Gadsden said that his firm's standard "is whatever has been approved by the scientists of Merck as appropriate," and for which evidence has been submitted to the FDA, even if the agency has not been persuaded by that evidence. Nelson did not remind Gadsden of FDA testimony the day before that the agency's counsel was considering whether a criminal prosecution of Merck for misleading advertising of Indocin in the United States should be recommended to the Justice Department. Instead, the Senator said in regard to drug promotion in less-developed countries, ". . . there are lots of companies in this business that might not be as conscientious as Merck . . ."

Surely a difficult and delicate problem is posed. Americans may be uneasy about how American firms promote medicines abroad; they may doubt the wisdom of applying the adage about doing in Rome as the Romans do. But they cannot lightly try to arrogate unto themselves power to tell other countries what to do. Maybe other countries could require as a condition of import that advertising and promotion conform to United States requirements. Maybe it's a problem for the World Health Organization. Maybe even there is no solution.

[From the Washington Post, Mar. 3, 1968]

LETTER MISLEADING, DRUG FIRM ADMITS

(By Morton Mintz)

For the second time since May, Geigy Pharmaceuticals has conceded that it engaged in a prescription-drug promotion that the Food and Drug Administration criticized as "potentially misleading."

A promotional letter to physicians, the company said, "presented only favorable information" about Persantine, which is used in long term therapy of patients with the intense chest pain known as angina pectoris.

Actually, the firm acknowledged, "there is a substantial body of opinion that does not support the claimed effectiveness" of Persantine, the Geigy brand of dipyridamole. This is one of the drugs marketed before 1962 for which claims of usefulness have been neither approved nor disapproved by FDA, pending an efficacy review by the National Academy of Sciences.

The promotional letter for Persantine claimed that several studies document its effectiveness "in extending walking distance and generally increasing exercise tolerance." The claim was backed up with an enclosure—a reprint of a study reported last March in the Journal of Chronic Diseases.

The claim was knocked down in September, the Geigy Chemical Corp. division has recognized, by a report in the Journal of the American Medical Association. There, telling of a six-month, so-called double-blind study that was designed to eliminate possible bias, two researchers said:

"The study failed to detect a statistically significant difference between the improvement in patients receiving dipyridamole and the improvement in patients receiving a placebo," or inert, dummy pill.

This conclusion was relayed by Geigy in a "corrective letter" sent individually on Feb. 15 to each of the country's prescribing physicians.

Geigy went on to recall that the AMA's Council on Drugs had said last year in its primary publication that double-blind studies comparing dipyridamole with a placebo "have shown equivocal results . . . the drug has not been shown to be effective in the long-term treatment of angina pectories . . .

"Our future promotion will express the range of expert medical opinion on the effectiveness of Persantine when any segment of that opinion" is cited in promotional material, the company said.

The earlier case involved two Geigy prescription drugs used to lower blood pressure. They are Hygroton (chlorthalidone), which the FDA said was misleadingly advertised in MD Medical News Magazine, and Regroton, (chlorthalidone plus reserpine), which was advertised in Circulation Magazine in a way also condemned by the agency.

In the earlier case the firm sent its first "corrective letter." Various firms have sent a total of 21 of them since February, 1967. Had they not been sent, FDA was prepared in each case to seize interstate shipments and announce the action in a press release.

Senator NELSON. We are adjourned subject to call of the Chair.

(Whereupon, at 1:55 p.m., the hearing adjourned subject to the call of the Chair.)