

the dissolution rate of drug from the large tablets was slower than from the old tablets. The tablets were reformulated to increase this rate, and these were then used to replace the stocks of older tablets in retail and hospital pharmacies. A surprising turn of events occurred. It became apparent that some patients who had their prescriptions refilled with the newest tablets showed prothrombin levels below the therapeutic range and, in some, bleeding occurred. The company alerted all physicians concerning the more intense therapeutic effect of the new bishydroxycoumarin tablets and urged that all patients on anticoagulant therapy with their brand of bishydroxycoumarin tablets be retitrated for their requirements. It is quite likely that no 2 manufacturers' brands of bishydroxycoumarin tablets will act alike in therapeutics, and it is conceivable that a change from a slow release brand to a fast release brand might even result in death if the necessity for retitration is not recognized.

Mr. CUTLER. Mr. Gordon—are you in agreement that doctors would be well advised to identify the manufacturing source rather than simply prescribing by a generic name?

Mr. GORDON. I think so.

I do not have any more questions.

Mr. CUTLER. I do not have any more questions, either.

Mr. GORDON. I would say I would go along with that.

Mr. GROSSMAN. I do.

Mr. CUTLER. Then I think we have closed a very large part of the gap between us.

Mr. GORDON. This is only my opinion.

Mr. CUTLER. Senator Nelson earlier disclaimed any recommendation that doctors should prescribe simply by the generic name, and leaving it to the pharmacist to pick out any old drug product meeting that generic name. If we are in agreement on that, I think we have closed the gap a good deal, and we might close in, then, on the next issue.

Mr. GROSSMAN. I would like to turn to another aspect of this.

Would you say that different PMA members—I assume you would—perform different quality controls?

Dr. SLESSER. Yes; I think there are variations in the type.

Mr. GROSSMAN. That you have mentioned here.

Dr. SLESSER. You can have different approaches to accomplish the same thing. And I think the magnitude of the quality control system will be directly related to the number of products and the number of people, and things of that sort; yes.

Mr. GROSSMAN. Would you say that some of your members are better at quality control than others?

Dr. SLESSER. I think they all do the best job they can. I do not think they knowingly—any of them knowingly slight quality controls.

Mr. GROSSMAN. But would you say probably that the leaders—I won't define it, because we do not define leaders—perform essentially similar quality controls?

Dr. SLESSER. Yes.

Mr. GROSSMAN. In other words, that the top firms would produce just about the same drug if they were given it from the beginning, if they had the same ingredients? Is that true?

Dr. SLESSER. I think they would all make sure the product behaved in the clinic the way it was supposed to, and then do whatever is necessary to make sure each batch resembled in its clinical effectiveness the prototype clinically tested batch.

Mr. GROSSMAN. Let me give you a hypothetical situation.

Suppose, for example, that Squibb produces a brand-name drug, and