

February 2, 1971

Dr. Marion J. Finkel
Deputy Director
Bureau of Drugs
Food and Drug Administration
Rockville, Maryland 20852

Dear Dr. Finkel:

Your thoughtful letter of January 25, is encouraging. As a participant in the evaluation of new drugs with industrial support and in attempting studies of drugs of limited commercial interest (notably the narcotic antagonists cyclazocine and naloxone), I would support your suggested use of seminars. These may provide the opportunity for researchers and administrators to reconcile differences in their opinions on the requirements for studies in man.

I would be willing to participate as a speaker or panellist.

The "criteria" of animal toxicology which must be satisfied before drugs are taken to man is an issue that has provided much travail in studying new drugs. Specifically, I have been repeatedly advised that certain trials in man were not "proper" or "legal" without extensive animal trials in 2 (or 3) species for 3 (or 6 or 12) months with a variety of pathological studies. An irony of these "recommendations" (or "guidelines") is the experience that teratogenicity and toxicity are determined as much by differences among species and among individuals as by dose, duration, and route of compound administration. A slavish recourse to a presumed minimum animal toxicology profile has made much research too expensive, especially where compounds do not have an immediate potential for financial success.

An issue that has been of personal interest is the improvement of methods for the assay of psychoactive drugs in volunteers by the use of physiologic indices, particularly measures of the CNS like the quantitative EEG. But this issue may be too technical for general discussion.

Dr. Finkel

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Such meetings should be encouraged, to allow additional intercourse between administrators and researchers, to allay the suspicions that have arisen since the guidelines were first proposed.

Thank you for your invitation, and I do believe that such public seminars will be popular and well subscribed, reflecting an important concern of researchers, industry and government.

Sincerely yours,

Max Fink, M.D.
Professor of Psychiatry

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