Actually, it is our view that far too much emphasis has been given to the question of generic versus brand name drugs. Just to give one example, the Compendium of Pharmaceuticals and Specialties, Fourth Edition, 1968, published by the Canadian Pharmaceutical Association, Inc., lists seventeen acetylsalicylic acid products, manufactured by 14 different companies, all of which are sold under a brand name. Only 4 of these manufacturers are listed as member companies of the Pharmaceutical Manufacturers Association of Canada. I am sure that this Association and others who have been most vocal on this subject, would not be prepared to class the remaining 10 as "brand name" manufacturers or their products as "brand name" products. The truth is that practically all drugs sold at the retail level carry brand names. Thus any attempt to divide the drugs on the Canadian market into "brand name" and "generic name" products is an exercise in futility.

I referred previously to the fact that drugs which meet official standards may be expected to show therapeutic equivalency. One of the most important of these standards relates to the rate at which the drug dissolves in artificial gastro-intestinal fluids. An officer of the Research Laboratories of the Food and Drug Directorate is a member of a joint committee of the United States Pharmacopeia and the National Formulary, which is studying various procedures for measuring the rate of dissolution of drugs. In our own research program, we are giving high priority to the development of simple physico-chemical methods for dissolution which will correlate as closely as possible with the physiological availability of drug products.

Opponents of the proposed legislation have claimed that Bill C-102 provides an invitation to counterfeiting. There is no evidence to support this contention. Drug counterfeiting has been a much more serious problem in the U.S., where legislation similar to that embodied in Bill C-102 does not exist. Only one instance of the sale of counterfeit drugs in Canada is known. Last Spring the Food and Drug Directorate of my Department became aware of counterfeit tablets of a tranquilizing drug known under the brand name of Valium. Investigations carried out in conjunction with the R.C.M.P. showed that counterfeit Valium tablets were being peddled to pharmacists in the Montreal area in unlabelled bags and bottles. Analyses conducted in the laboratories of the Food and Drug Directorate revealed that the active ingredient, diazepam, was present in the declared amount.

• (12:20 p.m.)

Furthermore, no impurities of significance were present. Therefore the counterfeit product was *not* a hazard to health but it was being sold in clear and obvious violation of the Food and Drugs Act and Regulations. Prompt action by the Food and Drug Directorate and the Company producing the genuine product brought the sale of these tablets to a halt, a few days after the counterfeit nature of the product had been confirmed. I should like to repeat that there is no evidence that the passage of this legislation will encourage the counterfeiting of drugs.

Finally I wish to refer to the reports of the Hilliard and Boyd Committees. It has been frequently said by opponents of this legislation, that if the recommendations of these two committees has been implemented, there would be no problem. Well, let me review the situation as it now stands.

As you will recall, the Hilliard Committee was appointed to examine the patent licensing arrangement with respect to drugs. The action taken to date on the report of this Committee can be summarized as follows:

1. Under present procedures the Commissioner of Patents requests the opinion of the Food and Drug Directorate regarding the compliance of an applicant for a compulsory license with the manufacturing facilities and control Regulations under the Food and Drugs Act. Under Section 1, Subsection 13 of Bill C-102, it will now be mandatory for the Commissioner of Patents to give notice to the Department of National Health and Welfare of an application for a compulsory license.

2. The intent of the recommendation that the definition of a "new drug" be amended to include a drug manufactured by a new process or if new or more serious side effects develop, has been included in modified regulations currently being reviewed by the Department of Justice.

3. Drug manufacturers have been advised that prior to the issuance of a notice of compliance on a submission for a new drug for human use, a factual scientific document on the drug products, devoid of promotional material, must be available for distribution to physicians and pharmacists. This product monograph is to serve as a reference standard