

the head is floating away or even separating from the body, and a feeling of detachment from reality.

Does this comment of evaluation by Dr. Rothermich compare with your own claim?

Dr. McCLEERY. The statements that you are reading are opinions of Dr. Rothermich that I haven't seen. They are similar to the kinds of experiences reported with Indocin, and which are included within the package labeling.

Senator NELSON. So they have played down in their instructional bulletin the effects that are described and required in the labeling, is that correct?

Dr. McCLEERY. Well, it seems that they have a diminution of the impact of the ideas which are being described.

Senator NELSON. On page 3 of the Bulletin No. 66 dated July 7, 1967, we find, you have mentioned this yourself previously:

Indocin should be tried promptly or tried first.

Now, in the AMA's 1967 edition of New Drugs, page 540, we find the following statement:

Present clinical experience indicates that this drug is as effective as the salicylates in patients with rheumatoid arthritis. However, its use is not necessary when salicylate therapy is effective. Although aspirin is still considered the drug of first choice, indomethacin may be tried if aspirin ceases to be beneficial or is no longer tolerated.

Is the statement by the AMA Journal representative of the viewpoint of the FDA?

Dr. McCLEERY. It squares with my own personal understanding of the view of men who are experts and have written on comparative drug trials. In the approved labeling of the drug Indocin, there are no such comparative claims of this sort. It is the kind of view that I was trying to express awhile ago. It is a most common view of the experts in the field that the salicylates are still the drug of first choice to use. They give much of the same benefits that Indocin does if not to all patients.

Senator NELSON. I want to thank you very much, Dr. McCleery. We appreciate your very fine statement and you and your staff associates coming here this morning to testify.

Does anybody have anything they wish to add to the statement?

We will resume hearings, then, again tomorrow morning at 9:30.

Thank you.

(Additional instructions from H. Glassner to All Western District Associates, undated, follow:)

To: All western district associates

From: H. Glassner

Subject: Indocin

The "Indocin" release meeting was great. However, several of you have asked for a concise Product Information Outline from which you can build your own presentation. Here are the "must know" facts on 'Indocin'. Put the words together so they sound like you. Remember, however, no presentation is a good presentation unless it creates prescription specification.

What is Indocin?

Indocin is an entirely new "anti-rheumatic" drug that affords ANTI-INFLAMMATORY ANALGESIC—AND ANTIPYRETIC ACTIVITY. The unique chemical structure of 'Indocin' differs entirely from salicylates, corticosteroids, colchicine and phenylbutazone.