

Our submission to the Hearing Clerk outlines these factors and describes our specific objections to the equivalency assumptions in detail.

If new and better drugs are to be developed in the future, it will be necessary to preserve an environment in which the capital needed to finance the search for them can be generated. The draft regulations ignore this primary social need. They propose to draw no distinction in determining the fair price of a drug product for a full-service, research-based firm as against that from a commodity supplier. In doing that, they hold out no prospect for reward to the firm interested in improving the quality, effectiveness, or stability of an MAC drug. Nor do they propose to allow an MAC drug of established dependability to carry any portion of its producer's research commitment toward the discovery of new therapy.

The CHAIRMAN. We are only referring, of course, in the MAC regulations to multisource drugs. So all the patents have run out, whatever patents there may have been, is that not correct?

Mr. STETLER. That is true.

The CHAIRMAN. What puzzles me is why the drug companies think that somehow or other they ought to be able to extend the practical effect of the patents beyond the expiration date.

You say they won't be able to get research money. Well, after all, if they had a patent, they charged enough to get back their research investment, and a very good profit, if it is a useful drug that is in sufficient demand. But just like any lawnmower manufacturer, or the inventor of a new technique, or any new process, when the 17 years are over, anybody in the United States can make his product. And there certainly isn't any valid argument for saying, well, the guy who invented it, after he has had patent rights for 17 years, should somehow or another be allowed to charge a higher price for his lawnmower forever, even though there are competing equivalent ones in the marketplace, because he was the inventor. The reward was in the patent.

Now, what is your response to that? You are making the argument that he ought to be rewarded forever.

Mr. STETLER. We don't say we ought to be the sole suppliers forever. Obviously competition is there and always will be there. What we are saying is that if you do review the economic facts of life in this industry, that the prices that are charged for some multisource drugs must cover more than the cost of the preparation and the marketing of that commodity. The price must also cover of the things I have mentioned here, that are spelled out in more detail in our longer statement.

But it is not like manufacturing lawnmowers, because there probably aren't 6,000 failures in lawnmowers for each one marketed. In the drug industry you might look at 6,000 compounds before you have a successful drug product. So you just don't pay for your research on the marketed product. You must also pay for your losers out of the relatively few successful products that are put on the market.

There is no doubt that the income from multisource drugs, to some extent, subsidizes the services, the increased capabilities, the quality