Senator NELSON. In the studies thus far of the NAS–NRC, apart from topicals, were there any fixed combination drugs that met the standard that you are talking about?

Dr. SIMMONS. Mr. Chairman, out of, I believe, over 1,300 combination drugs reviewed, excluding topicals and parenterals only a handful were rated effective.

Senator NELSON. A handful?

Dr. SIMMONS. Yes.

Senator NELSON. By the standards that you are reciting here.

Dr. SIMMONS. By the NAS–NRC standards themselves. You see, they had a basic standard at the beginning of the study that there should be substantial evidence that each drug contributes to the therapeutic effect claim.

Senator NELSON. And this is the standard that is being adopted or proposed for adoption by the FDA?

Dr. SIMMONS. Yes.

Senator NELSON. Now.

Dr. EDWARDS. Right.

Mr. GOODRICH. With some refinements. We want to improve on that to make sure that the combination itself is rational. For example, the oral contraceptive is a fixed combination product in which both components serve a useful purpose and for which the patient requires concomitant therapy in that combination.

What we are essentially saying is that a fixed combination should not be giving the patient a variety of drugs when he or she needs only one, and if a variety are given, there must be a situation in which the patient requires concomitant therapy with the two drugs in this particular dosage form as Dr. Simmons said, either in terms of increased safety or increased effectiveness.

Senator NELSON. Thank you.

Dr. EDWARDS. We have spoken briefly of the combination problem. The problem of internal delays is frustrating, as you know, to all administrators. We have provided extra resources in the Bureau of Drugs to expedite the handling of these cases. This has and continues to have high priority and these cases are handled as rapidly as possible. We have already published reports on 1,200 drugs and about 700 others are ready for publication. The remainder should be in the public domain by March of this year.

But only last Thursday, the District Court here in Washington heard the American Public Health Association's complaint that we are not moving fast enough. That suit seeks to set aside the internal rules we have developed which allow additional time for the development of appropriate medical evidence to support claims evaluated as "possibly" and "probably" effective.

Senator NELSON. These are the two that are questioned in the suit or are all standards you have set questioned?

Mr. GOODRICH. These are the main ones questioned. Actually, the suit questions the 30 days on the ineffectives and it does not question the rulings of effective. The suit says that once there is a finding by the NAS–NRC of anything other than wholly effective, we should take the product off the market without further delay. Our response was that in those products classified possibly and probably effective