Hey, Hey, FDA! How Many Americans Have You Killed Since May?

As I write this on December 17, the US Food and Drug Administration's Vaccines and Related Biological Products Advisory Committee is meeting to review a COVID-19 vaccine developed by biotech company Moderna. Likely outcome: The panel will recommend approval of the vaccine to FDA Commissioner Dr. Stephen M. Hahn.

My question: What took so long, and why?

As David Wallace-Wells reports at *New York* magazine, Moderna completed design of its vaccine on January 13 — only two days after the virus's genetic sequence was released to the public by Professor Yong-Zhen Zhang of Shanghai's Fudan University and before any US cases of the virus had been confirmed.

By May, Phase I clinical trials had established the vaccine's apparent safety.

Seven months later, we're finally about to get the vaccine (as well as one by Pfizer, approved earlier in December and based on the same "messenger RNA" approach).

Yes, the FDA's brief is to approve drugs based on two standards: Safety and efficacy.

And yes, more time spent testing for both safety and efficacy produces more trustworthy results.

But federal, state, and local government officials have been telling us, since at least as far back as March, that the COVID-19 pandemic is an emergency, and most people seem to agree with the claim.

In an emergency, we do things we normally wouldn't do, the immediate circumstance being so dire that we're willing to accept risks we usually wouldn't accept. Getting through, and out of, the emergency is the most important thing. Business as usual goes out the window.

That's what government always tells us when it wants to do something on an "emergency" basis. In the case of COVID-19, governments seized broad powers to shut down whole sectors of the economy and place untold millions of Americans under *de facto* house arrest though those Americans were accused of no crime.

Business closures. Capacity limits. Mask mandates. Travel bans. You name it, there was nothing governments weren't willing to do to address the emergency.

Except give up any of its own power.

At every step, the US medical response to COVID-19 has been constrained by “you must first ask if it please the Crown” considerations. Not just with respect to vaccine development, but even to the long-accepted practice of “off-label” prescribing of existing drugs — for example, hydroxychloroquine, FDA-approved since 1955.

COVID-19 has killed more than 300,000 Americans , more than 2/3 of them since the end of May, by which time the Moderna vaccine was deemed safe.

How many of those deaths might have been avoided if FDA had allowed Moderna to begin selling, and health providers to begin administering, the vaccine six months ago?

And when, if ever, will foot-dragging regulators be held responsible for those avoidable deaths?