In spite of the above, the statisticians were instructed to include all 122 in their computer analysis!

2. The above judgments of inadequacy were based primarily on the inadequacies of, and deviations from, the clinical protocols; the objections raised in my Medical Officer Reviews (copies of which were submitted to Commissioner Schmidt on March 7, 1975) included serious doubts as to the validity of some of the lab data and hence are additive, rather than merely corroborative of the above tabulation.

3. On June 27 and July 25, 1972, four outside clinicians headed by Dr. Prout and aided by two outside biostatisticians considered the computer-generated data prepared by the FDA staff and concluded that:

Perhaps even more surprising is that if the sample size were increased to 30, and all 30 were "good," you might still have 98 "bad" ones undetected!

In other words, such an approach would be a waste of time and effort and could be quite misleading.

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