

in one sense (not changed in the nature of the agreement that we reached with the companies before they went on the market). We came to feel that it might well need an "Important Note," of the kind that you are suggesting, to offer more detailed information as to what experience had occurred around the world, and why it was very important for physicians to consider the recommendations in the indications section.

So, in effect, I think we are delving, as nearly as we can see, with the problem that you are suggesting. What the response will be to this tighter and more informative labeling when it is applied to the whole class of products, of which dicloxacillin is a member, would be something that would have to be observed in somewhat the way as the Chloromycetin problem was handled.

We all believe, after considering the views of the experts that we consulted and that the company consulted, and of our medical advisory board, that this labeling is consistent with good medicine, and as much help to physicians as we felt we could—

Senator NELSON. Have you sent communications with good documentary evidence and so forth to all the medical journals in the country asking them to editorialize on this matter?

Dr. McCLEERY. No, sir.

Senator NELSON. Don't you think, if it is an important matter of public health and the practice of medicine, that you ought to use all the outlets available?

Dr. McCLEERY. Yes, sir. There already have been editorials in this country. Those editorials have appeared in such journals as the New England Journal of Medicine in 1967. These opinions of experts, both in editorials and in articles, formed a part of the basis for the stand that we took in reference to the company's request. They are available. Those opinions have been given broadly to the medical profession, and I am sure, if the need arises, that we would further consider the suggestions you make.

Senator NELSON. You have the medical schools and a whole series of outlets. It just seems to me that this is an important matter of public health, that the FDA ought to be moving heaven and earth to be sure that the education is gotten out to the profession and to be sure that the labeling is really strong enough and tough enough, so that it makes the point clear.

I understand why the companies don't like it. They won't sell as much. But the public health certainly has to come first, and there will be a continuous push by the companies to expand the use of their products. So in my judgment they will end up winning that battle, just as they did with chloramphenicol. That one went over a period of 15 or 16 years, from 1952 until right up through now, and they won the battle hands down.

Dr. McCLEERY. Well, it is certainly a logical possibility that it may occur again. We fervently hope it won't.

I might also say that one of the exhibits you will see is the remedial letter that went to 280,000-some physicians on the Dynapen problem. There was also a corrective journal ad, which we come to later, both of which were strong messages sent out by the company, in conjunction with us, that make all these points at this time. It may not be effective but we hope that it will. We will have to try to follow and see.