another brand of a generically equivalent product, identical in dosage form and content of active ingredients. If the prescribing physician does not agree to the use of a generic product he must check in the appropriate place provided on the form.

This encourages him to use the generic product but permits him to express his professional right to prescribe a particular item if he feels he can justify the request.

When we can be assured of effective safeguards to adequately assure that chemically equivalent drugs are also biologically and therapeutically equivalent, we promote actively the use of generically produced drugs.

At this time in the critical review and challenge of our historical methods of assuring the safety and efficacy of drug products, we are proceeding with greater caution. There is increasing evidence that many of the drugs marketed for some years as chemically equivalent drugs meeting USP or NF standards will not produce the same clinical response in patients. I am certain this subcommittee is aware of the National Academy of Sciences/National Research Council "white paper" which recommended that manufacturers of generic drugs available on the market for some years be required to prove that their products have the same therapeutic effectiveness as the original drugs they seek to imitate.

As I stated earlier, this entire area is one in which there are divergent views. The promotion of generic equivalent procurement and the criticism of marketing of so-called "me too" drugs is an example of the dichotomy of views.

Generically equivalent drugs almost universally enter the market as "me too" drugs.

Mr. GORDON. Mr. Johnson, may I interrupt for a moment? On the top of that page you say:

> There is increasing evidence that many of the drugs marketed for some years as chemically equivalent drugs meeting USP or NF standards will not produce the same clinical response in patients.

Would you please name these drugs?

Mr. STATLER. An example, Mr. Gordon, is chloramphenicol.

Mr. GORDON. That was a question of blood levels, and there was never any evidence to show that some were not just as good as others from a clinical point of view.

Senator NELSON. That is a batch-tested drug anyway. Do you have——

Mr. STATLER. But, the therapeutical response was not the same in all instances from company to company. We have in our VA an example, tetracycline.

Mr. GORDON. Is this on oxytetracycline?

Mr. STATLER. No, tetracycline hydrochloride, it was reported the patient was not getting the desired clinical response with this particular brand.

Senator NELSON. The statement suggests that clinically equivalent drugs meeting USP or NF standards will not produce the same clinical response in patients. Do you have any examples?

Mr. STATLER. Another example is Theophylline, a formulation for asthma. It has been documented in clinical case abstracts that with the use of Theophylline you do not always have produced the same