

ELI LILLY AND COMPANY

INDIANAPOLIS, INDIANA 46206

EDGAR G. DAVIS
VICE PRESIDENT
CORPORATE AFFAIRS

January 31, 1979

The Honorable Gaylord Nelson
Chairman
Select Committee on Small Business
United States Senate
Washington, D.C. 20510

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.