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From Innovation to Inquiry — COVID-19 mRNA Vaccination and Its Global Consequences with Special Reference to New Zealand

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Abstract

The COVID-19 pandemic involved the rapid deployment of novel biomedical technologies. Chief among them were synthetic RNAs, introduced with limited longitudinal data, yet supported by institutional consensus, and expedited regulatory pathways. Subsequent developments revealed questions regarding safety, ethics, efficacy, and governance. This formal review, with specific reference to New Zealand, examines the COVID-19 response, using synthetic RNA distributed under Emergency Use Authorizations. A range of post-deployment signals, including immunological anomalies (IgG4 class switching), clotting disorders, and residual DNA elements, remain insufficiently investigated. Regulatory responses have not met the standard of precaution typically applied to novel gene therapies. At the same time, low-cost interventions such as ivermectin were deprioritized, or suppressed. The temporal association between vaccine rollouts and excess non-COVID mortality in several high-uptake nations warrants systematic, transparent analysis. To date, no national authority has published comprehensive disaggregated mortality data by vaccination status.

Keywords: adverse events, COVID-19 vaccination, Emergency Use Authorization, EUA, genetic engineering, IgG4 class switching, mRNA vaccination, plasmid DNA, post-market surveillance, therapeutic suppression, ivermectin, spike protein toxicity, regulatory oversight failure, scientific censorship, turbo cancer, vaccine-induced thrombotic thrombocytopenia, VITT

A Personal Introduction

There are moments in a scientist's career when it becomes necessary to speak. Not out of defiance, but from a sense of duty — when the need for clarity outweighs the comfort of silence. This report

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is not written in opposition to science, or public health, but in support of both. It arises from a professional obligation to assess, reflect, and contribute constructively to our understanding of the global COVID-19 response. As a scientist trained in health and environmental disciplines, I am guided by evidence, ethical frameworks, and a longstanding commitment to minimizing harm. Over the course of the pandemic, I observed changes in how information was managed, how decisions were made, and how dissenting perspectives were handled within scientific and public institutions. Raising questions about emerging technologies — such as the novel use of synthetic mRNA-based products — resulted, in my case, not in debate, but in distance. Critical perspectives were often met, not with engagement, but by withdrawal. Relationships altered. Professional opportunities narrowed. Nevertheless, the available data did not fully support the level of confidence being communicated to the public. And the potential harms — initially dismissed — are now becoming increasingly visible.

What is currently unfolding is complex and evolving. It includes not only the consequences of the virus itself, but also those of our collective response. Many individuals have experienced serious, ongoing health effects following vaccination — ranging from cardiovascular to neurological and autoimmune conditions. These cases, though not universal, are not insignificant. Each one represents a life affected, a family disrupted, and a need for further investigation and understanding. The term "vaccine", as applied during the COVID-19 crisis, carried with it expectations of safety, transparency, and long-term benefit. While the phrase "safe and effective" may have facilitated regulatory approval and public uptake, it also contributed to a simplified narrative that did not reflect the full scope of available evidence. Questions regarding long-term safety, informed consent, proportionality of the response to the threat of harm remain open, and deserve ongoing attention.

The New Zealand Royal Commission of Inquiry into the COVID-19 Response

In New Zealand, a Royal Commission of Inquiry was established to examine the lessons learned from COVID-19 (Illingworth et al., 2025). As early as June 22, 2021, according to a CNN report, "at least 34 states had introduced bills that would limit requiring someone to demonstrate their vaccination status or immunity against COVID-19, according to the National Conference of State Legislatures, which has been tracking legislation related to coronavirus vaccines. At least 13 states — Alabama, Arkansas, Florida, Indiana, Iowa, Kansas, Missouri, Montana, North Dakota, Oklahoma, Tennessee, Texas and Utah — have passed them into law, according to the document, and "at least six of those include language pertaining specifically to schools or education" (Howard, 2021). Hear the well-known Sanjay Gupta, MD, at this link speak about the perceived threat. The rapid development and deployment of synthetic mRNA vaccines was publicized as a significant scientific achievement. However, as vaccination campaigns progressed, a more complex narrative emerged encompassing legal debates, public health policies, evolving medical observations, and discussions of alternative treatments. This submission explores the shifting landscape of COVID-19 vaccination, focusing on legislative actions, excess mortality trends, emerging health phenomena, and the evolving discourse on ivermectin, all within a framework of scientific and legal scrutiny.

acoustic health environments and is the author many books, 7 of them on the COVID-19 pandemic, and the global vaccine response. He continues to collaborate internationally on scientific and policy research while making complex science accessible to general audiences through his writing and public lectures.

LEGISLATIVE RESPONSES TO MRNA VACCINES

In the US, more than a few states have introduced legislation aimed at restricting or banning the use of the new mRNA vaccine technology. For instance, Iowa, Montana, and Idaho have proposed bills to limit mRNA vaccine usage (Nevradakis, 2025). In Iowa, a bill was advanced that would penalize providers with fines for administering mRNA-based vaccines, although it was later amended to require vaccine manufacturers to waive federal liability protections (Opsahl, 2025). Similarly, Idaho considered a bill to impose a ten-year moratorium on mRNA vaccines, categorizing them as "gene therapy products" (Wagner, 2025). These legislative efforts reflect a broadening skepticism towards mRNA technology and raise questions about the balance between public health initiatives and individual rights. While proponents of the restrictive legislation argue for caution and further research, opponents have argued from the outset of these discussions that such restrictions could hinder medical advancements and public health responses (see Gibney, 2025).

MANDATES AND INSTITUTIONAL POLICIES

The debate over vaccine mandates has also intensified. Thirteen states have now enacted laws prohibiting employers from mandating COVID-19 vaccines for workers, with additional states considering similar measures. In the educational sector, "seventeen states have laws preventing schools from requiring COVID-19 vaccinations for students" (Howard, 2021). At the federal level, an executive order was signed to prohibit federal funding for educational institutions that mandate COVID-19 vaccinations (The White House, 2025). These policy shifts underscore a growing emphasis on personal choice and autonomy in health decisions. They also reflect a response to public concerns about vaccine safety and the role of government in mandating medical interventions.

A FAILURE THAT DEMANDS RECKONING

In the United States, the testimony of Pierre Kory, MD, before the US Senate (Kory et al., 2021) in which he advocated for including ivermectin in early treatment protocols — was viewed millions of times, only to be followed by coordinated media backlash and institutional retaliation. In Brazil, doctors were criminally investigated for using ivermectin during the height of the pandemic (Meyer & Bustamante, 2021). In New Zealand, general practitioners (GPs) who followed international protocols were quietly removed from practice (McCarthy, 2022). This must now be redressed. This is not merely a story of differing interpretations of clinical data. It is a case study in therapeutic censorship: a moment in modern medicine where scientific heterodoxy was rebranded as misinformation (Malhotra, 2022), and the physician's right to exercise professional judgment was subordinated to centralized, politicized guidelines. Had these early outpatient interventions been explored with good faith, rigor, and transparency, the global trajectory of the pandemic might have been meaningfully altered. Hospital systems could have been spared collapse. Vulnerable populations might have accessed treatment sooner. The perceived necessity for mass vaccination, including coercive mandates, might have been diminished. Instead, a single-minded strategy took hold — one in which all alternative perspectives were treated not as contributions, but as threats (Wilson & Rudge, 2023).

The consequences were not only clinical, but constitutional. The scope of therapeutic choice narrowed. Clinical autonomy eroded. And healthcare decision-making was consolidated in a handful of agencies — largely unaccountable, internationally aligned, and financially entangled (Brown et al.,

2023). This is not how science functions in a democracy. Elected officials are not medical professionals, and their decisions should reflect that boundary. The conflation of political authority with medical expertise is not merely unwise — it is dangerous. When governments overstep and institutions silence dissent, the result is not public safety — it is public harm, cloaked in the language of protection.

Non-Vaccine Therapies: Legal and Scientific Perspectives

The deliberate obstruction of early treatment options was not a neutral act of scientific caution — it was a strategic and ideologically enforced suppression that placed narrative control above clinical reality. It disfigured the foundation of evidence-based medicine, silenced frontline clinicians, and denied millions the opportunity for timely, low-cost, potentially life-saving interventions. When public health policy excludes therapies not because they fail, but because they do not serve the prevailing agenda, that is not public health. It is policy capture. The consequences are irreversible for many. Patients who might have recovered with early intervention were instead hospitalized, ventilated, or buried. Doctors who upheld their oath to do no harm were punished for offering informed alternatives.

TREATMENT OPTIONS DENIED: TRUTH SUBVERTED

The public, in turn, was deprived not just of treatment options, but of the truth. This is why the suppression of early therapeutics — especially ivermectin — must not be dismissed as a policy misstep or excused as an emergency-era necessity. It was a coordinated abdication of scientific responsibility, institutional humility, and medical ethics. And its legacy is written not only in peer-reviewed rebuttals and redacted emails, but in the graveyards of every country that chose silence over scrutiny. The call for accountability is not academic. It is urgent. When medical freedom is revoked, and inquiry is crushed beneath the weight of political consensus, we do not arrive at safety. We arrive at suffering — manufactured, magnified, and avoidable.

IVERMECTIN: LEGAL AND SCIENTIFIC PERSPECTIVES

Ivermectin, traditionally used as an anti-parasitic agent, gained attention during the pandemic as a potential treatment for COVID-19 (Kow et al., 2021). Early in vitro studies suggested antiviral properties, leading to widespread interest (Formiga, 2020 Caly, 2020; Zaidi & Dehgani-Mobaraki, 2022). Subsequent meta-analyses based on 18 randomized controlled treatment trials indicated significant reductions in mortality, time to clinical recovery, and time to viral clearance (Kory et al., 2021). Furthermore, results from numerous controlled prophylaxis trials reported significantly reduced risks of contracting COVID-19 with the regular use of ivermectin (Kerr et al., 2022; Zalpoor et al., 2023). In response to public demand and emerging studies, several US states have enacted legislation to make ivermectin more accessible. For instance, Idaho and Arkansas have passed laws allowing the sale of ivermectin for human use without a prescription (Pfannenstiel, 2025; Bringhurst, 2025; KFF Health News, 2025). These legislative actions reflect a shift towards recognizing alternative treatments and granting individuals greater autonomy in their healthcare choices.

In India, ivermectin was incorporated into COVID-19 treatment protocols in several states. The state of Uttar Pradesh (Seth, 2021; Trialsitenews, 2021), for example, adopted ivermectin for both prophylactic and therapeutic use, reporting beneficial effects in reducing infection rates and

mortality. A matched case-control study conducted among healthcare workers in Bhubaneswar, India, found that two-dose ivermectin prophylaxis at a dose of 300 µg/kg with a gap of 72 hours was associated with a 73% reduction in SARS-CoV-2 infection among healthcare workers for the following month (Behera et al., 2021). However, it is important to note that subsequent evaluations by Indian health authorities led to the removal of ivermectin from national treatment guidelines in June 2021, citing insufficient evidence of efficacy (Thacker, 2021). This is widely understood to be a political response due to increasing pressure from world authorities including the WHO.

Major health organizations, including the US Food and Drug Administration (FDA), claimed that there was insufficient evidence to support the use of ivermectin for COVID-19 treatment (AMA, 2021; Office of the Commissioner US FDA, 2022). The FDA would not authorize or approve ivermectin for use in preventing or treating COVID-19 in humans or animals. The US Food and Drug Administration concluded that the available clinical trial data did not demonstrate ivermectin's efficacy in treating COVID-19 in humans. However, this position appears to have been adopted in the absence of a comprehensive evaluation of real-world evidence and emerging international studies. The consistency and timing of such regulatory statements suggest that institutional bias—potentially influenced by commercial alignments and patent-driven incentives — may have played a decisive role. This raises serious concerns about whether public health guidance was shaped more by economic and political considerations than by an impartial assessment of therapeutic potential.

The global narrative surrounding COVID-19 vaccination has undergone a profound transformation — from early optimism and mass mobilization to rising scrutiny, reassessment, and legislative backlash. While initial policy responses were driven by urgency and the promise of novel biomedical technologies, hindsight has introduced new dimensions of complexity: ethical tensions, legal challenges, and continually accumulating evidence of harm (Regenstein et al., 2022; Mead, Seneff, Wolfinger, et al., 2024; Mead, Seneff, Rose, et al., 2024). Emerging scientific analyses, such as those led by physicist and epidemiologist Rancourt, estimate that the global death toll from vaccine-related adverse events may now approach 30 million people (Rancourt & Hickey, 2023a, 2023b; Rancourt et al., 2023a, 2023b) — a figure derived from analyses of excess mortality temporally aligned with vaccination rollouts, independent of COVID-19 infection rates. Such findings challenge the prevailing public health narrative and demand rigorous investigation. This figure, though controversial and not widely accepted by mainstream entities, is grounded in excess mortality analysis and deserves independent scientific review. The scale of these claims, if further substantiated, would represent one of the most significant public health misadventures in history.

Simultaneously, alternative therapies once ridiculed or censored — such as ivermectin — are being reconsidered in both clinical and policy circles. Success stories from states like Uttar Pradesh in India, where ivermectin was integrated into early intervention protocols with notable reductions in hospitalizations and deaths (see *The Indian* Express, Seth, 2021; Turkia, 2021; Kory et al., 2021), stand in stark contrast to the centralized suppression of treatment options observed elsewhere. The recent legalization of over-the-counter ivermectin sales in parts of the United States marks a tectonic shift in regulatory tone and underscores the growing emphasis on therapeutic pluralism and patient sovereignty. What began as legislative changes in numerous US states — banning vaccine mandates for workers and students, and even restricting the deployment of mRNA technology itself (Perkruhn & Abbasi, 2022; Carbarjal, 2025; COVID-19 pandemic in Montana, 2025; COVID-19 vaccination mandates in the United States, 2025; Reed, 2025; Armour, 2025) — reflect a broader cultural reckoning with the coercive public health strategies of the past three years. Many nations are

now openly debating the role of global health institutions, the erosion of informed consent, and the economic and psychological toll of prolonged crisis management.

Ivermectin as a Zinc Ionophore: A Non-Technical Summary

While ivermectin is not traditionally classified as such (see Ionophore, 2025), mechanistic studies have shown it can dimerize into a molecular complex that behaves like an ionophore — upregulating chloride channel activity in concert and can facilitate apoptosis-related osmotic cell death (Zaidi & Dehgani-Mobaraki, 2022). If this is correct, it could enhance zinc uptake into cells and elevate intracellular zinc levels — thereby amplifying zinc's natural antiviral action against RNA-dependent RNA polymerase (Blaylock, 2021, 2022). These combined actions provide a biologically plausible rationale for continued exploration of ivermectin, particularly as an early intervention agent or as part of a multi-drug protocol. While more high-quality clinical data is needed to confirm these mechanisms and their practical relevance in treating COVID-19, the concept of repurposing existing drugs like ivermectin for their ionophoric and synergistic potential remains a promising area of research.

Grounds for Public Inquiry— Evidence of Coordinated Obstruction

From early 2020, a mounting body of preclinical and clinical data suggested that ivermectin, an off-patent medicine with an extensive safety record, could play a meaningful role in early intervention against SARS-CoV-2 infection. Meta-analyses of dozens of studies — compiled by independent researchers and international collaborations (Bryant, 2021; Kory et al., 2021) — demonstrated promising results in both prophylaxis and treatment. Its low cost, widespread availability, and known pharmacodynamics made it a logical candidate for repurposing in a global emergency. Yet instead of encouraging scientific exploration, the response from public health institutions was marked by systematic dismissal, reputational attacks, and regulatory obstruction (AMA, 2021; Kujur, 2022; McGill, 2023; Marcolino et al., 2023).

Medical journals declined to publish supportive studies. Research funding was withheld. Social media platforms censored discussion. In some jurisdictions, including New Zealand, doctors faced investigation, suspension, or deregistration for prescribing ivermectin or even publicly advocating for its study (Medsafe, 2021; McCarthy, 2022; Townshend, 2025). The stated justification — lack of robust evidence — was deployed selectively, often while simultaneously blocking the very research needed to produce that evidence, or allowing only trials designed to fail, such as late-stage administration or sub-therapeutic dosing. This pattern did not occur in isolation. It occurred in parallel across multiple jurisdictions, synchronized in timing and messaging. Regulatory bodies including the FDA, EMA, TGA (Australian Government), and Medsafe adopted near-identical stances (Office of the Commissioner US FDA, 2024). The TGA in Australia lifted prescribing restrictions on 3 May, 2023 (Calello et al., 2022; Therapeutic Goods Administration, 2023). Professional medical colleges issued uniform statements discouraging off-label use. Media narratives evolved rapidly from cautious scepticism to outright vilification of any deviation from the vaccine-only strategy (Semeraro, 2022; Fattorini & Loner, 2025).

The result was a coordinated narrowing of therapeutic discourse — one that eclipsed evidence-based medicine in favor of policy orthodoxy. This alignment of government agencies, professional institutions, and corporate stakeholders raises serious questions about the influence of commercial interests, particularly those connected to patented pharmaceutical products, vaccine procurement contracts, and global funding frameworks. The convergence of this institutional bias with

commercial alignment shaped not only public perception, but also clinical options, regulatory priorities, and ultimately, patient outcomes.

In New Zealand, the government not only followed this international pattern but embedded it in formal policy (Medsafe, 2021, 2022). The exclusion of early treatment options, the centralization of health messaging, and the delegitimization of medical dissent represent a profound departure from the principles of transparency, open scientific inquiry, and patient-centered care. By actively suppressing viable therapeutic alternatives, New Zealand authorities aligned themselves with a global strategy that prioritized uniformity over adaptability, and compliance over critical evaluation.

The precedent is not without comparison. History offers examples — from the suppression of early AIDS treatments in the 1980s to the delayed recognition of thalidomide toxicity — of how institutional inertia and commercial interests can derail scientific integrity. But what distinguishes this case is the global scale, the speed of synchronization, and the deliberate erosion of therapeutic plurality during a declared state of emergency. The time has come for a full and independent public inquiry into the suppression of early treatment protocols, including:

- The rationale behind ivermectin's exclusion from national pandemic strategies
- The funding sources and policy influences shaping institutional positions
- The communications between public agencies and pharmaceutical corporations
- The decision-making processes within regulatory bodies that delayed or obstructed alternative treatment trials

In the next section, given in finer print, I deal with some of the more technical details of ivermectin and the zinc ionophores.²

Ivermectin and COVID-19: The Role of Zinc Ionophores

The global response to COVID-19 has placed intense scrutiny on both novel and repurposed therapeutic agents. Among the most controversial is ivermectin, a well-established anti-parasitic drug that has been the subject of significant debate regarding its potential efficacy in treating SARS-CoV-2, the virus responsible for COVID-19. While regulatory agencies such as the US Food and Drug Administration (FDA) have stated that current clinical trial data do not demonstrate sufficient efficacy, emerging research has continued to explore plausible biochemical mechanisms that may justify further investigation. One of the most compelling arguments for ivermectin as an effective anti-viral medication follows directly from its ionophoric properties, particularly its potential to facilitate intracellular transport of zinc ions, which are known to interfere with viral replication.

1. What Is a Zinc Ionophore?

An ionophore is a molecule that facilitates the transport of specific ions across lipid membranes — structures that are typically impermeable to charged particles like metal ions. In the context of human cells, zinc ionophores help shuttle zinc ions (Zn²+) from the extracellular space into the cytoplasm, where they can exert various biochemical effects. Zinc is a vital trace element with multiple roles in immunity, inflammation, and cellular signaling, and has been shown to inhibit coronavirus replication via RNA polymerase suppression (te Velthius et al., 2010). It also has antiviral properties, particularly by inhibiting RNA-dependent RNA polymerase (see Blaylock, 2021, 2022) — an enzyme critical to the replication of many RNA viruses, including SARS-CoV-2. However, simply increasing dietary zinc intake does not

² At one point I proposed to put this material in an Appendix, but the editors persuaded me to place it here in the text to along with the rest of the discussion of ivermectin. Readers already familiar with the technical research and theory of how ivermectin works may choose to skip over the following fine print section.

necessarily raise intracellular zinc levels due to poor cellular uptake. Therefore, zinc ionophores are needed in order to literally "flood" the intracellular environment with zinc where it can exert its potent antiviral effects.

2. Zinc's Role in Inhibiting SARS-CoV-2

Zinc has long been recognized for its antiviral properties. In vitro studies, including those from the early 2000s during the SARS-CoV-1 outbreak, demonstrated that elevated intracellular zinc concentrations can inhibit viral polymerase activity, effectively shutting down the virus's ability to replicate its RNA genome. In the case of SARS-CoV-2, it is believed that similar mechanisms apply. Zinc may interfere with:

- RNA synthesis via inhibition of RNA-dependent RNA polymerase
- Viral protease activity
- Membrane fusion and entry
- Modulation of the host immune response, including reducing the severity of cytokine-mediated inflammation

Thus, increasing intracellular zinc has been proposed as a broad-spectrum antiviral strategy.

3. Ivermectin as a Zinc Ionophore

While compounds such as quercetin and epigallocatechin gallate are well-documented natural zinc ionophores (Xue et al., 2014), there is growing interest in ivermectin's potential to act in a similar manner (Huffman et al., 2022). Preclinical data have shown that ivermectin (Caly et al., 2020):

- Disrupts importin α/β1-mediated nuclear transport, a pathway hijacked by many viruses to suppress host antiviral responses.
- May alter membrane potential and facilitate increased permeability to metal ions.
- Exhibits synergistic effects when co-administered with zinc, implying a functional role in intracellular zinc
 delivery or potentiation.

Although direct evidence confirming ivermectin's ionophoric action is still emerging, its molecular structure and pharmacodynamics support this possibility. It possesses lipophilic properties and functional groups capable of chelating metal ions — hallmarks of ionophoric behavior. Further, clinical outcomes in observational studies and early trials show greater effectiveness when ivermectin is administered alongside zinc and other supportive micronutrients (Soto-Becerra et al., 2020; Bryant et al., 2021), reinforcing the hypothesis of complementary or facilitating roles.

4. Broader Mechanisms of Ivermectin Against SARS-CoV-2

In addition to its possible ionophoric function, ivermectin has demonstrated several other mechanisms that may be relevant to viral inhibition:

- Inhibition of viral entry by binding to spike protein or ACE2 receptor interface.
- Suppression of NF-xB and STAT3 pathways, both involved in cytokine storm and hyper-inflammation (DiNicolantonio et al., 2020).
- Immunomodulation, including downregulation of pro-inflammatory cytokines (IL-6, TNF-α).
- Antiviral activity against a range of RNA viruses, including dengue, Zika, and influenza, suggesting a nonspecific antiviral mechanism.

These properties make ivermectin a candidate for further exploration, particularly in early-stage infection or as part of combination therapy.

5. Controversy and Current Status

Despite a strong mechanistic basis and positive signals from several small clinical trials (Kory et al., 2021; Bryant et al., 2021), ivermectin remains controversial. Critics argue that the evidence is inconsistent or of low quality, and that enthusiasm outpaced regulatory caution. Defenders counter that:

- Many of the largest trials had confounding variables or were conducted in later-stage disease, where antiviral
 agents are typically less effective.
- Suppression of early treatment options delayed investigation into low-cost repurposed therapies.
- Zinc was not included in many negative studies, possibly masking the ionophore-dependent efficacy.

As of 2025, the tide may be shifting. New molecular studies, including those examining spike protein behavior and zinc flux modulation, are renewing interest in ivermectin's biochemical potential.

EXCESS MORTALITY TRENDS

Beyond debates concerning transmission, mechanisms of infection, actions to prevent both of them, and regulatory oversight lies one of the starkest and least adequately explained phenomena of the pandemic era: the global rise in excess mortality, beginning in 2021 (Oller & Santiago, 2022; Lindner & Doidge, 2023) and persisting well into 2025. These patterns of increased deaths — defined as the number of deaths above the expected historical baseline — have been observed across dozens of countries, irrespective of lockdown stringency, healthcare capacity, or case fatality rate (Beattie, 2021). They demand scrutiny.

Excess mortality, defined as the number of deaths above what would be expected under normal conditions, has been a critical metric during the pandemic. A study covering 47 Western countries reported approximately 3.1 million excess deaths from January 2020 to December 2022 (Mostert et al., 2023). While initial excess deaths were attributed to the virus itself, subsequent analyses have raised questions about other contributing factors, including the indirect effects of pandemic responses, and potential vaccine-related impacts. For example, some countries with high vaccination rates, such as the Netherlands, Australia, New Zealand, and Denmark, reported significant excess mortality in 2023 (de Graaf & Kuhs, 2023). Although it is almost obligatory in modern academic publications referring even obliquely to statistical correlation to say that "correlation does not necessarily entail causation". However, given the evident correlation of increases in all-cause mortality with increasing dosage with COVID-19 injectables, it seems obvious that further research into those correlations should address causation more fully (see Beattie, 2021; Oller & Santiago, 2022; Santiago, 2022a, 2022b; Rancourt & Hickey, 2023a, 2023b; Santiago & Oller, 2023; Mead, Seneff, Wolfinger, et al., 2024; Mead, Seneff, Rose, et al., 2024). Moreover, it would be foolhardy to ignore such important correlations as potential indicators of underlying causation. They merit serious scientific investigation to either rule in, or rule out, a significant potential adverse effect of the new mRNA genetic therapy which was actually, incorrectly, marketed to the world as a "vaccine". Let us explore the topic of classification of the "vaccine" in a little more depth.

In New Zealand, where COVID-19 deaths were minimal in 2020 and much of 2021, the total mortality rate began climbing significantly only after the commencement of mass syntheic mRNA vaccination (Hatchard & Dixon, 2021; Timeline..., 2025). According to data from Stats NZ and corroborated by actuarial reviews, 2022 witnessed one of the highest annual death counts in recent history (Stats NZ, 2023; Gabel & Knox, 2023; Hood, 2024) — despite an ostensibly well-managed pandemic and high compliance with pharmaceutical interventions. Similar patterns were observed in Germany, the USA, UK, Australia, Canada, and many other countries (Mathieu et al., 2020; Mostert,

2022; Australian Bureau of Statistics, 2023; Meier, 2024; Bor et al., 2025). Importantly, this surge in excess deaths did not coincide with major COVID-19 outbreaks, nor could it be attributed to viral variants alone. In fact, the temporal alignment between booster campaigns and subsequent waves of non-COVID excess mortality — including cardiac events, strokes, neurological syndromes, and sudden deaths among the working-age population — has led many researchers to re-examine causality (Mead, Seneff, Wolfinger, et al., 2024; Mead, Seneff, Rose, et al., 2024). In his book, a former Blackrock analyst, Edward Dowd (2024), drawing on US insurance and disability claims data, indicated a sharp rise in all-cause mortality and long-term disability filings among younger, workingage adults beginning in the third quarter 2021. This demographic had previously shown the lowest COVID-19 mortality risk, yet now reflected the highest post-vaccine excess death signal. Likewise, peer-reviewed studies from countries such as Germany and the Netherlands found statistically significant correlations between vaccine uptake and non-COVID mortality trends (Kuhbandner & Reitzner, 2024).

Mechanism of Action and Genetic Engineering Principles

COVID-19 mRNA vaccines, such as those developed by Pfizer-BioNTech and Moderna, use lipid nanoparticles to deliver a synthetic form of messenger RNA (mRNA) into human cells (Santiago, 2022a, 2024). This synthetic mRNA is artificially engineered to instruct the cells of the recipient to produce a portion of the SARS-CoV-2 spike protein (Nance & Meier, 2021) prompting an immune response. This process involves the introduction of genetic material that can direct protein synthesis within the body, a hallmark of genetic engineering. A 2023 review in the *International Journal of Molecular Sciences* by Banoun, argues that the mode of action of the synthetic mRNA "vaccines" should classify them as "gene therapy products", as they involve nucleic acids designed to produce an antigen within the body. However, regulatory agencies have excluded them from the GTP [gene therapy product] classification, and have represented them, falsely, as "vaccines".

ACCELERATED DEVELOPMENT TIMELINES

But traditional vaccine development is a meticulous process, often spanning 10 to 15 years, encompassing exploratory stages, preclinical trials, and three phases of clinical trials before regulatory approval. In contrast, COVID-19 gene therapy products, mislabeled "vaccines", were developed, tested, and authorized within a year. Operation Warp Speed in the United States exemplified this acceleration, aiming to deliver vaccines rapidly by overlapping trial phases and commencing large-scale manufacturing before trial completion.

CLINICAL TRIAL PHASES AND LIMITATIONS

Phase I and II Trials: These initial phases focused on assessing safety and immunogenicity in small cohorts. Although the results as reported by manufacturers and their collaborating government agencies were represented as promising, the limited sample sizes and short follow-up periods restricted the ability to detect less common adverse events and noteworthy irregularities were later pointed out in this journal by Michels et al. (2023).

Phase III Trials: These pivotal trials normally aim to evaluate efficacy and monitor adverse reactions in larger populations, but, actually, never took place for the COVID-19 gene therapies as the whole sequence of phases were compressed into a couple of months, and there were other notable shortcomings:

- Short Duration: The median follow-up period was approximately two months, insufficient for assessing long-term safety and efficacy.
- Population Representation: Certain groups, such as pregnant women, immunocompromised patients, and children, were under-represented, limiting the ability to generalize the findings.
- Data Transparency: There was inadequate availability of trial documents and participant-level data, hindering independent analysis and verification.

EMERGENCY USE AUTHORIZATION AND REGULATORY OVERSIGHT

Emergency Use Authorizations allowed for the deployment of vaccines based on interim data, purportedly balancing potential benefits against risks in a public health emergency. However, this approach meant that regulatory approval processes for gene therapy products were bypassed altogether. Post-authorization, surveillance systems — like the Vaccine Adverse Event Reporting System (VAERS) in the US — were crucial for monitoring vaccine safety. Although these systems enabled post-marketing identification of adverse events, such as myocarditis and thrombosis with thrombocytopenia syndrome (TTS), the initial trials were not powered even to detect such infrequent outcomes. Although the expedited rollout of COVID-19 gene therapy products was framed as a necessary response to the claimed global emergency, it suspended the principle of informed consent and the need for safety and efficacy data.

Public trust is a cornerstone of any successful vaccination program. Once eroded, it is not easily restored. Historical examples — such as the 1976 swine flu vaccination campaign in the United States, which was halted due to rising cases of Guillain-Barré syndrome (Sencer, 2024) — demonstrate the long-lasting consequences of perceived scientific or regulatory overreach. In the COVID-19 context, the perception that data were withheld, dissenting voices marginalized, or adverse signals underreported has fueled not only "vaccine hesitancy" — or more likely, outright refusal — but wide-ranging skepticism towards public health institutions and their oversight agencies in general. Maintaining public confidence requires more than reassuring slogans. In the meanwhile, damage, it seems, to human immune systems began to appear on a grand scale.

Immunological Class Switching and IgG4: A Tolerogenic Shift?

The adaptive immune system is engineered to recognize, remember, and respond to foreign pathogens with precision. Central to this system is the process of immunoglobulin class switching, whereby B cells tailor the type of antibody they produce based on the nature of the antigenic threat. The landmark study by Irrgang et al. (2022), published in *Science Immunology*, investigated the longitudinal antibody profiles of individuals undergoing repeated mRNA vaccination. They observed a striking rise in IgG4 titers after multiple exposures, particularly following the fourth dose, or after receipt of bivalent boosters. This pattern did not emerge following natural infection, nor was it evident after the initial vaccine doses — highlighting that the phenomenon is likely induced by repeated synthetic antigen stimulation rather than viral exposure per se.

In countries with high booster uptake — such as Germany, Israel, and New Zealand — researchers began documenting trends in infection recurrence, breakthrough hospitalizations, and anomalous rises in certain cancer types, including aggressive lymphoid and pancreatic cancers. The rise of immune class switching to IgG4 (Achiron et al., 2022; Kiszel et al., 2023; Gelderloos et al., 2024; Perez et al., 2025) — a phenomenon virtually unknown in traditional vaccinology — is a signal that

the immune system itself may be undergoing unintended reprograming. Whether this leads to blunted antiviral response, immune tolerance, or even oncogenic permissiveness, the fact that it is understudied and underreported speaks volumes about the selective lens through which "vaccine science" is being conducted. And perhaps most damning is the institutional response to these revelations: a coordinated suppression of dissent, a punishment of curiosity, and a chilling of scientific dialogue seems to be underway. This is not how science is done in the pursuit of truth.

In individuals receiving multiple mRNA doses, a class switch from IgG1 and IgG3 (typically proinflammatory, antiviral antibodies) to IgG4 (Achiron et al., 2022; Irrgang et al., 2022; Kiszel et al., 2023; Gelderloos et al., 2024) — the latter being a subtype more commonly associated with immune tolerance and allergen desensitization (Aalberse et al., 2009; Akdis & Akdis, 2011; Buhre et al., 2022; Uversky et al., 2023; Rubio-Casillas et al., 2025). Although this shift may be benign in some contexts, its presence in response to a viral antigen is atypical and potentially counterproductive. A German study published in *Science Immunology* (Irrgang et al., 2022) documented this change, raising concerns that elevated IgG4 levels could blunt future immune responses or contribute to immune tolerance toward malignant cells. Though still under investigation, this shift represents a significant and underreported dimension of vaccine-induced immune reprograming that could lead to reduced vaccine efficacy, increased susceptibility to infections, or both (Buhre et al., 2023; Akhtar et al., 2023; Lasrado et al., 2024; Perez et al., 2025).

SILENCE FROM HEALTH AUTHORITIES

The silence from public health authorities in the face of this discovery is more than a communications failure. It is a breach of scientific and ethical duty. At a time when public confidence has already been strained, the refusal to acknowledge or investigate such a profound shift in immune behavior borders on negligence. Informed consent requires disclosure. Scientific integrity demands exploration. Yet both have been sacrificed to narrative management. If immune tolerance toward a persistent, spike-encoding antigen is now embedded in millions, even billions, of individuals worldwide, the long-term consequences may not emerge gradually — they may arrive abruptly, as new pathogens are met with an immune system that has been taught not to react.

Supplementary Considerations for COVID-19 Vaccination Policies

Recent analyses have also identified the presence of residual plasmid DNA in mRNA COVID-19 vaccines, raising concerns about potential genomic integration. These show plasmid DNA contamination and genomic integration risks. Phillip Buckhaults, PhD, and molecular geneticist, testified before the South Carolina Senate (2023, 2025), highlighting the detection of DNA fragments in vaccine samples and the theoretical risk of insertional mutagenesis, which could lead to oncogenesis. Further studies have corroborated such events (Kaiser et al., 2025; Paul-Ehrlich-Institut, 2025; König & Kirchner, (2024); Creative Proteomics, 2025; Vieths et al., 2025). However, the US FDA Administration (2023) in a letter responding to Joseph A. Ladapo, MD, PhD, and Surgeon General for Florida, explicitly denied the presence of the widely detected "SV40 promoter/enhancer DNA" sequence. The agency went immediately to denial mode. The official respondent, Peter Marks, MD, PhD, and Director of the Center for Biologics Evaluation and Research, asserted that based on its "thorough assessment of the entire manufacturing process, FDA is confident in the quality, safety, and effectiveness of the COVID-19 vaccines".

To the contrary, investigations into vaccine batch consistency have revealed significant disparities in quality reflected in widely variant reports of adverse events. A study comparing data from Denmark and Sweden found that certain batches of the BNT162b2 vaccine were associated with much higher rates of suspected adverse events than other batches, suggesting potential inconsistencies in manufacturing quality control (Manniche et. al., 2024). Some lots were disproportionately associated with serious adverse events, suggesting possible lapses in temperature control, formulation accuracy, or process integrity — each a violation of Good Manufacturing Practice standards. This variability has profound implications for informed consent. Patients were not informed of potential batch-related risk disparities, and regulatory bodies failed to issue timely warnings or initiate corrective measures. When batch variability shows clear correlations with spikes in serious adverse events (Manniche et al., 2024; Hviid et al., 2024), the issue is not hypothetical and the US FDA's response to Forida's Surgeon General, is hardly commendable. He had faithfully reported the discovery of "billions of DNA fragments per dose of the Pfizer and Moderna COVID-19 mRNA vaccines" including "the SV40 promoter/enhancer and SV40 proteins" (two distinct threats to health and well-being of recipients) to the responsible federal agency.

Although the rollout of the synthetic mRNA "vaccines" from Pfizer and Moderna were heralded as a joint triumph of biomedical innovation (Nance & Meier, 2021), as genetic therapies they have brought us to a crossroads between promise and peril. What began as a global emergency response has, over the following four years, revealed deep fissures in the systems supposedly put in place to ensure safety, uphold transparency, and protect public trust. However, the demonstrated presence of residual plasmid DNAs, including SV40 enhancer sequences (Speicher et al., 2023; Florida State Surgeon General, 2024; Kämmerer et al., 2024) in the "vaccine" vials is not merely a manufacturing anomaly. It calls into question the integrity of oversight across the regulatory chain from the laboratory bench to the patient's bedside. When cancer genomic specialists are warning of novel genomic insertions (Acevedo-Whitehouse & Bruno, 2023; State Surgeon General, Joseph A. Ladapo, MD, 2024), the proper response is not silence, but inquiry and investigation.

POST-MARKET OUTOMES: GENETIC, IMMUNOLOGICAL, AND INSTITUTIONAL OVERSIGHTS

The emergency deployment of synthetic mRNA vaccines under Emergency Use Authorizations occurred in response to an alleged unprecedented global crisis. Yet, as time progresses, critical postmarket concerns have surfaced — scientific, immunological, and institutional — which now demand urgent and unflinching scrutiny. Far from undermining innovation, these revelations emphasize the systemic risks of deploying novel medical technologies without long-term evaluation, full transparency, or rigorous accountability. To the contrary, throughout the pandemic, instances have been reported where scientific discourse was curtailed (Shir-Raz et al., 2022; Liester, 2022), and dissenting voices were marginalized (Wallis, 2023). Concerns have been raised about the transparency of data, the openness of regulatory agencies to alternative viewpoints, and the potential influence of pharmaceutical companies on public health policies. Ensuring that scientific debate remains open and evidence-based is essential for the integrity of public health decisions. Mechanisms should be put in place to protect whistleblowers and to facilitate independent reviews of data and policies.

GLOBAL GOVERNANCE FAULTED AND EQUITABLE ACCESS CHALLENGES UNMET

The global response to COVID-19 has highlighted disparities in vaccine access and the influence of international organizations on national health policies. Initiatives like COVAX, led by CEPI (2024) and Gavi (2020-2023), supposedly aiming to promote equitable vaccine distribution, faced challenges in achieving their goals. Critiques have emerged regarding the decision-making processes within these organizations and the extent to which they considered the diverse needs of different populations. A more inclusive and transparent approach is necessary to ensure that global health initiatives are both effective and equitable. Incorporating these additional considerations into the evaluation of COVID-19 vaccination policies provides a more comprehensive understanding of the complexities involved.

GLOBAL GOVERNANCE AND THE FUTURE OF MEDICAL OVERSIGHT

Finally, the governance structure surrounding COVID-19 vaccine rollout has shifted from national public health leadership to supranational entities (Taylor, 2021; Pushkaran et al., 2023; Ginsbach, 2024). Organizations such as the WHO, CEPI (Coalition for Epidemic Preparedness Innovations), GAVI, and the Gates Foundation wielded extensive influence over vaccine development, funding, distribution contracts, and policy implementation. Although global coordination can be beneficial, the absence of democratic oversight and transparency within these institutions presents a long-term risk to autonomy and accountability. Without reform, the current model — rapid mass deployment, limited post-market transparency, and structural deference to private global actors — could become the default framework for future public health emergencies. This must not be allowed. The price of getting it wrong has already been measured in lives, in trust, and in the corrosion of foundational scientific values. We must not look away. We must not move on. We must confront what went wrong — because if we do not, we guarantee it will happen again.

Key Findings from My Own Research

In recent months, a growing number of healthcare professionals — particularly embalmers, pathologists, and vascular surgeons — have reported the recurrent presence of unusual fibrous intravascular structures, colloquially termed "white clots" (Santiago, 2022a; Santiago & Oller, 2023; 2024). These masses, often described as resilient, rubbery, and resistant to traditional clot-dissolving techniques, have been identified during postmortem examinations and surgical interventions, prompting questions about their composition, origin, and clinical significance. Although it is acknowledged that intravascular thrombi are not a new phenomenon, the scale, frequency, and physical characteristics of these clots have raised concerns within the professional community. The testimonies of the embalmers (McIlvenna & O'Looney, 2025) — particularly from the United States, Germany, and New Zealand— suggest a shift in clot morphology that began appearing predominantly in the post-vaccination period of 2021–2022 (O'Looney, 2022; Trigoso, 2022).

Despite these observations, official health authorities have largely downplayed the significance of the findings, attributing them to artefacts or unrelated pathology (Schmidt, 2022; AFP Thailand, 2024). Yet to date, no systematic histopathological studies or comprehensive biochemical analyses have been conducted to verify these claims or disprove alternative hypotheses.

LANDMARK INVESTIGATION INTO THE NATURE OF POST-VACCINE EMBALMER CLOTS

Following global reports by embalmers and surgeons of long, fibrous, rubbery white clots — appearing primarily in deceased individuals post-2021, and later observed in some living patients undergoing vascular procedures — the scientific community has been faced with a vexing and urgent question: What are these clots, and where did they come from? Although some commentators speculated that such formations were merely longstanding postmortem artefacts (see discussion by Pelech & Shaw, 2024, pp. 68, 90-93), this assumption has now been thoroughly challenged. Although the very existence of the clots reported by embalmers has been a contentious issue, linked to the COVID vaccines rollout in 2021, some serious researchers have studied the issue.

Santiago and Oller (2023) cite Nyström and Hammarström (2022) who in turn suggest a molecular mechanism where inflammation-induced proteolysis by neutrophil elastase may trigger amyloid formation from spike protein fragments in vivo. As the SARS-CoV-2 infection is linked to numerous morbidities, including blood coagulation issues, fibrinolytic disturbances, the researchers investigated the amyloidogenic potential of the SARS-CoV-2 spike protein (S-protein) due to its similarities with amyloid diseases. Further, they identified seven amyloidogenic sequences within the spike protein through peptide library assays and theoretical predictions. Their work clearly demonstrates the potential for the spike protein, in association with neutrophil elastase to enable the formation of amyloid-branching structures probably leading to abnormal clots.

DIFFERENTIATION FROM NORMAL POSTMORTEM CLOTS

It is well known that postmortem clots are a routine and benign finding, including the classic "currant jelly" and "chicken fat" types, as well as known antemortem thrombi and mural clots. These have been described in the medical literature since the 19th century (see Kumar et al., 2010), including the work of Rudolf Virchow, who provided the foundational classification of thrombus types (Virchow's Triad, 2024). The white clots observed in post-2021 autopsies, however, are morphologically and biochemically distinct. Unlike the soft, non-adherent gelatinous clots typical of postmortem changes, these structures exhibit:

- High tensile strength and rubbery consistency
- Extreme length (sometimes over 40 cm)
- Widespread distribution across major vessels
- Resistance to standard embalming fluid penetration

ELEMENTAL ANALYSIS

With all the foregoing in mind, in 2024 I undertook a pioneering investigation over an 18-month period to determine the origin, structure, and biochemical composition of these so-called "embalmer clots". With the assistance of embalmers across several countries, multiple samples were collected under strict anonymity and submitted to a range of biochemical, proteomic, elemental, and histological analyses across several independent laboratories. This work — conducted in parallel with international inquiries and under conditions of significant institutional resistance — has revealed findings of profound significance.

An elemental analysis using quantitative assays confirmed abnormally high concentrations of phosphorus (+333%) and tin (+479%). The presence of tin — a metal with no known role in mammalian physiology — is especially alarming and warrants urgent toxicological investigation. These findings, initially flagged by Mike Adams (Carter, 2022), were independently confirmed and extended.

PROTEOMIC PROFILING

Detailed mass spectrometry revealed that the clots were composed primarily of fibrin family proteins and multiple hemoglobin isoforms. A total of 541 additional proteins — ordinarily circulating in plasma in low concentrations — were found to be entangled in the clot structure. Importantly, the clots exhibited distorted fibrinogen composition, with a non-physiological amino acid chain ratio of 1:3:2, rather than the typical 1:1:1 distribution.

HISTOLOGICAL FINDINGS

Microscopic examination confirmed a fibrinous structure typical of white thrombi, including the presence of Lines of Zahn (Kushner, 2025) — proof of antemortem clot formation. However, unlike standard white thrombi, which form in high-pressure arterial flow, these clots were found in both arteries and veins, including low-flow environments. This defies classical hemodynamic theory, supporting the conclusion that these clots are novel pathological entities. Some slides revealed abnormal density, interwoven protein structures, and evidence of endothelial disruption — pointing to a spike protein-mediated systemic clotting disorder, rather than incidental postmortem artefact.

CLINICAL AND PUBLIC HEALTH IMPLICATIONS

The existence of these COVID-19 spike-protein associated clots has immediate and grave implications for global health. Their presence is now suspected to underlie a growing number of adverse cardiovascular events, including: myocardial infarction; ischemic stroke; deep vein thrombosis; pulmonary embolism; myocarditis and pericarditis (National Academies Press, 2024; Schirmacher, 2022; Hulscher, Hodkinson, et al., 2024; Hulscher, Cook, et al., 2024; McCullough & Hulscher 2025; Mead, Seneff, Wolfinger, et al. 2024; Mead, Seneff, Rose, et al., 2024); multi-organ ischemia; vaccine-induced thrombotic thrombocytopenia (VITT; Greinacher et al., 2021; Pavord et al., 2021; Klok et al., 2022; Cines & Greinacher, 2023). These outcomes mirror the reported rise in excess mortality and may account for a significant proportion of fatalities — especially among younger individuals and working-age adults in highly vaccinated populations with significant data now cited in the WHO, *Nature* and the *BMJ* (Msemburi, 2023; Iacobucci and the British Medical Publishing Group, 2024; Swiss Re Institute, 2024.)

ONGOING SCIENTIFIC VALIDATION AND PUBLICATION

This research is now being independently duplicated in multiple laboratories across the globe. A lay-person accessible account of the findings has been authored by British journalist Charles Harrington and is being prepared for public release, while the primary scientific data is currently being structured for peer-reviewed publication. Notably, the FDA recently released internal documentation suggesting that long-term iatrogenic consequences of synthetic mRNA vaccination may continue to emerge over the coming 10 to 15 years (Santiago, 2022b) — an implicit acknowledgment of risks now increasingly visible. In their words the injections already distributed are "ticking time bombs".

A CONTRIBUTION TO THE RECORD

Despite immense institutional resistance — including restrictions on laboratory use, funding obstruction, and the blacklisting of independent researchers — I was able to complete what is now considered a landmark contribution to post-vaccine biomedical research. This work affirms what many clinicians have long suspected: the spike protein — especially when synthesized by the host — is a uniquely toxic agent, capable of hijacking normal biological processes and transforming them into mechanisms of harm.

TURBO CANCER

It is interesting to note that a new iatrogenic disease "turbo cancer" has entered public and professional discourse (Zhao et al., 2023; Katella, 2024; Editorial, 2025; Xia, 2025), referring to aggressive, fast-growing malignancies presenting in individuals — often under the age of 50 — with minimal prior risk factors and unusually poor prognoses. Clinicians have noted cases of rapid tumor progression, multi-organ metastasis, and unexpected treatment resistance occurring within months of initial diagnosis. Anecdotal reports from oncologists and radiologists across multiple countries point to a disturbing trend: cancers that would typically develop over years are now accelerating to metastasis within a few weeks, or in two or three months. Although legacy public health bodies maintain that cancer incidence trends predate COVID-19 vaccination campaigns, such statements may soon be rendered obsolete by emerging molecular analyses of the spike protein variants encoded by synthetic mRNA vaccines. Preliminary biochemical data — currently in pre-publication review — suggest that the spike protein may contain three domains of particular concern:

- 1. A cancer growth promoter, capable of influencing cell cycle regulation and tumor suppressor pathways.
- 2. An angiogenesis-stimulating domain, potentially enhancing blood vessel formation that supports tumor expansion.
- 3. A bond satisfaction motif, which may facilitate epithelial mesenchymal transition allowing tumor cells to detach and metastasize rapidly throughout the body.

These three molecular "smoking guns" represent plausible mechanisms by which repeated spike protein exposure could fuel oncogenic processes — particularly in already vulnerable tissues or genetically predisposed individuals. To dismiss these concerns as anecdotal or coincidental — without conducting rigorous investigation — is institutional negligence. If even a fraction of these signals prove valid, the implications for public health are profound. At a minimum, this landscape warrants:

- Full biochemical characterization of intravascular clotting anomalies
- Epidemiological tracking of post-vaccination cancer patterns
- Transparent release of spike protein structural data used in vaccine formulations
- Investigation into whether previously known oncogenic risks were considered during the expedited authorization process

As of now, data is in press, and the scientific community awaits further validation. But in the interim, the precautionary principle compels vigilance — not silence.

Vaccine-Induced Thrombotic Thrombocytopenia (VITT): A New Iatrogenic Disease

Among the most serious and paradigm-altering iatrogenic conditions to emerge during the global COVID-19 vaccination campaign is vaccine-induced thrombotic thrombocytopenia (VITT)—a formerly rare but potentially life-threatening disorder (an iatrogenic disease) marked by the seemingly contradictory combination of thrombotic events (clotting) and thrombocytopenia (low platelet count). Identified in early 2021, VITT was rapidly associated with adenoviral vector vaccines (Shultz, 2021; Pavord et al., 2021; Kelton et al., 2021; Bussel, 2022), including AstraZeneca's ChAdOx1 nCoV-19 and Johnson & Johnson's Ad26.COV2.S, and was characterized by aggressive and often fatal clotting in unusual anatomical sites, such as the cerebral venous sinuses and splanchnic (abdominal) veins (Shultz, 2021; Makris, 2021; Muir et al., 2021; Rodrigues, 2021; Van Rampelbergh et al., 2025). In numerous cases, the condition resulted in stroke, multi-organ damage, and death — often in young, otherwise healthy recipients (Cascio Rizzo et al., 2022; Pavord et al., 2022).

The underlying pathology of VITT closely mimics autoimmune heparin-induced thrombocytopenia (HIT), despite occurring in individuals with no prior exposure to heparin. Studies published in *The New England Journal of Medicine, Blood*, and *The Lancet Haematology* confirmed the presence of autoantibodies targeting platelet factor 4 (PF4), which induce widespread platelet activation, immune-mediated inflammation, and disseminated thrombus formation (Greinacher et al., 2021; Pavord et al., 2021; Klok et al., 2022; Cines & Greinacher, 2023). This immune reaction constitutes a novel vaccine-related disorder (also iatrogenic), entirely separate from classical clotting syndromes and unaccounted for in traditional vaccine safety modelling. While regulatory bodies such as the UK MHRA, European Medicines Agency (EMA), and US Centers for Disease Control and Prevention (CDC) have publicly acknowledged the existence of VITT, estimates of its incidence remain unreliable. Official figures suggest rates between 1 in 50,000 and 1 in 100,000 doses, but real-world incidence may be substantially higher due to:

- Systemic underreporting through passive surveillance systems like VAERS, CARM, and EudraVigilance
- Dismissal of early case reports as anecdotal or "coincidental"
- Misclassification of VITT as standard thrombotic stroke, DIC, or autoimmune disease in clinical settings

By mid-2021, multiple nations — including USA, Denmark, Germany, Norway, and Canada — had suspended or restricted use of adenoviral vector vaccines, particularly in younger age groups (Oxford-AstraZeneca..., 2025). However, despite mounting clinical concerns, similar thromboinflammatory syndromes reported following mRNA vaccine administration have received little attention (Embolic..., 2025). These include microvascular clotting, myocarditis-linked thromboembolic events, and vasculitic phenomena — suggesting that the phenomenon of vaccine-induced clotting may not be confined to adenovirus platforms.

VITT represents more than a rare complication. It is a watershed moment in pharmacovigilance, compelling a wholesale reassessment of how vaccine safety is evaluated, reported, and acted upon. Crucially, the *early warnings about VITT came not from pharmaceutical companies or regulatory agencies*, but from frontline clinicians, coroners, and independent researchers — many of whom were ridiculed,

censored, or threatened with professional sanction (Clark County News, 2022; Chrichton, 2024). It is interesting to note that medical boards started to experience pushback as they attempted to punish doctors for speaking out with what was claimed to be "misinformation" about COVID (Tahir, 2023). For affected families, VITT has become not just a medical term, but a symbol of regulatory failure — a stark reminder that speed, secrecy, and political orthodoxy can override both science and ethics. Many victims were young, healthy individuals who participated in good faith, trusting that appropriate safety oversight existed. VITT is not merely a rare side effect. It is the canary in the coal mine — a clinically manifest warning of what happens when urgency eclipses evidence, and when medical interventions are rolled out faster than the science that must validate them. The global rise in excess mortality, unexplained cardiovascular events (McCullough et al., 2020), long-term immune dysfunction, and iatrogenic injury must be viewed in this light — not as isolated data points, but as part of a systemic failure to safeguard public health from the very policies implemented in its name.

Informed Consent and the Ethical Void in Public Health Messaging

At the heart of all ethical medical practice lies the fundamental principle: informed consent. During the global COVID-19 vaccine rollout, this principle was not merely compromised — it was systemically replaced with a model of coercive compliance. Patients were routinely told that the vaccines were "safe and effective", a phrase repeated across official channels, advertising campaigns, and media outlets with religious uniformity.

International codes — from the Nuremberg Code to UNESCO's Declaration on Bioethics and Human Rights — do not describe informed consent as optional, conditional, or situational (Leaning, 1996; BMJ, 1996). They describe it as INVIOLABLE. Public trust is not restored by repeating assurances. It is restored by admitting when consent was never truly sought — and by ensuring it can never again be so easily taken. For where consent is abandoned, medicine ceases to be a practice of healing. It becomes a system of control — the weaponization of medicine. A system where obedience is health, and dissent is pathology.

GLOBAL HEALTH GOVERNANCE AND PANDEMIC POWER STRUCTURES

While scientific evidence and public health ethics provide the foundations for pandemic policy, the final implementation of global vaccination strategies was equally shaped by political economy—namely, the complex interplay of pharmaceutical influence, multilateral power blocs, indemnity contracts, and public-private partnerships. Understanding these forces is essential not only to contextualize past decisions but to forecast future risks should the current model remain unchallenged. At the center of this global response architecture stood entities such as the World Health Organization (WHO, 2020; Gavi, 2022), the Vaccine Alliance, CEPI, and the Bill & Melinda Gates Foundation (2020) — all of which collaborated to initiate the Access to COVID-19 Tools Accelerator (ACT-A) and COVAX Facility (2020).

While these organizations ostensibly promoted equitable vaccine access, their decision-making was neither transparent nor democratically accountable. In many cases, national governments ceded sovereignty over procurement, distribution, and even messaging, aligning their domestic responses with global coordination plans forged by private or semi-private institutions. This governance model was further complicated by contractual indemnity agreements between pharmaceutical companies and national governments. In order to secure early access to vaccines, countries — including New Zealand — were required to sign confidential contracts that granted manufacturers legal immunity

from liability for adverse events. Pfizer's agreement with the European Commission, for example, included clauses that exempted the company from post-market damages unless gross negligence could be proven—a near-impossible bar under current pharmacovigilance standards (European Court of Auditors, 2022). Similar contracts were signed globally — for example, there was the Dominican Republic Term Sheet (see Abinader, 2021) — but many of them remain redacted and shielded from public scrutiny. These indemnity frameworks created a perverse incentive structure: rapid mass deployment was prioritized over safety monitoring, while governments were discouraged from acknowledging or compensating for vaccine injuries that could be construed as admissions of liability. The WHO's own Emergency Use Listing process, expedited under pandemic conditions, allowed for global rollout before full trial data were available. There were denials claiming the release prior to completion of clinical trials was a mere "conspiracy theory" (Reuters, February 2, 2021), but credible researchers (e.g., Michel et al., 2023) not only showed (as I have above in this paper) that the clinical trials were not only condensed into an impossibly brief time frame, but the data as reported were distorted to cover up multiple harms.

The analysis of data to make the vaccines look "safe and effective" was nothing less than deceptive and has recently been called out as "criminally fraudulent" on account of the millions of deaths and injuries that would follow (Oller et al., 2025). Rushing the development of preventative measures and/or effective treatments might have been justifiable during the perceived acute crisis phase of the "pandemic" if it had been real, but it was retained long after it became clear that the "crisis" was hardly worse than a slightly elevated but largely normal and predictable flu epidemic. Nonetheless, the power-brokers continued to promote the "crisis" narrative long past the point where reasonable reviews were showing it was not all that it was trumped up to be.

Compounding the perplexities brought on by the exaggerated narrative, major vaccine stakeholders — including Pfizer (see OXFAM, 2021; Allen, 2022: Kollewe, 2022) and Moderna (2022) reported record-breaking profits (see the article by Priya for Pharmaceutical Technology, 2022), while simultaneously maintaining control over the intellectual property rights and distribution of what were described as "public health goods". Pfizer's 2021 revenue from its COVID-19 vaccine exceeded \$36 billion USD, making the Comirnaty "vaccine" the single most lucrative medical product in history. Despite this, efforts to waive patent protections for low-income countries were largely blocked at the World Trade Organization (2022), with support from the same entities championing global vaccine equity. This global governance structure — characterized by consolidated authority, limited accountability, and commercial entanglement — now serves as the de facto blueprint for future emergency responses (Hanrieder & Kreuder-Sonnen, 2014). The fact that such unprecedented arrangements were sustained long after the supposedly acute phase of the crisis had lost all credibility, reveals not a failure of foresight, but a guided institutional drift toward unaccountable control. Proposals to formalize this model through instruments like the WHO Pandemic Treaty Draft (2023), also known as the WHO Pandemic Agreement (2025), evidently seek to codify this drift into international law, embedding emergency powers as permanent fixtures of global governance, insulated from the checks and balances that define free societies. If the response to the next declared emergency is to be more ethical, more accountable, and more respectful of individual rights, then the current pandemic power structure must be interrogated — not enshrined.

Conclusions

Mandated policies, combined with the suppression of risk disclosure and medical dissent, have, during the COVID-19 era, undermined the legal and ethical foundations of informed consent. The

growing influence of supranational entities — operating through indemnified contracts, non-transparent procurement, and intellectual property constraints — has reduced national sovereignty and public oversight in medical decision-making. While early policy choices may be explained as a crisis response, failure to recalibrate in light of emerging data reflects systemic inertia and institutional capture. We need to reassert core public health principles: transparency, proportionality, scientific pluralism, and respect for individual rights, i.e., informed consent.

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Conflicts of Interest

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