

Act. Our regulations in point are concerned primarily with advertisements and other promotional material directed to prescribers, not to the public.

About a year ago, we discussed with the advertising agencies and the pharmaceutical firms some of the problems that would arise if promotional labeling for prescription products, particularly oral contraceptives in that case, should be directed to the public. We concluded that such promotions would be acceptable provided that they included appropriate warning information and specified the particulars in a policy statement published in the Federal Register on September 13, 1967.

Since that time we have discussed with individual pharmaceutical firms the content of institutional advertisements which offered the possibility of crossing the line to product promotion. Advertisements that are product oriented (which the Reader's Digest article is not) would require a brief summary of indications, side effects, and contraindications and they would have to contain this information in a form that would be understandable to the non-professional audience.

The portion of the Reader's Digest reprint titled "What Ever Became of Those Quarantine Signs" has been reviewed for factual accuracy. No direct claim for pharmaceutical company research involvement is made except for whooping cough (pertussis) "vaccine," and in that case it appears that several pharmaceutical firms supported extramural basic research on pertussis immunization in the 1930's and 40's. The other "vaccines" were developed from basic research not supported to any significant extent by pharmaceutical firms. Although the function of the pharmaceutical industry in production of "vaccines" for marketing is an important credit in their favor, the tone and implications of this article for the general reader go beyond mere credit for manufacturing ability.

The facts stated in the article "The Anonymous Drug That Hospitalized a Patient" are in general agreement with those given in Dr. Arnold Carter's letter to the Canadian Medical Association Journal. Attached is a copy of Dr. Arnold Carter's letter to the Journal. The fact that this "generic" brand did not meet the official monograph specifications makes it improper to compare its effectiveness with a product meeting official compendium specifications. It cannot be determined whether only a batch failed in meeting the disintegration specifications or whether the manufacturer produced most of his tablets in this manner. Failures of this type can be checked in the laboratory and action taken accordingly.

The comparable product sold in the United States was introduced to the market in 1957 and has been subject to United States Pharmacopeia standards, including disintegration time testing, since 1960. To the best of our knowledge no comparable problem has been identified in the American product.

The facts in the section entitled "Medicines for the Troubled Mind" could present better historical perspective. By stating that "Dr. Kline reported to the New York Academy of Sciences in 1954 that reserpine had 'proved an effective sedative in mental hospitals,'" the unnamed authors of the article totally disregard historical fact. Reserpine was supplied by the Swiss from CIBA to the Psychiatric University Clinic Burghoelzli in Zurich, Switzerland, where in 1953 it was first used in the treatment of mental illness in the Western world and reported to the medical profession. Similarly the implication of the paragraphs relating to the use of the phenothiazine related compounds ignores the fact that the earliest useful member of this group, chlorpromazine (Thorazine), was synthesized in France in 1950 and first used clinically in France in 1952.

If we can be of further assistance, please let us know.

Sincerely yours,

HERBERT L. LEY, Jr., M.D.,
Director, Bureau of Medicine.

Senator NELSON. There is no question that the entire ad is designed to avoid disclosing that it is, in fact, advertisement paid for by the drug industry. This calculated deception even goes so far as to include a solicitation to the reader to write to an organization called Health for reprints of the section.

Even on the last page, the words, "Published as a Public Service by the Pharmaceutical Manufacturers Association," are misleading since advertising is not generally considered to be a public service.