Bad Pharma

by Pam Lazos and Abraham Johns, M.D.

Tagline: When the physician overseeing a failed clinical trial is fired trying to protect the health of the children enrolled, he subverts the system to save them, imperiling himself and those he loves most.

Warning: This story is inspired by actual events, dramatized, and embellished for entertainment. The underlying gravity of the situation — standard in the world of Big Pharma — is as real as it gets.

CHAPTER 1

Nora O'Connell snorted in disgust as torrents of rain turned the corporate office parking lot into a muddy brown river. Her computer screen, dark and uninviting, sat next to a single box of personal items, packed and ready to go: a few marketing books, a pair of stone pyramid bookends, a coffee mug with the Greek meander key ringed around the top, a carton packed with dozens of instant ramen packets, a small digital clock, and a picture of her and her best friend on a canopy tour in Costa Rica.

"Hey, Ed. Y'ever do something so foolish that you instantly regretted it?" Nora pushed a lock of her short, sandy blonde hair behind her ear and turned her svelte figure to face him.

The security guard stood at the door, picking at a hangnail on his left thumb. Nora took note of the Glock placed in the holster on his right hip and thought it more security than needed in a corporate pharma office in suburban Philadelphia.

"Yeah, sure, like once an hour." Ed tried for a bite at the wayward nail but didn't get much traction, spitting out what little his teeth could grab. "I'm real sorry about this, Nora. I wish there were something I could do."

Nora re-routed her gaze from the window as Ed's voice trailed into oblivion. He relinquished the hold on his cuticle long enough to give her a meaningful uptick on the right side of his mouth. Beneath Nora's neutral gaze lurked a facial expression indicative of pain, the fifth vital sign popularized by Big Pharma after body temperature, pulse, respiration, and blood pressure. The original four vital signs were described by Hippocrates, the ancient Greek who penned the catchy oath that doctors recited when they got their license to practice. The fifth one, pain, was "invented" by pharma marketers looking to give a whole new class of drugs a raison d'etre.

"Thanks Ed. If you had that kind of clout, it would be them walking out, not me." Nora reached for the box, but Ed got there first, hoisting it to his shoulder with ease. Nora graced him with a sad smile. Once outside, she opened the door, and Ed placed the box on the back seat of her silver Prius. Nora nodded her thanks, closing both the door and this chapter of her resume. Ed gave her a small salute, turned, and walked back inside the building. The sky opened as Nora pulled out of the parking lot, and a curtain of rain descended, pounding the Prius like rapid gunfire and obliterating her view on the street so Nora couldn't see the moving van, almost upon her, as she pulled out of the lot. The crunching, breaking, and grinding of metal, glass, and plastic infused the ambient air inside the car as Nora's world faded to black.

***

Two hours, a quick Peloton class, a cup of coffee, and a shower later, Nora managed to shake off the remnants of her unsettling dream as she drove her usual route from Center City Philadelphia to the King of Prussia suburbs where many of Philadelphia's Big Pharma companies resided. To Nora, every commute on the Schuylkill Expressway was a thrilling adventure. The two-lane highway had never been expanded to meet the population explosion of greater Philadelphia, so traffic waxed and waned like the tides. Nora couldn't help goose-necking whenever she drove out of town, looking with pity at the hordes of backed-up cars crawling toward town during rush hour. She was grateful for the reverse commute – giving her all the joy of an urban lifestyle without the pain of bumper-to-bumper traffic like those poor souls on the other side of the highway.

Nora walked the nine flights of stairs to her office. She prided herself on never taking the elevator, giving her a reliable comeback whenever Nick chided her for failing to work out regularly. At 8:30 a.m., a smartly dressed Nora, already at the office for the last hour, entered the conference room for the day's first sales meeting. Nick was sitting in the back, nervously twirling a pen like a drum

majorette with a baton. She watched him watching her through the glass wall of the conference room and graced him with a devious smile.

"You look like shit," Nora said upon entering.

"Thanks, Nora." Nick fixed her with a gimlet eye and a short smile.

Nick Rooney, Head of Vaccine Business Development, had defected from the competition three years earlier. He was a brilliant marketer, and Dr. Terrence Saunders, his old college buddy and the overall Franchise Lead of The Vaccine Division, had recruited Nick to take charge of OPL's — Onward Pharmaceutical Labs — flagging vaccine enterprise. A year ago, Nora heard via the office grapevine that Nick's marriage had dissolved from disinterest, so Nick had left his petty, money-loving wife and only daughter, Delilah — at the time thoroughly ensconced on Team Mom — and got himself a condo along the Delaware River. Six months later, he'd asked Nora out, and she'd accepted. Nora had taken note of his impeccable training: an MBA from Harvard after an undergraduate degree in biochemistry from Dartmouth, but what impressed her the most, outside of his obvious good looks, was his wise, thoughtful approach to leadership. She marveled at his unique ability to schmooze opponents silly while still following the science, and Terrence, especially, loved him for it. They'd spent the last six months together, and in Nora's opinion, they were a pretty good fit, although what Nick thought was anyone's guess, jaded as he was about love.

"You know, you have such beautiful blonde hair. Why do you dye the roots black?" he asked, one side of his mouth quirking up in anticipation of battle.

Game on. Nora lifted her chin, straightened the shoulders on her white silk blouse, and worked to tuck it in, accentuating her trim yet ample figure. She stuffed a lock of hair behind her ear, feigning injury.

"Lovely. Grand. I'll remember that one," Nora said in an Irish brogue that found its footing whenever she became animated.

Nora had come to the States in the 1980s when the U.S. was short on nurses. Many credentialed young Irish nurses had taken advantage of the offer of relocation fees and a chance for travel, coming over on limited visas, happy to see a bit of the world and make a few bucks in the process. Unlike the rest of Nora's friends, who returned to Ireland when their tenure was up, Nora had fallen for an American and never left. Her discontent with the practice of nursing — punishing hours, little respect, more patients than one person should reasonably be assigned — pushed her out of hospital nursing and into private practice. After watching the doctors in the practice burn out, one by one, she decided it was time

to jump to pharmaceuticals where the real money was. She was recruited by OPL's Vaccine Sales Unit as a Medical Science Liaison, a unit generally comprised of attractive females with a medical background who could use a tight skirt or an open blouse to get 5-10 minutes of a chauvinistic practitioner's time to explain the benefits of new drugs and vaccines springing forth from the OPL pipeline. Nora theorized that busting her ass working long hours would be better to do on weekdays rather than the evenings, nights, and weekends so often associated with clinical work.

Additionally, she preferred to be paid well, eat well, and sleep in fancy hotels. Being on call in pharma meant traveling to a lovely destination and enjoying a fine meal, followed by drinks, dessert, and seven hours of sleep in a five-star hotel, much nicer than being up all night checking vital signs, dumping bedpans, and responding to fever calls.

"You and Lovey have another spat?" Nora asked.

Lovey was Nick's ex-wife, Dana, who couldn't stop helping herself to Nick's money with her never-ending stream of requests on behalf of their daughter, Delilah, despite already taking more than 50 percent of the assets in the divorce. Nick always acquiesced because he felt guilty for getting Dana pregnant and encouraging her to quit school and finish her degree later when Delilah was older. Years turned into decades, and Dana started back to college around the same time as Delilah. With a child and an ex-wife now in college, the financial demands kept coming, and Dana, the canny opponent, was not averse to playing the guilt trip card to get what she wanted.

"No. Just work stuff. I'm a bit on edge. Terrence is pushing this new drug rollout, and the numbers aren't all in." He shrugged and pushed himself up to standing. "Showtime." The conference room with chairs for two dozen people was full of attendees who had arrived at the salesforce *Come to Jesus* meeting armed with their morning coffee.

"Ladies and gentlemen, shall we get started?" Nick asked as he walked to the front of the room.

Nick tossed Nora a *here-goes-nothin*' look that only she could decipher and began handing out packets of information several inches thick. He oozed a classic handsomeness and *joie de vivre*. A gal could do worse than a self-made, successful man with impeccable features and great taste in clothes. Nora's marriage had dissolved several years before when she chose her pharma career over a staid and lackluster husband, which Nick definitely was not. She noticed

his well-manicured hands as he passed out reports to those assembled, noting that his cuticles were better cared for than her own.

"Today we're talking about RSVIX. Tomorrow we'll be talking about RSVIX. Next week we'll be talking about RSVIX. Next year we'll be talking about RSVIX. That's because RSVIX represents our future, and we are all about making it the greatest medical advance since penicillin." A few people groaned. Nora rolled her eyes. Nick continued.

"True, we didn't make the first RSV vaccine, but we are just wrapping up our landmark Phase 3 BREATHE trial — Beat RSV and breathe easy! — with the new best-in-class vaccine for this indication, and that's what counts." Nick stopped and smiled at the sales team. "We've enrolled the last patient in the clinical trial — and you know what that means."

Sam, one of the sales team members, said, "It means the ball is heading over the fence and . . . IT'S TIME TO GO SHOPPING!" The room laughed before Nick continued.

"With a bit of marketing, some education of the professional community, and some good old-fashioned salesmanship, that's exactly what it means, but thank you, Sam, for giving us some insight into your personal motivations." Sam flashed a double thumbs up, and Nick continued.

"Anyway, it's full speed ahead until we cross the finish line, so much so that we're refocusing all efforts on this, people." The room burst into spontaneous applause. Nick raised his hands to silence the crowd like a politician at a campaign rally.

"We're crunching the numbers and are a few months away from an official marketing launch. You have a brief synopsis of results to date in front of you, but I wouldn't waste time reading it because the Phase 3 results will soon be coming, forming the basis of the pitch. Besides, there are only two things you need to know: 1) RESPIRWELL, the vaccine Beamer Labs released a year and a half ago, protects against four strains of the respiratory syncytial virus known as RSV. RESPIRWELL has a $7 billion market share. 2) Our vaccine, RSVIX, will cover all the RSV strains that Beamer's vaccine covers, plus five additional ones. That's nine strains covered — hence the IX at the end of RSVIX — and a pretty sweet name, I'd say. Better coverage equals better market share. The four serotypes that RESPIRWELL covers represent about 64 percent of the disease in North America. Our five new serotypes cover an additional 16 percent of disease getting the total coverage to 80 percent! Assuming this all plays out, we're about to get our hands on at least 40 percent of a $7 billion market in year one alone! More if

you get excited." Nick picked up the fat binder in front of him and held it up. "The financial projections are amazing. If this isn't a winner, I never saw one."

The room was quiet, expectant. Some looked at their binders reverently. Others sat open-mouthed, starstruck.

"We're about to raise the bar once again." Nick dropped the tome on the table. "RSVIX. We're not first in class. We are *Best in Class*. That's your mantra, people, and you need to start shouting it out loud to anyone who will listen. Call your docs. Call your hospitals. Call your clinics. Talk it up like it's the Second Coming. Insinuate that there may be a waiting list for doses if they don't act quickly. Create the need. Create the desire. Make them feel like they'll be left behind if they don't act now."

"Surely you're not proposing that we start selling a vaccine that hasn't even gotten FDA approval yet?" asked a voice from the back of the room. Nora turned. Siddhartha Kumar — Sid to his co-workers — the Indian doctor assigned to monitor the clinical trial, sat off to the side, apart from the group, his large black eyes scanning the room. Sid had worked at OPL for almost a decade, having had the unfortunate experience of being the medical monitor for the notorious weight loss drug Bonifidia, touted by OPL as the most important drug to hit the market since penicillin, only to find out it caused severe, life-threatening side effects, forcing them to take it off the market two and a half years after launch. The fallout from this misadventure was horrendous: lousy press, a terrible public image, and a litany of lawsuits. Sid took his share of the heat for all of this as he was the medical monitor assigned to the Bonifidia program and thus charged with safeguarding the patients in the clinical studies. A review of OPL's clinical trial data done after the cases surfaced showed subtle yet clear signals that side effects had been evident in the clinical trials done before licensure. Sid almost lost his job, but OPL ended up supporting him through the process – mainly because Sid had reported the signals to management before OPL applied for the drug's licensure and was overruled by superiors who wanted to suppress that specific information. Sid's records of these discussions were the reason he'd kept his job. Having learned from the Bonifidia fiasco, Sid refused to take any risks with RSVIX. His caution and meticulous record-keeping had become a necessity.

Nora gave Sid the once over — thick black hair, large eyes, straight nose, sturdy shoulders, and a strong neck — and a thrill ran through her body. Rumor had it that Sid was damaged goods, having lost a wife and a child in a horrible tragedy. Sid was a bit of a recluse who never put himself out there, so hard to know the real deal, but Nora understood firsthand what losing a loved one could do to a person and how tough it was to engage with the real world after that. It wasn't as if she was in the market for a new boyfriend. Nick made a sturdy and

thrilling partner, so it was hard to decipher why this study physician — the name given to clinical trial monitors — set her spirits rising like a reed-blowing snake charmer. A woman wants to be cherished, not tossed aside like smelly socks, only to be turned inside out and used again when there's no clean laundry. That was Nora's ex, for sure, but not Nick. He was a cherisher, and she had nothing to gain by looking elsewhere. Frankly, after such a bad turn at marriage, she'd be happy to land with Nick, but the jury was still out on whether he had what it took to get there. After six months of dating, they were still in the casual phase, and since nothing was permanent, it never hurts to raise one's head from time to time. From the looks of him, Sid had potential. Nora noted that he routinely saw the inside of a gym, unlike her ex, who only managed to visit the refrigerator and the television religiously.

Corinne, one of the salespeople in Nora's branch, leaned over and whispered, "Is he in sales now?"

"No," Nora said, "He's in research, but I'm pretty sure he's not happy that Nick's organizing the troops before he's had the chance to analyze the trial data and ensure the science is right."

"He's hot, huh?" Corinne said.

"Oh yes, he is," Nora responded, blushing. "But I never said that."

"Sid, c'mon up. Now would be a great time for a little tutorial," Nick said. Sid walked to the front of the conference room with the self-assuredness of a lion.

"Sid is the medical monitor in charge of the RSVIX clinical trial. You can direct all of your questions to him."

"Good morning, everyone. As Nick said, I am the medical monitor on the Phase 3 RSVIX study, also known as the BREATHE Trial. Phase 3 is the final phase prior to licensure and follows the positive results from the Phase 1 and Phase 2 studies. The BREATHE trial randomly assigned 520 infants either to RSVIX, our vaccine, or RESPIRWELL, the currently licensed product produced by Beamer Pharmaceuticals. Half received RSVIX, and half got RESPIRWELL. This was a non-inferiority trial, and therefore, there was no placebo group, just the head-to-head comparison. That's because it is deemed unethical to randomize a child to a placebo when there is already a licensed vaccine out there that is standard of care. The children were then followed for the next two years to compare both the immune response and the efficacy of the two different vaccines for the prevention of an RSV infection. With the last visit of the last patient now completed, we can wrap up the clinical trial, lock the database, and analyze all of

our information. However, until that point, we should not jump to any conclusions and not sell anything. Remember, the science drives the business, not the other way around." Sid smiled, but the seriousness of his tone belied the gesture. "Until I have finished my review of the data, I think the best course of action here would be temperance. We do not want to make any promises we can't keep, right?" Sid looked at Nick, who reciprocated with a smile resembling bared teeth.

"Why don't you give us a little rundown of the vaccine, Sid, so that the team can tailor their sales pitch?" Nick said. Sid leveled a gaze at him, nodded once, and began.

"You may recall from when you first joined the sales team that infectious disease is generally caused either by a bacterium—a single-celled organism that can live on its own — or a virus, an acellular entity that requires a living host for survival, kind of like your average teenager." Chuckles from the assembled group bounced around the table.

"RSVIX zeroes in on any one of nine common strains of the respiratory syncytial virus that it protects against by disassociating the virus from its host cell. It does this by locking these viral strains out of the human cells they need to live in, much like taking the car keys from your adolescent. Without a host to live off of, this viral teenager cannot survive. Without a home to hide in, the virus is identified and destroyed by the immune system and never gets a chance to colonize and reproduce in the lungs. Little Jimmy ends up with a runny nose and a mild cough but none of the life-threatening aspects of bronchiolitis that have plagued young children for decades.

"RESPIRWELL and RSVIX both target the same virus — RSV, the Respiratory Syncytial Virus. RSV is responsible for about 66,000 deaths in infants and 234,000 deaths in young children in the United States each year. Countless additional illnesses are associated with discomfort, difficulty breathing, and sometimes hospitalization. As you may know, RSV is the single most deadly virus targeting children under two years of age. The first experimental vaccine, developed in the 60s, made matters worse rather than better, setting up vaccinated children for more severe illnesses when they were exposed to the real virus. Several kids who had been vaccinated died following RSV exposure, presumably from an overactive immune response. That dark cloud discouraged vaccine manufacturers from opening Pandora's box again for decades until Beamer finally devised a vaccine that worked. RESPIRWELL targets the four most common strains of the virus in North America. Our vaccine, RSVIX, covers those same four plus five additional ones. We expect that RSVIX will reduce the number of RSV-related hospitalizations, sick visits, and deaths dramatically, but

until we crunch the numbers from the clinical trial, we won't know what we have, which is why we need to look before we leap."

The room went as still as the air inside a mausoleum. The sales force had received Sid's message; Sid and Nick were not on the same page.

"Thanks, Sid. We'll be looking forward to future updates." Nick dismissed Sid with a wave of his hand. Sid set his jaw but inclined his head graciously.

"Any questions about the clinical trial, feel free to contact Sid." He nodded in Sid's direction. "Although you guys already have most of the information you need in that packet. Any other questions, see Nora. She's been put in charge of this rollout, which is kind of a big deal," Nick said and started clapping.

The audience clapped, and there was even a whistle or two while heads nodded in approval. Nora smiled, surprised that Nick had chosen this moment for the shout-out, especially since she had not officially received the green light from Terrence.

"I'm looking forward to seeing what this team can do," Nick said. "If you get your game plan going now, by the time the trial is complete, you will have already launched us into the stratosphere with new sales."

With their next few months of work prescribed, the sales team filed out, and the meeting adjourned. Sid held back to talk to Nick, but Nora was already on her feet and at Nick's side before Sid could make his way across the room. She had a million things to say to him, the first of which was thanks, and from two dozen feet away, Sid could tell it would be a long wait.

Six weeks later.....

CHAPTER 7

Six weeks after the kerfuffle with Nick at the sales team meeting, Sid sat in a small conference room with Terrence Saunders, Senior Vice President of the Vaccines Group, Louis Poll, Sid's direct supervisor on the BREATHE trial, and Eugene Newman, overall Lead of OPL's Product Development Division. Everyone who even remotely dealt with vaccines at OPL ultimately reported to Terrence, who never tired of reminding them who was in charge. Terrence started his career at OPL as a medical monitor — the same position Sid currently held.

Terrence's salt and pepper hair, soft grey eyes, and rugged, outback looks gave him a likable, everyman appearance — the face of someone you could trust — and probably played just as much of a role in his meteoric rise up the ranks as did his combination of scientific and business acumen necessary for career success in Big Pharma. Sadly, that very rise altered him, and these days, he acted more like a businessman with a medical degree than a physician making business decisions.

Thanks for coming, Sid," Terrence opened. "We wanted to talk to you about your report." Everyone reached for Sid's conclusions, neatly printed in the binders before them. Terrence flipped to the executive summary.

Right here, after the finding of failure to reach non-inferiority on three of the four serotypes common to both RESPIRWELL and RSVIX, you state that 'RSVIX is ineffective.' Further, it is your opinion that 'all pediatricians involved in OPL's BREATHE Trial should be given a copy of the study results and offered the option of giving subjects who received RSVIX a dose of the licensed vaccine as a booster for added coverage of the four serotypes shared between the two vaccines. You then suggest that 'in cases where the pediatrician is uncertain of the recommended action, the licensed vaccine should be given as a precaution.'" Terrence stopped reading and locked eyes with Sid. "Putting aside the obvious — that we're all deeply disappointed our multi-billion-dollar asset is unlikely to be licensed — would you mind telling us why you think RESPIRWELL — our competitor's product — must be given at all?"

Sid had been expecting resistance, especially from Terrence who had previously denied Sid's appeal to take a closer look at the Bonifidia safety data when Sid brought it to the committee. Sid hated this guy, expected his response, and had practiced rage control in preparation for this meeting, imagining himself to be a leaf floating on a river, at ease and without a care for where the current might take him. When his anger flared, as he had expected it might, he turned his thoughts to the river, buoying his sense of weightlessness as he floated downstream.

It's a relatively straightforward medical argument," Sid said, almost swaying in his seat with the gentle flow, his mind in two places at once. "We know that RSVIX didn't meet the non-inferiority standard for at least three of RESPIRWELL's four serotypes. That means those receiving our vaccine did not get the immune response they would expect to have gotten from the licensed vaccine. The inferior response caused by RSVIX puts them at a higher risk of contracting RSV from the common strains the licensed drug was already protecting. To ensure protection, these children should receive a booster shot of Beamer's vaccine. It's not optimal, but failure to do so puts them at unnecessary

risk due to their participation in this clinical trial and is thus unethical." Sid's hands remained in his lap while his body floated on the river.

Well, Sid," Terrence cut in, "even though the vaccine didn't work as well as RESPIRWELL for some of the strains shared by the two vaccines, it added protection for five new serotypes that RESPIRWELL didn't cover, providing additional protection that wasn't previously available. Surely, that mitigates the additional risk." Terrence was not asking; he was telling.

Sid turned to face Terrence, disregarding his threatening tone. It's hard to get riled up while floating on a river.

Yes, RSVIX elicits an immune response to these five additional serotypes, but as of now, we have no idea whether that immune response translates to clinically proven protection from infection by those strains. We know they responded but don't know if their antibody levels were sufficiently high to afford protection. Only efficacy data can tell us that; all we have are antibody levels. Plus, the amount of disease caused by the four serotypes for which RSVIX performance is inferior is much larger than the five new serotypes we are protecting against — something like 64 percent versus 16 percent — so the chances are greater that those kids will get infected by one of the four original strains than the five we have added. It's not our place to make medical decisions about whether the vaccine is good enough. That decision belongs to the treating pediatrician. We are not the caretakers of these children; we're a pharma company. We don't have the authority to decide what's good enough here."

As these words left Sid's mouth and entered Terrence's brain, an internal debate played out inside Terrence's head. The physician-scientist in Terrence understood Sid's argument had a lot of merit, but the businessman in him stomped his greedy little feet and shouted to abort that line of reasoning as it could damage the company's reputation. In a few seconds, Terrence sided with his inner businessman and proceeded.

That's ridiculous. Doctors don't have time for this nonsense." Terrence rolled his eyes. "It's unfair to put the pediatricians who administered the vaccine in the middle of all this by giving them study results they're not used to seeing and then asking them to make a clinical decision based upon that information. They don't know how to interpret antibody responses. We need to think for them or, at the very least, give them the results with some guidance on interpreting them. We're the manufacturer. We deal with antibody levels all the time. That's our job."

A sunbeam argued its way past the blinds and landed on the corner of the desk. Sid smiled, happy to have an accomplice, and focused on the trickle of light. Sid's leaf had been traveling the calm, sunny side of the stream, but now, plunged into deep shade, it bounced along, encountering some difficulty in navigating a series of rapids.

He surveyed the conference room. Those present looked down at their notepads, or away, fidgeting with their coffee cups or pencils. Their body language did not convey comfort, and Sid didn't see a single supporter in the room.

The calm water had turned rocky, and the leaf was thrust about. Sid took two deep breaths, trying to find his way to placid waters before he spoke.

I understand, Terrence, but I respectfully disagree. The children in this trial may never even be exposed to the Respiratory Syncytial Virus. Still, the fact that we don't know who will and who won't, combined with whether the protection they got was adequate, puts the onus on us to take immediate action. I believe we should reach out to these pediatricians now."

Terrence jumped in. "Yes, yes, but the data, Sid? How are the pediatricians going to digest the immunogenicity data? It's like reading a foreign language. More importantly, there's no way to conclude that the risk of giving the test subjects an additional vaccination doesn't outweigh the positive aspects of such theoretical additional protection. How do we even know that the kids who received the experimental vaccine won't do worse once they get the booster of the licensed drug?"

The words oozing from Terrence Saunders' mouth did not sound genuine. Terrence was a good scientist, and he'd made several good points, but in his gut, Sid knew Terrence was trying to use his intellect for self-serving business interests. The Bonifidia nightmare had taught Sid all he needed to know about Terrence Saunders. He had witnessed Terrence incisively and accurately analyze complex medical data. His ascent up the ranks, however, had warped his perspective. Power and greed now ruled the day, biasing his decisions in a way they never had before. Whether or not Terrence had any insight into any of this was unknown. What was clear to Sid was that Terrence was lying — even to himself.

"We don't know, but this is a clinical decision and should be made by the patient's doctor, not the vaccine manufacturer. Our responsibility is to alert the physicians involved in the clinical trial, give them the information they need to make the best decisions they can for their patients, and then step back. We're a

drug manufacturer, not a caregiver. The parents who agreed to allow their children to be part of this trial have not entrusted their children's care to OPL but to their pediatrician, meaning those pediatricians must decide what is an appropriate means of best protecting them in this situation. You're removing the physician's choice while leaving them to handle the repercussions."

Let's not forget that these families consented to participate in the trial and, therefore, have waived certain rights," Terrence said. Saunders's tight-lipped response told Sid everything he needed to know. Sid's leaf was bobbing on the river, trapped in an eddy. He shifted in his seat and centered his breathing before trying again.

Please, Terrence. They didn't waive the right to be cared for by their pediatrician. You are making legal arguments, not scientific or ethical ones, and you know that as well as I do. There are 520 children in this clinical trial, and half of them got a vaccine that will never be licensed. We need to be certain that they are offered the option of standard of care treatment."

Certainty is an illusion," Saunders muttered.

Are you kidding me?" Sid said. "If even one of those kids dies because we didn't take this simple precaution, then we have failed as a company, and I have certainly failed as their medical monitor. Additionally, you'd have a PR problem that would make Bonifidia look like a misdemeanor."

So now you're talking about theoretical deaths?" Saunders said. Sid shot him an incredulous look.

A theoretical death is someone else's, Terrence. I can assure you the parent of a dying child sees nothing theoretical about it. Given our company's recent history, it's only right that we take every precaution."

Saunders banged his hand on the table. "Enough," he barked. "Look, Sid, we're not talking about history, but the here and now. If word gets out that RSVIX, a vaccine we spent millions of dollars developing, was such a bust that we had to use our competitor's vaccine to protect the subjects, the damage to OPL's brand will be insurmountable. We're still trying to put all the Bonifidia bullshit behind us. We can't afford another mistake like that. This is over. We're closing the trial. The vaccine is going back to the lab, and we'll repeat the trial if and when the problem has been fixed." Terrence spread his hands as if to appeal to Sid's good nature and continued.

The Bonifidia fiasco was caused by a faint signal that educated minds disagreed upon. It certainly hurt us badly, but we're finally getting past it. Giving Beamer Labs's vaccine to our clinical trial candidates will ensure that the dark days stay center stage. I refuse to risk it."

The leaf was submerged and pushed below a rock. Sid's anger broke free, swimming with everything it had to the surface. He could see his initial assessment was correct — Terrence's arguments were not based on science; instead, they were all about maintaining an image. Nothing repulsed him more than physicians who sold their souls to the corporation. He wrestled his fury into submission and clenched it between his teeth, pausing to swallow the white heat of it before continuing.

Terrence, have you done a risk/benefit analysis on that decision? I don't mean a full-blown economic review, just a quick back-of-the-envelope calculation. Do you think OPL could withstand even one wrongful death lawsuit or the publicity that goes with it? How would this look on the front page of the *New York Times*, especially after Bonifidia? It's the type of one-two punch from which we would never, and perhaps should never, recover." Sid looked around the room. His voice did not betray the raging fire inside him, stoked now by the apathetic faces he saw before him. Since no one responded, he continued.

We're a drug company with special knowledge of medicines and vaccines that can save or destroy lives. We must hold ourselves to a higher standard of practice than other companies simply because of what we do and our standing in the world." Sid turned to his supervisor, Lou, for some support. Lou looked at his hands.

The decision's been made," Terrence said. "There will be no booster shot using Beamer Labs's vaccine." Terrence rapped the desk twice with his knuckles. "That's all for today."

Sid understood all too well. He managed one slow, ragged breath of intentional calm before his accumulated rage suffocated him. The leaf was lost in the deluge.