

more than a dozen examples where the difficulty (questionable clinical equivalency of drugs meeting USP standards) has been discovered, and it is not generally true even for all of them."²⁵ My own evaluation of the "generic equivalency" or more precisely therapeutic equivalency dispute is that the brand name firms have greatly overstated the significance of any valid or partially valid elements in their position, and that the argument on the whole is without merit. The verdict of lack of merit seems inescapable since there should be no reason to assume that the therapeutic equivalency of two brand name preparations is any greater than that of a brand and a generic name preparation. As Dr. Martin Cherkasky recently testified before this Subcommittee, "I must tell you that I feel quite insecure at the same time about the performance of some of the major drug companies in this country."²⁶ The intensity of the dispute is all the more puzzling since it appears to take for granted that pharmacology is much more of an exact science in practice than in fact it is.²⁷

It would seem that the best argument which the major drug firms have in support of their charges that unsafe drugs are on the market is the contention that FDA inspection is not adequate. This is a perennial charge, and one which in recent years has become much less plausible because of long-needed increases in FDA staffs and budgets. But if any doubt remains as to the adequacy of FDA inspection, it should be resolved by providing FDA with still more funds to the full extent which may prove necessary. Perhaps. Still, it is the direct responsibility of the FDA to safeguard the public from poor drugs, in a much more immediate sense than this responsibility is shared by USP. Batch certification of all drugs might be one solution. Dr. Solomon Garb's proposal that all drug manufacture be subject to continuous federal inspection is another solution. Dr. Miller charges that the former proposal would be unnecessarily costly; Dr. Garb reports that drug makers contend that the costs of his plan would be astronomical (although, as he points out, there is private inspection today at less than astronomical cost, and it would seem quite feasible simply to substitute public for private inspection with avoidance of excessive duplication of efforts.) An economist would wish to make one point. Regardless of the methods adopted, the physician must be made confident that all drugs on the market are safe to use. Relative costs of the methods employed to bring about this confidence are important, but it is very unlikely that the costs involved would fail to justify the resulting benefits: complete elimination of substandard drugs and the opening up of much of the prescription market to price competition between low-priced generic drugs and currently high-priced brand-name equivalents. The cost of the industry's current system of "insuring" drug quality by advertising intensively to promote brand-name drugs and discourage generic prescribing does tend to increase the sales of the former drugs and reduce the sales of the latter. But beyond that, it perpetuates a great barrier to price competition and places an

²⁵ *Ibid.*, Part 2, p. 514.

²⁶ *Ibid.*, Part 2, p. 668.

²⁷ A layman can perhaps be forgiven for introducing into the record the idea that with few exceptions (but among them some admittedly very important ones) in the present state of our knowledge, drugs tend to be relatively blunt instruments when employed in human therapy, so that the question of "therapeutic equivalence" when generalized to include all drugs frequently becomes subsidiary to the question as to whether or not the drug can be depended upon, in a particular circumstance, to do its job at all. Placing some emphasis upon this may put the issue of therapeutic equivalence in a more adequate perspective. The significance of this issue would become much greater if one could always assume that if each drug is optimally manufactured and administered, it will accomplish a predictable, effective, and exclusively beneficial therapeutic result upon each administration. But where the effect of the drug is unpredictable, imperfect, and tempered by side-effects, therapeutic equivalence as such is a much less paramount consideration, and the importance of other factors, such as biological variations among human recipients, incidence of side effects, and the inherent uncertainty regarding the mechanism of action of the active ingredient itself, become more significant. The notion that many drugs are blunt instruments is not propagated by the industry, but it is hard to avoid drawing such a conclusion, if for no other reason than the inability, to date, of molecular engineers, to eliminate side effects. Candid doctors have submitted that these effects should not be regarded as incidental disadvantages, but are an integral part of the total action of the drug, and should rather be referred to as "concomitant effects." Just as burning down the house would be a "broad spectrum" recipe for roasting a pig, so also must one regard antibiotics which indiscriminately kill both harmful and beneficial organisms within their range of activity as being relatively blunt instruments. One is reminded of Buckingham's characterization of his parody of the dramatic hero, Drawcansir, in the play *The Rehearsal*. Drawcansir's battle cry was:

Let petty kings the names of factions know;
When e'er I fight, I slay both friend and foe.