

on Indocin, including one also taking aspirin, dropped out with "intolerable side effects." Another dropped out for an unrelated reason.

Among the remaining 21, one-third preferred aspirin and one-third indomethacin; one-third was unable to detect a difference. The physicians rated Indocin superior in five patients and aspirin in six.

10 WERE THE SAME

No difference was found in 10. "Side effects did not differ in frequency or severity," but headache was noted more commonly with indomethacin and auditory symptoms with aspirin, they said.

The study reported in the January-February Clinical Pharmacology and Therapeutics was sponsored by the American Rheumatism Association and was done by biostatistician Donald Mainland, primarily to establish objective standards for judging rheumatoid arthritis drugs.

No significant differences were found among patients taking Indocin and others taking a placebo. Patients in both groups were allowed to take as much aspirin as desired. Merck cited this in asserting that the study does not show that the relative effectiveness of Indocin and aspirin used separately.

[From the Washington Post, May 21, 1968]

DRUG AD EXPORTS POSE A PROBLEM

(By Morton Mintz)

In *Animal Farm*, the satirical fable by the late George Orwell, all the animals were equal, but only for a time. Then some animals asserted themselves to be more equal than others. A parallel may exist in the attitudes businessmen in one country take toward citizens of another when it comes to advertising prescription drugs.

American pharmaceutical companies hold a commanding position in the non-Communist world, and in promoting drugs it might be presumed that they would treat doctors abroad the same as doctors here. If a promotional claim is prohibited in this country because it might mislead a physician (and kill, injure, or at least exploit his patient), the same claim presumably would not be made in other countries. But that this is not always the case is suggested by a recent disclosure concerning Abbott Laboratories of North Chicago, Ill.

In March, 1967, this firm ran an advertisement in the *Journal of the American Medical Association* for Enduron, Abbott's trade name for a thiazide diuretic called methyclothiazide. The ad claimed that in removing excess fluids, Enduron caused a lesser depletion of potassium than rival prescription products. This claim was deemed by the Food and Drug Administration to be misleading. Under pressure by the FDA, the company then sent a letter individually to every prescribing physician in the Nation acknowledging that the loss of potassium with Enduron was not seen by experts as significantly different from the loss with other thiazide diuretics.

But a year later—in April, 1968—substantially the same claims were being made to physicians in Canada for the same product, which there is called Duretic. One ad in which this occurred was published in the *Canadian Medical Association Journal* by Abbott Laboratories Limited. Whether the claims which the parent company had repudiated were carried in other publications and in other countries, a spokesman in North Chicago refused to say.

Other incidents raising ethical questions in the same ballpark have cropped up in hearings held by the Senate Monopoly Subcommittee and troubled its chairman, Sen. Gaylord Nelson (D-Wis.). A recent one concerned indomethacin, a rheumatoid arthritis drug which Merck & Co. sells in the United States as Indocin and elsewhere as indocid. In this country, the FDA has refused to let Merck claim that the drug has been demonstrated to be safe and effective in certain additional medical conditions.

But these same medical conditions are freely promoted as appropriate for Indocid in about 100 other countries. To be sure, a few of these are highly developed Western nations which, it might be fairly argued, could have effective drug regulation if they do not now have it. What especially bothered Nelson, however, was that in countries with no regulation and no significant scientific community, drug promotion can be entirely free-wheeling, with resultant over-prescribing at the expense of the health and pocketbooks of innocent patients. In such countries, Nelson asked Merck president Henry Gadsden, "What is your standard of guidance for advertising?"