George Mason University
Antonin Scalia Law School

Standards for Judicial Education on Scientific Topics

The Weight of Evidence Approach to Understanding Scientific Issues

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Case Study: Glyphosate (Round-Up™) on Trial

- Agricultural herbicide used on genetically-modified (GM) crops.
- In 2023, 95% of U.S. soy was GM and tolerant to one herbicide.
- GM crops have increased the amount of DNA that produces an enzyme (protein) which synthesizes 3-essential amino acids (i.e., tyr, phe, trp) that are essential for growth. The enzyme is called 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS).
- Glyphosate starves weeds of these essential amino acids by inhibiting EPSPS. Without the amino acids, weeds do not grow or survive.
- Glyphosate-tolerant GM crops survive because they produce enough of the EPSPS and amino acids to tolerate the herbicide.

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Case Study: Glyphosate (Round-Up™) on Trial

Governments & Agencies

- In 2015, WHO-International Agency for Research on Cancer (IARC) categorized glyphosate as Group 2A (Probably carcinogenic to humans).
- In 2019, EPA stated that glyphosate, "not likely to be carcinogenic to humans."
- In 2021, Vietnam became the only Asian country to ban glyphosate.
- European Food Safety Authority (EFSA) recommends that glyphosate be approved until 2023. In 2023, the European Commission proposed approval for 10 years.
- In 2024, Mexico plans to ban glyphosate. US has filed for consultations, with Canada joining as a third party, saying that Mexico's decision is unscientific and violates USMCA.

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Journals

- The American Academy of Pediatrics suggests limiting intake of GM food products. Abrams, S.A. et al. 2024. Use of Genetically Modified Organism (GMO)-Containing Food Products in Children. **Pediatrics** 153(1):1-12.

NGOs

- In 2002 with 3-million starving, Zambia rejects U.S. biotech corn. Greenpeace applauds the decision. https://www.theguardian.com/science/2002/oct/17/gm.famine1
- "There hasn't been enough research to determine whether GMOs are harmful to people," says Michael Hansen, Ph.D., senior scientist at Consumers Union. Hansen is trained in evolutionary biology. https://geneticliteracyproject.org/glp-facts/consumers-union/

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U.S. Litigation

- "Attorneys for plaintiffs estimate that approximately 4000 lawsuits have been filed (US Right to Know) although verification is challenging." Richmond, M.E. 2018. Glyphosate: A review of its global use, environmental impact, and potential health effects on human and other species. J. Environ. Studies and Sci. 8:416-434.

- "The evidence that glyphosate is currently causing NHL in human beings [at current exposure levels is] pretty sparse." Rosenblatt, J. 2018. "Monsanto judge says expert testimony against Round-up is shaky." https://www.bloomberg.com/news/articles/2018-03-14/monsanto-judge-says-expert-testimony-against-roundup-is-shaky

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Scientific Method

- Define a question
- Observe
- Form a hypothesis
- Test the hypothesis with studies*
- Refine the hypothesis

*Studies should be:
  - Free of bias
  - Repeatable by independent group(s)
  - Of sufficient statistical power (adequate sample size)

Null-Hypothesis: This is the opposite of the hypothesis. By trying to prove the null-hypothesis instead of the hypothesis we are attempting to reduce bias.

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Weight of Evidence - Meta Analysis

"The statistical analysis of a large collection of analysis results from individual studies for the purpose of integrating the findings."

- Glass, G.V. 1976. Educational Researcher 5: 3-8.

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Hill Criteria of Causality (1965)

- Strength – strong association is better
- Consistency – repeated observation in different populations/circumstances
- Specificity – cause leads to single effect
- Temporality – cause precedes effect
- Biological Gradient – dose-response effect
- Plausibility – a logical or plausible mechanism
- Coherence – consistency between epidemiological and laboratory findings
- Experimental evidence – available evidence from laboratory experiments
- Analogy – when one causal agent is known but a similar agent is more likely

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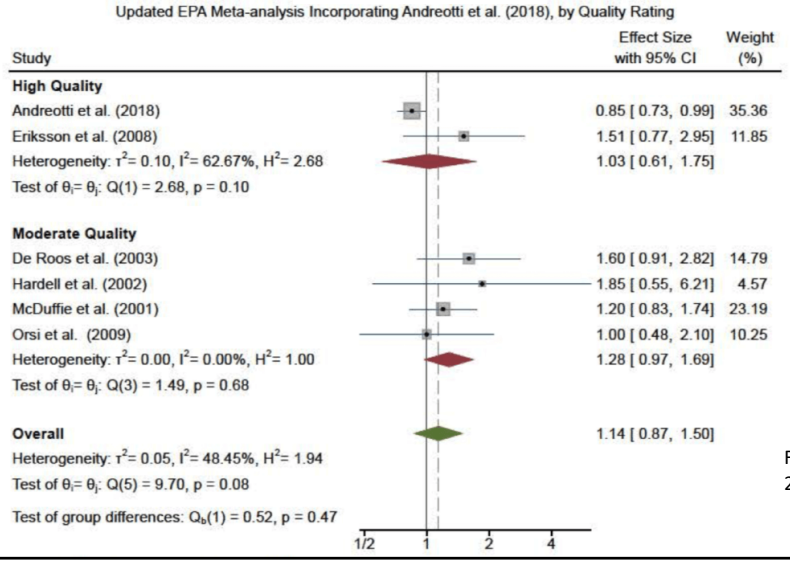
Meta Analysis – Glyphosate (Round-Up™)



From G. Kabat, ACSH, Feb. 27, 2020

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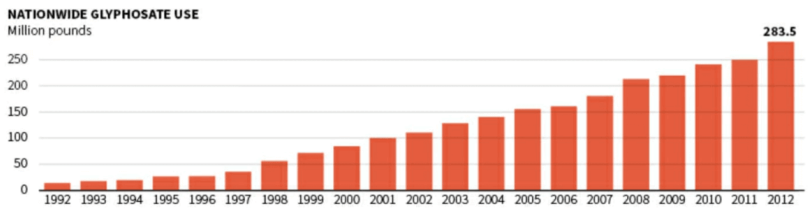
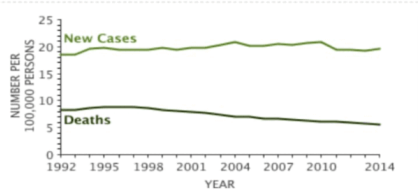
Glyphosate and Non-Hodgkin's Lymphoma



From 1974 to 2014, glyphosate usage increased by 200-fold



From 1992 to 2014, new cases of Non-Hodgkin's Lymphoma unchanged

Number of New Cases and Deaths per 100,000: The number of new cases of non-Hodgkin lymphoma was 19.5 per 100,000 men and women per year. The number of deaths was 5.9 per 100,000 men and women per year. These rates are age-adjusted and based on 2010-2014 cases and deaths.

Lifetime Risk of Developing Cancer: Approximately 2.1 percent of men and women will be diagnosed with non-Hodgkin lymphoma at some point during their lifetime, based on 2012-2014 data.

From G. Kabat, ACSH, Feb. 27, 2020

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Conclusions

- After billions have consumed GM crops, there has not been a single illness attributed to the consumption of these foods, including GM soy that was sprayed with glyphosate.
- Biotechnology is critical for international food security.
- A 'weight of evidence' assessment demonstrates that glyphosate is safe when applied according to the product label.
- The decisions surrounding glyphosate should be a wakeup call that our judicial process needs to improve. Courts are being influenced by those driving an agenda incl. agencies, journals, companies, NGOs, and scientists.
- A scientific expert could serve as a 'friend of the court' to help better understand the technical aspects of these cases.
- Changes to Federal Rule of Evidence 702 – "In making bold claims, witnesses must provide strong and sufficient evidence to support and show their work."
  https://www.acsh.org/news/2024/01/18/new-%E2%80%98rule-702%E2%80%99-will-it-require-courts-reexamine-baby-powder-claims-17591

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