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No More Tears

The Dark Secrets of Johnson & Johnson

By Gardiner Harris

Gardiner Harris is the public health reporter for The New York Times. Before working at the Times, he worked at The Wall Street Journal and lived for four years in Hazard, Kentucky, as the Eastern Kentucky bureau chief for The Louisville, Kentucky Courier-Journal. His reporting in Kentucky led to broad changes in laws governing coal-mine safety and black-lung compensation, and it earned him national journalism awards, including a George Polk Award and the Worth Bingham Prize for investigative journalism.

A Book Review by Soundview

Uncovering Shocking but Necessary Revelations

Family is one of the most important things to people. They will do almost anything to protect and care for them. Parents of newborns carefully select what medicine to give to the sick baby. Men and women will discuss the different uses of baby powder, swapping stories from their childhood, and associating certain people with certain smells. Nostalgia is real and plays a significant role in decision-making, particularly regarding medicines and medical procedures. However, what happens when hidden truths come out? Destroyed papers, doctored files, and experiments with falsified results. When these come to light, and consumers are told the depth of deceit, that trust is broken and is almost impossible to regain.

In ***No More Tears: The Dark Secrets of Johnson and Johnson***, Gardiner Harris explores the downfall of a company many Americans grew up fond of and use daily. He delves into the various products that Johnson & Johnson said were safe. Still, instead, they led to the death and permanent injury of consumers. No More Tears is broken down into four parts. Part One discusses two of the most well-known Johnson & Johnson products and the lengths they went to keep them on the shelves. Part Two is about their prescription drugs and their plans to keep their less-than-ideal findings hidden from everyone, including the FDA. Part Three sees the journey into medical devices and the problems and pain their consumers would endure. Finally, Gardiner explores Johnson & Johnson's attempt to save their face by taking part in the making of COVID-19 vaccines.

Part One

Gardiner shares that Johnson & Johnson (J & J) has been associated with families and their ability to care for them since its inception. They have been surrounded by the protective halo of various consumers, officials, and others have provided for them. This brand is closely associated with baby products, which affords them high emotional trust, particularly regarding Tylenol and Johnson's Baby Powder. Several experiments were performed to create Johnson's Baby Powder's distinctive scent, which has become one of the most recognized fragrances in the world. While these two products have not contributed signifi-

cantly in several years, their histories have become the company's defining history.

Johnson's Baby Powder

Talc blocks (soapstone) are found on almost every continent. They are used to make sinks, lab countertops, and electric switchboards. They are incredibly soft and, when finely ground, can be used in various ways. Still, most controversially, they were used in cosmetics and baby powder.

The first reports of danger came in 1922 when researchers saw babies grabbing bottles and showering the powder on their faces. Because it is not water-soluble, the particles would block the tiny air sacs where oxygen is passed into the bloodstream and asphyxiate them. The official journal of the American Academy of Pediatrics warned against using talcum powder in 1969 and 1981, and while J & J placed warning labels on the bottles and redesigned the spout, the risk of death never truly disappeared.

While there had been questions about the dangers of inhaling powders, researchers and industry officials wrote in 1956, 1963, and 1968 that asbestos was a common ingredient in talc-based powders. Talc and asbestos are similar in several ways, so much so that veins of one or the other are found sandwiched with the other. Though some concerns had been raised about the impact of talcum powder on consumers, reassurances and denials were always quickly released until the mounting evidence couldn't be ignored anymore. J & J finally stopped selling talc-based baby powder in 2020, blaming the spread of misinformation concerning the product's safety. The truth, however, couldn't be denied, and Harris says that J & J is likely one of the more litigious companies in the world. In their attempt to save face, they refused to release life-saving research and make the necessary change to save the people who trusted their word about the safety of their product.

Tylenol

In the 80s, there was a series of seemingly unrelated and unexplainable deaths, which seemed unrelated until samples were sent out and tests revealed cyanide was the cause. Since that was the case, how was that possible? Both J & J and the FDA knew that how they responded to this would define how they were seen for a generation, at the very least.

J & J had been considering tamper-proof containers for several years. Still, in light of these murders, they decided to recall the Tylenol products on the shelves and produce the new containers (every other manufacturer of over-the-counter medicines quickly followed these measures). While J & J emerged from this tragedy being lauded for their quick response and willingness to put safety first, there are a few footnotes on how they handled it that show J & J in a less commendable way. The FDA's funds were limited due to a government shutdown, the majority of the investigation was left up to J & J. The FDA also didn't have the authority to demand or inspect records until 1997, which allowed J & J to hide not only the extent of the problem but also keep the FDA almost entirely in the dark.

After this, questions about the safety of the main ingredient of Tylenol came to light. Even when it was used as directed, Acetaminophen is one of the leading causes of acute liver failure. J & J's advertisement of being safe, fast pain relief, and that it was the pain reliever used by hospitals, has proved deadly time and again. The FDA asked them to examine the issue of alcohol and acetaminophen, and while they initially said it wasn't necessary, they finally put a warning on the packaging in 1994.

Part 2: Prescription Drugs

J & J began exploring the pharmaceutical industry in the 1890s when aspirin was discovered. It accelerated in the 1940s with the production of penicillin. It peaked in the 1980s when there was a massive breakthrough in the discovery of medicines that would see the average older adult take six or more prescriptions at a time. A rise quickly followed this in insurance companies, both private and public, which would begin to affect the prices of medication and make it profitable. Why? Because insurance companies were beginning to shift from paying only for in-hospital prescriptions to all prescriptions.

To chase the gold mine that this was proving to be, J & J decided to sift from the stiff-button-down company they had been to one with young, ambitious, attractive sales representatives who marketed the products to the doctors. To reach their sales target, these representatives would offer gifts, compliments, favors, and more, and encourage them to use these medicines more than necessary in a wide variety of patients who may or may not have needed them.

Procrit

Interest in a synthetic bone marrow protein that increases red blood cells rose in the 1980s with the creation of erythropoietin [ih-rith-roh-POY-uh-tin] (or, EPO). Scientists at Amgen discovered and cloned this gene, but in deep debt, they needed a wealthy partner for FDA approval. J & J agreed to partner, leading to FDA approval of EPO for commercial sales in 1988. Initial sales were slow, prompting a strategy shift to market EPO to cancer patients instead of just dialysis patients. However, as EPO became available, researchers found that some cancer cells had EPO receptors, stimulating their growth. Harris notes that when a researcher presented these findings to J & J, two members agreed they must "kill this work."

As time passed, troubling findings emerged. While EPO's successful effects generated excitement, concerning effects surfaced in the hearts of elite athletes. J & J planned to enroll 400 women with cervical cancer to compare EPO users with non-users. In contrast, Amgen enrolled 1,233 dialysis patients to study EPO's effects at various levels. Both companies claimed no evidence of harm. These reassurances later proved false.

In 2003, a study suggested that EPO might be harming rather than helping patients. This dissenting research challenged Big Pharma's narrative. Despite known cardiac risks and suspected tumor growth promotion from EPO, most oncologists believed benefits outweighed risks, unaware of the mounting data revealing dangers. Both companies repeatedly faced issues in

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safely administering EPO in clinical trials. In 2004, the FDA announced a study to assess EPO's risks, meaning neither J & J nor Amgen could continue to conceal their results.

Risperdal

A surprising number of people experience psychotic breaks at least once or twice in their lives, and nothing has proven better to treat them than anti-psychotic medicine. For some, the medication has an immediate effect and allows them to lead everyday lives. For others, they experience side effects, such as weight gain, strokes, or dialysis. Still, in extreme cases, there are "extrapyramidal side effects." Those who suffer from those are often ostracized because of their uncontrolled facial movements. J & J sought the FDA's approval for a drug called Risperdal. This anti-psychotic was supposedly safer than its predecessors because it caused few tics and tremors. While approved, the FDA didn't allow J & J to compare it to a similar drug called Haldol. Hence, the executives decided to find a workaround and thus was born the selling to the symptoms.

Sales representatives would ask doctors if their patients suffered from specific symptoms, and a sales aid would list the same symptoms. If the doctors answered yes, the sales rep would tell them that Risperdal would effectively treat them. J & J would later say they knew this symptoms-based message was illegal. Still, this model had already been adopted across the industry. Despite serious red flags, J & J kept trying to meet its aggressive sales goals by marketing Risperdal to children and older people. Harris states that while there was no documentation stating J & J knew the decision to continue to market Risperdal would contribute to the deaths of millions of Americans and the disfigurement of thousands of young boys, they undoubtedly knew the number would be significant.

Duragesic

The opioid epidemic is said to have started in 1995 when the FDA approved the use of OxyContin. The delayed release effect wasn't new to J & J because they had created Duragesic. This patch was supposed to supply a supply of fentanyl over 72 hours. The problem with both of these drugs was that the slow-release mechanism could be easily bypassed, allowing for immediate and possibly fatal doses. Despite worries, Duragesic was approved, but even when it was used appropriately, it could prove fatal and addictive. J & J believed there was a market to be tapped. Since they had sales reps in this area, they started advertising Duragesic to relieve chronic pain.

Harris says the most remarkable thing that may have come from the opioid epidemic was the blind spot the FDA had toward J & J. They, along with other Big Pharma executives, had misled the regulators, doctors, and patients about its effects and potential abuse. The FDA had warned J & J to cease claiming that fentanyl was only minimally addictive, but did nothing when they didn't. No matter how hard J & J tried to find a workaround for medicines, it was clear they were the same as OxyContin; they were just given a different name.

Ortho Evra Birth Control Patch

The production of birth control revolutionized relationships and changed them forever. What isn't as well known is how it changed the FDA. Since J & J was already reaping rewards from the Duragesic fentanyl patch, they decided to apply the same technology to contraceptives. Still, they were quickly faced with problems, such as elevated estrogen levels and inconsistent doses being released. Based on these findings, J & J were facing several unpleasant options, and rather than go with any of them, they decided to willfully lie to the FDA about the patch's estrogen issues.

After the approval and subsequent release of Ortho Evra, reports started coming in of young women having surprise pregnancies, strokes, heart attacks, and, in some cases, dying. J & J had done extensive research and knew the dangers of the patch but chose to hide the evidence from the FDA and their consumers. A warning label was placed on Ortho Evra, but because of the need for as many contraceptives as possible, it has never been pulled off the shelf. Even though executives resigned, citing the lack of urgency for the deaths taking place and the dishonest research that was released, J & J chose to harm instead of protect their consumers.

Part 3: Medical Devices

J & J has been producing medical devices for several years, but deaths and injuries became more prevalent as these devices became more complex. Congress passed legislation stating that high-risk devices needed more extensive testing. Still, the FDA was so thoroughly captive to the companies instead of consumers that testing never fully occurred.

Pinnacle Metal-On-Metal Hip Implant

The day before J & J would apply for a Metal-On-Metal hip replacement called Pinnacle, they found one of the five pairs was falling apart in the simulator. They were again faced with less-than-ideal options: present their findings to the FDA and be forced to miss out on profits, perform trials on humans instead of simulators, or make an undisclosed change that could compromise the FDA's approval later. There was also

the dilemma of causing untold pain to those who received the device. So what could they do?

They decided to move from plastic to metal devices, thinking they would last a lifetime. Instead, the friction from the ball and cup joint causes metal shavings to kill the tissue and cause injury, strokes, or even death. J & J performed studies to see if they could solve the issue, but held back essential documents from the FDA, so they would assume that Pinnacle was working and not harming the recipients. But that was entirely untrue, and J & J was busy telling doctors who reported issues they were alone in having them, and they would see thousands of lawsuits related to Pinnacle pouring in.

Prolife Vaginal Mesh

Humans sag as they age, and J & J saw an opportunity to assist women with pelvic floor issues. Rather than doctors continuing to use women's tissue to strap down sagging organs, J & J created a plastic sling that would cinch around the bladder. However, the recipients would soon complain of painful, lengthy recoveries. To find an easier way to insert the anti-sag mesh, they decided to insert it through the vagina, which created a new set of problems. One of the mesh's inventors stated that because of the pain some women were experiencing, going back to the concept stages should be considered. He was not alone in his concerns, and while other surgeons expressed concerns, J & J ignored them and began selling Prolift without FDA approval.

Problems with Prolift continued to come forward, and rather than reveal the procedure risks to doctors, J & J decided to eliminate the problematic data they had found. An easy cure would have been not to promote or use Prolift, but instead, they continued moving forward until the FDA said that it was enough. First, they released a significant revision to its vaginal mesh alert. Still, they would finally ban the use of all vaginal meshes to repair prolapse due to recipients experiencing devastating results instead of the relief they sought.

Part 4: Vaccinations

As J & J's decades-long deceits came to the surface, they faced the wrath and lawsuits of the consumers they had knowingly harmed. From Johnson's Baby Powder to Risperdal, J & J knew that the results would be devastating if the emotional trust they had built with their customers were broken. Six out of their seven best-selling drugs would eventually be revealed to have been marketed using illegal tactics. However, the COVID-19 pandemic gave them a unique chance to save the world by creating a vaccine.

As the world began to shut down, J & J got to work, focusing on a single-dose vaccine that would set them apart from Pfizer and Moderna, whose vaccines would need a booster. They were confident it would work, but didn't have a manufacturing presence in the international market, so they partnered with Emergent BioSolutions to make it happen. However, they soon ran into serious issues, and the FDA demanded they do more extensive testing. They placed a mandatory pause on the administration of the J & J vaccine because of cases of rare blood clots, but before that, distribution sites that were only using J & J's vaccine were faced with supply issues. Slowly, nations worldwide started restricting access to the vaccine, and when the FDA finally revoked authorization for it, the company's effort to save the world officially failed.

Why was J & J allowed to continue this way for so long? Harris seems to propose that.

The FDA is being held captive by the companies it's supposed to regulate. J & J and others in the pharmaceutical industry perpetuate the myth of the FDA being a strict, powerful agency because it provides an essential defense against the legion of liability cases.

No More Tears: The Dark Secrets of Johnson and Johnson by Gardiner Harris is an in-depth look at how Johnson and Johnson went from one of America's most beloved, trusted companies to one riddled with lawsuits and scandals. It is an informative read that will help consumers understand and take more seriously the decisions they make regarding the health and well-being of themselves and their loved ones. Harris ends No More Tears by calling for several changes, including how the FDA is funded and an assessment of the system that allowed Johnson and Johnson to thrive.