March 2, 1967

up by Product A—the standard used in our studies on sugar coated phenylbutazone tablets.

One of the other brands did give depressed blood levels. However, at this time, we are not sure if the product is satisfactory or unsatisfactory.

We cannot, therefore, fail more than one of the four brands tested.

III. SUMMARY OF RESULTS

papers cited above twe found that five

We may now summarize all of our results. We examined 43 products. If I were the Director of Quality Control for the companies concerned, I would not permit the marketing of 14 of these products. This means that 32.6 per cent of the products failed either legally acceptable standards or standards which have been established in our laboratory or by other researchers.

It can be argued that some of the tests that we used in the laboratory are not described in the pharmacopeias or are not considered to be official by the Food and Drug Directorate. Furthermore, it can be argued that biopharmaceutics is still in its infancy and no one really knows its significance with respect to therapeutic activity. I understand both of these arguments and, if I were dealing with something other than a drug, I would not be too concerned. However, because I am dealing with a drug, I will not pass a product unless I am absolutely sure that it is satisfactory in all respects. Personal responsibility is just as important as legal responsibility.

Some of you may have observed that I have studiously avoided a direct comparison of brand name drugs with generic name drugs. You know that many generic houses market drugs only under a brand name. Similarly, many ethical manufacturers market drugs under their generic name. A comparison of brand name drugs with generic name drugs has, therefore, little meaning.

I realize, however, that I cannot avoid the final question. Who manufactured the 14 products that I find unacceptable? I will not list the companies involved but I can make certain generalizations. In pharmacy, we like to refer to "ethical" drug manufacturers. This word carries a certain meaning to most of us. It implies that we trust the products that are manufactured by these companies. Some of us like to be more specific and say that all of the members of the Pharmaceutical Manufacturers Association of Canada are "ethical" manufacturers. I am not too ready to accept this definition but to get myself into a position where I can comment on the products that we have tested I will assume this to be a fact.

Of the 14 products that failed one or more tests two were manufactured by companies that belong to the PMAC. The remaining 12 were manufactured by independent companies. You may draw your own conclusions from these figures.

In conclusion, my concern is with product quality only. We expect a certain level of performance from the students that we teach. We fail students for committing lesser sins in our dispensing laboratories that those committed by the manufacturers of the 14 products I have been discussing. Can we then give our blessing to these products? My answer is "no" because the final responsibility is not to ourselves but to the patients who will receive the medication that we dispense.

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