## Case 4

In June of 1998 the Food and Drug Administration (FDA) approved Thalidomide for use in the United States. In 1960 the FDA had denied approval to Thalidomide even though at that time it was used widely throughout the world as a sedative. Shortly after the FDA refused to approve Thalidomide unmistakable evidence emerged of gross birth defects in the babies of women who used the drug. The shockingly horrid nature of these defects attracted attention throughout the world, and led to a world wide ban on Thalidomide in 1962. As a result of the FDA's decision not to approve Thalidomide there were only 17 Thalidomide babies in the United States, compared with 10,000 world wide.

Despite the 1962 ban, use of Thalidomide did not cease completely. At some time in the mid 1960's an Israeli physician prescribed Thalidomide for leprosy patients (as a sedative) and to his great surprise the patients' lesions and fever quickly disappeared. Soon leprosy patients were treated with Thalidomide on an experimental basis, and by the 1970's the Public Health Service began a compassionate use program for leprosy patients, using Thalidomide obtained from foreign manufacturers. In 1989 a team of scientists at Rockefeller University reported finding that Thalidomide might have beneficial effects in the treatment of cancer and AIDS. Other scientists are currently experimenting with Thalidomide for treatment of lupus and other auto-immune diseases. In 1997 a panel of scientific advisers voted 8 to 2 that the FDA approve the use of Thalidomide for leprosy patients, of whom there are currently about 7,000 in the United States. In June of 1998 the FDA granted such approval. It did not approve Thalidomide for any other use besides treating leprosy.

Celgene, the manufacturer of Thalidomide, which sought FDA approval, proposed, and the FDA approved, a set of controls for distributing the drug. Under Celgene's plan drug stores must register in order to buy Thalidomide, pharmacists are forbidden from dispensing more than a month's supply to patients, and there are no automatic refills. Before receiving Thalidomide patients have to register in a national data base. Doctors and patients must undergo extensive education about Thalidomide. Furthermore, women of child bearing age using Thalidomide have to show proof they are using contraceptives, and must take pregnancy tests at least once a month.

Speaking of Celgene's plan, Dr. Murray Lumpkin, Deputy Director of the FDA's Center for Drug Evaluation, expressed the opinion that it makes Thalidomide the most heavily regulated drug in the United States. Dr. Norman Fost, a pediatrician and medical ethics specialist at the University of Wisconsin, observes that no control regulations, regardless of their stringency, can make it impossible that a pregnant woman who uses Thalidomide will give birth to a deformed baby. The goal, according to Dr. Fost, however, "is not to produce zero risk." Instead, says Dr. Fost, "you .. can get it close to zero without limiting access to women in a way that is unreasonable."

The FDA's decision to approve Thalidomide for use in treating leprosy has its critics, who believe that Dr. Fost severely underestimates the problems of putting an effective control procedure into place. In this regard, Roald Hoffman notes, in a New York Times Op Ed column, that recently Brazil attempted to implement controls similar to those contemplated by the Celgene plan, and there are now several dozen documented cases of Thalidomide deformed babies in Brazil. Apart from this concern, there is also the troubling question of whether any of the benefits associated with the use of Thalidomide warrant the risk that even one more Thalidomide baby will be born. Mr. Randy Warren, the leader of the Thalidomide Victims' Association of Canada, poses this question. Mr. Warren, who was born without hips, has feet where his knee caps should be, and underwent twenty four operations by the time he was sixteen, asks rhetorically: "One baby born for every hundred lives extended? If there is a number, I would like to know what it is? How are you going to measure that?"