need additional authority to impose a tax upon the industry. Such a tax might accompany the registration, for example, and say for every drug in the marketplace and for x number of units of that drug, so many dollars per annum might be charged for a revolving fund in order for the Government to cause a compendium to come into being.

Sir, I would like to avoid that. I would like to see us operate as men of science, with good reason behind this, a demonstrated need, a desire on the part of everyone to have this occur on a voluntary basis. Those who decry Government regulations, it seems to me, should be in the leadership of avoiding them by their own voluntary efforts, and I would hope this would occur.

Senator NELSON. Thank you.

Dr. GODDARD. To say that our agency has had some difficulty with claims made by many companies in drug advertising is to understate our experience of the past year or so. Basically, the issue has been the inclination of a number of companies to go beyond the approved claims in the inserts and to evade the requirements for a brief, honest statement of the bad and the good to be expected from a drug. In a way, this has been a remarkable situation because at times FDA has not been as rigid on the language in package inserts as it might have been. But even with some small latitude, a number of companies sought even more. At this time, I would like to deposit with this committee copies of eight so-called "Dear Doctor" letters concerning 14 heavily promoted prescription drugs. These letters were sent to the medical community during the past 7 months. You will note that these letters seek to correct misinformation contained in advertising and labeling. In each instance they were written and mailed at our insistence.

Would you like to have for the record, Senator Nelson, the "Dear Doctor" letters that have been sent out?

Senator NELSON. Yes.

Dr. GODDARD. Thank you.

(The documents referred to follow):

FLINT LABORATORIES,
DIVISION OF TRAVENOL LABORATORIES, INC.,
Morton Grove, Ill., July 20, 1967.

DEAR DOCTOR. The Food and Drug Administration has asked us to call your attention to the initial advertisements for Choloxin® (sodium dextrothyroxine), currently appearing in several journals, which are regarded by the FDA as misleading.

The headline, "A significant new advance in the management of hypercholesterolemia", does not include the qualification that Choloxin is indicated for the treatment of hypercholesterolemia in selected patients, i.e., euthyroid patients with no known evidence of organic heart disease. Also, the ads fail to stress that Choloxin is not intended to replace or to lessen the desirability of considering dietary regulation in the management of hypercholesterolemia.

The FDA points out that, while the ads emphasize that Choloxin effectively lowers blood cholesterol levels, they fail to emphasize that this effect has not been proven to alter the morbidity and mortality of atherosclerotic disease. The claim in the ads that Choloxin (sodium dextrothyroxine) is "significant in its accepted physiologic mode of action" is considered to oversimplify the extent of knowledge of its mode of action. Further, the reference to "over 6,000 patients treated in clinical studies" overstates pertinent clinical experience, since only 2,967 patients were in the diagnostic categories for which the drug is currently indicated.

The FDA also considers the summary of warning information in the ads to be incomplete. The enclosed "Brief Summary" contains information in capital letters that was not present in the current ads, but will be incorporated into future ads for Choloxin. We are discontinuing the ads in question. The safety