

by Parke, Davis and Company to whom these rights belonged. Tetracycline, on the other hand, was available and was marketed by at least four major ethical pharmaceutical houses. The urge for survival in such a climate should be sufficient to stimulate the utmost ingenuity among these competitors in the drug industry. It is, therefore, a curious coincidence that chloramphenicol with a spectrum of activity quite similar to that of tetracycline was never considered to benefit by fixed combinations with other antibiotics. Contrariwise, tetracycline appeared in combination with a variety of antibiotic and non-antibiotic substances, depending upon the pharmaceutical company responsible for its marketing and design, to provide promotional material which would convince physicians to use one tetracycline rather than another. The enormous success of this maneuver is best typified by the combination of tetracycline and novobiocin.

This combination with its fixed proportions was based upon the most fragmentary theoretical or objective scientific evidence yet, it was responsible for an estimated 20-25 million dollars in sales at its peak and in 1968, at a time when the panels of the National Academy of Sciences—National Research Council evaluated it as "ineffective as a combination" it was still responsible for generating \$16,860,000 in revenue.⁶

At this point we emerge into a phase of deterioration, disenchantment, and dismay which I would entitle the evaluation of drugs by the method of popular vote. This method, although courted several times previously, has been most recently and glaringly espoused by the Vice President and Director of a major ethical pharmaceutical house.⁷ From the outset, I must emphasize this is not to be misconstrued as a vicious attack on either the pharmaceutical industry in general or an individual in particular. The specific company in question is in excellent standing in its own peer group as well as with the physicians of this country. Its clinical and scientific organization includes men of the highest integrity and motivation as well as highly competent scientists, many of whom (at least up to the present) I count as close friends and valuable colleagues with whom I have had occasion to cooperate in scientific endeavors on a number of occasions. On the other hand, high and powerful position carries with it a requirement for responsible action.

The introduction of ill-founded, confusing, threatening, and dangerous methods for deciding scientific issues of medical practice requires close public scrutiny. Those who oppose such methods are entitled to be satisfied that they are, indeed, poorly conceived; and, if they are, such methods should be held up for all to see in order that the mistake need not be repeated. The appeal of the Dear Doctor letter in question represents, in my opinion, a bold, unscrupulous and selfish attempt to raise the spectre of government regulation against the inalienable right and, indeed, duty of every physician to manage his patient's problems to the best of his ability. I can understand the responsibility a corporate executive must feel for the financial welfare of his company. I am saddened by the prospect that he deems it necessary to resort to an appeal which I consider insulting to the intellectual and scientific training of physicians and detrimental both to the practice of medicine as well as to the necessary efforts of regulatory agencies to protect the public from truly unscrupulous promoters. This in no sense is to imply a blanket endorsement of the Food and Drug Administration with whose policies and methods I am by no means always in complete agreement. In this case, however, it is difficult to categorize their action as punitive when the demand is simply to provide evidence, thus far unavailable, that these drugs are effective for the claims they are purported to have. I am confident some pharmaceutical groups involved in this controversy will attempt to provide such evidence. These data should be evaluated critically, objectively, open-mindedly, and re-evaluations of efficacy considered and accepted, regardless of whether they agree or differ from the ones which now stand.

The implication that a large number of practicing physicians have gathered evidence which is valuable with respect to evaluation of drug efficacy and which has not been adequately considered by the panels deserves brief examination. It might be appropriate to consider the type of contribution which the practicing physician can best make which is valuable in the advancement of scientific and medical knowledge. It is a practical impossibility to project reliably all the results, good and bad, from extensive drug usage with the necessarily somewhat limited scientific investigations of each agent prior to its public release. To

⁶ Davee, K. M., *Pharmaceutical Market, Drug Stores, Hospitals*. Davee, Koehlein, and Keating Company, 111 West Jackson, Chicago, Illinois, 1968.

⁷ Gauntlett, J. C., *Dear Doctor Letter*, 28 January, 1969.