Contaminated Health Food Poisoned Consumers

Contaminated L-tryptophan, a nutritional supplement sold by grocery stores, health food stores, drug stores and many other retail establishments, sickened over 1,500 Americans and killed 27 in the United States. This outbreak of an autoimmune blood disorder was linked to tainted batches of the health food produced by a major lapanese petro-chemical manufacturer called Showa Denko. As a result, the Food and Drug Administration has ordered all L-tryptophan products off the market as of the end of 1989.



Some of the brand names that contain L-Tryptophan.

L-tryptophan, an amino acid, occurs naturally in foods such as milk and white turkey meat. Manufactured L-tryptophan was sold through retail outlets as a non-prescription remedy for conditions including insomnia, pain relief, obesity, and premenstrual syndrome. As an essential amino acid, normally Continued on Page Nine

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supplied by protein in the diet, L-tryptophan was not considered a drug. It had great appeal for health-conscious consumers who wished to avoid taking drugs for their ailments and was marketed as a miracle health food.

Millions of people had taken L-tryptophan with positive results, but by the mid to late eighties, adverse symptoms began to appear. At the time of the contamination, worldwide sales were estimated to exceed \$100 million, with one-third of the market in the United States.

The debilitating illness, caused by contaminated L-tryptophan, had a wide range of ailments including many that are catastrophic. Patients reported extreme fatigue, great pain in muscles and joints, high fever, shortness of breath, hair loss, severe skin lesions and paralysis. Many suffered symptoms so severe that they were hospitalized or could not work.

Doctors discovered unusual concentrations of white blood cells in the patients' muscle tissue. Over 1,500 patients who consumed L-tryptophan were diagnosed as having this potentially fatal autoimmune disorder Eosinophilia-Myalgia Syndrome (EMS). EMS causes respiratory and cardiac failure, muscle atrophy, neurological damage and skin that turns so leathery that blood vessels no longer are capable of carrying blood.

No cure has been found for EMS. The treatment consists mainly of the steroid prednisone which reduces swelling and some of the pain. The condition of a number of the victims is deteriorating and 27 of them have died.

Doctors and researchers initially traced the problem of contaminated L-tryptophan to that produced by Showa Denko K.K., Japan's third-largest petrochemical manufacturer. The company had created a process of genetic engineering which



manufactured the L-tryptophan at an accelerated rate. The substance was no longer derived naturally from organic products, but instead synthesized through biochemical reactions.

In addition, Federal health investigators isolated a chemical compound which they believed tainted batches of the dietary supplement either through the genetic process by which it was manufactured or through poor filtration. Changes in the manufacturing process included changing the filtration process to give the product a whiter, cleaner appearance. Either the genetic engineered bacteria or the lack of filtration resulted in the contamination.

In the 1980's Showa Denko set out upon an aggressive plan to corner the world market of L-tryptophan. By 1989, Showa Denko held 60% of the worldwide market of this nutritional supplement. In 1989, Showa Denko reported sales of all its products at \$3.5 billion and profits of \$223 million.

Searcy Denney Scarola Barnhart & Shipley formed its own litigation group, headed by partner, David Kelley, specifically to handle L-tryptophan cases. David Kelley represented 26 of the more seri-

ously injured victims of this crippling disorder. Cases were filed in Federal and State Courts. He handled cases as far away as California and Tennessee as well as various jurisdictions throughout the State of Florida. Palm Beach Medical Consultants, Inc. was retained to provide information about EMS.

Showa Denko's defense tactics used early on in the litigation included a motion to dismiss the cases on grounds that the United States court system had no jurisdiction over a Japanese company not doing business in America. They argued since they were in lapan they were immune from prosecution in the United States. Our courts found otherwise and denied their motion to dismiss. The company also tried to claim a statistical relationship between the amount of product sold and the number of those people stricken with the disease. Their argument was that hundreds of thousands consumed the product while only a few thousand contracted EMS. That argument was also unsuccessful in the courts.

After litigation extending over a period of five years, nearly all of the firm's cases have been successfully concluded. The actual amounts of the settlements are confidential.

