Mr. CUTLER. But only one submitted proof it was safe and effective. The other 19 did not. And the FDA did not find proof that the other 19 were safe and effective.

Senator NELSON. Are you talking about the case where a New Drug Application is approved and the company licenses 19 other companies to manufacture it?

Mr. CUTLER. No, sir.

Mr. STETLER. That could be one situation. But whether you have a licensing arrangement or not, the ones that come later with an identical or similar product, are not necessarily required to have proof of clinical effectiveness of their products. You cannot assume just because the first one who processed the NDA has proven up all these things, that everyone who follows has the same capabilities or that their drugs have.

One other thing on USP. We have talked about 7,000 drugs today. You know, USP only includes 600 drugs. So there is a question of coverage—even if you make the assumption, which is not valid, that because USP standards are identified, that you have the therapeutic equivalency.

Mr. GORDON. Dr. Modell says that if the drugs have the same chemical components, and they do meet USP standards, then the assumption has to be made that they are clinically effective.

I do not want to get the two terms mixed up—"effective" and "clinically equivalent."

Mr. STETLER. There is a good deal of difference between clinical equivalency and therapeutic equivalency. Dr. Modell may have said that the assumption can be made. The assumption does not have to be made and really should not be made, in our opinion.

Mr. GORDON. Dr. Garb says you cannot practice medicine unless you make the assumption that when a doctor prescribes something here or in California, or this year, or 20 years from now, that drug is the same—otherwise you cannot practice medicine.

Mr. STETLER. I think the doctors that prescribe generically probably make that assumption. But you realize that in 95 percent of the cases the doctor either prescribes by brand name or indicates the source. So he has not made that assumption. He practices medicine in 95 percent of the cases not making that assumption.

This is a statement in USP:

> The term physiological availability connotes an attribute of dosage form of a drug that constitutes a measure of the extent to which the active ingredient is taken up by the body in a useful form. Progress has been slow in developing methods to measure physiological availability that would be suitable for USP use. Consequently, however desirable it is to give assurance or complete availability to every patient requiring the USP article, the problem of providing objective standards and methods remains in the exploratory stage at this time.

The NF has the same paragraph.

I do not mean to say that Dr. Miller has made a misstatement. And we have no quarrel with the USP or NF. It is just that while it is an easy transition to make from USP standards to therapeutic equivalency, it is a faulty one, and one which we think should not be made.

Senator NELSON. Correct me if I am wrong about this.

If a New Drug Application is approved, its approval is based upon the testing that has been done by the applicant, in compliance with the