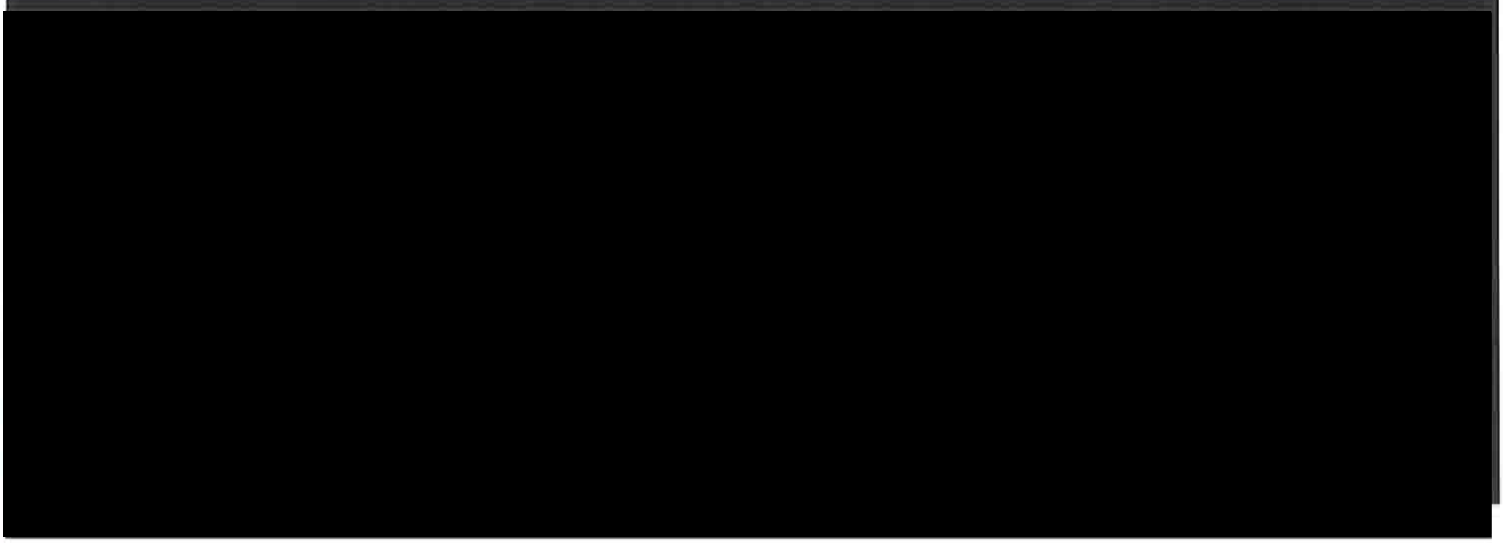
THE MIRACLE INDUSTRY

AMERICA'S MOST ADMIRED LAWBREAKER

Over the course of 20 years, **Johnson & Johnson** created a powerful drug, promoted it illegally to children and elderly, covered up the side effects and made billions of dollars. **This is the inside story.**

By Steven Brill



CHAPTER 1

THE CREDO COMPANY

By Steven Bril

Letter From the Editors

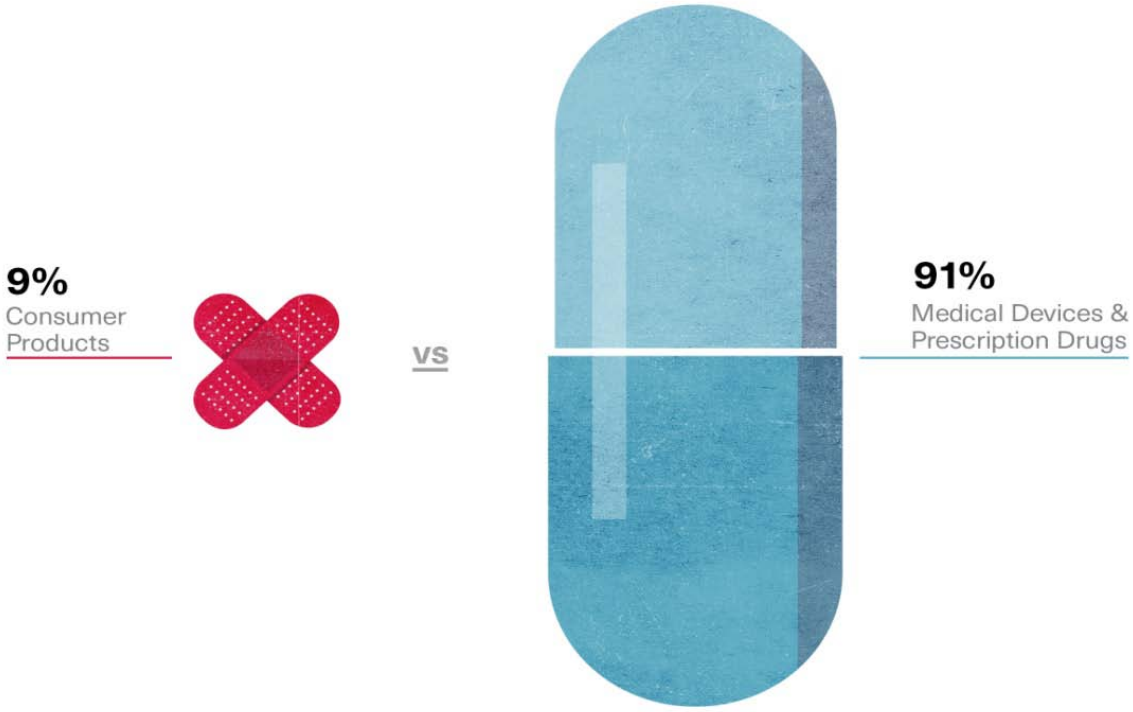
BACKSTAGE AT JOHNSON & JOHNSON

On May 20, about 100 stock analysts gathered in the ballroom of the Hyatt Regency Hotel in New Brunswick, New Jersey, to hear good news from top executives at Johnson & Johnson: The company had 10 new drugs in the pipeline that might achieve more than a billion dollars in annual sales.

For 129 years, New Brunswick has served as the headquarters of J&J, America's seventh most valuable public company. With consumer products from Band-Aids to baby powder, Neutrogena to Rogaine, Listerine to Visine, Aveeno to Tylenol and Sudafed to Splenda, Johnson & Johnson is the biggest and, according to multiple surveys, most admired corporation in the world's most prosperous industry—healthcare.

But the real money—about 80 percent of its revenue and 91 percent of its profit—comes not from those consumer favorites, but from Johnson & Johnson's high-margin medical devices: artificial hips and knees, heart stents, surgical tools and monitoring devices; and from still higher-margin prescription drugs targeting Crohn's disease (Remicade), cancer (Zytiga, Velcade), schizophrenia (Risperdal), diabetes (Invokana), psoriasis (Stelara), migraines (Topamax), heart disease (Xarelto) and attention deficit disorder (Concerta).

How J&J Makes Its Money



Ads for many of these products dominate our television screens and magazine pages. Each drug relies on its own elaborate marketing plan and carefully pitched promotional materials, used by hundreds of salespeople whose incomes turn on how much product they can push to the thousands of doctors who write prescriptions. All command increasing portions of our health insurance premiums and our own wallets, as well as our hopes and anxiety when we or our loved ones fall ill.

What follows is the backstage story of how an iconic company marketed a blockbuster drug that raised those hopes and fed on that anxiety. It is a story that in its depiction of strategies, tactics and mindset should make us wonder about the prescription drugs that are so much a part of our lives.

The show that Johnson & Johnson put on that morning for the analysts at the hotel, which the company owns, would produce positive headlines in the news that afternoon. But the upbeat talk in the lavishly appointed ballroom was a world apart from the drab setting where a Johnson & Johnson whistleblower says she sat in a sales meeting being drilled on promotional materials she was told should not be left behind for fear that federal regulators might see them.

In the ballroom, the Wall Street people watched J&J executives talk about the miracle drugs they were moving through clinical tests—not about how their colleagues might, as investigators later charged, massage data to conceal potentially damaging test results.

Whether it was the head of central nervous system research or the woman in charge of the drive to intercept diabetes before it strikes, everyone on the podium easily answered questions from the analysts on issues ranging from cell structures to potential market sizes to development timelines. They exuded passion and confidence—which was nothing like how Johnson & Johnson executives, however well-rehearsed by batteries of lawyers, would comport themselves under

oath when asked to answer for how they marketed Risperdal, the company's billion-dollar antipsychotic drug.

To sit in the back of the room watching the impeccably dressed, articulate men and women who are orchestrating Johnson & Johnson's trailblazing cures for cancer, Alzheimer's, diabetes, AIDS and mental illness, and to watch the Wall Street crowd digesting it and calculating the potential cash flows and returns on investment, was to watch the free market dream come true. The best and the brightest on that stage were doing well and doing good. Creating wealth by fighting pain, disease, death.

One could imagine Robert Wood Johnson, who founded the company with two of his brothers in New Brunswick in 1886 looking down proudly on the Hyatt ballroom—and in dismay at the grand jury hearings, depositions and trials that told the Risperdal story.

PUTTING PATIENTS FIRST

R.W. Johnson had worked at various jobs in and around America's fledgling patent medicine industry before launching Johnson & Johnson as the world's first supplier of surgical dressings and bandages. His enterprise was propelled by a single, big idea—that English scientist and surgeon Joseph Lister's pioneering adaptation of Louis Pasteur's work in microbiology could be turned into a worldwide market for antiseptic supplies that would ward off infections in wounds and surgery. With sales offices and factories spread across the globe and with annual revenues of $74.3 billion in 2014, his company had come a long way since creating a first aid kit for railroad workers in 1888 or the first prescription contraception product for women in 1931.

Even before Johnson & Johnson had grown little beyond a single factory with 14 workers in a small New Jersey town, its founder had donated supplies to soldiers in the Spanish-American War and to victims of a series of earthquakes and other natural disasters through the early 20th century. That public service ethic was memorialized in writing by Johnson's son Robert Wood Johnson II, who built the company mightily over a 31-year reign that ended in 1963. The founder's heir wrote what became the company's ubiquitous, even cult-like, "Credo"—a 308-word statement that declares, up front, "We believe our first responsibility is to the doctors, nurses, and patients, to mothers and fathers, and all others who use our products and services."

Robert Wood Johnson II

Employees and “the world community” come next. After them, the credo holds, the company’s “final responsibility” is to shareholders.

Patients first. Profits last.

The credo is mentioned seven times in the current chairman and chief executive’s latest annual letter to shareholders. As is tradition, it is reprinted in full at the beginning of the annual report. It is also carved in stone in the lobby of J&J headquarters and posted at all significant company events—including that morning’s stock analysts’ conference.

But the world in which Johnson & Johnson thrives today seems to have corroded the credo.

THE BOY WITH 46DD BREASTS

The morning of the conference, thousands of claims involving Risperdal were sitting on dockets across the country. Company lawyers had just filed motions appealing a $2.5 million verdict handed down by a jury in a Philadelphia courtroom 60 miles south of the Hyatt.

The jury found that Risperdal had deformed an Alabama boy after Johnson & Johnson had encouraged his doctor to prescribe it without warning of its risks. Austin Pledger, who suffers from severe autism and is now 21 years old, started growing breasts when he was 12 that eventually measured 46DD.

Jury Trial Verdict - Pledger v. Janssen
Feb. 24, 2015 (p. 6-7)

The Food and Drug Administration had prohibited Johnson & Johnson salespeople from trying to promote Risperdal to doctors to treat children because of its feared side effects, including hormonal disorders. The company was also not allowed to promote it to treat the elderly except for the most serious psychotic disorders; it was thought to cause strokes, diabetes and other ailments in that population. But by the time young Austin started growing breasts, Johnson & Johnson was reaping more than half of its Risperdal sales from prescriptions written for children to alleviate all kinds of behavior disorders, and for the elderly, who were given the drug for simple symptoms of dementia or restlessness.

Austin Pledger, at 2 years old

Johnson & Johnson emails, sales training manuals and business plans produced as evidence in the case revealed that the company organized special sales units illegally targeting doctors who treated the elderly and children. State mental institutions treating children, whose drugs would be paid for by Medicaid, were targeted, too.

When it came time to explain their conduct at trials and to federal investigators, Johnson & Johnson executives and salespeople have unwaveringly, even indignantly, defended themselves. One salesman, who otherwise fit the salt-of-the-earth mold that R.W. Johnson had envisioned for his company's employees, gave thousands of Risperdal samples in child-sized doses to Austin Pledger's doctor in Birmingham, Alabama. Yet he insisted under oath in February he didn't recall stepping around kiddie furniture and toys as he walked into an office with a sign that said "pediatric neurologist," and that he had no way of knowing that the doctor wasn't treating adults.

Pledger v. Janssen
Feb. 3, 2015 (p. 19-20, 51-52, 55-56)

Pledger v. Janssen
Feb. 4, 2015 (p. 31-32, 35-36, 38, 66-67)

More generally, Johnson & Johnson's defense—as expressed to me over three hours of conversations with lead in-house litigator Joseph Braunreuther, who asked not to be quoted, as well as by others working for the company—is that the drug benefits many people, which is true, and that the law governing promotion to prohibited populations, called off-label sales, is vague, unworkable and punishes companies for providing information about the drug to doctors who treat patients who could be helped by it.

Johnson & Johnson declined to allow anyone to speak on the record about any of the Risperdal litigation or investigations, but as company Vice President for Media Relations Ernie Knewitz put it, "In our opinion, significant ambiguity exists about what is or is not permissible regarding the communication of truthful and non-misleading scientific information about FDA-approved pharmaceutical products. Like doctors, patients, and others in the industry, we share an interest in greater regulatory clarity on the rules for appropriate promotion and scientific exchange, and we are working through industry groups to bring clarity and consistency to the rules that apply to those communications."

The Boy With 46-DD Breasts (video)

'THE COST OF DOING BUSINESS'

Johnson & Johnson has already settled thousands of cases involving illicit promotion of Risperdal, including Department of Justice civil and criminal complaints, for a total fast approaching $3 billion.

But on the morning of the analysts' meeting, the company was still manning the battle stations with squadrons of lawyers fighting off another 4,200 cases, apparently willing to risk a few more bad verdicts while hoping to weed out the weakest cases and wear the opposition down in order to save on final settlement costs of the strongest claims.

Yet all of that meant little to the stock analysts. "Oh, they've already reserved for that stuff," one of them told me during a coffee break. He meant that in Johnson & Johnson's financials, there had been money taken from earnings and put into a column vaguely called "accrued liabilities," in order to account for the expected billions that might still have to be paid out in verdicts or settlements.

"It's their cost of doing business," the analyst added, perhaps unintentionally echoing the view of one senior J&J lawyer who told me that the cases against his company are the unavoidable price of dealing with a litigation system easily abused by those targeting big corporations.

"All the big pharmas" have
lawsuits, the analyst concluded,
sipping an espresso.
"It's just not a big deal."

Indeed, with before-tax profits of $20.6 billion for 2014, putting aside $500 million or even $1 billion a year over 15 years to cover payouts for boys with 46DD breasts and other claims that might come along doesn't put much of a dent in the company's financials. As Johnson & Johnson declared in a filing with the Securities and Exchange Commission three weeks before the analysts' conference, "In the Company's opinion … the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position."

Thus, as Johnson & Johnson's press materials habitually point out, the company has recorded 51 years of increases in the dividends paid to shareholders.

"All the big pharmas have lawsuits," the analyst concluded, sipping an espresso. "It's just not a big deal."

THE INDUSTRY OF OUR TIMES

True, eight of the other nine largest pharmaceutical companies in the world have settled federal claims over the last decade related to allegations similar to what Johnson & Johnson was accused of in selling Risperdal, although their conduct was arguably less egregious. They, too, seem to have settled the charges without torpedoing their profit and loss accounts.

However, the fact that this illegal conduct is not a “big deal” on Wall Street and only the occasional subject of news coverage should make it a big deal to the rest of the world: The drug companies seem to be able to break the rules with relative impunity, or at least without suffering the kind of punishment that would actually hurt—their stock prices taking a hit or senior executives being held personally responsible.

Big Pharma is a big deal. The financial pages are filled almost daily with news of multi-billion dollar mergers and acquisitions among drug companies. Of the M&A deals announced so far this year in the United States, eight of the 30 largest involve drug-makers. Other headlines herald breakthroughs of the kind Johnson & Johnson executives were touting in the ballroom in New Brunswick. At the same time, healthcare policy wonks, government budgeters, insurers and patients are becoming increasingly panicked over who is going to pay for the miracle profits demanded by the manufacturers of these miracle products.

In terms of fortunes now being made and the industry’s impact on our economy, Big Pharma (or a little pharma that develops a miracle drug) is fast becoming today’s go-go industry. Profit margins often exceed those of industries, such as software, that we think of as modern gold mines. Only now the products have to do with life or death.

Amid the swirl of multi-billion dollar takeover deals generated by the prospects of a promising new drug, can we trust these companies? Can the data from the trials conducted to test their products that they submit to the Food and Drug Administration be trusted? Can we rely on corporations that are looking over their shoulders at Wall Street not to inflate revenue by selling a drug to people that the FDA has walled off as targets or for purposes that have not been sufficiently tested and for which the FDA has not granted approval?

Or are the lawsuits like those brought against Johnson & Johnson and other drug companies less about corporate wrongdoing and more about trial lawyers and whistleblowers (who get paid a portion of the winnings) looking for a payoff when drugs that comfort or even save the many result in side effects that afflict the few?

These questions are only going to loom larger as miracle drugs and miracle profits increasingly dominate the news, our budgets and our quest to live long, healthy lives. That is what makes the Johnson & Johnson Risperdal story important. It is why an examination of internal company and FDA documents produced in recent Risperdal suits and from Freedom of Information Act requests, supplemented by interviews with those involved in these events, is revealing.

The documents also demonstrate that as head of Risperdal sales and then head of the Johnson & Johnson subsidiary that marketed Risperdal, Alex Gorsky, the current Johnson & Johnson chairman and chief executive, had a sustained, hands-on role in what the company has since admitted in a plea bargain (that nonetheless named no individuals) was illegal activity. That raises significant questions about whether our legal system can, and will, ever hold the high-ranking people who run our largest corporations, rather than inert corporate entities, responsible for wrongdoing.

The Houdini act that enabled Gorsky, the then-Risperdal sales manager, not only to escape responsibility but also to be promoted to the top of his industry’s most admired company raises equally significant questions about the standards of conduct we can expect from those who run what is becoming the world’s most powerful industry, and about how much we can rely on the medicines they sell.

Through company spokespeople, Gorsky declined repeated requests to be interviewed about Risperdal, though he did testify in a deposition prior to the company's guilty plea, saying, "I don't believe that we … marketed the product in an inappropriate manner."

Deposition of Alex Gorsky
May 18, 2012 (p. 237)

THE DOCUSERIAL

The Johnson & Johnson Risperdal story is a complex, roller coaster tale. The details count. They are important in understanding the people and impulses behind the drugs we take. To tell that story in a way that is digestible but complete, The Huffington Post Highline and I are trying something new: a DocuSerial. It's a reconstruction of an old story-telling genre that allows us to deploy the modern tools of digital communication to engage readers in old-fashioned, long-form feature journalism.

Every day for the next 15 days, a new chapter of the Johnson & Johnson story will be posted here. Along with the text, we will post not only a rich array of photos and graphics, but also links to every document—court transcripts, internal emails, FDA staff memos—referred to in that day's chapter. That way, you will be able to delve more deeply into the materials that are quoted. (You'll also be able to make sure I held true to the context of the material I quote.)

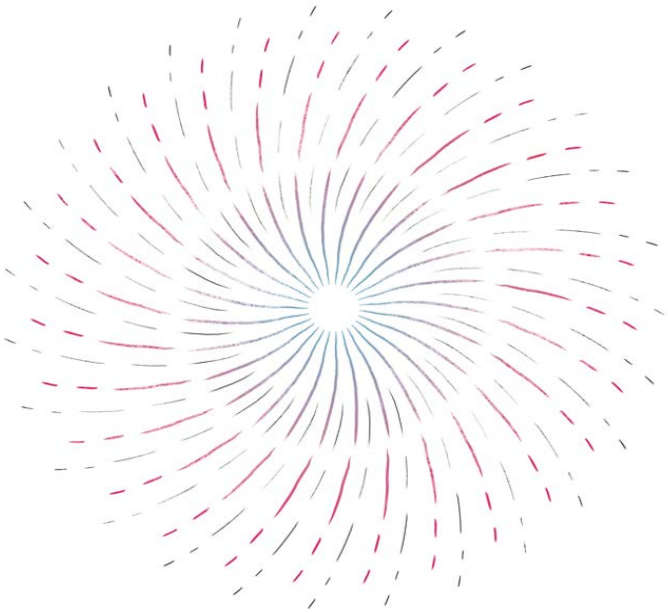
Those chapters already posted in prior days will be stored on a readily accessible, expanding file, so that you can catch up on, or review, the unfolding narrative. At the end of the 15 days, the entire story, along with all illustrations, videos and documents—as well as the most important comments on or critiques of the DocuSerial—will be available in a complete package, which will then be updated as events and the ensuing discussion evolve.

A PLAN TOO BIG FOR ITS LEGAL MARKET

Well before Risperdal was approved by the FDA and went on sale in February 1994, Johnson & Johnson had made the coming of the drug into something akin today to the launch of an Apple product.

The company needed a blockbuster that would replace and surpass its original antipsychotic drug, Haldol, which had gone on sale in the late 1960s.

Haldol had been invented in the laboratories of Paul Janssen, a legendary Belgium chemist whose father had founded a small pharmaceutical research lab in the 1930s. R.W. Johnson II had purchased the company in 1961 in what became a critical pivot by Johnson & Johnson away from medical supplies and toward the blossoming, high-margin prescription drug business.



Haldol and competitors, such as Thorazine, were considered “first-generation” antipsychotics—drugs that could treat symptoms associated with mental disorders such as bipolar disorder (manic depression, usually causing severe mood swings) and schizophrenia (typically defined as a severe brain disorder causing people to interpret reality abnormally, as with hallucinations).

In order to hit J&J's projections, Risperdal would have to be used by tens of millions—not simply a portion of the one percent of Americans having the most severe psychotic disorders.

But Haldol had come “off-patent” in 1986. That meant that the years during which the product was protected from being copied were over. Inexpensive generic versions of Haldol had decimated the brand name’s revenues by 1992.

The business plan the Janssen executives had drafted projected an average of more than $1 billion in U.S. sales of Risperdal every year through the turn of the century. (U.S. sales were about two-thirds of worldwide sales for these kinds of prescription drugs.) That meant that Risperdal would have to be used by tens of millions—not simply a portion of the one percent of Americans having the most severe psychotic disorders.

Right from the beginning, the FDA took a different view. In a memo to his colleagues a week before the final approval, the agency doctor in charge of the Risperdal application reported that he and Janssen scientists and executives had reached an “impasse” over the label that the FDA would allow.

Dr. Paul Leber memo
Dec. 21, 1993

A prescription drug’s label is a dense, multi-page document given to doctors so that they know what a drug is supposed to be used for, what side effects to look out for and what the appropriate doses are. It is based on a series of tests conducted by the drug’s manufacturer, or “sponsor”—first on animals, then usually on humans over three increasingly stringent phases. All the steps along the way, which can take three to 10 years, are done in close consultation with the FDA, which reviews the testing data that the sponsor submits.

Risperdal Label Current 2015

Janssen wanted the label for Risperdal to include “side by side” statistical comparisons with the wildly popular Haldol. This was unacceptable, the FDA doctor wrote, because it “invites a comparison that leads to the conclusion that Risperdal has been shown to be superior to [Haldol] when, in fact, it has not.”

In other words, Janssen wanted its new drug to seem like a step up from its now-generic, inexpensive product. But the clinical data didn’t prove that.

There was another issue lurking in Janssen’s push to have Risperdal compared to Haldol. By then Haldol and its generic knock-offs were being widely used to address a broad range of behavior disorders, including dementia in seniors and attention deficit disorders in children—not just severe “psychotic disorders,” such as hallucinations or delusions. Risperdal could never replace Haldol as Johnson & Johnson’s latest bestseller if it was sold as only appropriate for psychotic disorders.

An ambitious plan drafted by Janssen in anticipation of the drug’s 1994 rollout put the problem bluntly: “The anticipated growth of the antipsychotic market does not create enough room for the Risperdal sales forecast.”

Risperdal's Future in the
New Competitive Environment

But the FDA held firm. Its approved label limited Risperdal to the “management of manifestations of psychotic disorders” in adults—severe illnesses causing hallucinations or delusions.

FDA’s Original Risperdal Label
Approved 1993 (p.10)

Worse, drawing on the data Janssen had submitted, the FDA specified that the "antipsychotic efficacy of Risperdal was established in short term (6 to 8 weeks) controlled trials of schizophrenic patients." Schizophrenics were only about a third of the psychotic disorders market, which was itself a small subset of the target population Janssen had in mind.

"It would be misleading to suggest that the safety and efficacy of Risperdal has been established in the elderly," the regulators wrote.

Compounding the problem for J&J's business strategists, the FDA's December 29, 1993, letter officially approving the sale of Risperdal warned that the agency would "consider any advertisement or promotional labeling for Risperdal false, misleading or lacking fair balance" if it stated or implied that "Risperdal is superior to haloperidol [Haldol]."

The letter was signed by Dr. Robert Temple, a highly regarded specialist in clinical trials who had joined the FDA in 1972.

"Our role is not to decide that one drug is more effective than another drug, or to say that they're equally effective, even if one is much more expensive," Temple, now the FDA's Deputy Center Director for Clinical Science, told me. "If the data that the sponsor submits demonstrates that the drug is effective and the potential benefits of its intended use outweigh the risks, we approve it. But," he added, "it has never been clear to me that Risperdal was more effective than Haldol, and we never allowed them to claim that."

NO OLD FOLKS, NO KIDS

Later in 1994, when Janssen submitted for FDA approval some promotional materials meant for doctors who treat the elderly, it got back another letter bomb. This one struck at the heart of what the company's strategic planners envisioned as a key market. "It would be misleading to suggest that the safety and efficacy of Risperdal has been established in the elderly," the regulators wrote.

FDA Response
S. Danese, Oct. 4, 1994

The following year, Janssen submitted a new proposal to the FDA to conduct studies among geriatrics that would justify expanding the label to meet those market aspirations. Again, the FDA refused to go along.

FDA Response
Dr. Paul Leber, Apr. 28, 1995

"You appear to be exploring Risperdal's potential value for a much broader and more diffuse clinical target, namely 'behavioral disturbances in demented patients,'" Dr. Paul Leber of the FDA wrote. That label, he continued, "would also encompass a range of other clinical findings, e.g., anxiety, depression, agitation, aggressiveness, verbal outbursts, wandering, etc. that would not necessarily be considered psychotic manifestations."

Seeming to anticipate the mental institutions and nursing homes that were a big part of the market targeted in Johnson & Johnson's business plan, Leber added, "Some [of these symptoms] … might even be construed by some as appropriate responses to the deplorable conditions under which some demented patients are housed, thus raising an ethical question regarding the use of antipsychotic medications for inappropriate behavioral control."

Leber and the FDA appeared to have Johnson & Johnson boxed in.

A year later, in August 1996, Janssen submitted another proposal to the FDA. This time, it involved expanding the label to include children. Again, the agency rebuffed the company, declaring, “Your supplement [to the approved label] proposes the expansion of Risperdal use into pediatric patients, however, you never state for what child or adolescent disorders Risperdal would be intended. Indeed, you acknowledge that you have not provided substantial evidence from adequate and well-controlled trials to support any pediatric indications, nor developed a rationale to extend the results of studies conducted in adults to children.”

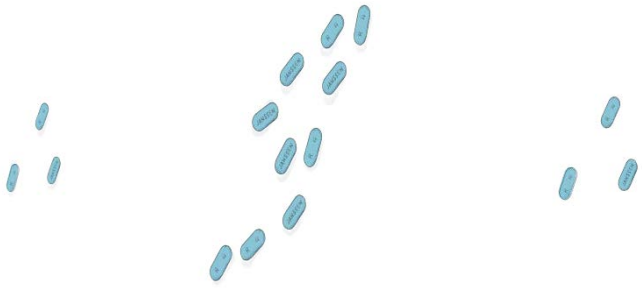
 FDA Response
Dr. Paul Leber, Sept. 17, 1997

“Your rationale for proposing this supplement,” the agency concluded, “appears to be simply that, since Risperdal is being used in pediatric patients, this use should be acknowledged in some way in labeling.”

That last sentence hinted at efforts Janssen had already quietly made to expand the sale of Risperdal beyond the limits of the label. By 1997, overall Risperdal sales in the U.S. had reached $589 million. That was a huge jump from launch-year revenue of $172 million in 1994, and it meant that the drug was somehow being prescribed for patients outside the narrow boundaries of the label.

How?

Chapter 2



BLOWING

PAST

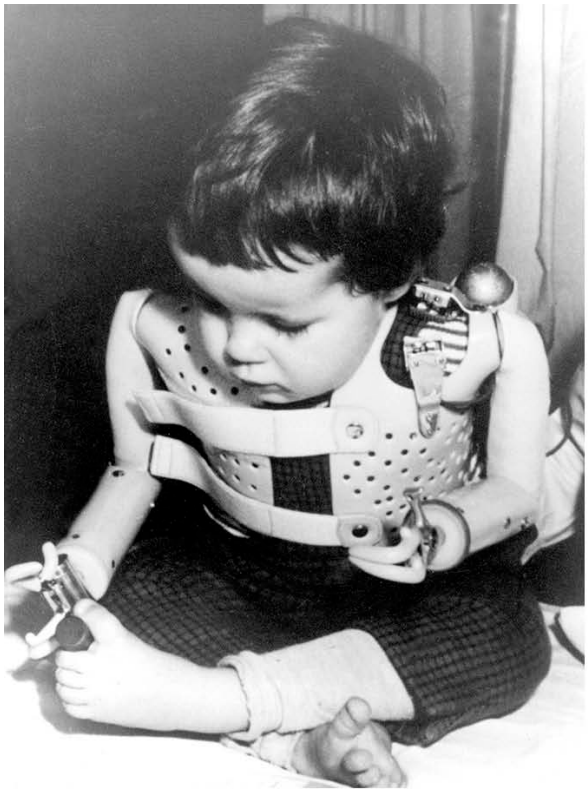
THE LABEL

By Steven Brill

What Happened in the Previous Chapter

‘OTHERWISE THE SKY WOULD BE THE LIMIT’

In 1961, newspapers around the world ran stories (accompanied by horrific images) of deformed babies whose mothers had taken a drug to curb nausea during pregnancy called thalidomide. A vigilant FDA inspector had refused to approve thalidomide for sale in the United States because she was worried about its safety. But the thalidomide story, along with persistent new reports about other drug company abuses, were highlighted in hearings convened by Senator Estes Kefauver, a Tennessee Democrat. This created a political climate for clamping down on the emerging pharmaceutical industry, and in 1962, President John F. Kennedy strengthened the landmark Federal Food and Drugs Act of 1906.



Thalidomide victim, right; Sen. Kefauver and President-elect Kennedy, 1960

A key provision of the new law made it a crime for drug companies to promote drugs to doctors for patients with illnesses for which the drug, according to its FDA-approved label, was not intended and approved for use.

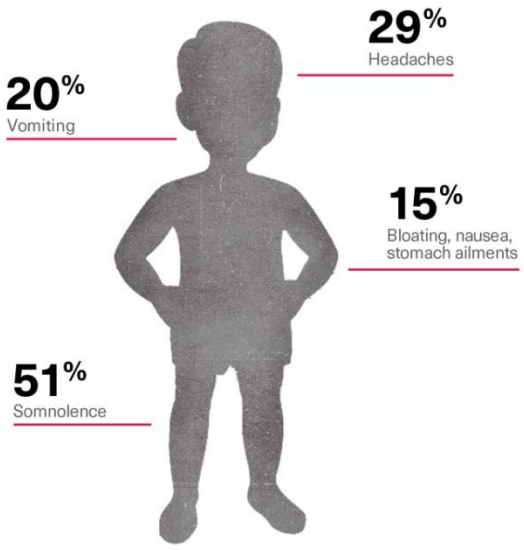
Kefauver explained his concern about tight labeling and the need to police off-label sales this way: Once a drug was approved for any initial purpose, “the sky would be the limit and extreme claims of any kind could be made” about the safety and effectiveness of selling that drug for other uses without the FDA vetting it. That would undermine the benefit-risk analysis that the new law required the FDA to weigh. A drug might be worth the risk of certain significant side effects if it helped alleviate a schizophrenic’s hallucinations or urge to commit suicide. But it might not be worth those risks if it was used to treat a restless nursing home patient or a child acting up in school.

Early Risperdal trial data

Nov. 7, 1993 (p. 8-10)

For Risperdal the risks were substantial. Even in the earliest trials, the data showed significant rates of side effects. These included involuntary twitches, somnolence, diabetes and, most frequently, significant weight gain. In the elderly there was a particularly high risk of strokes and other heart-related diseases. In children, Johnson & Johnson’s own data would ultimately count somnolence (51 percent of the time), headaches (29 percent), vomiting (20 percent) and bloating, nausea or other stomach ailments (15 percent), among other side effects.

Risperdal Side Effects in Children in Early Trials



Moreover, if the drug companies were not required to get a labeling change from the FDA before selling a product more widely, there would be little incentive to undertake the clinical studies necessary to test the safety of the drug when deployed for those new uses. Why test whether the drug is safe for children if you can market it to children anyway?

However, while under the law, the FDA controls drug companies, it cannot control doctors. A physician can prescribe any drug approved for sale by the FDA, even if the doctor wants to use it for a purpose not described as an intended use on the label.

The rationale is that the final decision on use, dosing and risks versus benefits should be up to the physician. He or she can review the detailed FDA-approved label and make a decision based on an evaluation of the patient’s needs. Of course, the doctor risks additional liability by prescribing an off-label use. But such decisions are not unusual, especially because

many in the medical community perceive a lag between a drug being identified as a promising solution to a given illness and the FDA's confirming it.

Thus, for Johnson & Johnson to expand the market to reach its business plan targets, doctors had to be *sold* on the value of Risperdal in populations that were not included on the label as the drug's intended users. Yet it was a crime for the company to *sell* the doctors on the benefits of using Risperdal to treat those populations.

"We started looking hard for ways to go after these customers—pediatricians, nursing home doctors, mental health facilities, even school guidance counselors," a former Janssen salesman recalls. "We had to."

A MAGIC ALGORITHM

Beginning in 1995, Janssen executives focused on a quick-win priority: make Risperdal the new drug of choice at state-run Medicaid programs that provide healthcare for the poor, including children in state-run mental health facilities and the elderly in state-run nursing homes. Promoting the drug quietly to institutions, rather than broadly to thousands of individual doctors, was more efficient—and less likely to arouse the suspicions of the FDA.

Risperdal pricing compared to Haldol

Jan. 10, 2012 (p.15)

The goal: get Risperdal at the top of the states' lists of approved drugs, called formularies, even though the price would be 40 to 50 times the cost per dose of first-generation antipsychotics, such as Haldol, that were now available as generics.

The path: Have a group of doctors, sanctioned by a state, evaluate all the available drugs and determine that the state's Medicaid prescribers should use Risperdal as their first choice.

In part with $1.8 million in funding from the Robert Wood Johnson Foundation—which was independent of the company, although it was a major shareholder—Johnson & Johnson found its first willing partners among Medicaid and health officials in Texas, some of whom were paid consulting fees by J&J's Janssen unit for their involvement. Thus was born the Texas Medical Algorithm Project, or TMAP.

Within a year, Johnson & Johnson was setting up what one internal memo called PR "SWAT" teams that churned out news releases and offered press availabilities with Texas officials touting the new "Expert Consensus Guidelines"—a manual that put Risperdal at the top of the recommended and approved list for doctors with Medicaid patients suffering from schizophrenia.

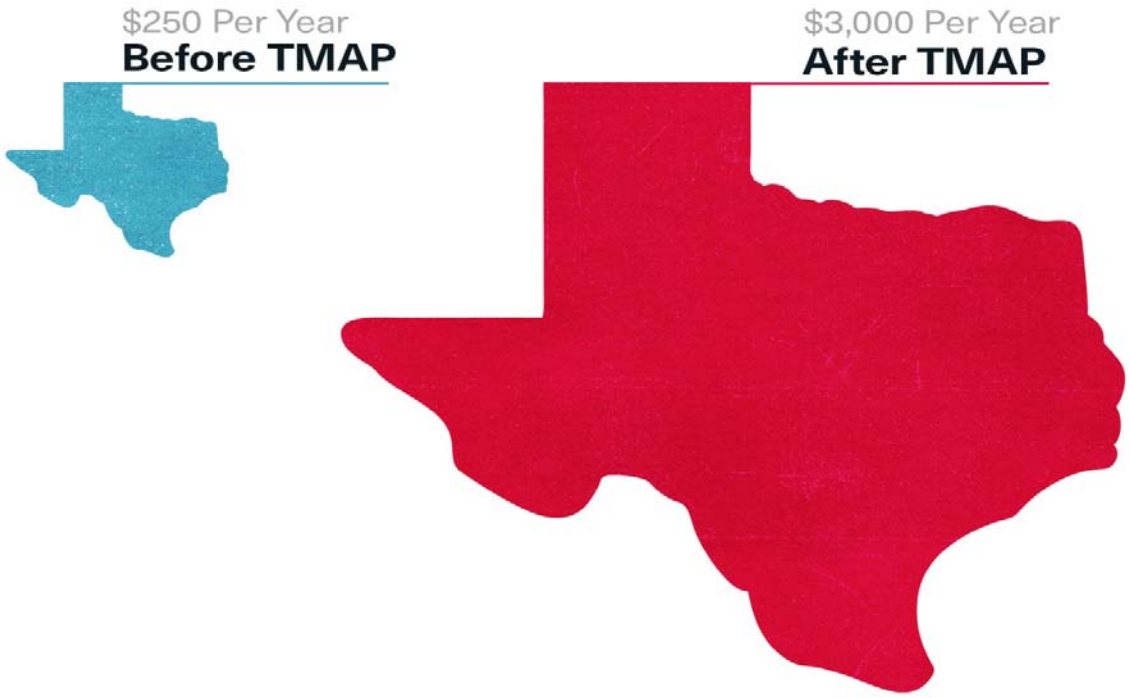
Risperdal 1997 US Strategic Offense Plan

The extra cost of the new drug was worth it, the doctors had concluded, because Risperdal was so much more effective than Haldol or other available options.

The payments to doctors and the PR firms were supplemented by contributions to patient advocacy groups, such as the Texas chapter of the National Alliance on Mental Illness, which is known as NAMI. One dividend was a conference in Austin, called a "Clinical Best Practices" symposium on "New Medications: Impact and Future Value in Treating Severe Mental Illness." The program presented the virtues of TMAP to mental health doctors from across the state. The Texas division of NAMI was featured as the lead sponsor. It wasn't disclosed that Janssen had paid for the event, and that some of the doctors who were dispensing their clinical advice or were in the audience chatting up the program with other doctors were on the Janssen payroll as consultants.

The FDA had warned Johnson & Johnson not to claim that Risperdal was more effective than Haldol. Now, the doctors in this new Texas program, financed by Johnson & Johnson, would do that.

Before and After TMAP: How Much Texas Medicaid Spent Per Patient on Antipsychotic Drugs



By 1999, Texas' Medicaid payments for antipsychotic drugs would soar, with Risperdal having the dominant market share. The state now paid $3,000 a year for each of its patients, compared to $250 a year for the generic first-generation drugs like Haldol. Some of J&J's competitors were "watching in awe at what J&J did," recalls one executive at another Big Pharma company. They also began chipping in for the "research," and getting their products up near Risperdal on the preferred list.

Meantime, Johnson & Johnson paid the Texas doctors who had launched TMAP to give speeches to colleagues across the country urging them to implement their own "MAPs."

'ACTIVE INTERVENTION'

AT NURSING HOMES

Another way for Johnson & Johnson to market Risperdal off-label without directly soliciting individual doctors involved nursing homes and a company called Omnicare.

By the mid 1990s, Omnicare had become a colossus in a growing corner of the healthcare industry. The company, then based in Covington, Kentucky, provided pharmacy management services for nursing homes with hundreds of thousands of patients across the country. As executives at Johnson & Johnson's Janssen pharmaceutical division reminded each other in an internal memo, Omnicare was the dominant player in deciding which drugs were dispensed to those patients. But, as one email would later explain, "In order to have the Omnicares of the world drive market share … it must be financially [worth] their while."

On April 8, 1997, Janssen signed an agreement with Omnicare that included an "Active Intervention Program" that explicitly paid Omnicare to favor Risperdal over other drugs a patient could be given. The point, the contract stated, was "to appropriately shift market share to [J&J]'s Product."

J&J'sOmnicare contract
April 11, 1997 (p.7)

Doctors would be offered paid speaking fees based on the number of Risperdal prescriptions they wrote.

Taken literally, the adverb "appropriately" should have rendered the deal meaningless. When this agreement was signed in 1997 and when it was renewed thereafter, the Risperdal label hadn't changed since the FDA had first approved the drug in late 1993. The label warned that the drug had not been determined to be safe for elderly patients. And as the FDA's Dr. Leber had written to Johnson & Johnson two years earlier, the regulators didn't want it to be used to treat symptoms associated with dementia or other behavior disorders, such as agitation. Yet the Johnson & Johnson literature distributed to Omnicare pharmacists urged it to be used to calm restless patients.

After the deal was signed, Janssen began paying Omnicare tens of millions of dollars in rebates and fees in return for multiples of those amounts in sales of Risperdal, paid by American taxpayers through Medicare and dispensed to Omnicare patients. By 1999, an internal Johnson & Johnson email explaining the Omnicare relationship would refer to the nursing home pharmacy management company as "an extension of [the J&J] sales force."

J&J Long-Term
Care Group strategy
Dec. 15, 1999

The Active Intervention method was deployed across the country at the retail level, too. Doctors would be offered paid speaking fees based on the number of Risperdal prescriptions they wrote. The government investigation of Risperdal sales later unearthed one email from a Johnson & Johnson salesperson that was typical of the approach. She told her supervisor that she was going to promise one doctor that if he raised his Risperdal market share from 16 percent to 50 percent in the coming 12 months he could become a paid speaker.

A WEST POINT MAN IN CHARGE

Beginning in 1997, the sales manager of the J&J division responsible for Risperdal sales in the U.S. was Alex Gorsky, a West Point graduate and former army captain. Slim, good-looking and described by everyone I spoke to at the company as a hard-charging, natural leader, Gorsky had started his J&J career as a salesman. He then earned an MBA from the Wharton School at the University of Pennsylvania while working his way up the sales ladder by constantly hitting his targets and ensuring that the growing number of sales reps working under him hit their targets, too.

As internal emails and business records would later reveal, as sales manager, Gorsky was involved in all key Risperdal sales and marketing initiatives, including meetings with Omnicare executives about the progress of their Active Intervention contract and its renewal. By 1998 Omnicare was Risperdal's single biggest customer.

It was at about this time that the company began to eye another weapon to get beyond the reach of the FDA's label restrictions: The First Amendment.

Many colleagues describe Alex Gorsky as a natural leader.

FREE SPEECH WARRIORS

In November 1997, the Washington Legal Foundation, a non-profit that champions free markets, filed suit charging that the FDA's guidelines on promoting drugs off-label deprived drug companies of their First Amendment right to offer information to doctors and deprived doctors of their right to receive it.

Although the foundation does not reveal its donors, Chief Counsel Richard Samp told me that the pharmaceutical industry "has supported some of our efforts."

The suit did not challenge the FDA's prohibition on creating explicit marketing plans and sales pitches for off-label use. Rather, it was aimed at the agency's guidelines declaring that drug companies might be subject to charges if they disseminated materials, such as articles from medical journals, that reported favorably on a drug's off-label uses unless the doctor had first asked for the information.

In July 1998, federal district court judge Royce Lamberth, a conservative appointed by President Ronald Reagan, prohibited the FDA from enforcing its guidelines on First Amendment grounds. But the U.S. Court of Appeals for the District of Columbia Circuit threw out that order after the FDA—clearly afraid of further damage from the courts—claimed that its guidelines were only meant to tell drug companies what kind of conduct would *not* be prosecuted as off-label marketing.

Conversely, the agency declared, the guidelines did not mean that articles and other promotional materials that *did* violate the guidelines would, in and of themselves, be considered illegal off-label marketing, because the guidelines were not

meant to prohibit speech. Instead the guidelines were meant to signal the type of speech that, to the agency, might be evidence of an off-label selling violation that needed to be investigated.

Put simply, the case did not, at least for now, free the drug companies to do whatever they wanted, including create whatever sales pitches they could dream up, if their intention in doing so was to penetrate unapproved markets. And it certainly didn't sanction business plans devoted, as the law put it, to introducing a drug into commerce for a purpose not approved by the FDA.

But that didn't keep the executives and their Risperdal salespeople from acting as if it did.

FULL THROTTLE

Beginning in 1998, the company's Risperdal promotional efforts began to escalate. Campaigns were launched to deploy sales teams to use explicit messages to pitch doctors, such as pediatricians, likely to have patients in the drug's off-label target populations.

An 83-person Risperdal ElderCare sales team was formed—creating a countrywide unit whose explicit, unabashed mission was to get Risperdal into the mouths of an off-limits population. Its only targets, according to internal budgets and sales plans, were doctors who primarily treated the elderly or who were medical directors at nursing homes.

The ElderCare campaign launch Nov. 4, 2013 (p.15)

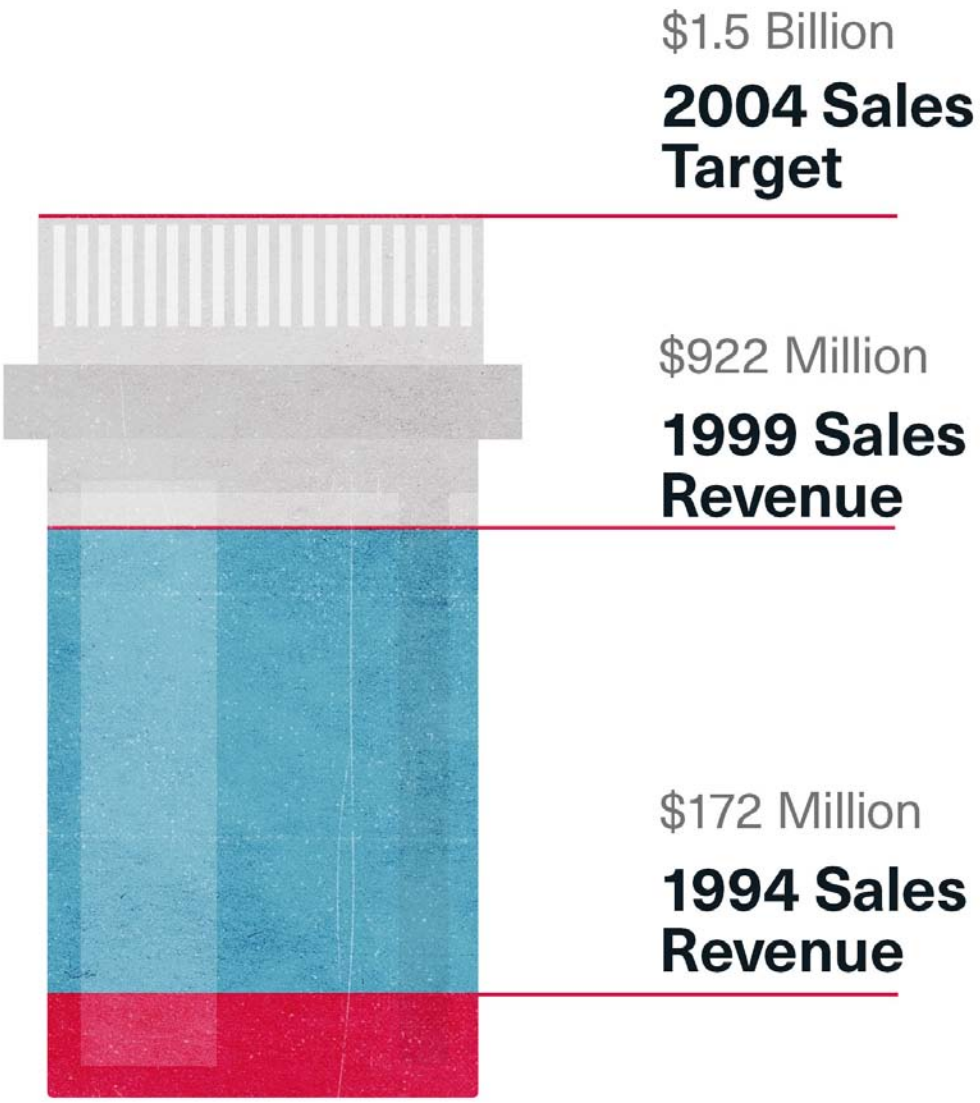
Risperdal 1999 Strategic Business Plan

Johnson & Johnson knew, and Wall Street knew, that they only had seven more years to cash in on Risperdal before its patent expired.

The Johnson & Johnson sales force is required to submit reports of all customer contacts. In 1998, a New York ElderCare salesperson wrote: "Discussed how Ris[perdal] is effective and safe in the Tx [treatment] of behavior disturbances in the elderly, especially those with dementia." Another in California said: "Left a note introducing myself and ElderCare [division] with Ref[erence] to Risp[erdal] for Geriatric hostility/behavioral problems."

By 1999 Risperdal sales in the U.S. were $892 million, up from $172 million in the 1994 launch year. But there was still a long way to go to reach the $1.5 billion in U.S. sales Johnson & Johnson was now targeting for five years out, in 2004. "The better we did, the more they ratcheted up the targets," one salesman recalls. "The word was we had to go full throttle, pull out all the stops."

Reaching for $1.5 Billion



A factor already weighing on Janssen executives and their bosses at Johnson & Johnson was the expiration of the Risperdal patent at the end of 2007. They knew, and Wall Street knew, that they only had seven more years to cash in on their drug. After that, Risperdal would go the way of Haldol.

One problem they encountered in 1999 had to do with Omnicare's Active Intervention agreement.

Under Medicaid's rules, a drug company must sell drugs given to Medicaid patients at a discount of either 15.1 percent off of the regular wholesale price or at the "best price" given to any other buyer if that price is lower than the 15.1 percent discount.

An Aug. 25, 1999, email from a J&J executive overseeing the Omnicare relationship worried that all the rebates that had been given to Omnicare might drop the actual price it was paying below that 15.1 percent threshold. That would mean that J&J would have to lower the price it charged for Risperdal for all other Medicaid patients across the country. According to an internal J&J memo, Omnicare was responsible "well over $100 million" in annual business, and it was insisting on being paid what it was owed under its deal for all of that volume.

So within two months, the company devised a way around the law: J&J would instead pay part of what it owed Omnicare under a different contract that ostensibly had J&J buying "data" from Omnicare related to Risperdal prescriptions. It was later argued by the government, using documents investigators had subpoenaed, that J&J was already getting this data for free.

J&J internal email
July 22, 2002

> *J&J found avenues less subtle than data purchases to get money to Omnicare. In June 1999, an Omnicare senior vice president emailed a Janssen executive requesting $45,000 for a summer golf outing for Omnicare senior executives on Amelia Island in Florida.*

Omnicare request for funds
June 15, 1999

"We will use these funds to further advance our expertise in management activities … " the Omnicare VP wrote in a letter that his J&J contact could pass on to the accountants.

‘GLAD YOU ARE KEEPING YOUR DISCUSSIONS AROUND DEMENTIA’

Johnson & Johnson managers regularly rode along with salespeople for meetings with doctors, keeping copious notes on everything from the cleanliness of their cars to how well they stuck to the pitches disseminated from the home office. One report, written in early 1999, noted that a district manager had told a rep, “I was glad to see that you are keeping your discussions around dementia, because we are a geriatric sales force that focuses on treatment of behavioral disturbances associated with dementia.”

Reports like this from the field were the first clear signs that when it came to Risperdal, sales and not the Credo seemed to have become the company’s mission.

Chapter 3

SALES OVER SCIENCE

By Steven Brill

What Happened in the Previous Chapter

PUTTING THE RISKS IN ‘TINY FONT’

Dr. Stockbridge FDA Letter

Jan. 5, 1999 (p. 1-4)

By the beginning of 1999, Johnson & Johnson had expanded the ElderCare unit to 136 salespeople from 83, and the materials they were using to pitch doctors had caught the FDA’s eye. On January 5, Lisa Stockbridge of the FDA’s Division of Drug Marketing, Advertising and Communications wrote to Janssen’s director of regulatory affairs complaining that “presentations that focus on this population are misleading in that they imply that the drug has been found to be specifically effective in the elderly population.

“Risperdal is indicated for the management of manifestations of psychotic disorders,” Stockbridge added. “However, Janssen is disseminating materials that imply, without adequate substantiation, that Risperdal is safe and effective in specifically treating hostility in the elderly.”

Stockbridge also cited a sales tactic that seemed to stand R.W. Johnson’s Credo of putting patients first on its head. Janssen’s materials, she wrote, “are lacking in fair balance because the risk information appears in pale and tiny font at the bottom or back of a journal ad or other presentation.” For example, she wrote, “the warning regarding tardive dyskinesia”—involuntary movements such as facial grimacing—“is minimized,” and “the claim[s] that ‘Risperdal can enhance daily living’ or that [it] offers ‘quality control of symptoms for daily living’ are considered to be false or misleading.”

Regulators noted that J&J had "failed to fully explore and explain what appeared to be an excess number of deaths" among the elderly treated with Risperdal.

Janssen responded by assuring the FDA that it was going to review its sales materials. However, the company argued that some information about the use of Risperdal among the elderly was appropriate because so many doctors were prescribing it for their patients.

Dr. Stockbridge 2nd FDA Letter
Mar. 5, 1999 (p. 1-2)

In March, Stockbridge wrote back that her agency "has considered Janssen's argument and is not persuaded." She particularly called out a sales flyer the FDA had since discovered headlined "Hostile Outside, Fragile Inside." That pitch, she noted, "implies without adequate substantiation that Risperdal has been specifically shown to be effective in treating psychotic elderly patients with hostility."

"The safety and efficacy of Risperdal in the elderly," she added, was "not particularly examined in 'fragile' individuals."

FDA Label Review
January 1999 (p. 8)

Meanwhile, another unit of the FDA told Janssen in January 1999 that its request a year earlier to extend the label for treatment of the elderly was denied because it had failed to “fully evaluate the safety of [Risperdal] for use” by that population. The regulators also noted that the company had “failed to fully explore and explain what appeared to be an excess number of deaths” among the elderly treated with Risperdal. The deaths the FDA was referring to mostly had to do with strokes and other heart-related fatalities.

The rejection letter again warned Janssen not to market the drug for use by seniors.

BOYS WITH BREASTS

Through the late 1990s, a different team of Janssen salespeople continued to promote Risperdal to the other forbidden population: children.

“Sold him on efficacy and safety in children,” one Michigan call report bragged.

Call Report Notes

1997-1998 (p. 25)

“Remind[ed] her that Risperdal is very effective and safe because she sees lots of children and adolescents,” a Maryland sales rep reported.

These were not instances of overeager troops straying off message. By 1999, more than 20 percent of Johnson & Johnson’s $892 million in U.S. Risperdal sales were to the pediatric market.

Tone Jones, a Texas-based Janssen manager, would later testify that the directive to focus on children came straight from the home office. Jones—who would win a 2001 sales award at a ceremony presided over by Alex Gorsky—was asked in court, “In your experience, would promoting Risperdal off-label to children get you fired?”

“No,” he replied.

“Would it get you a bonus?”

“Yes,” he answered, whereupon he produced a letter from a regional supervisor awarding him a bonus based on “your performance quotient of 131.05%.”

HORMONE ISSUES

By the late 1990s, studies of people using Risperdal and its competitor anti-psychotics had started to reveal that young patients showed an increase in levels of prolactin—a hormone that at its normal levels enables women to produce breast

milk. The data seemed to suggest that Risperdal was the worst offender. Raised prolactin levels in young boys, it was thought, might cause them to grow female breasts, a disease called gynecomastia.

Meeting Minutes

Oct. 19, 1998 (p. 134-138)

On October 19, 1998, Gorsky, who was Janssen's vice president of sales for its CNS (central nervous system) division, led a "Risperdal Brand Strategic Planning" meeting. One of the action items on the agenda was the need to examine the effect of these raised prolactin levels. According to the minutes, Eli Lilly—which was marketing the competing drug Zyprexa and whose salespeople were telling doctors that Risperdal had a prolactin problem—had three studies in the field to help drive home this competitive advantage. With that in mind, Janssen decided to push ahead with its own studies of whether Risperdal affected prolactin levels in children, and what side effects, if any, elevated prolactin might cause.

At the same time, the company focused on rounding up respected academics who could aid the cause by touting the results as they came in and make Risperdal the prime choice for pediatricians regardless of what the FDA label said.

'NOT SOMEONE TO JERK AROUND'

Biederman Resume

May 7, 2008

Chief among the academic luminaries Johnson & Johnson began to covet was Joseph Biederman, a pediatric psychiatrist. For more than a decade, Biederman had done pioneering work on the theory that behavior disorders among children and adolescents–such as attention deficit disorder (ADD) and attention deficit hyperactivity disorder (ADHD)—were the result of chemical imbalances in the brain that could be addressed with strong prescription drugs, such as Risperdal.

Joseph Biederman: the object of Janssen's attention.

Biederman was born in Czechoslovakia in 1949 and moved to Argentina when he was six months old. He completed medical school in Buenos Aires when he was 22 and went on to an internship at Hadassah University Hospital in Jerusalem. He then came to the United States to train as a child psychiatrist at the prestigious Boston Children's Hospital, which is part of the Harvard-affiliated Massachusetts General Hospital.

By the time Biederman got onto Johnson & Johnson's wish list, he had been credited as the author or co-author of hundreds of medical journal articles on the use of pharmaceuticals to address children's behavioral issues. In 2005, The Institute of Scientific Information would rank him number one for scholarly citations related to ADD or ADHD.

Biederman's supporters considered him a genius, even a savoir. "I've had people from around the country who were old friends or even people I hardly knew calling me to help get them an appointment with Joe for their kid," one former executive at Massachusetts General told me. His detractors, who generally were people worried about the effects of plying children with drugs, considered him a menace.

"Biederman is a very powerful national figure in child psych and has a very short fuse," John Bruins warned.

Johnson & Johnson's early encounters with the strong-willed Biederman had not gone well.

Email about Biederman

Nov. 17, 1999

On November 17, 1999, John Bruins, who was Janssen's liaison to the medical community in New England, emailed his supervisors asking them to expedite the approval of a $3,000 check to Biederman. The doctor had been promised the money, Bruin wrote, for his appearance at a symposium at the University of Connecticut, where he had spoken on the promise of drugs like Risperdal.

"Dr. Biederman is not someone to jerk around," Bruins warned. "He is a very powerful national figure in child psych and has a very short fuse."

As Bruins went on to explain, Johnson & Johnson had lit that fuse in the past—when expanding the FDA label, rather than working around the label, had been the company's priority for getting Risperdal into the children's market. "Three or four years ago," Bruins wrote, "Janssen … requested that he put together a study to evaluate RIS [Risperdal] in the child and adolescent population. He submitted a thorough and lengthy proposal, which amounted to approximately $280K. We dragged our heels on his request … for over a year. He finally received a standard ding letter.

"By the time I found out," Bruins added, "and went to see him, his secretary advised me of his fury. The sales representative who called on him and I took an hour of verbal beating. I have never seen someone so angry.

"Dr. Biederman is Head of Adolescent Psych at [Massachusetts General]. Since that time our business became non existant [sic] within his area of control," Bruins continued, adding this zinger: "He now has enough projects with [J&J competitor Eli] Lilly to keep his entire group busy for years. Although I occasionally call on him and invite him to our [paid Advisory] Boards, he acts with skepticism about our sincerity."

Biederman was quickly paid the $3,000, and the company began talking with him about what would become a multi-million dollar project to promote Risperdal, using his, Harvard's and Mass General's name.

14 PERCENT OF ALL OF J&J'S PROFIT

Getting Biederman on the team was part of a still-more aggressive business plan for the year 2000, drafted in July 1999.

Risperdal 2000 Business Plan

July 1999 (p. 1-4, 14-16, 22)

The plan targeted $1.059 billion in U.S. sales for 2000, through 707,000 in-person sales calls to doctors who would prescribe 452 million pills or oral doses, priced at about $2.50 per dose. Total costs—including $51 million for "public relations, grants, sales support and medical education programs," and $14.3 million for free samples—were budgeted at just $103 million. That included the salaries of all the salespeople and the cost of the drug itself, which was so low that it did not merit its own line item. The cost of PR and other marketing, about 12 cents per dose, was about twice the cost of the actual drug, according to other internal J&J budget analyses.

Profit for Johnson & Johnson ($1.050 billion in revenue against $103 million in costs) was projected at about $950 million. If that target was achieved, the yield from this one product would be 14 percent of all of Johnson & Johnson's total earnings for the year across all of its divisions.

The first objective listed in the plan was that "Risperdal will be the antipsychotic treatment of choice for both psychotic and non-psychotic disorders."

Non-psychotic disorders represented the "sky's the limit" problem that Senator Kefauver had had in mind in 1962 when he wrote restrictions against off-label sales. These less serious maladies were not included on the label as indicated treatments for the drug because the FDA was not convinced that treating them was worth the risk of Risperdal's side effects.

Nonetheless, the next line of the company's business plan listed dementia and conduct disorders (which include ADD and ADHD) as key targets, with the next page spelling out a grab bag of other off-label disorders for Risperdal to target, such as stuttering.

The business plan noted that Lilly's competing drug, Zyprexa, was beating Risperdal in market share, 34.7 percent to 25.2 percent, for bipolar-related prescriptions, the treatment codes most associated with children's more general behavior disorders. Thus, the strategies listed under "Bi-Polar Disorder" included "strengthen opinion leader and advocacy support for RISPERDAL." That was where big-name academics—including Biederman—would play lead roles.

Another goal for the coming year was to "maximize and grow Risperdal's market leadership in geriatrics and long term care." Risperdal was already well ahead of Zyprexa in dementia market share, with 50 percent of the entire market. The goal was to boost that share still higher, to 57 percent, with sales of $302 million.

2000 Omnicare Deal

J&J Internal Memo on Omnicare

The nursing home pharmacy manager, Omnicare, was a big part of that plan. By the summer of 2000, Johnson & Johnson would sign a new, more extensive deal with the company. One of the J&J executives on the account crowed in a memo about “Omnicare’s ability to persuade physicians to write Risperdal in the areas of Behavioral Disturbances associated with Dementia.”

He continued: “Omnicare, Inc. has demonstrated its ability to partner in a true sense of the word and has generated well over 100 million dollars of Johnson & Johnson pharmaceuticals annually.”

SELLING A ‘CHEMICAL STRAITJACKET’

The Food and Drug Administration consistently rates high among federal agencies in employee morale. Officials there, along with the doctors and scientists on the front lines reviewing drugs, like to think of themselves as professionals dedicated to a mission—keeping dangerous products off the market and helping drug companies get good products into the market. However, when they think they are being conned, they can be tough.

That was their posture on March 3, 2000, when about a dozen product development scientists and regulatory executives from Johnson & Johnson met to talk about Risperdal and children. Once again, the J&J team’s goal was to get the label extended to include “conduct disorders” in children. This would not only sanction the marketing that the company was already doing; it would also extend the overall Risperdal patent for six months under a law that gives pediatric drugs longer protection from generics.

FDA Meeting
March 3, 2000

According to minutes of the meeting recorded by someone on the J&J side of the table, the FDA officials wasted no time shooting down the premise of the proposal: “The FDA questioned the validity of conduct disorder (CD) as a diagnosis and even the concept of CD as a disorder,” the minutes reported, “because it is just a list of behaviors, mainly aggressive behaviors that annoy others. … Their main concern is that Risperdal or any other product would be used as a chemical straitjacket.”
“They really didn’t believe it,” recalls one FDA official who was at the meeting. “We were basically saying their plan, whatever data they presented, was not legitimate because conduct disorder could mean anything.”

According to multiple documents later produced in lawsuits and investigations related to Risperdal, it was following this meeting that the company stepped up its efforts to legitimize conduct disorder as a diagnosis in the academic medical community. That was what Biederman had made a career of.

POPCORN AND LEGOS

By the fall of 2000, 21 percent of Risperdal being sold was going off-label to children and adolescents, and the sales teams had been told that expanding that market was the company’s highest priority.

Tone Jones Testimony

Sept. 24, 2012 (p. 135-141)

Houston sales manager Tone Jones would later testify that “the message from headquarters” was that “hostility, aggression, agitation” was a “significant opportunity” for the company to achieve what was by then a target of nearly $3 billion in annual U.S. sales before the patent expired.
Jones brought a visual aid to spice up his testimony: a photo of popcorn, packaged and labeled as “Risperdal Popcorn,” to be given by sales reps to pediatricians. Its purpose, according to a sales primer, was “to butter up docs.”

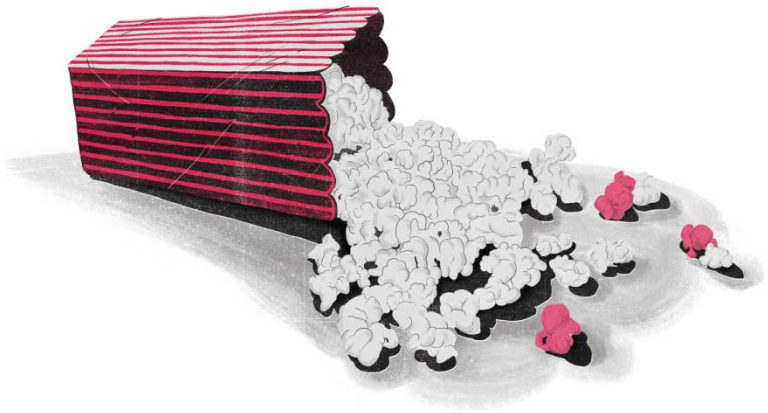
Curious promotional materials.

The doctors who prescribed the most Risperdal were recruited to be paid speakers, Jones would testify, and were called “whales.” They were so important to the business, Jones explained, “that we needed to see them for sure on a weekly basis, if not every day pretty much.”

Another favorite sales tool that began to be distributed in the waiting rooms of whales, or prospective whales, he added, were Legos imprinted with a Risperdal logo.

In early September 2000, a Johnson & Johnson email celebrated the full implementation of the TMAP program that put Risperdal at the top of the recommended list of second-generation antipsychotics and first-generation generics for doctors giving these drugs to Medicaid patients in Texas. “Let the butt kicking begin,” wrote a Janssen sales manager.

By the end of 2000, Alex Gorsky’s Risperdal sales team had beaten its ambitious sales goal of $1.05 billion, coming in at $1.08 billion.



SELL THE ‘SYMPTOMS, NOT THE DISEASE’

In September 2000, the FDA ordered a labeling change—but not one that J&J had pushed for. The agency told Johnson & Johnson that the indications on the label should be scaled *back*—from management of “psychotic disorders,” to just the “treatment of schizophrenia,” which is one of several psychotic disorders.

Of course, this technically constrained the market for Johnson & Johnson’s best-selling drug. But in the sense that the company was already selling into markets far beyond the label, it arguably didn’t matter. By the time the company implemented the FDA order in February 2002, a full 16 months later, the sales team had been prepared well. The pitch was now all about, as one salesperson put it, “the symptoms, not the disease.”

Doctors would be reminded that medical care was all about treating the symptoms that bothered their patients (or, in the case of nursing homes, the staff members who had to control patients). It didn’t matter whether a nursing home resident was acting out because she had Alzheimer’s or was just plain unhappy, or was acting out because she was among the less than 1 percent of the elderly who were schizophrenic. The pill would calm her down.

BAD BREAST NUMBERS

In November 2000, Johnson & Johnson research scientists got troubling numbers related to the goal Gorsky and his team had set at the Risperdal “Brand Strategic Planning” meeting two years earlier. They had hoped that the scientists would generate data that would rebut the competition’s claim that Risperdal raised levels of the hormone prolactin to a degree that could cause young boys to grow breasts. But the largest study done yet by J&J of the effects of long-term Risperdal use among children and adolescents—in which, according to the study’s protocol, “special attention” was paid to prolactin—had now found that of 319 children, including 266 males, 8.6 percent of the males had developed gynecomastia, or breasts. When the final results including more participants were tabulated, the percentage of males was 5.5 percent.

> **Attention deficit disorder was no picnic, but doctors and parents might not think treating it was worth those odds of their son having to wear a bra.**

Five and a half-percent was a big number. If 400,000 boys took Risperdal, that would mean 22,000 might end up with breasts. Attention deficit disorder was no picnic, but doctors and parents might not think treating it was worth those odds

of their son having to wear a bra. And that risk was in addition to all the other known side effects already listed on the Risperdal label, such as somnolence, nausea or significant weight gain.

Worse, none of Johnson & Johnson's competitors seemed to have the same gynecomastia problem.

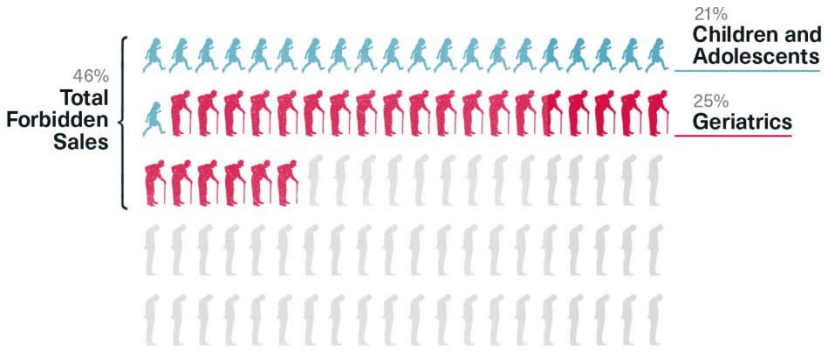
Until that time, J&J had told the FDA that it had no information on the relationship between prolactin and gynecomastia other than that in its studies of all patients taking Risperdal—including adults—gynecomastia was "rare," meaning it occurred one tenth of a percent of the time or less. And that, in fact, is what the approved label said about gynecomastia.

'DRIVING PEDIATRIC ACUTE MEDICAL EDUCATION'

An updated Risperdal business plan that management signed off on in September 2000 unabashedly signaled that Johnson & Johnson would ignore the regulators and any bothersome data and keep going after children.

The plan described the small—but legal—schizophrenia market as "flat." However, that did not present a significant hurdle, because schizophrenics were not the hard-charging sales team's target. "The RISPERDAL Base business is rooted in the Schizophrenia marketplace," the plan acknowledged—as if "legally allowed to be marketed in" really only meant "rooted." But that would not be an impediment, because, the plan noted, "The child/adolescent … segment (19 years and under) is growing at a rate of 17% and is currently valued at approximately $340 million. Use of RISPERDAL in this segment has grown 50% in the past two years, and prescriptions in this category account for 20% of overall RISPERDAL use."

The Risperdal Market in 2000



Children and adolescents were now the fastest growing segment of the market—and they accounted for 21 percent of all Risperdal users. The second fastest uptick was in the geriatric market, which comprised 25 percent of all Risperdal users. That meant markets that J&J was forbidden from promoting to accounted for 46 percent of all sales in the year 2000, a percentage that was likely to grow quickly because, as the plan noted, the legitimate market, schizophrenic adults, was "flat." In fact, a study later published by the Journal of the American Medical Association would put the off-label percentage at 66 percent in 2001.

The plan then mapped steps to be taken in the coming year to "grow and protect share in child/adolescents via medical education initiatives and effective [sales] rep-targeting, with a year-end exit share of 70%." Respected doctors—called "Known Opinion Leaders," or "KOLs"—would be paid to "drive pediatric acute medical education" with a blizzard of J&J-financed articles, symposiums and supporting PR.

Chapter 4

MASSAGING THE DATA, SPREADING THE WORD

By Steven Brill

What Happened in the Previous Chapter

THE GHOSTWRITERS

Description of Excerpta Contract
(p. 43-46, 51, 86-89)

In 1999, Johnson & Johnson had signed a contract with a company called Excerpta Medica. Its specialty was medical marketing. Its sub-specialty was producing ghostwritten, data-filled studies on the efficacy and safety of a client's drugs, finding the right academic scholars to be listed as the authors and then placing the articles in prestigious academic journals.

Excerpta's and Johnson & Johnson's partnership with academics and the journals that publish them was not unusual. Over the last 20 years, research into the effects of specific drugs has become almost exclusively funded by drug companies that have an interest in the results. The government, through agencies such as the National Institutes of Health, sponsors generic research related to various diseases, but beyond that initial stage, most of the work is paid for by the pharmaceutical or biomedical industries.

In a detailed presentation to Johnson & Johnson, Excerpta outlined one of its key selling points: "Ensuring Vast Opinion Leader Access."

"No other medical education company has the tremendous access to top opinion leaders that Excerpta Medica does … " Excerpta promised. "Our parent company, Reed Elsevier, is the largest supplier of medical information in the world, publishing over 700 medical journals in almost every conceivable therapeutic area. Each journal has an editorial board composed of renown [sic] specialists throughout the world who are available to us as consultants, advisory board members, speakers, and in other capacities. We provide this significant access to all of our clients." (The Excerpta connection to the giant Europe-based publisher would be severed in 2010, when it was sold to a unit of the giant advertising agency Omnicom.)

Now, in 2000, Excerpta began working on a plan to place dozens of Risperdal articles in medical journals. "Awareness articles" and "original reports," of which a total of 39 were planned, would cost $22,000 each in fees, plus fees for the "authors." Shorter pieces would be $9,000 each.

As Excerpta later explained when it presented its plan to Janssen executives, the goal was to publish clinical data and marketing that supported the use of Risperdal for mood disorders. "Overall, the plan supports risperidone's market expansion into the treatment of patients with bipolar disorder and, more broadly, into the treatment of patients with mood disorders," the presentation promised.

Significantly, one example of a "core message" piece, according to the Excerpta proposal, would be a scholarly article that conveyed the message that Gorsky and his team had decided that they needed to fend off attacks by competitors: "prolactin elevation sometimes seen with Risperdal treatment is not (directly) linked to clinical abnormalities."

To that end, in August 2000, Excerpta's Michelle Daniels emailed Dr. Robert Findling, a renowned child psychiatrist at Case Western Reserve University hospital (he is now director of child and adolescent psychiatry at Johns Hopkins), to ask if he would be a lead author of an article that would be based on the results of Risperdal studies involving children taking the drug over an extended period. The data was not in yet, but the working title was "The Safety and Efficacy of Open-Label Risperidone in Conduct Disorder in Mild, Moderate and Borderline Mentally Retarded Children Aged 5 to 12 Years."

"You have been identified as the lead author to this manuscript," Excerpta's Daniels wrote, noting that she had attached a "preliminary outline for your manuscript."

Findling agreed to attach his name to the article, but suggested that "some secondary analyses be performed in an attempt to identify risk factors for … prolactin increase." How steadfastly he stuck to his guns is a source of controversy that continues to this day.

'WE NEED TO BE PROACTIVE'

Description of Gorsky 2001 Email
(p. 143)

Excerpta's safety/efficacy messaging strategy was consistent with a January 2001 email that Gorsky, then Janssen's vice president of sales and marketing, sent to executives in New Jersey and Belgium (Janssen's birthplace and still a major outpost). "While we cannot respond to each and every competitive jab … we should expect that we will be challenged on a number of fronts due to our market position … therefore we need to be proactive in expanding on our strengths (efficacy long and short term, agitation, weight gain, etc) and defending our weak spots." The first "weak spot" Gorsky listed was "prolactin."

Gorsky re: "Perceived Weakness"
(p. 143-145, 200-205)

Although the results of the clinical studies of boys and gynecomastia that were tabulated in November 2000 seemed to confirm that prolactin vulnerability, Gorsky would later testify that when he wrote this email three months after those results had come in he thought of prolactin as a *perceived*weakness because of competitive claims, not a real one.

Whatever he already knew about the discouraging prolactin data, Gorsky was certainly on top of his competitors' potential vulnerabilities. The next day, a Janssen doctor wrote Gorsky saying that he had "spread the word" about the death of a patient enrolled in the trial of a Risperdal competitor drug.

Gorsky's reply: "Good. … It sounds like we have taken the right steps."

‘I AM VERY RELUCTANT TO HAVE THESE DATA IN THE PUBLIC DOMAIN’

In March 2001, Janssen doctors received the summary results of a study of Risperdal use among the elderly that was intended to get the FDA to include seniors with dementia on the label. The data revealed unmistakably that when compared to test subjects receiving a placebo, there was a statistically significant increase in what are called cerebrovascular adverse events, or CVAEs—including strokes.

Email re: Elderly Side Effects
March 22, 2001

One of the doctors reviewing the study said that the results should be publicized at an upcoming medical seminar. But a Janssen executive (not Gorsky) objected. “I am very reluctant to have these data in the public domain that soon,” this executive wrote to other members of the clinical studies team in a March 22, 2001, email. “You may have noticed that in the topline results there are substantially more [cardiovascular events] in the Risperdal group. These are of substantial concern to us. … I propose to keep this discussion in-house, though, until we have a better understanding.”

In May 2001, a Janssen statistician working on three elderly studies reported that in reviewing the first two and combining it with the third one that had been the subject of the March email, there was a statistically significant relation between taking Risperdal and suffering strokes and other CVAEs. In May, Janssen submitted that data to the FDA, as required by law. But the company continued not to make the information public until two years later, in 2003. (Data submitted to the FDA is generally not made public by the agency.)

SHIELDING THE SALES TEAM

Primer on Dementia
(p. 7-8)

By now, the J&J scientists and the sales teams seemed to be functioning in alternate universes. The worse the data on the elderly got, and the worse the potential for the FDA reaction to it got, the more J&J seemed to intensify its sales effort. That same month, Janssen distributed a “Primer on Dementia” to its ElderCare sales force. The marketing team also created a section for a training manual called “Handling the Most Common Objections Voiced By Prescribers,” which told the sales reps to remind doctors that “Risperdal has an excellent combination of efficacy and safety.”

At a fall 2001 training session in Pittsburgh, one sample dialogue that trainers acted out for the group instructed the team to “Bridge to Risperdal” this way: “Doctor, as your patient’s disease progresses into the moderate to later stages of AD [Alzheimer’s Disease] and behavioral type symptoms become more prevalent, Risperdal offers superior efficacy, an unparalleled safety profile, and dosing flexibility tailored to the geriatric patient.”

Geriatric Sales Plan
2001 (p. 7)

These ElderCare unit sales materials were part of a separate plan for the geriatric market that also included 1,100 “Senior Care Seminars” nationwide, or 21 a week, for doctors whose patients were most likely to be elderly. The events, typically luncheons, would deploy 250 paid physician-speakers. Like the pediatricians getting Risperdal popcorn and Legos, these speakers were “whales” —doctors already prescribing large quantities of Risperdal.

Prescriptions written by the doctors who attended would be tracked by J&J not only to gauge the effectiveness of the sessions, but also to identify emerging whales so that they, too, might be offered paid speaking engagements.

Omnicare Letter to Janssen
Feb. 14, 2001

At the same time, Janssen was pushing Omnicare to ratchet up its program to make Risperdal the drug of choice at the nursing homes where it ran pharmacies. At one point, after J&J found out that Omnicare had negotiated a similar, thoughwhich didn’t seem likely apparently not as favorable, deal with Eli Lilly and demanded that Omnicare cancel the Lilly deal, the pressure from Johnson & Johnson became more than the Omnicare executives were willing to tolerate.

In a February 14, 2001, letter to Janssen Long Term Care Account Director Bruce Cummins, Omnicare senior vice president Timothy Bien pointed out that “Omnicare will spend $173,128,000 on J&J products in 2001,” compared to $126.8 million for Lilly products, and that “head to head, Risperdal enjoys a 72.3% market share in number of scripts with Omnicare,” compared to 27.7 percent for Lilly’s Zyprexa. Complaining that his company needed the “$3.5-4 million the Lilly contract represents,” the Omnicare executive concluded, “I am angry by Janssen’s stance. We all need to keep in mind the very successful relationship we have built together.”

There was no trace of the Credo in the exchange between J&J and Omnicare—nothing about the comparative quality of the drugs involved or their effect on patients.

Market Share of Risperdal and Zyprexa in Omnicare Prescriptions, 2001

LIVING UP TO THE CREDO, ALMOST

On September 4, 2001, Janssen's top development executives met to discuss a subject that might have heartened Robert Wood Johnson II and anyone else who believed in the J&J credo. It seemed as if the company was finally reconsidering its marketing tactics and was about to stop pushing Risperdal on elderly patients.

ElderCare Meeting Presentation
Sept. 4, 2001

The headline of a PowerPoint presentation prepared for the meeting was non-committal: "Risperdal in BPSD"—Behavioral and Psychiatric Symptoms of Dementia. But the subhead was direct and seemed to signal an about-face from Johnson & Johnson's drive to promote Risperdal off-label to the elderly: "The BPSD project shall be terminated as ethically, legally, and quickly as possible."

The PowerPoint began by running through all the bad news—the various studies with negative findings and the fruitless data submissions to the FDA to get dementia treatment onto the label. It then outlined the steps that would have to be taken to ease patients currently in clinical trials of Risperdal off of the drug.

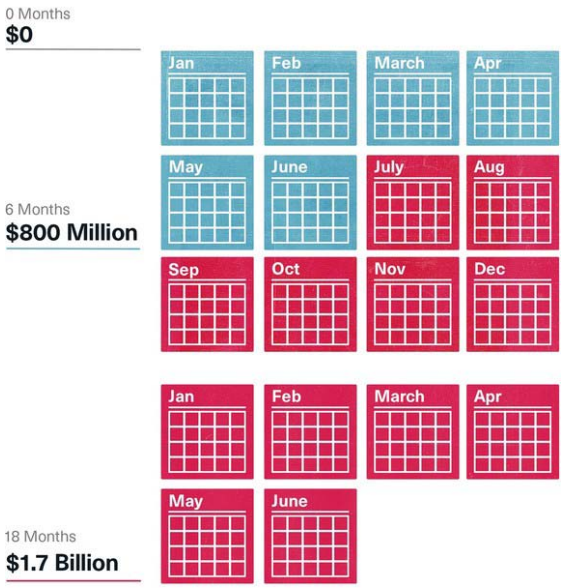
Next came a page entitled “Ethical/Moral” implications.

But it turned out that this was *not* about the ethical and moral implications of continuing to push Risperdal to the elderly. Rather, it was about the supposed ethical and moral implications of *ending* the elderly campaign, including the disruption to patients caused by the fact that Johnson & Johnson’s off-label marketing had been so successful that “over one half of all antipsychotic-treated dementia patients are currently using Risperdal in the U.S.”

The numbers were tallied on another page. The cost of three alternatives—suspending the project for six, 12 or 18 months until some solution could be found that would improve the data—were estimated and compared to staying the course. Even the briefest delay aimed at getting better data would cost $800 million in sales between 2001 and 2010, and an 18-month delay would cost nearly $1.7 billion. And all of the estimates assumed they would get the data they needed, which didn’t seem likely.

The meeting ended with a decision by the numbers. The ElderCare campaign would not be cancelled or suspended. They would keep going and keep trying to persuade the FDA to allow the label to include treatment for dementia.

Estimated Cost of Delaying Risperdal Campaign to the Elderly



MORE BAD BREAST NUMBERS

Janssen's Nondisclosure of Gynecomastia Data
(p. 74-76)

Soon after the meeting to deal with, and put aside, the concerns about the drug's safety when taken by seniors, it became clearer that serious side effects in children might be an equally significant problem. The Janssen doctors and statisticians now had more complete results from the long-term study of children and adolescents using Risperdal. They confirmed that the claim on the current label that gynecomastia was "rare" (meaning that it occurred in fewer than one-tenth of 1 percent of patients) was understated by a factor of more than 50. The final tally was 5.5 percent of the boys.

Children's Sales Pitch
(p. 25)

The numbers didn't dampen the sales pitch. In 2001, 1,106,000 prescriptions would be written for children and adolescents. "Discussed … proper dosing in children," reported one salesperson. "Warned him about competition putting side effects out of context regarding R[isperdal] in children."

However, not every sales rep was on the same page.

DOING THE WOLF HOWL

Victoria Starr, who everyone calls Vicki, had high hopes when she joined Janssen in the summer of 2001.

The daughter of a Nevada pharmacist, Starr, then 30, had always wanted to work in the industry. After getting a pharmacy degree from Washington State University and her pharmacy license, she went to work for Eli Lilly as a sales rep in and around her home in Portland, Oregon.

A roundtable "best practices" discussion turned into a primer from Starr's sales manager on "selling to kids, and telling doctors to give them smaller doses."

In 2001, after she had been at Lilly for six years, Starr decided to leave. She was fascinated with the science and the promise of central nervous system (CNS) pharmaceuticals, and Johnson & Johnson's Janssen unit had an opening in that division.

A short, outgoing brunette, Starr can be dead serious about business one moment and quick with a laugh the next. Janssen “might have been a little too straight-arrow for me,” she recalled, “with their car inspections and even checking out your driving record. But I thought they were serious about having people with pharmacy training sell doctors based on the chemistry of the drugs, the science of the nervous system, and all that.”

Her first meeting with the CNS Oregon division, in the fall of 2001, was not what she had anticipated. A roundtable “best practices” discussion turned into a primer from her sales manager on “selling to kids, and telling doctors to give them smaller doses,” she says.

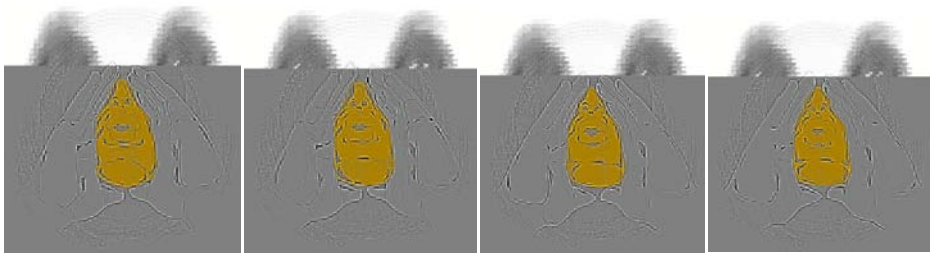
“I’m a label kind of person,” Starr adds. “I like to talk to my doctors about the label, about receptors, about how the drug actually works. And there were no studies in these materials about any of that—just how we could sell to the symptoms. That it would calm kids down.”

Starr remembers that she felt sorry for one of her new colleagues, whose prospects were mostly pediatricians. “He kept asking what he was supposed to leave behind. … He was told to use the stuff from the binder, but not leave it behind, because at that time they still weren’t actually leaving that kind of material behind. They knew it wasn’t allowed.”

A few weeks later, Starr found herself at a national Risperdal sales meeting at the Boca Raton Resort & Club in Florida. Market share numbers were reeled off by region, with exhortations that 2002 was going to be even better. The markets for kids and the elderly were called out as special priorities, Starr says, “because that’s where they saw all the growth. With adults, you pretty much have to focus on the actual diseases—like schizophrenia—because adults don’t end up at the doctor getting drugs for acting up. But kids, or the elderly with dementia, do.”

At one point, to amp up the troops, the CNS sales chief asked everyone in the ballroom to do the “wolf howl.”

“Everyone broke out into this weird howl,” says Starr, laughing. “It was a cross between what you’d hear at a Super Bowl and at a religious cult. … It was kind of fun, great team spirit and all.”



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‘MONEY ON THE TABLE’

Gorsky Email
Nov. 2, 2001

Back at Janssen headquarters, Gorsky, who had just been promoted from sale chief to Janssen’s president, sent a November 2, 2001, email to a group of his top executives asking that they set a date to “review ‘Growth Opportunities.’ … These are similar,” Gorsky wrote, “to the ‘Money on the Table’ exercises we conducted last year … that we feel can generate top line [revenue] growth in the 2002 and 2003 timeframe.”

Pandina Email
Nov. 2, 2001

Gahan Pandina, Janssen’s assistant director of CNS clinical development, then suggested in a follow-up email that this might “be an appropriate forum to discuss the J&J Center idea with Dr. Biederman.”

Pandina, a top Gorsky lieutenant in the Risperdal effort, was referring to an idea that Joseph Biederman, the star Massachusetts General/Harvard child psychiatrist, had recently pitched to Janssen. The doctor was apparently over his earlier piques about Johnson & Johnson brushing off his 1998 research proposal or being slow to deliver that $3,000 honorarium check. As another email picking up on Pandina’s suggestion explained, Biederman had recently “approached Janssen multiple times” to propose that Johnson & Johnson finance a center to study bipolar disorders in children and adolescents at Massachusetts General Hospital.

Follow-up to Pandina Email
Feb. 5, 2002

Email About Biederman
Nov. 17, 1999

According to the email, “the rationale of this center is to generate and disseminate data supporting the use of risperidone [Risperdal] in this patient population.”

By March 14, 2002, Johnson & Johnson had deposited the first $500,000 of what would be $2 million into an account set up for the center by Mass General—and Biederman was sitting at a kick-off meeting with a Janssen team to discuss the center's plans.

Biederman then quickly took to the speaking circuit to push the center's agenda. In an upbeat email, Pandina described a three-day educational seminar Biederman conducted for more than 1,000 physcians in child psychopharmacology and pediatric bipolar disorder:

"Dr Biederman was very well-received by the group. The validity of his diagnosis of pediatric mania was completely accepted and his diagnostic techniques deemed to be excellent. He was very balanced in his approaches to treatment and not perceived to be aligned with any company in particular."

Continuing his report, Pandina told his colleagues that although Biederman had not been "perceived to be aligned" with any drug company, the doctor had managed to get a dig in at Risperdal's main competitor:

"Evidently, he made quite a point regarding the metabolic issues related to olanzapine [the chemical term for Eli Lilly's rival Zyprexa] to the extent of stating that this drug should not be used in the treatment of children and adolescents, highlighting the issues with published data."

THE QUEST FOR 'REASSURING' DATA

It was unclear what Zyprexa data Biederman could have been referring to. In fact, the Risperdal data that J&J officials were now reviewing back home was causing heartburn. In late February, a new analysis of clinical data seemed to show that there was a relationship not only between Risperdal and raised prolactin levels, but, more crucially, a relationship between raised prolactin levels and instances of gynecomastia in young boys.

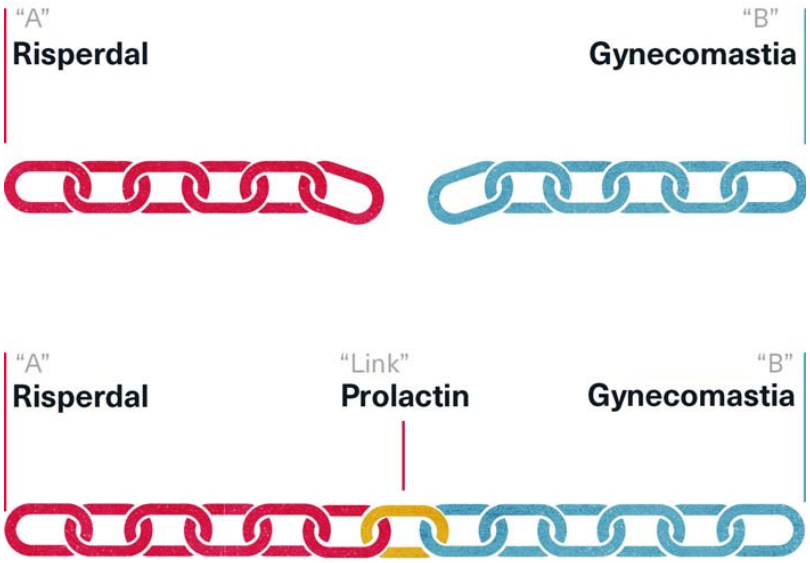
Although Johnson & Johnson never acknowledged it, the company, as well as its competitors, already knew from multiple studies that Risperdal alone caused highly elevated prolactin levels even at the recommended low doses for children. And the company already had studies seeming to show an alarming rate of gynecomastia in children using Risperdal.

But the most important question—the one for which new data was now being tabulated—was whether these raised prolactin levels were a temporary and harmless condition, or whether they actually caused diseases such as gynecomastia.

PROVING A CAUSE

The best science—and potentially the best legal case against Risperdal—would not only require determining whether a significant number of boys given Risperdal end up with gynecomastia, compared to those who do not get the drug. Some intervening factor would also have to be found that made it clear that this was not a coincidence. "A" might be *associated* with a high incidence of "B," but showing an *association* wasn't proof that "A" *caused* "B". Some kind of *causal* relationship had to be shown.

A Causal Relationship Between Risperdal and Gynecomastia



That is what made the prolactin and gynecomastia data so important. Could it be shown that raised prolactin, which Risperdal was known to cause, could in turn be the cause of gynecomastia?

Conversely, showing the absence of any causal relationship would be the best defense that Risperdal may be *associated* with gynecomastia but does not *cause* it.

This causal relationship data—whether there was any link between raised prolactin and gynecomastia—was the data that was going to be used in the paper that Excerpta Medica had recruited Dr. Findling to author about the long-term safety of Risperdal.

Pandina Email
Aug. 22, 2002

The goal, expressed in notes and emails referring to multiple meetings of Janssen scientists and sales and marketing people, was to trump their competitors' claims and prove that there was no causal link between Risperdal and gynecomastia. As an August 21, 2002, email from Pandina circulated to the "Pediatric Publication Team" put it, "If we can demonstrate that the transient rise in PRL [prolactin] does not result in abnormal maturation … this would be most reassuring to clinicians."

Children and Adolescents Advisory

Board Meeting Minutes

Accordingly, the minutes of a fall 2002 meeting of the Risperdal Children and Adolescents Advisory Board—a group of Known Opinion Leader-doctors, who were paid $2,500 each to attend—reported that the doctors were promised that the new data would be "reassuring." According to the minutes, the "KOLs" were also being trained to handle questions from the media about the reassuring data—data that had not yet been produced.

$2 MILLION TO MASS GENERAL / HARVARD TO ADVANCE THE 'COMMERCIAL GOALS OF J&J'

Description of 2002 Budget
(p. 35-37)

The 2002 budget earmarked $1.75 million for the Known Opinion Leaders' paid attendance at advisory board meetings, their subsequent speaking appearances at doctor symposiums and related expenses for "education" targeted at doctors who treat children and adolescents.

That was apart from the $2 million that would ultimately be spent on the salaries, studies, conferences and other activities of Biederman's Center for Children and Adolescent Bi-Polar Disorders.

An annual report on the work of the Biederman Center during 2002 presented by Janssen's marketing staff to justify the expense bluntly listed its value this way:

Biederman Center Annual Report
2002 (p. 3)

"An essential feature of the center is its ability to conduct research satisfying three criteria: a) it will lead to findings that improve the psychiatric care of children; b) it will meet high levels of scientific quality; and c) it will move forward the commercial goals of J&J."

The next paragraph added a clear call-out to Biederman's value: "Equally important to effective use of medications is the demonstration of the validity of disorders."

Those were the conduct disorders the FDA had repeatedly refused to ratify.

AUSTIN TAKES HIS MEDICINE

On June 20, 2002, a 7-year-old boy from Alabama named Austin Pledger took his first dose of Risperdal—0.5 milligrams dropped into a glass of water.

J&J Salesman Testimony
(p. 70-80)

A month before, a J&J salesman had made his first call on Jan Mathisen, a pediatric neurologist who was treating Austin. The salesman talked with Mathisen about the benefits of using Risperdal for children with behavior disorders and left him with samples—140 starter packages.

In early June, a second J&J salesman visited with Mathisen and left more samples. Between June 2002 and November 2004, that salesman would make 20 more visits, dropping off thousands of child-sized doses of the antipsychotic.

Around Austin's third birthday, his mother, Benita Pledger, had taken him to Illinois to visit her sister, who drove a school bus. She took Austin to ride the bus with her one morning. When she returned home, she told Benita, simply, "I think Austin is autistic."

"I was shocked," Benita Pledger recalls. "I mean, what is that?"

Her sister explained that Austin had seemed disconnected from the children on the bus, and that he hadn't responded to her sister at all—"he just repeated back whatever she said to him."

Austin was officially diagnosed with autism by a local pediatrician as he was about to begin kindergarten. Arrangements for a special education program were made at the local elementary school. "He could recite the alphabet from a poster at school, sing songs in English or even Spanish that he had heard once," his mother recalls. "But he couldn't read 'cat.'"

Austin would erupt suddenly into fits of apparent confusion or rage, banging his head against the floor, biting his hands and arms or even hitting some of the other special education children. "He couldn't handle any change," his mother explains. "Even moving from one room to another might set him off."

One day at kindergarten, "the school lost him," Benita Pledger recalls. "He just walked out." After that, she changed the hours she worked as a machinist at a paper mill. Then she quit altogether. That way, she or her husband—who operated a car repair shop out of a garage less than 100 yards from the family's modest home—would always be available to check on Austin at school and be with him when he got home. "We had tried 13 years to conceive Austin," Benita Pledger explains. "He was a gift."

In April 2002, as Austin was nearing the end of first grade, Benita met with his prospective second grade teachers and the school aides who would be working with him in the fall. A teacher's aide told her that her own sister had a troubled child and had consulted a specialist—Birmingham pediatric neurologist Jan Mathisen—who had helped enormously. Maybe she should take Austin to see him.

The Pledgers were skeptical, especially Austin's father, Phillip. "I figured we'd drive into Birmingham [about 50 miles] to see this guy," he recalls. "But if he prescribed some drugs right off the bat, that would be a negative. We weren't looking for drugs just to calm him down."

Phillip and Benita Pledger at their home in Alabama, 2015. Emily Kassie

Mathisen spoke of Austin's illness in a way that rang true to parents who treasured their son's bright moments as much as they dreaded the darker times, and had struggled to reconcile the two. "He explained that Austin cannot read any cues," Benita remembers. "That it's as if this wonderful, sweet

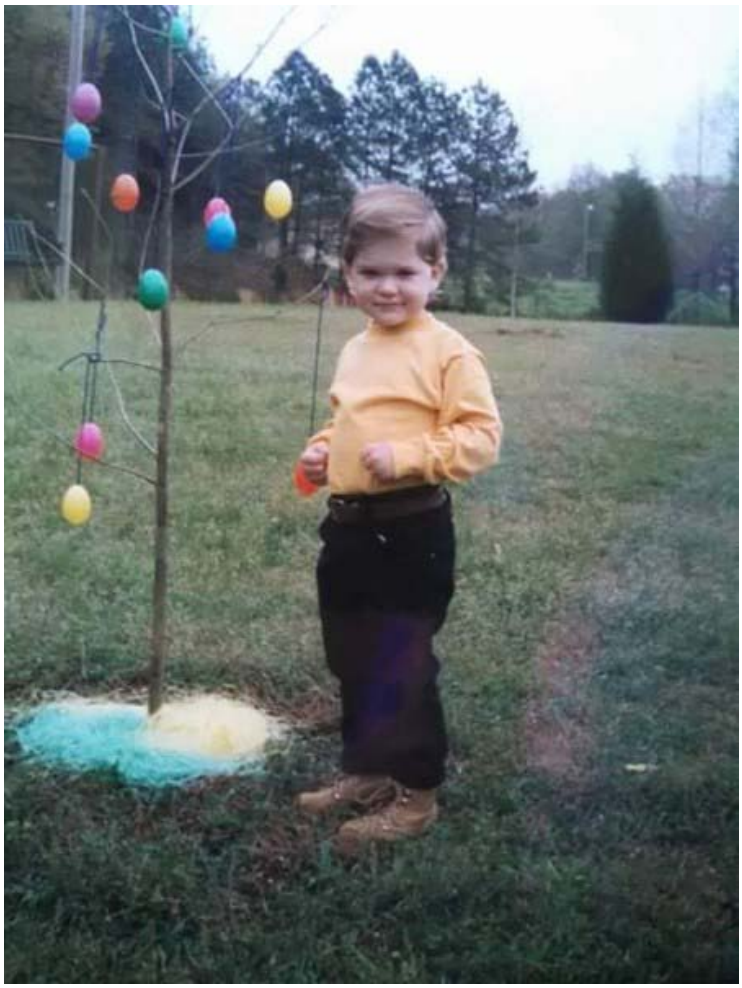
boy who knows so much has landed in a foreign land and doesn't understand the language and the social cues. It mystifies him and then it frustrates him."

Mathisen did not prescribe medication. "He told us he had started giving some patients something and it seemed to work, but he did not push it on us," Benita says. "He told us to think about it."

By mid-June, the Pledgers had become more troubled by Austin's frequent outbursts. Benita brought Austin to Mathisen again on June 17, this time to talk more seriously about medication.

The drug was called Risperdal, the doctor said. It would not "cure" autism, he explained, but it might ease the rough edges of Austin's frustration.

As for side effects, Mathisen said that Risperdal would likely cause some weight gain the way other drugs of its kind did. "We were okay with that," Benita Pledger explains. "Austin was pretty thin, and I'm big on healthy foods, so we thought we could handle that."



Three-year-old Austin Pledger enjoying Easter.Benita Pledger

Within a few days, the Pledgers had decided to give it a try, and on June 20, 2002, Benita drove back to Birmingham to get Austin's first prescription and pick up some samples to get him started. Both Austin's visits to Mathisen and his Risperdal prescriptions were paid by Medicaid, the federal-state program that in Alabama supplies health insurance to families living below the poverty line.

That night Austin's parents were still nervous. Unlike most consumers, they had taken a copy of the multi-page FDA "label" from the doctor and tried to read their way through it.

This was the label approved in 1994. It did not say anything about Risperdal's possible side effects when taken by children. It mentioned prolactin-related side effects (although using more technical medical terminology) as "rare," meaning that it was observed in no more than one-tenth of 1 percent of patients.

Still unsure, Benita dialed the Johnson & Johnson hotline number listed on the label. According to company records later introduced in court, she left a message with her name and number, saying she was wondering how Risperdal helps children with autism and what the "dangers" were.

She and her husband then decided to go ahead and give Austin his first dose.

A few days later, after not having heard back from J&J, Benita called the hotline again, with a specific question about whether Risperdal could be taken with an allergy medication that Austin was also using.[1] This time, she spoke with someone who told her to consult her doctor about that. She did not repeat her first question about side effects, although she did provide her address when asked.

The hotline operators didn't know it, but the questions Benita was asking about side effects had been a source of intense concern among Johnson & Johnson scientists and executives when they huddled in a hotel suite less than a week before.

[1] The company would later assert that a Johnson & Johnson staff person did try to call her back, but got no answer and that the phone had no voicemail recorder. Benita would claim that she was home during almost all business hours and never got a call. She also said she never got a mailing about side effects from Johnson & Johnson despite having left her address during her second call.

CHAPTER 5

THREE CARD MONTE

By Steven Brill

What Happened in the Previous Chapter

A Convenient Re-Analysis

New York Hotel Meeting
June 14, 2002 (p. 71-75)

Six days before Austin Pledger swallowed his first Risperdal, Janssen scientists and marketing executives met with an advisory board of doctors in a luxury hotel suite in New York. The group wrestled with problems concerning the prolactin and gynecomastia data that had come in from the clinical study Gorsky and his team had ordered up, hoping to put the issue to rest.

Description of Studies
(p. 63-67)

Testimony re: Study of Studies
(p. 67-72, 74-75)

This new study was actually a study of studies. It pooled the one study called “INT-41”—which had the largest number of participants and the worst results and had devoted what those who conducted it called “special attention to prolactin”—with four smaller, more general studies that had produced less troubling numbers.

Although this approach diluted the bad news for Janssen, there were still two problems.

First, the gynecomastia rates remained high.

Second, one table showed a statistically significant relationship between elevated prolactin and breasts among boys who had been taking the drug for eight weeks. In other words, it looked like causation had been established.

According to later testimony, at that meeting, the doctor advisors and the Janssen team came up with a solution that, they decided, could remove many of the gynecomastia cases but in a way that was scientifically legitimate.

Testimony About the Data "Re-Analysis"
(p. 67-74)

There would later be bitter disputes in court about whether it was the outside doctor-advisors or the Janssen people who came up with what they thought could be a defensible way of doing what notes of the meeting called a "re-analysis" of the data. But everyone in the room was being paid by Janssen, and there can be no dispute that the method they devised would make Janssen's numbers look a lot better. Nor was there any dispute that the idea of re-analyzing the data only came up *after* they had seen the initial negative numbers.

The retroactive redesign of the study began when someone pointed out that the children in the group who were 10 or over were likely to be going through puberty. Therefore, their hormone levels, including prolactin levels, were likely to be elevated. So why not remove them from the count of gynecomastia cases?

The group agreed to see how that "re-analysis" affected the numbers.

The Phony Denominator

Two months later, on August 22, 2002, a revised version of the all-important study was circulated among Janssen development executives.

The result was a table showing a much lower rate of gynecomastia—just eight-tenths of 1 percent. Moreover, the comparison of boys with raised prolactin levels who had ended up with the disease was now no longer statistically significant. Proving that that relationship was statistically significant – or, rather, that it wasn't – was the key purpose of the study.

> **You only need to have gotten past a third-grade math lesson to understand how scientists from the world's leading health care company and its hired-hand doctors distorted complicated clinical findings.**

The re-analysis had worked. The data that Gorsky and his team had envisioned nearly four years earlier to rebut competitors' claims about gynecomastia was finally ready.

However, even assuming the legitimacy of removing the boys who were 10 years old and over, the table produced numbers created by an obvious arithmetic sleight of hand. You just have to have gotten past a third-grade math lesson in numerators and denominators to understand how this group of scientists from the world's leading health care company and its hired-hand doctors distorted this series of complicated clinical findings and dense set of the data.

The cases of boys 10 and over with gynecomastia had been eliminated from the numerator—the group in the table that counted those suffering from gynecomastia. However, all the children, no matter their age, were still counted in the denominator. In other words, five boys under 10 years old had been shown to have developed breasts, but all 592 children—over *and* under 10—were

included in the total to tabulate the percentage: five is 0.8 percent of 592. However, only 358 of the children were under ten. Thus, the supposed 0.8 percent represented 0.8 percent of *all* 592 children, but the real number—the real denominator—should have been 358, which is the number of children under 10. That would have yielded a percentage of 1.4 percent, not 0.8 percent, because five is 1.4 percent of 358. In fact the *real* percentage should have been derived from the percentage of the number of boys, not boys *and* girls, under 10 with breasts, or 255. And five is 2.0 percent of 255, a number that likely would have gotten the attention of Benita Pledger and her doctor.

And, again, that assumes that retroactively removing the boys 10 and over was justifiable, which those who had originally designed the study had not assumed. Had those boys not been removed, the percentage of all boys with gynecomastia would have been 4.5 percent: 22 cases out of 489 boys. A J&J witness in a case brought by a boy who had developed male breasts later attempted to offer a rationale for including the original denominator, but even one of the doctors involved in the study would later concede that the denominator should have been changed.

J&J's 'Re-Analysis' of the Data

More important to the statisticians worrying about a statistically significant cause-effect relationship between raised prolactin levels and gynecomastia, the new table obscured a deeply troubling finding: that when all the boys who had been taking Risperdal for eight to 12 weeks were examined, those with raised prolactin levels tracked 98 percent of the time with those suffering from gynecomastia.

That eight-to-twelve week treatment time period, in fact, was consistent with medical theories that lawyers in suits against Johnson & Johnson would later introduce—that the gynecomastia didn't take hold and become permanent until the breast tissue fiber generated by the prolactin had been given time to grow.

Findling Article
Nov. 2003 (p. 1-2, 5, 7-8)

After going through various drafts and table reformulations, this re-done study, with the fictional denominator and without the table showing that statistically significant relationship, is what Dr. Findling and two other academic luminaries would ultimately attach their names to as co-authors. Also listed as co-authors would be three Johnson & Johnson employees—two doctors and Carin Binder, the executive spearheading the publication of the article. The article disclosed the affiliations of all of the authors and that a J&J Canadian subsidiary had "supported" their research. But that raised no eyebrows in the academic medical community because by now most such published research was paid for by the drug companies whose products are its subjects.

A Janssen executive complained that a J&J-funded article about Risperdal contained a "nauseating amount of information" about side effects.

The study's findings would immediately be circulated to the sales teams in the field and be formally published in the highly respected Journal of Child Psychiatry under the title, "Prolactin Levels During Long-Term Risperdone Treatment in Children and Adolescents."

Testimony re: Binder's email
(p. 53-57)

The original table that did not eliminate the boys ages 10 and older—and that was stipulated in the original protocol for the study—was removed after the first draft. It was then put back in the final draft of the article after some of the doctors asked that it be reinstated—over the complaint of Janssen's Binder, the article's only non-doctor, who wrote in an email to the team of Janssen marketers and scientists that it contained a "nauseating amount of information" about side effects.

However, that table was given little discussion in the text, except to explain why including boys 10 and over made the table unimportant. Moreover, the specific chart of data showing the statistical significance for the eight-week treatment period was neither mentioned in the text nor shown in any table.

Scholarly articles in medical journals always include an abstract at the top, so that doctors can glean the gist. The abstract of what would become known in court as “the Findling article” declared, without qualification, “There was no direct correlation between prolactin levels and [side effects].”

Pay No Attention to the Label

The data related to children’s prolactin levels may have been massaged into shape. But when it came to the other key Risperdal target that had been roped off by the FDA—the elderly—Johnson & Johnson faced a new threat by the fall of 2002.

re: FDA Label Change
(p. 14)

For more than a year, FDA staff had been reviewing the data about side effects experienced by the elderly who were taking Risperdal or its competitors. In September 2002, the FDA wrote to Janssen ordering that an additional warning be posted on the Risperdal label highlighting the

strokes and other cardiovascular adverse events related to its use among the elderly. This was the same month that an internal Janssen email from a woman working on the Omnicare deal had reported that the sales team had been "hammered" by the company's own lawyers because the carefully choreographed deal with Omnicare might look like an illegal kickback scheme.

Discussion of "Dear Doctor" Letter
(p. 9-11)

By engaging in a series of meetings and exchanging multiple written submissions, the company dragged out implementing the label change until April 2003, by which time J&J's sales force was armed with materials that attempted to make it a non-event. As the new label was being distributed along with an FDA-required "Dear Doctor" letter alerting physicians to the change, Janssen called an emergency meeting of its regional and district managers. According to a suit later filed by a Janssen saleswoman, they were told "to continue promoting the off label use of Risperdal because Janssen was going to eventually secure a dementia indication [on the label]."

Discussion of March 2003 Study
(p. 14-17)

However, the continuing flow of negative data from clinical studies did not make that seem likely. In March 2002 another study came in that showed not only a high incidence of strokes, but also that the drug was no more effective than a placebo in treating dementia.

J&J Scientist Gets Credo-itis
Aug. 31, 2003

One scientist involved in the study soon developed symptoms of Credo-itis. After the results had been kept locked up for nearly six months, he sent an email on August 31 to his boss. "Respecting fully any confidentiality agreement that I have with Janssen," he wrote, "it is obvious to me, and others who may not be so bound and who have learned about the data, that this trial is on its face nearly completely negative. … Janssen has been sitting on the trial results for a long time. Yet it has a moral and ethical responsibility to publish quickly and in a way that can be understood. …"

The study was not released to the medical community (via mentions in seminars) until 2004.

Meanwhile, call reports continued to reflect the team's focus on dementia-related and other mood disorders.

Sundowning Call Report
2003 (p. 21)

“Dr. ___ said he had little experience with Risperdal and the elderly,” a Michigan sales rep reported. “Explained how it could help with sundowning syndrome”—a term for confusion and agitation that occurs in the late afternoon among people with dementia. “Told me that he would try it on Gloria’s mother.”

The Michigan saleswoman did not know that her report and hundreds of others like it were destined to become evidence in a series of investigations about to be sparked by an auditor in Pennsylvania, and by a fellow saleswoman who didn’t share her enthusiasm for pushing Risperdal on people like Gloria’s mother.

CHAPTER 6

TROUBLE

TROUBLE

By Steven Brill

What Happened in the Previous Chapter

A PEST IN PENNSYLVANIA

Allen Jones had had an uneventful career working as an investigator for the Office of Inspector General in Pennsylvania. But in July 2002, he noticed that a new account had been set up to receive payments from the Janssen division of Johnson & Johnson. What was that for?

The bank account, he was told, was meant to cover travel expenses for health department officials so that they could examine a program that their colleagues in Texas had told them about. It seemed like a promising way to create modern prescription guidelines for Pennsylvania's use of antipsychotic drugs in state mental institutions and among Medicaid patients, including children, the officials explained to Jones.

J&J Pays Speaking Fees and Expenses 2001-2002

By September 2002, Jones says, he was "pretty sure something was wrong here." One of the state's pharmacists, he found, had been accepting speaking fees in addition to travel expenses. J&J was also paying to reimburse state employees for conducting seminars about the program throughout the state. By October, Jones had confirmed that the program—called PMAP in Pennsylvania, just as it had been called TMAP in Texas—was going to start using the guidelines, called algorithms, in January.

Jones began pestering state bureaucrats about why they were switching to all of these more expensive drugs, and why were they allowing prescriptions to people who had never been given medication before. Frustrated at being stiff-armed and told by his bosses to confine his investigation to the pharmacist who seemed to have taken personal fees and not reported them, he was soon taken off the assignment, and, he claims, "given a desk completely out of the way, with nothing to do."

Jones didn't waste his spare time. He began copying documents to take home. And he began thinking about finding a lawyer.

VICKI STARR GOES ROGUE

By the fall of 2003, Risperdal sales rep Vicki Starr was ready to quit. She had been working for Janssen in the Northwest region for a little over two years. During that time, her green manual full of sales material that at least devoted some attention to how the drug treated schizophrenia had been replaced, she says, by a "red binder full of material that directed the sales staff to sell to a full spectrum of symptoms that could be related to just about any mental health condition."

Lawyers planning to sue Johnson & Johnson would later refer to a sales aid depicting a girl playing a violin as the "Yo-Yo Ma" brochure.

To drive home that idea, some of the new materials, she says, “had pictures of high-functioning people. There was a girl with a violin.” Lawyers planning to sue Johnson & Johnson would later refer to this sales aid as the “Yo-Yo Ma” brochure.

Starr knew that the company had set up a separate ElderCare sales unit, and she had commiserated with one of the sales reps in her region who had been assigned to it. Starr had also been instructed to talk up the drug’s benefits for geriatrics when she called on mental health institutions or Veterans Affairs hospitals, which had elderly patients. Janssen’s targeting of the elderly bothered Starr, but she dreaded her calls with pediatricians the most.

“Some [pediatricians] told me about side effects they were seeing in kids,” she says. “I felt bad. … But to Janssen it was like this crazy old uncle in the attic. You don’t want to talk about it or deal with it. … Some were describing side effects in a way that was different from reading about percentages in a pharmacy book. But I was just as worried about the ones that were not seeing side effects because they might not have been looking. … Doctors wouldn’t know what the drug was doing unless patients complained.”

There was also a more personal element: “I had one family member and one close friend who had children taking Risperdal. One of them was 3 years old. I couldn’t interfere. It wasn’t my place, but it was something I kept thinking about.”

One afternoon in October, Starr called her friend Hector Rosado, a Lilly salesman she had worked with whom she considered a mentor.

Starr told Rosado a bit about her dissatisfaction with the sales she was being forced to make.

“I’m ready to quit,” she told him. “Do you know of any openings at Lilly?”

“Wait. Don’t. You need to talk to me,” Rosado shot back. “Let’s meet tomorrow. I think you should see a lawyer. I’ll explain.”

The next day, they met at a Starbucks in Eugene, Oregon. Over coffee, Rosado introduced Starr to the world of Big Pharma whistleblowers.

A CIVIL WAR LAW STALKS BIG PHARMA

During the Civil War, concern over corruption in the Union's procurement of war supplies moved Congress to pass the False Claims Act, which allowed citizens to bring what was called a *qui tam* action—a Latin phrase that loosely translates to "he who brings the action for the king as well as himself."

In plain English, the law allowed citizens to sue parties that had defrauded the government, on behalf of the government. And it provided an incentive: The citizen plaintiff, called a "relator," would be entitled to a share of the amount, if any, that was recovered. The bounty awarded by the judge overseeing the case was usually 15 percent to 25 percent.

The statute fell out of use after Reconstruction, until Congress passed the False Claims Amendments Act of 1986, which set rules for when the Department of Justice could intervene and join the relator in the case. Through the end of the 20th century, the revitalized law was mostly used in cases alleging fraud in conventional government procurements, such as those involving the Pentagon. Employees of defense contractors could blow the whistle and be paid for their efforts if their suits were successful.

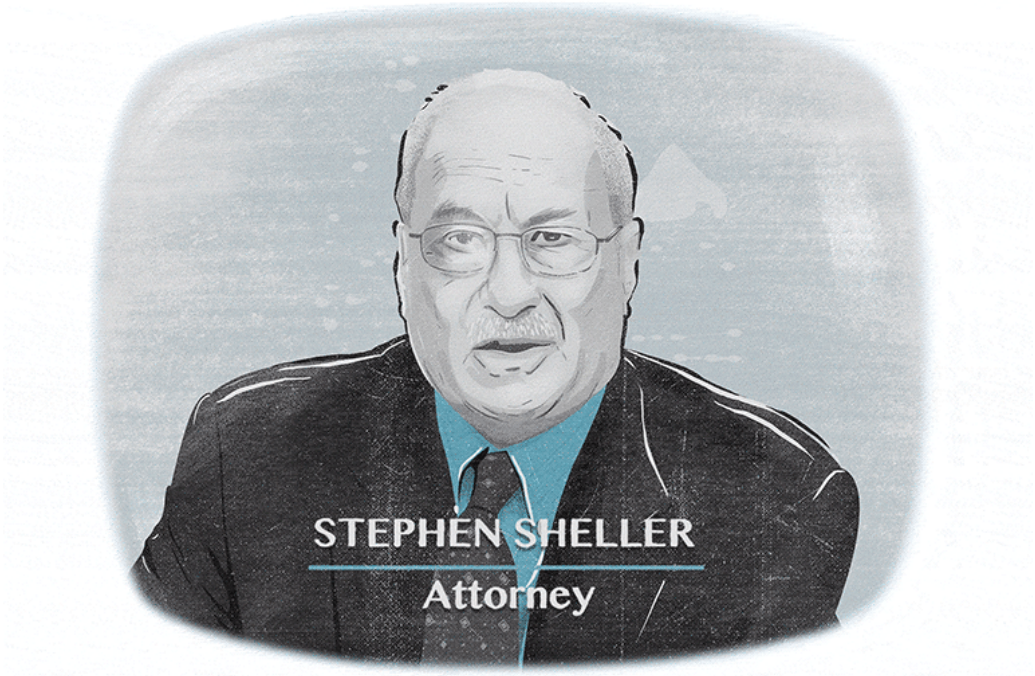
Beginning in 2002, more traditional plaintiffs lawyers—who usually pursue claims against corporations for injuries suffered by consumers because of faulty products, such as cars, tobacco or drugs—began to look at possible false claims related to Big Pharma.

The potential payoff had to do with the fact that so many prescriptions are paid for by the government. Off-label sales of Risperdal for someone on Medicare or in a veterans' hospital might merit a federal false claim. The sale off-label to someone receiving Medicaid, which is paid for with both state and federal funds, might constitute a false claim victimizing both the federal government as well a state government, because many states had enacted their own *qui tam* false claims acts.

But with *qui tam* suits still being relatively obscure, how were the plaintiffs lawyers supposed to find the whistleblowers?

BIG EGO, BIG CAUSES, BIG MONEY

Stephen Sheller, a rumpled figure who looks younger than his 76 years, made his name and his fortune fighting big tobacco and other deep-pocketed corporations. Living proof that trial lawyer with a big ego is redundant, Sheller has a garish website, full of testimonials and links to headlines and TV clips lionizing him as a champion of the little guy.



Sheller is forever eager for a new case, and, it seems, not simply because of the money. From his days defending Black Panthers, he has always seemed to get a kick out of fighting for causes. In 2001, his bottomless capacity for outrage, his quest for a good cause and, in this case, his devotion to family (two daughters, whom he brags on with no prompting, work at his firm), came together perfectly. One afternoon, the local police department impounded the car one of his daughters was driving for having expired registration and left her in a sketchy neighborhood. Sheller turned that into a class-action settlement against the department after charging that their abandonment of drivers was against police policy.

In 2001, Sheller got a tip from a Florida woman who had seen him on television. She claimed that samples of Prozac had been mailed unsolicited to her son. Sheller snooped around the way good plaintiffs lawyers do and soon found that Prozac's manufacturer, Eli Lilly, was apparently sending the samples all over Florida. Within a few months, Sheller was back on television—with a client who was wearing a hood to hide her identity—talking about the suit they had filed against Lilly for its allegedly indiscriminate Prozac marketing.

News of that traveled to California, where a Lilly sales rep ended up contacting Sheller to talk about more alleged Lilly shenanigans on the West Coast. That, in turn, led to five Lilly sales reps contacting him in 2003 about Zyprexa, Risperdal's Eli Lilly competitor. They told him that Lilly was selling the drug off-label to geriatrics.

By late 2002, Sheller had filed a *qui tam* charging Lilly with false claims, through illegal sales of Prozac, Zyprexa and two other drugs to patients whose prescriptions were paid for by the government.

Qui tam suits are governed by a strange set of rules that require the plaintiffs to file their cases under strict secrecy until the federal government decides whether to intervene. If the government does intervene, the cases are easier to prosecute because the government has subpoena power

and superior resources. If the government declines to join the case, the "relator" (the private plaintiff) can proceed on his or her own, and will get a higher fee because of all the extra effort and resources required.

In theory, the government has only 60 days to decide whether to step into a *qui tam* case. In practice, judges allow those decisions to drag on for years. That means that the case—and the employee' s role as a whistleblower—can stay secret for years.

One of Sheller's whistle-blower plaintiffs in the Lilly suit was Hector Rosado—Vicki Starr's former mentor whom she had called that day in October 2003 for advice about a new job. Instead, Rosado had told her to contact Sheller.

LOTTERY DREAMS

Vicki Starr was "stunned and scared," she says, when Rosado told her about the lawsuit and the federal agents who were pumping him for information and documents. "He said that there might be some money in it, but that that was all speculative. He just felt he was doing the right thing," she says, providing an impossible-to-confirm rationale that people cynical about trial lawyers and whistleblowers will undoubtedly dismiss.

The day after Starr met Rosado at Starbucks, she got on a conference call with his lawyers—Sheller and Michael Mustokoff, a former prosecutor who had become a partner at a Philadelphia firm that more typically represents corporate clients. Sheller had brought Mustokoff in on the *qui tam* drug cases once he began to sense their potential scope and realized that they typically begin as criminal investigations.

Sheller signed up Starr as his client. She would pay nothing, but he (and other lawyers, such as Mustokoff, with whom he split his fees) would get 33 percent of whatever winnings she got. Sheller and Mustokoff then negotiated a cooperation deal with federal prosecutors that assured that Starr could not be held responsible for any off-label selling she had done.

A J&J manager told one sales rep to be sure to include "lollipops and small toys" in the sample packages she gave to doctors.

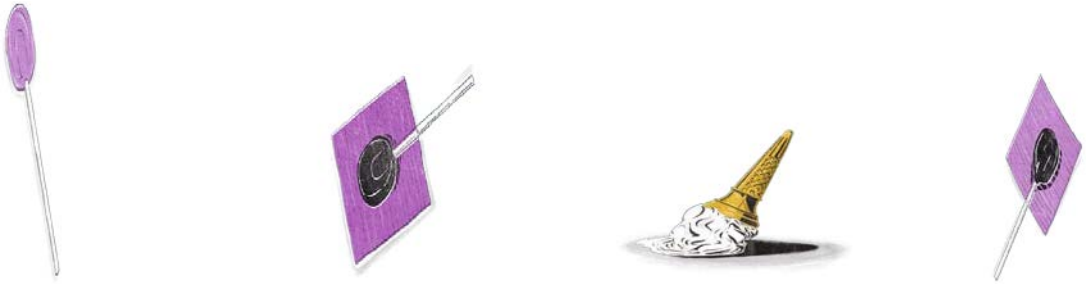
"At first, we had lottery daydreams," recalls Starr's husband, Jason, who works in real estate. "But the lawyers never mentioned any numbers."

Through fall 2003 and into the new year, Vicki Starr remained at work. She also began providing her lawyers with sales materials and other information about her employer. They packaged it up and passed it on to the prosecutors they were trying to seduce in the Philadelphia U.S. attorney's Office. The documents were enough to get the prosecutors interested; they were already pursuing Sheller's case against Lilly and were establishing their office, along with the U.S. attorney's office in Boston, as the place to go for drug company *qui tams*.

BACK TO SCHOOL WITH RISPERDAL

Back To School Campaign
2003 (p. 24-25)

Meanwhile, Johnson & Johnson was embarking on a 2003 “back to school” campaign (a district manager’s sales report actually called it that) to launch its M-tab version of the pill. M-tabs would dissolve in a child’s mouth and, presumably, quickly control classroom behavior problems. In San Antonio, a manager told his salespeople to hold ice cream parties in pediatricians’ offices to celebrate the launch. Another manager told a rep to be sure to include “lollipops and small toys” in the sample packages she gave to the doctors she called on.



SWEEPING THE FILES

By January 2004, Vicki Starr had had enough of being a mole. From the moment she had crossed the line and talked to the lawyers, she had wanted to quit, she recalls. So she found a job working for a company that operated pharmacy operations for nursing homes in the Portland area.

But first Starr did a sweep of everything she could find at Janssen to send to Sheller. Every sales brochure, interoffice strategy memo and office manual was loaded, she says, “into a huge box and shipped off to Philadelphia.”

Sheller had told Starr that he was preparing to file the suit, and that its prospects looked promising. She sensed that things might be resolved quickly, or at least that her role as a whistleblower would soon no longer be under wraps. She had told only her husband and parents about the world of lawyers, federal agents, debriefings and document hunts that Hector Rosado had introduced her to. No one else knew, including close friends, many of whom worked in the industry.

Starr worried that her friends in the industry would shun her.

“The whole thing was really making me nervous, creeping me out,” she recalls.

Almost from Starr’s first day at her nursing homes pharmacy job, the unsuspecting former Janssen colleague who had helped her get the new position began trying to sell Starr on stepping up her company’s Risperdal prescriptions. She knew, of course, that the drug wasn’t supposed to be given to seniors. But she played along, listening to the pitches, taking notes, then telling her lawyers.

At one point in March 2004, as Sheller was putting the final touches on the *qui tam* suit that he would file a month later, Starr was flown to Philadelphia to help her lawyers. When she had first gone over to the other side, Starr worried that what she was doing would jeopardize her pharmacy license. That somehow it would be seen as unethical. Or that her friends in the industry would shun her.

Now she felt better. The sessions with the lawyers, during which she got to spell out in detail the wrongs she believed she had witnessed, convinced her she had done the right thing, and that things were going to end well.

It was a friendly, upbeat discussion. Everyone in the room, of course, was on the same side.

WIRED

One day in April 2004, Starr was in San Francisco for a three-day seminar on elder care. The night she arrived, she recalls, she saw that Johnson & Johnson was “sponsoring a whole breakfast devoted to using Risperdal in elder care.”

She called one of her lawyers. “You’re not going to believe this,” she said before reading him the invitation.

Almost immediately, Starr got a call from a federal agent working her case. “We’re going to have agents meet you, and wire you up,” he told her.

At 6:00 on the morning of the breakfast, Starr told the woman sharing her hotel room that she had to go down to the business office to fax some documents. Instead, she took the elevator to another floor, knocked on the door of a guest room and was greeted by a female FBI agent who flashed her credentials and asked Starr to remove her blouse.

The agent taped a credit-card sized transmitter to the middle of Starr’s chest. “If you want to say something private, you have to whisper,” the agent warned. “If you have to cough, turn away. This thing picks up everything.”

“I was so nervous,” Starr remembers. “This was beyond anything I had imagined.”

A few weeks later, Starr was wired again for an “education” luncheon J&J was sponsoring at a nursing home. When she got there, she found that the event had suddenly been cancelled, with no explanation.

“I thought maybe they were on to us,” Starr recalls. It was at about that time that she got what she thought was a “fishing expedition” from a former Janssen colleague with whom she had not been close. Out of the blue, he texted her, asking simply, “What’s up.”

By now, Sheller had filed his *qui tam* suit in federal court in Philadelphia, and a judge had approved Starr’s wearing of a wire at that San Francisco conference. However, both court proceedings were secret. There was no reason to believe Johnson & Johnson knew that investigators were circling.

MAKING TROUBLE IN TEXAS

By November 2003, investigator Allen Jones was suing his bosses at the Pennsylvania Office of Inspector General. He claimed that they had frozen him out after he began investigating the algorithm campaign. But he wasn’t finished.

Jones had first consulted lawyers in Washington who referred him to a scrappy plaintiffs’ law firm in Texas. That firm realized the potential *qui tam* value of cases claiming that the entire scheme— TMAP in Texas, PMAP in Pennsylvania—was a plot to extract millions in Medicaid “false claims” from state and federal treasuries. However, the lawyers decided they were not equipped to handle a claim this big against a company like J&J, let alone on a contingent basis, under which they would have to front all the costs until they won (if they won) a verdict or settlement.

By the end of 2003, Jones ended up with Thomas Melsheimer, a well-known Dallas trial lawyer at the firm Fish & Richardson. Melsheimer had won big verdicts for defendants, as well as plaintiffs, in cases ranging from antitrust to insider trading to bank fraud.

Melsheimer set his sights on recruiting a key partner: Texas Attorney General Greg Abbott. Texas has its own version of a *qui tam* false claims law, and Melsheimer hoped he could entice the attorney general's office to join the fray. Across the country, whether state attorneys general are Republicans, like Abbott, or Democrats, they generally see headline cases in which they crack down on big corporations as helpful if the want to move up politically. (Abbott is now governor of Texas.)

Melsheimer and lawyers from his office immediately began preparing their case, using the documents that Jones had been gathering. Occasionally, they would tease Abbott's office with the best material. At the same time, Jones began, as he puts it, "seeding" the upcoming litigation with national publicity. On February 1, 2004, about two months before Vicki Starr was wired in San Francisco, The New York Times published a long article headlined "Making Drugs, Shaping the Rules."

It had now been almost 10 years to the day since Johnson & Johnson had launched Risperdal. This was the first major news story that raised questions about how the company had turned the drug into its top seller.

"Since the mid-1990's, a group of drug companies, led by Johnson & Johnson," the Times reported, "has campaigned to convince state officials that a new generation of drugs—with names like Risperdal, Zyprexa and Seroquel—is superior to older and much cheaper antipsychotics like Haldol. The campaign has led a dozen states to adopt guidelines for treating schizophrenia that make it hard for doctors to prescribe anything but the new drugs. That, in turn, has helped transform the new medicines into blockbusters. ... Texas, for example, says it spends about $3,000 a year, on average, for each patient on the new drugs, versus the $250 it spent on older medications."

The Times story then introduced Jones, who was pictured in the article sifting through documents.

Texas TMAP Suit
March 25, 2004

Seven weeks after the Times story appeared, Melsheimer filed Jones' suit.

"Through TMAP, the drug industry methodically compromised the decision-making of elected and appointed public officials to gain access to captive populations of mentally ill individuals in prisons and state mental hospitals," Melsheimer's complaint charged.

Significantly, Melsheimer's focus was on Risperdal being an overpriced and no better substitute for drugs like Haldol, not on the company's efforts to promote Risperdal to patient populations and for behavior disorders that were outside what was allowed under the label.

Again, because this was a *qui tam* suit, Johnson & Johnson had no way of knowing about it yet. Yet everyone involved in Risperdal had to have read the New York Times article, which had reported that federal healthcare officials were investigating Jones' charges. In fact, a Janssen spokesman was quoted in the story. He said that his company "did not participate in nor influence the content or the development of the guidelines."

Soon, the accusations and denials would involve more than marketing plans and conduct by state officials. The story was about to include the patients, too.

CHAPTER 7

A MULTI-FRONT WAR

By Steven Brill

What Happened in the Previous Chapter

HEAVY UP TOP

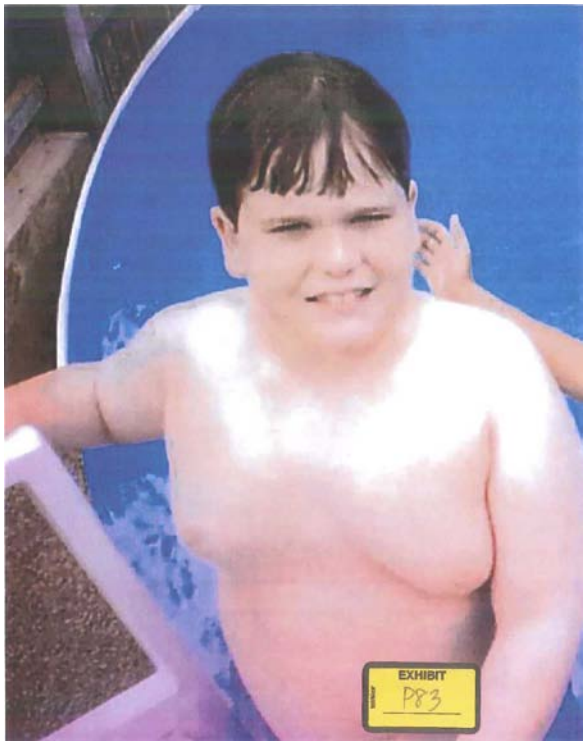
Since he had begun taking Risperdal, Austin Pledger was having fewer tantrums. The reports Benita Pledger read from her son's school reflected what she was seeing at home: "His frustration behavior has improved greatly," his special education teacher wrote in April 2004. But it was far from a complete turnaround. Austin would still erupt in volatile behavior, biting himself or suddenly dropping to the floor and pounding his head.

Benita and Phillip continued to dote on him, and marveled at his ever-amazing feats of memory. He could now recite long passages from books that he was starting to be able to read. He amazed his parents almost every day by completing the required phrase, when just a few letter clues had been posted, as he watched his favorite TV show, "Wheel of Fortune."

But despite Benita's incessant efforts to control Austin's diet, her son had gained an enormous amount of weight in the two years since he had started on Risperdal. Worse was where he seemed to be putting on much of the weight—up top, in his chest. "He started to get really self-conscious about it," Benita recalls. When summer came and it was time to swim in the family's above-ground pool, out back behind the house and the car repair garage, Austin's parents began to realize just how self-conscious their son was.

At some point, recalls Phillip Pledger, his son "became so embarrassed about how he looked up top that he didn't even want us to see him. So he began to wear a T-shirt, even in the water."

Before then, however, Benita Pledger happened to snap a photo of him climbing out of the pool.



Austin Pledger about ten years ago. Benita Pledger

‘MY SON HAS BREASTS’

While he pursued more evidence for the *qui tam* suit he had filed on behalf of Vicki Starr, and before he had ever heard of Austin Pledger, Stephen Sheller was on the lookout for more conventional personal injury cases he might bring—cases on behalf of patients who could claim to have been damaged because Risperdal had been sold to them off-label.

A mother called to say that she had noticed something strange about her son: He had grown female breasts and eventually needed a double mastectomy.

The sales reps who were his clients for the earlier *qui tam* case against Zyprexa, the Risperdal competitor, were useful sources for finding out what kind of damage Risperdal might have caused. They were well-versed in Risperdal’s rumored dangers, because those dangers had been part of their old sales pitches. They had harped on the point that patients who took Risperdal gained large amounts of weight and even ended up with diabetes. Before long, Sheller had a few prospective clients with possible diabetes claims against Risperdal.

Then, in the winter of 2004, the mother of one of those clients called to say that she had noticed something strange about her son. He had grown female breasts. By August he had been diagnosed with gynecomastia and had had a double mastectomy.

Sheller had never heard anything about Risperdal and male breasts and, of course, had no idea that Janssen’s top executives and scientists were by now fixated on the problem. “So I asked the Zyprexa guys,” he recalls. “And they said, ‘Yeah, that’s right. We’ve heard that, too.’”

Once Sheller figured out the medical term, gynecomastia, and then how to spell it, he tried, he says, “to read everything I could.”

Gynecomastia was on the way to becoming one of his causes.

It was during this time, while taping a television show talking about the evils of pharmaceuticals that Sheller met psychiatrist Joseph Glenmullen.

Glenmullen, who taught at Harvard Medical School and practiced at the university’s health service, had started to make something of a name for himself in medical circles as a skeptic of drug companies in general and of antipsychotics in particular. Glenmullen assured Sheller that he was on to something. Risperdal did raise levels of a hormone called prolactin, he said. Sheller had already read something about that.

“What about male breasts?” he asked his new friend.

Yes, Glenmullen said. From what he had read and heard from other doctors, it was likely that prolactin elevations would cause gynecomastia. Sheller kept digging—and kept talking up Risperdal among his trial lawyer friends, telling them to snoop around and send referrals his way.

THE BILLION-DOLLAR HAIL MARY

Gilbreath Testimony re: Risperdal Samples
Dec. 9, 2003 (p. 27-28)

On December 19, 2003—10 days after a Janssen salesman, making his bi-weekly visits, had dropped off another 1,592 sample doses for Austin Pledger's doctor to try out on new patients—Janssen's regulatory team had gone back to the FDA, in yet another effort to get children legally on to the Risperdal label.

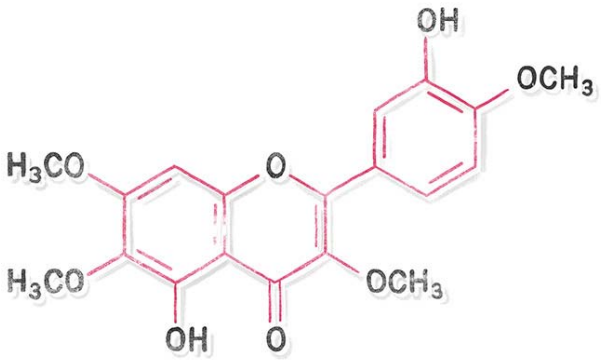
However, the company's strategy had changed. The rising sales numbers showed that Biederman's evangelizing about conduct disorder had obviously encouraged pediatricians to dispense Risperdal. But it had not swayed the FDA.

If the application extended the patent by a half-year, it could be worth as much as $1.5 billion in additional U.S. sales.

So the Johnson & Johnson strategists threw in the towel on conduct disorders. Instead they proposed that Risperdal be labeled as appropriate for the treatment of a specific, acknowledged psychiatric illness in children: autism.

That market was small, but at least it would give their salespeople an ostensible reason for talking to pediatricians and pediatric psychiatrists. Besides, under the law, a new indication that included children would extend the fast-expiring patent by six months for all sales of the drug. If this application extended the patent by that half-year, it could be worth as much as $1.5 billion in additional U.S. sales before Risperdal went generic.

One of the arguments the Janssen scientists and FDA liaisons used in the new FDA pitch was that multiple clinical trials had now proven that Risperdal was safe for kids—and that any elevation in prolactin levels had not been shown to cause side effects such as gynecomastia. A prime piece of new evidence that they cited was the study that became the Findling article.



Molecular structure of the hormone prolactin.

NO MORE SALES CALLS

Sales Calls Stopped
(p. 49-53)

In November 2004, Austin Pledger's doctor and thousands of pediatricians, pediatric psychiatrists and pediatric neurologists like him around the country suddenly stopped getting sales calls from their Johnson & Johnson reps. At the same time, and with no explanation, the company suddenly eliminated incentive bonuses for Risperdal sales to pediatricians. The abrupt change seemed especially surprising because bonuses for sales of Risperdal had until now been set higher than those for sales of other products, reflecting what had been the company's priorities since Risperdal's 1994 launch and the drive to make it a record blockbuster.

The proposed label change covering treatment for autism in children had still not been approved, and by now people at Johnson & Johnson who focused on legal and regulatory issues had become worried about these off-label marketing efforts.

Eli Lilly was well into discussions with prosecutors over off-label sales of the drug Evista. An investigation into sales of Lilly's Zyprexa, the key Risperdal competitor, was ahead of where the feds were on Risperdal. An investigation of another Risperdal rival—Astra Zeneca's Seroquel—was also further along. These and other cases against competing drug companies for off-label sales were becoming public or were being talked about in the Big Pharma and corporate defense legal communities because the subpoenas were starting to fly.

All of that activity, plus the Times article about Allen Jones' whistleblowing, had caused Johnson & Johnson and Janssen executives to order that the Risperdal off-label sales campaigns be throttled back.

Meantime, other plaintiffs lawyers across the country, feeding off of their professional grapevine, began gathering whistleblowers to file Risperdal *qui tam*suits of their own, all focusing on the claim that the off-label sales constituted false claims against the government's Medicare, Medicaid and other health care dollars.

DEATH OF A SALES MANAGER

From mid-2004 through 2005, Vicki Starr made more trips to Philadelphia to meet with her lawyers. She was also taken to see federal prosecutors in the U.S. attorney's office. "They recorded me for hours, asking really precise questions," Starr says, "about the wording of sales pieces. How they were used? What we were told to say? How the bonuses were paid? How had the messages changed in the year after I started?"

A startling event in 2005 unnerved her. One morning Starr's former sales manager did not show up for a scheduled ride-along with a sales rep. When the manager failed to call in or otherwise

explain his absence, the sales rep went to the marina where the manager was living while going through a divorce. He found him dead of an apparently self-inflicted gunshot wound.

Starr knew that federal agents were already investigating her case. Had they questioned him? “Was it my fault?” she remembers thinking. “I knew he was going through a divorce, but I couldn’t get it out of my head.” No evidence would ever surface that the man’s death had anything to do with the Risperdal investigation, and officials at the U.S. attorney’s office in Philadelphia would not comment as a matter of policy on who might have been questioned by that time about the case.

By now Sheller was working on a plan to consolidate the various Risperdal *qui tams* around the country in one suit to be given to federal prosecutors in Philadelphia. At the same time he and the other lawyers were working on gathering individual plaintiffs, whose claims would be that they were damaged by the drug, into another large group.

SUBPOENAS EVERYWHERE

Description of 2005 Subpoena (p. 62)

By November 2005 Johnson & Johnson knew for sure that the company was in trouble. Prosecutors in Philadelphia issued a subpoena demanding everything related to the sale of Risperdal—business plans, emails, sales reports, clinical studies.

The prosecutors had still not officially entered the *qui tam* cases, despite the theoretical 60-day deadline for making a decision once a relator and his lawyer filed a case in secret. They had repeatedly convinced judges in the cases that they needed more time.

Description of 2006 Subpoena (p. 96)

In January 2006 the Texas Attorney General weighed in, demanding that Johnson & Johnson produce what a subsequent J&J Securities and Exchange Commission disclosure called “broad categories of documents related to the sales and marketing of Risperdal.” Melsheimer had convinced the attorney general’s office to join forces for what would become a state *qui tam*alleging billions in false claims related to Medicaid payments to J&J.

Other inquiries and document demands poured in to J&J from Arkansas, South Carolina and California, among other states. Federal lawmen in Massachusetts soon joined the action when a whistleblower who had worked at Omnicare—the nursing home pharmacy manager that had negotiated that Active Intervention deal with Johnson & Johnson to increase Risperdal usage—had come to them with that story. The Boston prosecutors liked this one because it also might yield charges of Johnson & Johnson paying kickbacks to Omnicare.

Personal injury lawyers were piling on, too, using websites, Google search advertising, social media and TV ads to gather clients who could claim they had been injured by Risperdal—and in some cases the competitor drugs sold by Eli Lilly or AstraZeneca. (Their Google ads are still there; search "Risperdal lawsuits.") On July 20, 2006, the national plaintiffs firm of Weitz & Luxenberg filed on behalf of 208 such alleged victims. The claim mentioned off-label selling, but focused on diabetes as the injury the plaintiffs had suffered. Gynecomastia was not mentioned.

Yet by now Sheller was becoming convinced that gynecomastia could be the more severe injury—and the route to a bigger payday. Proving the drug had caused diabetes would be difficult, because, as he recalls, "They did warn about weight gain. So once people gained weight, diabetes was a likely result apart from any chemical in the drug. I'm not saying it was not a cause or the cause, but it was hard to prove they had caused it without warning."

But no matter what particular injury the suits alleged, all of them allowed the lawyers to join the hunt—via court-sanctioned pre-trial discovery—for damaging J&J documents.

'MAYBE THIS WAS NOT GOING TO AMOUNT TO ANYTHING'

In 2006 and into the first half of 2007, Vicki Starr continued her meetings with government prosecutors in Philadelphia. The questions got increasingly specific and those asking them seemed increasingly serious.

Starr connected best with Charlene Fullmer, who had returned to government service after working six years at a corporate firm. Before that, Fulmer had been a lawyer at the FBI. By 2007, she was on her way to winning a slew of Justice Department and other government service awards related to, among other cases, her investigation of the other drug company *qui tams* that Sheller and other lawyers had brought to her office.

One colleague of Fullmer's told me that Fullmer was especially incensed by the J&J case. Starr remembers thinking the same thing: "She looked shocked, she may have even said something like 'wow' when I told her they had set up a separate ElderCare sales unit."

However, after those intense meetings with the prosecutors, Starr heard nothing and was asked to do nothing for the next three years. Sheller continually assured her that the government would

come in—that these things take time. “We began to think that maybe this was not going to amount to anything, and that we should just go on with our lives, so we did,” recalls her husband, Jason.

WAITING AND GUESSING

A growing team of Johnson & Johnson defense lawyers from a half dozen outside firms waited, too. They had plenty to do, gathering the subpoenaed documents and contesting the demands whenever they could find some legal basis to do so. However, the real action would only come once the feds made the first move.

“In their minds, they had done nothing wrong,” recalls one senior outside lawyer who was working for J&J.

Description of Sleep Backgrounder (p. 9)

There was little the company could legally withhold, their lawyers said, unless somehow it was a privileged communication with a lawyer. That meant that all those business plans targeting dementia or children were fair game. So were the sales pitches, like the “Sleep Backgrounder” handout touting the drug’s potential for saving nightshift staffing costs at nursing homes, or the emails talking about Risperdal popcorn and Legos.

Based on what they had handed over, the Johnson & Johnson and Janssen executives who had helped to make Risperdal the company’s biggest hit could guess what the government might be planning to accuse them of. “But in their minds, they had done nothing wrong,” recalls one senior outside lawyer who was working for the company. “It was the doctors who made the decisions about who used the drug, not them. The docs were the ones who prescribed off-label. And they had a right to. All the J&J folks did was give them information—which is their First Amendment right.”

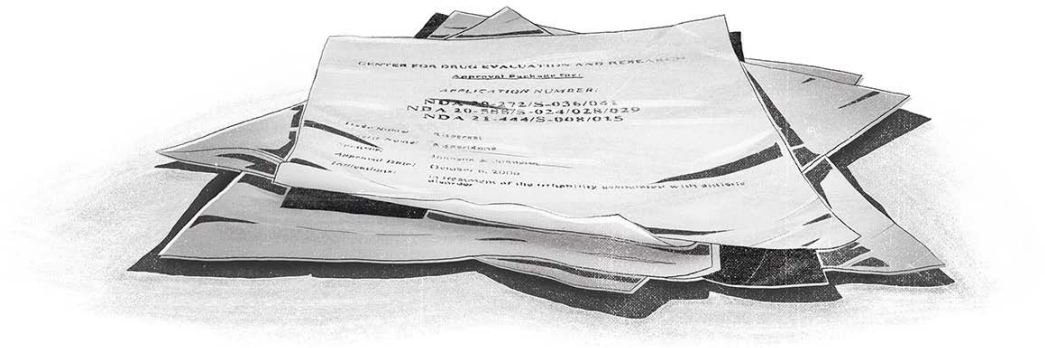
WEARING DOWN THE FDA

On October 6, 2006, the FDA handed Johnson & Johnson a win. As the Janssen team had requested nearly three years earlier, the agency approved a change in the label so that it would now include treatment for “irritability associated with autistic disorder” in children and adolescents. It was now entirely proper for Janssen sales reps to tout the drug to pediatricians. Almost immediately, they resumed the sales calls they had suddenly abandoned two years before, although they were only supposed to talk about treatments for autism.

It is difficult to tell why the agency put aside its prior concerns about safety—other than that J&J’s repeated efforts in multiple meetings and exchanges of long position papers over more than 10 years finally wore down the regulators.

Records of the discussions with the FDA about the new autism application Johnson & Johnson had filed reveal that the J&J team was repeatedly asked about the dangers to children that had long concerned the FDA’s doctors, including raised prolactin levels. Their answers, and the

agency's vetting of those answers, raise questions whether, when billions of dollars are riding on a government decision far removed from the headlines, the public can rely on what is essentially an honor system—in which the sponsor of a drug is expected to shoot straight with its regulator when submitting data.



J&J Assurances to FDA about Prolactin
Dec. 7, 2005 (p. 2)

Notes recorded by the FDA of a December 7, 2005, meeting about the drug's side effects when given to children reported that the J&J team had "argued that the expressed concern about unacceptable longer-term risks, in particular … hyperprolactinemia [elevated prolactin levels] … was not justified based on available data."

J&J Response to Concerns on Long-Term Safety
Aug. 16, 2005 (p. 6)

An FDA memorandum reported that J&J had assured the agency that "A detailed review of prolactin in children… did not show a correlation between prolactin levels and adverse events that are potentially attributable to prolactin."

2.3 PERCENT, NOT 5.5 PERCENT

Tellingly, the rate of gynecomastia that the FDA safety reviewer, Dr. Alice Hughes, reported to her colleagues—and the rate that would be reported on the new label—was 2.3 percent. That was the percentage derived when the Janssen team had added up the results of 18 different studies of children taking Risperdal, most of which involved children using the drug for short periods of time. It was only when Risperdal had been taken for eight weeks or longer that gynecomastia seemed to develop, as evidenced by the 5.5 percent rate found in that study, conducted in 2000, called INT-41. Moreover, only the INT-41 study had paid what the study characterized as "special attention" to prolactin and its related side effects, meaning that that study alone had

looked for what Vicki Starr had feared so many doctors would miss—that a patient's apparent weight gain in his chest was about more than some extra pounds.

FDA Safety Reviewer Gynecomastia Report
Oct. 5, 2006 (p. 2)

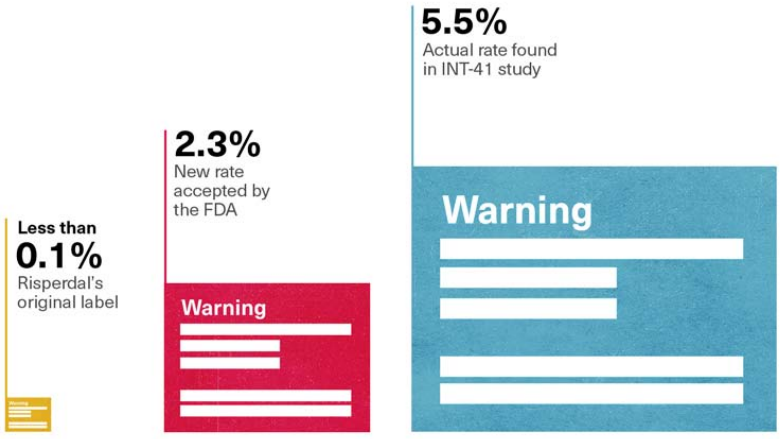
Final, Agreed-Upon Labeling
Oct. 5, 2006 (p. 24)

Mixing INT-41 with those other studies had watered down the rate—as had calculating the 2.3 percent rate of female breasts in males as a percentage of *all* children, instead of listing the higher percentage that would be derived by calculating the percentage among only the males in the studies. Yet the FDA had accepted Johnson & Johnson's 2.3 percent claim.

Moreover, when it came to the relationship between elevated prolactin and gynecomastia, Johnson & Johnson apparently still hadn't revealed to the agency the numbers for boys taking the drug for at least eight weeks that had been collected and turned into the table that had been prepared, then cast aside, for the study that became the Findling article. The result was the FDA reviewer's statement that there was no correlation between elevated prolactin levels and potentially prolactin-related side effects, such as gynecomastia.

Put simply, there was no reading of the real numbers that could produce anything as low as a 2.3 percent rate, and no way to justify the definitive statement that there was no relationship between raised prolactin and gynecomastia.

Rate of Gynecomastia – Risperdal Label vs INT-41 Study



The FDA final review memorandum that was prepared to justify the new approval of Risperdal for children also reported that "a worldwide literature review, did not reveal any previously unreported serious adverse events likely to be causally associated with risperidone." By this time, the Findling article had been published and, in fact, was being cited in other articles—exactly as the Excerpta Medica ghostwriters had promised their client.

However, in terms of all the litigation taking shape, the new label meant nothing. The legal storm brewing was about *prior* conduct—involving the information given to patients who had taken the drug well before 2006. A slightly expanded new label for 2006 onward wouldn't help Johnson & Johnson's defense in those cases.

If anything, the new label actually hurt J&J's defense when it came to the litigation about breasts that Sheller was planning. True, the 2.3 percent rate of gynecomastia about to be listed on the label was fictitiously low. But it was 23 times higher than the risk described as "rare" on the pre-2006 label that Austin Pledger's doctor and thousand of others had read. "Rare," as listed on the pre-2006 label, meant one-tenth of 1 percent or less.

More important, all of the data that had yielded the new risk rate of 2.3% –flawed thought it was– had been available to Johnson & Johnson much earlier than 2006. So why hadn't J&J warned Austin's doctor and others then with a "Dear Doctor" letter and a change in the label?

CALMING PATIENTS, NOT TREATING THEM

There was another memo in the FDA file about the new label application for treating children with autism that put in perspective the limits of the drug and the grudging risk-benefit analysis the agency was making. Its message, albeit in FDA-speak, was that Risperdal didn't actually treat autism or any other illness. It was really a way to calm patients so that symptoms of autism could be controlled, which in the agency's estimation was worth the high incidence of side effects the data they reviewed had demonstrated, such as somnolence (67 percent), appetite increase (49 percent) and fatigue (43 percent).

"There is no evidence that risperidone [Risperdal] treats the mental retardation or pervasive disruption of childhood development that are the core features of Autistic Disorder," the memo from the FDA's Dr. Paul Andreason conceded. "It is usually not the habit of the Division to approve drugs based on what might appear to be pseudo-specific effects of a drug on a disorder.

"However,"Andreason continued, "since there were no treatments for autism, the drug class was regularly used off-label for these symptoms, and there was little controlled trial data to support treatment for any part of autism, the Division decided to accept applications for the treatment of the irritability-like symptoms."

That rationale might not have prevailed had the FDA known about the actual risk of gynecomastia. Or the label might have been approved, but with one of those black box warnings to highlight an especially high risk that doctors like Austin Pledger's would have presumably have wanted to know about.

As revealing as these entries into the FDA's Risperdal file might have been, the lawyers circling J&J had none of that information. Their initial courtroom attacks on the company would demonstrate just how out of the loop they were and how much more ammunition they still needed.

CHAPTER 8

FIRING BLANKS, HUNTING FOR

SMOKING GUNS

By Steven Brill

What Happened in the Previous Chapter

A WEAK FIRST CASE

On December 14, 2006, Stephen Sheller filed his first case against Johnson & Johnson. The client was a New Jersey boy who had taken Risperdal beginning in 2001. When he had met the boy and his mother, Sheller thought the case would be about diabetes and weight gain. But then she and her son became traumatized by his growing breasts, and in August 2004, he had radical surgery to remove them.

Still, the suit focused on diabetes, and the complaint Sheller wrote was a hodgepodge of weak claims, in large part because the boy had also taken the Risperdal competitor drug Seroquel. Its manufacturer, AstraZeneca, was also named as a defendant, as was the boy's doctor, who was accused of malpractice.

The complaint claimed that Risperdal was the sole bad actor when it came to the boy's breasts. Yet even in late 2006 Sheller knew so little that the charges he drafted did nothing more than show off that he had learned some new medical terms. There was nothing—no studies cited, no data—suggesting he had any proof that the drug actually caused gynecomastia, much less proof that Johnson & Johnson knew about a link and failed to warn doctors.

BATTLE STATIONS

Whatever the suit's prospects, filing it gave Sheller a hunting license to demand all Risperdal documents related to the sale and marketing of the drug since 1994 and any tests that may have been conducted to determine its efficacy and safety.

At the same time he continued to spread the word among trial lawyer friends, looking for referrals. Sheller still wasn't allowed to mention the *qui tam* false claims suit he had filed with Vicki Starr and with another J&J whistleblower whom he had since found to join her suit as a "relator." But beating the drums to collect other patients claiming to have been injured by the drug was another matter.

Description of 2007-2008 Subpoenas (p. 19)

Other cases were now springing up in Texas and California. And state attorneys general were jumping into the act, apparently preparing their own *qui tam* cases. Through 2007 and 2008, each quarterly financial disclosure Johnson & Johnson filed with the SEC brought news of more subpoenas from state prosecutors.

"You'd get a document demand and you'd go to work seeing what you had and how much you had to give up," recalls one J&J lawyer. "You'd have someone subpoenaed to testify before a grand jury and you'd try to prepare him by anticipating what he might be asked. … And then you'd debrief the guy after the testimony. … But you really just had to sit and wait until they came to you to negotiate, which in this case took years.

"All the while, you've got the executives telling you, 'We've gotta fight this thing. We didn't do anything wrong, and, besides all the other guys [other drug companies] did just what we did.'"

NEXT IS 'GOD'

- **Question:** And what was it that bothered you so much? Is $2,500 a lot of money to you, or was it just that a deal is a deal?
- **Dr. Biederman:** A deal is a deal.
- **Question:** Is $2,500 a lot of money to you?
- **Dr. Biederman:** $2,500 is money.
- **Question:** Is it a lot of money?
- **Dr. Biederman:** I don't know. Define "a lot."


Biederman Deposition
(p. 104-106)

That exchange—between Dr. Joseph Biederman and a Houston plaintiffs lawyer whose firm had teamed up with Sheller in still more damage suits against Johnson & Johnson—was hardly the most combative or petty during one and a half days of a deposition that began on February 26, 2009. That morning, Biederman sat at a Boston law firm in front of five plaintiffs lawyers and six lawyers for the defense. In this instance, the verbal combat had to do with Biederman's supposed fury over the late payment of a Johnson & Johnson speaker's fee, a contretemps that had surfaced in emails that were among the millions of documents handed over to the plaintiffs. (Biederman denied that he ever gets "furious" because doing so would be "unprofessional.")

Biederman had become a central figure in the Risperdal battles. Although little activity other than the filing of the personal injury complaints was public, the swirl of all the investigations and subpoenas had generated leaks and news coverage. Some of the worst headlines involved Biederman. Two years before, the Boston Globe had reported that a woman who had committed suicide had been taking Risperdal. The reporter found that it was Biederman who had prescribed the drug and that he had consulting contracts with Risperdal's manufacturer.

The Globe story attracted the attention of staffers working for Sen. Charles Grassley, an Iowa Republican who had long been interested in conflicts of interest and other improprieties in the healthcare industry. Grassley wrote letters to Harvard, Mass General and Johnson & Johnson inquiring about Biederman's financial relationship with the company, only to find out that the disclosure rules governing doctors associated with Harvard and Mass General basically amounted to an honor system. And when Grassley compared what J&J and other drug companies told him they had paid Biederman from 2000 through 2007 to what Harvard and Mass General

told him Biederman had disclosed, he found, according to a speech he gave on the floor of the Senate on June 4, 2008, that Biederman had disclosed "a couple hundred thousand" but had actually received "over $1.6 million."

Alerted to Grassley's findings, the New York Times published a story outlining the discrepancies, noting that, "Dr. Biederman is one of the most influential researchers in child psychiatry and is widely admired for focusing the field's attention on its most troubled young patients. Although many of his studies are small and often financed by drug makers, his work helped to fuel a controversial 40-fold increase from 1994 to 2003 in the diagnosis of pediatric bipolar disorder … and a rapid rise in the use of antipsychotic medicines in children."

Biederman Center
2002 Annual Report

Five months later, in November 2008, the continuing fight by lawyers working for Johnson & Johnson and for Biederman (who were retained by Mass General) to keep him from having to testify at a deposition backfired. Papers filed by the plaintiffs lawyers to convince a judge to force his testimony contained a collection of juicy internal J&J documents related to Biederman's relationship with the company—including the one recounting his fury at not having been paid that $3,000 speaking fee and the internal annual report from his J&J-financed center, acknowledging that one of its purposes was to further Johnson & Johnson's business goals.

By the time Biederman—who declined repeated telephone and email requests for comment—appeared for his deposition three months later, in February 2009, the doctor had issued a statement attributing the gaps in his income disclosures that Grassley had identified to sloppy bookkeeping, and Harvard had said it had launched an investigation.

Asked about that in the deposition, Biederman said, "Senator Grassley claims to be interested in issues of conflict of interest and is interested in making sure that the universities have tight conflict-of-interest rules. I have no dispute with that."

A former colleague of Harvard psychiatrist Joseph Biederman argues that he was "susceptible to being used by a drug company that set out to use him."

Biederman Deposition
(p. 47-48, 123-132)

That in turn led to the heart of why the lawyers wanted to question Biederman—and how they hoped to nail him: whether the center he had established with $2 million in J&J funds was meant to promote Risperdal to children using his, Harvard's and Mass General's imprimatur.

One barbed question referred to the emails that had begun with Alex Gorsky's "money on the table" request to find ways to put J&J funds to work building revenue:

- **Question:** You never heard it in the context of your Center?
- **Dr. Biederman:** No. The Center did science only.
- **Question:** Well, the truth is the Center was just a marketing device for Janssen, right?
- **Dr. Biederman:** The Center was designed to advance the science of bipolar illness in children and ADHD across a large spectrum . This is what the Center did. … Janssen funded a center that was dedicated to the advancement of the science of the conditions for which they [Janssen] have effective treatments. …
- **Question:** So the truth is Janssen needed to make more money, they wanted to expand the pediatric market. They saw your center as a way to facilitate that, right?
- **Dr. Biederman:** I have no idea.
- **Question:** Do you think Janssen paid you millions of dollars to limit the use of Risperdal in kids?
- **Dr. Biederman:** Janssen funded a Center that was dedicated to the advancement of the science of the conditions for which they have effective treatments or potentially effective treatments.
- **Question:** I understand that's your interpretation of Janssen's intentions. However, having read this document that says we're looking for "money on the table" … how can you interpret that any other way than to mean than Janssen was looking to you to help them develop this off-label marketing campaign?
- **Dr. Biederman:** I have no idea what is in the mind of Janssen executives.

Biederman had conceded earlier in the deposition that he had spent the prior day and a half with Janssen lawyers preparing these answers. But a former Mass General colleague argues, convincingly, that it would be unfair to convict him of anything other than believing in his science and wanting to use it to help the horrendously troubled children who paraded before him every day. Given that mindset, the former colleague argues, he was "susceptible to being used by a drug company that set out to use him."

"This was not about money for Joe," maintains this former colleague, who was not involved in Biederman's work and who says he "really doesn't care for Joe" personally. "The money was not life-changing for him, however the press made it out to be. … For Joe, it was all about his work, advancing it and being the most revered person in his field."

True, Biederman brushed aside a question in the deposition about whether he knew that 20 percent of all Risperdal prescriptions were being written off-label for children: "I have no idea how much risperidone is used in children."

And he dismissed the idea that he should consider himself responsible for "what Janssen did with your research**"**to promote widespread off-label use**:**"I don't."

However, to Biederman, this colleague insists, it really was about producing a best of both worlds scenario.

As Biederman put it, when asked another version of the basic question about his dealing with a profit-seeking drug company: “We proposed to advance science. I believed that advancing science … is doing the right thing and could result in profitability, too.”

The doctor was certainly self-assured enough to believe that he was doing nothing less than rescuing children. Near the beginning of his deposition, Biederman was asked to explain why he had noted on his resume the fact that he was the academic with the most citations—6,866—for scholarly articles related to ADD or ADHD (including many that praised Risperdal). “Because it’s an honor to have citations of this magnitude,” he answered.

He was then asked to explain the hierarchy at Harvard and his place in it. After Biederman had provided a tour up the academic ladder—from instructor, to assistant professor, to associate professor, to his title, full professor—the Texas plaintiffs lawyer asked him what came next.

Answer: “God.”

J&J’S CONTRIBUTION TO OBAMACARE

More than two years after Biederman’s testimony, Harvard would complete its investigation of his drug company income. The university issued a reprimand and required that he refrain from accepting fees of any kind from drug companies for one year, and get advance approval before engaging in any such paid activities for the following two years.

Senate Testimony on Physicians' Financial Ties
Feb. 27, 2008

The publicity generated by Grassley's investigation into the disclosures of drug company payments to Biederman sparked interest on Capitol Hill about such conflicts. After Grassley began his investigation, a Senate subcommittee heard testimony that drug and medical device companies had some kind of financial relationship—from providing free samples to paying consulting or speaking fees to financing research —with 94 percent of all practicing physicians, and that drug companies spent $7 billion a year on visits to physicians by salesmen, who provided the doctors with $18 billion worth of free samples.

The Coziness Quotient

Source: Hearing Before the Senate Special Committee on Aging, Feb. 27, 2008.

As the senior Republican on the Finance Committee, Grassley was collaborating at the time with committee chairman Max Baucus, a Montana Democrat, on drafting what ultimately became Obamacare. Although he ultimately joined all of his Republican colleagues in opposing Obamacare, Grassley and his staff were instrumental in drafting provisions that remained part of the law when it was passed in 2010.

Grassley's—and, indirectly, Biederman's—contributions to Obamacare required full disclosure of financial relationships between drug companies and doctors, and provided for the Department of Health and Human Services to collect and post them on its website.

A NEEDLE IN A HAYSTACK

Priscilla Brandon was in her 40s and working at a healthcare-related software company when she started attending law school at Widener University. Struggling to earn a living after graduating in 2006, she ended up as a lowest-on-the-totem-pole lawyer at Stephen Sheller's firm, where she used her training as a programmer and analyst to do what was basically paralegal work—sifting through millions of digital documents. Precise and reserved, Brandon was the ultimate worker bee at a firm with eight other high-octane trial lawyers or lawyers who liked to think of themselves that way.

It is the Priscilla Brandons of the world who are on the receiving end when plaintiffs lawyers demand that the enemy turn over "any and all" documents related to a case, and then get what they ask for.

For Sheller's personal injury cases, Johnson & Johnson turned over what Brandon calculates were 3.5 million documents containing 21.7 million individual pages.

That may have seemed like a burst of "here's everything; we have nothing to hide" candor. But burying the opponent in documents hides the important needles in an impenetrable haystack.

Plaintiffs lawyers often grouse that this is deliberate obfuscation. Corporate defendants, of course, consider it fair play: *If the plaintiffs lawyers are going to come after us because we have deep pockets and think they can score a fat contingent fee, no matter how real their case is, why not make them invest big money in staff time? Maybe they'll settle quickly or just go away*.

Sheller understands the game, although he doesn't like it. "They keep trying to starve us into quitting," is how he puts it, adding that "it also drives me crazy that other plaintiffs lawyers will come in by gobbling up clients online or with TV ads, and get settlements after we do all the work"—something which the corporate defense bar would no doubt dismiss as dishonor among thieves.

Fair or not, Brandon was Sheller's go-to grinder when it came to dealing with the avalanche of Johnson & Johnson documents.

One night, three days before Christmas 2009, Brandon was going through some of the discovery documents J&J had delivered related to the personal injury cases Sheller had already filed. As with that first case brought in 2006 for the boy in New Jersey, Sheller's injury claims were still mostly about diabetes. And they were looking increasingly unlikely to bring in big verdicts or settlements because of the difficulty of proving that while Risperdal caused weight gain—which the company had clearly warned about on its label—it also caused diabetes apart from weight gain.

Brandon had been asked by one of the lawyers working the cases to go back through all of the clinical studies J&J had turned over, each of which typically contained dozens of pages of text

and tables attached to hundreds of pages of data. She was told to separate out the studies involving children and summarize them. It was a weeks-long project.

That night, on December 22, as Brandon continued sifting through the documents, she noticed one having to do with the drug's long-term effects on children. It was called INT-41, and a description included in it noted that this study had paid "special attention" to prolactin levels and gynecomastia.

She remembered some emails she had seen referring to prolactin. And, of course, she knew that her boss had been trying to read everything he could about it, and that he had even filed one case—that first claim, in 2006—involving a boy who not only had diabetes but also breasts, for which he had undergone a double mastectomy. Sheller had already settled the case for relatively small dollars, because the charges were so muddled, and because he still had no proof about prolactin and breasts. Yet Brandon knew that her boss had continued to insist that there had to be a way to nail Johnson & Johnson for it.

Brandon found the emails about prolactin that she remembered. And attached to them she discovered the three drafts and final version of the Findling study—the one that had concluded that the data showed there was no relationship between breasts and raised prolactin levels.

She then began to compare the drafts side by side, sketching a set of columns to chart the different tables and conclusions that had appeared in each version.

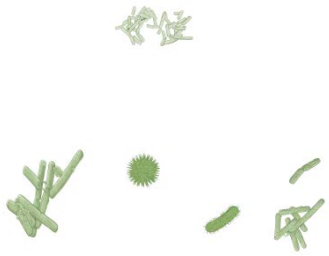
It seemed that the authors had changed the tables, and when she compared the numbers, she saw that they had added one table that kept the same number of total participants in the denominator but, according to the text, removed all of the children aged 10 and over from the study. Looking further, she saw that they had changed the text to base their conclusions on that new table.

Brandon thought she might be on to something. She sent an email to the lawyer who had asked her to review the studies, explaining what she thought she might have found and attaching the documents that seemed to demonstrate it.

Within a few days, she and the other lawyers in the firm, piqued by the different numbers in the different drafts, had homed in on the internal emails documenting the machinations around the Findling article—including the ones about "re-analyzing" the data to "reassure" doctors who were being encouraged to prescribe Risperdal to children, and the one complaining about the "nauseating" data about side effects. The boss loved what his people brought him. "We had discovered what this case was all about and what these people had done," Sheller later told me. "This wasn't just selling off-label; it was knowing that the drug caused gynecomastia and covering that up."

Beyond what that meant for his personal injury cases, Sheller thought that "the feds would love it" for their *qui tam* cases. "When I brought this to them," he recalls, "it took a lot of explaining, but they got it."

Chapter 9



UNDER SIEGE, DUCKING AND WEAVING

By Steven Brill

What Happened in the Previous Chapter

‘VIGOROUSLY CONTESTING

THE ALLEGATIONS,’

BUT…

By March 2010, when Johnson & Johnson filed its financial disclosure with the Securities and Exchange Commission covering the events of the year 2009, the world’s leading healthcare company was forced to list a daunting collection of suits and investigations involving Risperdal. Subpoenas seeking testimony of its executives “before a grand jury” had been received from the U.S. attorney’s office in Philadelphia investigating the marketing of the drug. Other subpoenas had been issued for company officials to testify before a grand jury in Boston looking into the Omnicare relationship. Two *qui tam* suits had been filed in Massachusetts related to that deal, too, and suits seeking damages and fines had been filed by nine different states.

J&J 2009 SEC Filing
(p. 46, 88, 100)

Beyond that, the company reported that “multiple products of Johnson & Johnson subsidiaries are subject to numerous product liability claims and lawsuits.” Two other allegedly faulty J&J products targeted by the plaintiffs lawyers were a device called a transvaginal mesh patch and an artificial hip implant. Suits involving these two products would soon end up competing with Risperdal for claims on the company’s reputation and treasury.

Johnson & Johnson seemed to take the threats in stride. “The Company and its subsidiaries are vigorously contesting the allegations asserted against them,” its SEC filing declared.

But just in case, the amount that Johnson & Johnson had removed from earnings for 2009 and reserved for liabilities was listed as $1.014 billion—or about 6 percent of its $15.755 billion in pretax earnings for the year. Putting that much aside each year over what was perhaps the fifteen-year life of these potential legal battles was not going to cut deeply into the company’s bottom line.

“In the Company’s opinion,” the filing declared, “based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities already accrued in the Company’s balance sheet, is not expected to have a material adverse effect on the Company’s financial condition.”

Perhaps, but its reputation was another matter. Its best known, family-friendly products were also about to take a turn in the penalty box. And in this case, the alleged misconduct went to the core of Johnson & Johnson’s reputation; it wasn’t about how the company marketed its products, but about the basic care it took in making them.

‘GRAM NEGATIVE’ BACTERIA
IN CHILDREN’S TYLENOL
AND THE ‘PHANTOM RECALL’

FDA Inspections
April 2010 (p. 1, 2, 5, 8-10)

Beginning in 2009 and extending into 2010, the FDA division that regulates the safety of over-the-counter products conducted inspections of factories at J&J’s McNeil Consumer Healthcare division. The result was a series of lurid reports documenting deficiencies in how the company was producing everything from Tylenol, to Pepcid, to Visine, to Rolaids, to children’s Motrin, to Benadryl, to PediaCare cough syrup for babies.

Many of the inspectors focused on what an April 2010 report described as “known contamination of gram negative organisms.” These are bacteria that can cause a variety of infections, such as E. coli and even cholera. The inspectors found routine contamination that included bacteria and metal particles in products such as children’s Tylenol, as well as haphazard controls on the precise mixes of the chemicals that were supposed to be contained in the products, causing some to be too strong and others to be too weak. The overall picture brought to mind production facilities in a developing country rather than the pristine factories of R.W. Johnson’s idyllic American enterprise.

Then-FDA deputy commissioner Joshua Sharfstein would tell a congressional committee in September 2010 that “one common concern the Agency has found across these facilities is the failure to investigate and correct product problems in a prompt and thorough manner.”

“In February of this year,” Sharfstein continued, “FDA called an extraordinary meeting with senior executives of Johnson & Johnson. … FDA confronted these executives about whether [its] corporate culture supported a robust quality system to ensure the purity, potency and safety of its products.”

Among the cultural issues Sharfstein raised was what he called J&J’s “phantom recall” of Motrin tablets in the spring of 2009. That was when, as he explained, “the company had paid a contractor to go into retail stores across the country to purchase all available product while acting like a regular customer, and not disclosing whether it was a recall.”

As a result of these FDA inspections, J&J was ordered to do a series of real recalls of a dozen of its consumer products. The agency also forced the company to shut down a factory in Pennsylvania until repairs could be made, sanitation safeguards could be implemented and entire processes retooled.

For students of corporate management, the phantom recall should have been especially emblematic of how a company could change.

Johnson & Johnson had burnished its reputation for honest dealing with customers and regulators in 1982, when it was discovered that Tylenol capsules had been poisoned with cyanide. Seven people died. Scary headlines about the dangerous product dominated the news.

From the moment the crisis began to unfold, James Burke, J&J's chairman and chief executive, took a series of extraordinary steps that he said he believed the company's Credo dictated. He immediately recalled all Tylenol products. He was readily accessible to the press. He went on television and issued press releases telling people not to buy any Tylenol that might still be on the shelves. He apologized. And he organized an all-hands-on-deck drive to repackage Tylenol and all similar Johnson & Johnson products in sealed containers.

It took a few years, but a brand thought to have been irretrievably damaged resumed its place as a consumer favorite.

In the years since, Burke's blunt, upfront handling of the Tylenol sabotage has been celebrated in management schools as *the* ultimate model of corporate crisis management.


THE LAWRENCE DAILY JOURNAL-WORLD

Sunday
October 3, 1982
Lawrence, Kansas
124 pages • Vol. 104, No. 276
50 cents

Chicago mayor bans Tylenol; trail of cyanide widens

Tylenol Claims Seventh Victim

Suspect Tylenol Found In Fla.

Primary

pain-killer
ve its latest
ering scare?

When seven people died after taking cyanide-contaminated Tylenol in Illinois in 1982, many marketing professionals said the brand was dead. But Tylenol bounced back.

Poison Tylenol claim

Examining Tylenol

Alarming Tylenol headlines dealt a major blow to J&J's image.

THE FEDS CLOSE IN

While Johnson & Johnson was wrestling with its un-Burke-like handling of the quality breakdowns in its consumer division, the government accelerated its pressure on the Risperdal front.

The news, on November 3, 2009, circulated not only in the conventional media, but also on the websites and in social media channels of lawyers seeking more Risperdal whistleblowers and personal injury clients.

Justice Department Announcement

Nov. 3, 2009

"The nation's largest nursing home pharmacy, Omnicare Inc. of Covington, Kentucky, will pay $98 million," Assistant Attorney General Tony West announced, to settle charges that it "solicited and received kickbacks from a pharmaceutical manufacturer, Johnson & Johnson (J&J), in exchange for agreeing to recommend that physicians prescribe Risperdal, a J&J antipsychotic drug, to nursing home patients.

"J&J's kickbacks to Omnicare took multiple forms," West's press release continued, "including rebates that were conditioned on Omnicare engaging in an 'Active Intervention Program' for Risperdal and payments disguised as data purchase fees, educational grants, and fees to attend Omnicare meetings."

Nothing was announced about the consequences for the payer of the "kickbacks"—Johnson & Johnson. West was silent about that, because J&J, unlike Omnicare, had not made a deal.

West, along with acting Boston U.S. Attorney Michael Loucks, had been making a name for himself in dealing tough with drug companies in a series of settlements. But J&J was in no mood to accept the bargain they had offered—yet.

"We wanted to resolve all the Risperdal issues at once—the one in Boston and the grand jury investigation in Philly," recalls one J&J lawyer, referring to the *qui tam* suits Sheller had initiated in Philadelphia. "And they were still being coy about what they had or what they wanted from us. So we said we'd fight this one until we could deal with everything."

Johnson & Johnson did not dodge headlines for long. On January 25, 2010, Loucks, joining a *qui tam* suit filed years earlier by two Omnicare whistleblowers, sued J&J alleging the same illegal dealings. "Johnson & Johnson accused of drug kickbacks," The New York Times declared.

Immediately, Loucks applied more pressure. Among other moves, he began what would be a two-year fight to force J&J to make Alex Gorsky—now thought to be in the running to become the next Johnson & Johnson CEO—available for a deposition in the case.

The company still wasn't ready to yield, according to the lawyer who explained the strategy of holding out on settling the Omnicare charges. "The top company people, Gorsky included and especially [then-CEO William] Weldon, were saying they were ready to fight it all if they couldn't resolve it satisfactorily," this lawyer recalls. "They thought this off-label stuff was bullshit."

J&J Responses

The company's view in that regard would be reflected in a memorandum sent to me by Vice President for Media Relations Ernie Knewitz as I was preparing this article. Knewitz quotes from various government hearings and documents that, in the company's view, acknowledge—indeed sanction—off-label sales of Risperdal and confirm that the drug was effective. The memorandum can be found here.

'WE THOUGHT WE HAD THEM'

In January 2010, Kurtis Berry decided to join what by now looked like a lucrative Johnson & Johnson *qui tam* party being organized by Sheller and his team. Berry was a big catch. He had been a regional sales

manager for Janssen in the Northwest and was easily able to tie J&J senior executives to information from Starr and from two other sales rep "relators" who had joined the group.

"When Berry came in, the government stopped beating around the bush," Sheller recalls. "They told us point-blank that they were in, and went into overdrive. It was a turning point. Now, we thought we had them."

At some point a year or two into what was now her nearly seven years as a secret whistleblower, Vicki Starr and her husband had mentioned to their accountant that she might be paid a substantial amount of money, well beyond their current earnings, for a project she was working on. They asked if there was any special planning they might need to do in case that happened.

There was one thing they might think about, the accountant told them: Oregon taxed personal income, but Washington, just over the border from where they lived, did not. If they really thought they might get a windfall, they could consider moving to Washington. They would have to establish residency there for at least six months in the calendar year in which the income was going to be received.

As a result, from time to time, and almost as an excuse to get into a conversation about how things were going, Starr, having told her lawyers about the accountant's advice, would ask them if she and her husband should be thinking about moving. Through 2010 their answer remained the same: no reason yet to go house hunting.

However, a Texas lawyer's revelation would soon help make that move over the border more likely.

A TEXAS LAWYER'S "A-HA" MOMENT

Good trial lawyers know they have to spin a story that jurors will understand. It has to be something that puts all the pieces together and explains (if you're a plaintiffs lawyer or a prosecutor) why the bad guy did something bad, or (if you're a defense lawyer) why this good guy is being accused of doing something he didn't do. Jurors need a reason to believe.

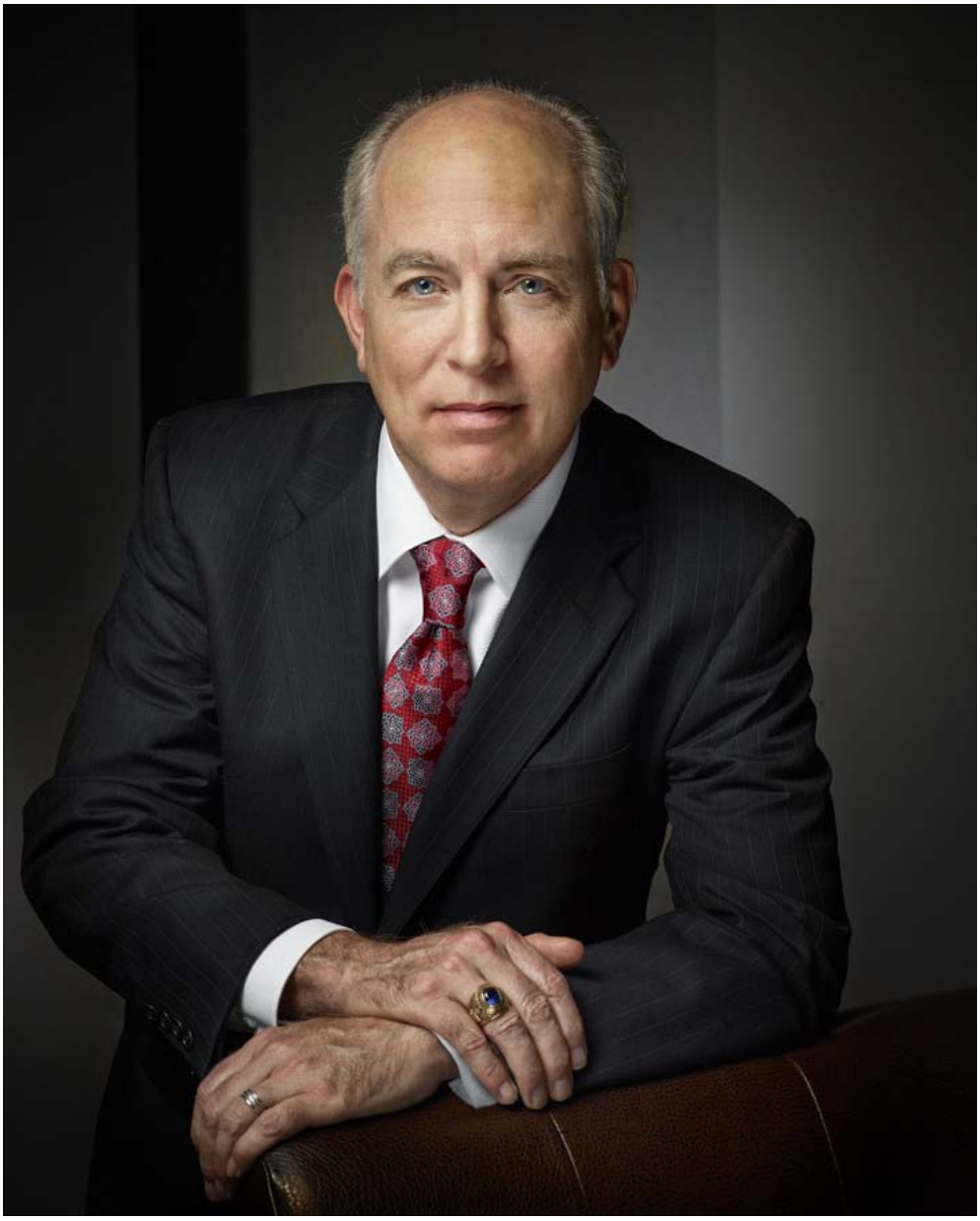
By 2011, Tom Melsheimer, who was beginning his 25th year practicing law, was already a celebrated storyteller. He had become famous in Texas legal circles in 1991 when, as a federal prosecutor, he won convictions in the locally famous "I-30 scandal." It involved a flamboyant real estate developer and 66 other defendants who were convicted in a scheme that defrauded the government of $1 billion. Melsheimer led a trial team that turned a byzantine set of corporate transactions and interlocking corporate entities into a caper that the jurors could understand.

Melsheimer's Mavericks Brief

June 22, 2011

As 2011 began, Melsheimer was also working on a case for the Dallas Mavericks basketball team, which was being sued by minority owner Ross Perot Jr. for mismanagement. A brief he would file in June for summary

judgment in that case generated publicity and praise far beyond the legal world for how he told the story. A local newspaper called it “The Greatest Legal Brief in the History of Jurisprudence,” and the sports website Deadspin dubbed it “The Ultimate F—You Legal Brief.”



By his 25th year of practicing law, Thomas Melsheimer was a celebrated storyteller.
Thomas Melsheimer

Melsheimer titled the brief, “World Champion Dallas Mavericks and Radical Mavericks Management’s Motion for Summary Judgment.” He then used an over-the-top (for a legal brief) visual aid—a picture of the Mavericks celebrating their recent world championship—to drive home his simple story: that it was beyond

the pale to claim that this championship team was the victim of mismanagement. Melsheimer would go on to win the motion—and get more accolades two years later when he successfully defended Mavericks owner Mark Cuban in a bitterly-fought trial against the SEC over insider trading charges.

Now, as he contemplated the documents he and the Texas attorney general's staff had subpoenaed from Johnson & Johnson for the *qui tam* suit brought to them by Allen Jones, the former Pennsylvania auditor, Melsheimer was struggling to figure out what story he could tell this time.

Yes, Jones had brought him persuasive evidence, now backed by the internal Johnson & Johnson documents Melsheimer had reviewed, that the company had improperly set up that TMAP algorithm. The allegedly phony TMAP algorithm had been used to replace Haldol with Risperdal, because Haldol was now off patent and, therefore, far cheaper. Yet studies never proved that Risperdal was more effective than Haldol, so the Texas taxpayers were getting cheated by the upsell.

But companies always try to sell as much of their most expensive product as they can, Melsheimer recalls thinking. It's a plausible story, but not terribly compelling or surprising. And it risks getting bogged down in studies comparing the two drugs. Experts could no doubt be found to testify on both sides.

It was on March 21, 2011, that Melsheimer realized there was a bigger, better story. He was meeting in Dallas with Joseph Glenmullen, the Harvard psychiatrist and outspoken antipsychotic skeptic whom Stephen Sheller had befriended and retained as an expert advisor. Sheller had referred Glenmullen to Melsheimer.

"Glenmullen began to talk about what the drug was *supposed* to be used for – psychotic disorders, meaning schizophrenia and other departures from reality," Melsheimer recalls, "and what it was *really* being used for in Texas under TMAP, which was any kind of behavior disorder, including in kids. And then he casually said, as if I knew it, that it was all about the population numbers."

Melsheimer asked the doctor what he meant. "He walked me through," Melsheimer says, "how the market for which Risperdal had been approved—psychotic disorders like schizophrenia—affected maybe 1 percent of the population. But behavior disorders were maybe 3, 4 or 5 percent."

Risperdal Marketing Plan
(p. 2)

At that point, Melsheimer remembered something he had seen in one of those internal Johnson & Johnson documents: the original Risperdal marketing plan for the 1994 rollout. Suddenly this statement in the plan, under "Conclusions" on page 4, took on new meaning: "The anticipated growth of the antipsychotic market"—the relatively small population of people with the most severe disorders—"does not create enough room for the Risperdal sales forecast."

“That was my ‘A-ha’ moment,” Melsheimer told me. “This wasn’t just about selling a more expensive product. It was about using TMAP and off-label promotion to radically expand the market, which is exactly what their own marketing plan said they *had* to do to hit their projections.

“I knew what my story was going to be.”

THE FEDS TEAM UP WITH THE WHISTLEBLOWERS

By the time Johnson & Johnson filed its report with the SEC for the first fiscal quarter of 2011, its disclosure of Risperdal’s assorted legal troubles had grown to three pages of small type describing multiple civil and criminal investigations.

SEC 1Q 2011 Filing
(p. 25-27)

Buried in there was this scoop: The government had finally jumped into Sheller’s *qui tam* cases brought by Vicki Starr and the others. “The Government has notified [Johnson & Johnson] that there are also pending *qui tam* actions alleging off-label promotion of RISPERDAL ®,” it read. “The Government informed [Johnson & Johnson] that it will intervene in these *qui tam* actions and file a superseding complaint.”

That acknowledgement was followed by a recitation of all the other cases now targeting Risperdal. Suits by a parade of attorneys general were listed, describing in repetitive language the allegations in each.

One such case, in South Carolina, was already on its way to resulting in a judge penalizing the company $327 million after a jury found J&J liable for improperly marketing the drug and concealing its diabetes risks, particularly to the elderly. In levying the penalty, the judge said the company’s off-label marketing campaign had demonstrated a “profit at all costs” mentality. (The verdict would ultimately be reduced by the state Supreme Court to $137 million.)

Following the list of Risperdal troubles in the SEC filing was a new entry—J&J’s McNeil Consumer Healthcare division. Here, the disclosures were all the new investigations and suits that had been launched as a result of the FDA inspections and the “phantom” recall.

Still, the company reported, as it had before, that “the ultimate resolution of these matters is not expected to have a material adverse effect on the Company’s financial position.”

Jonathan Rockoff and Joann Lublin of the Wall Street Journal caught wind of the SEC filing and added their own reporting the next morning. Noting that in its disclosure Johnson & Johnson "said it set aside an unspecified amount for a potential settlement, and said it would 'likely' face civil and criminal litigation if it didn't settle," the Journal reported that "federal prosecutors are seeking roughly $1 billion to resolve the charges."

SHUTTING OUT SHELLER

When Vicki Starr called Stephen Sheller to ask about the Journal's billion-dollar figure, he still told her nothing was certain and that there was still a long way to go.

In fact, her lawyers didn't know much more than Starr did. According to Sheller, "once the feds got in, we were shut out."

Sheller was spending his time pursuing cases for plaintiffs who claimed to have been injured by taking Risperdal. By now he had spread the word among trial lawyers that he had great information about Risperdal and gynecomastia. He had put deals in place to get referrals from across the country, and they were coming in by the dozens.

The referring lawyers would get a piece of his piece of any settlements or verdicts. At least one was buying TV time across the country to use a tested, if tacky, method of gathering clients en masse.

'DID YOUR SON TAKE RISPERDAL AND GROW BREASTS? CALL 1-800…'

One night in October 2011, Benita Pledger was watching television with her now 17-year-old son Austin in their two-bedroom, single-story home in Thorsby, Alabama. They were sunk into a soft couch, just off the kitchen and outside Austin's bedroom. The flat screen, which loomed like a Jumbotron in the living room, was showing a syndicated rerun.

Benita remembers that it was close to Austin's 8:20 bedtime. She also remembers that it was just before Halloween because, as Austin stared at the television, she was thinking about having a treasure hunt for him that year instead of taking him trick or treating.

Austin's weight became a near-obsession for Benita. Benita Pledger

As much as Austin loved candy, Benita and her husband, Phillip, had tried mightily to keep their son away from sweets. Austin's weight had become a near-obsession for his doting mother. He had grown so obese that four years before, in 2007, she had asked the doctor to take him off Risperdal. He was now on a different anti-psychotic. His weight was down, she recalls, but only slightly. At least he had stopped getting fatter.

As had been the case when Austin was taking Risperdal, the head-bangings or attacks on teachers or the other students in his special education classes—which happened most often when there was some change in his routine, or when he was otherwise confused—had been less frequent than before he had been given any drugs. But they still happened.

The Pledgers made it a point to be with Austin. They played along or cheered him on as he demonstrated his astounding capacity to recite book passages from memory, and laughed with him as he watched YouTube re-runs of Nickelodeon shows on the tablet he seemed always to have in his lap.

"When I was wearing my nightgown at night he looked at me and you could tell he thought he looked like me up there," says Benita Pledger. "Not like the other boys he knew."

They took shifts, which was made easier by the fact that Phillip could walk across the lawn to and from his car repair shop.

But other than Austin's sudden tantrums and his continuing inability to read social cues and engage in any kind of social conversation, the major shadow in the otherwise happy family life that they had established remained Austin's weight—and the unusual way it made him look and feel.

"It seemed that so much of it was up top, in his chest," Benita recalls. "He knew it wasn't right. … When I was wearing my nightgown at night he looked at me and you could tell he thought he looked like me up there. Not like the other boys he knew."

While watching television with Austin just after 8:00 on that Wednesday night, Benita Pledger realized that the fat might not just be fat.

"Suddenly a commercial comes on," she recalls, "You know one of those 1-800 things, and the announcer says something like, 'Did your son take Risperdal and develop breasts? If so, it's a condition called' and I guess he said gynecomastia, though I didn't know what that meant at the time. And then there was the 800 number you could call to talk to a lawyer about suing the drug company."

She says she was shaking as she grabbed for a pen to write down the phone number. "I did all I could do to pull myself together to put Austin"—who had not seemed to notice the commercial—"to bed."

Then she sat at the kitchen table just behind the flat screen, and stared at the phone number. Phillip was off practicing with a band he played in, and she was wondering if she should talk to him first. She knew that, like her, he was not the kind of person who thought about suing people. Bad luck was bad luck, or maybe God's will. It was not something to go to court about.

But then she got angry. Maybe this wasn't something that had just happened to them and their son. Maybe it was someone's fault. The company's fault.

She dialed the 1-800 number "It was a law firm in Texas," she says. "The young lady asked me a few questions, then asked if I had any way to email or text her a picture of Austin."

Austin was not yet asleep, so his mother stepped into his bedroom and said, "Baby, you know how you've been dieting and trying to lose weight? Can I take a picture of your muscles?"

"So he took off his shirt and flexed. He was so proud. Then I asked him to turn so I could take another picture from the side."

The woman from Texas called back almost immediately to tell Benita Pledger that it looked like she had a good case. They would be sending her some papers to sign.

When Phillip came home, his wife nervously told him about the ad she had seen.

"Benita thought I'd be angry," he recalls. "I wasn't angry at all with her. I was angry with the company."

The Texas number Benita had called belonged to the Thomas J. Henry law firm, which is based in Corpus Christi. Run by the brothers Thomas and Michael Henry, the firm seems to derive much of its income from investing in 1-800 ads seeking clients injured in a variety of mishaps, then referring them to lawyers who are actually deep into litigating those cases. They get a share of anything those lawyers win from any settlements or verdicts as their referral fee.

"They have quite a TV and telephone operation," says Stephen Sheller. "They send us clients and get maybe 5 or 10 percent of what we get"—which is typically a quarter to a third of the client's payout, but can be as much as 40 percent in some states.

"They sign up hundreds or thousands of people with those TV ads," Sheller adds, "It's a good business." (On the day Sheller spoke with me last winter from his office in Philadelphia, he noted, with a chuckle, that the night before he had seen the Corpus Christi firm's ads on local television seeking clients who had been injured or whose family members had been killed in an Amtrak accident in Philadelphia a few nights before. Henry firm spokeswoman Susan Harr declined to comment on the percent of cases the firm gets from television ads, or how many clients it had signed up stemming from the Philadelphia train accident.)

Of course, what the Henry firm does is only a good business if the lawyers have strong enough cases to win big verdicts or negotiate generous settlements. And when it came to Risperdal, that part of the equation had yet to be tested.

‘THERE’S NOT ENOUGH SCHIZOPHRENIC PEOPLE’

“I’m Tom Melsheimer. During my time with you today, I want to review what I expect the evidence will show in this trial. The gist of it is this: Janssen, a subsidiary of Johnson & Johnson, engaged in a wide-ranging fraudulent scheme to market and sell Risperdal, a drug that was no better and in some ways worse than older less expensive antipsychotic medications. …”

Melsheimer Opening
Jan. 10, 2012 (p. 14)

So began Tom Melsheimer’s opening statement on January 10, 2012, to a jury in Austin that would decide the case that former Pennsylvania auditor-turned-whistleblower Allen Jones had brought to Melsheimer.

Finally, Johnson & Johnson was facing off with accusers in court.

A lawyer from the Texas attorney general’s office had briefly preceded Melsheimer with a dry overview of the allegations. Her office was now partnering with Melsheimer in this state *qui tam* case, seeking to recover hundreds of millions of dollars of the state’s alleged overpayments stemming from the J&J-generated TMAP algorithm scheme that had dispensed so many Risperdal prescriptions in state mental institutions and to state Medicaid recipients.

Melsheimer covered all the elements that he was now convinced made for a compelling story: Johnson & Johnson had made false claims about the drug being better than Haldol. The company had failed to warn about the risk of stroke and other dangers to the elderly. And the TMAP guidelines dictated that Risperdal be used for state-paid patients, instead of the cheaper older drugs, only because TMAP was “a fraudulent scheme.”

Melsheimer promised to back that up by producing evidence—found in still more discovery documents—that the three doctors who drafted the TMAP algorithm guidelines set up their own company and that, “Janssen paid that company $600,000 to go out all throughout the country and promote these guidelines, seemingly as an independent third party.”

Then came Melsheimer’s roll out of his “A-ha” moment, which he was convinced would make the whole story something the jury could believe in: All of the TMAP scheming had happened, he charged, not simply because some sales manager wanted to squeeze out more revenue wherever he or she could, but because the business plan from headquarters demanded that the market for the drug had to be extended well beyond its approved label usage.

“This is an interesting phrase,” he began, reading from what he explained was the company’s 1994 marketing plan. “The anticipated growth of the antipsychotic market does not create enough room for the Risperdal sales forecast. … In other words, there’s not enough schizophrenic people to sell Risperdal to get our sales forecast hit. … That meant that they were going to have to establish it as a broad-use product. Again, this is in the fall

of 1994. And what does that mean? A critical success factor for them in that market expansion—they identified this back in 1994—was children. Children. Now, think about this. The success they're talking about here was not a medical breakthrough. It was a financial breakthrough. Janssen knew that if it could sell—push its drug on children, it could help make the drug financially successful."

LISTEN TO 'THE REAL DOCTORS WHO JUST TREAT FOLKS'

Stephen McConnico Opening Statement
Jan. 10, 2012 (p. 56-62)

Stephen McConnico, a veteran trial lawyer and partner at an Austin corporate defense firm, began his opening defense by promising to present, as his expert witnesses, "the doctors who treat more of these patients than anybody around." They would testify that Risperdal was, indeed, a lot more effective than Haldol or any of the other first-generation drugs.

"We went to the people that have treated adults, treated children," McConnico continued, "and said, 'What do you think?' They're not Johnson & Johnson employees. They're just doctors that treat these folks."

As for the higher cost of Risperdal, McConnico promised that his experts would provide this answer: “When we talk about cost-effectiveness … one other part of having a bad psychotic problem is what’s going to be called the negative effects of that psychotic problem. … A lot of people just suffer from absolutely no motivation. Kids don’t want to go to school. Older adults don’t want to go to work. … And every doctor that … we’re going to put here is going to say … we knew about these earlier drugs not taking care of the lack of motivation and ambition.”

“And what did the doctors do? You bet they kept giving the drug,” a lawyer for J&J told the court. “We don't run away from that. We admit it.”

McConnico then promised to disprove the idea that his client had pushed its product improperly: “It’s easy for somebody to get up and use a lot of words, but doctors that have to treat somebody day in and day out—and the idea that doctors don’t have their patients’ best interest foremost in their minds and they just want to help some drug company, doesn’t sail, doesn’t fly. And what did the doctors do? You bet they kept giving the drug. And that was the reimbursement. We don’t run away from that. We admit it.”

The J&J lawyer then tried to defuse the impact of the seemingly incriminating documents Melsheimer had previewed, offering his client’s answer to all the internal business plans and emails that seemed to belie its Credo.

“Now, are some of the call notes and some of the things that you’re going to see and already have seen—are they wrong? Talking about how to promote this with children. You bet they’re wrong. They shouldn’t have been done. They’re not defensible. Some of these people did make mistakes.

“It is a very large company. It has thousands of employees. And out of those thousands of employees, there were some mistakes, not a lot. They were pretty rare. They showed you some emails. When you have that big a company, are people going to write some emails that are a … little exaggerated in the heat of the moment? Yes. They’re correct. They’ve gone through millions and millions and millions of pages. And if you do that in any business, you’re going to pull out a few where people are exaggerating.”

It was not until the final minutes of his opening that McConnico turned to the heart of the case: “Now, let’s talk about TMAP. … Did Johnson & Johnson … help fund that? They sure did. That’s what they ought to be doing. They ought to try to see what the experts in the field are doing, and then they should tell people.”

“Folks,” McConnico concluded, “if it helps Texans stay in school, keep a job, stay out of a mental institution, not commit a crime, then it’s helped every one of us.”

McConnico had hung his case not on punching holes in Melsheimer’s story about TMAP, but on whether his experts could persuade the jury that, whatever the embarrassing emails or business plans generated by a few J&J employees said, everything that had happened to make Risperdal the antipsychotic of choice had improved the lives of their fellow Texans.

THE ‘TWO MILLION DOLLAR MAN’ STOPS THE FIGHT

One of the early witnesses Melsheimer called was Joseph Glenmullen, the Harvard psychiatrist retained by Sheller who was now also working for Melsheimer and the Texas attorney general. With Glenmullen’s hourly rate approaching $600, “we called him the two million dollar man,” says whistleblower-plaintiff Allen Jones.

They got their money’s worth.

Glenmullen Testimony
Jan. 18, 2012 (p. 215, 225-236)

Glenmullen calmly spewed out a series of damning allegations, resulting from what he said was more than 3,000 hours spent reading thousand of pages of text and data related to Johnson & Johnson’s handling, or mishandling, of clinical data. For example, of eight footnotes to an article J&J had published claiming Risperdal was safer or no more risky when it came to diabetes, two of the actual studies referred to in the footnotes had reported data that demonstrated the opposite of J&J’s claim, Glenmullen asserted. The other six studies were paid for by Johnson & Johnson, and one of those “manipulated” the results by excluding some of the participants in the study to make the results look better.

Anyone in the courtroom watching Glenmullen probably couldn’t wait to see how the McConnico would cross-examine him, to get a sense of Johnson & Johnson’s side of all of this.

That never happened. Apparently, Johnson & Johnson in-house lawyers, who watched McConnico’s opening statement and then Glenmullen’s testimony, decided against risking more. Soon after Glenmullen stepped down from the witness stand on the evening of January 18, Jones’ lawyers called him up to their Four Seasons war room.

“It’s over,” they said. “The company settled.”

J&J had agreed to pay $158 million to make the Texas case go away.

“My first reaction,” Jones recalls, “was ‘Oh shit.’ I thought we could demolish them the next day with more from Glenmullen. I just wanted it to keep going.”

Jones—who told me he went to live in “a cabin in the woods with no running water” after getting fired in Pennsylvania—says his whistleblower fee was “reported in the papers as twenty million. … The lawyers got 40 percent of that, then taxes took a big chunk.” His bottom line was about $8 million, he says, speaking from what he describes as a “modest” historic house he restored on 270 wooded acres in the Florida panhandle.

Jones had won the lottery, and Johnson & Johnson had avoided having a jury rule on its conduct.

CHAPTER 10

CHESS, AT

$1,000 AN HOUR

By Steven Brill

THE NEW CEO

J&J Press Release re: Gorsky's Promotion
Feb. 21, 2012

On February 21, 2012, five weeks after Johnson & Johnson paid $158 million to Texas and made Allen Jones a multimillionaire, the company announced that the board had appointed Alex Gorsky to succeed William Weldon as the new chief executive officer. The press release noted that Gorsky had began at J&J in 1988 as a salesman for Janssen and then worked his way up to president of the unit. Although he had left in 2004 to run rival Novartis' North American division, he had returned to the fold in 2008 to assume a variety of top positions, including vice chairman. The announcement quoted Weldon, the outgoing CEO, describing the "rigorous, thorough, and formal multi-year" board selection process.

Like all Johnson & Johnson CEOs before him, Alex Gorsky came from within the organization.

Board Members Who Appointed Gorsky

I tried to reach each member of the J&J board that chose Gorsky to ask how Gorsky's involvement in the Risperdal marketing and sales campaigns had factored into his or her decision. Of the 12—who include the former president of the University of Michigan and five retired Fortune 500 CEOs—I was able to reach eight by phone or email either directly or through their designated assistants. All declined comment on that question, and despite being independent board members, technically unaffiliated with the company, all referred me to J&J's public relations department.

But Michael Johns, a board member, physician and former chancellor of Emory, did say, "As I understand it, Risperdal was a drug that treats symptoms of a disease, not any disease. So maybe it's the system that's screwed up." That rationale aligns with how the company's lawyers, according to one of them, saw the cases—that the government's off-label argument puts the company in an impossible position when it comes to drugs like Risperdal. "These diseases," the lawyer explained, "don't have a blood test or anything else; they are all about symptoms. And many different types of people can have those symptoms, which our drug does a great job of alleviating."

Gorsky was described in the Wall Street Journal story covering his promotion as a "former Army ranger, who had "edged out fellow Vice Chairman Sheri McCoy, 53, for the top spot. Both inside and outside the company," the Journal reported, "Ms. McCoy was thought to have an edge over Mr. Gorsky in the horse race to become the 126-year-old company's ninth leader."

The story's concluding sentence quoted a health industry consultant saying he "thinks the board chose Mr. Gorsky partly because 'he has been responsible for the largest acquisition in the history of J&J,' the Synthes deal."

J&J Synthes Press Release
April 27, 2011

Synthes is a large manufacturer of surgical equipment and supplies whose $19.3 billion buy-out by Johnson & Johnson was announced in 2011. As Gorsky prepared to take over as CEO, the deal, which he had helped steer, was about to close.

For aficionados of illegal off-label sales, Synthes was a special company.

Synthes Accusations
June 16, 2009 (p. 1-2)

In 2009, a Pennsylvania-based subsidiary of Synthes was accused by federal prosecutors of illegally marketing and aiding in the misuse of "trauma products to treat damaged human bone" during surgery.

The subsidiary, called Norian, and Synthes itself, were charged with a total of 52 felonies and 44 misdemeanors, all involving an alleged conspiracy to encourage doctors to conduct unauthorized clinical trials of the company's products on patients being treated for compression fractures of the spine, a painful condition suffered mostly by the elderly.

"Before the marketing program began," federal prosecutors in Philadelphia alleged, "pilot studies showed the company that the bone cement reacted chemically with human blood in a test tube to cause blood clots. The research also showed, in a pig, that such … clots became lodged in the lungs."

The company had not stopped marketing the product "until after a third patient had died on the operating table," the government charged, adding that "after the death of the third patient in January 2004, Norian and Synthes did not recall the [bone cement] from the market—which would have required them to disclose details of the three deaths to the FDA. … Instead, the company compounded their crimes by carrying out a cover-up in which they lied to the FDA during an official inspection in May and June 2004."

In short, according to the government, the new J&J acquisition had, prior to being acquired by J&J, illegally experimented on humans and killed three of them in the process, then lied to the FDA about it.

What would become known as the bone cement case would end up with four Norian executives pleading guilty and serving five to nine months in prison, and Synthes agreeing in 2010 to pay a $23 million fine.

As follow-on suits by patients or the heirs of dead patients then worked their way through the courts, the case became the subject of a riveting September 18, 2012 story in Fortune Magazine. The most telling item in Mina Kimes' report might have been this: When Johnson & Johnson's purchase of Synthes was announced a few months after the highly publicized guilty pleas and fines, the Johnson & Johnson press release, Kimes wrote, cited "Synthes's 'culture' and 'values' as evidence of its appeal, even as former Synthes executives awaited sentencing on charges of grievous conduct."

TOSSING GORSKY A HAND GRENADE

Alex Gorsky was scheduled to become Johnson & Johnson's chief executive on April 26, 2012. Fifteen days before, an Arkansas judge ordered the company to pay $1.1 billion for illegal Risperdal marketing in his state. (The verdict would be thrown out two years later by the state Supreme Court, which ruled that the Arkansas false claims act did not apply to false statements about prescription drugs.)

Brief re: Gorsky Involvement
April 11, 2012 (p. 7-8)

But the Arkansas case wasn't the J&J lawyers' top concern that day. They were more worried, according to one company lawyer, about a brief that Boston federal prosecutors had just filed with a judge contesting the company's refusal to make Alex Gorsky available for a deposition in its civil suit over the Risperdal/Omnicare nursing home case.

In March, the prosecutors handling the Omnicare case had sent Johnson & Johnson's lawyers a letter matter-of-factly asking for dates when Gorsky could be deposed. The prosecutors knew that they were putting J&J and its new boss in a tight spot.

These kinds of chess plays are why lawyers on both sides of the highest stakes, white-collar litigation love the game.

Gorsky's lawyers could make him available and expose him to a barrage of questions under oath about the Omnicare deal and about the alleged off-label promotion of Risperdal to the elderly. Or they could refuse to make him available by arguing that his testimony was not necessary; federal rules give corporations the right to refuse to make a top executive available if the judge believes the purpose of deposing him or her is harassment rather than a quest for real information. However, arguing that Gorsky testimony wasn't relevant because he did not have direct knowledge opened the door for the government to go to the judge with a brief spelling out of why his testimony was relevant—in other words, all the details of his hands-on involvement.

These kinds of chess plays are why lawyers on both sides of the highest stakes, white collar litigation love the game. The prosecutors, who are typically lawyers with elite credentials, get to match moves with some of the most highly paid private-sector litigators anywhere. Like friends engaged in a fierce tennis match, there's a collegiality binding both sides.

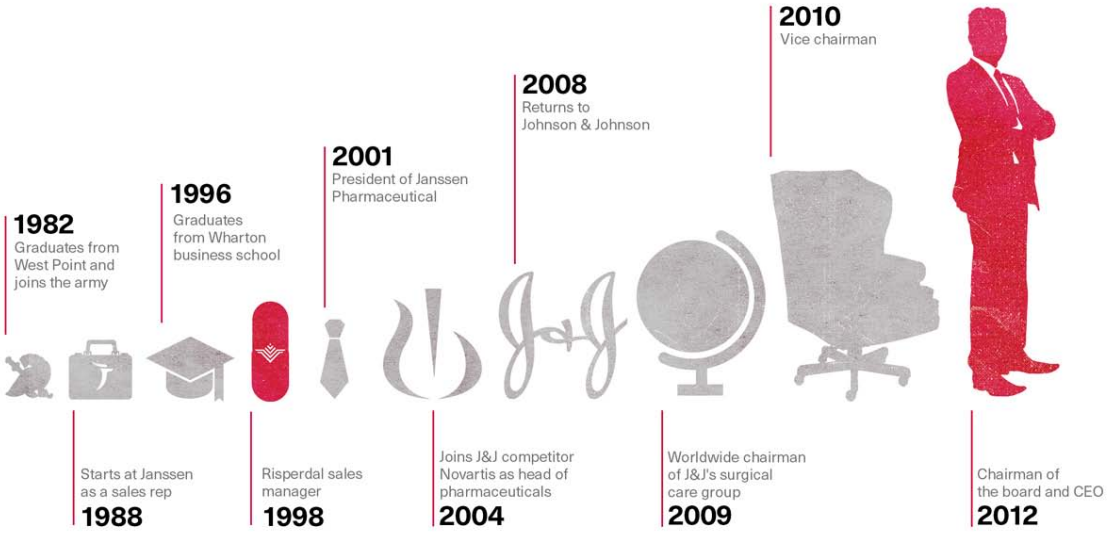
In fact, they often *switch* sides; by now, Michael Loucks, who had led the Boston office's drug company investigations, had left to become a partner handling corporate securities fraud and white collar criminal defense in the Boston office of Skadden, Arps, one of the country's top firms.

Gorsky and the J&J lawyers chose the lesser of the bad choices. "Mr. Gorsky had no reasonable connection to the subject matter of the Government's complaint and was not involved in the facts underlying this case," they wrote back on March 26, explaining why the new CEO shouldn't have to sit for the deposition.

The government responded to this invitation to spell out Gorsky's "reasonable connection" and his "involvement in the facts" underlying the charges that Omnicare had already settled. Its brief to the judge was not made part of the public record. But it was there for all the Johnson &

Johnson lawyers, and their client, to read—a hand grenade whose pin could be pulled with a leak to the press, or, if it came to that, by cutting and pasting much of it into an amended suit naming the boss.

The Rise of Alex Gorsky



This was the first time any government document had tied Alex Gorsky to the Risperdal scandal. It did so in unrelenting detail, with each point followed by a reference to a document that the government had obtained through subpoenas to Johnson & Johnson and Janssen:

- "From October 1998 to October 2001, Mr. Gorsky was Janssen's Vice President of Marketing, and from October 2001 to early 2003 he was President of Janssen."
- "During all of that time he was responsible for selling Risperdal, a drug whose biggest customer was Omnicare."
- "He regularly received Monthly Reports on J&J's Long Term Care Group, including reports which commented on Omnicare's efforts to promote prescribing of Risperdal and other J&J products."
- "He met repeatedly with senior Omnicare executives to discuss those efforts." (The meeting dates were then listed.)

As the government's brief went on, the description of Gorsky's involvement got more specific, as if the prosecutors meant to tighten the vise on the incoming CEO of the Credo company.

- "In advance of the May 1, 2000, meeting with Omnicare, for example, he received information that Risperdal's 53.3% market share of Omnicare 'represents Omnicare's ability in persuading physicians to write Risperdal in the areas of Behavioral Disturbances associated with Dementia.'" (This was a quote from a document, referenced as an exhibit to the brief.)

- "As Vice President of Marketing and having previously worked closely with J&J's Medical Development group (which was responsible for developing clinical trial data for Risperdal), he was in a position to know why J&J chose not to inform Omnicare (or members of Jansen's own sales staff) that, in January 1999, the Food & Drug Administration ('FDA') had warned J&J that marketing Risperdal as safe and effective in the elderly would be false and misleading."
- "Likewise, he was in a position to know why J&J did not disclose to Omnicare executives that, in 1999, the FDA had rejected J&J's attempt to get approval to market Risperdal for treatment of psychotic and behavioral disturbances in dementia (by far the most prevalent use of Risperdal in Omnicare-served nursing facilities) because of inadequate safety data."
- "Mr. Gorsky was also involved in approving payments [for data] to Omnicare under the 2000 Consulting and Services Agreement."

In short, the reason Johnson & Johnson's incoming CEO was needed to testify didn't have to do with his current position. It was all about the positions he had held and been promoted from—the positions where he had demonstrated that he had the right stuff to lead the entire company, according to the board that had just anointed him. It was simply a matter of getting a company marketing manager, who happened to have become the CEO, to explain his conduct on the way up the ladder.

"We wanted to deal with everything at once," recalls one Johnson & Johnson lawyer. "Just pay and be done with it all. And so did the government."

It seemed like a strong argument. But the government actually didn't care much about getting Gorsky's deposition. This was all part of the chess game, which by the early half of 2012 was being played across a national map. Boston had its Risperdal/Omnicare investigation. And Philadelphia had its *qui tam* suits brought by Vicki Starr (and, by now, four others in a group Sheller was leading) involving the broader off-label marketing allegations. There was even a smaller-bore federal investigation in San Francisco related to the marketing of another Johnson & Johnson product, the heart failure drug Natrecor.

Boston Risperdal Omnicare Complaint

Philadelphia *Qui Tam* Complaint

San Francisco Complaint

"We wanted to deal with everything at once," recalls one Johnson & Johnson lawyer. "Just pay and be done with it all. And so did the government."

For that reason, and because of the stakes and the big-name company involved, the Justice Department in Washington was now calling the shots. The man in charge was Tony West, who had been head of the Justice Department's civil division, but had since been promoted to associate attorney general.

Assistant Attorney General Tony West projected a "sense of disgust" at the conduct of drug companies. Getty Images

Although West had been a corporate lawyer in San Francisco, one line in his resume suggested that he was a bit more of a free spirit than other colleagues who rotate from corporate defense practices to the government and back again. In the aftermath of the September 11 attacks, while working at his San Francisco firm, he had vigorously defended, *pro bono*, John Walker Lindh, the alleged "American Taliban," who had been captured and tortured by American soldiers in Afghanistan. In fact, West's work for Lindh, which included charging the Justice Department with a variety of abuses, had almost sidetracked his Senate confirmation when President Obama appointed him to the Justice Department in 2009.

"Tony was determined to make a mark with these drug cases," says one defense lawyer. "He really projected a sense of disgust with the whole thing."

West allowed the talks in Philadelphia to proceed. That was the place where the offenses likely to yield the most money (through the *qui tam* false claims) were being negotiated. But he kept close tabs on their progress and made it clear that he would be involved in the final deal.

Negotiations between the two sides in Philadelphia, which had begun in 2011, had proceeded into spring 2012 according to what had become something of a standard script. It was a script that had been followed in deals for off-label offenses that had been completed, with West signing off, in Philadelphia with Eli Lilly (in 2009), AstraZeneca (in 2010) and Novartis (also in 2010); and in Boston with Pfizer (in 2009) and Merck (in 2011). In fact, for the drug companies, it was

sometimes the same lawyers representing different clients who were called in to lead the negotiations.

“We knew how this was going to be played,” recalls a defense lawyer who had been involved in one of those earlier deals and who was also involved in the J&J negotiations. “We also knew that these guys had a habit of wanting to raise the bar, so that if Lilly had paid $800 million and the guys they competed with in the Boston office had gotten $2.3 billion from Pfizer [although that involved allegations of four illegally marketed drugs], they were going to come after us hard.”

As was generally true in those cases, initially, the lawyers for the drug companies—one or two partners and a few lower-level associates each from as many as three different law firms hired by the company—would troop into a conference room at the prosecutor’s office and protest to Philadelphia U.S. Attorney Zane Memeger’s assistants that their client had done nothing wrong. The meeting might last an hour or two, during which the government would flash hints of its evidence and the defense lawyers would say something about how flimsy it all sounded.

The defense lawyers’ bills, at hourly rates of $400 to $1,000, totaled 7 to 12 thousand dollars an hour.

Sometimes Memeger would drop in to ask how things were going. It would all be friendly.

Memeger, an affable lawyer with a sterling resume, was part of the club. He had won awards as a government prosecutor before becoming a partner and white collar crime specialist at one of Philadelphia’s largest corporate firms. He had then been appointed U.S. attorney by Obama in 2010, allowing him to catch the tail end of the office’s high profile drug cases.

Months would go by as the government continued to examine documents and talk to witnesses, including some who would be put before a grand jury because this was proceeding as a criminal case, as well as a civil case potentially involving damages for false claims.

Then the defense lawyers would return and allow as how maybe *some* salespeople had gone off the reservation and done things they shouldn’t have done. The prosecutors would chuckle or feign outrage, and talk vaguely (or not so vaguely if the other side had managed to tempt them) about the evidence showing that higher-ups were involved and that this was all part of a company plan. Charlene Fullmer, one of the assistant U.S. Attorneys leading the investigation, would occasionally mention an especially bad piece of evidence, according to one lawyer. One of her favorites was the fact that an entire Risperdal ElderCare sales unit had been set up.

“There were innumerable meetings,” Memeger recalls. “They’d present. We’d present. Eventually, we would narrow the issues.”

HOLDING NO ONE RESPONSIBLE

Actually, the issues were only one issue: money.

Both sides had long since agreed in principle on a single misdemeanor criminal plea by the corporation—not by any individual.

The only question was how much all of this was going to cost Johnson & Johnson in civil damages and criminal fines.

Technically, the amount of the civil penalties was supposed to be calibrated to the amount of actual false claims—the amount paid by Medicare, veterans or others receiving federal health benefits resulting from the impermissible off-label selling. “We’d come in with economic analyses showing it was fifty or a hundred or two hundred million or whatever, but we knew they’d ignore that,” says one of the drug company negotiators. “They’d counter with three billion or something, maybe five. But they would never really tell us how they got there, because they had no idea. For them, it was easy.”

There was also the question of how the money would be split between a civil damages payment (for those false claims) and a criminal fine for the misdemeanor. In most situations civil payments are tax deductible; criminal fines are not. At a corporate tax rate of roughly 30 percent, that was a big difference; a lawyer who can move $100 million from the fine column to the civil column saves his client $30 million, making his $1,000 hourly rate negligible.

Meantime, according to another lawyer, the Johnson & Johnson executives, Gorsky included, were of two minds. They wanted to put this behind them, and the money, however off the charts by any rational standard, would not hurt the company’s financials too much or its standing on Wall Street. In fact, settling for almost any amount would help on Wall Street by resolving uncertainty. On the other hand, says this lawyer, “They were angry about the charges, because they thought they had a First Amendment right to sell products that they believed in, and they knew they were a good company.”

That single misdemeanor plea was also a standard part of the script. It was the deal all the big companies had made in their off-label cases, and, according to lawyers on both sides, nothing different was ever contemplated by either side in this case. This was despite the fact that the prosecutors in the negotiations with defense lawyers argued that the drug Johnson & Johnson sold was particularly powerful and that the off-label use was intended for the most vulnerable patients, the elderly and children.

‘WHAT CAN YOU PROVE TO A JURY?’

Misbranding Definition; Misdemeanor and Felony Penalties (p. 42, 49)

An individual is guilty of a misdemeanor, technically known as misbranding, if he or she causes an FDA-approved drug to be put into interstate commerce with the intention of having it be sold off-label. With all of the business plans and marketing campaigns targeted at children and the elderly that could be linked to Gorsky, that was something for which the prosecutors seemed to have convincing evidence.

The same offense is a felony if it is done with the intent to defraud. That’s a harder case to prove when it comes to the Janssen executives, such as Gorsky, although prosecutors might have been able to argue that this happened with the promotions to the elderly, especially through Omnicare, and with the company’s repeated efforts to get approval from the FDA to market to children at the same time that they were actually marketing to children.

“It’s really a matter of the quality of the evidence you have, and what you think you can prove to a jury,” Memeger told me, when asked about why no effort was made to name individuals.

“The statute of limitations also comes into play,” he added, referring to a federal criminal law that generally does not allow prosecutions to be initiated more than five years after the crime was allegedly committed. Had the government’s investigation not dragged out over so many years, that would not have been an issue, given that the prosecutors had begun their investigations in 2003 and the company’s allegedly illegal marketing had continued at least through 2004. And it would not have been an issue at all if the FDA had been monitoring the same prescription data that drug companies routinely purchase and if it had seen that within a year of Risperdal’s launch a high percentage of prescriptions were being written by doctors, such as pediatricians and those working at nursing homes, who treated patients in the prohibited markets.

However, as soon as the government and Johnson & Johnson began talks, the government asked that the company waive its statute of limitation protections for the corporation—in effect freezing the date for any criminal prosecution of the company as if it were occurring the day of the first discussions. Corporations almost always agree to the waiver, and J&J did in this case. Otherwise, the government lawyers told the J&J team, they might be forced to bring a criminal case immediately without considering all that the other side might offer in terms of countervailing evidence or settlement concessions. Waiving the statute of limitations for a corporation was also part of the dance that eased some of the rough edges off of the adversary process so that a deal could be struck.

As for the executives, “no lawyer is ever going to waive the statute for an individual,” Memeger explains. “The corporation, yes. But not for a person.”

TOO BIG TO NAIL

As with not holding any individual responsible, a misdemeanor plea for the corporation had also become almost automatic. This was true even if evidence proving intent to defraud was strong.

The government's explanation for this is a variation on the "too big to jail" rationale used to explain why errant banks were treated leniently following the 2009 financial collapse. Under the law, any health care company convicted of, or pleading to, a felony is automatically disqualified from selling any of its products to Medicare. That could effectively put the company out of business, because Medicare is the country's dominant health care buyer. Misdemeanors do not carry that penalty.

"These companies make hundreds of great products and have tens of thousands of people working for them," is how one prosecutor put it. "Do you really want to shut them down and eliminate those products?"

Per the usual playbook, the company would plead to one misdemeanor. No individual executive would be charged.

In fact, you don't have to. Under the same law, waivers of the disqualification provision are allowed so that Medicare can buy drugs or other products it needs, or so that the units of a company not involved in the wrongdoing can be walled off.

"Who wants to take a chance on a waiver?" was how one government lawyer responded when I raised that with him. "These companies would never agree to that."

VICKI STARR GOES HOUSE-HUNTING

By March 2012, according to lawyers on both sides, the prosecutors in Philadelphia and the Johnson & Johnson lawyers thought they had reached the broad outlines of a deal. J&J would pay fines and civil damages totaling about $1.3 billion. The numbers were still in flux and might go up or down a bit, but that was the target everyone was focused on.

And, per the usual playbook, the company would plead guilty to one misdemeanor.

No individual executive would be charged.

Ultimately the private *qui tam* lawyers led by Sheller had to approve any settlement, or their clients could withdraw and fight on. The discussions were now far enough long that the government lawyers thought it necessary at least to give their ostensible co-counsel the courtesy of sharing the $1.3 billion figure. The mix would be something like $300 million for the fine and $1 billion for the civil award under the False Claims Act.

“In April, I got the call,” Starr recalls. “The lawyers weren’t specific and said nothing was certain, but that I should think about being in a home in Washington [state] by the end of June.”

Starr started house-hunting. But then news began circulating in the financial press in May that the talks were, as the Wall Street Journal put it, “on hold.” The lawyers assured her, again, that nothing was certain but that the reason for the reported glitch was that the government wanted even more money. Everything seemed to be on track.

But, in fact, the process was becoming bogged down.

Memeger was not going to be allowed to close the deal by himself. Tony West had decided it was time to roll up all three prospective deals—the big case in Philadelphia, the not-as-big Omnicare case in Boston and the relatively small case in San Francisco—into one big deal. Besides, West didn’t think Memeger had been tough enough in negotiating his piece. In fact, he wanted the sum of each of the three pieces to be larger than their parts.

“What happened was that ultimately our friends at Main Justice stepped in and wanted more money for a global resolution,” explains Memeger, referring to his bosses in Washington.

According to one lawyer involved in the bargaining, West (who is now general counsel of PepsiCo and would not discuss any aspect of his work in his old job) wanted $3 billion to make all of J&J’s troubles go away.

The talks were moved mostly to a conference room at Department of Justice headquarters, where the same routine of seemingly endless back and forth presentations would start to play out.

It now looked like Vicki Starr might have plenty of time to get used to her new home before she realized any tax savings from it.

There was, however, one development, in spring 2012, that was a surprise: Starr’s former boss, Alex Gorsky, was about to be forced to testify under oath about how he had marketed Risperdal.

‘I DON’T REMEMBER THE SPECIFIC EXERCISE’’

“I may remember from time to time during the course of the year [that] their management may provide the opportunity for additional investment in different areas of the business that was called a ‘money on the table’ exercise. But I don’t remember the specific exercise.”

That was how Alex Gorsky answered a question about the “money on the table” reference in his email that precipitated the decision by his company to fund Dr. Joseph Biederman’s Center for Children and Adolescent Bi-Polar Disorders.

His reference to “their management” was, of course, a reference to himself. At Janssen during that time, he was management.

Gorsky Deposition
May 26, 2012 (p. 23-24, 50, 156-159, 237-238)

On May 26, 2012, Gorsky, supported by four lawyers, was forced to sit for a deposition at the Philadelphia office of one of Johnson & Johnson's law firms. But this was not the session that had been demanded by the government. Federal prosecutors had suspended that fight while they tried to iron out a settlement.

Instead, his questioner was a lawyer in Sheller's firm. The deposition was carried out in advance of the personal injury cases Sheller had brought on behalf of boys with gynecomastia, which were scheduled to begin later in 2012. This was Gorsky's opportunity to tell his and Johnson & Johnson's side of the story and explain all of those seemingly damning internal documents.

Most of his answers were similar to what he had to say about "money on the table." He either only vaguely remembered, or didn't remember at all. For example:

His favorite adjective was "appropriate." For example:

- **Question:** [About the FDA's warning that marketing Risperdal as safe andeffective in the elderly was "false and misleading"] Do you agree with that statement, Mr. Gorsky?
- **Gorsky:** I think throughout the time we felt that we were promoting Risperdal in an appropriate manner based upon the label at the time.

- **Question:** Well, if Johnson & Johnson marketed Risperdal to the children and adolescent market when Risperdal was not approved for a pediatric use by the FDA, would that be illegal?
- **Gorsky:** Based on my knowledge and my review of the information, I don't believe that we—that is, Johnson & Johnson or Janssen—marketed the product in an inappropriate manner.
- **Question:** If Johnson & Johnson promoted Risperdal to the children and adolescent market when it was not approved for any pediatric use by the FDA, would you consider that a breach of the Johnson & Johnson Credo?
- **Gorsky:** I would consider inappropriate promotion of our products not consistent with the Johnson & Johnson Credo. But I'm not aware, other than very unique or specific situations that can occur in a large organization, I'm not aware of any concerted effort on the part of Janssen or Johnson & Johnson to promote the drug inappropriately.
- **Question:** Mr. Gorsky, did Janssen or Johnson & Johnson market or promote Risperdal to the child and adolescent market before Risperdal was approved or indicated by the FDA for pediatric use?
- **Gorsky:** Based upon my recollection and the documents I've seen, we promoted it in an appropriate manner.

According to Gorsky, the various business plans he had been in charge of were not what they appeared to be. For example:

- **Question:** [Referring to one of the internal Janssen business plans] The next sentence says, "Although the RISPERDAL Base business is rooted in the Schizophrenia marketplace, another fast-growing portion of this market is in children and adolescents." Did I read that right?
- **Gorsky:** Yes, you did.
- **Question:** And because of the growth of the child and adolescent antipsychotic market … did Johnson & Johnson begin to approach this market in a different way in or around 2001?
- **Gorsky:** Not that I'm aware of, other than we were continuing to pursue the clinical development program of the product in that area.
- **Question:** Turn to the top of the next page, please. … Down below it says, "RISPERDAL use in the child/adolescent population is exploding." But in this time frame, 2001/2002, Risperdal is not indicated by the FDA for any pediatric use, is it?
- **Gorsky:** Again, we did not have the specific indication, as we discussed earlier, until 2006. I don't remember exactly what the labeling said regarding use in children, but as I discussed earlier, there was a significant—there appeared to be a significant increase in the recognition of this condition in children and adolescents during this time … which was substantiated by data and its occurrence. And physicians have an opportunity to use a treatment that they perceive to be appropriate and effective in a particular patient population, and that's clearly what we were seeing happening in this area.

- **Question:** Look down at the heading that says “Key Base Business Goals and Objectives.” Do you see that?
- **Gorsky:** Yes.
- **Question:** And the fifth of the Key Base Business Goals says, “Grow and protect share in child/adolescents.” Is that right?
- **Gorsky:** Yes, that’s correct.
- **Question:** My question is, how can Johnson & Johnson grow a share in a child and adolescent market when the drug isn’t even indicated for use in the child and adolescent market?
- **Gorsky:** Well, my interpretation of that is, this is in fact a marketing plan, not a selling plan. As a marketing plan, its intent is to cover a wide range of activities regarding the development as well as the promotion of Risperdal. That being said, all of our actual promotion to the physicians would follow what was outlined in our package insert and all of our materials went through a significant review process, and that’s the way our representatives were trained. And in an area such as this, this is a marketer versus a sales representative, their language.

It added up to an effective tap dance that must have made his lawyers proud. But Gorsky’s testimony was not nearly as important to his company as finishing the deal with federal prosecutors.

CHAPTER 11

FIGHTING OVER THE FINE PRINT, SHIELDING THE BOSS,

PLEASING WALL STREET

By Steven Brill

What Happened in the Previous Chapter

ONLY FOR THE ELDERLY, ONLY FOR A SHORT PERIOD

By fall 2013, the government and Johnson & Johnson had settled on a new number: $2.2 billion—$500 million in criminal fines and forfeitures and $1.7 billion for civil damages. Of the total, $335 million was to settle the Omnicare Boston suit and the San Francisco suit related to the heart drug Natrecor. This made the Risperdal portion the largest settlement ever for the illegal marketing of one drug.

What a Good Lawyer Can Save You
(Or Why J&J Wanted To Pay More in Civil Damages)

$2.2 Billion

Total proposed fine

Civil Damages
(Tax Deductible)

$170 Million

Criminal Fine
(Non-Tax Deductible)

$500 Million

Johnson & Johnson saves

$510 Million

(versus a 100% criminal fine)

As planned, Johnson & Johnson—actually the Janssen unit, a distinction that the J&J lawyers fought for—would plead guilty to one misdemeanor related to marketing to the elderly.

That infuriated Sheller and other plaintiffs lawyers for a simple if non-obvious reason: Getting J&J to admit to selling off-label to the elderly didn't help them nearly as much as getting them to admit to all of the alleged off-label activities related to children—from the Biederman effort, to the Lego toys, to the "re-analyzing" of the prolactin/gynecomastia data.

Why? Because the children offered far more winnable plaintiffs' damage cases.

Why? Because while it might be true that thousands, maybe tens of thousands, of elderly patients who took Risperdal had died of strokes or complications from related cardiovascular diseases or diabetes, how was a lawyer supposed to prove that an 80-year-old's stroke was the result of Risperdal or anything else? A boy with 46DD breasts was a different story.

But the government lawyers didn't care about the trial lawyers' problems. They wanted to complete the deal. And if the Johnson & Johnson lawyers wanted it to be about the elderly, that was fine with the government. The standard was one corporate misdemeanor plea. The specifics didn't much matter.

Besides, there seemed to be a certain symmetry in making the plea relate to the elderly, because the other big case being settled, Omnicare, was all about the elderly. And the FDA data about the drug causing strokes and J&J's refusal to pay attention to it was damning enough. Grandfathers and grandmothers in nursing homes suffering from Alzheimer's being given a drug approved only for schizophrenics would be a compelling story for the attorney general to tell when it came time to announce the deal at a press conference.

Still, Sheller thought Johnson & Johnson's distortion of the prolactin/gynecomastia data related to children was its most unforgiveable offense, and was what the company should have been forced to admit to. He threatened, he says, to withhold his approval. However, he knew in the end that he couldn't. How could he ethically serve his client in this case, Vicki Starr, if he tried to derail the deal just to help the cases he was gathering representing all of those young boys?

But there were other elements of the deal that the two sides still had to negotiate.

In a series of bargaining sessions that ate up months of meetings that were often weeks apart, the two sides fought over how long a period J&J would admit to pushing the drug off-label to geriatrics.

The government wanted the company to admit to off-label selling over the 12-year period that the evidence indicated: from the drug's introduction in 1994 to 2006, by which time the company had stood down and disbanded the ElderCare unit because it knew about all of the investigations. J&J wanted the shortest period possible, and argued that it should range only from March 2002, when the label had been narrowed from "psychotic disorders" to only schizophrenia, to December 2003, when the label had been expanded slightly to include short-term treatment for bipolar disorders.

Data on Off-Label Sales to Elderly

(p. 24)

In a way, this narrow window made sense. The data showed that 90 percent of prescriptions to the elderly were off-label during that abbreviated period, and 80 to 85 percent were during the time after December 2003. But an 80 to 85 percent rate of off-label sales was still glaring evidence of illegal promotion. In other words, the Johnson & Johnson lawyers were saying that their client was only willing to admit to the absolute worst of its conduct. That would allow the company to tell the press and Wall Street that the company had admitted to misbehaving for a period of months (21) rather than a period of years—a short blip in the Credo company's long history.

The company dug in, according to lawyers on both sides.

"It makes no difference to you—you get your plea and your money, but we need this," is how one lawyer said J&J's argument was expressed. "Otherwise, the company wants to fight it. These are proud people. Give us something to deliver to them."

Another argument they used was the corporate First Amendment claim.

That theory had been picking up steam in unrelated court decisions around the country—including some from the Supreme Court—since it had been tried against the FDA in 1997. That was the case that had resulted in a standoff after the FDA said that its guidelines related to off-label promotion did not make speech itself illegal. Then in December 2012, the Second Circuit Court of Appeals—the New York-based court that is just a rung below the Supreme Court—had thrown out the conviction of a drug company's salesman for selling drugs off label, ruling that his pitches were protected by the First Amendment.[1]

FDA First Amendment Suit

Nov. 24, 1997

Second Circuit Decision

Dec. 3, 2012

There were differences between that case and the issues in the Risperdal investigation. The appellate judges had ruled, consistent with the FDA's clarification of its guidelines, that the salesman's speech alone could not be grounds for a conviction. The reason they had overturned the conviction, the judges wrote, was that the prosecutors and the judge had told the jury at the close of the trial that his speech alone, in fact, could convict him. His speech could only be used as evidence, the judges ruled, that he or his company committed the act of putting the drug into interstate commerce for a purpose not approved by the FDA.

There was lots of that evidence in the Risperdal case—the explicit business plans, for example. And the Second Circuit had also confirmed that misleading or inaccurate speech was not protected. The Risperdal prosecutors had evidence of that, too.

Still, the First Amendment defense was not something the Justice Department lawyers in Washington were eager to test over something as incidental as the time period Johnson & Johnson was willing to agree to.

Months of intermittent meetings followed through the summer of 2012 and into the fall and then winter. Sometimes they were weeks apart. Johnson & Johnson was in no hurry to part with its money and admit a crime, and the Justice Department lawyers, especially those at Main Justice in Washington, always seemed to have other cases to deal with.

Finally, sometime in the winter of 2013, the government agreed to let J&J plead guilty to off-label promotion only to the elderly and only during that abbreviated time period.

But it still wasn't over.

WORRIED ABOUT THE CIA

All of these plea deals also require the offending company to negotiate something called a Corporate Integrity Agreement, which allows the government to play hall monitor inside the company. These agreements, negotiated and enforced by the staff of the Department of Health and Human Services' inspector general, had become so common that in healthcare industry circles the acronym CIA had nothing to do with spies.

The government was going to try its hand at enforcing the Credo.

A CIA forces a company to submit itself, usually for five years, to steps designed to reform its conduct. For example, the inspector general's lawyers demanded that Johnson & Johnson change the way it paid bonuses to salespeople so that they were no longer compensated for off-label sales. In short, the government was going to try its hand at enforcing the Credo.

Compliance with these and other changes was to be reviewed regularly by a new committee of the J&J board, whose members had to sign a report to the inspector general each year attesting that everything was in order.

All of this was negotiated in fine detail. How many reports a year, covering what subjects, and in what form? How many members of the new committee of the board set up to supervise compliance did there have to be?

Johnson & Johnson's CIA
Signed Oct. 31, 2013 (p. 17, 31-32)

It's a complicated process; the final document in this case was 66 single-spaced pages. However, it usually gets done without the kind of brinksmanship that accompanies the larger issues. This time, the negotiations dragged on because Johnson & Johnson—making the argument that it is an unusually decentralized company in which the parent gives its subsidiaries broad management responsibility—wanted everything to apply only to its Janssen unit, not to the iconic parent.

There was also an issue related to how the CIA might affect Gorsky. A controversy had erupted in the drug industry in 2011 when the inspector general tried to use certain clauses in the CIA it negotiated with Forest Laboratories to force the removal of the longtime CEO as a condition of the company not being barred from selling to Medicare or other federal agencies. Because the CEO had presided over the wrongdoing that had been uncovered, the inspector general argued, nothing in the Corporate Integrity Agreement could be relied on if he remained in charge.

In the end, the inspector general relented, but since then, defense lawyers had eyed the CIA and the inspector general with special care.

For that reason, Johnson & Johnson lawyers, according to one of them, thought they should get some kind of promise from the inspector general that they would not use Gorsky's involvement in the Risperdal sales campaigns to try to bar him from running J&J. However, getting such assurances in writing was a non-starter, because they would be publicly disclosed, causing further embarrassment to the boss.

The best they could do was get verbal assurances—"a series of meetings with lots of winks and nods," is how one lawyer described the process—from the inspector general that he had no intention of trying to force Gorsky's departure.

Finally, the deal was done.

A $2.2 BILLION PAYOUT, AND A BUMP IN THE STOCK

Justice Department Announcement
Nov. 4, 2013

On November 4, 2013, Attorney General Eric Holder announced the Justice Department's $2.2 billion settlement with Johnson & Johnson. The company had "recklessly put at risk the health of some of the most vulnerable members of our society—including young children, the elderly and the disabled, " Holder charged.

The text of the civil complaint spelled out all of the allegations about off-label selling to children, including Sheller's discoveries about prolactin, but focused more on illegal promotion to the elderly, which was the sole subject of the criminal charge and misdemeanor plea agreement.

Civil Complaint
Nov. 4, 2013

Criminal Complaint
Nov. 4, 2013

Misdemeanor Plea Agreement
Oct. 31, 2013

The New York Times' Katie Thomas wrote that, "Much of the conduct highlighted in the case, which for Risperdal extends from 1999 through 2005, occurred while Alex Gorsky was vice president for sales and marketing and later president of the company's pharmaceutical unit, Janssen. Mr. Gorsky became chief executive of Johnson & Johnson last year."

She then quoted a J&J spokesman, who "noted that the misdemeanor charge was being entered on behalf of the company and no individuals were charged with wrongdoing. 'Mr. Gorsky has been an outstanding Johnson & Johnson leader for more than 20 years,' he said."

In a separate statement, Johnson & Johnson declared that it "expressly denies" the allegations in the civil complaint—which the company had just settled, and which, unlike the criminal complaint, had detailed the evidence of off-label sales to children.

J&J Press Statement
Nov. 4, 2013

Civil Settlement
Nov. 1, 2013

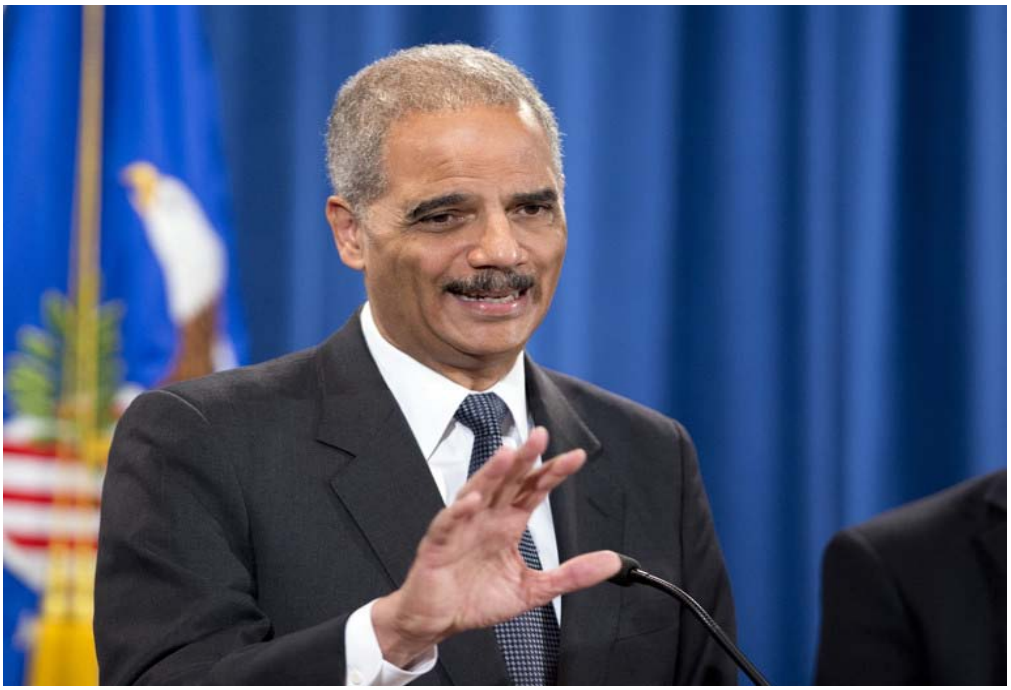
Court Hearing on Plea Agreement
Nov. 7, 2013

The only slight hitch for Johnson & Johnson came three days later when the prosecutors and company lawyers presented their plea agreement to Philadelphia federal district judge Timothy Savage for his formal approval. Company lawyer Joseph Braunreuther was tasked with pleading guilty in open court to the misdemeanor on behalf of the company and then confirming his agreement with the prosecutors about the fines to be paid. He began instead by describing how his client was "responsible for the delivery of valuable therapy that changes people's lives around the world…and remains committed to improving human life going forward."

Savage interrupted. "Does it do that from an altruistic motive or a profit motive," he asked. "It was the profit motive that drove this program, didn't it?"

After Braunreuther conceded the point, the judge vented about how the company had marketed the drug "in a calculated manner" to "elderly patients with dementia and mentally disabled children, which were not approved uses."

Asked whether he thought the outcome of the case was fair, Savage declined comment, except to remind me of the rule governing the type of plea J&J and the prosecutors had negotiated. It stipulates that a judge cannot toughen the penalty on his own, even if he wants to.



Eric Holder said that J&J "recklessly put at risk the health of some of the most vulnerable members of our society." Associated Press

'OUR MORAL COMPASS'

Less than two weeks after the settlement, Barron's published an exclusive interview with Gorsky. In recounting the challenges he confronted as he took over the company—the Tylenol recalls, the suits about allegedly defective hip replacements and the vaginal mesh product and, now, the Risperdal settlement—reporter Leslie Norton wrote, "Many faced with this particular set of challenges might turn to prayer. Gorsky did the corporate equivalent: He dusted off the company's 300-word credo, penned 70 years before by J&J's General Robert Wood Johnson, scion of the company's founders."

"It is our moral compass, and should stay the same," Gorsky told the reporter. As for the $2.2 billion settlement, "These settlements have allowed us to take appropriate accountability to move forward," he said.

The article ended with the CEO recalling what he had learned at Army Ranger school: "No matter what obstacle you face, you are going to find a way to get over it, through it, around it, under it."

On the trading day before the settlement was announced, Johnson & Johnson stock closed at $93.37. A week after the announcement, it closed at $94.29. A year later, as thousands of Risperdal personal injury suits were pending, it would close at $108.62.

Vicki Starr and Stephen Sheller refuse to discuss how much she, or he, earned from the government settlement. But it was more than what she expected back in 2012, when the lawyers on both sides thought they had agreed on a $1.3 billion deal, of which $900 million would be for the false claims in her *qui tam* suit. Now, the false claims related to her suit were about $1.2 billion, and the whistleblowers were entitled to 15 percent. Assuming that she and the four other whistle-blower "relators" who had come forward got equal shares (which they probably didn't because she might have gotten more for being the first, while the last relator might have gotten more for having pivotal information derived from his status as a former Janssen manager), and assuming 33 percent off the top in attorneys fees, Starr ended up with about $24 million, before taxes.

Starr has since moved back to Portland, where she and her husband have just finished remodeling a house they bought in a gated community on the water. Their boat is docked just below the living room. (According to a real estate website, their home was last purchased for $716,000 in February 2014.)

Starr says she has become “an avid food blogger” and an active volunteer pharmacist for a local mental health patients group. Once a year, she has what she calls “a celebratory dinner” with Hector Lopez, the Eli Lilly whistleblower, who set her up with Sheller (and who got his own payout when Lilly settled with the government for similar, though lesser, charges.)

For Sheller, however, the hardest work was just beginning: fighting the hundreds of personal injury cases he had now filed for boys with breasts.

*[1] On August 7 of this year, a federal district court judge in Manhattan, citing that appellate court decision, **ruled** that a drug company could provide truthful promotional materials about its cholesterol drug to doctors interested in using it for patients whose cholesterol levels were below the extremely high level for which the FDA had limited its approved use.*

CHAPTER 12

SHOWDOWN, ALMOST

By Steven Brill

What Happened in the Previous Chapter

THE 1-800 CASES COME TO PHILLY

Aside from Gorsky's deposition, Johnson & Johnson had still not had, or taken, the opportunity to offer its side of the story in any full-length, high profile adversarial hearing.

But in a Philadelphia courtroom in September 2012, that faceoff seemed imminent. Local judges had ordered all of the personal injury cases Sheller had gathered through his own office and through referrals—by now numbering over 200—to consolidate under one set of depositions, such as Gorsky's, and one set of document demands. Then the individual cases were chosen for trial in the order in which they had been filed.

Both sides expected a few or maybe a dozen would be argued to a verdict. By then, each would be able to gauge the cases' value in order to settle the rest. A loss or a lowball verdict in a few early cases would push the settlement in one direction; a few big wins would push the numbers the other way.

First up, on September 24, 2012, was Andrew Bentley of Houston. Then 17, Bentley had been prescribed Risperdal when he was 5 after being diagnosed with Asperger Syndrome . He started growing breasts at age 12.

Sheller was in court, but he was not the lawyer trying the case. By now 73, he had become convinced that he no longer could do jury trials himself, and he wasn't sure that the other lawyers in his firm were as ready for a big-stakes brawl as some outside talent would be.

So Sheller lined up Bob Hilliard of Corpus Christi to try the cases. Among the referral deals Sheller had made was one with Hilliard, a charismatic litigator who had won headline verdicts in cases ranging from defective cars to formaldehyde in the FEMA trailers used to house Hurricane Katrina victims. Lately, Hilliard has been in the news as a lead lawyer in the General Motors faulty ignition switch cases.

Hilliard, in turn, had made a deal to get referrals from the Henry law firm, also in Corpus Christi, which ran those 1-800 ads seeking injury victims. It was the Henry ad recruiting Risperdal male breast victims that Benita Pledger had seen watching TV with her son that night in Alabama.

Austin Pledger's case was among those Hilliard had brought to Sheller by way of the Henry brothers. Bentley was another, earlier Hilliard referral.

Sheller had agreed with Hilliard that Sheller's firm would contribute all of the research and other background work they had been doing for the last eight years, plus the clients they had gathered on their own or through other referrals. Hilliard would bring the clients he had—and he would try all the cases in Philadelphia. The partners would split all expenses and winnings.

RISPERDAL WAS 'A VERY GOOD CHOICE'

Outside the courtroom, on the day the Andrew Bentley trial opened, Sheller complained that the judge should reconsider a decision he had made not to force Gorsky to testify because the J&J lawyers said he had to be in Asia that week. The judge "was setting a terrible precedent because every corporate leader would suddenly find the need to be out of the country when subpoenaed by opposing counsel," Sheller told the Philadelphia Inquirer.

Hilliard Opening
Sept. 24, 2012 (p. 33)

Tone Jones Testimony
Sept. 24, 2012 (p. 118)

Gorsky or not, Hilliard opened the trial with a characteristic flourish, charging that although Risperdal was only approved to treat schizophrenia, Johnson & Johnson had decided that "schizophrenia in the United States did not meet the marketing requirements to make enough money for this drug." His first witness was Tone Jones, a former Oklahoma State quarterback turned Risperdal salesman and sales manager in Texas. Jones described being pressured by the home office to sell Risperdal to pediatricians. He brought along Risperdal popcorn and a picture of Gorsky presiding over a ceremony giving Jones an award for exceeding his Risperdal sales targets.

This photo, submitted as an exhibit in court, shows Tone Jones (center) receiving an award for superior salesmanship from Alex Gorsky (far left) and others.

Laura Smith Opening
Sept. 24, 2012 (p. 52-104)

Johnson & Johnson lawyer Laura Smith—a medical liability specialist, who had defended the company in its Arkansas case—assured the Philadelphia jury in her opening that Risperdal, which she called a "miracle drug," had been knowledgeably used by the pediatrician who had prescribed it to Bentley. She said that if any salesperson had been caught actually trying to sell it to pediatricians, rather than just respond to their questions about the drug, he would have been fired.

Apparently, the Johnson & Johnson lawyers from headquarters watching the opening of the trial didn't think Smith was winning over the jury. After the first week, they settled the case, along with four others scheduled to come next. Bentley was given what Sheller says was a "substantial sum; the client was very satisfied."

Once again, J&J had sidestepped a fight.

Press Release re: Settlement
Aug. 30, 2012

"Our company policy was to promote Risperdal in its FDA indication," a Johnson & Johnson spokeswoman told reporters. In a press release explaining the settlement, the company wrote*, "We take our obligation to ensure the safe and appropriate use of our medication very seriously."

Soon, Johnson & Johnson's lawyers began negotiations to settle other Sheller cases, including five more that had come to Sheller via Hilliard, and another 80 that he had gotten separately. Each case was negotiated, one by one.

By March 2014, all but five cases had been settled for what Sheller says were "very good amounts."

The next case on the list to be evaluated for settlement was Austin Pledger's.

AVOIDING PAYING FOR A JURY'S OUTRAGE

But then the courts threw J&J a lifeline.

Looming over all of these suits in the company's risk analysis was not simply a potential jury verdict for compensatory damages—the money, maybe two or three million dollars, that a boy and his family might get if Risperdal was proved to be the cause of his suffering. There was also the bigger question of punitive damages, the fine that juries can levy against a defendant for wrongdoing. It is supposed to be the jury's way of punishing and deterring particularly bad conduct.

Compensatory damages are based, at least in theory, on some calculations of future medical costs and the value of the victim's pain and suffering. Punitive damages are based on a jury's sense of outrage. A jury whipped up in one of these Risperdal cases by an effective plaintiffs' lawyer might levy millions, even tens of millions, more in punitive damages on top of compensatory damages. And that would bring on still more headlines, which would bring on still more hungry plaintiffs lawyers, with still more clients.

While one group of Johnson & Johnson lawyers were negotiating all of those settlements, another team had drafted a brief arguing that although the cases were being tried in Pennsylvania, a New Jersey statute banning punitive damages in cases of drugs approved by the FDA should apply because Janssen and Johnson & Johnson executives were based in New Jersey.

Punitive Damages Ruling
May 2, 2014

In May 2014, the judge ruled that there could be no punitive damages in the Risperdal cases. Johnson & Johnson immediately abandoned its settlement posture. The company and its teams of lawyers geared up to fight the next case all the way to a verdict.

"As soon as punitives were off the table, Hilliard took his money and went home," Sheller says. (Hilliard did not respond to repeated requests for comment.)

Hilliard then quickly settled a group of 1,200 cases he had collected in Texas for what was an undisclosed amount, but which Sheller says were "very small dollars for each case. … He wanted to wash his hands of the whole thing, and move on to General Motors." If Hilliard got as little as $50,000 for each case, that would still have been quite a haul—$60 million—especially in Texas, where lawyers' contingent fees are allowed to be as high as 40 percent.

Sheller suddenly had to scramble to find a new trial lawyer. By January 2015, he had made a new deal with **Thomas Kline**, another Philadelphia litigator, who, at 66, was nearly 10 years younger than Sheller.

"You know the expression, 'dog with a bone?'" Kline asks. "Steve is kind of a one-bone dog."

> Kline's website highlight reel includes multimillion dollar malpractice verdicts, suits against Penn State in the Jerry Sandusky sex scandal and mass torts brought against the manufacturers of Vioxx and the Dalkon Shield. That kind of work had netted him enough to be able to pledge $50 million to the law school of Drexel University, now named the Thomas R. Kline School of Law. (Sheller has given $1.5 million for a Center for Social Justice center in his and his wife's name at Temple University Law School.)** A smart dresser with wavy white hair, Kline is Sean Connery to Sheller's Detective Columbo. His firm, with about 30 lawyers and a support staff of 100, is three times the size of Sheller's

With Sheller, you get the impression that he goes through life not believing how lucky he is to be making so much money for causes he believes in, or makes himself believe in. Kline may get wrapped up his cases, but he also seems to get a kick out of the business he's in and think he deserves his success because he's so good at it. "You know the expression, 'dog with a bone?'" Kline asks. "Steve is kind of a one-bone dog." He gets all tied up in causes, like Risperdal and prolactin. I tend to take a broader view."

Kline told Sheller he would personally try the cases, as long as his new partner gave him, Kline says, "total control" of the litigation. But Sheller would still have to provide his new recruit with the firepower necessary to overcome what now promised to be Johnson & Johnson's all-out defense.

GATHERING AMMO

After Benita Pledger called that 1-800 number in 2011, she and her husband did not hear much beyond an occasional check in from the office of her lawyers in Texas. “My husband and I thought maybe it was some kind of scam,” she recalls.

Then, in 2013, she was asked to sign more forms. Soon, she got a call from a new lawyer—Christopher Gomez, one of Sheller’s partners.

Gomez explained that his firm was taking on her case in cooperation with the lawyers in Texas and arranged for her to fly to Philadelphia to begin preparing for trial. She would be the actual plaintiff, not Austin, because Austin was a year from his 21st birthday and was judged to be unable to handle his own affairs in any event.

Benita did not meet Kline, the lawyer who would actually argue the case in court and take her testimony, and she wouldn’t until just before the trial started. But she connected with Gomez, who told her about his own autistic child.

The case now appeared set to start in January 2015.

THE EXPERT WITH THE GOLDEN RESUME

Kessler Report
October 2012

As Kline prepared, Sheller gave him an encyclopedic report that he had commissioned in late 2012 that perfectly laid out the case. It was so complete and so compelling that it must have played a role in pushing J&J to settle those earlier cases when it was given to them as part of the pretrial discovery process (and while the threat of punitive damages had loomed). The author was David Kessler, an expert hired by Sheller at $1,000 an hour.

"What I saw surprised even me, and I think I've seen everything," said former FDA commissioner David Kessler. Getty

A Harvard-trained doctor with a law degree from the University of Chicago, Kessler had been a professor of pediatrics, epidemiology and biostatistics at, among other places, Yale, where he had also been dean of the medical school. To top that, he had also been commissioner of the Food and Drug Administration under presidents George H.W. Bush and Bill Clinton.

"I can't defend Johnson & Johnson," says Daneman. "What they did in withholding data was unconscionable."

Sheller had asked Kessler to immerse himself in all the J&J documents and any other evidence the lawyers had accumulated about Risperdal and children. Then he was supposed to draw on his legal and medical training and his background as the nation's top drug regulator to write a report detailing what it all amounted to.

The result was 111 dry but powerful pages laying out the facts in 386 numbered paragraphs.

Kessler is careful to point out that he is not a knee-jerk opponent of the drug industry—that he has been on the boards of two drug companies and that as FDA commissioner he led a drive to streamline the drug approval process, particularly drugs desperately needed at the time to control AIDS. "We approved more drugs during our tenure than at any other time in FDA history," he says.

However, he recalls that as he pored through the material, “what I saw surprised even me, and I think I’ve seen everything.” He was, he says, “deeply troubled by how this company had done off-label marketing involving the most vulnerable of children.”

“These are some of the most powerful drugs imaginable,” Kessler adds. “I do not understand how one of the most respected companies—with its Credo—went so far astray.”

Line by line, Kessler took the reader—ultimately, the lawyers on both sides who would use the report to question Kessler at the upcoming trials—through the business plans and charts targeting the children’s market; the sales call reports documenting the pitches to pediatricians; the rationale behind the law prohibiting off-label sales (which quoted Senator Kefauver’s “the sky would be the limit” argument); the details, based on Priscilla Brandon’s discovery while sifting through all those documents one night in December 2009, of the trick they had played with the numerator and denominator in the data that formed the basis of the Findling article; his discovery of clinical studies showing gynecomastia rates in boys of 5.5 percent that had been mixed with other studies to camouflage the results; the Excerpta Media contract and its promise to produce friendly articles and place them in top academic journals; and the partnership with Harvard’s Dr. Biederman.

A J&J AUTHOR BACKTRACKS

Daneman Deposition
Dec. 14, 2012 (p. 94-95, 110, 121)

In late 2012, Sheller secured a weapon to supplement Kessler’s report. It came in the deposition taken by his partner, Christopher Gomez, of Denis Daneman, a Canadian doctor who had been a co-author of the Findling article. (Risperdal has never been approved for the treatment of children in Canada.)

Gomez walked Daneman through the various drafts of the article and pressed him on whether the denominator should have been lowered, which would have shown a higher percentage of gynecomastia cases. “That’s how I would do the analysis,” he conceded.

Gomez pressed him on why the data showing the relationship between elevated prolactin and gynecomastia had been left out and in fact was contradicted in the article’s abstract. “That’s the complete opposite of what we see in the draft, correct?”

“Correct,” Daneman conceded.

Should the statistically significant relationship between prolactin and gynecomastia after eight weeks of boys taking the drug have been mentioned in the 2003 article?

“Probably,” Danamen said.

At one point in the deposition, Danemen tried to assure Gomez that the Journal of Clinical Psychiatry, where the article was published, has peer reviewers who vet everything for accuracy.

Medical journals make much of their so-called peer review process when touting the their scholarly credibility.

Anna Kwapien, the publications manager at the journal, which is owned by the Memphis-based, for-profit Physicians Postgraduate Press. Inc., told me that the journal "never discloses who its peer reviewers are."

Then how would one know the qualifications of the reviewers, or even that anyone did review an article, I asked, explaining that one such article had since been the subject of a dispute over its handling of data.

"We exist on trust," she said. "Doctors know us." She then referred me to two colleagues for further information. They did not return repeated calls.

Daneman, who is pediatrician-in-chief at Toronto's Hospital for Sick Children, told me that peer reviewers usually only see a draft of the article, not the underlying data.

'USED AND ABUSED'

Daneman also told me he was "surprised" by much of what the lawyers confronted him with at his deposition, including the misleading denominator. His involvement in the Findling article, he says, "was the most difficult thing in my career, and I'm 65 and ready to retire. … They never showed me that table [with the statistically significant relationship between prolactin levels and gynecomastia]. I felt used and abused by the entire process."

Daneman says he donated what he recalls was "only a $1,000 fee" to charity, because "I want nothing to do with this."

"I can't defend Johnson & Johnson," he adds. "There can be no debate about what they did. They crossed the line. What they did in withholding data was unconscionable."

Daneman says that he never saw the final version of the article before it was published. It has, he says, since been quoted 121 times in other medical journals—something that "pains me."

As for the article's lead author and namesake, Robert Findling, a spokeswoman at Johns Hopkins, where Findling is now director of child and adolescent psychiatry, emailed me this statement from him: "At the time of manuscript submission, I was confident in the accuracy of the information provided and in the interpretation of the study results. However, in light of ongoing scrutiny of Risperdal, I became concerned about the questions raised and if there were errors. I am committed to determining what they may be and to correcting them. … [A] review is currently under way. Based on the findings, we will decide whether the paper warrants full retraction, a partial correction or whether the original findings stand."

I sent a follow-up asking if the doctor had read every word of the first draft and the final article that bears his name. I received no reply.

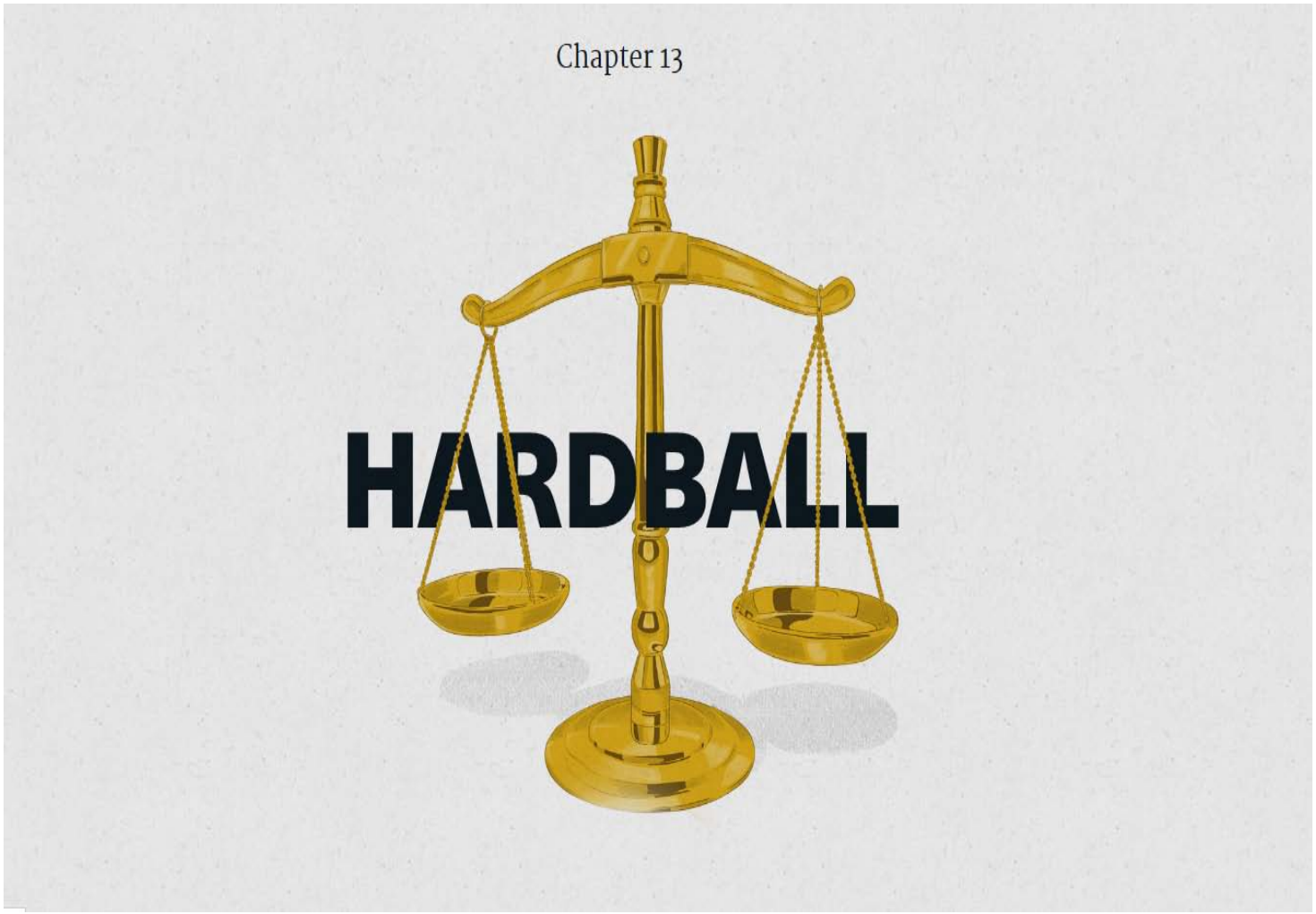
Binder's Description of Findling
(p. 84-85)

During their hunt through documents turned over by Johnson & Johnson, lawyers at Sheller's firm found an email describing Findling to a colleague from Carin Binder, the Janssen executive supervising clinical studies of Risperdal who had complained about the nauseating amount of side effects data in one draft of the Findling article. "He'll do/say whatever you want him to" was Binder's assessment, written in January 2003 (after the final version of the article bearing Findling's name had been put to bed).

How Johnson & Johnson planned to defend the Findling article and its seeming manipulation of the gynecomastia data was the key question Sheller and Kline contemplated as they prepared for Austin Pledger's trial.

**Correction: In the original version, we mistakenly called a press release a letter to investors.*
***Correction: The piece misstated the names of the law schools that Thomas Kline and Stephen Sheller attended.*

Chapter 13



By Steven Brill

What Happened in the Previous Chapter

A ‘HIRED BAZOOKA’

Question: Mrs. Pledger, I think you told our jurors that during the time that you’re taking Mr. Pledger to doctors while he was on Risperdal, none of his doctors ever diagnosed gynecomastia?

Benita Pledger: I never heard of gynecomastia. And, no, they did not.

Question: At some point … you saw a commercial on TV for a Plaintiff’s law firm about Risperdal and lawsuits running? … And it had a phone number 1-800, call if you have taken Risperdal?

Pledger: It had a number.

Question: **A**nd they would file lawsuits?

Pledger: That’s what the commercial was about, yes.

Question: And,Mrs. Pledger, it’s true that the first person to tell you that Risperdal caused your son’s gynecomastia wasn’t a doctor, it was a plaintiff’s law firm?

Pledger: True.

Johnson & Johnson was fighting back.

Cross-Examination of Benita Pledger
Feb. 6, 2015 (p. 33-35, 46-47, 58-59, 60-62, 103)

The Pledger trial had begun in Philadelphia on the afternoon of Friday, January 23, 2015. The plaintiff and her lawyers were now facing off against Diane Sullivan, a partner at Weil, Gotshal & Manges, a 1,100-lawyer Wall Street firm.

At a firm known for tough lawyers, Sullivan has a reputation as one of the toughest. She began her career, after graduating from the University of Pennsylvania Law School in 1987, trying cases at a much smaller New Jersey firm. After a few years, she told me, she was hired by Weil, Gotshal when breast implant liability cases started proliferating because the firm wanted a woman with trial experience who could sit at the defense counsel's table.

By now, Sullivan was widely recognized as a prime weapon for corporations defending high-stakes liability cases. One of her wins for Phillip Morris, in which she beat back a suit by Missouri hospitals seeking smoking-related damages, had earned her a "Litigator of the Week" profile in The American Lawyer. "She isn't a hired gun; she's more like a hired bazooka," the magazine declared. Sullivan had already saved one drug company, AstraZeneca, in a suit involving Risperdal competitor Seroquel.

Few corporate attorneys have Diane Sullivan's reputation for toughness. Getty

With Kline regarded as an equally zealous fighter for his alleged victims, the Pledger case promised to be a great battle.

It was also a mess—nothing like the smooth-flowing courtroom dramas on TV. Both lawyers constantly interrupted with objections, many of which forced a solicitous Philadelphia Court of Common Pleas judge named Rami Djerassi to referee prolonged, often heated debates between them.

During one argument, Sullivan told the judge Kline was "insane."

Almost every morning was delayed by fights over what a witness would or wouldn't be allowed to testify about. Snowstorms and even a courthouse fire drill threw things further out of whack, as did travel snafus delaying out of town witnesses, the need for some jurors to attend to personal business and the obligation of a school teacher-juror to conduct parent-teacher conferences. On some days, when witnesses were not available but their depositions had been taken, the jurors listened as junior lawyers from each side acted out the deposition transcript.

TWO QUESTIONS

The case was not about Johnson & Johnson selling off label. That was what the *qui tam* false claim cases were about. This was a personal injury claim.

The jury was made up of six men and six women, of whom 11 were African American and one was white. They included a security guard, a clerk at Macy's and a nurse's aide. Their job was to answer two questions: 1) Had Johnson & Johnson known and failed to warn Austin Pledger's doctor that Risperdal was dangerous when taken by children like him? 2) Had that failure to warn *caused* Austin's injuries?

If at least 10 of the 12 answered yes to both questions, they would then have to assess how much J&J should pay the Pledgers in damages.

Reduced to those two questions, it all seemed simple enough. But this would be one of those cases in which arcane medical terms and arguments over multiple sets of data and complex government regulations would test the patience and acuity of any lay jury, just as it would test the lawyers' ability to explain it all.

'G-Y-N-E-C-O-M-A-S-T-I-A'

Kline Opening
Jan. 23, 2015 (p. 21-26, 33, 55, 59)

Kline may have been the just-recruited gun-slinger, but it was clear he had channeled Sheller's anger about prolactin and Kessler's version of the 20-year history of the company's regulatory and marketing sins. Now, in his opening statement, he sought to combine that with the Pledgers' personal story and spin it into a narrative the jury could believe in:

"Austin was an autistic boy, now a young man, age 20. There will be no dispute he has … the most loving, wonderful mother. …

“Austin has a deformity. … He has … female breasts. … You’ll be seeing photographs during the case. They are, I think, what we could describe as large, pendulous breasts, not some small, little thing, but a significant, for a male, deformity.

“Janssen made the drug Risperdal. It caused him to develop those female breasts. … The condition…is known as—and you’ll hear this word over and over and over again — gynecomastia, G-Y-N-E-C-O-M-A-S-T-I-A. … It is permanent unless they were to be removed by a significant surgery. … Either way, he has disfigurement. …

“Janssen knew all the time that he was taking the drug … that this drug … had a greater incidence of the condition of gynecomastia than any of the other antipsychotic drugs. … [T]hey say it in their own internal documents. …

“Janssen Pharmaceuticals visited this doctor 21 times and never told him … the drug was known to raise—and I’m going to give you a little bit more than you might want at first, but I have to tell you—peak prolactin levels … that directly correlated to gynecomastia. … They never told Austin’s mom. They never told Austin’s doctor. …

[E]very time you see that picture, you look and you see, what do his breasts look like?. … Is this something that was right?”

Kline then delved into the details, risking turning off the jury with data about the prolactin study and the disputed Findling article. But he spiced it up, teasing the jury with what he previewed as an email from “the MBA lady whose name is Binder [who] said at one point that there’s a nauseating amount of gynecomastia.”

Kline closed with this plea: “When you’re dealing with the most fragile among us … in a drug that isn’t even approved for the indication, and you find a problem, a big problem, do you open the window for everyone to see in or do you try to pull the shades?”

Sullivan wasted no time hitting back.

Sullivan Opening
Jan. 23, 2015 (p. 68-76, 79, 81-84)

“You heard Mr. Kline talk for about an hour or so and he said a lot of bad things about the folks at Johnson & Johnson and Janssen,” she began. “And that’s too bad. And it’s easy for people to kind of throw mud and say a lot of bad things about folks in the interest of winning a lawsuit and—”

Lawyers are rarely allowed to interfere with opening or closing statements. But Kline jumped from his seat. “Objection, your honor, right from the beginning. This is not an outline of evidence. It’s an attack.”

“I will grant some leeway … in an opening argument,” the judge replied. “You may proceed, Ms. Sullivan.”

Proceed she did. After all the settlements, followed by all the bland statements from the PR people, and the vague assurances from Gorsky in his deposition that everything his company did had been "appropriate," the battle was on:

"It's easy to throw a lot of allegations out there, but it's going to be for you to decide what's the truth, what's the evidence. …

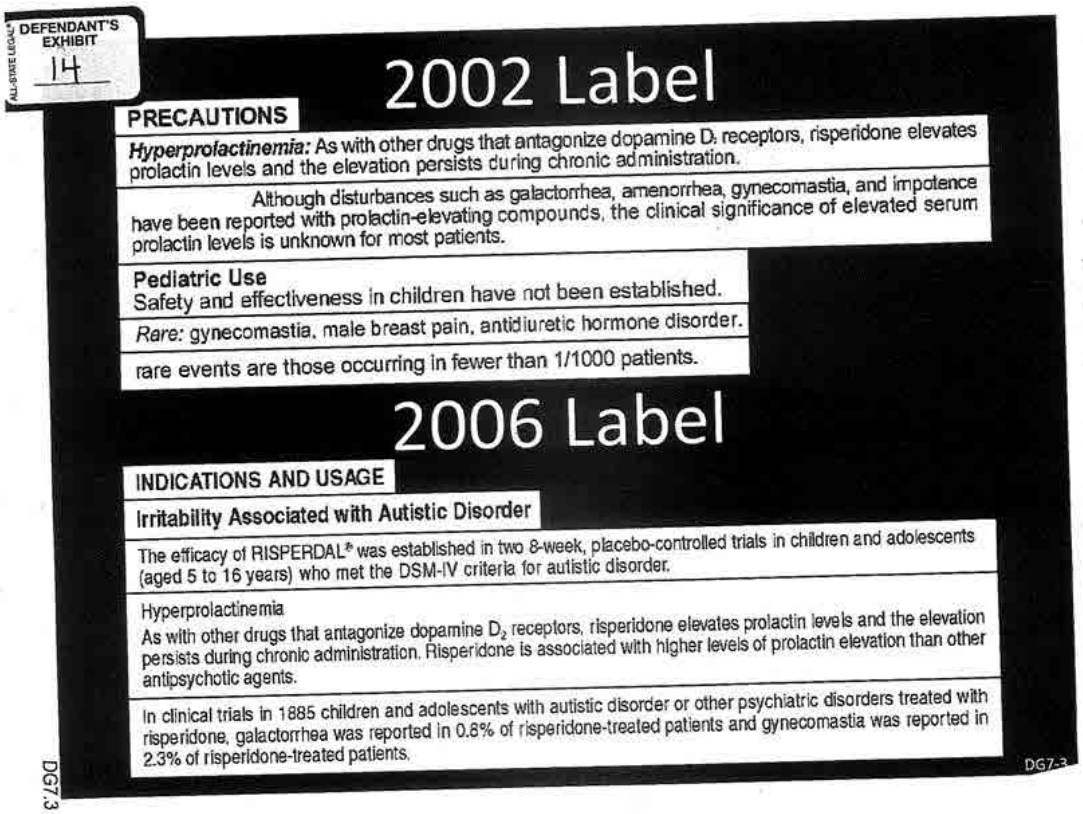
"Mr. Kline spent about an hour talking, and maybe some of you noticed, there's one thing that he didn't talk about … and that's the label that was on the medicine from the very beginning. …

"I think Mr. Kline said the medicine wasn't FDA-approved. It was FDA-approved from the beginning. It wasn't approved for autistic kids until later, and we'll talk about this. But from the beginning, it was approved by the FDA for adults. And on that FDA label from the beginning, in the precautions section—when the FDA approves your label, there's different sections of a label, and the two most important are precautions and warnings. …

"For ten years before Mr. Pledger took the drug, in the precautions section of the label that this doctor had, that's on every bottle of medicine that leaves the factory, that's in every doctor's office … it said—and Janssen and J&J told people—'that risperidone elevates prolactin,' and 'gynecomastia had been reported.' It was there right from the beginning in black and white. …

"Mr. Pledger's doctor testified he knew about both of those risks. He didn't know everything in the world. But he knew about the two risks that we're talking about in this case. Hormone elevation of prolactin and gynecomastia. And so you'll get to see that label as part of this case."

Sheller and Kline recall that they were stunned by Sullivan's argument. Was she really going to rely on the label approved in 1994, which had only said that gynecomastia was "rare," meaning that it occurred in one-tenth of 1 percent of cases or less?



The 2006 version of the Risperdal label (seen in this court exhibit) showed a much higher rate of gynecomastia than earlier versions. But J&J knew the numbers were worse than what the label said well before then.

Sullivan knew from reading Kessler's report in anticipation of the trial that he was on deck to testify that the company had studies as early as 2000—two years before Austin Pledger got his prescription with a label that still said "rare"—that showed 5.5 percent rates of gynecomastia among boys. She knew that the label had been changed in 2006 to admit that the gynecomastia rate was 2.3 percent, not "rare"—just as she knew that Kessler was ready to testify that that 2.3 percent rate was still too low and had been derived by distorting the studies. And she knew that Kessler was prepared to testify that the Findling article had hid damning data about the relationship between elevated prolactin and gynecomastia.

Was that the best she could do?

No, it wasn't, as the rest of her opening demonstrated. The old label wasn't really her defense.

The judge had told both sides that the case should be limited to a failure, if any, to warn about the dangers, if any, of Risperdal when Austin's doctor had prescribed the drug.

"If your defense is the kitchen sink, they're going to be able to bring in a washer and dryer," the judge said.

But now, Sullivan pivoted to a much broader argument: that the risks were worth it and that any warning about side effects, no matter how mild or dire, had to be weighed against Austin's desperate plight.

She was going to use sympathy for the boy to help her case, rather than hurt it.

In his deposition, Gorsky had talked about how Risperdal was his company's response to parents who were "at the end of their rope" in trying to cope with troubled children. Apparently, that was going to be Sullivan's rationale, too:

"[A]utism is a devastating mental illness. … You'll hear that Mr. Pledger … can have shrieking, screaming, head banging, tantrums … that last anywhere … from 45 minutes to two hours and could occur as many as eight times a day.

"You're going to hear that doctors talk about the fact that autism kind of walls these children off in some way from the rest of the world. … And you're going to hear that Austin had a very, very low IQ. So he really—he really got the short straw in life, the fact that he got autism and he also was developmentally disabled. …

"And so his mother … went to this doctor and said, 'Help. Is there a medicine for my son?'

"And Dr. Mathisen had treated other kids like Austin who had autism, and he had some success with Risperdal. It was approved for adults, but it was being prescribed for kids by many doctors….

"It's hard to have parents agree to put their kids in studies that you need to do to get a medicine approved. … And so doctors like Mr. Mathisen, Mr. Pledger's doctor, would prescribe medicines—what they call off-label—for things that they weren't yet approved for….

"Aspirin was originally approved by the FDA as an over-the-counter medicine for headache. But then doctors figured out … that it could reduce heart attacks and strokes. So doctors would tell some patients: Take an aspirin a day. … And that's what was happening with Risperdal. Mr. Pledger's doctor and a lot of doctors were prescribing Risperdal for kids off-label. Why? There was nothing else.

"And what happened when Mr. Pledger started taking Risperdal? Unbelievable. And you're going to see from the medical records … the benefits and the change in this child from Risperdal were dramatic and incredible.

"Risperdal worked for this kid and made his life and his family's life and his colleagues in school, his classmates, his teachers' life better. … And, you know, parents with kids who have problems like this, they have horrible choices."

Kline could not stay in his seat. “Your honor, objection,” he shouted. “This case is about the warnings. We’ve heard 15 minutes about how great the drug was.” Again, the judge overruled him.

Then, Sullivan went a step further, describing what she said were the terrible side effects of the drug Austin had been put on after the doctor decided he was gaining too much weight from Risperdal.

This time, Judge Djerassi sustained Kline’s objection. He told Sullivan to stick to an outline of the case she was going to prove, rather than make arguments about other drugs that were not part of the case.

But Sullivan then threw both the judge and Kline a curveball. In fact, she intended to make *that* her case, she said. She was going to present expert witnesses to opine on a comparison of the risks of various anti-psychotics. Her point would be to prove that no matter what the warning for Risperdal had been or should have been, the doctor had been right to prescribe it.

This was exactly what the judge had gotten both sides to agree in advance *not* to contest, because it had nothing to do with a more basic failure to warn. If they got into arguing all of that, the case would become a free-for-all about the efficacy and safety of an entire drug class.

As Judge Djerassi now told Sullivan from the bench in front of the jury, “If your defense is the kitchen sink, they’re going to be able to bring in a washer and dryer.”

Yet Sullivan pressed on, taking most of the rest of her opening to highlight Austin’s desperate straits, how well Risperdal had worked and how much riskier any alternative drugs would have been. That, in fact, might have been a good defense strategy; one could imagine a jury getting so mired in the science of deciding which among many alternatives was the riskiest drug that it decided it could not definitively rule against Risperdal.

Once Sullivan was finished and the jury excused, Kline vehemently renewed his objection to how Sullivan was trying to change the nature of the case.

Describing himself as “the son of a doctor” who understands these issues, the judge said that if Sullivan insisted in going that route, he was prepared to manage the open-ended trial that would result. “I’m here all summer,” he said.

Then he offered Sullivan an additional warning, having to do with the fact that the trial was supposed to be about what J&J had warned doctors about, not the relative merits of competitive drugs and the conduct of the companies that sold them: “The fact of the matter is that I don’t think that’s going to be beneficial for the defense, because in the end … if it can be shown by this plaintiff that the other drugs had sufficient warnings on these type of issues and you didn’t, that is devastating.”

In case she had not gotten the message, he added this ominous observation about the trouble that this kind of trial might bring for Johnson & Johnson: “That is a multi, multi, big-time …

potential verdict very different from the little case we're having here in this trial. … I know you are an extremely fine attorney and you're very experienced. Everybody knows who you are. So therefore, I'm just letting you know that these are decisions that your team has to make."

"Understood, your honor," Sullivan replied. She had tried to turn the case into something entirely beyond the issues the jury was supposed to decide, and the judge had stopped her in her tracks. For the rest of the trial, there would be no experts called to talk about how much better Risperdal was than the other drugs. Instead, Sullivan would try to convince the jurors that a mother's understandable, if unworthy, hiring of a 1-800 trial lawyer to extract big bucks from her careful, caring client should not be rewarded based on some "cherry-picked" data touted by a hired gun expert witness.

'I'M A NAÏVE PERSON. I THINK PEOPLE ARE GOOD.'

Lawyers on both sides knew from his report what former FDA Commissioner David Kessler's testimony was going to be.

But Benita Pledger didn't.

Austin's mother would spend the nearly five weeks of the trial watching the testimony all day, then retiring to a Holiday Inn. The longest she had ever been away from her son had been six days. However, she did not want to return home on weekends, she later told me, "because it would confuse Austin for me to come and go so much. … We just told him I was visiting my sister."

The lawyers hadn't told her much about her case, except that it looked promising. "They kept telling me how it was going to help all the others, because it was first," she recalls. "But I didn't have any idea of the details."

Kessler Testimony
Jan. 28-30, 2015 (p. 37)

On January 28, she began to grasp the details, or at least the details from her side's perspective. Amid repeated objections from Sullivan that were overruled by the judge, she and the jury now heard David Kessler recite the history of the FDA rebuffing J&J's efforts to get Risperdal approved for children, from before he was prescribed the drug to after he had begun taking it. She heard how the company had procured articles and speeches from academic luminaries to boost Risperdal sales to children. She became increasingly upset as Kessler continued in such painstaking detail that Kline's questioning stretched over almost four days.

Kessler took the jury through his explanation of the evolving drafts of the Findling article, the creation of the new table that eliminated the boys who were 10 and over but kept the original denominator that included all the boys, and the untrue conclusion that elevated prolactin had not

been shown to cause gynecomastia. “My real concern,” Kessler concluded, “is that you run data and then you get a series of results. … And then you have those results. What you don’t do is change rules after you get those results.”

David Kessler (left in the red tie) was FDA commissioner under Bill Clinton. AFP / Getty Images

Kessler proceeded to explain how the rates of gynecomastia had been manipulated, and how the other second-generation antipsychotics—the alternatives to Risperdal—did not have the same prolactin problems.

It was then, Benita Pledger recalls, that she “fell apart.”

“I’m a naïve person. I think people are good,” she says. “But I realized they absolutely knew. … I’ve tried never to cry, even when Austin had his worst fits.”

Sheller’s daughter, Lauren, who is a lawyer at her father’s firm and was sitting next to their sobbing client, took Benita out into the hall to collect herself.

Kessler’s testimony about the manipulation of the numbers was not lost on the jury. “Kline showed it to us pretty clearly with the FDA guy,” a woman who became the jury’s forewoman told me later. “He just repeated it over and over, and there was a chart of some kind that he used. You could see it—the thing with the numerator or denominator or whatever. You could see what they had done.” (The forewoman requested that her name not be published.)

Kline also had Kessler walk through what now seemed difficult to refute: how, all of that other evidence aside, the simple text of the changed 2006 Risperdal label was itself proof that the company had failed to warn adequately before then, when Austin had gotten his prescription—because by 2000 the company knew from clinical studies what it needed to know to include those additional 2006 warnings.

Cross-Examination of Kessler
Jan. 30, 2015 (p. 28, 59-64) , Feb. 2, 2015 (p. 41-47)

The real drama came next: Sullivan's cross-examination of Kessler. The former FDA commissioner's report and, now, his testimony, were at the heart of the plaintiffs' assault on the Johnson & Johnson Credo. How would Diane Sullivan shake him?

First, she moved to strike his testimony altogether. Despite how Kessler might have put the jury to sleep with his slog through an avalanche of numbers and percentages, Sullivan protested that he had only offered his "gut opinion." The judge denied her motion.

Sullivan did get Kessler to concede that lots of studies of children taking Risperdal showed no gynecomastia. But that allowed him to point out that those were studies of patients taking the drug over short terms, when no gynecomastia was likely to develop.

When Sullivan tried to question the importance of the study that had paid "special attention" to prolactin, she got trapped into having him reiterate why Johnson & Johnson should have changed its label and added a warning once it saw that study.

She even grilled Kessler on whether gynecomastia was "serious" enough under FDA rules to require a warning, whereupon the former commissioner was happy to opine why it was.

Throughout, he was unemotional, even clinical. Never raising his voice. Never using a gratuitous adjective.

Sullivan could not shake Kessler's conclusions about how her client had mishandled the data or otherwise dent his aura as an "expert." The transcript of her cross-examination of Kessler is here so you can decide for yourself. But here's an example of how she kept failing to score:

> **Sullivan:** Dr. Kessler, you agree … it's not right to cherry-pick out pieces of information and not tell the whole story?
>
> **Kessler:** When it comes to safety—let's say you have a red leg, your leg is all red and inflamed—and I don't mean to be personal, right—I have to look at that leg, okay. So of course my attention is selected on when there is a positive result.

Sullivan even failed with the standard attack on the other side's experts as unprincipled hired guns: "You just cut and paste your report and stick in the companies, right?" That allowed Kessler to point out that he had only testified for plaintiffs suing drug companies in three of seven prior cases in which he has appeared as an expert. Then, he added, "But to say that I've

testified each and every time the same way, I mean, I've been here for three days, I can assure you, no case has been like this."

"I thought he was by far the best witness," recalls the jury forewoman.

In short, the first days of the trial did not go well for Johnson & Johnson and Sullivan. But she had a surprise in store that could completely upend the case.

THE PENILE ENLARGEMENT GURU

By now, Benita Pledger had mostly given up trying to figure out what all the lawyers' arguments with the judge were about. She only knew that they ate up long stretches of time before the start of each day's proceedings and during the breaks when the jury had been excused.

As usual, on the morning of February 3, just before a doctor who had examined Austin was to testify as an expert for the family, there was a heated discussion among the lawyers and the judge that Benita did not fully grasp. When it ended, one of her lawyers came over and whispered, "How fast can you get Austin on a plane with Phillip [his father] to come up here? We need to have a new doctor examine him."

Argument Over Substitution of Doctor
Feb. 3, 2015 (p. 5, 8, 121)

Diane Sullivan had just sprung an objection on Kline and Judge Djerassi that belonged in the hardball litigators' hall of fame.

More than a year before, Sheller and Kline had retained an endocrinologist, the type of doctor who diagnoses gynecomastia, as an expert witness. Sullivan's team had taken his deposition in April 2014, more than nine months before the trial had started.

But on the eve of his scheduled testimony, the Johnson & Johnson lawyers had informed their opponents that Sullivan was going to move to disqualify the doctor. Her objection had nothing to do with his qualifications. Rather, it was because he lived and was licensed in California, not Alabama.

As the J&J lawyers explained to their stunned opponents, under an obscure Alabama statute—which, it later became clear, Sullivan and her team had known about for nearly a year—the doctor had arguably committed a felony, because examining Austin in Alabama in preparation for his testimony could be considered practicing medicine in Alabama without a state license.

When Kline had told the doctor (described by Kline as “a semi-retired practitioner”) that night that the opposing lawyers might report him for committing a felony, he had refused to testify.

Kline was outraged, but there was little he could do except promise the judge that he would find another doctor who would examine Austin in a matter of days, so as not to delay the trial too much.

However, Sullivan now objected to what she called Kline’s “last minute” pulling of a witness and substitution of a new doctor in his place. She insisted that Kline should now have no expert witness, meaning he would have no way to establish that Austin had gynecomastia, let alone present evidence that Risperdal had caused it.

“The plaintiff sending an expert to Alabama when he was not licensed under applicable Alabama law is not extenuating circumstances,” Sullivan declared. And allowing a last-minute substitute would be “enormously prejudicial.” Sullivan also protested that the new doctor Kline was offering up—the only one he could find so quickly—was a plastic surgeon, not an endocrinologist.

When the judge overruled her objections, she demanded a mistrial, which would mean she would get to start the trial over.

“It’s the first time I ever saw a lawyer try anything like that,” Judge Djerassi told me.

“My word,” Kline replied, using a phrase he would deploy often in the trial to express a mix of outrage and surprise. “We have been at this for years. And they knew about this issue, as the Court knows, a year ago and they are the ones who sat on it in ambush.”

The judge rejected Sullivan’s protests, making no secret of his disapproval of the surprise attack, especially one that had harassed a bystander-witness.

“It’s the first time I ever saw a lawyer try anything like that,” Judge Djerassi told me.

When Sullivan later ridiculed the plastic surgeon’s credentials in her closing argument and pointed out to the jury that the plaintiffs had not been able to find an endocrinologist, Kline immediately objected.

This time, the judge lost his cool: “The conduct by the defense on that entire episode was very, very disturbing,” he told Sullivan. “I found there was … character assassination. I would not permit him to come and testify with you screaming he could go to jail for ten years,” he added, implying that he would explain the situation to the jury during his jury instructions. Which he did: At the beginning of his charge to the jury, he told them that “it was suggested to you again by Ms. Sullivan that the plaintiff could not produce an endocrinologist and suggested that they

could not because they could not. You are instructed to disregard that line of argument in its entirety as it is not accurate and it's disingenuous based on matters of law that occurred outside of your presence."

"In 37 years practicing law I never heard a judge say something like that to a jury about another lawyer's closing argument," Kline says. (Sullivan refused repeated requests to comment about the trial.)

Nonetheless, Austin Pledger had to be examined again, and quickly. "My husband drove to the airport, and they got on a plane that night," Benita recalls. "It was really upsetting. … You know how Austin can't deal with changes in his routine."

What was still more upsetting to her was how Sullivan mocked the plastic surgeon as a "penile enlargement" specialist when he testified after examining Austin.

"She said penis so many times," Benita Pledger recalls. "They were trying to make a joke out of this."

It was true that Dr. Mark Solomon's website bragged of his talents in using a "penile stretching device," and "grafting procedures" that "widen the penis." But Solomon also practiced across the spectrum of plastic surgery needs, including performing reconstructive surgery for free at Philadelphia Shriners Hospitals for Children, and he boasted an array of academic credentials and hospital affiliations.

Once on the witness stand, despite Sullivan's repeated cross-examination of his penile surgery skills, Solomon also proved to be a by-the-books diagnostician of breast tissue.

"She said penis so many times," Benita Pledger recalls, "that it was almost funny. But I didn't think it was funny. They were trying to make a joke of this."

"The lawyer was too harsh with the penile doctor," recalls the forewoman. "She badgered him, insulted him. It was too much. … He was a real doctor."

CHAPTER 14

THE GOOD SOLDIER, THE GOOD MOTHER, THE FADED STAR

By Steven Brill

What Happened in the Previous Chapter

STEPPING OVER TOYS … AND ONTO THE STAND

Even one of the Johnson & Johnson's own employees hurt the cause when he was called as a witness for the other side.

Cross-Examination of Gilbreath
Feb. 3-4, 2015 (p. 13-15, 44, 60-61, 101, 55, 67)

After the fighting over the Alabama doctor and his substitute, Kline questioned as a so-called hostile witness Jason Gilbreath, who had worked for Johnson & Johnson in the South for what he said was "15-plus years." Gilbreath was the salesman who, according to records Kline's side had subpoenaed, had called on Austin Pledger's doctor 21 times over two years and dropped off samples equivalent to more than 16,000 children's doses.

Gilbreath seemed to be the model of the solid citizen R.W. Johnson had had in mind as he built his iconic company and resolved to make it a place where the working man could earn an honorable, secure living. He had gone to work for J&J after getting a degree in avian and poultry science. He and his wife, whom he had married just after high school, still maintained a farm in Alabama, he told Kline and the jury.

Sales rep Jason Gilbreath developed a close working relationship with Austin Pledger's doctor. LinkedIn

Gilbreath began by describing his duties: "to talk about our products to physicians where they are appropriate to use."

After testifying that he had met with three Johnson & Johnson lawyers to prepare for his testimony, Gilbreath ended up using a favorite word of defense attorneys—"appropriate"—13 more times as he soldiered through a barrage of questioning.

Over two days on the witness stand, Gilbreath claimed that he had no way of knowing for sure that Austin's doctor—whose Birmingham office plaque said "Pediatric Neurologist"—treated only children (except perhaps for children who had grown into adults and might have remained in his care).

He didn't "recall" noticing the children's furniture or decorations in the doctor's waiting room.

He didn't know "for sure" that the reduced doses that his company, according to its own internal documents, had packaged for children—and which were the sample packages he gave to Austin's doctor—were meant for children.

Kline asked Gilbreath if he had ever told Austin's doctor, "'Sir, I can't drop you off children's samples. That would be promoting.'"

"No, I could not describe where they can or cannot use their samples," Gilbreath answered. "Once it's in their custody it's their discretion where they use them."

Gilbreath testified that on every occasion he had begun his discussions with Austin's doctor by asking him to confirm that he treated adults, because, he said, "I know that Risperdal was being used in children, but bear in mind, we were under strict guidance not to promote outside the approved FDA label, and that's why I had the discussion that I did."

The only presentations he would give to this doctor or any other, Gilbreath maintained, were about how the drug worked on adult schizophrenia, "because it would be within the scope of the FDA-approved label."

"I felt bad for the guy they put on who had the farm," recalls the jury forewoman. "He was just doing his job, saying what he was told to say. … How could he not know the doctor was a pediatrician if he sees toys and kids' stuff all around his office?"

'IT WAS LIKE THERE WAS SOMETHING I SHOULD BE ASHAMED OF'

Testimony of Benita Pledger
Feb. 6, 2015 (p. 33, 38, 47, 58-59, 65-66)

Benita Pledger took the stand on February 6, not long after Alex Gorsky was given the Joseph Wharton Leadership Award by the Wharton School's New York alumni society.

Kline walked Austin's mother through the story of how, despite his illness, her son—whom she described as "just such a blessing," "a loving person"—is now able to navigate his tablet and guess the clues on "Wheel of Fortune" before she can.

Then he had her describe Austin's self-consciousness about his breasts: "I mean, he can see me with my clothes on. He can see my husband without his shirt on. And he knows. … He just doesn't have the capacity to ask me why."

Before she explained how she and her husband had been so concerned about Austin's medication that she called the company's hotline to find out about the risks, but had not gotten an answer, Kline asked her what she knew about those risks:

Kline:
And did you ever at any time have any discussion or any thought in your head that my boy is developing actual breast tissue?

Pledger:

No. I thought it was the weight gain, and I thought that as long as I kept trying to help him with his weight and exercise, that's all I could do. I would just have to fight the weight as much as possible. I did not know that his breasts were for any other reason than that.

Kline:
Okay. And did you at any time know that there was any increased risk, of any kind, of your son developing what we in this courtroom have been calling gynecomastia?

Pledger:
No. I knew nothing of that. … I did not know boys could develop breasts or [if] it was a side effect from the medicine at all.

Kline:
If you knew that, would you have allowed your son to be on this drug?"

Pledger:
No.

Kline:
Can you tell that to us absolutely and categorically?

Pledger:
Absolutely not. I—I can—I can't fight breast growth. I felt like with the weight gain, we could exercise. … You can't fight something like that. I didn't even know that was a possibility.

Kline then produced photos of Austin. The first was before he started taking Risperdal. Austin looked fit, arguably even lean. The second was a rare photo taken in 2005 of Austin coming out of the pool without a T-shirt. In the second photo, he looked much heavier; records indicated he had gained over 100 pounds. And his breasts were clearly visible. The third was a photo taken a few days before by Dr. Solomon, the new expert witness. Austin's breasts were equally apparent.

"The pictures [of Austin] made an impression on all of us," recalls the forewoman of the jury. "I still remember them."

"The pictures, I think, made an impression on all of us," recalls the forewoman of the jury. "I still remember them."

Benita Pledger Cross-Examination
Feb. 6, 2015 (p. 103, 33-35, 46-47, 58-59, 62)

Diane Sullivan began her cross-examination by getting Benita to agree that her son's autism was a serious disability and that she had turned to Risperdal because "of the challenges you and your family faced."

After a lunch adjournment, Sullivan asked Benita to describe how the drug had helped control Austin's tantrums, which she was glad to do. But she was not as sanguine when Sullivan began reading from vivid school reports that described the tantrums and violent episodes Austin had before going on Risperdal.

Next came reports recording Austin's improvement after starting his prescription. Then, Sullivan picked up another pile of reports describing his tantrums that were written after he had gone off the drug. She read from one after another, often loudly, recalls the jury forewoman.

To Benita, Sullivan's reading of excerpts from the various reports was the kind of "cherry picking" that the Johnson & Johnson lawyer had accused Kessler of doing when he had focused on the negative clinical data. "All his [school reports] were similar," she protested to Sullivan.

“Whether he was or was not on Risperdal. Every year I was always open and honest and I wanted them to know. They told me things and I told them. I never tried to candy-coat it. It’s hard. He had a hard time.”

Sullivan persisted: “And in 2009 [after he had stopped taking Risperdal] he was no longer welcome in school?”

“I never said that he was not a problem at school,” Benita answered.
“I have said the whole time he had problems. Risperdal did help. Abilify [a rival drug] helped. Geodon helped. But from kindergarten until the time they didn’t want him there anymore, he had a hard time. That is what the problem is. … There was no fix. Risperdal didn’t fix it, Abilify doesn’t fix it, and Geodon doesn’t fix it. And as he gets older, it’s better.”

Sullivan then showed the jury recent pictures of a smiling Austin Pledger. She got his mother to agree that he is “generally a happy kid.”

It was then that, with a closing flourish, Sullivan asked Benita the series of questions about how the first person to tell her about her son’s gynecomastia “wasn’t a doctor, it was a plaintiff’s law firm” through its 1-800 commercial.

“Yeah, it’s really a shame that a lawyer had to tell me about my son’s condition instead of the drug company or a doctor,” Benita Pledger later told me. “Like I’m supposed to be embarrassed about that? No doctor ever examined him with his shirt off. They thought he was just fat. So when she said that, it didn’t make me feel bad. ”

What bothered her more about Sullivan’s cross-examination was, she says, the way “Sullivan raised her voice when she read those school reports, and acted like she had caught me. It was like there was something I should be ashamed of. … Austin’s not some kind of juvenile delinquent. He’s an autistic young man.”

“I thought the mother was quite brave to subject herself to all of this,” recalls the jury forewoman. “I felt bad for her.”

In testimony, Benita Pledger described her son as “just such a blessing.” Emily Kassie

J&J’S STAR

Testimony of Ivo Caers
Feb. 10, 2015 (p. 13-14, 53, 71-73, 78-79, 101-102, 111-116)

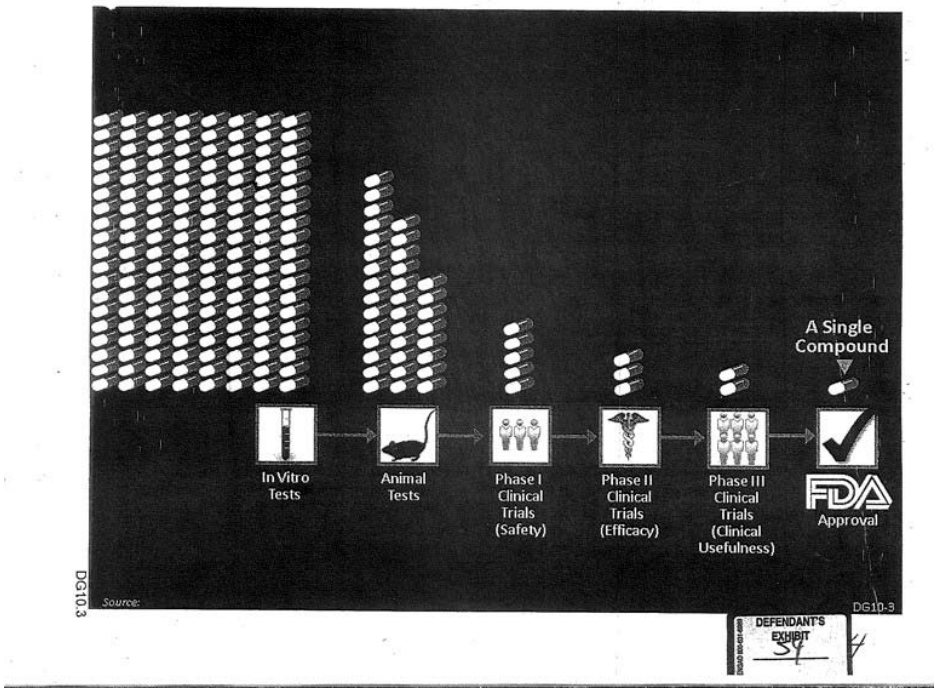
Diane Sullivan’s key witness for the Johnson & Johnson defense—her answer to former FDA Commissioner David Kessler—was Lodewijk Ivo Caers, who told the jury he went by the name Ivo. Caers seemed to be Sullivan’s bet that she could convince the jurors that Johnson & Johnson was a proud, meticulous, ethical company. That the Credo was real.

J&J development executive Ivo Caers testifying at an earlier Risperdal hearing.
Courtroom View Network

As Sullivan walked Caers through his biography, he explained to the jury that he had been doing research and development at Janssen's original home base in Beerse, Belgium, for more than 35 years. As a young scientist he had even worked in a laboratory "on the same floor" as his company's legendary namesake, Paul Janssen, who, he said, had been "the inventor of up to 80, eight-zero, new drugs for different areas of medicine."

Caers had worked his way up, he testified, until he had been put in charge of many of Janssen's clinical studies around the world and their release to regulators and through academic articles. From the beginning of Risperdal's pre-approval clinical studies through its rise to blockbuster status, he had been the man in charge of the drug's development and preparation for the market.

Caers walked the jury through all of the steps involved in getting a drug to patients—from scientists in a lab having a hypothesis about a molecule, to tests on animals, to tests on humans and, finally, to FDA approval following "thousands of pages" of data submissions.



The defense submitted this chart of all the steps a drug must go through to be FDA-approved.

Sullivan then turned to Risperdal specifically. That gave Caers the opportunity to talk about all the studies of side effects in children that his group had reported to the FDA, including data about gynecomastia—and about how, because he had three children and seven grandchildren, he knew how difficult it was to find children to enroll in drug studies.

Then came the crux of Sullivan's defense.

Sullivan:
And, Dr. Caers, in the adult label from 1993 [the label in use when Austin Pledger took the drug], is there a section that tells doctors about safety for children?

Caers:
The only reference to children in the label of '93 is a statement that the efficacy and safety of Risperdal in

children has not been established.

Sullivan:
Okay. And that was in the adult label from the beginning?

Caers:
That is correct. Well, it's in the Risperdal label, full stop.

Sullivan then got Caers to say that he had submitted data to the FDA about the raised prolactin levels in patients taking Risperdal.

In other words, the FDA had been told everything and even required Johnson & Johnson to say that efficacy and safety in children had not been "established." So, how could Johnson & Johnson be at fault? Any doctor reading the label knew, because J&J told them, that there was a risk in giving Risperdal to kids.

Sullivan now moved to have Caers sweep away all of those Kessler allegations. He rattled off the 18 different studies, one by one, that his company had done examining the safety of Risperdal when given to children. Most had been placebo-controlled, meaning half of the participants had been given a sugar pill instead of medication and the results had then been compared. All of those studies, which were designed with the help of "outside expert" doctors, had been reported to the FDA, Caers said, and then reported in medical journals.

Caers and Sullivan devoted particular attention to a report that combined all of these studies and involved 1,885 children taking the medication. It had yielded the finding—included in the 2006 label—that gynecomastia had resulted in 2.3 percent of the cases. Sullivan asked about "some criticism" from Kessler of how the pooling of the studies diluted the reality of a much higher percentage of gynecomastia cases in one of the studies, the so-called INT-41. Caers said, with no explanation, that the pooling had been the FDA's idea.

Sullivan then took aim at the INT-41 study.

INT-41, Caers explained, was not a placebo-controlled study, meaning everyone was given the drug. In testing efficacy, giving placebos to one group of the subjects is thought to be important because many patients will feel better or even exhibit improvement if they believe they have taken medication. But in studies meant to test a drug for side effects, placebos have far less import. Besides, INT-41 was designed as a long-term study, and as Caers himself had pointed out, it is difficult ethically and practically to ask children to take no medicine when medicine could help them, let alone ask them to do so for a long time.

This was the largest study by far. And it was one of only two out of the 18 that had studied the long-term use of Risperdal, which was crucial. As in the case of Austin Pledger, gynecomastia was only thought to develop after long-term use. Equally important, INT-41 was the only study designed to pay “special attention” to gynecomastia—which, if one believes Benita Pledger’s testimony, can go unnoticed if not looked for.

None of that was lost on Kline who was growing antsy, he recalls, to start his cross-examination.

Sullivan did not ask Caers to respond to Kessler’s assertion that it would have been legal, and indeed was required, for Janssen to have added a warning about gynecomastia in 2000 once it saw the 5.5 percent incidence rate in that INT-41 study. Kessler had testified that the company should have done that and also sent a warning notice to doctors, rather than wait until a new label was approved in 2006, long after the study had been completed.

However, Sullivan did try to refute Kessler by implication by having Caers testify that the FDA had rejected Janssen’s request to put children’s (lower) dosing suggestions on the earlier label. Apparently, she believed jurors would not appreciate the difference, as Kessler had claimed, between warning about a danger to children and adding language to the label explaining how to administer the drug off-label to them.

Finally, Sullivan turned to the Findling article and the addition of the table excluding boys 10 and over after the initial draft was written. Over a long series of questions and answers, Caers brushed off the issue as a simple matter of the company's outside expert advisors deciding that the new table made for better science.

As for why the table showing the statistically significant relationship between raised prolactin levels after eight weeks of treatment and incidences of gynecomastia had not been included, Caers dismissed that, too. It had just been one of many analyses that routinely get reviewed and discarded as scientific articles are prepared, he said.

And here, verbatim, is how the doctor explained why the original denominator including all the children had survived, despite the elimination of all of those boys aged 10 and over:

"Well, the whole analysis is done on the total population, and it is not because you exclude a couple of adverse events due to puberty, rather than prolactin, that you can remove those subjects from the denominator. That's clear."

The jury forewoman did not agree. "I never got the Johnson & Johnson scientist's explanation of the numerator-denominator percentage thing," she recalls. "I didn't know what he meant."

'WOW!'

Cross-Examination of Ivo Caers
Feb. 11, 2015 (p. 15, 28-29, 64-65)

Kline dove into his cross-examination of Caers by taking him through each of those 18 studies he had cited, and that had produced the 2.3 percent gynecomastia rate that was on the label since 2006. He had Caers recite the duration of each study, demonstrating that most, unlike INT-41, were short-term. He wrote Caers' answers on a whiteboard for the whole courtroom to see. He then got Caers to concede that all but one of the gynecomastia cases had turned up among the children in the smaller subset of long-term studies. That meant that a truly relevant sample—children taking the drug long-term—would have yielded a much higher percentage of cases than the 2.3 percent listed on the current label, let alone the "rare" description on the label when Austin Pledger was given the drug.

Kline then asked Caers about the decision J&J made in preparing the Findling article to eliminate children 10 and over from their conclusions about their data. He noted that none of the studies Caers had just been talking about, and that Caers had been in charge of designing had "used a cut-off age at ten, correct?"

"Correct," Caers acknowledged.

It went downhill from there. Kline confronted Caers with emails reporting on the meetings of the outside expert doctors and asked him to identify where any of them stated that the outsiders, not Janssen people, had suggested the elimination of the ten and over children. He could not find it.

Finally came the issue of the table that showed a statistically significant relationship between elevated prolactin and gynecomastia after eight weeks of treatment, but that had not been included or mentioned in the Findling article or anywhere else.

When asked about it by Sullivan, Caers had repeatedly referred to the table and its data as a routine "exploratory analysis"—something that may be looked at in the lead-up to a more formal study but that could eventually be excluded as not relevant.

> **"You're not supposed to ask a question if you don't think you know the answer," Kline says. "And we didn't know."**

Kline told Caers he had never heard a Johnson & Johnson witness use the term "exploratory analysis" before, and pointed out that in 12 hours of depositions Caers had never used it.

That seemed to suggest a question that Kline and the other lawyers on his team had debated on and off for weeks over whether he should ask: Had Caers failed to submit that analysis to the FDA?

"You're not supposed to ask a question if you don't think you know the answer," Kline says. "And we didn't know."

Under federal law, it is a crime for a drug company not to submit "a description and analysis of each controlled clinical study pertinent to a proposed use of the drug." Similarly, it is a crime to fail to submit "a description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from clinical investigations."

"I had a feeling about it," recalls Kline. "And as I heard him talk about it, I just decided to go ahead."


Re-Direct, Re-Cross of Ivo Caers
Feb. 11, 2015 (p. 112, 114-116)

Actually, Kline is giving himself too much credit. It was Sullivan who cleared the way for Kline to ask the question, at no risk—because she asked it first, indirectly, during her late-afternoon re-direct examination of Caers *after* Kline's initial cross-examination was over.

Sullivan: Dr. Caers, can you tell our jury why Table 21 wasn't given to the FDA?

Caers: Well, because obviously, this is not an analysis that was intended for the FDA because this is an explorative analysis.

Caers then said that the FDA could have found the relevant data that comprised the table among the thousands of pages of data the company had given the agency to review. Of course, the reviewers would have had to have found it, organized it and decided to make their own table

from it, which is why the law requires that tables analyzing data that are prepared by the drug company must be submitted.

"[T]he FDA had all those data available in the submission and even in the database and could do similar analysis," he said.

It was only after Sullivan had that exchange that Kline shot up from his chair for a brief re-cross examination:

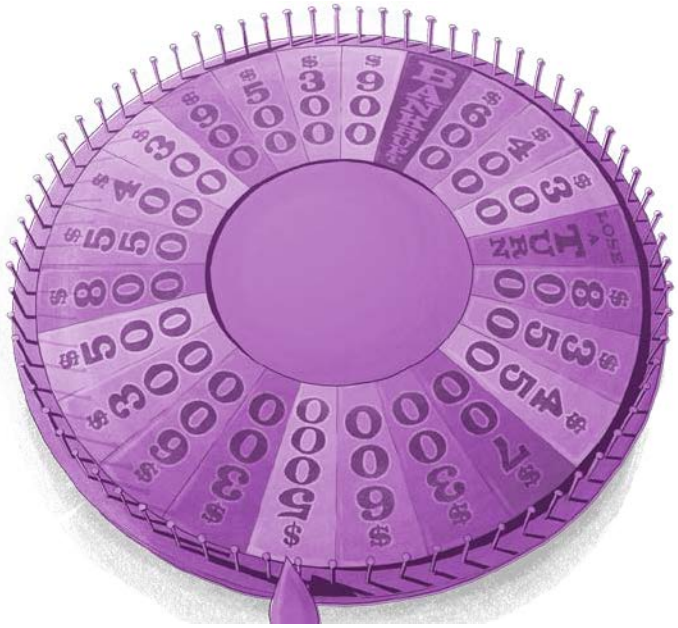
- **Kline:** Sir, table 21 was not given to the FDA?
- **Caers:** That's correct.
- **Kline:** Wow!
- **Sullivan:** Your honor, I object to the interpretation.

According to an experienced lawyer who was in the courtroom but was not allied with either side, "That moment seemed like a big surprise to the jury—that after all he had said about all the studies Janssen had turned over to the FDA, that he had never turned that one over. … There was a pregnant pause after that."

The jury forewoman agrees. "I thought that was really important, when he said he had thrown out that study. … What this was really about, was that you can't keep testing over and over again and then use the results you like and throw out the rest."

When witnesses finish testifying, the lawyers' closing arguments in a complicated case like this are especially important. Can they skillfully spin everything that the jurors have heard into a coherent story? Can they deploy the right metaphors or images to get the jurors to remember the points that help them the most? Can their tone get the jurors to trust them?

CHAPTER 15



THE VERDICT

… AND 'MOVING ON'

By Steven Brill

What Happened in the Previous Chapter

‘VERY FULL, PENDULOUS WOMEN’S BREASTS’

Kline Closing Argument
Feb. 19, 2015 (p. 28-29, 35, 51-52, 55, 57)

The following are excerpts from Tom Kline’s closing argument for the plaintiff:

- Ivo Caers confirmed for us Table 21 was never reported to the FDA. … We know now what’s behind the tables: The little girls with the lactating breasts … and the little boys even under ten who have gynecomastia. My word.
- And when Dr. Kessler told us, ‘Red flag. This isn’t cherry picking.’ When a pharmaceutical company acting reasonably and prudently has this kind of data, they investigate it, they report it, they tell the FDA. They tell the doctors. They tell the world. They don’t just go on selling, selling, selling, selling the drug. … Oh, and giving it away in doctor after doctor’s offices.
- Janssen [said] to the FDA: ‘A review of the safety information did not show a correlation between prolactin levels and adverse events that are potentially attributable to prolactin.…’
- The opposite of Table 21.
- And by the end you see what happened. He had full breasts … very full, pendulous women’s breasts, and today, after losing some weight, has the rock in the sock. Size 46 double D breasts. … Tell me anybody in your life that has size 46 double D women’s breasts, any boy that you know who has size 46 double D women’s breasts that he got from puberty. …
- Now look at him. Behind that beautiful smile … is the remnants of this horrible drug. All they had to do was tell the truth, the full truth, and nothing but the truth. Like when you put your hand on the Bible.
- My word, he had breast buds, they developed into women’s breasts.
- So please, please remember that in this case it’s really important for Austin, and through his mother, Benita. And I have just been the person who has had the good grace to be the one to argue to you.

‘DON’T BE SWAYED BY THE CROWD; STAND ON PRINCIPLE’

Sullivan Closing Argument
Feb. 19, 2015 (p. 61, 63-65, 67-68, 77, 107, 116-117, 134-135)

The following are excerpts from Diane Sullivan’s closing argument for the defendant:

- Thanks for sticking with us. It’s been a long couple of weeks, and you folks have come in here in the snow, in the rain, in the ice and even during the Polar Vortex, and we are grateful for your service. I am humbled by your service. You have come in here and served with grace and dignity, and great patience, even when the lawyers were all acting like children. …
- You learned that it took ten years from the time that Risperdal was discovered in the lab to do all of the testing in the lab, and animal testing, and to satisfy all the FDA requirements to test it in people. … And you heard the doctors and scientists from Janssen who talked about the fact that they know … they have a big responsibility to patients. They know that patients depend on them to get it right, to do the hard work and to do the science. …
- And you might have remembered when Dr. Caers, the scientist and doctor from Belgium, was on the stand and Mr. Kline was cross-examining him, and he said to Dr. Caers, ‘Dr. Caers, you ran the show … at Janssen in terms of drug development.’ And Dr. Caers said, ‘No, no, no, sir, it’s not a show. Discovering and developing medicines, it’s not a show. It’s hard work, and we take that very, very, very seriously.’ …
- But I submit to you that some of what you saw in this courtroom was show. …
- What did your common sense tell you when you heard that this lawsuit wasn’t started because a doctor told Mrs. Pledger that Risperdal caused a problem in her son? That this lawsuit wasn’t started because Mrs. Pledger or her son had any complaints to any doctors at all, but that this lawsuit started because Mrs. Pledger saw a plaintiffs’ lawyer’s TV commercial—1-800…
- And what did your common sense tell you when you heard that the only expert who could support their case that Risperdal caused Plaintiff’s enlarged breasts wasn’t an endocrinologist at all. I mean, we are in spitting distance of four major hospital systems. … They couldn’t find an endocrinologist not only in Philadelphia, they couldn’t find an endocrinologist who specializes in hormones anywhere in the country, anywhere in the world to support their case.
- The only expert they brought to say that Risperdal caused Plaintiff’s gynecomastia was a cosmetic plastic surgeon … who, as you heard, on his website is better known for turning Philadelphia into the penile enlargement capital of the world. …
- Now, Mr. Kline stood here and he told you we are going to talk about the facts and the evidence. I have been doing this a long time, not as long as Mr. Kline, and I have never seen a closing argument where the lawyer doesn’t show the jury a single piece of evidence. He stood here and he talked to you and he gave his version of the evidence, but he didn’t show you any. …

- What Dr. Mathisen saw, and what was on the label … was that—heads up—safety and effectiveness have not been established in children. …
- And then Mrs. Pledger claims—and, you know, you can't blame a mom, a mom would say, 'Yeah, if I had known something I wouldn't have subjected my kid to a risk.' But you have to test that against the evidence. She claims had she known about any risk of gynecomastia … she wouldn't have allowed her son to be on this drug. Well, Dr. Mathisen didn't tell her, but the truth is, she has got her son on another drug now that has far worse risks. …
- So while Mrs. Pledger says she wouldn't have let him take Risperdal had she known about the risk of gynecomastia, I am not sure that it adds up. …
- And so the science just doesn't support what they are arguing here, and that's probably why they couldn't find a single endocrinologist anywhere in the country to come in and support their case. They had to have a $20,000-a-day cosmetic surgeon, who admitted he doesn't know anything about hormones, doesn't do any research in hormones, and testified, yeah, like pornography, I know it when I see it. …
- I am going to briefly talk about this accusation and this Findling paper, this 8 to 12 week analysis. And I submit to you, it's the height of cherry picking. …
- You have had a hard job, but have common sense, and you folks have struggled to pay attention. We are all boring. And we appreciate it. …
- [S]ometimes it's easy to say let's give him a little money, or let's give him money and get out of here. But if you don't believe the plaintiffs have proved their case, stand your ground.
- Do justice. Put them to proof.
- Don't be swayed by the crowd. Stand on principle.
- And use your common sense. If Risperdal really caused Mr. Pledger's gynecomastia, why is the first [person] to tell them that a lawyer, not a doctor? And if Risperdal really caused plaintiff's gynecomastia, why do they get www-dot-whatever as their only expert?
- On behalf of the folks at Janssen, we appreciate your service, and I wish you the best in deliberations.

After the lawyers had finished on Thursday, February 19, Judge Djerassi gave the jurors that Friday and the weekend off.

We thought that Kline did a really good job communicating with us," says the jury forewoman. "Sullivan tried to, but she was too harsh at times. She badgered people, and kept going around and around when she questioned someone and got an answer she didn't like."

INSIDE THE JURY ROOM

The jurors spent Monday, February 23, going over the evidence, "trying to focus on the facts, not what we thought," recalls the forewoman. No vote was taken.

Tuesday morning, they took up more reviews of the evidence. By now, according to the jury forewoman, it seemed clear that most jurors thought the plaintiff should win. They voted in the middle of the day, she says, and it was 11-1 that Johnson & Johnson had failed to warn the Pledgers, and the same 11-1 that the failure to warn had caused Austin's gynecomastia. The juror

in the minority argued that the doctor was at fault for prescribing an off-label drug, the forewoman recalls.

That afternoon, they debated how much Johnson & Johnson should pay Austin's family. Some wanted to award as much as $5 million; others favored a far lower sum, even below a half million dollars. Soon, they focused on what they thought would be Austin's 50-year life expectancy and began to calculate what he should be paid per year. Dividing a hypothetical total into 50 parts seemed to make everyone more comfortable with a relatively high award.

By Wednesday morning, some of the jurors urged the others to consider that the lawyers, as the forewoman puts it, "were likely to get about a third of the money, and we needed to take that into consideration. … We spent a lot of time trying to calculate that."

Just before lunchtime, they arrived at a figure: $2.5 million, which worked out to about $33,000 a year after the expected 33 percent in lawyers' fees. The jurors sent word that they had reached a decision.

Pledger Trial Verdict
Feb. 24, 2015

The two sides quickly assembled in court in front of Judge Djerassi to hear the forewoman read the verdict.

"It was more money than I could comprehend," says Benita Pledger.

J&J Appeal
March 6, 2015

Sullivan began preparing her appeal, based on multiple decisions the judge had made, including having allowed Kline to bring in the plastic surgeon after the endocrinologist had been scared away on the eve of his testimony. Kline, also appealed, chiefly on the grounds that the decision by an earlier judge that punitive damages could not be granted was wrong.

If those appeals are not cut short by a settlement of the case—probably as part of a deal involving all of Sheller's and Kline's pending cases, which now number 413—Benita and Phillip Pledger are unlikely to see any money for years.

In June, I spent two hours with them at their kitchen table, while Austin surfed on his tablet. I have been writing about trials for more than 35 years. If the Pledgers were faking it when they seemed unexcited about the money they stood to get, they fooled me. Austin's mother seemed more eager to talk about the fact that now that her son is older, "his breasts are drooping down to his stomach, like an old lady's, so they aren't as visible under his shirt."

In July, the Pledgers did get one dividend from the trial. For Austin's 21st birthday Tom Kline bought him and his mother tickets to Los Angeles and arranged for them to visit the set of "Wheel of Fortune."

Tom Kline bought Austin and Benita Pledger tickets to Los Angeles to visit the set of "Wheel of Fortune." Benita Pledger

MOVING ON

Following the verdict, the two sides immediately began preparing for the next of the Sheller/Kline cases. Diane Sullivan was replaced by a lawyer from another New York firm.

When that trial began in March, the same witnesses said mostly the same things, although it was difficult to tell why Johnson & Johnson put Caers on the stand again; he seemed to fare even worse on cross-examination this time around. Also, the judge in this case allowed Kline to introduce more evidence of Johnson & Johnson's business plans to market to children. A sales manager was brought in, much to his discomfort, to take Kline through all the documents discussing those plans and describe meetings, including some that he said involved Gorsky, where the off-label targeting of children was mapped out.

However, the plaintiffs' lawyers were worried about the case, for two reasons.

First, they had no pictures, like the one of Austin Pledger, proving that the plaintiff had not had breasts before taking Risperdal and had grown them while on the drug. All they had was the boy as he now looked, years later. That made causation hard to prove. He could have grown the breasts after he stopped taking the drug, or before he had ever taken it.

Second, there was the boy himself, and his family. They were from Pennsylvania, and like the Pledgers, they were a working-class family. But unlike the Pledgers they were not the types who appealed to a jury. "The boy had killed cats," is how Sheller summed up the problem.

When this jury came back with its verdict slip, on March 20, its vote was 10-2 that Johnson & Johnson had, indeed, failed to warn.

However, on the second question, the jury ruled 10-2 that Kline had not proved causation.

Reuters called it a "partial victory" for Johnson & Johnson.

Still, it seemed that the company viewed the glass as half empty. On the eve of a third trial, scheduled for May, the company settled with Kline for what Sheller says "was a very generous amount."

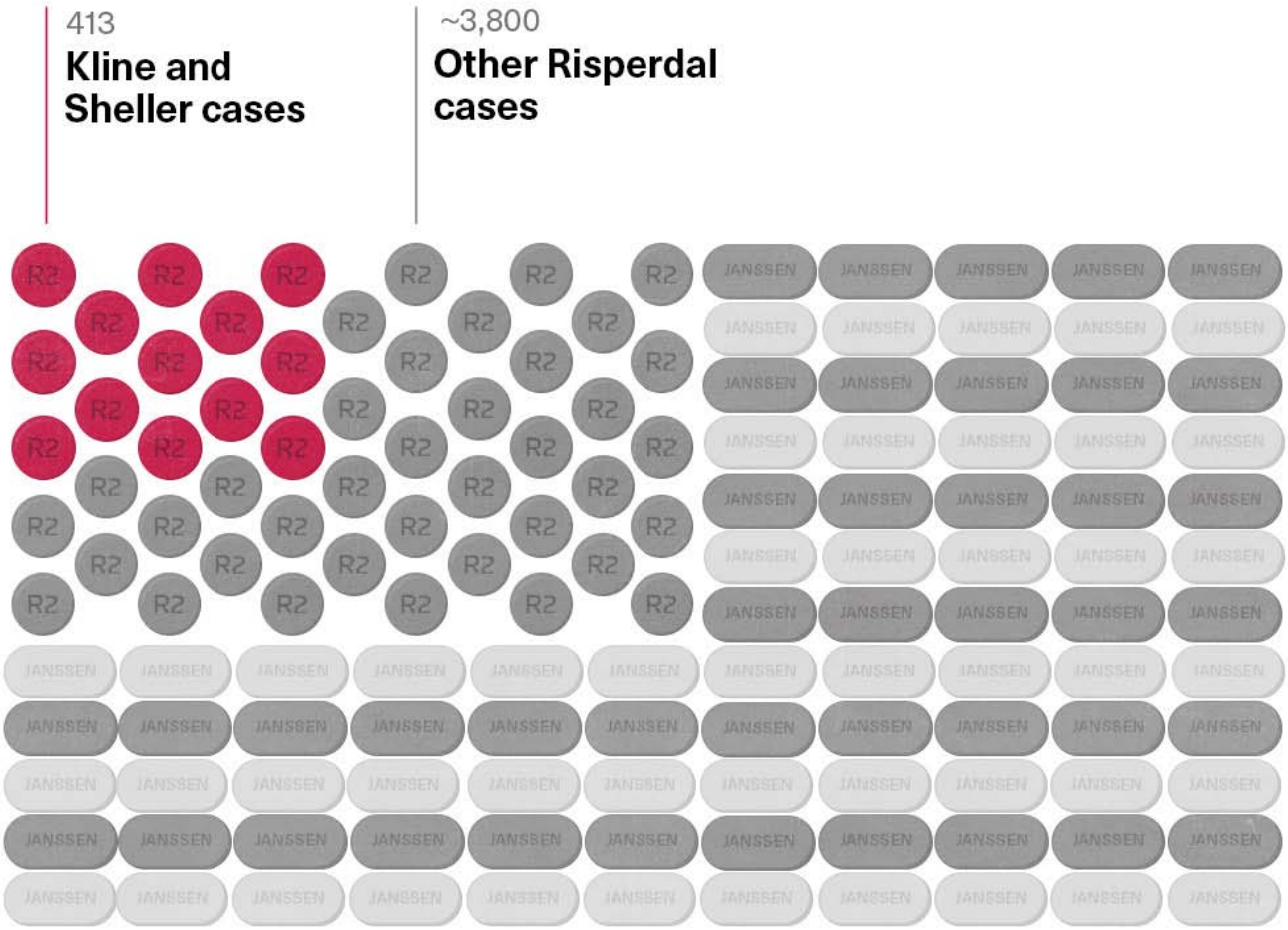
Kline is now in talks to settle all 413 of his and Sheller's cases. If settlement discussions fail, the next case is scheduled for trial in October.

J&J SEC Filing
July 31, 2015 (p. 20)

The company's latest SEC filing says there are 4,200 Risperdal claims on dockets across the country. Ernie Knewitz, Johnson & Johnson's vice president for global media relations, says that his company "hopes we can settle all of the cases."

"As with the government settlement," he adds, "which we only pled to a few months of off-label selling by some folks to the elderly, we have to put this baggage behind us. There comes a time when you just have to move on. I know Alex [Gorsky] believes that."

There Are 4,200 Risperdal Cases Left
(And Kline and Sheller Clients Only Represent a Handful)



MOVING UP

At Johnson & Johnson, everyone seems to have moved on. And up.

Starting, of course, with Gorsky. The man who is now Johnson & Johnson's chairman and chief executive got a 48 percent raise, to $25 million, in 2014—the year after the government settlement was completed for $2.2 billion, the components of which included the largest criminal fine and civil damages payment ever stemming from the illegal marketing of one drug.

Gahan Pandina, who was the executive who orchestrated the agreement with Biederman and led the Risperdal roll-out in North America, is now the senior director and venture leader at Janssen R&D.

Ramy Mahmoud, who put together a children and adolescents business plan in 2001, earned a series of promotions at the company before leaving to become president and chief operating officer of a healthcare startup. Its website notes that "Ramy participated in the development, launch and/or commercialization of dozens of pharmaceutical and medical device products spanning multiple therapeutic categories, including blockbusters such as RISPERDAL®."

Carin Binder, the Janssen executive whom Kline called the "MBA lady" and who wrote the email about the "nauseating amount" of side effects data, became the medical affairs director of Johnson & Johnson before retiring last year.

And Ivo Caers, as we know from his testimony, now runs most of Janssen's clinical development and studies around the world.

Johnson & Johnson has never come forward with any information that any of its employees was disciplined or fired for illegally promoting Risperdal.

As for the bottom line, Risperdal sales from 1994 through 2008 (when it went off-patent) have totaled approximately $30 billion, including approximately $20 billion in the U.S.

Expenses in the U.S., including all manufacturing and sales and promotion costs, probably amounted to $2 billion based on the business plans and budgets I have seen. That would yield a profit of $18 billion.

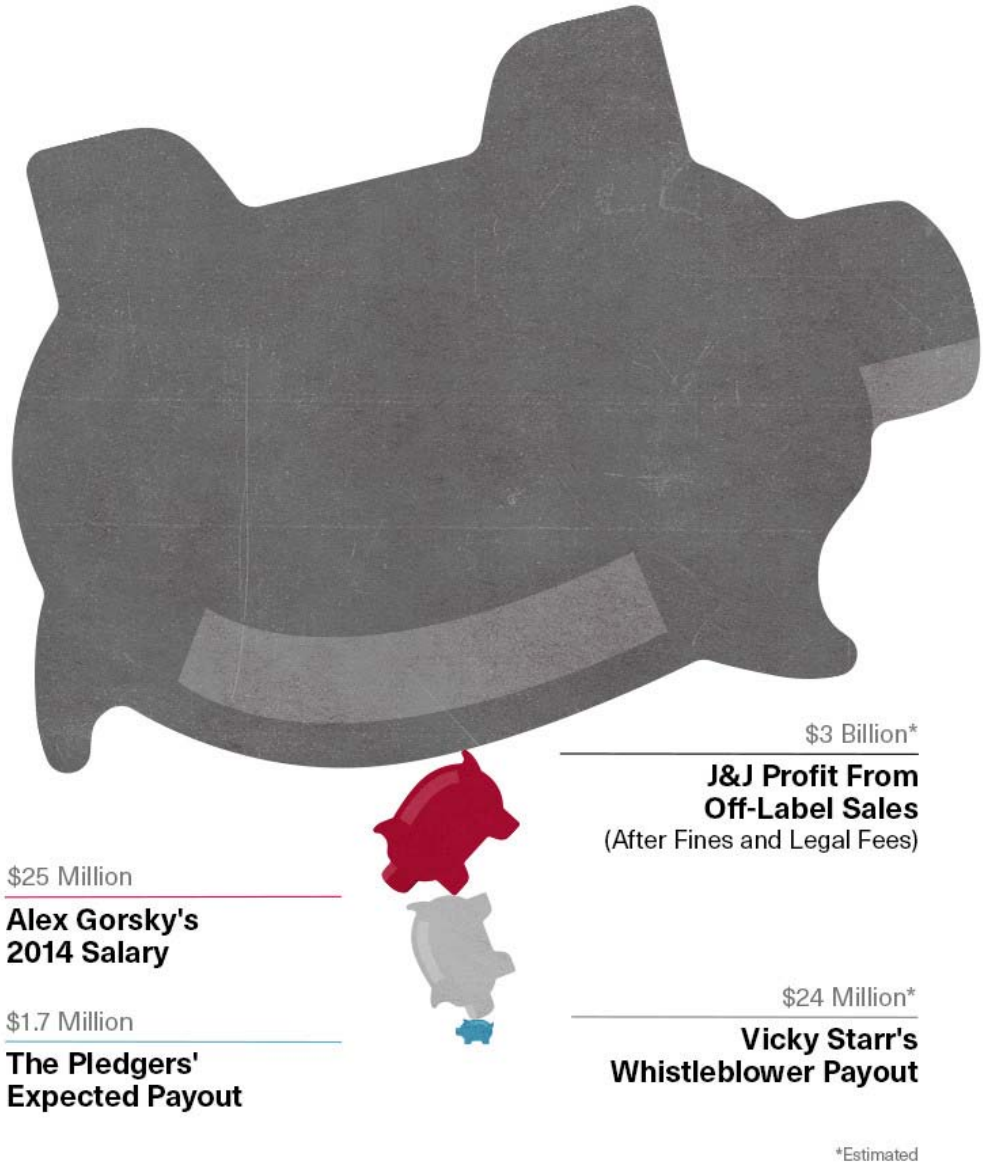
Assume half of those profits, or $9 billion, were derived from off-label sales to children and the elderly. Suppose that even $3 billion ends up being spent on all of the remaining litigation (which is my highest-end estimate). With about $3 billion already paid out in verdicts, settlements and legal fees, that would mean J&J will have spent $6 billion to clean up after all of the alleged illegal conduct. The company will still have cleared $3 billion from its off-label sales—*despite* getting caught.

In other words, the worst possible outcome for J&J—getting caught red-handed and being buried in lawsuits that end up with terrible verdicts or settlements—will still have been highly profitable. (J&J may also have had as much as $300 to $400 million in Risperdal research and development costs, but that money was spent before the first pill was sold and would have been more than recouped from permitted, on-label sales.)

All in all, in terms of the company's fortunes and the career trajectories of the people responsible for its conduct, it is hard to argue that the system produced much of a deterrent when it comes to illegally promoting its powerful products. It is equally hard not to wonder, considering the totality of the Johnson & Johnson Risperdal story, how much we can count on the integrity of a dominant industry whose most admired company admitted so little, promoted so many of those responsible and continues to thrive so mightily.

The whistleblowers did well, too. Then again, Alex Gorsky's $25 million 2014 paycheck was about the same as Vicki Starr's likely reward for 10 years of trying to blow the whistle on him and his colleagues.

The Final Tallies



Certainly the trial lawyers have cashed in. Sheller has gotten a piece—maybe 5 percent, after all the referrals and costs are factored in—of some $5 billion in drug company suits and settlements from four major drug companies. And that doesn't count the Risperdal personal injury settlements about to come.

Which is appalling until one realizes that if he hadn't encouraged, maybe even ambulance-chased, the whistleblowers, and if he and his fellow plaintiffs lawyers—including what Diane Sullivan might call the "1-800 crowd"—hadn't trudged through millions of documents, the companies' misconduct would have gone unchecked and their victims uncompensated.

The government didn't do that work.

Not a single *qui tam* case could have happened—none of those elite assistant U.S. attorneys would have had anything to add to their resumes—without the private plaintiffs lawyers gathering all of the initial evidence.

The FDA could have pulled the same data Johnson & Johnson regularly bought, and seen that Risperdal prescriptions were being written disproportionately by doctors who specialized in treating children and the elderly. But if someone there did, no one acted on it until the whistleblowers came forward.

Johnson & Johnson's conduct—and that of at least eight other of the 10 largest drug companies that have been caught and are forced to operate under Corporate Integrity Agreements—may have been cured, for now, when it comes to off-label selling. But investigations continue into new avenues of possible misconduct, such as whether the companies, including Johnson & Johnson, are illegally inflating what they say are their average wholesale prices so that they can make more money off of Medicare. (Scan J&J's latest SEC filing for a précis of these latest brushes with the law).

Beyond that, there's the larger question of whether the honor system works to ensure that companies with Johnson & Johnson's Risperdal record, run by the same people who created that record, tell the FDA everything, good and bad, about all of their clinical studies. Every day we read another headline about billion-dollar M&A deals involving drug companies boasting potential new blockbusters whose tests so far look great. Can we know that for sure?

Every time Sheller thinks of the current Risperdal label, with its still-declared rate of 2.3 percent for gynecomastia, he thinks he knows the answer. He is now litigating an FDA "citizens petition" he filed on his own behalf, demanding that the agency withdraw its approval of Risperdal (and its now-prevalent generics) for sale to children. He at least wants the FDA to issue a black box warning about gynecomastia and change the label to reflect a percentage of risk that is higher than what he argues is the fictitious 2.3 percent now on the label. After sitting on it for more than two years, the FDA denied Sheller's petition, defending its decision about the label and denying that the drug poses the dangers Sheller claims. A federal judge then upheld the FDA's decision, ruling that Sheller had no standing to bring the petition. Sheller is appealing.

Meantime, Johnson & Johnson spokespeople point to the FDA's rebuff of Sheller's charge that the agency unduly acquiesced to J&J as vindication.

There's no money in this petition battle for Sheller. "I'm just so angry about it," he says. "It makes me crazy."

If anything, the way the courts seem likely to handle these issues in the near future could make him crazier. The recent push from the bench, emanating from the Supreme Court, to expand the First Amendment rights of corporations could upend the core principle that a regulatory agency like the FDA can stop drug companies from spending whatever it takes to put their spin on what their products can be used for. That would not only allow promotion for off-label uses; it could ultimately threaten strict government control of the label itself. The country's most deep-pocketed industry, which markets the world's most important but potentially most dangerous products, would have finally been given the "sky's the limit" freedom Senator Kefauver feared in the wake of the Thalidomide tragedy more than 50 years ago.

Some may read the saga of Johnson & Johnson and Risperdal as a story of a company getting off easy—with fines, verdicts and settlements not coming close to erasing the profit from the company's illegal conduct, and with no one held personally responsible. But despite the company's guilty plea, nobody in the boardroom and executive suites at Johnson & Johnson seems to think Gorsky or anyone else did anything wrong when they deployed those ghostwritten "scholarly" articles, those "Bridge to Dementia" brochures or those Risperdal Legos to encourage doctors to use this powerful antipsychotic to treat restless nursing home patients or children with behavior disorders. Whatever the small print on a label said or didn't say about who should get the drug or about strokes, breasts or other side effects should not have been used to punish their passion for getting their drug to as many patients as possible.

Unless Risperdal becomes a cautionary tale, judges seem on their way to ratifying the view from the Johnson & Johnson boardroom.