Dr. MINCHEW. On Friday, May 24, 1968, the then Commissioner Goddard telephoned Mr. Morris Weeden, president of Bristol Laboratories, informed him that the certificates for marketing the drug had been withdrawn, and offered to meet with him at 9 a.m., Monday, May 27, to discuss Bristol's Dynapen promotional campaign.

Senator NELSON. What do you mean, certificates for marketing the drug? Are you saying you wouldn't do it?

Dr. MINCHEW. All antibiotics go through the certification procedure, and when they meet the standards of identity, strength, quality, and purity, there is issued a certificate which legally allows them to enter interstate commerce. Commissioner Goddard withdrew those certificates.

Senator NELSON. Which meant you withdrew the drug from the market?

Dr. MINCHEW. Which meant that the drug in interstate commerce was then illegal.

Senator NELSON. And was that amount of the drug which was already in the marketplace withdrawn?

Dr. MINCHEW. We will come to that subsequently. During that weekend, action was taken to determine the extent of the distribution of Dynapen, including all lots initially certified. All shipments were ordered embargoed at the wholesale level.

The meeting took place as requested. Mr. Weeden was accompanied by Dr. Peltier and his house counsel, Mr. Simonton, and by Messrs. Corcoran, Foley, Meers, and Lane of counsel.

Dr. Goddard and members of his staff presented the FDA's complaints against the promotional campaign in detail. The record of this meeting reflects that remedial action was accepted by the firm and the following pattern was established:

1. The Commissioner requested full reports as to what Bristol was saying to its detail men about Dynapen.

2. A remedial letter was to be sent airmail to some 280,000 practicing physicians, correcting the faults contained in the Bristol promotional letter.

3. A remedial ad; in this case, a correct ad bearing a legend stating it was to replace a previous ad which the FDA regarded as misleading. It was to be run in the journals where the defective ad appeared.

4. Each remedial form was to include a straightforward scientific statement of the place of Dynapen in therapy.

5. Bristol was to send drafts of proposed remedial actions to FDA by May 29, 1968, for consideration at a meeting with FDA on May 31.

Collateral action was taken to determine how far Bristol's initial campaign had been carried by their detail men. Our inspections of Bristol's plant showed that some 90,000 promotional folders for detail men had been produced. About 30,000 of these had been mailed to the approximately 300 Bristol representatives who were located west of the Mississippi and in Florida. Copies of these folders are being made available for the record—exhibits F and G.

Senator NELSON. They will be printed in the record.

(The information referred to follows:)