

Dr. McCLEERY. The approved package labeling—package insert—includes the allowable claims and the required precautionary and warning information which is to be included in advertisements and promotional labeling of a prescription drug like Indocin.

As you will see, the Indocin package insert limits the use of this drug to four indications: (a) rheumatoid arthritis, (b) rheumatoid (ankylosing) spondylitis, (c) degenerative joint disease (osteoarthritis) of the hip, and (d) gout. This labeling indicates that Indocin will relieve pain, reduce fever, swelling and tenderness, and increase mobility in patients with rheumatic disorders. Indocin is a potent drug and, as the package insert shows, it has many side effects, contraindications, precautions, and warnings that must be heeded for its safe and effective use. For these, and other, reasons, it was not approved for use in all rheumatic disorders, but only for those rheumatic disorders I have named.

The Indocin Bulletin No. 83, dated July 12, 1965, is typical of the group of instructions sent out during that time period. So that your committee may consider the bulletins as a group, I am including copies of the group as exhibit B for the record. These were sent out to Merck detail men.

Senator NELSON. They will be printed in the record at this point.
(The information referred to follows:)

BULLETIN No. 83, JULY 12, 1965

To: All Associates Western District.
From: H. Glassner.
Subject: 'Indocin.'

One of the reasons a real Senior Salesman like John Brekke consistently writes over \$300,000 a year is that the physicians in his territory believe him.

Physicians believe John because he tells them a concise, clear story that meets their needs, their wants, their desires, or allays their anxieties. Here is John Brekke's story on 'Indocin'. I'll bet he leads them with this.

"Doctor, I'm certain that in your busy practice no day passes without several patients seeking your help from the misery inflicted by painful, reddened, swollen, feverish joints—the classic signs of inflammation.

It is true that short term therapy with 'Decadron' has offered dramatic relief to many of these patients.

However, today, with 'Indocin', a new compound which is not a steroid—you can offer these patients new hope, new vistas of relief from their pain and an extended margin of safety.

More than 300 clinicians both here and abroad have concluded that when there is heat—redness—swelling—and pain in the muscle or joints—'Indocin' is usually effective.

'Indocin' is indomethacin—a modification of the naturally occurring amino acid tryptophan. 'Indocin' is chemically unique. 'Indocin' is not an aminopyrine derivative like phenylbutazone nor is 'Indocin' a steroid.

'Indocin' relieves stiffness, reduces swelling, alleviates tenderness, decreases fever, and above all soothes pain.

The advantages of 'Indocin' are these:

1. Therapy with 'Indocin' is safer. Clinical investigation in thousands of advanced cases has shown 'Indocin' to have a remarkable record of safety.
2. Therapy with 'Indocin' is rapid in onset of action. In many cases—particularly in acute flare ups of gouty arthritis—relief of pain is evident in 2–4 hours.

Usually on therapy with 'Indocin' tenderness and heat subside in 24–48 hours and swelling is reduced in 3–10 days depending upon the severity of the condition being treated.

3. Furthermore, unlike steroids, tolerance to 'Indocin' has not been reported.
4. The dosage schedule with 'Indocin' is simple and uncomplicated. Usual-