

Doctor, will you use 'Indocin' in the management of these arthritic disorders either after Aspirin or before Steroids, so your patient can benefit from 'Indocin' that much sooner?"

Remember, every bottle of 1000 'Indocin' that you sell, over your normal average, is now worth an additional \$2.80 in incentive payments. Pile it in!!!

Dr. McCLEERY. This Bulletin No. 83 advises the detail man to tell the physician:

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.

The bulletin goes on to promote Indocin for "pain in the muscles." It urges the detail man to "convince" the physician that Indocin should be used "when the muscles around an inflamed joint are in spasm causing a limitation in motion" and for "just plain musculoskeletal [sic] aches and stiffness * * *"

The unwarranted claims I have just mentioned appear repetitively in other bulletins of this same introductory time period. We regard these claims as outside the limits of indications in the approved labeling and therefore seriously misleading. In this connection, Bulletin No. 87, July 20, 1965, contains this statement of admission:

In fact, our guys are using a real expanded claim for "Indocin" on inflammation. They are consistently telling their doctors that * * *

They repeat the quotes similar to the ones I mentioned just above.

Senator NELSON. So in the drug company's own bulletin this sentence is a confession that they are making claims over and above those approved by the FDA, is that not correct?

Dr. McCLEERY. Yes, it is correct that that is what these bulletins say.

Senator NELSON. Please go ahead.

Dr. McCLEERY. It appears quite clear that the detail men were being told to influence physicians to use Indocin for unapproved uses.

But the instruction to Merck detail men did not stop with the promotion of unapproved uses. The detail men were given slanted information to deemphasize side effects and other warnings.

Mr. Chairman, in the interest of saving the committee's time I will not recount all of the information in the Indocin package insert on contraindications, precautions, adverse reactions, and other warnings. In the composite, all of this information suggests that Indocin must be used cautiously, if at all, and with the expectation that serious side effects may occur.

Notwithstanding all of the warning advice in the package insert, the bulletins representing the period July 12 to August 4, 1965, instructed Merck detail men to convince physicians that "therapy with Indocin is safer." The implication was that Indocin is even safer than aspirin. The physician was told that the drug is contraindicated in pregnancy but nothing was said in the bulletins of instructions about its being contraindicated in children. The instructions stated that the only contraindications are pregnancy, ulcerative colitis, active peptic ulcer, and gastritis. This was false.

The instructions went on to say:

The other side effects are not serious. Some patients on therapy with Indocin may experience headache, dizziness or lightheadedness, and even some minor G. I. disturbances.