also will be communicating with physicians, both directly and through their journals. We are now preparing a "Dear Doctor" letter describing our position on the combination antibiotics, using Novobiocin and Panalba as specific examples. We are providing major medical journals with copies of NAS–NRC efficacy reports and have asked their cooperation in getting this information to physicians.

We are exploring the possibility of developing an FDA publication specifically designed to alert the profession of significant new drug information. We may also utilize "white papers" to explain the scientific rationale for new prescribing information.

Before closing, Mr. Chairman, I would like to touch upon some of the broader implications of the drug efficacy requirements now set forth in law. After enactment of the 1962 Amendments, FDA at first attempted to accommodate its greatly expanded drug review functions within the same system employed to carry out the much simpler job of clearing drugs for safety. In short, these responsibilities were to be carried out wholly within the Bureau of Medicine.

The first departure from this pattern was the decision by Dr. Goddard to utilize the NAS–NRC in the efficacy review of pre-1962 new drugs. This contract opened up to a broad segment of the medical community the whole question of drug efficacy.

I am convinced that we must move farther in this direction. The FDA must be able to tap the resources of the outside medical community to properly carry out its own responsibilities.

During the time I served as Director of the Bureau of Medicine, I initiated the establishment of approximately 10 new advisory committees oriented principally toward classes of drug products. A number of these committees began functioning this past year. In time, I believe all of these committees will assume a role within the Bureau of Medicine as valuable as that carried out in regard to contraceptives by the Advisory Committee on Obstetrics and Gynecology.

Mr. Chairman, you and the other Committee members are undoubtedly aware of the recent proposals to have FDA's drug evaluation function turned over to a group similar to the Dunlop Committee in Great Britain. Presumably, these proposals rest on the assumption that the system in Britain is superior to ours. The British, however, indicated they were not satisfied with their system by enacting a new "Medicines Act." This legislation, not yet implemented, establishes new drug review requirements markedly similar to those of FDA. The chief difference between the projected British operation and our own, as I understand it, is a greater reliance in Britain on advisory committees whose members will serve on a part-time basis as consultants to the permanent staff. But even this difference will diminish in time as FDA makes greater use of outside medical experts.

FDA's determination to draw upon the best available scientific and medical expertise can be of only limited value, however, unless the drug industry shows a similar concern. The major problem in industry submissions to FDA is still the poor quality of both basic data and summaries. The most important single step that industry can take to speed up the processing of new drug applications by FDA is to ensure that data presented in support of efficacy are derived, as the law requires, from well-controlled studies. A single, well-designed study involving 200 patients can be far more convincing than masses of data on 2,000 patients studied by 100 different physicians, each of them using different criteria for patient selection and different protocols for drug administration. This fact is so obvious that it shouldn't bear repeating. But I am repeating it because of the equally obvious fact that the drug industry is not practicing the sound research it preaches so well in the READER'S DIGEST and elsewhere.

The conflict between commercial and therapeutic goals, a conflict as real as it is regrettable, stands as the major impediment to the prompt implementation of the NAS-NRC efficacy recommendations. It is now apparent that the resistance of industry is going to be both intense and prolonged when the effectiveness of a profitable product is challenged. We anticipate protracted legal confrontation between industry and FDA as the Agency takes the regulatory action necessary to carry out efficacy findings.

We now estimate that the Bureau of Medicine's work of evaluating and recommending appropriate follow-up action on NAS-NRC reports will be largely completed by the end of 1971. But the full implementation of these decisions in the face of industry opposition, will require a massive effort on the part of the Agency's regulatory and legal staff extending well beyond 1971.

Thank you. My staff and I will be happy to respond to your questions.