

pressure were diagnosed and treated. SKF did no more than pay the bills. The goal of the overall program happened to coincide with the goals of manufacturers of drugs used in treating hypertension and with good medical practice.

In many other cases, however, increased use of medication is not necessarily consistent with good medical practice.

One such example is a learning system on the subject of stroke developed by Health Learning Systems, Inc., and sponsored by Marion Laboratories. The learning system consists of two motion picture films, accompanying workbooks, tests to be taken by physicians, plus materials used to advertise the learning system to directors of medical education and to hospital medical staffs.

Marion Laboratories markets papaverine hydrochloride in a sustained release oral dosage form named Pavabid. The drug is claimed to be a cerebral vasodilator and to improve circulation to the brain; let me note parenthetically that the usefulness of this drug has not, in our view, been demonstrated.

Senator NELSON. How could you make that claim?

Dr. CROUT. It is a complex problem relating to the claimed "grandfather" status of the drug. We are currently planning to review its effectiveness, in spite of its status as an old drug and that point is now under review.

In the April 5, 1976, issue of the *Federal Register*, the FDA called for marketers of papaverine to submit evidence of safety, efficacy, and possible "grandfather" status of the drug. The *Federal Register* statement said that the drug would be removed from the market if such evidence were not submitted.

At a September 1974 meeting of the Western Pharmaceutical Marketing Research Group, held in Chicago, a representative of Health Learning Systems explained why Marion Laboratories was interested in sponsoring a learning system on stroke. Marion's Pavabid already had more than 60 percent of the cerebrovasodilator market and Marion felt that no amount of advertising would increase this percentage very much. It was also felt, however, that if the total market for cerebrovasodilators could be expanded, Marion Laboratories would get a high percentage of the increased sales. One way to expand the market for cerebrovasodilators was to convince physicians that these drugs were useful in the prevention and treatment of stroke.

The first segment of the learning system made no direct claims for the effectiveness of Pavabid in the treatment or prevention of stroke but simply focused on the transient ischemic attack [TIA], a brief episode of focal neurologic deficit, as an early warning sign of stroke. It then provided prescribing information for Pavabid and a logo of a linegraph superimposed over a longitudinal slice of a brain.

The second part of the learning system discussed the "Diagnosis and Treatment of Cerebral Vascular Insufficiency." The relatively uncommon cases which can be helped by surgical intervention were discussed in a superb presentation by Dr. Michael E. DeBakey, president of the Baylor College of Medicine.

The final segment of the learning system considered vasodilator therapy. The accompanying workbook pointed out that intravenous papaverine, which is not marketed in the United States, is one of the most effective vasodilating drugs and then proceeded, in a leap in