Mr. HUTT. In short, Mr. Gordon, what we are trying to do is to make as much information available to the public as we conceivably can, consistent with the laws of Congress, which they have enacted. We believe that the Congress has made it clear that the information is not to be available. The alternatives we have taken is to inform the public and the medical profession and other interested scientists the bases for our decisions.

Senator NELSON. I would like to clear up a few points before closing today. We would like to have in the record whatever basis there may be for the assertions in the Medical Tribune, and so-called Dripps Committee assertions about FDA. Perhaps we can conduct some hearings at a later date on the specific claims made by the Medical Tribune articles, editorials, and the Dripps Committee, as well as their claims and the responses to them by the FDA. That is, if you would be willing to come at a later date.

Dr. EDWARDS. We certainly will be, Mr. Chairman.

(The documents follow:)

UNIVERSITY OF PENNSYLVANIA,
Philadelphia, Pa., February 29, 1972.

HON. PAUL G. ROGERS,
House of Representatives,
Washington, D.C.

DEAR MR. ROGERS: We, the undersigned are or have been engaged in medical practice or medical research and are therefore deeply interested in the advancement of human therapeutics. For this reason, we are increasingly concerned with the present drug regulatory system and its effect on the practice of medicine and the development of new drug therapy.

We have concluded that the procedures by which new drugs are evaluated and approved for use in this country is causing us to fall behind in this important area of medical science.

We recognize the difficult task which confronts FDA. Many of us have worked with FDA and have deep appreciation of the efforts being made by its leaders and staff. At the same time, we have watched the research efforts of the pharmaceutical industry over the past few years grow in competence and depth. We are struck by the paradox of increasing excellence on both sides and decreasing productivity.

The system of drug regulation, which has evolved as a result of the 1962 Drug Act and Regulations, exposes the agency to a variety of pressures which make it difficult for rational decision-making to take place. In a recent speech before the National Institute of Medicine, FDA Commissioner Edwards put his finger on the problem: "It's a particularly difficult environment for the Food and Drug Administration because, in a sense, we're in the middle. We are, on the one hand, criticized for being 'soft' on industry and, on the other called repressive, an enemy of free enterprise: on *every* major decision we are accused by some of acting too fast without sufficient evidence, and by others of acting too slowly and too timidly to prevent unnecessary harm."

The FDA has long been the subject of study and investigation. In fact, there have been at least three Executive Branch studies of FDA in the past five years. The last, ordered by Commissioner Edwards, was a review and evaluation of the total scientific effort of FDA by an outside committee headed by Dr. Ritts. These reviews and reports, while critical of many aspects of FDA, have been useful and helpful, we are sure. But they have focused primarily on the internal structure and workings of FDA. As important as it is to improve the efficiency and scientific procedures and capabilities of the agency itself, there still remains the crucial question as to the effect the agency's administration of the 1962 Drug Act has had in actual practice on drug research, innovation, and therapy.

New pressures are now forming to add even more regulatory responsibilities to an already overburdened agency. Moreover, the Administration has proposed legislation which would consolidate all consumer protection activities of HEW in a new Consumer Safety Administration of which FDA would be a member; Senator Magnuson and others are supporting draft legislation which would abolish FDA and set up an entirely new and independent Consumer Safety Agency;