COVID

DNA Contamination in Pfizer COVID Vaccine Exceeded 500 Times Allowable Levels, Study Finds

A new peer-reviewed study raises concerns over inadequate testing methods for measuring DNA impurities in COVID-19 mRNA vaccines. Genomics expert Kevin McKernan critiqued the study's methods but argued that contamination is still over allowable limits and that current regulations are "entirely unfit for purpose."

by **John-Michael Dumais**

MAY 16, 2024

A new peer-reviewed study raises concerns about the methods used to test for potential **DNA impurities in the Comirnaty** COVID-19 mRNA vaccine produced by Pfizer and BioNTech.

In the study published this month in Methods and Protocols, German researchers Brigitte König and Jürgen O. Kirchner questioned the reliability of the **quantitative PCR** (qPCR) technique Pfizer-BioNTech used to measure DNA contamination in the vaccine's active substance.

The researchers experimented with dissolving **Comirnaty**'s **lipid nanoparticles**. They found DNA impurity levels ranging from 360 to 534 times higher than the **10 ng (nanogram) per dose limit** set by regulators globally.

The researchers proposed that **fluorescence spectroscopy** methods could more reliably quantify the total levels of DNA contamination present in the final, ready-to-use vaccine product.

Kevin McKernan, chief scientific officer and founder of **Medicinal Genomics**, told **The Defender** that while the authors raised some crucial points regarding DNA contamination in **COVID-19** mRNA **vaccines**, fluorometric dyes can be unreliable, leading to inflated readings.

'A massive under-detection of DNA impurities'

Manufacturers like Pfizer-BioNTech use **DNA contamination** testing that relies on a qPCR method applied to the vaccine's active substance before it is combined with lipid nanoparticles.

König and Kirchner pointed out that the qPCR test looks only for a tiny 69-base-pair segment of the original 7,824-base-pair DNA template used to produce the **mRNA vaccine**.

This means Pfizer checks less than 1% of the original template. The other 99% goes unanalyzed, resulting in "a massive under-detection of DNA impurities," they stated.

The researchers also argued that this small segment may get destroyed at different rates than the rest of the DNA template fragments during the enzyme digestion process, further confounding accurate measurements.

Another complicating factor is that the qPCR target sequence overlaps with a section of DNA called the **T7 promoter** used to produce the mRNA. Cellular machinery or byproducts could bind to this promoter region, blocking it from being detected by the qPCR test.

David Speicher, Ph.D., co-author with McKernan and others of a **preprint study** on DNA fragments in Moderna's and Pfizer's COVID-19 vaccines, expressed similar concerns.

PCR can quantify only a particular DNA/RNA sequence targeted by the primers used, he told The Defender. If there are any breaks or mutations in that target sequence, the "DNA will not amplify and the loads will be under-reported."

"There is also an assumption that the DNA in the vaccine is only from the plasmid and not bacterial or any other source," Speicher said.

McKernan pointed out another problem: Regulators allow Pfizer to use qPCR to measure the DNA and fluorometry to measure the RNA.

"The regulations from the EMA [European Medicines Agency] are a ratiometric measurement of RNA:DNA," he said. "The ratios should not be measured with inches for RNA and meters for DNA."

He said Pfizer should measure both the RNA and the DNA using fluorometry or qPCR. "When they allow them to mix and match tools like this, they enable overt deception."

McKernan also shared a portion of Moderna's patent application acknowledging that qPCR is inadequate for measuring **small DNA fragments**.

'We are no longer debating whether the shots are contaminated'

To avoid the pitfalls of qPCR, which targets only a tiny fraction of the contaminant DNA, König and Kirchner proposed using fluorescence spectroscopy techniques like **Qubit** to quantify total DNA levels in the final vaccine product.

These methods employ fluorescent dyes that bind specifically to nucleic acids like DNA and RNA.

Their experiments using the fluorescence technique with Comirnaty found DNA contamination significantly higher than the 10 ng/dose limit after breaking apart the nanoparticles.

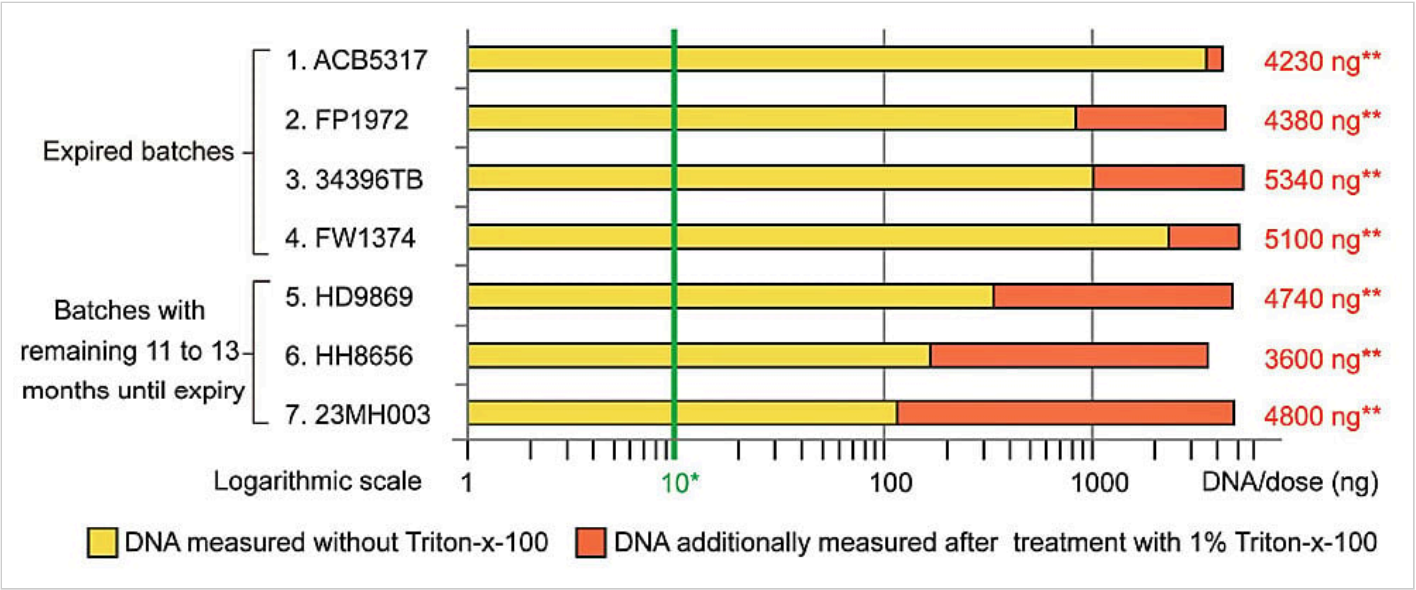


Figure 2. Quantification of total DNA in batches of Comirnaty using Qubit fluorometry without and with the addition of Triton-X-100 as a detergent to disintegrate the lipid nanoparticles contained in the vaccine formulation. Credit: ***Brigitte König and Jürgen O. Kirchner****.*

McKernan, who wrote about **fluorometry's limitations on his Substack**, urged caution when considering König and Kirchner's results.

"Fluorometric dyes can cross-talk between RNA and DNA such that large amounts of RNA present in the vaccine will trigger the DNA-specific dye to provide some signal from RNA," he told The Defender. "This is leading to inflated readings of the DNA in the König paper."

To address this concern, McKernan said the researchers should perform an **RNase control**. RNase is an enzyme that erases RNA, so there is no interference from RNA when measuring DNA.

Without this control, König and Kirchner "have left an easy attack surface for their critics," he said.

In research in preparation for publication, McKernan said several labs performing RNase experiments observed a 10-fold reduction in the DNA signal observed when using fluorometry.

"This still leaves the DNA contamination well over the FDA [U.S. Food and Drug Administration] limit," McKernan said. He emphasized that his "hair-splitting critique" of the study should not diminish or derail the call to reevaluate DNA contamination testing protocols for mRNA vaccines.

"We are no longer debating whether the shots are contaminated," he said. "We're just debating whether they are 10-fold or 100-fold over the limit and how much they vary from lot to lot."

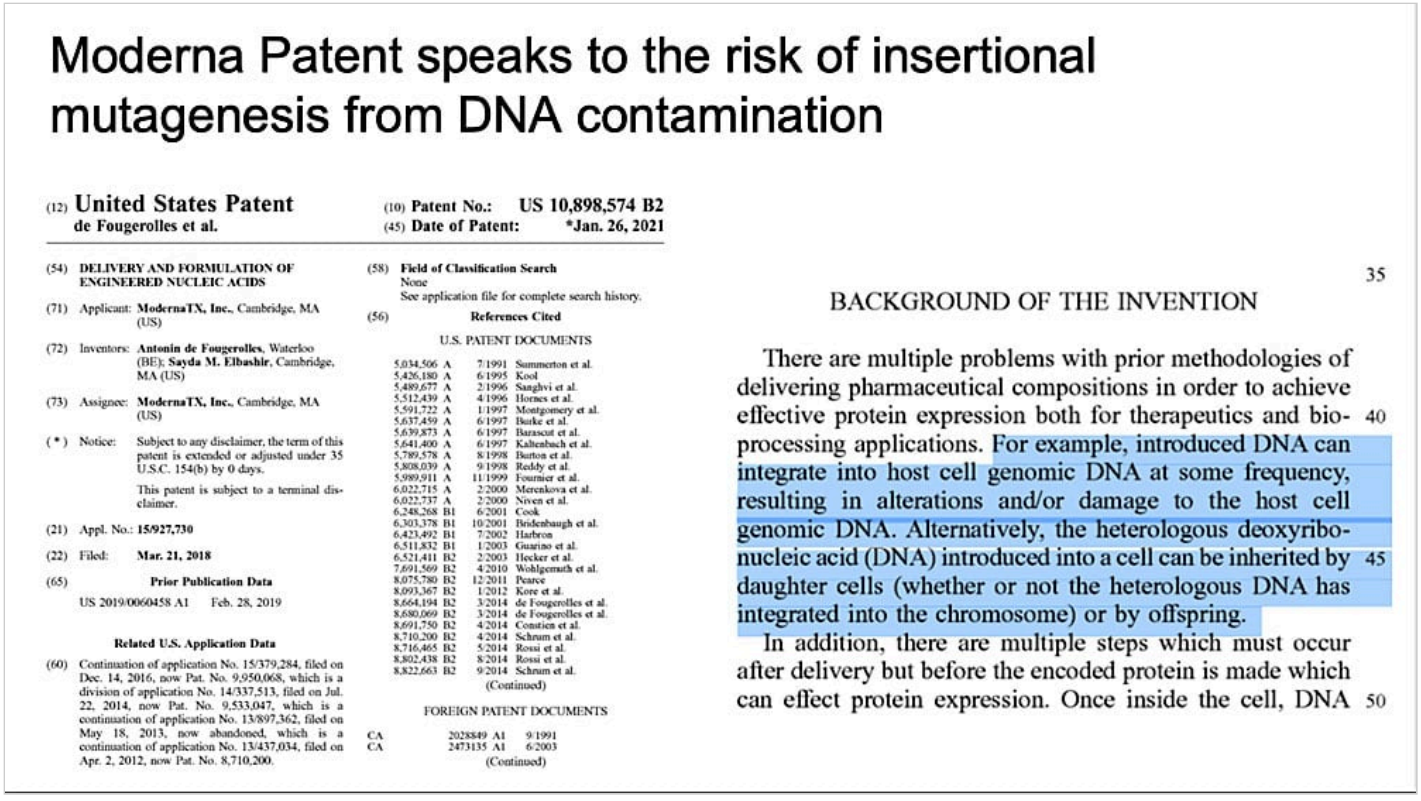
Potential risks of DNA contamination

König and Kirchner cited concerns that higher-than-expected levels of DNA contamination could be taken up into human cells during vaccination, with unknown consequences if that DNA integrates into the genome.

They cited the "risk of insertional mutagenesis," where foreign DNA segments disrupt normal gene sequences when inserted into the genome, possibly leading to mutations and associated diseases like cancer.

Researchers like McKernan have already determined that DNA in the mRNA COVID-19 vaccines includes the **simian virus 40 (SV40)** cancer-promoting gene and **E. coli plasmid DNA** sequences left over from the vaccine production process.

In a February presentation at the **International Crisis Summit-5 conference**, McKernan pointed out that **Moderna's patent application** for its COVID-19 mRNA vaccine acknowledged the risks of insertional mutagenesis.



Credit: McKernan ICD 2024 Presentation

The same patent application states that DNA contamination can cause cancer:

> "The DNA template used in the mRNA manufacturing process must be removed to ensure the efficacy of therapeutics and safety, because residual DNA in drug products may induce activation of the innate response and has the potential to be oncogenic in patient populations."

McKernan asserted in his International Crisis Summit presentation that "We are always cancering." He proposed the following "3 hit hypothesis" on the negative health impacts of mRNA vaccines:

> 1. Increased mutagenesis with dsDNA [double-stranded DNA] plasmid contamination.
>
> 2. The effects of **N1-methyl-pseudouridine** used to stabilize the RNA, causing **lymphocytopenia**, **neutropenia**, **IgG4-related diseases**, etc.
>
> 3. The inhibition of the "guardians of the genome," the **P53** and **BRCA1** tumor-suppressing genes.

DNA contamination regulations 'entirely unfit for purpose'

McKernan stressed that current regulations governing the allowable limit of DNA contamination in vaccines are "entirely unfit for purpose."

"The public must know that the DNA contamination guidelines assumed a 5-10 minute half-life of naked DNA in the blood," he said. "Once this DNA is protected by lipid nanoparticles, it is no longer naked and does not degrade but instead transfects your cells."

According to McKernan, mammalian-based DNA fragments are part of a "highly replicative gene therapy vector designed to make more of itself" and therefore can self-amplify indefinitely once transfected.

"What good is a 10 ng limit if **Pharma** can sneak an amplifiable DNA molecule through that regulation?" he asked.

Regulators established the **10 ng/dose DNA contamination allowance** in 1998.

"10 ng is an extra-cellular consideration," said **Karl Jablonowski, Ph.D.**, senior research scientist for **Children's Health Defense**. "If you were to ask how much foreign DNA should be allowed within the nucleus, the answer is zero," he told The Defender.

Speicher added that regulators ignore fragments under 200 base pairs long because these would not likely be problematic if the DNA remained outside our cells.

For perspective, with the DNA in the entire human genome averaging 6.41 pc (picograms), Jablonowski noted that "10 ng of DNA is our entire genome 1,560 times over."

'How reckless can they be with the human genome?'

Despite possible limitations, European regulators approved the qPCR method for checking whether Comirnaty meets the required DNA contamination limits of 10 ng/dose.

According to König and Kirchner, apart from the manufacturer's qPCR tests on the active ingredient, "no further experimental DNA quantification is carried out for the vaccine."

Regulators contend that testing the final product isn't feasible, citing potential interference of the lipid nanoparticles encapsulating the mRNA.

However, the researchers pointed out that manufacturers can accurately quantify the mRNA in those same nanoparticles. They criticized regulators for relying on manufacturers' limited qPCR data and not mandating direct quantification of total DNA in the final Comirnaty product.

After other scientists replicated McKernan's work, regulatory agencies like the FDA, EMA and **Health Canada** were compelled to acknowledge the presence of SV40 in the Pfizer vaccines.

However, according to McKernan, these agencies have maintained that the DNA fragments are too small in length and quantity to be functional and have taken no steps to further regulate or withdraw the vaccines from the market.

McKernan also pointed out that before the **National Childhood Vaccine Injury Act of 1986** (NCVIA), the DNA contamination limit was 1,000-fold lower than the current 10 ng limit.

This loosening of regulations, together with the NCVIA's liability shield and technology advancements, has made DNA sequencing technology "100,000 times cheaper," he said, allowing vaccine companies to add "transfection reagents [like LNPs] to ensure this DNA gets

into your cells, can self-amplify and tinker with cell circuitry."

McKernan said:

> "Why is the FDA not sequencing these vaccines? What excuse do they have to not know the precise sequence and frequency of every molecule of DNA and RNA in a vaccine they plan to inject into billions of people? How reckless can they be with the human genome?"

Despite apparent agency inaction, a recent **Freedom of Information Act request by a Canadian citizen** revealed "alarming activity behind the scenes," according to McKernan.

"The regulators are telling the public not to worry about the contamination but scrambling internally to have this DNA removed," he said.

John-Michael Dumais
John-Michael Dumais is a news editor for The Defender. He has been a writer and community organizer on a variety of issues, including the death penalty, war, health freedom and all things related to the COVID-19 pandemic.

Email..

SIGN UP

Children's Health Defense Comment Policy

We welcome relevant and respectful comments. Off-topic comments may be removed.

Please read our Comment Policy before commenting.

Got it

20 Comments

Rebecca Montrone ▾

Children's Health Defense requires you to verify your email address before posting. Send verification email to

Join the discussion…

6 **Share**

Best **Newest** **Oldest**

Gary Brown

3 days ago

All going as planned. May 30, 2024 US birth rate continues to drop, lowest in decades: CDC report

The U.S. birth rate has continued to decline, according to recently released statistics, with the reported number of babies born in 2023 being the lowest in decades.

Latest News

prev

Convenes Experts to Dissect
's Plans for a 'Pandemic
strial Complex'

Fauci Aide Bragged That He Could 'Make Emails Disappear' — Including 'Smoking Guns'

next

Latest Views

prev

Milk Under Attack Again
l Bird Flu Fearmongering

'Drop Monoculture and Industrial Thinking': Study Shows Diversified Farming Pays Off for People and Planet

next

Get Text Alerts

Sign up for breaking news from The Defender

123-456-7890

REQUIRED. Phone number must be in a standard 10-digit format: 1234567890 or 123-456-7890

CONTINUE

Currently only eligible for numbers in the U.S. and Canada.

THE DEFENDER IS AVAILABLE IN:

EN ES PT DE IT FR

Health Defense

Children's Health Defense® is a 501(c)(3) non-profit organization. Our mission is ending childhood health epidemics by eliminating toxic exposure. We will restore and protect the health of children by eliminating environmental exposures, holding responsible parties accountable, and establishing safeguards to prevent future harm of children's health. Protecting Children. Exposing Harms. Seeking Justice.

TAKE ACTION

DONATE **FREE SIGN-UP**

BECOME A MEMBER

Donations are tax deductible to the full extent of the law. EIN #26-0388604