Documents Reveal Lipid Nanoparticles in Pfizer Vaccine Travel From Injection Site, J&J Virus Particles Present Months After Jab



Judicial Watch <u>announced</u> Tuesday it received <u>466 pages</u> of records from the Department of Health and Human Services (HHS) containing biodistribution studies and related data for COVID-19 vaccines that show lipid nanoparticles (LNPs) contained in <u>Pfizer's COVID-19 vaccine</u> travel outside the injection site and settle primarily in the liver, adrenal glands, spleen and ovaries of test animals 8 to 48 hours after injection.

The records support censored <u>research by a group of scientists</u> who came forward in June 2021, claiming the spike proteins produced in the body from Pfizer's COVID vaccine travel from the injection site and settle in the spleen, bone marrow, liver, adrenal glands, and in "quite high concentrations" in

the ovaries — causing potential organ damage.

In addition to documents obtained regarding Pfizer, <u>Judicial</u> <u>Watch</u> received <u>663 pages</u> of records from HHS that reveal Johnson & Johnson (J&J) relied on studies showing DNA particles and injected virus particles were still present in test animals months after injection and did not include studies of the spike protein encoded in the J&J vaccine as part of its request for approval from the U.S. Food and Drug Administration (FDA).

"These documents show why many Americans have concerns about whether the novel COVID vaccines that were developed at such an accelerated pace were tested properly and thoroughly," said Tom Fitton, Judicial Watch President.

Biodistribution studies are used to determine where an injected compound travels in the body and which tissues or organs it accumulates in.

Pfizer and BioNTech's mRNA-based COVID vaccine depends on LNPs as a delivery system. Pfizer in a Jan. 10 <u>press release</u> confirmed Acuitas Therapeutics LNP technology is used in <u>COMIRNATY</u> and the Pfizer/BioNTech COVID-19 vaccines.

Judicial Watch obtained the records in response to a Freedom of Information Act (FOIA) <u>lawsuit</u> filed after the FDA, Centers for Disease Control and Prevention (CDC) and National Institute for Allergy and Infectious Disease failed to respond to a June 8, 2021, FOIA request.

In its FOIA request, Judicial Watch asked for "[a]ccess to biodistribution studies and related data for the Pfizer, Moderna and Johnson & Johnson vaccines used to treat and/or prevent SARS-CoV-2 and/or COVID-19."

The records received by the organization included a confidential Pfizer report on the distribution of Pfizer COVID vaccine LNPs in rats. The report stated that no safety

pharmacology studies were conducted with the Pfizer-BioNTech vaccine as they were "not considered necessary for the development of vaccines."

The report also states "nonclinical studies evaluating pharmacodynamic drug interactions with BNT162b2 were not conducted as they are generally not considered necessary to support development and licensure of vaccine products for infectious diseases."

Pfizer data show lipid nanoparticles travel from injection site

According to a Pfizer study obtained from the records, LNPs "with a comparable composition" to that used in the Pfizer COVID vaccine were injected into rats.

"Total recovery (% of injected dose) of LNP outside the injection site was greatest in the liver and was much less in the spleen, adrenal glands and ovaries. [...] In summary ... the LNP distributes to the liver," the study states.

"Over 48 hours, the LNP distributed mainly to liver, adrenal glands, spleen and ovaries, with maximum concentrations observed at 8-48 hours post-dose. Total recovery (% of injected dose) of LNP, for combined male and female animals, outside of the injection site was greatest in the liver (up to 18%) ..."

Despite discovering LNPs distributed to various areas of the body, Pfizer said no "genotoxicity studies" were planned for the Pfizer/BioNTech vaccine as the "components of the vaccine constructs are lipids and are not expected to have genotoxic potential."

Pfizer also did not conduct carcinogenicity studies to

determine whether their vaccine could cause cancer — as lipids and RNA are "not expected" to have carcinogenic or tumorigenic potential.

The study concluded the "nonclinical program demonstrates that BNT162b2 is immunogenic in mice, rats and nonhuman primates, and the toxicity studies support the licensure of this vaccine."

Furthermore, vaccine-related microscopic findings at the end of dosing for Pfizer's COVID vaccine were "evident in injection sites and surrounding tissues, in the draining iliac lymph nodes, bone marrow, spleen and liver."

In another Pfizer <u>report</u> titled, "Pharmacokinetics Tabulated Summary," a table in the report shows the biodistribution of lipid nanoparticles containing mRNA used in the vaccine using rats as the clinical trial subjects reported LNPs accumulating after 48 hours, primarily in the lymph nodes, ovaries, small intestine and spleen.

A summary of the study revealed concentrations of LNPs peaking in the plasma at 1-4 hours post-dose and distributed mainly into the liver, adrenal glands, spleen and ovaries over 48 hours.

A September 2020 "confidential" appendix to the <u>clinical trial</u> <u>studies</u> submitted for the Pfizer/BioNTech COVID vaccine that "no safety pharmacology studies were conducted as they are not considered necessary.

J&J documents show vaccine ingredients accumulate in the body

Records <u>obtained</u> by Judicial Watch on the J&J shot included a <u>2007 biodistribution study</u> of an intramuscular-administered <u>adenovector-based viral vaccine</u> using New Zealand white rabbits. The study showed vaccine ingredients

accumulated in "the spleen, iliac lymph node and the muscle at the site of injection."

An appendix of the study showed vaccine DNA particles were still present in the iliac lymph nodes 91 days after injection.

A chart of pharmacokinetics data from a <u>November 2020 report</u> on J&J's COVID vaccine in rabbits showed viral particles in the spleen and iliac lymph nodes up to three months postinjection. Particles were also found in the skin and muscle at the injection site.

In a Nov. 2020 <u>report</u> submitted to the FDA prior to the authorization of J&J's vaccine, the authors discussed the 2007 New Zealand rabbit study in which an adenovirus-vectored vaccine was studied, noting that "no pharmacokinetic or biodistribution studies have been conducted with AD26.COV2.S specifically."

The report noted metabolism, excretion, and pharmacokinetic interactions with other drugs were not studied in the trial because they were "not applicable to vaccines." It is also said "biodistribution studies have not been conducted" with J&J's COVID vaccine.

The study showed the virus contained in the shot continued to appear in the rabbits' iliac lymph nodes 180 days after injection.

A June 2020 "Pharmacokinetics Written Summary" for the J&J shot states:

"Ad26COVS1 (also known as VAC31518 or JNJ-78436735) is a monovalent, recombinant replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) Spike protein.... No specific pharmacokinetic studies have been performed with Ad26COVS1.

"However, to assess distribution, persistence, and clearance of the Ad26 vector (platform), biodistribution studies were conducted in rabbits using two other Ad26-based vaccines encoding [redacted] and [redacted] antigens.... [T]he available biodistribution results are considered sufficient to inform on the biodistribution profile of Ad26COVS1, for which the same Ad26 vector backbone is used."

Traveling spike protein could cause organ damage

COVID vaccine researchers had previously assumed mRNA COVID vaccines would behave like traditional vaccines. The vaccine's spike protein — responsible for infection and its most severe symptoms — would remain mostly in the injection site at the shoulder muscle or local lymph nodes.

But research obtained in June 2021 by a group of scientists showed the theory wasn't true.

"We made a big mistake. We didn't realize it until now," said Byram Bridle, a viral immunologist and associate professor at the University of Guelph, Ontario. "We thought the spike protein was a great target antigen, we never knew the spike protein itself was a toxin and was a pathogenic protein. So by vaccinating people we are inadvertently inoculating them with a toxin."

Bridle, who was awarded a \$230,000 grant by the <u>Canadian</u> government in 2020 for research on COVID vaccine development, said he and a group of international scientists filed a request for information from the Japanese regulatory agency to get access to Pfizer's "biodistribution study."

"It's the first time ever scientists have been privy to seeing where these messenger RNA [mRNA] vaccines go after vaccination," Bridle said in an <u>interview</u> with Alex Pierson

where he first disclosed the data. "Is it a safe assumption that it stays in the shoulder muscle? The short answer is: absolutely not. It's very disconcerting."

The Sars-CoV-2 has a spike protein on its surface. That spike protein is what allows it to infect our bodies, Bridle explained.

"That is why we have been using the spike protein in our vaccines," Bridle said. "The vaccines we're using get the cells in our bodies to manufacture that protein. If we can mount an immune response against that protein, in theory we could prevent this virus from infecting the body. That is the theory behind the vaccine."

However, when studying severe COVID-19, heart problems, lots of problems with the cardiovascular system, bleeding and clotting, are all associated with COVID-19, he added. "In doing that research, what has been discovered by the scientific community, the spike protein on its own is almost entirely responsible for the damage to the cardiovascular system, if it gets into circulation."

When the purified spike protein is injected into the blood of research animals, they experience damage to the cardiovascular system and the protein can cross the blood-brain barrier and cause damage to the brain, <u>Bridle explained</u>.

The <u>biodistribution study</u> obtained by Bridle showed the COVID spike protein gets into the blood where it circulates for several days post-vaccination and then accumulates in organs and tissues including the spleen, bone marrow, the liver, adrenal glands and in "quite high concentrations" in the ovaries.

"We have known for a long time that the spike protein is a

pathogenic protein, Bridle said. "It is a toxin. It can cause damage in our body if it gets into circulation."

A study in <u>Clinical and Infectious Diseases</u> led by researchers at Brigham and Women's Hospital and the Harvard Medical School measured longitudinal plasma samples collected from 13 recipients of the Moderna vaccine 1 and 29 days after the first dose and 1-28 days after the second dose.

Out of these individuals, <u>11 had detectable levels of SARS-CoV-2 protein</u> in blood plasma as early as one day after the first vaccine dose, including three who had detectable levels of spike protein. A "subunit" protein called S1, part of the spike protein, was also detected.

Spike protein was detected an average of 15 days after the first injection, and one patient had spike protein detectable on day 29 — one day after a second vaccine dose — which disappeared two days later.

The <u>results showed</u> S1 antigen production after the initial vaccination can be detected by day one and is present beyond the injection site and the associated regional lymph nodes.

Assuming an average adult blood volume of approximately 5 liters, this <u>corresponds</u> to peak levels of approximately 0.3 micrograms of circulating free antigen for a vaccine designed only to express the membrane-anchored antigen.

In a study published in <u>Nature Neuroscience</u>, lab animals injected with purified spike protein into their bloodstream developed cardiovascular problems. The spike protein also crossed the blood-brain barrier and caused damage to the brain.

It was a grave mistake to believe the spike protein would not escape into the blood circulation, said Bridle. "Now, we have clear-cut evidence that the vaccines that make the cells in our deltoid muscles manufacture this protein — that the

vaccine itself, plus the protein — gets into blood circulation."

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Once in circulation, the spike protein can attach to specific ACE2 receptors that are on blood platelets and the cells that line blood vessels, he said. "When that happens it can do one of two things. It can either cause platelets to clump, and that can lead to clotting — that's exactly why we've been seeing clotting disorders associated with these vaccines. It can also lead to bleeding."

Dr. J. Patrick Whelan, a pediatric rheumatologist, warned the FDA in December 2020 that mRNA vaccines could cause microvascular injury to the brain, heart, liver and kidneys in ways not assessed in safety trials.

In a <u>public submission</u>, Whelan sought to alert the FDA to the potential for vaccines designed to create immunity to the SARS-CoV-2 spike protein to instead cause injuries.