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# FINAL REPORT OF THE TWENTY-SECOND STATEWIDE GRAND JURY


- INTRODUCTION 3
  - OUR INVESTIGATION 4
  - OUR TASK 8
  - UNDERSTANDING SARS-COV-2 AND INDIVIDUAL RISK 10
- VACCINE APPROVAL IN THE UNITED STATES 13
  - THE LICENSING PROCESS 15
  - THE BENEFITS OF LICENSURE 17
- OPERATION WARP SPEED 19
  - THE WINNERS 23
- EFFICACY: THE FLAGSHIP TRIALS 26
  - THE FDA GUIDANCE 26
  - MRNA-1273-P301 28
  - C4591001 31
- EFFICACY: THE SURROGATE TRIALS 38
  - IMMUNOGENICITY: LATITUDE AND LONGITUDE 39
  - OBSERVATIONAL STUDIES AND HEALTHY VACCINEE BIAS 46
  - THE "FLU MODEL" 47

- SAFETY: THE CLINICAL TRIALS 48
  - CASE STUDY: PREGNANT WOMEN AND MRNA VACCINES 53
- SAFETY: PHARMACOVIGILANCE 60
  - POSTMARKETING STUDIES 61
  - POSTMARKETING SURVEILLANCE 65
  - VACCINE-RELATED MYOCARDITIS AND PERICARDITIS 70
  - MANUFACTURING AND DNA CONTAMINATION 105
  - RISKS AND BENEFITS OF MRNA COVID-19 VACCINES 107
- COVID-19 AND MEDIA MESSAGING 109
  - DRUG ADVERTISING 114
  - THIRD-PARTY INTERMEDIARIES 116
- CRIMINAL LAW ANALYSIS 118
- RECOMMENDATIONS 120
  - FEDERAL RECOMMENDATIONS 122
  - STATE RECOMMENDATIONS 126
  - DATA RELEASE 128
- CONCLUSION 130
- APPENDIX 1: SUBPOENA COMPLIANCE 131
- APPENDIX 2: THE IMPACT OF SCHOOL CLOSURES 135
- APPENDIX 3: PAXLOVID 138
- APPENDIX 4: GLOSSARY OF ABBREVIATIONS 140

## INTRODUCTION

COVID-19 vaccines were a triumph of science, technology and public health that saved countless lives. COVID-19 vaccines were heedlessly licensed, excessively recommended, and even mandated to broad swathes of people that did not need them, placing their health—and sometimes their lives—at unnecessary risk. Both of these statements sit on opposite ends of an ideological war that has been waged in public health, popular culture and media for the better part of the last four years. As it happens, both of these statements are true. The world's approach to SARS-CoV-2 exemplifies both the best and the worst our system has to offer. The invention, testing and licensing of these novel therapeutics required an unprecedented degree of coordination in the fields of science, engineering, politics and finance; and they produced an effective vaccine in early 2021 that dramatically reduced many of the risks associated with SARS-CoV-2.

Unfortunately, all the goodwill generated by that amazing achievement was squandered in the following years, as sponsors and federal regulators collaborated to push out booster after booster based on shallow, inaccurate safety and efficacy data, sidelining their own ombudsmen to get doses of these vaccines into the arms of every American, regardless of their underlying risk from the SARS-CoV-2 virus. Erstwhile gatekeepers became cheerleaders as federal regulators with the trust of the American people dragged their feet in publicly confirming important safety signals, and then sanctioned long delays in mandatory postmarketing studies involving those very same signals. Sponsors abused the scientific journal system and regulatory reporting requirements, delaying public disclosure of serious adverse events from their clinical trials for years. Experienced and respected scientists saw their careers turned upside down for dissenting from "the science," while experts with opinions matching those of regulators filled the gaps with contrived research and ill-conceived study designs, propagandizing citizens into believing things about the SARS-CoV-2 virus and the COVID-19 vaccines that simply were not true.

As we write this Final Report, we are keenly aware that the debate around all aspects of the COVID-19 pandemic, including vaccines, has become incredibly polarized. Given the political, social and cultural wars that have been waged over the last four years, asking those who read this document to keep an open mind is probably asking for too much. Instead, we will just say that no matter what anyone's prior opinions are regarding these issues, our findings will likely confirm some of them and debunk others. We did not draft this Final Report to win any arguments or settle any scores. Rather, this Grand Jury conducted a criminal investigation, just as we were

directed by the Florida Supreme Court. This document describes what we did, discloses what we found and provides recommendations for how to address the many acute and systemic problems that we identified in the course of that investigation. No more and no less.

We are also conscious of the fact that the COVID-19 pandemic was a dark period in our shared history. Most Floridians—and most Americans, for that matter—have moved on with their lives and would probably prefer to keep the events of those years in the rearview mirror. Any exhaustion the public feels around these issues is just as real to the members of this Grand Jury, who have all suffered some degree of personal and professional consequences for our service. Many of us took significant time off from our jobs, lost out on business opportunities, were passed over for workplace promotions and missed time with our own families. Many of us have also had to reexamine our own beliefs as a result of what we learned. It was not easy to do that, and we do not anticipate it will be easy for the public to do that either. As a body, however, we believe it is important for all of us to come to terms with what happened, and we hope that this Final Report can assist that process by shedding light on these important public health issues.

With that said, at over 140 pages, it is unquestionably a long document. Our Final Report covers a variety of issues related to COVID-19 vaccines, their history, their licensing, their efficacy, their safety and the public conversations around them. We have attempted, as best we can, to cover the issues we found in depth; but we have endeavored to explain their mechanics and their significance using language that nonscientists can understand and appreciate. If this Final Report accomplishes nothing else, we are optimistic that it can elevate the debate around the many nuanced and specific issues involving these pharmaceuticals by clearly describing and contextualizing them. Perhaps our findings and recommendations will provide a blueprint for a larger reckoning regarding the balance of power between federal regulators, public health officials, pharmaceutical sponsors and the citizens of the United States.

## OUR INVESTIGATION

Typically, reports from Statewide Grand Juries contain short introductory sections explaining their investigative efforts and detailing the sources they relied upon to reach their conclusions. In many ways, the Twenty-Second Statewide Grand Jury is unusual. We have been asked to conduct a criminal investigation into acts which largely occurred outside the State of Florida, though they clearly affected citizens from multiple judicial circuits within our state. These acts primarily involved transactions between agencies of the United States government and

multinational corporations. This was not a normal subject for a Statewide Grand Jury, and we have included a few recommendations below that are specifically designed to improve the ability of future Statewide Grand Juries to execute similar tasks in the future. In some ways, however, the Twenty-Second Statewide Grand Jury was not much different than an ordinary white-collar criminal fraud investigation: At the end of the day, it was a matter of witnesses and documents.

Our investigative efforts in both of those categories were directed in large part towards Pfizer and Moderna, whose mRNA-based vaccines were the primary focus of our investigation. We prepared a detailed summary of their cooperation, both in terms of witnesses and documents, in Appendix 1. Suffice it to say that while we are certain we have not seen everything these companies created with respect to these products (Pfizer essentially admitted this fact), we did receive a lot of relevant information from them, more than we could ever hope to meaningfully review in our limited term. Many of our conclusions are informed by documents we received or on testimony given by their representatives. We also sent long lists of detailed questions to these pharmaceutical sponsors through their attorneys, providing them with a chance to respond in every area we investigated. Where appropriate, we have included those responses in this Final Report. None of what follows should come as a shock to either of those corporations.

## Witnesses

Over the course of its eighteen-month tenure, this Grand Jury spoke to over 40 witnesses, nearly all of whom had expertise in the fields of public health policy, clinical medicine, epidemiology, virology, vaccinology, media or law. A few of the experts we spoke to were high-profile public figures. Many others had similar credentials, but less of a public profile. Not all the witnesses we invited agreed to appear. Most notably, a significant number of current or former federal officials refused to testify to us. As we mentioned previously, federal law prohibits us from compelling those officials to appear with state-level subpoenas *ad testificandum*, but we invited them all the same.

All the experts we invited to speak to this Grand Jury were offered compensation for their travel expenses and their time, which was remunerated at a rate commensurate with whatever they would have been paid in the private sector based on their qualifications and experience. This amount was considerably more than our statutory stipend of $35 per day. Most experts accepted remuneration, but some of them did not. Many of our testifying experts offered cogent, prepared, valuable insights that advanced our understanding of important issues; a few of them spewed

nonsense and wasted our valuable time. Regardless of the contents or the valence of their testimony, however, we paid them.

We consciously tried, whenever possible, to bring in experts with differing viewpoints on relevant issues, inviting them to consider counterarguments from their fellows and respond to them on the record. Many experts found this task difficult, struggling to reckon the research findings and clinical results they had been asked to examine with years of professional training and experience that had conditioned them to hold certain sources of information sacrosanct. Once those layers of presumption were removed, however, there was a surprising amount of agreement among the experts as to the data themselves. Most of the disagreements that remained concerned more nuanced issues, like how studies were structured, which data were more reliable or the meaning and importance of particular results. In areas where we could not find scientific agreement, we employed a "tiebreaker" of sorts; commissioning experienced research scientists without any background in a given area to reexamine controversial research findings and testify about the quality of the data upon which they were based. It was always a goal of this Grand Jury—and one we feel comfortable that we satisfied—to make sure we fully understood all relevant sides of each issue we analyzed before we formed our own opinion on it as a body.

**Documents**

This Grand Jury buttressed the witness testimony it received with documentary evidence. In addition to the millions of pages produced by Pfizer, Moderna and others in response to our subpoenas *duces tecum*, we collected thousands of pages of public records regarding the licensing, safety and efficacy of COVID-19 vaccines that were publicly available from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH) and other regulatory agencies. Among other things, we utilized information publicly posted on ClinicalTrials.gov, documents derived from Freedom of Information Act requests involving federal regulatory communications, sworn congressional testimony, meeting records and other data summaries we found on the webpages of these agencies.

In addition, we reviewed a large amount of published information from the private sector, including print interviews, news articles, "fact checks" and audio/video recordings appurtenant to our mandate. We also asked many of our experts to review and explain hundreds of scientific studies from a variety of journals on nearly every topic we cover in this Final Report. We often discussed the methodologies and results of these studies with multiple experts—including

qualified representatives from Pfizer and Moderna—in an effort to understand their meaning and importance. Where appropriate, we employed experts specifically to conduct meta-analyses of relevant studies or to review the data underlying meta-analyses of others.

**Currentness**

Regarding these studies, one common complaint we saw in the wake of our First and Second Interim Reports was that we did not cite or name as many of our sources as some of those who criticized our work would have preferred. There is a good reason for this. Section 905.28, Florida Statutes (2024), requires that individuals named in a Grand Jury report shall be "furnished a copy thereof and given 15 days to file with the circuit court a motion to repress or expunge the report or that portion which is improper and unlawful." This entire process acts as a stay of publication, meaning that a Grand Jury report may not be published until all pending motions to repress or expunge have been heard by the trial court and the appellate process for each of those motions has been exhausted. Often it can take anywhere from months to years for a Grand Jury report to clear these legal hurdles.

Because of Section 905.28, this Grand Jury has been intentional about individuals it has chosen to name. In our First and Second Interim Reports, we avoided the application of this statute entirely, but named less sources than we would have preferred. That made sense; our scientific analyses in those reports were all sourced from publicly available scientific studies that are not hard to find. The vast majority of these testifying experts did not produce any special or nonpublic information for us regarding risk, nonpharmaceutical interventions (NPIs), infection-derived immunity (IDI) or treatments. They only brought existing data to our attention and assisted us in understanding their meaning. This Final Report, however, is different. By necessity, it names Pfizer, Moderna and Janssen, the sponsors of the original three COVID-19 vaccines authorized for emergency use in late 2020 and early 2021. Pfizer and Moderna both independently requested that their representatives not be named in this Final Report. We have honored their request, primarily because they did not testify in their capacity as individuals, but as corporate representatives. In addition to the three sponsors, we named several other private entities including scientific journals, public figures and news agencies. Each of those entities must be provided with a copy of our Final Report and an opportunity to be heard regarding repression before the public has an opportunity to review this document.

It is possible that by the time this Final Report is made available to the public, some of the facts underlying our analysis may have changed. New information may be available. It is even possible that sponsors or regulators may act on one or more of our findings before the public even has a chance to know about the problem. Frankly, we hope that is the case. In any event, this Grand Jury today has no idea how long the publication of this Final Report may be delayed by the repression process, but it is only current as to the date it was signed. We will also never have a chance to respond to any criticisms of our work, because by the time this document is published, the Twenty-Second Statewide Grand Jury will have ceased to exist.

**OUR TASK**

By way of reminder, the Twenty-Second Statewide Grand Jury arose out of a Petition by Governor Ron DeSantis calling upon the Florida Supreme Court to impanel this body to investigate "criminal or wrongful activity in Florida relating to the development, promotion, and distribution of vaccines purported to prevent COVID-19 infection, symptoms, and transmission." That Petition contained various statements regarding attributes of COVID-19 vaccines, and the following charge:

> Questions have been raised regarding the veracity of the representations made by the pharmaceutical manufacturers of COVID-19 vaccines, particularly with respect to transmission, prevention, efficacy, and safety. An investigation is warranted to determine whether the pharmaceutical industry has engaged in fraudulent practices. The people of Florida deserve to know the truth.

(internal citations omitted). The Governor's Petition was ratified by an Order Directing Impanelment of a Statewide Grand Jury from the Florida Supreme Court, which charged this body to investigate "any offense listed in section 905.34" related to:

> Individuals, persons, and entities, including, but not limited to, pharmaceutical manufacturers (and their executive officers) and other medical associations or organizations involved in the design, development, clinical testing or investigation, manufacture, marketing, representation, advertising, promotion, labeling, distribution, formulation, packing, sale, purchase, donation, dispensing, prescribing, administration, or use of vaccines purported to prevent COVID-19 infection, symptoms, and transmission[.]

From this broad charge, we began the investigation we described above, which has produced two Interim Reports and this Final Report.

In our First Interim Report, this Grand Jury discussed our approach to this investigation, explaining that although the statements from the Governor's Petition emanated from many

different sources, were made at different times and ostensibly discussed different concepts, they all could be grouped into essentially two categories: They involved either the "safety" or the "efficacy" of the COVID-19 vaccines. Both of those concepts are important "terms of art" in pharmaceutical development, meaning their definition is slightly—but not wholly—different from their meaning in ordinary conversation. They are also inherently interrelated; what regulators may consider "safe" in the context of a therapeutic that is "effective" against a serious disease may not be considered "safe" in the case of a less serious disease or a less "effective" therapeutic. The interrelatedness of these definitions created a central conundrum for this Grand Jury: One cannot determine whether a given statement regarding the "safety" or "efficacy" of a pharmaceutical product is accurate without first understanding the risks posed by the disease that the product is designed to address. Understanding the "safety" and "efficacy" of the COVID-19 vaccines necessarily meant we had to understand the risks associated with the SARS-CoV-2 virus.

In our First Interim Report, we separated those risks into five primary categories: Infection risk, symptomatic infection (or disease) risk, hospitalization risk, death risk and long-term risk. We then went on to discuss the best available data on those risks and various factors that could modify them (either mitigating or aggravating them) at both a personal and societal level, including the most important risk modifiers of all: Age and comorbidities. We spent the remainder of the First Interim Report examining the effects and consequences of nonpharmaceutical interventions (NPIs) including stay-at-home orders, masks, social distancing and indoor air filtration. We touched briefly on the controversial issue of school closures, promising to gather "further empirical and anecdotal evidence about" this significant NPI and more deeply analyze its collateral impacts in a future presentment. That analysis has been attached to this Final Report as Appendix 2.

In our Second Interim Report, we examined two more modifiers of SARS-CoV-2 risk: IDI and the development of multi-drug treatment regimens for various stages of COVID-19 disease. We found credible research that IDI provided protection equal or even superior to that of COVID-19 vaccines, but it was routinely ignored by policymakers. Certain treatments, like hydroxychloroquine and ivermectin, were also dismissed by policymakers despite at least some evidence they could be effective and largely innocuous safety profiles. Regardless of these controversies, both IDI and effective treatments were important mitigators of the various risks associated with the SARS-CoV-2 virus. As part of our "treatment" analysis, we also examined nirmetrivir/ritonavir—more commonly known by its trade name of Paxlovid—but noted that we

were "still in the process of gathering data regarding this medication and intend to address it in the future once we have completed our investigation." That analysis has been attached to this Final Report as Appendix 3.

## UNDERSTANDING SARS-COV-2 AND INDIVIDUAL RISK

With the benefit of those prior analyses, we are now able to accurately describe several of the key features involving the primary risks associated with the SARS-CoV-2 virus. Our First Interim Report contained most of the "baseline" numbers associated with four of the five primary risks, but those numbers, by themselves, can be misleading. This brings us to the first and most important thing to understand about these risks: They are highly uneven across a variety of modifiers. An 80-year-old Californian in 2020, for example, faces dramatically different risks from SARS-CoV-2 compared to a 25-year-old Texan in 2024. Some modifiers between those two extremes can be lumped into useful categories such as viral incidence, viral virulence, age, comorbidities or the availability of effective treatments. Other modifiers, like the presence and recency of IDI, a person's lifestyle choices, living arrangements and general health status will almost certainly differ from individual to individual; and they can have a dramatic effect on the risks posed by the SARS-CoV-2 virus.

The second key feature of SARS-CoV-2 risks is that they are interrelated. Like a set of Russian nesting dolls, starting with SARS-CoV-2 infection, each subsequent risk is effectively a smaller subset of the risk above it. A subset of SARS-CoV-2 infections have symptoms, becoming "cases" of COVID-19 disease. A small subset of COVID-19 disease cases require hospitalization. And, unfortunately, a small subset of those hospitalization cases result in death. This interrelationship means that data regarding one or two outcomes are often used to infer other outcomes. IDI, which lowers infection, can be presumed to lower all "downstream risks," including disease, hospitalization and death. Outcomes can also be inferred "upstream," but the practice is less precise. As we will discuss below in this Final Report, the Randomized, Placebo-Controlled Clinical Trials (RCTs) for the COVID-19 vaccines showed that they dramatically lowered the incidence of COVID-19 disease. Would it be fair to infer solely based on those numbers that they also lowered the incidence of SARS-CoV-2 infection? Probably, but without specific data regarding that endpoint, it is difficult to infer upwards to say exactly how much and for how long.

The third key to understanding SARS-CoV-2 risks is that we do not have scientific consensus on the long-term risks of SARS-CoV-2 infection. There have been some studies looking at the incidence and burden of this phenomenon, but greater understanding has been hobbled by the lack of a consistent definition involving a reliable biomarker or test for post-acute sequelae. International health organizations have employed ***four*** different definitions for "long COVID," each with its own symptoms, time period and diagnostic criteria:

**Table 1** International health organisations' various definitions of long COVID

| Organisation | Definition |
|---|---|
| Centers for Disease Control and Prevention (CDC)[26] | 'Broadly defined as signs, symptoms, and conditions that continue or develop after initial COVID-19 or SARS-CoV-2 infection. The signs, symptoms, and conditions are present 4 weeks or more after the initial phase of infection; may be multisystemic; and may present with a relapsing–remitting pattern and progression or worsening over time, with the possibility of severe and life-threatening events even months or years after infection. Long COVID is not one condition. It represents many potentially overlapping entities, likely with different biological causes and different sets of risk factors and outcomes' |
| World Health Organization (WHO)[27] | 'The continuation or development of new symptoms 3 months after the initial SARS-CoV-2 infection, with these symptoms lasting for at least 2 months with no other explanation' |
| National Institute for Health and Care Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN) and Royal College of General Practitioners (RCGP)[28] | 'Signs and symptoms that develop during or after an infection consistent with COVID-19, continue for more than 12 weeks and are not explained by an alternative diagnosis. It usually presents with clusters of symptoms, often overlapping, which can fluctuate and change over time and can affect any system in the body. Post-COVID-19 syndrome may be considered before 12 weeks while the possibility of an alternative underlying disease is also being assessed' |
| Delphi definition for children and young people[29] | 'Post-COVID-19 condition occurs in young people with a history of confirmed SARS-CoV-2 infection, with one or more persisting physical symptoms for a minimum duration of 12 weeks after initial testing that cannot be explained by an alternative diagnosis. The symptoms have an impact on everyday functioning, may continue or develop after COVID-19 infection, and may fluctuate or relapse over time' |

These different criteria produce wildly different estimates of the incidence and burden of this condition, ranging from a low estimate of one long COVID case per thousand cases of COVID-19 disease, to a high estimate of as many as one long COVID case in five. We are not going to explore these studies further here, however, because the differences in their case definitions and methodologies make comparisons between them essentially pointless. To be clear, we believe that long COVID is a real disease with real sufferers. Large public health agencies have poured millions upon millions of dollars of research grants into the study of this phenomenon, but in what this Grand Jury sees as a case of too many dollars and not enough sense, their failure to converge around a single, reliable, testable set of criteria has effectively wasted much of that money.

## Vaccines and Risk Reduction

Just as there are prerequisites to understanding the risks posed by the SARS-CoV-2 virus, there are also some important basics about the risk reduction potential of vaccines that we will discuss in the future sections of this Final Report. There are two primary ways in which the risk reduction potential of a given therapeutic can be expressed: Absolute risk reduction (ARR) and

relative risk reduction (RRR). Each of these descriptions have strengths and weaknesses, but they both can be misleading if they are not understood and contextualized properly.

ARR starts with a numerator of people who have succumbed to some risk over a denominator of people who were susceptible to that risk (absolute risk #1), then compares that fraction to a second numerator and denominator of people who have received an intervention (absolute risk #2). The difference between the risks in those two groups is the "reduction" in ARR. Here is a simple example:

Absolute risk (without intervention): 10 cases per 100.

Absolute risk (with intervention): 2 cases per 100.

ARR: 8 cases per 100 (also expressed as "8%" ARR).

The problem with ARR is that it translates poorly across groups with differing risks. RRR on the other hand, is the pharmaceutical industry standard for expressing risk reduction precisely because it translates well across groups. Whatever the risk was for a particular group before, the intervention will lower it by the RRR percentage. In the example above, the ARR might only be 8%, but the RRR would be 80%.

Problems arise, however, when RRR is used to express risk reduction across populations with vastly different levels of absolute risk. For example, if the risk of some event was 10 per million, and that risk were reduced to 2 per million, that could still be expressed as a RRR of 80%, but it would be an ARR of 0.0008%. The difference between these two figures highlights a critical concept that RRR inherently fails to capture: The benefit of any intervention is necessarily limited by a person's absolute risk of a particular outcome. People with lower absolute risks of negative outcomes from SARS-CoV-2 will simply not be able to derive as much benefit from COVID-19 vaccines, while people at higher risk of negative outcomes will derive greater benefits. As a consequence, adverse events that might not be a concern for those who were getting a lot of benefit from a given vaccine might be more concerning if they occurred in a population that was getting very little benefit. For this reason, understanding the difference between ARR and RRR is a critical component to understanding vaccine effectiveness.

The final concept we wish to discuss in this section is that the quality of evidence supporting different types of risk reduction may vary. We touched upon this concept briefly in our Second Interim Presentment, which discussed the reliability of anecdotal evidence, observational cohort studies and results derived from RCTs in determining the efficacy of different COVID-19

treatments. It is just as relevant in determining the safety and efficacy of vaccines, where an RCT may be designed and powered to provide evidence about the reduction of a specific risk (like COVID-19 disease), but conclusions about that vaccine's ability to reduce other risks (like death) will be supported by less reliable observational studies. On the other hand, RCTs may be powered adequately to reach an answer as to a particular risk but their study protocols were not designed to capture information about that risk (like transmission). Statements about their efficacy in this regard are products of inference (less cases of COVID-19 disease will mean less transmission), which may or may not be reasonable depending on the strength of the evidence. Understanding and distinguishing between these different types of supporting data is an important part of understanding vaccine safety and efficacy.

The following sections of this Final Report will put all the concepts we discussed above to work. We will first examine the normal process of vaccine approval, then examine how that process was amended and abbreviated during the COVID-19 pandemic and how those changes affected the approval process for the COVID-19 vaccines produced by Pfizer and Moderna. We will then examine the scientific evidence supporting the efficacy and safety of these products and the claims made about them in popular media. Once that analysis is complete, we will do what we were impaneled to do: Analyze the conduct of these sponsors and related actors according to criminal law and provide a series of legislative recommendations aimed at improving the numerous problems and weaknesses we uncovered in the course of our investigation.

## VACCINE APPROVAL IN THE UNITED STATES

One of the overriding themes we will stress throughout this Final Report is that the mRNA COVID-19 vaccines were not developed, licensed and marketed in what one would consider to be the "normal" way when compared to any previous vaccines that have been developed and used in the United States. We will catalog the many major departures from "normal" throughout this report, but we want to stress that these departures did not render their development or their licensing illegal. Well before 2020, the regulatory infrastructure provided by the Public Readiness and Emergency Preparedness Act and other federal laws fostered precisely the kinds of emergency-based corner-cutting that characterized the development and licensing of COVID-19 vaccines. These procedures, in themselves, were not illegal, and they were also not violative of any fundamental rights established under the United States Constitution. To be clear, however, there is a big difference between ***licensing*** a vaccine to be administered to a broad group of people based

on limited data and ***mandating*** a broad group of people to take it. This Final Report only addresses the legality of the former, not the latter, which largely did not occur in the State of Florida. All of us, however, believe that vaccine mandates—their legality and their externalities—are worthy topics of discussion and debate. There are simply too many other topics of more immediate importance that we must cover to do justice to those issues in this Final Report.

To fully contextualize the normative departures that took place during the development, licensure and pharmacovigilance processes for MRNA-1273 and BNT162b2, it is important to first have a high-level sense of the "normal" process for vaccine development outside the context of the COVID-19 pandemic. For that, we must start with our vaccine licensing system's primary gatekeeper: The Food and Drug Administration (FDA). In the pharmaceutical industry, vaccines are one part of a larger category of therapeutics known as "biologics," which include several other products like monoclonal antibodies, immunomodulators and therapeutic proteins derived from plants, animals, humans, or microorganisms. A subcenter of the FDA called the Center for Biologics Evaluation and Research is charged with overseeing the development and licensure of all these products. Vaccines, however, are distinguishable from most every other biologic used by humans for disease treatment and prevention. Drugs and other biologics, for example, are given to people who are already suffering from a disease or condition; vaccines, by contrast, are prophylactic; they are routinely administered to people who are not sick and may never become sick. Drugs and other biologics are generally targeted at distinct groups of disease sufferers within a population. Vaccines, by contrast, tend to be broadly administered, so their approval process must often account for wide-ranging differences in the ages, genders, and health conditions of their target populations. Finally, drugs and other biologics often target conditions that are more or less stable and predictable in their burden and presentation; this may sometimes be true of vaccines where particular viruses have stable genomes, like measles, mumps or chicken pox, but RNA-transcribing viruses like SARS-CoV-2 mutate constantly, creating an unstable, moving target that could change any time before or after a vaccine is licensed.

With that said, there are some important similarities in the way the FDA treats vaccines, drugs and other biologics. The first and most important of these is that the FDA holds all of them to the same standard: Sponsors must demonstrate their products are "safe" and "effective" to be granted a license, and they must comply with whatever postmarketing requirements federal regulators set forth to maintain that license. As we discussed in our Second Interim Report,

however, regulators apply these concepts contextually. Chemotherapy drugs, for example, generally have serious side effects. They would never be considered "safe" enough to be administered to people who suffer even minor diseases, let alone healthy people. Cancer, however, is not a minor disease. If left untreated, most cancers will lead to increased suffering and death. In that context, a chemotherapy drug that is "effective" at reducing a person's overall risk of death—even one with serious side effects—may have a contextually favorable "safety" profile and could therefore be eligible for an FDA license. This type of reasoning is called a "risk/benefit analysis," and it is a concept we will revisit many times over the course of this Final Report.

The risk/benefit analysis for vaccines is not as direct a calculation as it would be for a cancer treatment, primarily because vaccines are almost always administered to healthy people who are not sick and may never get sick. This means that an individual who takes a vaccine may suffer some harm from side effects, even rare, serious side effects, but may never get the corresponding "benefit" of disease protection if they are never exposed to the disease. For this reason, a big part of the challenge in calculating the benefit of a vaccine is being able to determine the actual risk of acquiring the disease once a person is exposed to it. At an individual level, it is impossible to count a disease event that did not occur, just as it is often difficult to predict who exactly will suffer from a given side effect. Therefore risk/benefit analyses for vaccines are done at a population level, comparing disease reduction results between populations to infer "efficacy," then comparing the frequency of side effects to infer "safety." For this analysis to be accurate, the FDA and sponsors must have an accurate understanding of two things: (1) The baseline risks presented by a given disease; and (2) how often rare health events that may be associated with vaccine side effects actually occur.

## THE LICENSING PROCESS

The FDA's normal approval process for vaccines is designed to accomplish both of these ends mentioned above with the use of RCTs. These trials allow regulators to compare statistical results between an intervention group (those who received a vaccine) and a placebo group (those who did not) to determine whether the vaccine conferred a benefit, and whether some adverse outcome occurred more frequently in one of the two groups. Before a sponsor can begin an RCT, however, it must generally demonstrate promising results in "pre-clinical" trials, which principally involve animal testing and *in vitro* analysis. Once that hurdle is passed, the RCT process can begin, usually with phase one "first in human" trials primarily designed to assess the safety of a given

vaccine in a small, generally healthy denominator of participants. Assuming phase one goes well, sponsors then proceed to phase two "dose finding" trials, where various formulations of a vaccine are administered to a still small and still generally healthy population of study participants to determine what "dose" shows the most efficacy against disease while maintaining an acceptable side effect profile.

Phase three trials are where things get more mechanically, financially, and clinically serious. They are comprised of a much larger group of participants; large enough to satisfy the FDA that whatever risk reduction results or adverse events a sponsor may have reported in its phase two data were not just statistical flukes. These RCTs also tend to include participants with diverse demographic and health profiles, allowing sponsors to collect at least a modicum of safety and efficacy information for different subpopulations. The FDA communicates with sponsors and may review preliminary data throughout all clinical trial phases, but it does not actively participate in the clinical trial process. It is only at the conclusion of phase three trials that the FDA receives the full RCT results from all phases in the form of a Biologics License Application (BLA). The FDA independently reviews the sponsor's BLA and prepares a summary of sponsor's results for presentation to the Vaccines and Related Biological Products Advisory Committee (VRBPAC), a group of independent experts which meets periodically to determine various questions involving the safety and efficacy of new biologics. At a public meeting, the FDA and the sponsor both present their respective summaries of the RCT data and provide representatives to answer questions from the expert panel regarding all aspects of a candidate vaccine. These meetings also include a period for public comment, and they culminate in a vote by VRBPAC experts as to how to answer whatever question was posed for their consideration by the FDA. The FDA then considers the VRBPAC's vote, but ultimately decides on its own if a given vaccine is "safe" and "effective," so as to merit a license allowing it to be used in the United States. The FDA issues many types of licenses, but for the purposes of this Final Report, only two are important: "Full Approval" and "Emergency Use Authorization" (EUA).

We will explore some of the differences between these two types of licenses below, but they are similar in some fundamental ways. Most importantly, neither an EUA or a Full Approval ends the responsibilities of the sponsor as to a given vaccine. To maintain these licenses, sponsors must continue to engage in a series of pre-agreed postmarketing commitments. In this Final Report, we will focus on two important categories of postmarketing commitments related to vaccine safety

and efficacy: Postmarketing studies, a series of clinical trials or observational studies designed to elucidate lingering questions about safety or efficacy of a given vaccine; and postmarketing surveillance, the monitoring, collection, and assessment of vaccine side effects that may occur too infrequently to be detected in the RCT process. This latter process, known in the industry as "phamacovigilance," requires sponsors to accept reports of adverse events involving their product from a variety of sources and to have systems and protocols in place to capture potential "safety signals," statistical elevations of a given medical event that may be a cause for concern.

The FDA also conducts its own pharmacovigilance of vaccines, primarily utilizing two data sources: The Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD). VAERS is a self-reporting system which is most often utilized by medical professionals, but ultimately can be populated by anyone willing to provide information. VSD, by contrast, is:

> a collaborative project between CDC's Immunization Safety Office and healthcare organizations across the United States. Established in 1990, the VSD monitors the safety of vaccines and conducts studies about rare and serious adverse events following immunization.

VSD's dependence on healthcare organization records for safety signal detection is not perfect, but it tends to be more statistically reliable than the self-reporting VAERS system, which is primarily utilized to detect signals, not necessarily to reach statistical conclusions as to their frequency. When safety signals are identified and confirmed, regulatory authorities must decide how to handle them to best protect the health of the public. As we will discuss further below in this Final Report, some safety signals may be addressed by something as simple as a public warning, while others may require amendment, suspension or even outright revocation of the FDA license.

## THE BENEFITS OF LICENSURE

Full Approvals and EUAs for vaccines both confer substantial benefits to sponsors. First, unlike most consumer products, the makers of FDA-approved vaccines are largely immune from lawsuit. The source of this immunity is a federal law, 42 U.S.C. Section 300aa-22(b), which sets forth the following limitations on liability for vaccine manufacturers:

> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

> (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine . . . .

There is also a more specific statutory grant of immunity that applies to mRNA COVID-19 vaccines because they qualify as "covered countermeasures" under 42 U.S.C. Section 247d–6d(a)(1), which sets for that that:

> a [sponsor] shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration [of public health emergency] has been issued with respect to such countermeasure.

The statutory immunity above does nothing to change the underlying facts that gave rise to the lawsuits in the first place: Vaccines, even those that are considered "safe and effective," do occasionally cause injuries and deaths. To redress those adverse outcomes, the federal government administers two taxpayer-sponsored "programs" that provide individuals a narrow route to recover some compensation for injuries caused by vaccines. The first of these is called the Vaccine Injury Compensation Program (VICP), which was set up in 1986 to provide an avenue of relief for people with certain qualified injuries caused by vaccines listed on its registry—a list which, to date, ***does not*** include COVID-19 vaccines. The second "program" is the Countermeasures Injury Compensation Program (CICP), which provides an avenue for relief to anyone who sustained a "serious injury" or died from using any "covered countermeasure" administered or used pursuant to a public health emergency—a category which ***does*** include COVID-19 vaccines.

The degree of immunity described above is unique in the world of personal injury law. It does not apply to other products like cars, toasters, toys or even ordinary drugs. Congress's stated reason for this unique legal status is that vaccines are good for public health, and that research, development and distribution within this arena must be encouraged and conducted by pharmaceutical manufacturers without fear of excessive litigation. There are several inherent problems with this system. First, plaintiffs claiming to have been injured by a vaccine are only allowed under the VICP or CICP to recover based on a predefined set of identified injuries. For other kinds of injuries that occur outside this predefined category, claimants must show

"compelling, reliable, valid, medical and scientific evidence" that the injury was caused by the vaccine, but they do not have the benefit of a traditional, legal discovery process to find out how much a sponsor may know about the frequency or severity of these other kinds of injuries. Second, ***taxpayers, not sponsors***, must fund whatever injury-related payouts arise from both the VICP and CICP. The whole point of tort law is that the threat of financial liability will force those who offer products and services to conform their conduct to avoid unnecessary risk of injury. A taxpayer-funded system of recovery completely undermines this incentive.

Finally, the entire federal legal structure effectively preempts individual, personal state-level claims for relief, meaning that regardless of what any state government might believe or uncover regarding the safety and efficacy of a given vaccine, it is powerless to outright ban its use. Similarly, injured persons cannot utilize state law to circumvent the federal framework. This means that in a very real sense, our entire system of vaccine safety is built around the presumption that a small group of federal regulators are wholly responsible for ensuring the citizens of the United States that risks associated with vaccines are acceptable; and this same small group of regulators is also responsible for alerting people of health problems that may arise in vaccines it has already approved. Meanwhile, the manufacturers of these vaccines are fully insulated from any financial liability, and persons who experience adverse effects can only seek redress through a limited and highly bureaucratic federally-controlled program. As insular and limited as that may seem, this is the current design of our system.

## OPERATION WARP SPEED

On June 6, 1966, Senator Robert F. Kennedy gave what is largely regarded as the greatest speech of his career to a group of Students at the University of Cape Town, South Africa. The "Ripple of Hope" address, which compared the struggle against the then-apartheid conditions in South Africa to the Civil Rights Movement in the United States, contained the following passage:

> There is a Chinese curse which says, 'May he live in interesting times.' Like it or not, we live in interesting times. They are times of danger and uncertainty; but they are also the most creative of any time in the history of mankind.

As an aside, the provenance of this phrase as a "Chinese curse" is sketchy at best. It likely had its origins among British diplomats in the 1930s; but the underlying message—what one sensed in the moment as "danger and uncertainty" may be perceived by those after the fact as "interesting"—was as compelling in 1966 as it is today. By historical standards, the COVID-19 pandemic was

certainly an "interesting time." All of our lives were turned upside down and even the most basic of activities became burdensome chores. A task as pedestrian as buying groceries, for example, became an organizational exercise in determining hours of operation and considering wait times while avoiding prohibitively large crowds and one-way only aisles in stores. Even after those primary issues were sorted, there were still logistical hurdles like deciding which mask to wear, calculating the expected restocking schedule that would result in the highest chance of success and working the entire event into the family's new stay-at-home work and educational schedules.

All of this occurred against a backdrop of near-constant, often-histrionic reports of rising cases, hospitalizations and deaths associated with the SARS-CoV-2 virus. We have discussed the underlying risks posed by the COVID-19 pandemic at length in our prior reports. We do not wish to be perceived as dismissive of those risks, which were real and serious, but we do wish to emphasize that much of the reporting around those risks—especially the reporting occurring in 2020—was oversimplified, inaccurate and did little to adequately inform citizens as to the state of good science around SARS-CoV-2's actual incidence and disease burden. We discuss below how distorted science, politics and financial interests rode our nation's real fears, uncertainties and anxieties about COVID-19 disease. They infiltrated the vaccine development cycle, shaping and limiting available information about vaccine efficacy while studiously avoiding conversations about real and significant risks associated with these products. While that should not cause us to lose sight of the substantial, beneficial impact these products had for the most at-risk segments of our population, we return to the maxim that two things can be true: (1) COVID-19 vaccines offered dramatic risk-reduction benefits to substantial portions of our population and saved countless lives; and (2) COVID-19 vaccines were approved, recommended, and sometimes even mandated for substantial portions of our population who were not at high risk for complications from the SARS-CoV-2 virus. Regulators and prominent public health experts have repeatedly told us over the past three years that we needed to accept the latter to achieve the former. We disagree.

To the extent that the COVID-19 pandemic was an "interesting time," it would also be fair to say that Operation Warp Speed (OWS) was an "interesting" response. Almost immediately after the beginning of the pandemic came the hue and cry for a medical remedy—a vaccine—which was routinely described in the media and by government public health experts in 2020 as the best and most desirable solution to threats posed by the SARS-CoV-2 virus and our "way out" of the COVID-19 pandemic. The focus of the entire world shifted to the development process of

candidate vaccines. This should not have been surprising, given our society's expectations about the role that medical technology should play in their lives. With the president and prominent scientists on board, the media sensationalized the pace of vaccine development, creating celebrities out of regular participants in the drug approval process. Physicians, researchers and regulators were thrust into the limelight, making regular appearances on major news networks to elucidate details or explain away concerns. Scores of clinical trials were closely tracked by major newspapers, and pharmaceutical company representatives were routinely interviewed by major media outlets as their stocks soared in value. The president and his senior public health leaders spoke daily about the progress being made to develop a vaccine. Much of this activity was completely foreign in the history and scientific process of vaccine approval, even in the pharmaceutical-friendly United States.

From the very beginning, the United States Government, *vis a vis* the Trump Administration, was heavily involved in setting up OWS, which was described by the Congressional Research Service (CRS) as:

> [A]n interagency partnership between the Department of Health and Human Services (HHS) and the Department of Defense (DOD) that coordinates federal efforts to accelerate the development, acquisition, and distribution of COVID-19 medical countermeasures. Collaborating HHS components include the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA).

OWS was authorized to spend taxpayer funds in a number of areas related to the pandemic, but most importantly for the purposes of vaccines, it provided two critical funding streams: (1) it offered pharmaceutical sponsors "development money" to assist in the formulation and testing of candidate vaccines; and (2) it provided a series of lucrative guaranteed contracts to pharmaceutical sponsors who were able to produce an FDA-licensed product. According to CRS, here is how that money had been spent as of March 1, 2021:

**Table 1. Vaccine Candidates Supported by BARDA and Other Federal Agencies**

| Company | Type | Contract Value | Specifications | Doses per Person | Current Phase (Preliminary Effectiveness – U.S. Strain)[a] | Storage |
|---|---|---|---|---|---|---|
| Pfizer/BioNTech | mRNA[b] | $5.97B | 300 million doses | 2 | Phase II/III (95%) EUA Issued | Ultra cold storage (-70° C) |
| Moderna | mRNA | $4.94B<br>$954M | 300 million doses<br>Development | 2 | Phase III (94.5%)<br>EUA Issued | Cold storage (6 mos. -20° C)<br>Refrigerator (30 days, -2° to -8° C) |
| AstraZeneca/ Oxford Univ. | Viral Vector[c] | $1.2B | 300 million doses | 2 | Phase II/III (70%) | Refrigerator (-2° to -8° C) |
| Johnson & Johnson (Janssen Pharmaceuticals) | Viral Vector | $1B<br>$456M | 100 million doses<br>Development | 1 | Phase III (72%)<br>EUA Issued | Refrigerator (3 mos. -2° to -8° C) |
| Novavax | Protein[d] | $1.6B | 100 million doses | 2 | Phase III (95.6%) | Refrigerator (-2° to -8° C) |
| Sanofi/GSK | Protein | $2.04B<br>$30.8M | 100 million doses<br>Development | 2 | Phase I/II | Refrigerator (-2° to -8° C) |
| Merck/IAVI[e] | Viral Vector | $38M | Development[f] | 1 | DISCONTINUED | N/A |

These financial incentives set up a "derby" of sorts. Sponsors who were able to shepherd their candidate vaccines through the clinical trial process quickly would be able to reap the benefit of these initial guaranteed contracts, which would more than cover their development costs (even in cases where a sponsor did not receive development money). Beyond that, however, there was also the obvious potential of follow-up contracts. 300 million doses at two required doses per person would cover just under half of Americans. And of course, there was a whole world beyond the United States that would potentially be interested in acquiring these vaccines.

The EUA "finish line" for the vaccine development derby was described by the FDA in an important—but often overlooked—document called *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* ("the Guidance" or "the FDA Guidance"). There, the FDA set forth a series of "nonbinding recommendations" for sponsors participating in the OWS vaccine development process. These "nonbinding recommendations," which we will discuss below, described the FDA's preferences for various aspects of COVID-19 vaccine clinical trials including primary endpoints, cohort size, trial length and many other specifics. It also contained the following instructions:

> An Emergency Use Authorization (EUA) may be issued only after several statutory requirements are met. Among these requirements is a determination by FDA that ***the known and potential benefits of a product, when used to diagnose, prevent, or treat serious or life-threatening diseases, outweigh the known and potential risks of the product.***

> . . . . [F]or a vaccine for which there is adequate manufacturing information, issuance of an EUA may be appropriate once studies have demonstrated the safety and effectiveness of the vaccine but ***before the manufacturer has submitted and/or FDA has completed its formal review of the biologics license application***.
>
> In the case of investigational vaccines being developed for the prevention of COVID-19, any assessment regarding an EUA would be made on a case by case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the ***totality of the available scientific evidence relevant to the product***.

(internal citations omitted) (emphasis added). This was the state of play between sponsors and regulators in 2020. Effectively, the criteria above were the only thing that stood between sponsors and billion-plus dollar contracts for the distribution of their products, not to mention the adulation of a grateful nation. The FDA was also moving with abnormal speed. We know this because representatives of both Pfizer and Moderna described a previously unseen degree of cooperation, communication and flexibility from FDA officials throughout the development process for their COVID-19 vaccines. They also described prompt turnaround regarding their development milestones and rapid responses from agency officials regarding any questions that arose in the clinical trial process.

By itself, this made sense. OWS was a government-wide effort to reduce whatever rules or financial barriers stood in the way of the fast development of COVID-19 vaccines, which was the national priority. Society was focused on the singular goal of limiting loss of life and negative outcomes from the SARS-CoV-2 virus. The FDA and the sponsors, in that regard, were no different. Many compromises were made in that process, and while it is important to understand how those compromises shaped what was to come, this Grand Jury does not see the legal mechanics or the abbreviated clinical trial processes or the massive taxpayer-funded expenditures that arose out of OWS as altogether unreasonable given the character and perceived scope of the threat of SARS-CoV-2 at the time. ***We were at war.***

**THE WINNERS**

In every race, there are winners and there are losers. The vaccine "derby" created by OWS was no different. In late 2020 and early 2021, three primary contenders emerged from the clinical trial process and were able to cross the EUA "finish line": Pfizer's BNT126b2, known by its trade name of "Comirnaty"; Moderna's MRNA-1273, known by its trade name of "Spikevax"; and Janssen's AD26.COV2.S, known by its trade name of "Jcovden." Both BNT162b2 and MRNA-

1273 employed novel, mRNA-based platforms that had not previously been tested in large-scale clinical trials, while Jcovden employed a more familiar adenovirus-based "viral vector" platform. Pfizer's BNT162b2 was first to achieve EUA on December 11, 2020. Moderna's MRNA-1273 was seven days behind, achieving its EUA on December 18, 2020, and Janssen's AD26.COV2.S would not achieve its EUA until February 27, 2021. Each of these companies had unique attributes that enabled it to quickly develop its candidate product and matriculate it efficiently through the clinical trial process. Although our report focuses primarily on the mRNA COVID-19 vaccines produced by Pfizer and Moderna, we have included Janssen and AD26.COV2.S because it is useful as a comparator, especially with respect to vaccine safety signals, which we will discuss at length in later sections of this Final Report.

**Pfizer**

Pfizer is a large, multinational corporation with a wealth of experience shepherding new drugs and biological products through government approval processes around the world. This expertise often finds Pfizer either partnering with or licensing patented medical technologies from smaller firms and applying its own substantial expertise to guide those technologies to market. This is exactly what happened in 2020. Pfizer had an existing partnership with German pharmaceutical company BioNTech to produce an mRNA-based flu vaccine which could be quickly reoriented to produce candidate vaccines that were likely to be effective against COVID-19. After negotiating and signing a profit-sharing partnership with the smaller firm, Pfizer was able to immediately begin preclinical testing of candidate vaccine formulations and "ramp up" for human trials within a few months, giving it a substantial edge over other sponsors.

Pfizer's expertise and involvement in our healthcare system, however, does not end with the development, approval and marketing of new drugs and biologics. It is also an active player in the legislative space. Either by lobbying on its own or through one of many third-party advocacy groups representing the interests of pharmaceutical companies, Pfizer has had a substantial hand in shaping the law that undergirds the vaccine approval landscape we see today, just as it has had a hand in influencing many aspects of our modern healthcare system. Pfizer also reinvests a substantial portion of its revenue into third party grants for the research and development of technologies that may one day lead to new products; and into reputational initiatives, sponsoring countless events and conferences designed to address all manner of health-based topics, from vaccine law to journal publishing.

Even for an industry giant like Pfizer, BNT162b2 was a major boon. Pfizer did not accept OWS development money, but it was able to negotiate a rate of $19.50 per dose for its first 100 million doses, and it has been selling BT162b2 formulations in the United States and all over the world ever since. As of late 2023, the company's net revenue attributable solely to BNT162b2 was roughly $86 billion and climbing.

**Moderna**

In contrast to Pfizer, Moderna is a small company that has focused exclusively on developing therapeutics utilizing its mRNA platform since its founding in 2010. As of 2020, however, Moderna had not yet brought any of its mRNA-based products to market. The closest it had come was a phase two trial for a vaccine designed to prevent microcephaly associated with the Zika virus. Nonetheless, like Pfizer, Moderna found itself in the unusual position; it had a deep institutional understanding of mRNA technology which would quickly be reoriented towards a vaccine designed to be effective against COVID-19. Unlike Pfizer, however, Moderna needed help steering its candidate vaccine through the approval process. It accepted both OWS development money and assistance in its clinical trials from regulatory agencies like BARDA. Moderna's representative characterized its financial arrangement with these agencies as follows:

> It depends. Over all of the life of the contract, I can't tell you that. I don't know that number. What I can kind of directionally frame for you, though, is ***those early studies to receive a primary license in adults was nearly fully reimbursed by BARDA. So with allowable costs, roughly, 100% is kind of directionally where we would be.*** As we started to move into pediatrics, for the work that was within the initial proposal, we introduced cost sharing. So on an individual study, that might look like 30% for a study that was a few hundred million dollars.

(emphasis added).

If BNT162b2 was a financial boon to Pfizer, MRNA-1273 literally made Moderna the company it is today. The Moderna of 2019 was funded primarily by agencies within the United States Government and had been quietly researching the viability of its novel mRNA platform against various diseases for nine years without bringing any product to market. The Moderna of 2020 signed an OWS contract pricing MRNA-1273—a vaccine whose development had been fully funded by taxpayers—at $15.25 per dose for 100 million doses, with the option to purchase an additional 400 million at the discretion of the United States government. The Moderna of 2024 saw net revenues of over $42 billion based almost solely on sales of MRNA-1273. Only in 2023 did the company finally get a second drug approved: An mRNA-based RSV vaccine. According

to Moderna's representative, as of August, 2024 it had 53 candidate products in development, all based on the mRNA platform.

## Janssen

Because our investigation focused primarily on statements surrounding the safety and efficacy of mRNA vaccines, we did not devote much of our efforts to the AD26.COV2.S adenovirus vaccine, but the initial success of its viral vector-based formula merits its inclusion in this section—if only as a comparator. Janssen, a subdivision of pharmaceutical giant Johnson & Johnson, also used taxpayer-funded resources to fund the development of AD26.COV2.S, a single-dose vaccine which it agreed to sell to the United States Government at an initial rate of roughly $10 per dose for a total of 100 million doses. AD26.COV2.S was given an EUA in early 2021, but unlike MRNA-1273 and BNT162b2, it never achieved Full Approval. We did not speak directly to a representative from Janssen, but publicly available reports placed its total AD26.COV2.S-related revenue at roughly $2.4 billion by the end of 2021, far behind Pfizer and Moderna. That gap would only increase as a series of well-publicized issues ultimately derailed public interest in Janssen's product, leading it to withdraw its regulatory application for Full Approval in 2023.

## EFFICACY: THE FLAGSHIP TRIALS

As befits a once-in-a-hundred-year pandemic, the first clinical trials of COVID-19 vaccines conducted in the wake of the OWS contract derby departed in many ways from the ordinary vaccine approval process described above. Some of those departures were understandable given the extraordinary nature of the crisis, some of them less so. By another axis, some of these departures resulted in relatively little loss of safety or efficacy data, but others had catastrophic and long-term consequences for our understanding of the ability of these mRNA vaccine products to mitigate risks associated with SARS-CoV-2 infection. For discussion purposes, however, there is a clear dividing line between the era of the "flagship" trials, which occurred in 2020 and early 2021, and the era of "surrogate" trials that began in 2021 and continues today. Both of the trials we analyze in this report have rather utilitarian names that belie their immense importance. Moderna's flagship trial of MRNA-1273 (Spikevax) is known as MRNA-1273-P301, and Pfizer's flagship trial of BNT162b2 (Comirnaty) is known as C4591001.

## THE FDA GUIDANCE

Before we examine the events of these flagship trials, however, it is necessary to provide some context to their design. Importantly, however, many aspects of that design did not originate

with the sponsors; they came from the FDA Guidance, a detailed and comprehensive series of "nonbinding recommendations" meant to "reflect the Agency's current thinking" on every aspect of COVID-19 vaccine development and manufacturing. Many areas of the Guidance are relevant to this Report, and a few of its recommendations do a great deal to elucidate the "whys" behind decisions made in the flagship clinical trials.

One of the very first subjects the Guidance addresses is the type of trials FDA would consider appropriate to determine the safety and effectiveness of candidate COVID-19 vaccines, describing the Agency's position as follows:

> This guidance describes FDA's current recommendations regarding the data needed to facilitate clinical development and licensure of vaccines to prevent COVID-19. There are currently no accepted surrogate endpoints that are reasonably likely to predict clinical benefit of a COVID-19 vaccine. Thus, at this time, the goal of development programs should be to pursue traditional approval via direct evidence of vaccine safety and efficacy in protecting humans from SARS-CoV-2 infection and/or clinical disease.

With respect to trial design, the Guidance goes on to explain that "[l]ater phase trials, including efficacy trials, should be randomized, double-blinded, and placebo controlled" with "1:1 randomization between vaccine and placebo groups" and a primary endpoint of "[e]ither laboratory-confirmed COVID-19 or laboratory-confirmed SARS-CoV-2 infection." It further lays out that "severe COVID-19 should be evaluated as a secondary endpoint . . . if not evaluated as a primary endpoint[,]" and that even where it was not the primary endpoint, SARS-CoV-2 infection should, at the very least, "be evaluated as a secondary or exploratory endpoint[.]" With respect to cohort size and composition, the Guidance stressed that:

> To generate sufficient data to meet the BLA approval standard, late phase clinical trials to demonstrate vaccine efficacy with formal hypothesis testing will likely need to enroll many thousands of participants, including many with medical comorbidities for trials seeking to assess protection against severe COVID-19.

At various points, the Guidance further expressed the FDA's preference—where possible—to find ways to test the efficacy of COVID-19 vaccines in many other categories of potentially vulnerable participants, including the elderly, pregnant women and children.

The Guidance also contemplated a successful vaccine candidate as one with a "primary efficacy endpoint point estimate for a placebo-controlled efficacy trial [of] at least 50%[,]" but cautioned that:

> Follow-up of study participants for COVID-19 outcomes (in particular, for severe COVID-19 disease manifestations) should continue as long as feasible, ideally at least one to two years, to assess duration of protection and potential for vaccine-associated [enhanced respiratory disease] as immune responses to the vaccine wane[.]

In seeming contradiction of the two-year trial length advocated above, however, the Guidance further opined that:

> Efficacy trials should include contingency plans for continued follow up and analysis of safety and effectiveness outcomes in the event that a safe and effective vaccine becomes available (e.g., as demonstrated in a planned interim analysis or as demonstrated in another clinical trial). In that case, discussion with the agency may be necessary to address ethical arguments to break the blind and offer vaccine to placebo recipients.

This last paragraph previewed the effective ends of the flagship trials that would occur in 2021, but one of the most interesting things about the Guidance is how a document that completely escaped public debate, discussion and notice in 2020 was so instrumental in shaping what many consider some of the more egregious shortcomings regarding the RCTs of mRNA COVID-19 vaccines.

**MRNA-1273-P301**

Moderna commenced its MRNA-1273-P301 clinical trial (hereinafter "P301" or the "P301 trial") on July 27, 2020, quickly recruiting an initial cohort of 30,420 participants aged 18 and above, taking care to exclude certain categories of participants like pregnant women, individuals with prior SARS-CoV-2 infections or the immunosuppressed. This initial cohort was randomly divided into equal intervention and placebo groups of 15,210. As their names suggest, these two groups were to receive either two doses of MRNA-1273 or two doses of placebo spaced 28 days apart. The trial was also double-blinded, meaning that as the doses were being administered and results were being recorded, neither the participants nor the investigators knew who had received MRNA-1273 and who had received the placebo. P301 recorded all the standard safety endpoints, and it also featured four secondary endpoints related to serology, which would become highly significant to later trials of MRNA-1273.

As its primary clinical efficacy endpoint, P301 assessed the "[n]umber of Participants with a First Occurrence of COVID-19 Starting 14 Days after Second Dose of mRNA-1273." Importantly, this industry-standard language (referred to in clinical trial parlance as a "per

protocol" analysis) meant that for purposes of assessing this endpoint, any COVID-19 cases that occurred between the first and second doses were excluded, as were any COVID-19 cases that occurred within 14 days of the second dose. There were also several secondary clinical endpoints, notably including endpoints related to other SARS-CoV-2 risks like severe COVID-19 and SARS-CoV-2 infection. Nearly all these efficacy endpoints had similar language excluding any cases that occurred within 14 days of a second dose of either placebo or MRNA-1273.

With respect to timing, P301 was designed—per FDA's own guidance—as a two-year-plus RCT. This fact was well-understood by the trial participants, who all signed an informed consent document that clearly required a 25-month commitment. However, it was also understood between Moderna and the FDA that upon the accrual of at least 151 total COVID-19 cases in the placebo and MRNA-1273 cohorts combined, Moderna would assess the efficacy results; and should those results exceed the target RRR of 50%, Moderna would apply forthwith for an EUA of MRNA-1273. Importantly, however, as we mentioned above, ***the FDA Guidance explicitly stated that a grant of EUA would not end the clinical trial.***

Moderna met its 151-case target and applied for EUA on November 30, 2020, and the results as to the primary clinical efficacy endpoint were well above the 50% efficacy threshold required to secure EUA. A VRBPAC meeting was scheduled on December 17, 2020, where the expert panel was presented with a single question: "Based on the totality of scientific evidence available, do the benefits of the Moderna COVID-19 Vaccine outweigh its risks for use in individuals 18 years of age and older?"

After a lengthy discussion involving VRBPAC members, FDA officials, Moderna representatives and the public, the VRBPAC voted 21-0, with one abstainer, to answer the FDA's question in the affirmative. The FDA authorized MRNA-1273 on December 18, 2020. On February 4, 2021, Moderna shared some of the details regarding P301 with the broader scientific community in a New England Journal of Medicine (NEJM) article entitled *Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine*. This article walked its primary audience of interested doctors and research scientists through some of the available data from P301, most notably the topline RRR of 94.1% as to the primary clinical endpoint (shortened in this publication to "vaccine efficacy"). This percentage was derived from the ratio of 185/14,073 COVID-19 cases in P301's placebo group to 11/14,134 COVID-19 cases in P301's intervention group. In terms of absolute

risk, MRNA-1273 lowered the incidence of COVID-19 disease occurring more than 14 days after the second dose from 1.315% to 0.078%, an ARR of 1.237%.

The article also highlighted a significant reduction in severe COVID-19 cases occurring more than 14 days after a second dose of MRNA-1273, with 30 cases occurring in the placebo group and zero in the intervention group. In terms of the absolute risk, this is a reduction of a 0.21% chance of developing severe COVID-19 to an effective rate of 0.00%. Of those 30 severe COVID-19 cases, only one resulted in a COVID-19-related death. All these impressive statistics must be contextualized, however, by fact that the surveillance period during which they accrued was roughly 120 days. Indeed, the study's authors identified the "short duration of safety and efficacy follow-up" as a "key limitation" of the results, noting that "[t]he trial is ongoing, and a follow-up duration of 2 years is planned, with possible changes to the trial design to allow participant retention and ongoing data collection."

This, of course, was not how events unfolded. After the EUA was approved, the P301 protocol was amended in two critical ways. First, the trial was "unblinded," meaning that all participants were informed whether they had received MRNA-1273 or a placebo. Second, participants who had received a placebo in what was now called "Part A" of P301 were offered two doses of MRNA-1273 in what would now be called "Part B." Ultimately, the placebo group shrunk from roughly 14,000 participants to 2,500, all unblinded. Although P301 did in fact continue until December 29, 2022—surveilling participants in "Part B" and even administering over 19,000 booster doses as "Part C" in late 2021 and early 2022—the "randomized, controlled trial" and its attendant stream of unimpeachable, reliable clinical data had effectively ended.

In September of 2021, the NEJM published a second article detailing the findings of P301, *Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase*. This time, the median follow-up period for trial participants was 5.3 months, an average of roughly 41 additional days from the results described in the previous article. In that period, RRR in COVID-19 disease beginning 14 days after the second dose (or "vaccine efficacy") dipped slightly to 93.2% based off of 55/14,287 confirmed cases in the intervention group compared to 744/14,164 confirmed cases in the placebo group. Severe COVID-19 results also dipped slightly from 100% to 98.2% based on 2/14,287 in the intervention group compared to 106/14,164 in the placebo group. This article also included results for the secondary endpoint of SARS-CoV-2 infection with or without symptoms beginning 14 days after the second injection, with 280/14,287 infections in the

intervention group compared to 1,339/14,164 in the placebo group. P301's data on death risk reduction did not come anywhere near statistical significance, with 16 all-cause deaths in both the placebo and intervention groups. According to the article, four of those deaths were attributable to COVID-19; three of them came from the placebo group. The final death came from an intervention group participant who only received a single dose and therefore did not complete the "protocol." We searched through the records and found the narrative from this event, which involved a 74-year-old male who declined a second dose of MRNA-1273 after experiencing nausea and fatigue in the wake of his first. 119 days after receiving that first dose, he experienced symptoms of COVID-19. He died 56 days later.

**C4591001**

Pfizer commenced C4591001 (hereinafter "1001" or the "1001 trial") in April of 2020 as a phase one & two "dose-finding" study, testing various configurations and strengths of its BNT162b2 formula. Once the researchers settled on a regimen (two doses of BNT162b2 at 30μg, spaced 21 days apart), 1001 entered phase three, quickly recruiting a total participant cohort of over 43,000. Initially, the trial was limited to ages 18-85, but in September of 2020, the minimum participant age was lowered to 16; less than a month later, in October, the age range was lowered again to a minimum of 12, where it remained for the duration of the study. Like P301, the 1001 trial excluded pregnant women, individuals with prior SARS-CoV-2 infections and some types of immunosuppressive conditions or medications. Trial participants were randomized to two groups of roughly equal size and were administered either two doses of BNT162b2 or two doses of placebo. Like P301, participants in the 1001 trial were blinded, meaning they did not know whether they had received the intervention.

For its primary clinical endpoint, the 1001 trial chose "confirmed COVID-19," limiting its "per protocol" analysis to cases occurring seven days or more after administration of the last dose of the series. Like P301, 1001 also included an array of safety-related primary endpoints. Secondary clinical endpoints included severe COVID-19 seven days after administration of the second dose and six separate outcome measures related to serology.

The timing of 1001 was virtually identical to that of P301, featuring the same two-year time frame and the same understanding that upon the accrual of 151 total COVID-19 cases meeting its primary endpoint, Pfizer would assess its efficacy results and apply for EUA if those results exceeded a RRR target of 50%. Pfizer also built into its 1001 protocol an opportunity to "peek" at

the data at various predefined points to see how the case split was coming together, offering some advance insight as to whether its numbers were inching toward success or failure.

Pfizer met its 151-case target and submitted its application for EUA on November 20, 2020. Like MRNA-1273, BNT162b2's results as to its primary clinical endpoint were well above the 50% efficacy minimum. A VRBPAC meeting was held on December 10, 2020, where the expert panel was presented with the following question: "Based on the totality of scientific evidence available, do the benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its risks for use in individuals 16 years of age and older?"

After a lengthy discussion involving VRBPAC members, FDA officials, Pfizer representatives, guest speakers and the public, the VRBPAC ultimately answered the FDA's question in the affirmative by a vote of 17-4, with one abstainer. The FDA granted EUA to BNT162b2 on December 11, 2020. On the last day of the year, December 31, 2020, Pfizer shared some of the results of the 1001 trial in a NEJM article entitled *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine*. Once again, the most notable finding was that BNT162b2 was "95% effective" at reducing the incidence of COVID-19 disease as measured seven days after the second injection of BNT162b2, with 8/18,198 cases occurring in the intervention group compared to 162/18,325 in the placebo group. Stated in terms of ARR, BNT162b2 reduced the incidence of COVID-19 disease from 0.88% in the placebo group to 0.04% in the intervention group (a reduction of 0.84% over the surveillance period).

Compared to P301, there were less severe cases overall in the 1001 trial, with only 10 total occurring, even when the participant population was broadened to include people who only received one injection of BNT162b2; nine of those ten cases occurred in the placebo group. This is not a statistically significant finding, but it would be fair to infer from this number that BNT162b2 was having some positive effect on the incidence of severe COVID-19 disease and that a longer trial period with more severe cases would be likely to reach the bar for statistical significance. Six total deaths were reported—two in the BNT162b2 group and four in the placebo group—but none of them were related to the study intervention or to COVID-19 disease.

Once again, all these results must be contextualized by the short surveillance period, which the study authors identified as a key limitation of the impressive data 1001 had generated for BNT162b2, stating:

> This report includes 2 months of followup after the second dose of vaccine for half the trial participants and up to 14 weeks' maximum follow-up for a smaller subset. Therefore, both ***the occurrence of adverse events more than 2 to 3.5 months after the second dose and more comprehensive information on the duration of protection remain to be determined***.

(emphasis added). These study authors, however, appeared to be more in the loop than Moderna's study authors, delivering the news then and there to the broader scientific community that:

> Although the [1001] study was designed to follow participants for safety and efficacy for 2 years after the second dose, given the high vaccine efficacy, ethical and practical barriers prevent following placebo recipients for 2 years without offering active immunization, once the vaccine is approved by regulators and recommended by public health authorities. Assessment of long-term safety and efficacy for this vaccine will occur, but ***it cannot be in the context of maintaining a placebo group for the planned follow-up period of 2 years*** after the second dose.

(emphasis added). We read this language as a tacit admission that the change in protocol would hobble Pfizer's ability to assess the long-term safety and efficacy of BNT162b2. Like P301, the 1001 trial continued for years after 2020, administering a booster to trial participants and only sunsetting in February of 2023, but its status as a gold-standard "randomized, placebo-controlled trial" ended once its protocol was amended.

There was also a second article in NEJM, *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months*, detailing the available results prior to the unblinding of the 1001 study. This longer surveillance period saw a lowering of topline effectiveness against the incidence of COVID-19 disease from 95% to 91.3% based off of 77/20,998 cases in the BNT162b2 group compared to 850/21,096 cases in the placebo group. Stated in terms of absolute risk, the intervention lowered the incidence of COVID-19 from 4.03% to 0.37%—a total of 3.66%—over a six-month period. This amount of time was enough to reach a more definitive number of cases of severe COVID-19 at least seven days after a second dose, with only 1/23,040 occurring in the BNT162b2 group and 23/23,037 occurring in the placebo group, an ARR of 0.01%. According to the study authors, 15 total participants in the BNT162b2 group and 14 in the placebo group died of various causes and "[n]one of these deaths were considered to be related to BNT162b2 by the investigators." The authors did not present any statistic regarding COVID-19 deaths in the main body of their article, but supplemental appendices did reveal that two deaths from "COVID-19" occurred in the placebo group and one death from "COVID-19 pneumonia" occurred in the intervention group.

The similarities in the flagship trials do allow for some overall analysis. To begin with, we had gold-standard RCT evidence in early 2021 that both MRNA-1273 and BNT162b2 dramatically lowered the risk of COVID-19 disease in people who had completed the "protocol" associated with either the P301 or 1001 RCTs. We also had solid evidence that MRNA-1273 lowered the risk of serious COVID-19 disease, and slightly less solid, but still reasonably persuasive evidence that BNT162b2 did the same. MRNA-1273 also dramatically lowered asymptomatic infection. Though Moderna's results in this area were not published until September of 2021, because asymptomatic SARS-CoV-2 infection was a study endpoint, the FDA and VRBPAC had some evidence of efficacy against asymptomatic infection when Moderna's EUA was granted. BNT162b2 tested asymptomatic infection in C4591001, but it did not report those results in any journal and they were not formally presented to the VRBPAC, so there was no gold-standard RCT information available as to its mitigation potential in this regard. With seven total deaths attributable to COVID-19 across the intervention and placebo groups of roughly 73,000 participants in the entire blinded phase of the flagship studies, neither vaccine reached statistical significance as to this risk.

These are the principal efficacy results for MRNA-1273-P301 and C4591001. Other types of efficacy attributed to these vaccines, including efficacy against transmission, efficacy against long COVID, and even efficacy against hospitalization (for which "severe COVID-19" is an imperfect analogue), were products of inference. Frankly, many of these inferences are reasonable. A reduction in infections, for example, should theoretically reduce every downstream risk, including, eventually, death, but we did not know that from the RCTs. These results are also subject to the caveat that they are the product of an incredibly abbreviated time frame. The blinded, placebo-controlled period for MRNA-1273 lasted an average of 5.3 months; for BNT162b2, it was roughly four to six months. There was no direct evidence from the trials as to what would happen beyond that. It would be reasonable, of course, to assume that these efficacy numbers would not just fall off a cliff immediately after the blinded period ended but would instead diminish over time in some form of a smooth curve. Without a placebo group to compare, however, no one knew the shape or steepness of that curve, or how the vaccines would fare against SARS-CoV-2 variants like delta and later omicron. Had the original protocols for the P301 and 1001 trials continued for the two years they were originally planned, there would have been at least some RCT-based

evidence of their performance over time and against both of those variants. They did not, however, so we are left with only inferences and observational data to describe their efficacy in those regards.

Seen in this light, there are many common criticisms of the flagship trials which we do not agree with. We do not believe, for example, that the use of an abbreviated EUA procedure was inappropriate given the dramatic death risk of SARS-CoV-2 infection in the elderly population. Unlike the VRBPAC and FDA, however, we do not believe that the COVID-19 "emergency" necessarily applied to everyone; ***the EUA should only have been granted as to the elderly and comorbid populations most at risk from SARS-CoV-2 complications***. A broader authorization might have been appropriate had the flagship trials demonstrated efficacy against transmission, but the FDA did not require them to be designed that way, and neither Moderna nor Pfizer took it upon themselves to build transmission efficacy into their protocols. Similarly, by the historical standards of polio and smallpox, the cohort size was relatively small, but it was adequately powered to reach its primary and secondary clinical efficacy endpoints had the trials been allowed to run as originally designed for the two-year planned period.

In terms of trial endpoints, we believe SARS-CoV-2 infection would have been the most appropriate and informative primary endpoint because it would have forced sponsors to demonstrate efficacy not only against symptomatic COVID-19 disease, but against the large percentage of asymptomatic cases of SARS-CoV-2 infection. The FDA should have insisted on it as the primary clinical endpoint in the Guidance. We also understand, however, that SARS-CoV-2 infection is an upstream risk from COVID-19 disease, so we doubt insisting on that clinical endpoint would have affected the initial EUAs of BNT162b2 or MRNA-1273.

This brings us to the "original sin" of the flagship trials, the unblinding and vaccination of the placebo groups from P301 and 1001 after the initial EUAs were granted, which the sponsors referred to euphemistically as their "open label" period. We do not believe the sponsors are solely to blame for this decision. The FDA Guidance admonishes that "trials should include contingency plans for continued follow up and analysis of safety and effectiveness outcomes in the event that a safe and effective vaccine becomes available[,]" and that "discussion with the agency may be necessary to address ethical arguments to break the blind and offer vaccine to placebo recipients[,]" making it clear that unblinding and vaccination was in the agency's contemplation well before the first injection was ever given to the first trial participant.

We discussed this decision with representatives from Pfizer and Moderna, and they, like the FDA, pointed to the ethics of allowing placebo group deaths to continue in the clinical trials when a known effective treatment was widely available. Seven trial participants died of COVID-19 in the short surveillance period prior to the EUA, they opined, who knows how many more would have died had the surveillance continued for the full 24 months. Interestingly, both Pfizer's and Moderna's representatives—independently of one another—became emotional as they described the risks faced by the placebo groups and the unblinding process. Most of us found these displays disingenuous. Looking past that, however, we do agree with Pfizer and Moderna that continuing the trials as blinded and placebo-controlled would very likely have resulted in more deaths in their placebo groups. We disagree that this created an ethical necessity.

The primary reason we disagree is that nearly every expert we spoke to, regardless of their stance on the vaccines, acknowledged that the nature of RCTs—and the inherent reliability of their results—rest largely on the blinding of trial participants and the presence of a reasonably sized, randomized comparator group. This necessarily means that the comparator group will not get the treatment for the duration of the trial and may suffer negative outcomes from whatever disease the intervention is designed to prevent. The trial participants in P301 and 1001 understood this explicitly. The fact that they may not receive the intervention for the duration of the 1001 and P301 trials was written into the waivers each participant signed prior to entering those studies. Those at high risk for SARS-CoV-2 made selfless and courageous decisions to risk their own lives in those clinical trials to further the cause of science. Conducting that science, even at the cost of their lives, would have honored that choice, providing gold-standard data on how the efficacy of MRNA-1273 and BNT162b2 against risks associated with SARS-CoV-2 waned over time and how the original formulations fared against subsequent variants. These data would have been of immeasurable value in guiding future public health decisions regarding boosters and waning immunity.

But at what cost? Seven COVID-19-related deaths occurred during the roughly five-month blinded period for P301 and 1001, but only five of them occurred in the placebo groups. We recognize that both the attack rate and the disease burden associated with SARS-CoV-2 could (and did) change, but if those results held, the entirety of both trials may have seen a total of roughly 24 deaths in the placebo group. 19 more than the five that occurred during the blinded period. Given improvements in COVID-19 treatment and the likelihood that the disease burden would diminish over time, that number might even be on the high side. These lives must be weighed

against the consequences of the data lost, which can also be written—albeit more abstractly—in the language of morbidity and mortality. The surrogate and observational results we will explore in the next section were simply less reliable and less comprehensive than the RCT data would have been. Vulnerable people may have been unaware their protection had waned, resulting in extra COVID-19 cases and their attendant downstream risks. These 19 additional prospective deaths must be weighed against the paucity of data regarding the waning efficacy curves of the vaccines and their performance against SARS-CoV-2 variants, which—in a world population of billions of people—undoubtedly had population-level impact that would be impossible to quantify. How sure can we be that the number was less than 19?

It is not like nobody thought about this. The consequences of unblinding the placebo cohort and various options for how to continue the flagship trials without completely losing long-term safety and efficacy data regarding these first-of-their-kind vaccines were active topics of discussion at the VRBPAC approval meetings for both BNT162b2 and MRNA-1273. At the VRBPAC meeting regarding the EUA of BNT162b2, one speaker phrased the ethical dilemma in terms similar to ARR, noting that:

> [I]f the risk of death in the U.S. in the next six months is around one in 1,000, that means ***the maximum benefit of the vaccine for an individual, at least with respect to mortality, is also one in 1,000 or 0.1 percent***. So imagine if we had a drug that purportedly raised cancer survival from 40 percent to 40.1 percent. If there was more to learn—and we do have that here—***that's a setting where we would typically allow many placebo-controlled trials***. We see this in meta analyses all the time with multiple trials—placebo-controlled trials of agents with therapeutic benefit orders of magnitude larger than this.

(emphasis added). Several options for how to preserve the control group were discussed, including switching to a blinded crossover, where the positions of placebo and intervention recipients would be reversed but participants would not be told which arm they were in. Ultimately, however the FDA opted for the "open label" design in both trials.

Finally, we cannot ignore that there was another option which would have allowed for the gathering of this critical science data while putting less lives at risk: As we noted in both of our prior reports and in this one, the relationship between SARS-CoV-2 infection and mortality was well-understood—even in 2020—to be heavily associated with age and associated to a lesser extent with comorbidities. The P301 trial had over 22,000 participants below the age of 65 and the 1001 trial had over 21,000 below the age of 55. These groups would likely not have had a large

amount of severe COVID-19 cases, but they would have been more than sufficient to gather reliable data on how quickly and how dramatically the effectiveness of the vaccines waned with respect to SARS-CoV-2 infection and COVID-19 disease, and they would have done so at much lower risk of death. If comorbidities were a concern, participants with significant comorbid profiles could have been weeded out of the younger age categories as well while leaving the bulk of participants in place. ***We are not sure whether it was a lack of will, a lack of imagination or a lack of competence that led our federal public health agencies to ultimately sanction the "open label" model, but it was a disaster from a public health perspective, casting a cloud of scientific doubt and undermining public confidence for years to come.*** We wish we could say that the unblinding and vaccinating of the placebo groups was the first and last major public health blunder we would see in the COVID-19 pandemic. The reality, however, was that the real mess was just beginning.

## EFFICACY: THE SURROGATE TRIALS

As we mentioned in the prior section, the unblinding and vaccination of the placebo groups represents a clear line of demarcation in the clinical trials involving MRNA-1273 and BNT162b2. The first EUAs for these vaccines were granted based on clinical endpoints like infection, disease and death that had at least some direct connection to the primary risks associated with SARS-CoV-2. Every trial that came after was at least one step removed, using much smaller groups of participants and testing for "immunogenicity," the ability of MRNA-1273 or BNT162b2 to provoke an immune response, then using blood-based markers of that immune response in trial participants as "surrogate endpoints" for vaccine efficacy.

This procedure, too, was at least contemplated in the FDA Guidance back in 2020, where the FDA cautioned that:

> There are currently no accepted surrogate endpoints that are reasonably likely to predict clinical benefit of a COVID-19 vaccine. Thus, at this time, the goal of development programs should be to pursue traditional approval via direct evidence of vaccine safety and efficacy in protecting humans from SARS-CoV-2 infection and/or clinical disease.

However, it did hold out that:

> Once additional understanding of SARS-CoV-2 immunology, and specifically vaccine immune responses that might be reasonably likely to predict protection against COVID-19, is acquired, accelerated approval of a COVID-19 vaccine pursuant to section 506 of the FD&C Act (21 U.S.C. 356) and 21 CFR 601.40 may

> be considered if an applicant provides sufficient data and information to meet the applicable legal requirements. For a COVID-19 vaccine, it may be possible to approve a product under these provisions based on adequate and well-controlled clinical trials establishing an effect of the product on a surrogate endpoint (e.g., immune response) that is reasonably likely to predict clinical benefit.

Although the FDA refused to provide representatives to testify directly to this Grand Jury, its pattern of granting EUAs and Full Approvals for various populations, various dose strengths and various formulations in the three years following the initial licenses for MRNA-1273 and BNT162b2 suggests to us that the FDA believes the P301 and 1001 trials provided sufficient clinical and immunogenicity data to adopt the "accelerated approval" model described above.

To safeguard the risk that surrogate endpoints may not continue to reflect the clinical results of vaccines, the Guidance suggested that "[f]or drugs granted accelerated approval, postmarketing confirmatory trials have been required to verify and describe the predicted effect on clinical benefit." That language is just a restatement of Federal Regulation 21 CFR Section 601.41, which allows accelerated approvals based on surrogate endpoints, subject to the caveat that:

> [T]he applicant study the biological product further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome.

To be clear, we do not believe this requirement was outright ignored by Moderna, Pfizer, the VRBPAC or FDA. Indeed, there were observational studies conducted and presented that supported the efficacy results of the immunogenicity trials. For reasons we will delve into below, however, we are not sure these observational results are reliable enough to give anyone, including this Grand Jury, accurate information about the clinical risk reduction potential of these vaccines, especially across cohorts and over time.

## IMMUNOGENICITY: LATITUDE AND LONGITUDE

Our first task is simply to describe the sheer extent to which Moderna, Pfizer and the FDA relied upon immunogenicity studies to support further approval in the wake of the EUAs for MRNA-1273 and BNT162b2. Some of these studies have a lateral dimension, using surrogate endpoints to infer clinical results in groups not included in the flagship trials, like children or the immunosuppressed. Others have more of a longitudinal, time-related dimension, using surrogate endpoints to infer that the performance of a reformulated booster dose against a SARS-CoV-2 variant would be comparable to that of the original formulation against ancestral SARS-CoV-2.

As time went on, an increasing number had both lateral and longitudinal components, inferring in one direction that a clinical result would be similar in a different population, and inferring in another that a risk reduction result achieved against alpha SARS- CoV-2 in 2020 would still be valid against an omicron variant years later. Additionally, some studies explicitly reference the immunogenicity results from previous studies, while others rely implicitly on previous studies. Here are two relatively complete lists of immunogenicity studies undertaken by Pfizer & Moderna:

**Pfizer: BNT162B2 Immunogenicity Studies**

| Study # | Name | Cohort Size | Bridging From | Population vs. Bridge | Start Date |
|---|---|---|---|---|---|
| C4591001 | A Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals | 2260 | C4591001 | 12y-15y vs. 16y-25y | 4/29/20 |
| C4591007 | Study to Evaluate the Safety, Tolerability, and Immunogenicity of an RNA Vaccine Candidate Against COVID-19 in Healthy Children" | 11837 | C4591001 | 6m-15y vs. 16y-25y | 3/24/21 |
| C4591015 | To Evaluate the Safety, Tolerability, and Immunogenicity of BNT162b2 Against COVID-19 in Healthy Pregnant Women | 683 | C4591001 | 18y+ vs. Pregnant Women Weeks 24-34 | 2/16/21 |
| C4591017 | A Phase 3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of Multiple Production Lots and Dose Levels of BNT162b2 RNA-Based COVID-19 Vaccines Against COVID-19 in Healthy Participants | 1574 | C4591001 (implicit) | 12y-50y | 2/15/21 |
| C4591020 | A Study to Evaluate Safety, Tolerability, & Immunogenicity of Multiple Formulations of BNT162b2 Against COVID-19 in Healthy Adults | 629 | C4591001 (implicit) | 18y-55y | 4/1/21 |
| C4591023 | Study to Learn About Bivalent COVID-19 RNA Vaccine Candidate(s) in Healthy Infants and Children | 120 | C4591001 (implicit) | >6m | 1/6/25 (est.) |
| C4591024 | Study to Evaluate Safety, Tolerability & Immunogenicity of BNT162b2 in Immunocompromised Participants ≥2 Years | 124 | C4591001 (implicit) | 2y+ (immune-compromised) | 10/15/21 |

| | | | | | |
|---|---|---|---|---|---|
| C4591031 | To Evaluate the Safety, Tolerability, Efficacy and Immunogenicity of BNT162b2 Boosting Strategies Against COVID-19 in Participants ≥12 Years of Age | 16385 | C4591001 | 12y+ vs. 18-55yo | 7/1/21 |
| C4591044 | A Study to Learn About New COVID-19 RNA Vaccine Candidates in COVID-19 Vaccine-Experienced Healthy Individuals | 1454 | C4591031 | 12y+ vs. 55y+ | 7/26/22 |
| C4591048 *NCT05543616* | Study to Learn About Variant-Adapted COVID-19 RNA Vaccine Candidate(s) in Healthy Children | 3692 | C4591007 | 6m-11y vs. 6m-5y | 9/23/22 |
| C4591054 *NCT05997290* | Study to Learn About New COVD-19 RNA Vaccine Candidates for New Variants in Healthy Individuals | 1000 | C4591044 | 12y+ vs. 12y+ | 8/10/23 |

**Moderna: MRNA-1273 Immunogenicity Studies**

| Study # | Study Name | Cohort Size | Bridging From | Population vs. Bridge | Start Date |
|---|---|---|---|---|---|
| MRNA-1273-P201 | Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 COVID-19 Vaccine in Adults 18 Years and Older | 660 | mRNA-1273-P301 (for boosters) | 18y+ vs. 18y+ | 5/29/20 |
| MRNA-1273-P203 | A Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA-1273 Vaccine in Adolescents 12 to <18 Years Old to Prevent COVID-19 (TeenCove) | 4331 | mRNA-1273-P301 | 12y-18y vs. 18y-25y | 12/9/20 |
| MRNA-1273-P204 | A Study to Evaluate Safety and Effectiveness of mRNA-1273 COVID-19 Vaccine in Healthy Children Between 6 Months of Age and Less Than 12 Years of Age | 11950 | mRNA-1273-P301 | 6m-11y vs. 18y-25y | 3/15/21 |
| MRNA-1273-P205 | A Study to Evaluate the Immunogenicity and Safety of mRNA Vaccine Boosters for SaRs-CoV-2 (COVID 19) Variants | 5404 | mRNA-1273-P301 | 18y+ vs. 18y+ | 5/28/21 |
| MRNA-1273-P206 | Study to Evaluate the Safety, Reactogenicity, and Effectiveness of mRNA1273.214 SARS-CoV-2 (COVID-19) Vaccine in Infants (BabyCOVE) | 700 | mRNA-1273-P301 | 12w-6m vs. 18y+ | 9/30/22 |
| MRNA-1273-P304 | A Study to Evaluate Safety and Immunogenicity of mRNA-1273 Vaccine to | 234 | mRNA-1273-P301 (implicit) | 18y+ | 4/16/21 |

| | | | | | |
|---|---|---|---|---|---|
| | Prevent COVID-19 in Adult Organ Transplant Recipients and in Healthy Adult Participants | | | | |
| MRNA-1273-P305 | A Study to Evaluate the Immunogenicity and Safety of Omicron Variant Vaccines in Comparison with mRNA-1273 Booster Vaccine for COVID-19 | 3548 | mRNA-1273-P301 (implicit) | 16y+ | 2/16/22 |
| MRNA-1273-P306 | Study to Evaluate the Safety and Immunogenicity of the mRNA-1273.214 Vaccine for SARS-CoV-2 Variants of Concern in Participants aged 6 Months to <6 Years | 1860 | mRNA-1273-P204 | 6m-11y vs. 6m-11y | 06/21/22 |

Nearly all these studies do track clinical outcomes like SARS-CoV-2 infection, COVID-19 disease and severe COVID-19 disease as secondary or exploratory endpoints, but they rarely reach statistical significance as to these measures. Instead, sponsors often use "real world" observational studies to fill the gap after the immunogenicity results have been used to achieve EUA. This combination of immunogenicity data and observational studies has been employed repeatedly to expand the authorization of the COVID-19 vaccines to include boosters, different formulations and more demographics, like infants, pregnant women and immunocompromised individuals. For a known virus, even a rapidly mutating, RNA-transcribing virus like influenza, this model would be of less concern. ***The problem here is SARS-CoV-2 is not influenza, it is a novel coronavirus that infected its first human host only five years ago.***

This is an issue because the entire surrogate trial enterprise rests on three critical assumptions: (1) There is a stable incidence and disease burden associated with the virus; (2) the inferences being drawn are reasonable; and (3) the population the vaccine was designed to serve is well represented by the people who got the vaccine pursuant to the EUA. Unfortunately, in the case of SARS-CoV-2, there are compelling reasons to doubt these assertions.

With respect to the first assumption, the incidence of SARS-CoV-2 infection has decreased dramatically since 2020, meaning that less people overall will get the disease, and many of the related risks that COVID-19 vaccines were designed to reduce are simply not present due to some combination of existing vaccination and IDI. According to publicly available data, the number of confirmed COVID-19 cases began to trail off in fall of 2022 and reached such a trickle by 2023 that it no longer made sense to engage the large-scale pandemic-era testing and tracking apparatus

to continue to monitor these cases. As of today, we have little accurate data as to how many COVID-19 cases are occurring from week to week, but clearly, SARS-CoV-2 is not ravaging our population in the same way it did in 2020, 2021, and 2022.

The disease burden of SARS-CoV-2 has also changed dramatically, beginning in early 2022 with the rise of the omicron variant. Reliable data from that period estimated the pooled risks of serious clinical outcomes from SARS-CoV-2 omicron including hospital admission, Intensive Care Unit admission, mechanical ventilation and death to be a little more than half those of delta. Death, in particular, was greatly reduced. Whether because of the advancements in treatment or because of viral mutation towards less virulence, SARS-CoV-2 omicron is estimated to have killed at a rate only 1/5 that of delta. Even that number is subject to all the usual caveats regarding dying "with" versus "of" COVID-19 and the omnipresent risk multipliers of age and comorbidities. It is true that omicron was more infectious than delta, but once the incidence began to taper off, what was left was a less dangerous pathogen.

The second requirement for good use of the surrogate trial tool is that the inferences being drawn are rational and rigorous. If the studies above make one point obvious, it is that the chain of inferences linking many of these immunogenicity studies back to the clinical results of the flagship clinical trial results can be quite long. Occasionally, these inferences are even stacked. For example, Pfizer's C4591054 study bridges to C4591044, which bridges to C4591031, which bridges to C4591001. Another example of this issue can be found in Moderna's MRNA-1273-P306 study. This study, started on June 22, 2022, sought to evaluate the efficacy of a monovalent vaccine for immunization of individuals as young as six months against a new SARS-CoV-2 variant of concern. To infer the efficacy of that vaccine, the immunogenicity results are compared to those from MRNA-1273-P204, a study beginning on March 15, 2021, that did not involve a variant of concern but involved the same age group. But that study itself was bridged to MRNA-1273-P301, the flagship trial in adults that dates to July 27, 2020. The study, therefore, imputes the efficacy of one formulation of the vaccine (against one variant of SARS-CoV-2) to another formulation (against a different variant) in a population (which includes infants) that has never had the clinical efficacy of any formulation of the vaccine (against any variant) demonstrated in an RCT. Moderna's representative asserted repeatedly that these studies provided sufficient evidence that there would be a clinical benefit to MRNA-1273 in these populations. When he was challenged, the following exchange occurred:

Q. So you're looking—so—and we don't have enough clinical cases here to really be sure if the clinical results are correlating with immunobridging; right? There's not enough participants; there's not enough power.

A. No, because—that's a wrong assumption.

Q. Tell me why.

A. The assumption is that the immunobridging is sufficient to—to provide evidence that it—that the—in this case, this booster dose will provide clinical benefit.

Q. ***How can you be sure of that without a trial?***

A. ***On the basis of 100 years of vaccinology.***

Q. Okay. ***But this is a novel disease; right? Its profile in terms of immunogenicity and population level immunity is going to change very quickly; right? It's not a stable profile.***

A. ***But the fundamental principle around immunobridging is consistent from—across viruses, across bacteria.***

(emphasis added). The problem is that "100 years of vaccinology" does not appear to provide an appropriate frame to deal with the changing incidence and disease burden of this novel pathogen. We pressed Moderna's representative further regarding the company's use of immunobridging results from its P301 trial to infer clinical efficacy against subsequent SARS-CoV-2 strains:

Q. Okay. So I'll ask you not as a representative of Moderna but as an epidemiologist, right, ***there is a difference between the disease burden of Omicron SARS-CoV-2 and Alpha SARS-CoV-2?*** There is a difference. Its difference is right there in [this observational study]. I mean, you don't disagree with the science; right? It's pretty obvious that there is a difference; right?

A. That's true.

Q. Okay. And there is a set of clinical endpoints arrived at in the P301 study that are based on the Alpha variant to SARS-CoV-2?

A. Say that again, please.

Q. ***There is a set of clinical endpoints*** [for] the COVID-19 disease, right, asymptomatic COVID-19 infection, serious COVID-19 infection, in the P301 study ***that are based on the disease burden of the Alpha variant?***

A. The P301 study was based upon the Alpha variant, that's correct.

> Q. Right. So if the disease burden changes, doesn't that change the risk-benefit profile of Spikevax because it changes the risk?
>
> A. So—***yeah***, but the other—but other—***but the risks have also changed***. So, you know, we'll get into myocarditis, but the risk for myocarditis associated with additional doses declines compared to after the primary series. ***So it's not just the benefits changing, but the risks are changing as well.***

(emphasis added). On this point, we agree with Moderna's representative. The risks and benefits of MRNA-1273 have changed since the P301 trial. If that is the case, however, it necessarily means that P301 is no longer a valid comparator for immunogenicity studies.

Another point is more subtle, but possibly more concerning. The protocols of some of these studies do not explicitly reference the results of previous studies (marked as "implied" in the table above). In many of these studies, the stated objective is not to infer efficacy by comparing new immunogenicity results with the results from a specific, earlier trial that demonstrated efficacy. Instead, the objective is often simply to "describe" the immune response, reporting the raw results without any analysis of their meaning. In these studies, sponsors will often include some other immunogenicity response data, not as a statistical comparator, but "for reference." For example, the immunogenicity endpoints in Moderna's MRNA-1273-P304 study all state that, "[r]esults in healthy participants were included as reference not for any comparisons." What are the results of the comparison? The sponsors aren't saying.

The sponsors needn't worry, however, because the FDA is willing to pick up what they are putting down. For example, in summarizing its previous authorization of Pfizer's bivalent vaccine as a booster dose for individuals six months through four years, which relied on preliminary results from a subset of its C4591048 trial, the FDA describes the following process:

> "Neutralizing antibody levels following the fourth dose were summarized [in C4591048]. Data from a subset of participants 6 months through 4 years of age in [C4591007] who received 3 doses of Pfizer BioNTech COVID-19 Vaccine (3 mcg modRNA) were reviewed as a reference. ***There were no formal statistical comparisons of the immune response between the subsets from the two studies. Based on the totality of scientific evidence available, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be effective*** in individuals 6 months through 4 years of age . . . ."

(emphasis added). It is disconcerting to learn our regulators and sponsors chose not to be burdened with "formal statistical comparisons" in their efforts to get the latest formulations of BNT162b2

into the arms of children all over the United States. Was the administrative burden of performing these statistical comparisons too large? Was it determined to be not worth the effort? Maybe there is a good answer, but we did not see it in the volumes of records we reviewed, nor did we get it from the FDA or from the sponsors. Perhaps some enterprising member of the federal government could ask again on our behalf.

The third pillar of reliability for the surrogate trials is that for the chain of inferences to work, the observational results must reflect the actual population-level performance of the vaccine in the categories for which it was approved. This problem began early on, but it became more and more significant over time. In 2021, the BNT162b2 booster, for example, was studied in a cohort of roughly 10,000 participants, blinded and divided into equal groups that were designed to receive the intervention and a placebo. The primary endpoint for this trial was still clinical COVID-19 disease, and the data did show a dramatic and statistically significant reduction in COVID-19 cases. Even then, however, only two cases of severe COVID-19 appeared in the placebo group, not enough to draw any meaningful conclusion. Instead, the sponsor supplemented its data with an observational study published in the NEJM, *Protection of BNT162b2 Vaccine Booster against COVID-19 in Israel*. This study did show a significant reduction in severe COVID-19 infections, but that result was found in a population of patients 60 years and older. We agree that it is at least reasonable to infer a correlate of protection for a younger population from these data coupled with the clinical results for case reduction, but this was from 2021. Nevertheless, as the chain of inferences stretches farther, it only gets more tenuous.

**OBSERVATIONAL STUDIES AND HEALTHY VACCINEE BIAS**

As we can see in the example above, statistically underpowered clinical and immunogenicity data are commonly coupled with "real world" observational studies in an effort to bolster their reliability. In principle, this makes sense. In practice, however, observational studies are often a shoddy substitute for the RCT results they purport to replace. Some of these problems were discussed specifically in *Considerations in boosting COVID-19 vaccine immune responses*. The article, which included contributions from former FDA officials who resigned from the agency in protest less than a month before it was published, observed that:

> [T]here are substantial challenges in estimating vaccine efficacy from observational studies undertaken in the context of rapid vaccine roll-out. Estimates may be confounded both by patient characteristics at the start of vaccine roll-out and by time-varying factors that are missed by electronic health records. For example,

> those classified as unvaccinated might include some who were in fact vaccinated, some who are already protected because of previous infection, or some whose vaccination was deferred because of COVID-19 symptoms. The likelihood that there are systematic differences between vaccinated and unvaccinated individuals may increase as more people get vaccinated and as patterns of social interaction between vaccinated and unvaccinated people change.

The unreliability of observational results in vaccine studies is so well-known and common that it even has a name: "Healthy Vaccinee Bias"—the idea that better underlying health among the vaccinated population causes a vaccine to appear more effective than it is. There are also ways to test for it. One of the more reliable methods is to conduct a "covariate" analysis. To accomplish this, a researcher will examine some other characteristic of the study population to see how well it matches the broader population at large. One such analysis was published in a letter to the NEJM entitled *Potential 'Healthy Vaccinee Bias' in a Study of BNT162b2 Vaccine against COVID-19*. The letter pointed out that a recently published observational study that estimated a 94.6% COVID-19-associated death reduction in BNT162b2 booster recipients ***also*** showed a 94.8% reduction on non-COVID-19-associated deaths. The booster is designed to reduce COVID-19 deaths, but it should not be able to cure cancer, prevent heart attacks or make its recipients less likely to get into fatal car accidents. Once again, this is not an impossible problem to avoid. Observational studies used to support immunogenicity data simply need to be buttressed by a robust and meaningful set of prespecified falsification endpoints like the all-cause mortality results described above. Unfortunately, these endpoints do not appear to have been required, or even widely employed during the cycle of pandemic-era approvals.

## THE "FLU MODEL"

We spoke to representatives from Pfizer and Moderna on the record about this phenomenon and about their reliance on surrogate trials in general, and they both referred multiple times to the seasonal "flu model" of vaccine approval as their guiding principle for the testing and approval process related to current and future formulations of BNT162b2 and MRNA-1273. As we discussed above, however, there is a major problem with this model: The flu is not novel. Unlike SARS-CoV-2, the flu virus has been infecting humans for thousands of years. Variants may cause outcomes associated with the flu to change at the margins, but humans have an immunological relationship with influenza that is essentially stable. This disease burden of SARS-CoV-2 was essentially halved after roughly two years infecting human hosts. As our population-level

immunity improved, incidence of the virus dropped dramatically. Human beings did not have an immunological equilibrium with SARS-CoV-2 at a population level during 2020, 2021 or 2022. It is absurd and irresponsible for the FDA to allow sponsors to use results from that era as a correlate of protection for surrogate endpoints in 2024.

After all of this, we return to the essential question of risk, asking the fundamental question: How well are MRNA-1273 and BNT162b2 protecting people from the risks associated with SARS-CoV-2 disease in 2024? The answer is that these products may be affording at least some people of advanced age and with significant comorbidities at least some protection; we have no idea how much, in whom, or for how long—and we may never know. We had gold-standard RCT data regarding how vaccines affected COVID-19 outcomes in 2020 and 2021. The sponsors have been using those numbers ever since to infer correlates of protection, but the incidence, disease burden and population immunity today are very different than they were at the time those correlates were derived. We do not believe this is good science.

## SAFETY: THE CLINICAL TRIALS

To this point, our focus has been entirely on the evidence supporting the effectiveness of MRNA-1273 and BNT162b2, but that only covers half of the "safe and effective" equation. To execute our mandate, we must also understand the safety profile of these vaccines. While most efficacy information about these products has been gathered from clinical trials and observational studies, safety information can be derived from those sources as well as a process called pharmacovigilance, the analysis of post-release safety data gathered from a variety of sources. Understanding each of these sources, their reliability, and how their inherent limitations might potentially skew their findings one way or another is challenging work. This Grand Jury employed many experts and other professionals to assist it in this endeavor.

Before we delve into the data, we once again examine the assertion made by the FDA that both MRNA-1273 and BNT162b2 are "safe" biological products. What does that actually mean? We stress again that the FDA is not saying that a product it has deemed "safe" never causes any harm to anyone. Most people, for example, who have received the COVID-19 vaccines came away with, at the very least, some degree of injection site pain or soreness. This is a minor harm, but it is a harm. Some smaller cadre of people may have gotten headaches or nausea or fevers after taking a vaccine. These, too, are harms. As we will see below, there are even more serious harms that

occur less frequently. Nevertheless, a drug or biological product is considered "safe" by the FDA when the balance of those harms is outweighed by the balance of the benefits it provides.

The FDA principally characterizes the physical externalities of therapeutics in terms of adverse events, which can range in severity according to graduated scale:

- **Grade 1:** Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
- **Grade 2:** Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living.
- **Grade 3:** Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care [activities of daily living].
- **Grade 4:** Life-threatening consequences; urgent intervention indicated.
- **Grade 5:** Death related to AE.

There are also "serious" adverse events (SAEs) which are so-called because: (1) They result in death or are life-threatening; (2) they require or prolong hospitalization; (3) they result in disability or permanent damage, or they require medical intervention to prevent that outcome; or (4) they result in congenital anomalies or birth defects in unborn children. There are other subcategories of adverse events which are described in the literature regarding the safety of MRNA-1273 and BNT162b2, but these primary categories are enough to provide a starting point.

Just like efficacy, the best place to start evaluating vaccine safety is with the results of the clinical trials. Data about these trials are available to the public in three forms. First, sponsors may publish data about their products in major medical journals as a way of providing the scientific community information about their product's safety and efficacy. These articles—several of which we have discussed already—are generally drafted by authors who have some relationship to the sponsor and reviewed by qualified scientists known as "peers" who read those drafts and make sure the conclusions of the authors are consistent with their data. The journals themselves have a sort of pecking order, with high-caliber, high-prestige journals sitting at the very peak while lower prestige journals publish articles further down the academic and professional food chain. Most importantly, this entire process is normative, governed by custom and expectation rather than formal force of law. There is no legislation that requires sponsors to publish the results of their clinical trials in scientific journals at all, even if those results were used to get FDA approval. When articles describing the results of clinical trials are published, no statute governs who may write those articles or what safety information they must contain.

Information about clinical trials is also available from public VRBPAC meetings like the ones we described above, where both sponsors and the FDA publish summaries of their safety results right along with their efficacy findings, and those results are subject to review and debate by a team of qualified, ostensibly neutral scientists. The caveat with this second source of safety data is that a sponsor can only reach this stage by applying for licensure. Quite a few clinical trials never make it this far, however. If a trial is discontinued, or if a sponsor chooses not to use a given trial's data in its effort to acquire an FDA license (as we will see in some unfortunate examples below) the VRBPAC will never have a chance to review or interpret it.

Our third source of information about clinical trials—one that is available regardless of whether a sponsor publishes its results or applies for FDA licensure—comes from federal law. Title 42 CFR Part 11 requires that "clinical trial results information" (a term of art that includes primary and secondary outcomes, baseline characteristics of patient samples, participant flow, outcomes and statistical analyses, adverse event information, and administrative information) from any clinical trial authorized by the FDA must be made available to the public, regardless of whether it results in an approved product or not. The vehicle for the execution of this law is a website called ClinicalTrials.gov, which contains a treasure trove of safety and efficacy data on all manner of drugs and biologics. Details about primary and secondary endpoints, trial size, trial type, participant eligibility, published journal articles and even trial results are stored, regularly updated and kept publicly available in a searchable database. Like journal reporting and the VRBPAC, however, ClinicalTrials.gov is also not without its weaknesses. First, there is a significant lag time for the publishing of clinical trial results. The trials themselves can last several years, especially when they are allowed to be spun into one another. Pfizer's flagship 1001 trial, for example, was commenced in April of 2020 as a short-term dose-finding study, spun into a large-scale, 24-month phase three study, then spun again into a booster dose study before finally "completing" in February of 2023. In another example, Moderna's P201 short-term dose-finding study cohort—commenced in May of 2020 with an initial study term of 394 days—was repeatedly utilized to test MRNA-1273 boosters before the study finally "completed" in October of 2021.

Even when the trial is "complete," the data are not released right away. Instead, the operative rule is that sponsors have a year from the conclusion of a given clinical trial to publish their results. When that year is added to the already-extended terms of the clinical trials, this creates a significant delay in its availability to the public:

**Pfizer: Published Results from Clinical Trials**

| Study Number | Start Date | Completion Date | Date of Published Results |
|---|---|---|---|
| C4591001 | 4/29/20 | 3/10/23 | 2/9/24 |
| C4591007 | 3/24/21 | 10/4/23 | NA** |
| C4591015 | 2/16/21 | 7/15/22 | 7/14/23 |
| C4591017 | 2/15/21 | 7/22/21 | 7/18/22 |
| C4591020 | 4/1/21 | 12/1/21 | 11/30/22 |
| C4591024 | 10/15/21 | 7/23/23 | 7/3/24 |
| C4591030 | 4/20/22 | 10/5/22 | 10/4/23 |
| C4591031 | 7/1/21 | 3/26/24 | NA** |
| C4591044 | 7/26/22 | 3/26/24 | NA** |
| C4591048 | 9/23/22 | 8/11/25 (est.) | NA* |
| C4591054 | 8/10/23 | 3/19/25 (est.) | NA* |

**Moderna: Published Results from Clinical Trials**

| Study Number | Start Date | Completion Date | Date of Published Results |
|---|---|---|---|
| MRNA-1272-P301 | 7/27/20 | 12/29/22 | 12/21/23 |
| MRNA-1272-P201 | 5/29/20 | 10/28/21 | 10/21/22 |
| MRNA-1272-P203 | 12/9/20 | 6/14/24 | NA** |
| MRNA-1272-P204 | 3/15/21 | 3/15/24 | NA** |
| MRNA-1272-P205 | 5/28/21 | 11/17/23 | NA** |
| MRNA-1272-P206 | 9/30/22 | 3/8/25 (est.) | NA* |
| MRNA-1272-P304 | 4/16/21 | 5/22/23 | 5/22/24 |
| MRNA-1272-P305 | 2/16/22 | 6/23/23 | 7/11/24 |
| MRNA-1272-P306 | 6/21/22 | 10/27/25 (est.) | NA* |

*Study in progress
**Results not posted

As the tables above make clear, the most reliable and comprehensive data available about the safety and efficacy results of clinical trials often lags years behind what is published in the journals or discussed in VRBPAC meetings. This delay is an inherent feature of the existing legal regime around the reporting of clinical trial results.

Luckily, during the pendency of this Grand Jury, the results of both flagship trials were finally posted. Moderna initially posted its P301 results on December 12, 2023, where they went through two rounds of quality control rejections before Moderna submitted a version that satisfied the FDA on March 19, 2024. Pfizer initially posted its 1001 results on February 9, 2024, and is still locked in a quality control battle with regulators, its latest submission having been rejected on May 10, 2024. With all of that in mind, here is what information is available regarding the safety profile of MRNA-1273 and BNT162b2.

According to ClinicalTrials.gov data, in the blinded period of P301, ordinary adverse events occurred in 2,783/15,162 (18.36%) participants in the placebo group, and 2,247/15,184 (14.80%) participants in the intervention group. The occurrence of SAEs was similar between cohorts, with 308/15,162 (2.03%) in the placebo group and 292/15,184 (1.92%) in the intervention

group. All-cause mortality between the two groups was almost dead even, with 18/15,206 (0.12%) in the placebo group versus 16/15,209 (0.11%) in the intervention group.

In the blinded period of the 1001 trial, however, ordinary adverse events were much more common in the intervention group, with 9,520/21,910 (43.45%) versus the placebo group, with 3,807/21,911 (17.37%). This result is likely due to Pfizer's adoption of a lower reporting threshold and a more diverse set of reportable adverse events. In terms of SAEs, the results were more similar, but still slightly tilted towards the intervention group, with 428/21,910 (1.95%) in the intervention group versus 291/21,911 (1.33%) in the placebo group. The all-cause mortality results, however, were very uneven, with 60/21,910 (0.27%) in the intervention group versus 21/21,911 (0.10%) in the placebo group.

On the surface, these numbers look scary. One to two SAEs per every 100 vaccinated individuals would be an enormous problem. If those results held, it is very likely that neither MRNA-1273 nor BNT162b2 would be considered "safe" unless it was administered to an incredibly high-risk cohort. But there is more to it than that. Describing these results in the way we just did above highlights the second major weakness of the data available in ClinicalTrials.gov: Results are reported regardless of causation. It is probable that only a fraction of those SAEs, if any, are actually related to BNT162b2 and MRNA-1273. Rather, safety signals related to interventions are identified by the presence of a significant, unbalanced number of similar AEs that indicate issues meriting further exploration. Once those signals are detected, it is up to the sponsor, the FDA and the scientific community to uncover whether there is a causal link between the occurrence of an event and an intervention.

Sponsors do make an effort to determine whether adverse events that occur in clinical trials are related to interventions, especially when it comes to SAEs. Often, sponsor-employed investigators will take steps to gather additional information to determine whether there is a causal relationship between a clinical trial SAE and an intervention. They report these data, along with their "relatedness" or "causation" conclusions, back to the sponsors, but the sponsors are under no legal obligation to report those conclusions to anyone, often not even the FDA. This reveals a more subtle problem with the post-blind flagship trials: The lack of a large, blinded comparator group makes subsequent safety data from the open label phases of these trials essentially worthless to the public without some concomitant data on how many and which SAEs were related to the intervention. In P301, for example, we noted that SAEs in the blinded phase were reasonably

balanced between 2.08% in the placebo group and 1.92% in the intervention group. Once the study went open label, the numbers shot up, with 4.24% SAEs in the open label intervention group (those who had originally received the placebo but were unblinded and offered the intervention). Was the same formula of MRNA-1273 twice as dangerous in this population just six months later? Probably not. Rather, unblinding the participants most likely ruined the predictive value of the randomization. Here's the catch, though. Moderna has very likely sorted out whether many of those SAEs were related to its vaccine and whether the percentage of related SAEs was higher or lower. Sponsors do share these conclusions with the FDA when the FDA asks for them. Sponsors might even share their relatedness data in VRBPAC summaries or at meetings if they believe pushback from the VRBPAC might foul their licensure applications. Sponsors may even report these data in a journal if they believe the result will benefit the marketing of their product, but they are not obligated to fully and comprehensively report these determinations to the public. This Grand Jury believes they should be.

Even with all those caveats, most of the experts we spoke to—even those who had significant reservations overall about the COVID-19 vaccines—believed the adverse event and SAE results from the blinded portion of the flagship trials constituted acceptable safety profiles for BNT162b2 and MRNA-1273 in a majority of potential vaccinees. There is no reason to believe the safety profile of the vaccine changed dramatically once the formulae were changed to address subsequent variants, but without comprehensive causation analyses, we are forced to take FDA and the sponsors' words for it.

**CASE STUDY: PREGNANT WOMEN AND MRNA VACCINES**

One area that broadly illustrates some of the weaknesses of the system of clinical trial reporting we described above is the example of pregnancy. In June of 2020, the CDC's flagship journal, Morbidity and Mortality Weekly (MMWR) published an analysis of COVID-19 disease burden in pregnant women that contained several alarming statistics. According to the observational study, pregnant women were 5.4 times as likely as nonpregnant women of reproductive age to be hospitalized with COVID-19, 1.5 times more likely to be admitted to the ICU and 1.7 times more likely to receive mechanical ventilation. MMWR published a second analysis in November of 2020 had similar findings, but included an additional finding showing an increased risk of COVID-19 death. Both these studies drew their conclusions from a large dataset of reported positive tests known as the National Notifiable Diseases Surveillance System. Those

test results were divided by pregnancy status and compared to a denominator of nonpregnant women aged 15-44. The authors cited significant limitations in their data, including the fact that pregnancy status was not reported at all for over half the cases in the database and that the voluntary nature of reporting may cause a bias towards worse COVID-19 outcomes.

Over time, other observational studies have come out challenging the findings above. Many of these later studies are arguably of sounder design, and some even appear to show a protective immunological effect associated with pregnancy. We are not here to adjudicate whether these latter studies or the MMWR's findings were more correct or more reliable. We merely wish to stress that in 2020, as the vaccines were being developed, there were published observational studies finding a substantial increase in COVID-19-related risks in pregnant women, but those findings were subject to limitations so broad and obvious that even their authors acknowledged they may not ultimately be accurate.

The FDA appears to have been well aware of both the potential increased risk and the issues with the existing data. The Guidance mentions "pregnant women" no less than 14 times in its 24 pages, noting that "[p]re-licensure safety data in some subpopulations likely to receive a COVID-19 vaccine (e.g., pregnant individuals, or individuals with medical comorbidities) may be limited at the time of licensure[]" but "encourag[ing] vaccine developers to consider early in their development programs data that might support inclusion of pregnant women and women of childbearing potential who are not actively avoiding pregnancy in prelicensure clinical trials." The Guidance explicitly contemplated that there were likely to be clinical trials that involved pregnant women, explaining that "[a]ll pregnancies in study participants for which the date of conception is prior to vaccination or within 30 days after vaccination should be followed for pregnancy outcomes, including pregnancy loss, stillbirth, and congenital anomalies."

This last quoted section of the Guidance highlights a complication with pregnant women that the MMWR studies did not sufficiently address. Pregnancy is not just a comorbid condition like asthma, obesity or cancer. There is a whole other person to consider; a whole other health outcome separate and apart from the mother's. While it is true that a mother who dies too early in her pregnancy cannot deliver her baby, it is also true that most pregnant women who get COVID-19 do not die. Where a given intervention risks the health of her baby, a mother may not want that intervention, even at the expense of her own health. This is compounded by the fact that pregnant women can suffer a whole series of negative outcomes related to pregnancy that other women do

not have to worry about. Many of these outcomes, like preterm birth and miscarriage, are unfortunately quite frequent, often making it difficult to discern whether they are due to a disease like COVID-19, a dose of vaccine or some other cause. The FDA was right to single out pregnant women as a unique and exclusive cohort in need of study in the clinical trial context.

The flagship trials conducted by Pfizer and Moderna did not do that. Pfizer's 1001 trial excluded all "[w]omen who are pregnant or breastfeeding[,]" and Moderna went much further, only allowing "female participants of childbearing potential" in the P301 trial who:

- [had] a negative pregnancy test at Screening and on the day of the first dose[;]
- [had] practiced adequate contraception or [had] abstained from all activities that could result in pregnancy for at least 28 days prior to the first dose[;]
- [had] agreed to continue adequate contraception through 3 months following the second dose on Day 29[;] and
- [were] not currently breastfeeding.

Despite these safeguards, pregnant women made it into both flagship trials anyway. We know this happened because some of them had miscarriages. The 1001 trial saw three "spontaneous abortion" events (read: miscarriages) in the placebo group against six in its BNT162b2 group during its blinded period, and eight more in its open label period for a total of 17 miscarriages. These adverse events somehow did not make it into any of the articles published in the NEJM regarding the safety and efficacy of BNT162b2. The public only knows about them at all because, legally, Pfizer was required to eventually publish the results of the 1001 trial on ClinicalTrials.gov. We discussed these unsettling results with Pfizer's representative, which resulted in the following exchange:

> Q. So here's my question, though. You would agree with me that if there are 60 people in the BNT162b2, the first blinded group, and you have six miscarriages, that would be approximately 10%; right? Six out of 60 would be 10%; correct?
>
> A. Yes.
>
> Q. If you have seven people in the BNT162b2 group that are pregnant and six of them miscarry, that's not going to be 10% anymore; right?
>
> A. Right. Again, this is with a very small sample; right?
>
> Q. I agree.
>
> A. So that the confidence that you have about that particular number is not very good.

> Q. And would you agree with me that the way to build confidence would be to do a trial and to bring women in early pregnancy in and see if that result was a real result or a statistical anomaly?
>
> A. I think, again, the opportunity affords itself given that the recommendation was made generally that you get that with ***a lot better precision based on observational data*** that's available through the monitoring done by the CDC.
>
> Q. So if you're doing it based on observational data, ***the women, then, who are creating your observational data have no idea, right, what's going to happen***, because you don't [have] the observational data until you've given it to a whole bunch of people; right?
>
> A. Yeah, ***the observational data is after, obviously, you've given it to people***.
>
> Q. So ***they became test subjects***?
>
> A. ***Right***. But, again, I think the nature of what you're defining here on a limited number of our individuals, in our judgment, the judgment by the FDA, it was not—it was not judged a good idea to hold women hostage based on this limited amount of data where the incidence and ***the whole likelihood is at or below the expected rates of seeing spontaneous abortion***.

(emphasis added). There is an enormous problem with this answer that should be clear from the questions above, however, which is that Pfizer had no idea how big the denominator of pregnant women was in the 1001 trial. It wasn't counting that number because ***it was supposed to be zero***. The fact that there was ***any*** difference between the intervention and placebo groups ***at all*** should have been a cause of concern and a red flag that more study was needed.

In what should come as a somewhat comforting note, we searched the records Pfizer provided to us for additional information about these events. We were not able to find all of them, but the miscarriages we did find were all considered by Pfizer's investigators to be unrelated to BNT162b2 and did appear to be fairly remote in time from the administration of the vaccine. Still, we do not believe the choice to rely on observational data—whether it was initiated by Pfizer, the CDC or both—was appropriate for this population.

P301 had a similar issue, reporting two "spontaneous abortions" in its placebo group and two in its intervention group during the blinded period. As the trial went on, P301 saw more of this adverse event, recording a total of 11 events during its open label period and eight more during its booster phase; a grand total of 23 "spontaneous abortions." Somehow, none of these results made it into the journals either; and once again, the only reason we know they occurred at all is because

Moderna finally had to report them in December of 2023. Just as we did with Pfizer, we searched Moderna's records for information about these miscarriages. Once again, we were not able to find a great deal of information, but these events also appeared to be fairly remote in time from the administration of MRNA-1273 and were not related by study investigators to the intervention.

Of course, we have no real idea the total number of pregnant women in 1001 and P301 because they weren't supposed to be there in the first place. As we discussed with Pfizer's representative, the outcomes detailed above could be well within the roughly 10% of ordinary pregnancies that unfortunately end in miscarriages. The low numbers are also not statistically significant, so they could represent a statistical anomaly that returns to baseline when more outcomes are included. On the other hand, they could represent a real safety signal regarding women in early pregnancy and mRNA vaccines. We just don't know. The responsible and comprehensive way to get to the bottom of that question would be to enroll consenting pregnant women who are aware of the potential risks to themselves and their babies in an RCT.

Moderna did nothing of the kind; but to Pfizer's credit, in February of 2021, it began Clinical Trial C4591015 "[t]o Evaluate the Safety, Tolerability, and Immunogenicity of BNT162b2 Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older." A detailed description of the trial explained that:

> The Phase 2 portion of the study will include approximately 200 pregnant women randomized 1:1 to receive BNT162b2 or placebo (saline) at 27 to 34 weeks' gestation. IRC review of safety data through 7 days after the second dose for all Phase 2 participants will be completed.
>
> The Phase 3 portion of this study will assess the safety, tolerability, and immunogenicity of BNT162b2 among pregnant women enrolled at 24 to 34 weeks' gestation.
>
> Maternal participants who originally received placebo will receive BNT162b2 at defined time points as part of the study.

Though the study description did not specify the ultimate size of the phase three cohort, records submitted by Pfizer to ClinicalTrials.gov show an estimated final cohort size of approximately 4,000 women, which would have been similar in size to Pfizer's other immunogenicity studies.

While Pfizer was enrolling pregnant women to participate in this trial, however, the gears of the United States public health apparatus were already in motion. The CDC's Advisory Commission on Immunization Practices (ACIP) and the American College of Obstetrics and

Gynecologists (ACOG) had opined early on that COVID-19 vaccines should not be withheld from a woman on the basis of her pregnancy status, framing it in as something akin to a civil rights issue. In June of 2021, the NEJM published an article entitled *Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons*. The authors of the article used surveillance datasets from VAERS and V-Safe to conclude that:

> [e]arly data from the v-safe surveillance system, the v-safe pregnancy registry, and the VAERS do not indicate any obvious safety signals with respect to pregnancy or neonatal outcomes associated with COVID-19 vaccination in the third trimester of pregnancy. Continued monitoring is needed to further assess maternal, pregnancy, neonatal, and childhood outcomes associated with maternal COVID-19 vaccination, including in earlier stages of pregnancy and during the preconception period. Meanwhile, the present data can help inform decision making about vaccination by pregnant persons and their health care providers.

This finding, just like the findings from MMWR, came with two long paragraphs detailing the preliminary nature of the results, the inherent limitations of the VAERS and V-Safe datasets, possible bias in the data reporting and the possibility that the cohort—which was primarily composed of healthcare personnel who found themselves in the highest priority group for COVID-19 vaccination—may have been nonrepresentative of the population as a whole. At the end of July, however, the ACOG and the Society of Maternal-Fetal Medicine (SMFM) both advised their member doctors to "enthusiastically recommend vaccination" to ***all*** pregnant women, citing "evidence demonstrating the safe use of the COVID-19 vaccines during pregnancy from tens of thousands of reporting individuals over the last several months, as well as the current low vaccination rates and [a] concerning increase in cases." Soon after, in early August, the CDC changed its advice, which had been neutral, to affirmatively recommend vaccination for pregnant women.

When BNT162b2 was fully approved on August 23, 2021, the FDA failed to mandate or even acknowledge Pfizer's ongoing clinical trial of pregnant women as a postmarketing requirement, as it did with the pediatric cohorts Pfizer had included in its 1001 trial and recruited into other studies while BNT162b2 was in EUA status. Instead, it required Pfizer to conduct a new study, C4591002, which would be titled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry." The FDA required a final report by Pfizer as to these results on December 30, ***2025***.

With a fully approved vaccine that was being recommended by both ACOG, SMFM and the CDC, it apparently no longer made sense for Pfizer to continue C4591015. Pfizer officially concluded the RCT in July of 2022. ***No one ever published the results in a journal, and they never reached the VRBPAC because there was no need to apply for a license the FDA had already granted.*** During the pendency of the trial, however, Pfizer did actually recruit a cohort of 683 pregnant women and did study them. As a result, federal law required that the results of C4591015 eventually be posted to ClinicalTrials.gov. In July of 2023, the public finally got to see those results. For the most part, SAEs did look balanced between placebo and intervention cohorts during the blinded period, though the small cohort size meant the vast majority of them were not statistically significant. Unlike 1001 and P301, it did not appear that any "spontaneous abortion" events occurred in C4591015, but this, too, could be a function of the fact that the cohort in the trial was limited to late-term pregnancies between 24 and 34 weeks.

One exception to the findings above was Outcome Measure 19, the "[p]ercentage of infant participants who reported [adverse events of special interest] including major congenital anomalies and developmental delay from birth through 6 months of age[,]" which occurred in 5.1% of participants in the intervention versus 1.3% of participants in the placebo group. The information released on ClinicalTrials.gov does not provide any detailed descriptions of these adverse events. It is possible that this result, too, is just a statistical irregularity that would have evened out had the study continued. The fact that we don't know is an excellent argument to continue the trial, and possibly even conduct additional clinical trials on women at earlier stages of pregnancy.

Suffice it to say that we do not believe pregnant women were well-served by the United States public health apparatus, nor do we believe these troubling issues were properly and meaningfully disclosed and discussed over the last four years. Troubling results that occurred in newly pregnant women in the flagship clinical trials were not contemporaneously disclosed by the FDA, Pfizer or Moderna, nor do they appear to have been meaningfully investigated beyond allowing pregnant women to serve as human guinea pigs based on limited observational data that did not address infant health risks, then using statistically unreliable safety databases like VAERS to "enthusiastically recommend vaccination" to this vulnerable group. We believe RCTs in this population could have been conducted and completed with promptness, and the results would have affirmed public faith in our apparatus of vaccine testing and approval. Such studies possibly could have also saved lives. We also recognize our belief that RCTs were needed in this population places

this Grand Jury at odds with a number of major medical associations and agencies of the United States government. We are comfortable with that, however, because we believe their positions are at odds with common sense.

## SAFETY: PHARMACOVIGILANCE

In terms of safety, even the best clinical results can only take one so far. This is because even the most comprehensive RCTs are subject to the inherent limitations of their cohort size and surveillance period. An important safety event that occurs in one in a million people, for example, may not occur at all in a clinical trial of 25,000; and if that safety event did occur once, twice or even a few times, those events may not provide sufficient data to establish its significance and separate it from statistical background noise. Similarly, safety events may occur months or even years after a trial has ended, or in certain specific circumstances that do not ordinarily arise in clinical trial participants. Effectively, every biologic or drug the FDA licenses—even those that have survived robust clinical trials—are "experimental" in that sense that the sponsor and the FDA have only inferential data regarding safety events that may occur at a rate or in a time frame that would put them beyond the reach of those clinical trials.

For these reasons, both EUAs and Full Approvals routinely require sponsors to conduct pharmacovigilance, a set of mandatory post-approval safety activities managed in tandem with and under the supervision of the FDA. It is no exaggeration to say that new safety signals are discovered frequently in pharmacovigilance. A study from 2017 found that 32% of novel therapeutics approved by the FDA from 2001 to 2010 had "postmarket safety events" that required additional communications, boxed warnings, or, infrequently, full withdrawals of marketing approval by the FDA. According to the study's authors, the safety events precipitating these corrective actions occurred more frequently "among biologics. . . , those receiving accelerated approval, and those with near–regulatory deadline approval." These safety signals were often not discovered until several years after a given therapeutic's license had been granted. This is not necessarily a bad thing. Rather, it speaks to one of the principal characteristics of good science: Gathering new information and incorporating it over time.

To see the truth of this, one needs look no further than the COVID-19 vaccines, all three of which were associated with safety issues necessitating FDA intervention. Janssen's AD26.COV2.S vaccine was granted Emergency Use Authorization on February 27, 2021, but was subsequently connected via pharmacovigilance to a rare event known as cerebral venous sinus

thrombosis. This SAE, which—as of April 2021—had been reported just six times after the administration of 6.8 million doses of AD26.COV2.S, was much too rare to have been seen in Janssen's 43,000 clinical trial participants. Once the signal was uncovered, the FDA and CDC promptly issued a joint statement recommending a "pause" in the marketing of AD26.COV2.S and informing the public of the SAE's existence and its tendency to occur in women—to that point, exclusively in women aged 18-48. The FDA also promptly commenced an emergency meeting of the ACIP to decide the best way forward. The ACIP examined the available data and chose to reaffirm its prior recommendation. The marketing of AD26.COV2.S resumed with a warning regarding the "danger of rare blood clots after vaccination."

In July of 2021, AD26.COV2.S was associated with a second SAE, Guillain-Barré syndrome. This time, pharmacovigilance uncovered 100 preliminary reports—including one death—from a denominator of approximately 12.5 million administered doses. After examining the issue, the FDA announced "revisions to the vaccine recipient and vaccination provider fact sheets for the Janssen (Janssen) COVID-19 Vaccine to include information pertaining to an observed increased risk of Guillain-Barré Syndrome (GBS) following vaccination."

Janssen's vaccine may have been the first to uncover unexpected safety events via pharmacovigilance, but Pfizer's BNT162b2 and Moderna's MRNA-1273 were not far behind. In July of 2021, both vaccines were formally associated by the ACIP with rare instances of myocarditis and pericarditis (which we will explore in detail below). This serves to underscore the central thesis of the 2017 research study: The discovery of new SAEs after pharmacovigilance of biologics—including vaccines—that have already been found to be "safe and effective" by the FDA is unfortunate; to some extent, it is unavoidable, but it is not uncommon.

Ordinarily, post-approval pharmacovigilance will have two primary dimensions: (1) A set of required "postmarketing studies," which often involve specific questions or issues that arise from either the clinical trials or from some prior form of licensure (like an EUA); and (2) a more generalized obligation for a sponsor to conduct "postmarketing surveillance," gathering outcome data from a variety of sources to develop a robust safety profile on its product and uncover infrequent safety events that may represent significant health risks.

## POSTMARKETING STUDIES

Both Pfizer and Moderna were notified of the Full Approval of their COVID-19 vaccines, per FDA custom, via published letters. Those letters each contained a series of additional

interventional and observational postmarketing studies that sponsors were required to perform in order to maintain their licenses. Pfizer's first Full Approval letter, published on August 23, 2021, formally required the following:

| Req. # | Study Name | Due By |
|---|---|---|
| 1 | Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age. | October 31, 2023 |
| 2 | Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age. | May 31, 2024 |
| 3 | Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age | October 31, 2024 |
| 4 | Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY. | October 31, 2025 |
| 5 | Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY. | September 30, 2024 |
| 6 | Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY. | September 30, 2024 |
| 7 | Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network). | December 31, 2026 |
| 8 | Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age. | May 31, 2024 |
| 9 | Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age. | December 31, 2022 |
| 10 | Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry." | December 31, 2025 |
| 11 | Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age. | May 31, 2024 |
| 12 | Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine." | December 31, 2023 |
| 13 | Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California." | June 30, 2023 |

The requirements in this letter were amended in several subsequent published letters. In July, 2022, the FDA acknowledged that Pfizer completed Requirement #1. In September, 2023, the FDA waived Requirement #3 based on "evidence strongly suggesting that a single dose of COMIRNATY would be ineffective in this pediatric group[,]" but deferred as to "pediatric studies for individuals 6 months through 11 years of age" because those studies had "not been completed." The letter also formally required three additional postmarketing studies:

| Req. # | Study Name | Due By |
|---|---|---|
| 1a | Deferred pediatric study (C4591048 Substudy A) to evaluate immunogenicity and safety of COMIRNATY in infants and children 6 months through 4 years of age. | September 30. 2026 |
| 2a | Deferred pediatric study (C4591048 Substudy E) to evaluate immunogenicity and safety of a single dose of COMIRNATY in infants and children 2 years to <12 years of age. | April 30, 2025 |
| 3a | Study C4591054, Substudy B, to evaluate immune responses following a single dose of COMIRNATY (2023-2024 Formula) in individuals 12 years and older who are not previously vaccinated with a COVID-19 vaccine. | December 31, 2024 |

To date, Pfizer has completed its work on postmarketing requirements 1, 2, 8, 9, 11, 12 and 13. Postmarketing requirements 4, 5, 6, 7, 10, 1a, 2a and 3a are still underway. At the acquiescence of the FDA, Pfizer has missed its initial deadlines and received administrative extensions for postmarketing requirements 5 and 6.

Moderna's first Full Approval letter, published on January 31, 2022, also contained a number of formal postmarketing study requirements:

| Req. # | Study Name | Due By |
|---|---|---|
| 1 | Deferred pediatric study under PREA (Study mRNA-1273-P203) to evaluate the safety and effectiveness of SPIKEVAX in children 12 years through 17 years of age. | July 31, 2024 |
| 2 | Deferred pediatric study under PREA (Study mRNA-1273-P204) to evaluate the safety and effectiveness of SPIKEVAX in children 6 months through <12 years of age. | March 31, 2024 |
| 3 | Deferred pediatric study under PREA (Study mRNA-1273-P206) to evaluate the safety and effectiveness of SPIKEVAX in infants < 6 months of age. | December 31, 2024 |
| 4 | Required safety study under Section 505(o) (Study mRNA-1273-P903), entitled "Post-marketing safety of SARS-CoV-2 mRNA-1273 vaccine in the US: Active surveillance, signal refinement and self-controlled risk interval (SCRI) signal evaluation in HealthVerity", to evaluate the occurrence of myocarditis and pericarditis following administration of SPIKEVAX. | June 30, 2023 |

| | | |
|---|---|---|
| 5 | Required safety study under Section 505(o) (Study mRNA-1273-P904), entitled "Post-Authorization Active Surveillance Safety Study Using Secondary Data to Monitor Real-World Safety of Spikevax in Europe," to evaluate the occurrence of myocarditis and pericarditis following administration of SPIKEVAX. | December 31, 2023 |
| 6 | Required safety study under Section 505(o) (Study mRNA-1273-P911), entitled "Long-term outcomes of myocarditis following administration of SPIKEVAX (Moderna COVID-19, mRNA-1273)," to evaluate long-term sequelae of myocarditis after vaccination with at least 5 years of follow-up. | October 31, 2028 |
| 7 | Required safety study under Section 505(o) (Study mRNA-1273-P301) substudy to prospectively assess the incidence of subclinical myocarditis following administration of a booster dose of SPIKEVAX in participants 18 years of age and older. | June 30, 2023 |
| 8 | Required safety study under Section 505(o) (Study mRNA-1273-P203) substudy to prospectively assess the incidence of subclinical myocarditis following administration of a booster dose of SPIKEVAX in participants 12 years through <18 years of age. | July 31, 2024 |
| 9 | Required safety study under Section 505(o) (Study mRNA-1273-P204) substudy to prospectively assess the incidence of subclinical myocarditis following administration of SPIKEVAX in a subset of participants 6 months through | March 31, 2024 |
| 10 | Study mRNA-1273-P901, entitled "Real-World Study of the Effectiveness of Moderna COVID-19 Vaccine." | April 14, 2025 |
| 11 | Study mRNA-1273-P902, entitled "Moderna mRNA-1273 Observational Pregnancy Outcome Study." | June 30, 2024 |
| 12 | Study mRNA-1273-P905, entitled "Monitoring safety of Spikevax in pregnancy: an observational study using routinely collected health data in five European countries. | December 31, 2023 |

In September of 2023, the FDA acknowledged Moderna had fulfilled Requirement #1. It also "waiv[ed] the pediatric study requirement for ages younger than 2 years of age[,]" disposing of a portion of the cohort in Requirement #2 and all of Requirement #3. As it did with Pfizer, the FDA deferred submission as to the remainder of Requirement #2 because "the pediatric study ha[d] not been completed." To date, Moderna has not completed any of its other postmarketing requirements. All of the studies above except for 11, which was terminated, are still underway. To date, Moderna has missed its original deadlines and received administrative extensions for Requirements 2, 4, 5, 7, 8, 9, 10 and 12.

These missed deadlines do not give us confidence. Each one represents an opportunity for the FDA and the public to be better informed about the safety of these products that cost billions of taxpayer dollars to develop, manufacture and administer. We recognize that conducting these trials and studies can be challenging work, but we think the money Pfizer and Moderna made

should be more than enough to fund and timely administer these tasks as they have been directed. The FDA would not speak to us directly, so we are not sure what their excuse would be for not holding Pfizer and Moderna's feet to the fire. Frankly, we are not sure any answer would satisfy us at this point, nor should it satisfy anyone else.

**POSTMARKETING SURVEILLANCE**

Of course, postmarketing studies only tell half the pharmacovigilance story. The other half—and perhaps the more important one—is postmarketing surveillance. As we mentioned above, public health agencies have a set of primary databases like VAERS, V-Safe and more importantly the VSD, where they undertake surveillance of all licensed vaccines including MRNA-1273 and BNT162b2. In addition, Pfizer and Moderna are legally required to maintain their own "Global Safety Databases" (GSDs) for their vaccines. These GSDs include not only the results from the databases above, but also statistics from other public health resources around the world, like the European Union's EudraVigilance, the World Health Organization's VigiBase and various data streams from other countries who have licensed their products.

Sponsors use these GSDs to conduct "disproportionality analyses"—a fancy way of saying that a particular adverse event is happening more often than it should. Where a sponsor discovers a mathematically disproportionate outcome, the safety signal is considered to be "identified." The sponsor then undertakes a process called "validation," where it assesses whether there is a plausible causal relationship between vaccination and the adverse event. Often, however, safety signals are submitted directly to the sponsor from the FDA or the CDC, who have already undertaken the preliminary steps to identify and validate a safety signal using their own tools and are enlisting the sponsor's help to undertake the formal investigative process. This next part of the process is primarily characterized by an in-depth review of existing adverse events by qualified physicians and scientists employed by the sponsor. Sponsors will also gather and synthesize available research from outside sources like observational studies, case series and other resources in an effort to understand the population-level incidence, etiology and severity of a given safety signal. Once the necessary data are gathered and analyzed, sponsors will share their data with FDA and validated signals are either "confirmed" or "refuted."

If a signal is "confirmed," the FDA—in conjunction with the ACIP—must then decide what kind of response is warranted. Some of these safety signals may be deemed to require no more than a published communication or warning about potential risks. Others may require

updates to their physician or patient information. Other confirmed safety signals may require the adoption of additional procedures. A good example of this occurred with the COVID-19 vaccines, where recipients were advised to wait 15 minutes after they received their injections to ensure a timely dose of epinephrine would be available should they suffer a known SAE of anaphylaxis. Finally, some serious safety signals may require withdrawal of their approval in at-risk groups, or—in the case of a more widespread SAE—a complete withdrawal of the product from the market. If, on the other hand, a safety signal is "refuted," it just . . . goes away. There is no public ACIP meeting to decide what to do about it and no obligation on the part of the sponsor or FDA to disclose it. As a result, the public never finds out that there was a validated signal—a mathematically disproportionate result with a plausible connection to a product—because neither the signal itself nor the reasoning and result of the investigation are published.

Despite the conditions of the pandemic, pharmacovigilance surveillance of the mRNA COVID-19 vaccines did take place. In fact, according to the sponsors, it was significantly enhanced. The record supports this. Unlike the quarterly, bi-annual then annual obligation that would inure in ordinary drug and biologic approvals, Pfizer and Moderna were required to report safety results derived from their Global Safety Databases to the FDA for BNT162b2 and MRNA-1273 in the form of "Periodic Benefit-Risk Evaluation Reports" (PBRERs). This enhanced surveillance produced results. Sponsors identified, validated, investigated and ultimately confirmed several safety signals. To date, Moderna has confirmed five: Myocarditis, pericarditis, anaphylaxis, syncope (dizziness) and urticaria (hives). However, what the public likely does not know is that Moderna investigated a total of 65 safety signals, "refuting" 60 of them in consultation with the FDA. As for Pfizer, the company's representative had this to say:

> Q. I neglected to ask you something earlier. Do you know the total number of safety signals that Pfizer investigated with respect to BNT—do you know the number of total number of safety signals investigated with BNT162b2?
>
> A. Yes. ***About 100 signals we have investigated as validated signals for the vaccine***, and they were investigated at least once.
>
> Q. Okay. So—but you just said were validated. So those are 100 signals that were validated?
>
> A. Yes.
>
> Q. How many of those signals ended up being confirmed versus refuted?

A. ***Refuted means that we found other causes that led to them?***

Q. Right.

A. ***So actually, very, very few***. I can think of dizziness that was confirmed and was added to the label, and myocarditis, which is the most well-known signal.

Q. So what are the total number of safety signals that have been confirmed?

A. Confirmed to represent the risk of the vaccine?

Q. Correct.

A. I don't have that number.

Q. Okay.

A. I just remember dizziness and every signal that we would have confirmed, it would have went into the label, and they said there's an adverse reaction in the label.

(emphasis added). Based on its label and that conversation, BNT162b2, appears to have confirmed safety signals involving myocarditis, pericarditis, anaphylaxis, and dizziness.

What were the rest of these validated signals? On what basis were they refuted? How long and how thoroughly were they investigated? Only the FDA and the sponsors know.[1] We asked Moderna's representative, a friendly and qualified scientist, whether his company informed the public about validated safety signals prior to confirmation. This was his answer:

> No, it's irrelevant for them. There's no reason to. And the reason is that, these are issues that are unknown. . . . [a]nd if we were to advise the public of every theoretical safety concern, I think that would be a disservice to the public.

We emphatically disagree. In fact, we believe it perfectly illustrates the larger paternalistic attitude on the part of both government health agencies and the pharmaceutical industry towards the public. It is okay for citizens to see the gears of their public health system at work, especially in the case of the COVID-19 vaccines, where the citizens are the ones whose taxpayer dollars largely funded the enterprise in the first place. ***Hiding the details, methodology and results of scores of safety***

[1] This Grand Jury is fairly certain that at least some of the answers to these questions are inside the millions of pages of documents Pfizer and Moderna provided in discovery, which include thousands upon thousands of pages of PBRERs appurtenant to MRNA-1273 and BNT162b2. Unfortunately, we have neither the time nor the expertise at our disposal to meaningfully evaluate them. Nevertheless, electronic versions of all these records remain in the custody of the Clerk of the Florida Supreme Court.

***investigations from public view does not build public confidence; it undermines it.*** Ordinary people are entitled to know the details of these investigations. They are smart enough to understand them and they should be allowed to use this information to make their own health choices.

In January of 2024, a landmark observational study called *COVID-19 vaccines and adverse events of special interest: A multinational, Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals* was published in a highly prestigious and influential scientific journal. The study, just as its name says, examined the incidence of a multitude of adverse events of special interest (AESIs) derived from a denominator of nearly a billion doses of BNT162b2, MRNA-1273, and another vaccine formula we did not investigate. This is, by any measure, a huge number of events that—if what their representatives have said about the size and breadth of their data surveillance is true—likely reflects a good portion of what was captured in the GSDs of Moderna and Pfizer. The results were not comforting. Even when one excludes odds ratios for which any part of the 95% confidence interval falls below baseline, BNT162b2 was identified with statistically significant increases in the observed versus expected events for the following AESIs:

**Neurological Conditions:**
Bell's Palsy (dose 1)
Generalized Seizures (dose 4)
**Hematologic Conditions:**
Thrombocytopenia (dose 1)
Idiopathic Thrombocytopenia (dose 1)
Pulmonary Embolism (dose 1)
Cerebral Venous Sinus Thrombosis (doses 1 & 2)
Splanchnic Vein Thrombosis (doses 1 & 4)
**Cardiovascular Conditions:**
Myocarditis (all doses)
Pericarditis (all doses)

With those same exclusions applied, MRNA-1273 was identified with statistically significant increases in the observed versus expected events for the following AESIs:

**Neurological Conditions:**
Bell's Palsy (dose 1)
Acute Disseminated Encephalomyelitis (dose 1)
Febrile Seizures (doses 1 & 2)
Generalized Seizures (dose 1)
**Hematologic Conditions:**
Thrombocytopenia (dose 1)
Pulmonary Embolism (dose 1)
Splanchnic Vein Thrombosis (doses 1, 2 & 4)

**Cardiovascular Conditions:**
Myocarditis (all doses)
Pericarditis (all doses)

Pfizer and Moderna's products were each associated with nine noteworthy AESIs in this study, but their representatives tell us that they investigated a total of "around 100" and 65, respectively. Were these AESIs among those investigated? As it turns out, yes. We showed Pfizer the elevated risk ratios in this study, prompting the following exchange:

> Q. Okay. Of those conditions, ***how many of these conditions did you—did Pfizer look into?*** This is—
>
> A. ***All of them.***
>
> Q. All of them?
>
> A. Yes.
>
> Q. ***How many of those were treated as a safety signal?***
>
> A. Under—so they were all of them adverse events of special interest that's subject to special monitoring and the analysis. And to my recollection, ***all of them were actually validated signals at some point early in the days of the pandemic***.
>
> Q. Do you know if any of them were confirmed?
>
> A. No, they were not—so confirmed. ***Confirmed as to require further investigation, yes, they were further investigated, but they were not found to be induced by the vaccine.***

Once again, nobody outside Pfizer or the FDA knew anything about these investigations before the exchange above. There may well have been good reasons for the FDA and the sponsor to reach those conclusions, but nobody gets to know because those results are not public, even when taxpayer dollars largely funded the development and certainly paid for the administration of these products. Instead, this Grand Jury and the rest of the public get to learn about the existence of these validated safety signals years later from a third-party study, with no guidance whatsoever on whether they were promptly, properly and comprehensively addressed. Suffice it to say that we do not believe that is a good way to build trust in public health.

Even where safety signals are confirmed and made public, we are not sure that the corrective actions often recommended by ACIP and mandated by the FDA—specifically public

warnings and label updates—make much sense in the context of a vaccine that is administered essentially over the counter by pharmacy employees with minimal training. Ordinary people—like the ones who make up this Grand Jury—generally do not have clinical training or expertise of their own. They depend on healthcare professionals to help them navigate the risks, benefits and side effects of many of their medications. Those who get their shots at Publix or CVS or stick their arm outside of their car at one of the many public vaccination sites that dotted the State of Florida in 2021 may not have any idea that both BNT162b2 and MRNA-1273 come with long inserts full of important safety considerations, or that by choosing to be vaccinated, they are legally assumed to have read these inserts and been informed about these risks. Few of us, for example, knew prior to this Grand Jury that anaphylaxis was a well-known complication involving the administration of not just the COVID-19 vaccines, but any vaccine containing polyethylene glycol, including vaccines administered yearly for the flu. This is a systemic problem that is true of any vaccine that is delivered in this manner, and it is only aggravated by the issuance of broad mandates that do not distinguish groups more likely to suffer AEs from those who are not. Vaccine mandates supercharge this issue by removing the element of choice and compelling compliance.

**VACCINE-RELATED MYOCARDITIS AND PERICARDITIS**

Somehow or another, nearly every safety issue we have discussed so far in this Final Report is relevant to the safety signals of Vaccine-Related Myocarditis and Pericarditis (VRMP). Before we begin to delve deeper, however, we wish to make two things clear. First, VRMP events are very rare. The scientific community has been locked in a relentless three-year debate about exactly how rare, but no one should lose sight of the fact that nearly all sides of that debate agree that VRMP events do not happen frequently. One of Pfizer's representatives provided the most conservative VRMP rate estimate we heard: Ten cases per million vaccinated. At the other end of the spectrum, the most liberal estimate we saw came from *Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination*, which put the rate of VRMP in males aged 12 to 17 who received their second dose of BNT162b2 at 373.2 per million. It is also true that VRMP occurs more frequently in males aged between roughly 12 and 29, but that does not mean that it is not rare, even in that high-risk group.

Second, most clinical VRMP cases—roughly eight in ten—do resolve without permanent damage. This finding, too, is subject to controversy around the margins. People do die from so-called "fulminant" VRMP—we will even discuss some of those cases below—but these deaths are

very infrequent. It is also important to keep in mind that death is not the only negative outcome that can arise from VRMP. All myocarditis and pericarditis events can lead to long-term damage and scarring of the cardiac muscle. This scarring can permanently compromise the heart's performance, potentially causing serious problems later in life. The danger posed by these negative outcomes means that diagnoses of VRMP have a hospitalization rate approaching 100%. In short, the FDA classifies myocarditis and pericarditis as SAEs for a reason.

Before we delve too far into the details of this issue, it is also important to establish some working definitions. "Myocarditis" is, in simplest terms, an "-itis" (inflammation) of the "myocardium" (heart muscle). "Pericarditis" is, in simplest terms, an "-itis" (inflammation) of the "pericardium" (a double-walled sac containing the heart muscle). There is also "myopericarditis" (inflammation of the heart muscle and the sac). For simplicity's sake, we will refer to all these conditions—provided they are related to either BNT162b2 or MRNA-1273—as "VRMP."

"Normal" myocarditis and pericarditis cases tend to occur in tandem with viral, bacterial, fungal or other types of infections, including SARS-CoV-2. This means that much of the time, when a person gets one of these conditions, he or she is usually already suffering from some other health challenge, be it infection, heart trauma or some other disease process. The exact mechanisms that cause myocarditis and pericarditis are not well understood, but most of the experts we spoke with believe they are likely the result of poorly modulated immune responses. Usually, the recommended treatment regimens for these conditions involve supportive care, targeted cardiac medications as needed and restrictions on exercise and other rigorous physical activity until diagnostic imaging confirms resolution of the inflammation.

Myocarditis, the more serious of the two conditions, is very infrequent at baseline, occurring at a rate of roughly 21.6 per million according to an oft-quoted study of myocarditis and pericarditis in healthy military servicemembers from 2002-03. It does tend to occur more readily in young men between the ages of 12 and 29. Many experts believe—due to the fact that it appears most frequently in a demographic that is not known to regularly seek medical care—myocarditis is very likely chronically underdiagnosed. As we mentioned above, death is a possible, albeit rare outcome, but there is a risk of long-term or even permanent damage to the heart that can persist after recovery. This is particularly true where someone who has myocarditis or pericarditis is not diagnosed and therefore does not receive any care or make any adjustments to his or her lifestyle that would allow for a smooth recovery.

VRMP, as a disease, is not clinically different from other forms of myocarditis and pericarditis. It has many of the same symptoms and the same potential for damage. It does tend to have better outcomes than other forms of myocarditis and pericarditis, but this is probably because the people who get VRMP, as opposed to "normal" myocarditis and pericarditis, are not usually suffering from some other compromising condition like an acute infection. BNT162b2 and MRNA-1273 are also not the first vaccines to be associated with these conditions. Cardiac complications and some deaths were seen in the wake of worldwide vaccinations for smallpox in the 1950s and 1960s. As recently as 2015 a DOD study called *A Prospective Study of the Incidence of Myocarditis/Pericarditis and New Onset Cardiac Symptoms following Smallpox and Influenza Vaccination* found the smallpox vaccine to be associated with over 4,600 additional cases of "myopericarditis" (which the study authors used as a catch-all term for either myocarditis or pericarditis) per million vaccinated soldiers.

VRMP resembles "normal" myocarditis and pericarditis in that it is more frequent in males between the ages of 12 and 29, though it does not occur exclusively in that group. There also exists no consensus on exactly why it happens. Third-party sources suggest several different mechanisms of action; various internal documents produced by Pfizer and Moderna suggest several more, but there is nothing definitive in terms of etiology. This means, unfortunately, that clinicians face significant difficulty predicting who will get VRMP beyond simple demographics, and even those demographics are limited in their prognostic value.

**History of the Signal**

The public first learned about the possibility of a myocarditis signal in February of 2021 via published news reports following administration of BNT162b2 in Israel. It made sense that Israel would be the first to come across a safety signal because the country had secured enough vaccine doses to immediately administer COVID-19 vaccines to its entire population, unlike the United States, which had to ration its vaccine doses based on risk and exposure for the first part of 2021. This meant that millions of young Israeli men in the relevant age category for VRMP were the first of their demographic in the world to be vaccinated, and Israel had the means to monitor this population given its centralized healthcare system. It also made sense that the signal would appear in BNT162b2 because Israel immunized its population exclusively with Pfizer's vaccine.

At roughly the same time, however, there was also a less-publicized safety signal for myocarditis that appeared after the United States military began vaccinating its servicemembers.

This signal, which involved both BNT162b2 ***and*** MRNA-1273, was not made public until after the VRMP safety signal was confirmed on June 23, 2021. However, representatives from Pfizer and Moderna confirmed to this Grand Jury that several government agencies, including the DOD, were investigating it well before then. Documents this Grand Jury received from Moderna also confirmed that the VRMP safety signal was not one the company detected on its own, but rather was, as a representative for Moderna testified, "an area of intense interest [to regulators] in the springtime leading up to . . . June, 2021."

This was not the public message put forth by the CDC, however. On April 27, 2021, CDC Director Rochelle Walensky was asked about "reports that the Pentagon is tracking 14 cases of heart inflammation or myocarditis among service members and families" and whether those cases could be related to vaccination. She responded with the following:

> Yeah, I'm aware of those reports. I don't necessarily want to comment on what the DOD is doing in investigating in their own investigations.
>
> What I will say is we've delivered over 200 million doses of vaccine — of these vaccines. And after hearing about these reports, we, again, looked back in our vaccine safety data, and we have not seen any reports of those. Those have since been reported to us, and so those investigations are ongoing.
>
> But, you know, it is a—it is a different demographic than we normally see, and we will be working with DOD to understand what is happening in those 14 cases. We have not seen a signal, and we've actually looked intentionally for the signal in the over 200 million doses we've given.

Contrary to the statement above, contemporaneous communications between top CDC officials suggest that agency, along with the FDA, Pfizer, Moderna and the DOD were all actively investigating the VRMP safety signal right around the time Director Walensky was saying CDC had not seen one. Israel, for its part, publicly confirmed alerting the CDC in February of 2021 to "a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine." Furthermore, a large tranche of 2021 government emails recovered through FOIA requests demonstrating conclusively that in the late part of April and the early part of May, 2021, there was an active exchange of information between these government agencies above regarding the association of the mRNA COVID-19 vaccines and VRMP, including its likely risks and its possible mechanisms of action. In terms of public statements, however, nobody was talking.

Other public health entities were also getting involved. In an effort to standardize surveillance of prospective cases from different healthcare systems around the world, the Brighton Collaboration, a global network of vaccine safety experts, released updated definitions of myocarditis and pericarditis on May 1, 2021. Six days later, on May 7, 2021, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee publicly announced that it was also investigating reports of a VRMP safety signal from the mRNA COVID-19 vaccines. Two weeks later, on May 24, 2021, the ACIP confirmed that its COVID-19 Vaccine Safety Technical Work Group had indeed reviewed the available data regarding VRMP and made the following findings:

> Data from VAERS show that in the 30-day window following dose 2 mRNA COVID-19 vaccination, there was a higher number of observed than expected myocarditis/pericarditis cases in 16-24-year-olds.
>
> Data from VSD do not show that rates of myocarditis/pericarditis reports in the window following COVID-19 vaccination differ from expected at this time; however, analyses suggest that these data need to be carefully followed as more persons in younger age groups are vaccinated.

At this point, the cat was out of the bag. It had been ***four months*** since the first news reports of VRMP had appeared out of Israel. On June 23, 2021, the ACIP finally met to formally address VRMP. After reviewing myocarditis reports from the VAERS and VSD pharmacovigilance databases, the ACIP publicly confirmed the existence of the safety signal but concluded that the benefits of vaccination with mRNA COVID-19 vaccines still outweighed the risks, even in the age groups at highest-risk for VRMP. The ACIP recommended that the FDA address the VRMP signal by updating its EUA materials on BNT162b2 and MRNA-1273 to reflect the risk of VRMP, and that the CDC publish a warning and update its patient education and communications materials "to ensure that vaccine recipients, especially males aged 12-29 years, are aware of increased risk for myocarditis and to seek care if they develop symptoms of myocarditis."

There are some problems with this analysis. First of all, the ACIP used VAERS data from 1,226 myocarditis reports to establish a "reporting rate" of 40.6 myocarditis events per million second doses in males aged 12 to 29 years old. VAERS, however, is a passive reporting system well-known for its statistical unreliability. The scope of this problem has been discussed in detail in *The reporting sensitivity of the Vaccine Adverse Event Reporting System (VAERS) for anaphylaxis and for Guillain-Barré syndrome*, where a statistical analysis found that when VAERS

reports were compared to more statistically reliable data from VSD, "VAERS sensitivity for capturing anaphylaxis after seven different vaccines ranged from 13% to 76%; sensitivity for capturing [Guillain-Barré syndrome] after three different vaccines ranged from 12% to 64%." If the 1,226 reports to VAERS only constituted 76% or 64% of total VRMP events, the actual rate of events per million would definitely be higher than the ACIP's "reporting rate" of 40.6 cases per million. If, however, those 1,226 reports only constituted 12% or 13% of total VRMP events, the actual rate per million might be orders of magnitude higher than the ACIP's "reporting rate." Nevertheless, the ACIP had acted; confirming the VRMP safety signal and taking the action it believed appropriate. Its word, however, was far from final. It was just the first of many entries into what has become a contentious debate in science and in the media over the frequency and severity of VRMP.

## Frequency

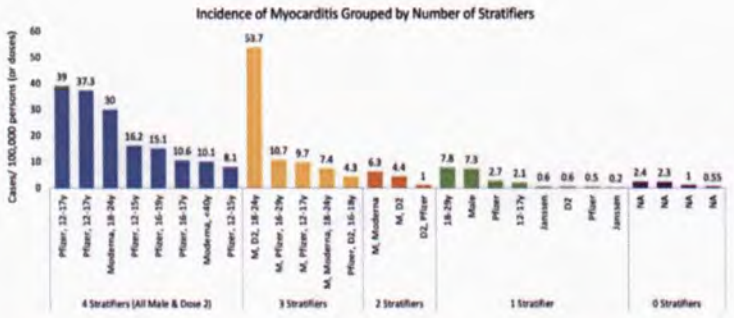
The ACIP's 2021 risk-benefit analysis may have been the first to compare the risks of VRMP to the risks of not getting vaccinated, but it would hardly be the last. Over the next two years, scores of observational studies were published comparing the risk of VRMP to the risk of eschewing vaccination and suffering a negative outcome from SARS-CoV-2 infection. These studies varied in quality and comprehensiveness; they drew different conclusions using different datasets; and many of them produced wildly different answers to the question originally answered by the ACIP. This Grand Jury has—for better or worse—reviewed and discussed all of these studies with qualified experts, who often held divergent opinions as to which studies had the best methodologies or the soundest conclusions. As nonscientists, we are in no position to litigate these disagreements, but we did notice some trends that seemed to us—as a matter of logic—to lead to more reliable study results.

### Cohort Stratification Makes a Difference

The first trend that we noticed is that several studies that purported to analyze VRMP frequency did not stratify their results by gender, age, dose and manufacturer, or they stratified their population by some of those factors, but not others. Skipping this analytical step masks risks that may be more prevalent in smaller subgroups. Breast cancer, for example, occurs in one out of eight women, but it also occurs in one out of 726 men. An analysis that combined those groups into one would do both subgroups a disservice; dramatically overstating the risk for men while dramatically understating the risk for women. Several of the VRMP analyses we reviewed made

this same mistake, and their failure to adequately stratify caused higher risk groups to be lumped in with lower risk groups, making risks appear lower in those at highest risk and ultimately biasing their conclusions. The phenomenon is clearly described in *COVID-19 vaccine induced myocarditis in young males: A systematic review*, published in January of 2023. It also is the source of this helpful chart:

FIGURE 1




Highest myocarditis incidence from each study. Each bar represents a unique study. Data are grouped according to the number of stratifiers used. Stratifiers are sex, age, dose number and manufacturer. Each bar is labelled on the x-axis with the stratifiers unique to the study that the estimate was obtained from. The number above each bar represents the myocarditis incidence. Male (M), Dose 2 (D2), Not Applicable (NA). In studies using four stratifiers, the stratifiers Male and Dose 2 were universally applicable

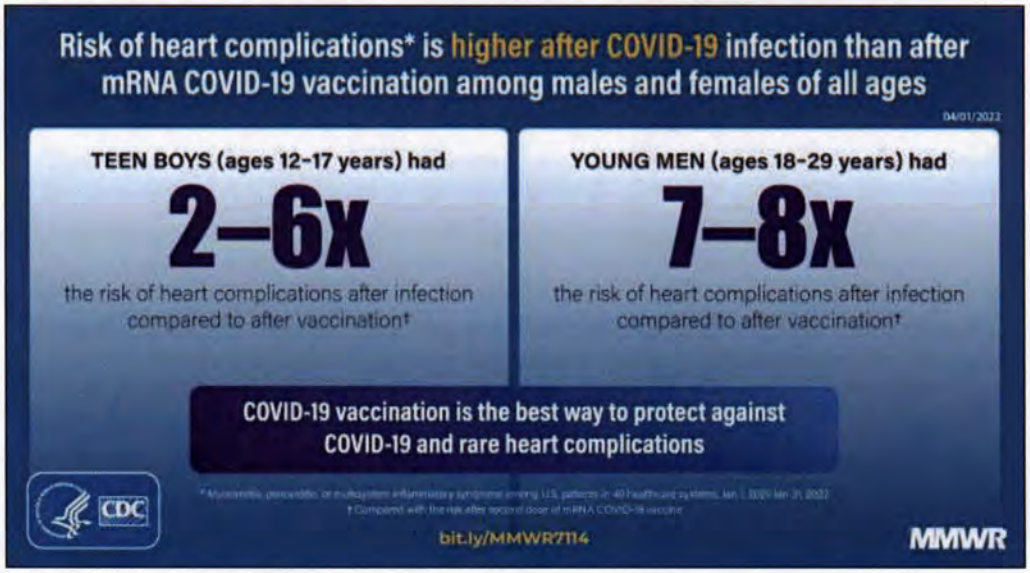
Although this study only looks at stratification in the context of VRMP, we found the principle the study authors described to have broader application, specifically in studies attempting to describe the rate of myocarditis and pericarditis following SARS-CoV-2 infection. Many of the studies we examined that found favorable risk-benefit ratios for vaccination were not stratified at all. Studies, by contrast, that took even a few steps towards stratification (separately analyzing men under the age of 40, for example) tended to find higher rates of VRMP in the highest-risk groups, yielding less favorable risk-benefit ratios for vaccine administration in those groups.

## Study Population Makes a Difference

Even the most well-designed observational study is only as good, as representative or as predictive as its population. The second trend we noticed was that study populations were often poorly calibrated to answer the questions these studies purported to address. Studies that use hospital admission data, for example, can only inform about hospital admissions. No matter how thorough they may be, hospital admission records necessarily miss all events that do not result in hospitalization. Similarly, studies that rely on electronic health records (EHR) can only give us information about people who frequent the places that generate them. While these latter studies are certainly less limited in scope than studies who use only hospital admissions, even EHR studies

necessarily miss people who venture outside the boundaries of that system when seeking care. We examined several VRMP studies that derived their risk-benefit analyses based on hospital admission data or on EHR, and they all had one thing in common: Extraordinarily high rates of COVID-19-induced myocarditis. This should not be a surprise. Any study that derives its cohort data from people in and around hospitals gathers those data from a sicker population. That population limits the utility of these studies because a sicker study population is likely to have more comorbidities, and therefore more likely to have complications from SARS-CoV-2.

One of the most notable examples of this population problem can be found in *Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 VACCINATION—PCORnet, United States, January 2021-January 2022* (the PCORnet Study), which used EHR data from a large group of hospitals and outpatient clinics to compare directly the rates of VRMP with the rates of COVID-19-related "cardiac complications," including myocarditis, pericarditis and multisystem inflammatory syndrome, a rare but serious complication of SARS-CoV-2 infection that frequently involves heart complications. For years, the CDC employed the PCORnet Study as a primary reference point for questions about post-vaccination myocarditis, publishing the following graphic on its website:




On the surface, these statistics look convincing. Someone browsing the CDC's website for practical information about VRMP could be forgiven for assuming that this study settles any debate about the risk-benefit analysis of vaccination for these age groups. But a closer examination reveals

cracks in its foundation. The ACIP found in 2021 that foregoing vaccination would result in 215 extra COVID-19 hospitalizations per million in the 12- to 17-year-old age group over a 120-day period; if those numbers held for a year, it would equal 653 hospitalizations per million. The PCORnet Study, meanwhile, looked at a year's worth of data from that very same demographic and found a rate of "cardiac complications" between 1,505 to 1,800 per million. How can it be that just ***one*** subset of COVID-19 hospitalizations in the 12- to 17-year-old age group—those occurring due to "cardiac complications"—occurs at twice the rate of ***all*** COVID-19-related hospitalizations?

The answer lies in the study population, which "included persons with documented SARS-CoV-2 testing, viral illness diagnostic codes, or COVID-19 vaccination during the study period." All of this testing, viral illness or vaccination had to occur within the PCORnet system of hospitals and clinics to be captured in the study. But how representative is that population? Between January of 2021 and January of 2022, SARS-CoV-2 testing was essentially free. Moreover, it was widely available outside of hospitals and health clinic settings. It stands to reason that, given the pandemic, lots of people—even members of PCORnet—were likely to avoid those hospitals and health clinics unless they had some other reason to go, like a significant health problem. This is all to say that the EHR analyzed in the PCORnet Study very likely represented a sicker population than a randomized sample of ordinary people in that same age group. Even the study authors understood this could be an issue, noting that "[u]nderascertainment of SARS-CoV-2 infections and mRNA COVID-19 vaccinations reduced sample size and might have introduced bias if capture of infection or vaccination within the EHR occurred differentially for those with cardiac outcomes." After comparing the results of this study with the results of other studies that did not use EHR, this appears to be exactly what happened.

A similar example of this problem can be found in *Risk of Myocarditis from COVID-19 Infection in People Under Age 20: A Population-Based Analysis* (the Preprint Study), which currently remains in preprint status despite being initially posted in July of 2021 and revised in March of 2022. This study is the original source of the widely-reported statistic that COVID-19-related myocarditis occurred at "an adjusted rate per million of 450 cases" in 12- to 17-year-olds.

Like the PCORnet Study, the Preprint Study was based entirely on electronic health records, this time from a database known as TriNetX, which describes its own data sources as follows:

> TriNetX datasets provide researchers access to de-identified ***patient data*** from networks of healthcare organizations (HCO) and other data providers.
>
> . . . .
>
> The majority of the HCOs are ***large academic medical institutions with both inpatient and outpatient facilities. Most of these HCOs are adult acute-care hospitals*** with multiple facilities and locations. All HCOs are currently located within the United States.
>
> HCOs provide TriNetX with both ***inpatient and outpatient data***. The data they provide is ***representative of the entire patient population at the HCO***. Most HCOs provide an average of seven years of historical data.

(emphasis added). In a step beyond the PCORnet Study, the Preprint Study's population was even more limited, including only patients who had "a first COVID-19 diagnosis during the April 1, 2020 - March 31, 2021 time period, with an outpatient visit 1 month to 2 years before, and another 6 months to 2 years before that." Once again, we are not scientists, but we do not believe it requires an advanced degree to understand that this population does not reasonably represent the broader population of 12- to 17-year-olds. To be fair, however, population is not the only problem in the Preprint Study. It also does not appear to have gathered enough incidents to produce statistically reliable results. Its "adjusted rate per million of 450 cases," for example, was derived from a total of ***six*** COVID-19-related myocarditis cases that occurred in its 12- to 17-year-old study population. In fact, the entire study population, including both genders and an overall age range of 12 to 19, saw just ***twenty*** COVID-19-related myocarditis codes and ***two*** hospitalizations.

Finally, at the other end of the population spectrum, there is *SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents* (the Nordic Study), which used nationwide ***resident-level*** data from public health registries in Denmark, Finland, Norway and Sweden to look at the incidence of VRMP and COVID-19-related myocarditis, reaching conclusions starkly different than the studies above. In the Nordic Study, VRMP risk in all age groups is elevated at least slightly with second doses of both MRNA-1273 and BNT162b2, but the risk was more pronounced in MRNA-1273 with 77.4 excess events per million per second dose. In the more limited demographic of males 16- to 24-years-old, of course, the number was much higher, with BNT162b2 being estimated to cause 83.0 excess events per million per second dose and MRNA-1273 being estimated to cause a whopping 265.1 excess events per million per second dose. Comparatively, the overall incidence of excess COVID-19-related myocarditis among males,

according to the Nordic Study, was 32.7 per million, and in the more relevant 16- to 24-year-old age group, the number was a significantly lower 13.7 events per million.

We are not saying any of these studies are necessarily bad, just that their findings must be understood in the context of their populations. For a population that felt the need to get vaccinated or get tested for COVID-19 within the PCORnet system, the PCORnet Study may have had predictive value. For people that visited hospitals within the TriNetX twice previously and then showed up a third time with COVID-19, the Preprint Study may have had predictive value. For residents of Norway, the Nordic Study may have had predictive value. The utility of all these results is based on how well those study populations reflect the characteristics of the person who is seeking the information. This Grand Jury believes that the Nordic Study is probably the most reliable overall result. For individuals who share some of the characteristics of the other two populations, however, the results of the PCORnet and Preprint Studies may be more predictive, but it is misleading to apply those results to broader populations.

Circumstances Have Changed

The overriding trend that we could not help but notice in virtually all the observational studies we examined is that regardless of their methods or the outcome of their analysis, none of the datasets they used go beyond early 2022. Several things have changed since then. First, the disease burden of COVID-19 is different. Omicron and its variants have a markedly lower risk of serious outcomes than the ancestral, alpha or delta strains of SARS-CoV-2. An observational study comparing clinical outcomes between patients suffering from omicron and delta variants of SARS-CoV-2 found that omicron infections were roughly half as likely to cause hospitalization with COVID-19 disease, and less than a quarter as likely to cause death when compared to delta infections. This reduction in disease burden necessarily changes the curve of any risk-benefit analysis at a population level, meaning that all of these studies using 2021 data have limited relevance in 2024. This is not what we saw in the vast majority of the studies we reviewed. Many of them did not even contain the word "omicron," let alone attempt to describe how that variant would affect their conclusions.

The second major thing that has changed is that, as of 2024, most of the world has been infected with some variant of SARS-CoV-2 at least once. We discussed the risk-reducing impact of IDI at length in our Second Interim Report. Suffice it to say that reliable, peer-reviewed studies have repeatedly found it substantially reduces the risk of future SARS-CoV-2 infections and

dramatically reduces the risk of serious outcomes for infections that do occur. Unlike omicron, which represents a generalized, population-level reduction in risk posed by SARS-CoV-2, IDI has the potential to reduce risk at an individual level. Therefore, it necessarily must be considered from an individual perspective. The fact that a person had a prior infection, as well as the length of time that has elapsed since that infection, are both highly relevant data points in any analysis of the risks and benefits associated with vaccination. Only now, in 2024, does the CDC's website even acknowledge that an immune response to COVID-19 "can protect you against reinfection for several months, but this protection decreases over time." It is good to see that its position on IDI has changed over the pendency of this Grand Jury, because it is an important part of the equation in determining the risks and benefits of vaccination going forward.

Unfortunately, however, the risk of VRMP does not appear to evaporate with subsequent vaccine doses. Many of the studies above did find increased risks of myocarditis following second doses of BNT162b2 and MRNA-1273, but subsequent studies have found that those risks did not disappear in subsequent booster studies, but rather seemed to return to a "baseline" roughly equivalent to the risks associated with first doses. One example is *Booster vaccination with SARS-CoV-2 mRNA vaccines and myocarditis in adolescents and young adults: a Nordic cohort study*, which looked at a large multinational group of 12- to 39-year-olds and found that while myocarditis rates peaked after second doses, subsequent booster doses still saw additional myocarditis events on the level of 8.6 extra VRMP events for BNT162b2 and 19.5 extra VRMP events for MRNA-1273 per million people vaccinated.

In terms of absolute risk, as we said at the beginning of this section, VRMP from booster doses is still a very rare event. If the incidence of SARS-CoV-2 infection were high enough, it might make sense even for younger males in these VRMP risk groups to get boosted because the potential benefit of avoiding SARS-CoV-2-related complications would be more salient. In 2024, however, the risk of even getting COVID-19 disease—to say nothing of having complications that would require hospitalization—is so low that most states have stopped publishing their weekly case rates entirely. This is the fundamental problem with VRMP frequency: A person between the ages of 12-29 who chooses to get boosted will be mostly protected from developing COVID-19 disease for some period which—for the purposes of this example—we will generously approximate to roughly six months. In order to get that protection, that young person must endure all of the nominal adverse events associated with vaccination and must accept a small chance of

developing VRMP. On the other hand, a person who chooses not to get boosted has a small chance of getting infected with SARS-CoV-2 in the first place—which may be dramatically reduced by IDI—followed by a small chance of developing COVID-19 disease, and finally, a small chance of developing complications requiring hospitalization. Scientists cannot reliably ascribe numerical values to these risks because there are no current data, and there are no current data because the numbers we describe above are so vanishingly small that they require populations of millions to study. Even if they could be studied, those results would be highly variable at an individual level.

**Events in the Clinical Trials**

While the safety signal for VRMP may only have been confirmed in pharmacovigilance, myocarditis and pericarditis cases also occurred in multiple phases of the flagship trials for BNT162b2 and MRNA-1273. According to ClinicalTrials.gov, Pfizer's 1001 trial saw a total of three cases: One case of pericarditis in its blinded phase, one case in its open label period and one case of myocarditis in its booster phase. Moderna's P301 trial, by contrast, saw a total of nine cases: Five cases of pericarditis in its blinded phase and two cases of both myocarditis and pericarditis in its booster phase.

None of these events, however, were described in Pfizer or Moderna's major journal publications regarding BNT162b2 and MRNA-1273. *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine* mentions "[f]our related serious adverse events were reported among BNT162b2 recipients (shoulder injury related to vaccine administration, right axillary lymphadenopathy, paroxysmal ventricular arrhythmia, and right leg paresthesia)." It does not mention pericarditis or myocarditis. *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months* does mention that "[n]o cases of myocarditis were noted[,]" but it says nothing about the pericarditis case that had occurred in the 1001 trial. *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine* states specifically at three separate points that "no cases of myocarditis or pericarditis were reported." However, records released by Pfizer on ClinicalTrials.gov in February of 2024 clearly show at least one myocarditis case in the booster phase of the 1001 trial. So why does it not appear in this publication?

Here is why: Pfizer administered over 23,000 doses of BNT162b2 boosters in the 1001 trial; but it did not use the results from those doses to support its booster application. Instead, it recruited a smaller cohort of roughly 10,000 participants from the 1001 trial into another study, C4591031, and used ***those*** results to lobby the FDA for approval of its booster. Those are the

results described in *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine*. We located Pfizer's internal report of this booster-related myocarditis event. As it turns out, Pfizer's investigators also affirmatively found it to be related to BNT162b2. The booster dose that caused this event was administered on November 19, 2021, and the actual VRMP (which occurred in a 16-year-old male) happened three days later. This was just over one month after the October 5, 2021, "data cutoff" for 1031, meaning that by the time this event occurred, 1031's 10,000 participants had already been pulled from the 1001 trial. At the end of the day, it was strictly true that "no cases of myocarditis or pericarditis were reported" from the 1031 trial. Still, this VRMP event did happen well before *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine* was published on the NEJM website on March 23, 2022. While the study authors were working on their manuscript in the months of November, December, January and February, this VRMP event involving the booster had either been confirmed to be related to BNT162b2 already or was being investigated.

Whether by luck or by design, this is how important safety events disappear. Pfizer certainly didn't tell the public about this VRMP event on its own. It would not ever come to the attention of the VRBPAC, which voted 14-2 ***against*** a BNT162b2 booster in September of 2021 based on data from the 1031 trial, but saw its own judgment overridden by the FDA, which issued an EUA for a BNT162b2 booster just six days later. It would not come to the attention of the NEJM, which published *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine*, or the peers who reviewed that article, because they are only provided summaries of the limited slice of 1031 clinical trial data that the study authors required to support their assertions. The fact that myocarditis occurred at all in the 1001 booster trial would only come to light on February 9, 2024, when Pfizer finally had to publish the results of the 1001 trial on ClinicalTrials.org. ***Even then, the event would just be an entry in a table, absent the critical relatedness information this Grand Jury was able to gather with its subpoena.***

The journal articles published describing the events of Moderna's clinical trials are similar. *Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine*, published in February of 2021, noted only that "[s]erious adverse events were rare, and the incidence was similar" between its placebo and intervention groups. The article said nothing about myocarditis or pericarditis events. *Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase*, published in September, 2021, stated that "[n]o cases of myocarditis were reported[]" but that "[p]ericarditis events

occurred in 2 participants each (<0.1%) in the placebo and mRNA-1273 groups (both events >28 days after the second dose) and were considered serious (Tables S20 and S21)." Once again, we were able to find internal records for all four of these events. As it turns out, both of the pericarditis events in P301's ***placebo*** group were found by investigators to be ***unrelated*** to the events of P301, while both of the pericarditis events that occurred in the ***intervention*** group were found to be ***related*** to MRNA-1273. This "relatedness" information does appear in *Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase*, but it is buried deep in the article's supplemental appendix, in Table S21, which is entitled "Serious and Severe Treatment-related AEs after Any Injection in Overall and Age Groups Safety Set."

Meanwhile, the authors readily and repeatedly described the "relatedness" of other AEs in the main text of the very same article. Here are some examples:

> The frequency of grade 3 and medically attended adverse events that were ***considered to be related*** to injection of placebo or vaccine was lower in the placebo group (0.2% and 0.6%, respectively) than in the mRNA-1273 group (0.5% and 1.3%) (Table S14).
>
> Adverse events that were ***considered to be related*** to the injections were reported by 8.5% of placebo recipients and 13.9% of mRNA-1273 recipients during the observation period of the study and were generally similar to those reported previously regardless of age (Tables S19 through S21).
>
> Serious ***injection-related*** adverse events occurred in 4 placebo recipients (<0.1%) and in 12 mRNA-1273 recipients (<0.1%).
>
> Three cases of Bell's palsy (<0.1%) were reported in the placebo group and 8 in the mRNA-1273 group (<0.1%); no case was ***considered to be related*** to the placebo or the vaccine (Table S24).
>
> A total of 32 deaths had occurred by completion of the blinded phase, with 16 deaths each in the placebo and mRNA-1273 groups; no deaths were ***considered to be related*** to injections of placebo or vaccine, and 4 were attributed to COVID-19 (3 in the placebo group and 1 in the mRNA-1273 group) (Tables S19 and S26).

(emphasis added). *Efficacy of the mRNA-1273 SARS-CoV-2 Vaccine at Completion of Blinded Phase* was published barely two months after the ACIP confirmed a safety signal for pericarditis following MRNA-1273 vaccination. That timing, taken together with the repeated references to the relatedness of other safety events adjudicated by Moderna's investigators, makes it difficult for

this Grand Jury to view the omission of the "relatedness" information regarding pericarditis from the article's main text as an accidental oversight.

That omission, however, was minor compared to what would happen in P301's booster phase. We know from ClinicalTrials.gov that Moderna issued boosters to a safety group that included over 19,000 P301 participants who had all previously received two doses of MRNA-1273. We also know that there were two cases of myocarditis in that group. From Moderna's internal documents, we know that both myocarditis cases were related by investigators to the intervention, making them VRMP events. One of these events occurred in a 42-year-old male five days after receiving his booster, and another occurred in a female recipient of unspecified age one day after she received her dose of MRNA-1273.

None of Moderna's publications regarding MRNA-1273 boosters describe these VRMP events. Moderna accomplished this in much the same way Pfizer did, by simply not publishing any journal articles regarding the experiences of the over 19,000 booster recipients from P301 and not using results derived from that group to support its booster application to the FDA. Instead, Moderna used a smaller dose-finding study, P201, to build an immunogenicity cohort of just 660 participants and compare these surrogate endpoints to the phase three results from the P301 trial. In March of 2022, these results of this smaller P201 cohort were published in an article named *Immune response to SARS-CoV-2 after a booster of mRNA-1273: an open-label phase 2 trial*, where Moderna proclaimed that "[n]o serious adverse events (SAEs) were reported up to 28 days after the booster injection." This completely ignored the experiences of the 32 times larger cohort Moderna had boosted in P301, which saw a total of 755 SAEs in 3.85% of its over 19,000 participants and, of course, the two VRMP cases. Because the P301 cohort was not utilized to secure an approval or reported on in a journal, no one would find out about these two VRMP cases for literal years. Even when their existence was finally disclosed on December 21, 2023, the summary tables Moderna published still did not contain the relatedness information we were ultimately able to gather with our subpoena.

There are several takeaways from this section. First, this Grand Jury believes that both Pfizer and Moderna took advantage of the scientific journal infrastructure to publish information that appears to have been designed to avoid reporting VRMP events related to BNT162b2 and MRNA-1273. Second, using the journal infrastructure in this way allows sponsors like Pfizer and Moderna years of lag time before they finally are forced to publish the fact that these events

occurred at all. Third, because sponsors are never required to post "relatedness" information, the public is never able—absent subpoena power—to get a clear picture of what SAEs were considered by the sponsor to be incidental and which SAEs were related to an intervention. Finally, several of the related VRMP cases, including all three myocarditis cases, occurred in study participants who were on their third dose of either BNT162b2 or MRNA-1273, which supports the data from the previous section that the risk for VRMP does not simply disappear after dose two.

**Events in Pharmacovigilance**

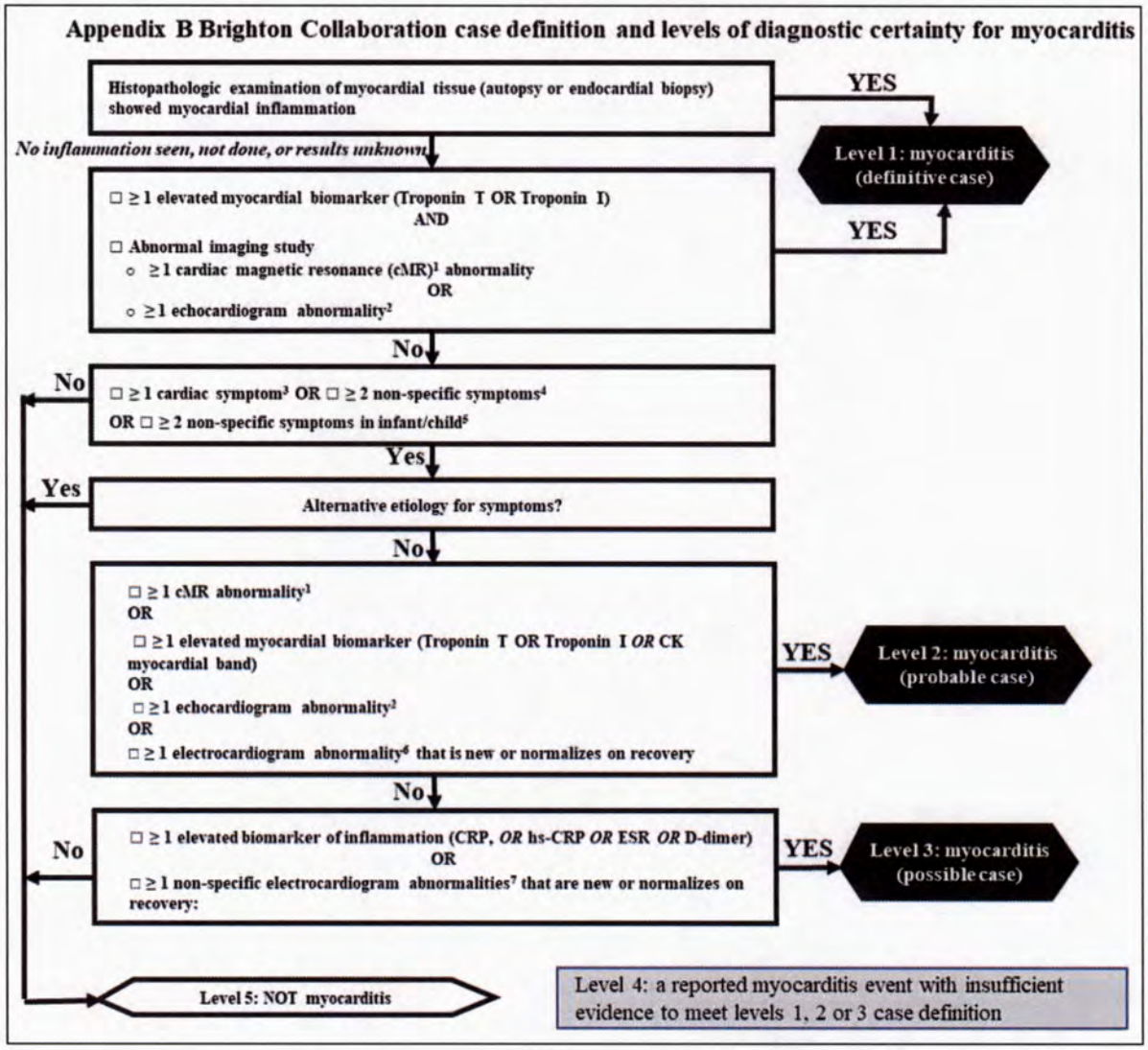
Investigators used by sponsors not only assess potential safety events in the context of their clinical trials, they also assess safety events that are reported in postmarketing surveillance. The process sponsors use is similar to the one described in the prior section. An event will be reported; investigators will follow up, if possible, to gather all the information they can from the reporter; then the investigators and safety specialists will review that information to see if it meets the necessary criteria to qualify as a "case" of a given SAE.

The criteria employed for what evidence qualifies as a "case" of myocarditis are propounded by the Brighton Collaboration, a non-profit global vaccine safety research network, and they are known as the Brighton Collaboration Criteria (BCC). The Brighton Collaboration describes the purpose of their case definitions as follows:

> [T]o enable cases of myocarditis and pericarditis to be ascertained in the context of safety assessments after immunization. ***It is not the purpose of the case definition to assess severity or causality***. The definitions have been formulated with three levels of certainty (LOC) for broad applicability in various settings. ***The Level 1 definition is highly specific*** for the identification of a case of myocarditis and pericarditis. As maximum specificity normally implies a loss of sensitivity, two additional diagnostic levels have been included in the definition, offering a stepwise increase of sensitivity from Level 1 down to Level 3, while retaining an acceptable level of specificity at all levels. In this way it is hoped that ***all possible cases of myocarditis and pericarditis can be captured***.

(emphasis added). The BCC are designed to provide a common language for the reporting of this SAE, which allows for meaningful comparisons between the results at different times, from different sponsors and utilizing different data sources.

To make the BCC for myocarditis easier for investigators and safety specialists to apply, the Brighton Collaboration has also translated them into a flowchart, which reads as follows:




According to this chart, there are two combinations of evidence that can produce a "Level 1: myocarditis (definitive case)." The first is a direct histopathologic examination of cardiac tissue, either via an autopsy or biopsy. The second is via the presence of both an "elevated myocardial biomarker," and an "abnormal imaging study." The biomarkers used in the BCC for myocarditis, "troponin t" or "troponin 1" levels, can be obtained easily by testing blood sera and have been found repeatedly to be reliable indicators of cardiac cell trauma. They are often used in hospital settings as a first-line diagnostic to determine whether a person may be having a heart attack. Levels are generally reported as nanograms per liter of blood. Any detectable level of troponins may be cause for concern, but roughly 99% of men have troponin levels below 35 ng/L, while roughly 99% of women have troponin levels below 14 ng/L. Observational studies, however, have

found sustained troponin levels above 12 ng/L in men and 10 ng/L in women to be associated with an elevated risk of future cardiac events. The "abnormal imaging study," per the BCC, may be the results of either a cardiac magnetic resonance imaging or an echocardiogram.

According to the BCC, it is only in the absence of these combinations that one goes on to evaluate whether any alternative etiology exists that could explain the symptoms. After all, the self-stated goal of the BCC is to capture "all possible cases of myocarditis" so their numbers may be meaningfully compared against a baseline to determine whether their frequency constitutes a safety signal. With that goal in mind, it would seem foolish to have all the evidence to confirm a "Level 1: myocarditis (definitive case)," according to the BCC, but instead classify that case as a "Level 5: NOT myocarditis" because the person who suffered the SAE suffered from some other medical event, especially where the records do not clearly establish whether the other medical event in question was caused or aggravated by the myocarditis.

This Grand Jury, through its subpoena process, was able to obtain a vast number of pharmacovigilance reports involving potential SAEs of VRMP that were submitted to Pfizer and Moderna from sources around the world. We examined selected samples of those reports to determine how these companies were applying the BCC, then discussed our findings with representatives from each corporation.

BNT162b2

Generally speaking, the manner in which Pfizer applies the BCC appears to be consistent with testimony of independent experts and the flowchart above. Initially, however, we were not so confident about this. While reviewing Pfizer's BCC classifications we located the following chart, which contained some myocarditis statistics that caught our attention:

**Table 2 – Brighton Collaboration level Assessment**

| Age group | Brighton Collaboration Level[a] | | | | |
|---|---|---|---|---|---|
| | **BC Level** | **Female** | **Male** | **Gender Unk** | **Total** |
| All 12-18 years | BC Level 1 | 11 | 87 | | 98 |
| | BC Level 2 | 11 | 66 | | 77 |
| | BC Level 3 | 3 | 13 | | 16 |
| | BC Level 4-5 | 77 | 475 | 7 | 559 |
| 12-15 years | BC Level 1 | 4 | 24 | | 28 |
| | BC Level 2 | 3 | 32 | | 35 |
| | BC Level 3 | 3 | 3 | | 6 |
| | BC Level 4-5 | 30 | 153 | 3 | 186 |

[a]BC assessment reflect cases received up to and including 15 December 2021. In order to provide a more specific analysis the MAH, starting with cases reported on 1 October 2021 forward, limited the BC criteria classification to cases of myocarditis and pericarditis that are both medically confirmed and having a time to onset ≤ 21 days.

Obviously, this appears to be a very high number of events classified as "Level 4: a reported myocarditis event with insufficient evidence" or "Level 5: NOT myocarditis." We showed this chart to Pfizer's corporate representative—a safety specialist with significant experience in pharmacovigilance surveillance—and asked that representative what we should take away from it. The representative responded that many cases are reported without key pieces of information and that Pfizer's investigators are often not able to gather additional data about those cases. This usually occurs, according to Pfizer's representative, where the report comes from an indirect source, like a government agency as opposed to a healthcare provider. Pfizer classifies those reports as "Level 4: a reported myocarditis event with insufficient evidence." Given the impossibility of follow-up, we agree with that assessment, at least in theory. We also were able to independently verify that most of the BCC Level 4-5 cases in the chart above are, in fact, classified as "Level 4: a reported myocarditis event with insufficient evidence to meet levels 1, 2 or 3 case definition," not "Level 5: NOT myocarditis," meaning they are still included in Pfizer's assessment of its total myocarditis reports.

In practice, however, we believe that at least some of these cases could be classified with a higher level of certainty. Here is an example we copied from a very large spreadsheet of similar myocarditis reports involving BNT162b2:

> ***An 81-year-old female patient received BNT162B2 (COMIRNATY) on 11 Jan 2021, at single dose, for COVID-19 immunisation.*** Medical history included COVID-19 from an unspecified date in Dec2020 to 29Dec2020 (not hospitalized), intraosseous meningioma (right sphenoid wing meningioma), lumboischialgia from 2017 to an unknown date, apoplexy for more than 40 years ago with residual hemiparesis symptoms (not ongoing), ongoing hemiparesis left, ongoing cough, ongoing hypertension arterial, ongoing common cold, type 2 diabetes mellitus. The patient's concomitant medications were not reported. According to the family doctor, he listened to the patient at the time of the vaccination and the lungs were clear. Afterwards, the reporter was told by the nursing home that the patient had a cough and cold for 2 days. ***The patient experienced septic shock, extensive myo- and pericarditis, multiple organ failure despite hemofiltration on 14Jan2021. The events were fatal. The patient died on 16Jan2021. An autopsy was performed and revealed carditis pericardium myocardium.*** The patient underwent lab tests and procedures in Jan2021 including lactate values and inflammation values: both increased. ***Reporter commented that the vaccination was certainly not causally responsible for the death of the patient, but may have intensified the course.***
>
> Comirnaty/ all events/ Primary source/ Certain.

> No follow-up attempts are possible; information about lot/batch number cannot be obtained.

(emphasis added). We asked Pfizer's representative to review this narrative and discuss it with us, leading to the following exchange:

> Q. I'm looking at a person who has an autopsy when they die that, quote, "reveals peri—carditis pericardium, myocardium." What level of certainty do you have that this person had myocarditis when they died?
>
> A. This is one type of the case that I would need to discuss with my colleagues to see how to best place it because, objectively speaking, it does not provide histopathological findings. It is just a statement.
>
> Q. Is it possible that—
>
> A. On the conservative side—no. This is a case from 11 January. We are not able—you see it's on the front, first row, that we cannot reach.
>
> Q. Right. But here's kind of my question. Is it—is it possible to reach an autopsy result of carditis myocardium, without doing a histopathological examination? If you assume that that is a well-done autopsy, that statement includes the histopathological findings. They're just summarized; isn't that correct?
>
> A. That could be true. And that case could make it to Level I as well. And oftentimes, in situations like this, we get more conservative, and we would eventually take these case as Level 1 if we were requested to do such an analysis.

The company had classified this case as a "Level 4: a reported myocarditis event with insufficient evidence." The same logic could be used to exclude evidence such as "troponins: High" or "MRI: Myocarditis," which appears contrary to the BCC's intent to accurately classify the event. Ultimately, however, we may just be splitting hairs over these definitions, as Pfizer's representative repeatedly assured us that the company includes all levels above "Level 5: NOT myocarditis" in its internal analyses of myocarditis events. We did see other evidence corroborating this assertion when we checked Pfizer's internal documents.

MRNA-1273

We identified potential problems with Moderna's BCC assessments by reviewing the very first PBRER the company submitted to the FDA as part of its pharmacovigilance obligation. In this report, Moderna submitted all the SAEs of myocarditis it had received in line with its own assessment of those SAEs according to the BCC. When we reviewed this PBRER, we were able to locate multiple instances where Moderna determined that a case was "Level 5: NOT

myocarditis" even where its records clearly indicated the presence of elevated troponin levels and abnormal imaging consistent with myocarditis. This is contrary to the instructions in the BCC flowchart and its stated purpose to capture "all possible cases of myocarditis and pericarditis."

Perplexed by this incongruity, we asked Moderna's representative, a licensed physician with over 20 years of experience in drug and vaccine safety, how the company classifies potential myocarditis cases using the BCC flowchart. This explanation of the process is at odds with independent expert testimony, the testimony of Pfizer's representative and the BCC flowchart itself. It is, however, consistent with systematically excluding cases of myocarditis as "Level 5: NOT myocarditis," despite definitive evidence to the contrary.

Moderna's representative started by explaining that, on the BCC flowchart, "you kind of start at the middle, you know, because you wouldn't start with 'is there histopathologic examination of myocardial tissue.'" This already did not seem to us to be correct, just based on our ability to read the arrows in the BCC's flowchart above, but the explanation got stranger from there:

> The question one is, are there symptoms of myocarditis, such as chest pain, such as difficulty breathing, such as a fever. There's a—and then a second question is, is there—if the answer to that is no, then go all the way to the bottom, which is Level V, not a case of myocarditis.

Setting aside the fact that this Grand Jury finds it difficult to imagine a circumstance where one would undergo the types of diagnostic tests described by the BCC in the absence of any symptoms, the BCC flowchart does not require symptoms for a "Level 1: myocarditis (definitive case)." This is probably because at least some of the time, patients with histopathological evidence of cardiac inflammation might be unable to report any symptoms because they are dead. This method of declassifying to "Level 5: NOT myocarditis" based on a lack of reported symptoms does not appear to be in line with the BCC, but we doubt many SAEs are really excluded under Moderna's "no symptoms" rule. What Moderna's representative said next, however, was much more significant:

> The next question, is there an alternative etiology an alternative explanation. So, for example, if someone was found to have chest pain due to, I guess—the motor vehicle accident example before—because they were in a motor vehicle accident and they—their chest hit the steering wheel, that's an alternative etiology. And alternative etiology as well could be they might have pneumonia. So the answer to the—if there's an alternative etiology, then you go down to the bottom again; not a case of myocarditis.

Moderna's expert went on to explain that only after these alternative etiologies have been excluded does the company go ***up***—in the ***opposite*** direction of the arrows from the BCC flowchart—looking for "additional information… elevated biomarkers and evidence of abnormal left ventricular function[,]" and only after that does the company reach the question of whether there is histopathological evidence of cardiac tissue inflammation.

To better understand this system of myocarditis case ***de***classification, we asked Moderna's representative to apply the BCC criteria to some of the case narratives we found in that very first PBRER. Here was the first one:

| Narrative |
| --- |
| This case was received via United States FDA VAERS (Reference number: 1347238) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021.<br>This regulatory authority case was reported by an other health care professional and describes the occurrence of CORONARY ARTERY DISSECTION (Coronary artery dissection), MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), BACK PAIN (Back pain) and PAIN (Pain) in a 25-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 032B21A) for COVID-19 vaccination.<br><br>Concurrent medical conditions included Seasonal allergy (Claritin (loratadine) for 2 days after mowing the lawn).<br>Concomitant products included LORATADINE (CLARITINE) from 12-May-2021 to 13-May-2021 for Seasonal allergy.<br><br>On 14-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) dosage was changed to 1 dosage form.<br>On an unknown date, the patient received first dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 1 dosage form. On 17-May-2021, the patient experienced CORONARY ARTERY DISSECTION (Coronary artery dissection) (seriousness criteria hospitalization, medically significant and life threatening), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization, medically significant and life threatening), CHEST PAIN (Chest pain) (seriousness criteria hospitalization and life threatening), BACK PAIN (Back pain) (seriousness criteria hospitalization and life threatening) and PAIN (Pain) (seriousness criteria hospitalization and life threatening). At the time of the report, CORONARY ARTERY DISSECTION (Coronary artery dissection), MYOCARDITIS (Myocarditis), CHEST PAIN (Chest pain), BACK PAIN (Back pain) and PAIN (Pain) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 19-May-2021, Angiogram: abnormal (abnormal) left main coronary artery (LMCA) and right coronary artery (RCA) showed Spontaneous coronary artery dissection (SCAD).<br>On 19-May-2021, Troponin: 1945 (High) Troponin peaked to 1945.<br>On 20-May-2021, Magnetic resonance imaging: myocarditis (abnormal) myocarditis.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>Symptom Text : Pt developed upper body pain 5/17, then back and chest pain 5/18. + Troponin. CT showed LMCA and RCA SCAD. Cardiac MRI showed active myocarditis.<br><br>Treatment medication was not reported.<br><br>Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. |

According to other experts who testified, this report should obviously be a "Level 1: myocarditis (definitive case)" based on the fact that this patient had elevated troponin levels and an MRI result of "myocarditis." Moderna, however, classified this case as "Level 5: NOT myocarditis" in its PBRERs. We did not provide Moderna's representative with the company's prior classification or that of our own experts, but instead asked the representative to evaluate the facts and classify the case based on their own training and experience as the company would. Here is that analysis:

> A. So the answer is: There are symptoms, but then if you go down, you look at alternative etiology for symptoms, ***there's a very clear alternative etiology*** for symptoms. This individual had a cardiac dissection; okay?
>
> Q. Okay.
>
> A. ***Coronary artery dissection. And that's a very distinct clinical phenomenon.*** It's fundamentally different than myocarditis.

. . . .

Q. ***With the dissection it's not a case of myocarditis?***

A. ***With the dissection it is not a probable case, that's correct.***

Q. You're—not a—***not a case, period?***

A. It is a—it's a level—***it's a Level IV***. It's a reported event with insufficient evidence to meet Level I, II, or III. And the reason it's insufficient evidence is because there's a competing diagnosis which could account for many of the findings, and that that competing diagnosis is the coronary artery dissection.

(emphasis added). After the exchange above, we presented Moderna's representative with a different case narrative. This one contained no mention of other cardiac problems or alternative etiologies:

| Case ID | Narrative |
|---|---|
| MOD-2021-225895 | This case was received via United States FDA VAERS (Reference number: 1334563) on 15-Jun-2021 and was forwarded to Moderna on 15-Jun-2021.<br>This regulatory authority case was reported by a health care professional and describes the occurrence of CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), TACHYCARDIA (Intermittent tachycardia), MYOCARDITIS (Myocarditis) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) in a 15-year-old male patient who received mRNA-1273 (Moderna COVID-19 Vaccine) (batch no. 002c21a) for COVID-19 vaccination.<br><br>The patient's past medical history included Wolff-Parkinson-White syndrome.<br>Concomitant products included HPV VACCINE VLP RL1 9V (YEAST) (GARDASIL 9) from 14-May-2021 to an unknown date for an unknown indication.<br><br>On 14-May-2021, the patient received second dose of mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular) 2 dosage form. On 15-May-2021, the patient experienced CHEST PAIN (Chest pain) (seriousness criterion hospitalization), CHILLS (Chills) (seriousness criterion hospitalization), FATIGUE (Fatigue) (seriousness criterion hospitalization), TACHYCARDIA (Intermittent tachycardia) (seriousness criterion hospitalization), MYOCARDITIS (Myocarditis) (seriousness criteria hospitalization and medically significant) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) (seriousness criterion hospitalization). At the time of the report, CHEST PAIN (Chest pain), CHILLS (Chills), FATIGUE (Fatigue), TACHYCARDIA (Intermittent tachycardia), MYOCARDITIS (Myocarditis) and SARS-COV-2 TEST POSITIVE (COVID-19 IgG Ab positive) had not resolved.<br><br>DIAGNOSTIC RESULTS (normal ranges are provided in parenthesis if available):<br>On 19-May-2021, C-reactive protein increased: 10.6 Increased.<br>On 19-May-2021, COVID-19: positive (Positive) Positive.<br>On 19-May-2021, Electrocardiogram: abnormal.<br>On 19-May-2021, Electrocardiogram ST segment: abnormal.<br>On 19-May-2021, Polymerase chain reaction: negative (Negative) Negative.<br>On 19-May-2021, Troponin: 16.72 (High) 16.72.<br><br>For mRNA-1273 (Moderna COVID-19 Vaccine) (Intramuscular), the reporter did not provide any causality assessments.<br><br>No concomitant medications were provided.<br>Treatment medications was not provided.<br><br>Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded. Based on the mechanism of action of mRNA-1273, a causal association between the event of positive COVID-19 antibody test and mRNA-1273 is assessed as not applicable. |

This patient presented with elevated troponins and an abnormal electrocardiogram. Moderna's representative rated this as a "Level 2: myocarditis (probable case)"—and we agree. The only problem is that the case was reported to the FDA as "Level 5: NOT myocarditis."

Before we continue, we should make two things clear. First, only 7.5% of the total incoming SAEs of myocarditis in that first PBRER were classified as "Level 5: NOT myocarditis," a raw number of five out of 77 total reports. This means that, at best, only a small percentage of these SAEs were being "disappeared" completely, at least in the beginning. Second, it is not clear to what extent the FDA relies on Moderna's BCC analysis. We know that Moderna treats "Level

5: NOT myocarditis" reports differently than other reports because it describes them separately to regulators. A 2022 slideshow Moderna prepared for Australia's Therapeutic Goods Administration described "65 cases with fatal events of myocarditis and/or pericarditis *excluding six level 5 cases*." What we do not know is whether regulators find Moderna's assessments persuasive.

They should not. Based on the testimony of its own representative and its own records, Moderna's approach to myocarditis classification—especially in cases involving alternative etiologies—is clearly at odds with the BCC. Not only does this apparently result in fewer SAEs of "myocarditis," the logic also conveniently excludes any reported cases of myocarditis that involve other cardiac complications, resulting in a less severe characterization of VRMP overall. Any potential complication appears to be used as a means for excluding the case altogether, rather than standing as a data point that VRMP may sometimes present with serious cardiac complications.

Unfortunately, Moderna's subsequent PBRERs do not list the BCC classifications for SAEs of myocarditis, meaning that we do not know the extent to which Moderna continued to classify these cases incorrectly. We asked that representative why the company stopped including its BCC analyses of myocarditis in its PBRERs, and that representative testified that "[o]nce a signal is confirmed . . . it becomes what's in this case classified as an important identified risk. It's a known risk, then there is less focus upon that particular topic than there was before it became a known risk . . . ." Consequently, as Moderna's vaccine became more widely used and more SAEs were being reported, it became less clear to what extent Moderna was misclassifying these cases and what effect that may have had on its understanding of myocarditis.

**Long-Term Sequelae and Fulminant Cases**

To this point in this Final Report, we have focused almost entirely on statistics. This focus has been appropriate. After all, our task requires us to determine what evidence supports the benefits and risks of disease and COVID-19 vaccines, which necessarily means we must analyze them at a population level. By necessity, this kind of analysis reduces entire lives to numbers on both sides of this calculation. Even so, the public has been inundated with stories humanizing the victims of SARS-CoV-2. Over the last four years, we have seen account after account of the untimely deaths of beloved family members taken too soon by the virus. The same dignity, however, has not been afforded to the sufferers of SAEs, who often just appear as a set of numbers in a flowchart, reluctant footnotes to the triumph of science and public health. Even when their

stories do get told, sufferers of SAEs are often viewed dismissively or even skeptically by a society that can seemingly bear to face only one side of the scale of suffering and loss.

For this reason, we feel compelled to discuss a case of an eight-year-old girl we saw in the internal documents of one of the companies. All we know about her is from the narrative of her adverse event report. In June of 2022, after receiving her second dose of vaccine, she experienced myocarditis and was taken to the hospital, where she stabilized, but continued to have a fever, fatigue and discomfort. According to the case narrative, after three days in the hospital "she asked for leave to recuperate at home[,] but on the same day, [she] experienced sudden collapse" from a cardiac arrest, was resuscitated and fell into a coma. Her troponin 1 levels were 22,493.9 ng/mL. This eight-year-old, comatose little girl was tested for multiple viruses known to cause myocarditis, including COVID-19. All those tests came back negative. She was admitted to the surgical intensive care unit where she was diagnosed with fulminant myocarditis. A CT scan "showed diffuse brain swelling and loss of differentiation of grey-white matter." The hospital decided to do a myocardial biopsy. Before that could happen she passed away, five days after she was vaccinated. An autopsy, which was preliminary at the time, reported her cause of death as "suspected myocarditis." Stories like this hide behind every statistic involving SAEs, just as they do with COVID-19.

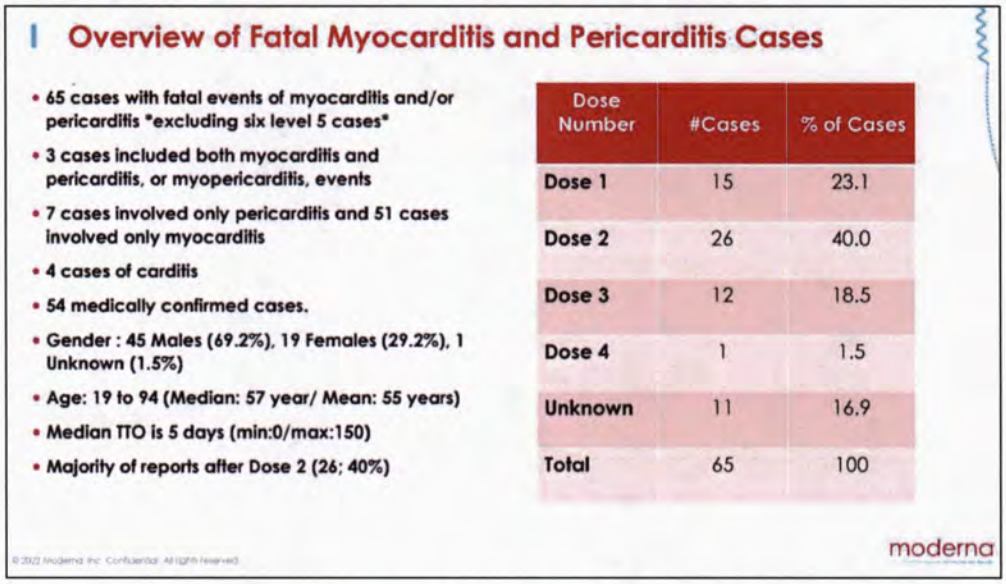
One of the most common aphorisms regarding VRMP is that these events are ***generally*** mild and ***tend*** to resolve on their own with no long-term effects. While this is certainly true, we are concerned that the aphorism has a way of devaluing the lives of those whose cases were not mild or did not resolve on their own. We reiterate that there is really no clinical distinction between cases of VRMP and "normal" cases of myocarditis or pericarditis. The reason the outcomes tend to be different is very likely because the people who have VRMP events are often younger, healthier and (often) better able to tolerate a bout with disease than "normal" myocarditis and pericarditis patients, who tend to already be suffering from some other health challenge. Since the time the safety signal was confirmed, there has been a great deal of research on the frequency of VRMP, but comparatively little on outcomes in people who suffered from this SAE. What little statistical research there is generally supports the common understanding we described above, but just like "normal" myocarditis and pericarditis, a small proportion of VRMP events can and do cause negative health outcomes, from ongoing health complications to true tragedies like the story of the eight-year-old girl above.

The FDA was clearly concerned about health outcomes from VRMP. In the first Full Approval letter for BNT162b2, the FDA specifically directed Pfizer to conduct "Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network)." The letter required that this study be completed by December 31, 2026. As of today, however, that study has yet to be even initiated. ClinicalTrials.gov reports that Study C4591036 is now expected to be completed by November 11, ***2030***. Similarly, the first Full Approval letter for MRNA-1273 called for a "[r]equired safety study under Section 505(o) (Study mRNA-1273-P911), entitled 'Long-term outcomes of myocarditis following administration of SPIKEVAX (Moderna COVID-19, mRNA-1273),' to evaluate long-term sequelae of myocarditis after vaccination with at least 5 years of follow-up." This letter required Moderna to deliver a report with the full results of this study by October 31, 2028. Luckily, according to Moderna's representative, the final report for mRNA-1273-P911 is still on track to be delivered by that date.

These long-term studies are sorely needed, because there is very little reliable information currently available about even the one-year outcomes from VRMP, to say nothing of the five-year outcomes. The small amount of actual data currently available suggests that VRMP might be more of an ordeal than its "generally mild" maxim suggests. In 2022, *Outcomes at least 90 days since onset of myocarditis after mRNA COVID-19 vaccination in adolescents and young adults in the USA: a follow-up surveillance study* looked at health outcomes in the months following VRMP. The study authors found that while 81% of patients either fully or probably fully recovered, 93% of them had to be admitted to a hospital, and 25% of those were placed in an ICU. The study authors also pointed out that "although most patients were considered recovered by health-care providers at least 90 days since onset, nearly half of patients continued to self-report symptoms, including chest pain, and a quarter were prescribed daily cardiac medications[]" including colchicine, beta blockers, ACE inhibitors and a number of others. Physical activity restrictions imposed by health care providers in the wake of VRMP lasted an average of 98 days. Finally, nearly half of patients that received follow-up cardiac MRIs had evidence of myocardial scarring, which may resolve over time or may be a harbinger of "future adverse cardiac events, including arrythmias, extra-corporeal membrane oxygenation, transplantation, and death[.]" In 2023, *Long term follow up and outcomes of COVID-19 vaccine associated myocarditis in Victoria, Australia: A clinical surveillance study*, which collected self-reports from patients covering longer post-

VRMP time frames, found that "around half of all patients experiencing myocarditis following COVID-19 vaccination still experience symptoms 6 months after initial diagnosis." Although the number of participants who had follow-up cardiac MRIs was small, more than two-thirds of those follow-up MRIs continued to show cardiac abnormalities months after the resolution of VRMP. "Generally mild," indeed.

***And then there are the people who die.*** In August of 2022, Moderna made a slideshow entitled *Fatal Myocarditis and Pericarditis* following an inquiry by Australia's Therapeutic Goods Administration (that country's version of the FDA) and produced that slideshow to this Grand Jury as part of its subpoena response. Australia's request for information on fulminant VRMP came on the heels of a widely publicized report regarding a 21-year-old woman who was admitted to the hospital in "cardiogenic shock" fifteen days after receiving an MRNA-1273 booster, was diagnosed with "fulminant myocarditis" and died 22 days later. Here is Moderna's overview of fatal myocarditis and pericarditis cases following vaccination as of August, 2022:



**Overview of Fatal Myocarditis and Pericarditis Cases**

- 65 cases with fatal events of myocarditis and/or pericarditis *excluding six level 5 cases*
- 3 cases included both myocarditis and pericarditis, or myopericarditis, events
- 7 cases involved only pericarditis and 51 cases involved only myocarditis
- 4 cases of carditis
- 54 medically confirmed cases.
- Gender : 45 Males (69.2%), 19 Females (29.2%), 1 Unknown (1.5%)
- Age: 19 to 94 (Median: 57 year/ Mean: 55 years)
- Median TTO is 5 days (min:0/max:150)
- Majority of reports after Dose 2 (26; 40%)

| Dose Number | #Cases | % of Cases |
|---|---|---|
| Dose 1 | 15 | 23.1 |
| Dose 2 | 26 | 40.0 |
| Dose 3 | 12 | 18.5 |
| Dose 4 | 1 | 1.5 |
| Unknown | 11 | 16.9 |
| Total | 65 | 100 |

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We do want to be clear, however, that the 65 deaths Moderna was discussing internally occurred against a backdrop of millions upon millions of doses that were administered in that time period. It may be—and it likely is the case—that fulminant VRMP cases are so rare that their rate per million is less than one. But how rare are they? What is that rate? We were not able to locate any information in Moderna's subpoena responses about the number of deaths attributable to MRNA-1273 past August of 2022, but we are confident that more of these events occurred. We also were unable to find any information in Pfizer's subpoena response about the rates of fulminant

myocarditis associated with BNT162b2. We asked Pfizer to provide a specific number of fulminant myocarditis cases, and it, too, initially demurred. Only at our insistence during the in-person testimony of Pfizer's representative did the company finally provide us with something resembling an up-to-date number: A total of 283 cases in its GSD were reported as "myocarditis" and had an outcome of "fatal." Were they all cases of fulminant VRMP? Were some of them? Only an independent examination of the thousands upon thousands of raw narratives these sponsors collected as part of their surveillance would yield anything approaching a reliable estimate.

It is frustrating to this Grand Jury, as it should be frustrating to everyone who reads this report, to know that ***these sponsors have taken in billions of taxpayer dollars for creating and selling their vaccines; they cannot be sued if something goes wrong with them; they have access to critical information about deaths related to a side effect of their products; and the public does not have access to that information.*** Instead, we are left to speculate, and the research community is left to draw inferences as one-off or two-off histopathological reports detailing the events of this death or that death that trickle into scientific journals slowly, year after year. Somehow, withholding this valuable safety information is not a crime. It certainly should be.

What is even more galling is comparing these VRMP deaths to the deaths that occurred in the flagship clinical trials. By way of reminder, representatives from Pfizer and Moderna both tearfully discussed the ***ethical necessity*** of offering vaccines to their placebo groups to avoid ***any deaths*** beyond the ***five*** COVID-19-related deaths that occurred in the blinded period of the 1001 and P301 trials. Moderna's representative specifically opined that "it felt really ***unethical*** to ask people to continue to put themselves at risk for another eight months when we knew that we had a vaccine that could help protect them from death and protect them from hospitalization and hopefully protect their families." (emphasis added). Pfizer's representative expressed similar sentiment, stating that:

> I think that would have been ***unethical*** for the people—you know, it's our job once we—and I believe this is similar in drug studies. You know, if you have a drug study and you're testing, you know, oncology patients, you know, with a placebo and an oncology drug, and the oncology drug shows efficacy, sometimes they curtail that study early and they open it up to everybody.

(emphasis added). Ironically, Pfizer was warned against precisely this kind of framing at its very first VRBPAC meeting regarding BNT162b2, where a speaker discussing the ethics of continuing the 1001 trial opined that:

> We can argue about how one principle takes precedence over another, but it's not helpful to hear assertions like "It's unethical to deny an effective vaccine to a placebo recipient." ***Asserting that anything is unethical effectively shuts down the debate and also demonizes people on the other side***. And I found it extremely healthy for committees not to use that word at all.

(emphasis added). When challenged, however, "it would have been unethical" is ***exactly*** how these sponsors framed their position, with all its attendant connotations.

Fulminant myocarditis cases illustrate the problem that framing can create. The five deaths from the P301 and 1001 trials occurred in clinical trial participants who explicitly understood the nature of the intervention, its unknown safety profile, the duration of the study and the fact that they may be assigned to a placebo. They knew and agreed to all those conditions, risking their lives to serve the public interest.

Contrast that with the 65 MRNA-1273 recipients who had died of fulminant myocarditis following their vaccinations by August of 2022, or the 283 who died following BNT162b2 vaccinations as of the date of this report. They did not sign any waivers. They were told these vaccines had been proven to be "safe and effective." They would only have been "informed" about the possibility of VRMP via package inserts that may or may not have been provided to them at the time of vaccination. Even if provided, those inserts did not say ***a single word*** about the risk of death related to VRMP. If these vaccine recipients who died had looked any further into the issue, they would have been assured repeatedly by both government and third-party sources that VRMP was rare, that it was "generally mild" and "tended" to resolve on its own. What are the ethics of that?

**Subclinical Myocarditis**

At the other end of the spectrum from fulminant myocarditis is a phenomenon called "subclinical" myocarditis (SCM). These adverse events have the elevated biomarkers and abnormal imaging studies characteristic of "normal" myocarditis but are not reported as adverse events. This could be due to a lack of symptoms, or because symptoms are present, but they are mild, or because the patients experienced significant symptoms but simply chose not to seek treatment. SCM as a discrete phenomenon does not benefit from a long tail of clinical research, but an influential article published in 2015, *A Prospective Study of the Incidence of Myocarditis/Pericarditis and New Onset Cardiac Symptoms following Smallpox and Influenza Vaccination*, offers a lens into why it could be significant. In that study, a small number of recently

vaccinated United States armed services members were actively tested for troponin levels following administration of the smallpox vaccine. Out of 1,081 servicemembers tested, five developed "clinical" myocarditis, but 31 had excess troponin levels indicative of "possible subclinical myocarditis." These results were compared to a small control group of flu vaccine recipients, who recorded zero "possible subclinical myocarditis" events.

Soon after the VRMP safety signal was discovered, third-party scientists began to research the possibility that MRNA-1273 and BNT162b2 may also be causing SCM events that would not be detected in normal surveillance. At least two studies have been published by independent researchers showing elevated troponin in conjunction with these vaccines. *Sex-specific differences in myocardial injury incidence after COVID-19 mRNA-1273 booster vaccination* tested blood samples from middle aged hospital workers in Switzerland three days after they received MRNA-1273 booster shots and found troponin concentrations significantly higher when compared to a matched group of controls. *Cardiovascular Manifestation of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents* (the Thai Troponin Study) found "one case of myopericarditis, four cases of subclinical myocarditis, and two cases of pericarditis among 301 participants . . . " who had been boosted with BNT162b2. These results are concerning, but it is difficult to draw broader inferences from them because both suffered from some limitations in terms of their populations and methodologies.

The FDA clearly was also concerned about the possibility of SCM because it required no less than five separate postmarketing studies in its approvals for MRNA-1273 and BNT162b2. Three of those studies were required of Moderna in its Full Approval letter of January 31, 2022. Here are the requirements, as quoted directly from that letter:

> 7. Required safety study under Section 505(o) (Study mRNA-1273-P301) substudy to prospectively assess the incidence of subclinical myocarditis following administration of a booster dose of SPIKEVAX in participants 18 years of age and older.
>
> We acknowledge the timetable you submitted on December 14, 2021, which states that you will conduct this study according to the following schedule:
>
> Final Protocol Submission: September 14, 2021 (completed)
>
> Study Completion Date: December 31, 2022
>
> Final Report Submission: June 30, 2023

8. Required safety study under Section 505(o) (Study mRNA-1273-P203) substudy to prospectively assess the incidence of subclinical myocarditis following administration of a booster dose of SPIKEVAX in participants 12 years through <18 years of age.

We acknowledge the timetable you submitted on December 14, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 12, 2021 (completed)

Study Completion Date: April 30, 2024

Final Report Submission: July 31, 2024

9. Required safety study under Section 505(o) (Study mRNA-1273-P204) substudy to prospectively assess the incidence of subclinical myocarditis following administration of SPIKEVAX in a subset of participants 6 months through <12 years of age.

We acknowledge the timetable you submitted on December 14, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: October 6, 2021 (completed)

Study Completion Date: December 31, 2023

Final Report Submission: March 31, 2024

As of today, ***Moderna has not completed any of these studies***. They have never been formally waived in any public FDA document that we were able to find; they simply were not done. On October 2, 2024, we asked Moderna's representative how "required safety studies" 7, 8 and 9 had fallen so far behind Moderna's own timetables for completion. This was the company's answer:

> [S]o the very key point here is that the troponin test was evaluated in individuals with underlying heart disease; okay? One of the really important points if you work in biopharmaceutical research is understanding how your tests perform.
>
> And this test—as you know, the issue about myocarditis was one that was disproportionately in younger individuals who did not have any prior known history of heart disease. So the test was not validated in those—that population.
>
> So what we—what we agreed to do and have done was store [blood] sera, okay, with the intent being to evaluate the sera if a validated assay for myocarditis in that population were identified; okay? So we fulfilled that aspect of it.

> At the present time—this has been going back and forth with the agency for some time. At the present time, we have approved and agreed with the agency to conduct a clinical—a clinical study to address this question. And that study is due to begin enrolling imminently.

There are several things about this answer that trouble us. First, Moderna's representative is strictly correct that troponin levels alone cannot determine whether someone has SCM, but troponins are a reliable marker of cardiac trauma and one element of the BCC for a "definitive" case of myocarditis. One could simply use troponin testing to identify study participants with cardiac enzymes, then follow up with a cardiac MRI or an echocardiogram to determine whether there was evidence that satisfied the second element of the BCC. If there were—with no symptoms—that would qualify as a "case" of SCM. If Moderna's study administrators were concerned that the troponin or imaging results were not reflecting changes wrought by MRNA-1273, they could simply image and troponin test everyone at the outset of the study and screen out those with abnormal results at baseline. If the study administrators were concerned that factors other than MRNA-1273 might be causing these abnormal changes, it could simply use a control group. These are not issues that should have taken three years to solve.

Second, each of these postmarketing studies submitted its "Final Protocol" to the FDA months before MRNA-1273 was fully approved. Good science would dictate that any disagreement as to the correct testing assay would have been fully resolved well before any protocol could have been finalized. Moreover, these studies were all still in progress in January of 2021, meaning that some proportion of their cohorts could easily have been recruited for a second round of boosters, at which point the study protocol we described in the previous paragraph could have easily been administered without any need for a brand-new testing assay.

As we know today, Moderna did not do that. Instead, according to its representative, Moderna stored blood sera from clinical trial participants from MRNA-1273-P301, MRNA-1273-P203 and MRNA-1273-P204 studies "with the intent being to evaluate the sera if a validated assay for myocarditis" in "younger individuals who did not have any prior known history of heart disease" is eventually identified. Given that the BCC call for autopsy, biopsy or cardiac imaging results to find a "definitive" case of myocarditis, we do not believe Moderna was holding those results for years in the hopes that someone would invent a test that would be so reliable it would essentially replace the BCC. We think it is more likely that Moderna understood a good portion of

the sera from these early trials would show high troponin levels, and while these sera alone would not definitively prove that BCC-qualified "cases" of SCM had indeed occurred in the clinical trials, it would certainly be "smoking gun" evidence that they did.

The other two of the five FDA-required postmarketing studies involving SCM can be found in Pfizer's Full Approval letter for BNT162b2, published on August 23, 2021, and quoted here:

> 8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.
>
> We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:
>
> Final Protocol Submission: September 30, 2021
>
> Study Completion: November 30, 2023
>
> Final Report Submission: May 31, 2024
>
> 9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.
>
> We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:
>
> Final Protocol Submission: November 30, 2021
>
> Study Completion: June 30, 2022
>
> Final Report Submission: December 31, 2022

To Pfizer's credit, it did produce a study. *Serum Troponin I Assessments in 5- to 30-Year-Olds After BNT162b2 Vaccination* (the Pfizer Troponin Study), which described the combined results of both of the required postmarketing studies above, was published on March 15, 2024, roughly 15 months after the initial "Final Report Submission" deadline for Study C4591031, but 45 days before the deadline for C4591007. Unsurprisingly, the study's authors concluded that their findings "did not provide evidence that BNT162b2 causes troponin elevations." But how reliable were these results?

To begin with, there were several aspects of the study protocols that Pfizer got right. It used a high-sensitivity assay to measure cardiac troponin levels in study participants before it

administered BNT162b2 so there would be a baseline measurement. It also had placebo controls for two of its three subgroups, allowing for comparisons between troponin levels of participants who did and did not receive BNT162b2. Unfortunately, there are also some important flaws in the study design and resulting data that undermine our confidence in its findings.

First, the placebo and intervention groups in the C4591031 part of the study were staggered to comply with the ethical framework of the EUA. This meant that one group would be vaccinated while the other served as a control, then after a month, the first group would serve as a control for the second. The problem with this design is that for the second half of study participants, the control will have already received BNT162b2 just one month prior, limiting its utility as a comparator.

Second, the study also saw a significant number of withdrawals: 27 in its "BNT162b2 → Placebo" cohort and 39 in the "Placebo → BNT162b2" cohort. While we recognize that some withdrawals are unavoidable in clinical trials, the Pfizer Troponin Study lost 4.44% of its original randomized cohort in what was essentially a ten-week protocol. The staggered design of this study, coupled with the relatively low numbers of raw events and the relatively high number of withdrawals do raise concerns regarding the credibility of its findings.

Third, the study's primary author ***failed*** to disclose a sizeable grant of $4.1 million he had secured from Pfizer in the months prior to the study manuscript's submission date. We do recognize that the journal system is normative, not legal, so different academics and scientists may interpret their duty to disclose possible conflicts of interest differently. Nevertheless, it is notable that many of the Pfizer Troponin Study's co-authors ***did*** declare their pharmaceutical company affiliations—including their affiliations with Pfizer—in the article's "conflict of interest" section.

Finally, and most importantly in our view, the study had "no specific cardiac inclusions or exclusions." This meant that many study participants who already had baseline high troponin levels (which this study pegged at >35 ng/L in males and >17 ng/L in females, unlike the Thai Troponin Study mentioned above, which considered >14 ng/L to be elevated in both genders) were included in the analysis. In and of itself, this is not an issue, but it creates a problem when the authors try to describe the results in a meaningful way. Records from C4591031 posted on the EU Clinical Trials Register website show the following results:

| | BNT162b2 - Placebo | Placebo - BNT162b2 |
|---|---|---|
| Participants with Elevated Troponin Prior to Dose 1 | 0.7% | 0.5% |
| Participants with Elevated Troponin ~4 Days After Dose 1 | 1.0% | 0.6% |
| Participants with Elevated Troponin I Prior to Dose 2 | 1.1% | 0.3% |
| Participants with Elevated Troponin I ~4 Days After Dose 2 | 1.5% | 0.3% |
| Participants with Elevated Troponin I ~1 Month After Dose 2 | 0.7% | 0.3% |

It is impossible to tell, from these statistics, how many of the 0.7% of participants with elevated troponin levels prior to dose 1 were also part of the 1.0% of participants with elevated troponin levels five days later. It is possible that the high baseline troponin levels could have resolved on their own, and all of those 1.0% were new troponin elevations caused by BNT162b2. It is also possible that the same 0.7% continued to be elevated and only 0.3% of those troponin elevations were actually "new." Without excluding high troponin levels at baseline, there is no way to tell whether the levels are going up, down or sideways. This is true for every single box above. It looks thorough, but it does not answer the question it says it does. Perhaps it is true that the results of the Pfizer Troponin Study "did not provide evidence that BNT162b2 causes troponin elevations[,]" but the way the data are reported does nothing to separate troponin elevations that may have been caused by BNT162b2 from troponin elevations that may have been incidental and transitive. It may be that if those incidental elevations were removed, the results would still not show a statistically meaningful elevation in troponin levels; or maybe they would. It is impossible to answer that question based on the data provided.

**MANUFACTURING AND DNA CONTAMINATION**

The development and manufacturing of mRNA vaccines is a monumental engineering challenge, and the ability of sponsors to manufacture these complex formulae at scale is, to say the least, an impressive accomplishment, but it is not without its imperfections. This section addresses one of those imperfections, which is known either as "DNA contamination" or "residual template DNA," depending on the speaker. What follows is our findings as to both the frequency of this phenomenon and the risk it presents to those who take MRNA-1273 or BNT162b2.

To reach these conclusions, this Grand Jury heard testimony from both companies and independent experts about the processes involved in the manufacture of the mRNA vaccines. As we said above, the process is incredibly complex, but for present purposes, a short overview should

suffice. First, a sponsor identifies a target genetic sequence it wishes to replicate—in this case, the spike protein of Sars-CoV-2. Next, the manufacturer cultures bacterial cells that ultimately produce "template DNA" containing the blueprint for its target genetic sequence. This template DNA is then used to create the mRNA that eventually goes into doses of its vaccines. The mixture then goes through a purification and mRNA extraction stage, where the template DNA from the bacteria is broken down and filtered out. The mRNA that remains is then encapsulated in lipid nanoparticles (tiny fat bubbles that stabilize the mRNA and allow it to infuse into the outer membrane of human cells). The product is purified again before it is ultimately put inside sterile vials and administered.

Sponsors test the product at multiple points in the process using methodologies approved by the FDA for each stage of manufacturing to ensure that the product is within specification. Of course, no process is perfect, and, perhaps understandably, the FDA does not demand literal perfection. Instead, it sets limits for how many unwanted "things" can be in the end product, which we will call "contaminants" (even if sponsors might disagree with that word choice). There are several different categories of contaminants, including a specific category for fragments of excess template DNA that survive purification and filtration. As with other contaminants, the FDA and the sponsors agreed during the licensing process on what levels of excess template DNA would be acceptable. There was evidence that vaccine batches were distributed with excess template DNA above those agreed-upon levels, but those data were gathered from testing assays that did not match those mandated in the FDA standards.

This Grand Jury heard testimony from multiple witnesses concerning DNA contamination, including testimony that excess template DNA could become incorporated into the genome of the recipient, causing any number of problems. We must separate what we ***know*** to be fact from what we can merely ***speculate***. There ***is*** excess template DNA in Pfizer's and Moderna's vaccines. That is a fact. The residual or excess DNA does not serve a therapeutic purpose. We also know that vaccine lots vary in the levels of excess DNA. Just like a carrot that has been grown in the dirt, the mRNA inside these vaccines is (metaphorically) "grown" in DNA. Just like a carrot will always have some dirt on it, no matter how hard they are scrubbed, the mRNA vaccines will always have some leftover template DNA in them.

The more important question, however, is whether this should be cause for concern. Eating a little dirt from time to time is generally not harmful, but nibbling on the occasional piece of lead could have significant long-term health consequences. Is the residual DNA more like dirt or is it

more like lead? The simple answer is that it looks like residual DNA contamination does not appear to be causing any direct or obvious harms, but nobody knows for sure. Multiple witnesses we heard from expressed concerns about this phenomenon, but we found no studies demonstrating ***clinical outcomes*** that could be reliably attributed to DNA contamination. On the other hand, there is a lot about this technology that we don't know, and none of the witnesses who we spoke to were able to definitively dispel our concerns. After all, there have been therapeutics that were associated with detrimental outcomes years, sometimes even decades, after they were approved for marketing. Without direct evidence, however, this Grand Jury cannot draw any conclusions, but we do believe further research in this area—especially research that is able to causally associate DNA contamination in mRNA vaccines with specific clinical outcomes—would be valuable for public health.

**RISKS AND BENEFITS OF MRNA COVID-19 VACCINES**

All of this brings us back to the central question: Do the benefits of these mRNA COVID-19 vaccines—as defined by reduced SARS-CoV-2-associated infection, disease, hospitalization and death—outweigh their risks—as defined by vaccine-associated adverse events and SAEs? The answer to that question in early 2021 was straightforward: At the time the EUAs for MRNA-1273 and BNT162b2 were granted by the FDA, there were reliable RCT results from the flagship 1001 and P301 trials describing the efficacy of these products against COVID-19 disease. Those results could be inferred to provide protection against other risks associated with the SARS-CoV-2 virus, and those inferences were supported by other results from observational trials as massive numbers of people around the world were vaccinated. At that time, we had limited information on the length of protection these vaccines would provide and about the prevalence of important SAEs that might affect too small a sample of the population to be detected in those RCTs.

In 2024, however, circumstances have changed. First, the SARS-CoV-2 virus is different. It infects and causes COVID-19 disease at a much lower rate than it used to. When it does occur, it causes fewer hospitalizations and deaths. It is hard to say how much of this change is due to the development of effective treatment regimens and how much of it is due to the natural mutation of the virus toward equilibrium with the human race, but the end result is the same. This virus is just not as dangerous as it used to be. Second, ***we*** are different. At this point, most human beings in the world have been infected by the SARS-CoV-2 virus—many of us more than once. A good portion of the world's population has also been administered one or more doses of a COVID-19 vaccine,

providing "hybrid immunity" that protects much better than vaccines alone, but only slightly better than IDI. In any event, at a population level and at an individual level, we are better protected than we were in 2020 and 2021.

The issue in 2024 is that the COVID-19 vaccines may not be different enough. The SARS-CoV-2 virus still mutates to new variants on a frequent basis. Even with the extra speed derived from the FDA's willingness to accept immunogenicity results rather than clinical endpoints, new formulations of BNT162b2 and MRNA-1272 regularly lag more than a generation behind the latest variants by the time they reach consumers, meaning that they provide less protection from SARS-CoV-2 risks, and that whatever protection they do provide is likely to wane quickly. The side effects of these vaccines, however, are still present. There is still a reasonable chance that people who take these vaccines will experience minor Grade 1 to Grade 3 adverse events such as headaches, fatigue, injection site soreness, fevers, vomiting, muscle and joint pain or diarrhea. There is also a risk that they might experience SAEs like myocarditis and pericarditis.

This is the primary lesson from our section on VRMP: For a sizeable group of healthy young men, there is credible evidence that the risk of side effects from second doses of BNT162b2 or MRNA-1273 ***always*** outweighed their benefits, even at the height of the COVID-19 pandemic. As time went on, however, the infection, disease, hospitalization and death risks associated with SARS-CoV-2 have become significantly smaller, meaning that these vaccines were no longer able to confer the same level of protective benefits. This is true for everyone, not just healthy young men. Vaccine side effects, even minor adverse events, that may have been tolerable consequences in 2021 must be reconsidered in the context of this reduced protectiveness. As the level of possible SARS-CoV-2 risk reduction shrinks, more and more people who previously derived worthwhile benefits from these vaccines will find themselves on the wrong side of that risk/benefit curve, just like healthy young men did in 2021. How big is this group in 2024? Does it end at age 30? Does it end at age 45? Does it include people who have been infected in the last six months? What about people who were infected two years ago? Nobody can reliably say where the "tipping point" is, because sponsors and federal regulators will not even admit that a "tipping point" ever existed. Instead, they rely time and time again on comparisons to data from 2020 to approve the latest MRNA-1273 and BNT162b2 formulations, supporting those outdated comparisons with observational studies that almost never include sufficient covariate information to independently gauge their reliability.

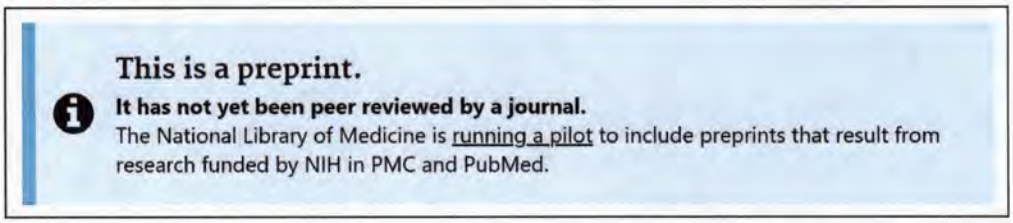
This is where we find ourselves in 2024. We no longer have a clear idea of which demographic groups are still deriving a meaningful benefit from BNT162b2 and MRNA-1273 and whether that benefit is worthwhile in the context of their side effect profiles. As difficult as the task will be, we need new RCTs to reevaluate their clinical benefit. If the benefits of these vaccines are so small that the number of participants required for those RCTs to reach statistical significance is impractically large, perhaps that would speak volumes about whether most of us really need them at all.

## COVID-19 AND MEDIA MESSAGING

This Grand Jury has spent a great deal of time chronicling the science of the SARS-CoV-2 virus and mRNA COVID-19 vaccines. As we said in the beginning of this Final Report, a good amount of the information we have covered is publicly available. Yet somehow, the public discourse around these important issues has lacked much of the nuance and depth that our experts were able to impart in their testimony. The discussions around these ideas never seem to focus on issues that matter, while zealots on both sides appear content to trade clever quips and snarky memes in place of civil discussion and scholarly debate. How did our collective discourse around science and public health reach this point? The simple answer to that question is that it had a lot of help. Much of it came from the United States government, but some came from sponsors and broad networks of affiliated third-parties. Each of these entities had its own role in shaping public discourse around the pandemic and injecting preferred ideas into the media ecosystem.

Take, for example, the Preprint Study; a work of such dubious design that to our knowledge, no peer-reviewed journal has published it as of 2024. Somehow, the primary conclusion of this flawed, misleading piece of scientific research—that young men aged 12 to 17 were likely to develop SARS-CoV-2-related myocarditis at a rate of 450 cases per million—made its way uncontested into the pages of several popular and reputable science publications, and from there into the wider media ecosystem, where it effectively became an accepted fact and a common retort to those with concerns about VRMP. Through all of this, no one even bothered to look closely at the Preprint Study to see if the underlying science even made sense. We have discussed its flaws at length in our VRMP sections above, so we will not reiterate them here, but this whole episode exemplifies many of the problems with the public discourse during the pandemic. The sources were skewed, the underlying science was often flawed, and one was liable to be publicly lambasted for any departure from the orthodoxy, even good faith disagreements.

The Preprint Study itself is hosted on the National Library of Medicine's "PubMed" journal server, a database containing thousands upon thousands of peer-reviewed scientific studies with the following disclaimer:




This study and several other studies we discussed above—especially studies published in MMWR—are examples of ***amplification***: An effort—in this case a government effort—to push certain messages and ideas into the public conversation around a particular topic. There are many other examples of government amplification in our reports. Our First Interim Report described "Key Messages" from the CDC involving the utility of masks in "preventing the spread of COVID-19." Our Second Interim Report highlighted FDA messaging around ivermectin; in particular, a controversial tweet characterizing the drug as something more appropriate for cows and horses than for people. The Governor's Petition, for that matter, references many statements clearly designed to influence public sentiment, like "[y]ou're not going to get COVID if you have these vaccinations," or even if a person chooses not to receive a vaccine, they might "go home and kiss their grandmother and wind-up killing their grandmother."

During the COVID-19 pandemic, our government's amplification of certain, preferred messages was coupled with something as ugly as it was new: A concerted effort by government officials, federal regulators and other public health actors to seek the ***suppression*** of opinions not in line with messages they wanted to amplify. At this point, it is well-established that government officials exercised considerable soft power during the COVID-19 pandemic by attempting to control vaccine-related narratives on social media websites, asking for specific posts or authors to be removed altogether, or even "blacklisted"—reducing their visibility to other users—on the grounds that they contained "misinformation" or "disinformation." We need not explore the details of those stories in this Final Report, as they have already been thoroughly described in other fora.

Government actors, however, are not the only participants in the amplification and suppression process. The public relies on a chain of parties who report, summarize, and scrutinize the safety and efficacy data reported by pharmaceutical sponsors. Those parties—primarily independent researchers, medical associations and science journalists—rely in large part on data

from sponsors to conduct their analyses, reach their conclusions and publish their articles. This means that sponsors can effectively exercise indirect control over potential narratives by selectively releasing efficacy and safety data regarding their products, taking advantage of the years-long gap in mandatory reporting requirements to force misleading ideas down the chain, amplifying them in the public discourse.

Pfizer, for example, employed scientists to write *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months*, which described clinical results from the blinded period of its flagship 1001 trial. The article was published in the November 4, 2021, issue of the NEJM, just a few months after the ACIP confirmed a VRMP safety signal in BNT162b2. It definitively stated that "[n]o cases of myocarditis were noted" in the 1001 trial. A second Pfizer-sponsored article, *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine*, was published in the May 19, 2022, issue of NEJM. It, too, highlighted that "no cases of myocarditis or pericarditis were reported" in its C4591031 booster trial, which featured a denominator made up entirely of "[m]ale or female participants ≥16 years of age . . . who participated in C4591001."

Once again, both claims are strictly true. The first VRMP event that occurred in the 1001 trial happened after the data cutoff date for *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months*. The event also made the trial participant who suffered from it ineligible for inclusion in the 1031 booster trial; therefore, it did not appear in those results. The second event that occurred in the 1001 trial happened during its booster phase, after all the 1031 participants had been pulled out of the 1001 trial, so it did not fall within the limited slice of booster data published in *Safety and Efficacy of a Third Dose of BNT162b2 COVID-19 Vaccine*. But the titles of these articles, backed by the reputation of the NEJM, certainly creates an imprimatur of credibility and finality regarding the claims inside of them, including the claims that myocarditis did not occur in the blinded or booster phases of the clinical trials associated with BNT162b2.

Given that Pfizer is the only organization (aside from the FDA, of course) with access to patient-level data involving SAEs, what responsibility does it have to correct that record? Here is what Pfizer thinks about that, according to the testimony of its representative:

> Q. Do you think a member of the public who read this article—this came out on November 4th, 2021—in mid 2022 or early 2023, would assume that myocarditis had not occurred in the clinical trials
>
> A. I think—

Q. —based on that language?

A. No. I don't know that I can assume what everybody would think, but what should be assumed is that at the time this trial is conducted and this report came out that no myocarditis was identified. But I don't know in perpetuity. Let's suppose somebody developed myocarditis ten years from now as part of this trial. Would we have an obligation to go and, essentially, report that out?

As long—in my view, as long as the information is out that there's a risk, and knowing that this one episode would not inform that risk is taken by itself is not substantive, that you needed this additional information, ***it seems to be that the public is adequately informed***. And if, you know, the reviewer or the person reading that article, you know, should be aware, then what else is in the public domain? It's in the label, you know, as far as risk is concerned.

(emphasis added). Dissatisfied with this response, we pressed the representative further regarding the second VRMP event in the 1001 trial, which occurred appurtenant to a booster dose that was given on November 19, 2021:

Q. So this is 15 days after [*Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine through 6 Months*] was published, right, 'cause this occurs on November 19th?

A. But by then it was public knowledge that myocarditis was a risk.

Q. So does public knowledge mean that you don't have to tell the public that what you wrote in this article—and I say "you," I mean Pfizer—that what you wrote in this article was inaccurate or misleading at the very least?

A. Well, again, you know, I understand your point, but I guess taking into the overall context, it wasn't as—again, ***the nature of this being a report didn't really further inform, in my view, the risk***. The risk was already evident based on the observational studies saying that there was a risk. So ***whether or not this is reported or not doesn't really change that perception of risk***.

Q. ***If it didn't inform the risk why write that sentence at all?***

A. Why—

Q. ***Why say there were no cases reported if it has nothing to do with risks?***

A. ***That was a fact. That was a fact at the time that the report was generated.***

Q. And that fact turned out to be incorrect; right?

A. That—in that, the individual that ended up having myocarditis in November did indicate, okay, there was a related case of myocarditis, but it postdated that

> publication, and it postdated information from a larger population that indicated it was truly a risk.

(emphasis added). Reporting from the period after these articles were published disproves Pfizer's assertions. The "fact" that no myocarditis cases occurred in BNT162b2's clinical trials appeared in the preambles of several scientific journal articles covering the issue of VRMP. It even found its way into a "fact check" article in March of 2022 entitled *Benefits of COVID-19 Vaccination Outweigh the Rare Risk of Myocarditis, Even in Young Males.* As of today, we know it is not true that "no cases of myocarditis occurred" among participants in the 1001 trial, but two separate articles in one of the most prominent and prestigious scientific journals in the world still can easily be read to say that. We do not blame the journals, the study authors or the peer reviewers for this misimpression. After all, none of the data Pfizer provided to them contained any SAEs of myocarditis or pericarditis. Rather, Pfizer "suppressed" certain parts of its clinical trial data to "amplify" an inaccurate message regarding VRMP that occurred in its clinical trials to the scientific community. From there, it found its way into public discourse. Unlike Pfizer, this Grand Jury thinks it did change the public perception of VRMP risk.

There are many discrete examples of similar problems which we have chronicled in other areas of this Final Report. The data from Pfizer's C4591015 study on the safety of BNT162b2 on pregnant women were never published in a journal or even presented at a VRBPAC meeting. We did not see any discussion of the "spontaneous abortion" events in Moderna's flagship P301 trial in scientific journals. This issue is not limited to trial data. Pfizer and Moderna have generated massive pharmacovigilance databases, but only a portion of the information inside them comes from publicly available sources. When a fulminant case of VRMP after MRNA-1273 was reported by the Australian press, Moderna pulled together and analyzed 65 similar cases the public knew nothing about.

These events, coupled with the testimony from both companies, persuade this Grand Jury that Pfizer and Moderna do not believe that the public or the third-party scientific community has any business independently assessing the risks and benefits of their products. We asked Pfizer's representative why the company did not simply publish anonymized individual patient data from all its trials, and this was the response:

> Well, so, again, I think individual patient data is pretty meaningless in and of itself. What you really want is the aggregate data so you can assess looking at placebo

> recipients versus vaccine recipients the impact of the vaccine in terms of efficacy as well as the safety profile.
>
> Databases are available to the public. ***The public can actually submit a research protocol to, essentially, have access to the raw data to do their own analysis, which is then peer reviewed and then decisions are made.*** So that sort of information can be made available, you know, for a specific research purpose.

(emphasis added). When pressed, however, Pfizer's representative could not recall a single time the company had granted third-party access to its individual patient data. Frankly, given what we have learned in our tenure, we find it difficult to believe the company would ever allow a truly independent scientific analysis of this data if it were not compelled to do so.

## DRUG ADVERTISING

Amplification and suppression are not the only methods sponsors can employ to shape the messaging around their products. The United States is one of two countries in the world that allows drug companies to advertise products directly to consumers. We received evidence from publicly available documents that Pfizer spent $1.8 billion advertising pharmaceutical products in 2020 and $2 billion in 2021. After BNT162b2's approval in late 2021, the advertising spend climbed precipitously to $2.8 billion in 2022 and a whopping $3.7 billion in 2023.

Historically, the FDA did not permit ***any*** broadcast advertising of pharmaceutical products, even in the case of fully approved prescription drugs. This changed in 1997, when the FDA loosened its previous restrictions on broadcast advertising, launching a multi-billion-dollar arms race that has continued for the last 27 years. All that money has found its way into our media ecosystem, where pharmaceutical sponsors can pick and choose which media sources get to receive portions of these incredible sums. These ads are already problematic in the case of prescription drugs, where consumers who see a given ad may not have all the information necessary to determine whether they need a particular therapeutic, but they are at least required to seek the assistance of a medical professional before they can access it. These problems are magnified in the case of the COVID-19 vaccines, which are often administered by pharmacy employees with only a modicum of training, who will almost certainly not be familiar with the individual health circumstances of a given vaccine recipient. On top of all of that, the COVID-19 pandemic heralded the rise of an even more insidious form of pharmaceutical marketing: Unbranded advertising.

In traditional pharmaceutical advertising, sponsors are required to disclose both the brand and generic names of their pharmaceuticals, their ingredients and a "major statement" about side effects and contraindications associated with their products. This is true for all fully approved drugs and biologics, even vaccines. Importantly, however, these requirements only applied to advertisements that ***promoted the vaccines***, not to advertisements that ***promoted vaccination generally***. If the advertisement did not mention the branded drug by name (hence the name "branded advertising"), the FDA did not enforce its marketing limitations. This meant that unbranded ads could even promote the use of products that were still in EUA status. After all, it was not the ***product*** that was being advertised, just the ***act*** of getting vaccinated.

In August of 2021, for example, Moderna published an unbranded ad while MRNA-1273 was still officially in EUA status. The ad started with a former athlete saying, "What's our Number 1 rule? Always protect the team." The athlete went on to opine that "with the vaccines here to help millions, we can take steps towards life as we knew it; a life with tailgating with family and friends, . . . and celebrations both on the field and in the community" as the on-screen visuals eventually resolved into Moderna's corporate logo. Although text at the bottom of the screen reads "[t]he vaccines may not be for everyone. Please consult your doctor[,]" there is no discussion or description of significant risks associated with ***any*** vaccine, let alone MRNA-1273.

Pfizer also got in early on the unbranded advertising with a series of "found footage" ads featuring a variety of "answers" to the question: "Why will you get vaccinated?" One of these commercials, published on February 3, 2021, captures a heartwarming pregnancy announcement, with the camera operator telling a grandmother-to-be "[y]ou're going to be a Nana!" and showing her an ultrasound. A caption then appears reading: "A: Because some people you just want to meet in person" as the family cries with joy. The final frame of this ad features Pfizer and its partner developer, BioNTech among a slew of other logos for third-party nonprofit organizations. None of these other organizations, however, had EUAs for their own COVID-19 vaccine formulae.

As we stated at the outset, the conceit of these advertisements is that they promote vaccination, not the vaccines themselves. At the time of the ad above, however, Moderna was a for-profit corporation that had a single commercial product: Spikevax. Even though Pfizer has a massive portfolio of drugs, it only has one BNT162b2. While this may be a fictional and outright silly distinction, it has real consequences, allowing the companies to avoid communicating the risk of their products while simultaneously reminding consumers of their existence and even extolling

their benefits. As of 2024, Pfizer and Moderna have each produced "branded" ads for BNT162b2 and MRNA-1273, but both continue to produce several "unbranded" ads per year, prominently featuring their corporate logos and urging consumers to "stay up to date" on their COVID-19 vaccines. Without FDA intervention, there is no reason to expect any of that to change. After all, these ads allow sponsors to accomplish the same visibility with little to no regulatory involvement or oversight.

**THIRD-PARTY INTERMEDIARIES**

Advertising is not the only method pharmaceutical sponsors have available to promote their products. Pfizer, for example, did not publicly take a position on the potentially fraught issue of vaccine mandates, but it donated significant sums of money to third party intermediaries who were willing to push for those mandates. In early 2021, for example, Pfizer donated $100,000 for a "Vaccine Safety and Effectiveness Campaign" to the Chicago Urban League, a nonprofit organization that describes itself as follows:

> Established in 1916, the Chicago Urban League helps people find jobs and establish careers, become homeowners, enhance their educational experiences, strengthen their leadership skills, and grow their businesses. One of the oldest and largest affiliates of the National Urban League, we promote strong, sustainable communities through advocacy, innovation, and collaborative community, corporate and civic relationships.

Following this donation, in August of 2021, Chicago Urban League officials made public appearances in various media outlets endorsing vaccine mandates. The fact of this donation never came up in any of these media appearances. Other nonprofit organizations received similar donations and produced similar statements. The National Consumers League, a century-old organization announced support for government and employer mandates requiring COVID-19 vaccination in August of 2021, right around the same time it received a $75,000 grant from Pfizer explicitly for "Vaccine policy efforts." The Immunization Partnership, a Texas-based organization styling itself as a "voice for Texans who want to prevent disease" did not receive as much monetary incentive; a Pfizer donation of only $35,000 was sufficient to drive its representatives to pen an op-ed advocating for the Texas Legislature to pass vaccine mandates in 2021.

Third party intermediaries did not only serve as mouthpieces for sponsor-friendly narratives, they also actively participated in the suppression of messages inimical to sponsors' interests, often partnering with social media companies to remove "dangerous information" and

deplatform its purveyors. One example is the Public Goods Project ("PGP"), which received roughly $1.3 million from the Biotechnology Industry Organization (BIO), a juggernaut trade association focused on vaccines that counts Pfizer and Moderna among its benefactors. Early on, BIO-funded PGP built a working relationship with Twitter (X), producing weekly misinformation reports for the company and asking for amplification tags to be placed on specific accounts of public health groups, academics, scientists and government officials, which put PGP officials in a position to amplify or suppress messages consistent with its sponsors interests on the grounds that it was fighting "misinformation" or "disinformation."

PGP is only one of scores of similar industry-funded cutouts that significantly shaped public debate and discussion around vaccines during the COVID-19 pandemic. These third-party organizations, which partnered with self-interested sponsors, naïve social media platforms and willing federal regulators, are a big part of the reason why much of the information we have described in this Final Report did not become a significant part of the public discourse regarding the safety and efficacy of BNT162b2 and MRNA-1273 over the last four years. These tactics do not appear to have worked to the sponsors' advantage in the long term. In October of 2023, Pfizer slashed its 2023 revenue projection by $9 billion, citing less demand for Paxlovid and BNT162b2, but its revenue appears to have stabilized since then. Moderna, too, reported a net loss of $4.7 billion early 2024, primarily due to a decline in sales of MRNA-1273. Frankly, the Twenty-Second Statewide Grand Jury might not even exist had these parties not been so heavy-handed in their efforts to control the narrative. But here we are, and we doubt the contents of this Final Report will do much to help their bottom line.

Nevertheless, we are compelled to point out that all the conduct and all the business relationships we described above are legal. The First Amendment protects speech, no matter who paid for it or what sponsor's interest it serves. It is up to the ***public*** to examine future claims about these products carefully and demand their representatives in government require pharmaceutical sponsors to release more information about their products, especially in the case of vaccines, where sponsors are immune from legal liability. It is up to the ***media*** to uncover relationships between sponsors and their complex and ever-growing web of third-party actors so the public can be aware of who is standing behind their messengers.

## CRIMINAL LAW ANALYSIS

Throughout our criminal investigation, this Grand Jury could not ignore the relationship between our federal regulators in public health and our for-profit pharmaceutical industry, whose agents and officers have a fiduciary duty to maximize all profit opportunities for the benefit of their shareholders. The sponsors' duty has never been a secret and should have been expected as a motive throughout the development and distribution of the COVID-19 vaccines. The regulators also had a duty. Unfortunately, they lacked either the will or the competence to meaningfully rein in the worst impulses of the industry. The COVID-19 pandemic gave sponsors enormous leverage over federal regulators, and they were certainly not afraid to use it. Still, regulators had the responsibility to recognize and temper these intentions. It is hard to lay blame solely at the feet of the pharmaceutical industry for cutting regulatory corners when government actors were holding their hand the whole way. The lack of tension between federal regulators and sponsors is a significant problem. Determining whether it was criminal is our charge.

As we described in the beginning of this Final Report, the Twenty-Second Statewide Grand Jury was impaneled by the Florida Supreme Court based on a Petition which called upon this body to investigate:

> [i]ndividuals, persons, and entities, including, but not limited to, ***pharmaceutical manufacturers*** (and their executive officers) and ***other medical associations*** or ***organizations*** involved in the design, development, clinical testing or investigation, manufacture, marketing, representation, advertising, promotion, labeling, distribution, formulation, packing, sale, purchase, donation, dispensing, prescribing, administration, or use of vaccines purported to prevent COVID-19 infection, symptoms, and transmission[.]

(emphasis added). The first giant step of this investigation was for us to deeply examine the available data—both public and internal—supporting the safety and efficacy of BNT162b2 and MRNA-1273 and draw as many conclusions as we could about the benefits and risks associated with these products. Having accomplished that task, we must now analyze whether we uncovered evidence of "any offense listed" in Section 905.34, Florida Statutes (2024). Many of the statutes described there were not relevant to our investigation, but we did closely examine Section 817.034, Florida Statutes (2024), Section 817.06, Florida Statutes (2024), Section 817.41, Florida Statutes (2024), Section 817.504, Florida Statutes (2024), Section 837.012, Florida Statutes (2024), and Section 895.03, Florida Statutes (2024). Ultimately, however, we did not find any statute that we

believed would be an appropriate vehicle for a criminal indictment based on the facts we have laid out in this Final Report.

There are a few reasons for this conclusion. First, our investigation did not uncover any activities by sponsors or other associated organizations with respect to COVID-19 vaccines that were not approved by federal regulators, either directly or indirectly. Some of the things these sponsors did should probably not be legal—we have discussed them at length in this report and many of them form the basis of our recommendations in the next section—but as far as we were able to determine, these entities operated within the boundaries of existing law. Records and testimony we collected in our tenure showed that time and again, sponsors operated hand-in-glove with regulators to promote their products in the marketplace. Often, the claims of sponsors and federal regulators alike were based on less-than-ideal supporting evidence, but we must presume from their conduct that these regulators understood the quality of this supporting evidence and they were satisfied with it. We did not uncover evidence that any sponsor withheld information from the FDA or acted outside its license, whether that was an EUA or a Full Approval.

Second, we did not uncover any sponsor or other private-party statements that were both objectively false ***and*** sufficiently precise to support a criminal prosecution. The Governor's Petition, for example, contains a large volume of statements from politicians, media figures and pharmaceutical sponsors. The evidence supporting those statements varies in quality. Some claims, like the initial vaccine efficacy figures publicly disclosed by Pfizer and Moderna, were industry-standard descriptions of RRR that were well-supported by clinical evidence from RCTs. We agree that these simple descriptions of RRR did not include all the necessary context involving durability of protection and absolute risk that the public would need to fully understand them, but they were not something the sponsors just made up. Other claims, like Pfizer's assertion that "[t]he ability to vaccinate at speed to gain herd immunity and stop transmission is our highest priority[,]" rely on inferences. We know from our investigation that Pfizer did not test efficacy against transmission as an endpoint in its flagship 1001 trial, nor did it appear to have a volume of internal information about how BNT162b2 would perform beyond its initial follow-up time of two months. Rather, in the assertion above, Pfizer inferred that the lower case counts it saw in its flagship 1001 trial would result in reduced transmission, and it inferred again that the protection afforded by BNT162b2 would last long enough to achieve "herd immunity." Three-plus years of hindsight has not been

kind to either of those inferences, but based on the evidence that was available in early 2021, we cannot say that there was no evidence to support them.

Just as all the conduct we investigated occurred under the supervision of federal regulators, all the statements we reviewed—including the ones in the Governor's Petition and many others we saw in the media—were supported by at least some existing evidence. We want to be abundantly clear that this does not mean we believe the actions of these sponsors were always appropriate, or that the statements they made turned out to be factually correct. It just means that those actions and statements are not sufficient bases to support criminal prosecutions.

## RECOMMENDATIONS

We find ourselves in an unusual position. This Grand Jury has expended a great deal of time and effort examining the activities of Pfizer and Moderna from 2020 to 2024. We have spent countless hours familiarizing ourselves with the process of vaccine development, approval and safety surveillance from a regulatory perspective to contextualize and understand those activities. We have spoken with many experts holding diverse opinions as to the overall rigor of the regulatory process and how it has fared over the course of the pandemic. While we did not find criminal activity, we did find a pattern of deceptive and obfuscatory behavior on the part of sponsors and regulators that often straddled the line between ethical and unethical conduct. More importantly, however, not finding any indictable criminal activity does not mean we did not find any problems. On the contrary, there are profound and serious issues involving the process of vaccine development and safety surveillance in the United States. Some of those are acute, COVID-19-era problems that are unlikely to occur outside the context of another once-in-a-hundred-year pandemic. Others, however, are systemic; they will occur over and over until someone fixes them.

Unfortunately, all these complications have something in common: They involve multinational corporations and federal regulators. The ability of sovereign states like Florida to resolve these issues or even influence these entities directly may be limited. This Grand Jury finds itself in the awkward position of advocating for a series of changes to a group of private and public entities who did not ask for them and are unlikely to be particularly interested in adopting them. Still, we feel compelled to point to what we have seen, if only to make the general public aware of the extent to which the massive systems upon which we depend for our health and welfare has failed to serve their interests.

Regarding the clinical trials and pharmacovigilance of MRNA-1273 and BNT162b2, it was genuinely striking to us just how many of the problems we found occurred at either the direction or acquiescence of the FDA, CDC and other federal regulators. Nearly every time we found an issue with MRNA-1273 or BNT162b2, the fingerprints of these agencies were all over the scene, advising that the flagship and surrogate clinical trials be performed in specific ways, authorizing dose after dose and formulation after formulation based on out-of-date immunogenicity comparisons and observational results, and even running interference for sponsors by misleading the American public about validated safety signals.

These regulatory issues are magnified in the context of vaccines, where consumers have effectively zero ability to hold manufacturers legally responsible for their injuries. Federal injury compensation systems like the CICP only allow limited recovery, while simultaneously protecting sponsors from the discovery process one would normally use to prove negligence and causation in liability claims involving any other product. Even in cases where compensation is awarded, it is the American taxpayer, not the sponsor, who must pay the claim. We understand that there is a desire on the part of the government to incentivize innovation in vaccine research and development, but the level of legal protection afforded to sponsors goes far beyond what is necessary to accomplish that goal, prioritizing development at the expense of public safety. We do not believe this system of legal protection is wholly without merit, but we also do not believe that the current incentives are structured to maximize benefit to the consumer, so much as they are structured to maximize benefit to the sponsor.

With that in mind, after 18 months of study, analysis and evidence-gathering, we have several recommendations that involve rebalancing the interests of vaccine development to the benefit of citizens of Florida and the United States. As a Statewide Grand Jury that is both unique in our composition and our charge, we sincerely hope that our fellow citizens of Florida—as well as citizens throughout the United States—will find our work useful. While a few of our recommendations are specific to the COVID-19 pandemic and COVID-19 mRNA vaccines, we also believe that our other recommendations could serve as a basis for substantive public policy changes that would be in the best interests of the American people, who rely upon the quality and safety of our regulatory system for all pharmaceutical products.

## FEDERAL RECOMMENDATIONS

***We need new clinical trials of BNT162b2 & MRNA-1273 to update the relationship between clinical results and surrogate endpoints.*** SARS-CoV-2 is a novel virus. As a species, our immunological relationship to this novel pathogen has changed dramatically since it first appeared in 2019. In 2024, it is simply less dangerous, and we are simply more immune. The concept of immunogenicity-based approval—which federal regulators predicated almost exclusively on the P301 and 1001 trials—relies on a stable relationship between disease and host which allows regulators to infer clinical outcomes from similar serological results. The issue is that the results regulators are currently using were derived from 2020, when the relationship between humans and SARS-CoV-2 was literally at its most unstable. We need reliable clinical trial data, not just observational studies, to understand the protection these vaccines are offering in 2024.

In addition, the limited age categories utilized in the 1001 and P301 trials are no longer sufficient to inform anyone today. To be of value, the population of these new trials will need to be stratified at least by age, IDI and prior vaccination status. These new trials should be required to include—at the very least—clinical endpoints for SARS-CoV-2 infection, transmission, disease, hospitalization and death. We would also recommend federal regulators structure the postmarketing requirements for future vaccine formulas to include substudies regarding the effects of these products on women at all stages of pregnancy and their unborn children, their effects on menstrual cycle function and their long-term effects on fertility.

If sponsors believe their products will only be effective in some subpopulations, they should limit the trials to those groups, and the FDA should limit future licenses accordingly. If sponsors are unable or unwilling to take these steps, we believe that speaks volumes about their understanding of the risks of SARS-CoV-2 and the efficacy of their products in 2024.

***The FDA should reinstate its pre-1997 ban on the direct-to-consumer advertising of therapeutics.*** Annoying and ubiquitous as they might be, pharmacological ads themselves are only a small part of the problem; the larger part is the money that pharmaceutical sponsors pay major media companies and scientific journals to publish these ads. This money distorts the incentives to report accurately on pharmaceutical products. The existing framework of advertising rules does not go nearly far enough, especially considering the vast, unregulated playground of unbranded advertising, where sponsors dance circles around the administrative requirements attached to their products. Does anyone really think that Pfizer's 2023 ad featuring a famous singer discussing "an

updated booster designed to protect against recent omicron variants" was designed to promote Pfizer's vaccines for pneumococcal pneumonia or RSV? What about Moderna, who was publishing unbranded corporate ads when it had literally one product on the market? The end of the COVID-19 pandemic and the associated abuses we have seen provides a prime opportunity to avoid another 27-year game of administrative "whack-a-mole" and join every other country on Earth (except New Zealand) in rejecting these ridiculous ads.

***The federal government should adopt some framework impeding the "revolving door" of private-sector employees and lobbyists in and out of the FDA, CDC and NIH.*** We understand that prior experience in the regulatory arm of a particular industry can be an attractive quality in a potential job candidate, just as private sector experience can help a regulator interface with these private actors. This phenomenon has clearly produced a "fellow traveler" attitude between the pharmaceutical companies and the agencies designed to regulate them. The boats of the regulators and the regulated are not supposed to be rowing in the same direction. If problems are discovered, they have to be timely disclosed to the public and meaningfully addressed by the sponsor and the regulator, lest the public lose faith in the system. There needs to be a healthy degree of tension between the industry and the regulators. Much of what we have learned about the regulatory process for the COVID-19 vaccines has demonstrated that—at least during this period—the FDA did not appear to be a responsible and effective gatekeeper.

***The VRBPAC should be restructured to determine the scope of approvals and authorizations it votes on for itself, and those votes should be binding.*** This is an adjunct to the recommendation above. During the pandemic, the FDA bulldozed over the concerns of its own ostensibly neutral—but still decidedly industry-friendly—data monitors, specifically in the context of EUA approvals. The storm clouds of this obstinance began to appear as early as 2020, when several members of the VRBPAC questioned whether the COVID-19 "emergency" necessarily applied to everyone above the age of 16, given how sharply the curve of complications varied by age. The FDA chose not to present the VRBPAC with a narrower approval, forcing the committee to choose between an authorization that was excessively broad and a disapproval that put the lives of elderly SARS-CoV-2 sufferers at unnecessary risk. But that was nothing compared to what we saw during the boosters, when the VRBPAC actually voted down Pfizer's EUA for boosters in people below the age of 65, only to see the FDA ignore its guidance and approve boosters for all adults anyway. We believe the VRBPAC is a great idea, but it has effectively become the United

Nations of drug approval, with all the moral authority in the world, but no actual power over the agency it purports to keep in check.

***Sponsors of pharmaceutical products should be required to publish the anonymized individual patient data—with all their attendant safety, efficacy and immunogenicity information—shortly after granting of any FDA license.*** As it stands, there are only three ways the world gets to know about what happened in clinical trials of new vaccines: (1) through articles published in the journal system; (2) through public VRBPAC meetings; and (3) through summaries of clinical trial data that are required by federal law to be published. We have discussed the problems with each of these sources at length; we will not reiterate their faults here. We merely wish to highlight how all those faults are magnified by the inherent liability, recovery and discovery protections afforded to sponsors by federal law. Consumers of vaccines have no way to directly hold sponsors responsible for their injuries, so they need more than the typical information provided for new drugs or other biologics. They need to know exactly what events happened, to whom, and how many times those events occurred. They need true data transparency.

To be clear, true data transparency means much more than just publishing summaries of outcome measures and safety events one year after the final ending of a clinical trial. By that time, a product has been widely administered and the damage has been done. Rather, what this Grand Jury refers to as "data transparency" would be nothing less than the near-contemporaneous publishing of whatever individualized patient data had been incorporated into that sponsor's BLA. This would allow independent researchers and the scientific community at large to "fact check" whatever information sponsors chose to include in their journal articles, effectively making it nearly impossible for sponsors to abuse the journal system to propagandize their products by cherry-picking specific results to write about. Above and beyond all the recommendations we have made so far, it is striking to us just how many of the problems we have identified—from the flagship trials to pharmacovigilance, to amplification and suppression, to legal protection—would be mostly if not completely resolved by timely, thorough data transparency requirements. As it stands, there is no federal or state law that forbids pharmaceutical companies from publishing anonymized versions of these data. In the context of COVID-19, a requirement like this would have made it possible for independent researchers to carefully and critically examine the safety and efficacy of BNT162b2 and MRNA-1273 in both the flagship and surrogate trials, providing valuable, independent assessments of the safety and efficacy of these vaccines. We believe that for

many at high risk for SAR-CoV-2 complications, these assessments would have increased, not decreased, their confidence in these products. We have learned what happens when the message from regulators is "do it if you want," now we should see what happens when the message is "you have to do it."

***Sponsors should be required to publicly disclose safety signals upon verification—not just confirmation.*** In the context of pharmacovigilance, we do not believe it is appropriate for a sponsor to withhold potentially important information about verified safety signals associated with its products from the public for months while it attempts to confirm or refute them. As we discussed above, at the point of validation, a potential safety signal has already been established to be both plausibly connected to the administration of a given therapeutic and to have occurred in excessive amounts over a numerical baseline. It is infantilizing and paternalistic for sponsors and regulators to assume that the public cannot distinguish between "we are investigating this potential problem" and "we have investigated, and this is a problem." With real transparency, consumers can make their healthcare decisions accordingly. Requiring sponsors to publicly disclose safety signals upon verification—not just confirmation—would incentivize those sponsors to get to the root cause of these verified signals quickly and transparently, if only so they could publicly announce those signals had been refuted as a way of bolstering public faith in their products and their processes.

***Sponsors who do not comply with data transparency requirements should not be allowed to retain federal legal immunity.*** As we said above, problems that do arise with vaccines are magnified by the fact that those injured by them have limited means to seek compensation. Federal law immunizes sponsors from negative outcomes related to their vaccines, only allowing limited recovery for injured parties through taxpayer-funded programs like the CICP and VICP. Those programs do not provide injured parties (or the public) with a means to determine whether tortious conduct occurred in the development or manufacture of the vaccines that injured them. Currently, only the FDA has unrestricted access to that information, and the events of the COVID-19 pandemic have not shown it to be a thorough and impartial referee when it comes to new vaccines.

We do not believe the federal government should continue to give sponsors this kind of broad immunity without asking for something in return. At the very least, sponsors should be required to comply with the data transparency recommendations we have outlined above if they are interested in retaining broad immunity. After all, without that transparency, the public is in no position to make informed decisions about the risks and benefits of vaccines.

## STATE RECOMMENDATIONS

In contrast to the issues described above, our state-level recommendations deal almost entirely with the Statewide Grand Jury process. This format, despite our best efforts, was a limiting factor in our ability to gather information. If Statewide Grand Juries are to be employed in the future to investigate large, multinational corporations (a prospect that seems increasingly likely in our interconnected world), we believe it would be appropriate to adjust their timing and capabilities in ways that would allow them to do this work more effectively in the future. Here are our recommendations:

***Chapter 905 should be amended to include a pre-swearing discovery period for the Statewide Grand Jury.*** Once an Order Granting a Petition to Impanel a Statewide Grand Jury is issued by the Florida Supreme Court, Section 905.37, Florida Statutes (2024), sets off a process of jury selection that is inherently time-limited. Once a Statewide Grand Jury is sworn, it may only sit—even with the benefit of a single six-month extension—for a total of eighteen months. This means that during that period, the Legal Advisor must continuously prepare and present testimony and witnesses while simultaneously continuing to gather new information through the use of investigative subpoenas. It also means that every corporation or individual the Statewide Grand Jury investigates can take advantage of this inherent time limitation, essentially "running out the clock" by not timely providing critical pieces of evidence and testimony. On the other hand, it might not be practical to convene a body of citizens to sit on a Statewide Grand Jury for longer than eighteen months. All of us who remain on this Grand Jury were committed to serving our full term, but many of us would not be able to continue to sit, even if we wanted to.

With that in mind, we suggest that Chapter 905 be amended to allow for a pre-swearing investigative period, during which the Legal Advisor could issue subpoenas on behalf of ordered-but-not-yet-sworn Statewide Grand Juries. This would begin the evidence-gathering process, allow for time to address whatever legal challenges were made to those subpoenas, streamline the presentation of evidence, and short-circuit some of the "clock running" we saw in our term. Formally allowing the Legal Advisor to issue subpoenas and collect evidence before future Statewide Grand Juries were sworn would further the interests of justice in the State of Florida.

***Failure to comply with Statewide Grand Jury Subpoenas should be a crime.*** Our approach to the subpoena process we described in Appendix 1 was heavily influenced by our limited time frame, and by the knowledge that the multinational corporations we were ordered to

investigate were headquartered outside of Florida. If those subpoena recipients had chosen to raise legal challenges to our subpoenas, it might have taken many months to shepherd those challenges through the trial and appellate courts before we could even begin receiving documents. This did not come to pass, but there is no reason to expect that will be the case in future Statewide Grand Juries. We believe that providing criminal sanctions in Florida law for noncompliance with Statewide Grand Jury subpoenas—in much the same way federal law criminalizes contempt of Congress—would provide an additional tool to incentivize the immediate meaningful production of documents and witnesses by recalcitrant subpoena recipients, heading off these potential problems before they have a chance to start.

***Perjury before the Statewide Grand Jury should be indictable by the Statewide Grand Jury and prosecutable by the Office of Statewide Prosecution.*** Late in our term, the Fourth District Court of Appeal reversed a circuit court dismissal of a perjury indictment issued by one of our predecessors, the Twentieth Statewide Grand Jury, on the grounds that a portion of that body's jurors were attending the proceedings remotely on the day when that perjury occurred, meaning that it "occurred in two or more circuits as part of a related transaction." In reaching that decision, the Fourth District rejected the State's broader position that the selection and swearing of a Statewide Grand Jury itself was a "related transaction" that "occurred in two or more circuits," making crimes against justice like perjury (and, potentially, contempt) that occurred in its presence inherently indictable by that body and prosecutable by the Statewide Prosecutor who serves as its Legal Advisor.

It is not hard to see the problems that could arise from this interpretation. A Statewide Grand Jury that cannot indict someone who perjures themselves before it has no effective means to ensure witnesses will testify truthfully. As the law stands, it may refer suspected perjury charges to local state attorneys for filing, but local state attorneys are not often an ongoing part of Statewide Grand Juries. They are not in a position to comprehend the context and the meaning behind why a given statement by a witness may be false and material without unsealing a large portion of the court-ordered secret proceedings. We believe it is necessary for the Florida Legislature to clarify—as it has done in the past with crimes facilitated by the Internet and crimes involving voting and voter registration—that perjury (and, potentially, contempt) that occur before the Statewide Grand Jury occur in every judicial circuit from which that Statewide Grand Jury is drawn.

***Florida should adopt more widespread monitoring of wastewater for pathogens of interest.*** During the pandemic, states were able to glean valuable insight regarding the geographic spread of SARS-CoV-2 by monitoring viral load in samples gathered from wastewater treatment facilities. This process even captured asymptomatic infection. Understanding these data allows resources and interventions to be tailored to the current situation. The strategy can be used to collect data on many different public health concerns, such as new pathogens of interest and antibiotic resistance. Some Florida wastewater treatment sites participate in this strategy for gathering public health data, but rural communities are underrepresented.

Florida law already requires wastewater treatment facilities to monitor their influent for various contaminants, including coliform bacteria. Monitoring wastewater for pathogens would facilitate the kind of targeted, science-driven public health that Floridians expect and deserve. Therefore, we recommend that Florida wastewater treatment facilities be required to monitor and report on identified pathogens of interest.

## DATA RELEASE

Due to the criminal subpoena process, this Grand Jury has been afforded an extraordinary degree of transparency into the clinical trials and pharmacovigilance for MRNA-1273 and BNT162b2. We have managed to collect more information regarding the approval and safety monitoring of these vaccines than is currently available from perhaps any other legal mechanism in the federal or state systems, bar the FDA. Bound as we are by our period of empanelment, this Grand Jury has only been able to scratch the surface of this vast sea of data. Given our limitations, we traded breadth for depth, reviewing largely that information we could corroborate with publicly available data. This necessarily means that there is a lot that we have not seen. There may be evidence of criminal activity, and there are certainly revelations beyond those we have described in this Final Report.

Much of this evidence is likely of enormous potential scientific value. Based on our review, there appears to be enough data—including individual patient information—to gain invaluable insight into the science reported by the companies, perhaps even recreating the statistical analyses conducted in the flagship trials or confirming the immunogenicity and safety analyses of the surrogate trials. MRNA-1273 and BNT162b2 are two of the most controversial, consequential and profitable pharmaceutical products of the past 50 years. From everything we have learned, they represent mankind's first foray into the use of mRNA-based lipid nanoparticle delivery systems in

human beings, but they will not be the last. We owe it to future generations to make sure these data are adequately deciphered, parsed and analyzed.

In addition, this evidence is of immense historic value. It describes the responses of our public health apparatus and the pharmaceutical industry to a once-in-a-hundred-year phenomenon that killed millions of people worldwide and drew a historic set of responses from those entities. As we said at the beginning of this Final Report, we believe that our collective response to SARS-CoV-2 represents the best humanity has to offer—innovation, cooperation and bravery—and the worst—greed, misfeasance and propaganda. The data we have collected allowed this Grand Jury to step inside the walls of these companies, where the public was previously only allowed to peer through the narrow windows provided by the journal system and federal reporting requirements. There is more to see within those walls than ten grand juries could absorb, and all this corporate activity was financed in no small part by public funds—our money. The public deserves to know what they did with it. All the data we have described above resides on a series of hard drives, where they will theoretically remain indefinitely, locked behind the confidentiality of Chapter 905, Florida Statutes (2024). Given the scientific and historic importance of these data, we believe it would be of enormous public benefit to revisit this law to the specific extent necessary to facilitate the availability of this particular evidence.

There are issues, however, that must be resolved. First of all, these hard drives contain safety and efficacy data for roughly 100,000 clinical trial participants and potentially millions of reported safety events involving the COVID-19 vaccines. All of this is private health information, protected under federal law by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and under state law by Florida Information Protection Act of 2014 (FIPA). Second, these drives also contain any number of "trade secrets" involving the design and manufacture of these therapeutics, the disclosure of which is also prohibited under federal law by the Defend Trade Secrets Act (DTSA) and under state law by Florida Uniform Trade Secrets Act (FUTSA).

We see two potential ways forward: One approach would be to simply redact every stitch of potentially violative data from the documents before making them publicly available. There are drawbacks to this approach: It would require a massive amount of time and money; we also do not have a perfect picture of what exactly Pfizer, Moderna or the federal courts would consider to be a trade secret; and redacting these data might ultimately limit their scientific and informational value. The second approach would be to remand these data to the custody of some qualified

research institution—perhaps some purpose-built entity within the state university system—with a mandate that allowed qualified researchers to view the data but prevented them from publicly disclosing information in their results that violated these state and federal statutes.

We do wish, however, to emphasize that the legal framework must contain a clear set of guidelines that allow researchers—regardless of bias—access to this evidence. It is our intent to facilitate transparency, not just replace a system with a pro-pharma bias for one with an anti-pharma bias. Ultimately, we believe that conflicts between the results of different researchers using the same data will reveal the whole story involving the COVID-19 vaccines.

## CONCLUSION

This Final Report marks the conclusion of the Twenty-Second Statewide Grand Jury. Though it was not always easy or comfortable, we have endeavored to execute the task assigned to us by the Florida Supreme Court carefully, thoughtfully and, above all, honestly. We are all aware that this Final Report has highlighted some painful truths about the COVID-19 pandemic, the pharmaceutical industry and our system of vaccine approval and licensing. We are hopeful, however, that our work will not be received as another entry in an ideological war, but a real call for systemic change and rebalancing.

As we said in our First Interim Report, this Statewide Grand Jury can only recommend these changes, we cannot enact them. It will be up to lawmakers and regulators to address the problems we have found with new laws and new rules, and it will be up to the media and the public to hold those regulators accountable. Our work is done.

## APPENDIX 1: SUBPOENA COMPLIANCE

This Grand Jury issued multiple subpoenas to Pfizer, Moderna and other third parties over the course of its investigation, including subpoenas *duces tecum*, which compelled the production of documents, and subpoenas *ad testificandum*, which compelled testimony from witnesses. We were able to gather a large amount of relevant information, some portion of which is chronicled in this Final Report, but time constraints inherent to the Statewide Grand Jury process made it challenging to gather these documents and testimony within the length of our term. We believe these constraints worked to the advantage of these corporations, allowing them to "run out the clock" involving many critical pieces of information about BNT162b2 and MRNA-1273. We cannot lay the blame for all of this at the foot of these companies. In many ways, these subpoenas are akin to eDiscovery in complex civil litigation—a process that requires careful management and can often take years to complete. We did not have years, however. A fact that was apparent to both this Grand Jury and these companies throughout the litigation process.

### Documentary Evidence

Regarding the subpoenas *duces tecum*, on June 29, 2023, the Florida Supreme Court, at the request of this Grand Jury, issued subpoenas to Pfizer and Moderna requiring them to produce various documents and records related to the COVID-19 pandemic and their vaccines. These subpoenas compelled production of information regarding a wide assortment of topics including vaccine formulations, the use of lipid nanoparticles, marketing and promotion of the vaccines, communications regarding safety and efficacy, studies on the SARS-CoV-2 virus, vaccine trials and studies, the company's deliberative process, and communications with regulators.

Upon receiving these subpoenas, Pfizer and Moderna both independently requested a "rolling production," whereby materials would be produced to us as they are collected and reviewed by the companies, rather than all at once. Cognizant of both our time limitations and the volume of documents requested, this Grand Jury agreed, in consultation with our Legal Advisor. Ultimately, the companies produced almost a terabyte of data, consisting of over 150,000 documents—about 21 million pages. Unfortunately, it appears to us that both Pfizer and Moderna took advantage in different ways of our time constraints, producing vast quantities of worthless, unintelligible, or specialized data, while simultaneously pushing the most valuable documents (internal communications and deliberations) to the end of the process, limiting our ability to timely review them.

Pfizer, for example produced a large volume of eCTD (electronic common technical documents) logs of its data transmissions to the FDA. These files, which are in XML format, contain logs of PDF documents that were sent from Pfizer to the FDA—many of which we cannot find in our production. Indeed, Pfizer produced over 8,000 XML documents, over 1.65 million pages of XML code. Pfizer also produced over 13,000 documents in an HTML format. Ultimately, most of these documents are completely and totally opaque, or they would take far longer than the duration of this Grand Jury to decipher. A good analogy for this state of affairs would be going to a restaurant and ordering a meal, only to be given no meal but a receipt a mile long covered in surveys and QR codes. We did not find this aspect of Pfizer's document production helpful or informative.

For its part, in the first six months following issuance of the subpoena, Moderna produced thousands of documents that consisted almost entirely of television advertisements; website and other graphic art mockups; peer-reviewed journal articles in the public domain, often with multiple duplicates; and data pulls or other regulatory documents. To dispel any notion that this final category could be useful, one example of such a document is a 26,688-page document consisting of pictures of data extracts from the statistical analysis platform SAS slammed together back-to-back. We confronted Moderna about the pace and content of its "rolling production" in December 2023, and to its credit, the company did begin to produce more useful documents on a more acceptable timeline. By that time, however, more than a third of our 18-month term had run its course. The damage was done.

Truly nothing embodies this Grand Jury's experience with the companies' document productions quite like the following. In early October of 2024, we asked Pfizer to produce a specific document—an internal "white paper" regarding myocarditis that had been leaked in 2023 to a popular muckraking website. Somehow, this document, which would have been relevant to our subpoena *duces tecum*, had not yet appeared in the mountain of records the company had provided, even though testifying witnesses confirmed that it did indeed exist. We were even able to identify its internal document control ID, because it was referenced inside other materials Pfizer had provided to us. Pfizer did not produce this document. Instead, it sent us an email, which included the following explanation:

> FDA regulatory submissions and agency correspondence relating to Pfizer's COVID-19 vaccine applications; clinical study documents (e.g. clinical study protocols, reports and statistical analysis plans); and meeting minutes from various

committees related to Pfizer's COVID-19 vaccine development (e.g., External Data Monitoring Committee, Risk Management Committee and Joint Safety Review Committee).

The document identified in your October 7, 2024 email does not fall under one of these categories. Rather, it is a purely internal, informal reference compilation on myocarditis. It was never formalized or finalized, was not intended to have been shared externally or submitted to a regulator and never was, and remained a draft that was never subjected to Pfizer's normal quality control. For these reasons, it was not identified as a potentially responsive document and was not produced in response to the July 29, 2023 Subpoena.

To be clear, our subpoena *duces tecum* specifically requested "[r]ecords of communications (including draft communications) related to any internal safety and efficacy monitoring of Your Company's COVID-19 vaccine products[.]" Its language ***did not*** exempt documents that are internal, informal, not finalized, drafts, not intended to have been shared externally, or not subject to the company's quality control. It appears to us that Pfizer unilaterally decided to withhold some categories of documents relevant to our subpoena *duces tecum*, contrary to the legal obligation imposed on it by the Florida Supreme Court.

That is not to say that everything these companies produced was worthless. We were able to dredge up a surprising amount of relevant information utilizing eDiscovery platforms. The fruits of many of those labors are contained in this Final Report, but we believe further analysis would likely produce more revelations regarding BNT162b2 and MRNA-1273, and further explain the internal processes and deliberations surrounding these important vaccines.

Throughout this process, we have been cognizant that these subpoenas, frankly, demanded a lot from these companies. We also understood that even if the companies had produced every shred of responsive materials, we would not have the time in our term to review them. As we mentioned above, the eDiscovery process in complex civil cases can often take years to complete. Therefore, there had to be some sort of tradeoff. However, the approach taken by the companies in producing documents clearly took advantage of this time constraint by prioritizing self-serving, voluminous nonsense over the substantive matters at the heart of the subpoenas.

Witness Testimony

Because of the time constraints inherent to the Statewide Grand Jury process and our need to take in expert testimony on a wide range of subjects, we chose not to issue subpoenas *ad testificandum* for specific employees of Pfizer and Moderna who may not have been able to answer

our specific questions. Rather, we sent the companies lists of subjects related to vaccine efficacy, safety, manufacturing and marketing, asking them instead to choose witnesses who would be qualified to speak on the company's behalf as to those subjects. We were assured by both companies that subpoenas *ad testificandum* would not be necessary for the companies to provide relevant testimony.

After some difficulty, both companies did eventually produce qualified witnesses to testify before this Grand Jury. Pfizer's counsel, from the beginning of our term, repeatedly stressed the company's commitment to open cooperation. True to its word, it voluntarily provided witnesses to testify in August of 2024. The problem was that it failed to provide almost all of those witnesses with the detailed series of questions our Legal Advisor had prepared in advance to maximize the utility of their testimony, ultimately wasting our limited time. We then issued a subpoena *ad testificandum* for representatives of the corporation to appear and answer those remaining questions, and that forced the full cooperation we initially sought. The witnesses Pfizer provided pursuant to that subpoena were much more prepared. They were not always as forthcoming as we would have liked regarding many of the shortcomings we identify in this Final Report, but to some extent, that is at least understandable.

Moderna, for its part, also agreed to voluntarily provide witnesses to speak on the company's behalf but rescinded this cooperation before those witnesses appeared. Counsel for Moderna cited the contents of our Second Interim Report as grounds to believe this Grand Jury would not treat the company fairly. We responded to its concerns by issuing a subpoena *ad testificandum* compelling their testimony, and Moderna did provide qualified witnesses who had reviewed our questions in advance and were prepared to discuss the issues. Once again, these witnesses were not always as forthcoming as we would have appreciated, but once again, given their affiliation, that is understandable.

## APPENDIX 2: THE IMPACT OF SCHOOL CLOSURES

As mentioned in our first interim presentment, school closures were one of the most concerning facets of lockdowns. School closures were communicated as a public health necessity to reduce virus transmission, yet science didn't support a long-term shutdown of schools. Preliminary results demonstrated that the SARS-CoV-2 virus was primarily spread amongst adults and mainly adults to children according to a study from the Netherlands published in June of 2020. To put it more plainly, transmission was mostly moving from adults to children and not child to child, thus negating one of the main arguments for initiating school lockdowns. In one observational study in January of 2021, seventeen K-12 schools in Wood County, Wisconsin, were assessed for incidents of SARS-CoV-2 infection, revealing reduced rates as compared to the overall county. Only 3.7% of all cases, all amongst students, were linked to in-school spread. This study demonstrated that transmission risk within schools appeared low and suggested that a safe return to in-person learning was possible. Many states still refused to re-open schools.

Serious collateral consequences of school shutdowns were felt, including the following: significant educational disruptions, negative effects on academic performance, decreased social development, increased mental health issues among students, economic impacts on families, and a reduction in total life expectancy for school age children. School closures had a profound and far-reaching impact on society in the United States, negatively affecting teachers, parents, school staff, and children differently. Our teachers and administrators should be recognized for their Herculean efforts to carry out the wishes of government officials while individually enduring the hardships of the pandemic themselves.

### Educational Disruption: Learning Loss and Achievement Gaps

Prolonged absences from the classroom environment are linked to setbacks in academic achievement. While some students managed the transition to digital platforms, others struggled due to a lack of essential resources. School administrators were expected to immediately address these issues by providing hot spots, computers, and other equipment to enable remote learning - a tall task given the limited resources and infrastructure. The result? Standardized test scores revealed that many students fell one to three grade levels behind acceptable academic standards.

The National Assessment of Educational Progress (NAEP) is the nation's report card and measures the learning progress of American students in various subjects. The NAEP collected data from January through March of 2022, measuring several educational factors for key

demographic categories and analyzed the temporal changes between national, state, rural and urban school districts. One concerning finding was the long-term trend for nine-year-olds in reading, pre- and post-pandemic, showed the largest score drop since 1990. Another was that mathematics testing revealed the first ever score drop since the formation of the NAEP in 1971. National scores also showed educational declines between pre- and post-pandemic scores across the country, in nearly all school districts, in the grade levels tested (fourth and eighth).

Social and Psychological Effects: Isolation and Mental Health Issues in Students

Schools are critical learning grounds for social development and provide foundational development of community interaction. The sudden switch to remote learning stripped this socialization away from developing children and replaced it with isolation, leading to diminished growth and mental health concerns. Heightened anxiety and depression materialized.

A German retrospective study in 2023 found that children between the ages of 11 and 17 experienced worsening health measures during the early months of the pandemic which directly correlated with remote learning, especially for children with limited living space. The effects of reduced physical activity was a direct corollary to weight gain and negative effects on emotional well-being. Schools serve as key sites for early intervention in issues like mental health, nutrition, abuse, and special education services. The closures led to a delay in identifying these concerns and have resulted in life-long consequences.

Economic Impacts on Families

The economic consequences of school closures were too often severe. Many parents, particularly those with younger children, struggled to juggle work and supervise their children's education. Some parents were compelled to quit their jobs or reduce their working hours to supervise remote learning. Loss of income placed additional stress on families already struggling through financial instability and food insecurity, affecting overall family dynamics. Additionally, school closures severed access to essential services provided by schools, such as free or reduced-price meals relied upon by many low-income families. This loss affected the ability of certain families to meet basic nutritional needs, which impacted children's overall health.

Long-term Societal Impact: Workforce and Life Expectancy

Long-term societal consequences will be felt for years to come. Students who experience academic delays are at risk of a failure to graduate on time, which can reduce their opportunities for higher education and career advancement. Experts anticipate an increase in dropout rates as

students struggle to catch up academically, thus disengage, and eventually leave the educational system. This trend will expectedly impact future workforce readiness, limiting economic mobility and perpetuating cycles of poverty. Most notably, one U.S. study in 2020 found that missed school instruction which occurred during the pandemic could be associated with loss of life expectancy. This loss in life expectancy was likely greater than what would have been experienced by leaving primary schools open.

Future health emergencies require more well-rounded consideration by educators, policymakers, and communities to develop balanced and effective public health strategies. This would minimize educational disruptions and promote the comprehensive well-being of students and families while considering the true risk profile associated with the particular health emergency.

## APPENDIX 3: PAXLOVID

In the wake of failed or disavowed treatments, a pharmaceutical giant has once again come to the rescue, or has it? "If it's COVID, Paxlovid." The FDA has authorized the emergency use of Paxlovid for the treatment of mild-to-moderate COVID-19 in adults and children 12 years of age and older weighing at least 88 pounds who are at high risk for progression to severe COVID-19, including hospitalization or death, under an EUA. But is it effective against hospitalization or death? Once again, we are faced with "following the science" and the conflicting "science" that is presented to the consumer public. There are expected potential side-effects and counteractivity, to include the following: gastrointestinal issues such as diarrhea and dysgeusia ("Zombie Mouth"); hypersensitivity reactions including Stevens-Johnson syndrome; some significant drug interactions requiring dose/frequency adjustment or avoidance; hepatic effects such as transaminase elevations, clinical hepatitis, and jaundice; renal impairment; and a risk of HIV-1 protease inhibitor drug resistance. Additionally, this Grand Jury has heard evidence related to Paxlovid rebound, which describes a resurgence of COVID-19 typically within a week after taking Paxlovid. This is usually milder than the initial illness but allows for continuing to spread the virus to others. There is great concern with a product which may very well extend the length of contagiousness and should be carefully evaluated against the true value of that product (value to the consumers, not the manufacturer).

What are the positives then? Reduced risk of death? Decrease in expected hospitalization? Less severe or maybe even a shorter duration of symptoms? Once again, we are left with an array of disagreeing studies all with apparent appropriate rigor and reliability. When a meta-analysis has been performed, any effectiveness of Paxlovid against mortality is not statistically significant—there is not an indication that Paxlovid reduces death. As it relates to hospitalization, the RCTs that focus upon this outcome have differing results. The RCTs available for analysis of Paxlovid's impact on hospitalization rates due to COVID-19 were high quality and are linked to Pfizer, the manufacturer of Paxlovid. The meta-analysis focusing exclusively on RCTs using Paxlovid to prevent hospitalizations failed a sensitivity analysis using fixed vs random models since they yielded different significance. The meta-analysis of RCTs indicates no efficacy in the use of Paxlovid as compared to placebo for prevention of hospitalizations when the random-effects model was used but indicated efficacy when a fixed-effects model was used. The effectiveness of this treatment was not statistically significant when a random-effects model was used but was

significant when a fixed-effects model was used. The studies were insufficient for a meta-analysis. However, there are clear distinctions between the two studies: The 2022 study found efficacy, but did not include anyone who had previously been infected by SARS-CoV-2; the 2024 study found no efficacy, but included participants who had been infected and vaccinated. The population of consumers for this biological product has changed in the years since COVID-19 was introduced. Understandably, the effectiveness of this product very well is also expected to change along with that population. Additionally, the 2022 study focused on a population that was high risk, whereas the 2024 study focused on standard risk. As expected throughout the pandemic and with the pharmaceutical remedies manufactured (vaccine and drug alike), an individual's level of risk is an integral factor that should be considered when evaluating the use of the product.

As infection-derived immunity continues and the severity of the SARS-CoV-2 variants decreases, what benefit does this treatment have? If we solely focus on the advertisements and marketing strategies of the company manufacturing this biological product, there is great utility. However, is the cost of this product truly worth the result? Interestingly to this Grand Jury, the answer to these questions are complicated by the fact that our country is in the extreme minority of places in which pharmaceutical companies are permitted to directly advertise to the consumer. In fact, only New Zealand also allows for such advertising to consumers. The rest of the world does not allow such activity - without any loss to freedom or free enterprise. Without such direct communication, would a product such as Paxlovid even be a consideration for almost all people who develop COVID-19 disease this year? Of course not. This is a crucial concern of this investigative body—that many of the treatments directly advertised to the public only obscure their perceived efficacy.

In early 2023, researchers have estimated the production cost of a five-day course of Paxlovid to be a relatively modest $13.38, but the retail cost of that same five-day course to the consumer is a staggering $1,390 per course, more than double the $530 per course that Pfizer charged the federal government in its initial contract. Paxlovid is a product under patent and one which is expected to generate substantial profit given its widespread use. While we understand that our free market system allows pharmaceutical manufacturers to profit from products they develop, the continued marketing of Paxlovid, which Pfizer's own research shows is ineffective, pushes the boundaries of ethical corporate citizenship. This is being allowed by our federal government at a cost to all consumers.

## APPENDIX 4: ABBREVIATIONS

**ACIP:** Advisory Commission on Immunization Practices

**ACOG:** American College of Obstetrics and Gynecologists

**AESI:** Adverse Event of Special Interest

**BARDA:** Biomedical Advanced Research and Development Authority

**BCC:** Brighton Collaboration Criteria

**CDC:** Centers for Disease Control and Prevention

**CICP:** Countermeasures Injury Compensation Program

**DOD:** Department of Defense

**EHR:** Electronic Health Records

**EUA:** Emergency Use Authorization

**FDA:** Food and Drug Administration

**GSD:** Global Safety Databases

**HHS:** Department of Health and Human Services

**IDI:** Infection-Derived Immunity

**MMWR:** Morbidity and Mortality Weekly

**NIH:** National Institutes of Health

**NPI:** Nonpharmaceutical Intervention

**PBRER:** Periodic Benefit-Risk Evaluation Report

**RCT:** Randomized, Placebo-Controlled Trial

**SAE:** Serious Adverse Event

**SCM:** Subclinical Myocarditis

**VAERS:** Vaccine Adverse Event Reporting System

**VICP:** Vaccine Injury Compensation Program

**VSD:** Vaccine Safety Datalink

**VRBPAC:** Vaccine and Related Biological Products Advisory Committee

**VRMP:** Vaccine-Related Myocarditis & Pericarditis

# CERTIFICATION

THIS REPORT IS RESPECTFULLY SUBMITTED in Open Court to the HONORABLE CHRISTOPHER C. SABELLA, Presiding Judge of the Twenty-Second Statewide Grand Jury, this 22nd day of November, 2024.

JUROR # 15
Foreperson
Twenty-Second Statewide Grand Jury of Florida

I, NICHOLAS B. COX, Statewide Prosecutor and Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

NICHOLAS B. COX
Statewide Prosecutor
Legal Adviser

I, JEREMY B. SCOTT, Chief Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

JEREMY B. SCOTT
Chief Assistant Statewide Prosecutor
Assistant Legal Adviser

I, BRIAN L. FERNANDES, Chief Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

BRIAN L. FERNANDES
Chief Assistant Statewide Prosecutor
Assistant Legal Adviser

I, PAUL DONTENVILLE, Chief Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

PAUL DONTENVILLE
Chief Assistant Statewide Prosecutor
Assistant Legal Adviser

I, JAMES R. HARRIS, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

JAMES R. HARRIS
Assistant Statewide Prosecutor
Assistant Legal Adviser

I, JAE HEE KIM, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

JAE HEE KIM
Assistant Statewide Prosecutor
Assistant Legal Adviser

I, NATHANIEL S. BAHILL, Assistant Statewide Prosecutor and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

NATHANIEL S. BAHILL
Assistant Statewide Prosecutor
Assistant Legal Adviser

I, ANDREW BUTLER, Assistant Attorney General and Assistant Legal Adviser, Twenty-Second Statewide Grand Jury of Florida, hereby certify that I, as authorized and required by law, have advised the Grand Jury which returned this report on this 22nd day of November, 2024.

ANDREW BUTLER
Assistant Statewide Prosecutor
Assistant Legal Adviser

THE FOREGOING Second Interim Report of the Twenty-Second Statewide Grand Jury was returned before me in Open Court this 22nd day of November, 2024, and is hereby sealed until further order of this Court, upon proper motion of the Statewide Prosecutor.

HONORABLE CHRISTOPHER C. SABELLA
Chief Judge of the Thirteenth Judicial Circuit
Presiding Judge, Twenty-Second Statewide Grand Jury

Received, Clerk, Supreme Court

NOV 22 2024

A True Copy
Attest:
John A. Tomasino, Clerk
Supreme Court of Florida
By
Deputy Clerk