The opioid crisis was the product of corporate greed run amok and a corrupted regulatory process. That crisis may have amplified deep distrust of the pharmaceutical industry and its government watchdogs — distrust that may now be reflected in vaccine skepticism.

First, a little history. The manufacturer, Purdue Pharma, aggressively promoted the use of oxycontin, courting doctors with promotional material and assiduously pushing individual doctors to make ever-more use of the drug. It also advertised directly to the public, trumpeting the claim that addiction was not a significant risk. All this continued even though company officials knew at an early stage about widespread abuse of the drug. Other pharmaceutical companies followed suite and happily promoted their own opioid-based products.

The industry has made billions from the opioid epidemic. The Sackler family, which owned and controlled the company selling oxycontin, accumulated vast wealth. The societal cost has been grim. Nearly 50,000 Americans died from opioids in 2019 alone, and the lives of many more have been devastated.

How did Purdue Pharma ever manage to get FDA to approve oxycontin? It's not a pretty story. A Purdue exec met the FDA official in charge of approving painkillers at a conference and developed a backchannel for informal influence while the FDA official was drafting the official approval report. A year after leaving FDA, that official landed a lucrative job at Purdue. I suppose things could have been worse: under Trump, regulatory officials were often former industry lobbyists.

When the FDA convened a panel of ten outside experts in 2002 to advise it what to do about the growing opioid problem, eight were from industry, including Purdue. Not surprisingly, they counseled against taking action.

According to a 2020 article in the AMA's Journal of Ethics, FDA may not have learned much from the experience:

"Despite this mounting criticism, FDA policies for approving and labeling opioids remain largely unchanged. The FDA has not undertaken a root cause analysis of its regulatory errors that contributed to this public health catastrophe, let alone instituted any major reforms. To the contrary, the agency has adopted a defensive posture and sought to shift blame."

Moreover, the ethics article points out, FDA uses a controversial methodology for

assessing opioids that may be biased in favor of finding the the drugs effective for chronic pain. The methodology was adopted after private meetings with drug companies, which paid up to $35,000 apiece to participate. There are arguments in favor of the methodology, but the process certainly provides ample grounds for skepticism.

FDA is an agency that has earned a reputation for technical competence and integrity, one that I think is generally valid. Its role in beginning the opioid crisis is deeply disappointing. Ok, that was me being the detached academic. Actually, “shocking and appalling” would be the right words.

Vaccination resistance today tends to be high in the largely rural, economically depressed areas where the opioid epidemic has hit hardest. There are surely many factors at work in producing this alignment. Still, a reasonable person living in those areas might well conclude that pharmaceutical companies are cold-bloodedly rapacious, with no regard for the health of consumers. That reasonable person might also be deeply skeptical about the trustworthiness of government regulators. It seems plausible that this effect has contributed to vaccine skepticism.

Memories of past government abuses can linger much longer than a decade or two. When the levees broke in New Orleans after Hurricane Katrina, many black residents were convinced they had been deliberately blown up. Eighty years earlier, during another great flood, the government actually had blown up levees south of the city. The action was taken at the behest of the New Orleans elite, while the those flooded out were poorer and politically powerless. When Katrina hit, people still remembered. COVID struck much closer in time to the opioid epidemic, which is still not over.

The vaccine approval process was far different than the process for approving opioids. It took place under an intense glare of publicity, with scientists around the world scrutinizing the results of clinical trials. Multiple countries have independently approved the vaccines. And the vaccines are needed to control a disease that has already caused over a half million deaths in the U.S. Within the FDA, no doubt the vaccine decisions got far more scrutiny, because everyone understood that an unsafe or ineffective vaccine would have massive, disastrous consequences. Still, it’s understandable that some people may not find these distinctions clear.

The lesson for the future is that FDA needs to sever its cozy ties with the drug industry. More transparency is needed in the regulatory process, with fewer

opportunities for industry representatives to privately interact with regulators. The revolving door between industry and FDA needs to be closed. Too many FDA officials go from approving drugs to working for the companies that make those drugs.

In more immediate terms, we have to understand that people who distrust both government regulators and the drug industry aren't necessarily being irrational. We need to work hard to regain their trust and to establish that COVID vaccines are different.