



## Magic in a Tiny Orange Pill

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By George Hisatomi, MD

**MAGIC CANCER BULLET**, by Daniel Vasella, MD, and Robert Slater. Harper Collins Publishers Inc, New York, 258 pp, ISBN 0-06-001030-4.

When I first spoke with Ted Fourkas, the managing editor of Sierra Sacramento Valley Medicine, he asked me to review the book *Magic Cancer Bullet*. I was hesitant. The author is Daniel Vasella, MD, the chairman and CEO of Novartis. Believe me, I am not a fan of books authored by CEOs tooting their own horns.

However, this story has personal implications. *Magic Cancer Bullet* tells the story of the development and ultra-fast FDA approval of the wonder drug Gleevec. This designer drug was made specifically for treatment of Chronic Myeloid Leukemia (CML). My mother had CML, and as I read the book, I relived a roller coaster of emotions.

Daniel Vasella could not believe his eyes when he read the results of the Phase I study on STI571 (the name for Gleevec during its development) in April of 1999. Of 31 patients with CML, all now had normal white blood cell counts. How astonishing! Dr. Vasella knew he had something special.

Gleevec was born in the age of the Internet. STI571 trial patients, excited by their results, were posting labs, side effects, and even Philadelphia Chromosomes levels, on the Internet. This was long before results were formally published. CML chat rooms were buzzing with excitement and hope.

My sister was one of those who were monitoring the latest developments of the war against CML. She was the one who first told my mother and me about STI571. We could not imagine that a little orange pill, that you took orally, could do so much. At that time the drug was in short supply, and the number of patients accepted in the studies was limited.

My mother did apply but was rejected. Our family, like many others, went through anger and disappointment. There was a drug that could help patients live a more normal life, yet it was unavailable. She would have to remain on Interferon, a drug that caused horrible side affects and led to a poor quality of life.

An Internet petition was soon to follow. It was sent directly to Dr. Vasella urging him to increase the supply and loosen the strict criteria. He was literally bombarded with e-mails, letters and phone calls. He responded to this "patient revolt and grass root rebellion." The production of the drug was increased and the study opened to more patients. In May of 2001, STI571, by now called Gleevec, made history by obtaining the fastest approval by the FDA for a cancer medication.

Although Dr. Vasella credits many individuals with the research and development of Gleevec, I must mention Dr. Brian Druker, an oncologist and researcher at the Oregon Health Science University in Portland, Oregon. He was instrumental in the development of Gleevec and is the main clinical researcher.

I first met Dr. Druker in the fall of 2000, when my mother was being interviewed for the Phase II Clinical trial. I brought a binder full of documentation and was fully prepared to talk him into accepting her. I did not have to. He reviewed her history right there and welcomed her into his study. As my mother did, I have great respect for Dr. Druker. He is a kind and compassionate man. In addition, he is wise and accomplished. His care for patients was outstanding; he was always available, answering our questions and returning phone calls and e-mails.

Gleevec has been nothing short of a miracle drug for most CML patients. Unfortunately, it proved to be unsuccessful for my mother. She had an excellent quality of life for two years, and for that I am truly grateful. In the fall of 2002, my mother's oncologist, Dr. Paul Rosenberg, told her he was seeing evidence of Gleevec resistance. He encouraged her to consider an immediate stem cell transplant, while she was still relatively healthy, and feeling good. He wanted her in the best condition possible to undergo this life threatening treatment. My mother agreed with one condition, she wanted to wait until after the holidays.

Sadly, a few days after New Year's, she went into blast crisis. She fought with courage and tenacity to get back into the chronic phase, but lost the battle and died a few months later at Duke University while awaiting a transplant.

What I find most remarkable about this story is Dr. Vasella's willingness to listen to the desperate pleas of CML patients across the world. CML is a rare form of cancer with 6,000 new cases reported yearly. Because it is rare, the funding for research and development was limited. But through his dedication and perseverance, thousands of CML patients have been given a better quality of life, and more importantly, hope. Magic Cancer Bullet is an interesting read, and describes well the politics and complicated process of getting a drug FDA approved. My personal involvement, and that of my family made this account poignant. I recommend this book to those who are struggling with CML, and to those interested in the process of new drug approval.

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