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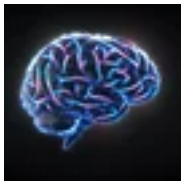
Did National Security Imperatives Compromise COVID-19 Vaccine Safety?



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Opinion Article

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Abstract

The US Department of Defense (US DoD) has had a dominant role in the response to the SARs CoV2 virus and in the subsequent development, manufacture and distribution of the Covid 19 vaccines. This has been kept hidden from the general public since early 2020. The US DoD clearly perceived a threat to national security and all decisions from that point onward to the present day were subject to full command and control from them. Strong evidence for this has now become readily available in the public domain, published on the US Food and Drug Administration website (US FDA). Many adverse consequences have been the outcome of this secret military response to a public health matter.

We present the key elements of what happened and warn that what took place was unwise. The lesson is that the development and production of vaccines and other therapeutic products for general civilian use should never again be allowed to be under full military command and control.

Many aspects of the Covid 19 event, which began in January 2020, and the responses to it have been confusing, especially to the general public but also to many scientific and medical observers. The origins of the SARS CoV2 virus itself have been shrouded in controversy. A debate has raged about whether the virus was of zoonotic origin or of laboratory origin. The clinical outcomes of infection were exaggerated from the very beginning in what looked like a coordinated bid to create a panic reaction in the general public. Other health consequences were ignored.

A globally coordinated program followed of suppression of well known pharmaceuticals and nutritional products which may have had utility as therapies in the early stages of viral infection. And only one solution was promoted -- a new vaccine technology that had never been used before in human beings on a large scale.

Since the introduction of the Covid vaccines, many questions have arisen about lack of adequate manufacturing practices, of quality control, of basic pharmacological and toxicological studies and of appropriate clinical safety and efficacy studies. There seems to have been a reluctance on the part of drug regulatory authorities in many nations to acknowledge both the unprecedented level of reported serious adverse drug reactions and deaths reported in association with these products.

Given the considerable safety concerns following the introduction of these gene-based COVID vaccines, why are governments around the world, including Australia, planning to make further significant investments in this unsafe, rushed vaccine technology driven by the US military?

Operation Warp Speed

Following the US Food and Drug Administration (FDA) Emergency Use Authorisation of the first COVID-19 vaccines in the US (FDA, 2020) and the Provisional Approval of the first COVID-19 vaccine in Australia (TGA, 2021), they were hailed as a remarkable and innovative life-saving response by the pharmaceutical industry to a deadly pandemic which was sweeping the world.

The development, testing and drug regulatory approval of these novel COVID-19 gene-based vaccines using messenger ribonucleic acid (mRNA) technology was said to be done in less than one year, as opposed to the normal development and approval time of about 10 years for conventional vaccines (Seneff and Nigh, 2021). The public was told this achievement was assisted by the financial support of the US government under Operation Warp Speed working to support vaccine companies including Pfizer, Moderna, AstraZeneca, Sanofi, Novavax and Biontech.

The public was told that these COVID-19 gene-based vaccines were proven to be "safe and effective" (CDC[a], 2022). This was echoed by the US FDA and other drug regulators around the world. We were also told these gene-based vaccines would prevent infection and reduce the chances of serious illness and death from the virus SARS-CoV-2. Furthermore, we were told these innovative gene-based vaccines would prevent transmission of the virus so everybody needed to be vaccinated to prevent the spread. Vaccine mandates were introduced to

coerce as many people as possible to be vaccinated. There was a relentless fear campaign generated by so-called "health experts" and epidemiologists predicting massive numbers of death.

Unprecedented lockdowns deprived the population of their freedoms, businesses were destroyed, children were denied education, psychological stress and depression was commonplace and those suspicious of the safety of the gene-based vaccines were ostracized from society and blamed for the viral spread ("pandemic of the unvaccinated"). Mass censorship by the media ensured that the public, and even the medical profession itself, were provided with only limited information about the true nature and risks involved in using the COVID-19 vaccines. The very worst of human nature was revealed.

However, since the introduction of these gene-based vaccines, disturbing facts are now emerging. We now know that these vaccines do not prevent infection nor transmission of infection as recently confirmed by a senior Pfizer executive in testimony before the European Parliament (News, 2022) and have not prevented a continuing high incidence of COVID-19. We now know these vaccines are not as safe and effective as originally claimed (Turni and Lefringhausen 2022; Altman, 2022; CMN, 2022; Blaylock, 2022). These vaccines appear to have been associated with an unprecedented incidence of serious adverse events and deaths compared to any other drugs in the history of the pharmaceutical industry.

Based on the US CDC Vaccine Adverse Event Reporting System (VAERS), there are now 1,476,227 adverse event reports through December 2, 2022 including 32,621 reported deaths and 185,412 hospitalizations associated with these gene-based vaccines (CDC[b], 2022). A disturbing rise in unexplained excess deaths including heart attacks, strokes, cancer and neurological diseases have been reported around the world coincident with the introduction of these vaccines. In Australia, up to August 2022 there were 18,671 excess deaths (17.0%) more than baseline average with most of these deaths not due to COVID-19 (ABS, 2022). Literally, millions of people around the world have either been seriously affected and/or died. 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 simple and plausible answer to this question has now emerged within the last few weeks.

A National Security Operation

There is now evidence to suggest that the SARS-CoV-2 virus was interpreted by the US as a national security threat in early 2020.

Furthermore, there appears to be strong evidence that the United States Department of Defence (DoD) was, and still is, in full control of the Covid Vaccine development program, including the clinical trials, development, manufacturing, quality assurance, distribution and administration since early 2020 (FDA, 2020; Rees and Latypova, 2022; KEI, 2022; Medical Defense Consortium, 2022; Rees, 2022). The evidence shows that the Chief Operating Officer for the Warp Speed vaccine program is the US Department of Defence. It also shows that the Chief Science Advisor is the US Department of Health and Human Services (HHS). It appears that all the pharmaceutical manufacturing and distribution is being done under contract with or by the US Department of Defense.

The major pharmaceutical companies, AstraZeneca, Janssen, Moderna, Novavax, Biotech/Pfizer and Sanofi, have been involved as "Project Coordination Teams" acting under contract to the US Department of Defense.

Communications to the American people by Anthony Fauci (Chief Medical Adviser to the President), Rochelle Walensky (Director of the CDC) and Alex Azar (Secretary of the US Health and Human Services) have been disingenuous from early 2020 to late 2022.

Contrary to popular belief that international pharmaceutical companies drove the COVID vaccine development programs, evidence published on the US FDA's website (FDA, 2020) reveal a chain of command and control under Operation Warp Speed whereby Covid vaccine manufacturers effectively performed as subcontractors to the DoD. Such overall authority and control could account for the apparent readiness of the FDA to significantly compromise or trade off the normal safety standards for the sake of expediency given the DoD imperatives and the perceived emergency.

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 these serious therapeutic agents consequently are poorly understood by the population at large. Referring to these products as "vaccines" led most people to consider these therapeutic products to be relatively safe and well researched and they readily accepted their widespread use without question.

However, these COVID-19 'vaccines' are not really vaccines – they are serious gene-based therapies which employ a gene-based technology which has never before been deployed in a fully approved therapeutic product. In this sense they should properly be considered to be experimental, and much safety and efficacy information has been gained since the introduction of these products almost two years ago.

COVID-19 'vaccines' fall under the US FDA Office of Cellular, Tissue and Gene Therapies' definition of "gene therapy products", in that these products involve "introducing a new or modified gene into the body to help treat a disease" (FDA, 2018). Despite this, the FDA did not evaluate this therapy in relation to the specialised and established gene therapy guidelines. Gene therapies have never been widely used in a general population.

While gene therapies have been the subject of considerable research over the last couple of decades their application has been limited to the treatment of usually rare, serious and debilitating disease or genetic conditions. The reason being is that these products have a potential to cause permanent intergenerational genetic damage, cancer and interfere with reproductive capacity. Gene therapies are viewed as a special class of therapeutic agents due to these potential risks including death and irreversible harm. For this reason, the US FDA and other drug regulatory agencies have put in place detailed rules and guidance documents to direct manufacturers in the development and testing of these products. These guidelines cover both preclinical (FDA, 2013) and clinical (FDA, 2015) research. Due to the obvious and accepted inherent risks, gene therapies have never before been considered for mass deployment in a population, especially to healthy individuals including children, infants and pregnant women.

To facilitate general population acceptance, there was a concerted effort to avoid referring to the COVID-19 "vaccines" as gene therapy products. However, the fact is that these products utilize the delivery of genetic

material to produce a pharmacological effect. Advocates of the gene-based vaccines argued that because the genetic material in the COVID-19 vaccines was not intended to be incorporated into an individual's DNA or modify the expression of genes within DNA, these products should not be considered as "gene therapy". However, such a distinction would appear to have more to do with market acceptance than with science.

Due to the risky nature of gene-based therapeutics, there are only a few examples of RNA based genetic therapies in early clinical research. Isolated examples of such products have been approved for serious and relatively rare genetic defects. The first such product ever to be approved by the FDA was Onpattro (patisiran) in 2018 (FDA, 2018). But even this RNA gene therapy was unlike the RNA payload contained in the COVID-19 vaccines because the RNA contained in Onpattro was only a very small short chain RNA called "short interfering RNA" or siRNA. This was only intended to silence or modify the expression of a target defective gene. The RNA in COVID-19 vaccines is much larger and coded for the production of a very large spike protein which was intended to induce the production of antibodies. Unfortunately, it is now understood that the spike protein itself has considerable toxicity in its own right and is responsible for the serious adverse effects of the COVID-19 vaccines (Cosentino & Marino 2022 and Seneff & Nigh, 2022).

No therapeutic products similar to the COVID-19 vaccines have ever been previously approved anywhere in the world. There was no prior short-term or long-term safety data in relation to these completely new gene-based vaccines with which to predict the safety of these products. Advocating the administration of this completely new class of therapeutic to the world population with no historical safety experience was an unprecedented risk in human health and it appears the gamble has not paid off.

Accelerating Development

The evidence suggests that the plan from the outset was to accelerate development of the messenger RNA platform vaccine technology involving lipid nanoparticles and viral vectors. RNA platform technology is not new to the DoD and has been under research by DARPA (Defense Advanced Projects Research Agency) since 2012 (McCullough, 2022).

The mRNA platform technology is an example of a dual use technology which can either be applied for vaccine use or for military use (Biodefense in the Age of Synthetic Biology, 2018) in much the same way as nitrogen-based fertilizer can be used for agriculture or to make explosives.

With regard to the COVID-19 vaccines, to save time, certain critical research and development activities were either not done at all, not done in a normal and logical sequential manner or not done to established laboratory or manufacturing standards normally required by the pharmaceutical industry. The failure to study the toxicology of the spike protein in animal toxicology studies is an example of critical research which was not done.

It has not been recognised or appreciated to date that the mRNA contained in the lipid nanoparticles in the case of the Pfizer and Moderna vaccines is actually, in pharmacological terms, a prodrug (Cosentino and Marino, 2022). It is the spike protein which is the active drug and which is directly responsible for the immune response. However, the pharmacology and toxicology studies of the spike protein in animals or humans were not done as would normally have been required. This is the major fundamental error in the research and

development of these COVID-19 vaccines and this oversight is directly responsible for the failure to predict the serious adverse drug reactions and mortality which have now been reported in association with these vaccines.

Other examples of the total failure to conduct critical research include the lack of properly designed carcinogenicity, mutagenicity, genotoxicity and reproductive toxicological studies in appropriate animal species. In particular, the potential for reverse transcription of mRNA genetic material into an individual's DNA was not investigated.

An example of the failure to conduct research and development in a logical and sequential manner included the premature scale up manufacture without adequate quality control to ensure that product made in large batches is the same as made in smaller batches. Without proper scale up research, the potency, mRNA integrity, presence of contaminates and stability cannot be guaranteed. There are problems in relation to scale up manufacturing even for conventional small molecule drugs. These gene-based vaccines are highly complex biopharmaceuticals where scale up problems would be expected. This would mean that any toxicological or clinical safety and efficacy data generated using early production batches of product may not be relevant or applicable to the safety and efficacy of product derived from large scale manufacture.

In order to mitigate risk, the plan 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. This approach necessarily embodied obvious and predictable product safety risks.

Avoidance of time consuming and conventional oversight and quality standards and guidelines such as Good Manufacturing Practice and Good Laboratory Practice guidelines was necessary to speed development. The plan also avoided conventional New Drug Application (NDA) and Biologics License Application (BLA) approvals, moving 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 clinical trials which may have contravened accepted codes of Good Manufacturing Practices.

Such circumvention of normal development and quality control systems and pathways was arguably a recipe for potential disaster. Safe drug development requires sequential, step by step, accumulation and verification of data upon which to plan and adjust the following research, development and manufacturing steps in light of the knowledge gained. In the rush to bring these novel gene-based vaccines to market as quickly as possible, the normal logical safety considerations were compromised (Latypova, 2022; Watt and Latypova, 2022).

The Legal Framework

Three key legislative elements enable the US government to authorise, fund, contract and control many DoD research programs including COVID-19 gene-based vaccine development, testing and manufacture. These elements are:

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

Two US Department of Defense Agencies, Defense Advanced Research Projects Agency (DARPA) and the Biomedical Advanced Research and Development Authority (BARDA), possess considerable resources themselves to undertake research and development and gain approval for various products themselves but they also contract with a large number of companies in relation to research and development programs.

The products of these research programs are sometimes classified or referred to as "countermeasures", "prototypes" or "demonstrations". This simple change in nomenclature permits these products to avoid conventional lengthy regulatory, commercial development and testing pathways in order to expedite their availability.

BARDA promotes the advanced development of medical countermeasures whether they be chemical, biological, radiological or nuclear (CBRN). With regard to COVID-19, the activities of BARDA include the diagnosis, detection, treatment, prevention and manufacture of medical "countermeasures" to combat COVID-19. The countermeasures include vaccine platform mRNA technologies, viral vector technology and protein expression technology.

One could imagine that such an operational system and legislative framework is necessary to respond to a biological, chemical or nuclear attack as quickly as possible. However, it appears that this infrastructure was used to rapidly develop the COVID vaccines for general civilian use without the application of the time-consuming safeguards normally required to produce safe therapeutic pharmaceutical products.

The capability of these Agencies is substantial and include raw material supply, manufacturing, testing and scale up facilities including large scale manufacturing facilities in parallel with clinical development.

Applying Emergency Use Authorizations to "countermeasures" appears to be a mechanism to avoid the normal, conventional clinical trial regulated pathways. However, "countermeasures" should not be conflated with conventional pharmaceutical products which are required to be extensively tested for safety according to established international guidelines (ICH, 2022).

Examples of technical areas of interest of DARPA and BARDA include: therapeutic prototypes targeting viral, bacterial, and biological toxins and other countermeasures. Enabling technologies include single and multiple-drug autoinjector delivery devices, vaccine-manufacturing platforms, prototypes for the prophylaxis, treatment and diagnosis of CBRN threats including Acute Radiation Syndrome and chemical nerve agents. Collaboration

also includes the development of systems to increase the speed, accuracy and confidence of agent identification and disease diagnosis and advanced development and manufacturing capabilities.

The Rush to Large Scale Manufacture

RNA technology has been an area of interest in relation to national security. However, COVID-19 vaccines using this technology, by their complex nature, are difficult to manufacture, stabilize and quality control especially on a large scale.

In the rush to make available the Covid vaccines, the bypassing or compromising of normal manufacturing and quality control safeguards has reportedly led to batch-to-batch variability whereby some batches are 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 Covid vaccine vials for which there is no satisfactory or official drug regulatory 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 from sale – but this has not happened. Pharmaceutical regulators around the world seem to be wilfully blind to the problems. Governments and the main stream media appear to show no interest in uncovering the truth or conducting a public debate on these critical matters of individual health, rights and wellbeing. 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 right from the very start of the perceived threat in early 2020. The panic that then ensued created the circumstances whereby the normal prudent quality, safety and efficacy considerations in the development of vaccines were compromised. Drug regulators played, and continue to play, an acquiescent role in approving these vaccines and declaring them "safe" based on an absolute minimum of quality, safety and efficacy data and no long-term safety data. After two years, we now see this was a mistake. Contrary to the governmental and main stream media narrative, many are 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 since December 2020. This has been exacerbated by the intense and unprecedented censorship of doctors and scientists which continues to this day.

Are the COVID-19 Vaccines Pharmaceutical Products?

The US DoD had complete command and control over the research, development, manufacturing, testing, distribution and release of the COVID-19 gene-based vaccines. However, under various specific US government regulations, the US Secretary of Health and Human Services (HHS) issued Emergency Use Authorisations for a number of "countermeasures" (called COVID-19 vaccines) to be released for use. This nomenclature is of critical importance. By designating the COVID-19 vaccines as "countermeasures" these products were (and are) not subject to regulatory control by the FDA because, by definition, they are not pharmaceutical products.

Under the US Emergency Use Authorisations the COVID-19 vaccines were not required to be proven safe and effective or conform to normal quality standards as do pharmaceutical products approved by the FDA. The Australian government, the Australian Therapeutic Goods Administration (TGA) and presumably other governments and their regulatory bodies, should have known that the COVID-19 vaccines they approved for use and contracted to purchase did not have the status of normal pharmaceutical products in the US and they should have never declared them "safe and effective".

Conclusion

Since the introduction of the Covid vaccines, many questions have arisen concerning the lack of adequate manufacturing practices, quality control, basic pharmacological and toxicological studies and the lack of appropriate clinical safety and efficacy studies. In addition, there seems to be a reluctance on the part of drug regulatory authorities to acknowledge both the unprecedented level of reported serious adverse drug reactions and deaths that have been reported in association with these products.

There is also the serious concern regarding the ominous rise in excess deaths from all causes in many countries suspiciously coincident with the introduction of the COVID vaccines – yet 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 compromised in the name of national security and not applied to the development and testing of these vaccines? Why was this kept secret?

Also, are these national security arrangements still in place for future vaccines and other pharmaceutical products?

Given the considerable safety concerns which have occurred following the introduction of these gene-based COVID vaccines, why are governments around the world including Australia, planning to make further significant investments in this unsafe vaccine technology driven by the US military?

The lesson to be learned here is that development and production of vaccines and other therapeutic products for general civilian use should never again be allowed to be under military command and control.

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

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