

13440 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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Senator Gaylord Nelson
Chairman, Monopoly Subcommittee
Senate Small Business Committee
424 Russell Senate Office Bldg.
Washington, D.C. 20510

Dear Senator Nelson:

I have reviewed the transcript of my testimony before your Committee on 31 January and I think it may be useful to restate the position I was supporting in our exchange.

First, it was entirely proper for the UGDP investigators to withdraw Tolbutamide from the study as soon as they had substantial doubts about its safety. However, as a consequence, they could not reach a firm conclusion about it. Their own conclusion was stated as follows:

"... the findings of this study indicate that the combination of diet and tolbutamide therapy is no more effective than diet alone in prolonging life. Moreover, the findings suggest that tolbutamide and diet may be less effective than diet alone or than diet and insulin at least insofar as cardiovascular mortality is concerned."

I think that statement should be taken at face value, and not as a polite substitute for a more forceful condemnation of Tolbutamide.

Second, in the light of all available evidence, a decision must be made about the appropriate legal or regulatory steps to be taken about the distribution of Tolbutamide. The suggestion made by Dr. Ricketts seems to me appropriate. Enough doubt about its effectiveness in ordinary use and concern about toxicity exists to warrant imposing some additional reporting burden on the physician who prescribes it.

Finally, of far more importance than the decisions to be made about Tolbutamide is the continuing lack of procedures for accumulating reliable information about the effects of drugs for which the balance of risk and benefit is uncertain. The answer cannot be entirely a matter of adding more and more requirements before a drug is released for marketing. I am not convinced that present regulations have substantially impeded the adoption of valuable drugs, but pushed too far,