

Senator NELSON. So you feel that your company, or any company, ought to be able to decide on its own what the standard will be in a country which has no scientific community or regulatory agency at all?

Mr. GADSDEN. No, sir, I do not think I have said that.

Senator NELSON. That is exactly what you said, that you decide what the standard is.

Mr. GADSDEN. I beg your pardon, sir?

Senator NELSON. Please repeat what you have said.

Mr. GADSDEN. I said that in this matter, Merck & Co.—and I refer to my earlier statement that I speak only for Merck & Co.—we have a code of ethics and principles. We assume responsibility for the positioning of the product. This reference to this was made in Dr. Lawrason's statement, I believe. We hold our medical staff responsible. They must approve what is said, whether it be in the United States or any country of the world. This, for Merck, is the restraint under which we operate.

Senator NELSON. I did not get the distinction between what you said and what I said. I said you set the standard.

Mr. GADSDEN. Sir, may I paraphrase what I understood you to say? I think you said, if I understand you correctly, that it is appropriate for Merck or any other company, in countries where there are no regulating agencies, to say what it wants in advertising.

Senator NELSON. To set your own standard, I think I said.

Mr. GADSDEN. I am sorry, perhaps I misunderstood you.

Senator NELSON. That is what I intended to say. In other words, you are saying that in another country where there is no scientific community to evaluate the evidence you have, a company sets its own standards without any outside control. Is that what you have said?

Dr. LAWRASON. Mr. Chairman, may I just say that we do not set separate standards for different countries. We have a single standard at Merck.

Senator NELSON. You mean you run precisely the same ad in the Philippines that you run in the British Medical Journal?

Dr. LAWRASON. No, I am referring to how the drug can be used and what indications are to be cited—in other words, the claims made for the drug and which diseases it should be used for.

Senator NELSON. I do not quite follow that. The FDA will not permit you to use it in this country for—what were the indications?

Dr. LAWRASON. Osteoarthritis.

Senator NELSON. And that involves tendonitis?

Dr. LAWRASON. No, sir; that was the musculoskeletal.

Senator NELSON. And that involves tendonitis and bursitis. The FDA says you cannot use it because you have not submitted, as far as they are concerned, satisfactory evidence or proof of its efficacy, for those conditions.

Dr. LAWRASON. That is correct.

Senator NELSON. Now you go to England and you advertise it for that purpose, and the British will say that it is all right for that purpose. Then, you may go to another country and they will say it is all right for all the purposes you use it for in America plus one other, but not two. Then you go to another country, that has no scientific community, and you claim that it is good for some other purposes and you advertise it and sell it for those purposes in that country if your