conferences to work out the labeling of the particular drug in question. All of the labeling claims on these some 2,000 drugs that are under review in the drug efficacy study, which will remain on the market in one category or another for the time being, will be reviewed and appropriate changes made in the labeling.

Senator NELSON. So, any labeling——

Dr. EDWARDS. I was going to say in addition to that, our current labeling policy on new drugs is a much tougher one than that in previous years in the FDA.

Senator NELSON. So, all labels that have been criticized by the NAS–NRC as being inaccurate for one reason or another will be revised.

Dr. EDWARDS. All of those will be revised and we are moving as I indicate later in my testimony, toward class labeling. In other words, and tetracycline is probably the best example, for a tetracycline drug, be it a brand name or be it generic, the labeling should be the same. I think this will do a great deal to clean up and to make more meaningful the labeling for drugs.

Senator NELSON. I do not know that I follow you on that. You mean that now if there are several brand names of tetracyclines that they may have different labeling?

Dr. EDWARDS. There may be some differences in labeling between various brands of the same drug. We are changing this. We are moving in the direction of class labeling across the board.

Senator NELSON. I do not know what the present practice is. It never occurred to me to look.

Does the labeling require, then, that the generic name of the compound be on the label?

Dr. EDWARDS. Yes. Do you want to add anything to this Dr. Simmons?

Dr. SIMMONS. Yes. Mr. Chairman, on the class labeling specifically, what we are trying to accomplish is this. At the present time—take tetracyclines for example, on which you had a lot of testimony, there are about five different chemical formulations of tetracycline. Now, all of them have minor differences which present and old labeling show, and on which advertising claims have been made.

The important thing, however, is that these minor differences, though there, are clinically insignificant. Therefore, there is no reason why a physician should choose one as opposed to any other.

Now, since there are, I think, over 50 tetracyclines available in these five different chemical classes, what we are trying to do is to simplify the labeling to point out to the doctor, in a simple, concise way, that basically they are all the same. He can expect the same result from any of them and he should base his therapeutic judgments on that statement.

That is what class labeling is and that is what we are trying to accomplish with it.

Senator NELSON. Well, if the distinctions in the formulations are of no clinical significance, are they permitted to make a claim in the labeling that they are?

Dr. SIMMONS. They will no longer be allowed to.

Senator NELSON. They will not be permitted to do that any more.