To: Brandon

From: Pritish

Subject: Coker v Austin Supplement Response

THE PFIZER KALAMAZOO FACILITY IS NOT AN APPROVED FACILITY FOR COMIRNATY GREY CAP VIAL

This is why the Defendants' claim regarding Kalamazoo is FALSE:

The ONLY mention of Comirnaty in Defendants' latest supplement is buried in a footnote (See ECF 118, page 9):

"Plaintiffs' last-ditch effort to salvage those claims in their latest filing, see ECF No. 117, fails because FDA has approved the manufacture of the Tris/Sucrose formulation of ***Comirnaty*** *in Michigan…"*

Defendants then refer to a declaration by Suzann Burk, where she does NOT mention "Comirnaty" when referencing the Kalamazoo facility. (See ECF 118-1, paragraph 5):

"*Attached hereto as Exhibit 1 is a copy of the redacted supplemental approval letter dated January 14, 2022, from FDA to BioNTech Manufacturing GmbH, adding 30 ug Tris/Sucrose formulated drug product manufacturing at the Pharmacia and Upjohn Company LLC facility in Kalamazoo, Michigan. I certify that Exhibit 1 is an official FDA record."*

Exhibit 1 of the Defendants' supplement does NOT mention the product "Comirnaty." (See Doc 118-1, letter from FDA to Pfizer dated January 14, 2022).

"We have approved your request submitted and received December 17, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act ***for COVID-19 Vaccine, mRNA*** *to add 30 µg Tris/Sucrose formulated drug product manufacturing in Building , with fill and finish operations on Line at the Pharmacia and Upjohn Company LLC facility in Kalamazoo, MI."* (Emphasis added).

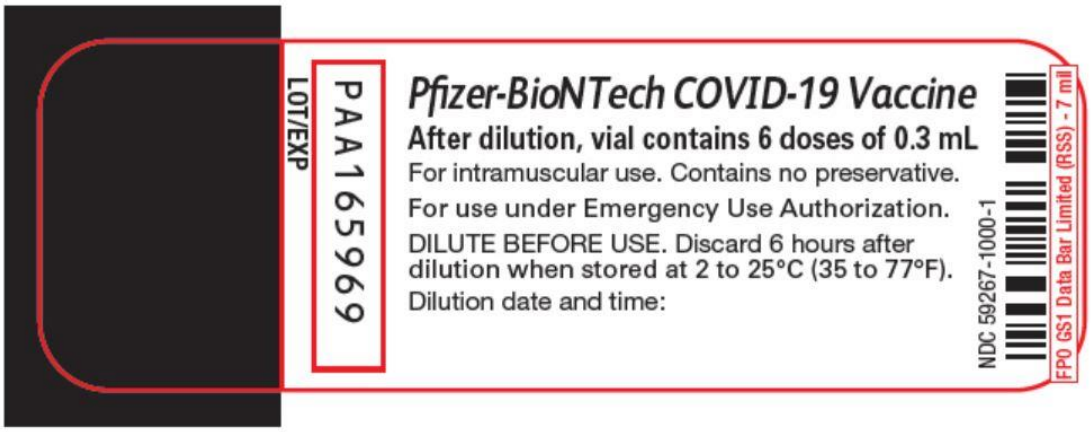
The letter is a phony, a fake. The Adobe signature by Carolyn Renshaw can easily be manipulated to "backdate" the signature for January 14, 2022.

TIMELINE OF THE PACKAGE INSERTS

I. The ORIGINAL Pfizer-BioNTech Covid-19 vaccine was an EUA product, with an EUA label. (Emphasis added). The label has an NDC (National Drug Code) identifier of 59267-1000.

The label can be found on NIH.gov and a picture of it is here:

PFIZER-BIONTECH COVID-19 VACCINE- bnt162b2 injection, suspension



As clearly stated on the label, the product is "For use under Emergency Use Authorization." This means it cannot be mandated by DoD.

As also clearly stated on the LABEL, it says "DILUTE BEFORE USE." This indicates the product is the Purple Cap vial, and originally marketed and distributed through interstate commerce.

This package insert has a "Marketing Start Date of 12/12/2020" which is the NEXT day after FDA authorized the emergency use of the product.

This package insert has NO "Marketing End Date" as the product is still being distributed through interstate commerce for the U.S. Military and the public.

The LABELER for this product is Pfizer Manufacturing Belgium NV. It has an FEI number of 370156507. "FEI" stands for FDA Establishment Identifier which is a number assigned by FDA and used for tracking inspections.

The link to confirm this fact regarding the definition of FEI is here:

https://www.accessdata.fda.gov/cder/Submissions_Pt1/topic3/topic3/da_01_03_0055.htm

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59267-1000-2	195 in 1 CARTON		
1	NDC:59267-1000-1	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:59267-1000-3	25 in 1 CARTON		
2	NDC:59267-1000-1	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EMERGENCY USE AUTHORIZATION		12/12/2020	

As the screen shot clearly indicates, the product is for "EMERGENCY USE AUTHORIZATION" and also clearly indicates the Marketing Start Date with no Marketing End Date, thus it is an EUA labeled Pfizer-BioNTech product currently available to the members of the Armed Forces. It is NOT "BLA compliant."

There are/were TWO facilities approved to conduct the analysis, manufacture, pack and LABEL of this product. The TWO facilities are Pfizer Manufacturing Belgium NV (i.e., Puurs, Belgium) and Pharmacia & Upjohn Company in Kalamazoo, Michigan.

The screen shot to confirm this fact is also in the EUA package insert:

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EMERGENCY USE AUTHORIZATION		12/12/2020	

Labeler - Pfizer Manufacturing Belgium NV (370156507)

Registrant - Pfizer Inc (113480771)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	ANALYSIS(59267-1000) , MANUFACTURE(59267-1000) , PACK(59267-1000) , LABEL(59267-1000)

Establishment

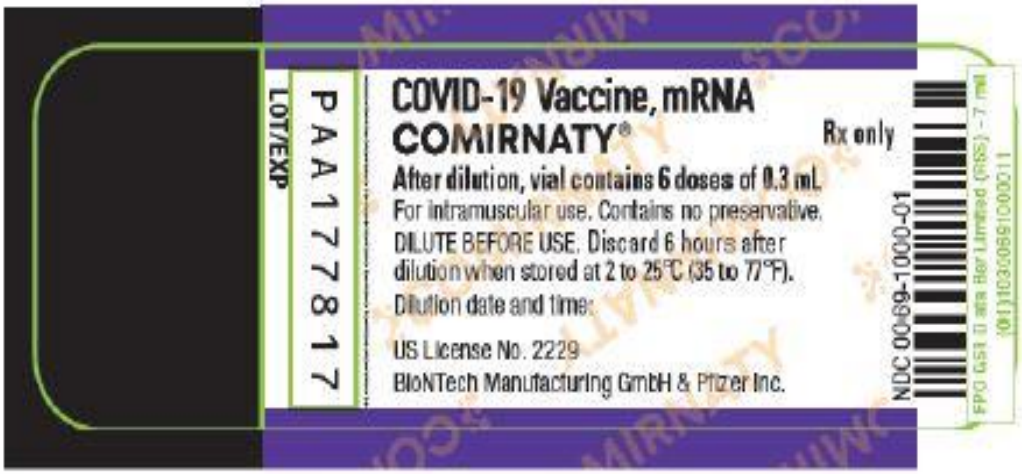
Name	Address	ID/FEI	Business Operations
Pharmacia & Upjohn Company LLC		618054084	ANALYSIS(59267-1000) , MANUFACTURE(59267-1000) , PACK(59267-1000) , LABEL(59267-1000)

The package insert was REVISED as of 9/2022 and is still in effect today. Defendants are playing a clever sleight-of-hand, as the Kalamazoo facility is/was a facility to conduct the analysis, manufacture, pack and label according to the package insert. However, this is for the original version of the Pfizer-BioNTech EUA vial (Purple Cap, must dilute), **NOT for Comirnaty**. (Emphasis added).

II. THE FDA APPROVAL OF COMIRNATY AND PACKAGE INSERT

The ORIGINAL product that was approved by FDA (i.e., Comirnaty, Purple Cap, must dilute) was NEVER produced, and thus was not ever available. This is factually stated in the Amicus Briefs and in the Federal Complaints.

The NDC label identifier was 0069-1000, which was NOT marketed through interstate commerce. A screen shot of the label is here, which clearly states "DILUTE BEFORE USE" which corresponds to the Purple Cap vial:



Unfortunately for Defendants, the package insert for the original Purple-Cap vial of Comirnaty has a marketing start AND end date of August 23, 2021, the SAME DAY as the FDA "approval" and the day PRIOR to the DoD mandate.

The screen shot below shows BOTH facilities listed to conduct the analysis, manufacture, pack and LABEL for the Purple-Cap Comirnaty:

Pfizer, Belgium (located Rijksweg 12, 2870 Puurs-Sint-Amands, Belgium)

Pharmacia & Upjohn Company, LLC (i.e., Pfizer Kalamazoo)

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125742	08/23/2021	08/23/2021

Labeler - Pfizer Laboratories Div Pfizer Inc (134489525)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	ANALYSIS(0069-1000) , MANUFACTURE(0069-1000) , PACK(0069-1000) , LABEL(0069-1000)

Establishment

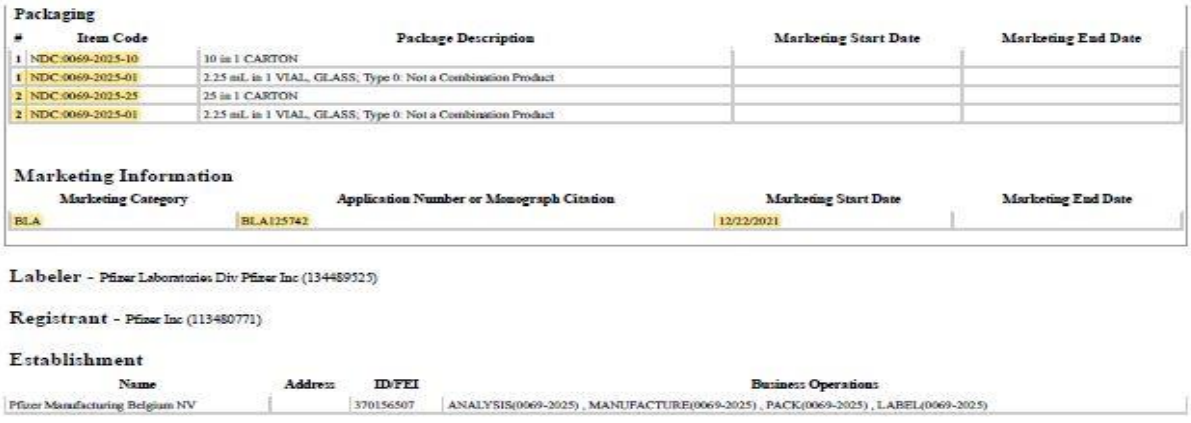
Name	Address	ID/FEI	Business Operations
Pharmacia & Upjohn Company LLC		618054084	ANALYSIS(0069-1000) , MANUFACTURE(0069-1000) , PACK(0069-1000) , LABEL(0069-1000)

The Kalamazoo facility was therefore ONLY approved to manufacture, pack and LABEL the following: the ORIGINAL Pfizer-BioNTech EUA Purple Cap vial (currently available) and the ORIGINAL Comirnaty FDA approved Purple Cap vial (which was NEVER available because it was never produced, despite the FDA claim that there was "not sufficient approved enough available").

The FDA granted BLA Supplement Approval on December 16, 2021, to include the new 30 microgram dose formulation of the Tris/Sucrose of COMIRNATY in a GREY CAP (non-dilute) and manufactured at the Pfizer Manufacturing facility Belgium, NV in Puurs.

The package insert for the Comirnaty Grey Cap vial has ONE, and ONLY ONE, facility approved to conduct all FOUR functions: analysis, manufacture, pack AND label: Pfizer Manufacturing Belgium NV (i.e., Pfizer, Puurs).

The package insert also has a marketing START date of December 22, 2021, with NDC label identifier of 0069-2025 (Grey Cap, Comirnaty-labeled, do not dilute). The package insert has no current marketing end date.



Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-2025-10	10 in 1 CARTON		
1	NDC:0069-2025-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:0069-2025-25	25 in 1 CARTON		
2	NDC:0069-2025-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125742	12/22/2021	

Labeler - Pfizer Laboratories Div Pfizer Inc (134489525)

Registrant - Pfizer Inc (113480771)

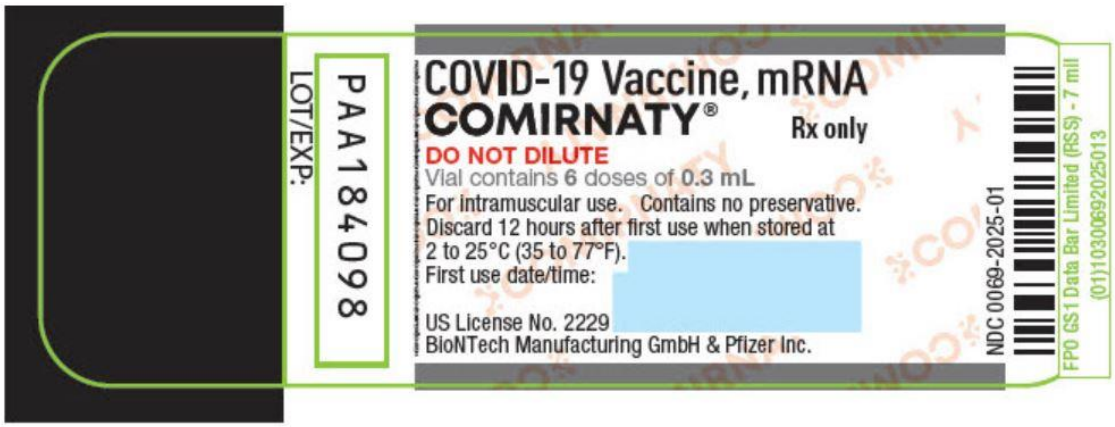
Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	ANALYSIS(0069-2025) , MANUFACTURE(0069-2025) , PACK(0069-2025) , LABEL(0069-2025)

The screen shot for the label and the package insert are found below. As one can clearly see, the label says "DO NOT DILUTE" which indicates it is the Grey Cap. It has the NDC number 0069-2025 that corresponds to the NIH.gov website. Unfortunately for Defendants, the PACKAGE INSERT does NOT list the Pharmacia & Upjohn Company, LLC (i.e., the Kalamazoo Pfizer facility) as an approved facility to manufacture, pack OR label the product.

Defendants' claim is false. Defendants will fail to show (and cannot show) any package insert that lists Kalamazoo, MI as an approved facility for the GREY CAP Comirnaty vial, because no such package insert exists.

COMIRNATY- covid-19 vaccine, mrna injection, suspension



The next package insert had a Marketing Start Date of May 18, 2022 (revised July 2022). This package insert ALSO shows Pfizer Manufacturing Belgium NV as the facility to manufacture, pack and LABEL the Comirnaty Grey Cap vial. Any claim stated otherwise is FALSE.

The Manufacturing "End Date" is blank because the Belgium facility is still approved to manufacture the product, pack the product and LABEL the product, even though NO such product is currently available through interstate commerce.

Defendants are thus operating by way of deception, to trick the Court into accepting the false narrative that the "Comirnaty-labeled" product was manufactured in Kalamazoo thus it is FDA approved. No! Even if it was manufactured in Kalamazoo, it is still an EUA vial mislabeled as an FDA vial.

Lt. Chad Coppin filed a FOIA request to the FDA. In that FOIA request, he specifically requested the location of the analysis, manufacture, pack AND label of

LOT FW1331. The FDA responded with the same information that Defendants filed on the Coker docket: that Kalamazoo was where the lot was manufactured. However, that is NOT an approved facility where the lot can be LABELED. **The Lot FW1331 is nothing more than an EUA product with an FDA label. It is a phony, a fake.** (Emphasis added).

Here is the screen shot of the Comirnaty Grey Cap Tris/Sucrose package insert that shows Belgium as the ONLY facility approved to label the product.

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0069-2025-10	10 in 1 CARTON		
1	NDC:0069-2025-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
2	NDC:0069-2025-25	25 in 1 CARTON		
2	NDC:0069-2025-01	2.25 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125742	05/18/2022	

Labeler - Pfizer Laboratories Div Pfizer Inc (134489525)

Registrant - Pfizer Inc (113480771)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	ANALYSIS(0069-2025) , MANUFACTURE(0069-2025) , PACK(0069-2025) , LABEL(0069-2025)

Defendants made a claim that they were only able to order the product on May 20, 2022. Yet, the LOT FW1331 was filled in January 2022. What happened in the interim? Where was the product distributed during this time, if ever?

Indeed, even the most recent FDA BLA SUPPLEMENT letter dated August 22, 2022, states the filling lines for the product is to be filled is in Puurs, Belgium.

https://www.fda.gov/media/161227/download

"We have approved your request received on June 10, 2022, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for COVID-19 Vaccine, mRNA (COMIRNATY), manufactured at the Pfizer Manufacturing Belgium NV, Puurs, Belgium (Pfizer, Puurs), Pharmacia & Upjohn Company LLC, Kalamazoo, Michigan (Pfizer, Kalamazoo) and Hospira, Inc., McPherson, Kansas (Pfizer, McPherson) facilities, to include the introduction of the Monovalent Tris/Sucrose (30 mcg) Single Dose Vial with 0.48 mL Fill Volume ***to be filled on and filling lines at the Puurs, Belgium location****, and associated labeling changes."* (Emphasis added).

There are several BLA SUPPLEMENT letters for Comirnaty on the FDA.gov site. The January 14, 2022 letter cited by Defendants via the Burk Declaration is NOT one of them.

The link for all the letters is here, and the screen shot appears on next page:

https://www.fda.gov/vaccines-blood-biologics/comirnaty

Where is the January 14, 2022 letter filed by Defendants? It magically arrived prior to the deadline for Defendants' supplement filing in Coker, what impeccable timing! Just as the "Comirnaty-labeled" vial magically arrived when Defendants were unable to get the case dismissed with their PRIOR supplement filing regarding Spikevax. The FDA.gov site ALSO lists a slew of documents regarding BLA SUPPLEMENT APPROVAL of Comirnaty.

This includes but is not limited to: The December 16, 2021 approval letter, the July 8, 2022 approval letter, and the August 22, 2022 approval letter. ALL of those approval letters use the word "COMIRNATY" within the body of the letter, **whereas the magical letter dated January 14, 2022 does not**. (Emphasis added).

The FDA did not use the word "Comirnaty" in that letter, because the FDA cannot legally link the Comirnaty-labeled vial to the Kalamazoo facility. As stated, and as evidenced by the package inserts, the Comirnaty-labeled Grey Cap vials can ONLY be manufactured, packed and LABELED in the Puurs, Belgium facility.

The link for the item “Approval History, Letters, Reviews, and Related Documents-COMIRNATY” does NOT include the January 14, 2022 letter. Instead, it opens up a zip file. When unzipped, it shows another slew of documents. The screen shot for the supporting documents is here:

Supporting Documents

- August 25, 2022 Approval Letter - COMIRNATY
- July 8, 2022 Approval Letter - COMIRNATY
- July 8, 2022 Clinical Review Memo - COMIRNATY
- Statistical Review - COMIRNATY
- December 16, 2021 Approval Letter - COMIRNATY
- November 8, 2021 Summary Basis for Regulatory Action - COMIRNATY
- August 23, 2021 Approval Letter - COMIRNATY
- Approval History, Letters, Reviews, and Related Documents - COMIRNATY

The zip file (when unzipped) does NOT include the January 14, 2022 letter.

Name

- Analytical Method Review Memo - COMIRNATY
- Benefit-Risk Assessment Review Memo - COMIRNATY
- Bioresearch Monitoring Discipline Review Memo, August 13, 2021 - COMIRNATY
- CBER CMC BLA Review Memo - COMIRNATY
- CBER Sentinel Program Sufficiency Memo - COMIRNATY
- Clinical Review Memo, August 23, 2021 - COMIRNATY
- CMC Review Memo, August 21, 2021 - COMIRNATY
- Employee-Officer List Memo, August 22, 2021 - COMIRNATY
- Pharmacovigilance Plan Review Memo - COMIRNATY
- Pharmacovigilance Plan Review-Addendum Memo - COMIRNATY
- Real World Evidence BLA Memo - COMIRNATY
- Statistical Review - COMIRNATY
- Statistical Review -- COMIRNATY
- Statistical Review-COMIRNATY
- Toxicology Review - COMIRNATY

CONCLUSION

Why has Judge Winsor not ruled on the Amicus motion for leave to file Amicus Curiae in January (ECF 66-1), the Amicus motion for leave to file the supplement brief (ECF 84-1), and the Amicus motion for leave to file in support of the Plaintiffs' motion to compel (ECF 99-1)?

The information supplied by the Amicus briefs supports the Amended Complaint, supports the motion to compel, and is quite damaging to Defendants. Judge Winsor knows it. Judge Winsor has clearly shown his bias in favor of the Defendants. It would be extremely beneficial to the Plaintiffs to reference and/or mention the Amicus briefs in the Plaintiffs' supplement response. This is because the information is vital to support the Plaintiffs' claims and will support the Plaintiffs in the event of an appeal to the 11th Circuit.

In a nutshell: The Defendants got sloppy. They created a "backdated" letter to support the false narrative of the Comirnaty Tris/Sucrose Grey Cap vial to be manufactured and filled in Kalamazoo, using the word "BLA" but omitting the word "compliant" or "Comirnaty." However, they neglected the fact that the **PACKAGE INSERT** for December 2021, May 2022 and July 2022 only lists the Puurs, Belgium facility to conduct the final FILL, PACK, and LABEL. (Emphasis added). The declaration by whistleblower Lt. Chad Coppin is factually correct. The declaration by Suzann Burk is more suitable for the shredder.

By now it should be abundantly clear to the Court that **NOBODY has received an FDA-approved Covid-19 vaccine, because no such vaccine is/was available**. (Emphasis added). To state otherwise, and/or for a Federal District Court Judge to opine otherwise, is to engage in a blatant act of willful blindness.