

Drug company rebuked for marketing thalidomide as cancer fighter

In 1957, the drug thalidomide was approved for use in Europe as a treatment for morning sickness caused by pregnancy. Thousands of women took the pills, assured by the drug maker that they were safe.

Unfortunately, the drugs had primarily been tested as a sleep aid for elderly patients -- not on pregnant women. By the time its tragic side effects were known, it was too late to help the than 12,000 babies born with severe birth defects.

Today, it is known that even one capsule of thalidomide can cause devastating defects, including the development of flipper-like limbs.

Yet, the Celgene Corporation has promoted the pill as a cancer treatment, despite warnings from the FDA.

On July 16, 1998, the FDA gave Celgene approval to market its brand of thalidomide -- Thalomid -- for the treatment of leprosy. It specifically told the company that "statements or implications by you that this product may indeed be safe and efficacious in the treatment of diseases or patient populations beyond that approved in your application may be considered a violation of the promotional provisions of the Act."

Just two weeks later, the FDA had to contact Celgene to discuss concerns that the company's promotional materials contained references to unapproved uses of thalidomide.

On Nov. 9, 1998, the FDA issued a letter to Celgene about several press releases it was distributing. "Those press releases were misleading (lacked fair balance) in that they presented little or no risk information," the FDA warned.

Despite repeated warnings, the FDA says Celgene has continued to promote the dangerous drug to the medical community for unapproved uses.

According to an FDA letter to Celgene dated April 21, 2000, "Celgene has also represented to physicians that Thalomid can be used to treat various cancers, for cancer patient 'weight loss,' and to promote a feeling of 'general well-being' in these same patients."

At a luncheon held by Celgene for an oncology practice group, a sales representative reportedly told doctors that thalidomide is "good for weight loss," that it could be used "as an appetite stimulant," and that it is a "great drug for feelings of general well-being." When asked if thalidomide had FDA approval for these uses, the sales representative stated "no, but do you want some material anyway?"

SOURCE: Warning Letter to Celgene Corporation, Food and Drug Administration, April 21, 2000.