LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371
www.science.house.gov

May 4, 2016

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator McCarthy:

The Committee on Science, Space, and Technology is conducting oversight of U.S. Environmental Protection Agency's (EPA) risk analysis prepared by the Cancer Assessment Review Committee (CARC). According to recent media reports, on April 29, 2016, EPA posted what appears to be the final risk assessment for glyphosate prepared by CARC (the CARC report).[1] The CARC report indicates that glyphosate is "Not Likely to be Carcinogenic to Humans."[2] Press reports indicate that EPA removed this document on May 2, 2016.[3] Subsequently, EPA has asserted that the analysis of glyphosate is not final and that the documents were posted "inadvertently."[4]

The Committee has reviewed the CARC report and point out that it is clearly marked as a "Final Report."[5] The report also contains the signatures of thirteen members of CARC.[6] However, EPA's removal of this report and the subsequent backtracking on its finality raises questions about the agency's motivation in providing a fair assessment of glyphosate – an assessment based on the scientific analysis conducted by CARC. Furthermore, EPA's apparent mishandling of this report may shed light on larger systemic problems occurring at the agency. In order to assist the Committee in its oversight of the EPA's assessment of glyphosate, please

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[1] P.J. Huffstutter, *EPA Takes Offline Report that Says Glyphosate Not Likely Carcinogenic,* Reuters, May 2, 2016, *available at* http://www.reuters.com/article/us-usa-glyphosate-epa-idUSKCN0XU01K.
[2] Evaluation of the Carcinogenic Potential of Glyphosate, Final Report, Cancer Assessment Review Committee, U.S. EPA, Oct. 1, 2015, *available at* http://src.bna.com/eAi.
[3] P.J. Huffstutter, *EPA Takes Offline Report that Says Glyphosate Not Likely Carcinogenic,* Reuters, May 2, 2016, *available at* http://www.reuters.com/article/us-usa-glyphosate-epa-idUSKCN0XU01K.
[4] *Id.*
[5] Evaluation of the Carcinogenic Potential of Glyphosate, Final Report, Cancer Assessment Review Committee, U.S. EPA, Oct. 1, 2015, *available at* http://src.bna.com/eAi.
[6] *Id.*

provide all documents and communications from January 1, 2015, to the present, referring or relating to the CARC report on glyphosate by 5:00 p.m. on May 18, 2016.

The Committee on Science, Space, and Technology has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X.

The Committee requests that you provide the requested documents and information, in electronic format. An attachment to this letter provides details on producing documents to the Committee.

If you have any questions about this request, please contact Joseph Brazauskas or Taylor Jordan of the Science, Space, and Technology Committee staff at 202-225-6371. Thank you for your attention to this matter.

Sincerely,

Lamar Smith

Lamar Smith
Chairman

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space and Technology

U.S. House of Representatives
Committee on Agriculture
Room 1301, Longworth House Office Building
Washington, DC 20515–6001
(202) 225–2171

May 11, 2016

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Administrator McCarthy:

The House Committee on Agriculture is conducting oversight of the U.S. Environmental Protection Agency's (EPA) recent actions related to its risk assessments of the chemicals glyphosate and atrazine. It has come to our attention that EPA recently posted and then removed reports on the carcinogenicity of glyphosate and the ecological risks of atrazine.

According to news reports, EPA simultaneously removed thirteen additional documents from the glyphosate review docket, including summaries of meetings with industry and a report on possible labeling amendments.[1] EPA officials have been quoted saying the glyphosate report and the accompanying documents were removed because EPA's review will not be final until the end of 2016, and the posting of preliminary documents was "inadvertent."[2] However, the report is clearly labeled "Final Report" and was signed by thirteen members of EPA's Cancer Assessment Review Committee.[3]

We are concerned that EPA has continually delayed its review of glyphosate. In a hearing before this Committee on May 13, 2015, one of our members specifically asked Assistant Administrator Jim Jones when EPA's glyphosate review would be complete and whether EPA

[1] P.J. Huffstutter, "EPA takes offline report that says glyphosate not likely carcinogenic," *Reuters*, May 2, 2016.
[2] *Id.*
[3] *Evaluation of the Carcinogenic Potential of Glyphosate*, Final Report, Cancer Assessment Review Committee, U.S. Environmental Protection Agency, October 1, 2015, available at: http://src.bna.com/eAi.

would continue to stand behind its previous assessment that glyphosate does not pose a serious cancer risk. Administrator Jones assured this Committee that EPA's review would be final in July 2015, and the agency would continue to stand behind its previous conclusions. Despite these assurances, no report was issued until the one posted on April 29, 2016 and removed on May 2, 2016.[4]

The same day EPA posted its glyphosate report, it also published a report on atrazine, which was also removed at a later date.[5] While this report was marked as a "Preliminary Risk Assessment" rather than a final report,[6] we are troubled that EPA mistakenly posted and later removed documents related to assessments of two different chemicals within one week. These mistakes indicate systemic problems with EPA's management of its chemical review and publication processes.

In order to assist the Committee with its oversight of EPA's glyphosate and atrazine risk assessments, we request that EPA respond to the following questions and requests for information:

1. Please provide a narrative explaining EPA's decision to post and subsequently remove these documents from public view.

2. Who at EPA is charged with overseeing the risk assessment process for chemicals, including but not limited to glyphosate and atrazine?

3. Please provide a step-by-step description of EPA's approval process for the publication of chemical risk assessments, registration reviews, and associated documents.

4. What steps remain to be completed in order to finalize EPA's review of glyphosate?

5. When will the EPA issue its final report on glyphosate?

The Committee on Agriculture is the principal authorizing committee for all matters related to agriculture in the House of Representatives and "shall have general oversight responsibilities" as set forth in House Rule X.

The Committee requests that you respond in writing on or before May 25, 2016. Your response should be addressed to the Majority Staff in Room 1301 of the Longworth House Office Building and the Minority Staff in Room 1010 of the Longworth House Office Building.

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[4] Huffstutter, *supra.*
[5] "Agri-Pulse Daybreak," *Agri-Pulse*, May 5, 2016, available at: http://www.agri-pulse.com/uploaded/daybreak_05052016.mp3.
[6] *Refined Ecological Risk Assessment for Atrazine*, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, April 12, 2016, available at http://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/AtrazinePreliminaryERA.pdf.

If you have any questions about this request, please contact Emily Wong of the majority staff at 202-225-2171 or Keith Jones of the minority staff at 202-225-0317. Thank you for your attention to this matter.

Sincerely,

K. Michael Conaway
Chairman
House Committee on Agriculture

Collin C. Peterson
Ranking Member
House Committee on Agriculture

Rodney Davis
Chairman
Subcommittee on Biotechnology,
Horticulture, and Research

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6301

(202) 225-6371
www.science.house.gov

June 7, 2016

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator McCarthy:

The Committee on Science, Space, and Technology continues to conduct oversight of the U.S. Environmental Protection Agency's (EPA) risk analysis for glyphosate prepared by the Cancer Assessment Review Committee (CARC). As stated in previous correspondence to EPA dated April 29, 2016, the agency posted what appears to be the final risk assessment for glyphosate prepared by CARC (the CARC report).[1] The CARC report indicates that glyphosate is "Not Likely to be Carcinogenic to Humans."[2] Press reports indicate that EPA removed this document on May 2, 2016.[3]

The Committee is also aware that the International Agency for Research on Cancer (IARC) conducted an evaluation of glyphosate over the period of March 3-10, 2015.[4] According to the IARC evaluation, it appears that EPA sent officials to participate in conducting the IARC study.[5] The CARC report noted that the IARC's analysis prompted EPA to re-evaluate glyphosate. In contrast to the CARC report, the IARC report found that glyphosate was harmful to humans. In several instances, the CARC report appears to dispute the findings of the IARC report and raises questions about IARC's analysis.[6]

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[1] P.J. Huffstutter, *EPA Takes Offline Report that Says Glyphosate Not Likely Carcinogenic,* Reuters, May 2, 2016, *available at* http://www.reuters.com/article/us-usa-glyphosate-epa-idUSKCN0XU01K.
[2] Evaluation of the Carcinogenic Potential of Glyphosate, Final Report, Cancer Assessment Review Committee, U.S. EPA, Oct. 1, 2015, *available at* http://src.bna.com/eAi.
[3] P.J. Huffstutter, *EPA Takes Offline Report that Says Glyphosate Not Likely Carcinogenic,* Reuters, May 2, 2016, *available at* http://www.reuters.com/article/us-usa-glyphosate-epa-idUSKCN0XU01K.
[4] IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112: Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos, March 2015, *available at* http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf.
[5] IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 112: Some Organophosphate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, and Tetrachlorvinphos, Participants List, March 2015, *available at* http://monographs.iarc.fr/ENG/Monographs/vol112/vol112-participants.pdf.
[6] U.S. EPA, Glyphosate: Report of the Cancer Assessment Review Committee, Memorandum, Oct. 1, 2015, *available at* http://src.bna.com/eAi.

Given the apparent contradictions of the CARC and IARC findings for glyphosate and the participation of EPA officials in IARC's report, the Committee has concerns about the integrity of the IARC process, the role played by agency officials in the IARC study, and the influence that EPA officials involved in the IARC process have on the agency's analysis of glyphosate. In order for the Committee to better understand the process that EPA is using to evaluate glyphosate, we request the following officials be made available for transcribed interviews in July 2016:

- Matthew T. Martin, Office of Research and Development, National Center for Computational Toxicology
- Peter P. Egeghy, Office of Research and Development
- Jesudosh Rowland, Deputy Director, Office of Pesticide Programs, Health Effects Division
- Charles Smith, Acting Deputy Director, Office of Pesticide Programs, Heath Effects Division

Please contact the Committee to schedule these interviews no later than 5:00 p.m. on June 14, 2016.

The Committee on Science, Space, and Technology has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X.

Furthermore, the Committee reiterates its request for documents referring to this matter as outlined in the letter dated May 4, 2016. The Committee requests that you provide the requested documents and information, in electronic format. An attachment to this letter provides details on producing documents to the Committee.

If you have any questions about this request, please contact Joseph Brazauskas or Richard Yamada of the House Science Committee staff at 202-225-6371. Thank you for your attention to this matter.

Sincerely,

Lamar Smith
Chairman

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space and Technology

ROBERT B. ADERHOLT
4TH DISTRICT, ALABAMA

235 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
TELEPHONE: (202) 225-4876

WEB PAGE: www.house.gov/aderholt

COMMITTEE ON APPROPRIATIONS

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AGRICULTURE

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COMMERCE, JUSTICE, SCIENCE

DEFENSE

Congress of the United States

House of Representatives

Washington, DC

June 7, 2016

Francis S. Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins:

The recent controversy regarding an International Agency for Research on Cancer (IARC) report entitled, "Evaluation of Five Organophosphate Insecticides and Herbicides" (IARC Monographs, Volume 112. 20 March. 2015) has elevated my awareness of this agency and the support it receives from the United States government.
According to a Reuters' investigative news report, this study concludes that glyphosate, an herbicide, is a 'probable' human carcinogen.

It is my understanding that the report findings contradict other U.S. government agency studies on the safety of glyphosate, the most commonly used herbicide in the world. In fact, the National Academies of Science just released a comprehensive report on genetically engineered crops ("Genetically Engineered Crops: Experiences and Prospects") in May 2016 and the report notes that several comprehensive international studies delink the connection between glyphosate and cancer, including the EPA's 2013 study that reaffirmed the agency's stance by saying "glyphosate is not expected to pose a cancer risk to humans." Additionally, some in academia have raised questions about the quality of the science and the transparency of the process.

Any study by IARC, regardless of its credibility, benefits from association with the National Institutes of Health (NIH) and its reputation as a premier research organization. The IARC study conclusions appear to be the result of a significantly flawed process; unfortunately, because the study was funded through the NIH, the conclusions will be taken more seriously than they might have been.

Millions of farmers throughout the world rely on this uniquely effective herbicide. Given the impact that diminished confidence in the use of this common and widely-used herbicide

247 CARL ELLIOTT BUILDING
1710 ALABAMA AVENUE
JASPER, AL 35501
TELEPHONE: (205) 221-2310

205 FOURTH AVENUE NE
SUITE 104
CULLMAN, AL 35055
TELEPHONE: (256) 734-6043

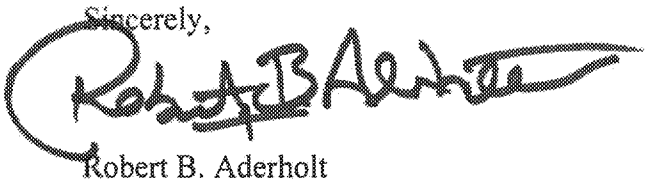
107 FEDERAL BUILDING
600 BROAD STREET
GADSDEN, AL 35901
TELEPHONE: (256) 546-0201

1011 GEORGE WALLACE BOULEVARD
SUITE 146
TUSCUMBIA, AL 35674
TELEPHONE: (256) 381-3450

could have on agriculture, I am writing to request a briefing on the IARC study and the standards that NIH places on research funded by the U.S. taxpayers.

Jennifer Groover is the contact person for my office for this issue, and she can be reached at Jennifer.groover@mail.house.gov.

Sincerely,



Robert B. Aderholt
Member of Congress

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510-6175

July 12, 2016

Thomas Burke, Ph.D.
Deputy Assistant Administrator &
Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Dr. Burke:

Thank you for your commitment to work with the U.S. Senate Committee on Environment and Public Works (EPW) as the Committee continues to evaluate your nomination to serve as Assistant Administrator of the Office of Research and Development (ORD) for the U.S. Environmental Protection Agency (EPA). Indeed, I appreciate your testimony at the June 11, 2015, EPW Committee nomination hearing and your response to questions for the hearing record. However, issues regarding EPA risk assessments (RAs) and failure to make risk-based decisions have been brought to my attention that require further inquiry before advancing your nomination. ORD serves as the scientific research arm at EPA and impacts how RAs are conducted and used across all of EPA. I also understand that you have an extensive background in the area of RAs and, as the Agency Science Advisor and Deputy Assistant Administrator for ORD, currently play a critical role in guiding the EPA's efforts in how RAs are conducted. Accordingly, I respectfully ask that you respond to the questions herein by August 2, 2016.

Risk Assessment

It has been EPA's long-standing practice to conduct RAs for pesticide products by balancing potential hazards of and exposures to a product against any benefits of the product. However, it appears that the Agency has recently deviated from this practice and has focused primarily on theoretical hazards that pose negligible actual risk, when exposure is taken into account, while discounting or ignoring product benefits. This shift has substantial implications for the products that EPA approved for use under its previous, science-based, reviews. It also creates vast uncertainty for stakeholders developing new products and could eventually have a chilling effect on investment in innovative products that may be even more protective of public health and the environment.

1. Have you, in your role as Science Advisor or Deputy Assistant Administrator for ORD, communicated to anyone at EPA, in general or relating to specific reviews, regarding how the Agency, or any office of the Agency, including the Office of Pesticide Programs (OPP), should take exposure into account when estimating the potential risk of a product?

a. If yes, please provide the Committee with copies of all such communications, including emails, memoranda, presentations, and any notes of oral conversations.

2. If confirmed as the Assistant Administrator for ORD, what recommendations would you make to EPA offices regarding how to take exposure into account when considering the potential risk of a product?

3. Have you, in your role as Science Advisor or Deputy Assistant Administrator for ORD, communicated to anyone at EPA, in general or relating to specific reviews, regarding how the Agency, or any office of the Agency, including the OPP, should consider product benefits when evaluating pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)?

a. If yes, please provide the Committee with copies of all such communications, including emails, memoranda, presentations, and any notes of oral conversations.

4. If confirmed as the Assistant Administrator for ORD, what recommendations would you make to EPA offices regarding how to take product benefits into account when evaluating pesticides under FIFRA?

Risk Communication

I am also concerned about the way in which EPA has conducted registration and deregistration review for pesticides where analysis of the potential hazards is maximized, while consideration of authorized exposure levels and product benefits are seemingly minimized. For instance, in March 2016, I sent a letter to EPA citing concern over the Agency's dissemination of the preliminary RA on imidacloprid.[1] EPA's press release on the findings of the preliminary RA inappropriately suggested more hazard than what the actual findings of the assessment warranted and singled out citrus and cotton as potential threats to pollinators.[2] The press release also failed to explain that the primary uses of imidacloprid were found to have little or no risk to pollinators and that the potential risks identified could have been easily mitigated by labeling changes.

1. Do you believe it is appropriate to communicate to the public about a scientific matter, such as a preliminary RA for imidacloprid, in a way that withholds information about a major finding of the scientific review, such as the finding in the preliminary RA for imidacloprid, that the primary uses of imidacloprid present little or no risk to pollinators?

[1] Letter from Sen. James M. Inhofe, Chairman, U.S. Sen. Com on Env't and Pub. Works, to Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Env'tl Prot. Agency (Mar. 23,2016), available at http://www.epw.senate.gov/public/_cache/files/8cc685a7-7b79-4127-a6b3-068ac9b7bb6f/03.23.2016-jim-jones-re-neonics-and-bees.pdf.

[2] Press Release, Env'tl Prot. Agency, EPA Releases the First of Four Preliminary Risk Assessments for Insecticides Potential Harmful to Bees (Jan. 6, 2016), available at https://yosemite.epa.gov/opa/admpress.nsf/0/63E7FB0E47B1AA3685257F320050A7E3.

Role of Public Opinion in Science-Based Decisions

RAs are to be purely science-based; however, EPA employees have suggested that public pressure is playing a role in the Agency's RAs and subsequent regulation of pesticides.

1. Have you heard of this concern?

2. In your opinion, what is the proper role of public opinion in a scientific review?

3. If risks associated with a beneficial pesticide product can be addressed through mitigation measures such as labeling, would it ever be appropriate to instead deregister or fail to register the beneficial product?

    a. If yes, please explain how that decision would be based on science?

    b. If not based on science or risk, would such a decision be based on public opinion? If so, is that appropriate?

Procedural Safeguards

EPA is required to comply with a number of procedural safeguards before a pesticide registration can be cancelled. However, last year EPA asked the Ninth Circuit Court of Appeals to vacate its own scientists' 2014 approval of the pesticide Enlist Duo.[3] This marked the first time EPA has attempted to vacate a pesticide registration through court action. The court denied EPA's request, which failed to comply with a number of procedural safeguards that must be met before a pesticide registration can be cancelled.

1. Who made the decision to ask a court to vacate the registration of Enlist Duo after the product was so recently approved for use?

2. Were you a part of and did you agree with that decision?

    a. Please provide the Committee with any documents relating to your involvement in or knowledge of that decision.

3. Do you think it is appropriate for the Agency to use the courts to change a regulatory decision?

    a. If so, under what circumstances is it appropriate for the Agency to attempt to use the courts to regulate instead of going through proper administrative processes that ensure a robust scientific review?

[3] Nat. Res. Def. Council v. EPA, 9th Cir., No. 14-73353, motion filed Nov. 14, 2015.

Spurious Rulemaking

EPA has recently issued letters that are the equivalent of a regulatory action. This type of action circumvents steps in the regulatory process required by the Administrative Procedures Act (APA). For example, in 2015 EPA's OPP sent registrants a letter notifying them of a moratorium on new uses of various neonicotinoid pesticides. In 2013 OPP mandated that registrants include pollinator statements and a graphic on certain products. In 2009 OPP launched the pyrethroid labeling initiative.

1. Do you think it is appropriate for the Agency to impose new requirements that have binding effect and legal consequences without going through notice and comment rulemaking under the APA and without complying with the Regulatory Flexibility Act? If so, how do you justify such action?

2. Are there circumstances where regulation by letter may be appropriate? If so, please describe them.

3. Do you think the public interest would be better served by reviewing such actions through the transparent and participatory rulemaking process required by the APA?

Reliance on Epidemiology to Make Regulatory Decisions

I am also concerned by EPA's increasing reliance on epidemiology as a basis for regulatory decisions. As an epidemiologist, you are well aware of how epidemiology can identify correlations between environmental factors and health conditions, but cannot establish a cause and effect relationship between a given factor and a given health condition. As a result, epidemiological data have a number of limitations. Epidemiology may identify associations that have no practical meaning or effect because epidemiology does not eliminate other potential causes of an observed effect. These limitations make epidemiology an inappropriate tool for regulatory decisions because a regulation that relies on epidemiology could target the wrong stressor, leaving an actual risk unidentified and wasting resources targeting the wrong exposures.

1. Have you, in your role as Science Advisor or Deputy Assistant Administrator for ORD, encouraged EPA offices to increase their reliance on epidemiological studies?

    a. Please provide the Committee with copies of all communications, including emails, memoranda, presentations, and any notes of oral conversations with EPA employees regarding the use of epidemiology.

2. Given the pesticide uses registered today, how does EPA use epidemiological studies that observe effects from exposure to previously registered pesticides?

3. Do you believe it is appropriate for the Agency to increasingly rely on epidemiological studies instead of toxicological and laboratory data?

Transparency

Concerns have been raised over the lack of transparency regarding an epidemiology study known as the Columbia University study,[4] which EPA used in its draft RAs for chlorpyrifos and seven other pesticides recognized as organophosphates. In fact, there have been reports the Agency does not even have access to the data underlying the Columbia University study. Public comments on these draft RAs objected to EPA's reliance on the Columbia University study, which EPA has seemingly ignored.

1. What steps have been taken by EPA to obtain access to the data underlying the Columbia University study? Will you commit to ensuring the Agency obtains full access to the raw data underlying this study before using the study to make any decisions?

2. Do you think it is appropriate for EPA to rely on a study that is based on data withheld from the Agency?

3. Has EPA considered establishing an independent panel of experts to review the raw data underlying the Columbia University study before continuing use of the study? If not, why?

4. In furtherance of your previous commitment to increase public access to data, will you commit to making this data publicly available?

5. Will you ensure that EPA responds to the public comments submitted on these draft RAs?

SAP Recommendations

Related to the use of epidemiology studies, in 2010, EPA convened a Scientific Advisory Panel (SAP) to review its draft framework for the use of epidemiological studies. EPA said it would revise the framework based on the SAP recommendations and would release the revised version for public comment later that year. To date, EPA has not released the revised framework.

1. What is the reason for delay in releasing this revised framework?

2. What is the current status of the framework?

3. Will you provide assurances that the Agency will, in fact, complete this task of releasing a revised framework for public comment?

4. Do you think it is appropriate that the Agency relied on the draft framework to integrate epidemiology studies into the RA for chlorpyrifos before EPA completed the revised version? If so, what is your rationale?

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[4] Rauh, et al., *Brain anomalies in children exposed prenatally to a common organophosphate pesticide,* Proceedings of the National Academy of Sciences, May 15, 2012, vol. 109, no. 20, available at http://src.bna.com/d4F.

Changing Scientific Conclusions

It has come to my attention that EPA is seemingly under pressure to come to a certain conclusion on its RA for glyphosate. EPA's cancer assessment review committee (CARC) published a report that concluded glyphosate is "not likely to be carcinogenic to humans" that was subsequently removed from the website. Despite the report being clearly marked as the "final version" as of October 1, 2015, and signed by members of CARC, EPA has claimed it is not finished with the cancer review and that publication of the report was accidental. EPA also announced it is undergoing a SAP panel process to further evaluate the cancer risk for glyphosate.

1. Did you or any ORD officials participate in meetings regarding the CARC report before its accidental publication in April 2016?

2. Did you or any ORD officials express a view about the scientific conclusions of the CARC report? If so, what was that view?

    a. Please provide the Committee with all documents from you or ORD staff expressing a view on this report.

3. Did you or any ORD official have any role in the decision to initiate a SAP panel process to further evaluate glyphosate?

    a. If so, please provide the Committee with all documents from you or ORD staff related to any request for EPA to initiate a SAP panel process to further evaluate glyphosate.

4. Do you believe this SAP panel process is necessary since CARC had finished reviewing the cancer risk of glyphosate?

5. Does ORD have a role in the SAP panel process for glyphosate? If so, please describe in detail ORD's role in the SAP panel process for glyphosate.

Thank you for your attention to this matter and for taking the time to answer these questions as the Committee continues to consider your nomination. Please direct any questions regarding this request to the EPW Committee Majority Office at (202)224-6176.

Sincerely,

James M. Inhofe
Chairman
Committee on Environment and Public Works

Breast Cancer.—The Committee understands a new Food and Drug Administration approved technology is available for breast cancer screening, called tomosynthesis (TM). The Committee encourages NCI to continue their vital research to help provide breast cancer patients and their physicians with a clear, informed picture of how breast cancer imaging should be considered for women's health. The Committee requests an update describing planned and on-going research related to TM technology and if any cohort studies are on-going and planned on TM imaging.

Colorectal Cancer.—The Committee encourages support of meritorious scientific research on colorectal cancer to better understand the biology of young-onset colorectal cancer. The Committee encourages additional research on the developmental pathway of colorectal cancer among patients with inflammatory bowel diseases.

Deadliest Cancers.—While overall cancer incidence and death rates are declining, the Committee is concerned that there are a group of cancers, defined in statute as recalcitrant cancers, whose five-year survival rates remains below 50 percent. Estimates are that half of cancer deaths are caused by eight site-specific cancers that meet this definition: pancreatic, liver, ovarian, myeloma, brain, stomach, esophagus and lung. The Committee applauds the NCI for launching the Molecular Analysis for Therapy Choice (MATCH), a potentially ground-breaking trial that analyzes patients' tumors to determine whether they contain genetic abnormalities for which a targeted drug exists and assigns treatment based on the abnormality. The goal for MATCH is for at least 25 percent of the patients enrolled in the trial to have rare cancers. Given the growing toll recalcitrant cancers take on society, and the enormous potential MATCH offers for our Nation's deadliest cancers, the Committee strongly urges NCI to increase the set-aside goal and to broaden it to include recalcitrant cancers.

Immunotherapy for Childhood Cancers.—The Committee encourages NCI to continue to further explore new interventions, such as immunotherapy, as a promising new treatment strategy for children with cancer.

International Agency for Research on Cancer (IARC).—The Committee recognizes that understanding the relationship among chemical agents and other hazardous substances and cancer is an important area of research. The Committee requests an update on NIH support for the IARC on Cancer Monographs on the Evaluation of Carcinogenic Risks to Humans.

Melanoma.—The Committee encourages consideration of a coordinated effort to analyze bio specimens across clinical trials. The Committee continues to encourage efforts to use advances in genomic, proteomic and digital imaging technologies for early detection research to understand genetic changes and mechanisms that underlie clinical dormancy. The Committee encourages NCI to consider convening a multisector, multidisciplinary strategic planning committee to provide recommendations and chart a collaborative path forward to support evidence for melanoma screening. The Committee requests an update on melanoma activities ongoing and planned in the fiscal year 2018 budget request.

NCI Designated Cancer Centers.—The Committee requests an update in the fiscal year 2018 budget request on how NCI supports

recently completed a preliminary step. As growers need additional modes of action to most effectively deal with this pest, the Committee notes its strong interest in a timely completion of the registration for this new mode of action.

Ecolabels for Federal Procurement.—Multiple forest certification programs have been recognized throughout the Federal Government as supporting the use of sustainable products in building construction and other uses. The Committee urges EPA to add additional forest certification standards that have been recognized by other Federal programs, including USDA's BioPreferred Program, to its Interim Recommendations under Executive Order 13693. The Committee urges EPA to report back on progress on implementation of the Committee's recommendation within 60 days of enactment.

Glyphosate Reregistration.—The Committee is aware that the Agency is currently in the process of reviewing the registration for glyphosate, which is a very important crop protection tool for America's farmers. Furthermore, glyphosate has been used for decades and, when properly applied, has been found to present a low risk to humans and wildlife by regulatory bodies around the world, including Australia, Canada, the European Union, Japan, and by the Joint FAO/WHO Meeting on Pesticide Residues. The Committee urges the Agency to complete its reregistration of glyphosate expeditiously.

Grant Guidelines.—The Committee is extremely concerned about reports that an Agency grant was used to support an anti-agriculture advocacy campaign. The campaign, funded in part by Federal funding, included billboards and a Web site that explicitly accused the agriculture industry as being a primary polluter of local waterways and urged increased regulation of agriculture. The use of Federal funds for such advocacy is inappropriate and may be in violation of Federal lobbying prohibitions. In response to this, the Agency must ensure there is sufficient oversight and training in place to avoid similar misuse of grant funds in the future. To achieve this goal, within 90 days of enactment, the Agency is directed to update its grant policies, training, and guidelines to ensure Federal funds are not used in this manner, including an update of the mechanism by which the Agency tracks the use of its grants, and to provide the Committee with a copy of its updated grant policies, training, and guidelines.

Fuel Standards.—The Committee supports efforts to reduce pollution from marine vessels that may be harmful to human health and coastal environments. While that is the case, the Committee is concerned the mandate for fuel with a sulfur content of 0.1% in the North American Emission Control Area is having a disproportionately negative impact on vessels which have engines that generate less than 32,000 horsepower. This impact may cause some shippers to shift from marine based transport to less efficient, higher emitting modes. In an effort to avoid negative environmental consequences and modal shifting, the Committee directs the Agency to consider exempting vessels with engines that generate less than 32,000 horsepower and operate more than 50 miles from the coastline. Within 180 days of enactment of this act, the Agency

International Agency for Research on Cancer

World Health Organization

150 cours Albert Thomas
69372 Lyon cedex 08, France

Office of the Director
Tel.: +33 4 72 73 85 77
Fax: +33 4 72 73 85 64
E-mail: director@iarc.fr
http://www.iarc.fr

Dr Francis S. Collins
Director
US National Institutes of Health
9000 Rockville Pike
Bethesda MD 20892, USA

E-mail: francis.collins@nih.gov

Ref.: IMO/75/2
CPW/mg

5 October 2016

Dear Dr Collins,

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans

The attached letter from the Chair of the Committee on Oversight and Government Reform is in the public domain (https://oversight.house.gov/wp-content/uploads/2016/09/2016-09-26-JEC-to-Collins-NIH-IARC-Funding-due-10-10.pdf) and thus came to my attention.

For more than four decades the International Agency for Research on Cancer (IARC), the specialised cancer agency of the World Health Organization, has convened Working Groups comprised of world-leading scientists to evaluate the evidence for carcinogenicity of a given agent. The evaluations published in the IARC Monographs are widely respected for their scientific rigour, standardized and transparent process and for the freedom from conflicts of interest of both Working Group members and the IARC Secretariat. The Monographs are used by regulatory agencies, scientists and the wider public across the world.

The letter from Mr Chaffetz contains a number of points about the IARC Monographs which I would like to address for the sake of accuracy and to further inform the important considerations of the Committee:

- The IARC Monographs adhere to a clear set of procedures as defined in the publically available IARC Monographs Preamble (http://monographs.iarc.fr/ENG/Preamble/index.php).
- The IARC Monographs is a hazard identification programme; risk assessments are left to national authorities or other international organizations, which may use IARC Monographs as part of their own processes.
- The IARC Monograph classifications relate to the **strength of evidence** that an agent is a carcinogenic hazard and not to the **magnitude of risk** associated with exposure: this is why different agents fall into the same classification. This distinction is made clear on the Monographs website (http://monographs.iarc.fr/ENG/News/Q&A_ENG.pdf).
- The IARC Monographs re-evaluate an agent when the scientific evidence significantly changes. In the case of coffee drinking, the previous evaluation as Group 2B "*possibly carcinogenic to humans*" was conducted in 1991. The report in 2016 was not a "retraction" but a re-evaluation based on an additional 25 years of scientific evidence.
- The IARC Monographs only evaluate agents for which there is evidence of human exposure and an existing body of scientific literature indicating a degree of carcinogenic hazard to humans. The non-random selection of agents explains why the evaluations extremely rarely find there is "*evidence suggesting lack of carcinogenicity*".

In light of your anticipated briefing to the Committee on Oversight and Government Reform, I am available to provide any additional information you may require.

Yours sincerely,

Christopher P. Wild, PhD
Director

ENCL.: Copy of letter from COGR Chair to NIH Director, dated 26 September 2016

cc: Dr Doug Lowy, Acting Director, US National Cancer Institute (dl60z@nih.gov)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 01 2016

OFFICE OF
CONGRESSIONAL AND
INTERGOVERNMENTAL
RELATIONS

The Honorable Lamar Smith
Chairman
Committee on Science, Space, and Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your letter of October 25, 2016, following up on testimony that U.S. Environmental Protection Agency Administrator Gina McCarthy presented at a hearing before your committee on June 22, 2016. Administrator McCarthy has asked that I respond to you on her behalf.

The EPA's review of the carcinogenicity of glyphosate is a complex process with many intersecting elements that draw from expertise both within and outside of the agency. We appreciate the opportunity to clarify this process, including the roles played by specific EPA scientists and the relationships between EPA officials and outside experts.

The information in the enclosure to this letter, prepared by the EPA's Office of Research and Development and Office of Chemical Safety and Pollution Prevention, provides additional details about the issues raised in your letter. We hope this information is helpful.

The EPA recognizes the importance of the Committee's need to obtain information necessary to perform its legitimate oversight functions, and is committed to continuing to work with your staff on how best to accommodate the Committee's interests.

Please feel free to contact me if you have any questions, or your staff may contact Kyle Aarons in my office at aarons.kyle@epa.gov or (202) 564-7351.

Sincerely,

Nichole Distefano
Associate Administrator

Enclosure

cc: The Honorable Eddie Bernice Johnson
Ranking Member

ENCLOSURE FOR THE EPA'S RESPONSE TO THE LETTER OF OCTOBER 25, 2016

The role of EPA scientists in the IARC

The EPA has a strong and serious commitment to sound science and scientific integrity. We are proud to have some of the world's best scientists, many of whom are internationally-recognized as leaders in their fields. Not only are the EPA's scientific experts vital for us to achieve our mission, but they also contribute to the broader scientific community and participate in activities outside of the EPA that help protect human health and the environment.

The EPA's Dr. Matt Martin and Dr. Peter Egeghy are two such experts. Because of their scientific expertise, the International Agency for Research on Cancer (IARC) invited them to participate in an IARC Monograph Working Group that was tasked with making an overall evaluation of carcinogenicity for a group of organophosphate insecticides and herbicides, including diazinon, glyphosate, malathion, parathion, and tetrachlorvinphos. It is an honor for a scientist to participate in such an internationally important and prestigious effort. It is important to note that IARC invited them because they are experts in their respective fields and not because they are EPA employees

IARC is the specialized cancer agency of the World Health Organization, and since 1971, it has evaluated 900 agents for their potential carcinogenicity. The process of developing an IARC Monograph is rigorous, intense, and complex. We would like to explain this multi-step process and clarify the roles of participants.

IARC forms Working Groups to conduct critical reviews and evaluations of chemicals. Working Group members are selected based on their knowledge and experience in the field and the absence of a real or apparent conflict of interest. IARC also considers demographic diversity and balance of scientific findings and views in assembling a Working Group. Working Group members participate as individual scientists and do not represent any organization, government, or industry. IARC Working Groups typically review several chemicals at one time, and each chemical evaluation requires a variety of different expertise (for example, toxicology, epidemiology, mode of action, computational toxicology, exposure, etc.). Because no one scientist will have all of the available expertise, individual scientists focus their expertise on certain components of the evaluation. However, the Working Group as a whole (all of the collective experts taken together) has responsibilities for:

- ensuring all appropriate data were collected;
- selecting data relevant for evaluation on basis of scientific merit;
- preparing summaries of data;
- evaluating results of epidemiological and experimental studies on cancer;
- evaluating data relevant to understanding mechanisms of carcinogenesis; and
- making overall evaluation of carcinogenicity of the exposure to humans.

The IARC preamble, which outlines this process in more detail, is available here: http://monographs.iarc.fr/ENG/Preamble/.

Dr. Martin participated in this IARC Working Group as an expert in high-throughput screening and computational toxicology. He was not present at the IARC Monograph meeting as a representative of EPA, as delineated in the IARC Monographs Preamble. Dr. Martin was part of the Section 4 Subgroup for Mechanisms and Other Relevant Data, which evaluated the mechanistic and other toxicologically-relevant information for each of the pesticides. As a member of this Subgroup, Dr. Martin prepared drafts of sections for the five pesticides in preparation for the IARC Monograph meeting. He was specifically tasked to aid in incorporating ToxCast and Tox21 high-throughput screening data (https://www.epa.gov/chemical-research/toxicity-forecaster-toxcasttm-data) into the mechanistic evaluation process for the organophosphates insecticides and herbicides for which there are relevant data. It is important to note that glyphosate was not tested in either the ToxCast or Tox21 research programs. Therefore, Dr. Martin did not incorporate any of these novel data streams into the glyphosate review, thus they did not play a role in the IARC evaluation of glyphosate.

Dr. Egeghy is an expert in human exposure assessment research and has published peer-reviewed journal articles on human exposure to pesticides. Dr. Egeghy was invited to participate because he is an expert in this area. Unfortunately, due to a death in his family, Dr. Egeghy was unable to attend the meeting, but in advance of the meeting, Dr. Egeghy prepared drafts of sections 1.1 through 1.3 (Identification, Production and Use, and Measurement Methods) for each of the pesticides. Dr. Egeghy was also a reviewer for the drafts of section 1.4 (Occurrence and Exposure) for each pesticide. All of these sections were revised by other Working Group members during the meeting, and after the meeting was over, he reviewed those revisions.

It is important to note that Dr. Martin and Dr. Egeghy were not there as EPA representatives, nor did they represent any Agency perspectives or conclusions regarding glyphosate. In addition, they played no role in the EPA's Cancer Assessment Review Committee (CARC) on the carcinogenic potential of glyphosate. In fact, because of the ways the two organizations consider the available scientific evidence, the conclusions of the EPA's CARC differed from the IARC conclusions.

Gathering the world's experts together to promote international collaboration in science is a noble purpose. It is important to advancing scientific knowledge and to protecting the health of people all over the world. That is why we are honored that the EPA's outstanding scientists are sometimes invited to participate in these evaluations. It is a tribute to the strong science of the EPA.

The relationship between EPA officials and IARC members

Science is a dynamic field and part of ensuring that the EPA is informed and our decisions are based on sound science is by maintaining relationships with competent global authorities assessing human health and environmental risks and engaging in peer review of the latest scientific developments. For example, it was important for the agency to consider recent developments in the assessments of glyphosate by IARC, EFSA, the Joint Food and Agriculture Organization/World Health Organization Meeting on Pesticide Residues (JMPR), the German

Federal Institute for Risk Assessment and Health Canada's Pest Management Regulatory Agency.

While Assistant Administrator Jones did receive an email from Dr. Chris Portier in which Dr. Portier attached a *Politico* article, this does not indicate that Assistant Administrator Jones was downplaying the EPA's work on glyphosate. The article referenced the EPA's CARC document that was inadvertently released in April 2016. This document was the final report of a committee within the EPA's Office of Pesticide Programs Health Effects Division, but it was not the EPA's final determination on whether glyphosate is carcinogenic. Ultimately, the CARC report was published in mid-September 2016 as part of the supporting materials for the agency's peer review meeting. Given the subtleties of the status of the agency's review and that the *Politico* article indicated that the EPA's CARC report could be used as information to inform an EU Parliament vote, Assistant Administrator Jones forwarded the *Politico* article to his staff to ensure that the agency was providing clear information on the status of glyphosate's classification. It is not uncommon for Assistant Administrator Jones to relay information he receives from external stakeholders, particularly when the agency's communication efforts may be causing confusion. As such, it is not credible to assert that Assistant Administrator Jones "acted to assist him *(Portier)* and IARC by publically downplaying scientific analysis conducted by EPA" especially when the EPA's *Glyphosate Issue Paper: Evaluation of Carcinogenic Potential* (September 12, 2016) proposed that glyphosate is not likely to be carcinogenic to humans at doses relevant for human health risk assessment.

The EPA is committed to what Administrator McCarthy said before the Committee, "When we have an issue that's important – as important as glyphosate is to the agricultural community, we want to make sure that we get the science right." This is why the agency is seeking peer review of its proposed classification of not likely to be carcinogenic. The EPA takes very seriously its commitment to sound science and getting the science right, and this includes robust representation of expertise and experience of its peer reviewers and a rigorous vetting of all members selected to participate on peer review panels. The agency's selection of Dr. Kenneth Portier, Vice President of the Statistics & Evaluation Center at the American Cancer Society, as a panel member illustrates the agency's commitment to making sure the decision on glyphosate is based on sound science. Dr. Kenneth Partier's professional experience amply qualifies him as a panel member for the glyphosate peer review. He has been named the chair of the recently created chemical scientific advisory committee (CSAC) and has also participated in over 60 FIFRA-SAP meetings and five Science Advisory Board (SAB) science review panels. We agree with your conclusion that it is reasonable to assume that siblings have different opinions and stand behind our decision to have Dr. Kenneth Portier serve as a member of the glyphosate peer-review panel.

Scheduling the glyphosate SAP

The agency's postponement of the glyphosate SAP meeting was to ensure that the agency is able to conduct an objective and unbiased review. Given the importance of epidemiology in the EPA's assessment, it was the agency's judgement that one epidemiologist on the panel was not adequate for this review. While other panelists have some expertise in evaluating human data, Dr. Peter Infante was the only member with a specific focus in this disciplinary area of

epidemiology. Rescheduling the glyphosate SAP is a priority for the EPA. Once the peer review panel meets, the experts' final meeting report is due 90-days after the conclusion of the meeting. Following consideration of public comments and peer review recommendations, the agency plans to release its preliminary ecological and human health risk assessments for public comment by summer 2017.

LAMAR S. SMITH, Texas
CHAIRMAN

EDDIE BERNICE JOHNSON, Texas
RANKING MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

2321 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6301

(202) 225–6371
www.science.house.gov

October 25, 2016

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator McCarthy:

The Committee on Science, Space, and Technology appreciates your testimony on June 22, 2016, at a hearing entitled "Ensuring Sound Science at EPA," where you attempted to address the concerns of Committee Members regarding EPA's review of the herbicide glyphosate. In the course of the Committee's oversight of EPA's review of glyphosate, the Committee has obtained documents and information that appears to contradict your responses to questions posed by Members of the Committee. In light of these contradictions, recent actions taken by EPA to further delay the Science Advisory Panel review for glyphosate do not instill confidence that EPA will fairly assess glyphosate based on sound science.

The Committee's Oversight on EPA's Review of Glyphosate: Determining the Role that EPA Officials Played in the IARC Review of Glyphosate.

The Committee has been engaged in ongoing oversight efforts to ensure that EPA's review of glyphosate is based on sound science and has sent two letters to EPA on the topic. On May 4, 2016, the Committee sent you a letter after it became aware that the Cancer Assessment Review Committee's (CARC) final report on glyphosate was erroneously posted on the EPA website.[1] This report stated that glyphosate was not likely to cause cancer.[2] The Committee's May 4 letter requested that EPA provide all documents and communications referring or relating

[1] P.J. Huffstutter, *EPA Takes Offline Report That Says Glyphosate Not Likely* Carcinogenic, Reuters, May 2, 2016, *available at* http://www.reuters.com/article/us-usa-glyphosate-epa-idUSKCN0XU01K.
[2] U.S. EPA, Cancer Assessment Review Committee, Evaluation of the Carcinogenic Potential of Glyphosate, Oct. 1, 2015, Final Report.

to the CARC's review of glyphosate.[3] The Committee then became aware that EPA officials participated in a working group for a study conducted by the International Agency for Research on Cancer (IARC). The IARC report found that glyphosate is probably carcinogenic in humans.[4] The IARC report was criticized heavily by the EPA's CARC report. The EPA has cited that IARC's glyphosate findings as a reason to submit the agency's review of glyphosate to further scrutiny. In light of this information, the Committee requested that EPA provide certain officials for transcribed interviews in order to better understand the role they played in the IARC study.[5]

In response to the Committee's May 4, 2016, letter, EPA provided the Committee with three document productions. The EPA also provided the Committee with a briefing by members of the Office of Pesticide Programs and the Office of Research and Development regarding the review for glyphosate. In response to the Committee's inquiry regarding the involvement of EPA officials in the IARC glyphosate study, the agency on numerous occasions informed Committee staff that two EPA officials, Matthew Martin and Peter Egeghy, who were listed as participants in the IARC Working Group for glyphosate, played only a minor or no role in the IARC's review of glyphosate.

Prior to your testimony before the Committee, Committee staff attempted to further clarify with EPA the role that agency officials played in the IARC review for glyphosate. According to email and phone communications with EPA staff, it was understood that Mr. Martin was not involved in the IARC review for glyphosate but did participate at the IARC conference on other matters.[6] With respect to Mr. Egeghy, it was understood that he did not attend the IARC conference, but that he did draft and review portions of the IARC glyphosate report with respect to human exposure but did not work on carcinogenicity.[7]

Administrator McCarthy's Testimony Before the Committee Shows Confusion, Misleading Statements on EPA Official's Role in IARC Review of Glyphosate.

The role played by both Mr. Martin and Mr. Egeghy in the IARC study was examined and discussed at the Committee's June 22 hearing. Your responses to questions about Mr. Martin's role in the IARC study appears to contradict the information that EPA staff provided to the Committee.

Representative Barry Loudermilk (R-GA) first asked you, "Was anyone at EPA actually working with IARC or participating in that review [of glyphosate]?" You responded,

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[3] Letter from Hon. Lamar Smith, Chairman, H. Comm. on Science, Space, and Technology, to Hon. Gina McCarthy, Administrator, U.S. EPA, May 4, 2016.
[4] Int'l Agency for Research on Cancer, Monograph on the Evaluation of Carcinogenic Risks to Humans, Vol. 112, Glyphosate, 2015, *available at* http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf.
[5] Letter from Hon. Lamar Smith, Chairman, H. Comm. on Science, Space, and Technology, to Hon. Gina McCarthy, Administrator, U.S. EPA, June 6, 2016.
[6] E-mail from U.S. EPA Staff to H. Comm. on Science, Space, and Technology Staff (June 16, 2016, 06:33 EST) (on file with author).
[7] *Id.*

> Administrator McCarthy: Actually, nobody was involved in the question of the carcinogenicity of glyphosate. We had three EPA employees. One was actually there as an observer.[8]

While your answer makes it clear that in your understanding no EPA employee was involved in IARC's review of the carcinogenicity of glyphosate, your statement lacked any specificity as to the involvement of Mr. Martin, whom EPA staff had indicated to the Committee was not involved in the IARC review. Rep. Loudermilk then showed you email communications within which Mr. Martin is included. These emails indicate that Mr. Martin was part of a specific subgroup that did participate on the IARC study of glyphosate.[9] You had the following exchange:

> Rep. Loudermilk: If Mr. Martin was not involved in glyphosate review, why is [he] on the email chain with the team that was working on that?
>
> Administrator McCarthy: I can go back and look but I am – I have asked a number of times, and my understanding is that none of these individuals were there in the EPA capacity to participate in the issue of carcinogenicity.[10]

Your response again reflected an understanding that no EPA official was involved in the IARC review of the carcinogenicity of glyphosate, which was the entire focus of the study. However, you failed to answer the question as to why Mr. Martin was included on an email alluding to his work on the IARC glyphosate study. Rep. Loudermilk displayed another email communication in which Mr. Martin was copied that contained talking points on how to answer questions on the findings of the IARC glyphosate study. Rep. Loudermilk expressed concern for the relationship between Mr. Martin's work at EPA and IARC, you interjected with the following:

> Administrator McCarthy: Could I just clarify on Mr. Martin? He apparently was involved in the review for glyphosate but he didn't participate in the issues relative to its carcinogenicity. So I just wanted to make that clear. That was an entirely separate part of the . . . .[11]

Upon seeing this email, it appears that you now agreed with Rep, Loudermilk that Mr. Martin was involved in the IARC review for glyphosate. It is important to note that your response completely contradicted the information that had been provided to the Committee by EPA staff, as it had been represented to the Committee that Mr. Martin did not participate in the review for glyphosate. However, despite being shown two email communications demonstrating

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[8] *Ensuring Sound Science at EPA: Hearing Before the H. Comm. on Science, Space, and Technology*, 114th Cong. (2016) (testimony of Hon. Gina McCarthy, Administrator, U.S. EPA).
[9] E-mail from Frank Le Curieux, European Chemicals Agency, to Matt Martin, et. al., U.S. EPA (Mar. 13, 2015, 02:16 AM) (on file with author).
[10] *Ensuring Sound Science at EPA: Hearing Before the H. Comm. on Science, Space, and Technology*, 114th Cong. (2016) (testimony of Hon. Gina McCarthy, Administrator, U.S. EPA).
[11] *Id.*

Mr. Martin's participation on the IARC glyphosate study, you then altered your response. You stated,

> Administrator McCarthy: Can I clarify? Because I made a mistake. . . . It says that Mr. Martin was a computational toxicologist. He wasn't involved in the IARC review for glyphosate but did participate in the IARC conference on other matters, and we have no toxicological data on glyphosate so he couldn't have contributed to the carcinogenicity issue.[12]

Over the course of Rep. Loudermilk's questioning, you appear to have provided misleading and contradictory statements with regard to Mr. Martin's involvement in the IARC glyphosate review. First, you stated that EPA employees participated in the IARC glyphosate review but did not contribute to any carcinogenicity findings, even though that was the purpose of the entire review to begin with. Then, with regard to Mr. Martin, you stood by his participation two additional times, admitting with specificity that he had contributed to the IARC study, contradicting what EPA staff told the Committee. Then you inexplicably changed your story entirely. Reversing all of your previous statements regarding Mr. Martin, you testified that Mr. Martin was not involved in the IARC review for glyphosate and further reinforced this statement by adding that there was no way that he could have had any involvement in the glyphosate study because he is a computational toxicologist.

Your contradictory statements in response to Rep. Loudermilk on this matter cast serious doubt on your specific knowledge of the role EPA officials played in IARC's glyphosate review. Moreover, your last minute statement change with regard to Mr. Martin's role in the IARC review, despite having just been shown documentary evidence to the contrary, calls into question your judgment and leadership on this matter. It appears that you had been provided with deliberately misleading information to prepare for your testimony before the Committee, which suggests an attempt by EPA staff to provide untruthful and misleading responses to Congress.

The Committee Has Determined that EPA Officials Participated in the IARC Study and Contributed to the Carcinogenicity Finding, Contravening Statements Made to the Committee by the Administrator and EPA staff.

Given the lack of clarity with regard to the role played by EPA officials in the IARC review of glyphosate, the Committee provides the following information uncovered in the course of its oversight of this matter. According to the IARC website, Mr. Egeghy and Mr. Martin were members of the IARC's glyphosate Working Group during Monograph 112, which took place in early 2015. The final product of IARC's glyphosate working group was a report stating that the Working Group determined that "Glyphosate is probably carcinogenic to humans (Group 2A)."[13] After releasing this report, it is important to note that IARC's conclusions regarding glyphosate

[12] *Id.*

[13] Int'l Agency for Research on Cancer, Monograph on the Evaluation of Carcinogenic Risks to Humans, Vol. 112, Glyphosate, 2015, *available at* http://monographs.iarc.fr/ENG/Monographs/vol112/mono112-09.pdf. (Stating "In making the overall evaluation, the Working Group noted that the mechanistic and other relevant data support the classification of glyphosate in Group 2A.").

have been consistently disproven by other international agencies such as the European Food Safety Administration as well as EPA's own CARC.

From documents it has obtained, the Committee has determined unequivocally that both Mr. Egeghy and Mr. Martin contributed to the glyphosate section of Monograph 112. These documents demonstrate that both Mr. Egeghy and Mr. Martin played a much larger role in the IARC's assessment of glyphosate than you or any EPA official has previously admitted to the Committee. A document entitled "Overview of Assignments" lists Mr. Egeghy as contributing to the IARC glyphosate study in the areas of chemical and physical data, production and use, and measurement and analysis.[14] This document also lists Mr. Martin's tasks as data relevant to comparisons across agents and endpoints and other adverse effects.[15] These documents further indicate that Mr. Martin was part of subgroup 4 (mechanisms) of the IARC Working Group for glyphosate.[16]

At the time of the hearing on June 22, 2016, the Committee had not yet determined whether Mr. Martin's work on the IARC glyphosate review had specifically informed the carcinogenicity finding. However, documents demonstrate that Mr. Martin's work for IARC did indeed drive the carcinogenicity finding for glyphosate, contradicting the assertion that you made three times that no EPA official had worked on the IARC's carcinogenicity review. In fact, the Committee has determined that the findings of subgroup 4, of which Mr. Martin was a participant, determined the status of glyphosate's carcinogenicity.[17] Documentary evidence specifically contradicts your testimony that Mr. Martin did not participate in the carcinogenicity finding of the report.[18] According to an email sent to members of subgroup 4, of which Mr. Martin is included, subgroup 4 provided "key conclusions" in the carcinogenicity findings.[19] That your testimony failed to disclose this information demonstrates that you either purposefully attempted to mislead the Committee or that you have been misled by your staff about the role that EPA officials played in the IARC glyphosate review.

EPA's Officials Appear to Maintain a Close Relationship with Members of the IARC Who Participated in the IARC Glyphosate Review.

EPA's connections to the flawed IARC glyphosate study do not end at the participation of Mr. Martin and Mr. Egeghy. Of particular note is the connection that Christopher Portier, an invited specialist for the IARC Monograph 112 that reviewed glyphosate, and a member of subgroup 4 along with Mr. Martin, has with EPA officials. Portier appears to maintain a close

[14] Int'l Assoc. of Research on Cancer, Monograph Vol. 112 – Overview of Assignments (on file with author).
[15] *Id.*
[16] E-mail from Frank Le Curiex, European Chemicals Agency, to Kathryn Guyton, Andy Shapiro, Matthew Ross, Matt Martin, Lauren Zeise, Ivan Rusyn (Mar. 13, 2015 9:00:14 AM) (on file with author).
[17] *Id.*
[18] *Ensuring Sound Science at EPA: Hearing Before the H. Comm. on Science, Space, and Technology,* 114th Cong. (2016) (testimony of Hon. Gina McCarthy, Administrator, U.S. EPA).
[19] E-mail from Frank Le Curiex, European Chemicals Agency, to Kathryn Guyton, Andy Shapiro, Matthew Ross, Matt Martin, Lauren Zeise, Ivan Rusyn (Mar. 13, 2015 9:00:14 AM) (Stating that the key role played by the conclusions sub-group had impacts on the carcinogenicity determination of glyphosate) (on file with author).

relationship with Jim Jones, EPA's Assistant Administrator for the Office of Chemical Safety and Pollution Prevention. Portier, who is also employed by the Environmental Defense Fund (EDF), has been criticized for an apparent conflict of interest between his role in the IARC glyphosate study and his work with EDF.[20]

Documents provided to the Committee show that Portier was the originator of a letter sent to the European Food Safety Authority (EFSA) regarding its study on glyphosate that was critical of IARC's report.[21] In fact, these documents show that Portier felt that the EFSA report "weakens [sic] the strength of the IARC Monograph program to stimulate change in how some of these agents are reviewed and addressed."[22] This statement demonstrates that IARC possesses an activist role in its evaluations. Portier also solicited his fellow IARC Monograph participants to sign on to the letter that he intended to send to EFSA.[23] Both Mr. Martin and Mr. Egeghy were asked by Portier to sign the letter. Documents provided to the Committee also show that Portier carbon copied Assistant Administrator Jones on the letter sent to EFSA.[24]

Furthermore, documents provided to the Committee by EPA show that Portier contacted Assistant Administrator Jones when news regarding the leaked CARC report broke. On May 4, 2016, Portier forwarded Assistant Administrator Jones a *Politico* article reporting on the posting of the CARC study and the implications it may have for a European Union decision on glyphosate. Understanding Portier's urgency in the matter, Assistant Administrator Jones forwarded Portier's email on to his EPA subordinates stating, "We need to think about a statement that goes beyond saying our assessment is not final. Looks like it will be used to inform other government decisions."[25] Given Portier's apparent efforts to use IARC to influence global policy decisions and his desire to discredit the EFSA glyphosate study, it is reasonable to assume that Assistant Administrator Jones acted to assist him and IARC by publically downplaying scientific analysis conducted by EPA.

<u>The Science Advisory Panel to Review Glyphosate has been Continuously Delayed and Contains Members Who May Constitute a Conflict of Interest.</u>

The relationship between EPA and Portier is not limited to these events. In early October, EPA announced the members of the Scientific Advisory Panel to review EPA's scientific white paper in the recertification of glyphosate. Listed among the panelists is Kenneth

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[20] Kate Kelland, *Is Your Weed Killer Carcinogeic?*, Reuters, Apr. 18, 2016, *available at* http://www.reuters.com/article/us-health-who-glyphosate-idUSKCN0XF0RL.
[21] E-mail from Chris Portier, to IARC Colleagues (Nov. 26, 2015 12:30:46) (on file with author).
[22] E-mail from Chris Portier, to Consalto Sergi,,et. al. (Nov. 9, 2015 6:29:20) (Containing email discussions of Christopher Portier's letter writing campaign regarding the European Food Safety Authority study of glyphosate).
[23] *Id.*
[24] Letter from Christopher Portier, Senior Contributing Scientist, Env. Defense Fund, et, al., to Vytenis Andriukaitis, Commissioner Health & Food Safety, European Commission, Nov. 27, 2015 (on file with author).
[25] E-mail from Jim Jones, Assistant Administrator Office of Chemical Safety and Pollution Prevention, U.S. EPA, to Jack Housenger, Andrea Mojica, Linda Strauss, U.S. EPA (May 4, 2016, 11:42:33 AM) (Forwarding *Politio* article sent by Christopher Portier to Jim Jones) (on file with author).

Portier, Vice President of the Statistics and Evaluation Center at the American Cancer Society.[26] Kenneth Portier is also Christopher Portier's brother. While it is reasonable to assume that siblings may have differing opinions, Kenneth Portier's selection to the SAP, given Christopher Portier's involvement with IARC, as well as his behind-the-scenes communications with EPA Assistant Administrator Jones, calls into question EPA's judgment and on its face raises serious conflict of interest issues. Your statement before the Committee that "when we have an issue that's important – as important as glyphosate is to the agricultural community, we want to make sure that we get the science right," gives the impression that you take this issue seriously.[27] However, EPA's actions contravene your statement by creating doubt that the SAP will act objectivity and be free from outside influence and pressure.

Additionally, EPA's recent decision to postpone the SAP meetings originally set for October 18-21, 2016, raises further doubt that the agency intends to conduct an objective and unbiased review of glyphosate. According to material posted on the EPA website on October 14, 2016, certain SAP members appear to have been unavailable to attend the scheduled meeting time.[28] However, EPA's announcement also makes reference to the need for additional epidemiological expertise on the panel.[29] The SAP already appears to contain at least five epidemiologists, raising doubts as to the veracity of the statements released by EPA for delaying the meeting. EPA staff was unable to confirm with Committee staff on October 14 whether the panel would have the same members as publically announced or if additional members would be added to the panel.

On June 22, you appeared to suggest to Committee Members that EPA would complete its review of glyphosate by fall 2016.[30] However, it is now unclear if the SAP will even meet in 2016, and EPA has already put off a final registration for glyphosate until 2017 under a new Administration. The constant delays to complete EPA's review only continue to cast doubt on the agency's ability to complete an objective review based on the science that has already been well documented on the carcinogenicity of glyphosate.

The Committee will continue its oversight efforts to ensure that EPA's review of glyphosate is free from outside influence and based on sound science. Your misleading and untruthful statements before the Committee do little to instill the confidence of the Committee. Moreover, the increasing amount of evidence depicting the close ties between EPA officials, Christopher Portier, and the IARC study of glyphosate show that there are activists working both inside and outside the agency to derail this process. The recent developments with regard to the constitution of the SAP and the delay in moving its review forward only serve to further sustain

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[26] U.S. EPA, FIFRA Scientific Advisory Panel Member Roster, *available at* https://www.epa.gov/sites/production/files/201610/documents/fqpa_sap_glyphosate_2016_panel_member_roster.pdf (last visited Oct. 25, 2016).
[27] *Ensuring Sound Science at EPA: Hearing Before the H. Comm. on Science, Space, and Technology*, 114th Cong. (2016) (testimony of Hon. Gina McCarthy, Administrator, U.S. EPA).
[28] U.S. EPA, Carcinogenic Potential of Glyphosate – POSTPONED, *available at* https://www.epa.gov/sap/carcinogenic-potential-glyphosate-postponed (last visited Oct. 25, 2016).
[29] *Id.*
[30] *Ensuring Sound Science at EPA: Hearing Before the H. Comm. on Science, Space, and Technology*, 114th Cong. (2016) (testimony of Hon. Gina McCarthy, Administrator, U.S. EPA).

the notion that EPA is not acting in good faith. In order for the Committee to better understand the role that EPA officials played in the IARC study and the subsequent review of glyphosate, we request that the following be made available for transcribed interviews:

- Matthew T. Martin, Office of Research and Development, National Center for Computational Toxicology
- Peter P. Egeghy, Office of Research and Development
- Jim Jones, Assistant Administrator for the Office of Chemical Safety and Pollution Prevention

Please contact the Committee to schedule these interviews no later than 5:00 p.m. on November 1, 2016.

Furthermore, the Committee urges you to revisit the statements that you made on June 22, 2016, and provide any clarifying information with regard to EPA officials' involvement in the IARC study of glyphosate. As it appears that you may not have received the best information from your subordinates as to the role played by EPA officials in the IARC study and the close ties these and other officials have to IARC, the Committee requests that you complete a full due diligence review of the actions of EPA employees as it pertains to glyphosate and report those findings to us as quickly as possible.

The Committee on Science, Space, and Technology has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X.

If you have any questions about this request, please contact Joseph Brazauskas or Taylor Jordan of the Science, Space, and Technology Committee staff at 202-225-6371. Thank you for your attention to this matter.

Sincerely,

Lamar Smith
Chairman

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space and Technology

