More specifically, our internal procedures require that every piece of advertising and promotion must have the approval of a physician and a lawyer, who are responsible for its medical accuracy and conformity with law. When it concerns a new product, it also undergoes final review by the new products committee.

The safeguards are necessary and proper. But I would not have you think that I conceive of advertising and promotion primarily in negative or restrictive terms. Properly carried out, it serves an altogether good and socially valuable purpose.

Through the process of discovery we have described for you, making a drug available is only the first long step toward the objective of having it used by those patients who need it. This objective can be attained only if physicians are aware of the availability of the drug, know what it can do, what its limitations are, and what undesirable effects may accompany it. Furthermore, we believe that this information should reach the physician as quickly as possible. The public interest would be poorly served if patients were denied the benefits of a good drug simply because its availability was not known.

Merck's experience with Benemid, a product for the treatment of gout, illustrates how marketing decisions can have social value. When we introduced Benemid in 1951, we felt that it was a major product because it forestalled attacks of gout instead of merely giving relief after an attack. Sales did not approach anticipated levels for years, apparently because there were simply not sufficient cases of gout. We continued to inform physicians about it, however, in the belief that gout was more prevalent than sales indicated. The past 8 years have justified this belief. The estimated number of cases of gout under treatment has risen from fewer than 350,000 in 1959 to approximately 1 million in 1966. Obviously, the incidence of gout has not increased threefold since 1959.

Mr. GORDON. Is this due to your advertising?

Mr. GADSDEN. As I am going to say, Mr. Gordon, in the next sentence, we would like to take partial credit for increasing the awareness of the symptoms of gout.

Recognition and subsequent treatment of gout have increased—due in part, we believe, to our communications program.

I have described the precautions we take with our advertising. Nevertheless, an occasional advertisement does run into trouble with the FDA. I think the reasons can be found primarily in the changing regulatory climate, and in the turnover of officials responsible for interpreting and applying the advertising regulations. As official attitudes have become increasingly critical of the motives and methods behind the advertising of prescription drugs, more and more companies have been embroiled in disputes with the FDA.

However, questions of interpretation to one side, Merck hopes and believes that the agency shares our belief that responsible and effective promotion is a necessity. It is particularly necessary in the case of a drug which offers the possibility of benefits to patients suffering from conditions for which there is as yet no fully effective or satisfactory method of treatment. Arthritic disorders represent just such a condition. Some patients obtain little or no relief from drugs which are available; side effects limit the benefits others may obtain. The availability of a new drug which can help those who cannot obtain relief from other measures becomes important.