Ecuadorian government should have been involved in the case as well, or that the case should have been filed against the government and the state-owned Petroecuador as well as Texaco. At that point, the Ecuadorian government did get involved and filed an appeal of the decision. This was the first time a foreign government had sued a U.S. oil company in the United States for environmental damage. In addition, in 1997, the plaintiffs in the Aquinda and Jota cases also appealed the district court's decisions.

On October 5, 1998, a U.S. court of appeals remanded both cases to the district court for further consideration as to whether they should proceed in Ecuador or the United States. Written submissions were filed on February 1, 1999. Texaco has long argued that the appropriate venue for these cases is Ecuador because the oil-producing operations took place in Ecuador under the control and supervision of Ecuador's government, and the Ecuadorian courts have heard similar cases against other companies. It is Texaco's position that U.S. courts should not govern the activities of a sovereign foreign nation, just as foreign courts should not govern the activities of the United States. In fact, Texaco claimed the ambassador of Ecuador, the official representative of the government of Ecuador, noted in a letter to the district court that Ecuador would not waive its sovereign immunity.

Notwithstanding Texaco's arguments, the case was sent back to the court that threw it out, on the basis that the government of Ecuador does have the right to intervene. The question of whether the case can and will finally be tried in the United States or Ecuador under these circumstances will now take many years to be decided. Texaco claims that it has done enough to repair any damage and disputes the scientific validity of the claims—the Amazonians (or their supporters) seem to have the resources to continue fighting this suit in the U.S. courts. Ultimately the company may prefer the fairness of U.S. courts.

### Questions

1. Should Ecuadorians be able to sue Texaco in U.S. courts?
2. If an oil spill was caused by an act of God, an earthquake, should Texaco be held responsible?
3. Do you find Texaco's arguments against the lawsuits convincing? Why and why not?

**Source:** Texaco and Chevron websites: http://www.texaco.com/sitelets/ecuador/en/default.aspx and http://www.chevron.com/ecuador/

## Product Safety Cases

### The Betaseron® Decision (A)

ETHICS CASE

On July 23, 1993, the United States Food and Drug Administration (FDA) approved interferon beta-1b (brand name Betaseron®), making it the first treatment for multiple sclerosis to get FDA approval in twenty-five years. Betaseron was developed by Berlex Laboratories, a United States unit of Schering AG, the German pharmaceutical company. Berlex handled the clinical development, trials, and marketing of the drug, while Chiron, a biotechnology firm based in California, manufactured it. The groundbreaking approval of Betaseron represented not only a great opportunity for Berlex but also a difficult dilemma. Available supplies were insufficient to meet initial demand, and shortages were forecasted until 1996. With insufficient supplies and staggering development costs, how would Berlex allocate and price the drug?

## The Challenge of Multiple Sclerosis

Multiple sclerosis (MS) is a disease of the central nervous system that interferes with the brain's ability to control such functions as seeing, walking, and talking. The nerve fibers within the brain and spinal cord are surrounded by myelin, a fatty substance that protects the nerve fibers in the same way that insulation protects electrical wires. When the myelin insulation becomes damaged, the ability of the central nervous system to transmit nerve impulses to and from the brain becomes impaired. With multiple sclerosis, there are *sclerosed* (i.e., scarred or hardened) areas in *multiple* parts of the brain and spinal cord when the immune system mistakenly attacks the myelin sheath.

The symptoms of MS depend to some extent on the location and size of the sclerosis. Symptoms include numbness, slurred speech, blurred vision, poor coordination, muscle weakness, bladder dysfunction, extreme fatigue, and paralysis. There is no way to know how the disease will progress for any individual because the nature of the course it takes can change over time. Some people will have a relatively benign course of MS, with only one or two mild attacks, nearly complete remission, and no permanent disability. Others will have a chronic, progressive course resulting in severe disability. A third group displays the most typical pattern, with periods of *exacerbations*, when the disease is active, and periods of *remission*, when the symptoms recede while generally leaving some damage. People with MS live with an exceptionally high degree of uncertainty because the course of their disease can change from one day to the next. Dramatic downturns as well as dramatic recoveries are not uncommon.

## The Promise of Betaseron

Interferon beta is a protein that occurs naturally and regulates the body's immune system. Betaseron is composed of interferon beta-1b that has been genetically engineered and laboratory manufactured as a recombinant product. Although other interferons (i.e., alpha and gamma) had been tested, only beta interferon had been shown, through large-scale trials, to affect MS. Because it is an immunoregulatory agent, it was believed to combat the immune problems that make MS worse. However, the exact way in which it works was yet to be determined.

In clinical studies, Betaseron was shown to reduce the frequency and severity of exacerbations in ambulatory MS patients with a relapsing-remitting form of the disease. It did not reverse damage already done, nor did it completely prevent exacerbations from occurring. However, Betaseron could dramatically improve the quality of life for the person with MS; for example, people taking Betaseron were shown to have fewer and shorter hospitalizations. Betaseron represented the first and only drug to have an effect on the frequency of exacerbations.

Betaseron is administered subcutaneously (under the skin) every other day by self-injection. In order to derive the most benefits from the therapy, it was important that the MS patient maintain a regular schedule of the injections. Some flu-like side effects, as well as swelling and irritation around the injection, had been noted; however, they tended to decrease with time on treatment. In addition, one person who received Betaseron committed suicide, while three others attempted to kill themselves. Because MS often leads to depression, there was no way to know whether the administration of Betaseron was a factor. Lastly, Betaseron was not recommended for use during pregnancy.

## The Betaseron Dilemma

In July of 1993, the FDA approval for Betaseron allowed physicians to prescribe the drug to MS patients who were ambulatory and had a relapsing-remitting course of MS. An estimated one-third of the 300,000 people with MS in the United States fell into that category, resulting in a potential client base of 100,000. However, the expedited

FDA approval process took only one year instead of the customary three years taken to review new drug applications. As a result, Berlex was unprepared for its manufacture and distribution in the anticipated amount needed. Chiron Corporation had been making the drug in small quantities for experimental use and did not have the manufacturing facilities to handle the expected explosion in demand. Chiron estimated that it would have enough of the drug for about 12,000 to 20,000 people by the end of 1993. By the end of 1994, Chiron expected to be able to provide the drug to 40,000 patients. Depending on demand, it might take until about 1996 to provide the drug to all patients who requested it. Chiron's expanded manufacturing represented the only option for Berlex because the process required for another company to get FDA approval to manufacture the drug would take even longer.

In addition to availability, price was a concern because successes must fund the failures that precede them. Betaseron represented the results of years of expensive, risky research by highly trained scientists in modern research facilities. Furthermore, genetically engineered drugs were extremely expensive to manufacture. In the case of Betaseron, a human interferon gene was inserted into bacteria, resulting in a genetically engineered molecule. The stringent quality controls on the procedure take time and are expensive. As a result, the price of Betaseron was expected to be about $10,000 per year for each patient.

Betaseron brought great hope to people with MS and a great quandary to Berlex. How should Berlex handle the supply limitations, the distribution, and the price of this drug?

**Source:** By Ann K. Buchholtz, University of Georgia. This case was written from public sources, solely for the purpose of stimulating class discussion. All events are real. The author thanks Dr. Stephen Reingold, vice president, Research and Medical Programs of the National Multiple Sclerosis Society and Avery Rockwell, chapter services associate of the Greater Connecticut Chapter of the Multiple Sclerosis Society, and two anonymous reviewers for their helpful comments.

ETHICS CASE

## Magnetic Toys Can Hurt

Mega Brands has been selling Magnetix toys for many years. It also sells Mega Bloks, construction toys based on Spider-Man, Pirates of the Caribbean, as well as other products in over 100 countries. In 2006, Mega Brands had over $547 million in revenue, including over $100 from magnetic toys, but its share price fell approximately $27 to $20.30 in mid-July 2007. One reason for the fall was that a child, who had swallowed a magnet that had fallen out of a toy, had died in the late fall of 2005. The U.S. Consumer Products Safety Commission (CPSC) had issued a product recall in March 2006.

Subsequently, a number of lawsuits appeared involving other children who had suffered bowel complications. The symptoms resulting from a child swallowing a magnet are similar to those of a stomach ache, cold or flu, and so the problem is sometimes misdiagnosed. The consequences can be much worse if a child swallows more than one magnet, particularly if they are the super-powerful magnets like those in Magnetix toys. They are so strong that they do not pass through the child's digestive system; instead, the magnets rip through tissue as they are attracted to each other. Complex surgery is required for extraction and complications can continue afterward.

After refusing twice, Mega Brands engaged in two voluntary recalls at the request of the Commission in March 2006 and April 2007. Defective merchandise was still found on store shelves by CPSC investigators in April. Even then, at a hearing on June 18, 2007, Senator Robert Durban stated: "The company did everything in its power to derail the commission's effort to take the product off the shelf." In frustration, Senator Durban commented: "When a company is selling dangerous products in America and refuses to co-operate with the CPSC, we have few laws and few tools to use to protect consumers."