Did National Security Imperatives Compromise COVID-19 Vaccine Safety?

BY PHILLIP ALTMAN JANUARY 5, 2023 12 MINUTE READ

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The US Department of Defense (US DoD) has had a dominant role in the response to the SARS-CoV-2 virus and in the development, and distribution of the Covid 19 vaccines, a fact hidden from the general public. In those processes many standard steps and procedures, otherwise required for pharmaceutical products, were omitted or circumvented.

Definition of these vaccines as “countermeasures” rather than therapeutic agents has permitted their expedited progression to

emergency use authorisation and widespread rollouts. Many adverse consequences have been the outcome of this secret military response to a public health matter. Why are governments around the world, including Australia, planning to make further significant investments in this rushed vaccine technology driven by the US military?

Operation Warp Speed

With the US Food and Drug Administration's Emergency Use Authorisation of the COVID-19 vaccines (FDA, 2020) and the Provisional Approval of the first COVID-19 vaccine in Australia (TGA, 2021), these agents were hailed as innovative life-saving responses by the pharmaceutical industry to a deadly global pandemic.

The development, testing and drug regulatory approval of these novel COVID-19 gene-based vaccines using messenger ribonucleic acid (mRNA) technology was said to have been done in less than one year, whereas development and approval of conventional vaccines normally takes about 10 years. (Seneff and Nigh, 2021). The public was told that this was assisted by financial support of vaccine companies by the US government under Operation Warp Speed.

The public was told that these COVID-19 gene-based vaccines were "safe and effective" (CDC[a], 2022): that they would prevent infection and chances of serious illness and death from the virus, and would prevent transmission of the virus. We now know they do not prevent infection nor transmission and have not prevented a continuing high incidence of COVID-19. Furthermore they are associated with an unprecedented incidence of serious adverse events and deaths compared to any other drugs in the history of the pharmaceutical industry. (Turni and Lefringhausen 2022; Altman, 2022; CMN, 2022; Blaylock, 2022).

Based on the US CDC Vaccine Adverse Event Reporting System (VAERS), there were 1,476,227 adverse event reports associated with these "vaccines" (CDC[b], 2022). through December 2, 2022, which include 32,621 reported deaths and 185,412 hospitalizations. Furthermore, a rise in unexplained deaths has been reported around the world coincident with their introduction. In Australia, up to August 2022 there were 18,671 excess deaths (17 percent) more than average, with most of these deaths not due to COVID-19 (ABS, 2022). We are probably facing the worst health disaster in history.

How did the pharmaceutical industry, our governments and our drug regulators get it so wrong? A plausible answer to this question has emerged within the last few weeks.

A National Security Operation

Contrary to popular belief that pharmaceutical companies drove the COVID vaccine development programs, the US FDA's website (FDA, 2020) reveals that the United States Department of Defence (DoD) has been in full control of the Covid Vaccine development program since its beginning. The DoD has been responsible for development, manufacturing, clinical trials, quality assurance, distribution and administration, since that time (FDA, 2020; Rees and Latypova, 2022; KEI, 2022; Medical Defense Consortium, 2022; Rees, 2022). The major pharmaceutical companies have been involved as "Project Coordination Teams" effectively performing as subcontractors to the DoD. The Chief Operating Officer for the Warp Speed vaccine program is the US Department of Defence, and the Chief Science Advisor is the US Department of Health and Human Services (HHS).

The Nature of Gene-based Vaccines

The true nature of the COVID-19 'vaccines' has been largely misrepresented by mainstream media, big pharmaceutical companies and governments and is poorly understood by the population at large. Referring to these products as "vaccines" led most people to consider them as relatively safe and well-researched and readily accept their widespread use. However, they are not really vaccines – they are serious gene-based interventions which have never been deployed widely in any population, especially never to healthy individuals including children, infants and pregnant women. In this sense they should be considered experimental.

COVID-19 'vaccines' fall into a special class of therapeutic agents under the US FDA Office of Cellular, Tissue and Gene Therapies' defined as "gene therapy products," which involve "introducing a new or modified gene into the body to help treat a disease" (FDA, 2018). Heretofore, use of gene therapy products has been limited to the treatment of usually rare, serious and debilitating disease or genetic conditions. They have potential to cause permanent intergenerational genetic damage, cancer and interfere with reproductive capacity.

The FDA and other drug regulatory agencies have specific rules and guidelines to direct manufacturers in development and testing of such products, for both preclinical (FDA, 2013) and clinical (FDA, 2015) research. However, the FDA did not evaluate these COVID-19 "vaccines" according to these gene therapy guidelines.

Instead, there was a concerted effort to avoid referring to them as gene therapy products, based, in part, on the argument that the genetic material in the COVID-19 vaccines was not intended to be incorporated into an individual's DNA, nor to modify gene expression. There was no prior short-term safety information and no long-term data on which to predict future effects. No similar therapeutic products have been previously approved anywhere in the world. Their widespread administration globally with no historical safety experience was an unprecedented risk in human health.

Accelerating Development

Messenger RNA platform technology has been researched by DARPA (Defense Advanced Projects Research Agency) since at least 2012 (McCullough, 2022). In early 2020, in the panic to develop the COVID-19 vaccines, certain critical research and development procedures were omitted, bypassed, curtailed, or not done in a logical sequential manner, or to established laboratory or manufacturing standards. Although the spike protein is the active drug and is directly responsible for the immune response, its pharmacology and toxicology have not been studied in animals or in humans as would normally have been required.

Other notable deficiencies include lack of critical research on carcinogenicity, mutagenicity, genotoxicity and reproductive toxicology in appropriate animal species. In particular, the potential for reverse transcription of mRNA genetic material into an individual's DNA was not investigated. Furthermore, scale-up manufacturing was premature and lacked adequate quality control to ensure that product made in large batches is the same as made in smaller batches.

Without such research, the potency, mRNA integrity, presence of contaminants and stability of the "vaccines" cannot be guaranteed. Such oversights are directly responsible for the failure to predict the serious adverse drug reactions and mortality which have now been reported in association with these vaccines.

To mitigate risk, the plan in vaccine development was to use multiple technologies, multiple facilities and redundancy. Leverage of existing facilities would also take place. In the interest of expediency, the plan was to avoid using traditional pathways from early development to large-scale production. Avoidance of quality standards and guidelines such as Good Manufacturing Practice and Good Laboratory Practice guidelines was necessary to speed development, and conventional New Drug Application (NDA) and Biologics License Application (BLA) approvals were bypassed.

Instead, the process moved rapidly using compressed timelines and overlapping stages of development towards Emergency Use Authorization (EUA). Scale-up and large volume manufacturing was planned in parallel with, instead of before, clinical trials which, again, may have contravened accepted codes of Good Manufacturing Practices. These approaches were probably a recipe for potential disaster. (Latypova, 2022; Watt and Latypova, 2022).

The Legal Framework

Key legislative elements enable the US government to authorise, fund, contract and control many DoD research programs, as follows:

- the Emergency Use Authorisation regulations (1997) allow, in cases of emergency, a new drug to be made available with less supportive safety and efficacy data than normally required for full approval.
- the Other Transaction Authority regulations (2015) permit contractual transactions that are not required to comply with Federal laws and regulations, and
- the Public Readiness and Emergency Preparedness Act (PREP Act 2020) establishes limited liability for the companies involved in the contract arrangements with the DoD.

Two US DoD agencies, the Defense Advanced Research Projects Agency (DARPA) and the Biomedical Advanced Research and Development Authority (BARDA), possess considerable resources for research, development and approval for various products. They also contract with a large number of companies for such functions.

The products of these programs, including the COVID-19 vaccines, are sometimes classified as “countermeasures,” “prototypes,” or “demonstrations” rather than pharmaceutical products. Those labels

permit a product to avoid lengthy conventional regulatory, commercial development and testing pathways normally required for pharmaceutical products (ICH, 2022) and to proceed to Emergency Use Authorization.

The Rush to Large-Scale Manufacture

The rush to make available the Covid vaccines has reportedly led to batch-to-batch variability, with some batches associated with a high incidence of adverse vaccine reactions and mortality (Gutschi, 2022). In addition, at least 26 researchers/research teams in 16 countries, using various microscopic methods of analysis, have reported the presence of undeclared microscopic geometric and tube-like structures in both the Covid vaccine vials, and in the blood of people in widely vaccinated populations, for which there is no satisfactory explanation at this time. Furthermore, various spectroscopic methods of analysis have detected the presence of undeclared and unexpected metals (German Working Group, 2022; Hughes, 2022).

Under normal circumstances, even a tiny fraction of the reported quality, efficacy or safety problems associated with the Covid vaccines would have led to their immediate withdrawal, but this has not happened. Pharmaceutical regulators globally seem to be wilfully blind to the problems. Governments and the mainstream media appear to show no interest in uncovering the truth or conducting a public debate on these critical matters. Why?

The answer appears to be that, in the interest of national security, the US DoD took charge of the Covid vaccine funding, development and testing from the very start of the perceived threat in early 2020. In the early panic, normal prudent quality, safety and efficacy considerations were compromised. Drug regulators played, and continue to play, an acquiescent role in approving and endorsing these vaccines. We now see this was a mistake. Many are now of the opinion that the Covid vaccines appear to have done more harm than good (Dopp and Seneff, 2022). Uncovering the truth has been a slow and arduous process, which has been exacerbated by the intense and unprecedented censorship of doctors and scientists, which continues to this day.

Conclusion

Many questions have arisen about the COVID vaccines concerning the lack of adequate manufacturing practices, quality control, basic pharmacological and toxicological studies and the lack of appropriate clinical safety and efficacy studies. Drug regulatory authorities seem reluctant to acknowledge the unprecedented level of reported serious adverse drug reactions and deaths associated with these products. There is also serious concern regarding the increases in excess deaths from all causes in many countries suspiciously with their use. Our health authorities steadfastly refuse to consider that the vaccines themselves may be to blame.

The public was told these COVID vaccines were "safe and effective" without qualification even though they were not fully approved. Why was the public not advised that the normal standards of quality, safety and efficacy were not applied to the development and testing of these vaccines? Why was this kept secret? Why are governments around the world, including Australia, planning to make further significant investments in this unsafe vaccine technology? Will these national security arrangements still be in place for future vaccines and other pharmaceutical products?

The fate of humanity and all future generations is literally at a critical tipping point and few global power brokers and political decision-makers appear to realise the gravity of the situation.

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