Big pharma's safety pledge isn't enough to build public confidence in COVID-19 vaccine–here's what will

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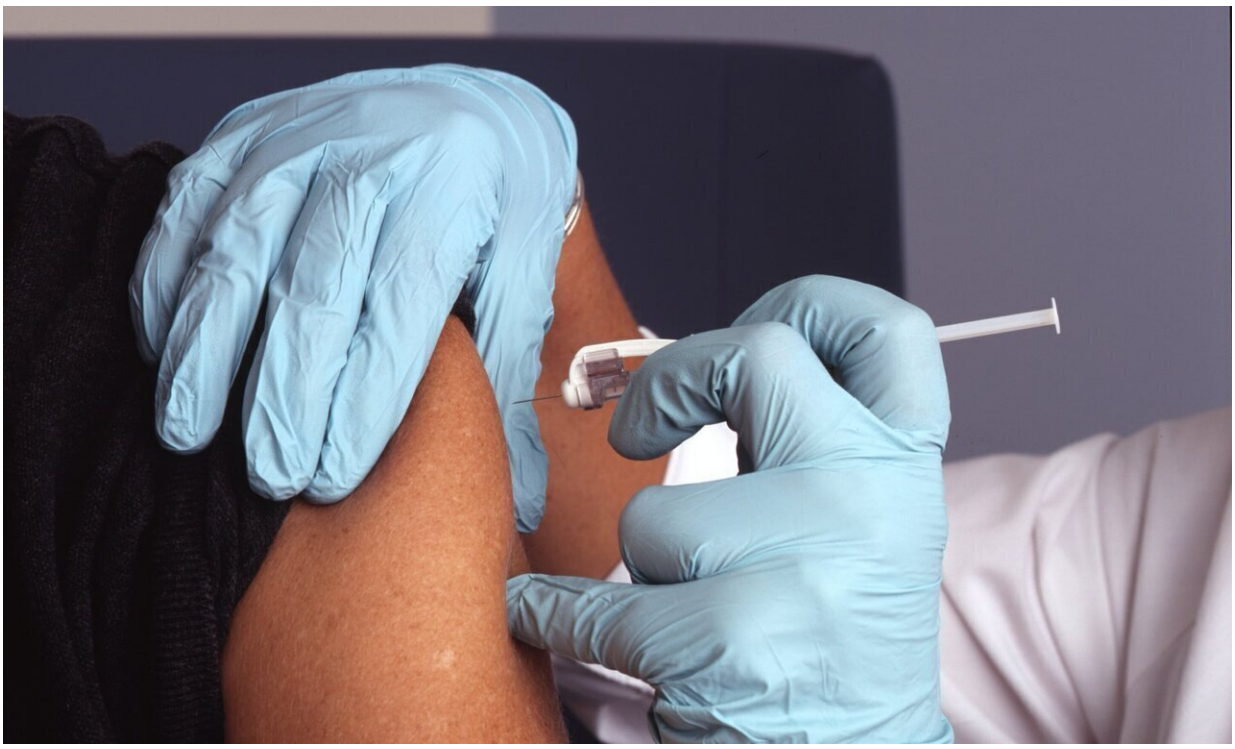

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Americans are increasingly concerned that regulators and manufacturers will rush a vaccine to market without an adequate review.

That prompted nine vaccine front-runners, including Pfizer and Merck, to promise to abide by clinical and ethical standards in an effort to increase the public's confidence in any vaccine that ultimately comes to market.

As a scholar of law, public health and bioethics, I have extensively studied vaccine policy, as well as the laws and regulations governing human subject research and FDA-regulated medical products. In my view, the pledge is little more than a public relations strategy, with companies simply reaffirming that they'll follow FDA guidelines and standard scientific practices.

While I doubt the biotech pledge will do much to increase public confidence in a COVID-19 vaccine, Congress can take meaningful steps to do so. Specifically, lawmakers can create what I call a coronavirus social safety net.

A relentless race

The Trump administration has exerted relentless political pressure on public health officials to approve a vaccine quickly, with the president pushing for a vaccine by Election Day.

Meanwhile, the global competition to get a vaccine first—and reap the economic and scientific rewards – is intense, withover 120 vaccines currently in development.

Experts, however, have cautioned against the rapid development of COVID-19 vaccines. Vaccine development takes time and requires carefully crafted studies to assess short-term and long-term risks and benefits. The fastest vaccine to ever come to market from scratch was the mumps vaccine, which took four years from the time virus samples were collected to distribution of the vaccine.

Nevertheless, biotech firms have every incentive to be the first to bring a coronavirus vaccine to market, even if it means cutting a corner or two.

The wrong kind of immunity

One of the key ways capitalism ensures companies act responsibly and produce safe and effective products is through fear of potential lawsuits.

This market mechanism is already utilized throughout the health care industry: Hospitals, nursing homes and physicians are all liable if they fail to exercise reasonable care. Within the field of health care, however, one notable exception involves vaccines.

Broad legal immunity for vaccine manufacturers has become a staple of America's legal framework governing vaccinations since the corporate welfare and deregulation days of the Reagan administration. The National Childhood Vaccine Injury Act of 1986 provided vaccine manufacturers with legal shields to protect them against lawsuits involving injuries. And in 2005, Congress enacted the Public Readiness and Emergency Preparedness Act, which expanded the liability shield to include any countermeasures utilized during a pandemic or national security crisis.

In April, the government invoked the 2005 law's protections for COVID-19 and granted extensive legal immunity to manufacturers of "any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19" or the virus that causes it.

Basically, this means companies cannot be sued for money damages unless a person who died or is seriously injured can demonstrate that the company engaged in "willful misconduct"—a very high legal bar that can

be satisfied only if a plaintiff can prove the manufacturer intentionally caused harm by disregarding a known or obvious risk. Even this small window of claims is closed if the person accepted compensation for their injuries or if the manufacturer abided by regulatory requirements prior to marketing the vaccine. Damages for pain and suffering are precluded, and a person cannot win unless and until government agencies have sued and imposed penalties on the manufacturer.

These stringent requirements make a lawsuit all but impossible, which leaves one less reason for biotech firms to put safety first.

The risks are amplified if the FDA utilizes its emergency use authorization protocol. Normally, the FDA requires a manufacturer to provide "substantial evidence" of a vaccine's safety and effectiveness. Under emergency use authorization, a vaccine can come to market if "it is reasonable to believe" that "the product may be effective."

Given this low bar and the need for public acceptance of a vaccine to create herd immunity, the best way I see to increase public confidence in a vaccine is by eliminating the liability waiver and holding companies accountable for anything they bring to market.

Providing a safety net

A second means of building public trust centers on creating a health care and compensation fund to accompany a vaccine rollout.

No vaccine is 100% safe, though most vaccine side effects are minor. For instance, clinical trials for one COVID-19 vaccine reported that 60% of recipients suffered swelling at the injection site, soreness, lethargy or a slight fever.

But more serious side effects can occur. On Sept. 9, AstraZeneca and the

University of Oxford halted worldwide testing of their vaccine because a person developed transverse myelitis, an inflammation of the spinal cord that can cause sensory problems, bowel and bladder dysfunction, and paralysis.

To handle compensation claims related to COVID-19, the government says it will turn to the Countermeasure Injury Compensation Program. The program, intended to compensate people who say they have been harmed by a vaccine administered during a public health emergency, lacks transparency and is known to be a difficult vehicle for obtaining redress for vaccine injuries—paying out in fewer than 10% of claims, according to Reuters.

For example, a person who had a baseball-size growth on his arm after a H1N1 vaccine in 2009 was denied compensation on a legal technicality because he filed the claim shortly after the one-year statute of limitations had elapsed.

A better tack would be to establish a fund similar to programs the government created for radiation exposure from nuclear tests and the 9/11 attacks. A dedicated coronavirus fund could provide health care for anyone who suffers a medical complication following administration of a COVID-19 vaccine. The fund could also provide compensation for serious vaccine injuries, including compensatory damages, such as for loss of work and out-of-pocket expenses, as well as damages for pain and suffering.

Moreover, death benefits could help the unfortunate few who may die from a vaccine-induced complication.

Building confidence 101

Building public trust in immunizations requires more than a pledge from

vaccine manufacturers.

It requires, among other things, ensuring that biotech companies have every incentive to release only vaccines that are safe, and giving citizens the assurance that if they do have an adverse reaction, they'll be taken care of.

Congress has spent over US$3 trillion dollars in coronavirus relief so far, including hundreds of billions of dollars for massive corporations. The U.S. can afford the few billion or less it would cost to set up a fund to make it more likely that Americans will have faith in a vaccine.

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