Senator NELSON. Is it indicated for any other purpose?

Dr. LAWRASON. In this country, it is not.

Senator NELSON. Do you get a different reaction in patients in another country?

Dr. LAWRASON. In some of the other countries some additional conditions for which we believe it is effective and safe for use are allowed. The Food and Drug Administration in this country has not allowed such other indications.

Senator NELSON. Which are the others?

Dr. LAWRASON. Osteoarthritis in general, rather than specifically of the hip, and musculoskeletal disorders, which involve numerous disorders such as bursitis.

Senator NELSON. Why does not the FDA allow you to make these claims in this country?

Dr. LAWRASON. I believe their reason is that they feel we have not presented them with sufficient evidence of its efficacy.

Senator NELSON. Have you presented these other countries with evidence of its efficacy?

Dr. LAWRASON. We have presented them with a great deal of evidence. There are a great many double-blind studies ongoing and completed, and we expect within a very short time to present to the FDA evidence that will be convincing to them for efficacy and safety in these two indications.

Senator NELSON. Well, now, in how many countries do you sell this drug?

Mr. GADSDEN. Perhaps I ought to answer that. I cannot be specific with reference to this drug, Mr. Chairman, but our drugs are sold in approximately 100 countries throughout the world.

Senator NELSON. Is indomethacin sold in these 100 countries?

Mr. GADSDEN. I know drugs of Merck origin are sold in 100 countries. I do not have at the moment information as to whether "Indocid," is the trademark which is used abroad, is sold in all of these countries. I would assume that it was sold in the great majority of them.

Senator NELSON. What proof did you present to these other countries that indomethacin is effective for the additional uses that you mentioned?

Dr. LAWRASON. In the original application, there was substantial evidence of its efficacy in these other indications. Since then, we have submitted a supplement to the NDA which provided additional evidence as to its efficacy and safety. This same evidence has been presented to other regulatory agencies in other countries. When reviewed by these other agencies, they have come to the conclusion that it is safe and effective in these indications and have allowed it use.

Senator NELSON. Do each of these 100 countries have an agency of scientists who evaluate the information you supply and make a judgment?

Mr. GADSDEN. May I respond to that, sir?

Senator NELSON. Yes.

Mr. GADSDEN. The answer, as I think you might know, is that not all do have such an agency. It is the more developed countries, particularly of Western Europe that do, and even there not all of them. But I would agree with you if your point is that there are countries which do not have such regulatory control.