



At Last a Vaccine — Maybe

Pfizer Pharmaceuticals and BioNTech announced the development of a vaccine that offered 90% efficacy against the Covid-19 virus, and Americans were dancing in the streets. Actually, they were dancing in the streets for reasons unrelated to this vaccine news, but the vaccine news was also cause for celebration.

The current administration quickly took credit for the vaccine development as a product of cooperative “public-private” efforts. The vice-president tweeted, “Thanks to the public-private partnership forged by President @realDonaldTrump, @pfizer announced its Coronavirus Vaccine ...”

That was of course not true since neither Pfizer nor BioNTech took funding for research or development of their vaccine from the U.S. government. Once again the aphorism that “Success has a thousand parents, and failure is always an orphan” proved true. Pfizer will get nearly \$2 billion in sales if it can develop and deliver several hundred million doses of an effective vaccine. Not unexpectedly Pfizer’s stock price soared on the

release of the announcement. And then it fell.

When the Challenger space shuttle exploded shortly after lift off, a scientific panel was convened to determine the cause of this catastrophe. As wise men and women examined the evidence, wiser men and women suggested that the answer could be found at the stock exchange. The thinking (and experience) behind this recommendation was that insiders know the undisclosed facts and will jump ship long before the general public gets the memo. This in fact did prove to be the case, and the manufacturer (Morton Thiokol) of the solid rocket boosters and the O-rings on the shuttle solid rocket boosters that failed saw a precipitous drop in its stock price long before the scientists concluded that the O-rings made brittle by the unusually low temperature at launch were the problem.

And so one must wonder why the Pfizer stock price fell from 41.9 on Nov. 9 to 37.3 on Nov. 12. For those of you without a calculator, this was more than a 10% drop. What was behind this rush to the exits? Was it the realization that this vaccine needed to be kept at -94 degrees Fahrenheit before being administered? Shipment of the vaccine at so low a temperature posed logistical challenges not previously faced with other widely distributed vaccines. Was there some issue in the trials not made public that frightened the fully informed? That would not be the first time a long-awaited breakthrough was announced prematurely or in carefully scripted wording.

I worked in the pharmaceutical industry for a few years and was familiar with the development and “launch” of an antiepileptic drug targeting refractory seizures in children. The studies released were especially encouraging since this drug appeared to have virtually no serious side effects. The studies were reviewed by the FDA and

approved for use in children who had failed to benefit from other antiepileptic medications.

Within months of the launch, reports surfaced of liver disease and bone marrow failure in some of the children treated with the new drug. Other drugs used for the management of seizures produced the same problems, but the newly released drug had shown no such adverse events in the trials upon which its approval had been based. The drug approval was not rescinded, but the FDA did require the manufacturer to alert physicians who might prescribe the drug of the problems developing in children who got the drug. Why these adverse events allegedly never occurred in the trials before the drug's approval was never explained.

Suffice it to say that my years of working in the pharmaceutical industry did not engender confidence in press releases distributed by these companies. On one occasion I was asked to supply five samples of my signature so that the clearest version could be attached to various press releases the marketing department had written. When I asked if I could see the information that was being attributed to me, I was told that would not be feasible. Management had already approved the content of the releases, and I was not allowed to review the carefully crafted messages that were going out to the lay press and medical professionals.

That these documents were being attributed to me was irrelevant as far as the company was concerned. They were paying me at least in part so that they could issue statements in my name that they felt served the company's best interest. I refused to sign and demanded that they not attribute these marketing tools to me. And so ended my career in the drug industry. I returned to clinical practice, and the marketing department

released glowing accounts of research developments authored by a physician who could not have written them since he was no longer with the company.

During my tenure in the drug industry I also discovered that statements attributed to doctors not salaried by the company were also pure fabrications. The marketing people would concoct a statement, such as “This drug is a giant step forward in the management of this terrible condition,” and decide to which of the “thought-leaders” they provided funding it should be attributed. They did make a courtesy call to their “thought leader” and ask if he or she had a problem with this statement being attributed to them, but I never heard of anyone refusing the attribution. Such a refusal would cost the independent thinker dearly.

This system undermined the integrity of information coming from the drug company, but even more egregious was the complicity of some physicians in extracting funding from companies by agreeing to withhold their criticism. A case and point was a researcher who had been highly critical of the results of drug studies on a medication that was to be publicly reviewed by an FDA advisory committee. This was a pivotal hearing that could determine the survival or failure of a drug. The physician was expected to be a major obstacle to the drug in question getting a favorable review at the hearing, but he advised the company management that he might be too busy to appear at the hearing if the company helped fund his research. He got a grant and stayed away. The drug was approved.

I certainly hope that the Pfizer vaccine is safe and effective and will soon be widely available. I hope that the common practices of Mad Men (and women) in the pharmaceutical industry are not in play, obfuscating, distorting and otherwise

undermining the truth.

I hope the stock market is wrong.

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