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# COVID-19 Modified mRNA "Vaccines": Lessons Learned from Clinical Trials, Mass Vaccination, and the Bio-Pharmaceutical Complex, Part 2

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## Abstract

The COVID-19 modified mRNA (modmRNA) lipid nanoparticle-based "vaccines" are not classical antigen-based vaccines but instead prodrugs informed by gene therapy technology. Of considerable note, these products have been linked to atypical adverse and serious adverse event profiles. As discussed in Part 1, health-related risks and drawbacks were drastically misreported and under-reported in the Pfizer and Moderna trial evaluations of these genetic products. Now in Part 2, we examine the main structural and functional aspects of these injectables. The COVID-19 modmRNA injectable products introduce a unique set of biological challenges to the human body with the potential to induce an extensive range of adverse, crippling, and life-threatening effects. Based on the fact that there is no current method to quantify host (cell-based) spike protein production *in vivo* following injection with these prodrugs, there *is* no standard "dose". This is in part due to differences in spike protein production output, which depends on cell metabolism and transfection efficiency. It is therefore difficult to predict adverse event profiles on an individual basis, but considering that millions of adults across the world have reported severe and serious adverse events in the context of these modmRNA COVID-19 products, valid concerns are raised regarding injection of infants and younger age groups for whom COVID-19 poses only minimal risks. We address the process-related genetic impurities inherent in mass production of these products, and the potential risks posed by these contaminants. We then categorize the principal adverse events associated with the modmRNA products with a brief systems-based synopsis of each of the six domains of potential harms: (1) cardiovascular, (2) neurological, (3) hematologic; (4) immunological, (5) oncological, and (6) reproductive. We conclude with a discussion of the primary public health and regulatory issues arising from this evidence-informed synthesis of the literature and reiterate the urgency of imposing a global moratorium on the modmRNA-LNP-based platform.

**Keywords:** *adverse events, COVID-19 modmRNA injectable products, vaccines, COVID-19 registrational trials, immunity, serious adverse events, gene therapy products, safe and effective, all-cause-mortality*

## Introduction

The synthetic, nucleoside-modified mRNA (modmRNA) lipid nanoparticle-based COVID-19 products, BNT162b2 (Comirnaty) from Pfizer-BioNTech and mRNA-1273 (Spikevax) from Moderna, are the most widely applied "vaccines" against SARS-CoV-2 infection. At the time of the Emergency Use Authorization (EUA) in December 2020, U.S. federal agencies hailed the injections as "highly effective", based on the trialists' claim of 95% relative risk reduction of symptomatic COVID-19 (Polack et al., 2020; Baden et al., 2021). The immense government-industry syndicate known as the Bio-Pharmaceutical Complex repeatedly assured a lockdown-weary public that the gene-based injectables were "safe and effective" in terms of reducing severe disease, hospitalization, and death (Doshi, 2020). Nevertheless, as we documented in Part 1 (Mead et al., 2024a), the initial claims to support this narrative were based on flawed investigations, inadequate analyses, and improper, often unethical, reporting practices. The chosen timeframes for these registrational trials (two months for Pfizer, three months for Moderna) were far too short to allow for an unbiased assessment of potential serious adverse events, and the usual safety testing protocols and toxicology requirements were bypassed (Wagner et al., 2021; Altman et al., 2023; McCullough, 2023). In addition to the faulty trial execution, as painstakingly documented in Part 1, numerous critical findings were either misreported or completely omitted from published reports, resulting in significant underestimates of actual risks as manifested in real injuries sustained by recipients.

Following the EUA, careful re-analyses of the data revealed that the modmRNA-related harms were initially more substantial than reported. The most rigorous re-analysis was conducted by an international team of established vaccine safety experts utilizing the Brighton Collaboration's Safety Platform for Emergency Vaccines in order to evaluate adverse events of special interest (AESIs) observed in the COVID-19 modmRNA trials (Fraiman et al., 2022). The more extensive Pfizer trial showed a significant 36% higher risk (RR 1.36; 95% CI 1.02 to 1.83) of serious adverse events in the modmRNA group versus placebo, as well as a four-fold higher risk of serious adverse events of special interest compared to the risk of COVID-19 hospitalizations (10.1 AESIs vs. 2.3 hospitalizations per 10,000 participants, respectively). Moderna trial data showed a greater than doubling in the risk of serious adverse events of special interest compared to the risk of COVID-19 hospitalizations (15.1 AESIs vs. 6.4 hospitalizations per 10,000 participants, respectively; Fraiman et al., 2022).

In both registrational trials, the modmRNA injections were linked with increased risks of ischemic stroke, brain hemorrhage, venous thromboembolisms, acute coronary syndrome, and other conditions known to reduce life expectancy (Fraiman et al., 2022). Because these are common clinical conditions, they can easily escape notice as consequences of the mass modmRNA "vaccination" campaign. This is why controlled clinical trials should have been an essential step revealing the true scope and nature of the harms associated with these products. Despite the numerous flaws in terms of the trialists' methodology, execution and reporting, many of the findings from the re-analyses pointed to devastating adverse events associated with these experimental gene-based prodrugs.

Additionally, as we noted in Part 1, the reclassification of these gene therapy products as "vaccines" meant that none of their components were thoroughly evaluated for safety in a manner consistent with the testing of genetic products (Mead et al., 2024a). To date, millions of severe and life-threatening events associated with the COVID-19 modmRNA products have been documented in the medical literature, as addressed in these reviews and analyses (Montano, 2021; Classen, 2021; Fraiman et al., 2022; Yan et al., 2022; Mörl et al., 2022; Karlstad et al., 2022; Oster et al., 2022; Shabu

et al., 2023; Tokumasu et al., 2023; Yasmin et al., 2023; Yoon et al., 2023; Villanueva et al., 2024; Padilla-Flores et al., 2024; Yang et al., 2024; Urdaneta et al., 2024; Glover et al., 2024; Lin et al., 2024; Kim et al., 2024a). In subsequent sections of this paper, we organize the main groupings of serious adverse events in terms of cardiovascular, neurological, hematologic, immunological, malignant, and reproductive conditions.

Systematic reviews, by comprehensively aggregating and critically evaluating all relevant studies, can play a useful role in assessing COVID-19 modmRNA adverse events and increasing the reliability of conclusions concerning specific groupings of those events. Such reviews help minimize bias and provide a robust overview of the existing research. Nevertheless, these systematic reviews are never bulletproof. This is largely because many of the COVID-19 "vaccine" trials included in these reviews were fundamentally flawed (lacking in internal validity), while the observational studies were riddled with numerous biases and systematic errors (Lataster, 2024; Neil et al., 2024; Fung et al., 2024). Despite these limitations, multiple systematic reviews have indicated that the modmRNA injectables are associated with an increased risk of adverse events following administration of these products (Alhossan et al., 2022; Cheng et al., 2021; Fan et al., 2021; Haas et al., 2022; Hossaini et al., 2022; Kouhpayeh et al., 2022; Oueijan et al., 2022; SeyedAlinaghi et al., 2022; Shafiq et al., 2022; Yuniar et al., 2022; Wu et al., 2024). A network meta-analysis of 25 randomized controlled trials involving 22 different vaccines (including the COVID-19 products) concluded: "None of the different types of vaccines were significantly superior in terms of efficacy, while the [COVID-19 modmRNA products] were significantly inferior in safety to other types" (Wu et al., 2024).

It should be noted that all of the above-cited systematic reviews focus on both efficacy *and* safety, and yet most reviews place disproportionate emphasis on the former. This overemphasis on efficacy, in turn, has helped reinforce the widespread perception that the modmRNA's efficacy in reducing hospitalizations and deaths significantly outweighs the associated risks of serious adverse events. Such claims now appear to have been groundless (and perhaps even propagandistic), based on a recent meta-analysis synthesizing findings from 68 studies to assess the efficacy of COVID-19 modmRNA injections (Wu et al., 2023). Despite clear evidence of publication bias, the analysis showed a significant decline in vaccine effectiveness over time, with the lower bound of confidence intervals suggesting it may diminish to near zero between 168 and 195 days post-injection. After the emergence of the Omicron variant, vaccine effectiveness *even at baseline* fell below WHO's "adequate vaccine response" threshold. Thus, since the inception of Omicron, virtually no significant benefit was seen with the modmRNA injections (both primary and booster doses) in terms of preventing SARS-CoV-2 infections, hospitalizations, and mortality. The authors noted that the lack of any impact on hospitalization and mortality outcomes must be interpreted with caution, given the studies' lack of control for confounding factors such as early treatment, natural immunity, and the emergence of progressively milder viral strains. Indeed, unlike the modmRNA injections, early treatment and natural immunity are likely to confer robust protection against hospitalization and premature death, as we documented in Part 1.

Another aspect of the existing research that has led to misunderstanding of the true scope of harms associated with the modmRNA products is the downplaying of serious adverse events. Most published reports and reviews with "safety" in the title are focused on short-term studies of basic side effects of the modmRNA injections (e.g., injection site discomfort and fatigue), rather than on the more serious cardiac and thrombotic events that often result in premature death. Information about adverse events, conflicts of interest and funding, remains under-reported in trials of both vaccines and antibiotics (Bakhit et al., 2021; Gøtzsche & Demasi, 2022). As alluded to in the preceding paragraph, strong publication bias can severely compromise the integrity of systematic

reviews by skewing the available evidence base: studies showing null findings, no benefits, or an excess of adverse events, may be less likely to be accepted for publication. In a systematic review of trial evidence by Graña et al. (2022), there was a clear overall risk of bias in at least 33 of the 41 randomized controlled trials assessing 12 different vaccines. In a systematic review of 61 randomized controlled trials (402,014 patients) of the COVID-19 "vaccines", all studies reported deaths and serious adverse events, but only 21 studies (34.4%) showed a low risk of bias (Yuniar et al., 2022). Such bias can often lead to an overestimation of the intervention's true "benefits", along with a concomitant underestimation of potential harms. All of these systematic reviews appeared to display a predetermined bias, even in the face of concerning risk-related data, offering a simple, unfounded conclusion of a favorable benefit-to-risk ratio with a recommendation to continue administering the injections on a population-wide basis.

Intriguingly, many of the initial revelations about adverse events arose from the Bio-Pharma Complex itself, following the rushed EUA process. Confidential Pfizer documents showed approximately 1.6 million adverse events as of August 2022 (Pfizer, Inc., 2022; Pfizer, Inc., 2022b; Horowitz, 2023). One-third of these events were classified as "serious", invariably resulting in emergency care, hospitalization, permanent disability, or even death. Numerous modmRNA-related injuries and deaths have been reported to official databases, notably VAERS in the USA, Yellow Card in the UK, EudraVigilance in the European Union, and VigiBase, the WHO's global database reporting adverse effects of medicinal products (VAERS, 2024; European Medicines Agency 2024; Medicines & Healthcare Products Regulatory Agency, 2024; World Health Organization, 2024). An investigation of adverse event reports to VAERS and EudraVigilance found "a large excess risk of death, hospitalization and life-threatening reports for all COVID-19 vaccines in comparison to the influenza vaccines, and particularly large relative risks of thrombosis, coagulation and sexual organs reactions…" (Montano, 2021). A 2022 systematic review listed myocarditis, pericarditis, thrombocytopenia, and various neurological effects (such as seizures and orofacial events) as among the serious adverse events linked with the modmRNA injections (Oueijan et al., 2022). In comparisons with their DNA adenoviral vector counterparts, the COVID-19 modmRNA injections consistently resulted in more serious adverse events (Fan et al., 2021). Serious adverse reactions generally occurred within the first seven days after the injection. Such severe outcomes have amplified skepticism regarding the products' safety and efficacy, with some speculating that the rise in mortality in heavily "vaccinated" countries observed between 2020 and 2022 is more strongly linked with the worldwide gene-based injection campaign than with SARS-CoV-2 infection (Kuhbandner & Reitzner, 2023; Aarstad & Kvitastein, 2023).

Disappointingly, now four years after the Registrational Trial reports that led to the rushed and massive worldwide "vaccination" campaign, not a single large controlled clinical trial has demonstrated that the modmRNA injections can reduce severe disease, hospitalization, and mortality. In light of this fact, the "safe and effective" mantra issued by the Bio-Pharmaceutical Complex throughout the pandemic must be deemed scientifically fallacious and moreover dangerous from a public health perspective. Contrary to the pharmaceutical industry's relentless messaging, three large well-designed cohort studies have demonstrated that repeated modmRNA injections lead to *increased* rates of COVID-19, with zero injections offering superior protection when compared to one or more injections (Shrestha et al., 2023; Shrestha et al., 2023b; Shrestha et al., 2024). These findings are further reinforced by real-world observations of negative protection associated with COVID-19 modmRNA injections in various populations (UK Health Security Agency, 2022; COVID-19 Vaccine Surveillance Report, 2022; Eythorsson et al., 2022; Hatchard, 2022; Altarawneh et al., 2022; Gazit et al., 2022; Rzymski et al., 2021; Adhikari et al., 2024).

In November 2023, the CDC alarmingly inserted the COVID-19 modmRNA injections into the childhood immunization schedule, with a recommendation to have one dose of the updated or "current vaccine" administered to all children after six months of age (Cottrell, 2023). The recommendation is groundless and morally abhorrent, given that infants and children have only very rarely suffered from COVID-19, at rates that must be considered extremely minuscule when compared to the myocardial damage and other well-documented harms incurred by the modmRNA injections. Furthermore, no controlled clinical trials involving children have been conducted to adequately test the safety of the modmRNA "booster" products (in accordance with established scientific standards for either classical vaccines or gene-therapy products). The American Academy of Pediatrics has blithely endorsed the CDC's decision, stating that "it is safe to add the COVID vaccine to the current recommended vaccine schedule" (Cottrell, 2023). Even with the Biden administration's official declaration of an end to the "national COVID emergency" in May 2023, many school systems are astoundingly still pressuring — and in some cases, requiring — students to "get vaccinated" against a disease that has a near-zero infection fatality rate for people under age 40 (Pezzullo et al., 2023).

Virtually all children have now been exposed to the coronavirus and thus harbor enduring T-cell immunity (Turner et al., 2021; Patalon et al., 2023) that is vastly superior to any theoretical protection conferred by these untested modmRNA injectables (see Part 1). The harm-to-reward ratio may be incalculably large in light of the various cardiovascular, neurological, and malignant events (many of which may have a long latency) discussed in subsequent sections. Even if some of these conditions are indeed "rare" as many papers claim, given the vast numbers of these conditions and the likelihood that many disorders have a long latency, this would suggest a high harm-to-reward ratio for children and young adults. Data from a large pharmacovigilance study indicate a disproportionate reporting of immune-related adverse events among adolescents following the COVID-19 modmRNA injections (Kim et al., 2024a).

It is vital to reiterate, as discussed in Part 1, that the modmRNA COVID-19 injectable products are by definition *prodrugs*: they do not become active until administered to the human body, and, following administration, there are no studies to definitively ascertain how much spike protein will be produced in the host, much less *where* that production will take place. The publicized *modus operandi* of this technology is to introduce the coding material for the spike protein to human cells, such that the cells themselves will produce the protein by ribosomal translation. The number and identity of the cells likely to be transfected are unknown, and therefore we have no method to quantify either spike protein production or off-target protein production per cell in the *in vivo* setting. This means that variability of foreign protein-induced adverse event reactions are currently unpredictable, ranging from headaches, fatigue and fever symptoms on the "moderate" side of the adverse events spectrum, to paralysis, strokes, and sudden cardiac death on the "serious" side of the spectrum. Since we currently have no discernible way to predict serious adverse event occurrences, it seems criminal to allow this Russian roulette schema to persist in the context of injecting infants and young children, especially by coercion or mandate. For example, see Santiago (2022b). We revisit this point in greater depth in the **Discussion**.

In this second part of our narrative review, we address the key structural and functional characteristics of the modmRNA products, the problem of process-related genetic impurities that are intrinsic to largescale manufacture of these products, and the main groupings of adverse events that have been linked with the COVID-19 modmRNA products in terms of their epidemiological, biological, and biochemical aspects. The modmRNA products pose a unique set of biological problems for the human body and moreover can elicit far more extensive adverse effects that can

potentially impact the entire human population, including the younger, healthier age groups for whom the coronavirus infection poses no risk whatsoever. We conclude with an overview of the primary public health problems that have emerged as a consequence of this scientific inquiry, review some of the key public health tactics and stratagems used to manipulate the general public and medical communities, and finally reiterate our clarion call for a global moratorium on these products.

### *Structural and Functional Aspects of the modmRNA Injectables*

The synthetic, modified mRNA of the Pfizer and Moderna products encode for the spike protein of SARS-CoV-2. Originally, molecular biologists had theorized that this bioengineered aspect of the chimeric virus would serve as the common link between the coronavirus infection and modmRNA injections in terms of overlapping biological effects. If we accept the proposition that the spike protein was fundamental to the facilitation of COVID-19 infections, it may be inferred that the antigenic proteins generated by the modmRNA products would be associated with adverse events ostensibly triggered by the injectables (Trougakos et al., 2022; Parry et al., 2023). This inference is consistent with certain results from Pfizer's Registrational Trial: in the modmRNA "vaccine" group, symptoms associated with the serious adverse events of "special interest" appear to overlap with what has been diagnosed as acute and chronic COVID-19 (Fraiman et al., 2022). Both the COVID-19 modmRNA injectables and SARS-CoV-2 infections can trigger immune dysfunction along with a host of pathophysiological effects, including chronic inflammation, thrombogenesis, prion-related dysregulation, and endotheliitis-related tissue damage (Parry et al., 2023). These findings may suggest that perhaps some of the adverse events caused by the modmRNA products occur through spike-mediated impacts by which the SARS-CoV-2 virus also may induce similar harm. Essentially, apart from their primary role in coding for spike protein expression by antigen-presenting immune cells, the modmRNA injections and the virus both have the potential to cause certain pathological effects in a percentage of individuals receiving the injections.

Despite the overlap in effects between the COVID-19 modmRNA inoculations and coronavirus infection, it is important to emphasize that there may be substantial differences between the impacts of injection versus those that may be caused by infection. For example, we noted in Part 1 that the modmRNA-induced spike protein allegedly differs from the wild-type viral version due to specific amino acid modifications, purportedly keeping the protein in a prefusion state in order to amplify immunogenicity (Heinz et al., 2021). One of the untoward consequences of this may be that the modmRNA injections may induce potentially toxic concentrations of spike protein within tissues before leaking into the circulation (Cosentino & Marino 2022a, 2022b). Consistent with this theory, plasma spike protein levels were elevated by 100-fold in a patient with vaccine-induced immune thrombocytopenia (Appelbaum et al., 2022). The spike protein appears to exhibit cytotoxicity within cells in part through its interaction with tumor suppressor genes, resulting in mitochondrial damage (Parry et al., 2023; Seneff et al., 2023). When spike proteins are present on the cell surface, they can apparently trigger a cytopathic autoimmune response; there is a problematic homology between spike protein and certain proteins within the adaptive immune system, thereby potentially triggering a distortion of immune tolerance following the modmRNA injections (Parry et al., 2023; also see Lyons-Weiler, 2020; Vojdani, et al. 2020). These effects may help to explain the wide range of well-documented modmRNA-induced toxicities that impact the nervous, gastrointestinal, hepatic, renal, hematological, immune and reproductive systems (Blaylock, 2022; Parry et al., 2023; Seneff et al., 2023).

Originally, the COVID-19 modmRNA products were administered following the claim that the synthetic mRNA, encapsulated within the supposedly protective lipid nanoparticles (LNPs), would

remain in the deltoid muscle following the injection. This claim turned out to be patently false, as biodistribution studies subsequently revealed whole-body dissemination of the synthetic nucleic acids followed by systemic generation of spike protein (Heinz et al., 2021). When the spike protein enters the bloodstream, it spreads systemically, and persists for at least 6-8 months (Brogna et al., 2023; Patterson et al., 2024). As a result, it seems capable of contributing to a range of adverse events (Trougakos et al., 2022). One reason the long-lasting systemic distribution of modmRNA is problematic is that the substitution of N1-methylpseudouridine for uridine in these products has been shown to promote errors during reverse transcription (Kim et al, 2022). Even minor transcription errors can result in significantly harmful disease-related effects. When they are scaled to a large population (Gutschi, 2022), the effects are multiplied so as to become catastrophic. We are now looking at gene-based prodrugs administered to over half of the global population over a period of four years, an uncontrolled global experiment with potential adverse outcomes likely manifesting for decades.

The persistent nature of these products *in vivo* may be attributed to the fact that the nucleic acids in the COVID-19 modmRNA injectables exhibit enhanced base-pairing stability compared to natural nucleic acids (Duffy et all., 2020) as well as the fact that they tend to produce a plethora of proteinaceous material that the body seems unable to break down (Santiago, 2022a, 2022b; Santiago & Oller, 2023). In addition to being a kind of wild card in the genetic codons calling for certain amino acids in protein sequences, as Santiago has argued, the N1-methylpseudouridine modification (mentioned above) also results in greater resistance to enzymatic degradation (Nance & Meiers, 2021), contributing to the persistence of the modmRNA and spike protein in the body (Bansal, 2021; Brogna, 2023; Ho et al., 2024; Nance & Meier, 2021). Brogna et al., (2023) initially reported that spike protein was detected after the modmRNA inoculation up to 187 days (about six months) post-injection. However, Patterson et al. (2024) found modmRNA-generated spike protein in immune cells of recipients for up to 245 days (about eight months).

This extended *in vivo* half-life was initially deemed advantageous because the modmRNA technology was designed to substitute or deliver biotherapeutic (or in this case, immunogenic) proteins. Nevertheless, we have come to learn that the modmRNA injectables may also transform the transfected cells into viral protein factories that have no off-switch (i.e., no built-in system to stop or regulate such proliferation), with the spike protein being systemically generated for prolonged periods (Trougakos et al., 2022; Acevedo-Whitehouse and Bruno, 2023). This protracted production of spike protein may be the basis for chronic, systemic inflammation and immune dysfunction, all of which are associated with disease outcomes, which may have a long latency (Seneff et al., 2022; Qin et al., 2022; Klingel et al., 2023; Giannotta et al., 2023). Spike protein can promote chronic inflammation in liver, spleen, heart, ovaries, and nervous system (Baumeier et al., 2022; Seo et al., 2022; Sriwastava et al., 2022; Trougakos et al., 2022). This may help explain long-term vaccine-related adverse events (Sadat Larijani et al., 2023), some of which have only begun to come to light.

When comparing the potential harmful effects of modmRNA injections to those of SARS-CoV-2 infection, it is important to emphasize that the infection is typically contained in the respiratory system (for a more detailed explanation, see Mead et al., 2024a), resulting in mild or no symptoms in relatively healthy people (O'Driscoll et al., 2021). Moreover, the SARS-CoV-2 RNA detected in blood is invariably *not* associated with actively replicating virus (Andersson et al., 2020; Wölfel et al., 2020). In contrast, however, the spike protein generated from the modmRNA injection represents a chronic source of systemic antigenic stimulation and inflammation (Pfizer Report, Japanese Government, 2020; ElSawi & Elborollosy, 2022). An acute inflammatory response may be elicited through spike protein-induced activation of the NF-κB signaling pathway (Khan et al., 2022).

Whole-body biodistribution of the modmRNA is enabled by injection of whatever the payload may be along with the lipid-nanoparticle (LNP) delivery system itself. Injecting such products under the skin and into muscle tissue where they have access to the body's fluid transport systems (mainly via the blood, lymph, and cerebrospinal fluids) is likely to result in systemic biodistribution. The idea that such distribution is blocked by locating the bolus of injected material into muscle tissue has always been a doubtful proposition. To dispose of such products they must enter the fluid transport systems, including the renal and gastrointestinal systems.

In addition to the modmRNA itself, the LNP platform itself accounts for some of the prolonged inflammatory effects of the modmRNA injections, as evidenced by activation of an array of inflammatory pathways along with overproduction of various cytokines and chemokines (Di Gioacchino et al., 2011; Ndeupen et al., 2021). Pre-exposure to mRNA-LNPs in mice led to long-term inhibition of adaptive immunity and reduced protection against fungal infections (Qin et al., 2022). Ionizable lipids within LNPs can elicit potent proinflammatory responses by activating toll-like receptors (TLRs; Verbeke et al., 2019). LNP-treated mice showed hepatotoxicity, excessive inflammation, and activation of TLR4, which plays a role in cancer progression (Kedmi et al., 2010; Kashani et al., 2021). In animal models, these inflammatory responses were further exacerbated by pre-existing inflammatory conditions (Parhiz et al., 2022); in the human realm, this background effect is likely to be of special relevance to the phenomenon of age-related, chronic, low-grade inflammation, also known as *inflammaging* (Soegiarto & Purnomosari, 2023). The significance of the inflammatory components in the modmRNA-LNP platform is demonstrated by the fact that highly purified mRNA (lacking detectable contaminants) combined with LNPs that lack the inflammation-inducing ionizable lipid fails to trigger innate and adaptive immune responses *in vivo*; however, LNPs containing the ionizable lipid, when mixed with either mRNA or protein, effectively supported similar adaptive immune responses (Ndeupen et al., 2021; Alameh et al., 2021).

In summary, components of the modmRNA products contribute directly to complex, poorly understood, and unpredictable adverse events. These components include the following:

(1) **Lipid nanoparticles**. In particular, we are concerned with the ionizable cationic lipids (lipids that become positively charged in acidic environments). Ionizable cationic lipids are known to be toxic, inducing pro-apoptotic and pro-inflammatory cascades (Cui et al., 2018). Nevertheless, they are an essential component of the modmRNA products, intended to bolster the prolific synthesis of spike protein from the modmRNA.

(2) **Polyethylene glycol (PEG).** As one of the primary adjuvant components of the COVID-19 modmRNA vaccines, PEG is widely considered to be a major factor in vaccine-induced anaphylactic shock, a well-established potential immediate serious adverse events in susceptible individuals following the modmRNA injections (Sellaturay et al., 2021; Segalla, 2023a, 2023b). Conjugation of PEG to the nanoparticles increases its immunogenicity, causing complement activation and a subsequent acute and life-threatening reaction (Bigini et al., 2021).

(3) **Process-related genetic impurities**. For purposes of mass production, the modmRNA used in these products is synthesized using a bacterial plasmid as a template. Large quantities of these DNA templates are used for modmRNA production. Plasmid *E. coli* DNA was recently detected by independent researchers (Hou et al., 2021; Speicher et al., 2023; Segalla, 2023a, 2023b, 2023c, 2023d). Other genetic impurities that may be associated with the modmRNA technology include residual DNA, DNA-RNA hybrids (or their fragments), double-stranded (ds) RNAs, and short, truncated mRNAs (Ouranidis et al., 2021).

Additional components of the modmRNA injections have been identified but are beyond the purview of this paper. In our view, the COVID-19 synthetic modmRNA, modmRNA-induced spike protein, PEG, LNPs, and ionizable lipids, are the most salient components for purposes of this narrative review. We will refer back to these components in the discussion of adverse events.

## Quality Control Issues and Process-Related Genetic Impurities

Given the novelty of the synthetic mRNA technology used in the SARS-CoV-2 "vaccines", it would have been prudent to establish regular production inspection and quality assurance along with long-term safety monitoring protocols and to perform the requisite tumorigenicity, genotoxicity, neurotoxicity, immunotoxicity, and reproductive toxicity studies. The fact that no safety and toxicity studies appropriate for these gene-based or GTP products were ever performed is concerning.

One plausible explanation for why some individuals succumb to modmRNA-induced serious adverse events while others do not is product type and batch variability. Due to the inherent instability of modmRNA technology, some batches may contain extremely low levels of intact mRNA (Tinari, 2021). All batches tested were contaminated with dsRNA, as documented by the EMA for both the Pfizer and Moderna products (European Medicines Agency, 2021a; European Medicines Agency, 2021b). The dsRNA can cause unwanted activation of innate immune responses (Karikó et al., 2011; Rosa et al., 2021; To et al., 2021). Innate immune activation via dsRNA results in the upregulation of various pro-inflammatory cytokines, inducing chronic inflammation and increased morbidity (Sales-Conniff et al., 2022; Luo et al., 2023), such as myocarditis (Milano et al., 2021) and hyper-progressive cancers (Seneff et al., 2022; Angues & Bustos, 2023). The Pfizer modmRNA product contains physiologically relevant levels of dsRNA, suggesting that the adaptive immune responses it induces in mice are partially dependent on the MDA5 protein, a dsRNA sensor (Li et al., 2022). Ideally, the bacterial DNA template would be completely eliminated from the final product to ensure short- and long-term safety and minimize the disease-related risks mentioned above.

Quality control is central to any discussion of batch variability and process-related impurities, and yet, in practical terms, evaluating such control for individual vials has heretofore been impractical. The requirement of maintenance at extremely low temperatures may not always be practical, and the consequences of improper handling (e.g., cold chain breaching) are not well characterized. Recent development of a rapid, sensitive, convenient method of detecting dsRNA impurities in the modmRNA (including 15-minute detection of N1-methyl-pseudouridine-containing dsRNA) may help improve quality control of the synthetic mRNA technology (Luo et al., 2023). It has been hypothesized that variability in adverse reactions might be caused by quality differences among different batches or even different individual vials, due to variabilities in both contaminants and handling histories (Bruce Yu et al., 2021).

Along these lines, Schmeling et al. (2023) analyzed data from serious adverse event cases with corresponding modmRNA "vaccine" batch labels reported to the Danish Medical Agency (classified by the agency according to seriousness), along with numbers of Pfizer modmRNA doses in individual batches registered by the Danish Serum Institute. Unexpectedly, the rates of serious adverse events per 1000 doses varied significantly between different vaccine batches, with a median of 2.32 events (interquartile range: 0.09–3.59) per 1000 doses. There was significant heterogeneity ($p < 0.0001$) in the relationship between the number of serious adverse events per 1000 doses and the number of doses in each individual batch. Overall, the Danish analysis indicates the existence of a batch-dependent safety signal for the Pfizer modmRNA injections, although the study had several

limitations—in particular, temporal trends in the observed batch-dependency of serious adverse events were not specifically examined (Schmeling et al., 2023).

The issue of batch variability is further complicated by recent findings of DNA contamination based on multiple sequencing assays of both the Moderna and Pfizer modmRNA "booster" products (Speicher et al., 2023). In an analysis of multiple vials of the bivalent Pfizer and Moderna mRNA products, McKernan et al. (2023) found "high levels of DNA contamination in both the monovalent and bivalent vaccines" that were "orders of magnitude higher than the EMA's limit" of 330 nanograms of DNA per milligram of RNA. The DNA process-related impurities also exceeded the safety limits of the FDA (10ng/dose). Ideally, the plasmid and other components are eliminated during the mRNA purification step.

In a follow-up attempt to disprove this claim, Buckhaults and his genomics research team examined two batches of Pfizer mRNA vials and confirmed contamination with the plasmid DNA vector that had been used as the template for modmRNA vaccine production (McCullough, 2023; Zylo, 2023). At a South Carolina Senate hearing, Buckhaults reported having consistently sequenced substantial quantities of plasmid DNA, 200 billion DNA fragments per vial (Zylo, 2023). Subsequently, König and Kirchner (2024) used a bleaching method to dissolve the lipid nanoparticles of the Pfizer modmRNA product, Comirnaty. Fluorescence spectroscopy revealed DNA impurity levels ranging from 360 to 534 times higher than the 10 nanogram per dose limit now used by regulators worldwide. The authors noted that the qPCR test employed by Pfizer to detect DNA impurities is able to find only a tiny 69-base-pair segment of the original 7,824-base-pair DNA template used to synthesize the modmRNA product. Therefore, at least 99% of the original template goes unanalyzed, resulting in gross under-detection of DNA impurities. Moreover, the 69-base-pair segment may get destroyed at different rates than the rest of the DNA template fragments during enzymatic degradation, further diminishing the measurement's accuracy. The approach used by König and Kirchner, however, remains to be validated, as the use of fluorometric dyes could lead to distorted measurements of the impurities.

With reference to the spike protein coding, there is the problem of replacing all the uridines in the RNA molecule with N1-methylpseudouridine. This strategy was represented as a useful way to enhance protein expression as part of mRNA therapeutics (Nance & Meier, 2021). This was also said to be a breakthrough innovation, since the CureVac modmRNA vaccine (CureVac N.V., Tübingen, Germany), lacking this innovation, was supposedly less effective than the Pfizer and Moderna formulations (Morais et al., 2021). The claimed boost in effectiveness may have been because the substitutions retard degradation causing the modmRNA to persist. While N1-methylpseudouridine is a natural molecule, normally it is only present as a substitute for uridine in a small percentage of the uridines in any natural sequence but never in human beings. An experiment with computer modeling published in May 2024 found that 100% substitution of uridine with methylpseudouridine in the modmRNA product as delivered to melanoma cells resulted in increased cancer growth and metastasis, whereas the model suggested that modmRNA vaccine without methylpseudouridine would produce the opposite effect (Rubio-Casillas et al., 2024). The trouble with this kind of modeling, however, is that it can be massaged and adjusted in many ways to create the illusion of some desired effect. The fact that it produced the undesirable predictive outcome with cancer cells is interesting in view of results being reported from around the world from doctors treating recipients of the modmRNA products for cancers.

Among the as-yet-undetermined effects of the largescale introduction of N1-methylpseudouridine into human bodies are those pertaining to the synthesis of new mRNA molecules (Rose, 2023). Given the high error rate caused by the modified nucleosides, the intended spike protein is just one

of the many possible peptide sequence products of the mRNA that might be produced. Oller and Santiago point out that the processes occurring in the ribosome are complex and poorly understood, involving the actions of many short-lived RNAs with context-dependent functionality, which are part of the "irreducibly complex system of systems" that constitute an integral part of the body's integrated and holistic maintenance, repair, and defense systems (Oller & Santiago, 2022). Their point is that the systems involved are not mechanistic as is so often falsely claimed.

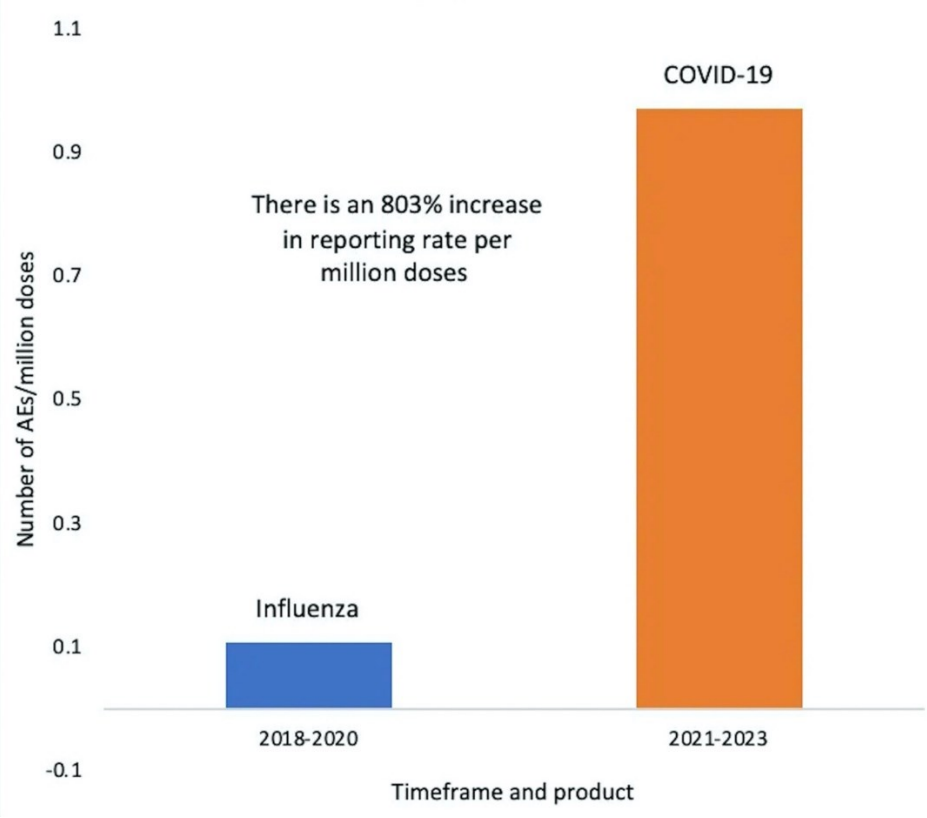


Figure 1. VAERS reports of autoimmune disease per million doses of COVID-19 mRNA (2021-2023) compared to Influenza (2018-2020) vaccinations. Based on a VAERS query (https://vaers.hhs.gov/) using the MedDRA code "Autoimmune disorder", there was an 803% increase in reporting rate per million doses administered when comparing Influenza vaccines administered from 2018 through 2020 to COVID-19 mRNA injections administered from 2021 through 2023. Notably, the reports exclude individuals with a history of an autoimmune disorder. Image credit: Jessica Rose (2023b).

In a remarkable demonstration in mice, Mulroney et al. (2023) found that the modmRNA vaccines induced antibodies in mice to proteins that could be synthesized from the mRNA code if it were frameshifted by one nucleotide. This was not seen in cells challenged with just the spike protein, or in mice injected with the Astra-Zeneca prodrug (AstraZeneca plc, Cambridge, United Kingdom), which is a DNA-based product. They suggested that it was the N1-methylpseduouridylation that caused the frameshift. Such unintended, off-target proteins have "huge potential to be harmful", to quote Mulroney et al. (2023). Part of the problem is near or complete homology with certain human peptides and longer protein sequences that can induce autoimmune disease (Kanduc & Shoenfeld, 2020; Lyons-Weiler, 2020; Vojdani et al., 2020).

Based on a query of the MedDRA code "Autoimmune disorder" in the Vaccine Adverse Events Reporting System (VAERS), there was an 803% increase in autoimmune disorders per million doses administered when comparing the administration of Influenza vaccines from 2018 to 2020 with

COVID-19 vaccinations from 2021 to 2023 (**Figure 1;** Rose, 2023b). This represents an immense safety signal for the entire population, especially the older age groups. Such fundamental problems with the technology should have been addressed before the products were delivered to hundreds of millions of people (Wiseman et al., 2023).

### *Residual DNA Fragments Containing SV40 Sequence*

A surprising and potentially alarming discovery in samples of the Pfizer modmRNA product was the presence of the Simian virus 40 (SV40) promoter; this was notably absent from the Moderna product samples (Speicher et al., 2023). In October 2023, the regulatory agency Health Canada confirmed the presence of this genetic sequence in modmRNA samples (Horwood, 2023). SV40, an oncogenic DNA virus originally isolated in 1960 from contaminated polio vaccines, induces lymphomas, brain tumors, and other malignancies in laboratory animals (Vilchez & Butel, 2004). Immunological data from cancer patients have indicated that their sera had a higher prevalence of antibodies against SV40 compared to healthy subjects (Rotondo et al., 2019). A meta-analysis based on pooling diverse data from 1,793 cancer patients identified a significant excess risk of SV40 in association with brain tumors, bone cancers, non-Hodgkin's lymphoma, and malignant mesothelioma (Vilchez et al., 2003; Šenigl et al., 2024). It seems improbable, however, that SV40 exposure alone results in human malignancy, as suggested by the absence of a cancer epidemic (at least in the short term) following the distribution of SV40-contaminated polio vaccines. A more plausible scenario is that SV40 functions as a cofactor in the genesis and progression of tumors, as indicated by laboratory studies revealing its cocarcinogenic potential with asbestos, an established carcinogen (Qi et al., 2011).

The SV40 promoter has found potential use as an enhancer in gene therapy treatments based on DNA plasmids. In a 2001 study on somatic gene delivery to skeletal muscle cells, it was shown that incorporation of the SV40 enhancer into DNA plasmids could increase the level of exogenous gene expression by a factor of 20 (Li et al., 2001). According to an insightful editorial on the implications of process-related impurities, the packaging of DNA fragments into lipid particles enhances the possibility that the DNA fragments will integrate into the human genome (Aldén et al., 2022; Orient, 2023).

While absent in the vials utilized during the registrational trials, the SV40 promoter has been identified in all tested BioNTech vials drawn from batches that have been distributed to the public. On December 6, 2023, Florida's surgeon general Joseph Ladapo contacted the FDA and CDC with questions about safety assessments and the discovery of billions of DNA fragments per dose of the modmRNA vaccine products (Baletti, 2024; McCullough, 2024). A week later, the FDA responded in writing by citing genotoxicity studies (which are inadequate for evaluating the risk of DNA integration) and by blurring the distinction between the SV40 promoter/enhancer and SV40 proteins, erroneously treating these elements as interchangeable (McCullough, 2024). Because the agency has thus far failed to provide any evidence of conducting DNA integration assessments to address the risks highlighted by the agency itself back in 2007, Ladapo called for a complete halt on the use of all COVID-19 modmRNA vaccines (Baletti, 2024; McCullough, 2024).

The residual DNA fragments from SV40 present in the COVID-19 modmRNA injectables are likely remnants from the mass production process. In a presentation at the International Crisis Summit-5 conference in February, McKernan noted that Moderna's patent application for its modmRNA product explicitly acknowledges the potential risks associated with insertional mutagenesis (Anandamide, 2024a). The patent further specifies that residual DNA contamination could pose a carcinogenic risk, stating: "The DNA template used in the mRNA manufacturing process must be

removed to ensure the efficacy of therapeutics and safety, because residual DNA in drug products may induce activation of the innate response and has the potential to be oncogenic in patient populations" (Issa et al., 2018).

A joint statement offered by an international expert advisory panel sponsored by the World Council for Health included the following: "There are multiple completely undeclared genetic sequences in both Moderna and Pfizer vials, with the SV40 sequence found only in the Pfizer vials. However, latent SV40 infections in a significant portion of the population could present the same SV40 risk to Moderna recipients. Even in the absence of chromosomal integration, the DNA plasmids could generate mRNA for the spike protein toxin and other harmful proteins for prolonged and unpredictable periods of time. Integration of foreign DNA into the human genome disrupts existing natural genetic sequences; this carries further risk of disease including cancer" (World Council for Health, 2023).

### *Foreign DNA Contamination, Reverse Transcription, and Oncogenesis*

We have already seen that the substitution of methylpseudouridine for all the uridines in the modmRNA products can evidently promote proliferation and metastasis in cancer cells (per the modeling of Rubio-Casillas et al., 2024). Another way by which the prodrugs may promote cancer is through reverse-transcribed sequences that are integrated into the human genome, as discussed by Zhang et al. (2021) and demonstrated to occur experimentally in certain liver cell lines by Aldén et al. (2022). ModmRNA from the Pfizer product was reverse-transcribed *in vitro* into liver cell line Huh7 DNA in as little as six hours upon exposure to BNT162b2 (Aldén et al., 2022). The insertion of new DNA into the human genome becomes a much greater problem if it occurs at the level of stem cells within the reproductive system.

The potential for DNA integration is especially problematic in the context of oncogenesis. Insertions of prodrug nucleic acid in native DNA can disrupt normal gene function and activate oncogenesis, leading to out-of-control cell growth. A recent paper by Igyártó and Qin (2024) lays out a comprehensive argument for the biological plausibility for such integration, noting that the modmRNA sequence characteristics of these products fulfill all known criteria for retroposition via LINE-1 elements (Domazet-Lošo 2022) as experimentally demonstrated by Aldén et al. An increase in overall LINE-1 retrotransposon expression levels and its localization to the nucleus suggests the likelihood of reverse transcription being a very general danger not merely to liver cells on any account. Earlier studies also documented the localization of spike protein in the endoplasmic reticulum of impacted cells and in mitochondria (Zhang et al., 2020; Kim et al., 2021). A preprint report suggested that the SARS-CoV-2 spike protein, unlike that of other SARS viruses, possesses a nuclear localization signal (NLS), which in turn facilitates the transport of the spike protein to the nucleus and appears to also shuttle the spike mRNA to the nucleus (Sattar et al., 2023). Collectively, these reports support the probability that the synthetic modmRNA and/or spike protein can be transported to the nucleus and moreover reinforce the possibility that the modmRNA is reverse-transcribed into DNA, which could then integrate into the genome of gamete cells transmitted across generations (Domazet-Lošo 2022).

Double-stranded DNA breakage and subsequent repair are ongoing cellular processes. Double stranded breaks (DSBs) may result from the accumulation of reactive oxygen species, exposure to ionizing radiation, and interactions with various chemical agents. However, cells possess robust processes for repairing these breaks to prevent apoptosis and avoid genomic rearrangements (mutations) that are frequently observed in oncogenesis. This array of repair processes is referred to as the DNA damage response (Groelly et al., 2022). A compromised or inefficient repair system can

lead to malignant disease, highlighting the importance of these repair processes in maintaining genomic integrity (Groelly et al., 2022).

It has been shown that billions of foreign DNA fragments are being introduced to following LNP transfection (Fleming, 2021; Speicher et al., 2023). More recently, it has also been demonstrated that integration has occurred, specifically in human chromosomes 9 and 12 (Anandamide, 2024b). Preliminary findings of Kämmerer and McKernan also demonstrate *in vitro* that transfected cells may also promote foreign DNA replication as they have been found to exhibit mutations. These mutations occur at origins of replication (ORIs), including the SV40 ORI, and are uniquely observed in the context of the cells exposed to COVID product, rather than in the COVID product in isolation. Since it is widely accepted that integration of foreign DNA into host cell genomes may result in heightened cancer risks, these findings highlight the necessity to examine the potential for oncogenesis in individuals injected with the COVID products built using modified mRNA technology.

## Six Domains of Adverse Events Associated with modmRNA Injections

In this section, we consider the following six groupings of adverse events that have been linked with the COVID-19 modmRNA products: (1) cardiovascular, (2) neurological, (3) hematologic; (4) immunological, (5) oncological, and (6) reproductive. The categories are listed in order of clinical priority based on relative severity as well as the overall impact of the respective adverse events on health outcomes. Cardiovascular events often have immediate and major consequences, including either death (often sudden) or disability. Neurological and hematological events can similarly cause severe disability, often adversely impacting the quality of life and resulting in premature death. Immunological issues, notably autoimmune disorders, encompass a wide range of conditions, many of which are not as immediately life-threatening. Oncological and reproductive events or conditions tend to have longer-term impacts rather than immediate critical outcomes. Thus, this sequence reflects a hierarchy whereby conditions with the highest potential for severe and immediate harm are listed at the top, followed by those that are generally less life-threatening or clinically critical.

Ascribing adverse events to specific domains can be challenging due to the considerable overlap in underlying processes, in particular the ones systemically linked with immunological response to the injections. Many adverse events attributed to the modmRNA injections can result from autoimmune processes that impact multiple organ systems, i.e., a single autoimmune event can also impact any of the other five domains of adverse events. For example, autoimmune reactions could result in the increasingly common cardiovascular event called myocarditis as well as the once exceedingly rare neurological event known as Guillain-Barré syndrome (Khan et al., 2022; Abuawwad et al., 2024; Faksova et al., 2024). Autoimmune processes can also promote the recently designated hematologic event called Vaccine-induced Immune Thrombotic Thrombocytopenia (VITT), which can result in life-threatening strokes (de Buhr et al., 2022; Mingot-Castellano et al., 2022). These interrelationships with autoimmune etiologies complicate the categorization process and necessitate a more nuanced inquiry into the underlying pathophysiological processes. Therefore, while categorizing adverse events can aide in organizing and prioritizing them for clinical and epidemiological analysis, it is helpful to keep in mind the potential for pleiotropic effects stemming from fundamental modmRNA-induced immunological responses on a whole-body level.

### *ADVERSE EVENTS #1: POTENTIAL IMPACT OF MODMRNA ON CARDIOVASCULAR DISEASE AND CARDIAC EVENTS*

Among the most stunning findings from post-EUA re-analyses of the Pfizer registrational trial data, as we noted in Part 1 (Mead et al., 2024a), was the significant 3.7-fold (OR 3.7, 95% CI 1.02-13.2, $p = 0.03$) increase in serious cardiac events among subjects injected with modmRNA when compared to placebo participants (Michels et al., 2023). Moreover, for both trials combined, the re-analysis by Benn et al. (2023) showed a 45% increase in cardiovascular deaths (relative risk=1.45; 95% CI 0.67-3.13) in the respective modmRNA study arms. Although not statistically significant, the upward trend is concerning, particularly in light of numerous reports of COVID-19 modmRNA-related cardiovascular pathology (Jeet Kaur et al., 2021; Oster et al., 2022; Almas et al., 2022; Rees, 2022; Shiravi et al., 2022; Gao et al., 2023; Yasmin et al., 2023).

Myocarditis and cardiac arrhythmias account for the lion's share of modmRNA-related cardiovascular risks, particularly in younger adults, sometimes resulting in sudden death (Milano et al., 2021; Oster et al., 2022; Bozkurt, 2023; Cocco et al., 2023; Gao et al., 2023; Kim et al., 2023; Hulscher et al., 2024b). A large, population-based cohort study in South Korea ($n = 4.5$ million), with 15 months of observation following the day of COVID-19 modmRNA injection, revealed a 620% increased risk of myocarditis and a 175% increased risk of pericarditis compared to historical controls (Jung et al., 2024). The study also noted elevated risks of serious neurological conditions and certain autoimmune diseases.

Bardosh and colleagues (2022) estimated that the bivalent booster mandates in the university setting will likely result in net harms for younger adults, with at least 18.5 serious adverse events from the modmRNA injections for every COVID-19 hospitalization hypothetically prevented. This estimate includes about 1.5 to 4.6 cases of booster-associated myopericarditis in males, typically resulting in hospitalization (Bardosh et al., (2022).

Biological plausibility for a causal relationship between the prodrug COVID-19 products and their adverse effects is now well-established. The following five findings are particularly relevant:

- The spike protein persists in circulation in young adults who developed myocarditis post COVID-19 modmRNA injection, but not in injected individuals who did not develop myocarditis (Yonker et al., 2023).
- The COVID-19 modmRNA was isolated in the human heart at autopsy out to 30 days post-injection (Krauson et al., 2023).
- Direct cardiotoxicity of the Pfizer and Moderna modmRNA on rat cardiomyocytes has been documented 48 hours after the injection, resulting in specific dysfunctions that correlate pathophysiologically to cardiomyopathy (Schreckenberg et al., 2024).
- Spike protein and active inflammation were observed upon biopsy in young individuals hospitalized with COVID-19 modmRNA-related myocarditis (Baumeier et al., 2022).
- A surge of adrenalin may be the major precipitating factor in triggering cardiac arrest in young persons in the setting of clinical or subclinical myocarditis (Cadegiani, 2022).

An additional cardiotoxic process may involve downregulation of angiotensin-converting enzyme 2 (ACE2) receptor expression following its binding to the spike protein. This can lead to unopposed ACE expression, increased angiotensin-2 levels, inflammation, and, ultimately, apoptosis in cardiac muscle cells (Bozkurt, 2023). Elevated angiotensin-2 causes inflammation and oxidative stress, which are major contributing factors in the progression of cardiomyopathy (Kim et al., 2017).

The general public has been repeatedly told by public health officials that cardiac risks are greater for SARS-CoV-2-infected individuals than for those injected with the modmRNA. This is a false assertion stemming from large, poorly designed surveillance studies (see **Discussion**). When we consider prospective studies with careful assessments of potential myocardial damage, the risk of ambulatory young individuals developing myocarditis is unacceptably high at about 2.5% (2500 per 100,000 recipients) for either BNT162b2 or mRNA-1273 following the second or third injections (Mansanguan et al., 2022; Buergin et al., 2023). As shown in **Figure 2,** the estimated 2.2% myocarditis risk in adolescent teens following the COVID-19 mRNA injection is approximately 37 times the risk associated with SARS-CoV-2 infection (0.06%) in that same age group (Mansanguan et al., 2022; Singer et al., 2022). Given these estimates, the ongoing recommendation to administer modmRNA injections to this age group seems unconscionable in the extreme.

Underscoring the gravity of the modified mRNA-myocarditis connection, Rose et al. (2024) recently reported that the incidence of myocarditis cases in VAERS following the COVID-19 rollouts in 2021 was 223 times higher than the combined average of all vaccines over the preceding three decades. This equated to a staggering 2500% surge in reported cases compared to pre-2021 levels. Analysis of demographic data revealed that myocarditis predominantly affected youths (50%) and

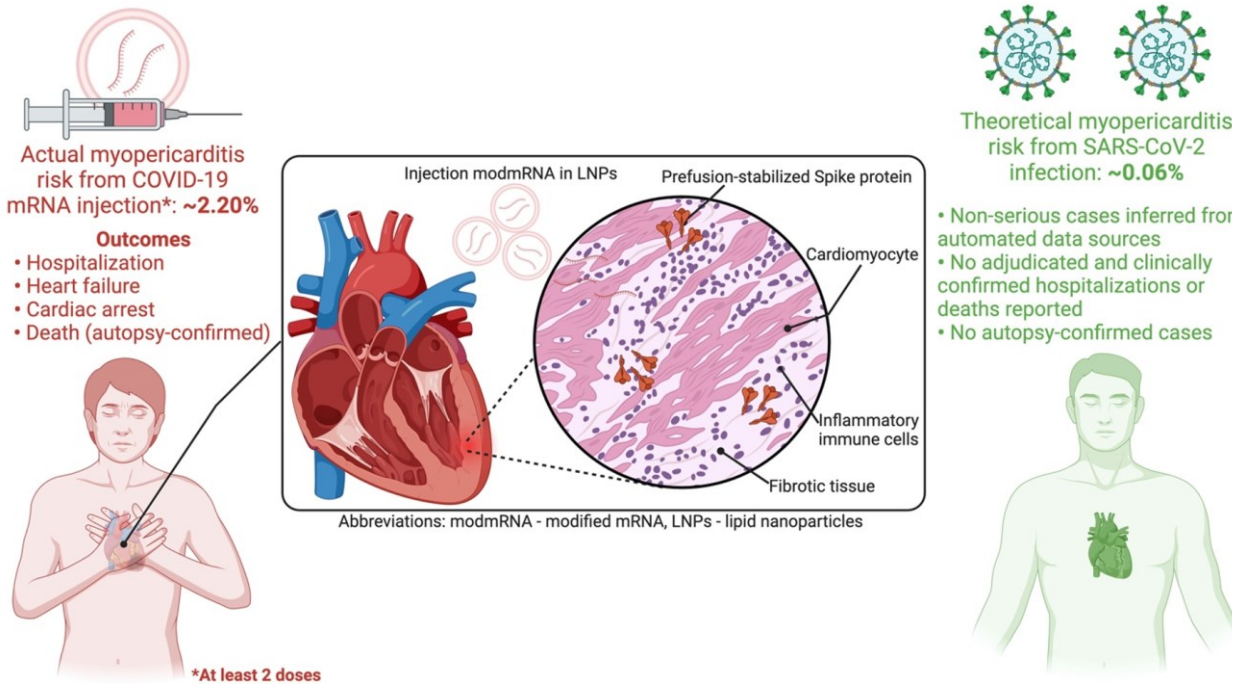


Figure 2. Actual risk of myocarditis in modmRNA-injected individuals (based on prospective studies, with clinical testing for asymptomatic myocarditis) greatly surpasses the theoretical risk of myocarditis in those infected by the wild-type SARS-CoV-2 (based primarily on passive surveillance reporting of symptomatic cases).

males (69%). Alarmingly, 76% of cases required emergency medical attention and hospitalization. Out of the total cases of myocarditis, 92 individuals succumbed (3%). The study identified a higher likelihood of myocarditis occurring after the second vaccine dose ($p < 0.00001$), with those under 30 years of age being significantly more susceptible compared to their older counterparts ($p < 0.00001$). These findings firmly establish a strong correlation between COVID-19 vaccination and a cardiac serious adverse event signal for myocarditis, particularly impacting young males and leading to hospitalization and fatalities (Rose et al., 2024). As noted above, multiple autopsy studies have confirmed that serious cardiac events are the primary cause of sudden deaths following the

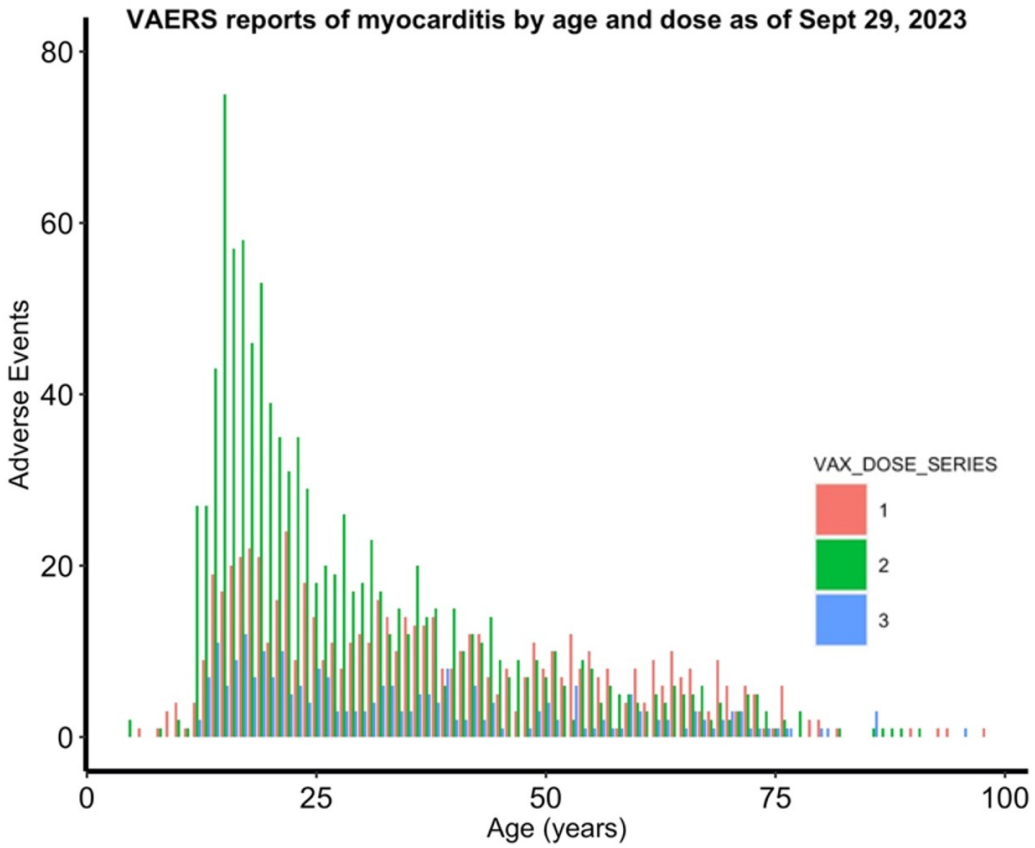


Figure 3. **Myocarditis reports in VAERS Domestic Data as of September 29, 2023, plotted by age and dose. Myocarditis reports are plotted according to age and dose — dose 1 (pink), dose 2 (green), and dose 3 (blue). After dose 2, there was a 5-fold increase in myocarditis cases among 15-year-old males. Source: VAERS: Vaccine Adverse Event Reporting System; COVID-19: coronavirus disease 2019. Image Credit: Jessica Rose.**

modmRNA inoculations, with most cases occurring within 14 days, though some have occurred months or even years after the injection (Hulscher et al., 2024a; Hulscher et al., 2024b).

Regardless of age, myocarditis cases were more frequent following dose 2, which is suggestive of a causal link between myocarditis and the COVID-19 mRNA inoculations. The data depicted in the chart are further reinforced by a recent disproportionality analysis of VAERS data showing a statistically significant association between cardiovascular events and COVID-19 vaccinations (Amir et al., 2023).

### *ADVERSE EVENTS #2: POTENTIAL IMPACT OF MODMRNA ON NEUROLOGICAL DISORDERS*

Early in the pandemic, experts reported that the spike protein derived from SARS-CoV-2 and produced by the current vaccines could cross the blood-brain barrier, potentially causing neuroinflammation and/or blood clots in the brain (Oldfield et al., 2021). The speculation was that if the expression of spike proteins induced by the modmRNA was not confined to the injection site and nearby lymph nodes, there could be a risk of the same types of neuroinflammatory effects and neurological complications as those observed in patients who had been infected with SARS-CoV-2 (Sodagar et al., 2021). It was further speculated that repeated injections with the gene-based prodrugs, by enabling ongoing spike protein production for many successive months, could have

even more severe consequences, most likely resulting from the phenomenon of molecular mimicry with subsequent neuronal damage (Garg & Paliwal, 2022).

Neurological conditions and complications associated with the modmRNA injections have often been described as "rare" and typically mild, as well as of short-duration and self-limiting. With ongoing worldwide distribution of the injectables, however, many more case reports have accumulated, and post-injection adverse events can no longer be considered "rare". These events include cases of encephalitis, other encephalopathies, meningitis, myelitis, autoimmune nervous system disorders, cerebrovascular events, facial palsy, and many other neuropathies (Tondo et al., 2022). In a systematic review of electroencephalographic findings following the modmRNA injections, the most commonly diagnosed adverse events were encephalitis, encephalopathy, and acute disseminated encephalomyelitis (Fazlollahi et al., 2023). Numerous case reports and case series analyses have indicated a causal relationship between the injectables and subsequent development of acute disseminated encephalomyelitis, with most cases developing after the first dose (Nabizadeh et al., 2023). Symptoms of this neuroinflammatory disorder included muscle weakness, urinary complaints, visual impairments, seizure, unconsciousness, and death.

In addition, some investigators have reported a higher than expected post-modmRNA injection incidence of facial paralysis (Bell's palsy or facial nerve palsy), ischemic stroke, intracerebral hemorrhage, and cerebral venous sinus thrombosis, along with more common effects like headaches, dizziness, myopathy, malaise, and olfactory and gustatory disturbances (Shimohata, 2022; Sriwastava et al., 2022; Finsterer, 2023; Mohseni Afshar et al., 2023; Chatterjee & Chakravarty, 2023; Elfil et al., 2023). The modmRNA injections have also been linked with increased rates of demyelinating disorders such as multiple sclerosis, transverse myelitis, new demyelinating brain lesions, and Guillain-Barré syndrome, whether or not specific antibodies are detected (Mohseni Afshar et al., 2023; Chatterjee & Chakravarty, 2023; Finsterer, 2023; Fazlollahi et al., 2023).

The following points are germane to the etiology of adverse neurological events associated with the COVID-19 modmRNA injections:

***ModmRNA-induced neuroinflammation and autoimmunity.*** Once the modmRNA passes through the blood-brain barrier and begins generating spike protein in large amounts, the resultant chronic neuroinflammation within the brain may engender a wide spectrum of psycho-neurological disorders. A host of acute inflammatory diseases and functional impairments of the central nervous system have been linked with the modmRNA injectables (Francis et al., 2024; Hamed et al. 2024). In a case-series study, for example, vertigo, ataxia, optic neuritis, myelitis, and recurrent attacks of loss of consciousness, were all reported within 14 days following the Pfizer modmRNA injections (Hamed et al. 2024). The polyneuropathy subtypes of Guillain-Barré Syndrome entail neuroinflammation can be triggered by the modmRNA injections (Abuawwad et al., 2024). Many serious neurodegenerative conditions, including Parkinson's disease, Alzheimer's disease, and dementia, have been associated with the presence of abnormal neuroinflammation, often secondary to immune dysregulation (González-Reyes et al., 2017; Tansey et al., 2022; Thakur et al., 2023; Ahmad et al., 2022). The modmRNA injectables' well-documented connection with psychosis (Lazareva et al., 2024) might also be related to neuroinflammation (Barron et al., 2017; Vallée, 2022). Moreover, autoimmune-inflammatory disorders within the nervous system may underlie many of the adverse neurological events that have been associated with these products. Amplifying those effects observed with SARS-CoV-2 infection, excessive modmRNA-induced generation of the spike protein might trigger an inflammatory reaction with high levels of pro-inflammatory cytokines leading to neurological autoimmune complications (Khayat-Khoei et al, 2022; Finsterer, 2023). Guillain-Barré syndrome, facial palsy, and other neuropathies appear to be linked with

immunopathologic mechanisms such as autoantibody production, bystander effects, or uncontrolled cytokine release (Eslait-Olaciregui et al., 2023).

***Latency and exacerbation of pre-existing neurological disorders.*** Many neurological diseases (e.g., Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis, and multiple sclerosis) have latency or incubation periods of a decade or perhaps much longer. Because most of the severe neurological complications linked with the modmRNA injections are reported in isolated case reports or small case series, establishing a clear causal relationship between these products and adverse neurological events that have a long latency poses a major challenge for epidemiologists (Sriwastava et al., 2022). The exacerbation of epilepsy and other pre-existing neurological disorders is also a significant concern (Garg & Paliwal, 2022). It seems likely that the modmRNA injections could be accelerating the progression of these diseases, given the known neurobiological effects (Francis et al., 2022; Hamed et al. (2024); Kostoff (2023a) proposes that the use of early warning biomarker indicators could be useful for assessing the potential risk of developing modmRNA-related events in the future.

***Long-term pathogenesis.*** Along similar lines, neurological diseases potentially initiated by the modmRNA injections may take years to develop and would be extremely difficult to identify as having been caused by the shots. Examples include Parkinson's disease, amyotrophic lateral sclerosis, multiple sclerosis, Alzheimer's disease, and frontotemporal dementia, a group of related conditions resulting from the progressive degeneration of the temporal and frontal lobes of the brain. Unfortunately, no well-designed long-term studies have been conducted to assess such outcomes. As noted in the preceding paragraph, short-term studies have only been able to suggest that these long-latency neurological conditions may be exacerbated by the modmRNA injections. It is likely that patients with an autoimmune predisposition are particularly vulnerable to the long-term development of neurodegenerative diseases in relation to these genetic products.

***Protein misfolding and amyloidogenic potential.*** Many neurodegenerative diseases are characterized as "prion-like" because they entail protein misfolding and are marked by the aggregation of fibrillar proteins (fibrillization), including amyloid-β, tau, α-synuclein, and polyglutamine proteins (Frost & Diamond, 2010). Examples of severe "prion-like" neuropathologies include Parkinson's disease, Alzheimer's disease, and frontotemporal dementia. There is evidence that modmRNA-induced spike protein synthesis may facilitate the accumulation of toxic prion-like fibrils in neurons, thereby promoting neurodegenerative disease (Seneff et al., 2023). Of great concern is the modmRNA's amyloidogenic potential, which may play a significant role in the broad spectrum of neurological symptoms (Nyström & Hammarström, 2022). This amyloidogenic potential may underlie the apparent association between the COVID-19 gene-based injections and development of Alzheimer's disease. In large population study ($n$ = 558,017) out of Seoul, South Korea, the "vaccinated" cohort showed a significantly higher incidence of Alzheimer's disease (OR: 1.225; 95% CI; 1.025-1.464; p=0.026) and mild cognitive impairment (OR: 2.377; CI: 1.845-3.064; $p < 0.001$) compared to the "unvaccinated" (Roh et al., 2024). The "vaccinated" cohort of this Seoul population included subjects who had received either the modmRNA injections or the DNA-based adenoviral vector injections.

Among the most commonly reported neurological "side effects" of these genetic injectables are headaches, dizziness, facial palsy (numbing or paralysis), intracerebral hemorrhage, sinus venous thrombosis, and Guillain-Barré syndrome, also known as acute demyelinating polyneuropathy (Finsterer, 2023; Chatterjee & Chakravarty, 2023). In a randomized cross-sectional study of healthcare workers receiving the Pfizer modmRNA injections, the most common adverse effects

included soreness, myalgia, and headache, followed by dizziness, muscle spasms and brain fog (Kadali et al., 2021). Prolonged headaches and dose-specific headache patterns have been reported in migraine patients ($n$ = 732) following the modmRNA injections, with the frequency of headaches increasing with multiple boosters (Kuan et al., 2023). A recent prospective cohort study ($n$ = 843; 411 non-injected vs. 432 injected cases) found that the modmRNA injections were associated with a significant three-fold increased risk of functional neurological disorders along with a doubling in the risk of headaches requiring hospitalization in an acute neurological setting (Pilotto et al., 2024).

Kostoff (2023a) counted 920 adverse neurological events that had been recorded in VAERS, with a total of 1.2 million neurological events. Given that this number may represent only about 1% of the true incidence reported to VAERS (Lazarus et al., 2021), the actual number of neurological events may be orders of magnitude higher, after taking into account the underreporting factor. Highly prevalent conditions such as dizziness would likely be the most under-reported, despite being quite common adverse side effects of the modmRNA injections based on reliable analyses (Kadali et al., 2021). It should be noted that filing a VAERS report is a time-consuming process that requires adherence to strict guidelines, with false reports being a violation of Federal law under 18 U.S. Code § 1001, punishable by fine and imprisonment. Most reports are filed by medical professionals. It is therefore reasonable to assume that the 920 different neurological events reported to VAERS were reliably reported and either accelerated by or caused — in part if not entirely — by the modmRNA injectables.

Table 1 shows the number of symptoms reported in VAERS, restricted to the US population, for the year 2021, for various disorders linked to neurodegenerative disease, showing total counts for COVID-19 modmRNA injections and for all classical vaccines. In summary, a diverse spectrum of adverse neurological events may develop following the administration of any type of COVID-19 gene-based injectable product. These conditions can range from mild to moderate afflictions (e.g., dizziness, depression and anxiety), to serious disabilities (e.g., chronic migraines, epilepsy, multiple sclerosis, amyotrophic lateral sclerosis, psychoses, and postural orthostatic tachycardia syndrome), and finally to potentially fatal diseases (e.g., Alzheimer's disease) and events such as intracerebral hemorrhage, arterial ischemic stroke, and cerebral venous sinus thrombosis. Most challenging from an epidemiological standpoint is the assessment of modmRNA-related risks for neurodegenerative diseases that have a long latency. During the genesis of such diseases, the central and peripheral nervous systems gradually accumulate damage without overt or readily noticeable effects. By the time symptoms emerge, significant and often irreversible neural damage has already occurred, and determinations of temporal causality are readily obscured, thus often becoming hotly (and perpetually) debated. Nevertheless, delineation of the processes involved in neurodegenerative diseases with a long latency, such as the modmRNA-induced upregulation of neuroinflammatory pathways, allows for early identification of biologically plausible risks. By adopting the precautionary principle and abstaining from the modmRNA injections, the likelihood of triggering such neuropathological processes is reduced, ultimately helping to lower the incidence and severity of these devastating neurological disorders.

**Table 1**
**VAERS Reports of Neurological Disorders Linked with COVID-19 ModmRNA Injections ("COVID Shots") Compared to All Classical Vaccines**[1]

| Symptom | COVID Shots | All Vaccines | % COVID Shots |
|---|---|---|---|
| Alzheimer's dementia | 37 | 39 | 94.9 |
| Parkinsonian symptoms | 83 | 89 | 93.3 |
| Memory impairment | 1,681 | 1,720 | 97.7 |
| Anosmia | 3,657 | 3,677 | 99.5 |
| Mobility decreased | 8,975 | 9,743 | 92.1 |
| Cognitive disorder | 779 | 815 | 92.1 |
| **TOTAL** | **15,212** | **16,083** | **94.6** |

### *ADVERSE EVENTS #3: POTENTIAL IMPACT OF MODMRNA ON HEMATOLOGIC DISORDERS*

Blood clotting problems and COVID-19 have been inextricably linked since 2020. It has been speculated that the body's immune-inflammatory response to SARS-CoV-2 alters blood coagulation parameters and causes thromboinflammation (Thomas et al. 2022). Activation of coagulation pathways during the COVID-19 infection may facilitate SARS-CoV-2 entry into cells (Kastenhuber et al., 2022). After the rollouts, there were reports of increased blood coagulation and blood clotting disorders among recipients of the COVID-19 gene-based injections, though such effects were more commonly associated with the adenovirus vector products from Oxford/AstraZeneca and Johnson & Johnson (Ostrowski et al., 2021). (These adenoviral vector products use recombinant, non-replicative adenoviruses that serve as carriers for the DNA strand that codes for the spike protein.) In head-to-head comparisons with the modmRNA products, the adenovirus vector products were found to trigger a more consistently substantial rise in several inflammatory and platelet activation markers, along with higher post-injection thrombin generation (Ostrowski et al., 2021).

Nevertheless, increased blood coagulation and other blood disorders are also adverse effects of modmRNA injections (Abbattista et al., 2021; Brambilla et al. 2023). Complex interactions between the coronavirus infection, vascular endothelial injury, and multiple immune-inflammatory and coagulation pathways can promote both microvascular and macrovascular thrombosis (Levy et al., 2021). To date, most published reports of serious clotting problems associated with the gene-based injectables have focused on thromboembolic events (Afshar et al., 2022; Iba & Levy, 2022; Dag Berild et al., 2022; Cines et al., 2023; Abrams & Barnes, 2023; Sekulovski et al., 2023; Schönborn et al., 2023; Rogers et al., 2024). In some instances, however, the coagulopathy-related effects of the modmRNA injections were either weakly significant, mixed or inconsistent (Burn et al., 2022; Dag Berild et al., 2022; Shoaibi et al., 2023). Burn et al. (2022) detected a small increase in pulmonary

[1] Table adapted from Seneff S, Nigh G, Kyriakopoulos AM, McCullough PA. (2022). Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs. *Food Chem Toxicol.* 164:113008. https://doi:10.1016/j.fct.2022.113008

embolism risk following the modmRNA injection, and yet the risk was substantially higher following SARS-CoV-2 infection. However, the study was not stratified by age. In a well-powered study of elderly persons (>age 65; $n$ = 30,712,101), Wong et al. (2023), found a 54% increased risk of pulmonary embolism following the Pfizer (BNT162b2) injections, evidence of a robust signal.

It is important to note that most of post-injection thromboembolic cases reported to date have involved no known prior susceptibility to thrombotic or bleeding events, i.e., previously healthy individuals who developed severe thrombosis (often cerebral and/or splanchnic vasculature) and thrombocytopenia after the gene-based injections. In a cohort of 123 healthy younger individuals (18-30 years of age) embedded within a randomized clinical trial, there was a marked yet transient prothrombotic state associated with the inflammatory response following the Moderna (mRNA-1273) injection (van Dijk et al., 2024). In a study by Li et al., (2023), recipients of the Pfizer and Moderna modmRNA injectables showed a doubling in risk of all forms of retinal vascular occlusion in two years after the injections, with an overall hazard ratio of 2.19 (95% CI; 2.00-2.39). In a comparison study of VAERS data, there were 5,137 reported events of cerebral thromboembolism linked with the COVID-19 products, compared to only 52 such adverse events ascribed to the influenza vaccines delivered over 408 months (34 years), and 282 such adverse events for all other vaccines (excluding the COVID-19 injectables) during that same 34-year period (Rogers et al., 2024). The proportional reporting ratios, or PRRs, were significant when comparing adverse events by time from the COVID-19 injectables to that of the influenza vaccines ($p < 0.0001$) or all other vaccines ($p < 0.0001$).

Repeated modmRNA injections may increase the likelihood of more serious hematologic events such as acute de novo immune thrombocytopenic purpura in previously healthy individuals (Lee et al., 2022; Kobayashi et al., 2023). Younger women (<age 50) have consistently been at greater risk of the more severe events, such as thrombosis with thrombocytopenia syndrome (See et al., 2021). New onset and relapsing immune thrombocytopenia are among the most common autoinflammatory conditions that have been linked with the COVID-19 modmRNA injections (Rodriguez et al., 2022). The once rare adverse event known as *vaccine-induced thrombotic thrombocytopenia* has been associated with production of antiplatelet factor 4-polyanion autoantibodies, along with activation of endothelial and inflammatory cells, and an abundance of circulating soluble spike protein following the injections (McGonagle et al., 2021; Tsilingiris et al., 2021; Greinacher et al., 2022).

Elevations in D-dimer, a biomarker for blood clot formation and breakdown, can be used to indicate that excessive clotting is occurring, primarily in the form of microscopic clots (micro-clots). D-dimer is an independent prognostic risk factor for non-severe Omicron patients progressing to severe illness (Wang et al., 2023a). In earlier research, individuals who died following a diagnosis of COVID-19 had higher levels of D-dimer (Rao et al., 2022). However, Garabet et al. (2023) observed no changes in either D-dimer or thrombin levels on average 11 days after the gene-based injections, which might be too long after the inoculation to detect small or transient changes. Other researchers have reported statistically significant post-injection increases in D-dimer and fibrinogen levels, regardless of dosing and gene-based product type (Brambilla et al., 2023).

In 2021, numerous anecdotal reports described abnormally large, irregular-shaped clots that had been removed from both living and deceased persons previously injected with the COVID-19 gene-based products (Crowder & O'Looney, 2022; O'Looney et al., 2022; Horwood, 2023). Reports of exceedingly long "white clots" were issued by competent and independent observers (Crowder & O'Looney, 2022; Horwood, 2023). Detailed accounts from experienced embalmers confirmed that the abnormal clots were exclusively seen in the corpses of previously injected individuals (O'Looney

et al., 2022; Harris, 2024). Additionally, independent research scientists have begun to link the abnormal clotting directly to the COVID-19 injectables, usually in recipients of two or more doses (Santiago & Oller, 2023).

In terms of the underlying biology, there is evidence that the SARS-CoV-2 spike protein may trigger the coagulation cascade by binding directly to angiotensin-converting enzyme 2 (ACE2) on platelets and endothelial cells, and that circulating spike protein alone may cause a hypercoagulable state by directly interacting with fibrin and fibrinogen (Grobbelaar et al., 2021). Spike protein generated by either the infection or the modmRNA injections could trigger platelet and endothelial activation, thereby promoting clot formation and thrombotic events (De Michele et al., 2022). As noted above, the spike protein of SARS-CoV-2 interacts with the enzymatic domain of ACE2, which typically cleaves angiotensin II into angiotensin I-VII. It seems reasonable to surmise that the modmRNA products, having been designed around the SARS-CoV-2 envelope protein, are capable of inducing virus-like effects (mimicry) via binding to ACE2 with the potential to cause severe thrombotic events (Devaux & Camoin-Jau, 2023).

The synthetic modmRNA's ability to persist and engage in extended production of spike proteins could, in principle, result in chronic systemic inflammation and immune dysfunction, potentially causing a variety of diseases, some with long latency (Seneff et al., 2022; Qin et al., 2022; Klingel et al., 2023; Giannotta et al., 2023). However, if the billions of supposedly perfect coding sequences delivered to recipient cells via the modmRNA injectables are flawed from the start, enabling what is known as "frameshifting" as shown by Mulroney and colleagues (2023), the accumulation of proliferating imperfect proteinaceous material could theoretically result in the dangerously harmful clots that other researchers are documenting (Nyström & Hammarström, 2022; Santiago & Oller, 2023).

Angeli et al. (2022) have hypothesized that adverse reactions to the modmRNA injections, which they attribute to angiotensin II accumulation and refer to as the "Spike Effect", are likely to be more common in younger, healthy individuals. The authors further postulate that alcohol consumption, which is known to increase ACE2 expression, may amplify this "Spike effect" risk (Angeli et al., 2022). Such effects could help explain some of the serious adverse cardiovascular events that have been observed in this otherwise low-risk population (with a near-zero infection fatality rate) following the modmRNA injections, as documented in the preceding section. Such pathophysiological phenomena warrant our attention, particularly when they occur in young healthy individuals. Devaux & Camoin-Jau (2023) note that such events are more likely with inappropriate use of modmRNA products, such as during an active immune response either during or preceding a mild infection. Such an overlap between the infection and injection could lead to chronic angiotensin II-induced inflammation, with subsequent tissue damage and overactivation of coagulation pathways (Devaux & Camoin-Jau, 2023).

Adverse hematologic reactions to the COVID-19 modmRNA products might be somewhat underestimated because a significant number of elderly people are already receiving cardiovascular medications for pre-existing conditions, thus potentially diminishing the appearance of vascular and coagulation dysfunctions caused by the injectables. Concerns regarding the spike-induced alterations of coagulation parameters have led some medical scientists to urge caution when administering the modmRNA products to patients with pre-existing cardiovascular and/or coagulation disorders, and to recommend closer surveillance of modmRNA-injected patients with a history of cardiovascular diseases (Devaux & Camoin-Jau, 2023). Individuals at risk of stroke should be similarly forewarned, based on the new VAERS analysis by Rogers et al. (2024). At this time, no controlled clinical studies

have examined whether the modmRNA injections may cause more serious coagulation and thrombotic disorders than those associated with infection by the Omicron subvariants.

### *ADVERSE EVENTS #4: POTENTIAL IMPACT OF MODMRNA ON AUTOIMMUNE DISEASE AND OTHER IMMUNOLOGIC DISORDERS*

Immunological effects of the COVID-19 modmRNA injections were broadly addressed in Part 1 of this review when we explained why and how the injections failed against COVID-19 (Mead et al., 2024a). Here we dive more deeply into the adverse immunologic aspects of the injections, notably modmRNA-induced autoimmunity and immune suppression. We also lay out various mechanism-based scenarios that may help clarify the complex biological plausibility of these immunological connections. Because systemic autoimmune diseases were excluded from the Pfizer and Moderna registrational trials, the potential autoimmune outcomes associated with COVID-19 modmRNA injections remain to be more fully elucidated. Several key clinical research questions warrant consideration. Can these COVID-19 gene-based injectables trigger systemic autoimmune disease or cause a disease flare-up? What potential adverse reactions might these modmRNA products cause in patients with preexisting systemic autoimmune diseases? Are individuals with systemic autoimmune disease who receive these injections at a greater risk of developing thromboinflammation, along with a heightened potential for venous and arterial immunothrombosis? Additionally, what is the most appropriate clinical setting to administer the COVID-19 modmRNA injections to a patient with systemic autoimmune disease, and is it necessary to stop immunosuppressive treatment prior to the injection?

In 2021, clinical reports began to emerge concerning individuals who received the COVID-19 modmRNA injections and then presented with de-novo or flares of existing autoimmune conditions (Ishay et al., 2021). The concept that viral infections can worsen inflammatory or autoimmune conditions is well-established and has been observed in various contexts. Since the modmRNA injections are believed to achieve their immunologic effects in part by triggering an inflammatory immune response, this could logically trigger the onset or worsening of hyperinflammatory changes in susceptible individuals. Additionally, some of the autoimmune-inflammatory impact may be linked to the modmRNA products' inherent adjuvanticity (i.e., the products' ability to stimulate the immune response without the need for added adjuvants) though nonspecific immune responses or molecular mimicry events may play an even larger role (Talotta, 2021; Rodríguez et al., 2022; Rojas et al., 2023).

It seems abundantly clear that the modmRNA injections may unmask autoimmune diseases (many of which have a long latency) in predisposed patients. Individual comorbidities, concurrent infections, and genetic factors can further exacerbate many of the immunopathological processes linked with the modmRNA injections. Repeated ongoing boosters are likely to perpetuate the various forms of immune dysfunction, which is why studies that only focus on the effects of a single dose often give way to misleading conclusions. As we will show, some aspects of modmRNA-induced immune dysfunction (e.g., antibody class-switching) can engender both autoimmunity and reduced protection against infectious disease. Multiple immunologic processes are often working in tandem. For example, the modmRNA injections may cause innate immune suppression by significantly impairing type I interferon signaling while also disrupting the regulatory control of protein synthesis and cancer surveillance (Seneff et al., 2022).

The strong autoimmune-inflammatory responses triggered by these injections can lead to serious adverse events such as myocarditis, pericarditis, acute coronary syndrome, and even death (Fraiman et al., 2022; Polykretis et al., 2023). Such responses have the potential to foment a vast array of

autoimmune inflammatory pathologies, including cardiovascular diseases, malignancies, and many other diseases with a chronic inflammatory etiology (Akinosoglou et al., 2021; Polykretis et al., 2023). Indeed, autoinflammatory dysregulation can contribute to tissue damage *in any organ in which spike protein tends to accumulate,* the liver being a prime example (Bril et al., 2021; Chow et al., 2022; Sergi, 2023; Zaiem et al., 2023). In a study of hepatobiliary and gastrointestinal adverse reactions to 16 different vaccines across 156 countries from 1967 to 2023, the majority of reports were attributed to COVID-19 modmRNA injections, with a significant association seen for ischemic hepatitis (Lee et al., 2024). Note: ischemic hepatitis and autoimmune hepatitis can overlap in terms of clinical presentation, with both causing elevated liver enzymes along with jaundice, fatigue, and abdominal pain. Autoimmune hepatitis and other autoimmune disorders can remain asymptomatic for a very long time (Domerecka et al., 2021), so the true impact of these modmRNA injections on such diseases may not be recognized for years.

Other autoimmune adverse events attributed to the COVID-19 modmRNA injections include myocarditis and neurological conditions like Bell's palsy, Guillain-Barre syndrome, and transverse myelitis (Kim et al., 2024b; Shumnalieva et al., 2024). New-onset IgA nephropathy, rheumatoid arthritis and systemic lupus erythematosus are increasingly counted among these modmRNA-induced new-onset autoimmune phenomena (Chen et al., 2022). The newly recognized condition, *vaccine-induced immune thrombotic thrombocytopenia,* is the latest immunologic addition to the category of vaccination-related "adverse events following immunization" or AEFIs. This disorder is thought to arise from autoantibodies targeting platelet factor 4, triggered by the gene-based injectables and a proinflammatory milieu (Greinacher & Warkentin, 2023).

Systemic autoimmune conditions have also come under scrutiny in relation to these gene-based products. In a cross-sectional study ( $n$ = 16,750) of self-reported new-onset systemic autoimmune diseases using the COVID-19 Vaccination in Autoimmune Diseases study dataset (a validated, patient-reported e-survey-to analyze the long-term safety of the COVID-19 modmRNA products), the main new-onset conditions reported were rheumatoid arthritis, polymyalgia rheumatica, and idiopathic inflammatory myopathies (Shumnalieva et al., 2024). The risk of these systemic autoimmune diseases was approximately three times higher among Moderna modmRNA recipients compared to their Pfizer counterparts (OR: 2.7; 95% CI, 1.3-5.3; $p$ = .004).

In addition, relapses of multiple sclerosis have been linked with the injections (Nabizadeh et al., 2022). Numerous reports of new-onset modmRNA-induced rheumatoid arthritis have been published, with the disease symptoms often arising soon after the injection (Iwamura et al., 2024; Matsuda et al., 2024). Patients with lupus erythematosus are more prone to developing severe adverse events following the modmRNA injections (Dey et al., 2023). Various autoimmune hematologic complications may be either caused or exacerbated by the injections, including secondary immune thrombocytopenia, immune thrombotic thrombocytopenic purpura, autoimmune hemolytic anemia, Evans syndrome, and vaccine-induced immune thrombotic thrombocytopenia (Mingot-Castellano et al., 2022). The last condition listed is a newly described disorder with potential lethal consequences.

One component of the modmRNA injections that is often overlooked in discussions of adverse effects it the lipid nanoparticle delivery system. More than three decades ago, researchers were aware of the unusual potential for synthetic cationic lipid nanoparticles to form amphiphilic aggregates, disrupt the cell membrane, induce an inflammatory response, and suppress immune function (Ashman et al., 1986). Indeed, there is growing interest in an emerging new theory for immune function that can explain immune activation in the absence of overt infection. Seminal research by Matzinger and her immunogenetics research team at the US National Institute of Allergy and

Infectious Diseases has pioneered the concept that immune responses are primarily driven by the need to defend against what is dangerous instead of what is foreign (Matzinger, 1994).

The modmRNA injections offer unique mechanisms of immune activation that are quite distinct from the response to a viral infection. These mechanisms help explain the adverse vent profile of these gene-based products. The spike protein itself is arguably the most toxic protein produced by the virus (Parry et al, 2023). The distribution of mRNA-LNP across a diverse array of tissues facilitates the expression of Spike proteins on cell surfaces across multiple cell types (Hou et al., 2021). This, in turn, renders the target tissues susceptible to T-cell-mediated attack and subsequent destruction (Talotta, 2021; Rodríguez et al., 2022; Rojas et al., 2023). Notably vulnerable are tissues such as cardiac muscle and neuronal tissues (Seneff et al., 2023; Schreckenberg et al., 2024), both characterized by limited repair and regenerative capacity. Furthermore, vascular tissues show widespread targeting and assault throughout the body (Parry et al, 2023).

The fundamental immunologic mechanisms of molecular mimicry, antigen cross-reactivity, pathogenic priming, viral reactivation, immune exhaustion, and other factors related to immune dysfunction all reinforce the biological plausibility for vaccine-induced pathogenesis of malignant and autoimmune diseases (Lyons-Weiler, 2020; Kanduc, 2021; Seneff et al., 2022; Syenina et al., 2022; Devaux & Camoin-Jau, 2023). These may be further summarized as follows:

***Molecular mimicry and cross-reactivity with the spike protein.*** Concerns have arisen about the possibility of molecular mimicry triggering autoimmune-related adverse events following the modmRNA injections. Molecular mimicry occurs when a foreign antigen, such as the modmRNA-generated spike protein, bears structural similarities to host tissues, potentially resulting in autoimmunity in which antibodies against spike glycoproteins cross-react with structurally similar host peptide sequences (Vojdani & Kharrazian, 2020). Multiple immunogenic epitopes in the spike protein have shown genetic homology to human proteins, thus reinforcing the concern that encoding entire SARS-CoV-2 spike antigens in these genetic "vaccines" was ill-advised (Kanduc & Schoenfeld, 2020). It has been postulated that post-injection pathophysiological phenomena are more likely to occur with inappropriate use of modmRNA products, e.g., at the time when the immune response is activated by a low-noise, subclinical infection (Devaux & Camoin-Jau, 2023). This could result in molecular mimicry of the spike protein transiently dysregulating angiotensin converting enzyme 2 (ACE2) function, thus causing angiotensin II-induced inflammation and tissue damage (Devaux & Camoin-Jau, 2023).

***T-cell exhaustion and IgG4 class switching.*** Generic immune suppression emerging after repeated booster injections poses another major concern. T-cell exhaustion refers to an immunologic condition in which CD8+ T cells show a progressive loss of cytokine production and cytotoxic potential (McKinney et al., 2015). Such dysfunction is known to occur in conditions such as chronic infections, cancer, and autoimmune diseases (Collier et al., 2021; Liu et al., 2021). A reduced T-cell response against SARS-CoV-2 was observed one month after receiving the third and fourth doses (Chevaisrakul et al., 2023). Such T-cell exhaustion in the wake of multiple COVID-19 mRNA inoculations could help explain the findings from studies showing increased rates of COVID-19 with increased frequency of boosters (Shrestha et al., 2023; Shrestha et al., 2023b; Shrestha et al., 2024). Other researchers observed a diminished T-cell response against the Spike protein that was associated with a class switch to IgG4, again after three and four doses of the COVID-19 modmRNA vaccine (Irrgang et al., 2023; Espino et al., 2024). Other research has shown that the switch towards spike-specific IgG4 appears almost exclusively in individuals who received only modmRNA injections or who were infected *after* receiving the modmRNA inoculations (Kiszel et al., 2023). This phenomenon aligns with the theory posed by Geert vanden Bossche (2023) and

helps explain why COVID-19 waves and mortality spikes in heavily "vaccinated" countries consistently follow the modmRNA rollouts (Cao et al., 2023). Not only does IgG4 not protect from infection, but it actively blocks other IgGs to suppress their action, leading to immunosuppression and *increased* infection rates (Uversky et al., 2023), again consistent with the Cleveland Clinic study findings (Shrestha et al., 2023; Shrestha et al., 2023b; Shrestha et al., 2024). The combination of T-cell exhaustion and IgG4 class switching could result in higher rates of cancers and autoimmune diseases. Because both immunologic effects (T-cell exhaustion and IgG4 class switch) have been associated with immunotolerance and numerous health-negating effects, the policy of administering successive booster injections could account for the tragic increases in both malignant and autoimmune diseases in heavily "vaccinated" countries.

***Pathogenic priming.*** Pathogenic priming, also known as *antibody-dependent enhancement*, occurs when the immune response to a pathogen or antigenic source intensifies and becomes excessive upon subsequent exposure to the same or a related pathogen (Lyons-Weiler, 2020). Concerns have been raised about this same phenomenon occurring in the context of the modmRNA injectables, which may cause the immune system to overreact to the modmRNA-induced overproduction of spike protein upon subsequent exposure to SARS-CoV-2 or Omicron variants (Lyons-Weiler, 2020). Such an overreaction could result in excessive production of non-neutralizing antibodies as well as severe autoimmune-inflammatory disease and death, as detailed by vaccinologist Geert vanden Bossche (Bossche, 2023). In two early animal studies of SARS, researchers observed a priming of the immune system with SARS spike protein-based vaccines. The first study found that recombinant SARS spike protein-based vaccines not only failed to protect mice from SARS-CoV infection but also caused increased immunopathology, including eosinophilic infiltrates in their lungs (Chatterjee et al., 2023). A second study observed that ferrets vaccinated against SARS-CoV developed hepatitis, a strong inflammatory response in the liver tissue (Cao et al., 2021). Thus the initial priming led to increased morbidity and mortality in the laboratory animals upon post-vaccination exposure to the SARS virus.

***Epitope spreading and bystander activation.*** Epitope spreading and bystander activation are among the main autoimmune mechanisms that, along with molecular mimicry, may be triggered by the modmRNA injectables. Epitope spreading occurs when the focus of an immune response, though initially targeted against a specific antigen, spreads to target additional endogenous epitopes secondary to the release of self-antigens (Vanderlugt & Miller, 1996). Bystander activation refers to non-specific activation of lymphocytes, with auto-reactive B and T cells undergoing activation in an antigen-independent manner (Pacheco et al., 2019). It has been hypothesized that the modmRNA injections may trigger pre-existing, dysregulated immunologic pathways, perhaps manifesting as a polyclonal B-cell expansion and resulting in immune complex formation and vasculitis phenomena (Akinosoglou et al., 2021). Notably, in modmRNA-injected individuals with genetic susceptibility, this dysregulation may be exacerbated by epitope spreading and bystander activation, potentially leading to chronic autoimmunity following post-injection SARS-CoV-2 or Omicron infection (Caso et al., 2020).

***Viral reactivation.*** Reactivation and new onset of viral infections following the modmRNA injections has been documented in at least 80 peer-reviewed articles to date (Shafiee et al., 2023). These viral infections include onset and reactivation of herpes simplex virus as well as reactivation of Epstein-Barr virus (EBV), cytomegalovirus, and varicella zoster virus (Shafiee et al., 2023; Martora et al., 2024; Herzum et al., 2022; Navarro-Bielsa et al., 2023). Potential pathogenetic mechanisms for these viral phenomena may entail altered immune function following the modmRNA inoculations. Because the human herpesviruses may underlie some of the clinical

manifestations initially attributed to SARS-CoV-2, the modmRNA-triggered reactivation could be misdiagnosed as a "COVID case" (Navarro-Bielsa et al., 2023). EBV reactivation is particularly concerning since latent EBV infections are a risk factor for lymphomas (Asano et al., 2013), which have been strongly linked with administration of the modmRNA products (Goldman et al., 2021; Sekizawa et al., 2022; Zamfir et al., 2022; Hobayan & Chung, 2023; Tachita et al., 2023). It should also be noted that reactivation of human CMV, a common yet "silent" herpesvirus (infecting between 40% and 95% of the global population), could also play a role in oncogenesis (Herbein 2022a; Herbein 2022b).

***Thymus and immunosenescence.*** In a recent preprint paper, it was hypothesized that circulating dendritic cells and mTreg cells would migrate back to the thymus following activation by the COVID-19 modmRNA injection, carrying a payload of spike protein and spike protein mRNA. The spike protein synthesized in the thymus by these returning immune cells would then bind to ACE2 receptors on thymic epithelial cells, inducing apoptosis. The loss of these cells leads to thymic involution, a hallmark of immune system aging. Hence, these well-established responses to stressors by immune cells would be predicted to cause accelerated aging, ostensibly due to the toxic effects of the spike protein (Kyriakopoulos et al., 2024).

### *ADVERSE EVENTS #5: POTENTIAL IMPACT OF MODMRNA ON PREGNANCY AND REPRODUCTIVE DISORDERS*

The rapid development and deployment of the COVID-19 modmRNA injectables under the Trump administration's Operation Warp Speed meant that no long-term safety studies had been completed by the time these products became available to the public. Furthermore, the COVID-19 modmRNA products were promptly authorized for use in pregnant women, an unprecedented and abhorrent move in medical regulation. By contrast, for example, the influenza vaccine underwent nearly 60 years of continuous development and testing before it was approved for use during pregnancy in 1997 (Thorp et al., 2022). The rushed authorization process for these modmRNA products, the virtually non-existent safety studies, and subsequent clinical observations of adverse events all raise questions about the safety of these injections during pregnancy. The argument for administering the modmRNA injections during pregnancy has been that "maternal infection with SARS-CoV-2 can increase risk of miscarriage, preterm birth and stillbirth, which is likely due to damage to the placenta" (Sun, 2021).

In 2021, however, among 221 pregnancy-related adverse events reported to the Vaccine Adverse Event Reporting System, the most frequently reported event was spontaneous abortion (Shimabukuro et al., 2021). Some authors conjecture a high risk (82%) of spontaneous abortion for women exposed to the first dose of the COVID-19 gene-based injectables during the first trimester and who have completed their pregnancy (Stroobandt & Stroovandt, 2021). However, Stuckelberger et al. (2021) have questioned the interpretation of these same data on the basis of selection bias. In general, there has been a tendency to dismiss the widespread claims concerning fertility, spontaneous abortions, and stillbirths following injection of the COVID-19 gene-based products during pregnancy (Markert et al., 2021; Fell et al., 2022; Kauffman, 2024). Most published reports defer to the U.S. Food and Drug Administration's official position that these gene-based injectables are safe for use in pregnant women (even without the requisite clinical trials) and moreover should be encouraged because they purportedly reduce the serious pregnancy-related complications due to SARS-CoV-2 infection (Kumar et al., 2023). However, a comprehensive meta-analysis (177 studies involving 638,791 participants from 41 countries) concluded that evidence in support of the claim that the modmRNA injections may reduce severe cases or hospitalizations in pregnant women with

COVID-19 is considered to be of poor quality, specifically based on "low to very low-certainty evidence" (Ciapponi et al., 2024).

Menstrual health is a general indicator of health and fertility, and yet menstrual outcomes (e.g., cycle length, days of flow, volume/intensity of flow, regularity or associated symptoms) have been omitted from the COVID-19 "vaccine" trials. Despite women comprising approximately half of the participants in the founding trials, no data were collected on menstrual cycle effects. Nevertheless, there have been numerous reports of menstrual disturbances following the COVID-19 modmRNA injections, potentially impacting preventable morbidity and mortality. Of considerable concern, given the well-established underreporting factor in passive surveillance systems, were the 554 postmenopausal bleeding reports filed in the Vaccine Adverse Event Reporting System between December 13, 2020, and December 13, 2021 (Strid et al., 2024). A relatively high prevalence of menstrual cycle irregularities was recorded among Saudi women who had received the gene-based injections (AlRawi et al., 2024).

A recent *BMJ* review concluded that the COVID-19 gene-based injections disrupted menstrual cycles in women, causing changes in cycle length, flow, and menstrual pain (Payne et al., 2024). This comprehensive review included 53 studies published before October 31, 2023: 11 prospective cohort studies, 11 retrospective cohort studies, and 31 cross-sectional or retrospective case-control studies. The authors assessed these studies for bias and summarized the findings, confirming that the COVID-19 modmRNA injections are associated with changes in cycle length in adult women, though data on adolescent girls was less conclusive. Most studies indicated an association between the modmRNA injections and longer menstrual cycles, with cycle length being a well-tracked and easily defined outcome.

Thorp and colleagues (2022) conducted a population-based retrospective cohort study to assess the rates of adverse events following COVID-19 modmRNA injections in women of reproductive age, with a specific focus on pregnancy and menstruation-related outcomes. This study utilized data from the Vaccine Adverse Event Reporting System maintained by the CDC. The data analyzed spanned from January 1, 1998, to June 30, 2022. The authors conducted a proportional reporting ratio (PRR) analysis in order to compare the adverse events reported after the modmRNA injections to those reported after influenza vaccination. The primary findings indicated that COVID-19 modmRNA injectables were associated with a significant increase in adverse events compared to influenza vaccines, with all PRRs exceeding 2.0. The specific adverse events with elevated PRRs included menstrual abnormalities, miscarriage, fetal chromosomal abnormalities, fetal malformations, fetal cystic hygroma, fetal cardiac disorders, fetal arrhythmia, fetal cardiac arrest, fetal vascular mal-perfusion, fetal growth abnormalities, abnormal fetal surveillance, fetal placental thrombosis, low amniotic fluid, and fetal death/stillbirth. All associated p-values were well below 0.05, indicating high statistical significance even after adjusting for multiple testing. When adjusted for factors such as time-available, doses-administered, or persons-receiving the vaccines, the incidence of adverse events following COVID-19 modmRNA injections consistently surpassed established safety thresholds across all recognized metrics (Thorp et al., 2022).

The modmRNA-LNP is known to diffuse throughout the body, potentially accumulating in the ovaries and testes, thereby potentially reaching the stem cells within reproductive organs. Referring to the Zhang et al. (2021) study indicating that reverse transcription in human cells is feasible, Domazet-Lošo (2022) offers the following well-substantiated statement:

> While, to our knowledge, similar studies have not been performed with COVID-19 [modified] mRNA vaccines that code for full-length pre-fusion fixed form of SARS-CoV-2 spike protein, comparable transport of spike protein/mRNA to the nucleus could be expected. Because the [modified] mRNA can enter the nucleus, where

> it might be reverse-transcribed into DNA, this increases its potential to integrate into the genome. Furthermore, the [modified] mRNA-LNP diffuses throughout the body and can accumulate in both the testes and ovaries and is reported to alter the menstrual cycle in women. Therefore, it could potentially be reaching the stem cells of the reproductive organs. These findings highlight the need to take these data and concerns seriously and conduct specific experiments to address them.

If indeed the integration occurs in stem cells, it can propagate the genetic alterations to a large number of descendant cells. During cell division, the nuclear membrane of a cell disassembles to facilitate the duplication and distribution of DNA to daughter cells. When it reassembles, any exogenous DNA present in the cytoplasm could be packaged along with the host cell DNA. Cells do not need to be dividing, however, in order to translocate foreign DNA material to the nucleus. Due to the presence of the SV40 enhancer nuclear localization sequence, DNA can also reach host cell DNA this way. Facilitation of translocating any foreign DNA promotes the potential for integration of the DNA and compromising host cell genomic integrity.

Given the uncertainties and potential risks identified in this section, we contend that assessments of the safety profile of the COVID-19 modmRNA injections warrant an objective, precautionary perspective, and that the risks are sufficiently evident to justify a policy of advising pregnant women and women of reproductive age to forgo these injections. Furthermore, to recapitulate the position we adopted in Part 1 (Mead et al., 2024a), we wholeheartedly support the immediate removal of COVID-19 vaccines from the childhood immunization schedule, the suspension of booster doses, and a comprehensive investigation into potential misconduct by the vaccine industry and regulatory agencies in relation to ongoing efforts to promote, distribute, and administer these COVID-19 modmRNA products to younger women, pregnant women, infants, and children without any well-powered clinical trial data to demonstrate safety in these populations.

### *ADVERSE EVENTS #6: POTENTIAL IMPACT OF MODMRNA ON CANCER GROWTH AND PROGRESSION*

Factors related to the oncogenic potential of the COVID-19 vaccines have become a focus of intensive inquiry. *In vitro* studies indicated that spike protein significantly inhibits DNA repair, which is required for effective adaptive immunity and cancer prevention (Jiang & Mei, 2021). Spike protein became localized in the nucleus and subsequently blocked DNA repair by impeding the repair protein BRCA1 and 53BP1 recruitment to the damage site (Jiang & Mei, 2021). In older individuals, humoral responses to the modmRNA injections are weaker when immune cells are under oxidative and genomic stress, as is typical in the context of inflammaging (Soegiarto & Purnomosari, 2023). In this same *in vivo* context, however, DNA repair systems were not influenced by short-term vaccine-induced immune stimulation (Ntouros et al., 2022). As noted elsewhere, spike protein may block activation of p53, which ordinarily helps protect against genomic damage (Wang et al., 2023b). Dysregulation of the system for both preventing and detecting genetically driven malignant transformation within cells and the consequent potential for modmRNA products to enable those transformations may have serious oncogenic consequences (Seneff et al., 2022).

Various lymphomas have been linked with the COVID-19 modmRNA injections (Goldman et al., 2021; Kreher et al., 2022; Sekizawa et al., 2022; Zamfir et al., 2022; Hobayan & Chung., 2023; Tachita et al., 2023). The genesis of these lymphomas may be traced to the presence of the SV40 in plasmid DNA found in Pfizer mRNA vaccine vials (see earlier discussion of process-related genetic impurities; also see Butel et al., 2003; Kostoff, 2023b). SV40 sequences can transport the DNA to the nucleus, where they may be inserted into oncogenic genes, thus inducing cancer. Relapses and/or hyperprogression of leukemias, melanomas, basal cell carcinomas, sarcomas, and otherwise rare cancers are also suspected of being causally associated with the gene-based injections (Bae et al.,

2023; Kyriakopoulos et al., 2023; Laderoute, 2023; Makis, 2023a; Makis, 2023b; Petersen & Bjørn, 2023).

A recent review by Angues and Bustos explores the hypothetical capacity of COVID-19 products to activate biological signals that may collectively create a microenvironment conducive to cancer progression, either accelerating existing macroscopic disease, or awakening dormant micrometastases (Angues & Bustos, 2023). These suspected processes relate primarily to the pro-inflammatory effects of the spike protein and LNPs, disruptions in the body's ability to generate type I interferon, and disturbances in the regulation of cellular microRNAs caused by the altered structure of mRNA within the COVID-19 modmRNA prodrugs (Angues & Bustos, 2023). Additionally, they elicit elevated concentrations of interleukin-17 (IL-17) and upregulation of Th17, thereby disrupting Th1-Th2 immunity, escalating the chronic inflammatory condition of cancer patients, and further amplifying tumor growth and progression (Echaide et al., 2022; Gandolfo et al., 2022; Echaide et al., 2023). It is plausible to posit that the modmRNA injections may be accelerating tumor progression in patients with preexisting tumors.

Another process by which cancer may establish itself following the modmRNA injections is via T-cell exhaustion, which is associated with a progressive loss of cytokine production and cytotoxic potential (McKinney et al., 2015; Collier et al., 2021; Liu et al., 2021). As we discuss in more detail in the autoimmune section, the combination of T-cell exhaustion and IgG4 class switching after several doses of the modmRNA injectables (Irrgang et al., 2023; Espino et al., 2024) would be conducive to higher cancer rates (Dolina et al., 2021). This could also translate into higher cancer mortality via increased susceptibility to life-threatening infections (Uversky et al., 2023), the leading clinical basis for cancer-related deaths.

Loacker et al. (2023) demonstrated a significant increase in the expression of programmed death ligand 1 (PD-L1) on the surface of immune cells, measured two days following the second modmRNA injection. The binding of PD-L1 to PD-1 found on cancer cells restricts the power of T cells to eliminate cancer cells, thereby facilitating the tumor's evasion of immune-mediated destruction (Jiang et al., 2019). Elevated levels of PD-L1 on immune cells may predispose cancer patients to unfavorable outcomes, and treatments that target PD-L1 suppression (anti-PD1 blockade) are gaining traction as viable therapeutic options (Ai et al., 2020). Rapid progression of various lymphomas has been linked to COVID-19 modmRNA vaccinations (Goldman et al., 2021; Sekizawa et al., 2022; Zamfir et al., 2022; Tachita et al., 2023), and elevated PD-L1 may play a role in this context.

The foregoing considerations may explain the rise in cancers in young adults recently reported from population-based studies all over the world (Ledford, 2024). A study in Japan used official statistics obtained from the country's robust surveillance and data reporting systems in order to examine changes in mortality rates for cancers and all causes during 2020-2022 (Gibo et al., 2024). Logistic regression analyses were conducted to compare observed age-adjusted mortality rates against pre-pandemic projections from 2010-2019. Although no excess mortality occurred in 2020, the two subsequent years showed a surge in excess cancer-related mortality and all-cause mortality, the latter showing a 2.1% increase in 2021, and a stunning 9.6% increase in 2022. In the first year of the injection program (2021), excess deaths were observed for specific cancer types; for example, excess breast cancer mortality increased by 4.3% while excess prostate cancer mortality rose by 5.3%. However, the biggest elevations in age-adjusted mortality rates occurred in 2022, after most of the population had received their 3rd dose (Gibo et al., 2024). In that year, large excess mortality increases were observed for leukemias (8%) and cancers of the ovaries (9.7%), prostate (5.9%), oral cavity (5.5%), and pancreas (2%), and liver (2%). It is important to emphasize that these *excess*

mortality trends are far more concerning from a public health perspective than, say, the increased mortality that may occur from year to year. The findings strongly indicate a connection to Japan's aggressive nationwide modmRNA campaign rather than to pandemic-related disruptions in cancer care or direct impacts of COVID-19, which, thanks to the population-wide dominance of Omicron, was symptomatically akin to the common cold by 2022. This study indicates that cancer mortality escalated during the "vaccination" phase of the pandemic, warranting further investigation into the malignant potential of COVID-19 modmRNA injections.

Moreover, according to Kory and Pfeiffer (2024), data from both the CDC and American Cancer Society indicate a disturbing new pattern in US cancer mortality, with deaths increasing markedly among younger segments of the population. For example, from 2019 to 2023, these data sources show deaths from colorectal cancer rising 17% among people ages 15 to 44, *four times* the population-wide increase. Whereas uterine cancer deaths rose 15% for the entire US population during this period, these deaths rose 37% among 25-to-44-year-olds (American Cancer Society, 2024; Kory & Pfeiffer, 2024). Highly significant increases in excess cancer deaths were also observed among younger age groups (ages 15-44) in the UK in 2022, mostly attributed to melanomas and cancers of the breast, colon, brain, and pancreas (Alegria, 2023).

Cancer is a complex disease driven by multiple factors, involving an immense range of cellular and molecular processes that contribute to its growth and progression (Hanahan, 2022; Ravi et al., 2022; Pavlova et al., 2022; Gryder, et al., 2013). For example, inflammatory and oncogenic processes seem to share many elements of normal cell-division and repairs with modmRNA-induced reactivation of latent viral infections such as Herpes and Epstein-Barr Virus (Lee et al., 2022b; Musialik et al., 2022; Navarro-Bielsa et al., 2023). In susceptible individuals, modmRNA-induced activation, or reactivation of Epstein-Barr Virus could promote the development of lymphomas and lymphoproliferative disorders (Arand et al., 2023; Tanaka et al., 2023). Various lymphomas have been linked with the COVID-19 modmRNA injections (Goldman et al., 2021; Sekizawa et al., 2022; Zamfir et al., 2022; Tachita et al., 2023). The genesis of these lymphomas may be traced to the presence of the SV40 in plasmid DNA found in Pfizer modmRNA "vaccine" vials (see previous section on SV40, and discussion of DNA contamination citing Butel et al., 2003; Kostoff, 2023b). SV40 sequences can transport the DNA to the nucleus, where they may be inserted into oncogenic genes, thus inducing cancer. Relapses and/or hyperprogression of leukemias, melanomas, basal cell carcinomas, sarcomas, and otherwise rare cancers are also suspected as being associated with the modmRNA injections (Bae et al., 2023; Kyriakopoulos et al., 2023; Laderoute, 2023; Makis, 2023a; Makis, 2023b; Petersen & Bjørn, 2023). At this time, the complex intersection of oncogenesis, cancer progression, and COVID-19 modmRNA injections is based primarily on laboratory studies, case reports and observational studies. Clinical trial data are urgently needed, and the long-range cancer-related impacts of the gene-based prodrugs have yet to be elucidated.

## Links Between modmRNA Products and "Long COVID"

Also germane to this discussion is the phenomenon known as "long COVID". Typically, it appears in some individuals after an acute phase of what is diagnosed as a SARS-CoV-2 infection. Characteristic symptoms may include extreme and persistent fatigue, brain fog, muscle pain, breathing difficulties, tingling extremities, and chest and throat discomfort for extended periods. This has come to be known as post-acute COVID-19 syndrome (PACS). It is a multifactorial, multisystemic condition encompassing dysautonomia, encephalitis, chronic fatigue syndrome, immune dysfunction, cardiovascular and clotting abnormalities, and it involves multiple organ systems (Davis et al., 2023). Specific types have been proposed on the basis of symptoms

(Raveendran et al., 2021; Yong et al., 2022). Early in the pandemic, CDC officials stated publicly that the modmRNA injections would actually lower the risk of post-acute COVID-19 syndrome, and this claim was used to convince many young people to get the injections. More recent data indicate, however, that the opposite scenario is more likely to represent reality.

Because the spike protein is the common denominator between SARS-CoV-2 infection and modmRNA inoculation, it is not surprising that the latter produces long-term symptoms that share many features with PACS (Arjun et al., 2022; Hulscher et al., 2023). The condition may be triggered by an immune overreaction to the modmRNA-generated spike protein (Vogel & Couzin-Frankel, 2023), which has been shown to persist at least six months after the injection (Brogna et al., 2023). Post-injection spike protein has been found in PACS patients (Craddock et al., 2023; Dhuli et al., 2023). Diexer et al. (2023) observed that 70% of PACS cases occurred in individuals who had received full course of modmRNA injections, indicating that the modmRNA injections may exacerbate PACS in most cases. The group with the lowest risk of PACS was the unvaccinated individuals who contracted Omicron as their first infection.

Thus, contrary to media messaging asserting that "COVID vaccination helps prevent long COVID", modmRNA-injected individuals are much more likely than uninjected ones to be impacted by PACS. Unsurprisingly, several new syndromes associated with the modmRNA inoculations have been introduced that encompass conditions very similar to PACS, and it has been proposed that the forthcoming version of the International Classification of Diseases diagnostic codes should incorporate a new code specifically for "post-COVID-19 vaccination condition, unspecified" (Scholkmann et al., 2023). Given the known facts, PACS should probably be re-named "post-acute COVID-19 injection syndrome" (PACIS). It is logical to surmise that the vast majority of reports of "long COVID" since early 2021 are in fact referring to this modmRNA-induced condition, particularly in those countries with the most extensive distribution of the gene-based prodrugs.

## Revisiting Censorship by the Bio-Pharmaceutical Complex

In his highly-cited 2005 publication, "Why Most Published Research Findings Are False," epidemiologist John Ioannidis argued that research findings might be influenced by the inherent biases of researchers towards their preferred hypotheses or prior findings. He further noted that the peer-review process could be manipulated by reputable scientists to suppress findings that contradict their own biases and claimed findings, thereby encouraging the establishment and continuous propagation of false dogmas within their fields of study (Ioannidis, 2005). It must be noted that medical schools and their mainline pharma-supported publications are permeated by such false dogmas about medicinal products and procedures. Such problematic dogmas have run out of control in the context of COVID-19 "research" that aligns itself obediently with funding mechanism biases and the prevailing mainstream narrative, despite obvious flaws, including a complete absence in many instances of well-designed critical research, or deliberately cherry-picked or massaged data sets, enabling "research" teams to find a smoother path to support and publication (Finley, 2023). Conversely, research findings that challenge the dominant narrative now face remarkably increased marketing barriers to publication, as well as heightened risk of weaponized retractions (Shaw, 2020, 2021a, 2021b).

We, the authors of this paper, experienced this censorship phenomenon firsthand. The original version of this "Lessons Learned" narrative review, despite having undergone an intensive 2.5-month peer-review process involving deep and thorough resolutions and consensus among eight expert reviewers, was retracted under what we believe were patently

false pretenses one month after publication (Mead et al., 2024b; McCullough, 2024). This was after the article achieved over 330,000 downloads, already the second highest total in *Cureus* history. We have subsequently expanded and improved the work and divided it into two parts. In Part 1, we discussed very concerning aspects in the registrational trial data along with our experience with other examples of censorship that have resulted, we believe, in misunderstanding or intentional misleading by the medical community and the general public of harm attributable to the COVID-19 modmRNA products. Here in Part 2, we discuss in depth the strong scientific bases and wide-ranging adverse events that completely undermine the narrative so aggressively pushed worldwide.

Several other examples of what we see as weaponized retractions are worth mentioning. We begin with the 2021 paper by Jiang and Mei. The authors had reported that the spike protein generated by the COVID-19 modmRNA injections became localized in the nucleus and subsequently blocked DNA repair by impeding the repair protein BRCA1 and 53BP1, thus creating problems of long-term genetic stability and cancer risk. Jiang and Mei were later pressured to retract their paper on the basis of questionable criticisms. However, their results have been corroborated by two subsequent papers, one by Singh & Singh (2020), which showed that the S2 subunit of the spike protein interacts with the tumor suppressors p53 and BRCA, and a subsequent bioRxiv preprint by Zhang & Eldeiry (2024), which showed that this interaction suppresses the power of p53 to activate critical genes involved in DNA repair. As reviewed by Zhang et al. (2019), p53 plays a central role in the DNA damage response.

Another noteworthy example of weaponized retraction was the 2021 paper by Kostoff et al., presenting an array of cogent arguments against the use of the COVID-19 vaccinations in children (Kostoff et al., 2021). The Kostoff paper was subsequently retracted (Kostoff, 2022). Removing these modmRNA products from the childhood immunization schedule would impose liability on the manufacturers for any potential damages attributed to the injections. Under the National Childhood Vaccine Injury Act of 1986, pharmaceutical companies that manufacture these products are indemnified from liability for deaths or injuries caused by vaccines listed on the childhood immunization schedule. As with our own narrative review as originally published in *Cureus* prior to the retraction (Mead et al., 2024b), the Kostoff paper called into question the ongoing recommendation to administer these gene-based bivalent "vaccines" to children despite the complete absence of the controlled clinical trial data normally required to validate such a recommendation.

Autopsies play a crucial role in establishing the lethality of modmRNA products by revealing direct physiological damage, such as pathological changes in organs and tissues. The postmortem exam enables a definitive assessment of the fatal impact of the injectables, ensuring accurate medical and legal conclusions. The largest autopsy study to date was a systematic review of published reports that provided strong evidence of modmRNA-induced mortality (Hulscher et al., 2023). The authors analyzed 325 autopsy cases in which 73.9% of deaths ($n = 240$) were independently adjudicated as "directly due to or significantly contributed to by COVID-19 vaccination", thus suggesting a high likelihood of a causal relationship. The most common fatal modmRNA-related syndromes identified were myocarditis and blood clots. The authors recommended autopsies for all deceased individuals who had received COVID-19 modmRNA injections and advocated for clinical monitoring of "vaccinated" individuals for at least one year post-injection, calling for further research on this issue.

This landmark study was initially posted on July 5, 2023, on *The Lancet* preprint server SSRN, and immediately garnered a great deal of attention, with very large numbers of downloads and reads (Hulscher et al., 2023). Within 24 hours, however, the autopsy review was removed from the SSRN, because according to *The Lancet*, "the study's conclusions are not supported by the study methodology." This course of action raised suspicions that *The Lancet* had sought to suppress information revealing that independent adjudication attributed every three out of four autopsied post-injection deaths to the gene-based prodrugs. These suspicions seemed justified, given that the study had satisfied all SSRN screening criteria

Approximately a year later, on June 21st, 2024, the study was published after successful peer-review in *Forensic Science International* (Hulscher et al., 2024a). On July 3rd, 2024, the study was the #1 trending research paper worldwide across all subject areas within the preceding two weeks as indicated by Altmetrics (OOIR, 2024). One can reasonably assume that the general public and scientific communities were eager to learn about critical post-mortem safety data regarding COVID-19 injections. Unfortunately, in a striking act of censorship, Elsevier and *Forensic Science International* withdrew the article on August 2nd, 2024 in flagrant violation of their own withdrawal policy (Elsevier 2024) and COPE guidelines (COPE, 2024). Anonymous sources, identified only as "members of the scientific community", declared that the study contained "inappropriate citation of references, inappropriate design of methodology, errors, misrepresentation, and lack of factual support for the conclusions, and failure to recognize and cite disconfirming evidence". A comprehensive rebuttal against the unfounded concerns was provided to the journal, which was concerningly rejected in accordance with two anonymous post-publication reviewers. Elsevier and *Forensic Science International* failed to follow the proper scientific discourse method of allowing debate in Letters to the Editor.

On April 8, 2024, the journal *Cureus* accepted and published the previously discussed Japanese study by Gibo and colleagues (2024) that found statistically significant increases in cancer mortality following the COVID-19 modmRNA rollouts. Less than a month after the paper was published, Reuters conducted a "fact check" on a social media post and labeled the analysis as "flawed", arguing that the study "assumes without evidence that vaccines are responsible for the observed cancer death rates". The fact check article also mentioned that the paper provided no evidence of "turbo cancers", even though Gibo et al., never actually made this claim. In late June, approximately three months after publication, *Cureus* retracted the paper, despite the authors' having completed a rigorous peer-review process. On its website, the journal offered this explanation: "Upon post-publication review, it has been determined that the correlation between mortality rates and vaccination status cannot be proven with the data presented in this article." However, dismissing the correlation between mortality rates and vaccination status solely because it could not be "proven" with the data is fallacious. The strong correlations identified by Gibo et al. for this large population study warrant further epidemiological investigation. Moreover, the medical journal *Cureus* seems to draw the line at mortality: while it has published multiple papers on adverse events associated with the COVID-19 modmRNA injections, it has retracted those that primarily focus on mortality-related outcomes and risks (Mead et al., 2024b).

Censorship in the form of these weaponized retractions poses a major threat to the progress of scientific discovery. To justify such retractions, individuals aligned with the Bio-Pharmaceutical Complex have repeatedly issued false statements (often through centralized media channels such as Reuters and the Associated Press) and applied specious reasoning to

argue that there is insufficient scientific evidence to justify publication of papers that run contrary to the misleading biases of mainstream pharma-supported medical journals. We anticipate that, in the coming months, there will be intensified efforts by the Bio-Pharmaceutical entities to suppress and distort any serious discussion or reporting on the process-related DNA impurities issue and the integration of COVID-19 modmRNA plasmid DNA into the human genome. Based on our post-retraction investigations and in light of the precautionary principle, this DNA contamination issue provides a potent scientific justification for immediately halting the worldwide distribution of these potentially lethal gene-based prodrugs.

## Discussion

In this second part of the "Lessons Learned" narrative review, we have laid the groundwork for an evidence-informed rationale linking successive booster injections with a wide panel of serious adverse events, thereby paradoxically contributing to heightened susceptibility to COVID-19 infections and a vast array of health problems. As of this writing (August 2024), numerous clinical and observational studies have reported that modmRNA injections are associated with increased risks of cardiovascular, neurological, hematologic, and autoimmune disorders (see **Table 2**).

**Table 2**
**Overview of Four Domains of Primary Harms Linked with the COVID-19 ModmRNA Injections, Selected Citations**

| Harm Domain | Selected Citations |
|---|---|
| **Cardiovascular** | Keshavarz et al., 2022; Krug et al, 2022; Mahroum et al., 2022; Patone et al., 2022; Pillay et al., 2022; Wong et al., 2022; Buergin et al., 2023; Chiu et al., 2023; Gao et al., 2023; Yonker et al., 2023 |
| **Neurological** | Francis et al., 2022; Chatterjee & Chakravarty, 2023; Eslait-Olaciregui et al., 2023; Fazlollahi et al., 2023; Finsterer, 2023; Ghaderi et al., 2023; Hamed et al., 2024; Pilotto et al., 2024; Willison et al., 2024 |
| **Hematologic** | Ostrowski et al., 2021; Abbattista et al., 2021; Brambilla et al. 2023; Afshar et al., 2022; Iba & Levy, 2022; Dag Berild et al., 2022; Cines et al., 2023; Abrams & Barnes, 2023; Sekulovski et al., 2023; Schönborn et al., 2023; Rogers et al., 2024; Burn et al., 2022; Shoaibi et al., 2023; Wong et al. 2023; van Dijk et al., 2024; Li et al., 2023; Rogers et al., 2024; Lee et al., 2022; Kobayashi et al., 2023; Rodríguez et al., 2022; Santiago & Oller, 2023 |
| **Autoimmune** | Ishay et al., 2021; Caron, 2022; Chen et al., 2022; Mahroum & Shoenfeld, 2022; Poli et al., 2022; Ju et al., 2023; Polykretis et al., 2023; Kim et al., 2024; Shumnalieva et al., 2024 |

A smaller body of evidence also suggests an increased risk of cancers and reproductive disorders. For other reviews addressing the myriad of adverse events linked with the COVID-19 modmRNA injections, we refer readers to these papers (Kostoff et al., 2020; Ostrowski et al., 2021; Seneff et al., 2022; Bellavite et al., 2023; Giannotta et al., 2023; Halma et al., 2023; Parry et al., 2023; Seneff et al., 2023b).

The various serious adverse events that have been documented in conjunction with the Pfizer and Moderna modmRNA injectables represent a clear set of real, observable harms, sharply contrasting with the claimed or theoretical benefits ascribed to these gene-based products (see **Figure 4**).

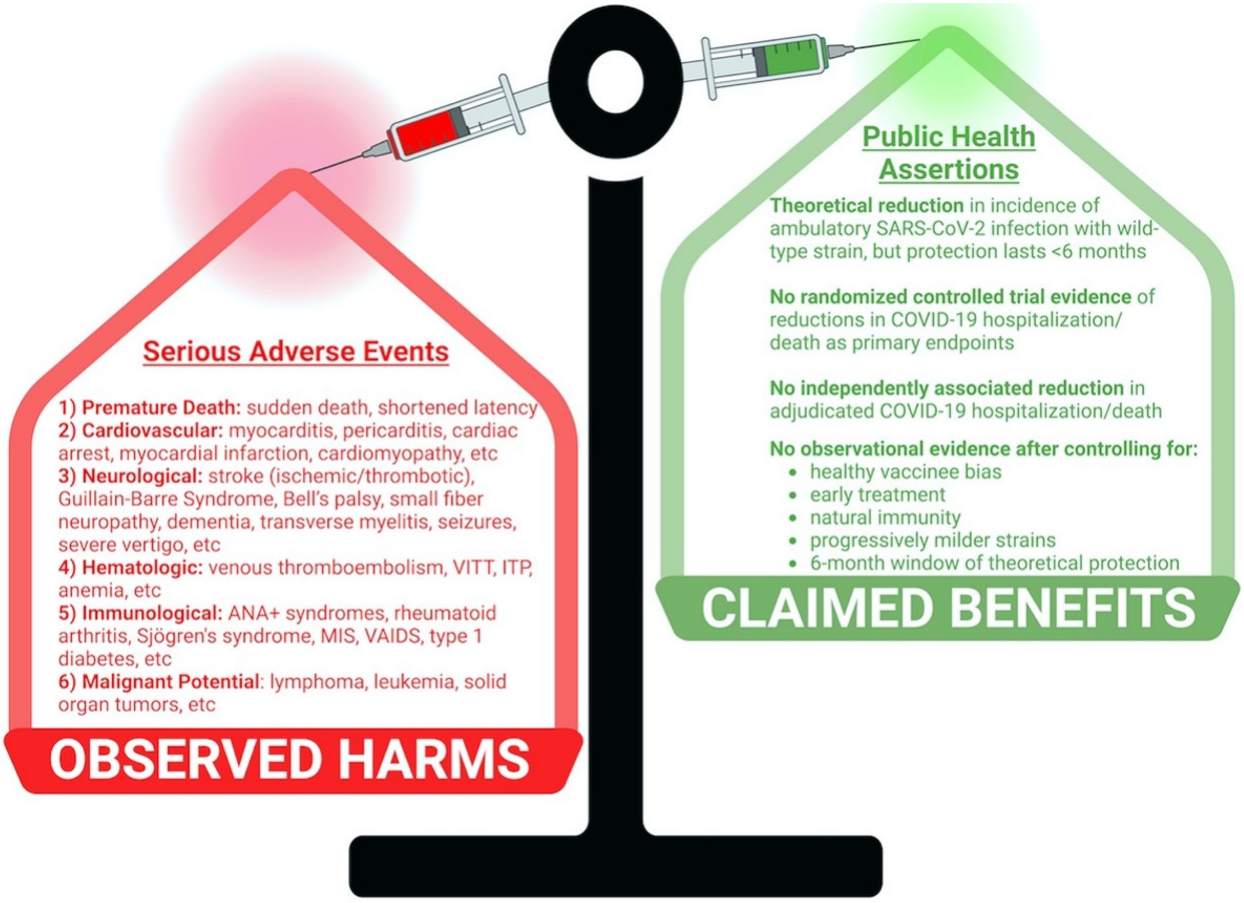


Figure 4. Harm-reward analysis: observed harms vs. claimed benefits of the modmRNA injectables. Serious adverse events include premature death, cardiac arrest, and other well-documented harms ascribed to the COVID-19 modmRNA injections. The claimed benefits are based on theoretical estimates and extrapolations from clinical trial data, as well as numerous observational studies that claim to support for the "safe and effective" narrative yet cannot be trusted because they contain multiple biases, relying on flawed methodologies and spurious data.

We list premature death at the top of the serious adverse events to emphasize that some serious cardiac events can result in sudden death, while many other serious adverse events can translate into a shortening of the latency period for many cardiovascular, neurological and autoimmune diseases. Even in the randomized Pfizer trial that was used to grant the modmRNA products EUA status in late 2020, there was evidence of a 31% mortality trend in the COVID-19 modmRNA group versus the placebo (Mead et al., 2024a). On the "claimed benefits" side, it is important to emphasize that the reductions in ambulatory SARS-CoV-2 infections are *theoretical*, based on the following post-injection facts:

1. Natural immunity often eclipses any protection ascribed to the modmRNA injections; previously infected persons have acquired immunity against COVID-19, regardless of any claimed benefits of the "mRNA vaccines".
2. Not all persons are equally exposed to SARS-CoV-2 in the environment. Many are either never exposed or minimally exposed; the injections are not affording any measurable protection for these individuals.

3. Not all patients who were "unvaccinated" or "partially vaccinated" get tested for COVID-19 when they develop an upper respiratory infection. Many who are tested have false-positive results (ranging from 30-90%).
4. Progressively milder strains of SARS-CoV-2 or Omicron subvariants are not accounted for; by definition and based on multiple studies conducted since late 2021, these milder strains invariably produce symptoms resembling the common cold or, at worst, a mild flu.
5. Use of nasal sprays, gargles, and early treatment markedly reduces symptomatic illness from COVID-19. Any use of these strategies completely nullifies the perceived benefits of the modmRNA injections, effectively obviating any assertion of a public health "need".

For these reasons, calculations of "vaccine effectiveness" must be deemed purely theoretical, with too much credit given to the modmRNA injectables instead of to the above effects and conditions.

In autopsy studies, prior administration of the modmRNA products was linked with myocarditis, encephalitis, intracranial haemorrhage, diffuse thrombosis, and immune thrombotic thrombocytopenia (Wünstel, 2020; Bjørnstad-Tuveng et al., 2021; Choi et al., 2021; Sessa et al., 2021; Wiedmann et al., 2021; Sanning, 2022; Chen et al., 2023; Schwab et al., 2023; Hulscher et al., 2024a, Hulscher et al., 2024b). These postmortem investigations play a crucial role in helping to establish causation between the modmRNA injections and disease risks and/or outcomes: the studies provide direct evidence of pathological changes in tissues and organs, enabling examination of the modmRNA's impact on the body. As early as July 2021, the FDA had announced that the following potentially serious adverse events of the Pfizer modmRNA product deserved careful monitoring: acute myocardial infarction, pulmonary embolism, immune thrombocytopenia, and disseminated intravascular coagulation (US Food and Drug Administration, 2021). However, careful review of the literature reveals that the Moderna modmRNA product, mRNA-1273, seems to have an even more problematic track record in terms of adverse events when contrasted with the Pfizer injectable, BNT162b2 (Polack et al., 2020; Baden et al., 2021; Beatty et al., 2021; Kitagawa et al., 2022; Valera-Rubio et al., 2022; Chapin-Bardales et al., 2021; Chapin-Bardales et al., 2021b).

Analyses of dosing, brand, and type of injectable may be conducive to a better understanding of the modmRNAs' biological fallout. For example, the analysis by Villanueva and colleagues (2024) showed that, "…after the second [modmRNA] dose, the incidence of *any systemic reaction* was higher in BNT162b2 recipients" [emphasis added] when compared with other "vaccine" types". A Taiwan study of 1711 booster recipients found that simply switching from Moderna's mRNA1273 product to another brand significantly reduced the adverse event risk by 18% (Lin et al., 2024). In a large two-year study of the Moderna product (>772 million administered doses), 0.7% of the over 2.5 million adverse events resulted in death (Urdaneta et al., 2024). Extrapolating to the 13+ billion doses already administered to the global population, it is difficult to Grok the scope and magnitude of this unfolding global public health tragedy, and to comprehend why so many governments continue to vigorously disseminate these dangerous gene-based products, with ongoing accusations of "misinformation" directed at those who openly question the policy.

One of the common refrains we hear from the Bio-Pharmaceutical Complex is that the COVID-19 modmRNA products generate robust immune responses, thereby justifying their ongoing distribution on a population-wide basis. As we noted in Part 1, it does appear that the spike protein induced by modmRNA, along with the other toxic ingredients in the injections (Segalla, 2023a, 2023b, 2023c, 2023d), provokes a more intense immunological response than its coronavirus counterpart, leading to a stronger humoral response, as evidenced by higher antibody titers. By the same token, however, this heightened response is also linked to hyperinflammation and more severe

immunopathology and reactogenicity, along with a diverse array of adverse effects (Debes et al. 2021; Naaber et al., 2021; Rechavi et al., 2021; Takeuchi et al., 2021; Çalık et al., 2022; Sugiyama et al., 2022; Kobashi et al., 2022; Levy et al., 2022; Pozdnyakova et al., 2022; Uwamino et al., 2022; Brisotto et al., 2023). This may also help explain why individuals exposed to infection close to the time of modmRNA injection are at heightened risk of experiencing serious adverse events (Bossche, 2023). Thus, from a risk-benefit perspective, one that is hard to conceptualize in a context of hypothetical benefits swamped by debilitating and lethal risks, whereas the modmRNA-induced spike protein does seem to heighten the adaptive immune response, it dramatically increases the likelihood of adverse events and immunopathology. Especially, given the the low infection fatality rate (0.05% for individuals under 70; 0.1-0.3% for older adults; Pezzullo et al., 2023) associated with COVID-19, the harm-reward tradeoff seems absurdly lopsided in the direction of harm.

Stated another way, while most recipients of the modmRNA injections have an extremely low risk of COVID-19 hospitalization and death, they face a relatively high risk of serious adverse events (conservatively, as shown in Pfizer's registrational trial, one serious adverse event for every 800 injections) following the COVID-19 modmRNA vaccination (Fraiman et al., 2022). This disturbing dichotomy is most pronounced in the context of the childhood immunization programs, although in fact all ages under 40 show near-zero infection fatality rates. Pezzullo et al. (2023) calculated median infection fatality rates of 0.0003% at 0-19 years, 0.002% at 20-29 years, and 0.011% at 30-39 years. As noted earlier, death rates among children have been extremely low even in countries showing excess mortality during the pandemic (Islam et al., 2021), and allowing children to attend school freely, as occurred in Sweden, resulted in zero COVID-19 deaths among this younger age group (Baral et al., 2021). Given this very low risk to children, we must reject the policy of administering an experimental vaccine to these age groups. Against the (then dominant) Omicron subvariant, BA.5, the bivalent modmRNA vaccines were only tested in eight mice, never in humans (Rodriguez, 2022). Following this authorization, noted vaccinologist Paul Offit, a member of the VRBPAC, wrote: "We should stop trying to prevent all symptomatic infections in healthy, young people by boosting them with vaccines containing mRNA from strains that might disappear a few months later" (Samanovic et al., 2021). Based on the best available evidence, the potential risks of these mRNA inoculations have consistently outweighed the benefits for younger generations (Bardosh et al., 2022; Palmer et al., 2022). Consideration of a harm-to-reward calculus weighs heavily on factors like lymphomas (Goldman et al., 2021; Sekizawa et al., 2022; Zamfir et al., 2022; Tachita et al., 2023) and heart damage (Jeet Kaur et al., 2021; Oster et al., 2021; Almas et al., 2022; Rees, 2022; Shiravi et al., 2022; Gao et al., 2023; Yasmin et al., 2023) in these younger age groups.

The adverse impacts on younger cohorts were also reflected by the extraordinary reports from US life insurance companies for the latter half of 2021. According to the Group Life survey data, during Q3 and Q4 of 2021, the general US population experienced a 32% increase in mortality compared to 40% in the Group Life count (8% difference; Hurley et al., 2023). Group Life Policyholders are well-employed, young, and generally healthy adults, previously dying at about one-third the rate of the US population, based on a 2016 Society of Actuaries (SOA) analysis (Hurley et al., 2023). Thus, the mortality observed among the Group Life cohort in 2021 represents an inversion of previous trends. The excess deaths in the Group Life data were determined by comparing average death rates in the Group Life data from the 2017-2019 baseline, adjusted for seasonality and combined with CDC data. Between Q2 and Q3 of 2021, the beginning of the second US vaccination rollout, the SOA analysis showed a 36% increase in excess mortality for ages 25-34, a 50% increase for the 35-44 age group, and a 52% increase for the 45-54 age group (Hurley et al., 2023). These numbers represent colossal (insurance industry data analysts would even use the term "catastrophic") and unprecedented increases in excess mortality for the 25-54 age range, with an average increase of 46%

(though averaging the percentages tends to mask the severity of the impact on specific age cohorts) (Hurley et al., 2023).

As mentioned above, these were younger, healthier adults, and thus it is illogical to suggest that COVID-19 had any substantial influence on mortality, especially given the extremely low infection fatality rate associated with the younger age brackets. Indeed, according to the most recent Group Life report, the excess mortality in each of the age groups applied only to "non-COVID-19" deaths; there was no excess mortality directly attributed to COVID-19 (Hurley et al., 2023). Importantly, the surge in excess mortality among the 25-54 age group was also temporally associated with the introduction of US vaccine mandates among military and hospital personnel from the summer into the fall of 2021 (Phinance Technologies, 2022). From March 2021 to February 2022, there were approximately 61,000 excess deaths among Americans under age 40, equivalent to all US servicemen lives lost during the Vietnam War (The Vigilant Fox, 2023). This tragedy was never reported by any of the major US news media.

The health-related repercussions of these vaccine-related heart risks have been manifesting on the public stage since 2021. Prior to that year, the average annual number of cardiac arrests on the field for professional athletes in Europe was 29; this number has risen to 283 per year, an approximately 10-fold increase, based on the annualized rate of cardiac arrests following the rollout of COVID-19 injectables to active players aged 35 (Polykretis & McCullough, 2022). Two-thirds of the players were not resuscitated (Polykretis & McCullough, 2022).

The World Council for Health (2023) has demanded an immediate moratorium on these novel products, due in part to the issue of extensive DNA contamination. Florida's Surgeon General has echoed this request (Baletti, 2024; McCullough, 2024). These statements have helped spark a larger movement within the scientific community. The Hope Accord is an international group of healthcare professionals, scientists, and academics calling upon regulators to suspend the use of COVID-19 modmRNA products "as a matter of standard medical precaution" (Dumais, 2024). Other groups that have called for removal of the COVID-19 modmRNA products from the market include the McCullough Foundation (McCullough Foundation, 2024), Doctors for COVID Ethics (D4CE, 2021), and the Association of American Physicians and Surgeons (AAPS, 2024).

On a precautionary basis, we agree with the above recommendations for the immediate removal of the COVID-19 injectables from the childhood immunization schedule along with the suspension of boosters and a full investigation of the misconduct regarding safety assessments and data from the founding trials of the entire vaccine industry and its various regulatory agencies.. It is criminal to administer a likely harmful and probably lethal (over the long term) experimental injection to a child who has a near-zero risk of dying from the possibility of a COVID-19 infection (infection fatality rate, 0.0003%) but a well-established 2.2% risk of permanent heart damage, not to mention all the other injuries that can occur, based on the best prospective data available. Additional risks for these otherwise healthy young individuals include seizures, cancers, autoimmune disorders, and numerous other life-stealing conditions post vaccination, as documented in Pfizer's own records released under the Freedom of Information Act (Pfizer, Inc., 2022). Despite these revelations, the Bio-Pharmaceutical Complex has been quite successful in (a) censoring scientific discourse critical of the COVID-19 vaccine enterprise and (b) infiltrating the mainstream media and social media messaging in order to try at least to keep the general public believing in the "safe and effective" narrative (Shir-Raz et al., 2022; Bhattacharya & Kulldorff, 2024).

Another relevant aspect of this unfolding tragedy is the issue of reduced life expectancy. In many developed countries, the most publicized causes of reduced life expectancy include smoking, obesity,

opioid overdose, homicides, suicides, and infant mortality (Roser, 2023). Most public reports, however, conveniently omit life-ending iatrogenic events where an error in a medical procedure or the administration of prescription drugs occurs. According to research by Johns Hopkins professor Barbara Starfield published in 2000,as many as a quarter of a million deaths per year were of that kind (Starfield, 2000). Now, with the widespread lethal impact of COVID-19 injectables, that number seems to have already sky-rocketed into the millions.

It is obvious, in any case, that the risks associated with the COVID-19 injections that have already been administered to more than 5.1 billion people (Pharmaceutical Technology, 2024) may translate into premature death for a great many people in the long term. Among the poor people of the world, untreated bacterial pneumonia is a major cause of reduced life expectancy and may be further exacerbated by COVID-19 injections (Rancourt et al., 2022). Strokes and myocarditis associated with COVID-19 vaccinations may cause premature death years after the initial event. A longitudinal study of stroke patients found that fewer than 28 days after a stroke, the risk for death was 28%; this increased to 41% at one year and 60% at five years (Sennfält et al., 2019). Undiagnosed heart and clotting problems can persist asymptomatically for years. As noted above, multiple autopsy studies provide definitive evidence of serious post-injection damage to the heart, including sudden cardiac arrest and sudden death, all associated with the COVID-19 modmRNA injections (Hulscher et al., 2024a). In adolescent males, however, myocarditis can have a mild outward clinical appearance yet result in severe cardiac fibrosis (scarring), with permanent damage to the heart muscle (Barmada et al., 2023; Yu et al., 2023). Such damage can eventually lead to congestive heart failure and death many years later (Brociek et al., 2023). The registrational trials were insufficient for detecting these long-range hazards, most of which only became evident after 2.5 years of follow-up observation and over a billion modmRNA injections.

This leads us to consider how and why so many published papers and authorities have claimed that myocarditis shows a stronger association with SARS-CoV-2 infection than with the COVID-19 modmRNA injections. This single claim is patently false, and yet it has been used to justify ongoing injections despite myocarditis being recognized as a signal by the CDC and other authorities. Based on their careful systematic review, Knudsen and Prasad (2023) suggest the reason for this widely held claim relates in part to basic differences in the epidemiological study of infection versus injection. They note that calculating the incidence of myocarditis in relation to the modmRNA injections is relatively valid, if not exactly precise, because both the number of myocarditis cases and the modmRNA doses administered are approximately known. Estimating the incidence of myocarditis after SARS-CoV-2 infection is much more challenging and far less reliable, therefore, less valid. The total number of infections always remains largely unknown and cannot be accurately determined no matter how many seriously flawed PCR tests are conducted (Kämmerer, et al., 2023a, 2023b; Franchi & Tomsic, 2023). Studies generally depend on documented infections, which are likely underreported because not everyone with the infection has a confirmed positive test and many of the positive tests are known to be false positives. Therefore, the reported incidence of myocarditis may be inflated and inaccurate in the context of SARS-CoV-2 infection studies (Knudsen and Prasad, 2023). Logically, the use of seroprevalence data instead of documented infections would better reflect the actual number of infections in a population and provide a more accurate estimate of myocarditis post-infection. This would also likely result in a shift in the narrative concerning the association between myocarditis and modmRNA injections.

Another critical issue identified by Knudsen and Prasad (2023) relates to stratification. Most of the published epidemiological reviews on myocarditis have limited the analysis to reports from vaccine safety surveillance databases. However, about 70% of the studies reporting adverse events associated

with COVID-19 modmRNA injections have not sufficiently stratified by age and other confounders (Knudsen and Prasad, 2023). This means that most of these studies fail to reliably shed light on myocarditis incidence in the demographic group at highest risk: men under age 40, and in particular males aged 12–24, following the second dose of either the Pfizer or Moderna modmRNA injections. Studies that do not adequately stratify by age and sex appear to dilute the risk estimates for the higher-risk subgroup (men <40 years old), while at the same time inflating them for lower-risk groups such as older women (Knudsen and Prasad, 2023). According to Knudsen and Prasad (2023), studies that have stratified data by at least three or four confounding variables (e.g., age, sex, and dose number) consistently report the highest incidence of myocarditis, with few exceptions. From an epidemiological perspective, it seems inappropriate to use non-stratified, population-wide myocarditis incidence estimates when forming immunization policies for young men, which is clearly the most at-risk population. Failure to stratify the data has most certainly resulted in a minimization of the critical safety signal for males under age 40 (Knudsen and Prasad, 2023).

Before closing, five practical issues are worth highlighting from the standpoint of encouraging the public to receive regular boosters. The first is that repeated administration of the COVID-19 modmRNA inoculations increases the likelihood of adverse outcomes. In the Moderna trial, for example, the modmRNA injections showed approximately 3 times as many Grade 3 or 4 adverse events after the 2nd dose than after the 1st dose (Classen, 2021). Adverse reactions also appear to be more severe with multiple or periodic COVID-19 modmRNA inoculations (Kwon et al., 2023; Pasternak et al., 2023). Repeated injections several months apart may stimulate "non-specific" reactivity leading to autoimmunity and chronic inflammation (Bellavite et al., 2023). If an individual is also exposed to the coronavirus soon after a booster injection, the probably of an adverse event may be greatly increased (Bossche, 2023). Thus, not only are ongoing injections resulting in diminishing returns in terms of protection against COVID-19, as the Cleveland Clinic studies clearly demonstrated, but the booster campaign itself carries with it all the attendant risks described in this paper, and a great deal more. There is no upside to the repeat administration of these genetic products, only a downside.

The second practical concern is that some of the modmRNA product lots may be relatively innocuous while other lots are more toxic and potentially harmful. Instability of the manufacturing process, resulting in heterogeneity in the composition of the products, may be expressed in different levels of contaminants as well as variations owed to storage, transportation, and clinical handling. Such factors may account for recent findings from Denmark indicating that different lots of the Pfizer modmRNA products induce different levels of adverse events when administered to demographically similar groups (Schmeling et al., 2023). Some of the modmRNA lots resulted in almost no side effects, while others were linked to a moderate or very high incidence of adverse events and related deaths (Schmeling et al., 2023). It is crucial to investigate how specific modmRNA lots performed across diverse countries and demographics to determine if these findings are generalizable. While contaminants likely play a role in the inflammatory nature of this experimental gene-based platform relative to adverse events, recall that the ionizable lipid component of the LNPs in the COVID-19 modmRNA products is highly inflammatory itself and supposedly critical for the reactogenicity and immunogenicity (Ndeupen et al., 2021; Alameh et al., 2021). Consequently, another potential explanation for the distinct levels of adverse events triggered by different lots could be variations in the amounts of mRNA-LNP or the mRNA:LNP ratio between lots (Tinari, 2021). This heterogeneity can result in a false sense of security among those COVID-19 modmRNA recipients who just happened to receive injections from the less harmful batches.

A third point of emphasis pertains to individual susceptibility to adverse events for individuals who continue to receive the modmRNA injections. As noted previously, some people react badly while others do not react at all. Men under age 40 are at the greatest risk of modmRNA-induced myocarditis (Barda et al., 2021; Knudsen and Prasad, 2023). Women suffer the vast majority of clotting disorders and other adverse events that have been attributed to these products (See et al., 2021). Elderly individuals are more likely to experience the modmRNA-related adverse cardiological, neurological, hematologic, and autoimmune events (Kountouras et al., 2023; Wong et al., 2023). A large meta-analysis encompassing multiple UK populations found that people ages 80 and older are a heightened risk of COVID-19-related hospitalization and mortality following the initial modmRNA booster (Agrawal et al., 2022). The authors reported that the initial booster conferred no protection in this older age group (RR 3.60 [95% CI 3.45–3.75]) when compared to younger adults (18–49 years); those elderly persons with multiple comorbidities (>4) had the worst outcomes when compared to those with no comorbidities (RR 9.51 [9.07–9.97]). The Excess Mortality Project found large increases in excess mortality in 2022 compared to the two previous years for people over age 60 in all Nordic countries except for Sweden (Phinance Technologies, 2022). Given that Omicron was dominant throughout 2022 and had a very mild or non-lethal disease course, any age-stratified evidence of excess mortality for elderly populations in that year suggests a potentially lethal impact of the COVID-19 vaccinations (Dhama et al., 2023). In a comprehensive investigation of the first 100 suspected "vaccine-related" deaths among nursing home residents in Norway, the investigative committee attributed 10 fatalities to the COVID-19 modmRNA injections (Wyller et al., 2021). When compared to the same age groups in the general population, the nursing home populations show a higher incidence of comorbidities, including diabetes, cardiovascular diseases, cerebrovascular diseases, chronic obstructive pulmonary disease, and dementia (España et al., 2021). These connections help explain the significantly higher incidence of myocardial infarction in individuals over age 85 following the modmRNA injections, when compared to younger age groups; acute kidney injury was also more common in these very elderly individuals post injection (Li et al., 2021).

Aside from age, gender, and comorbidities (diabetes and obesity, in particular), other predisposing factors may include preexisting low-grade inflammation and a tendency toward hypercoagulable states, all of which may interact in additive or synergistic ways with the inflammatory processes triggered by the COVID-19 modmRNA injections. Numerous polymorphisms and other genetic factors are thought to increase an individual's susceptibility to the modmRNA-related adverse events (Ittiwut et al., 2022). This emergent "profile of susceptibility" is largely uncharted territory from a research perspective.

In consideration of the observable, variable natures of adverse event profiles in people injected with the modmRNA-LNP-based prodrugs, it seems prudent to cease their use, first and foremost, and to determine a way to quantify the amounts of protein production on an individual basis in order to establish adverse event profiles based on specific demographics such as age, sex, location, and genotype. Ideally, we should establish a spike-dose-adverse-event response curve. This may prove to be a very tall order. The only thing that we can currently measure is the amount of modmRNA and DNA, but this has nothing to with the output of protein: *the relationship is not linear*. In other words, the dose of modmRNA injected does not straightforwardly or predictably correlate with the amount of spike protein produced in each individual, making it difficult to define or predict the biological effect (in terms of spike protein output) solely based on the injected amount of modmRNA. Therefore, given the complexity of modmRNA translation and protein production, and given that a dose typically refers to a specific amount of a drug administered (with an expectation that this will

lead to a predictable concentration in the bloodstream or at the target site), there is no way to define a "dose" based on what was injected into the individual.

Fourthly, the COVID-19 modmRNA "vaccines" produced via its original manufacturing process and evaluated in the trials were not the same products eventually distributed worldwide. All of the COVID-19 mRNA products released to the public were produced via a different manufacturing protocol and have been shown to have varying degrees of DNA contamination. The failure of regulatory authorities to disclose process-related genetic impurities (e.g., SV40) has further eroded any reasonable trust in the safety and quality control of the modmRNA manufacturing processes. Preliminary laboratory investigations indicate the problematic possibility of integration of foreign DNA fragments into the host genome, with ominous implications for oncogenesis, and increasing the likely incidence of cancers in the coming years.

Fifthly, the Bio-Pharmaceutical Complex and its stakeholders have been dramatically increasing pressure on medical journal editors and publishers to retract papers pointing out and empirically documenting such issues in order to suppress key findings. Doing so destroys trust in the integrity of the mainstream sponsored research, and tarnishes the reputations of all those "scientists" participating in it. At the same time, legitimate research is "retracted" in a pernicious and destructive form of censorship. This ongoing censorship of studies that illuminate the harms associated with the COVID-19 modmRNA injections is deeply concerning.

The COVID-19 pandemic has highlighted significant gaps in the knowledge of vaccine and gene-therapy product safety among medical professionals who recommend and administer these products to the global population. More concerning is the apparent neglect by federal regulatory agencies and institutions responsible for safety oversight. These agencies have failed to rigorously evaluate products promoted for their role in preventing severe disease and reducing hospitalization rates. Moreover, they have failed to meet the essential requirements of vaccine safety research including: 1) identification of unsafe products to remove from human use, 2) methods to improve safety such as more restrictive use according to individual parameters, 3) development of safer products by the pharmaceutical companies, 4) effective management strategies for injury syndromes sustained following the injections. In a commentary for the *New England Journal of Medicine*, renowned vaccinologist Stanley Plotkin and colleagues addressed critical issues related to vaccine safety (Salmon et al., 2024). They recommended comprehensive monitoring of adverse events not initially reported in clinical trials to ascertain their relationship to the modmRNA injections. Additionally, they noted that the FDA did not adhere to its Standard Operating Procedures and Policies for the timely identification, review, and communication of certain safety concerns (SOPP 8508.2, 2008). In response to a Freedom of Information Act request, the FDA could not provide documentation confirming adherence to these procedures or evidence of communication to senior management regarding these safety issues (Brehm, 2021).

## Conclusion

In this paper, we first examined the main structural and functional aspects of the modmRNA products, before addressing the process-related genetic impurities inherent in their mass production, along with the potential risks posed by these contaminants. Next, we presented an evidence-informed overview of the six major domains of harms associated with the injections. The mainstream narrative about COVID-19 "vaccine" effectiveness in 2021 and 2022 has, it seems, boasted of non-existent benefits while greatly underestimating very real, empirically verified, cardiovascular, neurological, hematologic, and immunologic harms associated with these synthetic, modified mRNA products. Since early 2021, excess deaths, cardiac events (notably myocarditis and

myocardial infarction), strokes, and other serious adverse events have often been wrongly ascribed to COVID-19 infections rather than to the COVID-19 modmRNA products.

Ongoing administration of the COVID-19 modmRNA injectables presents a distinct set of biological challenges, with the potential to induce a wide range of serious adverse events. A significant limitation is the current inability to quantify in vivo spike protein production by host cells following administration of these modmRNA products, resulting in the absence of a standardized dosing metric. The inherent variability in spike protein production is influenced by factors such as individual cell metabolism and transfection efficiency, making it challenging to predict adverse event profiles on a per-dose or case-by-case basis. Given the extensive reports of modmRNA-related harms among millions of adults globally, there are legitimate concerns regarding the administration of these gene-based prodrugs to infants and younger age groups, who are at extremely low risk for severe outcomes from COVID-19. We once again urge governments worldwide to mandate a moratorium on the modmRNA products until proper safety and toxicological studies are performed and openly shared with the scientific community.

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