As Dr. Donald F. Hill stated in his presidential address to the American Rheumatism Association in June 1967:

> Our patients come to us discouraged. Arthritis is a discouraging disease. Too many of our patients are further discouraged by what the doctor tells them. Too many of them hear him say: "There is not much we can do for you."
>
> Our failure to keep up with, and apply, the latest treatments and medical information in arthritis may not have . . . final and fatal results, but if it means the difference between a useful and productive life, or a life as a cripple, the point may be lost on the patient.[1]

It is true that a company promotes a drug in order to sell it. But such a statement is an oversimplification which ignores the full facts. A drug sells because it is promoted, and because physicians are familiar with it, and finally because they have found that it fills a real need in their practice.

That Indocin does fill such a need in medical practice has been amply demonstrated. The purpose of clinical investigation is to assure safe and effective medicines. Added evidence that we have provided such a medicine in Indocin is to be found in the high refill rate of prescriptions for this drug. Because it is a useful drug, it deserves appropriate promotion.

We have promoted Indocin in many ways, but have consistently sought to follow the principle of supplying accurate and useful information in a manner complying with our understanding of the regulations.

When Indocin was first made available in this country, we had accumulated experience based on nearly 5 years of investigation by more than 300 physicians in the United States and abroad, as well as extensive experience gained from overseas marketing. Our best knowledge was incorporated into our promotional materials.

The initial promotion pieces very clearly stated that in patients with rheumatoid arthritis, ankylosing spondylitis, arthritis of the hip, and gout—the four indications for which the safety and effectiveness of Indocin had been established—overall improvement considered to be excellent or good had been reported in 65 percent of those patients. This not only established the usefulness of the drug to the physician but, equally, it advised him that the drug had limitations and could not be considered effective in all patients.

Furthermore, prominently presented in these promotional pieces was a table showing the incidence of adverse reactions. It not only listed those adverse reactions the physician could expect to encounter, but what their probable incidence would be. And it also included the statement:

> In about 10 to 15 percent (of the patients), adverse reactions may be of a severity requiring dosage reduction or discontinuance of therapy.

After the introductory phase of our promotional efforts, and as physicians became more familiar with the drug, our themes were varied, but our presentations continued to include the limitations of the product. In many of the advertisements the negative aspects of the drug actually consume the bulk of the text.

As my scientific colleagues have stated, many, if not most, distinguished rheumatologists believe that the use of objective measurements alone in arthritic disorders fails to take adequately into account the

[1] "Progress for the Patient," Hill, Donald F., M.D., "Arthritis and Rheumatism," vol. 10, No. 5 (October 1967).