the brief summary more and more containing the full story about the warnings and precautions because the regulations do require the same emphasis and the same wording for those essential warnings.

Senator NELSON. Go ahead, Doctor.

Dr. EDWARDS. Continuing on with regard to the drug efficacy study per se, the panel reports evaluated the indications for use as "effective," "probably effective," "possibly effective," "ineffective," "ineffective as a fixed combination" and "effective but." The results of the evaluations are the following. Again, I emphasize, too, here our percentage numbers are based upon the total number of claims on these drugs of which there were some 16,500. Of those 16,500 claims, approximately 14.7 percent were found to be ineffective. Approximately 35 percent were found to be possibly effective. 7.3 percent, probably effective. 19.1 percent, effective, and 24 percent, effective "but."

I might say at this time that we have returned the "effective but" ratings to the National Academy of Sciences for clarification but we did begin to implement the other reports in 1968.

The NAS–NRC reports and our medical reaction to them are not self-executing. They trigger the administrative process of labeling and product reform.

As soon as the first report classifying a drug as "ineffective" was announced, industry resistance appeared. The first line of defense was to throw the issues into hearings, from which protracted delays could be anticipated. There were court suits seeking exemption of a great number of drugs from the efficacy review—on the ground that they were excused by the grandfather clauses.

The real test of the Agency's determination and ability to translate the scientific reviews into patient benefits came in mid-1969 with the now quite famous *Panalba* case. The Agency took two important steps to minimize hearing delays. It defined the scientific content of adequate and well-controlled clinical investigations to provide a regulatory base against which medical documentation would be measured, and it established summary rules to limit its hearing procedures to those cases in which the sponsor of the drug could establish that there was a genuine and substantial issue of fact requiring a hearing.

The *Panalba* case was taken first to the district court and then to the court of appeals. After an expedited appeal, FDA prevailed. The principles on which we would proceed were then firmly established.

There was a temporary setback in the District Court in Wilmington, Del., a short time before the *Panalba* decision came down with the consequence that we had to repromulgate the interpretive and procedural rules. In May 1970, the rules were reissued; a pharmaceutical manufacturers association challenge failed when the district judge sustained the rules in late October. Thus, only 8 months ago the roadblocks were removed and the stage was set to move ahead with the administrative proceedings in an expeditious fashion.

From the drug efficacy study arose two areas of special concern; fixed dose combination drugs and the elimination of unnecessary internal delays in processing cases.

Senator NELSON. May I ask a question, Doctor? The table on page 6, appears to show that almost 60 percent of the claims lack adequate