8

Device Makers, Drugmakers, and the FDA

> My children, some in high school and college by then, often sided with the critics [of the pharmaceutical industry]. They listened to my logic, but I could tell they weren't convinced, and to tell you the truth, I wasn't either.
>
> —Dr. Hank McKinnell, CEO, Pfizer[1]

In the past, Dr. Charles Rosen had looked forward to attending the North American Spine Society's annual meeting. A spine surgeon for 17 years and the founding director of the spine center at the University of California at Irvine, Rosen had attended NASS's first meeting. But in September of 2005, the 50-year-old couldn't help but feel apprehensive as he boarded the red-eye to Philadelphia. Over the past year Rosen had found himself at the center of what was becoming an increasingly bitter controversy over an artificial spinal disc manufactured by Johnson & Johnson. He had an uneasy feeling that some of his colleagues might be lying in wait for him.[2]

A device about the diameter of a quarter and made of two high-density plastic pieces sandwiched between two metal plates, the spinal disc, called "Charité," had been approved by the FDA 11 months earlier and now was being hailed by its promoters as a revolutionary alternative to fusion surgery

for severe back pain. Fusion stops the painful motion of a severely degenerated disc and associated arthritic joints by "fusing" the adjoining vertebrae so that they grow together—sometimes with the help of metal rods and screws. By contrast, the artificial disc is designed to replace the old disc. After removing it, a surgeon slips the plastic disc in between the vertebrae as if sliding a coin into a slot.

The advantage of Charité, according to J&J, is that rather than immobilizing the spine, the artificial disc lets the body move naturally. Because fusion limits the spine's range of motion, it can transfer extra stress to discs above and below the fusion site, causing them to degenerate. Charité, by contrast, allows continued motion, offering hope—though as yet no proof—that adjacent discs might be less likely to deteriorate.

But Rosen was not at all sure that the artificial disc would prove safe over the long term. Charité had been used in Europe for nearly 17 years, and after reviewing mixed data from the Continent, he was concerned that thousands of patients could wind up prisoners of their own bodies—in chronic pain, with no solution.[3] "I don't know how anyone, in good conscience, could put these things in knowing the past history and the potential for so many failures," said Rosen. "It's just money over everything else, and it's just cruel."[4]

Still, Rosen realized, he could be wrong. That was one reason why he was attending the NASS conference: he hoped to learn more.

As Rosen checked into Philadelphia's Crowne Plaza hotel and gave his name to the clerk, his premonition that Charité was going to haunt him for the next few days was realized. "Are you the Dr. Rosen who asked the FDA to recall all of those *terrible* disc replacements," asked the man standing beside him at the desk, his voice heavy with sarcasm.

"That's me," Rosen acknowledged.

The man handed him a card, identifying himself as "Mark Mintzer, Patient Advocate."

Rosen had heard of Mintzer from one of his own patients, a man who came to him after a failed disc operation left him in excruciating pain—just one of several disc implant patients who had gone to Rosen for help. Mintzer, who also had a spinal disc implant, had been far luckier. His operation had been an enormous success, and now the 48-year-old former computer consultant had become a familiar name in chat rooms for back pain sufferers, where he referred potential patients to spinal surgeons.[5]

Later in the day, as Rosen wandered through the convention center,

things only got stranger. Outside all the meeting halls, signs announced that anyone attempting to record or film the presentations would be escorted out by security guards. Rosen couldn't remember ever having seen such a sign at past conferences. The next day, at a presentation about the artificial spinal discs, the moderator reminded the audience of the warning, and indicated that at least one person already had been removed from the conference.

It was not necessary for anyone to record anything, he explained, because a CD of all the presentations would be mailed out later. "What's the difference between recording the presentations now or getting a CD from NASS later?" Rosen asked himself. He couldn't help but wonder if the conference's organizers planned to edit the proceedings, eliminating any embarrassing questions that might be asked by the audience.

The next day, he went to hear a presentation on complications following Charité disc replacements. Afterward, Rosen asked the presenter what years the disc replacements were done, and he replied, "2000 to 2002." Rosen had barely finished thanking him, when suddenly, the moderator interrupted him: "Why do you want to know? What are you getting at?" he demanded.

Rosen wanted to think that he was just being paranoid—until the last day of the conference, when he went to hear another paper about disc replacements. As he entered the large room, he noticed huge projection screens on either side of the stage. But it didn't occur to him that he was about to see his own name blown up on one of them.

At first, it seemed like a normal panel discussion. Toward the end of the session one of the last speakers began to talk about evidence-based medicine, comparing disc replacements to fusions, and acknowledging that there was disagreement among spinal surgeons as to how well the implants worked. "He was bringing up pertinent questions—I was surprised," Rosen recalls. "This is why I had come to the conference." But then, suddenly, the tone of the presentation changed.

"The speaker warned us that we had better get used to evidence-based medicine, because it's here to stay," Rosen remembers. "And he suggested that if physicians didn't deal with it, other people would bring it up. Then, suddenly, he put a slide up on the two projector screens."

Rosen expected a diagram of the spinal disc. Instead, he was stunned to see page A1 of *The Wall Street Journal,* June 7, 2005. One story was circled:

J&J's New Device
For Spine Surgery
Raises Questions
Artificial Disk Aims to Help
Body's Natural Movement;
Some See Risk if It Slips
'Big Money Riding on This'

Rosen recognized the headline. And he could visualize the paragraph later in the piece where he was quoted saying that the FDA's approval of the disc "puts the American people potentially at great risk for receiving operations that could fail at a high rate and result in untreatable pain and disability."[6]

Rosen remembers what happened next: "The speaker pointed to the screen and said: *'Our dirty laundry should not be aired in public.'* It was clear that he was very angry," says Rosen. "Then he told us, *'If you do that'*—and he pointed to the *Journal* story—*'this will happen'*—and a second slide popped up on the screens."

The new slide displayed a page from a class action lawyer's website. Rosen didn't recognize the attorney's name, but he did recognize his own name. There it was, in the very first paragraph. Again he was quoted saying that he couldn't imagine using the spinal disc that Johnson & Johnson was promoting. At the bottom of the attorney's webpage was the pitch to clients: "If you or a loved one suffered complications after artificial disc surgery for back pain or Degenerative Disc Disease, you have legal rights. Fill out our contact form for a free case evaluation."

Rosen groaned. Given the size of the screen, it was hard to miss his name. Although he didn't know the lawyer, he recognized the source of the quote: a story that appeared on TheStreet.com. Melissa Davis, a well-respected reporter who covered the health care industry for the online financial news site, had interviewed him about Charité, and he'd told her what he thought. "Now someone is trying to associate my name with this ambulance chaser," Rosen later told a friend, "implying that I am a shill for a plaintiff's firm, and that my criticism of the disc can be written off as unethical and financially motivated."

"Where There Is Big Money, There Are No Disinterested People"

The Wall Street Journal story made it clear that the debate over the disc had become acrimonious, and that some of Charité's most vocal fans—not to mention some of its critics—had a financial stake in the outcome.

Charité's detractors pointed to patients like 52-year-old Susan Whittaker, who woke up one morning a month after a disc replacement with a badly swollen leg. Tests showed that her Charité had slipped out of its niche between the bones of her spine and become intertwined with blood vessels. During a nine-hour surgery to remove the disc, she lost pints of blood. "I'm lucky to be alive—I almost died twice on the table," said Whittaker.[7]

Ten months later, Dr. Joseph Riina, the Indianapolis surgeon who performed Whittaker's disc replacement and emergency surgery, still didn't know why her disc had slipped out of place. "We've sent films to surgeons all over the country," said Riina, who has taught other doctors how to use the device. "No one has been able to give a reason for what happened. . . . It's like hip replacement; the first ones didn't always work."[8]

Critics worry not just about slippage but about wear and tear. They point out that that no one knows how soon an artificial disc might wear out, and everyone agrees that replacing a worn disc can be extremely tricky. In June of 2005, eight months after the FDA approved the device, Dr. John Peloza, a spine surgeon in Dallas, told *The Wall Street Journal* that J&J's device would be "a nightmare to fix."

Earlier in the year, at a packed meeting of spinal surgeons in Canada, the same Dr. Peloza had attacked Dr. Fred Geisler, a Chicago surgeon who served as a consultant to Johnson & Johnson, accusing Geisler of hyping J&J's device.

Now Geisler saw his chance to reply: "Peloza is aligned with Medtronic [a competing device maker] so he thinks the Medtronic disc is better," Geisler told the *Journal*. "There is big money riding on this. Where there is big money, there are no disinterested people."[9]

But in fact, there were some disinterested parties in the spinal disc controversy—and Rosen was one of them. He had never had any financial ties to any device maker or drug company. He didn't hire himself out as a consultant; he didn't invest in their stocks.

"I'm whistle-clean—the people who want to discredit me hate that," he said a week after the NASS conference. "In the past, company reps have begun to suggest that I might consult for their company, but I always nip the conversation in the bud. Why? Because it leaves me free and clear to decide what's best for my patients. I don't want to be beholden to any company. As a surgeon, I make a fair living. I don't need to compromise my objectivity in dealing with patients. If you consult, all of a sudden you get wrapped up in that whole guilt game.

Guilt game? "You try some device, and it seems to work," he explains. "That's great. But if you begin using it—and you have a reputable name—the rep comes to you and suggests that you become a 'consultant.' Of course, you're compensated somehow . . . I just can't imagine not feeling obligated if they were paying me some huge amount of money. They're not paying you because they like you, you know—they expect you to use their product and keep using it.

"The majority of doctors aren't willing to be bought," he adds. "I counted one day—there are only about two dozen surgeons who have been really pushing the disc replacements. Many of them *do* have a financial interest—and the company has been pushing hard to offer incentives. One surgeon at the conference told me, in confidence, that a J&J rep in her town offered her $1,000 for every disc that she implanted. He told her that they would list it as some type of fee for consulting. She refused—she's not going to use the disc. But she was scared. Like me, she was also very discouraged. We both found the whole meeting to be about industry and profit, not doctors and data."

Johnson & Johnson denied the allegation that one of its reps offered a surgeon a bounty.[10] But stories of kickbacks to spine surgeons are not limited to J&J. In 2001 a lawsuit brought by Scott A. Wiese, a former sales representative for J&J rival Medtronic, accused the company of trying to persuade surgeons to use its products with offers of first-class plane tickets to Hawaii and nights at the finest hotels. Some of those lucrative consulting contracts, the suit claimed, involved little or no work. Medtronic denied the accusations in the lawsuit, which it settled in 2002 for an undisclosed amount.

In interviews with *The New York Times,* two other former Medtronic employees confirmed the outlines of Wiese's story, revealing that Medtronic's sales representatives routinely offered enticements to surgeons to use the company's hardware, including visits to a strip club in Memphis. The former employees said they had spent as much as $1,000 per doctor for a night on

the town, and a document provided by one of them listed about 80 surgeons who had consulting agreements with Medtronic that paid as much as $400,000 a year.

"It's a business deal," confided one of the employees, who declined to be named because he still works in the medical device industry. "It takes money to make money."[11]

NASS—A Secret Society?

By the time Rosen got back to the University of California at Irvine (UCI), he wasn't just discouraged—he was angry. The controversy was turning ugly, and personal. He had heard that his name was coming up in NASS subcommittee meetings: "Who is this guy?" one doctor asked. "What's his game?" Someone on the subcommittee was assigned to call one of Rosen's colleagues at UCI to check him out.

On the Web, someone spread a rumor that Rosen was "in cahoots" with Jim Cramer, the former hedge-fund manager turned TV host, suggesting that Cramer was shorting J&J and paying Rosen to talk down the device. Rosen had never spoken to Cramer and doesn't even watch the show.

At UCI, Rosen received full support from his colleagues. No one was troubled by the fact that he spoke his mind. Many agreed with him. Everyone believed that he had a right to his opinion: without open debate, medical science could not advance.

With that in mind, Rosen sat down to write a letter to the speaker at the NASS conference who had displayed the slides of the *Wall Street Journal* story and the plaintiff's attorney's website: "You mentioned at NASS that our 'dirty laundry shouldn't be aired in public,' " Rosen wrote. "I was unaware that NASS is a secret society . . . Certainly you cannot suggest that I not provide my honest and fact-driven opinion when someone asks me in an interview. [You are welcome to] debate my opinions with hard facts and data," Rosen added. "However, I find it inappropriate that you endeavored to publicly humiliate me based upon the use of public information."

Behind the Scenes: The FDA Panel Meets

Looking back on his experience at the conference, Rosen still isn't certain how he became the villain in this story. "The irony is that I got embroiled in this only because I wanted to *use* the disc," he explains. "I'm not a social crusader. It's just that I had been following the development of the artificial disc for 10 or 15 years, and I thought it might be suitable for some of my patients."

But before experimenting on patients, Rosen wanted to do what he calls "due diligence": "In my position, I want to make sure I know everything about a new device before I try it." So, in January of 2005, he sat down to read the 300-page transcript of the 2004 meeting where the FDA's Orthopaedic and Rehabilitation Devices Panel considered the application for Charité's premarket approval.

Rosen read the minutes of the meeting twice—and was disturbed by what he found. First, the clinical trial of 275 patients lasted only two years. Second, in the trial Charité had been compared to an outdated fusion procedure that was still in use when the trial was designed but not by the time Charité was approved. But what was most startling was that the results for the first 71 patients in the trial were not counted when deciding whether or not to approve the device. Although this first group represented roughly 25 percent of the patients in the trial, their outcomes were reported separately on the grounds that these early subjects were "training patients."[12]

The physicians were "just getting their feet wet," with those first 71 patients, Michael Courtney, project manager of the FDA's orthopedic branch, would later tell Rosen, explaining that surgeons implanting the device faced a steep learning curve.

"Just getting their feet wet?" asks Rosen. "How do you tell the child of a man who is now disabled that the doctor operating on his father was 'just getting his feet wet'? The arrogance of that . . ."[13]

Meanwhile, at the FDA panel meeting, J&J's representatives acknowledged that the rate of "adverse events" was higher among the training patients. For example, one patient had lost 1,800 cc of blood during the operation—"and that's a lot of blood." Rosen notes. "Put it this way: 1,000 cc is a liter—we're talking almost two liters of blood. What I would like to know is, which vein was cut and how? What was the problem with the ap-

proach? That's what I need to know so that I don't have the same problem if I decide to implant one of these discs."

The benefits of the disc also seemed ambiguous. Even among the later patients, 13 percent experienced "no change or an increase in pain" while 12 percent reported only "some pain relief" after the operation—which is to say that when it came to reducing pain, the implant proved, at best, marginally more successful than the fusion procedure it was supposed to replace. And since the long-term success of the operation remained unknown, it was, by definition, riskier.

Nevertheless, the FDA approved Charité—in large part because the agency had set a very low bar for approval. J&J was not required to show that Charité was superior to the outdated fusion procedure, only that it was "not inferior"—a standard that insures that the marketplace will be crowded with me-too devices which may not be better, but are almost always more expensive than the products they replace.[14]

Reading through the transcript, Rosen also discovered that approval was not, as advertised in most press reports, "unanimous." Two of the eight voting members on the panel had initially moved to postpone approval: they believed that a two-year trial did not provide adequate information on the sensitive device.

At the hearing, Charité's defenders countered that a two-year trial was sufficient because the disc had been used in Europe for nearly two decades. But when Rosen investigated further, he found that the disc's track record abroad was sketchy, at best. A 2003 article in the *European Spine Journal* summed up the state of the research: "Despite the fact that these devices have been implanted for almost 15 years . . . there are currently insufficient data to assess the performance of total disc replacement adequately. . . . Total disc replacement seems to be associated with a high rate of reoperations, and the potential problems that may occur with longer follow-up have not been addressed. Therefore, total disc replacements should be considered experimental procedures and should only be used in strict clinical trials."[15]

The high rate of reoperations posed the greatest problem. Charité was designed for younger patients: the ideal candidate, everyone agreed, would be in his midforties—which meant that at some point, the device might well wear out and have to be replaced. But no one knew how long it might last—10 years? 15 years? 20 years?

During the hearing, Dr. Paul McAfee, a consultant with J&J with a finan-

cial interest in the product, was candid: "I hope they will last 40 years. I tell my patients to look at the LeMaire data [from France], which goes back 11 years—which is pretty good" he added. But "honestly, to talk to the patients, 10 years is a pretty good outcome."

Rosen was shocked. Ten years would be pretty good? As other speakers acknowledged, if a surgeon was forced to go back in to try to replace the disc, he faced what one of the panel's experts described as a "potentially life-threatening operation."

"The problem is scar tissue," Rosen explains. "When you first implant a spinal disc you have to enter through the abdomen and navigate around the iliac veins and arteries, the major vessels that move blood throughout the body, in order to get access to the spinal column. The approach is done from the front of the body because the disc is in front of the spine. But after the initial operation, it's much harder to go back in. Scar tissue sets in, and it's very difficult to move the major veins and arteries to gain access to the spine. They can rip open—you can't imagine how quickly the whole wound fills up with a liter or two of blood.

"In a virgin operation, you can find the tear and fix it," he adds. "A second time, it's hidden by the scarring. By the time you find it, the person could be dead. We're talking about a couple of minutes here."

After hours of discussion, debate, and questions, one member of the committee finally took a stand: Dr. John Kirkpatrick, associate professor of orthopedic surgery at the University of Alabama, moved that the panel recommend against approving the device without more data. Before making his motion, Kirkpatrick pointedly reminded the panel of "a recent editorial in the NASS *Journal* discussing the fact that there are a number of spine surgeons who will do things on patients that they would never consider for themselves. This reminds me of what the FDA's purpose is," Fitzgerald added: "First, to protect the public."

Dr. Maureen Finnegan of the University of Texas Southwestern Medical Center, seconded the motion. Earlier in the all-day discussion, Finnegan had made it clear that she did not think there was enough data to approve a device that was going to have to last for years.[16] Responding to Finnegan's comment, five of the voting members of the panel concurred.[17]

But now Sally Maher, an attorney representing the device industry, jumped into the discussion. Noting that she was not a voting member of the panel, Maher declared that, nonetheless, "I have to take exception, Dr. Kirk-

patrick, to what you're saying. I have some deep concerns that if you tell a company they can't launch something for five years after they have started developing it, you're going to put a stop to new product innovation in the medical device or the orthopedic world. And I'm wondering why you feel that that's more appropriate than having a postmarket study, where you can follow the device and look at what's happening after it comes to market."

Immediately, two voting members of the panel weighed in, agreeing with Maher. One cited the 17 years of clinical evidence from Europe—skipping past the fact that this data was less than encouraging. Another complimented J&J on having "gone out of its way to document every complication that has occurred," apparently unperturbed by the number of complications.

Now Dr. Finnegan was on the defensive: "I'm not sure that some of the panel members understand that just because we say [that we're not recommending approval] that doesn't mean this is going into the closet. 'Not approval' means that, at the present time, the panel is not comfortable with all of the data. . . . It just means that certain things have to be done before the FDA makes a decision . . ."

But clearly, other members of the panel were swayed by the argument that delay might dampen J&J's "spirit of innovation." Earlier, Dr. Choll Kim of the University of California, San Diego had agreed with Dr. Finnegan: "This is a complex device," said Kim. "It's the first of its kind and designed to last for a long time, and we can't get at that question [of how long it will last] until we wait."

Now, however, Kim seemed to have changed his mind: "I think by requiring much longer follow-up, [we] will deter companies from being able to produce these innovative materials—the burden will be too onerous," Kim declared.

And so, when it came down to a vote on Kirkpatrick's motion to delay approval, six panel members backed off. Once again citing extensive European experience with Charité, the panel voted 6 to 2 against postponing approval.

Ultimately, the group compromised, and voted unanimously to recommend approval—with the understanding that after bringing the device to market, J&J would have to meet a list of conditions which included five-year follow-ups on outcomes for patients in the clinical study, and mandatory training for surgeons who wanted to implant the device. Dr. Fernando Diaz, a professor of neurosurgery at Wayne State University, emphasized the need for intensive training: "Of all the things we do in spine surgery, this is going

to be the one that will require the most supervision, monitoring and critical analysis."

J&J agreed, and when the device came to market, the company set out to train 3,000 physicians in the first year. "Before we make an initial sale to a physician, we tell him that he has go to our two-day training course," explains William Christianson, vice president for clinical and regulatory affairs of DePuy Spine, the division of J&J that produces Charité.[18] "The first half is a lecture, emphasizing selecting the right patients for the procedure, complications, and how to get reimbursed. The second half is hands-on training using animals. First the surgeons watch the procedure, then they do it themselves. They all do one operation, and they take home a CD-ROM."

But is one operation enough to become proficient? During the FDA trials, J&J considered the first five patients at each site "training patients." Meanwhile J&J consultant Dr. Paul McAfee cautioned surgeons that anyone planning to implant Charité faces a "steep learning curve."[19] Five training patients multiplied by the 3,000 surgeons who went home with J&J's CD-ROM means that up to 15,000 patients could find themselves lying face up on that learning curve.

Mark Mintzer, the patient who had a successful implant and now helps other patients find surgeons, is concerned: "I see a wave of patients going to inexperienced surgeons," Mintzer confided in the fall of 2005. "These surgeons are telling patients that the implant is little different from a fusion—and they've done hundreds of fusions. In fact the implant is very different. These doctors are misrepresenting their experience."[20]

Perhaps, rather than training 3,000 physicians in one year and sending them out to operate on thousands of patients while they "get their feet wet," it might have made more sense to limit the number of surgeons doing the operation to a small number who were involved in the original clinical trials. Their hospitals could be designated "centers of excellence" for disc replacement. And in those centers, experienced surgeons could begin training both their own students and physicians from other hospitals who had time for more than a one-day hands-on session.

But, as Rosen saw it, the problem was not just that thousands of inexperienced surgeons might do irreparable harm as they practiced on their patients. As he reread the transcript, he kept coming back to expert testimony offered by Dr. David Polly, chief of spine surgery at the University of Minnesota, reminding the panel that it was "inevitable" that over time some

discs would have to be replaced, or, in the language of spine surgery, "revised":

"These revisions will be due to infection, dislodgement, malposition and eventually to wear or wear debris," said Polly. "It is imperative that implanting surgeons understand the difficulties associated with revision procedures and that these revisions are potentially life threatening," he added. "They must then ask themselves if they are prepared to undertake such revision cases. If they are not prepared to do so, then they must ask themselves if they ought to be implanting the device [in the first place].

"I know that my . . . regional referral center will be facing these difficult revision cases whether we ever implant a single device or not," he concluded, "and I expect this will be a daunting task."

Polly was not a voting member of the panel. He had been sent to the hearing by Medtronic, one of J&J's rivals, to add his expert opinion to the discussion. "Medtronic paid my expenses, and I think their concept was to have me say a series of negative things. But I wasn't willing to say that the disc shouldn't be approved," Polly explains. "I was willing to say that once the disc was implanted, replacements would be a serious challenge—and I said that.

"I think Charité is 'okay,' but I don't think it's perfect," he adds. "Will some things go wrong? Absolutely. Will some people will die? There have been two deaths since the disc came on the market. The next generation of 'follow-on' devices that companies are developing right now will be better," says Polly. "But somebody has to be first."[21]

"Trade Secrets"

After reading the transcript of the FDA panel's deliberations, Rosen was still undecided as to whether he should try the operation. He wanted to know more, and late in January of 2005, he contacted both the FDA and J&J.

Rosen was particularly interested in more detail on the "adverse events" that the first 71 patients in the two-year trial had suffered. Seven percent needed a second operation (vs. 5.4 percent of later patients); 33.8 percent suffered severe neurological pain (vs. 16.1 percent in the later group).

To Rosen's surprise, the FDA told him that if he wanted in-depth information, he would have to file under the Freedom of Information Act. Rosen did that and was informed that his request had been denied. According to

the FDA's Michael Courtney, the results could not be released because they were "trade secrets."

Rosen appealed: "I am concerned that the initial results of the procedure as reflected in the 71 patients may be bad," he explained. "The public has a right to know whether this is the case or not. I, as a spine surgeon being asked to put these artificial discs in, have a right to know. I also have a right to know in order to handle the possible failures that may come to me."[22]

With that end in mind, Rosen began exchanging letters with William Christianson, vice president of clinical and regulatory affairs for DePuy Spine. Christianson forwarded summaries showing the percentage of patients who suffered problems such as "neurological pain"—but again, no detail. Were they still in pain after they healed from the surgery? Why had some patients needed a second surgery? Rosen was frustrated. He could try to avoid these outcomes—but only if he had some clue as to what went wrong. He wasn't going to operate in the dark.

"I chose not to respond to his request," Christianson explained in the fall of 2005. "I thought he was being unreasonable . . . And given his negative characterization of Charité [in the press] I thought that [if he had the information] he wouldn't give us a fair shake."[23]

When asked, in the same interview, whether patients who experienced "neurological pain" were still in pain months after they had healed, Christianson explained: "We checked the patients at 6 weeks, 3 months, 6 months, 12 months, and 2 years. At each point, some patients reported pain. We added them all up and the total was 33.8 percent in the trial group—and 16.1 percent in the later group."

The next question seemed obvious: "What share of the patients in either group were still experiencing neurological pain at the end of two years?"

Christianson refused to answer: "If I tell you that," he said, "you'll want to know how many experienced pain after one year."

This was true. But wouldn't any prospective patient want to know how many patients were in agony a year later?

"We gave that information to the FDA," said Christianson. "We do not have to release it." He was correct. Legally, the level of detail Rosen was asking for is considered proprietary information, and neither the FDA nor the company is required to make it public.

And to be fair, even if Rosen had that information, he still could not be certain whether Charité's benefits would outweigh its risks over the long

term. But he would be in a much better position to outline the immediate risks when describing the operation to a prospective patient.

The Risk of Being "Left Behind"

By the fall of 2005, more than 3,000 of J&J's spinal discs had been implanted. Although only two of the nation's eight largest insurers had agreed to pay for the operation, some hospitals were willing to absorb the cost of the $11,500 device. Earlier in the year, Dr. John Boockvar, chief of neurosurgery at Wyckoff Heights Hospital in Brooklyn, told Dow Jones Newswires that his hospital gave him permission to implant the device even though insurance would not reimburse "because it was important to be on the leading edge."[24]

Patients who read favorable reports of Charité online or in the press were beginning to demand the operation. "Some doctors say they're worried they will lose business if they don't offer the Charité option to patients," *The Wall Street Journal* reported, quoting Dr. Bernard Guiot, director of the spine program at the University of South Florida. "There's a feeling that it isn't adequately proven, but there's anxiety about being left behind."[25]

As for Rosen, he had no plans to use Charité: "Based on the evidence we have, I don't think it works," he said. "I like to do the newest things in spine surgery, but I'm interested in practicing evidence-based medicine—and we don't have the evidence."

Not everyone agreed. In the fall of 2005, Cedars-Sinai hospital continued to plug the procedure both in radio ads and on its website. There, a 1,400-word advertorial for Charité managed to avoid using the word "risk" even once. Instead, the Beverly Hills hospital assured prospective patients that the "revolutionary" spinal implant was "routine and safe."[26]

By then Dr. John Regan had performed some 200 Charité operations at Cedars-Sinai with what he described as a "90% success rate." And he agreed that the procedure is "routine and safe—most of the time." Much depends on both patient selection and the skill of the surgeon, said Regan: "I wouldn't want to see every spine surgeon in the country doing this operation—but then I wouldn't want to see every spine surgeon in the country doing many spine operations."

Regan knew the procedure better than most. "I helped develop the technique and some of the surgical instruments used to implant the disc," he ex-

plained. As a result, he has received royalties from J&J. Although he declined to divulge just how much J&J paid him, Regan insisted that the royalties had not influenced his professional judgment about the procedure.[27]

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Drugs and Devices: Prices and Profits

The story of the Charité disc captures the secrecy, the scientific uncertainty, the financial pressures, and the potential for conflict of interest that clouds the development, approval, and marketing of new drugs and medical devices in the United States.

The amount of money at stake is staggering. In 2006 drugmakers and device makers will take in well over $300 billion—or roughly 15 percent of the nation's health care dollars.

The prescription drug industry tends to downplay the cost of its products, pointing to government reports which suggest that drugs account for roughly 11 percent of health care spending. But in fact, that figure represents only those drugs sold directly to consumers at pharmacies and other outlets. (See pie chart on page xii: "What Are We Paying For?") Hospitals, doctors, nursing homes, and other health care facilities also buy drugs, and when those purchases are included, spending on prescription drugs alone could hit $270 billion to $280 billion in 2006.[28] Add on the $36 billion that hospitals and other health providers will lay out for devices such as spinal discs, stents, and artificial hips, and the total tab for prescription drugs and devices approaches $310 billion to $320 billion.[29]

And in recent years spending on drugs and devices has become the fastest-growing component of health care costs, with outlays for drugs alone doubling between 1995 and 2003, thanks to a combination of higher prices (driving 58 percent of the rise), plus greater demand.[30] Over that span, prescription drug prices jumped by an average of 7.4 percent a year—almost three times the inflation rate of 2.5 percent.[31] In 2004 spending on prescription drugs rose another 7.2 percent, with pharmaceuticals accounting for nearly one-quarter of the total increase in the nation's health care bill.[32] Meanwhile, Americans popped more pills: from 1993 to 2003 the number of prescriptions purchased climbed by 70 percent while the U.S. population grew by only about 13 percent.[33]

Over the same span, the device industry took off. From 1993 through 2003 the industry's average revenues rose by an eye-popping 23 percent a year.[34] Looking ahead, as bionic boomers begin to replace body parts, the market for everything from artificial knees and hips to cardiovascular devices like defibrillators and pacemakers is likely to snowball—assuming that boomers can afford all of that hardware.

Just as Americans shell out far more for prescription drugs than the citizens of other countries, we also pay a premium for devices. "Europeans spend an average of just $1,270 for an artificial hip—or about one-fourth of what Americans spend," points out Sanford Bernstein analyst Bruce Nudell.[35] Stents that sell for roughly $1,500 in Europe command $2,200 in the United States.[36] And spare body parts are fast becoming luxury items: by 2005 a single screw used in spinal surgery fetched as much as $1,600, while the latest in artificial knees cost close to $10,000.[37]

Why are prescription drugs and devices so expensive in the United States? Manufacturers argue that Americans must pay dearly because in other countries, where governments regulate prices, consumers pay too little. Without U.S. dollars, the industries' supporters argue, drugmakers and device makers would not be able to cover the cost of research and development. "Implicit in this claim is a kind of blackmail," former *New England Journal of Medicine* editor Dr. Marcia Angell observes. "If you want drug companies to keep turning out lifesaving drugs, you will gratefully pay whatever they charge. Otherwise, you may wake up one morning and find there are no more new drugs."[38]

The threat is absurd. The truth is that the pharmaceutical industry spends approximately one-and-a-half times as much on marketing and sales as it spends on research and development.[39] If manufacturers slashed their bloated ad budgets, they could accept lower prices for their drugs without touching R & D.

Drugmakers themselves know that they are spending far too much on promotion. As Sanford Bernstein stock analyst Richard Evans pointed out in chapter 2, they've reached a point of diminishing returns. "Up until 1998—and for many companies through 2000—you were being paid to hire that next sales rep; you were being paid to do that next consumer ad," Evans explained. "You were generating returns for your shareholders by doing that. It is a strategy that worked. After 2000, however, even industry insiders privately admitted that billions were being wasted."[40]