Censorship and issue-specific advocacy: Is “consensorship” the new paradigm?

SOT Webinar
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Virtual Meeting

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What is Scientific “Consensus”

*Scientific Consensus is a state in which the range of interpretations consistent with a sufficiently probative dataset is so narrow as to have no practical significance.*  [CJB]

Science is a process wherein facts are asked to speak for themselves to enhance objectivity, and by which *consensus can be achieved only as an increasingly broad and probative dataset narrows the range of interpretations consistent with the data.*

Compromise and vote are anathema, as competing theories vie for prominence on the merits of the evidence rather than on the agreement of affiliated practitioners.

Summary

“Consensorship” is a term invented by the author to convey the intersection of two claims that are increasingly advanced in controversial areas of science:

1. There is “consensus” among the experts, therefore, the science is settled.
2. Since there is “consensus,” those who disagree are simply “deniers”
   a. Deniers’ motives and intelligence is suspect
   b. Deniers’ views need not and should not be heard
3. “Endocrine Disruptors” is a prime example of the advancement of Consensorship
4. New examples covered in this presentation:
   a. LNT (Linearized No-Threshold Model)
   b. Key Characteristics
   c. SAB-Packing
Example: Blatant Consensorship


“It is often argued that in the developing organism, homeostatic mechanisms are not sufficiently developed such that a threshold of adversity cannot be assumed for EDs acting during the developmental stages of the life cycle of an organism (Zoeller et al. 2012). Again, this position is rather extreme and not supported by decades of observations and safety testing of developmental toxicants, with little evidence suggesting that the fundamental rules governing endocrine function cease to apply during this life stage (Borgert et al. 2013).”

The first author of Brescia’s citation for this statement has been barred from “EDC Advocacy Strategy” sessions of The Endocrine Society, of which he is a full member . . . because . . . according to Mila Becker, Chief Policy Officer of the Endocrine Society:

“I’m sorry. This is a policy session that is bringing together people who have endorsed the Society’s official policy on EDCs. You have said quite publicly that you disagree with that...”
Consensorship is not new: the LNT scandal - 1

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<tr>
<th>Year</th>
<th>Event</th>
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<tr>
<td>1927</td>
<td>Herman J. Muller demonstrates that ionizing radiation caused mutations in germ cells of male fruit flies. Muller worked hard to convince others of the implication of his findings; in the era of the nuclear bomb, he focused on the broad implications to humans exposed to radiation. Evolutionary geneticists used this discovery to argue a mechanism for evolution. Both arguments were undermined by the existence of a threshold for radiation effects</td>
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<td>1946</td>
<td>Herman J. Muller awarded Nobel Prize for 1927 discovery In his acceptance speech, Muller claimed there was no longer any doubt that the dose-response for radiation lacked a threshold [CONSENSUS claimed] • Muller knew of contractory data and ignored it; • Muller side-stepped the fact this experiments were conducted at radiation doses thousands of times higher than human exposures (1,000 chest X-rays in 3.5 minutes); • Muller and his long-time colleague, esteemed radiation geneticist Curtis Sterns collaborated to repress publications showing a dose-threshold, including data from Sterns’ own laboratory, and limit the participation of ‘deniers’ in NAS BEARS Panel [CONSENSORSHIP ACHIEVED]</td>
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Consensorship is not new: the LNT scandal - 2

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<tr>
<th>Year</th>
<th>Event</th>
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<td>1950’s</td>
<td>U.S. National Academy of Sciences Biological Effects of Atomic Radiation panel (BEAR) – Muller and Stern worked to solidify agreement with the LNT theory of radiation dose-response.</td>
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<td>1977</td>
<td>U.S. EPA adopts LNT for carcinogens under Safe Drinking Water Act</td>
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Concensorship is alive and well:  

*Key Characteristics - 1*

- KC Concept: chemicals that produce certain types of adverse effects exhibit common “key characteristics” that serve as distinguishing features.
- Examples
  - Carcinogens (Smith et al., 2017)
  - Male reproductive toxicants (Luderer et al., 2019)
  - Female reproductive toxicants (Arzuaga et al., 2019)
  - Endocrine Disruptors (La Merrill et al., 2020)
- Concept formulated during so-called “expert workshops” (e.g., La Merrill et al., 2020)
- Concepts applied in recent publications
  - Agrochemicals
  - Glyphosate
  - Others – see bibliography
Concensorship is alive and well:  

**Key Characteristics - 2**

The KCs for EDCs were developed based on KCs for carcinogens.

Flaws in the KC approach for carcinogens have not been addressed or corrected and were repeated in the KCs for EDCs.


The KC approach requires less data and fewer resources than the WoE approach but lacks the basic elements of rigor and reproducibility that should be a standard requirement for regulatory science.


Birth Defects Research and Prevention Society 2021 Annual Meeting, Session on Key Characteristics presented only viewpoints favoring the approach. A “response” session will follow in 2022.


IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

DR. S. STANLEY YOUNG, 3401 Caldwell Drive Raleigh, NC 27607, Plaintiff, v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, 1200 Pennsylvania Avenue, NW Washington, DC 20460, Michael S. Regan, in his official capacity as Administrator of the EPA, 1200 Pennsylvania Avenue, NW Washington, DC 20460, SCIENCE ADVISORY BOARD, 1200 Pennsylvania Avenue, NW Washington, DC 20460, Alison C. Cullen, in her official capacity as Chair of the Science Advisory Board, 1200 Pennsylvania Avenue, NW Washington, DC 20460, CLEAN AIR SCIENTIFIC ADVISORY COMMITTEE, 1200 Pennsylvania Avenue, NW Washington, DC 20460, and Elizabeth A. Sheppard, in her official capacity as Chair of the Clean Air Scientific Advisory Committee, 1200 Pennsylvania Avenue, NW Washington, DC 20460, Defendants.

Concensorship is ubiquitous: we all play the game
Concensorship is ubiquitous: we all play the game

Plaintiff Dr. S. Stanley Young, by and through his undersigned attorneys, alleges as follows:

INTRODUCTION

1. The Environmental Protection Agency (“EPA”) has a problem with dissent. In an unprecedented purge, EPA eliminated all industry representatives from two important advisory committees in order to stack those committees with academics who are financially beholden to EPA for multi-million dollar research grants. Through this mass dismissal, EPA guaranteed that the committees will rubber stamp the new administration’s regulations without the inconvenience of an objecting voice from the very industries targeted by those regulations and bearing the cost of those regulations, to the tune of billions of dollars a year. These newly constituted, industry-free advisory committees are neither fairly balanced nor protected from inappropriate influence in violation of the Federal Advisory Committee Act (“FACA”)…..

Defendants contend the last administration did the same.
Conclusions ... what do YOU think ....?

➢ Is Consensorship Real ?
➢ Is Consensorship Pervasive ?
➢ Is Consensorship increasing ?
➢ If real, pervasive, and increasing how will Consensorship affect new chemistry?
➢ Is Consensorship a problem that scientific societies should address ?
➢ If so, what are the solutions. . .

. . . . Stay tuned.
Toxicology and Legal Testimony

• Can be either criminal or civil actions

• Typical areas of testimony by toxicologists
  • Forensic toxicology (cases involving death, injury, intoxication) typically involves interpretation of chemical analyses of tissues and fluids (e.g., blood, vitreous fluid, urine)
  • Causation assessment (linking an injury to exposure)
  • Exposure assessment (including pharmaco-/toxicokinetics)
  • Regulation of chemical substances (state and federal)

• Science not advocacy
Legal Work and Methodology

• Judges perform “gate-keeper” duties related to expert testimony
• State vs. Federal courts may differ in standards applied
• Federal court = Daubert Standard (1993)
  • Assess whether an expert witness’s scientific testimony is based on “scientifically valid reasoning” that which can properly be applied to the facts at issue
• Frye Standard (1923)
  • Scientific evidence must be interpreted by the court as "generally accepted" by a meaningful segment of the associated scientific community
Methodology (cont.)

• Methodology used may depend on the area of testimony
  • Weight-of-the-evidence (WOE)
  • “Bradford-Hill” criteria (general causation)
  • Differential diagnosis (specific causation by clinical toxicologist)
  • Human health risk assessment (individuals versus population)
  • “Experience and training”
  • Area-specific methods (e.g., analytical data)

• Toxicologists should choose method(s) appropriate to the scientific questions being asked

• KEY = “sound science” based on “reliable” information
Ethics As a Core Principle

• Toxicologists should adhere to ethical principles in all work, including in the legal arena (science not advocacy)
• “Ethical” in this context is “performing work in accordance with the rules or standards for right conduct or practice, especially the standards of a profession”
• In toxicology, there are several organizations that set forth ethical “standards” such as the SOT, ACT, SOFT
  • Organization websites specify the ethical standards to be adhered to by members (e.g., https://www.soft-tox.org/ethics; https://www.toxicology.org/about/vp/code-of-ethics.asp; https://www.actox.org/about/code-of-ethics.asp)
Key Concerns for Toxicologists

• A toxicologist’s role should be
  • Stay within bounds of your training and expertise!
  • To teach complex issues to non-scientists
    • It can be helpful to visually convey complex information
    • Jurors and judges should not be assumed to have a science background
    • In cases where “novel” substances/chemicals are at issue, the “unbiased” viewpoint of the jurors can be important (no pre-conceived opinions)
  • To apply the same methodology in legal work as would be applied outside of court
    • Carefully lay out the scientific methodology used
    • Address the limitations (if any) of the methodology
    • Ensure that you have access to all relevant information (important issue)
  • To acknowledge any biases in methods and/or opinions (credibility)
    • Actual as well as perceived