Praise for *Bottle of Lies*

'Gripping … an invaluable exposé, a reportorial tour de force and a well-turned epic.'

—New York Times

'Should make Indian readers furious … [A] powerful book.'

—The Hindu

'An extraordinary international corporate crime thriller … a horror story that features large decades-old award-winning pioneer companies.'

—Hindustan Times

'A fantastic work of investigative journalism … begs to be turned into a movie.'

—Business Standard

'The gory details still shock … an arresting narrative … a great example of rigorous investigative journalism.'

—Mumbai Mirror

'An urgent, alarming work … that will make you question every drug in your medicine cabinet … An eye-opening exposé … excellent.'

—Kirkus Reviews

'Reading *Bottle of Lies* turned out to be more expensive than I anticipated. Sure, there was the … [money] I shelled out for the Kindle edition. But that's nothing compared to the price of vowing to never buy another generic drug. Pills containing incorrect dosages, unstable compounds, ground-up glass, and even insects? I'd rather keep my kidneys, thanks.'

—Sandra Upson, Senior Editor at *WIRED*

'An eye-opener … a chillingly dark exposé that you wish were not true and merely a work of fiction.'

—*Deccan Chronicle*

'Disquieting, often unnerving and at times infuriating.'

—*New York Review of Books*

'Reads in part like a detective novel … a massively thorough act of journalism … Superbly structured, in a complex yet accessible narrative.'

—**Moneycontrol.com**

'Vivid … almost like a movie script.'

—**Moneylife.in**

'[A] propulsive narrative investigation … Eban paints a full and disturbing picture that anyone concerned with the pharmaceutical industry should read.'

—**NPR**

'Fast paced, gripping.'

—**Bloomberg Quint**

BOTTLE OF LIES

A NOTE ON THE AUTHOR

Katherine Eban, an investigative journalist, is a *Fortune* magazine contributor and Andrew Carnegie fellow. She has also written for *Vanity Fair*, the *New York Times*, *Self*, *The Nation*, the *New York Observer*, and other publications. She is the author of *Dangerous Doses: A True Story of Cops, Counterfeiters, and the Contamination of America's Drug Supply* and lectures frequently on the topic of pharmaceutical integrity. Educated at Brown University and Oxford, where she was a Rhodes scholar, she lives in New York City with her husband and two daughters.

BOTTLE OF LIES

Ranbaxy and the Dark Side of Indian Pharma

KATHERINE EBAN

juggernaut

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Designed by Michelle Crowe

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For my mother, Elinor Fuchs, and my father, Michael Finkelstein,
the first and best writers and editors in my life

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AUTHOR'S NOTE

Back in 2008, I did not expect to be investigating the Indian pharma industry.

At that point, I was an investigative journalist in the United States. I'd reported on brand-name drug companies, including efforts by opioid makers to increase sales by concealing addiction risks. I'd broken big stories about gun trafficking, as well as the U.S. government's use of torture in interrogations during the post-9/11 war on terror. To the extent that I thought about generic drugs, I knew they comprised the majority of the U.S. drug supply. I also knew that India had played a critical role in manufacturing AIDS drugs cheaply enough that it had allowed governments, including our own, to purchase and supply those drugs to afflicted African nations.

But that year, my reporting on generic drugs began—like so many investigative projects do—with a tip. It was a phone call from a man named Joe Graedon, who co-hosted a U.S. radio program called the People's Pharmacy. I'd been a guest on his program a number of times. But this time he wanted my help. Patients had been calling and writing to him with serious complaints about generic drugs that either didn't work or caused devastating side effects. The drugs, though made by different manufacturers and for a range of conditions from depression to heart disease, were all generic—less expensive versions of brand-name drugs, made legally after the patents on those medications lapsed.

Graedon had forwarded the patients' complaints to top officials at the U.S. Food and Drug Administration (FDA), but they insisted

that generics were equivalent to the brand and the patients' reactions were subjective. Their response struck Graedon as more defensive than scientific. As in most countries, generic drugs had become essential to balancing budgets across America. Without them, every large-scale government health program—from Medicare to the Veterans Health Administration—would be unaffordable. Graedon himself had long advocated making generic drugs more widely available. But the complaints were compelling and similar in nature. He posed a single question to me: *What was wrong with the drugs?* He wanted someone with "investigative firepower" to look into the patients' claims.

I began exactly where Graedon pointed me: with the patients. In June 2009, I published an article in *Self* magazine that documented how patients who had previously been stabilized on brand-name drugs relapsed when switched to certain generics. Their doctors had little data and no significant comparative studies to explain these reactions. Although the FDA reviewed data from the generic drug companies and inspected manufacturing plants, it was not systematically testing the drugs. As Dr. Nada Stotland, a psychiatrist in Chicago and then the president of the American Psychiatric Association, told me, "The FDA is satisfied that generics are okay. My question is, are we satisfied?"

While reporting this article, I first learned about a company well known to most Indians: Ranbaxy Laboratories Ltd. It was a jewel in the crown of Indian pharma and one of the fastest growing generic drug manufacturers supplying the U.S. market. But I discovered that a cloud hovered over the company. American regulators were investigating whether Ranbaxy had fabricated quality data in order to gain approval to market its drugs. The allegations had first been made by a company whistleblower who had contacted the agency.

As I discovered, roughly 40 percent of America's generic drugs are manufactured in India. A full 80 percent of the active ingredients in all U.S. drugs, whether brand-name or generic, are made in India and China. As one drug-ingredient importer told me, "Without

products from overseas, not a single drug could be made." Though I had begun my reporting with patients, I realized that the answers I was seeking most likely lay in the laboratories, manufacturing plants and corporate boardrooms of the drug-making companies, the majority of which operated overseas.

It was ultimately two sources who redirected me to look at the distant manufacturing plants making drugs for the U.S. market. One was a generic drug executive who contacted me anonymously under the pseudonym "4 Dollar Refill." The phrase referred to the cost of refilling a low-priced generic drug prescription at one of America's big pharmacy chains. The source explained that there was a gulf between what the regulations required of generic-drug companies and how those companies behaved. To minimize costs and maximize profit, companies circumvented regulations and resorted to fraud: manipulating tests to achieve positive results and concealing or altering data to cover their tracks. By making the drugs cheaply without the required safeguards and then selling them into regulated and more costly Western markets, claiming that they had followed all the necessary regulations, companies could reap enormous profits.

Another source, an FDA consultant who had spent considerable time in overseas factories, also contacted me. She was an expert at examining the cultural "data points," or situational forces, that drive corporate behavior and saw those forces at work in India and in other countries with less regulation. One factor is company culture—the tone set by executives, the admonitions or slogans that hang on office or manufacturing-plant walls, the training that workers receive. Ranbaxy's company culture was unequivocally focused on profit. A framed poster that hung on the walls of the New Jersey office reminded employees of the company's priority: "USA: $1 billion sustainable profitable business by 2015."

But company culture is also affected by country culture, the FDA consultant explained: Is a society hierarchical or collaborative? Does it encourage dissent or demand deference to authority? These factors, though seemingly unrelated, can impact manufacturing

drug quality and lead to variance between certain generics and brand-name drugs, as well as between generics that are supposedly interchangeable with one another, the consultant posited.

In 2013, I published a 10,000-word article on *Fortune* magazine's U.S. website about fraud at Ranbaxy. It detailed how the company had deceived regulators around the world by submitting fraudulent data that made its drugs appear bioequivalent to brand-name drugs. It also featured the story of Dinesh Thakur, a former Ranbaxy executive who had alerted the FDA to data fabrication.

As the article circulated around the world, Indian readers responded on *Fortune*'s website. Reading those comments, I learned a word I had never heard before: Jugaad. The Hindi word, which had both positive and negative connotations, essentially encapsulated Ranbaxy's approach to business—taking ethically dubious shortcuts to get as quickly as possible to the desired goal.

I wondered, was this approach to manufacturing a wider issue in the global generic pharma industry? Did Ranbaxy's conduct reflect a one-off scandal or an industry norm? That question led me into the book project and further reporting in India. I also reported in China and examined the country's well-documented manufacturing failings, including how adulterated heparin there had killed over 81 Americans and others around the world. But to some extent, India's surge in manufacturing sterile finished doses for the U.S., and the world, felt like a newer story.

As I delved into that reporting, two storylines—and two types of companies—emerged. There was Cipla, where the managing director Yusuf Hamied had been a disruptor of the status quo. He had used his position in the pharmaceutical marketplace to help bring price relief and needed medicine to the world's most disadvantaged patients. One expert described Hamied's efforts as an example of Gandhian innovation: using the inventions of science for the public benefit. But there was another business model, that of Jugaad, one that aimed to get to the desired outcome by the shortest means

possible. That had been Ranbaxy's approach to getting approvals and market share.

As I reported, whistleblowers began to contact me. They were former or current employees of specific drug companies. The majority were Indian. They were concerned on several levels. One had resigned after being asked to alter data. He wept during our first in-person meeting, as he explained that the generic drug industry was "very dirty." Several flagged a critical issue: that the big exporting companies were making drugs of different quality for different markets. This meant that, even with the manufacturing shortcuts and sterility lapses in drugs bound for the E.U. and U.S. markets, the drugs being sold into developing markets, including India, were even worse.

My reporting revealed that the drug manufacturers operating in India had little to fear from Indian regulators, who rarely scrutinized applications or censured companies for quality lapses. As one Ranbaxy staffer told the company executive Dinesh Thakur before he became a whistleblower, testing the drugs for India was just "a waste of time," because no regulators ever looked at the data. What was needed to get approval from the Drug Controller General of India was not real data, but good connections, the man explained. On a reporting trip to India, I met with a senior pharma journalist in Mumbai who told me, "The nexus between the regulators and the industry is so tight, you won't be able to break it."

The lower-quality manufacturing and lax regulation meant that individual Indian patients were getting substandard and ineffective drugs. But the poor quality of those drugs had a larger public-health implication: they were contributing to the problem of drug resistance globally. Subpar drugs, which essentially underdosed patients, allowed pathogens to mutate and develop resistance, even to effective drugs.

Though I am an American journalist, I followed a trail of clues halfway around the globe. Ultimately, my effort to answer a single question—*What is wrong with the drugs?*—launched me into a

decade-long reporting odyssey on four continents as I delved into how globalization had impacted the drugs we all need to survive. I followed the trail of certain drugs around the world, trying to connect the dots. What had patients complained of? What had FDA investigators found? What actions had regulators taken? What had companies claimed? What had CEOs decided? What had criminal investigators turned up? I mined thousands of internal company documents, law enforcement records, FDA inspection records, and internal FDA communications, stacks of which piled up in my office.

The result is a true account of a group of characters struggling to protect global public health, among them Indian heroes; some Indian companies who strove to aid the world's most vulnerable patients and others who sought to profit at their expense; and patients, Indians among them, who were both helped and harmed by a generic drug industry claiming to have only their welfare in mind.

World events have shown how fragile our pharmaceutical interdependence is. Six months after *Bottle of Lies* was first published in India, reports began to circulate of a mysterious pneumonia in Wuhan, China. Within a few months, SARS-CoV-2 had rocketed around the world, upending our lives as we knew them. So began a global scramble for treatments that reflected many of the challenges and conflicts I had reported on for years. After U.S. President Donald Trump hyped up hydroxychloroquine, an old malaria medication, as a cure for COVID-19, the ensuing shortages led India to ban exports of the drug's active ingredient.

In the second half of 2021, the lurching effort to vaccinate the world suffered as India halted exports of its COVID-19 vaccine Covishield, manufactured by the Serum Institute of India. As low-income nations waited for the more affordable vaccine, the Omicron variant emerged from southern Africa, dashing what looked like a long-hoped-for recovery. Throughout the pandemic, the U.S. drug inspectors who had uncovered staggering fraud in Indian drug plants have been largely grounded, leaving the big exporting

manufacturing plants to operate on an honor system. For now, it seems, hopeful signs of reform have taken a back seat to the sheer effort to survive in a world plagued by supply chain disruptions and pharmaceutical nationalism.

When generics work perfectly, and many do, the results can be miraculous. "Basically, the ability of India and other countries to produce generic medicine at a fraction of the cost of the patented drugs saved the lives of millions of people in developing countries," said Emi MacLean, formerly the U.S. director of the Access to Essential Medicines Campaign at Doctors Without Borders. The plunge in prices has also made medicine affordable and treatment possible for millions of Americans who have no alternative to generics without significant price regulation of brand-name drugs.

Generic drugs are essential to health care systems around the world, and their quality is critical to us all. Nonetheless, in my effort to answer the question that Joe Graedon posed ten years ago—what is wrong with the drugs?—I uncovered the labyrinthine story of how the world's greatest public health innovation also became one of its greatest swindles.

Katherine Eban
Brooklyn, New York
January 2022

ABOUT THE REPORTING

This book, including all the scenes, dialogue, and assertions in it, is based on extensive interviews, firsthand reporting, and documentation. I interviewed over 240 people, a number of them multiple times, including regulators, drug investigators, criminal investigators, diplomats, prosecutors, scientists, lawyers, public-health experts, doctors, patients, company executives, consultants, and whistleblowers. Primary reporting for this book took place between January 2014 and November 2018, and included on-the-ground reporting trips to India, China, Ghana, England, Ireland, and Mexico and travel throughout the United States. The book also includes material I gathered from 2008 to 2013, while reporting a series of articles about generic drugs in both *Self* and *Fortune* magazines.

In every scene with dialogue, I have reconstructed quotes from the recollections of participants as well as documentation, including meeting minutes, handwritten notes, and memoranda of interviews by criminal investigators. The quotes I use from emails and other documents are verbatim, and I have not corrected spelling errors. No names of characters have been changed.

In the course of reporting, I obtained a significant number of confidential documents. These include roughly 20,000 internal documents from the U.S. Food and Drug Administration, including emails, memorandum, meeting minutes, reports, and data; thousands of internal government records related to the investigation of the generic drug company Ranbaxy; and thousands of internal corporate records from several generic drug companies, including

emails, reports, strategy documents, correspondence, and sealed court records.

Documentation also came from sixteen Freedom of Information Act requests that I filed with the FDA, as well as from a lawsuit I filed to obtain calendar and meeting records for an FDA official. I also read through years of publicly available FDA inspection records.

Wherever an individual or company has chosen to respond to questions or allegations, relevant portions of their statements can be found incorporated into the book's endnotes or main text. The endnotes are intended to guide readers to publicly available resources and documentation or to offer more detail on certain topic areas. They do not contain citations for nonpublic material, such as private emails, sealed court records, or other confidential documents.

Funding for this book came only from impartial sources with no stake in the outcome of the events described. These include an advance from HarperCollins and grants from the Carnegie Corporation, the Alfred P. Sloan Foundation, the McGraw Center for Business Journalism at Craig Newmark Graduate School of Journalism, and the George Polk Foundation.

IMPORTANT PEOPLE AND PLACES

Affiliations listed are those held at the approximate time characters appear in the book. Dates have been included for titles held by multiple characters. The names of some FDA divisions have since changed due to government reorganization.

Drug Companies

Ranbaxy

MANAGING DIRECTORS

Arun Sawhney, CEO and managing director, 2010–2015

Atul Sobti, CEO and managing director, 2009–2010

Malvinder Singh, CEO and managing director, 2006–2009

Shivinder, brother

Brian Tempest, CEO and managing director, 2004–2005

Davinder Singh "D.S." Brar, CEO and managing director, 1999–2004

Parvinder Singh, chairman and managing director, 1992–1998; joint managing director, 1976–1991, with his father, Bhai Mohan

Bhai Mohan Singh, chairman and joint managing director, 1976–1991; chairman and managing director, 1961–1975

RESEARCH AND DEVELOPMENT

Rajinder "Raj" Kumar, director, 2004–2005

Rashmi Barbhaiya, director, 2002–2004

Rajiv Malik, head of formulation development and regulatory affairs

Arun Kumar, associate director of regulatory affairs

Dinesh Thakur, director and global head of research information & portfolio management

Sonal Thakur, wife

Andrew Beato, attorney at Stein, Mitchell, Muse & Cipollone LLP

U.S. BUSINESS

Jay Deshmukh, senior vice president of global intellectual property

Abha Pant, vice president of regulatory affairs

OUTSIDE LAWYERS AND CONSULTANTS

Kate Beardsley, partner, Buc & Beardsley

Christopher Mead, partner, London & Mead

Warren Hamel, partner, Venable LLP

Agnes Varis, consultant

Cipla Limited

Yusuf "Yuku" Khwaja Hamied, chairman and managing director

Khwaja Abdul "K.A." Hamied, founder

Daiichi Sankyo Company

Tsutomu Une, head of global strategy

Mylan N.V.

EXECUTIVES

Heather Bresch, CEO
Rajiv Malik, president
Deborah Autor, senior vice president, head of global strategic quality

Indian Government

Central Drugs Standard Control Organization

Gyanendra Nath "G.N." Singh, drug controller general

Ministry of Health and Family Welfare

Harsh Vardhan, minister

U.S. Government

Congress

David Nelson, senior investigator, House Committee on Energy and Commerce

Food and Drug Administration

OFFICE OF THE COMMISSIONER

Scott Gottlieb, commissioner, 2017–present
Margaret Hamburg, commissioner, 2009–2015

OFFICE OF THE CHIEF COUNSEL

Marci Norton, senior counsel
Steven Tave, associate chief counsel for enforcement

CENTER FOR DRUG EVALUATION AND RESEARCH

Janet Woodcock, director

Robert Temple, deputy center director for clinical science

OFFICE OF COMPLIANCE

Deborah Autor, director

Thomas Cosgrove, director, Office of Manufacturing Quality

Carmelo Rosa, director, Division of International Drug Quality

Edwin Rivera-Martinez, chief, International Compliance Branch

Douglas Campbell, compliance officer

Karen Takahashi, compliance officer

OFFICE OF PHARMACEUTICAL SCIENCE

Office of Generic Drugs

Gary Buehler, director

OFFICE OF GLOBAL REGULATORY OPERATIONS & POLICY

Office of International Programs

FDA India Office

Altaf Lal, director

Atul Agrawal, supervisory consumer safety officer

Muralidhara "Mike" Gavini, senior assistant country director

Peter Baker, assistant country director

Regina Brown, international program and policy analyst for drugs

Office of Regulatory Affairs

Dedicated Drug Team
Jose Hernandez, investigator

Office of Criminal Investigations
Debbie Robertson, special agent

Department of Justice

OFFICE OF CONSUMER LITIGATION
Linda Marks, senior litigation counsel

U.S. ATTORNEY'S OFFICE, DISTRICT OF MARYLAND
Stuart Berman, assistant U.S. attorney

Doctors and Patient Advocates

Joe Graedon, cohost of the NPR program *The People's Pharmacy*
William F. Haddad, generic drug advocate
Harry Lever, director, Hypertrophic Cardiomyopathy Center, Cleveland Clinic
Randall Starling, head, Section of Heart Failure and Cardiac Transplant Medicine, Cleveland Clinic

Manufacturing Plants

Fresenius Kabi
Kalyani, Nadia District, West Bengal, eastern India

Mylan
Morgantown, West Virginia, southeastern United States
Nashik, Nashik District, Maharashtra, western India

Pfizer

Dalian, Liaodong Peninsula, Liaoning Province, northeastern China
Ringaskiddy, County Cork, southern Ireland
Zhejiang Hisun (affiliate), Taizhou, Zhejiang, eastern China

Ranbaxy

Dewas, Dewas District, Madhya Pradesh, central India
Mohali, SAS Nagar District, Punjab, northern India
Ohm Laboratories, New Brunswick, New Jersey, northeastern United States
Paonta Sahib, Sirmour District, Himachal Pradesh, northern India
Toansa, Nawanshahar District, Punjab, northern India

Wockhardt

Chikalthana, Aurangabad District, Maharashtra, western India
Waluj, Aurangabad District, Maharashtra, western India

PROLOGUE

MARCH 18, 2013

Waluj

Aurangabad, India

Peter Baker, a drug investigator for the U.S. Food and Drug Administration, traveled two hundred miles east of Mumbai, along a highway choked by truck traffic and down a road with meandering cows, to get to his assignment. Behind a metal fence lay a massive biotech park, run by the Indian generic drug company Wockhardt Ltd. Amid the dozens of buildings, Baker's job was to inspect a particular area of the plant—Plot H-14/2—to ensure that it could safely make a sterile injectable drug used by American cancer patients.

Baker, thirty-three, had arrived lightly provisioned. He had just a few items in his backpack: a camera, a gel-ink pen, a green U.S. government–issued notebook, and his FDA identification. He had a graduate degree in analytical chemistry and a command of the Code of Federal Regulations, Title 21, the rules that governed drug

manufacturing. But more importantly, he had his instincts: a strong sense of what to check and where to look, after completing eighty-one inspections over four and a half years at the FDA.

At 9:00 a.m., the sun already burning, Baker and his colleague, an FDA microbiologist, showed their identification to guards at the gate and were ushered into the plant, where the vice president of manufacturing and other company officials waited anxiously to greet them. In a world of drab auditors toiling with checklists, Baker stood out. He was handsome and energetic. He wore his brownish-blond hair in a buzz cut. On one bicep, he sported the oversized tattooed initials of his motorcycle group. As the officials began their opening presentation, he interrupted with a staccato burst of questions. Was there any other manufacturing area on-site that made sterile drugs for the U.S. market, aside from Plot H-14/2? he asked repeatedly. No, the officials assured him.

Baker's job—part science and part detective work—had been transformed by the forces of globalization. From 2001 to 2008, the number of drug products imported into the United States had doubled. By 2005, the FDA had more drug plants to inspect abroad than it did within U.S. borders. Baker had been dispatched to Wockhardt, in an industrial area of Aurangabad, because of a global deal that had evolved over more than a decade. Drug makers in India and other countries gained entry to the U.S. pharmaceutical market, the world's largest and most profitable. In return, the American public got access to affordable versions of lifesaving drugs. But this boon came with a serious caveat: foreign drug manufacturers had to comply with the intensive U.S. regulations known as "current good manufacturing practices" (cGMP) and submit to regular inspections. If everything went according to plan, the result was a win-win for foreign drug makers and American consumers alike.

Though few Americans knew Wockhardt by name, many took its medicine. The company manufactured about 110 different generic drug products for the American market, including a beta blocker—

metoprolol succinate—to treat hypertension, which reached about a quarter of U.S. patients taking a generic version of the drug. Because the Aurangabad plant manufactured sterile injectable medicine, the regulations it had to follow were particularly strict.

Every detail mattered. Every digit of data had to be preserved in its original form. As one moved closer to the plant's sterile core, where vials of medicine sat exposed, the rules became even more restrictive. Employees there had to move slowly and deliberately, so as not to disturb the unidirectional air flow. Even to take notes, FDA investigators had to use sterile, lint-free paper. There was a good reason for these rules. One small slip—a failure to filter air properly, a misreading of bacterial samples, the exposed wrist of a technician—could result in a contaminated product that would kill instead of cure.

Given the high stakes—lives on one side, and profits on the other—fear governed the inspection. Baker feared that he would miss something that would endanger the lives of U.S. patients. Wockhardt officials feared that he would find something that would restrict the company's access to the U.S. market. They needed every advantage to survive the FDA's inspection. Here, Wockhardt had several things stacked in its favor. The plant was massive, roughly the size of a small city. Baker and his colleague had just one week to inspect the site. With only five working days, how much could they find?

But Wockhardt had an even bigger advantage. Company executives had known for weeks that Baker was coming to inspect their factory. In the United States, FDA investigators simply showed up unannounced and stayed as long as was needed. But for overseas inspections—due to the complex logistics of getting visas and ensuring access to the plant—the FDA had chosen a different approach: to announce its inspections in advance. As was typical, Wockhardt had "invited" the FDA to inspect and the agency had accepted. Plant officials served as hosts and Baker was their guest—albeit one whose arrival they dreaded.

Given weeks of lead time, the officials worked feverishly to prepare for Baker's arrival. They polished floors, cleaned equipment, and combed through files to rid them of anomalies. They warned their employees to remain polite but silent, and to let their supervisors answer questions. They had fixed everything in every place where investigators were likely to look, a drill they'd endured fifteen months earlier when a different inspection team had arrived from the FDA.

On that visit, the investigators had found some troubling shortcomings: live bugs in a water storage tank, flooring in disrepair, ineffective cleaning procedures. But the investigators had recommended, not demanded, that the plant make corrections. In the FDA's coding system, they had given the plant a passing grade, one known as "Voluntary Action Indicated" (VAI). This meant that the Wockhardt operation had survived the inspection with no restriction to its most lucrative franchise—the sale of drugs to the United States.

This time, though company officials had planned for an inspection, they had not planned for Peter Baker. Unlike so many other FDA investigators, he was hard to prepare for—and control. He wouldn't tolerate an opening slide show or a guided tour, which were typical ways for plant officials to run down the clock. He seemed to be everywhere at once. He studied the employees for signs of evasion as he questioned them repeatedly. Company officials quickly ascertained that his visit posed a serious threat, one that would require drastic action on their part if the plant was to emerge unscathed.

On the second day of his inspection, Baker and his colleague entered a hallway far from the sensitive areas of the facility. It was a place where he could let down his guard. But as he looked down the long, gleaming corridor, he noticed a man at the far end who was walking toward him just a little too quickly. The man, a

plant employee, had a furtive demeanor. In one hand, he carried a clear garbage bag full of papers and assorted refuse, making his hurried walk seem even stranger. As the man glanced up, he noticed Baker and momentarily froze. The two men locked eyes.

Abruptly, the man pivoted and returned the way he had come. Baker followed him, quickening his pace. The employee sped up, too, until the two men were engaged in a low-speed chase beneath the fluorescent lights.

"Stop!" yelled Baker's colleague, the microbiologist. The man broke into an open run. As he bolted, the investigators gave chase until the employee flung open a side door, careened from the hallway, and hurled the bag onto a pile of garbage in a dim storage area beneath a stairwell, then scrambled up a flight of stairs and vanished into the building's concrete maze.

Baker, close behind, retrieved the bag. Inside, he discovered roughly seventy-five manufacturing records for the company's insulin products. They had been hastily torn in half, but he was able to piece some together. As he did, his concern grew. They revealed that many of the vials contained black particles, potentially deadly contaminants, and had failed visual inspection.

Under good manufacturing practices, every record created at the plant had to be made available to regulators. But these documents were marked "for internal dept. use only." Baker suspected that the records were secret for a reason. The testing results were so bad that, had they been disclosed, the plant would have had to launch a costly internal investigation and likely reject every batch it produced.

Over the next three days, Baker demanded that Wockhardt officials open their computers, as was his right, and he began scouring records. One by one, he uncovered the company's deceptions. As he suspected, the records from the garbage bag had not been logged into the company's official system. The drugs flagged in the records had been released to patients in India and the Middle East. Baker discovered that the drugs had been manufactured in a secret formu-

lation area that the FDA had never known about or inspected. Once he arrived there, he learned that Wockhardt had used the same defective equipment, in the same secret area, to make medicine for the U.S. market—including the injectable drug adenosine, which treated irregular heartbeat.

The result was a disaster for Wockhardt. Two months after Baker's inspection, the FDA restricted the import of drugs from the Waluj plant into the United States, a potential $100 million loss in sales for the company. The next day, Wockhardt's CEO held an emergency conference call with anxious investors to assure them that the company would bring the plant into compliance "in a month or two months maximum."

At a glance, the plant appeared perfectly run, the equipment shiny and new, its procedures meticulous and compliant. But the torn records Baker had uncovered led him beneath the plant's impeccable surface and into a labyrinth of lies, where nothing was what it appeared to be. The records were false. Drugs were manufactured in a secret area. Some of them contained visible contaminants that endangered patients. Baker, who had pieced all this together over the course of five punishing days, was left to wonder: if so much inside this plant was fake, what, if anything, was real?