" * * inevitably a useless drug will not be used because of the training and experience of physicians because of their experience with this useless drug, if it is permitted to be marketed.*

" * * We feel that a profession fully knowledgeable in a free market economy will soon bring about the withdrawal from the market of a useless drug."*

What do you think about this?

Answer. I believe this is much more a semantic exercise than a statement that requires refutation. In the first place, if we use the AMA's definition of utility, there is no such thing as a "useless drug". Milk sugar or any other inert ingredient when put into the form of a tablet, a capsule, a solution for injection, or any other dosage takes on the properties of any placebo. Administered as a drug it can produce temporary relief in a host of disorders and even cure in disorders that are self limited. It can also produce side effects that lead the patient to refuse to take the "medication". If we use a *pharmacological* definition, milk sugar is a useless drug. If, on the other hand, we use changes that may be observed in some patients by physicians who do not know that it is an inert substance, and especially if they have been preconditioned to expect beneficial effects, milk sugar becomes a useful drug. This is the yardstick used by the AMA.

A combination of meprobamate and benactazine (Deprol) has been marketed as a useful agent in the treatment of depression for at least ten years. Most experts agree that it has no demonstrable value in the condition for which utility is claimed. Yet it has withstood the "Hussey-Stetler Test of Time" which the AMA, by its own admission, feels is the ultimate test of the utility of any drug.

Vitamin B 12, especially in the form of 1,000 microgram injections, has an extremely limited use. If its use were restricted to those patients who really need it I would guess that the amount now used in one year would be enough to treat patients with true Vitamin B 12 deficiency for almost one hundred years.

The absurd limits to which average practitioners go is illustrated by my own experience with Vitamin B 12 during the time I was Medical Director. Because claims for its utility in many neurological disorders ranging from peripheral neuritis to trigeminal neuralgia and herpes zoster, as well as claims for utility in loss of appetite, underweight, poor growth, etc, were based purely on testimonial evidence I refused to approve such claims in our literature on the drug. I answered the detailmen's immediate complaint by pointing out that our brand of Vitamin B 12 was therapeutically equipotent with any brand on the market. If the doctor believed that it was indicated in any condition other than true Vitamin B 12 deficiency, our brand would meet the need as well as any other brand. For many months after I made this decision I received letters of complaint not only from detailmen but also from practitioners (who were probably told by detailmen that I would like to hear from them). Our sales volume fell off, and there is adequate reason to conclude that many practitioners actually believe that the pharmacological effects of a drug are dependent upon the labeling that accompanies a drug. This is true not only of labeling that makes claims but also of labeling that does not make claims. Many physicians obviously believe that a drug that is identical with competitive drugs becomes inferior by virtue of the fact that it makes fewer claims than the competitive products. This is one of the more obvious illustrations of the irrationality of practitioners and the irrationality of their prescribing habits.

The rapid rate of obsolescence of drugs is dependent not on the wisdom imputed to the average practitioner by the AMA, but rather on his lack of wisdom. "Since so much depends on novelty, drugs change like women's hem-lines and rapid obsolescence is simply a sign of motion, not progress as the apologists would have us believe . . . with a little luck, proper timing, and a good promotion program any bag of asafoetida with a unique chemical side chain can be made to look like a wonder drug. The illusion may not last, but it frequently lasts long enough. By the time the doctor learns what the company knew at the beginning it has two new products to take the place of the old one." Not infrequently the doctor never learns and the obsolete drugs remain on the market. Oral Mephenesin is a good example.

The "Hussey-Stetler Test of Time" deserves the contempt that Morton Mintz heaped on it. The uncontrolled observations of average practitioners constitute testimonials and as such have zero validity in the scientific evaluation of a drug. Whether we multiply zero by 1,000, 10,000, or 300,000 the answer is still zero. The contention that the fate of a drug in the market place is an accurate index of its value as a drug simply is not true.

Actually my first exposure to the principle of the test of time and the market