The letter is dated January 31, 1979, and reads as follows:

DEAR SENATOR NELSON: We were dismayed by the reckless and irresponsible suggestion made by Dr. Wolfe at page 2 of his prepared statement that Lilly had not submitted to the FDA "critical information" with respect to certain dog studies conducted in 1976.

The facts are to the contrary. After the experiments were completed, in accordance with accepted research procedure, the scientists involved prepared an abstract of the work which contained all the critical information. This was published in 1977 in Federation Proceedings, Vol. 36, page 586. The authors presented their findings at the Federation meetings in March 1977. The abstract was submitted By Lilly to the FDA in the same month.

Following this, the scientists undertook the preparation of a manuscript for journal publication, expanding on the abstract. This manuscript was submitted in March 1978 to the Journal of Toxicology and Applied Pharmacology for consideration, was accepted for publication in May 1978, and will appear in the January 1979 issue of the Journal. While this time period may seem lengthy to a layman, it is consistent with the publication practices of scientific journals.

The abstract and the forum presentation included all the essential information on the experiments. Lilly takes strong exception to Dr. Wolfe's characterization and unwarranted insinuations.

Lilly, in more than a century of service to the medical profession and to the ill, has developed and maintained a merited reputation for integrity. The Company has always shared scientific information concerning its pharmaceutical products with the appropriate agencies of government. It does not withhold information bearing on the safety and efficacy of its products.

We respectfully request that this letter be read into the record during Dr. Wolfe's appearance today. We resent this unfair attack on Lilly's scientific integrity and public responsibility.

Dr. WOLFE. I would like to respond to that.

The statement is misleading, to be generous with it.

First of all, I have copies of the abstract that was sent in, the abstract they referred to, and that I referred to in the testimony.

The abstract was sent to the FDA, as I said in the testimony, and it did not contain critical information as I also said in the testimony.

The critical information I am referring to which is contained in the full report that was provided by a source in the company, is that the drug can cause second degree heart block. There is no mention in the abstract that the drug can cause second degree heart block.

Even though, as the company states in its letter that you just read, they submitted a copy of the manuscript to the Journal of Toxicology and Applied Pharmacology, they in fact did not submit a copy of the manuscript at least as of a couple of weeks ago to the FDA. Whereas I can well understand it may take some time to get a paper published, I think it is indefensible they did not submit to the FDA as they promised to do 2 years ago, the full study, including the fact it caused second degree heart block, therefore, I think that their statement is extremely misleading. The information I referred to was omitted from the abstract, and FDA, as I mentioned, is considering reprimanding the company for this, even though technically they cannot bring criminal proceedings against the company.

I would like to add one other thing which I left out.

Senator NELSON. Wait a minute.

I will ask the FDA to comment on that issue, as well, of course, as the Lilly Co., when they testify next Monday.

Mr. TWARDY. I would like to submit for the record a copy of the letter which was sent by Eli Lilly & Co. to the FDA and the abstract which accompanied it.

[Original copy of letter and abstract follow:]