The authors discuss recent declines in exposure but, based on traditional latency, exposures pre- 9/11 are more relevant for the cancer timeframe they covered.
2. Perhaps we were told something different during the part of the meeting I missed, but it seems to me that we will likely be asked to address cancer again as a committee regardless of what we conclude now. Therefore, starting by recommending inclusion of cancers that are most scientifically supportable (given the existing data limitations and uncertainties) and adding additional cancers in the future should result in more credibility for our conclusions than adding

controversial cancers now and having the initial work product of the committee criticized in the scientific community. As we learned from the U.S. Preventive Services Task Force's experience with mammography in women age 40-50, it is much easier to add than take away. Is there a role for a focused set of cancers initially with NCI input going forward that would allow us to end up with a final robust list?

**Paul Middendorf [sent to Virginia Weaver, Elizabeth Ward, and Emily Howell]**

Tuesday, March 06, 2012 3:14 PM

I think it's ok to share information that is being submitted for the report. What we need to avoid is discussion of the information in the email traffic that occurs. That discussion needs to take place, but it needs to occur in an open meeting. The report needs to include the various viewpoints and the rationale for those viewpoints to help the program administrator when he has to make decisions.

**Virginia Weaver [sent to Liz Ward, Paul Middendorf, and Emily Howell]**

Tue 3/6/2012 3:17 PM

So does this mean I should send my edits to the group but not the comments below? Or both but the group can then not have an email discussion on those comments? Thanks for the clarification.

**Paul Middendorf [sent to Virginia Weaver, Elizabeth Ward, and Emily Howell]**

Tuesday, March 06, 2012 3:19 PM

Sorry, I guess I wasn't clear enough. I think it's ok to share the report info, but #1 and #2 are discussion issues that should be raised in the open meeting.

**Julia Quint**

Wed 3/7/2012 12:04 AM



Cancer Recomm  
Draft Table 5 JQ



Mech of Carc and  
.do role of Inflamm JQ



Draft to Stac  
ed Committee Feb 24 20

My comments on the draft letter and document are attached. As indicated, I made substantial changes to the Mechanisms of Carcinogenesis section, so I am also including my rewrite so that it is easier to read. A new Table 5 that I constructed and refer to in the text is also attached. Please let me know if you have questions.

I wasn't sure whether I was supposed to send a copy of my comments to the committee, so I am only planning to send them to Susan Sidel, in response to her request. Please let me know if that is OK or if I

should circulate them to the committee.

Many thanks for your tireless efforts on behalf of our committee.

**Elizabeth Ward**

On Mar 7, 2012, at 3:13 AM

Thanks Julia. You can send to the whole committee. We just can't get into a "dialogue" via email.

**Virginia Weaver [sent to Paul Middendorf, Elizabeth Ward, and Emily Howell]**

Wed 3/7/2012 10:02 AM

Paul – So I will email my edits to the group. My remaining questions are:

1. Should I include table 5 from LeMasters in the email so people can see it if I have the opportunity to mention it during our conference call?
2. Should I add my first comment below into Table 4 as a comment before I send my edits?

Thank you

**Paul Middendorf**

Wed 3/7/2012 10:34 AM

As for table 5, I think if you want it shared during the meeting you should send it to me and I will be able to post it when you want to refer to it. That way everyone can see it –including the public. And this suggests to me that I need to send an email to everyone suggesting that if they have graphics that they will want to refer to they should send them to me so I can preload them and have them available. Hopefully I won't get overloaded.

You should suggest adding text to the report that will cover the gist of the comment. If you think that adding a table demonstrating the overlap between Zeig-Owens findings and Lemasters findings would be helpful, providing that would be appropriate.

**Virginia Weaver**

Wed 3/7/2012 7:29 PM

Paul – here is Table 5 for posting. I'm not sure we need a table of comparisons yet. I added comment #1 as a comment in the section on Zeig Owens written by Tom Aldrich in attached. I'm not sure if it can stay as a comment. If not, I will remove it and try to raise it during the call.

**Paul Middendorf [sent to Virginia Weaver and cc'd Elizabeth Ward]**

Thursday, March 08, 2012 8:53 AM

Stepping back for just a moment, my goal is to give you guidance on how to write the document, but not to tell you what to put in it. What the report needs to do is provide the various viewpoints and the rationale for those viewpoints.

So, I think most of the comment should be reserved for the discussion. What should be done is to suggest wording on how you think the report should be written to incorporate your thoughts while not eliminating others' thoughts and perspectives.

If this isn't clear enough, let me know and I'll try to help some more.

**Virginia Weaver [sent to Paul Middendorf and cc'd Elizabeth Ward]**

Thu 3/8/2012 9:26 AM

**Elizabeth Ward**

Thursday, March 08, 2012 10:59 AM

Dear WTC STAC Committee members:

Apparently there is some confusion about the deadline for receipt of edits on the draft document. Here is the timeline I sent out with the draft:

As promised, attached please find a first draft of our response to Dr. Howard regarding the cancer petition and supporting documentation. The references are incomplete as my reference manager program has not been working remotely so I will have to add them when I'm back in the office next week.

Specific writing requests are highlighted in yellow for John, Glenn, Virginia, Bill, Tom, Steve M and Leo.

Requests for additional input from the committee on several topics are highlighted in yellow as well.

I hope everyone will provide comments on what is written so far and on any additional topics that should be covered.

Please return new text and comments to me as soon as possible, but no later than March 12. Please feel free to share comments with all members of the STAC Committee when you send them to me.

I will revise the document and get a draft back to you by noon on March 23.

If there are significant disagreements or issues related to the March 23 draft, I will highlight them in an email message so everyone will have the opportunity to think them over before the call.

Let me know if you have any questions.

**Julia Quint**

Wed 3/7/2012 11:15 AM



Draft to Stac  
Committee Feb 24 20



Cancer Recomm



Mech of Carc and  
role of Inflamm JQ ed

My comments on the draft recommendations on the cancer petition are attached. A new Table 5 that I constructed and refer to in the revised text on Mechanisms of Carcinogenesis, and a copy of the Mechanisms of Carcinogenesis section (with changes saved) to which I made substantial changes, also are attached.

**Bob Harrison**

Wed 3/7/2012 12:05 PM

May I suggest we place the issue of dose and duration of exposure on our agenda? We have not mentioned anything in the current draft about whether there ought to be a "threshold" for dose or duration of exposure to WTC dust. I like Julia's additional sentence about short term exposure (1 to 90 days) in experimental systems that can lead to cancer, but we may want to expand on this point and add some references about relatively short term exposures leading to increased cancer risks. Relative to many worker health studies, for most individuals the WTC exposures were relatively "brief," (eg. months and not years), and our recommendations that cancer be covered under the Zadroga Act will add important foundational rationale for the concept of relatively short term exposure.

Likewise, we have not discussed the issue of latency (as defined by either the time between first exposure or last exposure to disease onset). I am not sure if the Zadroga Act covers only newly cancers going forward (in which case latency might not be important as it is now >10 years out), but if the coverage is applied retrospectively to previously diagnosed cancers this could be important to discuss.

**Virginia Weaver**

Wed 3/7/2012 7:29 PM



Draft to Stac  
Committee Feb 24 20



LeMasters JOEM  
2006 Table 5.pdf

Paul – here is Table 5 for posting. I'm not sure we need a table of comparisons yet. I added comment #1 as a comment in the section on Zeig Owens written by Tom Aldrich in attached. I'm not sure if it can stay as a comment. If not, I will remove it and try to raise it during the call.

**Virginia Weaver**

Thu 3/8/2012 10:09 AM



Draft to Stac  
Committee Feb 24 20

Attached please find the text I added on metals and VOCs as well as an edit on interpretation of Zeig-Owens et al.

**Virginia Weaver**

Thu 3/8/2012 10:14 AM

I agree, I think these are important items to discuss in the document as well.

**Paul Middendorf**

Thu 3/8/2012 10:19 AM

Because it will not be possible to add information after the meeting, and the meeting is very short, it would be best to get any suggested wording into the document that will be posted ~March 23 for discussion at the meeting.

**Leo Trasande**

Thu 3/8/2012 10:27 AM

Paul

Can you clarify the deadline for submitting proposed edits?

**Paul Middendorf**

Thu 3/8/2012 10:35 AM

The draft version to be discussed at the meeting needs to be provided to me by noon on March 23 so it can be posted on the Committee's website. This will allow the public a reasonable amount of time to download and read it so they can make comments to the committee if they choose.

Liz will need to address when the last of the proposed edits need to be to her so she can finish the draft for posting.

Any final content changes must occur during the open meeting. Only minor copy editing changes can be made by the Chair (or whichever committee member is designated to accomplish that task) after the meeting.

Let me know if I need to clarify anything further.

**Julia Quint**

Fri 3/9/2012 2:19 PM



Draft to STAC  
CommitteeFeb24Quin

I found another reference related to the duration of exposure and cancer. I have attached my additional edits (in bold) to the information in the draft on pages 4 and 5. The reference is provided.

**Steve Markowitz [Paul Middendorf excluded]**

Saturday, March 10, 2012 3:18 PM



Draft to Stac  
Committee Feb 24 20

All - Attached is Liz's chain email draft (received from Virginia on 3/8/12) with my edits. I added a small section on rare cancers at the end of the text and made some phrasing suggestions.

On the issue of prostate cancer, i don't think the scientific facts that we have in hand, both WTC-related (including FF cancer study) and the overall field, permit us to say that prostate cancer is reasonably likely to be related to WTC exposures. I agree with Liz and Bill that the cadmium and arsenic non-WTC literature are weak. However, given the fact that at least two new epidemiological studies will likely be published soon (though not before April 2) and that they may shed light on this issue, we should say, both in general and about prostate cancer in particular, that forthcoming epidemiologic studies of cancer among WTC-exposed populations may shed further light on these issues and that our recommendations should be viewed in light of the new findings.

**Tom Aldrich [Paul Middendorf excluded]**

Saturday, March 10, 2012 4:27 PM



Draft to Stac  
Committee Aldrich, H

I added a few items to Steve's version. Some of these were items I had previous inadvertently sent to Liz w/o cc'ing the rest of the STAC and some are new

One issue that bothers me a bit is latency, esp for solid tumors. The ~20 year latency we talk about is an average. There must be a few percent of persons whose latency is much less than that (and a few percent with much longer latencies). So, if we see 20-30% more cancers in exposed than unexposed at 7 years, that can either mean the data are wrong (due to surveillance bias or something else) or that we're seeing the low-end tail of a much bigger phenomenon.

**Leo Trasande [Paul Middendorf excluded]**

Sun, Mar 11, 2012 9:56 pm



STAC input w  
ref.docx

I've added two paragraphs outlining rationale for inclusion of pediatric cancers.

**Kimberly Flynn [Paul Middendorf excluded]**

Sun, Mar 11, 2012 11:24 am



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itions.pdf



caplan-shaw\_JOEM\_  
Article\_2011.pdf



Friedman\_wtc\_reg\_2  
011.pdf



9'11survivor\_health\_  
studies.doc

I am attaching a list of abstracts for the major studies of 9/11-related physical health impacts to survivors. I am also attaching the studies to this email and to my next.

One study I would especially like to bring to the attention of STAC members is the 'adverse home conditions' study by Lin, et al., for which the link on the NIOSH website is currently malfunctioning.

More to come.

**Kimberly Flynn [Paul Middendorf excluded]**

Sun, Mar 11, 2012 11:50 am



Attached are 3 additional studies of 9/11-related physical health impacts to survivors. Below, I am pasting in the medline abstracts for the studies of window films conducted by the Diamond group, referred to on p.4 of the current draft STAC recommendations document. If someone has those studies handy, I would be grateful if you would provide them to us.

Environ Sci Technol. 2005 Apr 1;39(7):1995-2003.

**Polychlorinated dioxins and furans from the World Trade Center attacks in exterior window films from lower Manhattan in New York City.**

Rayne S, Ikonomou MG, Butt CM, Diamond ML, Truong J.

**Source**

Department of Chemistry, University of Victoria, Victoria, BC, Canada.

**Abstract**

Samples of ambient organic films deposited on exterior window surfaces from lower Manhattan and Brooklyn in New York City were collected six weeks after the terrorist attacks at the World Trade Center (WTC) on September 11, 2001 and analyzed for polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/Fs). Total tetra- through octa-CDD/F concentrations in window films within 1 km of the WTC site in lower Manhattan ranged up to 630,000 pg/m<sup>2</sup> (estimated as a mass concentration of ca. 1,300,000 pg/g) and a maximum toxic equivalent (TEQ) concentration of 4700 TEQ/m<sup>2</sup> (ca. 10 000 pg TEQ/g). Measurements at a background site 3.5 km away in Brooklyn showed lower concentrations at 130 pg TEQ/m<sup>2</sup> (260 pg TEQ/g). Ambient gas-phase PCDD/F concentrations estimated for each site using an equilibrium partitioning model suggested concentrations ranging from ca. 2700 fg-TEQ/m<sup>3</sup> near the WTC site to the more typical urban concentration of 20 fg-TEQ/m<sup>3</sup> at the Brooklyn site. Multivariate analyses of 2,3,7,8-substituted congeners and homologue group profiles suggested unique patterns in films near the WTC site compared to that observed at background sites in the study area and in other literature-derived combustion source profiles. Homologue profiles near the WTC site were dominated by tetra-, penta-, and Hexa-CDD/Fs, and 2,3,7,8-substituted profiles contained mostly octa- and hexachlorinated congeners. In comparison, profiles in Brooklyn and near mid-Manhattan exhibited congener and homologue patterns comprised mainly of hepta- and octa-CDDs, similar to that commonly reported in background air and soil.

PMID:

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Environ Sci Technol. 2004 Jul 1;38(13):3514-24.

**Semivolatile organic compounds in window films from lower Manhattan after the September 11th World Trade Center attacks.**

Butt CM, Diamond ML, Truong J, Ikonomou MG, Helm PA, Stern GA.

**Source**

Department of Geography, University of Toronto, Toronto, Ontario, Canada.

**Abstract**

The September 11th World Trade Center (WTC) terrorist attacks resulted in the large-scale release of contaminants that were deposited on the environment of New York City (NYC). Six weeks after the attacks, samples of an organic film on window surfaces were collected and analyzed for polybrominated diphenyl ethers (PBDE), polychlorinated biphenyls (PCB), polychlorinated naphthalenes (PCN), polycyclic aromatic hydrocarbons (PAH), and organochlorine pesticides (OCPs). Concentrations dropped by an order of magnitude within 1 km of the WTC and reached background concentrations by 3.5 km. Concentrations within 1 km of the WTC averaged 3280 ng/m<sup>2</sup> for sigmaPBDE, 900 ng/m<sup>2</sup> for sigmaPCB, 33 ng/m<sup>2</sup> for sigmaPCN, and 77100 ng/m<sup>2</sup> for sigmaPAH. Congener profiles of the sites nearest the WTC suggested a combination of combustion and evaporative sources of all compounds, whereas the background sites exhibited profiles consistent with evaporative sources. PBDE profiles showed enrichment in lower molecular weight congeners near the WTC, suggesting that these congeners were formed as a result of the combustion conditions. Homologue fractions of PCN combustion markers were approximately 2-9 times greater at near WTC sites compared to background NYC. Gas-phase air concentrations were back-calculated from measured film concentrations using the film-air partition coefficient (KFA), and calculated air concentrations followed spatial trends observed in films.

**Kimberly Flynn [Paul Middendorf excluded]**

Tue, Mar 13, 2012 4:47 pm



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8(1)3-222008.pdf



Flynn\_draft\_commen  
ts\_mar\_2012.doc

Please accept my sincere apologies for getting these comments to you after the deadline. Locating documents and studies took much longer than I had anticipated.

**Susan Sidel**

Tue 3/13/2012 5:07 PM



Draft to Stac  
Committee Feb 24 20

Follows are some comments and questions as well as my edit.

1. It seems no one has just one WTC health issue: do we know many issues most R's and S's have on average?
2. With the aforementioned in mind, will the existence of multiple chronic illnesses compromise the body's ability  
to fight cancer *and* withstand treatment and cancer drugs?
3. In the case of cancers unrelated to the WTC, if treatment is drawn out due to pre-existing WTC health issues, is that an issue we should address?
4. Do we know how many people in the various populations receive chest X-rays versus CT Scans?
5. Should STAC explore the collection and filtering of WTC data in real-time by the WTCHP's.

For many reasons including lack of funding, it was not feasible for the programs to do this work. Has that changed?

On another note, I am really moved by the time and energy you all have dedicated to writing and reviewing this paper.

Thank you so much.

**Elizabeth Ward**

Mon 3/19/2012 6:55 PM



March 18 Master  
WTC STAC.doc



LeMasters JOEM  
2006 Table 5.pdf

Dear STAC members:

Thank you all for your comments and contributions to drafting the recommendations. I am attaching a draft of the document in which I have tried to capture all comments and additions:

A couple of important points to understand before you start reading:

- Based on the comments received, Paul and I thought it would be best to allow the committee to discuss and vote on the option of including all cancers again before discussing the alternative of listing only specific sites and discussing (and then voting on) the rationale for each. Thus, the draft text for both options is included in the draft cover letter to Dr. Howard. If we do choose to list all cancers, we can use the text regarding evidence for specific sites or site groupings as supplementary material.
- I ran out of time to complete my final editing of the document so the last sections still need work, and there are still formatting problems and references to add, especially later in the document. I will be working on these problems. I recognize that some of the table numbers in the text need correction as I was vacillating about whether the newly added Table 1 should stay in or go out.
- As has been pointed out by some committee members, there are some inconsistencies between NIOSH's lists and my lists for some agents and cancer sites. We have reconciled most of them and will add a footnote that we are standardizing agents to the IARC listings and relying on the IARC evidence for human cancer sites. There is still one important inconsistency on whether to list 2,3,7,8-TCDD, which is currently included in Table 2 and 4, which I created, but not in the NIOSH list. I only realized this inconsistency today, so need to get with Paul and Glenn to figure out what to do (I know why the inconsistency occurred based on reading the NIOSH document but it may (in my opinion) make sense to include it and note the reason for the inconsistency, especially since it has some bearing on the arguments for whether to include cancer of all sites).
- Please read through the document as a whole before commenting. I really tried hard to incorporate everyone's perspectives even though you may not see specific suggestions incorporated at the exact place you would expect to find them.
- 

In commenting on this version, please note that this document should capture a synopsis of the views and perspectives of the committee on the petition to add cancer, or a type of cancer, to the list of WTC-related conditions in the Zadroga Act, the recommendation(s) of the committee at this time, and the underlying scientific rationale for the recommendation(s). The purpose of circulating the document at this point is: (1) to give you the opportunity to bring to my attention any serious omissions or errors before the document is posted for public comment on March 23 and (2) to give you the opportunity to let me know if you feel that the draft does not adequately express your views & suggest specific revisions if it does not. Please try to have any comments to me by noon on Wednesday March 23 so I can have time to incorporate them in the draft for public comment.

It is important that everyone understands that any revisions to the document posted on March 23 must be made and approved by the committee during the March 28 meeting. The time we have available for the meeting is limited, so committee members should not attempt to restate all of the issues and details of their perspectives that were addressed and expressed in the previous meetings because those are already part of the public record in the transcripts. The Program Administrator has access to all of those documents and can use them as needed to inform decisions going forward. During the meeting the

committee members should focus on whether the document summarizes those perspectives and suggest edits needed to ensure the concepts are embodied in the document. Major editing will not be possible during this short meeting, so some judgment should be exercised to suggest changes that substantively alter the document rather than minor issues.

In addition to the draft recommendations in a Word document, I am also circulating a PDF of a Table from a meta analysis of studies of cancer in firefighters which Virginia suggested that I add. The document also makes reference to an Appendix with site and histology codes for lymphatic and hematopoietic cancers which I will add to the final document.

Thanks in advance for your understanding of any rough spots in the document.

**Bob Harrison**

Tue 3/20/2012 1:12 AM

thanks Liz this looks very good to me. I have 2 general comments:

1- I am still not clear on the issue of latency as it pertains to the Zadroga Act. If our recommendations eventually are accepted and become regulation, will cancers be covered retroactively? If this is the case, the issue of latency for solid tumors becomes important (generally I believe the literature would support at least 10 years). If cancers are only covered prospectively, then this issue is moot. Can you or Paul clarify that point?

2- I recommend making a distinction between non-Hodgkin and Hodgkin lymphoma. I believe the epi and animal data in support of the latter is weaker, and so we ought to recommend covering only the former. I suspect that is what we intended, but now the document states "lymphoma" which may be unclear. The most current classification system is the WHO 2008.

**Guille Meija**

Wed 3/21/2012 11:04 AM



March 18 Master  
WTC STAC.doc

Liz: Attached is the doc with my comments. I apologize for not thanking you earlier for your great effort and success in capturing all that has been discussed. Your leadership is greatly appreciated.

Paul Middendorf  
Mar 21, 2012, at 11:16 AM



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2012.pdf

Good morning,

Some concerns have been expressed about the process of developing the Committee's draft report which will support the recommendations the Committee will make during the March 28, 2012 meeting. Dr. Howard, the Program Administrator, has been advised of these concerns and is sending the attached letter to the Committee explaining the nature of "preparatory work" under FACA. Please take a few minutes to read it.

In addition, to ensure the openness of this process, the string of emails and documents attached to those emails related to development of the draft report have been compiled into a document which will be posted to the Committee's docket (#248). The letter and a link to the document will be posted on the Committee's website.

Please contact me if you have any questions or comments.

**Susan Sidel [sent to Paul Middendorf]**

Wed 3/21/2012 3:12 PM

Does this mean prostate and thyroid will be on the draft discussed on 2/28?

**Paul Middendorf [sent to Susan Sidel]**

Wed 3/21/2012 3:19 PM

I'm assuming you mean 3/28.

If you look in the draft Liz sent out on Monday, it contains both prostate and thyroid for discussion:

From p. 7 in the draft:

- The committee recommends that prostate cancer be listed as a WTC-related condition. IARC has found limited evidence that exposure to "arsenic and inorganic arsenic compounds" and "cadmium and cadmium compounds" causes prostate cancer. Although arsenic and cadmium were present in dust samples from the WTC area, concentrations of these metals were relatively low compared to other metals such as lead and zinc (Plumlee, Hageman et al. 2005) The Zeig-Owens study found a significantly elevated SIR of 1.49 for exposed firefighters compared to the general population, but risk was also significantly elevated for non-exposed firefighters (SIR=1.35). The SIR for exposed compared to non-exposed firefighters was 1.11 and nonsignificant. Correction for surveillance bias for exposed

firefighters reduced the SIR to 1.11 (non-significant). The elevated SIR observed for non-exposed firefighters is consistent with a recent meta-analysis of 32 epidemiologic studies of firefighters which found a statistically significant summary risk of 1.28 for prostate cancer (LeMasters, Genaidy et al. 2006). Prostate cancer is also recognized to be more likely than other cancers to be over diagnosed, a term used to mean that a cancer is diagnosed and treated that would not otherwise go on to cause symptoms or death (Welch and Black 2010), and a 2-year lag period may not be sufficient to fully account for surveillance bias.

And later....

- The committee recommends that thyroid cancer be listed as a WTC-related condition. Thyroid cancer has not been associated with any of the agents known to be present at the WTC and the primary evidence for an excess risk comes from the Zeig-Owens study. In that study, 17 thyroid cancers were observed and 6 expected based on national rates, yielding a statistically significant SIR of 3.07. The SIR was 5.21 and statistically significant compared with unexposed firefighters, and was 2.17 and significant after a two year lag was applied. The magnitude of the SIR for thyroid cancer was relatively large, although the significance of this finding is tempered by the possibility that a 2 year lag would not fully account for medical surveillance bias.

**Susan Sidel [sent to Paul Middendorf]**

Wed 3/21/2012 3:49 PM

I'll check my laptop, but I did not get Monday's draft. Can you pls send it.

**Paul Middendorf [sent to Susan Sidel]**

Wed 3/21/2012 3:52 PM



March 18 Master  
WTC STAC.doc



LeMasters JOEM  
2006 Table 5.pdf

Let me know when you get this.

**Susan Sidel**

Wed 3/21/2012 4:17 PM

Not sure why I didn't get this. We had problems with VIOS last Monday, but they were fixed by 6 pm...

Thank so much Paul.

Did I miss anything else?

**Paul Middendorf [sent to Susan Sidel]**

There were several emails sent to the Committee and I will forward each of them.

*[Note – the emails from Bob Harrison to the full committee on Tuesday, March 20, 2012 1:12 AM, and from Guille Mejia on Wednesday, March 21, 2012 11:04 AM to the full committee were forwarded to Susan Sidel at 4:20pm on 3/21/2012]*

**Susan Sidel [to Paul Middendorf]**

Wed 3/21/2012 6:44 PM

I seem to also be missing the email Bob sent to the STAC this week.

Is it possible my address was not on the last draft?

We had VIOS out here on Monday to work on our land line, which could explain the draft, but not Bob's email.

It's kind of weird b/c even if VIOS was down, I should have received the draft emails on my 3G iPhone. Or emails should have been on the mac server.

It's all I can think of...

Arghhh! Technology!

**Paul Middendorf [sent to Susan Sidel]**

Thu 3/22/2012 6:52 AM

Your email was on the "TO:" line for all of the emails, so something happened in transit. Technology is wonderful when it works, but it clearly isn't 100% effective.

**Kimberly Flynn [Paul Middendorf excluded]**

Thu, Mar 22, 2012 1:10 pm

Subject: Re: Draft of STAC Committee recommendations

Thank you for your March revision of the STAC's draft recommendation in response to the petition to add cancers. First, I wish to express my appreciation for your work and the work of all the STAC experts in providing sections of the draft, especially in light of the extremely tight deadline for the recommendation to be provided to NIOSH.

I apologize for the lateness of these comments, but find that it is difficult as a layperson for me to respond to a lengthy and technically detailed document under the time pressures we are all facing.

I hope to give you a small set of edits as 'track changes' to the document later today.

Below are a number of additional issues and concerns I would like to raise.

### Letter

It is critical that the letter to Dr. Howard include survivors in the list of populations with high prevalence of acute symptoms and chronic conditions. There is a substantial body of peer-reviewed studies finding WTC health impacts to residents, students and area worker, and not only 'qualitative descriptions of exposure conditions in downtown Manhattan,' etc.

### Option 1

I believe the bracketed text in italics on page 4 should be deleted from the recommendation. As I understand, implementation of the STAC's recommendation does not fall within the STAC's purview. The regulations that will implement the recommendation will be the product of a legally mandated process that includes, most prominently, the WTC Administrator, along with the medical, scientific and administrative expertise at the WTC Health Program's Clinical Centers and Data Centers and the public.

I took it to be the understanding that Options 1 and 2 would be presented as two alternatives, with the strongest possible scientific case being presented for each. In the rationale put forward for Option 1 (all cancers), the Edelman paper is cited as "reasonably strong evidence against substantial dioxin exposures" in a highly exposed population, undercutting the possibility that WTC-related exposures to 2,3,7,8 TCDD could have increased the risk of 'all cancers combined' that IARC associates with dioxins. Given the serious limitations of the Edelman study (discussed below), this dismissal of dioxins seems unjustified.

Option 1 is extremely compressed. Some of the arguments given in the list of reasons supporting Option 1 at the bottom of page 3 warrant further elaboration.

In addition, the current text for Option 1 should be strengthened to include the example of the synergistic effects of combined exposures to tobacco smoking and asbestos, and any other evidence of synergies that multiply the harm to human health, along with evidence of additive risk.

### 2,3,7,8 TCDD

As you know, 2,3,7,8 TCDD was present at high levels in pollution released from the WTC site on and after 9/11. Page 18 of the revised draft cites findings of this most toxic of the dioxin congeners at hundreds of times background levels in window films. The inconsistency between the NIOSH list and the IARC list that you refer to in your March 20 email with respect to 2,3,7,8 TCDD should be resolved in favor of inclusion of the congener in any and all lists of cancer-causing substances present at WTC.

Edelman, et al.

Too much emphasis is being placed on the Edelman study, which has serious limitations. Its findings are being used as if they can serve as 'surrogates' for the exposures of all WTC-affected populations. We do not know how representative these findings are, as a gauge of exposures. If antimony was significantly elevated in exposed firefighters' urines, then we should assume it was present and available in WTC dust/aerosols. The same is not true for negative findings. Given the uneven distribution of toxic substances released on 9/11 and suspended or combusting thereafter, a negative finding does not indicate the absence of exposures. To cite one example, the low finding on lead by Edelman has always been puzzling to anyone who has reviewed EPA sampling data showing lead contamination in WTC dust in buildings which contain no lead paint, at levels of concern.

Major limitations of the study are stated in the revised draft on page 17 and include:

- the fact that sampling did not begin until approximately 3 weeks after 9/11;
- the fact that the study considers only exposures averaged across a cohort in which there may have been subgroups getting much higher doses; and
- the study fails to relate the dates of exposure to the dates of sampling.

I will venture another limitation, as regards exposures to WTC dioxins, including 2,3,7,8 TCDD, a long-lived toxin known to accumulate in the body. Biomonitoring of exposed and control group firefighters was not repeated and thus could not capture exposures to dioxins that would have continued into late November and included 'some of the highest ambient concentrations ever recorded.' In order to more fully consider the role a chemical might play in causing cancer, especially if, like dioxin, the chemical is persistent and bioaccumulates, it is essential to have data re: cumulative exposures.

**Kimberly Flynn [to Paul Middendorf]**

Thu 3/22/2012 1:40 PM

Several sets of comments re: the STAC recommendation have not been included among the emails posted today to the NIOSH docket.

Here is one email, and I will be re-sending 2 others

**Paul Middendorf [to Kimberly Flynn]**

Thu 3/22/2012 1:46 PM

Since I was not included on the emails I had no way of including them in the list of emails.

**Kimberly Flynn [to Paul Middendorf]**

Thursday, March 22, 2012 1:47 PM

Thanks, Paul. I had no idea that you were not included and would never have knowingly excluded you. Is there a way to get my communications included now?

**Paul Middendorf [to Kimberly Flynn]**

Thu, Mar 22, 2012 1:49 pm

Possibly.

**Kimberly Flynn [to Paul Middendorf]**

Thu 3/22/2012 1:53 PM

I would appreciate it. It is particularly important to include the survivor health studies I provided to the STAC. In the future, I will check to make sure that your email is on the send list!

**Paul Middendorf**

Thu 3/22/2012 2:05 PM

Hi, All

It has just been brought to my attention that the listing of emails related to the development of the Report is missing emails. Several have been forwarded to me. In looking at them I was not on the "To:" or "CC:" lines. For all future communications with the STAC you must include me.