

company is in the hands of the physician, and unless he is operating under a formulary of some kind or another, which is a very good system, he is frequently working with inadequate information. So it is my position that what we are trying to do mostly is to be sure that the doctor gets adequate information about drugs. I think if he had the kind of information that is found in the Medical Letter he would be prescribing one of the cheaper brands, of prednisone, in this case, as is recommended by the Medical Letter itself.

So what we are trying to do is not interfere with the physician's discretion, but to see to it that he gets enough information so that he can exercise wisely the discretion that he has.

Go ahead.

Dr. APPLE. There has been much discussion about patents for "molecular manipulations." This form of research sometimes leads to new discoveries of considerable value. To the extent that potential patentability for "molecular manipulations" leads to new compounds and therapeutic entities, it serves a useful purpose for society.

We do, however, believe that the patent system and not the trademark statute provides the incentive for research and innovation in the pharmaceutical world. It is the patent system which provides a modicum of protection for risk capital, for investment in product and market development, and for investment in the education of the prescribing and dispensing practitioners. In our view, there is nothing wrong with this system and its rewards.

A patent on a drug product marketed under its generic name provides as much protection, revenue, and benefit as does the same product marketed under a brand name. Briefly stated, the nomenclature under which a drug product is distributed has no effect on its therapeutic value or safety for the patient. The patentee can set a price on his product, however named, to return more than his investment in research, development, production, and distribution. These basic facts have not been sufficiently emphasized in the current discussion.

Also overlooked is the fact that the patentee of a drug is the sole source of that drug unless he, voluntarily, licenses someone else to enter the market. Where a licensee is also marketing the same product, we would expect that the licensee's price would be much less because of the absence of research, development, and other costs which justify the patentee's price. When such a situation exists, we would expect pharmacists to act as the public's purchasing agents and obtain the drugs as economically as possible.

Mr. GORDON. You mean as economically as possible consistent with quality; isn't that correct?

Dr. APPLE. Yes; we certainly do. Quality is certainly a factor. We would have to take into consideration whether the drug was a post-1962 drug, whether it had an NDA, whether safety and efficacy had been approved by FDA, whether it was a certified drug, but we are certainly not talking about the cheapest drug, Mr. Chairman.

In testimony before the Senate Committee on Finance, during September, we reported that the "brand-name era" in pharmaceuticals is coming to an end. We were merely reporting an observation about prescription drugs as we and others have seen it.

Senator NELSON. What do you mean, the brand-name era coming to an end?