

THEY KNEW AND FAILED TO...



True stories of corporations
that knew their products were
dangerous, sometimes deadly

They Knew and Failed To

Table of Contents

Introduction

Medical Devices

Drugs

Consumer Products

Food Safety

Automobiles

Environmental

Conclusion

Sources

Introduction

Every day there is another recall or warning of a product that turned out to have design flaws or unexpected problems - a drug with an unanticipated side effect, a toy with a sharp piece that can injure a child, or a popular food product that may have been contaminated in production. These recalls and warnings are so frequent that consumers are no longer surprised.

What would surprise consumers is the fact that sometimes those who are responsible for these dangers know about the problem and do nothing about it. People find it hard to believe that anybody would cover up a product's danger and then market that product to the very people it is likely to kill or injure.

Yet, that is exactly what happens time and time again. The following pages contain true stories of corporations that have known their products were dangerous, sometimes deadly, but continued to push them onto unsuspecting consumers. Stories that include:

- A company that discovers its medical device is little more than a bomb waiting to go off in people's hearts... and decides not to tell anyone.
- A pharmaceutical company that discovers that its drug causes severe side effects in pediatric patients... and then spends hundreds of millions of dollars marketing to children.
- A company that discovers its bulletproof vests are defective... and then sells them anyway to be worn by law enforcement, the military, and the President of the United States.
- A company that discovers rodent droppings are contaminating its food products... and then orders them re-cooked and sold anyway.
- A car company that discovers that if it does not spend \$11 per car to fix a defect, hundreds of people will be horribly burned... and decides it would be cheaper to let them burn.

Unfortunately, as shocking as they are, these stories are not isolated incidents. They run the gamut of products, from toys to toxic waste. Some happened decades ago, some are still going on. What they all have in common is that they were exposed by America's civil justice system. The civil justice system does not only offer those who have been hurt by a defective product a chance to hold the wrongdoer accountable, it also shines a light on behavior that would otherwise never see the light of day. It exposes corporate CEOs who choose to cut corners or cover up dangers in order to make a bigger profit. These are stories about corporations that knew of the dangers and failed to protect their customers. These are stories about corporations that knew and failed to.

They Knew and Failed To - Medical Devices

Guidant Heart Defibrillators

On a spring day in 2005, 21-year-old Joshua Oukrop went for a bike ride on trails through the canyons near Moab, Utah. The Minnesota native was enjoying a spring break trip with his girlfriend, Jessica, when he went into cardiac arrest. Joshua suffered from a genetic heart disease and had taken steps to prevent this event by having a defibrillator implanted in his chest. The medical device was supposed to shock his heart back to a normal rhythm in the event of an irregular heartbeat. On this day, the device short circuited and failed to shock his heart as intended and Joshua died.



Joshua Oukrop

It was, however, not a one-off tragedy. The manufacturer of the defibrillator, Guidant, had learned three years earlier that there was an electrical problem in its defibrillators; fluid could penetrate a seal, causing the device to short circuit when it needed to deliver an electrical shock to the heart. Executives at Guidant decided to continue selling the inventory of defective devices, even after a safer version was in production. The company also chose not to inform doctors that there was a problem with the defibrillator, a decision it later defended by saying it did not want doctors to remove the devices unnecessarily or put patients through the risks of surgery.

In the months after Joshua Oukrop's death, it was becoming clearer to those outside the company that the malfunction of Joshua's defibrillator was not an isolated event. Two months after Oukrop's death, executives from Guidant met with his doctor, Barry Maron, and admitted that they were aware of 25 other instances in which the same model defibrillator had short circuited. While the company insisted that the likelihood of the defibrillators malfunctioning was very small and the risks of replacement surgery outweighed the risks of the device, Maron was not convinced. Knowing that it was only a matter of time before another person died when a defective defibrillator failed, Maron notified the media.

As the FDA and the media began investigations into what Guidant knew and when they knew it, details emerged that showed the company had put patients at risk to protect its bottom line. Guidant had changed the design of the device in April 2002, but continued to sell approximately 37,000 devices that had already been manufactured, and made

By the Numbers

- 2002** Year that Guidant discovered a potentially fatal design flaw in its defibrillators.
- 2005** Year that Guidant executives finally issued a warning notice to doctors. The company still would not recommend their replacement.
- 37,000** Number of defective devices Guidant had continued to sell even after the redesign.

no effort to warn doctors, regulators, or patients of the defibrillators' dangers. In May 2005, after learning that *The New York Times* was about to publish a front page article exposing the company's handling of the design flaw, Guidant finally issued an advisory to doctors outlining the dangers of the device. Even then, the company would not recommend that the devices be replaced.

In January 2006, the U.S. Department of Justice, conducting an inquiry into Guidant's handling of the matter, requested that Bob Hilliard, a Texas attorney representing plaintiffs in lawsuits against Guidant, turn over 10 pages of documents he had acquired during discovery. The documents included PowerPoint slides and handwritten notes by Fred McCoy, president of the company's Cardiac Rhythm Management unit, which showed that executives made a decision to sell defective inventory even though they were aware of the dangers the products posed. Hilliard described the company's reaction to the faulty defibrillators as "consistent, bad decisions based on profit, not patient health," adding, "[t]he documents I received from Guidant showed they were basically making the equivalent of the Ford Pinto."

Guidant promised to cover the cost of a replacement device for patients who had received a recalled defibrillator, but declined to cover the cost of the surgery to replace the old model. This action forced patients to make a difficult decision: take the risk that the device will work properly when necessary, even though it is obvious that this will not always happen, or incur the expense and danger of a second operation.

Medtronic Sprint Fidelis

Medtronic's Sprint Fidelis lead, a cable that connects defibrillators to a patient's heart, was prone to crack, which could cause electrical problems, such as short circuiting when the defibrillator needs to shock the heart or causing the defibrillator to repeatedly shock the heart for no reason. The Sprint Fidelis was recalled in October 2007, nearly three years after Medtronic first received reports of the cable fracturing.

Documents released by the FDA prove that the company opened an investigation into the leads in 2005 after receiving 30 complaints about the product malfunctioning. Up until the recall, Medtronic concealed the defects and continued marketing its cardiac defibrillator as a safe product, without any regard to the 268,000 patients who would eventually be surgically implanted with the faulty wire. Since removing the devices now would require invasive and often risky surgery, Medtronic has advised some patients to walk around with a magnet that may or may not help curb shocks whenever the lead begins to short-circuit. For those who did opt for the surgery, Medtronic offered to replace the lead but would only cover \$800 of the \$12,500 procedure.

Despite the known dangers of the product and the efforts of Medtronic to hide damaging evidence, many patients injured by these defective leads may not have the opportunity to seek justice in court. The Supreme Court's ruling in *Riegel v. Medtronic* gave complete immunity to device manufacturers who fail to adequately warn consumers about the device risks.

Bjork-Shiley Heart Valve

The Bjork-Shiley heart valve was marketed by Pfizer-owned Shiley Inc. from 1979 until 1986. The device was used to replace diseased and deformed heart valves, but even before it hit the market, company executives became aware of incidences of the device cracking, a problem that would later be described as akin to having a time bomb in your heart.

In 1980 company executives asked the valve's inventor, Viking O. Bjork, not to publish data on strut failures.

~~WE WOULD PREFER THAT YOU DID NOT PUBLISH THE DATA RELATIVE TO STRUT FRACTURES. WE EXPECT A FEW MORE AND UNTIL THE PROBLEM~~

-- Correspondence between a Shiley executive and valve inventor Viking Bjork

When Bjork was still warning of failures two years later, one company executive wrote that they needed to "settle him down." The company put off informing the FDA, and subsequently tried to change the production process to prevent failures. However, reports that the device was still suffering cracks continued to roll in. On the production line whistleblowers warned that employees were polishing over cracks, faking rewelding, and even working on the devices while drunk or high. Shiley executives rebuffed the whistleblowers.

"Settle him down."

-- Shiley internal memo

In 1986, seven years after its launch, the reports of device failure were too common to be ignored, and parent company Pfizer finally stopped selling the device. At this point more than 80,000 valves had been sold. At least 660 patients experienced complete catastrophic failure of their valves, often with fatal results.

A.H. Robbins Dalkon Shield IUD

In 1971 A.H. Robins began marketing the Dalkon Shield, a contraceptive intrauterine device (IUD). Almost immediately the company began receiving reports of serious problems with the device. A design defect was causing women to frequently suffer severe infections, miscarriages, stillbirths and even death. A.H. Robins, however, continued to heavily promote the product for several more years. When one company employee complained he could not in good conscience continue to cover up the infection problem, an A.H. Robins executive told him his conscience did not pay his salary.

"[I]f this product is taken off the market it will be a 'confession of liability' "

-- A.H. Robins executive to a company employee

One company memo stated, "if this product is taken off the market it will be a 'confession of liability' and Robins would lose many of the pending lawsuits." In 1974, the FDA halted distribution of the device, but the company did not recall the existing stock, and continued to sell the product overseas. For 10 years, A.H. Robins promoted and defended the device and eventually sold more than 4.5 million Dalkon Shields. At least 66,000 women were known to suffer septic spontaneous abortions, and at least 18 women were killed by infections caused by the device and hundreds more were rendered sterile.

G.D. Searle Copper-7 IUD

In 1974, ironically the same year the Dalkon Shield was suspended by the FDA, G.D. Searle began marketing the Copper-7 IUD. Like the Dalkon Shield, the Copper-7 was sold to millions of American women despite the company's internal doubts about its safety. Company executives knew that the Copper-7 had an infection problem and was causing ectopic pregnancies and infertility, yet not only did they continue to sell the device, they marketed it specifically to young women. A document obtained during litigation showed that the company directed their marketing efforts toward young women who had never been pregnant, even though their own research showed that this population was at particular risk.

"The group considered highest risk for infection and subsequent loss of fertility is that consisting of nulligravida, under 26, with multiple sex partners. It seems to be that the identification of such a group by the Food and Drug Administration, mishandled by the lay press, might have an impact on our marketing strategy."

-- G.D. Searle *internal document*

Searle settled the Copper-7 lawsuits shortly after this document surfaced.

Playtex Super-absorbent Tampons

In the 1980s Playtex began marketing super-absorbent tampons that soon became associated with Toxic Shock Syndrome (TSS). The tampons were made with polyacrylate fibers, which increased the chances of the introduction of a staph infection. The company disregarded studies linking their product to toxic shock, and sought to market the product's extra absorbency when other manufacturers were reducing absorbency in reaction to medical information. At least 2,000 women suffered toxic shock syndrome and approximately 100 died as a result.

Playtex removed the tampons linked to TSS from the market only after a court awarded \$10 million in punitive damages to the family of a woman who died from an infection after using Playtex tampons.

Renu Contact Lens Solution

Zoe Wade had worn contacts for years without experiencing any negative effects. Then, in January 2005, the 69-year-old Florida resident purchased ReNu with MoistureLoc contact lens solution. The solution was contaminated with a fungal infection that would later force her doctor to remove her left eye before the infection could spread to her brain. Wade was just one of more than 700 people exposed to the infection. Seven needed to have an eye removed and over 60 more needed corneal transplants.

ReNu's maker, Bausch & Lomb, had been receiving reports of unusual outbreaks of eye infections in foreign markets. The company eventually stopped selling the product in those markets. However, the solution in question was manufactured in Bausch & Lomb's factory in Greenville, S.C. and the same solution remained on the market in the United States. A subsequent FDA investigation found numerous violations at the plant. In mid-2006, after the Centers for Disease Control and Prevention (CDC) linked ReNu to 109 reports of fungal eye infections, the company stopped shipping the product in the U.S. but continued to sell the solution already on shelves.

They Knew and Failed To – Prescription Drugs

Johnson & Johnson's Propulsid

Scott Stevens and Gretchen Stewart of Munhall, Pennsylvania, took their three-month-old son, Gage, to Pittsburgh Children's Hospital when he did not respond to their pediatrician's treatment. Gage suffered from heartburn and diarrhea, and frequently cried and vomited. At the hospital a specialist recommended the anti-heartburn drug Propulsid. Six months later Gage died from a cardiac arrhythmia—a heartbeat anomaly—and a side effect of the drug known to its manufacturer, Johnson & Johnson.

From 1993 to 1998, pharmaceutical manufacturer Johnson & Johnson made over \$1 billion in sales from Propulsid, a prescription heartburn medication, even as the company knew hundreds of patients were dying from lethal side effects.

Shortly after Propulsid was approved by the FDA to treat heartburn in adults, regulators and doctors began noticing deaths and serious heart problems in patients taking the drug. By early 1995, the Food and Drug Administration (FDA) had received reports of 18 patients who had developed serious heart problems after taking the medication. Within 18 months, the number had risen to 57. Children were at particular risk, and federal regulators told the company it would not approve the drug for pediatric sales. The warning, however, was not made public.

Documents from lawsuits on behalf of injured patients against Johnson & Johnson showed that the company did not conduct studies recommended by federal regulators and never published other studies that might have warned physicians of possible risks associated with the drug. Moreover, while Johnson & Johnson agreed not to market Propulsid directly for children because of their increased risk of side effects, the company did push so-called educational efforts advocating the drug's use in pediatric patients. The educational efforts had the effect of sidestepping the agreement not to market for children. Documents would show that Johnson & Johnson knew that 90 percent of the company's cherry-flavored liquid Propulsid went to children, even though the company claimed it was aimed at geriatric patients. These educational efforts included funding seminars, books, and patient advocacy groups. Pediatricians responded, writing half a million prescriptions for the medication for use in infants and children in 1998 alone.

By the Numbers

- 1995** Year that Johnson & Johnson became aware of serious heart problems developing in patients taking Propulsid.
- 2000** Year that Johnson & Johnson executives finally took Propulsid off the market.
- 300** Number of people killed by Propulsid. An additional 16,000 were injured.

As incidents of infant deaths and serious heart problems continued to mount, some Johnson & Johnson executives began to question whether the company should limit Propulsid's pediatric use. The company banned sales for premature infants in some European countries, but senior executives overruled a ban in the United States.

In August of 1997, the FDA proposed major changes to Propulsid's warning label. Johnson & Johnson's internal analysis estimated the changes would cost over \$250 million a year in lost sales, and so, in June 1998, nearly a year later, it rejected almost all of them. Over the next three years, over 100 infants were injured and at least 24 died.

"Do we want to stand in front of world
and admit that we were never able to
prove efficacy!"

-- from the notes of a Johnson & Johnson executive

In all, at least 300 people died and as many as 16,000 were injured by Propulsid. By 2000, the FDA was no longer able to overlook the connection between Propulsid and the heart conditions appearing in patients who took it. The agency announced a public meeting to discuss the safety concerns with the drug. One Johnson & Johnson executive wrote a note during a "brainstorming" meeting, "Do we want to stand in front of world and admit that we were never able to prove efficacy!" The words "never able" were underlined. Three weeks before the meeting was set to occur, Johnson & Johnson announced it would stop selling Propulsid.

Bayer's Trasylol

In 2005, 52-year-old Joe Randone checked into a Long Island hospital for what should have been a relatively routine surgery to replace a heart valve. His doctors gave him Trasylol, a drug commonly used in open heart surgeries to prevent excessive blood loss. Immediately after the surgery, Randone suffered two heart attacks and renal failure. Once his kidneys stopped working, other systems started to shut down, forcing doctors to sew his eyes shut to protect his corneas, remove his gallbladder, and amputate his legs due to poor circulation. Eight months after receiving Trasylol, Joe Randone died.

What Randone and his doctors did not know, but what Trasylol's manufacturer, Bayer, had known since the early 1980s, was that the drug can cause kidney failure. In January 2006, just 10 days after Joe Randone's surgery, the *New England Journal of Medicine* published a study linking Trasylol to increased risk of kidney failure, heart attack, and stroke. The study estimated that halting use of Trasylol would prevent 11,050 cases of kidney failure annually and save more than \$1 billion in dialysis costs. In response, an FDA panel of experts convened to further review the safety of Trasylol. To prepare for the meeting, Bayer commissioned its own study on Trasylol. But when the results confirmed that the drug causes kidney failure, Bayer chose not to inform the FDA of the results or that the study even existed. Trasylol is no longer sold in the U.S.

GlaxoSmithKline's Avandia

GlaxoSmithKline's Avandia had already become one of the most popular diabetes drugs when researchers revealed that the drug increases the risk of heart attacks and other cardiovascular problems. Avandia was approved by the FDA in 1999 and quickly drew the attention from doctors who warned the agency of "a worrisome trend in cardiovascular deaths and severe adverse events" as early as 2000. GlaxoSmithKline (GSK) downplayed the risks and pursued a marketing campaign that was repeatedly rebuked by the FDA for understating the dangers posed by Avandia.

Sixty-year-old Larry Alan Stanford of Beaumont, Texas, was taking a form of Avandia when he suffered a fatal heart attack on May 21, 2007. That same day, an article written by a top cardiologist at the Cleveland Clinic and published in the *New England Journal of Medicine* alerted the public to what GSK already knew: Avandia increases the risk of heart attacks and potentially fatal cardiac events. GlaxoSmithKline kept Avandia on the market, though sales plunged. The FDA ordered GSK to include a black box warning of the risks of heart failure on the drug's label.

Eli Lilly's Zyprexa

Since it was approved by the FDA in 1996 to treat schizophrenia and bipolar disorder, Zyprexa has grown to become one of Eli Lilly's best-selling drugs. Eli Lilly proudly declared it "the number one psychotropic in history," but the company also covered up data showing that the drug causes dangerous side effects, including diabetes.

"Don't introduce the issue!!!"

-- *Eli Lilly's instructions to its Zyprexa sales representatives*

As early as 1999, company executives were aware of a serious link between Zyprexa and diabetes. The company's own data showed that 16 percent of patients were gaining at least 66 pounds a year, and doctors were reporting unusual frequencies of high blood sugar and diabetes at levels unprecedented for antipsychotic drugs. Despite this, Eli Lilly downplayed the concerns, telling its sales reps, "Don't introduce the issue!!!"

In fact, instead of warning doctors and patients, Eli Lilly used ghostwriters to obtain favorable literature on Zyprexa. Eli Lilly also developed a stealth marketing strategy that targeted the two groups most at risk from the drug's side effects, children and the elderly, despite the fact that the FDA had not approved such use.

In 2009, the Department of Justice fined Eli Lilly \$1.4 billion for its duplicitous marketing of Zyprexa. However, by this point the company was making \$4.4 billion a year from the drug.

AstraZeneca's Seroquel

For years, AstraZeneca marketed its antipsychotic Seroquel as a safe and effective treatment for schizophrenia and bipolar disorder. And for years, AstraZeneca buried studies showing that the drug causes weight gain and diabetes. In 2000, the company notified Dutch regulators of a causal relationship between the drug and diabetes. Wayne Geller, a doctor for AstraZeneca notified regulators that “[t]here is reasonable evidence to suggest that Seroquel therapy can cause impaired glucose regulation including diabetes mellitus in certain individuals.”

“ [G]reat smoke-and-mirrors job”

-- *Richard Lawrence, AstraZeneca commercial strategist*

AstraZeneca was not as forthcoming about the negative side effects of Seroquel with U.S. regulators, physicians, and patients. Internal company emails obtained during litigation showed that the company cherry picked data from clinical trials to show that Seroquel was safe. As early as February 1997, a company official praised the “great smoke-and-mirrors job” being done to thwart regulatory investigations into clinical trial data. That same official advocated that “[a]dopting the approach Don has outlined should minimize (and dare I venture to suggest) could put a positive spin (in terms of safety) on this cursed study.” Yet in August 2000, AstraZeneca informed the FDA that “preclinical data has provided no evidence that Seroquel treatment in man may be associated with diabetes.” Despite unfavorable studies linking the drug to diabetes, the company marketed Seroquel as safe and effective. AstraZeneca is currently involved in 9,000 lawsuits over its failure to warn patients of the drug’s harmful side effects.

Johnson & Johnson's Ortho Evra

Stephanie Rosfeld was preparing to return to her job as a volleyball coach at the University of Cincinnati after several weeks of maternity leave when the unthinkable happened: the healthy, 25-year-old, new mother suffered a fatal heart attack. At the time of her death, no one in her family suspected that the birth control patch she had been wearing for less than a month was to blame. But Johnson & Johnson probably did.

Before the FDA approved the Ortho Evra birth control patch, researchers from Johnson & Johnson became aware that the patch delivery mechanism was releasing far more estrogen into the bloodstream than low dose birth control pills. Because higher levels of estrogen increase the chances of blood clots and strokes, Johnson and Johnson tried to hide the evidence by reducing the numbers it reported in a clinical trial by 40 percent.

“ [T]oo high a chance that study may not produce a positive result for Evra.”

-- *Johnson & Johnson internal memo*

FDA scientists were troubled by what they saw as puzzling discrepancies when reviewing the clinical trial data, but not knowing the data had been doctored by the researchers, approved the patch in 2001. Once on the market in 2002, Johnson and Johnson refused to conduct comparison trials with its Ortho Cyclen pill because it was worried there was “too high a chance that study may not produce a positive result for Evra” and there was a “risk that Ortho Evra may be the same or worse than Ortho Cyclen.” Between 2002 and 2006 the FDA received reports of at least 50 deaths associated with the contraceptive patch. Johnson & Johnson has since paid over \$68 million to settle hundreds of lawsuits from women who suffered blood clots, heart attacks, and strokes as a result of using the patch. Despite the known risks associated with the patch, Ortho Evra is still sold with a black box warning.

SSRIs – Prozac, Paxil and Zoloft

In the late 1980’s several major pharmaceutical manufacturers developed a new generation of antidepressants, which they hailed as a breakthrough in the treatment of depression. The drugs, including Eli Lilly’s Prozac, GlaxoSmithKline’s Paxil, and Pfizer’s Zoloft among others, were part of a family of drugs called selective serotonin reuptake inhibitors (SSRI). However, even before the drugs reached the market the manufacturers became aware that the drugs posed an increased the risk of suicide, a fact they tried to brush off for decades.

In fact clinical trial data showed that 3.5 percent of children and adolescents taking the antidepressant expressed an increased risk of suicidal thoughts, compared to 1 percent of those receiving a placebo. Not only that, but this increased risk of suicide was not balanced about by a greater benefit. Clinical trials also showed that the drugs were often no more effective in treating depression than a placebo, a fact also hidden from regulators and patients.

When the serious side effects with SSRIs eventually brought the manufacturers into courts, nearly 20 years after the drugs had been introduced, the companies still refused to hand over important internal safety data. When plaintiffs’ attorneys asked GlaxoSmithKline’s permission to share previously undisclosed documents with the FDA, Glaxo denied the request, saying “[i]f FDA wanted additional information, such as the internal documents you propose providing it, FDA could have requested them from GSK.” This would have been a difficult request for the FDA to make, as it was unaware that the documents existed.

Chiron’s Flu Vaccine

In March 2004, executives at Chiron, manufacturer of more than half the U.S. supply of flu vaccine, became aware of unexpectedly high levels of bacteria in vaccine produced in its Liverpool, England, plant. It was the natural result of cost-cutting and chronic under-investment that had previously resulted in the plant’s health citations by British authorities. This time, however, authorities did not know about the contamination. Chiron waited 184 days and shipped a million doses of flu vaccine to the United States before telling the FDA there had been a problem.

"Company aware of the problem since April!"

-- *Notes of an FDA official*

Finally, in August, Chiron notified regulators of the contamination. The company promised to destroy four million contaminated vials and conduct a full investigation, yet still pledged to deliver between 46 million and 48 million doses of the flu vaccine to the U.S. by October.

Soon after, Chiron executives claimed to have found the source of the contamination and isolated infected lots. The company produced a 100-page report of its investigation to reassure inspectors. Far from being reassured, the inspectors viewed the report as a red flag, concluding that the company had failed to consider all sources of possible contamination.

Days later, British regulators barred Chiron from selling any vaccines and suspended their license. An FDA official on a conference call with British counterparts and Chiron executives wrote "company aware of the problem since April!" next to a doodle of a sinking ship.

They Knew and Failed To – Consumer Products

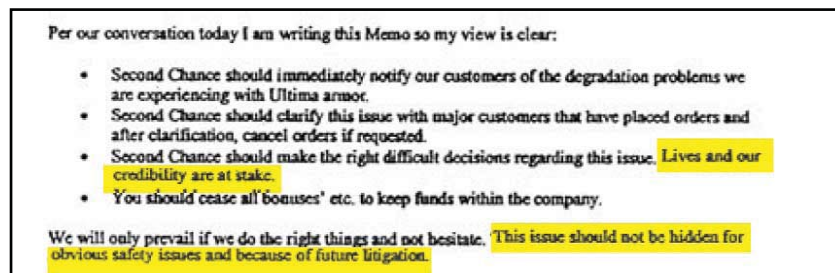
Second Chance Body Armor Bulletproof Vests

In June of 2003, 27-year-old Oceanside, California, police officer Tony Zeppetella got up early to spend a few precious hours with his six-month-old son Jakob before leaving for work. He would never return home from his shift. Zeppetella pulled over a car during a routine traffic stop later that day. When he stepped to the car's window, a gang member inside shot him with a stolen Ruger handgun. The bullet penetrated Zeppetella's bullet proof vest and hit him in the chest, severing an artery. Zeppetella returned fire but eventually died from his wounds. Soon after his death it would come to light that the manufacturer of the bullet proof vest had known for years that its products were defective, but the company had decided not to warn its customers.



Tony Zeppetella

Executives at Second Chance Body Armor knew as early as 1998 that the Zylon material in its vests that was supposed to be durable enough to stop a bullet was suffering from degradation problems that could render the vests penetrable. In a 2001 memo, written before Zeppetella's vest had even been manufactured, a Second Chance executive recommended the company "immediately notify our customers of the degradation problems," and went on, "lives and our credibility are at stake." In another memo dated 2002, company president Richard Davis outlined one of the company's "options," which included "operating as though nothing is wrong until one of our customers is killed or wounded."



-- Second Chance internal email

Second Chance did not warn its customers until September 2003, when it recalled 130,000 vests. In 2005, Second Chance recalled a further 98,000 vests, but even then did not recall all of its Zylon products because it claimed it did not have enough money to replace them.

Between the time the company discovered the vests' problems and the recall Second Chance sold vests to hundreds of thousands of law enforcement and military personnel. The vests were even worn by President George W. Bush and Mrs. Bush. Zeppetella had originally been issued a different vest but paid \$313 of his own money to "upgrade" to the Zylon vest.

Mega Bloks Magnetix

When Penny Sweet purchased two boxes of Magnetix toys from the supermarket for her son's 10th birthday in 2005, she could not have imagined that the building sets would cause lethal injury to her 22-month-old son, Kenny, comparable to a gunshot or stab wound. But that is exactly what happened.

Kenny was not allowed to be in the room when his older siblings played with the small plastic pieces that encased powerful magnets because they were a potential choking hazard to the young boy. But what the family did not realize was that some of the plastic pieces broke open, spilling small, powerful magnets into the carpet, where they could remain unnoticed by an adult or older child but could be found and easily swallowed by a curious toddler.

Kenny fell ill not long after ingesting the magnets. At first, his parents thought he had caught a stomach bug. What the Sweets did not know was that nine tiny magnets had attached together in Kenny's intestines and were slowly cutting off the blood supply to parts of his bowels, causing the tissue to die and allowing gangrene to set in. He died that night.

Following the death of their son, the Sweets filed a complaint with the Consumer Product Safety Commission (CPSC), the federal agency responsible for regulating consumer products, including the Magnetix toys. The toy's manufacturer, Mega Bloks, released a statement saying it had "no record or knowledge of a similar occurrence involving this toy." In fact, the company had received several complaints of magnets falling out of the plastic pieces and knew of at least one case in which a ten-year-old had suffered life-threatening intestinal injuries after ingesting magnets from the toy.

The company left more than 3 million building sets on store shelves for several more months. By the time the CPSC announced a voluntary recall of the product in March 2006, the agency had received notice of 34 injuries to children caused by the toy. At least 15 of those injuries occurred after Kenny died.

By the Numbers

1998	Year that Second Chance became aware of serious problems with the Zylon material in its bullet proof vests.
2003	Year that Second Chance executives finally took the defective vests off the market.
228,000	Number of vests eventually recalled. The vests were sold to law enforcement and military personnel and were even worn by President and Mrs. Bush.

Simplicity Cribs

In April 2005, nine-month-old Liam Johns of Citrus Heights, California, slipped through a gap in his crib after the drop rail on his Simplicity crib detached. His head became stuck and he suffocated to death. Over the next two years millions of Simplicity cribs, the most popular cribs in the U.S., were recalled in four separate recalls after multiple reports of failures and at least two more infant deaths. However, nearly two million more Simplicity cribs remained on the market. These, too, would eventually be recalled, but before that happened the company took an unusual business step to avoid responsibility for the deadly cribs.

One of Simplicity's creditors, Blackstreet Capital, acquired Simplicity in a foreclosure sale. Simplicity For Children (SFC) had now become the newly created SFCA Inc. The cribs were now resold under SFCA Inc.'s brand. Yet Blackstreet claimed it had bought the assets of the company, but not its liabilities. It would not be held responsible for the deadly cribs. It would not agree to issue a recall. When the CPSC issued its own warning, Blackstreet executives went so far as to criticize the agency, because they believed it might affect sales of their non-recalled cribs.

In 2008, a further 1.5 million cribs were recalled and two years later, in July 2009, 400,000 cribs with defective upgraded plastic hardware were recalled after at least 25 more incidences of drop-sides were reported to the CPSC.

They Knew and Failed To – Food Safety

Tainted Peanuts

Seventy-two-year-old Minnesota grandmother Shirley Almer was known for her can-do attitude and sheer determination in the face of adversity. She had survived lung cancer, a brain tumor and other illnesses, and was described as a “shining light” by her rehab nurses. But not long before she was due to check out from her rehab facility she began complaining of stomach cramps. Her family was with her as her health suddenly deteriorated and, the day before her scheduled release, she died. The cancer survivor was killed by salmonella-contaminated peanut butter in December 2008.

A month later in Oregon, three-year-old Jacob Hurley began vomiting and suffering from bloody diarrhea. His parents took him to a pediatrician, who encouraged them to try and get him to eat again. Jacob’s parents gave him his favorite food—Austin Toasty Crackers with Peanut Butter. When Jacob did not recover, his parents notified Oregon’s Office of Disease Prevention and Epidemiology (ODPE). ODPE tests found that three out of six packets of the Austin Crackers were contaminated with salmonella. Jacob’s parents had unwittingly been feeding him the very source of his problems. It took Jacob 11 days to recover.

Executives at The Peanut Corp. of America (PCA) knew their products were contaminated with salmonella, but put profits ahead of safety and continued to ship them to unsuspecting customers. The contaminated peanuts were distributed for use in more than 3,600 products. At least nine people died and over 700 were sickened before PCA finally agreed to recall all products it had produced in the previous two years. After the recall was announced, food manufacturers scrambled to determine if the contaminated peanuts could have made their way into other foods, including ice creams, cookies, cereals, and even dog biscuits.

Investigators eventually traced the problems to PCA’s Blakely, Georgia, plant where investigators found unsanitary conditions, including machinery held together by duct tape, roof leaks, mold and roaches. Until it was shut down, the plant had processed 35 million pounds of peanuts annually.

Food and Drug Administration (FDA) investigators reported “12 instances where the firm, as part of its own internal testing program, identified some type of salmonella,” and yet still released the product. In one instance, PCA President

By the Numbers

- | | |
|-------------|--|
| 2006 | Year that Peanut Corporation of America (PCA) executives became aware of salmonella contamination in its products. |
| 2009 | Year that PCA orders a full recall of contaminated products. |
| 700 | Number of consumers sickened by the contaminated peanuts |
| 9 | Number of people who died from eating contaminated peanuts |

Stewart Parnell concluded an email exchange about positive salmonella tests with the Blakely plant manager by saying, "turn them loose."

From: Stewart Parnell [REDACTED]
Sent: Thursday, August 21, 2008 1:31 PM
To: 'Sammy Lightsey'
Subject: RE: Micro

okay, let's turn them loose then...Stewart

-- Internal PCA email between PCA President Stewart Parnell and plant manager Sammy Lightsey

In another email discussing positive salmonella tests, Parnell wrote, "We need to protect ourselves and the problem is that the tests absolutely give us no protection, just an indication at best." Parnell would later refuse to answer questions at a congressional hearing.

"We need to protect ourselves and the problem is that the tests absolutely give us no protection."

-- PCA President Stewart Parnell

As the investigation into PCA intensified, the company was forced to shut down another plant in Plainview, Texas, after laboratory tests showed that products were contaminated with salmonella. State health investigators found unsanitary conditions, including dead rodents, rodent excrement, and bird feathers in a crawl space in the vicinity of production equipment. A ventilation system pulled air from the crawl space and circulated it into the production area.

The foul conditions at the Texas plant went unnoticed in part because the plant operated without a food manufacturer's license for nearly four years. The Texas Department of State Health Services fined Peanut Corp. \$14.6 million for its combined violations. The fine was the largest ever imposed by the department.

The FDA lacks the resources to regularly inspect food plants. Typically, the agency sends inspectors to facilities just once every five to ten years. In the absence of FDA presence, state health inspectors conduct food safety inspections. Georgia agricultural inspectors visited the plant in 2006, 2007 and 2008 and found only minor problems. Oscar Garrison, Georgia's assistant agriculture commissioner, defended the state's work, saying it is difficult to find deficiencies when the company is intent on "breaking the law."

PCA had hired private inspectors to conduct safety audits in an effort to strengthen its credibility with purchasers. One inspection firm, JLA USA found salmonella in 10 of 1,000 samples in 2007 and 2008. JLA's executives later told congressional investigators that PCA stopped using the lab because it found contaminants more

frequently than other labs. PCA instead turned to another lab, AIB International. Investigators found that AIB gave PCA a month's notice before conducting the audit, allowing the company to do a thorough cleaning in advance of the evaluation, and awards a "superior" or "excellent" rating to 98 percent of its clients.

Pistachios

In the wake of the peanuts scandal, another company, Setton Pistachio of Terra Bella, Inc., was forced to recall an entire crop of pistachios after one of its customers discovered salmonella during routine quality tests. A subsequent FDA investigation found cockroaches and rodent droppings at the pistachio plant and revealed that Setton executives had known for nearly six months that its products were contaminated but continued to sell them.

Pilgrim's Pride Poultry

In July 2002, executives at food company Pilgrim's Pride Corporation became aware of high amounts of a deadly strain of listeria in one of its poultry processing plants in Franconia, Pennsylvania. However, the company continued to distribute poultry products from the plant and issued no warning or recall notice to the public. The poisoned meat killed eight people, caused three miscarriages and sickened at least 50 more across the Northeast region of the U.S.

Karen Wysocki was seven months pregnant when she started to feel sharp abdominal pains. She was rushed to the emergency room where doctors discovered she was suffering from an infection that threatened her life and that of her unborn child. Doctors performed an emergency cesarean section. The infection was caused by listeria, which Karen ingested from eating Pilgrim's Pride products. Unfortunately for the Wysocki family, the infection spread to Matthew's brain and was more than he could fight off. He died six days after his birth.

The Centers for Disease Control and Prevention eventually traced the outbreak back to the Franconia plant, where regulators reported unsanitary conditions in processing areas, including roaches, flies, old meat left on the machinery, algae on the walls, and employees picking meat off the floors and sending it to the packaging area.

In November, four months after first finding the listeria in its plant, Pilgrim's Pride agreed to recall 27 million pounds of poultry products.

Excel Corporation Beef

Executives at Excel Corporation were repeatedly warned by regulators that food safety at its Fort Morgan, Colorado, meatpacking plant was in dire need of improvement, yet the company took no action to improve its food safety systems. The plant was cited 26 times in 10 months by the United States Department of Agriculture (USDA) after investigators found meat contaminated with bovine feces, mice, unsanitary knives and equipment, grease and rainwater coming into contact with beef, and carcasses being dragged across floors.

In July 2000, three-year-old Brianna Kriefall slipped into a coma after she and her family ate at a suburban Milwaukee restaurant that had received a shipment of beef contaminated with E. coli from the Fort Morgan plant. Brianna died of heart failure days later.

USDA investigators had found E. coli at the Fort Morgan plant, and Excel executives had pledged to eliminate it. The plant was shut down several times over the next few days as new violations were discovered almost immediately each time it reopened.

Oct. 1: "Fecal contamination observed...sample failed to meet zero-tolerance requirements."

October 2: "Identifiable fecal deficiencies on two carcasses (out of 11)."

Oct. 4: "Fecal contamination splotched in an area 1 inch by 4 inches...carcasses retained."

Oct. 9: "Deficiencies were observed in six carcasses (out of 11)."

-- USDA records of the Excel meatpacking plant

Just two weeks before Brianna came into contact with the E. coli, Excel invited the Associated Press to tour the Fort Morgan plant, where a reporter asked about the probability of tainted meat finding its way to the dinner plates of consumers. Dan Allen, Excel's food safety director, gave a cryptic response, saying "It's like a roll of the dice or a game of Russian roulette." Weeks later, Brianna was dead.

They Knew and Failed To - Automobiles

Firestone Tires

On a beautiful Saturday in March 2000, Donna Bailey, a 43-year-old mother of two, traveled with two friends to a climbing expedition in Texas in a Ford Explorer equipped with Firestone tires. One of the tires suddenly started to separate, and the Explorer skidded and rolled. Despite wearing her seatbelt, Bailey was left paralyzed from the neck down.

Defective Firestone tires on Ford Explorers took the lives of at least 271 people and seriously injured many more before the companies issued the largest tire recall in history. Internal company documents would later show that the two corporations had known of the deadly tire separation and associated rollover problems for years. Firestone knew by at least 1997 that there were serious problems with its tires. Vehicle owners began sending complaints of tire failures in a rate 100 times greater than normal. Firestone employees would later state that they punctured bubbles in tires to conceal flaws and that inspection of finished tires was nonexistent.

By the Numbers

- 1997** Year that Firestone executives began discussing concerns about the ATX and Wilderness AT tires.
- 2000** Year that Firestone finally announces a recall of more than 6.5 million tires.
- 271** Number of people killed in accidents involving Firestone ATX and Wilderness AT tires.

So I am asking what is going on? Do we have to have a fatality before any action is taken on this subject?

-- 1998 letter from Ford dealer to Firestone executives complaining that nothing had been done about tire problems he had highlighted 12 months earlier.

In May 2000, at least three years after Firestone had learned of serious problems with its tires, the National Highway Traffic Safety Administration (NHTSA) opened an investigation into the tread separations. In August 2000, Firestone recalled 6.5 million tires. The following month, NHTSA warned the company that over a million more tires had worse problems than the recalled tires. Firestone refused to order another recall.

Firestone officials later defended their lack of action, saying, "We've got such a high volume of tires that looking for the root cause of the problem is like looking for a needle in a haystack." They were undeterred by federal regulators at the National

Highway Traffic Safety Administration, which only had the power to impose a maximum fine of \$925,000.

It was through the civil justice system that Donna Bailey was able to obtain some measure of justice. As part of her settlement, Ford agreed to release internal documents about the tire and rollover problems, and executives visited her to personally apologize.

Ford's "Illusory Park"

Between 1970 and 1979 the Ford Motor Company manufactured automobiles with a defective automatic transmission design. This defect produced an "illusory park" position, giving the driver the impression that the car was secured when in fact it was not. Vibration or slamming of a car door could cause the car's transmission to slip out of the "park" position and into reverse gear. About 90 injuries and deaths were reported as a result of this defect.

A "smoking gun" interoffice memo discovered during litigation established that Ford engineers had been aware of the "illusory park" problem since 1971 but had taken no action to correct it. The trial jury found the transmission design defective and, critically, that Ford had failed to give drivers adequate warnings of the problem. Ford finally eliminated the "illusory park" position hazard after it lost two lawsuits filed by people injured as a result of the design.

Chevy Malibu

General Motors knew for several decades that the placement of the fuel tank in the Chevy Malibu created an unreasonable risk of exploding in the event of a rear collision. An internal GM memo obtained during litigation over injuries sustained from the defective design showed that the company estimated

1. In G.M. automobiles there are a maximum of 500 fatalities per year in accidents with fuel fed fires where the bodies were burnt.
2. Each fatality has a value of \$200,000.
3. There are approximately 41,000,000 G.M. automobiles currently operating on U.S. highways.

Analyzing these figures indicates that fatalities related to accidents with fuel fed fires are costing General Motors \$2.40 per automobile in current operation.

$$\frac{500 \text{ fatalities} \times \$200,000/\text{fatality}}{41,000,000 \text{ automobiles}} = \$2.40/\text{automobile}$$

that deaths resulting from post-collision fuel-tank fires cost General Motors \$2.40 per car. This calculation was based on an estimate that each life "has a value of \$200,000." Internal memos also showed that the company had developed an improved design that would do a better job of protecting the gas tank in collisions. Improving the design would cost the company \$8.59 per car. Yet, GM executives decided not to make this change.

-- Internal GM analysis document

GM managed to hide the memo from civil justice attorneys and keep it out of court for decades until 1998, when a judge allowed it to be entered into the record as

evidence, saying, "This Court advised General Motors that it is not 'big enough to thumb its nose at the court,' and that it is not 'big enough to interfere with the orderly administration of justice,' and that it is not 'big enough to obstruct justice or conceal evidence.'"

Ford Pinto

Arguably the most infamous example of "they knew and failed to," Ford Motor Company was well aware that its Pinto was a potential death trap, but chose not to fix the problems. Ford knew from crash tests that the Pinto's design rendered it liable to explode in rear-end collisions at speeds as low as 20 miles per hour. An internal memo from 1973, just two years after the Pinto's launch, estimated that fixing the problem would cost just \$11 per car, but that it would be cheaper to let people die. The same memo estimated the eventual death total at 180, with another 180 suffering serious burn injuries. Ford did not recall the 1.5 million Pintos for another five years.

BENEFITS & COSTS ANALYSIS		
<i>Excerpt: Ford Inter Office Memo, September 18, 1973</i>		
BENEFITS		
180 burn deaths	\$200,000 per death	\$36,000,000
180 serious burn injuries	\$67,000 per injury	\$12,060,000
2,100 burned vehicles	\$700 per vehicle	\$1,470,000
		\$49.5 Million
COSTS		
11,000,000 cars	\$11 per car	\$121,000,000
1,500,000 light trucks	\$11 per truck	\$16,500,000
		\$137.5 Million

-- Internal memo from Ford Motor Co.

They Knew and Failed To - Environmental

BP Refinery

In 2005, a catastrophic explosion at an oil refinery in Texas City, Texas, owned by the British industrial giant BP, killed 15 refinery workers and injured 170 more. The blast was felt up to five miles away. In the weeks leading up to the blast the Occupational Safety & Health Administration (OSHA) had warned BP of serious safety violations and placed it on a watch list of companies “with the gravest violations who have failed to take their safety and health responsibilities seriously.” In the previous decade BP was responsible for a quarter of all refining industry deaths in the U.S. An investigation after the Texas City explosion found numerous safety protocols had not been followed or had not worked correctly.

Twenty-year-old Eva Rowe lost both parents in the blast. While BP tried to settle all claims stemming from the explosion confidentially to avoid publicity, Rowe refused to accept justice in secret. On the day jury selection was due to begin, the corporation agreed to a remarkable public settlement. BP admitted that it had been negligent, apologized to Rowe and the other families and injury victims, and donated more than \$32 million to medical and safety-oriented institutions and to two of the family’s favorite organizations. The first donation went to the Blocker Burn Unit in Galveston, where nearly two dozen BP victims were being treated.



-- Eva Rowe with a photograph of her parents,
James and Linda Rowe

BP also agreed to release internal documents from the case, so that the public could see the evidence of the corporation’s negligence and the energy industry could analyze how future refinery explosions could be prevented. The lessons learned from those records will set new industry standards and prevent future accidents.

Asbestos

Perhaps no product in history is a better example of corporations knowing that they were marketing deadly products and covering up the evidence for profit. By the 1930s, asbestos manufacturers were aware that their workers were dying at alarming rates. Yet they covered up the dangers for more than half a century. Between 1979 and 2001 approximately 230,000 people died from asbestos-related causes.

My answer to the problem is: if you have enjoyed a good life while working with asbestos products why not die from it. There's got to be some cause.

-- 1966 internal memo from the Canadian Johns Manville Co.

In 1966, one company executive wrote, "if you have lived a good life from asbestos, why not die from it." It was just one of many internal documents from asbestos company executives acknowledging that they were killing people. An 1988 industry memo concluded "there are so many embarrassing documents that people disagree as to which group of any ten documents is the worst."

DuPont's Benlate Fungicide

DuPont came under fire in the early 1990s when its fungicide, Benlate DF 50, was linked to serious birth defects, including children born without eyes (anophthalmia) or with microphthalmia (underdeveloped eyes). As early as the 1970s, scientists were linking exposure to benomyl, the primary chemical in Benlate, to anophthalmia and microphthalmia in lab rats. The EPA even recommended that DuPont add a warning label to the chemical, saying "Exposure to benomyl during pregnancy should be avoided." DuPont refused. DuPont faced numerous lawsuits over Benlate from parents whose children were born with abnormalities, as well as farmers who claimed that the company was aware that the fungicide caused serious damage to crops yet continued to market it anyway. DuPont pulled Benlate from the market in 2001. Additionally, the EPA filed a complaint against DuPont for failing to report possible human adverse events in a timely manner.

Velsicol Chemical Co.

In 1964, city officials in Memphis, Tennessee, ordered Velsicol Chemical Company, a pesticide manufacturer, to stop pouring chemical byproducts into city sewers and dumps. Rather than incinerate its waste, Velsicol chose the cheaper alternative of burying its toxic chemicals in 55-gallon drums on farmland in Hardeman County. The company buried over 300,000 drums between 1964 and 1973, many of which were broken by bulldozers making room for more. The chemicals seeped into the water supply.

By 1977, Hardeman County residents were developing serious health problems. Daniel and Patsy Johnson's daughter got sick and her vomit bleached their wood kitchen floor. Others noticed that their eyes burned when they showered, that white powder would be left on dishes after they went through the dishwasher and that the air constantly smelled like bug-spray. The EPA found carbon tetrachloride, chloroform, benzene and trichloroethane in the water.

Over 100 residents of Hardeman County filed a lawsuit against Velsicol for negligently contaminating the groundwater with toxic chemicals. After two years, the judge found that Velsicol engaged in "gross, willful and wanton negligence." The case produced a landmark ruling, as it represented the first time a court said that chemical waste dumping is inherently dangerous.

Hayden and Craig Power Plants

The Mt. Zirkel Wilderness Area in Colorado is popular among hikers, fisherman, and outdoorsmen for its breathtaking mountain views, glacial lakes, and abundant wildlife. Unfortunately, for years, the area has not been as pristine as it appears. Pollutants from the coal-fired Hayden and Craig Power Plants in Yampa Valley, Colorado, would travel miles downwind and land in the forest, marring the area with the highest acidity levels of any federally monitored site west of the Mississippi.

In 1993, the Sierra Club sued the Hayden plant's owners for 17,000 violations of the Clean Air Act. The owners of the Hayden plant argued that their own emissions records from smokestacks should not be considered evidence in the lawsuit. The judge disagreed. Once their own records could be used against them, Tri-State settled the case, agreeing to spend \$130 million for pollution control upgrades, pay the U.S. government \$2 million in civil penalties, and spend \$2 million on environmental conservation projects in Yampa Valley.

After the settlement, it was expected that the owners of the Hayden plant, who were part owners of the Craig Power plant, would voluntarily upgrade the second plant to the same standards. They did not do so, forcing the Sierra Club to file a second lawsuit against the Craig Power Plant in 1996. Lawyers for the defense tried to prohibit evidence from the Hayden case from being used in the Craig case, but were denied. In 2001, the owners of the Craig plant were ordered to spend \$160 million on pollution controls, pay \$500,000 in penalties and pay \$1.5 million into a renewable energy fund.

Conclusion

The stories mentioned here are just a sample of “they knew and failed to.” There are, unfortunately, many more stories. Drugs such as Zelnorm, which was used to treat irritable bowel syndrome but also increased the risk of heart attack and stroke, the Duragesic patch, which could administer a lethal dose of powerful narcotics, toys made with lead or the children's CSI Fingerprint kit, made with asbestos; the devastating effects of toxic pollution in the Love Canal, the PG&E case, or the Woburn case made famous by the film “A Civil Action.” The list goes on and on.

The fact that corporate executives so frequently make such callous decisions, and have always done so, shows the need for America's civil justice system. At a time when many advocate closing the courthouse doors, these stories give an indication of the dangers we would be exposed to without its protections. When government regulation can offer little more than a slap on the wrist and a small fine, the civil justice system is necessary to both detect such outrageous behavior and deter it in the future.

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