

BOOK REVIEW

Unsafe at any dose

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Gardiner Harris. *No More Tears, the Dark Secrets of Johnson & Johnson*. Random House; April 2025. 444 pages, \$32.00 (USD), ISBN: 978-0-593-22986-6.

Nothing beats reading a gripping crime thriller on a cross-country flight. Recently enduring three flights and over 12 hours from one North American coast to the other, I devoured Gardiner Harris's new book, *No More Tears: The Dark Secrets of Johnson & Johnson*. If you're in for the ride you'd best buckle up — this one delivers serious turbulence, a roller coaster of corporate malfeasance of one of the most storied companies in American history.

I have researched and written about the drug industry and pharma policy for over 30 years. My bookshelves sag with hundreds of books about pharma policy, drug safety, evidence-based medicine, pharmacy regulation and prescribing. A key theme of these books focuses on the actions (and notable inactions) of drug companies, specialists and doctors whose Hippocratic "First do no harm" credo frequently gets called into question because so much money is sloshing around. Among that batch of books, *No More Tears* might be the only compilation of drug disasters committed by a single company that I have ever encountered.

Luckily for us, this task was taken on by a first rate pharmacologist, Gardiner Harris, who has covered the pharmaceutical industry for years for some of the biggest media outlets in the United States, and never takes his eyes off a central tenet of investigative reporting: Follow the money.

The "dark secrets" covered by Gardner Harris are a litany of misdeeds in Johnson & Johnson's (J&J) development and marketing of everything from asbestos-laced baby powder (chap 4), to the dangers of Tylenol (acetaminophen or paracetamol), the largest selling drug in the history of the world (chaps 10-13), and an assortment of other drugs, with a death count that would rival any medium-sized genocide. As the chapters sail by, we learn of J&J's egregious marketing of the antipsychotic drug Risperdal (risperidone) (chaps 20-27), pushed on the elderly, despite black box warnings of increased risk of death in older people with dementia, and children (where it causes boys to grow breasts and lactate). We learn of the opioid Duragesic (fentanyl transdermal patch) (chaps 28-31) and J&J's outsized role in the opioid epidemic that shows no signs of letting up in much of North America. In addition to drugs, J&J's marketing of faulty medical devices — hip replacements (chaps 34-36) and vaginal mesh (chaps 37-38) — that caused serious disability in patients, and a Covid

vaccine (Jcovden) (chap 39) that turned out to be a dangerous dud, are all part of the list.

While many experts estimate the death toll due to prescription drugs between the fourth and sixth most common cause of death among Americans [1], it is a toll so outrageous most people can't believe it. We do so at our peril. As this book demonstrates, if gargantuan drug companies like J&J can literally get away with murder, we have a system in deep need of reform.

Sailing through the skies at 30,000 feet brought me to thinking about the contrast between airline safety and drug safety. In nearly forty chapters that rip along like lightning, Harris reminds us that companies like J&J are corporations, structured as legally accountable only to shareholders, a fact that should be deeply troubling to all of us. Why? Because in case after case of J&J's history, replete with criminality and disturbing abuses of authority, law and human ethics, profit comes first. If vulnerable patients suffer and die, well, that's simply the cost of doing business. And if a regulator has the temerity to try to stop them, good luck. Regulator and regulated, in Harris crystal-clear analysis, are both batting for the same team.

The Food and Drug Administration both approves drugs and evaluates their safety. They sometimes require safety warnings, or, if the body count gets too embarrassingly high, recall drugs from the market. Compared to what happens in the airline industry, the US FDA seems only performatively involved in investigating drug safety disasters and asked in any given year how many planes fell out of the sky that year they wouldn't be able to tell you. It's a perfect drug safety system set up to fail.

In their own documentation FDA officials routinely brag about how well the FDA works with its "partners in industry,"¹ including company executives like those at J&J, where the revolving door between regulator and regulated is a perennial and serious problem. This coziness leaves the FDA mostly negotiating and composing believable narratives about drug safety that satisfy the companies whose fees pay for the FDA's operations.² In practice, this allows recidivist drug manufacturers to criminally market products they know are lethal, pay fines when they are caught, and then go forth to kill again. On the scale of the problem, Gardiner Harris notes that in 2003, of J&J's top seven selling drugs, the company used "illegal marketing tactics—including bribes, kickbacks and lies to the FDA—for six of them." (p 317)

I learned a lot from this book but the question I most asked myself was: How come J&J was never on my radar? *No More Tears* shows J&J's mastery in not only having their way with the FDA; but deploying weapons-grade PR to continually polish its myth of corporate virtue. It did this by being one of the most successful drug companies in the history of the world, with mountains of cash to monopolise the two biggest weapons in a drug company's arsenal: Big PR and Big Law. Big PR can help keep the bad news off the front pages of the nation's newspapers. Big Law, including the same companies hired to plead the cases of Big Tobacco, are ready, willing and able to legally threaten anyone going after J&J in court. Only a rare few law firms would be willing to challenge J&J's legal firepower, or, conversely, to turn their backs on such a lucrative client.

Perhaps it is J&J's role in the opioid epidemic which I found most truly jaw-dropping. While almost everyone knows that Purdue's marketing of Oxycontin put jet fuel on the fire of the opioid epidemic (and they have faced huge lawsuits for doing so), almost no one knows what Harris meticulously outlines half-way into the book. He cites Andrew Kolodny, the world's foremost expert on the opioid crisis: "J&J was clearly the kingpin of the opioid epidemic, not Purdue Pharma. They were not only marketing their own branded opioids but were supplying almost every manufacturer with the crucial active pharmaceutical ingredient."

In every chapter, you'd be compelled to ask, "Where was the FDA when all the bribing, coercing, and criminality at the hands of J&J was going on?" It's a good question.

This incredible book is not just about Johnson & Johnson; it's about the way we fail disastrously in regulating drugs in America. In that vein, one might rename it, "Unsafe at any Dose", riffing on Ralph Nader's 1965 groundbreaking book *Unsafe at any Speed* which catapulted automobile safety into the public consciousness³. Nader demonstrated that a single person, fuelled by dogged determination, persistent use of litigation and a true commitment to the public interest could force regulators to adopt car safety modifications that today saves hundreds of thousands of lives a year. A federal drug regulator that was serious about preventing unsafe drugs and devices from harming people would be part of a very different system from the one we have now. Right at the end of the book, Harris asks the question that percolated at the back of my mind the whole flight: He writes:

For all intents and purposes, Johnson & Johnson was a criminal enterprise. Indeed, mafia families get a large share of their income from strictly legal activities. But no mafia outfit ever consistently targeted the kind of vulnerable people that J&J exploited. And if one of the most admired corporations in the world is in reality a criminal enterprise and a killing machine, what else are we missing? How many other killers are out there?

An unsettling thought to be sure....

I know the plane will land and I expect the wheels won't fall off. As for my next encounter at the pharmacy counter? We're sailing on a wing and a prayer.

Harris' prescription for reform includes many points made by other commentators over the years (including myself). That list includes prohibiting physicians from taking money or gifts from pharmaceutical companies while treating patients, banning continuing medical education funded by drug companies, and switching to a system where the US taxpayers (and not the drug companies) pay the bill for regulating and approving drugs. He also suggests the model I riffed on at the beginning of this review, that the drug world needs to adapt an "airline-level" system of safety monitoring, where approval of new planes and the investigation of crashes are done by separate agencies.

His final critique is hardly radical and echoes many of the themes found in the books lining my shelves: We have to stop letting dirty money write the rules of drug approval, marketing, and prescribing, and build a regulator that fears patients' funerals more than industry displeasure.

Notes:

¹Official documents at the FDA.gov archives talk of "Public-Private Partnerships" (PPPs) or "Critical Path" initiatives, explicitly listing "Industry" as a partner in these initiatives to "modernize" drug development.

²The Congressional Research Service (CSR) produces non-partisan reports for US Congress members. Citing the FDA Human Medical Product User Fee Programs for fiscal year 2023, the CRS documented that user fees account for roughly three-quarters of the funding for the drug review process.

³Ralph Nader's book *Unsafe at Any Speed: The Designed-In Dangers of The American Automobile* (Grossman Publishers, New York;1965) made a strong case for the US automotive industry to be forced by government to pay greater attention to safety, in the face of mounting evidence about preventable death and injury. The book resulted in U.S Senate hearings and led to the creation of the United States Department of Transportation in 1966 and the predecessor agencies of the National Highway Traffic Safety Administration in 1970.

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