Testimony of

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(Biography at end of testimony)

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To

The U.S. House of Representatives

Committee on Science, Space, and Technology

Hearing Title:

In Defense of Scientific Integrity: Examining the IARC Monograph Programme and Glyphosate Review

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Change or Abolish the IARC Monograph Program

The International Agency for Research on Cancer Monographs[1] program is an antiquated review process that is based on the state of scientific knowledge a half a century ago. It has done little to keep up with advances in science and the protection of human health in the intervening years. While cancer classification systems such as IARC's may have served a useful purpose when they were created, they are as irrelevant today as the telegraph or 8-track tape player. They provide little to no useful information and do more to confuse the public – and policy makers -- than to protect public health.

In addition to being out of step with 21st century science, the IARC Monograph program has lost credibility because of serious flaws in its process. Lack of transparency and accountability in this once venerable program have led to numerous allegations of questionable ethical practices, undisclosed conflicts of interest, and opinions that run counter to worldwide scientifically-based consensus conclusions.

Outdated science and flawed process are not without consequence. Declarations by the Monograph program have sown unnecessary fears about useful and safe products and deflected enormous resources away from useful investments in public health. The science and process of the IARC Monograph program needs to be either significantly reformed or abolished.

Why is the IARC Monograph program so out of step with advanced health protection agencies such as the US EPA, Health Canada, the European Food Safety Authority (EFSA), and the United Kingdom Committee on Carcinogenicity, just to name a few? There are several reasons articulated in a publication[2] co-authored by myself and nine other senior scientists from academia, government, and private enterprises, but the primary issue is that the program fails to consider key factors such as potency and potential human exposure in its declarations of carcinogenicity.

Back in the 16th century, Paracelsus noted that "the dose makes the poison." He understood that anything – anything at all – at a high enough dose is poisonous, but at a low enough dose that same substance will be completely harmless. The same holds true for substances that could possibly cause cancer. Many things that could cause cancer at extremely high doses are harmless at levels likely encountered by human beings.

IARC simply ignores this essential fact. As a result, it lumps bacon, sausage, sulfur mustard gas, and plutonium together in the same category, Group 1, as definitely carcinogenic. IARC makes this declaration based on its *confidence* in the information it reviews and NOT on the likelihood that a particular substance has the potency or levels of human exposure that would cause cancer. Many of its conclusions are based on long-term, multi-year dosing of animals with unreasonably high amounts of a substance – well beyond what a human will ever be exposed to. Despite the absurdity of this kind of test, IARC nonetheless declares a substance to be carcinogenic. This approach is now being realized as

[1] This testimony focuses on the IARC Monographs program and not on the broader IARC institution, which is highly respected as a key center for cancer research and awareness. References in this text to "IARC" should be inferred as the IARC Monographs program.

[2] Boobis, A.R., et al., Classification schemes for carcinogenicity based on hazard-identification have become outmoded and serve neither science nor society, Regulatory Toxicology and Pharmacology (2016), http://dx.doi.org/10.1016/j.yrtph.2016.10.014

untenable and disconnected with 21st century science, modern public health protection, and communication of appropriate health practices.

In fact, if one were to take IARC seriously, there would be little if anything we could eat because many of the foods that contribute to what is universally considered a healthy diet would be suspected as causing cancer. To give just a few of many possible examples, take caffeic acid, which IARC classified as a Group 2B carcinogen, and which is found in a wide variety of fruits, vegetables and other foods, including grapes, apples, wine, blueberries, lemons, oranges, beets, broccoli, cabbage, carrots, cauliflower, lettuce, kale, onions, peas…not to mention coffee. And that's the short list. What do we do with a declaration that caffeic acid is a "possible human carcinogen"?

Or take acetaldehyde in bread and the popular plant-based remedies, ginkgo biloba and aloe vera, all of which are also classified by IARC to be group 2B, "possibly carcinogenic to humans."[3]

This kind of classification has almost zero informational value if, as IARC does, it ignores the all-important considerations of potency and exposure. Potency is important because it is the "punch" or power a substance has to induce a carcinogenic effect. Exposure is important because it considers how much of a substance we are likely to be exposed to under any reasonable scenario in the real world. This is an absolutely key element in limiting adverse effects. There are a wide variety of substances that may be labeled as carcinogenic based on high-dose, long-term studies, but in real life we could never consume enough or be exposed to enough to suffer adverse consequences.

How much is too much? This is the central question. In our personal lives, we spend considerable parts of our day considering that very question on so many critical issues. How much sugar should I put in my coffee? How much coffee should I drink today? Should I have **one** beer or two or more? What might be too much? Yet this important consideration is absent in IARC cancer classifications.

Let's take sunlight, for instance, which IARC classifies in Group 1 ("carcinogenic to humans"). We should indeed consider the adverse consequence, or hazard, we might encounter from too much sunlight, i.e. sunburn or skin cancer. The solution is not to simply stay inside all day. Sunlight is also important in enabling the body's production of Vitamin D.[4] So do we make the decision about going outside ONLY considering the adverse consequences, or hazard, in mind? Or do we make a rational decision and control our overall exposure – maybe wear a hat -- and enjoy ourselves in the meantime.

What we are doing when we quantify how much is too much is the same as what risk regulators must do in setting permissible levels of exposure. Risk assessors use this same procedure with chemicals: what is the hazard and how much exposure is too much? Declaring that a chemical causes cancer or is an endocrine disruptor is only half the story. The other half is declaring the amount that could cause that adverse effect and setting limits that protect the public from being exposed to too much. This is what is known as a "risk assessment."

Regulatory agencies around the world follow this straightforward "risk assessment" technique to protect public health. The United States Environmental Protection Agency has very clear guidance on how it identifies a chemical hazard, quantifies potential exposure, and manages risk. The policies and

[3] https://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf

[4] at least 50% of the world's population suffers from Vitamin D insufficiency, which can lead to increased mortality (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3356951/)

procedures to do so have been developed over the years, and have evolved as scientific knowledge has evolved and deepened since the inception of the USEPA in the early 1970's. The USEPA and other national and international risk-based health protection agencies have kept up with the science and are continuing to develop better ways to identify hazards of chemicals and couple that knowledge with exposure science. Science marches on.

Unfortunately, the IARC Monographs program has not kept up. Originally established a half century ago to identify agents that CAN cause cancer, the IARC Monograph program stops at what is called "hazard identification." It provides a simple yes/no and then, if yes, a classification category (1, 2A, 2B, 3, or 4), depending on the degree of confidence for a causal link to cancer (not, as many assume, the degree to which an agent is likely to cause cancer). IARC still uses this outmoded scheme despite advances in the sciences that have illuminated better ways to understand and regulate potential cancer-causing agents. The program must shift from a "hazard-only" scheme to a process that incorporates potency and exposure, and expresses its conclusions in risk assessment terms.

Furthermore, the IARC Monographs program, with its antiquated classification system, has taken on the evaluation of extremely well studied and carefully regulated chemicals such as glyphosate. At best this is a duplication of effort and at worst is an opportunity to sow confusion in the public's mind.

Along with being a scientifically antiquated program, serious questions have been raised about the integrity of IARC's process. Any agency whose evaluations are used to influence public health decisions must be transparent and fully accountable to the public. If this committee and the member countries of IARC do not address the numerous allegations of questionable ethical practices, undisclosed conflicts of interest, and lack of transparency, then the scientific reforms suggested here will be irrelevant.

There are certain basic standards of accountability, transparency, and simply good science on which IARC presently falls short that should be the guideposts for any effective reform of the monograph process. These include:

- Selecting working group and other advisory members with necessary expertise, regardless of affiliation;
- Declaring the affiliation and potential conflicts of interest of all participants;
- Considering ALL available data;
- Providing a clear explanation why certain data are or are not included in the review;
- Adhering to the principles of systematic review, such as those described by The National Toxicology Program's Office of Health Assessment and Translation (OHAT) and Cochrane Consumer Network;
- Fully communicating the results of the agency's review in a timely manner;
- Including the opinions of all reviewers and the degrees of consensus and dissent.

In conclusion, the IARC monograph program served its purpose 50 years ago to flag substances, including chemicals, that may be of concern. But it is now outmoded. Every effort must be made to bring their review process up-to-date with advances in scientific knowledge, focus on those substances not otherwise well regulated, and communicate that process openly and accurately to the public. The alternative is to abolish the program.

Biography

Timothy Pastoor, PhD, DABT, ATS

Dr. Pastoor obtained his PhD in toxicology from the University of Michigan, is certified by the American Board of Toxicology (DABT) and is a Fellow of the Academy of Toxicological Sciences (ATS). Dr. Pastoor is president of the Health and Environmental Sciences Institute (HESI) and is a Board member of the International Life Sciences Institute (ILSI) and the American Council on Science and Health (ACSH). Dr. Pastoor retired in 2015 from Syngenta as Principal Scientist and founded the company Pastoor Science Communications, LLC that is centered around his passion for sound science, communicated well.

Dr. Pastoor has over 35 years of international experience in fundamental toxicity testing, mode of action research, and human health risk assessment. For most his career, including positions with DuPont, ICI, Zeneca, Novartis, and Syngenta, Dr. Pastoor led toxicology and risk assessment experts in the conduct of safety, health, and environmental studies to assess risk to humans and the environment. In those roles, he was involved in toxicological research projects and product development and was frequently asked to interact with media, community groups, legislators, and regulatory agencies. He is a frequent lecturer on toxicology and risk assessment subjects.

In his "retirement" Dr. Pastoor has remained actively engaged in science, toxicology, risk assessment, and science communication. He is also finding time to help the University of North Carolina develop the Professional Science Masters program in toxicology. As founder and CEO of Pastoor Science Communications and through his role as HESI president, he is leading global groups from academia, government, and corporations in developing consensus on difficult scientific issues.

Tim is an avid fly fisherman and photographer, and hopes his knees allow him to continue playing tennis for many years to come.

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Abstracted biography for introductions:

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