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Assessing America's Vaccine Safety Systems, Part 2

Testimony Before

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David Gortler, Pharm.D. FCCP
Senior Research Fellow in Public Health and Regulation
Center for Health and Welfare Policy
The Heritage Foundation

My name is David Gortler. I am the Senior Research Fellow in Public Health and Regulation at The Heritage Foundation. The views I express in this testimony are my own and should not be construed as representing any official position of The Heritage Foundation.

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Chairman Wenstrup, Ranking Member Ruiz, distinguished members of the Subcommittee. Thank you for providing me the opportunity to testify at today's hearing about the United States' vaccine safety system. My name is Dr. David Gortler. I am a pharmacologist and pharmacist and refer you to my submitted biography. I currently serve as a Senior Research Fellow of Public Health Policy and Regulation at The Heritage Foundation.

I have dedicated years of my career working to protect the American people in investigational medicine and drug development, researching and evaluating the efficacy and safety of drugs. My work has brought me through about a half-dozen universities, Big Pharma, and at the Food and Drug Administration (FDA) under three presidential administrations.

What is the most regulated item in the marketplace? One might think it is the cars we drive, airplanes we fly, or even firearms. But they are not. It is actually the food we eat and the drugs we put in our bodies. Studying drug safety helps researchers figure out why one person may take a drug and have zero adverse effects, while another person takes the same product and ends up sick, in the hospital, permanently disabled, or worse.

COVID-19 Injection Development

Drug safety is one of the most critical complex topics in pharmacology and pharmacy today. The study of drug safety includes the studying of potential adverse events in a clinical setting, but also considers non-clinical aspects, including manufacturing, complexity, and quality.

In an effort to simplify the process and since most people know at least a little bit about cars, I would like to put the development of COVID-19 mRNA injection technology in the context of building a new car via a metaphor.

Let's suppose that under normal circumstances, it takes 10 to 12 hours to assemble a car, that period being analogous to the 10 to 12 years that it takes to bring a vaccine or other drug to market.

Let's also say that due to an emergency, these new cars are instead being assembled in *45 minutes* instead of *10 to 12 hours*, representing the relative nine months it took to bring COVID-19 mRNA injections to market.

Now let's also suppose that these new cars were something completely different from what you know as cars. I do not just mean the next iteration of the latest modern vehicle, I mean something visibly and technologically unrecognizable.

Whatever "advanced" car you are picturing in your head right now, it is not that; it is something much

more complex and unconventional. For instance, the "45-minute" car might not have wheels, a brake pedal, seats, seat belts, or a windshield. Let's also say that it did not use electricity or internal combustion for power. Instead, this new car uses *your own body* to as its source, analogous to COVID-19 RNA injections using your body's own cells to replicate the s-protein of COVID-19.

On top of the novel *design* of the car, all of the *parts* of that car are different—with essentially nothing duplicated from what is currently found in existing cars. These new parts are additionally comprised of synthetic *materials* that are new in the sense that they have never been used in cars before now and are extremely large and complex, compared to any other part used in a car before. Decades of prior research have shown that these various materials are often extremely delicate, finicky, and toxic. To continue the analogy, these materials represent the fully synthetic, long, intricate, delicate RNA nucleotide and the various lipid nanoparticle components found in the mRNA COVID-19 injections.

Remember, the normal development and review time for the COVID-19 injections was reduced by over 90 percent and accordingly the "new cars" were researched, manufactured, and distributed to drivers on the road at "warp speed," meaning that even the slightest error to the ultracomplex design of the new car would mean that it might not work at all, and/or could be extremely unsafe, and/or highly unpredictable for you, your family, friends, and potentially other drivers on the road.

Let's also say that the so-called "new car" was so novel and so different from every other car on the road that it did not even meet the current definition of a car. Instead of correctly calling it what it was, the National Highway Traffic Safety Administration (NHTSA) unilaterally altered its century-plus-old definition of a "car" on its website, almost overnight, without seeking input from outside design, safety, material, or mechanical engineers, among others. This analogy represents the actions of the Centers for Disease Control and Prevention's fall 2021 abrupt definition change of the definitions of "vaccines"—a dictionary term which has officially existed since 1882.[1] "Vaccines" now include novel, cutting-edge mRNA "gene therapy" products. COVID-19 mRNA injections are unquestionably gene therapy via their methodology of discovery *plus* their inherent mechanisms of action.

If a curious, independent materials scientist or engineer wanted to perform research about the design, configuration, and technical aspects of the materials used in this car and attempted to download information at the NHTSA website, they would find around 70 percent of that document redacted, making the entire document indecipherable. In place of technical data or product design information about the car's engine parts there would be extended, greyed-out sections with Freedom of Information Act exemption (b)(4) redactions translating to: **"*protects trade secrets and confidential commercial or financial information*."**

Put another way, the engineering, blueprints, and materials used to build that car would be considered secret, despite the fact that the government had given billions of America's taxpayer dollars to private companies both to develop and mass produce those new cars. In the context of COVID-19 mRNA injections, basic information like RNA sequence, molecular weight and quantitative breakdown, of lipid nanoparticles, their structure, and the number of pseudouridine substitutions are withheld from the same public in which RNA injections are mandated, despite the massive taxpayer investment to develop, produce, and distribute these products.

[1]The existence of the word vaccine was coined in 1796 by British physician Edward Jenner but was only introduced into the dictionary in 1882.

The FDA also appeared to use an unusually relaxed, deeply questionable "mail-in" methodology[2] in assuring quality and consistency of these ultracomplex RNA products.

Now, let's compare the "45-minute" car to older and currently available cars made in the normal 10- to 12-hour time frame. Some of these traditional cars have been on the market for years and have a proven track record of safely and efficiently (i.e., efficaciously) getting their owners from point A to point B. These old cars are nowhere near as fancy as the "45-minute" cars, but they are reliable and inexpensive to maintain. Let's say those old cars were so safe and effective they had even been awarded a Nobel Prize for their safety and reliability.

Now, despite the proven safety track record of traditional 10- to 12-hour cars, the government declares by fiat that the "45-minute" car is not only the best—but the *only*—car to be used on its roads, and older, traditional cars should only be driven by horses and cows, corresponding to the FDA's famous Twitter posting deriding and denigrating the use of ivermectin and hydroxychloroquine. Now, the NHTSA will tell you that they are not exactly recalling older cars, but they are screaming from on high their unmistakable disapproval, in no uncertain terms. Of note, the NHTSA has no authority to tell you which of the available cars on the market you should or should not drive, just as the FDA has no congressional authority to recommend one medical/drug treatment over another.

Let's further suppose that my old car was so very safe and reliable that it had previously won the Nobel Prize in Medicine (as Ivermectin had in 2015, the last drug and one of very few drugs to win a Nobel prize). Despite that, I would no longer have the freedom to drive it. In fact, in order to travel or be part of society, I would be required to only drive this new "car" (representing COVID-19 mRNA injections and mandates). Not genuflecting to the government's demand means I would lose my job, lose my friends, have my life threatened, my home vandalized, be fined, labeled selfish and stupid, and derided as a peddler of misinformation across the Internet, around the world, and into outer space.

This is analogous to what happened the COVID-19 mRNA injections (the "45-minute car") and well-known drugs repurposed for COVID-19 like Ivermectin, hydroxychloroquine, and vitamin D. Even mentioning these drugs in the context of COVID-19 would lead to public ridicule, career destruction, and worse. Furthermore, the FDA Tweet still exists. The federal government's orthodoxy on COVID-19 injections, endorsing an all or nothing approach in favor of a brand new ultracomplex technology whose real-world application had never been used, and "warp speed" implementation that had never been tested, eroded public confidence in those historically safe products.

COVID-19 mRNA claims of sterilizing individual immunity and claims of "prevent the spread" were not accurate. The distrust among Americans is clear: According to an October 24 *Politico* article—almost two months after the 2023 updated COVID-19 boosters were authorized—only a mere 3.6

[2]U.S. Food and Drug Administration, "Updated Instructions for Submitting Lot Release Samples and Protocols for CBER-regulated Products During the COVID-19 Pandemic," January 25, 2021, https://archive.ph/iIv4b#selection-923.0-923.126 (accessed March 19, 2024).

percent of Americans have gotten their COVID-19 updated shot[3] and only about 4.8 percent have gotten the influenza vaccine as of the established CDC deadline of October 31.[4]

We know with a very good deal of certainty that older, established therapies could have been inexpensively and successfully deployed, during which time novel approaches could have carefully and slowly tested at "*non-warp* speeds."

Questioning the FDA Not Allowed?

Just because some people in the government and private industry have a loud, powerful voice does not mean that they are right. It just makes them seem like bullies. Bullying has no place in medicine OR any other scientific discipline. Bottom line: Intelligent scientific dialectic should not only be encouraged; it should be *required*. Instead, it was *quelled*.

Medical scientists have not only the *right*—but the *duty*—to ask well-founded and basic questions about the quality and consistency of an unnecessarily complex pharmaceutical jammed through an expedited review process when inexpensive, *legitimately* safe and effective alternatives exist. The professions of medicine and pharmacy—especially their leadership—have *outrageously* failed to foster an intellectual exchange and have behaved obsequiously to FDA approvals and government mandates even though product transparency was non-existent.

Vaccine Safety Surveillance and the FDA's MedWatch Surveillance System

The drug safety researchers can learn important lessons from the development, production, and distribution of the COVID-19 injections. The United States' MedWatch surveillance system which includes the Vaccine Adverse Event Reporting System (VAERS) could be used more aggressively to warn patients about adverse events. In fact, the FDA's office of post-marketing safety of drugs and therapeutic biologics has stated in official proceedings that "just one well-documented report [of an adverse event] can be viewed as a safety signal."[5]

According to published literature and FDA regulatory action, VAERS is an understated, underemphasized, underutilized system for reporting adverse reactions to drugs. Despite being an imperfect system, it has historically been used to make official, important labeling changes.

FDA officials have stated that adverse event reports to AERS and VAERS are followed up via requests for status updates and official requests for medical records as part of its duties, including during Part One of this hearing in February 2024. That sort of follow-up documentation in addition to the initial routine data collection vigilance used during verbally submitted reports by intake personnel certainly seems to indicate that the collected events, if not initially confirmed, are later verified with empirical

[3]"'On Track' 3 Percent of Americans Have Gotten the New Covid Shot, but the CDC Director Remains Confident," *Politico*, October 24, 2023, https://archive.ph/w36En (accessed March 19, 2024).
[4]"The CDC recommends that people ages 6 months and older get a flu vaccine by the end of October." U.S. Food and Drug Administration, "It's a Good Time to Get Your Flu Vaccine," September 14, 2023, https://archive.ph/8tX0d#selection-835.0-835.40 (accessed March 19, 2024).
[5]U.S. Food and Drug Administration, Office of Special Health Issues, "Webinar on Postmarketing Safety of Drugs and Therapeutic Biologics," June 7, 2010, https://archive.ph/ob2tB (accessed March 19, 2024).

medical documentation.

Comparing Historical Threshold for Labeling Changes Related to Adverse Events

Fluroquinolone antibiotics as an entire class, for instance, now have a very prominent boxed warning on its labels to inform pharmacists, physicians, and patients of "tendonitis" as a non-lethal adverse event, relative to the adverse events of COVID-19 RNA injections. Tendonitis is a relatively minor to moderate pain that typically resolves on its own with drug discontinuation, rest, and non-prescription treatments such as ACE bandage wraps or ice compresses.

In fact, back in 2008, there were only 341 reported cases of tendonitis reported over a 10-year period in AERS for fluroquinolone antibiotics (November 1997–December 2007).[6] The same AERS review reported only 407 cases of tendon rupture, which can sometimes be a more painful, but ultimately non-lethal adverse event. Study authors acknowledged that only a small fraction of cases is typically reported to the FDA, the actual number of ruptures and other tendon injuries attributable to the antibiotic is much higher. Furthermore, those few hundred cases occurred across four different fluroquinolone antibiotics (levofloxacin [Levaquin], ciprofloxacin [Cipro], moxifloxacin [Avelox], and ofloxacin and gemifloxacin [Factive]), which are in turn found in more than 60 different prescription products.[7]

Now, compare those 341 (or 407) cases to the *over 1 million adverse* event reports shown in VAERS from just two COVID-19 RNA products. Those include but are not limited to:

- >18,000 deaths
- >89,000 hospitalizations
- >118,000 emergency department visits
- >2,000 anaphylaxis cases
- >6,000 cases of Bell's palsy
- >2,000 miscarriages
- >9,000 heart attacks
- >18,000 cases of permanent disabilities
- >15,000 cases of life-threatening adverse events
- >36,000 allergic reaction cases
- >8,000 shingle cases

Reported with the administration of mRNA COVID-19 injections *in the United States alone*. That number would putatively be many orders of magnitude larger if it were collected across *all* countries worldwide where COVID-19 RNA injections were given.

[6]Janice Hopkins Tanne, "FDA Adds 'Black Box' Warning Label to Fluoroquinolone Antibiotics," *British Medical Journal*, Vol. 337: a816, July 19, 2008, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2483892/ (accessed March 19, 2024).
[7]News release, "FDA Updates Warnings for Fluoroquinolone Antibiotics," U.S. Food and Drug Administration, July 26, 2016, https://www.fda.gov/news-events/press-announcements/fda-updates-warnings-fluoroquinolone-antibiotics (accessed March 19, 2024).

Few MedWatch Adverse Events Reported

Both FDA officials and published works, including those published by Harvard and sponsored by the Agency for Healthcare Research and Quality (AHRQ) have confirmed that only very low numbers (fewer than 1 percent) are ever reported to VAERS (the largest adverse event surveillance system), in particular.[8] If extrapolated as per the estimations in that Harvard study, the numbers listed above would be much, *much* higher than the figures listed above—which include those in the United States alone, but the FDA makes no attempt to perform *any* extrapolation and discourages anyone else from doing the same without a clear explanation as to why.

According to the published information on fluroquinolones labeling changes in Medline, the FDA *appears to be* duplicitous about its relative consideration of adverse events. When it suits their narrative, the FDA *appears* to make major labeling changes following a few hundred reported adverse events spread out over *an entire decade* involving *dozens of different products*, yet the FDA *appears to* simultaneously decline to issue warnings following tens of thousands of critically important adverse events currently related to just two COVID-19 mRNA injections spread out over just two to three years, as detailed above. Even then the *British Medical Journal* study authors derided the FDA for not making their labeling changes earlier in the case of fluroquinolones, stating that the correlation was seemingly clear and that the labeling change should have been made years before – and that was just for cases involving tendonitis and/or tendon rupture.

Is Correlation *Never* Causation at the FDA, Even With so Many mRNA Adverse Events?

Correlation tests for a relationship between two variables. As is known in epidemiology, seeing two variables moving together does not necessarily mean we know whether one variable causes the other to occur.

Like the Members of Congress on this panel, even with two decades of experience in drug development, pharmacology, pharmacy, and two tours of duty at the FDA, I have technical unanswered questions as well. Some of those questions regarding the FDA's MedWatch system would be: Is correlation *never* causation? If not, what about relative correlation to the fluroquinolone tendon-related adverse events? Is that relative "low bar" not extrapolatable to other adverse events, as in the case of COVID-19 RNA shots, especially considering the increased severity of COVID-19 adverse events? If not, why not? If the currently *over one million* adverse events reports are not causation, what alternative explanation is there for this deluge of adverse events? Would the FDA or manufacturers change its thinking if there instead were *two* million adverse event reports? What about *three* million reports? These questions become more poignant when one considers the fully FDA-acknowledged under-reporting in VAERS and other MedWatch databases and what *appears to be* a remarkably lower threshold for labeling change as compared to fluroquinolone antibiotics.

Thank you again for the opportunity to testify here today and I would be happy to foster an intellectual

[8]Ross Lazarus, "Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)," U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality (AHRQ), Grant ID: R18 HS 017045, https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf (accessed March 19, 2024).

exchange on this critically important topic.

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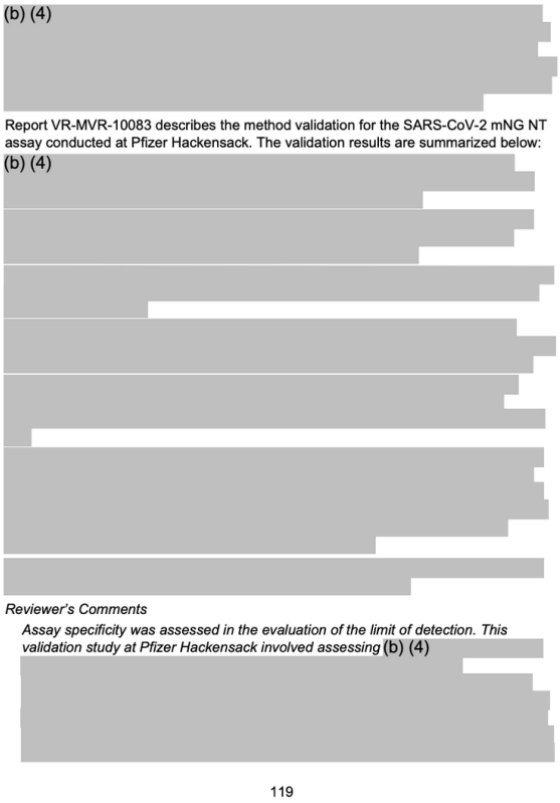
APPENDIX 1: SAMPLE REDACTED PAGE

One such sample page containing manufacturing and testing information is shown below:


(b) (4)

Report VR-MVR-10083 describes the method validation for the SARS-CoV-2 mNG NT assay conducted at Pfizer Hackensack. The validation results are summarized below:

(b) (4)

Reviewer's Comments

Assay specificity was assessed in the evaluation of the limit of detection. This validation study at Pfizer Hackensack involved assessing (b) (4)

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In the sample immediately above, a tremendous amount of critically important information from the official FDA Chemistry Manufacturing and Controls report[1] (ie, how its manufactured and tested for quality assurance) including FDA critique/commentary are redacted to the point that nobody other than the FDA or manufacturers could ever test the quality or fully know the ingredients in COVID-19 mRNA shots. In this 127-page document, about half of the pages were 100% redacted and the remaining about 30% redacted making the entire document unintelligible, such as the one sample page shown above. Those FDA (b)(4) redactions[2] specified detailed redactions used to "*protect[s] trade secrets and confidential commercial or financial information*." But is it really appropriate to label COVID-19 mRNA injections "commercial" if the research/development/product was funded with hundreds of millions of *taxpayer dollars*?[3]

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[1]U.S. Food and Drug Administration, Chemistry Manufacturing and Controls Review Memorandum, August 21. 2021, p. 119, https://web.archive.org/web/20240105112728/https://pink.citeline.com/-/media/supporting-documents/pink-sheet/2022/05/cmc-review-memo--august-21-2021--comirnaty.pdf?rev=9f926c57796f427eb7da8ccf8d5fdf53&hash=26A228D0AA3A554A05096716961D817E.

[2]U.S. Food and Drug Administration, Freedom of Information, https://www.fda.gov/regulatory-information/freedom-information/foi-information.

[3]Niall McCarthy, "The Top Recipients of Covid-19 R&D Funding," Statista, May 6, 2021, https://www.statista.com/chart/24806/main-recipients-of-covid-19-investments/.

In fair defense of the FDA, it is unclear if those documents were hyper-redacted by the FDA or if there was some codicil within the Public Readiness and Emergency Preparedness Act (PREP Act) or something with the Emergency Use Authorization (EUA) authority or liability protections for pandemic and epidemic products in the Public Health Services Act that grants manufacturers the ability to redact technical data as they see fit, despite making technical documents impossible to decipher to anyone other than the FDA or manufacturers.

Obviously, it is problematic to attempt to assess the safety of any product without being able to know and compare the exact quality, quantity, structure to the known ingredient list of the product. One study has shown a widely differing adverse event profiles relative to lot/batches, potentially meaning that variable product quality could play an important role in the safety of COVID mRNA injections. One such example is a Danish safety study[4] which detailed a highly deviant pattern of adverse event reports from COVID mRNA injections based on different batches, as correlated with the Danish adverse event reporting system.

[4]Max Schmeling, Vibeke Manniche, Peter Riis Hansen, "Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine," European Journal of Clinical Investigation, Volume 53, Issue 8, August 2023, https://onlinelibrary.wiley.com/doi/10.1111/eci.13998.