

(ankylosing) spondylitis, acute attacks of gout, or osteoarthritis of the hips." On the surface, when this goes by quickly, it sounds like it is entirely within the indications described by the approved package labeling. But the fact of the matter is that it is an open-ended statement of indications, because it says "Wherever there is a pain, inflammation and swelling" use this drug, and the only limitation, and it is not a real limitation, is in bringing in the proper indications by the statements "as there is in rheumatoid arthritis." This is not a limiting statement. It only says wherever there is inflammation use Indocin, and there is inflammation in rheumatoid arthritis, and so forth. This runs through the whole time period of 1967.

Senator NELSON. And that statement I read to you previously about the older patients, that is:

Now, how many older patients, patients with most aches and pains, the real crocks and cruds seen in everyday practice, just how many of these patients do not have some degree of cardiac decompensation or degree of edema?

What is that in there for, cardiac decompensation and some edema?

Dr. McCLEERY. Well, there are competitive drugs which are mentioned throughout the bulletins of this time period. The characteristic of this time period is competitive selling, giving the detail men information which may or may not be proper about the dangers or effectiveness of competitive drugs. One of the competitive drugs does have warnings in its labeling about the possibility of causing edema. Therefore, they are saying that this would limit the value of the competitive drug in this particular class of patient. There is some truth in that.

Senator NELSON. Is it common that you may end up with muscular soreness and tenderness as a consequence of the edema?

Dr. McCLEERY. That would be difficult to answer, Mr. Chairman. As far as the patient is concerned, he might feel that he had aches in his muscles, because of the swelling, and very likely wouldn't himself localize it to muscle, but just to his lower extremity.

We said in our testimony that there was some slanting of information and I would like, if you wish, to describe what we meant by that statement.

Senator NELSON. Yes, if you would, please.

Dr. McCLEERY. I mentioned that the need to sell a product by one company in competition with somewhat similar products by other companies creates the need to draw limits of value between it and its competitors' products. This is going on a great deal during this time period.

One of the drugs which has to be discussed, in this competitive way, for the treatment of rheumatoid arthritis and other inflammatory diseases, is plain aspirin. The bulletin of July 7, 1967, Bulletin No. 66, on page 2, is an example of a description of the value of aspirin in comparison with Indocin. It says:

From those severely afflicted patients who are not adequately controlled by aspirin or Darvon, i.e., when pain killers are no longer giving adequate control—

I am sorry, it says—

when pain killers no longer give adequate control or when they only kill pain without reducing inflammation or improving joint mobility, Indocin should be tried promptly or even tried first.