lists[1] of chemicals pulled at random from suppliers (who do not make drugs and therefore are not involved in the drug price controversy) demonstrate very readily that if they have to go through further steps of purification beyond U.S.P. purification standards, the price is higher per unit weight. Our inability to use them in the laboratory and the price differential suggest that the requirements of chemical purity of U.S.P. chemicals are so low as to be of very questionable use in the area of human therapeutics.

The United States Pharmacopeia in cooperation with United States Adopted Names Council controls the generic or public name of drugs. For some reason they have tried to use a chemical basis for naming new drugs. The result has been names so long that most physicians can not even pronounce some of their tongue twisters, let alone remember or spell them for writing prescriptions. The contractions of chemical nomenclature that result are also of no value in deciphering the structural formulae of the compounds. For good or bad, most physicians have to use trade names short enough for them to remember in their practice.

Moving still closer to the problem of generic versus trade name drugs, we found very little scientific evidence on either side of the fence. The companies with the brand name products maintain that their products are better, while the generic equivalent companies maintain that theirs are equal but cheaper per unit. It is unfortunate, but true, that at present one is forced to rely not on scientific data, but on the gross reputation of past performance of the manufacturers in the selection of drugs for the patient.

The U.S.P. criteria are for a tablet to *contain* a drug while the experience of a company as it develops new agents indicates that the tablet *delivers* a certain pharmacologic effect. Several of the bad experiences with generic drugs have already been pointed out by others to your distinguished committee, and do not need to be repeated here. There must be good experiences with these agents also, but in the area of health it is not wise to experiment broadly.

Having no other basis other than the gross past performance of an older established company to rely on and being fully aware that the other possibility is a vast experiment too broad to foster on an aged and/or poor population group, who could not even give their informed consent to participate in such an experiment. I sympathize with you and your distinguished colleagues in this dilemma.

My suggestions would be that before you reach any conclusions in this matter: (1) wait until the special study committees on Efficacy Review of the National Academy of Science, National Research Council report to Commissioner Goddard of the Food and Drug Administration on those drugs that were on the market prior to the new F. and D.A. regulation on efficacy; (2) request that the pharmaceutical industry provide over the next few years proof that their particular brand name or generic name drug will pass certain rigidly controlled tests of blood levels of the drug, efficacy, stability, etc. so that at some point in the reasonable future there can be some scientific basis for a rational judgment; (3) study means by which to reward scientific investigations and the development of new therapeutic concepts to such an extent that this is significantly more profitable than simply marketing someone else's drug or a slight modification thereof, (my statement here is meant to be positive and not negative since being restrictive will do no good in the long run to advance medical care and this must be an overriding interest); (4) contemplate new methods of distribution such as automation to cut the very major costs created by a group that contributes nothing to the therapeutic agent; (5) determine what can be done to update the U.S.P.; (6) avoid highly inflammatory issues directed at the public, such as Dr. Burack's book since this approach generates a lot of glib opinion and little or no scientific data on which to base a rational decision, and (7) lastly develop bold new concepts that will succor the truly productive aspect of the only industry that can make new therapeutic agents available to the public, while weeding out those aspects that contribute little to the long-term advancement of the human race.

Thank you for your kind consideration of these remarks. I do hope that they can be made a part of your hearing record. I have taken the liberty of sending copies of this letter to all the members of your subcommittee.

Sincerely,

CLARENCE L. GANTT, M.D.,
Associate Professor of Medicine and
Assistant Director of Clinical Research Center.

[1] Retained in committee files.