Senator NELSON. Go ahead.

Dr. STEINFELD. FDA has for some time been issuing routine publications on adverse drug reactions reported to FDA, general news releases, and, in extreme emergencies, telegrams to county and State medical and pharmacy societies.

This overall goal of communicating with the physician is being developed in a new unit established for this purpose in the FDA's Bureau of Drugs. The Assistant to the Director for Medical Communications is responsible for continual development of communication techniques designed to reach the physician and to promote rational drug therapy.

The Department is taking the approach that continuing education is the best method of bringing about rational drug therapy. As you know very well, most people, especially physicians, resent edicts of "you shall" or "you shall not." We plan to appeal to the logic of the Public Health Service physician by bringing to his attention the results of important published studies on individual drugs and classes of drugs. The information will be conveyed by a short covering statement that summarizes the study or studies with a copy of the published article attached. Copies of the NAS–NRC report and Federal Register material pertaining to the drug may also be included.

Three such statements have been prepared and distributed for the programs in Health Services and Mental Health Administration an amphetamines, mixed dose combination drug products, and on propoxyphene hydrochloride.

I have copies for the committee available here.[1]

These statements are designed to bring potential problem areas in drug usage to the attention of physicians and pharmacists in the Public Health Service.

You have already been advised by Commissioner Edwards that the FDA is giving priority to insuring the biological equivalency of drugs sold under the same name. This meets recommendation 14, that present clinical trials to determine the biological equivalency of important chemical equivalents should be continued.

Mr. GORDON. Dr. Steinfeld, may I interrupt a moment?

Do you see any trend in the direction of more rational drug therapy? Actually I have three questions. That is one of the three. Two, is it your opinion that FDA will have to take the lead in bringing this about? And three, would it not be helpful if the Government presented a good example in its usage and purchasing of drugs?

Dr. STEINFELD. First, I do think that we are making progress in rational prescribing. We are making it particularly as a result of the Kefauver amendments and the requirements that drugs shall be proven efficacious as well as safe for use.

I certainly agree that the Government should be a leader in good rational prescribing practices and it is apparent from the hearings which you have been carrying out these past several months that the Government has not always been a leader in this area.

[1] See pp. 8331–8339.