

Cornell, Susan (NIH/OD) [E]

From: Bucher, John (NIH/NIEHS) [E] <bucher@niehs.nih.gov>
Sent: Thursday, September 29, 2016 7:52 AM
To: Andrews, Danica (NIH/NIEHS) [E]
Subject: FW: Please read: Report Posting

Importance: High

From: "John R. Bucher" <bucher@niehs.nih.gov>
Date: Thursday, May 26, 2016 at 5:20 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <Lawrence.Tabak@nih.gov>, "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, "Birnbaum, Linda (NIH/NIEHS) [E]" <birnbaum@niehs.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <Michael.Lauer@nih.gov>, "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>, "Burklow, John (NIH/OD) [E]" <BurklowJ@OD.NIH.GOV>, "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>
Subject: Re: Please read: Report Posting

Dear Dr. Tabak,

We have carried out a detailed comparison of the March and May versions of the report. There is one substantive change. We added historical control tumor information from 3 additional NTP studies to the May version. This changed the historical rates slightly, but did not change our presentation, interpretation or discussion of the findings. We corrected errors in the footnotes, made grammatical and minor editorial changes to improve clarity, added information to clarify the basis of the IARC conclusions and a citation to the IARC reference. We are satisfied that the two versions are essentially the same.

Thanks for your patience.

John

From: "Tabak, Lawrence (NIH/OD) [E]" <Lawrence.Tabak@nih.gov>
Date: Thursday, May 26, 2016 at 2:33 PM
To: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, "Birnbaum, Linda (NIH/NIEHS) [E]" <birnbaum@niehs.nih.gov>, "John R. Bucher" <bucher@niehs.nih.gov>, "Lauer, Michael (NIH/OD) [E]" <Michael.Lauer@nih.gov>, "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>, "Burklow, John (NIH/OD) [E]" <BurklowJ@OD.NIH.GOV>, "Myles, Renate (NIH/OD) [E]" <mylesr@od.nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>
Subject: UPDATE: Please read: Report Posting

Thanks to you all for your comments. Here is the summary as I understand things.

Assuming the March version of the manuscript reporting the partial findings of the study is the same as the latest version, (i.e. the changes are only footnotes, grammar and spelling, and addition of a citation), then NIEHS will post this latest version of the manuscript on the bioRxiv pre-print server together with the reviews by NTP-selected reviewers and all of the NIH reviews (except that of (b) (5), (b) (6) who wishes to remain anonymous).

In the space provided for a separate abstract, a summary of the manuscript will be provided and the fact that the data contained in prior versions of the report were reviewed by NTP-selected reviewers and NIH-selected

reviewers will also be stated. The abstract would also identify the 4 supplemental papers. Here is the abstract (as provided by John Bucher):

The US National Toxicology Program (NTP) has carried out extensive rodent toxicology and carcinogenesis studies of radiofrequency radiation (RFR) at frequencies and modulations used in the US telecommunications industry. This report presents partial findings from these studies. The occurrences of two tumor types in male Harlan Sprague Dawley rats exposed to RFR, malignant gliomas in the brain and schwannomas of the heart, were considered of particular interest, and are the subject of this report. The findings in this report were reviewed by expert peer reviewers selected by the NTP and National Institutes of Health (NIH). These reviews and responses to comments are included as appendices to this report, and revisions to the current document have incorporated and addressed these comments. Supplemental information in the form of 4 additional manuscripts has or will soon be submitted for publication. These manuscripts describe in detail the designs and performance of the RFR exposure system, the dosimetry of RFR exposures in rats and mice, the results to a series of pilot studies establishing the ability of the animals to thermoregulate during RFR exposures, and studies of DNA damage.

Capstick M, Kuster N, Kühn S, Berdinas-Torres V, Wilson P, Ladbury J, Koepke G, McCormick D, Gauger J, Melnick R. A radio frequency radiation reverberation chamber exposure system for rodents

Yijian G, Capstick M, McCormick D, Gauger J, Horn T, Wilson P, Melnick RL and Kuster N. Life time dosimetric assessment for mice and rats exposed to cell phone radiation

Wyde ME, Horn TL, Capstick M, Ladbury J, Koepke G, Wilson P, Stout MD, Kuster N, Melnick R, Bucher JR, and McCormick D. Pilot studies of the National Toxicology Program's cell phone radiofrequency radiation reverberation chamber exposure system

Smith-Roe SL, Wyde ME, Stout MD, Winters J, Hobbs CA, Shepard KG, Green A, Kissling GE, Tice RR, Bucher JR, Witt KL. Evaluation of the genotoxicity of cell phone radiofrequency radiation in male and female rats and mice following subchronic exposure.

NIEHS is not ready to post these 4 manuscripts (either under preparation or submitted). This will take coordination with a number of authors in the US and Europe. NIEHS does not feel that this information is absolutely essential and agrees with Kathy that posting the manuscript which reports the partial findings of the study can proceed.

Please acknowledge that we can proceed with this plan, or let me know if you have any remaining concerns.

Thanks
Larry

From: "Tabak, Lawrence (NIH/OD) [E]" <Lawrence.Tabak@nih.gov>

Date: Thursday, May 26, 2016 at 11:31 AM

To: "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, "Birnbaum, Linda (NIH/NIEHS) [E]" <birnbaum1s@niehs.nih.gov>, "John R. Bucher" <bucher@niehs.nih.gov>, "Hudson, Kathy (NIH/OD) [E]" <Kathy.Hudson@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <Michael.Lauer@nih.gov>, "Burklow, John (NIH/OD) [E]" <BurklowJ@OD.NIH.GOV>, "Hallett, Adrienne (NIH/OD) [E]" <adrienne.hallett@nih.gov>, "Myles, Renate (NIH/OD) [E]"

<mylesr@od.nih.gov>

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Folks,

There may be a bit of confusion as to what should or should not be posted on the bioRxiv pre-print server and to the extent that I contributed to this confusion I apologize.

NIEHS wishes to post the latest version of their manuscript. Understandably, the latest version may differ from the one that the internal NIH group reviewed and commented on. It is therefore possible that some of the comments made by the internal reviewers are no longer germane because of these edits.

To avoid any confusion I propose the following:

1. NIEHS will post the latest version of their manuscript. My understanding from John Bucher is this is version some of have seen in preparation for the May 19th meeting with the FDA and FCC. NIEHS staff are removing the "confidential" watermark and the internal deliberative draft header, and adding a missing reference that they noted at that meeting.
2. As a comment, NIEHS will post the version of the manuscript that was reviewed by the 5 individuals. They should indicate that this was an early draft that was reviewed by NIH staff and the critiques follow. My understanding is that one of the individuals, (b) (5), (b) (6) wanted to post his comments anonymously; however bioRxiv does not permit this and so his critique should not be included (Mike please confirm that it was (b) (5), (b) (6) who did not want his identity revealed).

Will that work for everyone?

Thanks for all your help.

Larry