

The Cell Game: Sam Waksal's Fast Money and False Promises – and the Fate of ImClone's Cancer Drug

By Alex Prud'homme

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While the technical nature of advancements in biotechnology may elude and confuse the public, the impact of progress in this field is best understood by this same class of individuals through the pharmaceuticals that serve to enhance and prolong the quality of American lives. Pharmaceutical companies devoted to the research, development and growth of biotechnology encounter a multitude of legal challenges in terms of licensing, patenting and regulating their discoveries. Moreover, despite their noble pursuit in finding cures for disease, pharmaceutical companies are not immune from the legal duties imposed upon fiduciaries and corporate executives.

The best example of an attempt to pursue the noble search for a cure for one of the world's deadliest diseases gone awry can be found in Alex Prud'homme's book, *The Cell Game: Sam Waksal's Fast Money and False Promises – and the Fate of ImClone's Cancer Drug*. Prud'homme's book chronicles the downfall of an ambitious scientist on the brink of producing a promising new cancer drug only to destroy his reputation and that of his scientific research by succumbing to the avaricious behavior of insider trading. The book serves to captivate the reader with the larger premise of the revelation of the insider trading scandal while simultaneously

educating the reader on the Food and Drug Administration (FDA) approval process¹, as well as the complexity of licensing and patenting pharmaceuticals.

Alex Prud'homme, a journalist from New York, has written for *Vanity Fair*, *The New Yorker*, the *New York Times*, *Time* and *People* magazine. In *The Cell Game*, Prud'homme delivers a biographical account of brothers Sam and Harlan Waksal. The two are talented scientists who attempt to achieve the American Dream of financial spoils, fame and glory through their blockbuster cancer drug developed by their fledgling biotech company, ImClone Systems.²

At some point on their path to greatness the brothers become more fixated on the wealth and glory of their potential scientific breakthrough at the expense of accurate scientific and clinical data. As they pushed for FDA approval of their colorectal cancer drug, called Erbitux, and made a \$2 billion deal to market the drug with pharmaceutical giant, Bristol-Myers Squibb, they were faced with the harsh reality that the FDA was poised to reject their application for Erbitux due to defective and insufficient data. It was this moment on December 27, 2001 that Sam Waksal, the chief executive officer of ImClone, made the fateful decision to set in chain a course of events that led to his violations of securities regulations, and his and Martha Stewart's convictions for insider trading. Ultimately, Sam Waksal deceived his own corporation, shareholders, Wall Street, his close friends and family and most devastating, cancer patients, with his inflated claims of the success of his drug combination and the likelihood of rapid FDA approval.

¹ *Drug Approvals – From Invention to Market ... A 12-Year Trip*, MEDICINET.COM, (July 14, 1999), available at <http://www.medicinenet.com/script/main/art.asp?articlekey=9877>, last visited Mar. 4, 2005.

² http://www.imclone.com/index_start.php. Last visited, Mar. 11, 2005. ImClone System's webpage details the history and background of the company.

Prud'homme essentially furnishes an account of the ImClone scandal, which details the violations of securities regulations committed by Sam Waksal, the barriers to drug development posed by patenting and licensing requirements, and the harrowing process of achieving FDA approval for a promising new pharmaceutical. Prud'homme, throughout the account, never fails to remind the reader of the devastating impact of Sam Waksal's behavior upon the hopes and fears of suffering cancer patients who were convinced that Erbitux would be their knight in shining armor.

The licensing and patenting issues arise as the story hints that broadly construed patents prevented Erbitux from being developed as a single agent therapy, thus prompting the combination antibody and chemotherapy drug. It is also speculated that Waksal wanted to avoid heavy licensing fees by developing this combination therapy. Some critics touted these issues implying that Waksal's insistence on the combination therapy was a way to earn greater profits in the race to develop and exclude other companies with similar combination therapies.

The book continually weaves in the controversy between fast tracking the approval of potentially life-saving pharmaceuticals with the underlying threat to public health if certain safety measures are ignored in implementing the review and approval process. While patients may become understandably frustrated with the hyper-regulation and delays in approval by the FDA, Prud'homme is quick to balance out that frustration with tales of the history of the development of this bureaucratic clearing house and the potentially devastating effects on public health that have ensued in its absence.

Prud'homme succeeds in capturing the impact of Waksal's self-dealing in terms of the loss of trust by the public and the financial world in the biotech industry in the wake of the ImClone controversy. It is painful from the patient perspective to see the ripple effect of this loss

in confidence on drug research and development as investors remove much needed resources from the marketplace. Ultimately, despite the heavy financial losses suffered by investors in the biotech industry, it is the dashed hopes and unfortunate deaths of cancer patients who endured the greatest damage from Waksal's greed.

Since this book was published in 2004, readers may find it interesting to glimpse at the aftermath of this scandal, as Prud'homme questions the possibility that Erbitux will come to market, and the fate of Martha Stewart. As of February 12, 2004, the FDA approved the drug for colorectal cancer³, and on March 5, 2004 Martha Stewart was convicted of obstructing justice and lying to investigators.⁴ She has since been released from prison and remains on house arrest a year later.⁵ Prud'homme's journalistic style inspires his readers to explore the various controversies he details in this gripping narrative.

The Cell Game will entertain not only those fascinated by the downfall of prominent public figures such as Martha Stewart and high-powered executives like Sam Waksal, but will also incite the average American who has been affected by the deadly disease of cancer. Although Prud'homme incorporates technical scientific information, a layperson can easily keep up with his explanations. The legal quagmire in which these individuals eventually find themselves entrenched may paint a negative picture of corporate America, but serves as a warning to those who seek to achieve the American dream not to lose sight of the ultimate moral responsibility to society at large.

³ Press Release, FDA Approves Erbitux for Colorectal Cancer, (Feb. 12, 2004), available at <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01024.html>. Last visited, Mar 11, 2005.

⁴ *Stewart Convicted On All Charges*, CNNMoney, (Mar. 5, 2004), available at http://money.cnn.com/2004/03/05/news/companies/martha_verdict/. Last visited, March 15, 2005.

⁵ Associated Press, *Martha Stewart Back at Work* (Mar. 7, 2005), available at <http://www.msnbc.msn.com/id/7078053/print/1/displaymode/1098>. Last visited, March 15, 2005