APPENDIX

MATERIAL SUPPLIED FOR THE RECORD BY THE SUBCOMMITTEE ON MONOPOLY

[September 17, 1975]

STATEMENT OF COMMITTEE ON SCIENTIFIC EXHIBITS IN REGARD TO PHARMACEUTICAL SUPPORT OF SCIENTIFIC EXHIBITS

The scientific exhibit is an established and efficient method of continuing medical education that brings new information from the research scientist and revised correlations of old information from the academic community for the attention of the practicing physician. A scientific exhibit is designed to emphasize a few points and not to be an in depth presentation of any subject. Because exhibits that contain too much information seldom attract a large audience, it is necessary that the amount of information on any exhibit be limited.

By reviewing scientific exhibits, physicians are able to learn more in less time about a wider variety of subjects than by any other educational method. The depth of the education is regulated by the interest and perceived needs of the physician. Those who wish a superficial knowledge of the advances in specialities other than their own, may take a quick walk through the entire exhibit. Those who wish to learn more about a subject may spend considerable time asking questions of the exhibitor. This informal discussion between the exhibitor and the practitioner is a valuable learning experience for both and not infrequently leads to further correspondence between the two. The scientific exhibit has been one of the main attractions of the American Medical Association meetings for the past seventy-five years and this educational method should be preserved.

Recently, the Food and Drug Administration has ruled that those exhibits which have been sponsored by pharmaceutical companies should be considered to be promotional rather than educational even though no trade names and no names of a pharmaceutical company are used. The fact that the exhibitor has tabulated the data and is responsible for the editorial content of the exhibit, does not keep those exhibits from being promotional. If an exhibit is designated as promotional it must conform to the Standards of approved labeling. This means that unapproved indications and unapproved dose schedules cannot be used. All data in regard to comparative efficacy and safety must be based upon controlled clinical trials and not upon clinical experience. By this definition, approximately 80 percent of the scientific exhibits at the AMA meeting are promotional and probably half of these are in non-compliance with the regulations for the labeling of pharmaceutical products as set forth in the federal register.

If these proposed FDA regulations are complied with, few pharmaceutical companies will be willing to sponsor scientific exhibits. The scientific exhibit will degenerate into a collection of homemade displays prepared by a few physicians who feel strong enough about a given subject to spend several thousand dollars of their money. Past experience has shown that few of these unsponsored exhibits are worthwhile. Strict interpretation and enforcement of the proposed rules would seriously retard medical communication. It is recommended that the AMA should take a strong stand in attempting to persuade the FDA to adopt more reasonable and permissive attitudes toward the scientific exhibit.

A knowledge of the logistics and the costs involved are necessary before anyone can formulate reasonable regulations for scientific exhibits. Presenting a scientific exhibit involves the following steps:

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