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LETTER TO THE EDITOR, NEWS AND VIEWS

An abuse of risk assessment: how regulatory agencies improperly adopted LNT for cancer risk assessment

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Abstract The Genetics Panel of the National Academy of Sciences' Committee on Biological Effects of Atomic Radiation (BEAR) recommended the adoption of the linear dose–response model in 1956, abandoning the threshold dose–response for genetic risk assessments. This recommendation was quickly generalized to include somatic cells for cancer risk assessment and later was instrumental in the adoption of linearity for carcinogen risk assessment by the Environmental Protection Agency. The Genetics Panel failed to provide any scientific assessment to support this recommendation and refused to do so when later challenged by other leading scientists. Thus, the linearity model used in cancer risk assessment was based on ideology rather than science and originated with the recommendation of the NAS BEAR Committee Genetics Panel. Historical documentation in support of these conclusions is provided in the transcripts of the Panel meetings and in previously unexamined correspondence among Panel members.

Keywords Mutation · Linear non-threshold (LNT) · Risk assessment · Carcinogen · Threshold dose response · Ionizing radiation

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The most significant event in the history of environmental risk assessment was the recommendation by the United States National Academy of Sciences (NAS), Biological Effects of Atomic Radiation (BEAR) Committee, Genetics Panel in 1956 to switch from a threshold to a linear dose–response model for the assessment of genomic mutation risk (Anonymous 1956; NAS/NRC 1956). Within a brief period of time, this recommendation became generalized to somatic cells by other governmental advisory committees and was eventually applied to cancer risk assessment. Although this linear dose–response paradigm was originally intended to be used for ionizing radiation, it would later be adopted by the US Environmental Protection Agency and directly applied to chemical carcinogens (Albert 1994; Calabrese 2013a, b), thereby affecting worldwide cancer risk assessment for the past several decades.

Given the significance of this action by the NAS BEAR I Committee, Genetics Panel and the long history of the threshold dose–response model in regulatory practice, I was interested in learning the answers to several key questions: how was this recommendation made, what was the nature of the debate, what were the persuasive and compelling arguments, and what were the roles played by various individuals on the Panel? I therefore obtained transcripts of the BEAR I Committee, Genetics Panel meetings in 1955 and 1956. It was a bit like reading the book after seeing the end of the movie. To my surprise, the BEAR I Committee, Genetics Panel was uniformly confident in their belief that linearity for genomic risk assessment was the correct perspective, while being arrogantly dismissive of both the threshold perspective and those who supported it. So dismissive of the alternative model was the Genetics Panel that it was never viewed as a debatable issue, nor was it ever debated. What a disappointment. I had so looked forward to retrospectively witnessing how the leading thinkers of

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their time confronted this seminal issue on dose–response, how they intellectually sparred with one another, and whose logic and facts helped carry the day for the linearity model. The NAS BEAR I Committee, Genetics Panel made the switch from a threshold to a linear dose–response risk assessment model by "proclamation," with no debate and without providing a detailed (or actually even any) evaluation, such as would be expected of any scientific advisory group—most certainly of one at the level of the National Academy of Sciences on such matters of national and international significance. In retrospect, this should not have been too surprising as I had documented in previous publications (Calabrese 2011a, b, 2012, 2013a, b) the inherent intellectual dishonesty of key leaders of the radiation genetics community, such as Curt Stern and Hermann Muller on the issue of threshold versus linear dose–response and how they successfully distorted the scientific record in order to achieve their goal of a linear dose–response for risk assessment. The linear dose–response recommendation by this Genetics Panel would be broadly extolled by leading media outlets on the day of its release as the most extensive assessment ever undertaken on the topic by a most prestigious group of American scientists. The National Academy of Sciences report was literally a front-page story in the New York Times with the linearity risk assessment framework leading the way.

Despite the widely acknowledged success of the BEAR I Committee, Genetics Panel in getting their message out to the scientific community, governmental bodies, and the public, the reports of the BEAR I Committee, Genetics Panel were eventually read by members of the scientific community. This resulted in a number of leading biologists challenging the Genetics Panel, demanding to know the scientific basis of the decision in favor of linearity. However, as noted above, the Genetics Panel had not undertaken such an assessment and was not in a position to explain their actions nor to defend a report that lacked a scientific foundation. Showing its disdain for those challenging this report, the Genetics Panel decided not to provide the information to the scientific community. This decision was rendered to the President of the National Academy of Sciences without any evidence of his objection. The adoption of the linear non-threshold (LNT) dose–response model by the National Academy of Sciences therefore was made without a scientific assessment and, of course, a refusal to provide one when challenged.

The recommendation to switch to a linear dose–response by the NAS BEAR I Committee, Genetics Panel, as announced to the world by leading media outlets, reflects an abdication of societal responsibility on a critical and enduring public health issue. This paper provides the first reporting of these actions in the history of the National Academy of Sciences and in governmental risk assessment practices for cancer. It reveals that current cancer risk assessment practices originated from an ideological set of beliefs from leading scientists rather than a scientific assessment. A fully documented assessment of this story is provided in the Supplementary Data section.

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