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Congress of the United States House of Representatives 2321 Rayburn House Office Building Washington, DC 20515-6301 United States of America

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Dear Congressmen Smith, Biggs and Lucas,

I refer to your letter dated 8 December 2017. I welcome the further opportunity to address the Committee's questions and to provide additional clarifications regarding the issues you raise about the Monographs Programme of the International Agency for Research on Cancer (IARC).

Regarding your allegations concerning Dr Christopher Portier, IARC is not aware of any contractual relationship existing between Dr Portier and litigation lawyers relating to glyphosate at the time of the Monograph meeting in March 2015, when glyphosate was evaluated. However, IARC did take account of other real or apparent conflict of interests declared by Dr Portier, specifically his part-time role with the Environmental Defense Fund. On this basis, IARC invited his participation in the meeting as an *Invited Specialist*<sup>1</sup> and his declared conflict of interest was made public on the IARC Monograph website.

Like all other meeting participants, including *Observers*<sup>2</sup> and *Representatives*<sup>3</sup>, Dr Portier had full access to draft documents and discussions during the meeting, and was recognized to speak at the meeting. However, as an Invited Specialist, Dr Portier was not a member of the *Working Group*<sup>4</sup> that was responsible for the critical reviews and evaluations developed during the meeting, including the work performed in sub-groups assessing the epidemiology, animal bioassays or other relevant mechanistic data. Moreover, none of the 16 Working Group members - or any other meeting participant (including the *Observer* from Monsanto, other *Observers*, and the US EPA *Representative*) - signaled any attempt at undue influence by Dr Portier. Accordingly, any

- <sup>3</sup> Id.
- <sup>4</sup> Id.

<sup>&</sup>lt;sup>1</sup> As specified in IARC (2006). Preamble to the IARC Monographs. <u>http://monographs.iarc.fr/ENG/Preamble/</u>.

<sup>&</sup>lt;sup>2</sup> Id.

allegation that Dr Portier unduly influenced the Working Group and the consensus evaluation reached does not, to my knowledge, have any factual basis.

Regarding Dr Portier's activities subsequent to this meeting, IARC does not have any official relationship through which to influence such activities and can bear no responsibility for them. You additionally refer to Dr Portier having chaired a "glyphosate Advisory Group"<sup>5</sup>, but there was no such group. What Dr Portier chaired, in April 2014, was the "Advisory Group to Recommend Priorities for IARC Monographs during 2015-2019". This Advisory Group comprised 21 members from 13 countries and recommended over 80 different agents for IARC to consider for evaluation over the five-year period mentioned, one of which was glyphosate. The IARC Secretariat took the decision on the five agents to be reviewed at the Monograph meeting in March 2015.

With respect to the Agricultural Health Study (AHS), it is important to recognize that this is a prospective study that has been ongoing since the 1990s in two US States (lowa and North Carolina). Publications about the AHS date back more than 20 years<sup>6</sup>, and incremental updates are published periodically. It is therefore incorrect that "the study was just recently published for the first time"<sup>7</sup>. Even the most recent publication, appearing in 2017 - some 30 months after the Monograph evaluation of glyphosate - is not a "final" publication, as the study is ongoing.

At the time of the Working Group's 2015 classification of glyphosate, several peer-reviewed publications from the AHS were available<sup>8</sup>. As the AHS is a large and well-conducted study, it was one of the key ones evaluated by the Working Group. The AHS is mentioned in the IARC Monograph on glyphosate<sup>9</sup>, counter to any suggestion that it "should have been mentioned"<sup>10</sup> but was not. In fact, in the Monograph<sup>11</sup>, the published AHS results are tabulated, described in text, and analysed as part of the Working Group's meta-analysis of non-Hodgkin lymphoma risk.

At the time of the IARC evaluation, the AHS did not report an association between non-Hodgkin lymphoma and glyphosate. However, this null finding in the AHS did not outweigh the positive associations found in other epidemiological studies. The Working Group took this into account in concluding that there is "limited"<sup>12</sup> evidence of carcinogenicity in studies of cancer in humans. While it is accurate that "much of the research relied upon by the Monograph was on animals"<sup>13</sup>, it should be noted that the classification of glyphosate in Group 2A is also based on this "limited" evidence of cancer in humans, inclusive of the AHS, as well as on the "strong evidence that glyphosate causes genotoxicity"<sup>14</sup>.

The latest publication from the AHS, in 2017, is an incremental update with a longer time of followup that includes more cancer cases. Consistent with the prior results included in the IARC Monograph, the newly published AHS update did not find an association between non-Hodgkin lymphoma and glyphosate. New data on increased leukemia risk with glyphosate exposure in the

- Letter from Hon. Lamar Smith, Hon. Andy Biggs and Hon. Frank Lucas to Dr Christopher Wild (Dec 8, 2017).
- <sup>8</sup> See <u>IARC Monograph on glyphosate</u>; IARC Working Group on the Evaluation of Carcinogenic Risk to Humans (2017). Some Organophosphate Insecticides and Herbicides. International Agency for Research on Cancer, Lyon, France.

<sup>&</sup>lt;sup>5</sup> Letter from Hon. Lamar Smith, Hon. Andy Biggs and Hon. Frank Lucas to Dr Christopher Wild (Dec 8, 2017).

<sup>&</sup>lt;sup>6</sup> See Alavanja et al. (1996). Agricultural Health Study. Environ Health Perspect, 104(4):362–9, as cited in the <u>IARC Monograph on</u> glyphosate

http://monographs.iarc.fr/ENG/Monographs/vol112/index.php 9 Id.

<sup>&</sup>lt;sup>10</sup> Letter from Hon. Lamar Smith, Hon. Andy Biggs and Hon. Frank Lucas to Dr Christopher Wild (Dec 8, 2017).

<sup>&</sup>lt;sup>11</sup> See <u>IARC Monograph on glyphosate</u>; IARC Working Group on the Evaluation of Carcinogenic Risk to Humans (2017). Some Organophosphate Insecticides and Herbicides. International Agency for Research on Cancer, Lyon, France. http://monographs.iarc.fr/ENG/Monographs/vol112/index.php

<sup>&</sup>lt;sup>12</sup> As specified in IARC (2006). Preamble to the IARC Monographs. <u>http://monographs.iarc.fr/ENG/Preamble/</u>

<sup>&</sup>lt;sup>13</sup> Letter from Hon. Lamar Smith, Hon. Andy Biggs and Hon. Frank Lucas to Dr Christopher Wild (Dec 8, 2017).

<sup>&</sup>lt;sup>14</sup> See IARC Monograph on glyphosate; IARC Working Group on the Evaluation of Carcinogenic Risk to Humans (2017). Some Organophosphate Insecticides and Herbicides. International Agency for Research on Cancer, Lyon, France. http://monographs.iarc.fr/ENG/Monographs/vol112/index.php

AHS were not, however, available to the Working Group in 2015. Because the IARC Monograph classification reflects the consensus view of an independent expert Working Group, based on a systematic review of all publicly available studies, it is inappropriate to speculate about how new data from one study (including on increased leukemia risk) might change that expert opinion.

With regard to the quotation of Dr Aaron Blair, this appears selective and therefore is prone to misinterpretation. As a whole, the testimony given by Dr Blair does not support any change in the classification of glyphosate. To the contrary, when asked, "Has anything you've been shown by Monsanto's lawyers in the 3 hours and 40 minutes that he questioned you changed the opinions that you had at the IARC meeting about glyphosate and non-Hodgkin lymphoma?", Dr Blair answered, "No"<sup>15</sup>.

With respect to the confidentiality of deliberative documents, we note that reports from the US National Research Council routinely indicate that, "*the review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.*"<sup>16</sup> The European Food Safety Authority (EFSA) differs from the US National Research Council on several key procedural aspects, including not publically disclosing the identity of the peer reviewers and the meeting attendees. EFSA also differs from other international agencies (including IARC) with respect to some transparency issues, including "*public access to data used in determining scientifically significant conclusions that affect policy*"<sup>17</sup>, and the reliance on draft materials developed by those with vested interests. Options to improve transparency and conflict of interest disclosure in EFSA decisions are currently being explored<sup>18</sup>.

The Monographs, in full agreement with the principles of transparency and importance of "*public access to data used in determining scientifically significant conclusions that affect policy*"<sup>12</sup>, rely on published research, and do not cite unpublished or "secret data". IARC invites scientific stakeholders, in limited numbers, seeking to balance participation "*from constituencies with differing perspectives*" to participate in its meetings. All participants at Monograph meetings have full access to the draft documents and discussions, and may be recognized to speak. As publicly announced two months in advance of the meeting on glyphosate, IARC included various *Observers*, including from Monsanto, noting their disclosed conflicts of interests. However, only the Working Group of independent experts drafts the critical reviews and evaluations. Individuals with real or perceived conflicts of interest of any kind may not draft text that pertains to the description or interpretation of cancer data.

Finally, like the US National Research Council, the IARC Monographs assure the integrity of the process by maintaining confidentiality of draft documents and of the scientific peer review comments. IARC's practices are also consistent with the Joint Meeting on Pesticide Residues (JMPR) (jointly administered by the FAO and WHO), which evaluated glyphosate in 2016, particularly with regard to the confidentiality of draft and deliberative documents, the determination of conclusions and decisions by consensus from all participants, and the adoption of the final report by the "entire Meeting"<sup>19</sup>.

In all, the rigorous published procedures followed in every Monograph meeting reflect IARC's close adherence to the highest principles of transparency, independence and scientific integrity.

<sup>&</sup>lt;sup>15</sup> Videotaped deposition of Aaron Earl Blair, PhD. March 20, 2017. MDL No. 2741, Case No. 16-md-0271-VC. United States District Court, Northern District of California.

<sup>&</sup>lt;sup>16</sup> Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011).

https://www.ncbi.nlm.nih.gov/books/NBK208227/; Review of EPA's Integrated Risk Information System (IRIS) Process (2014). https://www.ncbi.nlm.nih.gov/books/NBK230074/;

<sup>&</sup>lt;sup>17</sup> Letter from Hon. Lamar Smith, Hon. Andy Biggs and Hon. Frank Lucas to Dr Christopher Wild (Dec 8, 2017).

<sup>&</sup>lt;sup>18</sup> See <u>https://www.efsa.europa.eu/en/corporate/pub/independencepolicy171026</u>

<sup>&</sup>lt;sup>19</sup> See http://www.who.int/foodsafety/publications/jmpr\_guidance\_document\_1.pdf?ua=1

This approach has permitted the Monographs to thoroughly evaluate many important agents, including tobacco, hepatitis and human papilloma viruses, alcohol, air pollution and radiation, providing a foundation for many effective cancer control measures.

In this regard, I wish to acknowledge the valuable support of the US National Institutes of Health and our other sponsors. We recognize the importance of awards such as the one to the Monographs Programme in enabling scientific excellence at IARC, and also that such awards are only merited based on successful scientific peer review of the sponsor. In respect of oversight and accountability, the Programme is also responsive to IARC's governing bodies (Scientific and Governing Councils) and to the international scientific community. Accordingly, each IARC scientific Section is subject to in-depth external peer-review on a five-year cycle with a panel comprised of IARC Scientific Council Members and additional subject-specific external scientists further information about the governance of IARC is available at <a href="http://www.iarc.fr/en/about/governance.php">http://www.iarc.fr/en/about/governance.php</a>. These scientific peer reviews have had an essential role in maintaining the scientific excellence of IARC, as reflected in an independent assessment, based on scientific bibliographic analysis, placing IARC in the top 2% of medical research organizations worldwide<sup>20</sup>.

While assuring you of my commitment to the oversight and accountability of the Agency to its funding sponsors, its governing bodies and the international scientific community, I remain available to respond to further questions you may have about the IARC Monograph Working Group evaluation of glyphosate. Without prejudice to IARC's willingness to facilitate your review by voluntarily responding to reasonable and substantiated requests for information received from appropriate authorities, IARC would be grateful if the House Science Committee would take all necessary measures to ensure that the immunity of the Organization, its officials and experts, as well as the inviolability of its archives and documents, are fully respected.

Yours sincerely,

Christopher P. Wild, PhD Director

<sup>&</sup>lt;sup>20</sup> See <u>http://www.excellencemapping.net/</u>