

utility. The drug industry can answer the FDA's objections better by collecting and submitting those data than by blowing up an emotional storm over 'interference' with the physician's prerogatives . . . the real need is for data not protest."

At the same time I sent a personal letter to one of the members of Dr. Dowling's panel in which I exhorted him to stand fast and to urge the panel not to be swayed by irrational protest regardless of its volume. I pointed out that if the panel and the FDA capitulated they would set a precedent for an incredible policy, namely drug evaluation by mass protest and by testimonial.

Subsequent events demonstrated that the majority of practicing physicians with "irregular and inadequate exposure" had the "political leverage" and prevailed. The FDA retreated and extended the period for filing comments for two months. Subsequently, it appears, both the FDA and the panel did capitulate and this bold, but rational, step toward sound medical practice came to naught. Capitulation in the face of voluminous and vehement protest is understandable, but nonetheless regrettable. It is incredible that testimonials and irrational protest can be so effective.

If scientific data ever were presented I have no knowledge of such data. Even the AMA (in the article quoted above) gave a pathetically weak and specious argument to justify the continued use of these irrational combinations of drugs. In defense of these products the AMA said: "It seems that many physicians in practice prefer to prescribe such a mixture of drugs because they believe that each drug in the mixture will have a specific desirable purpose." The AMA still clings to the fiction that every physician is his own Pastuer. It would probably prefer to forget that there was a time when it refused to accept advertising for drug combinations.

The AMA also gave its usual glib solution as the answer to the problem of irrational antibiotic-cold preparations. According to the AMA the answer lies not in FDA action but in "education of physicians" and "labeling." If the experience with chloramphenicol is an example of what can be accomplished by physician education and labeling, it is high time we began to search for other solutions.

The weight that should be given to the average practitioner's concept of the problem is reflected in one of the letters to the FDA quoted by John Troan. The latter came from a small local medical society and said: "We deeply resent this proposed usurpation of our prerogative to *treat and diagnose* our individual patients and our prerogative to err if that be the case." I have added the emphasis because as a psychiatrist I have always found the Freudian slip that reverses the order of the terms *diagnose* and *treat* of special interest. I am still awed by the arrogance the latter expresses.

According to the PMA and the AMA these views should be given the same or greater weight than that given to scientific evidence derived from controlled studies. Testimonials are still testimonials regardless of their numbers. The irrational does not become rational by virtue of volume.

If the entire antibiotic combination episode is an illustration of how the drug industry, the medical profession, and their chosen representatives the PMA, and the AMA seek to enhance the scientific stature of the FDA and how they seek to promote sound medical practice, it leaves much to be desired.

Curiously, all the sound and fury was over nothing since the proposed ban did not interfere with the physician's prerogative to prescribe as he chooses. It did proscribe the marketing of certain irrational mixtures, but the physician was still free to prescribe a cold preparation and to write a prescription for any antibiotic of his choice in those cases where it was indicated.

If the FDA cannot proscribe the marketing of irrational mixtures of drugs because that proscription infringes on the privileges of physicians, Congress and the people should re-examine those privileges. This is clearly an abuse of privilege and should not be tolerated. According to a Supreme Court decision the people give privilege to professions and the people may take it away.

The stage for the pending confrontation between the FDA and the drug industry was set in 1962 when Congress approved the efficacy provisions of the Kefauver-Harris Amendments of the Drug Act. At that time Congress had a clear choice between exempting drugs approved for safety only during the period between 1938-1962, under a grandfather clause, or making the efficacy provisions retroactive. In choosing the latter course Congress gave the FDA a clear mandate to re-evaluate all such drugs for efficacy and unleashed forces of explosive potential.