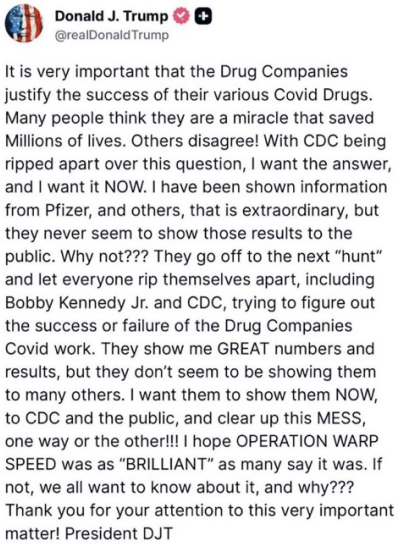
DNA Integrity Project, LLC
1245 Hewlett Plaza Suite 213
Hewlett, NY 11557

October 23rd, 2025

Dear President Trump,

On September 1st, you stated that companies participating in 'Operation Warp Speed' should release the efficacy and safety data they provided to you so that everyone can assess the truth.



Donald J. Trump
@realDonaldTrump

It is very important that the Drug Companies justify the success of their various Covid Drugs. Many people think they are a miracle that saved Millions of lives. Others disagree! With CDC being ripped apart over this question, I want the answer, and I want it NOW. I have been shown information from Pfizer, and others, that is extraordinary, but they never seem to show those results to the public. Why not??? They go off to the next "hunt" and let everyone rip themselves apart, including Bobby Kennedy Jr. and CDC, trying to figure out the success or failure of the Drug Companies Covid work. They show me GREAT numbers and results, but they don't seem to be showing them to many others. I want them to show them NOW, to CDC and the public, and clear up this MESS, one way or the other!!! I hope OPERATION WARP SPEED was as "BRILLIANT" as many say it was. If not, we all want to know about it, and why??? Thank you for your attention to this very important matter! President DJT

That goal, however, assumes that the data shared with you in the fall of 2020 were timely, accurate, and complete. We believe the data supplied by Pfizer/BioNTech concerning their Covid Vaccine BNT162b2, was ***incomplete***, ***manipulated*** and ***delayed***, leading to emergency and full authorizations without a full understanding of the vaccine's true efficacy and risks.

On January 6, 2022, U.S. District Judge Mark T. Pittman ordered[1] the FDA to disclose records provided by Pfizer and BioNTech - the sponsors of trial C4591001 - in response to a FOIA request from Public Health and Medical Professionals for Transparency (PHMPT). This Order enabled independent experts to examine the sponsors' data.

Analyses of those records, ***drawn from the sponsors' own documents and datasets***, indicate that information you received in the fall of 2020 may have been delayed and modified in ways that made the product appear safer and more effective than was observed in the clinical trials. Examples include undisclosed participant deaths and severe adverse events, major infringements to the blinding of patient data during the trials and to Good Manufacturing Practices (GMP), not fully conveyed to regulators (or, in the case of DNA plasmid contamination within Pfizer vials, elements were intentionally hidden from regulators).

The 90 day post-marketing data collected by Pfizer included 1223 patients who died shortly after taking the vaccine. This number of deaths should have immediately halted distribution and use of the product. The average number of annual vaccine deaths in the US before the COVID-19 vaccines was less than 150. This is unacceptable to the American public and was an early sign the product was not safe for human use.

FDA's Application Integrity Policy (AIP) authority remains fully intact during PREP Act coverage. The PREP Act immunity shields manufacturers from civil litigation for data integrity violations but does not prevent FDA from investigating fraudulent applications, data manipulation, or systematic regulatory violations.

Statutory Authority:

- 21 U.S.C. § 355 (New Drug Applications)
- 21 U.S.C. § 360bbb-3 (Emergency Use Authorization)
- 21 CFR Part 312 (Investigational New Drug Applications)
- 21 CFR Part 314 (Applications for FDA Approval)
- 21 CFR Part 601 (Biologics License Applications)

Based on the evidence above, we believe the threshold has been met to invoke the AIP for the Pfizer BNT162b2 clinical trial and to audit all of the trial site data to determine if fraud occurred, untruthful statements were made, and to demand that the various, required documentation (which as of September 23, 2025, has not been submitted to the FDA) be immediately supplied to the FDA and evaluated in consideration of their continuing licenses or potential revocation of their product(s) for the treatment of Covid-19.

Executive Summary

I **Trial blinding failures:** Independent analysis of FDA-released documents shows evidence that clinical trial staff **knew** which participants received the vaccine vs. the placebo and treated them differently - undermining the scientific validity of the trial results that supported the vaccine's emergency authorization.

II **High-stakes instances of dataset discrepancies:** There are more than 300 randomization numbers missing from the trial datasets, etc] and Pfizer also failed to report at least 2 known cardiac deaths in the vaccine group to regulators **despite having this information before the EUA deadline**. These omissions and concealed deaths suggest a systematic manipulation that hid potential safety signals,

delaying regulatory recognition of cardiac adverse events and likely influencing the EUA decision based on incomplete information.

III **The manufacturing process for the commercially distributed vaccines is more hazardous and differed from the one tested:** The vaccine tested in the clinical trial used a different manufacturing process ("Process 1") than the product distributed to the public ("Process 2"), with less than 1.2% of the vaccine recipients in the trial receiving the Process 2 version prior to EUA. Process 2 showed higher adverse event rates in the trial data, yet this critical difference/risk was not adequately disclosed to regulators or the public.

IV **DNA Contamination:** Multiple, independent laboratory analyses have detected variable levels of DNA contamination in commercially produced (Process 2) vaccine vials, indicating quality control failures in the manufacturing process. This contamination raises concerns about potential long-term safety implications that were not identified during the original regulatory review; in fact, Pfizer **intentionally withheld** information regarding certain components (the SV40 promoter, for example) from the FDA in its EUA submission, which increases the cancer risk from this DNA contamination.

V **Gene Therapy Misclassification:** Independent analysis of FDA released documents and regulatory submissions reveals that COVID-19 mRNA vaccines meet the agency's own definition of gene therapy products, yet were systematically routed through inappropriate regulatory pathways to avoid gene therapy oversight. This misclassification enabled the circumvention of mandatory safety assessments, advisory committee review, environmental impact analysis, and long-term monitoring requirements - creating a regulatory framework that concealed the true nature of these products from both regulators and the public

Methods.

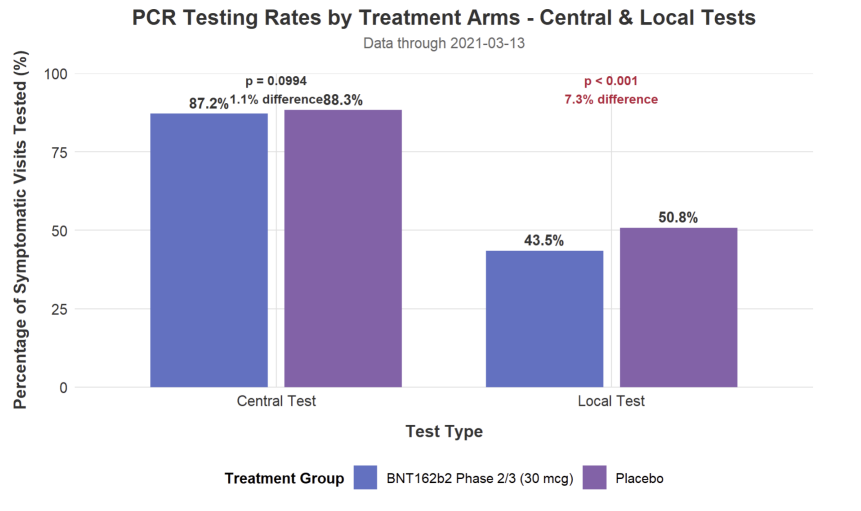
The newly released C4591001, trial records have been methodically analyzed.[2]
These have enabled a comparison of the clinical trial data submitted to FDA for Emergency Use Authorization (EUA) (Dec 2020) and Biologics License Application (BLA) (May 2021).[3]

I. The data demonstrates multiple breaches of blinding:

The data analysis highlights the fact that some trial teams did not abide by ethical guidelines - and did not maintain 'blinding.' In practice, staff knew which participants received which product and treated them differently, materially influencing the study's results.

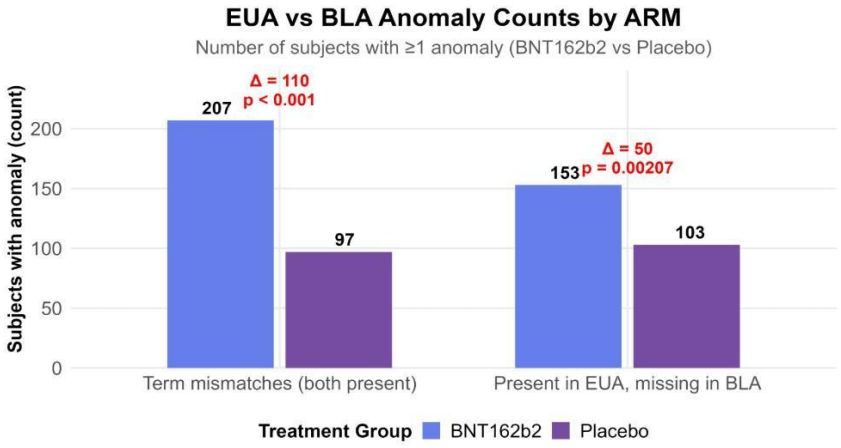
These breaches of blinding are corroborated by multiple anomalies in the data - unlikely due to chance alone ($p<0.01$) - that affect the trial's primary endpoints:

- Among symptomatic participants, placebo recipients were tested for SARS-CoV-2 significantly more often than BNT162b2 recipients.[4] According to the protocol, samples taken during symptomatic visits were to be tested locally and "centrally," at the Pfizer Pearl River laboratory, Pearl River, New York, USA. The central laboratory tests were the preferred method for a COVID case to be confirmed,[5] although depending on protocol variations, local tests approved by the FDA could be used.[6] A total of 9474 central tests and 5489 local tests were recorded at the BLA cut-off date of March 13, 2021. 87.2% of the 4421 symptomatic visits made by subjects in the BNT162b2 group resulted in PCR tests being sent to the central laboratory, compared with 88.3% of the 5798 visits made by subjects in the placebo group. This minor difference was not significant. In contrast, by the same date, only 43.5% of the 4421 symptomatic visits made by subjects in the BNT162b2 group had resulted in local PCR tests, compared with 50.8% of the 5798 visits made by subjects in the placebo group. This demonstrates that a significant difference in treatment between the groups, by the teams in charge, occurred at certain sites ($p < 0.00001$).

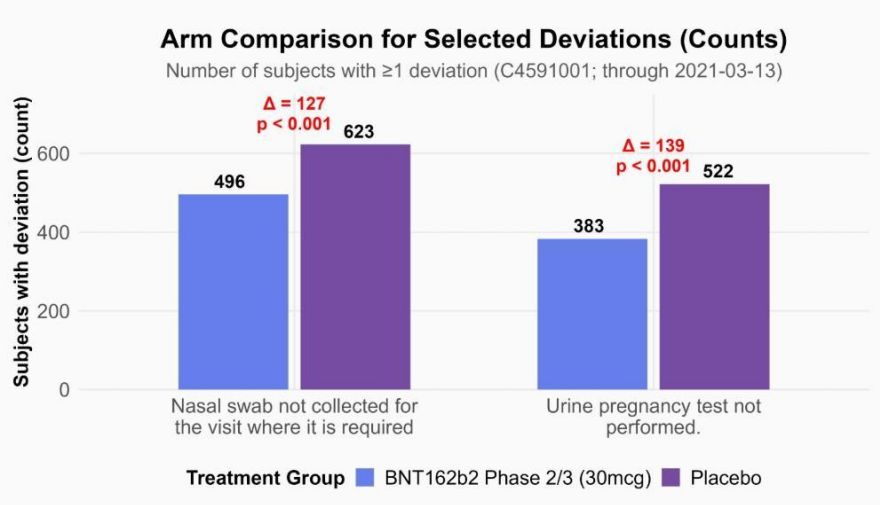


- Protocol deviations, which record departures from required procedures, show significant imbalances when compared to the rest of the population which does not present the anomaly (22

085 BNT162b2 & 22 080 Placebo), using a chi-square test, including “Nasal swab not collected for the visit where it is required” (BNT162b2 : 496, Placebo : 623, p-value : <0.001) and “Urine pregnancy test not performed” (BNT162b2 : 383, Placebo : 522, p-value : <0.00001).



These patterns indicate differential handling of participants, depending on which treatment arm they were attributed by site staff.[5]



- Edits between the EUA and BLA releases - including term changes[7] that requalify adverse events and removals of adverse events present at EUA time, further suggest that blinding was not consistently maintained at scale, as they impact the BNT162b2 group significantly more, when compared with the rest of the subjects sample without anomalies (BNT162b2 = 23226, Placebo =

23254) using a ‘chi-square’ test. Terms designating adverse events are requalified on 207 cases for BNT162b2 against 97 cases for Placebo subjects ($p < 0.0001$). Adverse events removed from the BLA datasets are impacting 153 BNT162b2 against 103 Placebo recipients ($p < 0.01$).[8]

AIP Analysis: Trial Blinding Failures

Nature of Violation: Systematic compromise of randomized controlled trial integrity through differential participant treatment based on treatment arm assignment.

Specific Evidence:

- Protocol deviation analysis showing statistically significant imbalances between vaccine and placebo groups
- "Nasal swab not collected" deviations: 496 BNT162b2 vs. 623 Placebo ($p<0.001$)
- "Urine pregnancy test not performed": 383 BNT162b2 vs. 522 Placebo ($p<0.00001$)
- Pattern indicates site staff knowledge of treatment assignments affecting data collection

AIP Criteria Satisfied:

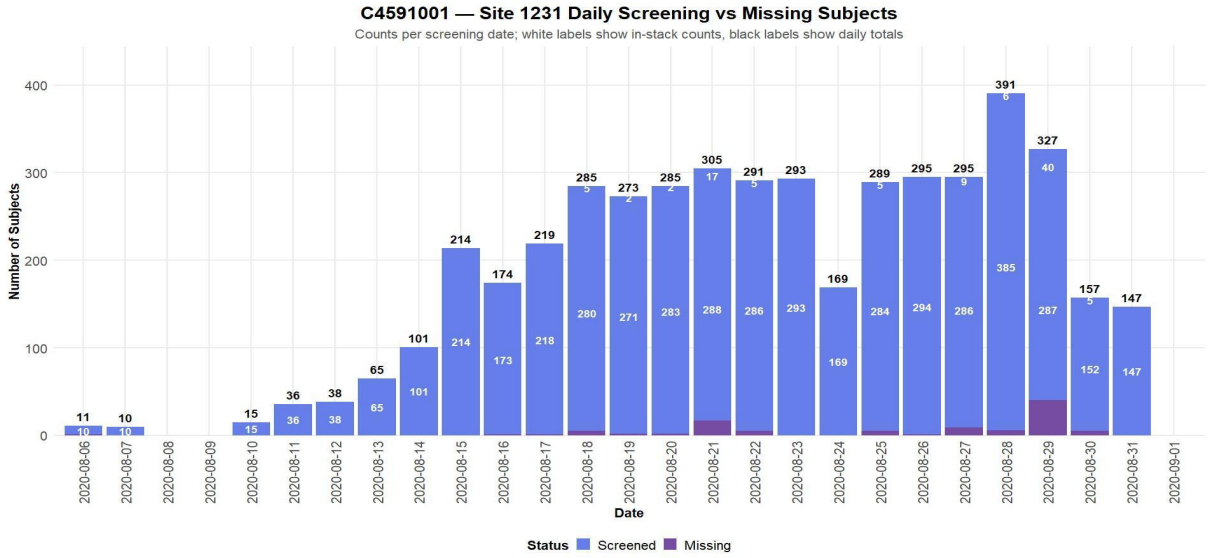
- Pattern of wrongful conduct: Statistical evidence demonstrates systematic rather than random deviations
- Data reliability questions: Compromised blinding undermines fundamental trial validity
- Material fact implications: Trial integrity is material to efficacy and safety determinations

II. <u>High-stakes instance of dataset discrepancies</u>:

II.a Missing/altered IDs and counts

While clinical trials commonly include minor data entry errors that require corrections, such as removing duplicate subject entries, the data shows numerous signs that complete subject records were removed from the datasets. For instance, 301 subject id numbers are missing in the normal randomization increments- with 111 of these missing identifiers in Argentina (Figure 1).[9] Notably, 17 of these missing subjects - one of the largest single-site, single-day gaps - would have been recruited on August 21st, 2020. This was the same day as Augusto Roux, participant #12312978, who experienced severe adverse effects after receiving the second vaccine dose, including pericarditis, which was initially misclassified as a potential COVID-19 case at the request of the sponsor. Roux’s reports of adverse effects were inadequately documented, and attempts were made by BioNTech to obtain reclassifications of his

symptoms by the trial site team.[10] This case highlights serious violations of 'Good Clinical Practices' and criminal investigations are ongoing in Argentina regarding the events he witnessed.[11] Augusto Roux's story is particularly relevant as it connects closely to potential missing subjects' records. A Criminal Complaint has been filed in Argentina and attached (the 600+ pages of supporting documents are part of the supplemental section, translated and indexed).



Other significant anomalies are affecting the figures communicated by the sponsors to the regulators; for example, the total number of subjects randomized goes backward by 1,203 subjects between two versions (EUA vs BLA) of the investigators' lists, and this discrepancy isn't documented.[12]

AIP Analysis: Dataset Discrepancies and Manipulation

Nature of Violation: Systematic removal and alteration of subject records and adverse event data between regulatory submissions.

Specific Evidence:

- 301 missing randomization numbers with 111 concentrated in Argentina
- 17 missing subjects from August 21, 2020 (same day as whistleblower Augusto Roux case)
- 1,203 subject count reduction between EUA and BLA versions without documentation
- 207 adverse event term changes disproportionately affecting BNT162b2 group ($p<0.0001$)
- 153 adverse events removed from BNT162b2 vs. 103 from placebo ($p<0.01$)

AIP Criteria Satisfied:

- Fraudulent application elements: Systematic data removal suggests intentional manipulation
- System-wide data integrity failures: Pattern spans multiple database systems and timeframes
- Untrue statements of material fact: Modified data presentations to regulators

II.b Mortality case study:

Another highly problematic case of data discrepancy is that cardiac deaths among BNT162b2 recipients, while known to the sponsors, were not disclosed to regulators at EUA time.
The December 2020 New England Journal of Medicine article by Polack *et al*[13] and the FDA's VRBPAC EUA briefing materials[14] reported six deaths - two in the BNT162b2 arm and four in the placebo arm. Internal records indicate Pfizer had contemporaneous knowledge of two more deaths in the BNT162b2 arm and should have reported them to the FDA. The two unreported BNT162b2-arm deaths suggested a potential cardiac signal, and not reporting these probably delayed the later acknowledgment of cardiac adverse events[15] by the regulatory authorities.

- Subject 11141050[16] died on October 19, 2020 - well before the November 14, 2020 data cutoff. Clinical staff entered the death into Pfizer's records 37 days later. As a result of this delay, the sudden cardiac death was not included in the EUA submission. Per the trial protocol, this should have been reported within 24 hours.[17]
- Subject 11201050[18] died on November 7, 2020 - 72 days after receiving Dose 2. Her husband notified the clinical site the same day. There was no hospital visit or autopsy; a coroner certified the death as cardiac arrest - yet the death was ruled unrelated to the vaccine (The trial protocol required all severe adverse events to be reported without any implication of causality).[19] Pfizer documented receipt of the notification on November 7, 2020, prior to the November 14 data cutoff.
- The rationale for not disclosing these vaccinated-arm deaths at the December 10, 2020 VRBPAC meeting or in the Polack NEJM publication requires clarification; the FDA itself[20] may have been who concealed these deaths.[21]

AIP Analysis: Concealed Mortality Data

Nature of Violation: Failure to report known cardiac deaths in vaccine recipients to regulatory authorities despite protocol requirements and contemporaneous knowledge.

Specific Evidence:

- Subject 11141050: Sudden cardiac death October 19, 2020 (before November 14 data cutoff), entered 37 days later
- Subject 11201050: Cardiac arrest November 7, 2020, notification received same day, excluded from EUA submission

- Both deaths occurred before regulatory deadlines but were not disclosed to FDA VRBPAC

AIP Criteria Satisfied:

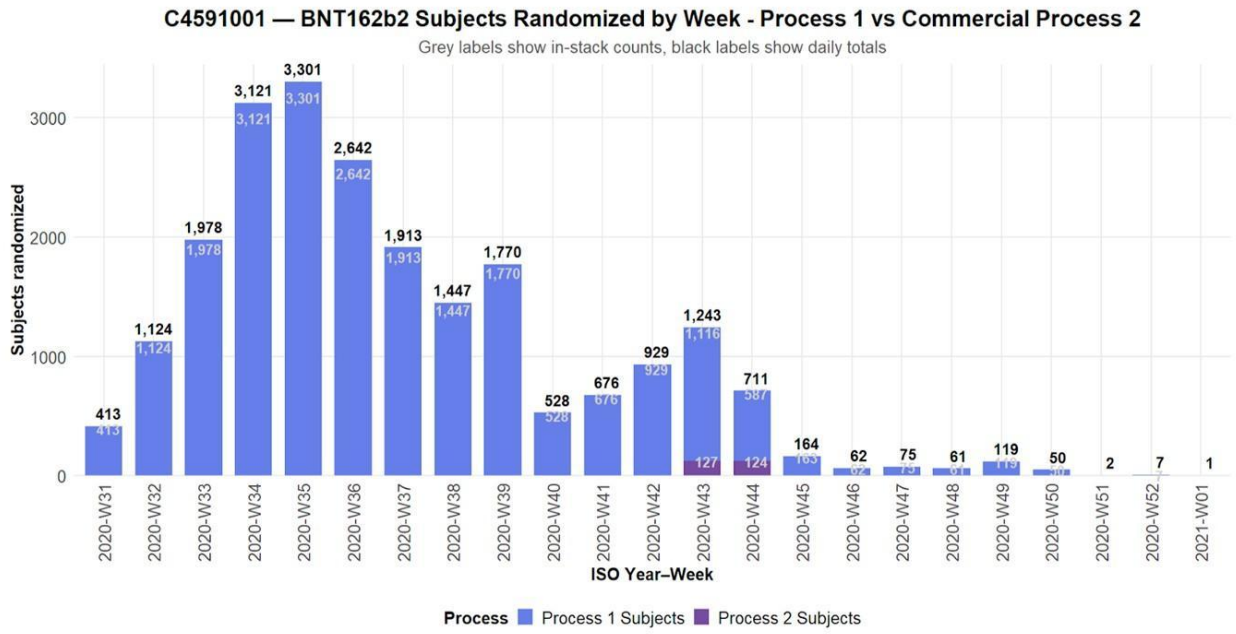
- Untrue statements of material fact: Omission of known material safety information
- Pattern of wrongful conduct: Systematic exclusion of safety-relevant data
- Fraudulent application elements: Concealment of information material to risk-benefit assessment

III. The commercially distributed process – more hazardous – differed from the one tested:

Good Manufacturing Practice (GMP) for biologics rests on the principle that "the process is the product."[22] The idea, reinforced by historic lessons (e.g., the 1955 Cutter incident) and later examples such as the early-2000s Eprex/epoetin-α PRCA cluster,[23] is that analytical testing cannot fully characterize every clinically relevant attribute of a biologic;[24] therefore, tight process control is essential to ensure lot-to-lot consistency and reproducibility.[25] Small changes in process or formulation can alter clinical outcomes, which is precisely why GMP ties product quality to the manufacturing process.

In the Pfizer/BioNTech program, the product was presented as "rigorously tested" in a 1:1 randomized, placebo-controlled trial of 43,538 participants.[26] At EUA time, however, the clinical product ("Process 1") differed materially from the commercial product ("Process 2").[27] Process 1 supplied clinical doses, whereas Process 2 supported scaled-up commercial supply,[28] with key differences in the DNA template method (PCR vs. linearized plasmid DNA in E. coli),[29] purification steps, and large-scale LNP manufacturing.[30]

Although the protocol envisioned evaluating several Process 2 lots (250 subjects per lot) and comparing outcomes between Process 1 and Process 2 recipients, only a single Process 2[31] lot (EE8493)[32] was administered prior to the EUA - to **252 subjects** aged 16-55 at sites 1133, 1135, 1146, and 1170 beginning October 19, 2020.[33] These were identified via lot-shipment records[34] and randomization-window analysis. Figure 2 shows how few active-arm participants actually received vaccines manufactured using the commercial process.



While the two processes were presented to regulators as comparable, available data indicate that Process 2 was associated with higher adverse-event rates among trial participants[35]. Moreover, substantial manufacturing-process changes may help explain why certain events that were infrequently detected during the pivotal trial,[36] such as lymphadenopathy[37] (swollen lymph nodes) and menorrhagia[38] (prolonged or heavy menstrual bleeding), were reported much more frequently in post-authorization settings. The comparative analysis originally scheduled was abandoned on Protocol Amendment 20 in September 2022 due to "the extensive usage of vaccines manufactured via 'Process 2."

Further, Pfizer and Moderna illegally obtained categorical exclusions from submitting Environmental Assessments (EAs) for their COVID-19 mRNA vaccines,[39] when such assessments were legally required.[40] Under 21 CFR 25.15(a),[41] all Biologics License Applications must include an EA unless a valid categorical exclusion applies, but these products don't qualify for exclusions under 21 CFR 25.31(a)[42] or (c) because modRNA is a novel molecular entity and the synthetic/recombinant materials don't occur naturally in the environment—characteristics that should have disqualified them from exemption.

By wrongfully granting these exclusions, the FDA failed to subject the applications to review by the appropriate Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC), improperly routed them to the Vaccines advisory committee instead, and circumvented the National Environmental Policy Act's requirement for public disclosure and comment periods that would have informed the public of the gene therapy nature of these products—thereby violating informed consent principles and rendering the BLA approvals void from the beginning (void ab initio).

AIP Analysis: Manufacturing Process Substitution

Nature of Violation: Clinical trials conducted with different manufacturing process ("Process 1") than commercial distribution ("Process 2"), with inadequate bridging data. This is key, as it is ***illegal*** to sell a product that wasn't subjected to a clinical trial.

Specific Evidence:

- Less than 1.2% of trial participants received Process 2 product before EUA
- Only 252 subjects received commercially distributed formulation (lot EE8493)
- Process 2 showed higher adverse event rates in limited trial data
- Material differences in DNA template method, purification, and LNP manufacturing

AIP Criteria Satisfied:

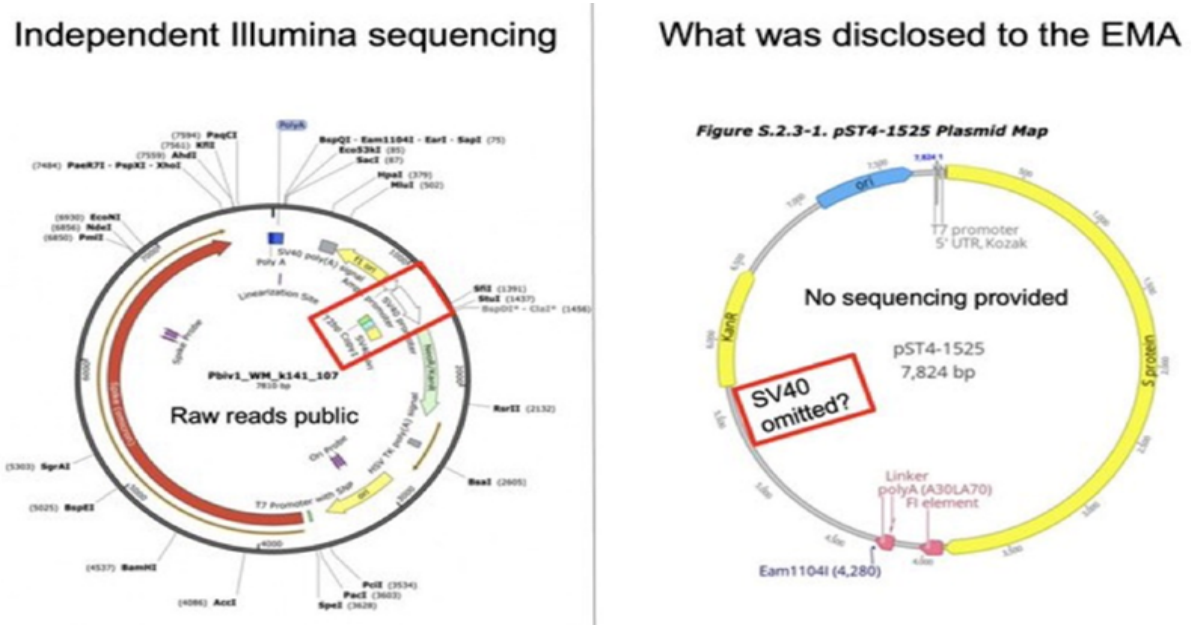
- System-wide manufacturing failures: Different products tested versus distributed
- Untrue statements of material fact: Presenting Process 1 data to support Process 2 approval
- Pattern of wrongful conduct: Systematic misrepresentation of product equivalency
- The synthetic modRNA and lipid nanoparticles do not ***occur naturally in the environment***, thus the requirement for exemption of an environmental assessment has not been met

IV. DNA contamination within Pfizer's vaccine vials:

A recent peer-reviewed publication,[43] just discussed (and entered into the Congressional record) this week in a Senate hearing,[44] shows that the Process 2 manufacturing method for Pfizer's mRNA COVID-19 vaccine left large amounts of DNA contamination within the vials; the study analyzed 32 vials and found that every one exceeded permissible thresholds by 36-627 times. Regulators have relied on qPCR testing methods that are fundamentally flawed, potentially underestimating DNA contamination 100-fold depending upon which DNA fragment is targeted.

Further, SV40 promoter-enhancer sequences were detected, which could act as a 'passport' helping genetic material cross into the cell nucleus, as Moderna explains within its own patent.[45] The most serious concern involves potential cancer risks; once in the nucleus, contaminant DNA could theoretically integrate into the human genome and activate cancer-causing genes. This could be one of the drivers of increasing rates of certain types of cancer, as well as the rise of rapid-onset and rapidly-developing cancers.

Crucially, the plasmid map that Pfizer submitted to regulators in the US and other countries, including Canada and the European Union, omitted the SV40 sequence; an ***intentional edit***, as this required making changes to the image auto-generated by software which labels all elements automatically: [46][47]



AIP Analysis: DNA Contamination

Nature of Violation: Multiple, independent laboratory analyses have detected variable levels of DNA contamination in commercially produced (Process 2) vaccine vials, indicating quality control failures in the manufacturing process.

Specific Evidence:

- DNA contamination 36-627 times above permissible thresholds in all 32 vials tested
- SV40 promoter-enhancer sequences detected but not disclosed to regulators
- Intentional omission of SV40 sequences from plasmid maps submitted to FDA, EMA, and Health Canada
- qPCR testing methods fundamentally flawed, potentially underestimating contamination 100-fold

AIP Criteria Satisfied:

- System-wide manufacturing failures: Quality control failures across commercial production
- Untrue statements of material fact: Omission of SV40 sequences from regulatory submissions
- Pattern of wrongful conduct: Systematic concealment of contamination risks and cancer-causing potential

V. Gene Therapy Classification Concealment and Systematic Regulatory Bypass

The COVID-19 mRNA vaccines unambiguously satisfy FDA's regulatory definition of ***gene therapy*** products as "the administration of nucleic acids, viruses, or genetically engineered microorganisms that mediate their effect by transcription and/or translation of the transferred genetic material."[48] Moderna acknowledged this reality in their 2020 SEC filing, stating "Currently, mRNA is considered a gene therapy product by the FDA."[49] BioNTech's founder similarly noted in 2014 that "One would expect the classification of an mRNA drug to be a biologic, a gene therapy or a somatic cell therapy."[50]

Despite this clear classification, internal documents show a coordinated effort to present these products as conventional vaccines. This misrepresentation enabled systematic bypass of gene therapy regulations through four critical regulatory violations:[51]

- **Jurisdiction manipulation:** Both Pfizer and Moderna's mRNA injections were deliberately shifted from the FDA's gene therapy advisory committee (CTGTAC) to the vaccine advisory committee (VRBPAC) during their approval process, despite FDA regulations that restrict gene therapies to the former.[52] This meant that gene therapy-specific safety questions were never addressed by the appropriate experts during the approval process.

- **Illegal category exclusions:** Both mRNA injections received illegal category exclusions from gene therapy environmental assessment requirements,[53] despite the FDA's own regulations which prohibit gene therapies with synthetic sequences from such exclusions. Under 21 CFR 25.15(a), failure to submit adequate Environmental Assessments renders the BLA approvals "void ab initio" - legally invalid from inception.[54]

- **Bypass of long-term safety monitoring:** Gene therapy products require 15 years of safety monitoring to look for "delayed malignant, neurologic, autoimmune, hematologic, other disorders or effects on the genome or gene expression."[55] Instead, standard vaccine safety surveillance protocols were substituted – which means that potential delayed effects, including genomic integration and the triggering of cancers and autoimmune disorders – remain unmonitored.

- **Genotoxicity and DNA contamination assessment failures:** As mentioned above, elements like SV40 sequences were not disclosed to regulators, and no genotoxicity studies were conducted despite regulatory requirements. The documentation trail shows that this was not regulatory oversight but systematic circumvention - a deliberate restructuring of established safety frameworks to expedite authorization of products that, under standard gene therapy protocols, would have required years of additional safety assessment, specialized expert review, and comprehensive long-term monitoring that continues today.[56]

AIP Analysis: Gene Therapy Classification Concealment

Nature of Violation: Systematic regulatory bypass through misclassification of gene therapy products as conventional vaccines to avoid appropriate oversight requirements.

Specific Evidence:

- Products meet FDA gene therapy definition: "administration of nucleic acids...that mediate their effect by transcription and/or translation"
- Moderna 2020 SEC filing acknowledges "mRNA is considered a gene therapy product by the FDA"
- Systematic routing to VRBPAC instead of appropriate CTGTAC (gene therapy committee)
- Illegal categorical exclusions from Environmental Assessment requirements under 21 CFR 25.31
- No 15-year gene therapy follow-up protocols established
- DNA contamination 6-470x above thresholds with undisclosed SV40 sequences

AIP Criteria Satisfied:

- Fraudulent application elements: Misrepresentation of fundamental product classification
- System-wide regulatory failures: Coordinated bypass of multiple regulatory frameworks
- Untrue statements of material fact: Concealment of gene therapy nature from regulators and public

Conclusion and Recommendations:

Based on the evidence above, we believe the threshold has been met to invoke the AIP for the Pfizer BNT162b2 clinical trial and to audit all of the trial site data to determine if fraud occurred, untruthful statements were made, and to demand that the various, required documentation (which as of September 23, 2025, has not been submitted to the FDA) be immediately supplied to the FDA and evaluated in consideration of their continuing licenses or potential revocation of their product(s) for the treatment of Covid-19.

Immediate AIP Actions Recommended:

1. **Invoke AIP** on all Pfizer/BioNTech COVID-19 vaccine applications (EUA, BLA, supplements)
2. **Defer scientific review** pending completion of validity assessment
3. **Issue preservation notices** for all relevant documents and electronic records
4. **Coordinate with OCC** regarding potential criminal referrals

Investigation Scope:

1. **Comprehensive data audit** of all clinical trial databases and regulatory submissions

2. **Manufacturing facility inspections** focused on Process 1/Process 2 documentation
3. **Digital forensics** of electronic records and communication systems
4. **Witness interviews** of key personnel and external stakeholders

The evidence from five categories of violations demonstrates systematic wrongful conduct that clearly satisfies AIP investigation criteria. The coordinated nature of these violations across clinical operations, data management, manufacturing processes, safety reporting, and fundamental product classification suggests institutional-level decision-making to circumvent established regulatory safeguards. Immediate AIP invocation is warranted to preserve the integrity of remaining evidence, conduct comprehensive validity assessment of all submissions, ensure appropriate regulatory oversight commensurate with product risks, and restore public confidence in regulatory decision-making processes.

Sincerely,

Eric Feintuch, D.C., C.C.S.D.
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Charles Rixey, M.A.
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[1] PHMPT.org - https://phmpt.org/wp-content/uploads/2022/01/ORDER_2022_01_06.pdf

[2] We performed a document-based reanalysis of the C4591001 trial using sponsor records released under FOIA (FDA via PHMPT, TGA, MHRA), including EUA and BLA SAS datasets (ADSL, ADAE, ADVA, MB), site/investigator files, protocol amendments, CRFs with audit trails, and lot shipment logs. Calculations are documented in the R scripts provided in the footnotes.

[3] Pfizer, "Pfizer and BioNTech Initiate Rolling Submission of Biologics License Application for U.S. FDA Approval of Their COVID 19 Vaccine," Pfizer press release (May 7, 2021). https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-biologics

[4] tests_on_symptomatic_visits.R - https://github.com/OpenVaet/pfizer_docs_R/blob/main/brief/tests_on_symptomatic_visits.R

[5] PHMPT.org - 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf - https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, Page 63

[6] PHMPT.org - 125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf - https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M5_5351_c4591001-interim-mth6-protocol.pdf, Page 9, deviations.R - https://github.com/OpenVaet/pfizer_docs_R/blob/main/brief/deviations.R

[7] OpenVAET, "Pfizer/BioNTech C4591001 Trial - Data Altered Between EUA & BLA Submissions: A brief look at the latest EUA release, resulting in a few additional evidence of blatant data manipulation," Substack (August 27, 2025). https://openvaet.substack.com/p/pfizerbiontech-c4591001-trial-data

[8] verify_aes_eua_to_bla.R - https://github.com/OpenVaet/pfizer_docs_R/blob/main/brief/verify_aes_eua_to_bla.R

[9] R script - verify_missing_randomization_numbers.R - https://github.com/OpenVaet/pfizer_docs_R/blob/main/brief/verify_missing_randomization_numbers.R

[10] Daivd Healy *et al*, "The coverage of medical injuries in company trial informed consent forms," *International Journal of Risk and Safety in Medicine* 34, issue 2 (May 1, 2023). https://journals.sagepub.com/doi/full/10.3233/JRS-220043

[11] David Healy, "Disappeared in Argentina," *DavidHealy.org* (March 1, 2022). https://davidhealy.org/disappeared-in-argentina/

[12] R script - investigator_files_reported_subjects.R - https://github.com/OpenVaet/pfizer_docs_R/blob/main/brief/investigator_files_reported_subjects.R

[13] Fernando Polack *et al*, "Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine," *The New England Journal of Medicine* 383, no. 27 (December 10, 2020). https://www.nejm.org/doi/full/10.1056/nejmoa2034577 \

[14] Pfizer BioNtech, "COVID-19 Vaccine VRBPAC briefing document," *FDA*, page 9 (December 10, 2020). https://www.fda.gov/media/144245/download

[15] Dror Mevorach *et al*, "Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Israel," *The New England Journal of Medicine* 385, no. 23 (October 6, 2021).- https://www.nejm.org/doi/full/10.1056/NEJMoa2109730

[16] PHMPT.org - https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf

[17] Fernando Polack *et al*, "Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine," *The New England Journal of Medicine* 383, no. 27, page 74 (December 10, 2020). https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_protocol.pdf
[18] PHMPT.org - https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf
[19] Fernando Polack *et al*, "Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine," *The New England Journal of Medicine* 383, no. 27, page 115 (December 10, 2020). https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_protocol.pdf
[20] Ciara O'Rourke, "Two vaccine trial participants died, but the FDA didn't connect their deaths to the vaccine," *Politifact* (December 11, 2020). https://www.politifact.com/factchecks/2020/dec/11/blog-posting/two-vaccine-trial-participants-died-fda-didnt-conn/
[21] Daniel Perrier *et al*, "Forensic analysis of the 38 subject deaths in the 6-month interim report of the Pfizer/BioNTech BNT162b2 mRNA Vaccine Clinical Trial," International Journal of Vaccine Theory, Practice and Research 3, no. 1 (October 17, 2023). https://ijvtpr.com/index.php/IJVTPR/article/view/86
[22] NIH, "Regulatory Knowledge Guide: Biological Products," *NIH* (March, 2024). https://seed.nih.gov/sites/default/files/2024-03/Regulatory-Knowledge-Guide-Biological-Products.pdf
[23] Charles Bennett *et al*, "Pure Red-Cell Aplasia and Epoetin Therapy," *The New England Journal of Medicine* 351, no. 14 (September 30, 2004). https://www.nejm.org/doi/full/10.1056/NEJMoa040528
[24] CDER, "Guidance for Industry - Process Validation: General Principles and Practices," FDA (January, 2011). https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf
[25] ICH working group, "ICH Harmonized Tripartite Guideline - Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products," *ICH* (March 10, 1999). https://ntp.niehs.nih.gov/sites/default/files/iccvam/methods/biologics/vaccine/ich-q6b.pdf
[26] Pfizer, "Pfizer and BioNTech Announce Vaccine Candidate Against COVID-19 Achieved Success in First Interim Analysis from Phase 3 Study," *Pfizer press release* (November 9, 2020). https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-vaccine-candidate-against
[27] European Medicine Agency, "Product Assessment report (PAR)," Committee for Medicinal Products for Human Use (CHMP), page 18 (February 19th, 2021). https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf
[28] Pfizer BNT162b2 Trial Protocol (April 15, 2020). https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_protocol.pdf
[29] I. Rabe *et al*, "In vitro transcription technologies," United States Patent and Trademark Office (2023). https://patentimages.storage.googleapis.com/03/aa/75/b6d7d2995c9653/US20230183769A1.pdf
[30] TGA, "BNT162b2 TGA Pre-Submission Meeting briefing slides," *Pzifer/BioNTech* (September 18, 2020). https://www.tga.gov.au/sites/default/files/foi-2389-03-1.pdf, Pages 21 to 23
[31] Australian TGA, FOI 3659, "BNT162b2 (PF-07302048) Comparability Report for PPQ Drug Product Lots," *Pfizer/BioNTech*, pages 4 & 5. https://www.tga.gov.au/sites/default/files/2022-08/foi-3659-04.pdf
[32] PHMPT.org - 125742_S1_M5_5351_c4591001-fa-interim-patient-batches.pdf - https://phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_5351_c4591001-fa-interim-patient-batches.pdf
[33] FOI 23/510, MHRA - https://drive.google.com/file/d/19lVCVO9wyR_sFYFxhiBMmE8tnsmVDNnX/view
[34] R script - process_2_subjects_by_sites_and_date.R - https://github.com/OpenVaet/pfizer_docs_R/blob/main/process_2_subjects_by_sites_and_date.R
[35] Josh Guetzkow & Retsef Levi, "Covid-19: Researchers face wait for patient level data from Pfizer and Moderna vaccine trials," *BMJ* (July 12, 2022). https://www.bmj.com/content/378/bmj.o1731/rr-2
[36] R script - parse_medical_history.R - https://github.com/OpenVaet/pfizer_docs_R/blob/main/parse_medical_history.R - 4 cases of Menorrhagia had been reported as Adverse events during the trial. Posterior studies found high rates of Menorrhagia ; for example a meta-analysis, by Al Kadri *et al*. (Journal of Infection and Public Health - Hanan M. Al Kadri *et al*. - COVID-19 vaccination and menstrual disorders among women: Findings from a meta-analysis study - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9979695), found a pooled prevalence of 24.24 % (95 % CI: 12.8–35.6 %).
[37] MHRA's Public Assessment Report for the Authorisation for Temporary Supply of Pfizer/BioNTech's COVID-19 mRNA Vaccine BNT162b2 - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1112667/COVID-19_mRNA_Vaccine_BNT162 b2__UKPAR___PFIZER_BIONTECH_ext_of_indication_11.6.2021.pdf - Differences in the reported rate of lymphadenopathy between the first two vaccine doses in the clinical trial (C4591001) and the rate of lymphadenopathy from the third (booster) dose are indicative (5.2% vs 0.4%) of the different adverse event profiles of process 1 versus process 2 vaccine product. The reason is that the first two doses in the clinical trial were overwhelmingly from vaccine doses made with process 1, whereas booster doses given many months later would have been manufactured using the process 2 for commercial supply.
[38] Nahid Ibrahim Fallatah *et al*, "Menstrual Changes Following COVID-19 Vaccination: A Cross-Sectional Study," *MDPI Medicina* (January 25, 2024). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10890281/
[39] Julian Gillespie *et al*, "Citizen's Petition: Petition for Administrative Action Regarding COVID-19 modRNA Vaccines of Pizer & Moderna, *FDA Docket* (January 21, 2025). https://www.regulations.gov/document/FDA-2025-P-0335-0001
[40] Federal Register, "§601.2 Applications for biologics licenses; procedures for filing," *FR 64, no. 202* (October 20, 1999). https://www.govinfo.gov/content/pkg/FR-1999-10-20/pdf/99-27159.pdf
[41] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-25/subpart-B/section-25.15
[42] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-25/subpart-C/section-25.31
[43] David Speicher *et al*, "Quantification of residual plasmid DNA and SV40 promoter-enhancer sequences in Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada," *Autoimmunity* (September 6, 2025). https://www.tandfonline.com/doi/full/10.1080/08916934.2025.2551517#abstract
[44] Senate Homeland Security & Government Affairs Committee, "Examining Science, Vaccines and Public Perception," *YouTube* (9/9/2025). https://www.youtube.com/watch?v=1RofqrkIPHI
[45] A. de Fougerolles & SM Elbashir, "Delivery and formulation of engineered nucleic acids." *United States Patent and Trademark Office, Modernatx, Inc*. (2021). https://patents.google.com/patent/US10898574B2/en
[46] David Speicher *et al*, "Quantification of residual plasmid DNA and SV40 promoter-enhancer sequences in Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada," *Autoimmunity* (September 6, 2025). https://www.tandfonline.com/doi/full/10.1080/08916934.2025.2551517#abstract

[47] There is a CDC Advisory Committee on Immunization Practices (ACIP) hearing to discuss DNA contamination; one of the authors of the paper, Kevin McKernan, will be discussing the results with the committee. https://www.cdc.gov/acip/meetings/index.html

[48] FDA, "Transfer of Therapeutic Biological Products to the Center for Drug Evaluation and Research," (March 7, 2022). https://www.fda.gov/combination-products/jurisdictional-information/transfer-therapeutic-biological-products-center-drug-evaluation-and-research

[49] Moderna, "QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the quarterly period ended June 30, 2020," (August 6, 2020). https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm.

[50] Ugur Sahin, Katalin Kariko & Ozlem Tureci, "mRNA-based therapeutics--developing a new class of drugs," *Nat Rev Drug Discovery* 2014; 13:759-80. http://doi.org/10.1038/nrd4278

[51] The evidence for these four points are argued within: David Wiseman & Maria Gutschi, "Great expectations and generous reading of guidelines underestimate potential risk in oversight of COVID-19 pro-vaccine quality, safety testing, and manufacturing: 248 questions for FDA," *VRBPAC/ACIP submission* (September 13, 2025). https://www.researchgate.net/publication/395467231_Great_expectations_and_generous_reading_of_guidelines_underestimate_potential_risk_in_oversight_of_COVID-_19_pro-vaccine_quality_safety_testing_and_manufacturing_248_questions_for_FDA

[52] FDA, "Transfer of Therapeutic Biological Products to the Center for Drug Evaluation and Research," *FDA Jurisdictional Information* (June 30, 2003). https://www.fda.gov/combination-products/jurisdictional-information/transfer-therapeutic-biological-products-center-drug-evaluation-and-research

[53] Center For Biologics Evaluation and Research, "Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products: Guidance for Industry," *FDA* (March, 2015). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/determining-need-and-content-environmental-assessments-gene-therapies-vectored-vaccines-and-related

[54] 21 CFR Chapter 25:15(a). https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-25/subpart-B/section-25.15

[55] FDA, "Food and Drug Administration. Long Term Follow-up After Administration of Human Gene Therapy Products: Guidance for Industry," FDA-2018-D-2173 (2020). https://www.fda.gov/regulatory-information/search-fda-guidance-documents/long-term-follow-after-administration-human-gene-therapy-products https://www.fda.gov/media/113768/download

[56] Marc Bonara & Jordan Lipp, "An overview of the PREP Act's liability immunity for products meant to counter COVID-19," *Docket* (April 15, 2020). https://docket.acc.com/overview-prep-acts-liability-immunity-products-meant-counter-covid-19