

scientists and you come to the conclusion that it is useful for those purposes, would you not?

Mr. GADSDEN. Perhaps I should explain to you, sir, what is the procedure. In the internal workings of Merck & Co., a scientific and medical evaluation is made which ultimately results in an application for new drug approval. The thing I want firmly on the record, in case there is any question about it, is that we do not sell abroad—I think I am right—anything for which approval has not been requested of the Food and Drug Administration in the United States.

Senator NELSON. I do not understand.

Mr. GADSDEN. Well . . . if we are not willing to report it to the Food and Drug Administration, we are not going to say in an underdeveloped country that it will cure something for which we are not requesting approval in the United States.

Senator NELSON. I understand. But if you request approval in the United States for its use for a certain purpose and the FDA says that so far as they are concerned, your scientific submission of evidence does not support its use for that purpose, and they turn you down, you still will sell it for that purpose in an underdeveloped country that has no scientific community at all?

Mr. GADSDEN. Yes, sir; we will.

Senator NELSON. I am not saying that some company may not make a mistake; it may turn out to be right and the FDA wrong. The principle that bothers me is there are lots of companies in this business that may not be as conscientious as Merck, and you will end up with all the companies supplying drugs to other countries that do not have drug standards, so that a drug might be used for purposes that it should not be. We have had testimony here that drugs which could not be sold in this country because they did not meet U.S.P. standards were shipped overseas—not your company. I am just raising the question, because it seems to me that if that testimony was correct on subpotent drugs which could not go on the market here being sold in South America, I think it ought to be explored from the standpoint of some legislation. I do not think anybody ought to have a license to put drugs on any market that do not meet a reasonable standard in this country.

Mr. GADSDEN. I agree with you, but I think you yourself said earlier that there are differences in medical opinion, and this can result in the Food and Drug Administration's concluding in all sincerity that they do not think the evidence complies with the law and regulations under which they operate, and yet in the opinion of the American scientists it is believed that there is substantial evidence.

Senator NELSON. That is bound to be the case; there is no question about that.

While I am on that point, it is agreed, as I understand it, that indomethacin is not indicated for use in children?

Dr. LAWRASON. Indomethacin?

Senator NELSON. That is right. It is not indicated for use in children; is that correct?

Dr. LAWRASON. It is contraindicated in this country at the request of the Food and Drug Administration.

Senator NELSON. Is it indicated in other countries for use in children?