

These panels were directing their attention to that aspect of the 1962 law that required adequate proof of efficacy—

Dr. EICHENWALD. Yes, sir.

Senator NELSON (continuing). In order to stay in the marketplace. You have commented, as did Dr. Kirby, on other problems of combinations including safety. As I understand it, prior to 1938, there was no necessity for proving either safety or efficacy. Would it be your judgment as to this question: Do the combinations pose a sufficient safety consideration to justify their removal on that basis?

Dr. EICHENWALD. I believe some of them do while others do not. Certainly, in my judgment, the combinations of tetracycline and novobiocin and tetracycline and oleandomycin, possess sufficient hazard that on the basis of toxicity alone they should not be on the market. Some of the other combinations are more innocuous. Erythromycin and sulfa and this would not be—

Senator NELSON. What about the question of any antibiotic sensitizing a patient so that a subsequent administration may be serious?

Dr. EICHENWALD. This is true for all antibiotics, of course. This has an inference by use of combinations.

Mr. GORDON. Dr. Ernest Howard, who is now executive vice president of the American Medical Association, stated before the Kefauver committee—

Inevitably a useless drug will not be used because of the training and experience of physicians, because of their experience with this useless drug, if it is permitted to be marketed. * * * We feel that a profession fully knowledgeable in a free market economy will soon bring about the withdrawal from the market of a useless drug.

What do you think about that?

Dr. EICHENWALD. Well, I would not agree with that statement for a number of reasons. As I mentioned earlier, drugs have a certain placebo value. Giving the patient anything, particularly if it is injectable and if it hurts, will make the patient feel better whether the patient is in fact, improved or not.

Secondly, also I think the whole history of medicine has indicated that this statement is not correct. I might refer to a drug that was removed prior to the Kefauver hearings from the market, a drug called Altafur, which was marketed by a pharmaceutical house under the advertising slogan: "A new star on the antibiotic horizon."

Mr. GORDON. What did you say? New star?

Dr. EICHENWALD. Yes. New star on the antibiotic horizon. I remember that very well. The drug was totally ineffective. A variety of therapeutic trials indicated it to be totally ineffective. In fact, it produced no blood levels that were measurable. However, because the Kefauver amendments had not been passed, the only recourse FDA had to remove this drug from the market was because of its toxicity. It was a highly toxic agent. It had, unfortunately, been allowed on the market and a series of hearings was held. I testified as to the toxicity of the drug. But here is a good example that an agent that was totally devoid of any therapeutic activity was widely used and could only be removed from the market because of its high toxicity. I think this would go against the statement made that the drug would not have sold. It sold quite well.