

important molecular evidence that supports the concept of multistage carcinogenesis, presented a questionable method (Abbott's formula) to account for background tumor incidence, distorted the IARC definitions of sufficient and limited evidence and failed to adjust for a major confounding factor (age) in their analysis of the DDT data. In spite of all this, I share in large measure their skepticism about the scientific value of routine risk assessments that use statistical models fitted to limited animal data obtained at high doses to predict the human response at low ones. Society needs critics like Freedman and Zeisel to challenge establishment viewpoints, lest the repeated use of "inference guidelines" such as low-dose linear extrapolation lends them undeserved credence. Hopefully, other scientists will continue their constructive efforts to improve the biological and statistical models and to contribute their expertise to the decision making process.

ADDITIONAL REFERENCES

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Comment

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I was disappointed to find Freedman and Zeisel taking such a one-sided and negative position concerning the scientific value of laboratory animal studies for assessing possible cancer risks to humans. The scientific merits of laboratory animal studies and quantitative risk estimation have been debated for years, and Freedman and Zeisel raise no new points that have not been considered extensively elsewhere. The difference between their article and more definitive publications (e.g., Office of Science and Technology Policy, 1985) is that Freedman and Zeisel make no effort to present a balanced view on the major issues.

Freedman and Zeisel utilize several questionable techniques to achieve their objectives. These include (1) selectively citing references that appear to support their point of view while ignoring other publications

that express contrary views, and (2) misrepresenting or misinterpreting data from various sources, in some cases reaching the opposite conclusion to that given by the original investigator. Examples of this will be given throughout these comments, which will be limited primarily to the area of qualitative risk assessment.

Throughout the paper Freedman and Zeisel display an arrogant attitude toward nonstatisticians, (e.g., assuming that investigators do not randomize properly unless the randomization scheme is stated explicitly; claiming that "pathologists see themselves as professionals exempt from bias"). This air of superiority, especially when considering biological issues, reduces their own credibility and the credibility of all statisticians in the eyes of biologists, many of whom feel that statisticians and lawyers debating science is no more meaningful than biologists debating *p*-values.

The major criticisms of laboratory animal carcinogenicity studies cited by Freedman and Zeisel include the following.

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