

Senator NELSON. In discussing the question of the advertising and promotion of drugs, is it your view that someone, perhaps the FDA, ought to more carefully supervise and approve the claims of drug ads appearing in medical journals and elsewhere?

Dr. KUNIN. Yes, I believe so.

Now, it is my understanding that there are two mechanisms. One is the Federal Trade Commission's role here, and the Food and Drug Administration's role, and I have difficulty in distinguishing between whose responsibility belongs where. It is my understanding that the Food and Drug Administration is able to examine these advertisements and see that they follow to the letter the package insert.

Senator NELSON. The committee counsel informs me that the Federal Trade Commission deals with over-the-counter drugs.

Dr. KUNIN. Pardon me, sir?

Senator NELSON. Exclusively.

Dr. KUNIN. O.K.

Senator NELSON. Aspirin is aspirin, you know.

Dr. KUNIN. Right.

Senator NELSON. If you read Time magazine, you can find out.

Dr. KUNIN. There is a committee that has been set up by the National Academy of Sciences, which is dealing with review of drugs for efficacy, those drugs licensed from 1938 to 1962, I believe. A considerable length of time has been spent analyzing this problem, and their report, of course, is not ready yet, but I believe that this is a tremendous effort and a step in the right direction. Thus there is a major effort being undertaken. Of course, this was begun by Dr. Goddard and the Food and Drug Administration in conjunction with the National Academy of Sciences.

Mr. GORDON. This deals with efficacy?

Dr. KUNIN. Yes, sir.

Mr. GORDON. But not relative efficacy?

Dr. KUNIN. That is right.

Now, this next section of my text deals with relative efficacy, especially of antibiotics.

It is certainly true that antibiotics differ in relative efficacy for various infections. The subject, however, is very complex because of the great variety of disease states which must be treated and the large number of good drugs that are available. And I want to point out here that an agent may be the drug of choice under one circumstance while another drug be the secondary agent, but in another circumstance the second agent may be the primary drug. I cite Rocky Mountain spotted fever, for example, where one would use tetracycline whereas in pneumococcal pneumonia one would prefer to use penicillin, so that tetracycline would be a secondary drug for pneumonia but a primary drug for Rocky Mountain spotted fever. One has to relate it to specific disease efficacy.

This is covered in textbooks of pharmacology and the AMA new book "New Drugs" which makes an effort in this direction.

One of the factors that play a very important role in the hospital should be emphasized. This is the problem of antibiotic sensitivity testing.

This laboratory test will be misleading if one does not know how to interpret it properly, and one requires a fair amount of sophistication