Message

From: D'Amico, Louis [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=78A91F83C4414910BE286EFE02004DBC-D'AMICO, LOUIS J.]
Sent: 1/26/2015 11:03:39 PM
To: Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]
Subject: RE: ToxForum Session - a heads-up

I might actually be a little bit more assertive about this.

Deliberative Process / Ex. 5

-Lou

Louis D'Amico, Ph.D.
Acting Communications Director, ORD/NCEA
damico.louis@epa.gov
O: (703) 347-0344 Personal Phone / Ex. 6

From: Cogliano, Vincent
Sent: Monday, January 26, 2015 3:13 PM
To: D'Amico, Louis
Subject: FW: ToxForum Session - a heads-up

Hi Lou – Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Please advise,
Vince

From: Minsavage, Gary D [mailto:gary.d.minsavage@exxonmobil.com]
Sent: Sunday, January 25, 2015 10:35 PM
To: cportier@mac.com; Cogliano, Vincent; Schoeny, Rita; James Bus; Gamboa, Goncalo
Cc: Kevin Merritt (kevin@toxicology.org); tmasson@toxforum.org
Subject: ToxForum Session - a heads-up

Dear Drs. Bus, Cogliano, Gamboa da Costa, Portier and Schoeny – a heads-up

[Kevin/Tonia – please clarify/update/correct the below note as needed.]

ToxForum Offices informed me that there will likely be at least one reporter at the ToxForum Meeting.

Specifically, a reporter (Pat Rizzuto, Chemicals Reporter, Bloomberg BNA, Inc) has registered for the meeting and has expressed interest in speaking with the speakers in your and other sessions.

If you do have interest to speak with this reporter, please respond to the ToxForum Offices (Kevin Merritt (kevin@toxicology.org) and Tonia Masson (TMasson@ToxForum.org) so that they can facilitate the discussion.

If you do not have interest to speak with the reporter, please respond to Kevin and Tonia so they can try to communicate to the reporter(s) not to contact you during the meeting.

If you do not want your presentation materials quoted/cited by the reporter(s), please let Kevin and Tonia know so they can work with/communicate to the reporter(s) as appropriate.

I hope everyone is able to stay safe during the forecasted inclement weather.

Looking forward to the session on Wednesday.

Gary D. Minsavage, Ph.D., DABT
Section Head, Toxicology

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1545 US Highway 22 East
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From: Minsavage, Gary D
Sent: Tuesday, January 13, 2015 12:55 PM
To: 'cportier@mac.com'; 'cogliano.vincent@epa.gov'; 'Schoeny, Rita'; 'James Bus'; 'Gamboa, Goncalo'
Cc: Kevin Merritt (kevin@toxicology.org); tmasson@toxforum.org
Subject: RE: ToxForum Session - Actions and Alignment

Dear Drs. Bus, Cogliano, Gamboa da Costa, Portier and Schoeny

Thank you for your time on today's alignment call.

We agreed to circulate draft presentations to each other to maximize efficiency / effectiveness and minimize overlapping messages.

Regarding the action I had to determine the ToxForum approach to disseminating speaker content -- Speakers will be asked by the ToxForum to consider making their slides available to meeting attendees only after the meeting. The speaker can decline to share them, if they so choose, or the speaker can modify their slides for dissemination (e.g., they can remove potentially sensitive information prior to making available).

From our discussion today, I captured the below potential topics/questions for the panel discussion in the event there are no / limited comments or questions from the audience:

1) Consequence of advances in exposure characterization in integration / interpretation of MOA type science
2) Mechanisms datasets are typically very large – should we do a complete review of such data before the data are used to inform hazard classification
3) If compound "x" only had mechanistic data, how would each panel member utilize the data in classification decision making
4) …..(feel free to circulate your thoughts on other potential panel topics/questions)

I and the ToxForum thank you, again, in advance, for your time and expertise!

Please let me know if you have any additional questions.

Gary D. Minsavage, Ph.D., DABT
Section Head, Toxicology

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From: Minsavage, Gary D
Sent: Tuesday, December 23, 2014 4:50 PM
To: 'cportier@mac.com'; 'cogliano.vincent@epa.gov'; 'Schoeny, Rita'; 'James Bus'; 'Gamboa, Goncalo'
Cc: Kevin Merritt (kevin@toxicology.org); tmasson@toxforum.org
Subject: RE: ToxForum Session - Actions and Alignment

Dear Drs. Bus, Cogliano, Gamboa da Costa, Portier and Schoeny

First, I'd like to wish you very Happy Holidays, and all the best wishes for you in the New Year.

Second, I am sending this email as a very brief status update for your information.

I realize this time of year has been, as expected, difficutt to get us all coordinated, but thank you for those that could find the time to provide specific titles (updates for titles I've been provided are below) and exchanged a few emails with me to start to get aligned.

The ToxForum Offices will send an email to all of you with a doodle poll for the first part of January (dates including Jan 5-13). Please provide your availabiltiy for a 1 hour call to get aligned for the January ToxForum Winter Session.

Looking forward to a great ToxForum Winter Meeting. Thank you again, in advance, for your time and energy on this session. We'll be in touch soon.

Happy Holidays!

Gary D. Minsavage, Ph.D., DABT
ToxForum Winter Planning Committee Representative

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From: Minsavage, Gary D
Sent: Wednesday, November 19, 2014 11:08 AM
Subject: ToxForum Session - Actions and Alignment

Dear Drs. Bus, Cogliano, Gamboa da Costa, Portier and Schoeny:

On behalf of the Planning Committee for the 39th Annual Winter Toxicology Forum I wanted to again thank you for accepting the invitation to present at the Forum regarding standardization of criteria and approach to use of mechanistic/mode of action data in cancer classification decision making.

May I please ask you to take note of and reply to the following actions/requests -

1) **REPLY TO FORMAL INVITATION:** By now, the Toxicology Forum Office has been in touch with you with a formal invitation. Please reply to the Office as soon as possible, if you've not already done so. Thank you.
2) **REVIEW AGENDA:** see below for your session details with full agenda available at ToxForum 39th Annual Winter Meeting.
3) **PREPARE FOR SESSION:** I'd like to propose that the speakers and session chair work to fully align on focus/intent of the session, minimize overlap of background information across presentations, and maximize sharing information in presentations that drives dialogue across presenters and with the audience. A goal of ToxForum is to build better understanding through dialogue. You are each preparing a 20 minute presentation that will be followed by a 10 minute Q&A session aimed at your presentation. There will be a 30 minute panel discussion at the end of the session in which all of the speakers/chair will participate.
    a. **EXCHANGE OF INFORMATION BY SPEAKERS:** Toward this end, I'd be happy to arrange a (series of) conference calls. At a minimum, particularly with holidays approaching, I'd propose email exchanges with this full group may help get everyone aligned.
        i. **INITIAL THOUGHTS / QUESTIONS:** if you've got burning questions or ideas on the content and/or flow of this session, please email them to the group.
        ii. **CALL NEXT WEEK?** Please let me know if you are available for a call in the afternoon of 24 Nov ("kick-off call") and if so, what timeslots are available for you? If not, please offer blocks of time that may work through Dec 5th
    b. **PROPOSED TIMELINE (for your consideration):**
        i. "Kick-off email exchange/call": by Dec 5th
        ii. FIRST DRAFT SLIDES: December 20th
        iii. Alignment email/call: week of January 6th or early week of 13th
        iv. FINAL DRAFT SLIDES: January 10th
        v. FINAL SLIDES: January 17th

Thank you, again. Please do not hesitate to contact me with any questions.

Session Details (also found on ToxForum Website):

MEETING LOCATION AND DATES
January 26-28, 2015
The Fairfax at Embassy Row Hotel, Washington, DC

SESSION TOPIC
Debating the Varying Criteria for Incorporating "Mechanistic Data" into Cancer Classification

BACKGROUND TO PROPOSED SESSION
As you are likely aware, IARC recently published a report "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Report of the Advisory Group to Recommend Priorities for IARC Monographs during 2015-2019". It is understood that the Advisory Group was asked to consider prospects for the evaluation of mechanistic data in the

context of Monograph evaluations. A key element of the recommendation is to understand the criteria for utilizing "mechanistic data/mode of action" in classification decision making. In addition, other organizations consider how to utilize mode of action / mechanistic data to guide decisions on cancer hazard assessments. This ToxForum session will allow for discussion about the approaches various organizations take or are considering taking in the future; criteria and standards of acceptance and specifically what and how such information is needed for decision making will be discussed.

SESSION TIME
Wednesday, January 28, 1:30 p.m. – 5:00 p.m. EDT

FINAL SPEAKERS AND TIMESLOTS

1:30-1:50 (+10 minute Q&A)
Jim Bus
Toxicology and Mechanistic Biology, Exponent
Session introduction and overview of the issues and opportunities

2:00- 2:20 (+10 minute Q&A)
Christopher Portier
Title: Mechanistic Data, Cellular Pathways and Cancer Classification
Title provided by Dr. Portier: *Mechanistic Data, Cellular Pathways and Cancer Classification*

2:30-2:50 (+10 minute Q&A)
Gonçalo Gamboa da Costa
FDA NCTR
Title provided by Dr. Gamboa da Costa: *NCTR perspective on the incorporation of mechanistic data in cancer studies*

3:00-3:30 break

3:30 -3:50 (+10 minute Q&A)
Rita Schoeny
EPA ORD
Perspectives from EPA ORD regarding standardization of criteria and approach to use of mechanistic/mode of action data in cancer classification decision making

4:00-4:20 (+10 minute Q&A)
Vincent Cogliano
NCEA - EPA IRIS
Perspectives from EPA IRIS regarding standardization of criteria and approach to use of mechanistic/mode of action data in cancer classification decision making

4:30 – 5:00
Panel Discussion: Panel Members will include Chair, Invited Speakers, and others

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Kind regards,
Gary

Gary D. Minsavage, Ph.D., DABT
ToxForum Winter Planning Committee Representative

Contact information:

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