trolled from identity, strength, quality, and purity, how it is going to be labeled, how it is going to be controlled, and that it is indeed the drug that has been tested and has shown itself to be safe and effective.

Now, all that is in the literature does not necessarily mean that is all the knowledge about this drug.

Senator NELSON. But it is clear to me in any event—that when somebody licenses 25 other companies, the licensees do not really have to meet the same standard as somebody who applies for a New Drug Application for the same compound.

Mr. GOODRICH. They have to meet the same standard.

Senator NELSON. We went through that. If they all meet USP standards they are allowed to manufacture the drug because we assume the clinical results will be good. But the one new applicant is not automatically approved, because we assume that he has to prove safety and efficacy.

Mr. GOODRICH. We do not make any such assumptions. We make the decision on the basis of the data and the data is used to make that decision depending on whether it is in the public domain and all comers can use it or whether it is private business information in which the owner of that information controls its use. But we would not approve a new drug simply because a second company was licensed. We require the presentation of hard scientific data showing——

Senator NELSON. But you remember that you require from the licensed people that they meet standards of production and USP standards.

Mr. GOODRICH. We require the presentation of clinical data and this may take the form of incorporation of the previous clinical data on a business arrangement.

Senator NELSON. Does that improve the quality and the proof of the clinical value of that company's drug, whereas B can't incorporate the data and therefore he does not? That is nonsense.

Mr. GOODRICH. I do not agree with that, but since you are the chairman, I will have to.

Senator NELSON. You would be better off if you said there is no justification at all for allowing one company to license five companies, incorporate their clinical tests and then because the licensees incorporate the application of the original company, say that the proper standards are being met.

Senator SCOTT. I do not want you to feel you have to agree with Senator Nelson, because none of us——

Senator NELSON. None of us do.

Senator SCOTT. We have various degrees of blood pressure up here and each of us would require different medical treatment, probably.

Senator NELSON. My 6-year-old gives me arguments like this sometimes.

Senator SCOTT. I have found that sometimes the children are right.

Dr. GODDARD. The New Drug Application is evaluated by FDA scientists, medical officers, pharmacologists, chemists, who are now organized along team lines handling similar action drugs. We must reach a decision as to whether the usefulness of the drug outweighs its possible dangers. All the experimental data—both animal and human—are reviewed. During this past fiscal year—the year in which we