

EXIT

INVESTIGATING IMCLONE

A “miracle” cancer drug made ImClone the hottest firm in recent biotech history and its high-flying C.E.O., Sam Waksal, the darling of New York’s A-list. But since December, when the F.D.A. gave a thumbs-down to his \$2 billion breakthrough, Waksal has been under a financial, scientific, and personal microscope
BY ALEX PRUD’HOMME

CAUTION
LABORATORY
Potentially Hazardous Substances

BEFORE THE FALL Sam Waksal, photographed at ImClone’s laboratories on Varick Street, New York City, December 18, 2001.

On the evening of December 6 last year, Sam Waksal’s spacious duplex loft in SoHo was packed with a rollicking, eclectic crowd for his annual Christmas party. Martha Stewart held court on a couch near the door, while the celebrity photographer Patrick McMullan snapped recognizable

faces such as Mick Jagger, Patricia Duff, Lally Weymouth, Mort Zuckerman, Marvin Traub, Andrew Stein, and Andrew Cuomo mingling with less recognizable scientists, lawyers, and bankers associated with their host’s biotech firm, ImClone Systems. This year’s party, one reveler noted, featured more Wall Street analysts and

fewer long-legged women with impressive cleavage in tiny black dresses than in the past. And there, in the midst of the swirl, was smiling Sam Waksal—a reedy, charming bachelor biotech entrepreneur—dazzling guests with his quick mind, fabulous art collection, and self-deprecating jokes. That night Waksal had particular reason

to celebrate: not only was the party a perfect amalgam of all that he had aspired to—big money and serious science spiced with celebrity and society—but 2001 had been the defining year for his long-struggling business.

Since founding ImClone with his brother, Harlan, in 1984, Waksal had toiled in the fickle biotech industry with mixed success. In 1992, Waksal bet the company on a potentially revolutionary cancer treatment called Erbitux, and then spent the next decade convincing others that it was destined to become a blockbuster.

"Erbitux is going to be huge," he had promised me many times in his Tribeca offices last winter. "It's going to be one of the biggest drugs in the history of oncology—a drug that is going to alter the way cancer therapy is done."

Back then, his dream seemed to be taking shape. In February 2001, Erbitux was granted fast-track status by the Food and Drug Administration (F.D.A.). In July the drug landed on the cover of *BusinessWeek*. In September the pharmaceutical giant Bristol-Myers Squibb bought a 20 percent stake in ImClone for \$1 billion, and pledged another \$1 billion for the rights to market Erbitux in North America and Japan—the largest single-product deal between a biotech firm and a pharmaceutical giant. In October, Sam and Harlan sold some of their stock for \$57 million and \$54 million, respectively. They were rich, even by their ambitious standards. And on December 6, the day of Sam Waksal's Christmas party, ImClone shares reached an all-time high of \$75.45. That day Harlan sold another chunk of stock for a further \$50 million. The only piece missing from the puzzle was the F.D.A.'s stamp of approval, which would allow the Waksals to start manufacturing and selling the drug.

That *ought* to have been no problem. According to Sam Waksal, Erbitux is a leading monoclonal antibody, part of a new class of "targeted therapies"—drugs such as Gleevec and Herceptin—that doctors hope will revolutionize cancer treatment. In the 22 years since its discovery by Dr. John Mendelsohn, now president of the University of Texas M. D. Anderson Cancer Center in Houston, it has been in development, at a cost of well over \$100 million. Once it reaches the marketplace, analysts have predicted, it could generate up to \$1 billion in annual sales. (Each year about a million Americans are diagnosed with cancer, and it will kill some 550,000 of them.)

No one could have promoted the drug better than the ubiquitous Waksal. Flitting

from oncology conferences to government hearings to investor meetings, networking on tennis courts in the Hamptons and in the Grill Room at the Four Seasons restaurant, he has won over pillars of the scientific and financial communities. The ImClone board is stocked with respected names, including Dr. Mendelsohn; Dr. Vincent DeVita Jr., the former head of the National Cancer Institute and now executive director of the Yale Cancer Center; Robert Goldhammer, the former vice-chairman of the investment-banking firm Kidder Peabody; and attorney David Kies, a partner at Sullivan & Cromwell. Last November, Blackstone Group chief and former secretary of commerce Peter G. Peterson joined their ranks.

Sam Waksal single-handedly made biotech sexy," says Ian Alterman, a one-time ImClone employee, "which, for a fairly conservative stock, is amazing. He was a pioneer of bringing biotech to

"Erbitux is going to be huge," Sam Waksal promised. "It's going to alter the way cancer therapy is done."

New York City. It's hard to forget someone like him."

On Friday, December 28, 2001, three weeks after his party, Waksal paced his office as he waited to hear from the F.D.A. Despite misgivings by some analysts, he was confident that the agency would green-light his drug and that Erbitux would be on the market by this spring. He glanced out the window. As dusk settled over Lower Manhattan, the hole in the skyline where the World Trade Center towers once had stood began to fill with a harsh white glow from the giant work lights at Ground Zero. At 7:14 P.M., after the market closed for the weekend, the fax machine buzzed and began churning out a nine-page letter informing him that the F.D.A. had made a highly unusual decision: ImClone's application for Erbitux was so badly flawed, the letter said, that the agency refused even to consider it.

"I was in shock," Waksal told me a few days later. He was dressed in a dark-blue suit, his face looked drawn, and his slender frame was folded into a chair. We were sitting in an ImClone conference room, where a cabinet holds some of his collect-

ibles—ancient Jewish coins, Roman oil lamps, baseballs signed by Willie Mays and Ted Williams, and a crystal pyramid inscribed "Who Dares Wins," the motto of the British Special Air Service. "I was very disappointed," he said.

Waksal scrambled to control the damage. In a conference call with investors and journalists early on Monday, December 31, he downplayed the F.D.A.'s response, insisting that there is no question that Erbitux is safe and effective. He said that the agency's concerns were mostly about ImClone's "train of documentation." He said he could supply the missing information, and predicted that Erbitux would be approved by the third quarter of this year. At one point he explained it to me by using a typically homespun analogy: "It was a question of showing the work. We were like the kid who writes down the answers to his math equations but doesn't show how he got them. The F.D.A. wants to see the work. So now we're working with Bristol to fix it." But that morning the market was not reassured, and when it opened, ImClone's stock fell 19 percent.

Four days later the news grew dramatically worse when *The Cancer Letter*, an industry newsletter, leaked excerpts from the F.D.A.'s confidential refusal-to-file letter, indicating that ImClone's problems were far more serious than Waksal had acknowledged. Not only was ImClone's application "scientifically incomplete" and filled with "deficiencies," but the pivotal clinical drug trial was not "adequate and well controlled"—something, the letter revealed, that the F.D.A. had repeatedly warned ImClone about in a series of meetings, letters, and phone calls since August 2000. In January, after serving for only two months, Pete Peterson resigned from the board.

The rash of newspaper reports that appeared did not neglect to mention the very timely sale the Waksal brothers had made of their shares. Last July, Sam borrowed \$18.2 million and Harlan borrowed \$15.7 million from ImClone in order to acquire 4.2 million more shares of the company's stock. Shares in ImClone were trading at about \$45 at the time, but the Waksals, along with other insiders, bought their shares from the company at a steep discount for about \$8. After the Bristol-Myers deal, ImClone executives sold their shares to Bristol-Myers for \$70, a sharp premium; the Waksal brothers' net totaled some \$111 million. Had the shares been sold after the F.D.A.'s rejection, they would have been worth far less. Did the Waksals know something that their shareholders and Bristol-Myers did not? "The timing [of the F.D.A.'s rejection]

tion] is unfortunate but not something I could foresee," Harlan told *The Wall Street Journal*.

In February, Peter R. Dolan, the 46-year-old C.E.O. of Bristol-Myers—which had already paid ImClone a nonrefundable \$1.2 billion—threatened to cancel the deal and withhold the remaining \$800 million step payment. Most extraordinarily, Dolan demanded that the Waksal brothers step down from ImClone until Erbitux received the F.D.A.'s marketing approval, and that they allow Bristol-Myers to take control of the development of Erbitux. The ImClone board rebuffed Dolan's demands, and a standoff ensued.

Then, also in February, it was discovered in a document released by the Securi-

ImClone officials defraud their investors and Bristol-Myers? Did they engage in insider trading?

Enraged shareholders filed two dozen class-action lawsuits seeking hundreds of millions in damages from ImClone and its officers. They alleged that the Waksal brothers gave "false and misleading" statements about the drug's prospects for F.D.A. approval. More recently investors have filed a lawsuit accusing Bristol-Myers Squibb of allowing ImClone to mislead them about Erbitux's status.

At an important industry conference in San Francisco in early January, Waksal struggled through his presentation and, in a hoarse voice, admitted, "We screwed up." That accurately summarizes the view of

Oncology-industry insiders were also mystified by ImClone's blunder. "Sam Waksal says, 'We screwed up.' But the shareholders' suits paint the ImClone guys as 'the Producers,'" says Paul Goldberg, editor of *The Cancer Letter*. "Where's the truth here? That's the \$2 billion question."

In a rush of contrition Waksal has hired a crisis-management firm, Abernathy MacGregor; he has reimbursed ImClone \$486,051 he made on sales of company stock last year, and has engaged in vigorous dialogues with the F.D.A. and his irate partners at Bristol-Myers Squibb.

As for the criticism about the timing of his financial transactions last July, Sam, like his brother, maintains that no



"We were like the kid who writes down the answers to his equations but doesn't show how he got them."

PRESSING THE FLESH Waksal in a festive mood, with friend Terry Cahan on his left, at Sam's annual holiday party, December 1999; with Patricia Duff and Jason Pomerantz at Thom on July 18, 2001; with Mick Jagger at Waksal's home in New York City, December 6, 2001; with Martha and Alexis Stewart, back when Alexis and Sam were an item, at the winter armory antiques show, New York City, 1990.

ties and Exchange Commission (S.E.C.) that Sam Waksal's youngest daughter, Aliza, a 28-year-old actress, sold nearly 40,000 shares of ImClone—worth almost \$2.5 million—on December 27, the day before the F.D.A.'s rejection of the Erbitux application. Angered by Waksal's refusal to voluntarily supply financial records, investigators have demanded that he appear before Congress to detail his family's ImClone stock transactions.

Today three federal bodies—the House Committee on Energy and Commerce (which is also investigating Enron), the S.E.C., and the Department of Justice—are investigating ImClone's business practices. It is an ominous development at a time when the nation is wary of Enronesque malfeasance. The government is pursuing two central lines of questioning: Did

cancer patients who have been waiting to receive the drug.

"It was a huge blow," says Addison Woods, a 50-year-old software salesman from Houston who has colon cancer. "Our expectations had been built up that Erbitux would be available early this year. I thought of it as my magic bullet, and had gotten physically and mentally prepared to take this drug. Now I have to find another treatment to save my life."

Vee Kumar, a 47-year-old school psychologist from Kirkland, Washington, who also has colon cancer, says, "There is no excuse for raising patients' hopes and then not delivering. There's been a lot of talk about ImClone's monetary rewards from Erbitux, but not enough about getting it to the patients who need it. They really ought to have done their homework better."

one at ImClone had any foreknowledge of the F.D.A.'s decision.

He says he plans to donate to charity and invest in biotech and health-care startups. "Has anybody ever said to Bill Gates, 'Gee, you've made a lot of money on the company you built—that's really terrible!'"

By March, ImClone had reached an understanding with its partner: the Waksals would keep their jobs; Bristol-Myers would reduce its payments by \$100 million and gain more control of the drug's development. And the share price was starting to rise again. Still, the cloud of the lawsuits and investigations hovers on the horizon and the repercussions are potentially far-reaching. As a result of Bristol-Myers's botched handling of Erbitux and an experimental hypertension drug, Vanlev, the com-

pany's stock price has hit a five-year low and C.E.O. Dolan is on the hot seat.

Those who know Sam Waksal well are sympathetic to him following his sudden fall from grace, if not entirely surprised. "Sam is brilliant, relentless, and charming. He sweeps you up into his dream," observes Elena Castaneda, a friend and former girlfriend. "But he never thinks about the downside—which is his flaw, but also his asset. Without that, he wouldn't have gotten this far. He built ImClone from nothing! But he can't say 'No.' He wants to please everyone, and by doing that he hurts many people."

As I spoke to those who have known Waksal over the years—a wide range of people from very different walks of life—the stories began to show a pattern: he launches into an endeavor with great hope, but then something goes wrong; the project often ends in confusion, bruised feelings, or acrimonious lawsuits. Indeed, the corporate ethos of ImClone seems to have been determined to an unusual degree by the supremely optimistic, risk-taking personality of its C.E.O.

Sam Waksal put Erbitux on the map. The question now is whether his impatient ambition has put a potentially revolutionary drug in jeopardy. "Who fucked up? That's what you want to know," Wak-

sal asked rhetorically last January, when he was still talking to me—before his advisers muzzled him. After a long critique of the Independent Response Assessment Committee (IRAC), which reviewed the Erbitux data, and a lecture on the workings of the F.D.A. bureaucracy, he answered his own question: "It was our fault."

Last winter I spoke to Waksal more than half a dozen times; I interviewed him in his large, disheveled corner office; I watched him charm a roomful of biotech analysts at New York's Plaza hotel; I ran into him at one of the heavy-duty A-list Upper East Side parties he attends each week; I also had numerous phone conversations with him. A lean, balding man with roaming eyes and a quick smile he uses to great effect, he was gracious and entertaining. Unusually, he can quote Davy Crockett, Camus, and his mother all in the same conversation. And though he's not an oncologist (or even a medical doctor, for that matter; he's got a Ph.D. in immunology), Waksal speaks with fluid enthusiasm about the world of cancer research, translating complex scientific language into layman's terms and dramatic visualizations.

"Look," he once exclaimed, jumping up from his chair to flick off the lights. "That's

pretty much how Erbitux turns off the E.G.F. [epidermal growth factor] receptor."

Then he led me on a whirlwind tour of the ImClone office and lab, located on two floors of a former shoe factory in New York's Tribeca. (The company has a manufacturing facility in New Jersey.) Striding down hallways and through laboratories, introducing me to scientists, lawyers, and secretaries as he went, he suddenly pulled open a door and led me into an antiseptic air-conditioned room filled with cages. "This is where we keep the lab mice," he said conspiratorially. "We're not supposed to be in here without protective footwear, but c'mon, take a peek. Pretty neat, huh?" Later, he regaled me with stories—about the night Sean Connery, Dustin Hoffman, and Matthew Broderick had been here shooting the movie *Family Business* with his friend the director Sidney Lumet; about buying a meal for Joe DiMaggio in return for his signature; about watching the World Trade Center towers collapse from his office.

After moving to Manhattan from Boston in 1982, Waksal, now 54 (publicly, he maintains he is 52) and the divorced father of two grown daughters (Elana, 29, a former New York City Council candidate, and Aliza), set out to create a name for himself in the world of biotech. "I'm not

your run-of-the-mill scientist," he concedes with a grin. "My interests are eclectic. I think about doing lots of different things—creative, important things."

For years he determinedly put the pieces together, one by one—parlaying one connection into another in the intertwined scientific, financial, and social circles that count. He dated high-profile women such as Martha Stewart's daughter, Alexis (Martha too, according to the *New York Post*, although both the Stewarts and Waksal deny it), and the socialite Patricia Duff. Alexis Stewart, 36, says, "I learned a lot about science from Sam. He's a great teacher." She laughs when recalling the time the Waksal brothers took her and Harlan's wife, Carol, on a rented sailboat in the Bahamas, "cockroaches and all." She is scared of the water, she says, "and they didn't make me feel that comfortable. They say they can sail, but ... luckily we didn't hit any storms. We had a good time. ... My favorite thing about Sam is you can ask him anything, and even if he doesn't know the answer, he'll give you a great answer and make you feel really comfortable. For a long time you'll be totally thrilled. I don't think he's usually wrong."

Waksal's interests range from reading philosophy and attending the ballet to playing poker with men such as Triarc C.E.O. Nelson Peltz, newspaper publisher James Finkelstein, and financier Carl Icahn. In the summer he shuttles in fancy cars (he's a notoriously absentminded driver) between his 7,000-square-foot SoHo loft and his house in the Hamptons. His friends, he'll tell you, range from the British actor Terence Stamp to U.S. Supreme Court justice Antonin Scalia.

Raised in Toledo, Ohio, the son of Holocaust survivors from Poland, Waksal invariably cites his background as the reason for his driving ambition "to do positive things for mankind." Indeed, in discussing his parents' struggles he paints a picture of tragedy and heroism. His mother, Sabina, he says, watched her mother being dragged away to the gas chambers at Auschwitz. His father, Jack Waksal, witnessed the Germans shooting his three-year-old sister through the head and fought in the Polish Resistance; during the day Waksal would hide next to a corpse in a crypt, Sam tells me, and at night he would sneak out of the cemetery to steal food and fight the Nazis. In Ohio, Jack ran a scrap-metal business.

"My father was an incredible hero," Waksal says. "I feel there is nothing I could ever do that could match the things he did. ... The way my parents survived affects every day of my life."

When you ask people about Waksal, virtually everyone cites his intelligence and charisma. Friends insist that any doubts about his integrity are simply the result of the fact that Waksal is a loud, flamboyant personality making waves in the conservative and competitive world of medicine.

"I've invested in ImClone since the beginning," says Martha Stewart. "I was almost Sam's mother-in-law! He dated my daughter, Alexis, for a very long time—until my daughter threw him away. ... Even though people complain that Sam's wacky, and that he runs around, his attention to the real fundamentals of research and science are there. We've always kept our ImClone stock and profited handsomely from it. ... My driver bought a house in Connecticut on ImClone."

At the same time, others say that Waksal habitually overextends himself. "Sam is not a bad person," says Elena Castaneda. "He never intentionally goes into something trying to burn or hurt someone. He

In early January, Waksal struggled through his presentation and admitted, "We screwed up."

believes what he tells you, and in his head it's done already. But getting it executed—that doesn't always happen."

Sometimes he simply stretches himself too thin: in 1993, Waksal's friend the venture capitalist Charles Antell sued him in order to recoup a \$100,000 loan. An \$85,000 check Waksal wrote to partially repay the debt bounced. With the check, Waksal had sent a personal note to Antell, saying, "Thanks for being such a good friend. I do not deserve it I know." Antell eventually recouped most of the loan.

"Sam is a very clever guy, but he's a nebbish—a nerd—whose desperation to be part of the fast crowd is so obvious that people joke about it," notes an old friend. "He is prepared to do whatever it takes, at whatever cost, to become 'a player.' From the moment I met him I felt he was going to trip himself up by trying to be something he isn't."

At times, Waksal's extra-scientific business ventures have turned into costly distractions. He has invested in movies such as *The Last Party* (starring Robert Downey Jr.); restaurants such as the ill-fated Sam's in Midtown Manhattan (with Stephen

Crisman, Mariel Hemingway's husband); Manhattan real estate; the downtown style magazine *Nylon*; and a dot-com venture, *ibeautey.com* (an on-line beauty-products site).

Last August, just days before the Bristol-Myers deal was signed, Waksal was sued again—to the tune of \$57.4 million this time, for fraud and "extreme emotional distress"—by Gabriella Forte, the notoriously energetic former top executive at Giorgio Armani and Calvin Klein, Inc., now the president of Dolce & Gabbana USA. According to the suit, Waksal recruited her as C.E.O. of *ibeautey.com*, where he was chairman and chief stockholder. Forte claims that he lied to her about *ibeautey's* financial state and didn't pay her at a time when her husband was suffering from cancer and heart disease. "Gabriella quit *ibeautey*. She wasn't fired," Waksal says. And in March, James Neal Jr., the former C.F.O. of Scientia Health Group, a small biotech company that operates from ImClone's offices, sued Waksal for fraud, charging him with "illegal and unethical conduct."

Waksal's overreaching started early—in his 20s, when he was at Stanford University School of Medicine, working in the lab of Dr. Leonard Herzenberg, a noted genetics expert.

"Waksal was a very bright guy, a charmer, but not completely straightforward," recalls Herzenberg. In 1974, Waksal claimed to be in possession of some rare antibodies. Herzenberg didn't believe him. "[Waksal] became a 'big man' in the laboratory by saying he had these antibodies that we weren't able to get. But when a postdoc [post-doctoral fellow] used them in an experiment, the results weren't right. Then one day we found his test tubes—and his only—spilled in the bottom of the lab fridge," which destroyed the evidence. "So I called the supposed source of the antibodies at Sloan-Kettering, and he had not given them to Sam. ... I don't know what he had in those test tubes. When I confronted him, Sam insisted they were real. A few years later he called my wife, admitted he hadn't told the truth, and apologized," Herzenberg says. He remains nonplussed. "Why would someone so brilliant lie?" (Waksal declined requests for comment.)

From 1977 to 1982, while Waksal was assistant professor of pathology at the Tufts Cancer Center in Boston, the eccentric behavior reportedly continued. Former colleagues recall Waksal as an "unusual" character. Odd people, they say, would call Waksal's extension at all hours—they included bill collectors, Waksal's irate ex-wife, Cindy, and "slimy characters"—until co-workers disconnected his line. He surrounded himself with a coterie of attrac-

tive lab technicians—"The profile was tall, legs-legs-legs, dark hair," says a former colleague—known around the Center as the Disco Techs. His lab appeared dark and unused much of the time, and people who were clearly not scientists dropped by late at night. "It was kind of scary," says a source. A rumor sprang up that Waksal was somehow involved with cocaine, although no one ever saw him with the drug. "The joke was that the only piece of equipment used in his lab was the balance," says a person who worked nearby.

The joke suddenly gained credence on February 14, 1981. At nine o'clock that evening two undercover sheriff's deputies noticed Harlan Waksal, then a 27-year-old Tufts medical student, in the Delta ticket area of Fort Lauderdale International Airport. Harlan—who today is 49, looks like a more robust version of Sam, and lives in a genteel New Jersey suburb

ron's reports that at least two potential institutional investors shied away from ImClone because of the incident. And a surprising number of people mentioned it to me, unbidden.

There is a postscript to the story: after hearing of his brother's arrest, Sam allegedly put on Harlan's lab coat and did his brother's medical rounds at Tufts. "It's a great story, but silly," Sam says, a vein in his forehead throbbing. "I have my own coat, thank you. I did not leave [Tufts] because I did rounds for my brother. It would've been a nice thing for me to do, but I didn't. He's my brother and a jewel of a human being. It's not something I think should be brought up 21-plus years later."

Speaking to *Barron's*, however, he answered the same question differently. When asked about impersonating Harlan, he said, "There was a patient of Harlan's who ... only spoke Yiddish. And Harlan, when

tor of the immunology division in the department of pathology at New York's Mount Sinai School of Medicine. This was a prestigious post, but Waksal left after only three years. Again there are many rumors about why—one being that he misrepresented data—and again he denies there was a problem.

"There were people at Mount Sinai that I had some big fights with. [They] hate me. I, at times, am arrogant and abrasive," he told *Barron's*.

"I don't think anybody *hated* him," says Dr. Stave Kohtz, who worked as Waksal's graduate assistant at Mount Sinai in the early 1980s and is now an associate professor in the department of pathology. "I just think he was not appropriate for the position. There were certainly a lot of heated arguments, but that wasn't un-



"Has anybody ever said to Bill Gates, 'Gee, you've made a lot of money on the company—that's really terrible!'?"

Doctor indicted after drug charge dropped locally

By Ott Celkin
Staff Writer

FORT LAUDERDALE — A Boston physician was reportedly indicted by a federal grand jury yesterday on drug charges previously rejected by the Broward State Attorney's Office. Why state prosecutors dropped charges against Dr. Harlan W. Waksal, 27, resident physician at Tufts New England Medical Center, isn't clear, but the same set of circumstances was apparently sufficient for the federal panel.

TWO OF A KIND Harlan Waksal, left, and his brother, Sam, in an ImClone lab, New York City, June 19, 2001; August 27, 1981, clipping from the Fort Lauderdale *Sun Sentinel* reporting the indictment of Harlan Waksal, which charged him with possession of cocaine with intent to distribute.

with his wife and two children—appeared nervous. He had used cash to purchase a one-way ticket to Boston and did not check any luggage. The police felt that he fit a "drug-courier profile," took him to a storage room, and searched him. Stashed in Harlan's underwear, bag, and coat pocket was a kilo of cocaine.

When I asked Sam about this incident his face turned red and he replied, "This is a very difficult subject, one that I prefer not talking about. It's a matter of public record. Harlan was never finally convicted of anything. He had an unfortunate incident when he was very, very young."

After being sentenced to nine years in prison for possession of cocaine with intent to distribute, Harlan appealed; in 1983 his conviction was overturned on the grounds that "the search resulted from an illegal seizure without a valid consent."

The case was never re-tried, and Harlan served no time. He wasn't compelled by the S.E.C. to disclose the incident when ImClone went public in 1991. Nevertheless, the episode has shadowed the brothers ever since. A 1993 article in *Bar-*

he wasn't in town at one point, wanted me to go talk to her. ... So I went and talked to her. That was the scope of it." When I asked about the discrepancy, he looked away and said, "Umm, I might've gone to visit an older Jewish woman. But not as Harlan. As Sam." In an icy voice he added, "I think she would've known the difference if she was his patient."

I was never able to speak to Harlan Waksal. He canceled three interviews and refused to return my phone calls. When *Barron's* asked Harlan about the drug bust, he maintained that he hadn't used drugs then or since, and that that was the only time he'd ever transported drugs: "It was a dramatic mistake in judgment. I did it as a favor for someone, and it's a favor I have obviously regretted."

Sam Waksal believes his detractors bring up the story out of envy: he's successful, so they want to knock him down. This rationale has popped up before. In 1982, in his last job before starting ImClone, Waksal was named associate professor of pathology and direc-

usual. ... Sam is very smart, but he didn't fit the stereotype of a rigorous, conservative 'bench' scientist. ... At the time, Sam told me that Dr. [Jerome] Kleinerman [who headed the department and is now deceased] called him into his office and said he loved Sam like a son, but couldn't keep him there. Sam was very upset. I think it was a bad fit, rather than bad faith."

"It wasn't a bad fit," Waksal snaps. "When I left Mount Sinai I was going on sabbatical. I was founding ImClone at the time." When I ask him to explain the pattern of his career, he shrugs and says, "I do lots of things in ways that academic centers don't always love to do. ... Life has ups and downs."

Dr. Kohtz hasn't seen Waksal in years, but he says, "I've spent many hours thinking about Sam. ... He affects everybody he comes in contact with. Some people just disapprove of him. I admire him, in a sense, although I couldn't be him. Most people facing what he's faced would have a huge therapy bill, but Sam comes out of it with the biggest biotech deal in history. ... He's certainly unique. He's got some-

thing that you can learn from him—I'm just not sure what it is."

"I've never been driven to therapy by issues—that's a great luxury that most people outside of New York's Upper East Side don't have," Waksal says defiantly. "When one hits a roadblock, one's job is to correct things and succeed."

How did Waksal continue to fail upward all these years? Waksal-ologists point to the series of influential mentors he has cultivated. A partial list of these father figures includes, along with Herzenberg and Kleinerman: Dr. Michael Feldman at the Weizmann Institute of Science in Israel, Dr. Robert Schwartz, formerly of the Tufts Cancer Center, and Dr. Zvi Fuks at Memorial Sloan-Kettering Cancer Center. At ImClone, Waksal's intellectual mentor has been Dr. Mendelsohn and his protector has been the chairman of the board, Robert Goldhammer. But perhaps Waksal's most significant backer has been his longtime poker companion and tennis partner Carl Icahn.

When things have turned sour for Waksal, some of these men have staunchly defended him. But one of his early champions says, "A number of us recognized that Sam was very smart and articulate. We said, 'If there's any way we can help, you let us know.' We pushed hard to get him into [prestigious positions]. But then we did site visits later; his work never seemed to pan out. I felt betrayed."

Sam and Harlan started ImClone Systems in 1984 with \$4 million in venture capital. Ian Alterman, who worked at ImClone as a legal assistant from 1987 to 1992, recalls it as "a professional, but collegial, place to work." He didn't have to wear a tie, and the atmosphere was familial—employees were encouraged to wear costumes on Halloween, and Sam would dress as Santa at Christmas. The Waksals, he says, "have great integrity. They truly cared about the work their company was doing."

The company, named for the three fields it hoped to enter—immunology, DNA cloning, and medical-information systems—initially focused on products such as diagnostic kits, gonorrhea vaccines, and AIDS drugs. Despite a few successes ImClone never turned a profit. In 1987 the company's planned I.P.O. was a victim of the stock-market crash, and it was only because Waksal was able to persuade friends and investors to keep the company afloat that ImClone could finally launch its I.P.O., in 1991.

In April 1992, Dr. Zvi Fuks introduced Waksal to Dr. John Mendelsohn over breakfast. Waksal could scarcely believe his good luck when Mendelsohn told him

about a drug—C225, now known as Erbitux—he had developed while researching cancer at U.C. San Diego. Essentially, Mendelsohn explained, that drug "put chewing gum in the lock" to stop tumor growth.

"It was an 'Aha' moment—I got the drug's potential immediately," says Waksal. "We bet the house. But the biologics made such sense [that] it was not a blind bet. It was an intelligent bet. We simply understand the biology better than other people do."

Cancer is so difficult to treat because it is not just one disease: it's an umbrella term

"You can ask Sam anything, and even if he doesn't know, he'll give you a great answer."
—Alexis Stewart



THE ORIGINATOR Dr. John Mendelsohn, who developed Erbitux, at the M. D. Anderson Cancer Center.

for hundreds of similar diseases, each of which is driven by a different set of factors and behaves in different ways in different patients.

The most promising cancer therapies today are so-called targeted treatments, which are based on our increasingly sophisticated understanding of diseased cells. Small numbers of E.G.F. receptors exist on the surface of normal cells, but cancerous cells can have a million or more receptors. E.G.F. binds to its receptors on the surface of a cell and then sets off

a chain reaction of enzymes inside the cell that keeps the tumor nourished: the cell "auto-stimulates" and grows rapidly. In the early 80s, Mendelsohn knew that E.G.F. receptors are found in a third of all solid tumors; he surmised that blocking the E.G.F. receptor would stop the tumor from growing. He spent a decade developing C225, which blocked tumor growth in cells.

His work had generated excitement in the scientific community, but the financial community was another matter. Despite grants from the National Cancer Institute and the National Institutes of Health, funding was scarce. By 1984, Mendelsohn had used C225 to stop the growth of human tumors transplanted into mice. In the mid-1980s he was working at Sloan-Kettering and looking for funding in order to turn the mouse antibody into one with human protein. U.C. San Diego owned the license to C225, but did nothing to attract a licensee, and Mendelsohn says he "wanted to do the research and let someone else raise the money."

Enter Sam Waksal.

Although the Waksal brothers had no clinical experience, no manufacturing capability, and very little money, they decided to aim for the skies with C225. For a nominal processing fee, U.C.S.D. gave ImClone permission to convert the mouse antibody into a mostly human antibody in the lab. Then the Waksals bought a bankrupt computer-chip manufacturing plant in Somerville, New Jersey, and turned it into a biologic-drug production facility. But in the early 90s the biotech market collapsed: ImClone pink-slipped a third of its workforce, and others left; a skeleton crew of 50 kept the place going. "We were completely out of money," Waksal recalls. To avoid bankruptcy ImClone sold its stake in the Cadus Pharmaceutical Corporation to Carl Icahn for \$6 million. They poured the money into full-scale development of Erbitux.

To help finance the costly process of bringing a drug to market—it often takes a decade and anywhere from a \$300 to an \$800 million investment to prove a drug's effectiveness—many fledgling biotech companies partner with a larger pharmaceutical company. This helps them to survive, but also limits the profits the principals can bank. The Waksal brothers, however, made the unusual decision to go it alone, claiming ImClone would be one of the first biotech companies in history to take a product from the laboratory to commercial launch without teaming up with a partner. It was an audacious move, and it meant that ImClone would have to shepherd Erbitux through the exacting F.D.A. approval process on its own—something the company had never

done with any other drug. (Waksal says Bristol signed the deal too late to be involved in ImClone's application to the F.D.A.)

May 19, 1995, was the turning point for ImClone. On that day Dr. Mendelsohn presented his C225 data to the annual meeting of the American Society of Clinical Oncology, the world's largest gathering of cancer researchers. "Our stock started going up the next day," Waksal says. "The oncologists started buying it." Major pharmaceutical companies began sniffing around for a deal.

ImClone didn't really hit it big, however, until Shannon Kellum's survival story made headlines.

In April 1998, Kellum, a fresh-faced 28-year-old Florida state tax auditor, was diagnosed with colon cancer. Her colon was

plained that C225 had been tested only on patients with head and neck cancer; if Kellum was granted special "compassionate use" permission by ImClone and the F.D.A., she would become the first to use the drug for colon cancer. Was she willing to try it?

"I really didn't have any choice," recalls Kellum. "If the tumors got any bigger they were going to take over my liver. At that point I was willing to eat or drink anything to [save myself]. So I became the guinea pig."

Unlike chemotherapy's shotgun blast, which kills both healthy and cancerous cells and causes terrible nausea, Erbitux acts like a sniper shot aimed precisely at the growth signal in malignant tumors; one of its few side effects is a mild skin rash. Erbitux is not a cure: it stops tumors from spreading, which is significant because it is a tumor's ability to reproduce and metastasize throughout the body that kills. By stopping cancer growth, Erbitux allows other kinds of therapy to shrink or destroy the tumors. Used in conjunction with chemotherapy, it may prove to be highly effective against colon cancer, the nation's second-most-deadly form of cancer.

"When you are [facing death], even a few more months, or even days, of life makes a huge difference," Kellum says.

Granted permission to take Erbitux, Kellum became the first person with metastatic (spreading) colon cancer to use the drug. Beginning in April of 1999, it was ad-

Because of her remarkable response to the drug, Erbitux suddenly caught the attention of the legions of colon-cancer patients who have few therapy options. In May 2000 her story was featured in *USA Today*, and on *Good Morning America*. Within hours of these reports, ImClone employees and even friends of friends of the Waksals' found themselves bombarded with requests from cancer patients around the country desperate to try the "miraculous" but still experimental drug. Between May 2000 and February 2001, Waksal says, ImClone received more than 10,000 requests for "compassionate use" of C225. President Clinton reportedly intervened on behalf of a patient, who got the drug. Many others, however, did not.

In May 2001, CBS's *60 Minutes* aired a story on the debate. The show featured two women, 51-year-old Ruth-Ann Santino and 36-year-old Amy Cohen, both of whom were mothers with colon cancer, "begging for their lives." Despite months of effort, Santino was unable to get the drug and died. Cohen, however, managed to reach Sam Waksal on the phone very early one morning, persuaded him to give her C225 on a compassionate-use basis, and survived. She credits the phone call with causing him to see her as "a real live person" and not "just a patient."

Overwhelmed with requests for the drug, ImClone no longer gives out Erbitux on a compassionate-use basis—a decision that worries and angers patients. Last June, at a congressional hearing chaired by U.S. representative Dan Burton (Republican, Indiana), Kellum testified in favor of allowing more cancer patients access to Erbitux. She recalls, "One person recently lost his wife. Another lost his daughter. A gentleman spoke of his 16-year-old son who was dying. It was very, very emotional. I didn't cry, but I felt a little guilty. They all lost someone and I was still alive." Yet she remains frustrated: "I made a big effort. I got up there and testified for four hours, but nothing's changed. I'm spinning my wheels."

Kellum, now 32 and married, has had part of her liver and both ovaries removed in cancer surgeries. Recently, Dr. Rubin told her he'd found a new tumor on her spine. She is one of the lucky ones; she continues to use Erbitux and tries to remain upbeat, but says she feels "very, very nervous." The drug, she says, "is keeping me alive. I need it. And there are a lot of other very sick people out there waiting for it, too. Some of them have died waiting. This is their last hope. Now their hope is going to fly out the window. It's very disheartening. I don't know who to blame: The F.D.A.? ImClone? We've got Erbitux sitting right in front of us, but if we can't use it, what good can it do?"

On the morning of September 11, 2001,



"From the moment I met Sam I felt he was going to trip himself up by trying to be something he isn't," says an old friend.

THE SURVIVOR Shannon Kellum and her oncologist, Dr. Mark Rubin, standing outside his clinic in Bonita Springs, near Naples, Florida, January 2002.

surgically resected, but over the next year her condition worsened. "I tried every kind of chemotherapy available," she recalls, "but nothing even fazed the tumor." Twelve months after her initial diagnosis, the tumors had spread to her abdomen and had grown "as big as grapefruits," she says—too big to be removed surgically. She was "out of options," and facing death.

Then her oncologist, Dr. Mark Rubin, suggested that Kellum might be eligible to try an experimental treatment known as C225. (Rubin had once worked with Dr. Mendelsohn at Sloan-Kettering.) Rubin ex-

ministered intravenously once a week along with irinotecan, the chemotherapy that had previously failed to help her. The results were astounding: within a month Kellum's tumors had shrunk by 50 percent; by September the tumors had shrunk 80 percent. In December, surgeons were able to remove two tumors completely.

"I call Erbitux my 'miracle drug,'" Kellum says. "It has given me a lot more years of life than I expected. I am very, very fortunate. If Dr. Rubin hadn't [had the foresight to use Erbitux], you wouldn't be talking to me right now."

the Waksals gathered their top executives to announce a \$2 billion deal with Bristol-Myers Squibb, once the world's leading maker of oncology drugs. But just before nine that morning terrorists attacked the World Trade Center, and the announcement was canceled. "People were dying just a few blocks away. I couldn't focus on this," Waksal recalls. "But the next day we decided that it was important to continue our work. We're supposed to make the world better. To not come in to work allows evil to win. I'm a child of survivors. What did people do as they walked out of a concentration camp? I'm watching people jumping out of the World Trade Center. Sartre said, 'Life begins on the other side of despair.' I have always believed that. Our job is to move forward."

The deal was theoretically great for both partners. Bristol-Myers no longer controlled the patent for its key oncology drug, Taxol, and its own drug pipeline was running dry; the deal with ImClone allows it to receive 39 percent of the profits on Erbitux sales in North America and to stay ahead of the competition. ImClone benefits from Bristol-Myers's financial muscle and its enormous sales force. The pharmaceutical company paid \$1.2 billion for 19.9 percent of ImClone and for the right to sell Erbitux. Had the F.D.A. accepted the drug's application, ImClone would have received another \$300 million, and full F.D.A. approval would have brought a further \$500 million.

On September 19, the agreement with Bristol was finally signed. "When you spend so long working against the established paradigm, then the vindication feels good," Waksal told me. But the elation would prove short-lived.

"After the Bristol-Myers deal, Sam was God for a while," says Elena Castaneda. "We all felt happy for him—he'd finally made it. But when you're at the top, there's only one place to go: down."

At the core of the F.D.A.'s rejection of the Erbitux application is the fact that the clinical trials were not constructed in a way that shows the drug is an effective weapon against cancer on its own. In other words, no one really knows if Erbitux works.

In February, *The Cancer Letter* obtained a copy of the confidential protocol on which the Erbitux clinical trials were based, and which was written by someone at ImClone, and had three prominent, independent cancer-trial experts review it. The experts agreed that it was vague and slipshod. It "generates far more questions than it could ever answer," one wrote.

"You couldn't design a worse protocol if you tried," says Paul Goldberg, *The Cancer Letter's* puckish editor. "You don't know

who's in the trial, and you don't know which drug does what."

Critics such as shareholder Ira Gaines, who filed a lawsuit claiming Bristol-Myers "knew all along" that ImClone's application to the F.D.A. was flawed, have charged that Bristol-Myers failed to exercise due diligence with regard to ImClone, the Waksals, and Erbitux before signing the landmark \$2 billion deal last fall. In January, Richard J. Lane, the president of Bristol's worldwide medicines group, told *BusinessWeek*, "The company remains confident about the future of Erbitux. There is no doubt it works." Nonetheless, Bristol was forced to take a \$735 million write-down of its ImClone investment in January, and in April, Lane was forced out of the company.

Last December, when I asked Brian Markison, Bristol's president of oncology and virology, about the company's due diligence, he replied, "We approached [ImClone] two years ago, looked through

**Says Martha Stewart,
"We've profited
handsomely. My driver
bought a house in
Connecticut."**

the information, and decided to let it wait. As the data matured, we went back to them at the beginning of summer. We [did an] extraordinarily rigorous review of every piece of information: lab data, X-ray scans, the toxicity—every single thing." Bristol officials have not returned subsequent calls.

On February 15, Waksal's old backstop, the corporate raider Carl Icahn, announced his intention to buy up to \$500 million in ImClone stock—nearly 40 percent of the company. For ImClone it was a welcome endorsement, yet the company quickly installed a "poison pill" anti-takeover defense. The move, which would dilute the company's outstanding shares if any investor were to buy more than a 15 percent stake, may have been aimed at Icahn, or at Bristol-Myers. Since his announcement, however, Icahn has not actually purchased a large stake in the company. While he has reportedly had a change of heart about ImClone, Icahn's true intentions are a mystery. Some speculate that he is sending mixed messages as part of an elaborate arbitrage.

At the end of February—after a meeting in Washington, D.C., among ImClone, Bristol-Myers, and the F.D.A.—investors sent ImClone shares shooting up 32 percent on hopes that the F.D.A. might accept a new Erbitux application this year. A new application would have to contain more data from ImClone's completed clinical trial, plus data from a 225-patient clinical trial being performed by Merck KGaA, ImClone's European partner (no relation to the American Merck). If the F.D.A. were to accept the new application, which is far from certain, Erbitux could reach the market sometime in the next 18 months—later than Waksal had initially promised, but a lot earlier than if a new round of clinical trials is required.

Robert L. Erwin, a patient advocate for the Marti Nelson Cancer Research Foundation (he is also C.E.O. of a biotech company), attended the meeting and says, "Both the F.D.A. and ImClone seemed to be working together in a constructive, not hostile, way to move Erbitux along. The Waksals admitted that mistakes had been made, but they committed to correct them. When the F.D.A. saw that attitude, they got specific about what needs to be done. The encouraging news is that it looks as if the drug will be available sooner than I [previously] thought."

Finally, in early March, ImClone and Bristol-Myers announced a thaw in their Cold War. Andrew Bodnar—a Bristol-Myers senior V.P. who is on ImClone's board—would lead the effort to shepherd Erbitux through the F.D.A.'s approval process. Further, the new agreement caps royalty payments at 39 percent, delays Bristol's milestone payments to ImClone, and cuts them by \$100 million. Wall Street generally viewed the announcement as a compromise that would benefit both sides, and a sign that the partnership is on the mend. But the damage may have already been done. In April, Bristol chairman and C.E.O. Peter Dolan shocked Wall Street when he acknowledged that the company's sales and earnings were dramatically off track. In addition to the ImClone debacle, he is facing an empty pipeline for new products, a clogged inventory of existing treatments, and increased competition from generic-drug makers. Bristol's earnings for the year are expected to fall as much as 30 percent, a development analysts call an utter disaster. Indeed, some predict that Bristol, the world's fifth-largest drugmaker, is ripe for a takeover.

The importance of targeted treatments such as Erbitux is that they may render cancer a chronic, treatable disease like diabetes. The hope is that one day an oncologist will be able to look at a tumor

and choose a drug specifically designed to shut it down; the patient would take intravenous doses of the drug once a month, perhaps for years.

As with other existing targeted treatments, such as Gleevec (for leukemia) and Herceptin (for breast cancer), Erbitux (for colon, pancreatic, head and neck, and lung cancer) doesn't work for everyone. At a recent health-care conference Harlan Waksal reported that in a 57-patient "single-agent" clinical trial, the response rate for patients using Erbitux without chemotherapy was only 10.5 percent. One participant in a similar trial says that "Erbitux stopped my tumor growth for seven months—and it was really easy to take, with no side effects. But then my tumor started growing again."

Important voices in the medical community believe that Erbitux is an important step forward, and have urged its prompt release. Dr. Leonard Saltz of Sloan-Kettering, who was the lead investigator on the drug's clinical trials, showed that 22.5 percent of his colon-cancer patients—27 people—responded positively to a combination of Erbitux and irinotecan, meaning that their tumors shrank by more than 50 percent. The others died. Nevertheless, this was still the best response rate ever achieved in patients who previously had no hope of survival. "In this setting, [such results] were unheard of," he says. "I'm very positive about the drug. It's not a home run. I look at it as a single, but in an area—colorectal cancer—where we are desperately in need."

Dr. Larry Norton, head of the Division of Solid Tumor Oncology at Sloan-Kettering, and president of the American Society of Clinical Oncology, is also a believer. "Once Erbitux is used in a front-line setting it's going to show much more pronounced activity. That will reassure all the critics. I'd like to see Erbitux's approval as rapidly as possible so that patients will benefit."

While Sam Waksal has sharply curtailed his public pronouncements on ImClone, he has not skipped a beat in his high-profile socializing. "I just saw him the other night," reports a friend. "If I were in his shoes I'd be moving to Minnesota, but he seemed fine." Waksal can be spotted on a regular basis at hip New York restaurants such as Da Silvano, and he continues to host monthly salons at his SoHo loft.

Recently, the author Francine du Plessix Gray, whose book *At Home with the Marquis de Sade: A Life* was nominated for a Pulitzer Prize, gave a talk about the genre of biography to a literary group in Waksal's living room. Waksal introduced her

and handled the Q&A with aplomb. "I [didn't] know him at all, but he was extremely pleasant," she reports. Noting his art collection, especially "extraordinary [Cy] Twomblys and an extraordinary Richard Serra painting," she adds, "He has impeccable taste." Another guest that evening, *Vanity Fair* contributing editor David Margolick, says, "He was obviously feeling the pressure of his situation. He brought it up and even cracked several jokes about it—saying how, because of the torture he was going through, he could relate to the Marquis de Sade. He was funny and charming. He's sardonic."

Some predict Waksal will be vindicated. "Sam's at his best in this kind of [adverse] situation. He'll bounce back," says his friend Elena Castaneda. "He's pulled the rabbit out of the hat before." Bob Erwin, the cancer-patient advocate, says, "The Waksals have devoted so much time and money to this effort that if they were just motivated to get rich, well, there's a lot of faster ways of doing it." And the Waksals' sister, Patti, a Maryland

"Most people would have a huge therapy bill. Sam comes out of it with the biggest biotech deal in history."

antiques dealer, says, "Whatever [negative] spin people want to put on it, my brothers have been doing this for all the right reasons. ImClone has tried very hard to help people."

While that may be true, the ImClone case has been viewed in the dark light of the Enron scandal. The press has made much of the fact that Dr. Mendelsohn—a renowned oncologist with a squeaky-clean reputation—is on the board not only of ImClone (he sold \$6 million worth of stock last October) but also of Enron. "It's a coincidence," he says. Another person caught in the tangle is Charlotte Beers, the former head of Ogilvy & Mather, who is now undersecretary of state for public diplomacy. In 1999 she and Waksal paid \$37.5 million for ibeauty; she has held stock in ImClone, Enron, and Martha Stewart Living Omnimedia Inc. (The last two have been audited by Arthur Andersen.) In a further odd twist, Arnold J. Levine—an award-winning biologist who is an ImClone board member

and also sits on the company's scientific advisory board—abruptly resigned as president of Rockefeller University last February. Levine, 62, says he resigned for health reasons, but his departure was reportedly triggered by a drunken fling with a twentysomething grad student in a campus lounge in January.

A friend worries about how the investigations will affect the Waksal brothers. "Either Harlan will take the fall," she predicts, "or the government will try to turn Harlan and Sam against each other, which could bring the whole company down."

"I don't think the Waksals will be around by the middle of 2003," Morningstar analyst Todd Lebor has said. "Their credibility is shot. When you are dealing with a drug company, trust in management is very important. ImClone is lacking that."

On the evening of January 15, a highly agitated Sam Waksal called me on his cell phone. It was the last time we spoke; indeed, it was one of the last times the usually press-friendly Waksal spoke one-on-one to any journalist.

The day before, the *New York Post* had run a gleeful story about ImClone's predicament—deeming it the "newest scandal to sweep Wall Street" and saying that "Sam has been loitering at the fringes of the New York society crowd for two decades, leaving an oil slick behind him that has been colorful, to say the least." Waksal hotly disputed some of the facts in that story, and complained that he was becoming the target of unfair "slam pieces." His mood swinging from combative to self-pitying, he gave me his version of events.

"Two thousand two was going to be a big year—and it still will be a big year. It just didn't begin the way I thought it would," he said. "The truth is Erbitux works. Yes, there are regulatory hurdles, but there have been for tons of drugs. This will go away. And ImClone will be a very successful company."

With a snort, Waksal dismissed the myriad class-action lawsuits he's facing: "Every time a stock drops in price [the lawyers charge in]—you know that. We have to deal with those. And when our stock goes back up, that will change."

In an earlier conversation Waksal said, "To run a biotech firm you have to be real quick. I liken it to being a scrambling quarterback on a football team. Pharmaceutical companies [can have] a big fullback: you give him the ball, and he'll just keep running. In biotech, if you see you're not going anywhere, you'd better be quick enough to run in the other direction—otherwise you're gone." □