

Glyphosate on Trial: The Search for Toxicological Truth

By Sheldon Krimsky, PhD

In 2015, the International Agency for Research on Cancer (IARC), an independent research group under the auspices of the World Health Organization, issued its toxicological evaluation of the herbicide glyphosate. IARC concluded: "Glyphosate is probably carcinogenic to humans."¹ The release of its report created a firestorm of activity throughout the world. Glyphosate is the most widely used herbicide on the planet. Since it first came into use in 1974, it has been evaluated many times by a number of governmental bodies including the U.S. Environmental Protection Agency (EPA), the European Union, and the European Food Safety Authority (EFSA), where it was found safe for human use with no strong evidence that it was a probable human carcinogen.²

Monsanto, manufacturer of one formulation of glyphosate called Roundup™, sold both for farm and domestic use, took aggressive action against the findings of the new study by funding counter studies, reviews, data reanalysis, lawsuits, and media campaigns to protect its product from IARC's negative report. On March 28, 2017, California's Office of Environmental Health Hazard Assessment (OEHHA) announced it was adding Roundup™ as well as other glyphosate-based weed killers to the state's Proposition 65 list of cancer-causing chemicals. In a letter to Monsanto, OEHHA wrote, "Proposition 65 required the listing of certain chemicals and substances" when found to be cancer causing agents. "Under the statute, case law and regulations, chemicals identified by IARC as carcinogens with sufficient evidence of carcinogenicity in humans or animals must be listed under Proposition 65."³ Under the law, California was not required to, nor did it, do additional testing or risk analysis. Monsanto challenged OEHHA's listing; its challenge was defeated at the trial court and was appealed. If the final judicial approval is given for the glyphosate listing,

companies will have to label the glyphosate-based weed killer as a “probable human carcinogen.” On April 19, 2018, a California Appellate Court ruled that Monsanto’s glyphosate herbicide can be labeled as a probable human carcinogen under Proposition 65.

Meanwhile, the toxicology of glyphosate is being debated within the scientific community. The goal of this chapter is to examine the different interpretations of the scientific literature on the health and safety of glyphosate and its formulations among herbicides. Why does one World Health Organization agency reach a decision that glyphosate is a probable human carcinogen while others, including the EPA, conclude, with equal confidence, that it is not a human carcinogen? How should consumers respond?

Before I answer these questions, I begin with the backstory—the story not found in the scientific literature but that can have a profound effect on it. The backstory is as important as the science because the evaluation of glyphosate is embedded in an intensely corporatized climate of agricultural chemicals. We have learned that some scientists are paid by companies to reach conclusions that support their profit margins. Unfortunately, there are always a minority of scientists who are willing to act as shills for a corporate benefactor.

Like the hidden story behind tobacco⁴ and lead science,⁵ the purpose of the corporate funding of glyphosate research was not to find the truth but to protect the product from regulation commensurate with its risk. We have learned much about rogue tobacco and lead science when the corporations involved in their manufacture and promotion, complying with court orders, released discovery documents during litigation. Similarly, Monsanto is being sued by hundreds of plaintiffs with claims that Roundup™ has harmed them, in some cases claiming it afflicted them with non-Hodgkin’s lymphoma, a form of blood cancer.

The discovery documents released by Monsanto reveal a backstory of corporate malfeasance.⁶ The documents provide evidence that Monsanto was engaged in ghostwriting (that is, writing articles for established scientists to submit as sole authors without revealing the company’s role),⁷ hiring contract research companies to undertake invalid toxicology studies, exerting undue influence on regulatory agencies,⁸ threatening lawsuits against publishers and journals, creating so-called expert panels comprised of individuals who sign on to a study vetted and funded by Monsanto without

acknowledging the company's role, hiding the fact that its own formulation for Roundup™ was never tested for its carcinogenic effects, and campaigning against the credibility of published scientific studies and their authors that reached conclusions it disliked.

These are just a portion of the corporate malfeasance cases revealed in the discovery documents. Similar attacks have been reported in Europe of scientists who have reported adverse effects of glyphosate or Roundup™.⁹

It should be understood that the controversy over the toxicity of glyphosate or Roundup™ is not a debate over neutral sectors of the scientific community at odds over the intricacies of toxicological methods. The issues are replete with political overtones. Yet, we can discuss the front story of glyphosate toxicology as it appears in the scientific literature. There is much to be learned about the way honest science should proceed.

First, I shall discuss the background of IARC and its standing in the world health community. Second, I shall give a short history of glyphosate and its use as a weed killer. Third, I shall discuss the basis of IARC's decision summarizing the evidence it used. Fourth, I shall summarize the criticisms of IARC's decision, including its evidence and its methods of analysis, and the role of corporate science in the support of glyphosate. Finally, I shall conclude by examining why different agencies reach different conclusions and where that leads the cautious consumer and environmentalist. My conclusions about which science is trustworthy is based on the transparency of those doing the research, the ethical standards of the agencies interpreting the weight of evidence, whether the research is done without funding from stakeholders, and the precautionary principle—when sufficient, albeit not definitive, evidence dictates regulatory protection.

IARC's Origins

IARC was established in May 1965 by a resolution of the World Health Assembly, under Article 18(k) of the World Health Organization (WHO) constitution, as a specialized cancer agency of WHO. Its fifty-year anniversary volume noted, "The International Agency for Research on Cancer (IARC) is the outcome of an initiative by a group of leading French public figures, who succeeded in persuading President [Charles] de Gaulle to accept a project to lighten humanity's ever growing burden of cancer."¹⁰

An open letter signed by thirteen leaders in the fields of cancer research, physics, journalism, engineering, architectures, and religion was delivered to Elysee Palace on November 7, 1963; it jump-started the initiative for a world cancer agency. *Le Monde* described the event in a headline: "Pour développer la lutte contre le cancer des personnalités françaises lancent un appel en faveur d'une institution internationale de recherche pour la vie"¹¹ (In developing the struggle against cancer some French personalities have issued a call for an international organization to look for ways to save lives.)

The idea behind the letter was that nations should re-direct military budgets to fund the battle against cancer and to promote international collaboration in cancer research. It called for an allocation of 0.5 percent of the military budgets of participating nations. The initial participating countries were Germany, France, Italy, the United Kingdom, and the United States, soon followed by Australia and the Soviet Union. By 1972, ten nations signed on to IARC.

IARC launched its monographs program in 1971. Its aim was "to develop an instrument capable of evaluating the best evidence available at a given time on carcinogenic agents, in order to provide a sound scientific basis for cancer prevention."¹²

Science and ethics were at the core of IARC's approach to understanding cancer. On the science side, the agency has supported the best expert knowledge in publishing statistical methods guiding its analysis of case-control studies and cohort studies, two of the seminal methods for understanding cancer etiology.¹³ IARC emphasized two innovative features of its work: the systematic approach to examining and evaluating each agent by the same procedures, and the proposition that the soundest way to reach the "truth" about the carcinogenicity of an agent is through open discussion and reciprocal cross-checking by leading experts. "Given the imperfect nature of all human knowledge, the truth is always approximate, but it can be explicitly stated and qualified by the degree of confidence attached to the statement."¹⁴ Trust was critical for gaining confidence in the science.

On the ethics side, IARC noted, "In practice, scientific judgment can be distorted by secondary interests and goals extraneous to, and interfering with, the primary goal of pursuing scientific, reasonable truth, such as financial incentives or advocacy standpoints. Hence, the experts chosen to

participate in evaluations had to be as free as possible of such conflicting interests." This becomes a critical element in developing trust in its risk assessment of financially lucrative chemicals that have been on the market for decades and for which there is a powerful constituency for supporting its continuous use. That was certainly the case with DDT, PCBs, asbestos, and benzene.

IARC's monographs program was founded by Lorenzo Tomatis and introduced in 1971 to develop the best scientific evidence to evaluate whether a chemical was carcinogenic. Tomatis was IARC's director from 1982 to 1993. He articulated IARC's precautionary approach in evaluating a chemical's toxicology. He wrote, "In the absence of absolute certainty, rarely if ever reached in biology, it is essential to adopt an attitude of responsible caution in line with the principles of primary prevention, the only one that may prevent unlimited experimentation on the entire human species."¹⁵ Each monograph is produced by a Working Group of international experts who meet in Lyon for seven to ten days. With the help of IARC's professional staff, the Working Group reviews the scientific literature on the carcinogenicity of human exposures to the chemical under study.

Evidence of carcinogenicity is classified into one of five categories: carcinogenic, probably carcinogenic, possibly carcinogenic, not classifiable, and probably not carcinogenic to humans. "Intensive discussions and repeated revisions of the monograph text take place during what is nowadays an eight-day long meeting."¹⁶

History of Glyphosate

Glyphosate, or chemically named N-(phosphonomethyl) glycine, is a derivative of the amino acid glycine. It is a white odorless crystalline solid. While working at the pharmaceutical company Cilag, Swiss chemist Henri Martin discovered the compound glyphosate in 1950.¹⁷ It never was advanced as a drug. Johnson and Johnson acquired Cilag and sold its research samples, including that of glyphosate, to Aldrich Chemical.¹⁸ Two decades later, Monsanto scientists were investigating compounds as potential water-softening agents. They synthesized over one hundred related analogs. Some of these compounds, closely related to glyphosate, had herbicidal properties. Monsanto scientist John Franz worked on the compounds to determine

what gave them their herbicidal properties, and glyphosate was synthesized in 1970.

Monsanto eventually patented glyphosate under the trade name Roundup. The first U.S. approval for glyphosate came in 1974. In 1985, the EPA classified glyphosate as a Group C chemical, which means under its designation that it is a possible carcinogen to humans based on rodent studies. Glyphosate was re-registered in the United States in 1993 as a Class E chemical on the finding that it “does not pose unreasonable risks or adverse effects to humans or the environment.”¹⁹

Since that time, it has become the most widely used herbicide in agriculture, and the second most widely used herbicide in home gardens next to 2,4-D. When Monsanto developed herbicide resistance in plants, it linked the genetically engineered crops to their formulation of glyphosate, under the trade name Roundup.

The EPA's mandate under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is to evaluate pesticides for registration. Unlike IARC, there are no legal requirements that the reports and studies companies submit to EPA are published or peer reviewed. Also, the EPA only evaluates the active ingredient, glyphosate, and not the whole formulation with adjuvant chemicals, or Roundup™. Around 1996 when Roundup Ready seeds entered the commercial markets, glyphosate use increased dramatically.²⁰

IARC reviews Glyphosate Toxicity

IARC was engaged in a study of the toxicology of glyphosate in 2015. It published the results of its assessment of glyphosate along with other chemicals in a 2017 document titled *Some Organophosphate Insecticides and Herbicides*,²¹ reflecting the views and expert opinions of an IARC Working Group on the “Evaluation of Carcinogenic Risks to Humans,” which met in Lyon in March 2015. The glyphosate assessment appeared in volume 112 of its monograph series on cancer.

IARC's finding that glyphosate is a “probable human carcinogen” was immediately criticized in the media. Scientific articles were soon published citing shortcomings or errors in its assessment of the ubiquitous herbicide. To fully understand the different viewpoints, it is important to understand

the procedures taken by IARC in its review. Because toxicology involves the selection and interpretation of scientific studies, which may differ among toxicologists, and because biases can enter the process, gaining trust in the institution that undertakes the analysis contributes to one's confidence in the outcome.

IARC begins preparing for an evaluation of a chemical in its Monograph Programme a year before the meeting is scheduled. In the case of glyphosate, IARC established a Working Group consisting of eighteen scientists from France, Chile, Italy, Australia, Canada, Finland, the Netherlands, New Zealand and the United States. Two were listed as unable to attend the meeting where the consensus statement was developed; however, later reports indicated that seventeen members were present. Eight members of the working group were from the United States and worked at government agencies, universities, and a consulting group. Only one of these was listed as not attending the meeting. Also invited was one retired scientist from the Centers for Disease Control and Prevention in the specialist category, four representatives from national health agencies, and six observers, including one academic scientist who acted as an observer for the Monsanto Company. There are five categories of participants to the Monograph meeting: the Working Group, invited specialist(s), representatives of national and international health agencies, observers with relevant scientific credentials, and the IARC staff secretariat.

The Working Group with the help of the IARC staff is solely responsible for issuing the final risk assessment of the chemical. IARC is autonomous to a significant degree, while a part of the World Health Organization and the United Nations. There are strict conflict of interest rules for the members of the Working Group and others involved in the discussions and assessment. Each participant, including the IARC secretariat, is required to disclose pertinent research, employment, and financial interests related to the subject matter of the meeting, covering the past four years or anticipated in the future. IARC officials evaluate the declarations of interest to determine if a conflict of interest warrants modification of participation. All financial interests are disclosed in the published Monograph.

Once the Working Group is established, some members are asked to prepare working papers in their areas of expertise. Four subcommittees were

formed to revise and summarize the findings of the working papers and strive to reach a consensus.

The Working Group will accept certain types of studies as part of its assessment of the human carcinogenicity of chemicals: cohort studies, case-control studies, correlation or ecological studies, intervention studies, and case reports. A cohort study is a longitudinal study of a group of people who share a common experience or environmental exposure compared to a similar group whose members do not share that experience or exposure. Investigators follow the people in these groups to determine the risk factor from the exposure, in this case glyphosate. A case-control study is always retrospective. It starts with an outcome, i.e., a disease like non-Hodgkin's lymphoma, and then it traces the outcome back to investigate exposures of a group that has the disease and also a similar group that does not have the disease, to determine the possible cause. Ecological studies investigate outcomes based on populations defined either geographically or temporally. Thus, farmers using glyphosate in one region of the country or during one time period may be compared to farmers who do not use glyphosate in another region or another time period.

Any risk factors are averaged for both of these populations and compared, using statistical methods. Intervention studies involve two groups, one of which receives some intervention and another that does not. In the case of glyphosate, one group of farmers may receive special protective clothing and masks while another group of farmers use standard protections. Or one group has stopped its exposure to glyphosate while the other continues to be exposed. The disease outcomes of these groups are compared. The Working Group reviews medical reports of individual cases of disease and examines the historical background and exposures of the patients.

In a legal deposition, the chair of the glyphosate Working Group, Aaron Blair, was asked about the importance to IARC of a paper by DeRoos et al. (2003), which studied people exposed to glyphosate in Nebraska, Iowa, Minnesota, and Kansas between 1979 and 1986. The paper found a doubling of the risk for non-Hodgkin's lymphoma.²² The exchange follows:

Q: Is this one of the pieces of evidence upon which your committee based their opinion [where] there was a positive association between exposure to glyphosate and non-Hodgkin's lymphoma

from exposure to Roundup or glyphosate outside the realm of chance?

A.: [from Aaron Blair] Yes.

The exchange goes to the heart of the matter. The chairman of the IARC Working Group affirms that his committee was swayed by statistically significant studies linking glyphosate or its formulations to cancer. There is not the slightest hesitancy in his response.

IARC imposes some strict criteria on the types of data it will accept in its Monograph assessment. "IARC evaluations rely only on data that are in the public domain and available to independent scientific review. Data from government agency reports and doctoral theses that are publicly available can also be considered. The evaluation of glyphosate by the Working Group included only industry studies that met these criteria. However, they did not include data from summary tables in online supplements to published articles, which did not provide enough detail for independent assessment."²³ This is a critical piece of information because Monsanto argued that some industry data were not included in IARC's glyphosate Monograph that may have been included in other assessments. The EPA, on the other hand, does accept registrant generated studies that are unpublished and not peer reviewed.²⁴

Primary Evidence

IARC began its analysis by indicating that the study of primary significance for the Working Group review of glyphosate was a prospective cohort study conducted in Iowa and North Carolina called the Agricultural Health Study. It was the only cohort study to have published findings on the exposure of people to glyphosate and the associated risk of cancer at many different sites. Among the goals of the study was to identify and quantify cancer risks among men, women, and minorities associated with their direct exposure to pesticides and other agricultural agents. When the total cohort was assembled in 1997, there were about seventy-five thousand adult study subjects. Prior studies of farmers throughout the world indicated that they had higher rates of non-Hodgkin's lymphoma than non-farmers.

A questionnaire developed by the National Institutes of Health was administered to pesticide users. About fifty pesticides were in the survey, which included questions about crops grown, livestock raised, pesticide application methods, and personal protection equipment used.²⁵

The IARC Working Group identified seven reports from the Agricultural Health Study (AHS) and several reports from case-control studies related to glyphosate. These studies were considered important because of the relative size of the study populations. The studies that grew out of the AHS surveys and state cancer registries allowed investigators to develop relative risks and calculate correlations between glyphosate and disease endpoints. In reviewing the studies, the Working Group reported no association between exposure to glyphosate and prostate, breast, colorectal, skin, and pancreatic cancers.²⁶ There was one cancer endpoint which IARC found correlated with glyphosate exposure: non-Hodgkin's lymphoma (NHL). The report stated: "Two large case-control studies of NHL from Canada and the U.S. A., and two case-control studies from Sweden, reported statistically significant increased risks of NHL in association with exposure to glyphosate."²⁷ The risks the Monograph cited persisted even in studies that adjusted for exposure to other pesticides.

The animal carcinogenesis studies were mixed—some showed a significant increase in cancer, while others found no significant increase in tumors at any site. After referencing 269 scientific studies in its ninety-four-page glyphosate Monograph, IARC reported that there is limited evidence in humans for the carcinogenicity of glyphosate from the positive associations it found between the herbicide and NHL. By "positive association," IARC meant that there were studies that showed an excess risk for people exposed. It also stated that "there is sufficient evidence in experimental animals for the carcinogenicity of glyphosate."²⁸ Based upon the weight of human and animal data IARC concluded "Glyphosate is probably carcinogenic to humans."²⁹

Divergent Scientific Results

Why did other government health agencies reach a different conclusion on the carcinogenicity of glyphosate? There are three main reasons to expect divergence in the findings of the toxicology for the herbicide:

- The other agencies used different sets of evidence because there were different selection criteria for choosing the studies or IARC did not have the latest data.
- They used different methods for aggregating or weighing the evidence.
- They interpreted the same evidence differently.

A group of scientists from two agencies that undertook an assessment of glyphosate and reached a much lower risk value than that of IARC published a paper that tried to explain the different outcomes. They were from the European Food Safety Authority (EFSA) and the German Federal Institute for Risk Assessment. According to the authors, "Uses of different data sets, particularly on long-term toxicology/carcinogenicity in rodents, could partially explain divergent views. . . . The EU evaluation, which considered studies not available to IARC, also updates the toxicological profile of glyphosate proposing new toxicological reference values."³⁰

After reviewing the evidence of both IARC and the evaluations of the other European agencies, the authors concluded that the same epidemiological studies were used in all the assessments. "The same weak evidence in humans for the carcinogenicity of glyphosate was interpreted differently by IARC and EFSA. IARC considered the association between exposure to glyphosate and non-Hodgkin lymphoma as *limited evidence* in humans, while in the EU assessment, most experts considered the evidence as very limited and insufficient for triggering the classification."³¹ IARC used the information about glyphosate's carcinogenicity in animals, and for two mechanisms of action, namely genotoxicity and oxidative stress, to buttress the plausibility of the limited evidence in humans.

According to the authors, the source of the divergence in assessing glyphosate is in putting the pieces of all the studies together and in reaching the weight of the evidence. The EU evaluation from EFSA and FAO was based on the likelihood of getting NHL from low dose exposures. IARC was less interested in the probability of contracting NHL, but on the possibility. "Definitions for limited and sufficient evidence in humans and animals are identical for IARC and the UN-GHS [United Nation's Globally Harmonized System of Classification and Labeling of Chemicals]; however, differences in criteria and methodological considerations for weighing and assessing the evidence can lead to divergent interpretations between the

IARC assessment and regulatory evaluations following UN-GHS criteria, even when based on the same evidence."³²

Critics of IARC claimed that data available to the Working Group showed no correlation between glyphosate exposure and NHL; some of this was from a pooled study (data are aggregated for more statistical power), which had more exposed subjects in them. At least one of the unpublished studies found no evidence of a link between glyphosate and cancer. Even though the chair of the Working Group knew of the data, it was not shared with the other members or considered as part of IARC's analysis. This information was revealed when the media got hold of court documents in a trial with the plaintiff suing Monsanto, attributing glyphosate as the cause of its clients' NHL illnesses.³³ The deposition of Aaron Blair was one of the documents. Dr. Blair was questioned by Monsanto's attorneys for over three hours on the issue of why he and the Working Group did not use the new data that was available before they met. Monsanto's lawyers argued that farmers were acquiring NHL before glyphosate was on the market dating back to the 1960s, and that there were many factors, other than glyphosate, that could have explained the excess of NHL among farmers. Under oath, Blair testified that he was involved in a study with data that showed a two-fold increase in the risk of NHL of farmers handling glyphosate for greater than two days a year. He could not report this study to IARC because it had not been published by March 2015 when the Working Group had met. That speaks to the even-handedness of the process.

The plaintiff's attorney posed the following question to Dr. Blair after he was cross-examined by the defendant's attorney as an independent expert witness, not as a plaintiff's expert:

Q: Has anything you have been shown by Monsanto's lawyers in the three hours and forty minutes that he questioned you changed the opinion that you had at the IARC meeting about glyphosate and non-Hodgkin lymphoma?

A.: No.³⁴

IARC provided an official response to many of the allegations appearing in the media. It emphasized that "the IARC Monographs evaluations are based on the systematic assembly and review of all publicly available and pertinent

studies by independent experts, free from vested interests.”³⁵ In response to claims that it omitted certain critical information, IARC stated that it had reviewed about 1,000 studies and cited 269 references. In response to the question about why IARC’s outcome for glyphosate was at odds with the assessments of major regulatory agencies, it noted that “many regulatory agencies rely primarily on industry data from toxicological studies that are not available in the public domain. In contrast, IARC systematically assembles and evaluates all relevant evidence available in the public domain for independent scientific review.” One of the strongest criticisms of the IARC raised in litigation by the defense was that it neglected to incorporate all the data of the Agricultural Health Study (AHS), a U.S. two-state health study of farmers’ and their families’ exposure to agricultural chemicals. The IARC reported that the AHS study was large and well-conducted but that it was incorrectly described as the “most powerful” study. “The weakness of the study is that people were followed up for a short period of time, which means fewer cases of cancer would have had time to appear.”³⁶

On December 12, 2017, the Environmental Protection Agency issued its glyphosate assessment.³⁷ This was a follow-up to a series of risk assessments for the herbicide. The agency classified glyphosate as a possible human carcinogen in 1985. Then in 1986 it asked the FIFRA Advisory Panel (SAP) to evaluate the carcinogenic potential of glyphosate. Based on the available evidence, SAP recommended that the herbicide be classified as a Group D classification (not classifiable as to its human carcinogenicity) but asked that EPA obtain new studies. With the addition of rodent studies, in 1991 the EPA’s Carcinogenicity Peer Review Committee classified glyphosate as a Group E chemical (evidence of non-carcinogenicity for humans), downsizing its risk. In 2015, the EPA’s Cancer Assessment Review Committee concluded that glyphosate is not likely to be carcinogenic to humans.

In its most recent report, the EPA stated, “Due to study limitations and contradictory results across studies of at least equal quality, a conclusion regarding the association between glyphosate exposure and the risk of NHL [non-Hodgkin’s lymphoma] cannot be determined based on available data.”³⁸ The EPA’s conclusion was based on six human studies, which were also a part of the IARC’s review. Unlike the EPA, the IARC used animal studies as a central part of its decision about the probability glyphosate causes non-Hodgkin’s lymphoma in humans.

Conclusion

Several historical points should be stated before we put a coda to this story of glyphosate risk assessment. First, regulatory agencies are notoriously lobbied by chemical manufacturers to prevent or lower the regulation of the chemical products. The political climate can determine the effectiveness of the lobbying efforts. Second, when regulatory agencies in the United States undertake a chemical assessment, the panels established have been replete with conflicts of interest usually unnoticed by the public.³⁹ Third, if a regulatory body issues an order limiting the exposure or use of a substance, litigation by the manufacturer almost always follows, derailing or slowing up the process. It has taken between twenty-five and fifty years to remove highly toxic products such as asbestos, PCBs, and lead from the marketplace in the United States. In the forty-year period since chemical regulations for industrial, non-agricultural chemicals were fully in place in the United States, of the estimated eighty-five thousand chemicals in commerce a mere five have been fully regulated or banned for use.⁴⁰ Although the law covering agricultural chemicals is stronger than the law covering industrial non-agricultural chemicals, many of the same biases and influences apply equally. Fourth, no single test can determine conclusively that a chemical is unsafe or safe enough. Each of the tests has its own limitations. Epidemiological studies address human exposures, but they do not produce causality, as one would get in a controlled experiment. Animal studies have all sorts of confounding factors, even as they can offer causal explanations for effects. And there are always questions about whether humans and animals react similarly to chemicals.

I began this paper with a description of the IARC's structure and principles. No regulatory body in the United States can meet this agency's independence, diversity, and integrity. It does not mean that it cannot miscalculate a risk of a chemical. Given that an entire private industry-funded sector is devoted to producing uncertainty in risk assessments, critiquing methods of experiments that demonstrate toxicity, and influencing regulatory bodies to establish a risk standard that would permit all chemicals regardless of what public health scientists say about their hazards, confidence that an agency is using the best, peer-reviewed, unbiased science not funded by the product manufacturers would help societies navigate across the dueling claims as reflected in the search for toxicological truth of

glyphosate and Roundup™. Critics of the IARC would like to have another twenty-five years of research to narrow every area of uncertainty before the product could be adequately regulated. There is another way to think about it. Glyphosate, as well as many other chemicals and their formulations, are put on the market when there are large gaps of uncertainty about their safety as indicated by the questions being posed a quarter century after glyphosate was approved. Why not spend twenty-five years closing all the gaps of uncertainty *before* a chemical like glyphosate is allowed to be used in the first place?

My review of the case suggests that the attack on the IARC's assessment of glyphosate is driven by financial rather than scientific interests. The IARC acknowledges that there remain uncertainties, but with the scientific evidence at hand, the precautionary principle impels one to accept its finding and for regulatory bodies to act on it. The EPA and its advisory panels keep requesting more and better human data on the relationship between glyphosate and non-Hodgkin's lymphoma because glyphosate is assumed safe unless definitively proved otherwise by evidence that could take decades to obtain. The IARC's approach operates from the precautionary principle where strong suggestive evidence is enough to stop the usage of a chemical until a definitive answer is found.

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