

In this statement, I have four points to make:

First, indomethacin is a useful drug for the treatment of at least four different forms of arthritic disease. It is effective and safe as described to the medical profession.

Second, Merck answers to its own standards of research as well as to the regulatory judgment of this country and other countries throughout the world. Our standards are based upon several decades of notable accomplishments in medical research, and we give ground to no one as to the integrity of our standards and performance.

Third, the validation of the merits of our work since our studies began in 1961 up to the present can be found in the collective judgment of several hundred investigators of recognized authority in this country and abroad.

Fourth, there does not exist in this world today a generally accepted test design for the study of drugs or of any other type of therapy in rheumatoid arthritis. If there were, we would be the first to use it.

Mr. Chairman, I shall explain what we do in the study of drugs in rheumatoid arthritis. In addition, I want to point out what neither we nor others can do to study drugs in this field and why the studies conducted on indomethacin fully warrant its right to be available for physicians who wish to prescribe it for their patients.

The study of indomethacin in man dates back to 1961. At that time the cooperating clinics project of the American Rheumatism Association was still in the primitive stages of its long effort to improve clinical design in this field. We faced the task of studying a new drug shown in animal testing to possess anti-inflammatory activity comparable to steroids. The patients could not wait, nor would we wait for the design of a wholly satisfactory double-blind study for rheumatoid arthritis.

We performed what was the best method of study in 1961, and what still remains the best method in 1968. We took the drug to a handful of expert physicians in rheumatology. They began with very low doses, gradually increasing them. Under careful observation they determined the patients' positive or negative reactions. When these men told us the drug worked—that it provided relief of pain and reduction in inflammation—we accepted their judgment, both because of their knowledge and experience and also because it provided significant confirmation of the laboratory and animal work that had preceded it. After that we put the drug in the hands of additional specialists having particular expertise in a variety of arthritic disorders—rheumatoid arthritis, spondylitis, gout, osteoarthritis, musculoskeletal disorders, and so forth. As experience with the drug accumulated, we obtained the cooperation of investigators in more than 60 major medical centers in the United States and abroad. If the committee wishes, I will provide a list of these institutions for the record.

Senator NELSON. If you would, please.

(The document referred to follows:)