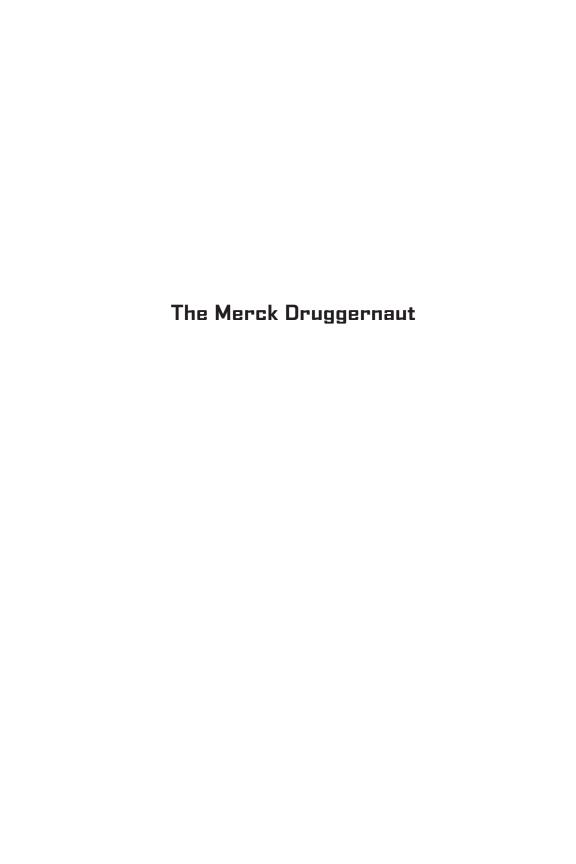
The Merck Druggernaut

The Inside Story of a Pharmaceutical Giant

FRAN HAWTHORNE



John Wiley & Sons, Inc.



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Published by John Wiley & Sons, Inc., Hoboken, New Jersey. Published simultaneously in Canada.

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Library of Congress Cataloging-in-Publication Data

Hawthorne, Fran.

The Merck druggernaut : the inside story of a pharmaceutical giant $\,/\,$ Fran Hawthorne.

p. cm.

Includes bibliographical references.

ISBN 0-471-22878-8

 Merck & Co. 2. Pharmaceutical industry—United States. I. Title. HD9666.9.M4H39 2003 338.7'616151'0973—dc21

2003000567

Printed in the United States of America

10 9 8 7 6 5 4 3 2 1

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Acknowledgments

or all the people who are quoted in an article or book, there are always far more who don't appear by name, but whose assistance seeps through so many of the sentences.

Some of them I can't name even here, even in a mass listing that doesn't connect any names to any specific pieces of information. I can only thank them anonymously—the sales reps, factory workers, clerks, middle managers, and executives who work and have worked at Merck; the doctors; the reps from rival drug companies; the veterans from Madison Avenue; the relocation advisor; the consultants. I know that many of them were nervous about talking to me. They worried that they were revealing the secrets of a very secretive company, or that it might be hard for them to work in the industry if their names were made public, or that outsiders would consider the practices they described unethical. So I want to thank these people especially for being willing to share their information.

Even when it comes to those I can name, it's hard to single out anyone in particular; I feel as though I should cite every one of the 175 or so people I interviewed, because almost every one was so incredibly helpful. But a few definitely need to be mentioned.

- David Goetzl of Advertising Age (my former Crain Communications colleague), who helped me understand the peculiarities of prescription drug advertising.
- Bruce Booth of McKinsey, Don Drakeman of Medarex, and David Perlin of the Public Health Research Institute, who walked me through the process of drug discovery from microorganisms to genomics and patiently answered my elementary questions.
- Boyd Clarke of Neose Technologies, who not only spoke with me in depth about his years at Merck—and again and again over the months after our first interview, as I kept checking in for updates—but also took on the role of booking agent, putting me in contact with new sources every time he ran into another former Merck colleague.
- Guy Fleming of the PACE union, who may not have realized what he was getting into when he showed me around the Rahway plant, and similarly, Larry Naldi, the plant manager. (But what happened took me by surprise, too.)
- My agent, Susan Barry of the Swayne Agency, who made this whole project possible by putting me together with Jeanne Glasser at Wiley, and then calmed me down and

- got me back on track so many times when I thought this would never work.
- My editor at Wiley, Jeanne Glasser, who had the great idea of doing a book on the pharmaceutical industry to begin with, and whose advice was always wiser than I realized at the time.
- My husband, Pete Segal, and my son, Joey Hawthorne, who were there for me even though I was hardly there for them for seven months, plus all the other family members and friends who had to put up with my obsession.
- All the friends and fellow journalists who helped in so many ways, by introducing me to sources, finding obscure clips and data, sharing child care, sharing their investment strategies, and debating the merits of the pharma industry—Jennifer Airley, Marian Baskin, Andrea and Alan Bloomfield, Matthew Boyle, Michael Cacace, Ann Cohen, Elizabeth Cummings and Steven MacBride, Anna Domanowski, Steve Gandel, Jan Koch, Debbie Majerovitz and Wrolf Courtney, Bethany McLean, Michael Peltz, Rebecca Reisner, Faye Rice, Portia Richardson, Mary Sisson, Vera Titunik, Barry Weinbrom, and Craig Winer.
- And everyone who was willing to take a few hours to talk with a complete stranger: Here is the result of your words.

Introduction

called Greg Reaves, one of Merck's top PR people, from the patio of my parents' house in California four days before New Year's Eve of 2001.

Did he remember how I'd told him, at Merck's meeting with Wall Street analysts a couple of weeks ago, that I was working on a big project involving his company? And I'd like to get together and talk about it with him? Well, I continued, the project was that I was writing a book about Merck.

"Do you know where I am now?" he replied, seemingly apropos of nothing. "I'm on the floor."

"You're on the floor in shock because I'm writing a book?"
"No. I'm on the floor trying to fix an electrical connection."

It was classic Merck. On the surface, what a refreshingly different kind of company, so egalitarian, so genuine. Even its suit-and-tie guys get down and dirty and do their own electrical work.

But we were on the phone, for Heaven's sake. I couldn't see what Greg was doing; whether he was truly looking for an

electrical connection was as much a secret as the ingredients in the vials in Merck's labs. He could just be stalling for time while he digested the implications of "book." Still, if he was, it was a pretty clever stall—which, in executing a tough maneuver better than your average company, was also classic Merck.

here was a point during the writing of this book that my publisher and I seriously debated using the subtitle "The Last Good Drug Company." To many people, that might seem like a nonstarter, because for most of the world today, no drug company is considered good. They are greedy Godzillas, they charge impoverished grandmothers outrageous prices for medicines the grandmas can't live without, they spend billions of dollars on commercials to tempt us to buy expensive drugs we don't need, they try to muscle out cheaper generic rivals and keep their own drugs on patent longer than the law allows-all so that they can rake in the highest profits of any industry in America. And much of that litany (with the rhetoric toned down) is basically true. On the other hand, it is also true that these companies, by and large, produce socially beneficial products. They pour billions of dollars and years and years of effort into solid, sometimes groundbreaking research that can result in medicines that genuinely make people's lives better.

Whether the pharmaceutical makers are villains or heroes, Merck has traditionally been seen as a little better than the rest. It is, supposedly, more scientifically pure: It focuses on breakthrough R&D, not frivolous copycat drugs, and it doesn't try to keep generics off the market. It is, supposedly, more community-minded: When it stumbled upon a cure for river blindness, a horrible disease that affects millions of the poorest people in the world, Merck agreed to give the drug away for free. It is, supposedly, more ethical: It was never as extravagant as others in wining and dining doctors in order to get them to prescribe its drugs, and when public outrage built up over what looked suspiciously like quid pro quo's, it was among the first to declare that it would drop the freebies altogether. For a long time, it managed to accomplish all that while also being the biggest and most successful drug company in the world, doing what a business is supposed to do—making money and beating the competition. If you were going to write about the pharmaceutical industry—and as the subject of so much popular anger, it was a hot topic to write about—the obvious company to focus on was Merck. It was the example of what a good drug company could really be. When I first began considering taking on this project in the spring of 2001, Merck was still a star on Wall Street.

By the time the project was under way in late autumn, it wasn't.

Patients taking its newest blockbuster drug seemed to be suffering an unexpected number of heart attacks and other cardiovascular complications. Other blockbusters were facing competition from cheaper generic drugs, and its oncepowerful pipeline of future products was only dribbling. Its earnings didn't meet Wall Street's forecasts. Its stock dropped and dropped. Later, with names like Enron and WorldCom tumbling all around, the "ethical" company even got caught up in its own mini-accounting scandal.

Now this would be a different book, not the last good drug company, but the struggles of a once-shining star.

n the end, this book is a combination of the books it might have been—an inspirational piece about an industry leader, a cautionary tale of a falling star, and something more: a what-if question.

Once upon a time, Merck seemed to prove that nice guys could finish first, that it could be a profitable business and a social service at the same time. Then both aspects fell apart.

"As a scientist, I love them, the idea that you only work on breakthroughs. But the economy has no respect for virtue," says Richard Evans, an analyst with Sanford C. Bernstein & Company, who argues that Merck needs to put more effort into uninnovative but profitable "me-too" drugs.

He may be right. The first priority of a business is to make an honest profit for its shareholders. I don't want to make Merck out to be some kind of crusading charitable foundation. A drug company is not, as Princeton Unviersity economist Uwe Reinhardt puts it, "a Catholic nonprofit hospital."

But the pharmaceutical industry isn't like any other industry. By virtue of what it produces—and the respect it demands for what it produces—it does carry some social service obligations. The public expects drug makers to be more ethical than the proverbial widget makers; prescription drug commercials prompt public outrage in a way that McDonald's ads do not. If the industry is ever to gain the public's trust, more companies will have to behave like the old Merck. In fact, Merck will have to behave like the old Merck.

Because of that—because of what Merck was and could be— I'll give Greg the benefit of the doubt on his electrical work.

In the Bull's-Eye

n a February morning, snow is falling lightly outside Kathy Maglione's fifth-grade classroom in the blue-collar town of Linden, New Jersey, some 10 miles south of Newark. Gianna, Amanda, and Raquel are in close consultation at a table near the back, huddled over a clear plastic funnel and some coffee filters, screen filters, disposable cups, and plastic bags. They are variously pouring gravel, salt, and diatomaceous earth—earth containing the ground-up remains of tiny aquatic organisms—into cups of water; then, they'll try to separate the ingredients again by pouring the mixtures through some kind of filter.

"I don't think the sodium chloride will go through this."

"Well, I don't want to use a coffee filter. The powder will go through it."

"Are you serious? This is grounded-up bones?"

"We're touching people's bones here?"

"The salt won't go through. It's too thick." "It's not people's bones, it's animals."

wo months later and 30 miles away, on an unusually chilly late-April afternoon, a fleet of blue buses ferries several hundred shareholders across the wooded, dandelion-strewn sprawl of Raritan Valley Community College to the 2002 annual meeting of Merck & Co., Inc.

The mood in the purple and burgundy college auditorium is amiable and polite. Most of the questions to Raymond V. Gilmartin, the company's chairman, president, and chief executive officer, are on the order of, Why is my pharmacist always out of Timoptic eyedrops? or, Are you doing any research into obesity? The officially nominated directors are all approved; the unofficial shareholder resolutions are all defeated. Everyone nibbles melon slices and chocolate pastries.

The amiability is tinged with resignation, however. The past six months, for people who own pharmaceutical stocks, have been a long parade of bad news. Patents on numerous key products are expiring—five for Merck alone. Earnings at many companies are flat or falling, and even firms with good numbers are seeing their share prices slide. But it's not just the financials that are nagging at the people in the Raritan Valley auditorium. Every day some government official or consumer group in the United States is questioning something the industry does. Even as Gilmartin is fielding the queries on eyedrops and obesity, the chairman of the Federal Trade Commission is complaining to the Senate Committee

on Commerce, Science and Transportation about the way pharmaceutical companies try to keep less expensive generic drugs off the market. Congress is considering an array of measures that challenge the industry from every angle, measures to allow cheaper drugs to be imported from Canada, to make it harder to block generics, to tighten the rules on clinical testing, to put more restrictions on advertising, and—the granddaddy of them all—to add prescription drugs to Medicare coverage, with the potential that would bring for regulating prices. State politicians, too, are pressuring the industry to lower prices by filing lawsuits and demanding discounts for their Medicaid programs.

Worse news—though the retired Merck scientists and secretaries in the purple auditorium don't know it—is yet to come. Within the next three months, there will be regulatory questions about their company's hot new arthritis drug and accounting questions about its Medco subsidiary, and their stock's value will plummet.

A onetime administrative assistant has stock options that will expire at the end of the year. "I might as well throw them out," she jokes bleakly, staring at herself in the ladies' room mirror.

"It's almost like pin-the-tail-on-the-donkey, which pharmaceutical company you buy," shrugs a former temp worker who lives in one of Merck's hometowns.

Sheldon Schwartz worked at Merck for 14 years in the 1950s and 1960s, rising from mailroom to marketing. Now he does industrial lighting, and he's worried about the implications of some of the news stories he's read. Why does one say Merck is going "back" to basic research? Hasn't Merck

been doing research all along? Why doesn't Merck have more blockbuster drugs ready to replace the ones that are about to go off patent?

He's been going to the company's annual meeting for years. But this time, he says, "it's not the same."

Both these scenes are stories of Merck.

The first is the story Merck likes to tell the world—the Merck of the two legendary leaders, George W. Merck and P. Roy Vagelos; the Merck beloved by small investors; the Merck that discovered a treatment for river blindness in Africa and then handed out the drug for free. This Merck develops groundbreaking medications for tuberculosis, high cholesterol, osteoporosis, and AIDS. This Merck is also an upstanding member of the community. It provides child care for its employees. It gives away tens of millions of dollars.

In that fifth-grade classroom, Gianna, Amanda, and Raquel were part of a unique 10-year, \$20 million project that Merck launched in 1993 to completely revamp the way science is taught in four New Jersey and Pennsylvania school districts, including the one where Roy Vagelos graduated from high school in 1947. With its own money plus \$2.5 million from the National Science Foundation, Merck hired consultants, trained hundreds of teachers, sent some of the teachers out to Arizona and to Washington, D.C., for further training, bought new science materials, helped set up community science fairs to draw in parents, arranged professional evaluation, and essentially rewrote the curriculum for all the districts' elementary and middle school science classes to

emphasize learning by doing rather than learning by textbook reading.

"If it weren't for Merck, this initiative would not have happened," said Dolores Maslo, the tall, elegant, perfectly coiffed director of science for the Linden public school district, as she showed off class after class on that snowy February morning. There was a glimmer of tears in her eyes.

That Merck certainly exists. However, it was the second Merck that looked to be the Merck of the twenty-first century—its labs struggling, its profits slipping, and under attack from politicians, consumers, doctors, other businesses, and insurance companies.

Of course, it was not alone. All the multinational pharmaceutical giants—collectively known as Big Pharma—were facing an overwhelming and unprecedented barrage of scientific, financial, and political problems, much of it their own fault. But that was just the point. Merck was supposed to be different from the rest. If even Merck couldn't come up with good drugs or win the public's love, then the industry really was in trouble.

To understand what was happening to the pharmaceutical industry as the twentieth century moved into the twenty-first, the best place to start is probably with the dollars. Politicians, employers, and patients saw general inflation rising only 3 to 4 percent, overall health care up 5 to 7 percent, health insurance premiums jumping 12 to 14 percent—and spending on prescription drugs soaring almost 20 percent. News stories showed grandmas forced to choose between food and medicine, or elderly couples taking turns filling their prescriptions each month because they couldn't afford two sets of pills. Then, in the same newspapers and magazines, the business pages reported that the pharmaceutical industry was raking in profits of 17 or 18 percent, making it the most profitable industry in the United States. The public connected the dots: Big Pharma is making obscene profits from the pockets of starving grandmothers

Overseas, the headlines were even worse. Millions of impoverished children were suffering from AIDS in Africa and Brazil. Lifesaving medication was available, but incredibly, the drug makers were charging the same \$10,000 to \$12,000 a year that they billed in the United States. Under the glare of publicity, the companies slashed their prices, to the point where they claimed they were just breaking even. The price cutting didn't do much for their image, however, because they seemed to be dragged kicking and screaming to do it.

Actually, there were plenty of drug companies eager to provide the most popular drugs cheap: generic drug-makers like Barr Laboratories, Inc. and Mylan Laboratories Inc.

The way it was supposed to work, under a 1984 U.S. law governing drug patents, was that the big pharmaceutical companies would do the research, discover the drugs, and get exclusive rights to market the products at their comfortable profit margins for, typically, 20 years. Then, the generic drug makers would get to jump in with copycat versions, selling for one-fifth or less of the patented drug's price. Health insurance plans would include financial incentives to encourage people to use the generics. At that point, the so-called branded

companies would forget all about their old drugs and go discover new ones.

That was all very nice in theory. But when the crunch came—as a rush of blockbusters began to come off their patents like dominoes between 2000 and 2002, including such make-or-break names as the allergy pill Claritin and the antidepressant Prozac—the theory fell apart. Instead of simply kissing good-bye to their steady moneymakers, the industry desperately began looking for new ways to patent the old drugs in order to eke out another 6, 12, or 30 months of exclusive rights and keep the generics off the market. Anything would do: the markings on the pill, the color of the bottle it came in, or the chemical compound it produced in people's livers.

In their defense, the pharmaceutical companies pointed out that groundbreaking new drugs don't grow on trees, or even in too many test tubes. Experts argued about how much it really cost to discover the average new drug. Was it \$200 million? \$500 million? \$800 million? Still, there wasn't much debate that it's a long, hard, expensive slog. Although the industry upped its spending on research by close to 70 percent (after inflation) from 1990 to 2001, the number of new drugs approved by the Food and Drug Administration (FDA) pretty much held constant, at around 30 per year, according to The Boston Consulting Group. In other words, more money did not buy more results.

Again, though, as with AIDS, the industry managed to pull the rug out from under its own defense. A sizable number of the FDA approvals weren't for new cures for cancer or other serious ailments; they were for questionable "improvements" to existing brands or the fifth cholesterol drug of the same type. Instead of focusing their millions of research dollars on cures that were needed, too many drug makers took the easy way out.

The mapping of the human genome was supposed to be the answer to Big Pharma's research problems. Yes, it had given the industry an important new tool, and computer modeling had made research faster and more efficient. But the study of genes was turning out to be even more complex than expected. There are something like 30,000 genes in the human genome, each of which can produce up to a dozen proteins, which in turn may (or may not) catalyze a reaction that will act on a particular disease. It could be 2010 or later before any products from genomics research would be ready for market—by which time a lot more patents would have expired.

And after all that, after struggling through those years of decoding and genomics research, what kind of product would the pharmaceutical labs end up with? Most likely a narrowly targeted niche drug that wouldn't make much money.

All of which meant that, even as the public was howling over obscene profits, the days of 18 percent returns might not be around much longer. For many companies whose hot-selling drugs had lost their patents, those days were already gone.

So if big new products were going to be sparse and the generic drug makers couldn't be blocked, the pharmaceutical industry turned to the other tried-and-true business strategy for pumping up the bottom line: marketing. From time beyond memory, drug companies had wooed doctors with

everything from free samples to doughnuts to hard-to-get theater and sports tickets, hoping the doctors, in return, would prescribe their drugs. Then, in 1997 Big Pharma was handed a magnificent new weapon, thanks to changes in federal rules—TV advertising. The companies poured in a billion dollars, then two, then two and a half. They hired the best of Madison Avenue, who in turn brought in celebrities like Olympics skater Dorothy Hamill and erstwhile presidential nominee Bob Dole. The aim, Big Pharma said, was to "empower" consumers so that they would crack their doctors' omniscience and demand the brand-name medication they saw on TV. Unfortunately for the pharmaceutical world, it's hard to calibrate empowerment.

Pretty soon, people started asking a lot of questions, and the questions weren't necessarily, "Will you prescribe Vioxx for me?" AARP, the powerful lobbying group for seniors, warned that the ads might entice people to demand expensive medicine they didn't really need. Believers in natural health said American society relied too much on pills, anyway. Ethicists worried that there was something wrong about advertising serious medicine as if it were toothpaste. Consumer advocates said that all the money that was going into commercials ought to be used instead to keep prices down. Doctors weren't exactly thrilled to have their opinions challenged (or to waste nonbillable hours arguing with patients). Even the hoary old wining and dining of physicians came under so much attack that the industry's trade group, Pharmaceutical Research and Manufacturers of America (PhRMA), had to produce a code of conduct drastically curtailing all the freebies.

Popular culture was quick to latch onto the newest villain. In 2001, John le Carré came out with a thriller, The Constant Gardener, about a rapacious pharmaceutical giant that hides evidence of the fatal side effects of its TB drug and blithely kills anyone who threatens to reveal the truth. Within that same year, two other novels also featured greedy drug companies or overdependence on prescriptions. The hero of the 2000 movie The Family Man, in his soulless Wall Street incarnation before he discovers the True Meaning of Life, finds his greatest satisfaction arranging a multibillion dollar drug company merger

To Frank R. Lichtenberg, a professor of economics and finance at Columbia University's Graduate School of Business in New York who specializes in the pharmaceutical industry, the outpouring against the big drug giants wasn't all that surprising. "If their access to pharmaceutical products is limited by price or other reasons, people get upset," he points out. "That's testimony to the pharmaceutical companies' activity and their contribution to society."

And that was exactly the way the companies had always wanted to see themselves-contributing to society. They were the good guys, the purveyors, after all, of something that saves lives and improves health. In his speech in March 2002 to the PhRMA annual meeting, the lobbying group's president, Alan F. Holmer, even dared compare drug makers to the nation's newest heroes, the firefighters who risked their lives when the World Trade Center was attacked on September 11—because drug companies risk millions of dollars researching new cures that may never pay off. Typical

lobbyist hype, of course. But Holmer could be confident he wouldn't be laughed off the podium by his members.

As things degenerated in the winter of 2001–2002, top executives from a big manufacturer brought one of their most vocal critics, Ron Pollack, executive director of a Washington, D.C.-based consumer group called Families USA, to their headquarters to explain what was going on. Pollack, in a backhanded way, actually sympathized with Holmer's point of view. "Here were people seated around the table who thought they were heroes," he later recalled. "They were finding the medicines that were cures for diseases. They thought they were on this great mission. They were profoundly perplexed and hurt that they were being vilified."

How could they be lumped now with the dregs of the business world, with the oil companies and the tobacco industry?

f the pharmaceutical industry was supposedly somehow a little more pure, a little better than the rest of the business world, Merck was the best of the best.

If the scene at the annual meeting could have taken place at almost any other pharmaceutical company, the scene in the fifth-grade classroom was Merck's alone.

Simply put, whether in terms of product or philanthropy, numbers or niceties, no other pharmaceutical company, and perhaps no other U.S. company of any sort, has ever had a reputation like Merck's:

- Number one on Fortune magazine's "Most Admired Companies" list for an unprecedented seven years in a row, from 1987 through 1993.
- The only company to stay on BusinessWeek magazine's annual ranking of the top 50 performers in the Standard & Poor's 500 index (based on sales growth, earnings growth, total return, and other bottom-line considerations) every year for the first six years running since the list began in 1997.
- The only pharmaceutical company to be included in the bellwether Domini 400 Social Index—a diversified group of 400 companies screened for factors such as product quality, employee relations, community relations, and environmental practices—when the index began in 1990 and for three years afterwards.
- The only pharmaceutical company, as of 2002, to make the National Association for Female Executives' roster of the top 25 companies for executive women each year since the list was launched in 1999.
- A perennial on Working Mother magazine's ranking of "100 Best Companies for Working Mothers," qualifying as one of the 10 best for 9 of the list's 16 years.
- The only pharmaceutical company to rate as one of Fortune's "100 Best Companies to Work For" every year since the list started in 1998, and the only pharmaceutical company to qualify for the precursor list, initiated by veteran business writer Milton Moskowitz in 1984, for every year of its existence but one.
- The first pharmaceutical company to win the U.S. Commerce Department's Ron Brown Award for Cor-

porate Leadership, launched in 1997 to honor "companies that have demonstrated a deep commitment to initiatives that empower employees and communities while advancing strategic business interests."

• The only pure-play drug company in that icon of leadership and might, the Dow Jones Industrials.

By the mid-1980s, "Merck was both the Arnold Schwarzenegger and Mother Teresa of American businesses," journalist Barry Werth wrote in The Billion-Dollar Molecule, his 1994 book about the founding of a biotech company by a group of ex-Merck scientists.¹

The double-barreled Merck reputation goes back at least to the 1940s and the discovery of streptomycin. Merck had agreed to provide facilities and staffing to a Rutgers University professor named Selman A. Waksman in return for exclusive marketing rights to any of his results. One of those results was streptomycin—a new, powerful antibiotic that could be used against tuberculosis. The potential market was millions of people, untold millions of dollars; it was like holding the patent on a cure for breast cancer. And Merck, in the public interest, waived its exclusive rights, handing over the patent gold mine to a Rutgers-based foundation.

Through the 1980s and 1990s, the company's research and development prowess was unparalleled in the industry. When Ernst & Young launched an index in 1993 to evaluate R&D spending, revenue, and other financial signposts among the biotechs, the standard it used for comparison was Merck. The company prided itself on creating entire new classes of treatments, on coming out with revolutionary drugs way ahead of anything else on the market, or even better, on being the only one on the market. It had the first or second significant products for cholesterol, hypertension, osteoporosis, asthma, and a class of pain medications known as COX-2 inhibitors, as well as certain broad-spectrum antibiotics. From the 1960s onward, it produced more breakthrough medicines than any rival. "It means something when someone says, 'We've just hired that R&D person and that person came from Merck.' That carries greater weight than if that person came from wherever," Edward Pittman, the investment analyst specializing in pharmaceuticals for the giant New Jersey public employees' pension fund, asserts. "They are the pharmaceutical company that many in the industry see as the quintessential R&D entity. Merck has become the benchmark for the whole biotech industry," says the chief executive of one of the largest of those biotechs, Don Drakeman of New Jersey-based Medarex, Inc., which genetically engineers mice to carry specific antibodies.

That's not all. The Merck Manual—a massive compendium of descriptions and treatments for probably every known human ailment—is a staple of doctors' bookshelves. Merck could boast of never having a drug recalled in the United States (unlike some other pharmaceutical makers it could name). It was the first company to volunteer under the 1983 Orphan Drug Act to manufacture a product that was desperately needed by only a handful of people—the drug industry's version of pro bono work. It was one of the first two companies to sign up with the Council of Institutional