

from my years with the Food and Drug Directorate, that there can be differences between lots of drugs but this doesn't detract from the statements I have made.

I am enclosing several copies of a speech that I made here at U. B. C. Unfortunately, I do not have sufficient copies for all the Committee members but you may wish to circulate those that I have enclosed. I have sent one copy to Dr. Brand, who appears to be interested in drug quality.

I would like to thank you and the Committee for the courteous treatment that I and Dr. English received when we appeared last fall. I only hope that we contributed something to the solution of a very complex problem.

Sincerely yours,

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Associate Professor.

### THE QUALITY OF GENERIC DRUGS

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The pharmaceutical analyst's world is filled with numbers and words that have little meaning to the average person. He speaks of "quality" and "potency", quotes liberally from his pharmacopeia, and confuses all with the subtlety of his art. Because his basic approach to quality control is chemical rather than physiological, his results may be misleading and are often misunderstood. By tradition, he is a chemist. By force of circumstances, he is asked to assess the products that are prescribed by physicians and dispensed by pharmacists.

It should be obvious that we cannot comment on product quality unless we first define certain words that are part of the vocabulary of the pharmaceutical analyst. The dictionary states that quality is a "distinctive trait" or "excellence of character". Potency, on the other hand, is the quality of being "highly efficacious chemically or medicinally." It is at this point that the pharmaceutical analyst comes in conflict with himself. Can he show, by chemical means, that a product is "highly efficacious medicinally"? Many pharmaceutical analysts to speak of "excellence of character", are readily able to comment on the *chemical* characteristics of dosage forms, but will not comment on the therapeutic efficacy of the products they are asked to assess. They know that chemical equivalency is not the same as therapeutic equivalency. They know that the test procedures described in the pharmacopeias and in the scientific literature are, too often, completely unrelated to the processes that occur in the body. Knowing this, they are ready and willing to do two things.