drug therapy and the imprecision of the art of medicine, we believe the FDA should limit its mission to what Congress specified and intended.

The FDA may not be consciously building a case for the doctrinaire control of all aspects of drug therapy, but it would be difficult to draw any other conclusion from the testimony of January 18.

For example, on the issue of relative efficacy, FDA's assertion of authority would enable it to become the decision maker as to how many drugs should be on the market and from what source as well as what medical practitioners may prescribe in any given case. Such action would contravene the clear intent of the 1962 Amendments to the Food, Drug, and Cosmetic Act. Even a cursory review of the legislative history shows that Congress decided unequivocally not to give the FDA such authority.

We also object to the causal linking of such a grave social problem as drug abuse to the alleged "over-prescribing" of legitimate medicines. Given the current mores, attitudes and conditions of society, we would have the drug abuse problem of the same dimensions regardless of the status of prescription drugs. Consequently, this linkage permits conclusions and implications which are unfair and which I hope were not intended.

Early in your testimony you estimated that prescriptions will increase from two billion to three billion per year in five years—as if this were inherently bad. I would assess such growth as a consequence of expanding health care, in private and governmental programs, to growing populations, to rising family incomes, and to the overall effectiveness of drug therapy in prevention and treatment disease.

The studies you cite on adverse reactions, hospital-acquired infections, and number of drugs received by hospital patients cannot be applied to the total patient population. As you know, these are isolated studies of limited magnitude which hardly meet standards of "substantial evidence".

While a few examples of agency-industry cooperation are noted, the overall tenor of the statement and the responses to questioning suggest a derelict industry which must be held in line by a vigilant agency, whose wisdom and rectitude surpass that of the companies. It would have been appropriate to mention, for example, the extensive cooperative effort that went into the preperation of the recently published regulations on Good Manufacturing Practices. Nowhere is the scientific and technical proficiency of the industry acknowledged as integral to the regulatory area. Yet, as you know, our companies are constantly improving the quality and diversity of our drug supply and with a dedication that is surely the equal of the effort exemplified by the FDA. Moreover, regulations in general are based on the experiences and practices of competent manufacturers. The in-depth inspection program to which you refer is possible because of the cooperation of our member firms as training sites for FDA personnel.

We find the discussion of brands, generics, and equivalency especially contradictory. Much of the testimony discloses the practical problems of assuring the safety and equivalent effectiveness of all drugs, and it also discloses how far we are from achieving such a goal. The extent of recalls, inspections leading to the closing of plants and numerous instances of equivalency failures, indicate that there are fundamental differences among manufacturers. Hence, there must be fundamental differences in the quality of drugs. Skills, experience and competence do count. Even your recital of the situation with Digoxin simply reemphasizes the subtle problems of producing quality medicines. Drugs that go through the NDA process are not always equal, much as FDA wishes that they were. Many studies show otherwise, and we wlil document this matter shortly in a new PMA publication.

As you know, Food and Drug Administration experts recounted one important study in the January 11 issue of *JAMA*. Surely this example of oxytetracycline *un*equivalence signalled the potential extent of the problem, just as earlier studies did on Chloromycetin and its "copy" products.

If studies undertaken so far illustrate significant differences in biological response, what would happen if all drugs had to undergo such rigorous testing? A projection of the results so far compiled points to the probability of a *very frequent phenomenon*, not an infrequent one, as suggested. I find it disturbing that you did not emphasize the fact that the agency cannot possibly assure biological equivalency, even for NDA'd products, in the foreseeable future.

On page 9056 of your testimony, in response to a question from Senator Nelson, you stated that batch-testing applied to all "imported anti-infectives" as well as domestic batches. This contradicts past testimony which indicated that FDA has