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Glaxo and Zantac: The Life, Times, and Near Death of the World's Best-Selling Drug

Introduction -

In 1977, Glaxo watched as competitor SmithKline introduced Tagamet, the first "acid blocker" for ulcer treatment. Its own drug, Zantac, was still in development and it would be another six years before it was introduced to the United States market, becoming the second "acid blocker." By late 1987, Zantac overtook Tagamet as the leading "acid blocker" and also the best-selling drug in the United States and the world. By 1993, Zantac's annual sales level reached more than \$2 billion in the United States and \$4 billion worldwide—making up about half of Glaxo's sales. By 2007, Zantac's sales rate had fallen to the point where it was less than 1% of Glaxo's worldwide sales. This is the story of how Zantac got from there to here.

An ulcer is small erosion in the gastrointestinal tract, commonly caused by destruction of the lining by hydrochloric acid, an acid normally found in the digestive juices of the stomach. Ulcers were a common occurrence, with about 20 million Americans developing an ulcer sometime in their lives.

Until 1977, no effective drug treatment was available, meaning stomach surgery was often required to resolve severe cases. In 1977, SmithKline introduced Tagamet into the United States, the first of the "H2-antagonist" class of drugs, so-called "acid blockers." Acid blockers worked by reducing the amount of hydrochloric acid released into the digestive tract through blocking the "signal" calling acid-secreting cells to work. Three other acid blockers, each from a major drug company, would follow Tagamet to the market:

- Zantac—introduced 1983 by Glaxo
- Pepcid—introduced 1986 by Merck
- Axid—introduced 1988 by Eli Lilly

The Pharmaceutical Industry —

The pharmaceutical industry in the United States had some important characteristics. First, the Food and Drug Administration (FDA) had to approve any drug before it could be marketed. The FDA also designated the particular conditions a drug could be marketed as addressing. Formally, this was known as the FDA granting "approval" for an "indication." The FDA specified the testing process that a company had to follow to provide data to support any application for drug approval.

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