

only to drugs that are given as capsules, tablets or pills and exert their effects following absorption, a process that is seldom 100-percent efficient. It may be an individual matter involving only a few patients or may hold true for all patients who get the same batch of tablets. Regardless of whether the failure of absorption is an individual or a general characteristic, the end result is that one or more patients fail to get well. The physician has reason to be perplexed, and at the very least, his therapeutic plan has gone awry.

Generally less frustrating to the physician are the situations in which the effect exceeds expectation as the result of better-than-expected absorption. This has been reported for at least three drugs. In each case, physicians were accustomed to using a specific dose that suddenly proved to be too much. Immediate checks showed that the right amount of drug was present and that other relevant USP standards were met. In due time, allowance was made for the more complete absorption by reducing the dosage and thus restoring the desired level of effect. The only possible explanation was that greater efficiency had been achieved as the result of some subtle change. Subsequently, it was confirmed that the manufacturer had changed his process of making the tablets and accidentally has discovered how to make a smaller amount of drug do what had required a larger amount previously. Greater physiological availability had been achieved, which simply means that the absorption of the tablets was more nearly 100-percent complete.

The important point, however, is that not more than a dozen drugs have presented problems with respect to physiological availability. Thus, to damn the entire Pharmacopeia of some 2,000 drugs for the failure of a mere handful is unscientific in the extreme. It would be just as illogical to strip a regiment of its honors each time one of its privates went AWOL. Yet this is what is suggested by those who would destroy our faith in all USP standards because pharmaceutical and medical science has not yet advanced to the point of providing the required test methods for the few demonstrated cases that require extra precaution. In short, let us not throw out the baby with the bath water.

Now I would like to turn to something that has been mentioned in these hearings and concerns a special area of the pharmaceutical world, and deal at some length with that, because I have had rather close experience with it for some years. It is drug nomenclature.

DRUG NOMENCLATURE

Drug nomenclature is an area in the pharmaceutical world that is distinguished by a maldistribution of too little information among too many self-styled experts. Suggestions are being made for more laws on the subject; but it will be a pity if more legislation is added before we learn to cope with the unfortunate enactments of 1962.

Senator NELSON. Why were they unfortunate?

Dr. MILLER. They were unfortunate because they put the emphasis in the wrong place. I am confining my remarks here to drug nomenclature. Some two pages of the Kefauver-Harris Act are devoted to drug names.

Senator NELSON. What is that?

Dr. MILLER. Drug names, how to correct difficulties with drug names.