

Testimony  
Before The  
Senate Committee on Aging  
Regarding The  
Marketing of Dietary and Nutritional Supplements  
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Testimony of J. Joseph Curran, Jr., Attorney General for the State of Maryland

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Chairman Breaux and members of the Committee, on behalf of consumers who purchase dietary supplements, I thank you for inviting me to testify today regarding the issues consumers face when they purchase and use dietary supplements. I am testifying today in my capacity as Attorney General for the State of Maryland. I was asked to share with you the circumstances regarding a particular case brought by my Office that involved the sale of dietary supplements throughout the country because many of the product benefits that were claimed by the seller, including that their products were powerful immune boosters, were false and, as a result, consumers were severely harmed.

This case, *Consumer Protection Division v. T-Up, Inc.*, involved the sale of two products, a concentrated aloe product called "T-Up" and a mineral called cesium chloride, which were offered and sold to consumers to both generally improve immune function and to treat cancer, AIDS and other diseases. Although most of the sales of these products were for oral consumption, the company also sold products for intravenous administration at a cost of \$12,000 to \$20,000. The company's claims that their products would help consumers were grossly misleading, if not false, because they were unsubstantiated. Similarly, the company's claims concerning the safety and quality of their products were baseless. Many of the consumers who purchased these products were particularly vulnerable because they were facing life threatening diseases such as cancer or AIDS. They paid hundreds to thousands of dollars for these products hoping to be cured, and instead received little or no benefit, and in some cases were actually harmed. Moreover, some consumers chose these products over other more proven treatments or therapies that might have otherwise helped them.

- This case needs to be viewed against the background of federal regulation of dietary supplements. In 1994, Congress passed the Dietary Supplement Health and Education Act of 1994 (DSHEA).<sup>1</sup> Among the stated purposes the Act was to promote the right of access of consumers to safe dietary supplements.<sup>2</sup> Since the passage of DSHEA, the dietary supplement industry has experienced enormous growth. In 1994, the industry's total sales were estimated to be at least \$4 billion annually.<sup>3</sup> More recent estimates place the industry's annual sales between

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<sup>1</sup> Pub. L. No. 103-4127, 108 Stat. 4325 (codified at 21 U.S.C. §§ 321, *et seq.*).

<sup>2</sup> *Id.* at sec. 2.

<sup>3</sup> *Id.* at sec. 2, subpart 12(C).

\$10 and \$12 billion.<sup>4</sup> One need only to walk into any health food store, supermarket or shopping mall, to find a myriad of vitamins, minerals or other dietary supplements being sold. These products are advertised for a wide variety of purposes including weight loss, nutrition, anxiety relief, memory enhancement, or to treat serious illnesses or diseases such as cancer or AIDS. They are widely advertised in magazines, over the Internet, and on radio or television.

As the market for dietary supplements has grown, the risk of consumer harm as a result of misleading claims and potentially hazardous unregulated products has also grown. There appear to be few standards governing the claims that can be made concerning the content of dietary supplements and in some cases the manufacturing practices of the industry have come into question. In some instances supplements have been marketed as being safe when in fact they contained harmful substances. For example, in June 1997 the FDA issued a warning to consumers against a dietary supplement product containing digitalis, a powerful heart stimulant with side effects that may include nausea, vomiting, dizziness, headache, confusion, hypotension and an abnormal heart rate.<sup>5</sup> More recently, the FDA warned consumers against using certain Chinese herbal products containing aristolochic acid because they may present a serious risk of kidney damage or cancer.<sup>6</sup>

My Office's experience is that with DSHEA's liberalization of the controls over the dietary supplement industry, there has been a corresponding increase in false or misleading claims that are being made in the advertisement of dietary supplements, including misleading claims of safety, unsubstantiated claims of "miracle cures," and false claims about the ingredients or integrity of products.

In 1997, we learned that a company located in Baltimore, Maryland was marketing its products as treatments and even cures for diseases that included cancer, AIDS, herpes, arthritis, chronic fatigue syndrome, lupus, multiple sclerosis, pneumonia, Chron's disease, emphysema, and a wide variety of other diseases and illnesses.<sup>7</sup> The name of the company was T-Up, Inc. It

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<sup>4</sup> See *Herbs and Supplements: A Year in Review*, The Hartman Group, Bellevue Washington (1999) (reporting the sale of dietary supplements in the United States to be \$10.4 billion for the period July 1998 to June 1999); Michael Higgins, *Hard to Swallow*, ABA J., June 1999, at 60 (estimating the total 1997 sales of dietary supplements at \$12 million).

<sup>5</sup> See <http://www.fda.gov/bbs/topics/NEWS/NEW00570.html>.

<sup>6</sup> See FDA Press Release, P01-14 (June 20, 2001), found at <http://www.fda.gov/bbs/topics/NEWS/2001/NEW00765.html>.

<sup>7</sup> Attached to this testimony is the "T-Up Desk Reference Manual," in which the company listed the many illnesses and diseases it claimed its products could effectively treat.

was owned and operated by "Dr." Allen Hoffman.<sup>8</sup>

According to T-Up, Inc., its T-Up aloe vera product could be used to boost the human immune system and fight cancer and all diseases associated with either a weakened or malfunctioning immune system. The company further claimed that its cesium chloride product could attack and kill cancerous cells by altering the body's pH on a cellular level.

The T-Up aloe product was typically sold in two ounce bottles for oral consumption. Each bottle of T-Up aloe was sold for \$75.00 and was supposed to last one week. Each bottle of cesium was also sold for \$75.00 and would also last about one week if the optimal dosage was used. Accordingly, the typical consumer using T-Up, Inc.'s products spent \$150 a week to treat their illness or disease. The length of the treatment could last years depending on the nature, course and severity of the disease or illness that was being treated. Consumers were also encouraged by T-Up, Inc.'s advertisements to continue using their products after their diseases were cured in order to prevent them from reoccurring.

T-Up, Inc. also sold sterile aloe vera products that were designed for intravenous administration. The intravenous treatments usually lasted two to three weeks and sold for between \$12,000 and \$20,000.<sup>9</sup>

Although T-Up, Inc. never provided my Office with its complete sales data, the evidence that we were provided established that between April 1, 1997 and October 16, 1998, T-Up, Inc. sold products costing \$2,364,783 to 3,706 consumers. These sales figures did not include the larger amounts paid by consumers for T-Up, Inc.'s intravenous treatments. Many of the consumers who used T-Up, Inc.'s products were middle or lower income families who could ill afford to spend the amounts they spent on T-Up, Inc.'s products, but nevertheless chose to do so based on the company's promise of a cure.

T-Up, Inc. promised consumers that its products could boost the human immune system. One of its primary advertisements, a brochure entitled "The Most Powerful and Natural Way to Boost Your Immune System," promised consumers that T-Up aloe vera can boost and strengthen the human immune system. A copy of the brochure is attached to this written testimony. However, when asked to produce any scientific evidence to support this claim, the company was unable to do so.

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<sup>8</sup> Although Allen Hoffman claimed in his advertisements that he was a former Johns Hopkins medical researcher the evidence showed that Hoffman had never performed medical research and that his doctorate was fraudulent.

<sup>9</sup> The intravenous administration of aloe vera into humans has not been approved by the United States Food and Drug Administration. However, despite the lack of FDA approval for its IV product, T-Up, Inc. referred consumers to physicians willing to illegally perform the intravenous procedure, or Allen Hoffman performed the illegal procedure himself.

Even more outrageous than the company's claim that its aloe vera product could boost the human immune system were its claims that its products could effectively treat or cure cancer, AIDS and other diseases. Typical and illustrative of the many excessive claims made by the company to sell its products is its claim on the first page of the "Boost Your Immune System" brochure that "T-Up appears to be capable of increasing T-lymphocytes and attacking cancer, AIDS, herpes, and other viruses like nothing else before it." The brochure also purportedly describes the results T-Up users experienced, including consumers who allegedly were successfully treated for breast and liver cancer, as well as AIDS. Equally striking were claims made in T-Up, Inc.'s other advertisements.

In a cassette tape distributed to 125,000 consumers through the mail, the company claimed:

The cesium chloride begins to destroy malignant tissue in three days. And my experience recently is that in ten days 50% of a malignancy will disappear. The rest of the malignancy based upon scientific literature should disappear within two to three months.

Very exciting.

The same statement was contained in a Desk Reference Manual supplied by T-Up, Inc. to its employees, portions of which are also attached hereto. Other claims made in the Desk Reference Manual pertaining to the company's successes treating cancer included the following:

- All soft tissue cancers - in arms, legs, chest, etc. We are approaching 100% success rate.
- Breast Cancer - We have had 100% success rate.
- Lung, Esophagus, Colon and Stomach Cancer - almost 100% success rate.

In its advertisements the company also claimed that its T-Up aloe products were "literally 100% effective" at treating HIV. In its Desk Reference Manual, T-Up, Inc. promised that persons with AIDS who used their products regularly "could control the infection and that "98% will live normal lives."

The efficacy claims made by T-Up, Inc. in its advertisements and Desk Reference Manual were further embellished when T-Up, Inc.'s employees met face-to-face with consumers. Wendy Daly, a resident of Alabama, reported that she was told by Allen Hoffman that her father's cancer would be "gone in three to six months" and that "in three to six months daddy would be completely cured of his cancer." Similarly, Hoffman told Delores Triplet, a Maryland resident, that through his research he had discovered how to cure her husband's colon cancer, and Ray Osborne, an Alabama resident, that T-Up, Inc.'s products had cured many other persons' cancers and that it would "take care" of his wife's cancer as well. Dr. Robert Knudsen, a California resident, testified that when he approached T-Up, Inc. concerning its products, he was told that they "will kill . . . [malignant] cells every time."

Jeanne Hammond, T-Up, Inc.'s office manager, admitted that T-Up employees had told consumers that their products were 100% successful in treating breast cancer. Similarly, when Deanna Crabbe and her husband Douglas were considering using T-Up, Inc.'s products to treat Douglas' cancer, T-Up, Inc.'s employees told Ms. Crabbe that T-Up's products were a "miracle," would "work" for her husband, and would "take care" of her husband's cancer. After Douglas Crabbe began using Respondents' products, his condition deteriorated and his cancer spread to his liver. When the Crabbes voiced their concern that the products were not working, Hoffman told them: "Don't worry, by this time next year you'll be laughing about all of this" -- so Mr. Crabbe continued using the products until he died from his cancer one week after completing T-Up, Inc.'s intravenous therapy.

Obviously all of these efficacy claims were false. There is no evidence that aloe vera and/or cesium chloride can boost the immune system, cure cancer, or be used to effectively treat AIDS. During an administrative hearing that lasted 27 days, in which 45 witnesses testified and more than 400 exhibits were introduced as evidence, the Judge who heard the T-Up case could not find a single piece of credible evidence in the record supporting any of the efficacy claims made by T-Up, Inc. and its employees. Despite claiming to possess "stacks" of medical and scientific literature that substantiated their claims, T-Up, Inc. was unable to produce a single credible study that supported the claimed efficacy of their products for the treatment of any disease or illness. Quite to the contrary, the only well controlled studies performed on aloe vera demonstrated that it in fact had no significant beneficial impact on the human immune system. Of course, these studies were not mentioned in any of T-Up, Inc.'s advertisements.

Contrary to T-Up, Inc.'s advertising, in fact, very few of the consumers who utilized T-Up, Inc.'s products reported any positive effects from the products. The vast majority of customers interviewed by my Office reported they experienced no improvement in their health by using T-Up, Inc.'s products. Among the consumers known by my Office to have received the IV treatments, very few remain alive today.

Many of the consumers who used T-Up, Inc.'s products did so instead of using more conventional treatments. For example, one consumer delayed the chemotherapy that his oncologist had recommended because he believed the T-Up would be effective and less painful. Unfortunately, after the T-Up treatment failed and his cancer progressed, this consumer underwent the chemotherapy that he had delayed, but it could not stop the spread of his cancer. I believe this unfortunate consumer's experience is not an isolated case. In fact other witnesses who testified during our case also described delaying or forgoing recommended treatments, opting instead to use T-Up, Inc.'s products.

I was also troubled by T-Up, Inc.'s claims that its products had been proven safe. Although T-Up, Inc. claimed in its advertisements that its aloe products were so safe, the only way you could be injured by them were to "drown" in them, the evidence developed during our investigation proved otherwise. No testing had ever been performed on either T-Up aloe vera or cesium chloride to establish their safety. Moreover, evidence during the case demonstrated the potential for very serious side-effects caused by T-Up, Inc.'s products.

Existing scientific research establishes that cesium chloride causes cardiac arrhythmia in animals. Although no well controlled studies have been performed establishing the same risk in humans, T-Up, Inc.'s employees acknowledged receiving reports of customers who experienced arrhythmia while using T-Up, Inc.'s products. The wife of one consumer who testified at the hearing described her husband having repeated episodes of irregular heart beat while using cesium. His cardiologist, who treated him during one such bout, confirmed the consumer experienced cardiac arrhythmia caused by his use of cesium chloride supplied by T-Up, Inc. Despite the fact that its cesium products could potentially cause this very dangerous side-effect, T-Up, Inc. sold its cesium chloride product to consumers without the supervision of any physician.

Equally alarming were the side-effects reported by consumers who underwent T-Up, Inc.'s intravenous therapies or who witnessed the side-effects experienced by their loved ones during the treatments. Among the side-effects reported by consumers were significant weight loss (as much as 50 pounds during a two week treatment) accompanied by loss of appetite, diarrhea, and swelling so severe that it caused patients' skin to crack open.

In addition to misrepresenting the safety and efficacy of its products, T-Up, Inc., also misrepresented the nature and ingredients of its products. T-Up, Inc. marketed its aloe product by claiming it was specially filtered and cold processed in order to prevent contamination and to preserve its active ingredient. However, T-Up's manufacturer confirmed that T-Up aloe was not specially filtered and was actually heat treated. Testing of the product by the FDA revealed a wide variety of contaminants in the aloe products.

In its brochure that is attached to this testimony, T-Up, Inc. claimed its aloe vera was superior to other products because of its concentration, a claim the company was also unable to substantiate. In fact, despite the repeated emphasis in its advertisements concerning the concentration of its product, no testing or analysis had been performed by T-Up, Inc. on its products before it made its claims. Evidence presented by the makers of T-Up suggested that other sellers of aloe vera products in this country also sell products that do not contain the concentration or amount of ingredients claimed in the seller's labeling.

In investigating the T-Up, Inc. case, my Office demanded that the company produce adequate substantiation for each of its claims. In defense of its claims, T-Up, Inc. argued that DSHEA relieved it from having to substantiate its claims. My Office and a Circuit Court Judge who has reviewed our case rejected this defense.

My Office has ordered T-Up, Inc. to cease making any claims regarding the efficacy, safety or quality of its products unless they can be substantiated. We have also ordered T-Up, Inc. and its principals to make full restitution to consumers victimized by their unfair and deceptive trade practices, and to pay a substantial civil penalty. While I am pleased that my Office has protected consumers from being victimized by T-Up, Inc., I am concerned about other consumers who will purchase these types of products based on false claims concerning what the products can do and what they contain.

My office believes that consumers who are faced with decisions regarding their own health must make them with the most complete and accurate information available to them. I believe the promises made by T-Up, Inc. regarding the efficacy, safety and quality of its products illustrate the very serious problems consumers face when attempting to decide whether to use a dietary supplement when such products remain largely unregulated.

With a growing market that is becoming increasingly competitive consumers must rely almost exclusively on the manufacturer of the supplement to provide them with accurate information regarding the safety and efficacy of the product, as well as the contents of the product. Frequently, consumers are reluctant to turn to their physicians for such advice<sup>10</sup> and in the current marketplace, consumers can no longer assume that the safety, efficacy and product claims that are being made by the manufacturers of dietary supplements have been proven to be true. With an increasingly competitive market, and a lesser role by FDA regulating that market, I believe companies such as T-Up, Inc. will continue to make unsubstantiated claims regarding their products that will continue to harm consumers in the manner I have just described. Consumers who are considering whether to use dietary supplements must be protected from charlatans who lie about their credentials, exaggerate and distort existing science, and make unsubstantiated claims that, when relied on by consumers, can cause serious financial and physical harm.

This Committee's examination of the marketplace as it pertains to the sale of dietary supplements is appropriate and should be applauded. I believe that any measures considered by this Committee should be recommended with the goal of creating a marketplace where consumers can have access to dietary supplements, but also be confident that the products they are purchasing are safe, effective, have been produced using good manufacturing practices, and contain the ingredients or qualities promised by their manufacturers. I want to commend you, Chairman Breaux, and the members of this Committee, for your recognition of the issues we as consumers face when considering the purchase and use of dietary supplements. I thank the Chairman and each member of this Committee for allowing me the opportunity to appear today and give my testimony.

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<sup>10</sup> In its 1998 study of trends in the use of alternative medicines, the Journal of the American Medical Association found that 60% of Americans who use alternative treatments, including dietary supplements, do so without informing their physicians. See Eisenberg, *Trends in Alternative Medicine Use in the United States, 1990-1997*; 280:18 (November 11, 1998).