clinical response in a patient, you do not get the immediate relief of the asthmatic attack. For example, we have cases where the tablet will not produce the response in the patient because they did not dissolve in the patient and were passed through.

Senator NELSON. That obviously did not meet the USP standard if it did not dissolve. The USP standard requires a certain dissolution rate.

Mr. STATLER. I beg to differ. It did meet the USP standard and it met the so-called in vivo tests, disintegration tests, but in actual practice in the patient the physicians were documenting that the drug was passing through the patient undissolved and, therefore, was not producing therapeutic response.

Mr. GORDON. Could this be due to the patient?

Mr. STATLER. There are physiological differences in make-up of the patients, and this could be, but they have tried no controlled test. But, other drugs have produced the same response.

Mr. GORDON. Have you done any double blind control tests which indicate that certain brands of, let us say, tetracycline——

Mr. STATLER. Not on a daily treatment. Research programs——

Mr. GORDON. You have done no double blind studies to show that?

Mr. STATLER. No; we do not do this in patient treatment. This is reported in other cases of clinical pharmacologists on double blind studies.

Mr. GORDON. Could you give us the studies to which you refer which show that the drugs marketed are such?

Mr. STATLER. These are alluded to, of course, in the white paper produced by NAS–NRC.

Senator NELSON. What white paper is that?

Mr. STATLER. The white paper on the generic equivalency that is alluded to in the National Academy of Sciences and National Research Council, that not all drugs are therapeutically equivalent and do not produce the same therapeutic response.

Senator NELSON. I think that is an entirely different question. Is that not referring to the NAS–NRC study in which they made certain recommendations, for example, that all mixed combination antiinfectives be removed from the marketplace? Is that it?

Mr. STATLER. No; I am referring to the paper that is alluded to as the white paper, as published in the Journal of the American Medical Association in which it was pointed out that not all drugs being chemically equivalent produced the same therapeutic response in all patients.

(The information referred to follows:)

[From the Journal of the American Medical Association, Vol. 208, No. 7, May 19, 1969, pp. 1171–72]

SPECIAL COMMUNICATION—WHITE PAPER ON THE THERAPEUTIC EQUIVALENCE OF CHEMICALLY EQUIVALENT* DRUGS

(Prepared by a subcommittee of the Policy Advisory Committee, Drug Efficacy Study)

Recent reports of considerable variation in the serum levels, and therefore in the probable biological activities, of equal doses of certain drugs marketed by different manufacturers, focus attention upon an important determinant of

* Drugs that meet the current standards of identity, purity, and quality, and quality of the active ingredients established by competent authority.