

The trials could not substantiate any of the claims made in previous reports, which had indicated that 60 per cent of patients had improved.

The company declared some of these trials were totally invalid and in later testimony urged that drugs be evaluated in an uncontrolled fashion by physicians who were expert in the treatment of rheumatic diseases. While no one could question that many of the company-sponsored physicians were expert clinicians, the question of whether they were performing scientific experiments remains unresolved. The company also implied in later testimony that the controlled trial is something new in medicine. An excellent controlled trial was performed in 1747 on board the British warship *Salisbury* by Dr. James Lind. Twelve seamen with scurvy were divided into six groups of two. He tried different therapeutic regimens on the similar groups and found that only the two sailors who received citrus fruits were cured. The technique of controlled experimentation is hardly anything new in either science or medicine and the issues in drug testing really boil down to art versus science and testimonials of "experts" versus numerical evidence.

Certainly the public desperately hopes that the medical profession will provide a pill for every ill. The public realizes that pharmaceuticals are important and represent a potential cure for any disease. But the public is also coming to realize that they may be killed by drugs, and particularly, that they may receive new and untested drugs without even being informed of the potential dangers. Even worse, the physician himself may be unaware of the potential dangers of the drug. The medical profession responds that every physician should use new drugs and get acquired with them and that it is only in this way that the public will receive instant benefit from latest advances. Doctors certainly like to try the newest remedies. About one third of American thalidomide babies were born to wives of physicians who had received free samples of the drug.

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The average physician's utilization of drugs is at best disturbing. In a study of 408 cases of bone marrow depression due to chloramphenicol, of which one half resulted in death, the drug was prescribed for a valid reason in only six per cent of the cases, and was given for common colds in 12 per cent. The drugs industry spends about \$3,500 per physician on salesmen who personally "detail" the doctor on the latest breakthroughs. A total of \$900 million is spent on advertising, about three times the amount spent on medical education. And the advertising is successful. A recent survey of drugs dispensed by the mail order drug service of the American Association of Retired Persons revealed that Peritrate, an expensive, long-acting dilator of the coronary arteries, was the most commonly prescribed drug in old persons. This is indeed a triumph for the hard sell Madison Avenue campaign which modestly billed the drug as "life sustaining," for several careful scientific trials have shown the drug has no pharmacologic effects of any kind on coronary artery disease. Of the 12 top drugs prescribed for these retired persons, two were expensive substitutes for aspirin, and four were expensive substitutes for phenobarbital. The use by physicians of fancy, dangerous, and expensive substitutes for old standard remedies undoubtedly contributes to the staggering costs of medical care.

In a survey of 1,014 consecutive medical admissions at Yale University's teaching hospital, 10.3 per cent of patients had a drug reaction; in 1.4 per cent the reaction threatened the patient's life; and in 0.4 per cent the patient died as a result of the reaction. A similar survey at Johns Hopkins of 714 medical patients revealed 17.1 per cent had reactions and 1.55 per cent were fatal. Even if only one-tenth of one per cent of all hospital admissions died of drug reactions, the deaths would approach 29,000 per year. Deaths due to drugs would be a major public health problem comparable in importance to infectious disease, cancer of the breast, and nephritis as a cause of mortality. I would be the first to admit we have no idea what the magnitude of the problem is, but I would violently disagree that no problem exists.

Physicians are not legally required to report drug reactions to the FDA. In fact, it is to their advantage not to report reactions since it might involve them in a possible lawsuit on the part of the injured patient. Just what percentage of drug reactions are not actually reported is unknown, but most informed sources feel that it is less than one per cent. Lowinger recently reported in *Science* magazine that only 10 of 26 reports on drug safety which he had submitted to 19 pharmaceutical manufacturers had ever been forwarded to the FDA. He further