

# Pfizer ‘Chose Not to’ Tell Regulators About SV40 Sequence in COVID Shots: Health Canada Official

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*A senior Health Canada official **says pharma giant Pfizer made a conscious decision not to advise regulators that its mRNA COVID-19 vaccine contained a DNA sequence from the Simian Virus 40 (SV40).***

This information appears among multiple emails between staff from key drug regulators, including Health Canada (HC), the U.S. Food and Drugs Administration (FDA), and the European Medicines Agency (EMA). The information was obtained through an access-to-information request.

On Aug. 23, 2023, [Dr. Dean Smith](#), a senior scientific evaluator in Health Canada’s Vaccine Quality Division, wrote an email to a colleague at the FDA about SV40.

Health Canada had [obtained](#) confirmation two weeks earlier from Pfizer that SV40 DNA sequences were present in its COVID-19 vaccine.

“I understand that there have been internal discussions at CBER [Center for Biologics Evaluation and Research] regarding the presents [sic] of an SV40 enhancer/promoter sequence, noting that its presence is unrelated to the purpose of the Pfizer’s plasmid as a transcription template for their mRNA COVID-19 vaccine,” wrote Dr. Smith.

“Pfizer has communicated to us recently, that they apparently chose not to mention this information to EMA, FDA or HC at the time of their initial or subsequent submissions.”

Dr. Smith added the information had been independently made public in April 2023, via a pre-print study from U.S. scientist **Kevin McKernan**.

Mr. McKernan, a genomics expert, had found quantities of DNA in the mRNA shots above the regulatory threshold set out by the health agencies. Dr. Smith wrote that the study had resulted in “questions coming to agencies.”

The Epoch Times contacted HC on the matter on July 17, 2023. The first SV40-related email released in Health Canada’s access-to-information package was sent two days later, on July 19.

In that email, [Dr. Tong Wu](#) of Health Canada’s Vaccine Quality Division reached out to his colleague **Dr. Michael Wall**, a senior biologist evaluator.

“Co [Pham, executive director of HC’s Centre for Vaccines, Clinical Trials and Biostatistics] agreed to have an IAS [possibly a reference to an Issue Analysis Summary to evaluate a new regulatory affair] for the SV40 promoter sequence as we discussed today. We can talk about it tomorrow,” Dr. Wu wrote.

As first [reported](#) by The Epoch Times in October, Health Canada was not aware of the SV40 enhancer presence. Since then, the FDA and the EMA have both [confirmed](#) they also weren’t aware of its presence.

Health Canada has since [maintained](#) that the SV40 enhancer/promoter sequence is a “residual DNA fragment” in Pfizer-BioNTech COVID-19 vaccine. “The fragment is inactive, has no functional role, and was measured to be consistently below the limit required by Health Canada and other international regulators,” the agency has repeatedly said.

## ‘ZERO Checks’

This view has been challenged by Mr. McKernan and others, including **Dr. Philip Buckhaults**, professor of cancer genomics and director of the Cancer Genetics Lab at the University of South Carolina.

In response to the information released by Health Canada, Mr. McKernan posted a thread on the X platform. “No prior vaccine in Canada has been approved with such a sequence contaminant,” he [said](#).

Well, well, well,

As health agencies assure the public that the DNA contamination is of no consequence, behind the scenes they are scurrying to have it removed from future vaccines!

No prior vaccine in Canada has been approved with such a sequence contaminant. [@FLSurgeonGen](#)

— Kevin McKernan (@Kevin\_McKernan) [April 23, 2024](#)

“Pfizer assured [HC] the sequence is not material to plasmid manufacturing,” he [added](#). “This is an overt lie. You cannot make plasmids without the promoter for the antibiotic resistance gene. It is active in mammalian cells. If it’s not needed, why is it in there?”

**Mr. McKernan also noted that HC has asked Pfizer for its Polymerase Chain Reaction (PRC) protocol, saying this means**

**“they have performed ZERO checks on this DNA contamination themselves and are entirely relying on the word of the manufacturer.”**

A response to a Canadian Member of Parliament’s question tabled by Health Canada in the House of Commons appears to be in line with this observation.

“It is important to assess the results using the authorized validated assays performed by the vaccine manufacturers to ensure that the quality of commercial vaccine lots are comparable to lots shown to be safe and efficacious in clinical studies,” [said](#) Health Canada in December.



Concerns raised by some scientists about the presence of unintended DNA in the mRNA shots relate to their potential to integrate into the human genome and cause issues like cancer. The Florida State Surgeon General **Dr. Joseph A. Ladapo** has [called](#) for a halt of mRNA shots over these risks.

In March, Health Canada said in a [document](#) tabled in Parliament that “any claims that the presence of the SV40 promoter enhancer sequence is linked to an increased risk of cancer are unfounded.”

Dr. Buckhaults has [started](#) a scientific study to ascertain those risks. On April 23, he [wrote](#) on X that he had confirmed previous findings that the amount of DNA in mRNA shots exceeds the limit set by regulators.

“Yes, there was more than 10 ng/dose,” he wrote, referencing the threshold applied by Health Canada. “I am sure of it now.”

Even if the amount of DNA had been lower, concerns remain that the threshold was set for regular vaccines and not the new technology using lipid nano particles (LNP).

Dr. Buckhaults [wrote](#) that the “10 ng limit is not appropriate for LNP encapsulated DNA,” adding that “as far as I know there have been no safety studies for this situation. It was not possible because of the abbreviated timeline during the emergency you saw authorization.”

yes, the 10 ng limit is not appropriate for LNP encapsulated DNA. as far as I know there have been no safety studies for this situation. it was not possible because of the abbreviated timeline during the emergency you saw authorization. But now that we are no longer under an...

## Seeking ‘Remedy’

In his Aug. 23 email to an FDA colleague, Dr. Smith said Health Canada did not view the SV40 issues as an “urgent risk topic,” although he expressed concerns about how the SV40 news could impact the upcoming fall 2023 vaccination campaign.

“It would be unfortunate if the information circulating had a negatively [sic] impact on public acceptance of the vaccine this year or in the future,” he said.

Despite having that concern, Dr. Smith, the official responsible for evaluating the safety of vaccines, said regulating agencies should work to encourage Pfizer to “remedy the situation” before the campaign.

In the email, Dr. Smith said Health Canada believed the upcoming rollout of the fall COVID-19 vaccine campaign meant the agencies should be “on the same page.”

Dr. Smith’s email was written a day after Pfizer provided a response to a [Quality Clarifax](#)—a Health Canada request for additional information if deficiencies are identified in clinical trial applications—related to the SV40 promoter.

On Aug. 29, Health Canada senior biologist Dr. Wall wrote an email to Dr. Wu, the senior evaluator, saying he and Dr. Smith agreed they should not inform Pfizer of their interaction with the EMA and U.S. FDA on the SV40 promoter, “especially they [sic] do not seem to care much at this moment.”

Dr. Wall then added, “However, we can not say nothing! Please see the following text that Julie and I worked out.” He provided a blacked-out draft comment to Pfizer’s response.

The same day, Dr. Wall also sent an email to Dr. Wu with a draft of the Clarifax questions to be sent to Pfizer, which included the statement, “Health Canada would continue to work with international regulatory partners to achieve harmonisation regarding removal of these sequence elements from the plasmid for future strain changes.”

Pfizer did not respond to a request for comment from The Epoch Times

Commenting on DNA contamination, Health Canada reiterated its previously-stated position on the matter.

“Based on its evaluation of the data and scientific information for the vaccine, Health Canada has concluded that the risk/benefit profile continues to support the use of the Pfizer-BioNTech vaccine,” said spokesperson **Anna Maddison**.

**Dr. David Speicher**, a Canadian virologist who replicated the findings from Mr. McKernan and Dr. Buckhaults with Canadian mRNA vials, told The Epoch Times he’s preoccupied with the revelations in the internal Health Canada emails. He notes that while Health Canada has dismissed the DNA fragments as biologically inactive with no functional role, they were judged important enough to discuss with other regulators.

“We know from testing several vials that the level of SV40 enhancer-promoter in the

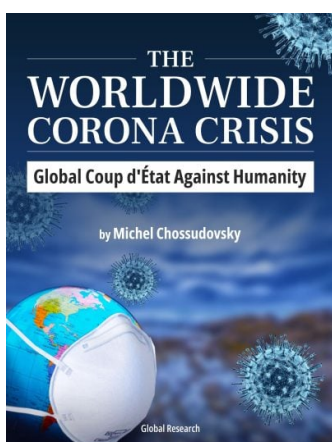
XBB.1.5 booster is at similar levels as the others Pfizer COVID modRNA vaccines, making it just as problematic,” he said. “Pfizer has not cleaned up the vaccine, yet the regulators are sadly more concerned about vaccine uptake in the population rather than the health risks from these vaccines.”

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Featured image: A sign is displayed in front of Health Canada headquarters in Ottawa on Jan. 3, 2014. (The Canadian Press/Sean Kilpatrick)



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