Analysis: mRNA Shots for COVID Bypassed ‘Laws and Regulations’ Protecting Americans

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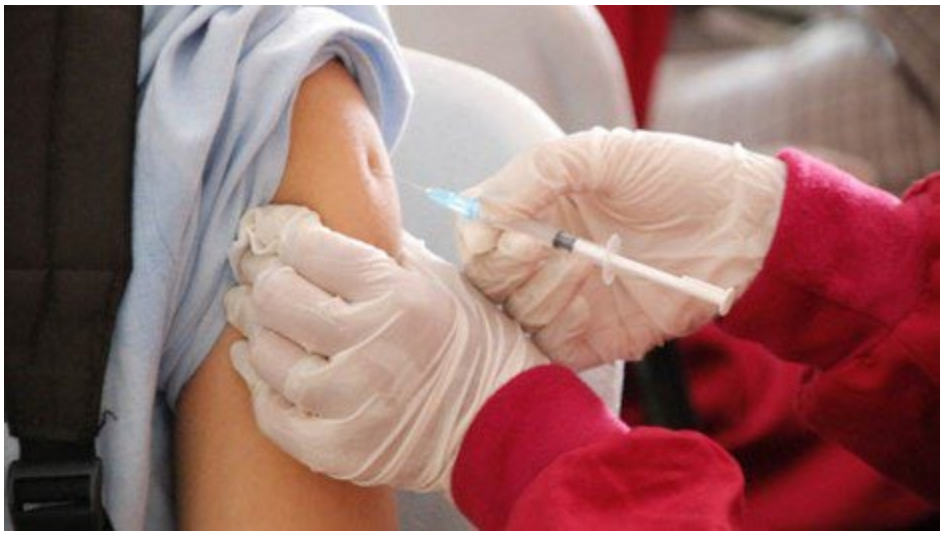

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Guest by post by Bob Unruh

Used provisions intended to let military move quickly

A new analysis on the creation of the mRNA shots that were purported to help victims fight the COVID-19 virus that came out of a Chinese research lab and killed millions worldwide shows that they were imposed on Americans by bypassing all of the “laws or regulations that we count on to protect use from potentially harmful, or deadly, medical products…”

The analysis by Debbie Lerman, a graduate of Harvard who is a retired science writer, charged in the article that: “The COVID-19 mRNA vaccines were acquired and authorized through mechanisms designed to rush medical countermeasures to the military during emergencies involving weapons of mass destruction (WMD).”

Secondly, she said, “These mechanisms did not require the application of, or adherence to, any laws or regulations related to vaccine development or manufacturing.”

And then, too, “The Food and Drug Administration’s (FDA) Emergency Use Authorization for the vaccines was based on clinical trials and manufacturing processes conducted with no binding legal standards, no legally prescribed safety oversight or regulation, and no legal

redress from the manufacturer for potential harms. (This last point is being challenged in multiple court cases, so far to no avail.)"

In the aftermath of COVID, there has been confirmed an epidemic of "suddenly died" cases. There are epidemics of myocarditis and pericarditis, and "turbo cancers." There are rampant heart problems among the young, and there are uncounted vax injuries and deaths documented on the government's VAERS website.

"What all of this means is that none of the laws or regulations that we count on to protect us from potentially harmful, or deadly, medical products was applied to the COVID-19 mRNA vaccines," she charged. "The assertion of 'safe and effective' was based entirely on the aspirations, opinions, beliefs, and presumptions of government employees."

She wrote that the government contracted for shots with Pfizer, which was acting for the BioNTech/Pfizer partnership, to produce 100 million doses of a "vaccine to prevent COVID-19" for $1.95 billion, at least.

Additional doses also were contemplated.

The analysis explained that was not normal, but then the pandemic was not in normal times.

"The government declared that we were 'at war' with a catastrophically dangerous virus that would kill millions and millions of people of all ages unless we could develop 'medical countermeasures' (a military term) and get everyone to take them as quickly as possible."

She explained on the government's side of the deal, it was the Department of Defense that made the deal, and its organizations that "are charged exclusively with military objectives."

"This is crucial, because the laws and procedures governing military procurement have a very different set of assumptions and cost-benefit considerations than those used in civil society. In fact, agencies governing civilian and public health, such as the National Institutes of Health, the National Institute of Allergy and Infectious Diseases, and the Department of Health and Human Sevices (HHS), do not have the authority to grant certain types of special acquisition contracts, which is why the COVID-19 vaccine contracts had to be overseen by the DOD," she wrote.

Then the government used an "Other Transaction Agreement" process that involves procedures that operate "outside the Federal Acquisition Regulations."

That means standard requirements for competition, accounting, cost management, records and more simply don't apply.

Also rules regarding research on people, and privacy laws.

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The specific OTA for Pfizer, the analysis confirms, was set up to have the government pay Pfizer "to show that it can manufacture 100 million doses of a never-before produced or tested product, while also acquiring those 100 million doses, and potentially hundreds of millions more."

And as for regulatory oversight of the development and manufacturing processes, the analysis revealed, "Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials, and with its collaboration partner, BioNTech, will seek FDA approval or authorization for the vaccine, assuming the clinical data supports such application for approval or authorization."

And, it revealed, the rules say "an emergency use authorization can be granted by the Food and Drug Administration once HHS and/or the DOD have declared that there is an attack, threat of an attack, or national security threat created by a CBRN agent (a weapon of mass destruction)."

A Harvard Law article noted at emergency authorization wasn't intended to cover new vaccines.

The analysis pointed out: "Here's the kicker about EUA: because it was intended to be issued only in war and WMD-related emergencies, there are no legal requirements for how it is issued, beyond the determination of the FDA that such authorization is appropriate. There are no legal standards for how clinical trials are conducted. There are no laws regulating the manufacturing processes. There are only 'reasonable beliefs' based on whatever evidence is available to the FDA at the time that it makes its determination."

Finally, federal law immunizes those providers from lawsuits over injuries they case.

"This is provided by the PREP (Public Readiness and Emergency Preparedness) Act, which was designed to go hand in hand with EUA. Again, it is possible to envision a bioterrorism scenario, such as an anthrax attack, in which the government needs to get lots of countermeasures very quickly. Many people will inevitably die in the attack, but if there's a chance that the countermeasure will work, it needs to get made and distributed as quickly as possible. If it has some bad side effects, or even if it kills some people, one could argue that the manufacturer should not be held liable."

That that process, again, the analysis charged, wasn't intended to apply to untested shots.