human patients. Except perhaps in rare circumstances, such a comparison is neither practical or necessary. It would be extremely costly and very time consuming even if the required personnel and facilities could be found for such investigations. In many instances it would be contrary to medical ethics, since it would involve human experimentation under conditions in which a lack of therapeutic efficacy could have undesirable or even fatal results. Furthermore, objective clinical comparisons between drugs are notoriously difficult to achieve, because of differences between patients and differences in the symptoms or diseases under consideration. Therefore, our attention has been directed to use of an indirect measure of therapeutic equivalence—termed physiological availability. In determining physiological availability, the concentration of the drug being studied is determined in the blood and/or urine of human patients at intervals after dosing.

The problem of therapeutic equivalence—or the lack of it—received great prominence last year when it was found in the U.S. that certain brands of chloramphenicol, an antibiotic, gave reduced blood levels of the drug. These products also showed abnormal dissolution characteristics when examined in the laboratory. In Canada, our Food and Drug Directorate also found that one lot of chloramphenicol from each of two companies dissolved at significantly lower rates than that of the first brand of chloramphenicol marketed in Canada. Although this did not necessarily mean that these products were clinically ineffective, the Directorate as a precautionary measure advised the manufacturers involved to recall those lots of chloramphenicol from the market. The companies agreed and carried out a voluntary recall of the products involved.

The problem of therapeutic equivalence has been studied in detail by a task force of the United States Department of Health, Education and Welfare. A senior officer of the Food and Drug Directorate has served on one of the expert panels of the task force, concerned with the conduct of clinical trials carried out by various agencies of the U.S. Government to assess the biological equivalency of a variety of drugs. The task force in an interim report issued in mid-September of this year, concluded that instances of therapeutic non-equivalency have seldom been reported, and few of these have had singificant therapeutic

[Mr. Gendron.]

significance. The lack of therapeutic equivalency among drugs meeting all official standards for parameters such as identity, purity, potency and dissolution rate, has been grossly exaggerated as a major hazard to public health, the task force reported.

Despite the unequivocal nature of the task force's statement, so-called brand name manufacturers of drugs and their associations, both in the United States and Canada, have made much of the supposed therapeutic advantages of brand name products, for which they claim to have demonstrated evidence of clinical superiority. My officials, however, agree with the American task force. We feel that lack of therapeutic equivalency among drugs meeting all official standards has been grossly exaggerated as a major hazard to public health. With the exception of chloramphenicol, to which I have referred, we know of no documented instance of therapeutic inequivalence among drug products which are physically and chemically equivalent. Our views on this matter coincide exactly with those of Dr. Philip Lee, Assistant Secretary in the U.S. Department of Health, Education and Welfare, who testified to this effect recently to the Nelson Committee of the U.S. Senate. The question of therapeutic equivalence has been used as a convenient bogeyman by certain drug manufacturers in attempts to document unsubstantiated claims for therapeutic superiority of their products. They got a great deal of mileage out of the chloramphenicol incident, and have used it to make unwarranted generalizations about all drugs.

The plain facts—and they are abundantly documented in the scientific and medical literature—are that so-called brand name manufacturers of drugs do not have valid grounds for objection to so-called generic drugs on the basis of lack of therapeutic equivalence. Nor do they have evidence that brand name products are of better quality in other ways. The Director-General, Food and Drugs, testified in January, 1967 before the Special Committee of the House of Commons on Drug Costs and Prices (the Harley Committee) that on the basis of laboratory examination the Directorate had no evidence drugs sold under a brand name differed in quality from those sold under a generic name.

The Directorate's experience and views, have not changed since that time. It is clear that some so-called brand name products are lower in quality than they should be, and so are some so-called generic products.