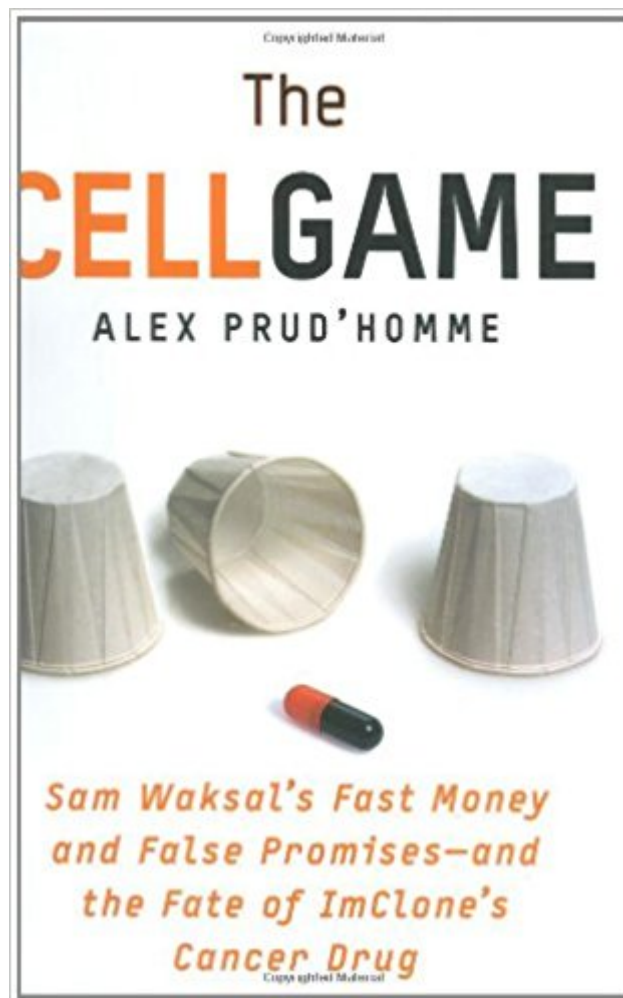




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The Cell Game: Sam Waksal's Fast Money And False Promises--and The Fate Of ImClone's Cancer Drug



Synopsis

It began with a promising cancer drug, the brainchild of a gifted researcher, and grew into an insider trading scandal that ensnared one of America's most successful women. The story of ImClone Systems and its "miracle" cancer drug, Erbitux, is the quintessential business saga of the late 1990s. It's the story of big money and cutting-edgescience, celebrity, greed, and slipshod business practices; the story of biotech hype and hope and every kind of excess. At the center of it all stands a single, enigmatic figure named Sam Waksal. A brilliant, mercurial, and desperate-to-be-liked entrepreneur, Waksal was addicted to the trappings of wealth and fame that accrued to a darling of the stock market and the overheated atmosphere of biotech IPOs. At the height of his stardom, Waksal hobnobbed with Martha Stewart in New York and Carl Icahn in the Hamptons, hosted parties at his fabulous art-filled loft, and was a fixture in the gossip columns. He promised that Erbitux would "change oncology," and would soon be making \$1 billion a year. But as Waksal partied late into the night, desperate cancer patients languished, waiting for his drug to come to market. When the FDA withheld approval of Erbitux, the charming scientist who had always stayed just one step ahead of bankruptcy panicked and desperately tried to cash in his stock before the bad news hit Wall Street. Waksal is now in jail, the first of the Enron-era white-collar criminals to be sentenced. Yet his cancer drug has proved more durable than his evanescent profits. Erbitux remains promising, the leading example of a new way to fight cancer, and patients and investors hope it will be available soon.

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Customer Reviews

Since the ImClone scandal first broke, most of the media's attention has focused on CEO Sam Waksal's insider trading and the charges filed against Martha Stewart, a close friend and investor in the pharmaceutical company. Prud'homme, who first reported on ImClone for Vanity Fair, reminds readers of the bigger story, the one that set the financial hijinx in motion: ImClone's failed attempt to bring a potentially groundbreaking cancer medication, Erbitux, to market. This story tells of scientists like John Mendelsohn, who led the research into C225, the antibody at the heart of Erbitux, and patients like Shannon Kellum, a 28-year-old woman diagnosed with colon cancer for whom the medication was a "miracle drug" that added a few years to her life. She was one of the rare lucky ones; Prud'homme's reporting is especially strong when he delves into the seemingly haphazard way in which ImClone distributed C225 for "compassionate use" during the clinical testing period. The FDA's rejection of ImClone's "scientifically incomplete" test data was the immediate motivation for Waksal's crimes, but Prud'homme's portrayal suggests it was completely in character for the reckless social-climbing executive, described by acquaintances as a "pathological liar" who cared more about making money than about curing cancer. Prud'homme ends his compelling account with Waksal's sentencing, and even though he'll inevitably have to update the paperback to wrap up coverage of the Martha Stewart trial, it's well worth reading the book now to appreciate what's really at stake in ImClone's downfall. Copyright © Reed Business Information, a division of Reed Elsevier Inc. All rights reserved.

As this is written, jurors are being selected for lifestyle-marketing entrepreneur Martha Stewart's trial on charges of insider trading of her shares in the small drug-development company ImClone. Stewart was a friend to ImClone CEO Sam Waksal, and he is already in prison for doing as she allegedly did on a much larger scale. As large as that scale was, Waksal's ill-gotten gains didn't begin to match his personal indebtedness. He loved living large, knowing the stars, and being part of the in crowd. The son of Holocaust survivors, a medical researcher who shifted from the lab to a front office, and charming as the day is long, Waksal had waited long enough to cash in when, in the mid-1990s, he seized on a promising cancer drug as ImClone's and his winning ticket. He cut a deal with pharmaceutical giant Bristol-Myers Squibb to produce the substance and launched the tests necessary to get the drug FDA approval. But he was living so high that he felt compelled to cut corners and rush the payoff. When the FDA balked--as it should have--his personal house of cards collapsed. The drug and ImClone didn't fall with him, which is fortunate mostly because, as Prud'homme shows in the most interesting pages of his long, exemplarily written report, the stuff remains very promising as a specific against tumors. Ray Olson Copyright © American Library

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This is an awesome book! A real page turner. Sam Waksal was not the normal pharma founder. You hate the guy but also fall into caring.

Book is very interesting. Takes you onto the world of the diabolical. I would make love to the book if I could

I could hardly put this book down. Never mind the Martha Stewart trial, this is where the excitement and drama in the ImClone story lies. Sam Waksal, a scientist and business developer with a checkered past, lives a celebrity lifestyle, hanging out with the rich and famous, owning several fancy houses, driving fast cars, and heading a firm that is working on a cancer drug so promising that people with no other hope of treatment are flinging themselves at ImClone, begging for a merciful dose of "Erbix." The drug apparently does reverse inoperable tumors in a few test patients who had no other hope of living. Now the race is on to fast-track the drug through the FDA approval process based on the glowing clinical trials. But the FDA reviewer is unaccountably unencouraging when meeting with one of ImClone's top scientists. What is wrong? Is Erbix, instead of being approved, instead going to have its application refused? Why! And what will this mean for the high-flying ImClone stock? The book reads like the best thriller, and author Alex Prud'homme is adept at making you feel like the proverbial fly-on-the-wall during the action. If you are at all interested in what happened behind the Martha Stewart debacle, you must read this. It's fantastic.

This is about the Cancer Game, which might be seen as a part of the Cancer Industry, a kind of bizarre and ghoulish phenomenon of modern times that exists precisely because there is no cure for cancer. Indeed, Alex Prud'homme, who is a gifted researcher and prose stylist, whose work has appeared in such prestigious journals as The New Yorker, Vanity Fair, The New York Times, etc., might very well have called his book "The Cancer Game." I wonder why he didn't. Would such a title have offended those who play the game? It is specifically about the rise and fall of one Sam Waksal, oldest son of Jewish emigrants and Holocaust survivors, a man of irresistible charm, fabulous energy, and great intelligence, a man driven to success and the high life, a man who had bounced around academia without much success until in the 1980s he saw an opportunity to become a player in the cancer game, and, along with his younger brother Harlan, founded ImClone Systems, Inc. It is also about an anticancer drug called Erbix, originally known as C225 because it was the

225th drug tested by its discoverers, John Mendelsohn and Gordon Sato in 1980. It showed promise because in tests it stopped the growth of tumors in mice. And finally it is a story about how drugs get discovered, how they are developed, and especially how they get approved (or not) by the Food and Drug Administration. And of course it is about the Byzantine and incestuous relationship that exists between that August government agency and the massive pharmaceutical industry. The curious thing about all this is that Imclone never turned a profit, Erbitux never came to market, and most of the people associated with Waksal and ImClone either made out like bandits or got stuck holding the bag. The drug itself, which works against cancer tumors, particularly colon cancer, by cutting off the blood supply to the tumors (an "antiangiogenesis" drug), was touted as a miracle that would save the lives of innumerable patients and make possibly billions of dollars for ImClone. At least this was the hype delivered by Sam Waksal, and bought hook, line and sinker by pharma giant Bristol-Myers Squibb, and by desperate cancer patients as well as salivating Wall Street investors who jumped on the bandwagon as ImClone's stock rocketed skyward. Because of the promise of the drug, Waksal himself was able to live his dream life as a New York socialite, throwing lavish parties for celebs (including Martha Stewart while he dated her daughter), collecting fine art, popping open \$600 bottles of Chateau Lafite-Rothschild while secretly selling stock on the side, sending the proceeds overseas, buying expensive apartments and houses for himself, etc., etc. But the cold hard facts of Erbitux, like those of almost any cancer drug one can name, are very far from the hype. As Prud'homme notes on pages 332-333, "these agents...[Erbitux and others like Avastin and Iressa] are remarkable scientific advances, [but] they still only benefit some 10 to 20 percent of patients, and they only extend patients' lives by a matter of months." That's it. That's the bottom line. And yet these drugs are so valuable that the companies that end up selling them can make hundreds of millions if not billions of dollars. Waksal apparently came to this understanding sometime during the early eighties. He realized first the simple fact that the way the cancer industry works is doctors have to prescribe something rather than nothing. Then he realized that living a few months longer can mean a lot to people. Therefore any FDA-approved cancer drug will automatically fill a need. What this means is that the PROMISE of a cancer drug, if cleverly promoted, will spark a rally in the shares of the company that owns the patent. If, like Sam Waksal, you own millions of those shares, you can get rich on mere promise alone. Furthermore, should the drug have any real value at all, and be approved (or even look like it's going to be approved) by the FDA, you might be able to get some pharmaceutical giant like Bristol-Myers Squibb to front a whole lot of money on that promise since they are desperate to find a cancer drug to replace those that have gone generic. This works because even drugs with very limited effectiveness are better than no

drug at all. This is true for many patients, for many doctors, and is especially true for the big pharmaceutical companies. Note that these drugs are valuable because the people who need them are typically people of relative means who can afford to pay large sums of money for them, either through their HMOs, their government, or their own funds. In contrast a drug that would prolong the life of poor people in third world countries would be of only marginal value to the big pharmaceutical companies. I should also mention that Prud'homme spends some serious ink in this book on Waksal's long-time friend Martha Stewart and her troubles. Her personality, her empire, and the way she handles herself are vividly detailed. In fact, some readers might find her story the most interesting part of the book.

This book is a fine character study of an amazingly talented man whose endless need to gratify his own appetites and emotional needs led him to careless and even cruel behavior. There is no denying the great talent of Sam Waksal, but to this day he doesn't seem to understand that his talent and accomplishments do not provide a license to indulge himself at other's expense. It is amazingly sad that all of this misery was so pointless because Erbitux has at last been approved. It almost certainly could have been approved earlier if the talented team at ImClone would have had a culture of discipline and getting things done and documented in ways that everyone knew the FDA required. If they had, all this pain and loss would never have occurred and Dr. Waksal would be a real hero instead of the one he only pretended to be. Mr. Prud'homme writes with style and vitality. The book moves along well and has a great feel for keeping the story personal and emotionally accessible for the reader. We don't get overwhelmed with the scientific side of things, although it is always interesting to read about this emerging science and the wizards who are making it happen.

The author does an admirable job in capturing Waksal's persona and the regulatory framework in which he was operating. But above all this is a cautionary tale for those who might have tendency to go a step or two too far in spruiking their product and lining their pockets at the same time.

This fascinating story has appeared just as the Martha Stewart trial is getting underway. The book is crammed full of details not only concerning the principal characters, but also cancer treatments and the burgeoning world of biotechnology. Sam Waksal comes across as a mercurial salesman with no true sense of right or wrong, a classic striver seeking recognition and aspiring to great wealth, but also dissing the hopes of many with cancer. It's a good read -- fast-paced, up-to-date and accurate. If you really want to know why Waksal is in jail for seven years and how Martha Stewart became

involved with his world, read this amazing and well-researched tale.

This book is beautifully written and the story is powerfully, artfully told. Alex Prud'homme's eye for telling details and anecdotes brings to life all of the egos, greed, outsized appetites, and fat wallets that intersected in Sam Waksal and Martha Stewart's world. I couldn't put it down.

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