

Beyond Negative Evidence: Lessons from the Disputes on DNA Contamination of COVID-19 Vaccines

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Introduction

The COVID-19 pandemic was unlike the typical plagues that have afflicted humanity in the past. It was a worldwide multifaceted calamity. In addition to being a global health emergency, this pandemic—or rather the unprecedented response to it—caused economic, political, social, and cultural damage that was unseen during former pestilences. Actions triggered by this pandemic have added additional burdens to international economic and political crises that were already in need of urgent solutions.

Long before the COVID-19 pandemic, the U.S. and the rest of the world were experiencing a prolonged economic downturn affecting the previously flourishing middle class—the social group that is the backbone of Western economies and representative government.¹ The slow downfall of the typically right-leaning middle class was accompanied by the rapid ascendancy of the professional managerial class (PMC), which was predominantly left-oriented.

These economic, cultural, and social hierarchy shifts resulted in unprecedented political polarization, politicization of virtually all aspects of life, and advancing power asymmetry between the power-dominant Left and still relevant but power-deprived Right.^{2,3} This severe ideological division has led to creation of the two competing partisan narratives describing the origin of COVID-19, its significance, treatment, and prevention.⁴ (“Partisan” here denotes the broad socio-ideological identity of the person, not membership in the Democratic or Republican parties.)

Given the power asymmetry, the Left was better able to propagate its pandemic-related narratives to justify imposing its agenda-driven solutions. Consequently, the truth about numerous aspects of the COVID-19 pandemic has been suppressed and distorted by various power-wielders. However, while the view of objective reality was being obstructed by the deceptive narratives, the truth about this pandemic has been sought by many scientists, health professionals, journalists, whistleblowers, and even regular citizens. Those brave individuals have risked their livelihoods and careers to challenge misleading narratives by gathering and analyzing the data in order to inform the public. The previously published editorials on the negative evidence for the adverse effects of COVID-19 vaccines were intended to be a humble contribution to those benevolent truth-seeking efforts.⁵⁻¹¹

The term “negative evidence” refers to the unexpected absence of something that should be present based on logic and reason. This kind of evidence is very important for any fact-finding process, as it often reveals that someone intentionally tried to hide the clues leading to truth that could expose them to legal or moral consequences for their sinister actions. Negative evidence is easy to miss, since most investigators tend to automatically focus on examining what is there rather than on looking for what is not.

While the negative evidence method still applies to concerns about potential DNA contamination of COVID vaccines, the heated dispute about this subject also illustrates that while knowing the truth is of utmost importance, finding it is very challenging. Yet, this difficult quest has to be endured for the

sake of liberty and justice.

The Hardships and Perils of Truth Seeking

Truth, by exposing the lies, corruption, and injustice that sustain any tyranny, is the most powerful weapon against it. Knowing the truth can inspire the oppressed to resist and revolt, and can undermine the legitimacy and authority of the oppressors. Truth can also awaken the conscience and compassion of the bystanders, and can mobilize the support of allies. Truth is the greatest threat to any tyranny because it can set the people free. That is why any tyranny fears the truth more than anything else, and tries to suppress, distort, or deny it by any means possible.

Unfortunately, the way to discovering the truth is typically long and difficult, filled with errors, false hopes, and disappointments. This is especially true during times of extreme political polarization associated with politicization of all aspects of life.^{2, 12} In such settings, inconvenient truth will be suppressed by politically motivated governmental agencies and non-governmental power players. The ideologically divided society can become so dogmatic that its members will be more interested in confirming their partisan biases than in knowing objective reality. Consequently, truth-seekers will not only encounter censorship, intimidation, and repression from the agenda-driven authorities, but also vigorous resistance, rejection, and hostility from factions of their own side who feel offended by the “blasphemous” questioning of their favorite dogmas. Ultimately, those who want to know the truth may experience physical violence from those who have an interest in maintaining the lies-based status quo, or in hiding their wrongdoing.

In this turbulent and confusing era, we have to deal with the expanding complexity of scientific knowledge, while the credibility and impartiality of traditional scientific experts is decreasing due to their entanglement in political matters. The quest for the truth is further slowed by the variable quality of scientific dissidents. Some are brave, honest, and knowledgeable, but others are fame and profit-seeking charlatans or cranks.

Those hardships are compounded by the unreliability of both mainstream and alternative press, and by big-tech censorship of social media. Consequently, truth-seekers face difficulties in finding credible sources of information, validating the evidence, and communicating their findings to the public. Last but not least, they have to deal with their own ideological biases, prejudices, and limitations in their knowledge and training.

Causes for Skepticism about COVID-19 Vaccines

The causes for the skepticism about the safety and effectiveness of the COVID-19 vaccines have been amassing in a crescendo pattern. Since the onset of the COVID-19 pandemic, along with implementing the unprecedented draconian measures to “stop the spread,” authorities around the world have been touting the development of the COVID-19 vaccine as the best and only solution to end the global health emergency and therefore to “return to normal.”¹³⁻¹⁵

Officialdom, citing “evidence-based medicine” dogma, has summarily rejected any alternatives to vaccination, such as early treatment with repurposed or even with novel anti-viral drugs, as “lacking the best evidence.”¹⁶⁻¹⁹ However, the same officials have enthusiastically supported a wide array of so called non-pharmacological interventions (e.g. wearing facial masks, social distancing, school and business lockdowns) that were based on dubious or zero evidence.^{20,21} The staggering hypocrisy of those decision-makers became even more apparent when their recommendations started to change dramatically, in order shamelessly to accommodate political events they favored.²² For all those reasons, a large part of society was already very skeptical about the forcibly imposed vaccine solution even before vaccine development.

After the COVID-19 vaccine rollout, it became obvious that this “preventive measure” is causing more harm than prevention. Officials kept insisting that vaccines are safe and effective, even in the face of obvious failure. Consequently, numerous hypotheses have been proposed by vaccine skeptics to explain the reasons for various COVID-19 vaccine-associated harms. Those theories could be divided into two main categories: (1) theories that known, disclosed components caused adverse effects;²³⁻²⁵ and (2) ideas that the contamination of vaccines with various undisclosed elements was mostly to blame for adverse reactions.

The second category of ideas of contamination was initially filled with sensational, extravagant, and extraordinary claims. For instance, the social media posts and even alternative media articles were claiming that COVID-19 vaccines contain microchips or nanobots that can track or control people, high-tech substances such as graphene, snake venom, and even small octopus-like living creatures.²⁶⁻²⁷ Many of those disturbing theories sounded so uncanny that they could be easily dismissed as delusional rumors originating in the “fever swamp.”²⁸ Some of them could be considered as naïve attempts to answer hard questions. Others looked like deliberate “well poisoning” tactics. Not surprisingly, virtually all those theories had short-lived popularity on social media, and ultimately have been stashed away.

The Novel Plasmid DNA Contamination Theory

An intriguing new concept of COVID-19 vaccine contamination emerged in early 2023. Described succinctly as “the plasmid DNA contamination theory,” it is the antithesis of the previously mentioned sensational and uncanny rumors, which were developed and promoted by over-enthusiastic but frequently underqualified internet personalities. It is a reality-based hypothesis prompted by standard laboratory research performed by professional researchers.²⁹⁻³²

Three elements constitute the nidus around which the DNA contamination theory started to crystalize. Those were a preprint by McKernan et al.,²⁹ a preprint by Speicher et al. (with McKernan as last author),³⁰ and testimony before the South Carolina Senate delivered by Dr. Philip Buckhaults.^{31,32}

Subsequently, findings and ideas contained in those original materials have been reviewed and expanded by numerous established vaccine skeptics.³³⁻³⁷ This theory is still evolving, but in its essence it propounds that: (1) the COVID-19 mRNA vaccines may contain larger than acceptably safe levels of plasmid DNA that are leftovers from the manufacturing process,^{29,30,32} and (2) those plasmid DNA contaminants may not be biologically inert as is claimed by the regulatory agencies and the vaccine manufacturers.

Leftover Plasmid DNA

The general concepts of the mRNA vaccine manufacturing

have been available to the general public for a long time.^{15,38-43} However, the details were kept secret until the “Rapporteur’s Report” from the European Medicines Agency (EMA) was obtained through a cyber-attack and disseminated on a public forum.⁴⁴ That document contains the specifics of Pfizer’s vaccine production. Apparently, there is no similar public text describing the process used by Moderna, but it is likely quite similar to Pfizer’s.

The revealed details of mRNA vaccine production were so complex that they surprised even many scientists who were familiar with genomics but did not have a background in pharmaceutical industrial processes. In brief: In order to produce the mRNA, a DNA template is needed. That template has been changed. Initially Pfizer used a PCR DNA template (“Process 1”). However, that was changed (“Process 2”) to linearized plasmid DNA in order to meet commercial demands.⁴⁴ Plasmids have been chosen as such templates since they are easy and cheap to make and replicate compared to the PCR method. Plasmids are small circular, double-stranded pieces of DNA that can be found naturally within bacterial cells, or can be produced artificially to serve as vectors in procedures used in genetic engineering.⁴⁵ In simple terms: to produce the vaccine used in the clinical trials, a cleaner and more elegant process was used (“Process 1”). For mass production, a cruder but faster and cheaper method, said to yield “similar product” per manufacturer and regulators, was selected (“Process 2”).

Out of an abundance of caution, the level of such residual DNA is to be kept to a minimum through careful purification steps taken during the vaccine production, and every vaccine lot is to be carefully tested for the residual level. Regulators claim that vaccines with higher-than-accepted levels are not supposed to be released for public distribution.^{46,47}

Biological Activity of Plasmid DNA

Although manufacturers and regulators assert that any leftovers of plasmid DNA are biologically inert,^{46,47} there are plausible mechanisms for unwanted effects when DNA fragments are transfected (i.e., introduced into eucaryotic cells) during the vaccination process. Those adverse effects may occur mainly via DNA integration into and hence modification of the genomes of the transfected cells. This possibility is enhanced when those DNA fragments are packaged in lipid nanoparticles, along with the mRNA particles. Compared with accidentally encountered free strings of DNA, those peculiar DNA contaminants may have enhanced persistence and increased transfection efficiency.^{29,30,32} Regulatory authorities and manufacturers of vaccines make the argument that integration of isolated fragments of foreign DNA into the human genome is a very rare and complex event that requires several factors and steps to occur. This is correct. Humans, like other vertebrates, are exposed to fragments of foreign DNA entering their gastrointestinal tracts and even bloodstream in various ways. Therefore, the authorities argue that evolution took care of protecting humans from foreign DNA integration by assuring that this process is not easy. However, until recently, organisms did not encounter DNA fragments packed into a protective lipid layer and injected deliberately deep into the tissue rather than being ingested or entering via a superficial wound. Therefore, those arguments of authorities are no longer so persuasive.

Some researchers have argued that serious adverse effects from the plasmid DNA contamination may include, but are not limited to: autoimmune responses, such as myocarditis,³² and induction or acceleration of various malignancies.^{29,30,32} Some contributors to this theory purport that this scenario is especially likely since the promoter sequence of the infamous simian SV40 virus was detected in the DNA contaminants present in the

COVID-19 vaccines.^{29,30} SV40 virus is known to cause malignancies in animals and was detected in several rare human tumors (e.g. ependymomas, osteosarcomas, and mesotheliomas). In the past, it was identified as a contaminant in polio vaccine, causing long lasting and still unresolved debate about its carcinogenic effects in humans.⁴⁸⁻⁵²

Is It Adulteration?

The possibility of this accidental contamination was not disclosed to the general public,^{30,35,36} nor was the public informed of the need to change Pfizer's manufacturing process in order to manufacture huge amounts of mRNA vaccine for mass immunizations. Pfizer's new faster and more productive process, similar to the one used all the time by Moderna, has been shown to demonstrate significant variability in presence of residual DNA in mRNA products.^{29,44,53}

It was also suggested that plasmid DNA sequences coding for SV40 promoters were not disclosed to regulators at the time of filing.^{35,36} However, there are contradictory statements about this issue. Opinions vary on how much was not explained by manufacturers to regulatory agencies, and how much agencies knew about it but "glossed over it," considering it to be "a routine matter."^{36,54-56}

It is claimed that the DNA contamination of COVID-19 vaccines is so high and so dangerous that it may meet the legal standard for "adulteration" as defined by the 21 U.S. Code § 351, "Adulterated drugs and devices."^{35,36,57} If that is true, in accordance with the existing laws such as Section 420 of FDA's Compliance Policy Guidance, the vaccine may be subject to recall, seizure, banning, etc.⁵⁸ In addition, unequivocally proving the adulteration of the vaccines may enable piercing the shield of legal immunity from liability afforded to COVID-19 vaccine manufacturers under the PREP Act.^{36,59}

Negative Evidence Finally Triggered Independent Investigation

Previous editorials⁵⁻¹¹ observed that the vacuum created by the deliberate inaction of officialdom was not filled by adequate actions of scientific dissidents, mainly because of the power asymmetry between vaccine promoters and vaccine skeptics.^{2,4} This time, however, the challenge of negative evidence has been answered by courageous industry researchers and even by a team of academic scientists.²⁹⁻³² For reasons beyond the control of those brave investigators, that answer may not be as robust as many of us would wish, but it is a great start. We are finally moving beyond negative evidence. It is an important opportunity for the future that should not be wasted.

Double Standard for Risk Aversion

The mRNA production process has been revealed to be much more complex and therefore riskier than the non-initiated members of the public would ever think. Due to its enormous complexity, vaccine manufacturing may contain much wider security gaps and many more opportunities for things to go wrong. For instance, now we know that regulators recognize a **quantitative risk** of producing vaccines containing too much of residual plasmid DNA. But what about **qualitative risks**? Authorities dismiss the significance of encoding for the SV40 promoter that is contained within plasmids used for vaccine production, claiming it to be "inert." However, authorities now admit that plasmids used in production contain many other "inert" sequences. Are they truly inert? What if they code for something worse than SV40 promoter that has not been discovered yet? What about contamination from the E. coli coming from outside

of plasmids? Are all the purification procedures "fail proof" as claimed? Clearly, the "fail proof" DNA purification failed—at least in the samples that were tested. Could other purification procedures fail as well?

These concerns are related only to truly accidental risks. What about the risk of terrorists doing something deliberately to interfere with this complex production process in order to cause harm? Something that will be overlooked due to the complexity of the method? The obvious bottom line question is: ***"Why in the era of the heightened risk aversion (leading to mass lockdowns, mask mandates, shoe removal at airport security, etc.) is such an enormously risky method of vaccine production even allowed?"*** Especially when with mass employment of vaccines, the risks associated with them can affect virtually all humanity. Should such a risky method not be stopped, not just because of the past risks but because of the high potential for future ones? The obvious double standard here is staggering.

Public Reception to the Plasmid DNA Contamination Theory

The basis of this theory is rather mundane, as it pertains to "mere" manufacturing process contamination, not to a sensational science-fiction type scenario. However, its implications, if true, are much more chilling than any of the "fever swamp" fanciful tales. Moreover, if confirmed, this hypothesis could constitute the much-desired "smoking gun" proof of COVID-19 vaccine harmful effects. It could set into motion history-changing events, resulting in the full vindication of the COVID-19 vaccine skeptics and downfall of vaccine proponents. Not surprisingly, social media chatter has been extremely excited.

However, some well-known vaccine skeptics expressed doubts about the scientific and legal claims, calling them "red herring distractions" or even "fake victory."^{60,61} On the other hand, this novel contamination theory has gained very unexpected sympathy from a few prominent members of mainstream academia, which traditionally promoted vaccines—a development that shocked some ardent vaccine proponents.⁶²

Simultaneously, the well-known vaccine promoters posing as "fact-checkers" responded with exceptionally angry and emotionally charged criticism of the accuracy of reports about DNA contamination in general and its potential for carcinogenic properties in particular. The internet has been inundated with an unusually large number of irritated "fact-checking" articles, condescending "debunking" videos, and insolent "deconstructing" blogposts, which are too numerous to reference here.⁶³⁻⁶⁵

The angry attacks against the authors of the DNA contamination reports by self-proclaimed "fact-checkers," who ironically could not get their own facts right, for example on the SV40 promoter and the p53 "guardian of the genome," are discussed and refuted on social media: "It's as if every contaminant instantly becomes a beneficial adjuvant the moment it's found"—call it "Schrödinger's Adjuvant."⁶⁶ This clearly excessive and evidently nervous activity of the professional refuters evokes two well-known aphorisms: "The lady doth protest too much, methinks"⁶⁷ and "The flak only gets heavy when you're over the target."⁶⁸

Critical Appraisal Methodology

The plasmid DNA contamination theory has been received with enormous enthusiasm and excitement by the vast majority of the vaccine-skeptical community and with significant anger among avid vaccine-promoters. However, we need to set aside the emotional aspects of this event. Heightened emotionality is perfectly justifiable under the circumstances. However, even the strongest emotions of the oppressed, if not backed by trustworthy evidence, have rarely if ever resulted in liberation

from the oppression.

Although truth is the most powerful weapon against any tyranny, to be effectively liberating, the information containing the truth has to be powerfully trustworthy: (1) Its credibility has to be so strong that it cannot be easily ridiculed or dismissed and therefore plausibly denied by the tyrants. (2) Its believability should be such that many, not just a few, supporters of the tyranny would be persuaded by it, and would start to serve the cause of liberty. (3) Its legal claims should be so impeccable that even the tyranny-controlled court system would not dare to rule against it, from fear of bringing down the wrath of society enraged by such blatantly unjust judgment.

The most crucial question related to the DNA contamination concept is how objectively trustworthy it is in its current form. The issue of trustworthiness of any research study comes down to its internal and external validity.⁶⁹⁻⁷¹

Internal validity refers to the question of whether the results of research are correct for the subjects/elements that have been studied.⁶⁹⁻⁷¹ Internal validity examines whether the way in which a study was designed, performed, and analyzed allows trustworthy answers to its research questions. One of the crucial parts of internal validity analysis is examination of the extent to which systematic errors (i.e., various forms of bias) are present.⁶⁹⁻⁷¹

External validity (generalizability) examines whether the findings of a specific study of a narrow sample taken from the population or from a large set of materials can be generalized to the whole population and to the whole set of materials.^{69,70,72}

The internal and external validity of research studies is typically examined by using the systematic assessment process known as **critical appraisal**.^{70,71,73-75} There are many kinds of critical appraisals that vary in formality, complexity, and sophistication. Very formal critical appraisals that employ a variety of "testing templates" are used by advanced experts for selecting the best scientific publications during writing systematic literature reviews on specific subjects. This method is heavily used by evidence-based medicine (EBM).⁷⁶ Many very useful critical appraisal templates have been developed by EBM followers.⁷⁷⁻⁸² Many practicing physicians including those skeptical of EBM are intuitively using a simplified version of critical appraisal (and not even calling it by that name) while assessing the value of published research for use in their clinical practices.

Using the formal critical appraisal process should help to answer the following most critical questions about the studies that constitute the nidus of the DNA contamination theory: (1) Is this perfectly trustworthy information with flawless internal and external validity that allows filing impeccable legal claims and therefore achieving instant ultimate victory, as some vaccine skeptics have enthusiastically propounded? (2) Is this a "red herring" distraction and "fake victory" as others have alleged? (3) Is it material of limited trustworthiness currently, but still very useful work due to its future potential?

Unfortunately, even with the use of critical appraisal, formulating the answers to those questions remains difficult. This level of difficulty reminds us about how hard the road of truth seeking can be.

Critical Appraisal of the Nidus of the DNA Contamination Theory

While the plasmid DNA contamination theory is simple in its premise, assessing the validity of its technical aspects (especially those related to genomics) requires complex scientific expertise that is possessed only by highly trained specialists. That type of knowledge is not easy for the uninitiated to acquire, since it requires a lengthy formal education under the guidance of

experienced scientists. Moreover, the opinions of even similarly credentialed experts can vary considerably and certainly can be influenced by their own personal and ideological biases.⁷³ This last part is especially important in the current era of rampant political polarization and politicization of science.^{2,12,83}

In such a setting, the application of the critical appraisal method can help us to see through the thick fog of the raging "culture war." At the same time, we should keep in mind that critical appraisal, in addition to its advantages, also has its limitation, as accurately described by Tod et al.:⁷³

A well-conducted critical appraisal: (a) is an explicit systematic, rather than an implicit haphazard, process; (b) involves judging a study on its methodological, ethical, and theoretical quality, and (c) is enhanced by a reviewer's practical wisdom, gained through having undertaken and read research [citation omitted]. It is important to remember also that no researcher can stand outside their history nor escape their human finitude. That means inevitably a researcher's theoretical, personal and so on history will influence critical appraisal.

It's also important to note that good critical appraisal requires a balance between methodological scrutiny and contextual understanding of the study's implications within the frames of continuing scientific and public discourse.

Keeping all the above in mind, it must be understood that the informal attempts at critical appraisal of the essentials of the DNA contamination theory presented below represent intellectual exercises. Those exercises should not be confused with authoritative opinions on the subject or position statements of any organization or group.

Readers are encouraged to study the original sources²⁹⁻³² very carefully.

It should be noted that all of the researchers involved in those projects showed remarkable bravery, resilience, and civil courage by addressing the issues that are well known to be taboo to current authorities. It is clear that they did the best they could under the circumstances of limited funding, restricted access to samples, and other limitations. It is also notable that they were very restrained and cautious in their conclusions, and they themselves did not make any extraordinary claims. To the contrary, they fully disclosed all the limitations and drawbacks of their studies and called for better work to be done. Many commentators have misinterpreted their work, and the authors took the time to defend themselves and clarify their positions using social media platforms such as Substack or X (formerly Twitter).^{66,84}

Tentative Critical Appraisal of Preprint 1 by McKernan et al.²⁹

The article is entitled "Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose."

Concerning Internal Validity:

Regarding **robustness of technique**, the study employs multiple methods like Illumina sequencing, qPCR, RT-qPCR, and Qubit™ 3 fluorometry. The Qubit™ 3 fluorometry has its drawbacks and was the subject of criticism, but it is not sole method used. Hence, the use of diverse techniques that can complement each other strengthens the findings' reliability.

Samples source and size and reproducibility is a major problem that is emphatically disclosed by the authors. Due to circumstances beyond their control, there is no chain of custody here. The samples were received from an anonymous source. This is not, however, the fault of the researchers but a result of the current political climate. The investigators did the best they could, but unfortunately, no complex statistical analysis is needed to see that the sample size is small. The sources of the samples are

unknown. The accusations of tampering with samples by a third party, which the vaccine promoters are likely to make, are hard to dismiss. Authors themselves acknowledge that with more samples, obtained from controlled sources and with a chain of custody present, the quality and the persuasiveness of the study would be much higher. The authors call for performance of such improved studies to replicate and enhance their results.

Interpretation of the sequencing data, especially of the implications of DNA contamination, requires careful consideration to avoid overestimating risks. The authors do not make any extraordinary claims, and are restrained in their analyses.

Concerning **external validity, generalization of results** is limited because of the small number of samples. It's very hard to make a strong argument that those results are applicable to all vaccine doses produced. However, the authors do not assert that. Rather, they point out realistically that their findings are cause for alarm since they may represent not an isolated irregularity but a dangerous pattern. More studies are needed to clarify this matter.

The **implications** of the study are that there is a need for more rigorous examination not only of known vaccine components, but for potential accidental contaminants that could be present due to the overly complex nature of the production process. The study raises important considerations about vaccine mRNA surveillance that have been glossed over by regulators.

Tentative Critical Appraisal of Preprint 2 by Speicher et al.³⁰

The article is entitled: "DNA fragments detected in monovalent and bivalent Pfizer/BioNTech and Moderna modRNA COVID-19 vaccines from Ontario, Canada: Exploratory dose-response relationship with serious adverse events."

Concerning **internal validity**:

Regarding **robustness of techniques**, the study used quantitative polymerase chain reaction (qPCR), Qubit® fluorometry, Oxford Nanopore sequencing, and analysis of the Vaccine Adverse Events Reporting System (VAERS) database. The diversity in methods supports the reliability of the findings.

The **sample selection** offers a relatively broader perspective compared to previous study as it analyzed 27 mRNA vials from 12 unique lots. However, the source of the vials and the condition of their contents (e.g., expired or remnants) may impact the **generalizability** of the findings.

For **quantitation**, the study used qPCR and fluorometry to measure DNA. It acknowledges the methodological differences in these techniques, which can lead to varying estimations of DNA quantities.

The exploratory analysis using VAERS data is insightful but has limitations, such as the potential for under- or over-reporting and the inability to infer causality that are inherent to VAERS reports. The authors acknowledge this limitation, do not misinterpret or over-value their observations, and explain why they chose to use this approach.

The study calls for replication of its results under strict forensic conditions, a process needed for verification of those findings and for proper regulatory actions if such controlled verification occurs.

While the study's findings are not ultimate proof of DNA-caused adverse effects, they unquestionably show the need for updated regulatory standards for residual DNA in the light of new vaccine technology. It is a sobering wakeup call for more actions to obtain truly persuasive evidence. The study explicitly mentions the need to compare its findings with other research, indicating that the authors are not afraid of outside scrutiny and in fact would welcome it.

Tentative Critical Appraisal of the Presentation by Phillip J. Buckhaults, Ph.D.^{31,32,84}

This appraisal is an especially difficult task since the claims made by Prof. Buckhaults of the University of South Carolina College of Pharmacy were delivered in the form of an oral presentation along with informal slides, not in the form of an organized traditional scientific paper.^{26,27} This is understandable, since his role was to provide testimony before the South Carolina Senate, and that is a format appropriate for that task.

Regarding **internal validity**, the methodology, based on PCR and nanopore sequence analysis, seems robust, but the specifics of the study, such as sample size, control measures, and detailed procedure, are not explicitly provided in the materials available for review.

Data interpretation was given by Dr. Buckhaults, who is an academic researcher fully qualified to make such interpretation. He stated that the plasmid DNA could cause rare but serious side effects such as cardiac arrest or autoimmune diseases. However, we were not provided with the details, and that makes the interpretations look speculative and without presentable direct evidence. That could be remedied by the release of more details about Prof. Buckhault's current work in a formal manuscript.

The strong claim that the plasmid DNA can integrate into the human genome and cause mutations or sustained autoimmune attacks is a significant assertion coming from a mainstream academician. However, strong assertion requires more rigorous scientific proof than what has been released so far. Typically, mainstream academicians assert that integration of foreign DNA into human genomic DNA is a complex process and does not readily occur. Since Dr. Buckhaults seems to contradict this prevalent notion, it is expected that his colleagues would press him for presentation of very persuasive evidence supporting his conclusion. It is unclear whether Prof. Buckhaults is able or willing to provide such evidence.

While it is biologically plausible for foreign DNA to integrate into the human genome, the frequency and efficiency of such events, especially for the small fragments mentioned, do not appear to be well established so far in the specific context of mRNA vaccines. However, such possibilities have not been ruled out. Clearly we are at the beginning of a new, unexplored path—not at its end.

The **generalizability** of these findings to the broader vaccinated population is uncertain without a formal presentation of the evidence, like in the preprints described above. The concerns about regulatory standards in the historical context of vaccine development are very valid. It is important to remember that mRNA vaccine platforms are relatively new, and the large-scale manufacturing processes are even more novel than the laboratory research in this area. It is unlikely that the old regulatory standards would sufficiently assure the safety of a novel vaccine produced using novel complex technology. The issue of the change of the manufacturing process that could result in the DNA contamination that was not present in clinical trial materials is worrisome, significant, and warrants further investigation.

Prof. Buckhaults recommended that stem cells of patients suffering adverse reactions should have their DNA sequenced, looking for integration of plasmid DNA. The presence of this "calling card" would help to establish causality. This should be undertaken, he said, by many different laboratories to establish trustworthiness. If genomic integration is occurring, it is critically important to remove fragments of plasmid DNA if the potential of mRNA technology is to be realized.^{31,95} The research needs to be encouraged, and the barriers Prof. Buckhaults alluded to in his testimony need to be removed. Knowledge of this issue needs to be part of informed consent.

He notes that: "Twenty Greek soldiers wandering around outside the walls of Troy are not a big deal. Twenty Greek soldiers packed inside a large wooden horse [such as lipid nanoparticles enabling the DNA to penetrate into the cell nucleus] are a different matter."³²

Conclusions

An unemotional analysis of the current DNA plasmid contamination theory represents an important major step on the long road leading to finding the truth about COVID-19 vaccines. It may not yet be the "smoking gun" evidence, but it is also not a "useless distraction." Emergence of this evidence, and the response to it, clearly reminds us that the process of discovering the truth requires a lot of time, effort, patience, perseverance, courage, and critical thinking. By its very nature it involves many trials and errors, many disappointments, but also many hopes.

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