

persons performing clinical investigations can be matters for honest differences of opinion.

The substantial evidence standard itself concedes that room must be left open for well-founded differences of opinion. That standard would become rigid, and precisely what Congress expressly intended to avoid, if one point of view about the proper methods of testing drugs were allowed to dominate and exclude other points of view. As long as a sound professional difference of opinion about the merits of different methods of drug investigation exists with regard to particular drugs, it is clear from the legislative history of the 1962 amendments that a single view, especially one which seeks exact answers in inexact areas, cannot properly be considered the "only scientifically sound method for drug testing."

Senator NELSON. I have a letter that I received from the Department of Health, Education, and Welfare, signed by Theodore Cron. Mr. Cutler has a copy of this letter as does the press. I will ask to have it put into the record at the appropriate place after yesterday's testimony.

Mr. GADSDEN. I might ask, are we going to revert for a moment to—you are putting Mr. Cron's letter into the record? I am asking the privilege now or later of talking on the substance of what is going in the record.

Senator NELSON. All right. The appropriate place for this, I would assume, is after yesterday's testimony.¹ If you would like to comment on it now, I will ask that your comments be placed in the record after this letter.

Mr. GADSDEN. Yes, sir.

Senator NELSON. Or, if you wish to submit something later that you will prepare, you may do so.

Mr. GADSDEN. I would like to comment here, and then we can decide into what degree of detail you want to go, sir.

First, I think it is important to record that at the time of the release of indomethacin by the Food and Drug Administration, I, as the chief executive officer of the company, issued an order that under no circumstances were we to seek any lay publicity in connection with it—its benefits, or anything else. I assume, lest we have any confusion here, that you are alluding to the same Mr. Cron letter which I have in front of me?

Senator NELSON. It has no date.

Mr. GADSDEN. The first sentence begins "You will recall that Dr. McCleery."

Senator NELSON. Yes, that was delivered here this morning at about 10:45. I am referring to that letter.

Mr. GADSDEN. I would like to make a statement on that, sir.

A free-lance writer and TV fellow, Mr. Goldman, called our director of public relations, Mr. Fletcher. Mr. Goldman said his wife had suffered from tennis elbow and had been unable to play and that her doctor prescribed "Indocin" and it worked miraculously. He had checked around and found a lot of doctors who were using it effectively, and said he was going to write a story about it. He was upset with the company, namely Merck & Co., for not telling people about the drug, and he asked the company for background materials, which we sent him.

He was told that tennis elbow is not an approved claim, and he was also told why the company had elected not to publicize the drug.

¹ See p. 3294, *supra*.