Australian Standfirst

COVID-19 Vaccinations – Efficacy, Safety, Tort Litigation & Data Deficits:
An Economic + Financial Markets Bet Like No Other

Risk Management
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Justifiable questions surrounding the *bona fides* of recently announced SARS-CoV-2 ('COVID-19') vaccinations remain.

On 10 December, the eminent Food and Drug Administration ('FDA') Vaccines and Related Biological Products Advisory Committee (VRBPAC) panel meet in open session to discuss ***Emergency Use Authorisation (EUA)*** of the Pfizer [PFE:US] - BioNTech [BNTX:US] COVID-19 Vaccine and on 17 December, meet again deliberating upon Moderna Incorporated's [MRNA:US] EUA application.

Both leading cohorts depend upon ***messenger "RNA" science*** – Ribonucleic Acid, a nucleic acid present in all living cells, principally acting as a messenger carrying instructions from DNA for controlling the synthesis of proteins however importantly, in some viruses, RNA rather than DNA carries the genetic information – and this is a novel platform with **no previous commercial experience** and is fundamentally different to other traditional vaccine platforms, which buttressed Zika, SARS coronavirus (2003) and H1N1 viruses.

To boot, Moderna Inc., has only been in existence for precisely a decade this quarter and has never received FDA approval for any of its products.

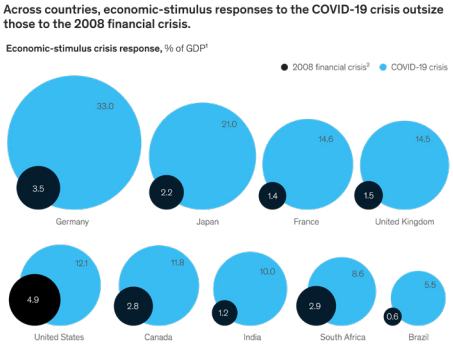
Unproven scientific approaches, greenhorn biotechnology companies and a transnational contagion still outspreading within its first year, these, in the gambling vernacular are as "***high stakes***" action as it gets.

Cite:- A 2021 COVID-19 Vaccine Likely But Remains Underpriced: Ignore the Pollyannas & Identify The Winners, Early, 25 August 2020

As **recently argued**, not only do all roads surrounding the ***Global Corona Crisis (GCC)*** lead to Reflation, they are also all anchored to the premise a genuine vaccine will arrive in the foreseeable future: if the novel ***messenger RNA delivery approach*** fizzles, *pandora's box opens* politically, economically and even potentially militarily.

Above and beyond a **Game Theorists** risk assessment about winners and losers in the race towards a commercial vaccine, legalities and tort litigation idiosyncrasies remain unanswered, especially due to the unstable nature of known RNA technologies that exist today.

Organisms that need to change rapidly tend to use RNA as their genetic material; viruses, such as influenza and HIV, choose RNA rather than the more stable alternative of DNA so they can change and keep one step ahead of the immune system of their hosts. We make RNA copies of our DNA genes, the messages, or **mRNAs**, reflect the sequence of bases in our DNA and travel out of the nucleus (where our DNA is stored) into the cytoplasm where they are translated into proteins. The proteins go on to do jobs in the cell and the unstable **mRNAs** simply decay or are degraded.



The legalities regarding such a nascent and fragile technique are not new but they do raise issues for manufacturers, sovereign-state actors making executive purchasing decisions for entire nation-states and vaccine distributors, whom, ultimately, carry the legal burden if inoculation goes awry.

At this point there is no evidence to suggest that this virus (SARS-CoV-2) will mutate away from a vaccine and a potential analog to point to is the **measles vaccine** which has not mutated away in sixty years (measles is also single stranded RNA virus, not a segmented virus like the seasonal flu).

Watch:- Infinity Black Guest Associate Professor Dr Michael Ben-Meir & Kwame Owusu, 23 March 2020

As past experience has shown, concerns over the potential legal liability for any adverse effects of a vaccine can have a disruptive effect on the willingness of manufacturers and others in the vaccine supply chain to participate widely in a vaccination campaign.

Historically, similar fast-moving, large-scale vaccination programmes in the United States could have stalled when pharmaceutical companies were reluctant to begin production because of what they perceived as the risks of lawsuits over side effects and other adverse medical consequences of vaccinations.

In 1976, when an influenza outbreak in Fort Dix, New Jersey was determined to have been caused by a virus related to the one responsible for possibly 675,000 deaths in the United States during the 1918–1919 worldwide pandemic, President Gerald Ford quickly announced a plan to "*inoculate every man, woman and child in the United States*" with a vaccine against the newly discovered strain (popularly referred to as the swine flu but not to be confused with the ***1968 Hong Kong Flu*** which affected Australia as well).

But there was immediate pushback from vaccine manufacturers over their potential liability exposure and when their insurers began to refuse to provide policies that included coverage for such losses, large-scale production of the vaccine was placed in significant jeopardy. In response, US Congress rushed through legislation that substituted the United States as the defendant in any lawsuit filed against a vaccine manufacturer, a vaccine distributor, or any entity providing free vaccinations.

In effect, a person who believed that he or she had been harmed by a swine flu vaccination could sue to recover losses (e.g., medical expenses, lost income, loss of financial support as a result of death, compensation for pain and suffering) but the US Federal Government would defend such suits and pay any resulting verdicts or settlements.

Liability concerns also were at the centre of a vaccination campaign first proposed in 2001, spurred by the potential threat of a bioterrorism event involving the release of smallpox virus, the US Federal Government began to contract with manufacturers to stockpile enough vaccines to inoculate every American if necessary.

In a section inserted into the Homeland Security Act of 2002 (HSA) just before final consideration, every smallpox vaccine manufacturer or distributor, healthcare entity providing the vaccine and health care professional or other individual authorised to perform the vaccination would be deemed "*an employee of the [Federal] Public Health Service with respect to liability*" arising from the administration of that vaccine.

Unlike the situation involving the swine flu and smallpox campaigns, liability protections are already in place for all vaccines developed in response to SARS-CoV-2. As a result of the Public Readiness and Emergency Preparedness Act of 2005 (PREP), manufacturers, distributors and other actors can be provided tort immunity related to the development, manufacturing, testing, distribution, administration and use of certain countermeasures against epidemics, pandemics and acts of bioterrorism.

Previous declarations have covered vaccines for the 2009 H1N1 pandemic flu, Ebola virus and Zika virus. On March 17, 2020, the HHS secretary issued the required liability protection declaration, which covered any antiviral, drug, biologic, diagnostic, device, or vaccine "***used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.***"

The only meaningful exception to that immunity would be for acts or failures to act that constitute "*wilful misconduct*" on the part of the covered entity or person—an extremely rare event in the context of vaccine side-effect litigation.

All considered, one may well argue that yet unproven scientific approaches, greenhorn biotechnology providers and erratic State actors carving out exclusion and limitation clauses on experimental twenty-first century *avant-garde* vaccine ***crapshoots***, is anything but **bona fide**. ■