COMMENTARY

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Commentary: IARC Monographs Program and public health under siege by corporate interests

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The International Agency for Research on Cancer (IARC) evaluates causes of cancer with help from independent international experts in an open and transparent manner. Countries, research and regulatory agencies, and other organizations adopt IARC evaluations for communication of human cancer hazards, and for strategies to prevent cancer. Scientists worldwide endorse IARC cancer evaluations and process. Those with economic interests, however, challenge IARC's cancer evaluations, most recently for glyphosate and red and processed meats, and are conducting a campaign including intervention from US Congressional Representatives to discredit IARC's review process and to undermine financial support-a campaign intimidating to IARC and Working Group members. Challenges to scientific interpretations serve to advance science and should be resolved by scientific experts who do not have conflicts of interest. Such interference does not bode well for the free flow of scientific information that informs and protects the public from risks of cancer.

KEYWORDS

cancer prevention, corporate influence, glyphosate, IARC monographs, monsanto, roundup

1 | INTRODUCTION

The International Agency for Research on Cancer (IARC) was established in Lyon, France in 1965 as a specialized cancer research agency of the World Health Organization, with founding members Germany, France, Italy, United Kingdom, and United States. Currently, IARC has 25 member countries. Since 1970 the IARC Monographs Program, created by Lorenzo Tomatis, MD, has been evaluating chemical substances, agents, exposure circumstances, and lifestyle factors for evidence of carcinogenicity. IARC Monographs provide a unique and valuable objective international health service to evaluate and inform the public about cancer hazards. IARC Working Group (WG) meetings held in Lyon, France, thrice a year, are comprised of independent scientists from throughout the world, providing a truly international perspective. Meetings are openly transparent and members are vetted for conflicts of interest. The primary objective

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of the Program is to publish in the form of agent/substance-oriented Monographs, critical reviews and scientific evaluations written by an international WG of experts on evidence of carcinogenicity for a wide range of human exposures. IARC staff coordinates the process and provides scientific and material support to WGs. The authors of this commentary have participated in the IARC Monographs Program meetings. Also, Harri Vainio and James Huff have served as Chiefs of the IARC Monographs Program.

Levels of evidence for an agent causing cancer are agreed upon by WG members as detailed in IARC Monographs,^{1,2} and shortly after WG meetings are concluded, summary evaluations with supporting evidence are published in Lancet Oncology. Monographs report on human cancers observed with available measures of exposures as an integral part of hazard characterization, the initial step in the risk assessment process, but do not ordinarily perform quantitative doseresponse risk assessments that extend beyond the range of observed data. Countries and research and regulatory agencies adopt IARC classifications for communication of potential human cancer hazards,³ and for developing strategies to control and prevent cancer.

In Monographs Volumes 1-120, IARC evaluated available experimental, epidemiological, and mechanistic evidence of carcinogenicity for IARC's 1003 agents.¹ The selection process for agents relies upon published scientific findings indicating human exposures and potential cancer risk based on studies in humans and experimental animals along with information on mechanism.^{4,5} Agents without evidence of carcinogenicity and human exposure are not selected for review. Centered on these selection factors, one would a priori expect a significant percentage of agents reviewed and evaluated to provide evidence of carcinogenicity. Categorical results for 1003 evaluations are:⁶ Group 1 "carcinogenic to humans," 120 agents; Group 2A "probably carcinogenic to humans," 81; Group 2B "possibly carcinogenic to humans," 299; Group 3 "not classifiable as to its carcinogenicity to humans," 502; Group 4 "probably not carcinogenic to humans, 1. Based on selection criteria, it is thus surprising that only ~20% of agents/exposure circumstances reviewed are classified as human carcinogens or probable human carcinogens.

Likewise, selection of chemicals for animal cancer testing by the US National Toxicology Program based on widespread human exposure, and not suspicion of carcinogenic activity,⁷ resulted in only 6.8% of substances giving positive cancer results in two species (one requirement for IARC sufficient evidence of cancer in experimental animals). These results further support the observation that the slightly higher percentage of carcinogens identified in IARC reviews is a reflection of the chemical selection criteria. Yet, despite this selection bias for agents that demonstrate evidence of carcinogenicity, only 120 of 1003 IARC agents (12%) evaluated were considered unequivocally carcinogenic to humans; adding those 81 agents evaluated by IARC WGs as "probably carcinogenic to humans" still results in only 20%; while 50% of agents evaluated by IARC were not classifiable as to their carcinogenicity to humans. Nonetheless, in light of this low percentage of agents reviewed, evaluated, and considered to be carcinogenic by IARC, the American Chemistry Council (ACC), a trade association which promotes the interests of US chemical companies has voiced its opinion that IARC is "dubious and misleading" in classifying potential carcinogens.⁸ ACC and its consultants further criticize IARC for misleading the public by over-evaluating agents that cause cancer in humans.9,10

We mention two IARC Monographs that have recently received considerable attention: red and processed meats¹¹ and glyphosate (two other chemicals evaluated at the same meeting as 2A, diazinon and malathion, engendered no criticism).¹² In October 2015, after an 8-day meeting, an independent IARC WG of 22 scientists from ten countries concluded consumption of "processed meat" is "carcinogenic to humans" based on sufficient evidence for colorectal cancer from epidemiology studies; and "consumption of red meat" is "probably carcinogenic to humans" based on credible studies showing associations with colorectal, pancreatic, and prostate cancers. Differences in these evaluations center on strength of available epidemiological evidence: consumption of processed meat was classified as Group 1 on sufficient evidence in humans, whereas consumption of red meat was classified as Group 2A on substantial epidemiological data and strong mechanistic evidence. Significantly, the IARC WG "assessed more than

800 epidemiological studies that investigated the association of cancer with consumption of red meat or processed meat in many countries, from several continents, with diverse ethnicities and diets.^{*11,13} [Note: the IARC definition of *sufficient evidence of carcinogenicity* to humans signifies "a causal relationship has been established between exposure to the agent and human cancer." *Limited evidence of carcinogenicity* to humans means that "a positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence."^{1,6}

Glyphosate was discovered in 1970 and brought to the market in 1974 by Monsanto under the trade name Roundup. Glyphosate, a broad-spectrum herbicide, currently the highest production volume of all herbicides, is promoted and sold worldwide by many agrochemical companies, in different solution strengths and with various adjuvants, under dozens of trade names, as more than 750 glyphosate products.¹² In March 2015, after an 8-day meeting, an independent IARC WG of 17 scientists from 11 countries concluded glyphosate, an herbicide widely used to control weeds in nonagricultural and agricultural settings primarily on geneticallyengineered crops, was "probably carcinogenic to humans" [2A] based on sufficient evidence of carcinogenicity in experimental animals and limited evidence of cancer in humans for non-Hodgkin lymphoma. In addition, there was strong evidence that glyphosate operates through two key characteristics of known human carcinogens: exposure to glyphosate or glyphosate-based formulations is genotoxic based on studies in human cells in vitro and studies in experimental animals, and strong evidence that glyphosate, glyphosate-based formulations, and aminomethylphosphonic acid (major metabolite) induces oxidative stress in experimental animals, and in studies of humans cells in vitro.^{12,14} Some have questioned this conclusion,^{15,16} whereas 94 international independent scientists agreed with and support IARC's evaluation for glyphosate¹⁷ as do others.^{18,19} Further, IARC, the German Federal Institute for Risk Assessment (BfR), and the European Food Safety Authority (EFSA) found increases of tumors in seven carcinogenicity studies in mice and rats.²⁰However, BfR and EFSA opined five reasons for dismissing these carcinogenic effects, using a "weight of evidence" (WOE) approach. Clausing²⁰ and Clausing et al,²¹ however, have adequately challenged the validity of the BfR and EFSA approach, and their five WOE reasons for dismissing evidence of carcinogenicity.

Regarding the worldwide credibility and public health value of IARC Monographs, 124 scientists with expertise in chemical carcinogenesis have praised and endorsed the IARC Monographs for the transparency of their review process and IARC's impartial high quality evaluations in identifying cancer hazards in the environment and workplace.²² IARC allows observers and representatives from government agencies, industry and other organizations to attend and participate in WG meetings; however, they are not permitted to vote on evaluations of carcinogenicity.

For the past 47 years, IARC Monographs have contributed to improving public health by providing evidence-based unbiased expert evaluations to identify carcinogens and to support cancer prevention and control.²² Nonetheless, vested-interest criticisms of IARC cancer evaluations,¹⁰ supported by pro-industry consultants,²³⁻²⁵ have centered particularly on the scientific credibility of IARC evaluations. Pointedly, in response to IARC evaluations for red and processed meat and glyphosate, the ACC initiated a Campaign for Accuracy in Public Health Research (CAPHR) with the proclaimed aim "to promote credible, unbiased, and transparent science" to assist public health and policy makers in their evaluation and interpretation of evidence for cancer causation.⁹ The ACC further states "IARC's Monographs Program suffers from persistent scientific and process deficiencies that result in public confusion and misinformed policy-making." Yet, most of the authoritative sources cited in an article critical of the IARC Monographs Program¹⁰ appear to have conducted research or consultations that has been supported by industry.^{23,24} Monsanto, through membership in the ACC, has lobbied extensively, and paid scientists to author papers on the safety and continued use of glyphosate,^{25–28} and that contradict the findings of IARC despite recognized human health hazards. McClellen.²⁷ as editor of Critical Reviews in Toxicology, has published 10 articles dealing with glyphosate and health effects; most dispute IARC's conclusions in its evaluation of glyphosate or otherwise conclude that glyphosate's risk is minimal, or non-existent.^{26,29-37} These authors have been supported/funded directly or indirectly by Monsanto, the primary producer of glyphosate and products containing this active ingredient. Additionally, Monsanto has sent a threatening letter of intimidation to IARC staff.³⁸ Ominously, EPA staff has been accused of collusion with Monsanto to downgrade the health hazards of glyphosate.³⁹⁻⁴¹

Ironically, from recently released documents, Monsanto thought their herbicide would indeed fit into the IARC category of either "possibly," or "probably carcinogenic to humans" long before the IARC Monographs review meeting and yet mounted a campaign to criticize IARC's evaluation.^{42,43} Further, a Monsanto internal confidential memorandum states "And while we have vulnerability in the area of epidemiology, we also have potential vulnerabilities in the other areas that IARC will consider, namely, exposure, genetox, and mode of action ... If there is a force working against glyphosate, there is ample fodder to string together to help the cause [presumably to make glyphosate/Roundup viewed as safe] even though it is not scientifically justified in its purest form."⁴²

The ACC has lobbied US Congress to investigate IARC's review of glyphosate.⁴⁴ Now, because of successful lobbying, US Congressional Republicans are questioning the credibility of IARC Monographs and funding from the US National Institutes of Health (NIH). They further question the ability of EPA to objectively evaluate the carcinogenicity of glyphosate because one staff member participated in the IARC review as a WG member. A six-page letter from the Chairman of the Committee on Oversight and Government Reform⁴⁵ to Francis Collins, Director, NIH, questions NIH support for IARC Monographs, and requests a briefing on NIH funding to such "foreign" entities in light of IARC's cancer evaluations being inconsistent with other entities, particularly on red meats, processed meats, and glyphosate.

Additionally, an eight-page letter⁴⁶ from the chair of The Committee on Science, Space, and Technology to Gina McCarthy, Administrator, US Environmental Protection Agency, admonishers her for EPA staff members apparent role in the IARC Monograph WG's evaluation of glyphosate. Congressman Smith expressed concern that "activists" working both within and outside of EPA might derail the EPA preliminary evaluation of glyphosate¹⁶-an evaluation not yet finalized that is contradictory to the IARC conclusion on the probable carcinogenicity of glyphosate. Further, Kelland,⁴⁷ a defender of Monsanto, has contacted IARC glyphosate Working Group members and has accused IARC of altering the Working Group's evaluation. IARC⁴⁸ has rebutted these accusations. Further, congressional hearings are being considered to investigate IARC and the Monographs Program evaluation process and requests have been made for IARC to provide names of potential witnesses.⁴⁹ The Director of IARC has responded to the inquiry of Smith and Biggs,⁵⁰ but declined to provide witnesses for any potential congressional hearing. The response from IARC⁵⁰ apparently did not satisfy Congressman Smith et al⁵¹ who continue to question the integrity of the IARC Monographs Program, US funding for the program, and to again request that IARC provide names of potential witnesses. Such tactics are intimidating to IARC, to IARC Working Group members, and to research and regulatory agencies reliant on IARC's science-based cancer causation evaluations.

Potential inconsistencies or relevant challenges in scientific interpretation often serve to advance science and should be resolved by scientific experts who do not have a conflict of interest in these evaluations, and certainly not by politicians with vested interests who lack understanding of the strength of scientific evidence supporting or opposing a particular scientific determination.

The interferences by economic interests in cancer evaluations conducted by public health institutions^{52,53} do not bode well for the free flow of scientific information that informs and protects the public and workers from clear risks of cancer.

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All authors participated in the conception, design, analysis, interpretation of the work and in the revision of drafts, and all authors agreed with the final version of the commentary. PFI and JH participated in the acquisition of the documents included in the analysis and the first draft, and are accountable for the accuracy and integrity of the documents cited in the report.

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None.

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