

patients or case reports per study with the cost. Where a minimum amount of laboratory work is required and the patients may not be seen by the physician more than three or four times during the course of the study, the cost of studying 50 patients may not be more than \$5,000. On the other hand, studying six patients for six weeks in the hospital or in a metabolic ward, at the rate of possibly \$100 a day, may cost \$25,000 or more. Costs vary with the degree of patient or hospital care needed, the extent of laboratory work, and the number of individual technical or professional tests to be done.

Today, when hospital, laboratory, and research costs are skyrocketing, and when the expense of conducting clinical research on a new drug may extend over a period of three to five or more years, the cost of clinical investigation has become substantial. Indomethacin studies extended over a period of three and one-half years, from November 1961 to NDA approval in June 1965—and indeed a large program still continues.

It is rare for a clinical research program involving a new drug to cost less than a half million dollars. Most are closer to one million dollars before an NDA has been achieved. Even after NDA approval, there are aspects of clinical research which may be pursued for years thereafter.

It should be pointed out that a sponsor would be foolish—in this developing age of clinical science—to undertake to “pay” an investigator for positive data which cannot be substantiated. This could not be done with responsible clinicians. In any case, the cost of conducting medical research is already so high that to add a factor of cost to this by trying to buy data which could not be confirmed would be not only bad ethics and bad research but also bad business. A well-established research enterprise such as ours, with its scientific and medical reputation at stake and investing very heavily in obtaining clinical data, has much more to lose than to gain from this inaccurate data.

It is the policy of the Company to seek out the best and most experienced clinical investigators it can find to evaluate its new drugs or to explore new uses of existing drugs. In 1967, we invested to \$2,000,000 in the clinical investigative phase of our research effort, supporting the work of several hundred investigators here and abroad. Although averages are not always meaningful or as accurate as one might wish in describing such a program, we estimate our “average” clinical research grant to have been approximately \$5,000 during 1967.

This compares with the average for an NIH clinical grant of perhaps \$15–25,000 during the same year . . . it is recognized, of course, that the NIH grants are more broadly based and for a longer term. But there are other comparisons that can be made with NIH grants as well. Like the NIH grantee, the Merck grantee is free to and encouraged to publish his data, whatever they may be. Like the NIH grantee, the Merck grantee is committed only to the accomplishment of a study, not to results. Like the NIH grantee, the Merck grantee is drawn from a cross-section of the nation's and the world's resources in the health sciences. The excellence of the performance and the quality of the data depend not so much on the sponsoring institution as on the state of the art and the state of the science in a given field. Thus, clinical research supported by Merck is and will be qualitatively similar to research supported by Federal funds. At the same time, both companies such as Merck and Federal agencies such as NIH have a responsibility to do what they can to help strengthen the resources for better and ever better research, including clinical research.

The key thing, from the Company's point of view, and the key message it would wish to communicate to a Committee of Congress that has interested itself in this question, is that the objective of the Company is quality performance in clinical research yielding reliable data. This represents an ever-present goal. We do not suggest that we are universally successful in achieving this goal; to attain such a level in any human endeavor is perhaps impossible. But our record has been good.

Indeed, there is no other course for a responsible company to take. We are dealing with products related intimately to man's aspiration for health and freedom from pain and suffering. All such products have a great capacity for good or for harm. In the final analysis, we are responsible for our drugs and have nothing to gain and everything to lose by performing inadequately in our own laboratories, or by permitting sloppy performance by outside investigators, or by knowingly—in our evaluation of preclinical and clinical data—ignoring and neglecting the facts as they bear on the safety and effectiveness of a new drug.