

A Deadly Epidemic and the Attempt to Hide its Link to Genetic Engineering

By Jeffrey M. Smith, author of the international bestseller, *Seeds of Deception*
<http://www.responsibletechnology.org/gmo-dangers/health-risks/articles-about-risks-by-jeffrey-smith/A-Deadly-Epidemic-and-the-Attempt-to-Hide-its-Link-to-Genetic-Engineering-August-2005>
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In my book *Seeds of Deception*, I bring out new information about the genetically engineered food supplement L-tryptophan, which was responsible for a deadly epidemic in the United States in the 1980s. Much of the research for the chapter came from the work of investigator William Crist. The book cited Crist's report, which was expected to have been posted on a website well in advance of my book's publication. Unfortunately, Crist was unable to update his report at that time. It is now available at <http://www.responsibletechnology.org/gmo-dangers/health-risks/L-tryptophan/introduction>, and provides important new evidence, including ways in which the U.S. government apparently hid information in order to protect the biotech industry.

In October, 1989, 44-year old Kathy Lorio arrived in the medical office of Dr. Phil Hertzman in Los Alamos, New Mexico. Lorio, who had been healthy and active, was suddenly struck with severe pain and a host of debilitating symptoms. Blood tests revealed that her eosinophil count had skyrocketed. The normal concentration of this white blood cell is about 10 per CC. Allergies or asthma can make it rise to 500. Lorio's was over 10,000.

In a coincidence that was destined to save lives, Hertzman referred her to Santa Fe rheumatologist James Mayer, who happened to have recently seen another patient, Bonnie Bishop, with similar symptoms. Bishop was in severe pain, her arms and legs were filled with fluid, she had trouble breathing, and her muscles were so weak she couldn't even sit up. "She slumped like a rag doll." [1] And her eosinophil count was extremely high.

Patient histories revealed that both Bishop and Lorio were taking the food supplement L-tryptophan. Although it was the only supplement common to both patients, the doctors were hesitant to blame L-tryptophan for the disease. It is an essential amino acid, naturally found in turkey and milk, and in supplement form had been consumed safely for years as a treatment for stress, insomnia and depression.

Hertzman checked the literature on eosinophils. One author's name kept coming up—Dr. Gerald Gleich of the Mayo Clinic. Hertzman gave him a call. Gleich told him that two cases weren't enough to draw a conclusion about L-tryptophan. Better wait. They didn't wait long. That same day a third case, also linked to L-tryptophan, was reported in New Mexico. Gleich called the Center for Disease Control (CDC) in Atlanta and told them about the cluster of patients in New Mexico and the possible link to L-tryptophan.

Within two weeks, three other patients checked into the Mayo Clinic with serious symptoms—one needed a respirator to breathe. All had taken L-tryptophan and they were from different parts of the country. Gleich called the CDC again. He told them it's not limited to New Mexico—it's out and it's deadly. An L-tryptophan alert went nationwide.

Articles began circulating about the mysterious disease. The *Albuquerque Journal* ran a series

about it that eventually won the Pulitzer Prize. The *New York Times* covered it. As more articles appeared, the phone calls started coming in—first dozens, then hundreds, then thousands: individuals with incurable symptoms, doctors with incurable patients, and stories of horrific symptoms. Some had coughs, rashes, physical weakness, pneumonia, breathing difficulties, hardening of the skin, mouth ulcers, nausea, shortness of breath, muscle spasms, visual problems, hair loss, difficulty with concentration or memory, and paralysis. Not everyone had all the symptoms, but everyone seemed to be in pain—greater pain than doctors had seen before. The disease was named eosinophilia myalgia syndrome, or EMS—eosinophilia because of the high cell count, myalgia because of the muscle pain. In all, about 5,000—10,000 people got sick; some are permanently disabled. About 100 people died.

Disease Traced to Genetic Modification

The *Journal of the American Medical Association (JAMA)* reported on July 11, 1990 that people only got EMS from pills made by Showa Denko, one of the six manufacturers whose L-tryptophan was imported into the U.S. from Japan. Showa Denko's pills had several unique contaminants that were likely to be responsible for the epidemic. Moreover, the manufacturer was genetically engineering bacteria to produce the L-tryptophan more economically. Genes had been inserted into bacteria's DNA in order to produce high concentrations of several enzymes used in its production.

Epidemiologist Michael Osterholm, who helped track the source of the epidemic, said in a *Newsday* article on August 14, "This obviously leads to that whole debate about genetic engineering." Two weeks later, FDA spokesperson Sam Page was quoted in *Science* magazine "blasting" Osterholm for raising the issue of genetic engineering, "especially given the impact on the industry." [2]

Diverting Blame

There are numerous ways in which genetically engineered bacteria might lead to unpredicted contaminants. For example:

1. The process of inserting genes can create significant changes in the expression of natural genes throughout the DNA, causing changes in proteins (including enzymes) and their interactions.
2. Genetic engineering can cause mutations and deletions in the DNA, altering its natural functioning and changing what is produced.
3. The bacteria were engineered to produce ingredients in larger concentrations than were normally part of the process to create L-tryptophan. These higher concentrations might interact in unpredictable ways to create new compounds.
4. The L-tryptophan is toxic to the bacteria that create it. As a means of self-preservation, the bacteria might have modified the L-tryptophan, itself, or its environment.

The press reported that Showa Denko had introduced a GM strain of bacteria at Christmas time in 1988. Soon after, they also reduced the amount of carbon in the filter of the manufacturing process from 20 kilos to 10. This change in the filter was just what the young and vulnerable

biotech industry needed to protect its reputation. The alternative story diverted the blame away from genetic engineering. This explanation circulated around the world. "The change in the filter was responsible for the epidemic." Or more simply put, "It was bad manufacturing—not genetic engineering."

In 1996, writer William Crist began what would become an eight-year investigation into the cause of the EMS epidemic. He contacted the FDA's biotechnology coordinator, James Maryanski, who told him "We can not rule [genetic engineering] out...However, we are aware of close to two dozen cases of L-tryptophan-linked EMS that occurred before Showa Denko began using their engineered strain. So, there would have to be a cause other than just the mere engineering of the strains. Now, I can't say that definitively because we don't have a lot of information on these earlier cases." Maryanski asserted that "either L-tryptophan itself, or L-tryptophan in combination with something that was the result of the purification process, was probably the more likely cause." [3]

Crist decided to track down the EMS cases that Maryanski described—those caused by L-tryptophan produced before the genetically altered bacterium was introduced in December 1988. He quickly discovered CDC studies that identified about 100 pre-epidemic cases, not two dozen. And since reported cases of EMS were far less than actual cases, the true number, using the CDC's estimated ratio for unreported incidents, was in the hundreds—all apparently from individuals who had ingested Showa Denko's pills manufactured before December 1988. This fact clearly dismantled the change-in-the-filter theory as the cause of the disease. But it didn't explain how the contaminants got into Showa Denko's L-tryptophan.

Crist spoke with several attorneys who represented EMS victims. They had gathered significant evidence for their lawsuits, which were eventually settled with Showa Denko for about \$2 billion. In one company memo obtained by an attorney, Crist discovered a significant fact. The bacterium introduced in December 1988 was called Strain 5. The preceding three strains, introduced starting on October 22, 1984, were all genetically modified. This was a revelation. It countered the FDA's argument that illnesses "that occurred before Showa Denko began using their engineered strain" meant that "there would have to be a cause other than [genetic engineering]." But they were all engineered!

As he looked at the memo, Crist wondered why the FDA didn't know about the earlier GM strains. They had access to a lot more information he did. Then his eyes rose to the top of the document to see a fax imprint: "FDA September 17, 1990." It had been faxed by the FDA! They knew back in 1990 that the earlier strains were modified, but in 1996, the FDA's biotech coordinator James Maryanski was still claiming ignorance.

An even greater omission occurred when Douglas Archer, deputy director of the FDA's Center for Food Safety and Applied Nutrition, testified before Congress in July 1991 about the epidemic. Not only did he not discuss the earlier bacterial strains, he never even mentioned genetic engineering. Instead, he blamed the disease on "the dangers inherent in the various health fraud schemes that are being perpetrated upon segments of the American public." The FDA used this logic to take all L-tryptophan, GM or not, off the market.

According to a 2000 article in the *Rutgers Law Journal*, "Political pressures have played a role in the FDA's decision to ban L-tryptophan as well as its desire to increase its regulatory power over dietary supplements." [4] In its FDA Dietary Supplement Task Force report on June 15, 1993, it states, "The Task Force considered various issues in its deliberations, including... what steps are necessary to ensure that the existence of dietary supplements on the market does not act as a disincentive to drug development." According to the Rutgers article, "This is a particularly disturbing issue," as it shows that developing FDA guidelines "has far more to do with eliminating competition in the pharmaceutical industry than preserving the public health." In the case of L-tryptophan, the FDA simultaneously protected prescription drugs for stress, insomnia and depression, as well as the entire biotech industry. In retrospect, when FDA's Sam Page told *Science* that it was better not to discuss genetic engineering, "especially given the impact on the industry," it turns out he was describing the motivation and strategy that would guide the agency for years.

Sobering Lessons Unheeded

Many studies have verified that the process of genetic engineering can produce unpredicted toxins or allergens. Nevertheless, the FDA does not require any additional safety testing for GM products, whether they are food crops or supplements. Thus, if that same deadly L-tryptophan were first introduced today, it would get on the market.

The EMS epidemic took years to identify and was almost missed. The only reason it was discovered was because the disease had three concurrent characteristics: it was rare, acute, and came on quickly. What would happen if all three characteristics had not been in place? What if it took 20 years for onset or only impacted the next generation? What if it produced only mild symptoms like frequent colds? What if it created serious diseases that were common, like cancer, heart-disease, obesity or diabetes? The epidemic might remain undiscovered for decades.

What then of the thousands of products currently being fed to US citizens that contain ingredients from genetic modification? Might they be creating problems that don't have all three characteristics? Are they contributing to the doubling of food-related illnesses in the United States between 1994 and 2001, corresponding to the time when many of these products were introduced? We don't know, because no one is looking. And even if we were, derivatives from the four major GM crops, soy, corn, cottonseed, and canola, are found in the majority of processed foods. Unlike L-tryptophan, if common food ingredients were creating health problems, identifying the source might be impossible.

In spite of these facts, and ignoring the thousands of victims of GM L-tryptophan, U.S. regulators continue to make the baseless statement that "millions of people have been eating genetically engineered products for years and no one has gotten hurt."

Dissatisfied with the way that the FDA is protecting their health, more and more people have chosen to protect themselves by avoiding GM foods altogether. Here too, the FDA stands in the way. More than 90 percent of Americans want GM foods labeled. Most industrialized nations require labeling. But the FDA has an official mandate to promote biotechnology. They know that more than half of those surveyed say they would avoid GM foods if they were labeled. To

protect industry profits, the FDA ignores the desires of nine out of ten Americans.

There is no indication that another EMS epidemic will emerge from another GM food or supplement. But with obesity, diabetes, migraines, allergies, and many other ailments skyrocketing in the U.S., there is no guarantee that another GM-related epidemic is not already upon us.

To learn more about the potential dangers of GM foods, to find out how to shop GM-free, and to read the excellent report by William Crist, visit

<http://www.responsibletechnology.org/gmo-dangers/health-risks/L-tryptophan/introduction>
(corrected link)

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References

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- [2] P. Raphals, "Does medical mystery threaten biotech?" *Science*, vol. 249, no. 619, 1990
- [3] William E. Crist, The Toxic L-Tryptophan Epidemic, see (corrected link)
<http://www.responsibletechnology.org/gmo-dangers/health-risks/L-tryptophan/introduction>.
- [4] Joshua H. Beisler, L-tryptophan Section from "Dietary Supplements and Their Discontents: FDA Regulation and the Dietary Supplement Health and Education Act of 1994," *Rutgers Law Journal*, Winter 2000, see <http://www.responsibletechnology.org/gmo-dangers/health-risks/L-tryptophan/rutgers-article>.