his condition; and being now deemed pretty well, was appointed nurse to the rest of the sick.

Mr. GORDON. So I might point out to you that a well-controlled trial was conducted as far back as the 1700's.

Mr. GADSDEN. I think the thrust of the remarks of the witness, Mr. Chairman, deals strictly with whether, in order to have a well-controlled test, it must be a double blind.

Senator NELSON. Please go ahead.

Dr. LAWRASON. When we take a drug such as indomethacin to the clinic, we go to the expert in the relevant discipline or specialty. We bring him in as an independent but full-fledged member of the research team. He collaborates in the planning and execution of the studies. Such experts are experienced investigators whose judgment is respected. They are independent in their actions and decisions. Their research is supported with grants for studies that often yield negative as well as positive results. I stress this relationship because we rely heavily on these investigators for the acquisition of objective observations and data on the effectiveness and safety of our drugs.

The experience and authority of the physicians who studied indomethacin, and whose judgments provided the basis for the approval of the drug, is evidenced by the following facts. Two-thirds of the indomethacin investigators in this country were Board-certified in their specialty, which is an unqualified endorsement of their training and experience. Three-quarters of them had full-time appointments with a university or a teaching hospital. Over half of them were active members of the American Rheumatism Association. I can say that the major investigations were carried out by some of the most eminent members of the American Rheumatism Association.

I would like to emphasize that we also went to the best clinics and hospitals throughout the world. These institutions are under the direction of distinguished rheumatologists. They came to the same conclusion regarding the effectiveness and safety of indomethacin as did the chemical investigators in this country.

If the cumulative judgment of this body of men is taken into account, the committee and the Food and Drug Administration, and the physicians and patients using indomethacin can be assured that the value of the drug was confirmed in the clinical judgment of an outstanding group of physicians. The criticisms that have been voiced earlier in these hearings about the testing of this drug do not represent the majority of experienced medical opinion.

The clinical program was completed in the spring of 1964. We had collected a large amount of data from 150 investigators here and abroad. The massive amount of evidence supporting efficacy and safety was submitted to the FDA for evaluation. It contained well-controlled studies and met the requirements of the preclinical and clinical standards of the day. It showed indomethacin to be safe and effective for the uses claimed. The application was approved by the FDA in June of 1965, after approximately a year of review, for the four indicated conditions for which it is labeled and promoted in the United States today.

Senator NELSON. Those four are rheumatic arthritis ——

Dr. LAWRASON. Rheumatoid arthritis, gout, rheumatoid spondylitis, and osteoarthritis of the hip.