

Senator NELSON. I would assume, in any event, that there must be a mass of clinical evidence on widely used drugs that were discovered prior to 1962, is there not?

Dr. VAN RIPER. That's right. And that was all submitted by the company that markets the drug at the time they made the information available for this review.

Senator NELSON. This committee isn't attempting itself, then, to do independent clinical studies of these drugs.

Dr. VAN RIPER. No. They are simply reviewing the clinical evidence that has been published, or it may be in the hands of the company that markets the drug, though it has not been published.

Senator NELSON. Do they have any kind of a timetable on how soon they expect to report on the balance?

Dr. VAN RIPER. We were told a month ago they hope to complete their reviews in about a year. Then those reviews will be submitted to the Food and Drug Administration who in turn will make a review and make final judgment as to whether the drug is effective, not effective, or probably effective.

Senator NELSON. Am I correct that if under the law any one of them turns out not to be therapeutically effective, it may be taken off the market? Is that what the law is?

Dr. VAN RIPER. Dr. Leahy has advised us they would undoubtedly give the company time to conduct clinical research to determine its effectiveness.

Mr. CUTLER. Senator, the law would require that the Food and Drug Administration at that point afford the company an opportunity for hearing.

Senator NELSON. I am talking about the end result. What will be done if the FDA concludes that there is no proof.

Mr. CUTLER. If FDA concludes—with the exception of a small class of grandfather drugs—if FDA should conclude that there is inadequate evidence of therapeutic effectiveness, it could require the drug to be taken off the market.

Senator NELSON. Have they grandfathered some drugs?

Mr. CUTLER. You did grandfather some drugs.

Senator NELSON. Not I.

Mr. CUTLER. The Congress did.

Senator NELSON. Some old drugs that professional oldtimers can't get along without?

Mr. CUTLER. It is a very complicated question and there is disagreement today as to just how many drugs are grandfathered. But it is a small number.

Senator NELSON. OK. I don't want to catch my wife paying for any of them, that's all.

Dr. VAN RIPER. The current regulations have placed under much closer scrutiny the evaluation of chemical substances employed in the treatment of human disease.

The first phase of a drug's evaluation is confined to study in appropriate species of animals. As much as a year may be required to establish the systemic absorption, tissue distribution, metabolism and elimi-