

From: Cagen, Stuart Z SCC <szcagen@Shell.Com>
Sent: Monday, August 6, 2001 8:50 PM (GMT)
To: Cagen, Stuart Z SCC <szcagen@Shell.Com>; 'Carol Fairbrother (E-mail)' <carol.a.fairbrother@exxonmobil.com>; 'Patrick Beatty (E-mail)' <pwbe@chevron.com>; 'Donald Burnett (E-mail)' <burnetdm@bp.com>; 'Chris Roythorne (E-mail)' <roythorc@bp.com>; 'Shan Tsai (E-mail)' <sptsai@shellus.com>; 'William Broddle (E-mail)' <bill.d.broddle@usa.conoco.com>
Cc: 'Lorraine Twerdok' <twerdokl@api.org>; Clegg, Patsy M SCC-CHSE-PC <pmclegg@Shell.Com>; 'George Woodall' <Woodallg@api.org>
Subject: RE: Technical Review Committee Conference Call Summary
Attach: cv2.doc

CV of Dr. Li, provided by Shan Tsai:

<<cv2.doc>>

> -----Original Message-----

> From: Cagen, Stuart Z SCC

> Sent: Monday, August 06, 2001 1:18 PM

> To: 'Carol Fairbrother (E-mail)'; 'Patrick Beatty (E-mail)'; 'Donald
> Burnett (E-mail)'; 'Chris Roythorne (E-mail)'; 'Shan Tsai (E-mail)';
> 'William Broddle (E-mail)'

> Cc: 'Lorraine Twerdok'; Clegg, Patsy M SCC-CHSE-PC; 'George Woodall'

> Subject: RE: Technical Review Committee Conference Call Summary

>

> All:

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> Although I have not heard much of a response regarding my other comments
> regarding (not in any order of importance): the need for the entire
> technical committee to move together on issues and plans (large and
> small), relationship of technical committee to the communications
> committee, participation of the technical committee (not just the chair)
> in scientific review panel / investigator meetings - separate or
> collective, timing, Albertini/Delzell in, Julian Preston in, etc....., I
> have a few additional and important suggestions to make regarding
> potential members of the science review committee:

>

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> Dr. Guilan Li, Chinese Academy of Preventive Medicine, Institute of
> Occupational Medicine, Director of Toxicology, Beijing, China (we feel
> very strongly about representation of a Chinese scientist in general and
> Dr. Li , in particular).

>

> Alternative scientists from Europe: We would not recommend Franz Oesch,
> but alternatively would recommend: Dr. Richard Peto, Dr. Helmut Greim, or
> Johannes Filser.

> Please let me and Shan Tsai know how we can move these recommendations
> further.

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> Thanks
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> Stuart
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> -----Original Message-----
> From: Cagen, Stuart Z SCC
> Sent: Wednesday, July 25, 2001 9:47 AM
> To: 'George Woodall'; Cagen, Stuart Z SCC; Carol Fairbrother
> (E-mail); Patrick Beatty (E-mail); Donald Burnett (E-mail); Chris
> Roythorne (E-mail); Shan Tsai (E-mail); William Broddle (E-mail)
> Cc: Lorraine Twerdok; Clegg, Patsy M SCC-CHSE-PC
> Subject: RE: Technical Review Committee Conference Call
> Summary
>
> All:
>
> George: Thanks for providing a quick summary of our call. You
> correctly captured what was discussed. I would add my request that the
> technical committee act as a whole for all questions - big or small, and
> not the alternative model where day to day questions would be only brought
> to Pat (the Chair). The main reason for this is for educational purposes;
> that is, for me to be well informed to explain progress and problems of
> the program to the folks back here. I think this will work as we only
> have 5 sponsors.
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> Some comments:
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> Regarding the relationship of the technical committee to the
> oversight committee as well as the relationship of the technical committee
> to the investigators: I would favor an active role, where the technical
> committee should have an obligation to seek and recommend program issues
> on behalf of the oversight committee. Although scientific issues will be
> the purview of the investigators and the scientific peer reviewers, study
> monitoring might be expected to raise programmatic implementation issues
> (timing, protocol, other modifications) needing sponsor input. These
> issues should be directed to the oversight committee via the technical
> committee.
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> Regarding reports or manuscripts: The investigators should have
> full authority over publications with their option to consider sponsor
> comments.
>
> Via the technical committee, the sponsors should participate in
> discussions between the scientific review panel and the investigators, and
> their role in meetings should be passive.
>
>

> Additional issues: the technical committee should also have some
 > sort of relationship with the communications committee to help with the
 > translation of study intent and findings.
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 > Regarding the scientific review panel: timing: do we think the
 > official scientific review panel will (functionally) be arriving a bit
 > late in the game if the current cadre of 4 or 5 reviewers (with some
 > overlap) will be the only ones technically commenting on the protocols
 > before IRB review. Can the university review wait until the full panel in
 > engaged or are there timing issues. Anticipating a yes to the timing
 > issues question: What are these timing issues.
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 > The scientific review panel: I would recommend Julian Preston as he
 > would bring experience and knowledge in the area of genetic toxicology and
 > the relationship of biological markers of exposure to markers of potential
 > biologic activity. Would work well together with Albertini.
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 > Other comments on the scientific review committee:
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 > I do not agree with the comment about Elizabeth Delzell and would
 > still keep her on the list of possibles. She is a fair and thoughtful
 > scientist.
 >
 > I am still working on possibles from Europe.
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 > I hope this helps.
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 > Thanks
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 > Stuart
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 > -----Original Message-----
 > From: George Woodall [SMTP:Woodallg@api.org]
 > Sent: Tuesday, July 24, 2001 10:28 AM
 > To: Stuart Cagen (E-mail); Carol Fairbrother (E-mail);
 > Patrick Beatty (E-mail); Donald Burnett (E-mail); Chris Roythorne
 > (E-mail); Shan Tsai (E-mail); William Broddle (E-mail)
 > Cc: Lorraine Twerdok
 > Subject: Technical Review Committee Conference Call
 > Summary
 > Importance: High

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> To all,
>
> Attached is the draft summary from yesterday's conference
> call. Since then I have also done a little digging to come up with some
> names for a Genetic Toxicologist and this is what I found.
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> Julian Preston (EPA) He is the head of the Environmental
> Carcinogenesis Division at EPA (Part of the National Health Effects and
> Environmental Research Laboratory which is under ORD), and was formerly
> head of a department at CIIT and previous to that, at Oak Ridge. He is a
> world-class cytogeneticist.
>
> Ray Tice (Integrated Laboratory Systems) Also a world-class
> cytogeneticist, he was formerly at Brookhaven. ILS is a contract lab
> located in RTP, NC doing a lot of work for NIEHS.
>
> Regards,
>
> George
> << File: TechCommCallSummary23July2001.doc >>