Melissa McAtee
Pfizer Testimony

Employed by Kelly Services to be a temp for Hospira in September 2012

First job was a Pharmaceutical Assistant for P6

Converted to full time Hospira Employee April 2013

Pfizer Purchased Hospira in 2015

Promoted to Manufacturing Quality Auditor in April 2017

Went on a Mental Health LOA August 24, 2021

Project Veritas Interview aired October 6, 2021

Terminated by Pfizer October 20, 2021

KANSAS GAS SERVI MELISSA STRICKLER ACH DEBIT UTIL PAYMT AUG 06, 2021	-$52.00
PFIZER INC MCATEE,MELISSA K. ACH CREDIT PPD AUG 06, 2021	$791.65

My Maiden name is Strickler

- I was Married July 3, 2021
- Pfizer had not given me a new badge by the time I left.

Manufacturing Quality Auditor

SAVE

Pfizer
McPherson, KS

Apply on Levels.fyi | Apply on Jooble | Apply on Trabajo.org | Apply on Lensa | Apply on JobsinSAS.com

20 days ago | $ 41,600–68,640 a year | Full-time | No degree mentioned | Health insurance | Dental insurance | Paid time off

Job highlights

Identified by Google from the original job post

Qualifications

- High school diploma with a minimum of 1+ years of related experience in a regulated industry with knowledge to provide guidance on quality related topics
- Knowledge of FDA regulations, specifically cGMPs
- Computer skills (Microsoft Office, Excel)
- Excellent organizational, interpersonal and communication skills (oral and written)
- Proven ability to make decisions and work with minimum supervision
- Decision making and problem-solving abilities
- Previous QA or QC experience in a regulated industry
- Previous experience in a field that requires priority on detail management in a self-regulated work environment
- Knowledge of specialized processes that require attention to detail such as basic accounting, operation of equipment, basic computer operations or bookkeeping software
- Previous experience in controlled records documentation
- May require lifting 35 lbs
- or less, sitting, standing for periods of up to 90 minutes, walking, bending for extended periods of time, and performance of repetitive motions for up to 60 minutes
- Must also be able to perform mathematical calculations and some data analysis
- Non-Standard Work Schedule, Travel, Or Environment Requirements

Responsibilities

- The MQ Auditor is the primary quality contact for production personnel
- This role will monitor production processes for compliance to cGMP standards
- Auditors perform and document the testing and inspection results to support product disposition and decisions based on inspection outcomes
- Performs multiple functions and makes decisions in support of production processes
- Ensures quality of finished product through sampling, testing and evaluation of drug products, as well as accuracy and completeness of batch record and audit documentation
- Audit compliance of product and processes against governing documents
- Obtain a representative number of samples for visual inspection, physical testing (where applicable), retains and stability studies
- Inspect and verify critical product labeling information for accuracy to ANSI AQL Z.14 standards
- Manage multiple priorities and effectively communicate priorities to interdepartmental partners
- Perform calibration of tools used for inspection activities
- Use critical thinking and problem-solving skills to identify and correct situations which would create delays and/or downtime of equipment
- Perform review of environmental conditions for controlled areas
- Act with ownership and make quality decisions

Why I am speaking out

[16]*Qui tam* is shorthand for the Latin phrase, *qui tam pro domino rege quam pro seipso*, meaning "He who is as much for the king as for himself." *Qui tam* statutes date back to thirteenth-century England. The actions were a means of enabling private parties to allege the king's interest and therefore gain access to the royal courts.

The *qui tam* provisions of the federal False Claims Act allow any citizen who has knowledge of fraud that has taken place against the government to bring a civil action in federal court in the name of the United States. In return for his or her efforts, the citizen is entitled to share in the proceeds of the recovery. The *qui tam* provisions raise the incentive for insiders to put the spotlight on the criminals, thereby providing the government with tangible and detailed evidence upon which to base an investigation and prosecution.

In 1986, Congress enacted amendments to the False Claims Act which strengthened the law and increased monetary awards. When hearings were held in 1985 and 1986, the climate was favorable for strengthened antifraud legislation, and Congress expected that most *qui tam* cases would involve defense contractor fraud. In the last decade, the majority of cases have instead been against the health care industry.

[17]Even so, factual questions will be raised, including: (1) Even with the false representations, was a false claim "caused" to be submitted? (2) Had the FDA known about the falsities, would it have enjoined the manufacturer from any further production, etc? (3) What about the false record or statement made the claims for such drugs false?

Congress stated the rationale for imposing cGMP on the pharmaceutical industry this way[1]:

> The manufacturing of drugs is a business that requires highly qualified and trained personnel, and special laboratory and other facilities and most careful internal manufacturing, packaging, and labeling controls. These requirements are necessary to the assurance that the drugs will be safe for the user and will have, and so far as possible retain, the identity, strength, quality, purity, and effectiveness that they purport to have.

The purpose of the cGMP requirement is to prevent injury and death "by building quality into the design and production of pharmaceuticals," [2] so that substandard prescription drugs do not jeopardize the health and safety of the patients.

The cGMPs require manufacturers to have adequately equipped manufacturing facilities, adequately trained personnel, precisely controlled manufacturing processes, appropriate laboratory controls, complete and accurate records and reports, appropriate finished product examination, and so on. Current GMPs are not "best practices"; rather, they establish threshold or *minimum* standards which must be satisfied in order for a pharmaceutical manufacturing operation to be compliant.

Qui tam whistleblowers,[16] however, have already begun bringing such cases. Because the False Claims Act imposes liability on any government contractor which knowingly submits false claims to the United States or which uses false documents to get a false claim paid, a pharmaceutical manufacturer which knew or was recklessly indifferent to the fact that the manufacturing process was compromised by cGMP violations is in the same position as any other contractor which is required to conform to contractual or regulatory standards. The basis of liability under the False Claims Act is that false records have been generated which caused (false) claims for drugs to be paid by the United States.[17] The monetary damages result because the payor (in this case, the United States) is potentially paying for substandard drugs due to the cGMP violations—later covered up by false statements in documents required to be completed under the cGMP.

It makes sense, too: The cGMPs are a set of regulations which, by their very nature, are designed to ensure that drugs are manufactured in such a way that they meet the requirements of the federal Food, Drug and Cosmetic Act as to safety and have the identity and strength and meet the purity characteristics that they purport or are represented to possess. The major federally funded government health care programs, Medicare and Medicaid, operate under the express provisions that they will only pay for medical services and products that are "reasonable and necessary." Unsafe or ineffective drug products are neither reasonable nor necessary. Accordingly, as the theory goes, the United States suffers monetary damages if Medicare and Medicaid programs pay for unsafe or less effective products. These and other federally funded health care programs spend billions of dollars every year on pharmaceuticals.

False representations concerning minor or technical violations will not be the basis for FCA liability. Distribution of products that are not totally cGMP compliant (but have been falsely documented to be) does not necessarily result in unsafe (or subpotent) products. Substantial violations of the cGMP, later covered up in writing, however, could very well be the basis for FCA liability. The common thread through each violation is that the violation is severe enough so that the drug product that

1.3.5.2 Process Validation

Process validation is an important part in the implementation of a postapproval change. It establishes the documented evidence of conformance of a pharmaceutical operation in accordance with specifications. FDA "Guideline on General Principles of Process Validation" describes in detail the principles and practices of process validation and documentation required by the regulatory authority [13]. In general terms, process validation may be defined as the procedure which generates sufficient assurance and documented evidence that a particular operation is operating and producing drug products in accordance with the specifications and process controls.

Prospective validation, retrospective validation, concurrent validation, and revalidation are the four validation components. Prospective validation is performed before the distribution of drug products in the market or after the manufacturing of a drug product using revised changes that can affect product quality and characteristics. Retrospective validation is conducted for an established drug product whose manufacturing process is stable to ensure that the current pharmaceutical operation is performing as per the protocols and specification and yielding satisfactory product. Concurrent validation is conducted by monitoring in-process critical manufacturing parameters and end-product testing to ensure that the current manufacturing process is per the in-process control specifications. Revalidation is performed after changes to an approved drug product are implemented to ascertain that there is no adverse effect on the quality and performance of a drug product [16].

During a validation process, the products and processes are subjected to testing at extreme conditions of in-process limits and their performance is evaluated against the acceptance criteria. The parameters of different pharmaceutical operations are varied and product properties are recorded and evaluated (Figure 3). When it is found that adjustment is required, necessary actions are taken in consultation with R&D personnel. Generally, validation data of three production scale batches are compared to generate a high level of quality assurance.

1.1.2 21 CFR 210 AND 211: CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Parts 210 and 211 of CFR Title 21 are the laws defining good manufacturing practices for finished pharmaceutical products. All manufacturers must follow these regulations in order to market their products in the United States. When a firm files an application to market a product in the United States through a New Drug Application (NDA), abbreviated NDA, (ANDA), Biological License Application (BLA),

or other product application, one of the last steps in approving the application is a preapproval inspection of the manufacturing facility. A major purpose of this inspection is to assure adherence to the GMP regulations. Preapproval inspections are a part of every application approval. Thus, if a firm has 10 applications pending, it should expect 10 inspections. The fact that the manufacturing facility has already been inspected will not alter the need for another inspection.

The FDA also has the right to visit and inspect any manufacturing facility that produces a product or products sold in the United States. Such inspections are unannounced. A manufacturer must admit an inspector when he or she appears at that facility and must do so without undue delay.

GMP requirements for manufacturers of pharmaceutical dosage forms are discussed below. This information should not be considered to be an exact statement of the law. We have attempted to show intent and, occasionally, add some comments that will clarify how that particular regulation is interpreted. For precise wording of a regulation, refer to the CFR and then check the *Federal Register* to determine if there have been any changes since the last update.

Click here to learn more about the current Covid-19 Pfizer information.

Pfizer

More Info

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Covid-19 IVE Method Implementation Report

19 In Vitro Expression (IVE) assay is ... level of the SARS-CoV-2 Spike1 protein in **HEK293T** cells transfected with **Covid**-19 vaccine PF-07302048 drug product (DP)...

Date: May 19, 2021 Application: PDOCS Author: Toelly,Daniela

Pdf

COVID19-DOF110

quite clear, however, I have an ... the UK: In the testing process for **COVID**-19 mRNA Vaccine BNT162b2, a cell line known as **HEK-293** was utilized. This cell line...

Source: SharePointOnline / GMI SharePoint / DOF / PBG / COVID-19 mRNA vaccine (BNT162)

Date: Jun 24, 2021 Application: SharePoint Author: Qureshi, Ambereen PREVIEW

Word

Covid-19 IVE Method Implementation Plan

19 In Vitro Expression (IVE) assay is ... level of the SARS-CoV-2 Spike1 protein in **HEK293T** cells transfected with **Covid**-19 vaccine PF-07302048 drug product (DP)...

Date: Apr 8, 2021 Application: PDOCS Author: Toelly,Daniela

Pdf

/Root/PDM/Groton/Mathialagan, Sumathy VBN#00702073/PDM-NC...

In house data **UCSF, Solvo and UW DIDB data base Page: 73 of 74 Title: Inhibition **assay_COVID**-19_PF- 00835231_PF- Time Stamp: Mar 3, 2021 10:13:49...

Date: Mar 4, 2021 Application: Chemistry eLN Author: Mathialagan, Sumathy

Pdf

【参考】 COVID-19 Vaccine (BNT 162) IB (BioNTech) V6_29-Jan-2021

desired antigens. In vitro expression and co-localization of ... was shown using immunofluorescence in **HEK293T** cells expressing BNT162b1 (modRNA encoding...

Source: SharePointOnline / HC共有用_IB|PRT|ICD / Documents / IB / PF-07843470 IB 2021 Version 1.0 (modRNA Herpes Zoster Vaccine) / 翻訳依頼 / 参考資料

Date: Jun 21, 2021 Application: SharePoint Author: Sembongi, Akiko PREVIEW

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or

FIND SOMEONE WHO MIGHT KNOW

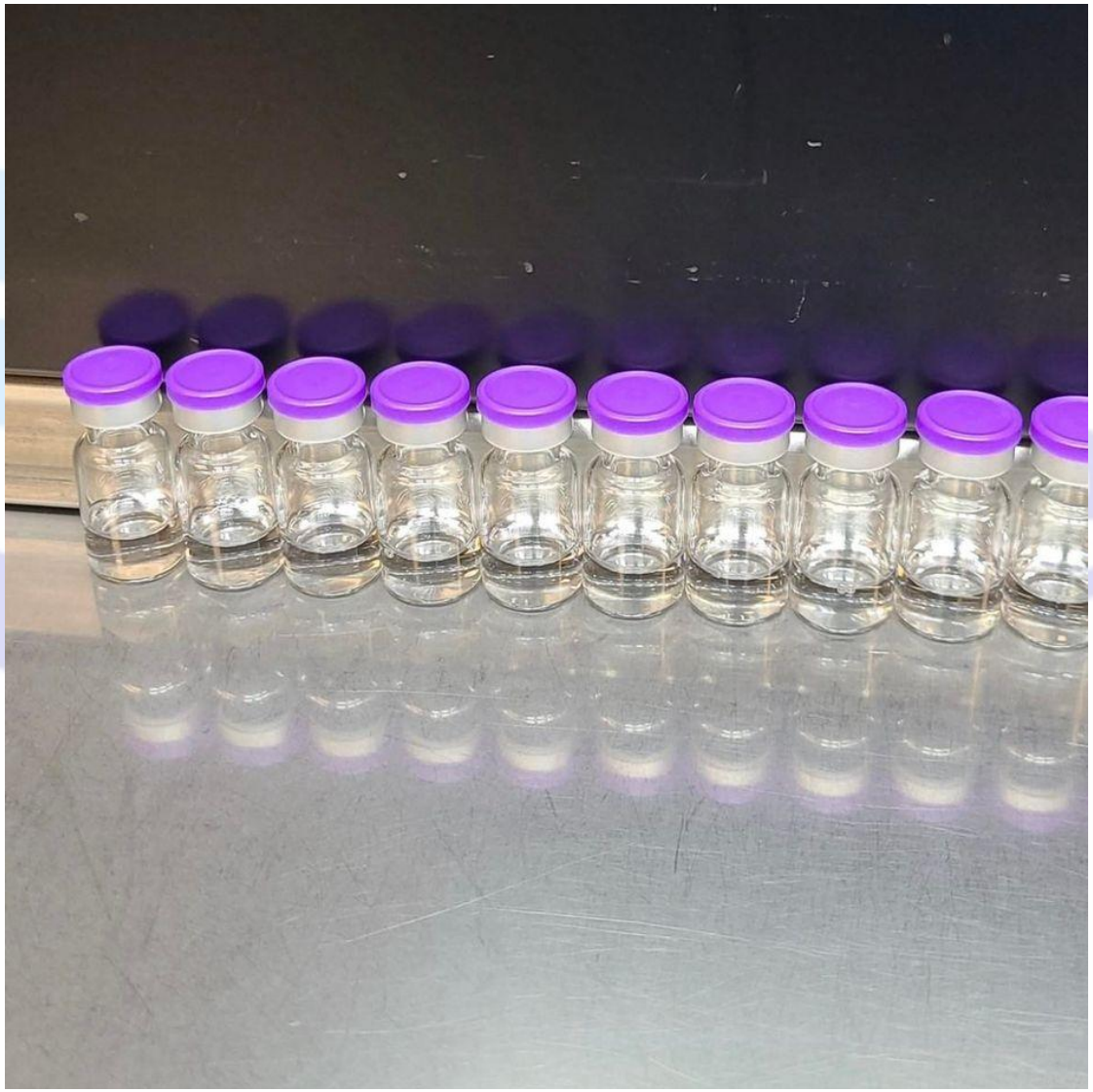
or

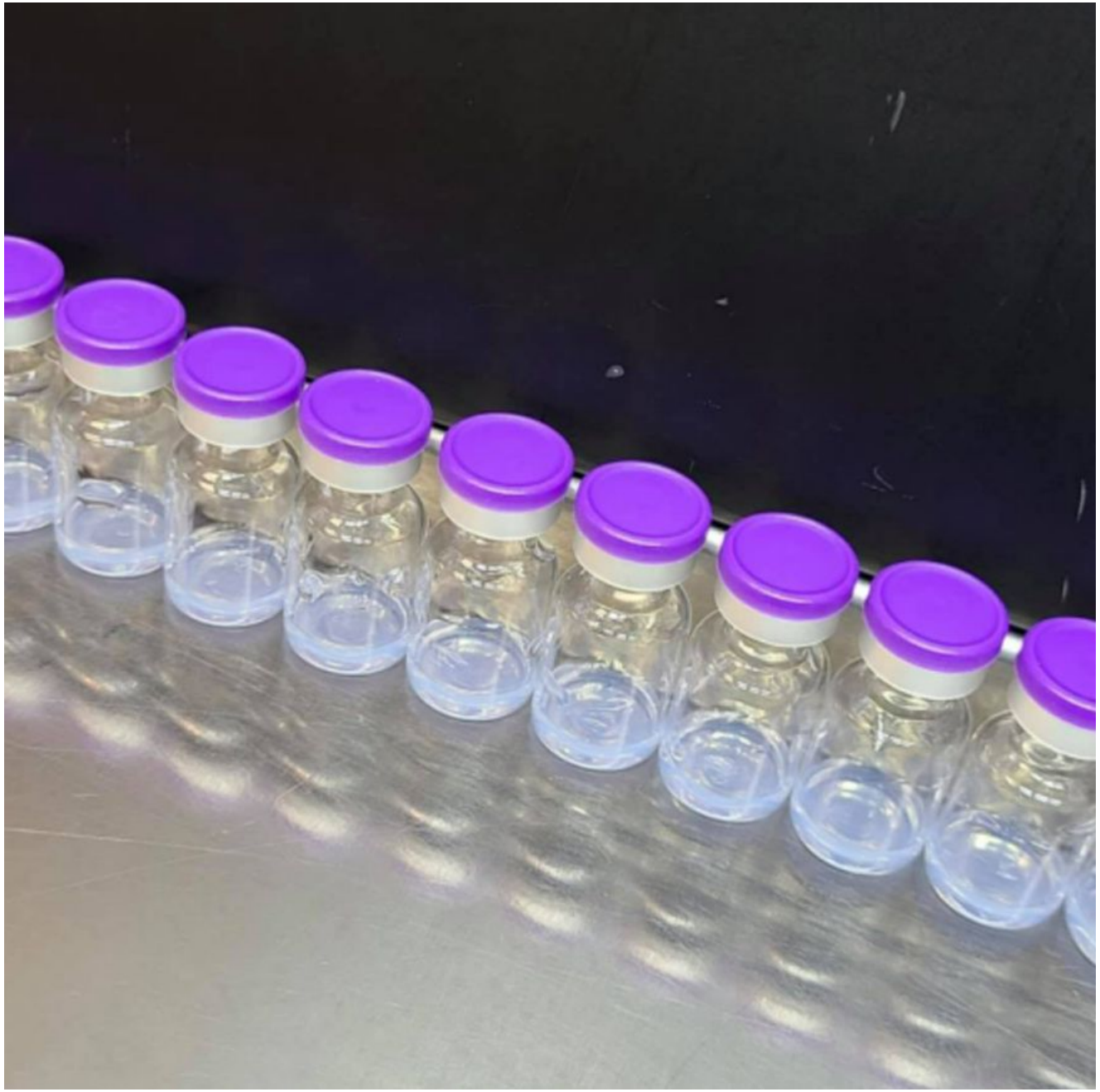
LET US KNOW

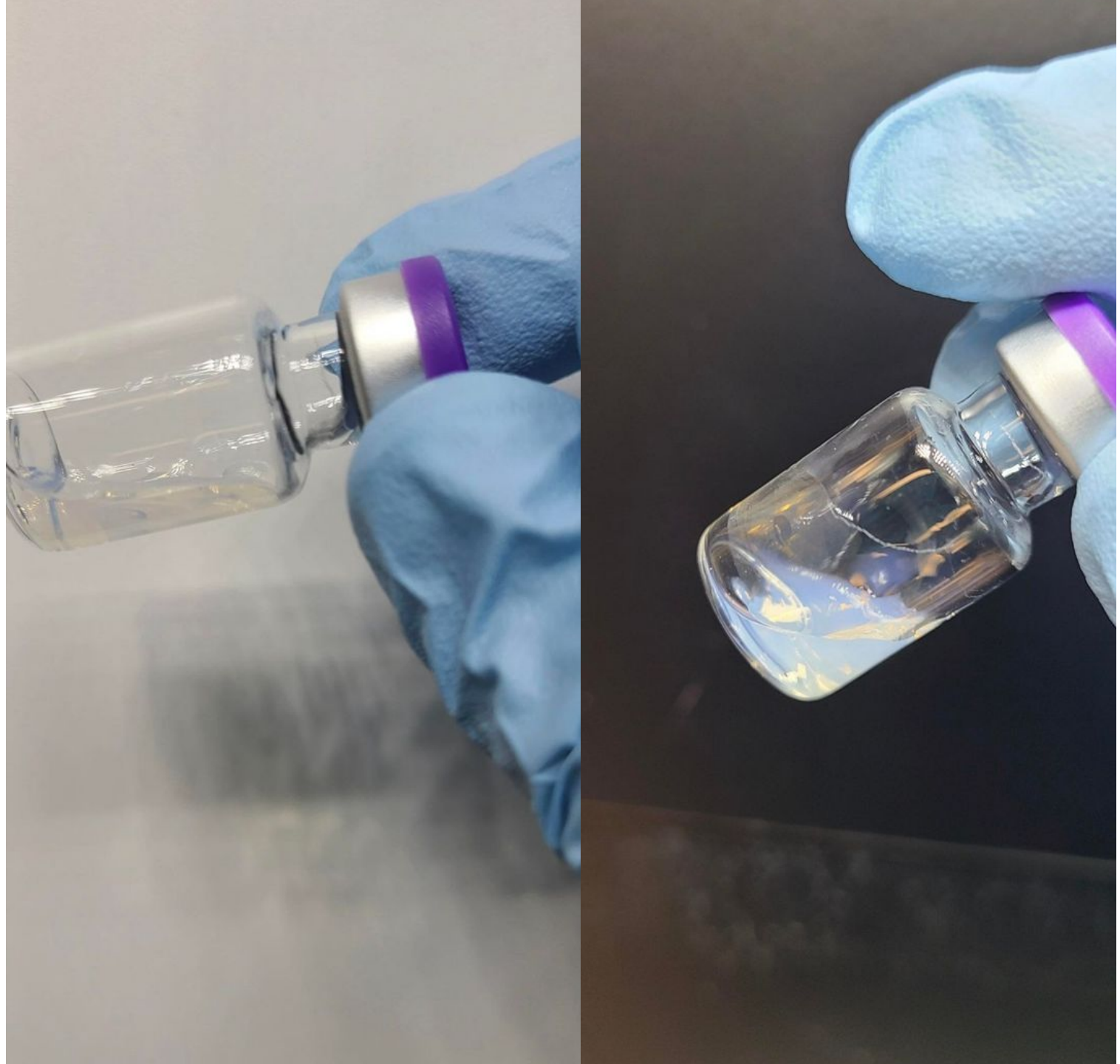
You will only see search results that you have permission to see.

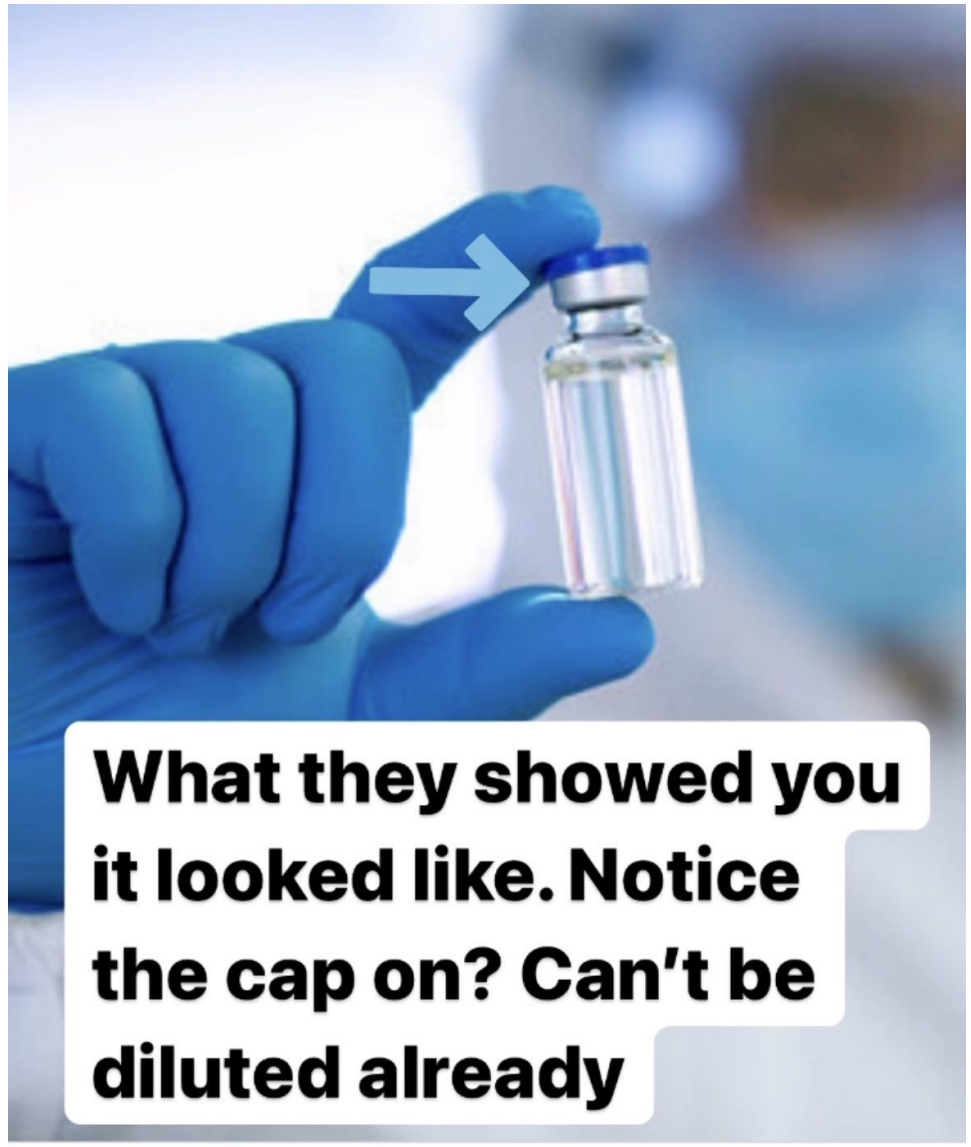
FIND OUT MORE

The Glowing Vials









Pfizer

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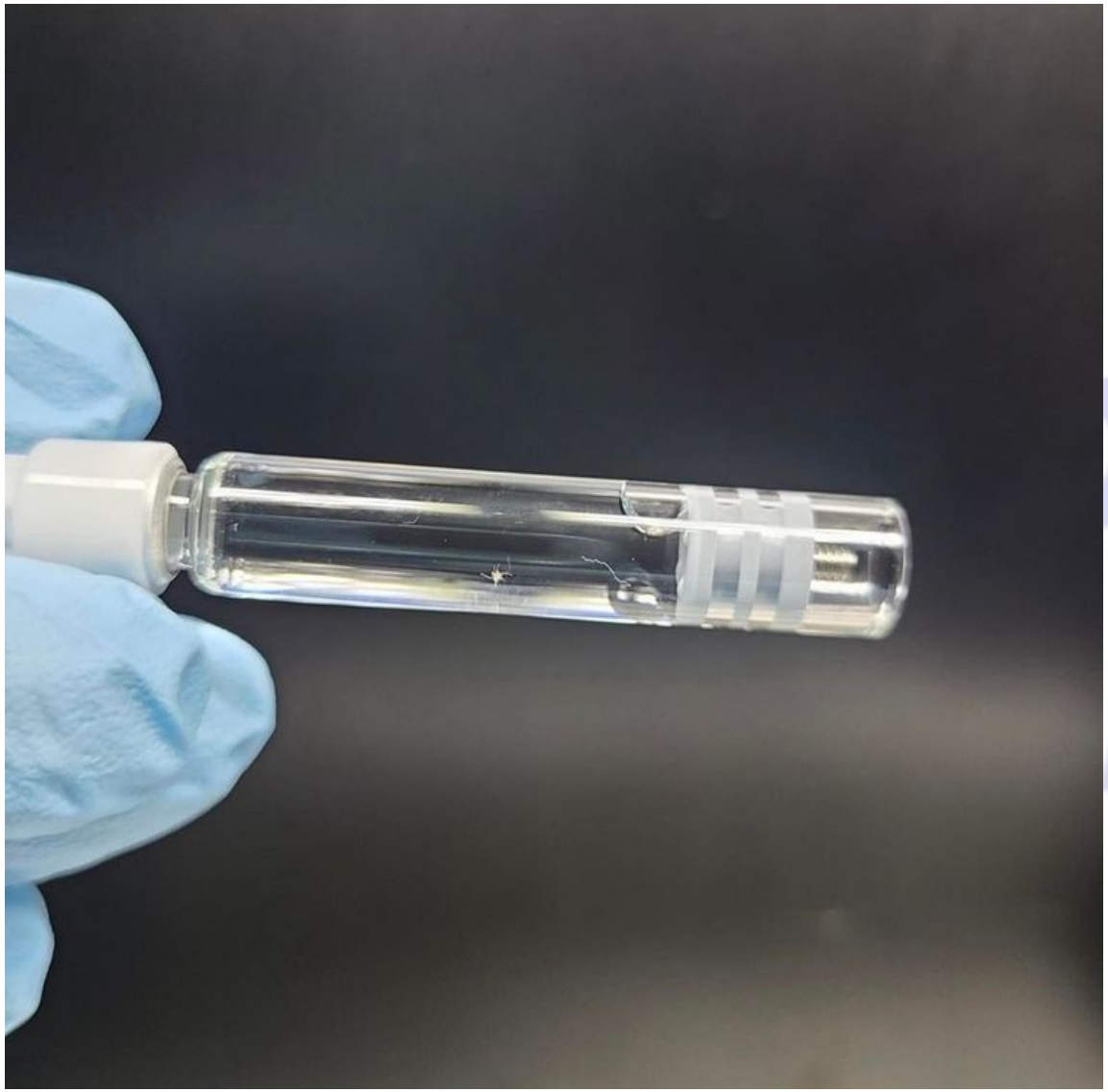
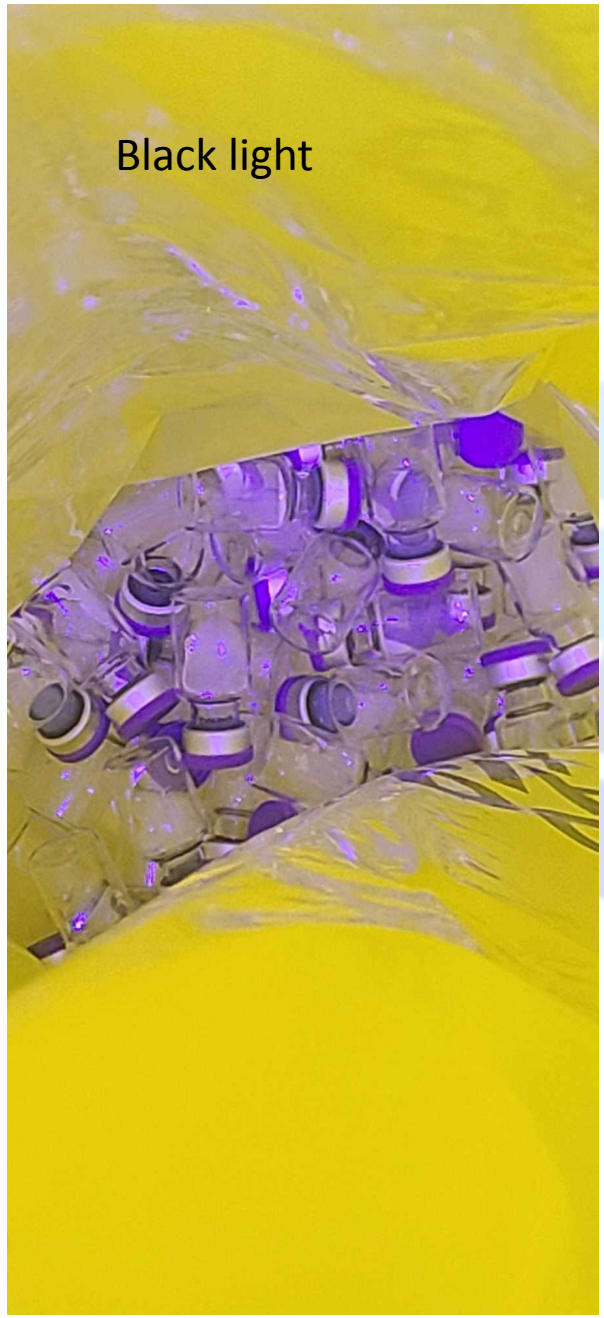
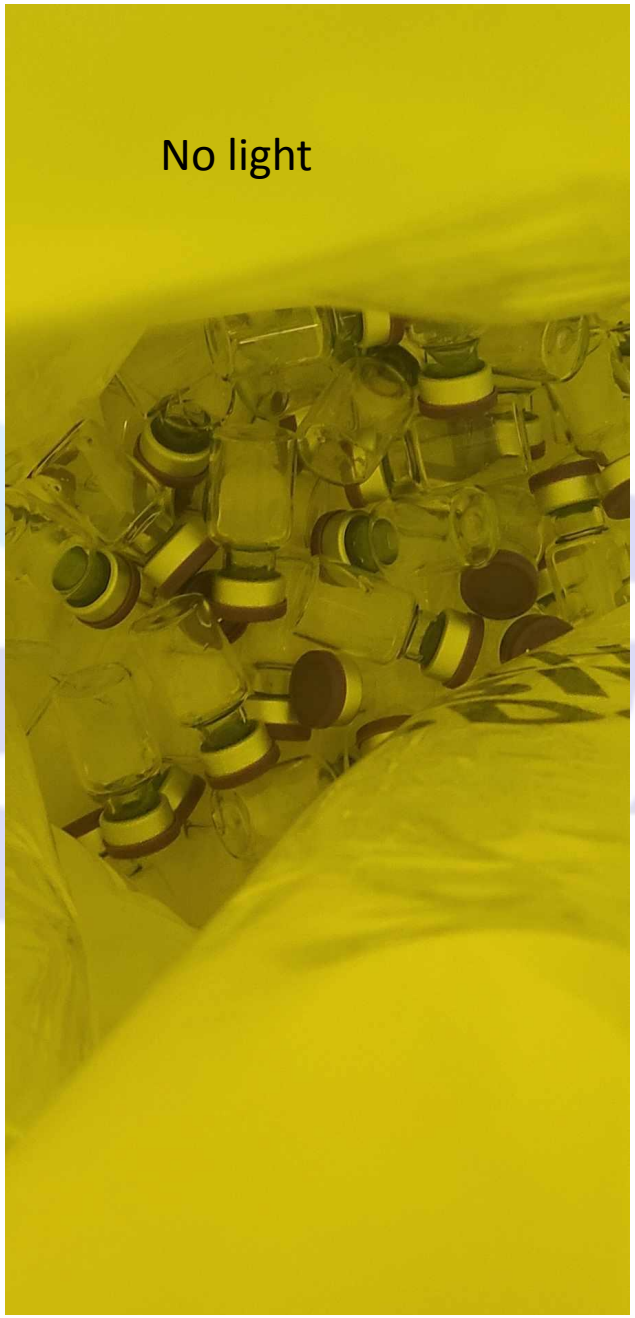
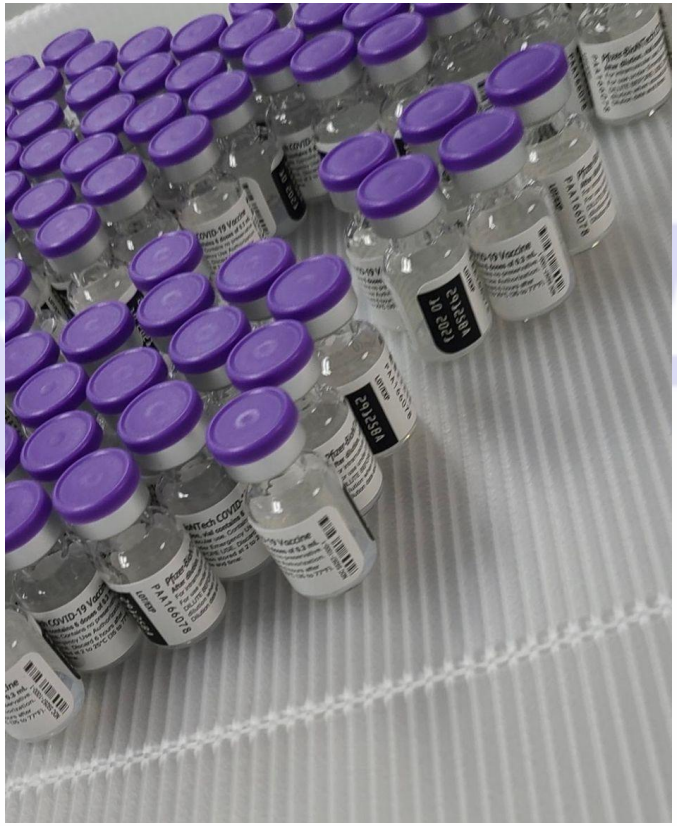
Coronavirus disease (COVID-19) Facts, News & Information ...

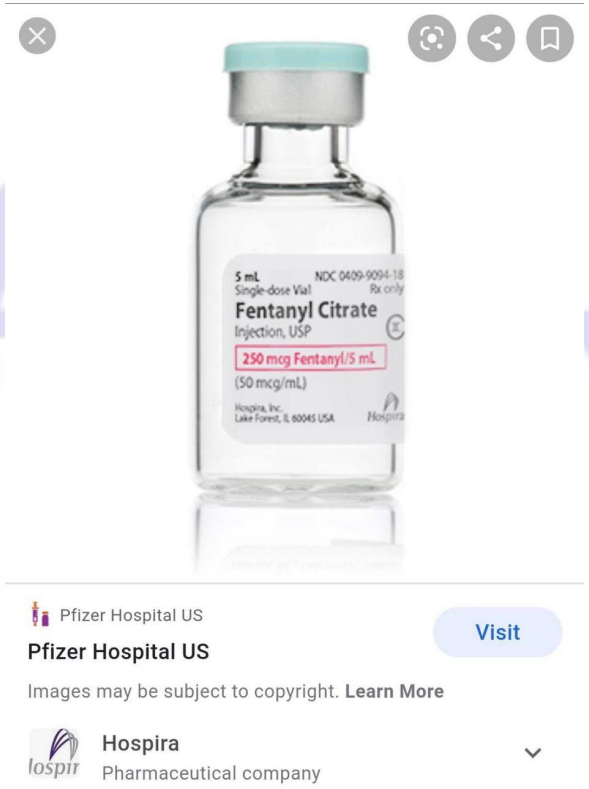



Black light


No light


Regular Flashlight





Pfizer Hospital US

Pfizer Hospital US

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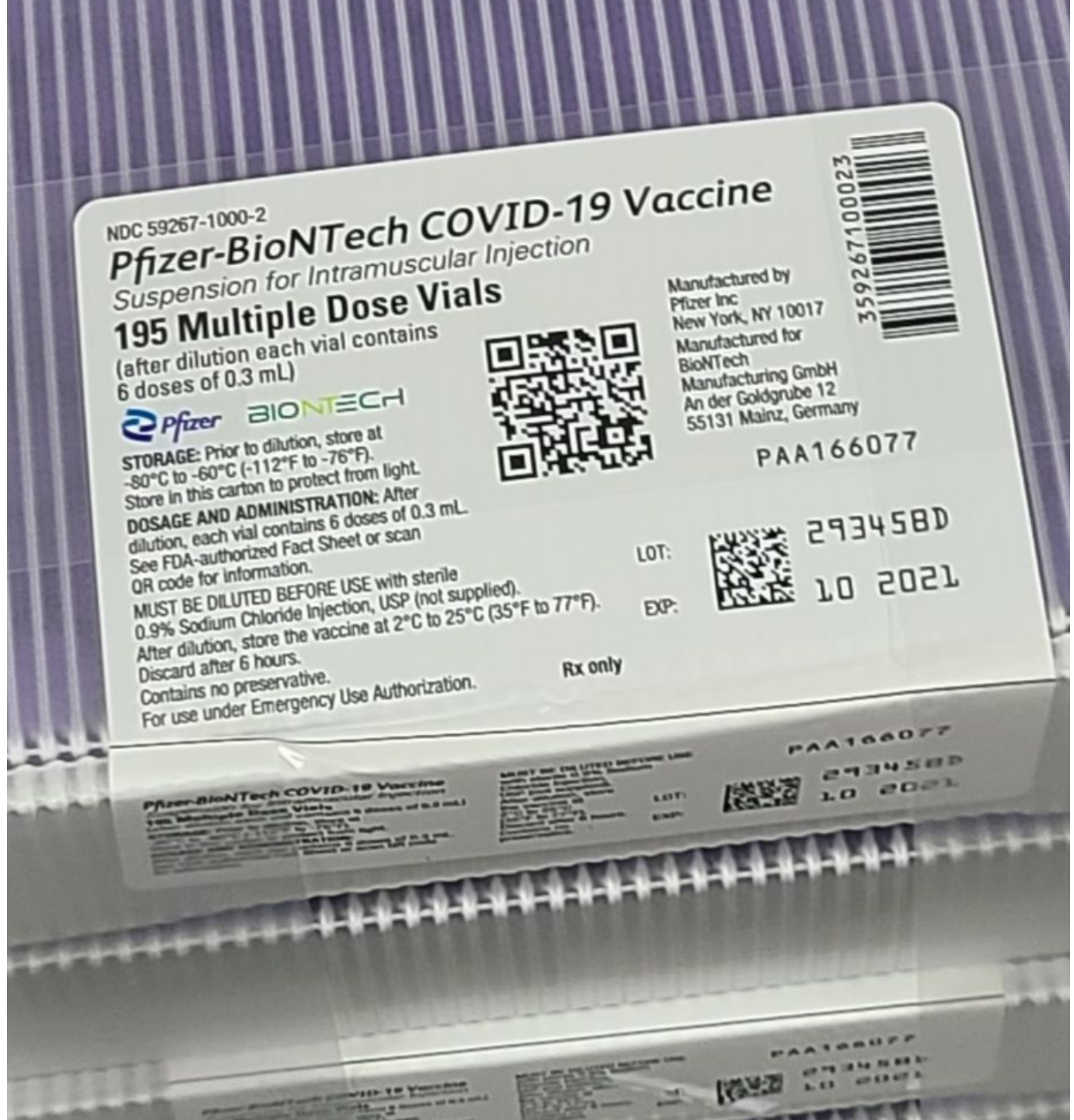
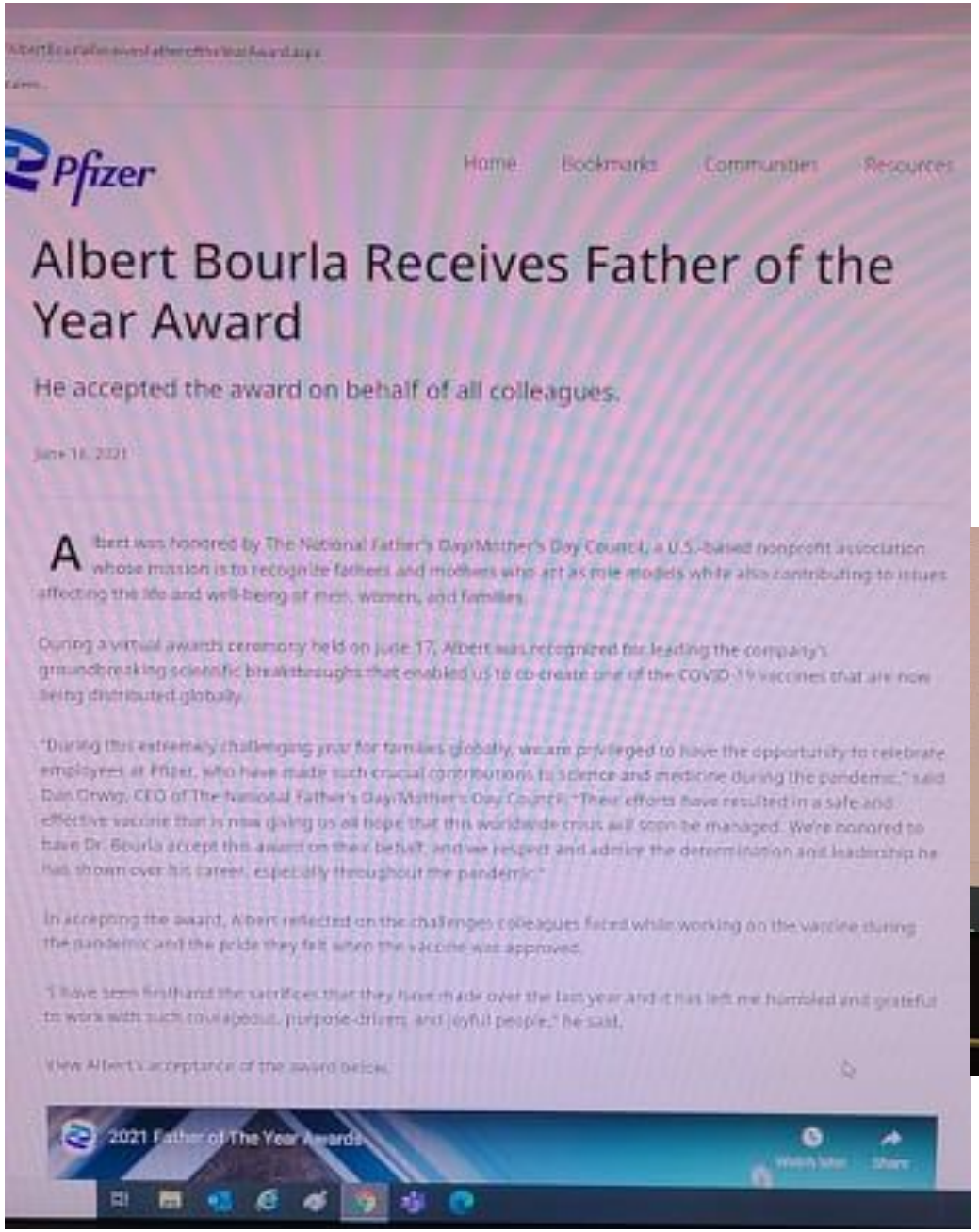
Hospira

Pharmaceutical company


NDC 59267-1000-2
Pfizer-BioNTech COVID-19 Vaccine
Suspension for Intramuscular Injection
195 Multiple Dose Vials
(after dilution each vial contains
6 doses of 0.3 mL)
Pfizer BIONTECH
STORAGE: Prior to dilution, store at
-80°C to -60°C (-112°F to -76°F).
Store in this carton to protect from light.
DOSAGE AND ADMINISTRATION: After
dilution, each vial contains 6 doses of 0.3 mL.
See FDA-authorized Fact Sheet or scan
QR code for information.
MUST BE DILUTED BEFORE USE with sterile
0.9% Sodium Chloride Injection, USP (not supplied).
After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F).
Discard after 6 hours.
Contains no preservative.
For use under Emergency Use Authorization.
Rx only
Manufactured by
Pfizer Inc
New York, NY 10017
Manufactured for
BioNTech
Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
359267100023
PAA166077
LOT: 293458D
EXP: 10 2021


Pfizer
Home
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Albert Bourla Receives Father of the Year Award
He accepted the award on behalf of all colleagues.
June 18, 2021
Albert was honored by The National Father's Day/Mother's Day Council, a U.S.-based nonprofit association whose mission is to recognize fathers and mothers who act as role models while also contributing to issues affecting the life and well-being of men, women, and families.
During a virtual awards ceremony held on June 17, Albert was recognized for leading the company's groundbreaking scientific breakthroughs that enabled us to co-create one of the COVID-19 vaccines that are now being distributed globally.
"During this extremely challenging year for families globally, we are privileged to have the opportunity to celebrate employees at Pfizer, who have made such crucial contributions to science and medicine during the pandemic," said Dan Craig, CEO of The National Father's Day/Mother's Day Council. "Their efforts have resulted in a safe and effective vaccine that is now giving us all hope that this worldwide crisis will soon be managed. We're honored to have Dr. Bourla accept this award on their behalf, and we respect and admire the determination and leadership he has shown over his career, especially throughout the pandemic."
In accepting the award, Albert reflected on the challenges colleagues faced while working on the vaccine during the pandemic and the pride they felt when the vaccine was approved.
"I have seen firsthand the sacrifices that they have made over the last year and it has left me humbled and grateful to work with such courageous, purpose-driven, and joyful people," he said.
View Albert's acceptance of the award below.
2021 Father of The Year Awards
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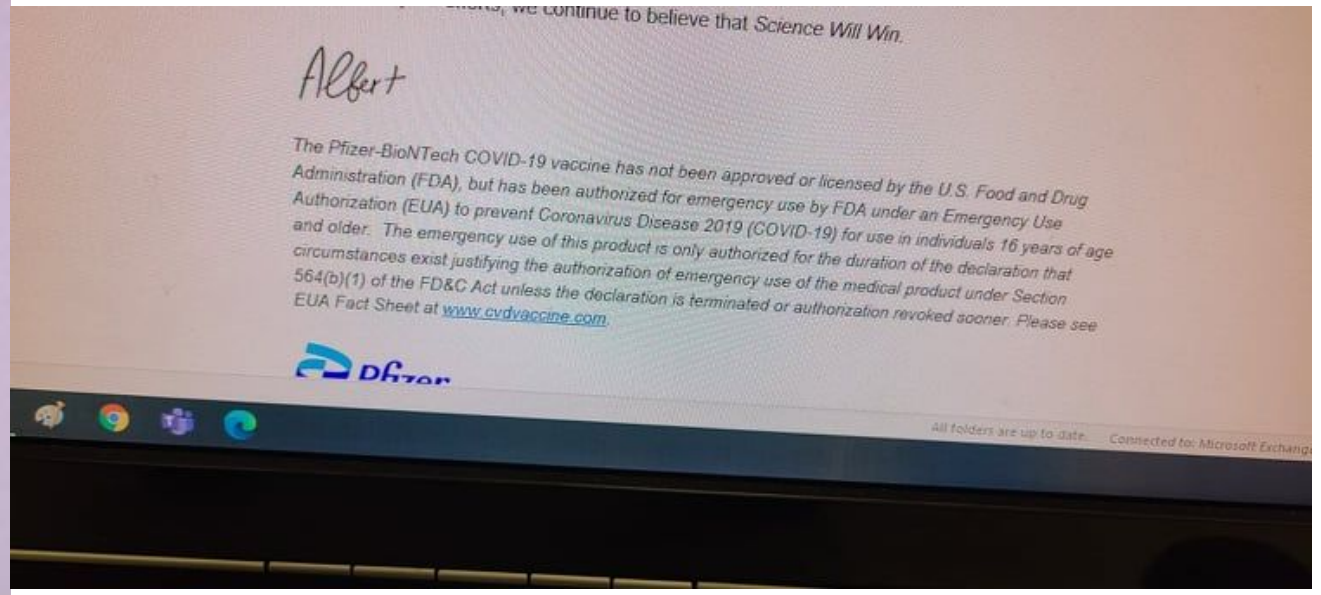
Conjugate Vaccine
Albert Bourla Receives Father of the Year Award
Read More
FATHER OF THE YEAR
AWARDS
WINNER
Dr. Albert Bourla


we continue to believe that Science Will Win.
Albert
The Pfizer-BioNTech COVID-19 vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheet at www.cvdvaccine.com.
Pfizer
All folders are up to date.
Connected to: Microsoft Exchange

Packaging and Labeling Control

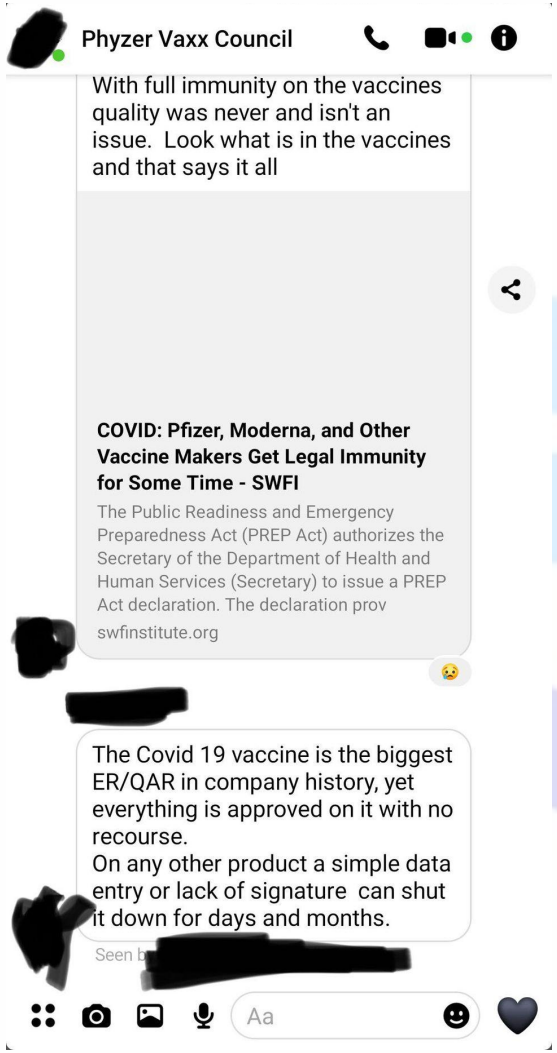
1. Materials examination and usage criteria
   (a) Written procedures describing in detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials must be developed, approved, and followed. These materials must be representatively sampled, examined, or tested on receipt and accepted by the quality control unit before use.
   (b) Any materials that do not fully meet acceptance criteria must be rejected to prevent their use.
   (c) Records of each receival of each different label and packaging material must be maintained indicating receipt, examination or testing, and whether accepted or rejected.
   (d) Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents must be stored separately with suitable identification. Access to the storage area must be limited to authorized personnel.
   (e) Obsolete and outdated labels, labeling, and other packaging materials must be quarantined and destroyed.
   (f) The use of gang-printed labels for different drug products or different strengths or different net contents is prohibited. The only exception to this rule is if labels from gang-printed sheets are adequately differentiated by size, shape, or color that will prevent mixing of labels.
   (g) If cut labeling is used, packaging and labeling operations must include one or more of the following special control procedures:
      (i) Dedication of a labeling and packaging line to each different strength of each different drug product.
      (ii) Use of appropriate electronic or electromechanical equipment to conduct a 100% examination for correct labeling during or after completion of the finishing operation.
      (iii) Use of visual inspection to conduct a 100% examination for correct labeling. If visual inspection is used, the inspection should be performed by one person and independently verified by a second individual.
   (h) Printing devices on or associated with the manufacturing line used to imprint labeling upon the drug product unit label or case must be monitored to assure

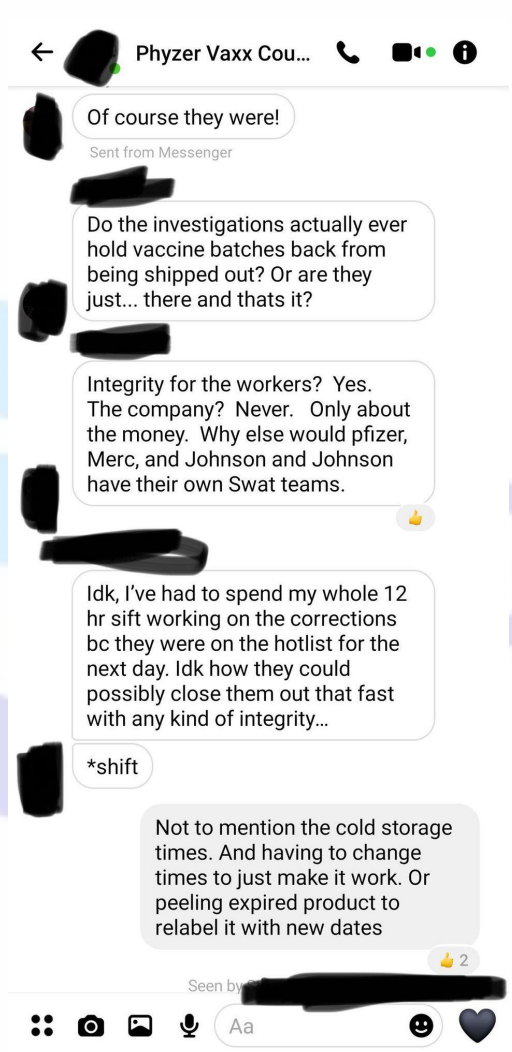
that the printing conforms to the print specified in the batch production record.

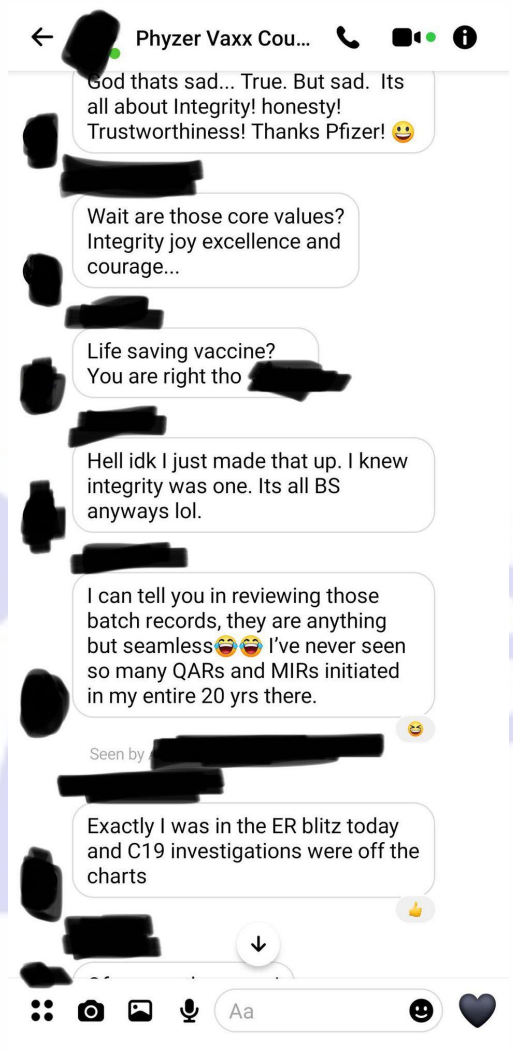
2. Issuance of labeling
   (a) Strict control should be exercised over the issuance of labeling for use in drug product labeling operations.
   (b) Labeling materials issued for a batch must be carefully examined for identity and conformity to the labeling specified in the batch production record.
   (c) Procedures should be written and followed for reconciliation of the quantities of labeling issued, used, destroyed, and returned. Procedures should require evaluation of discrepancies found between the number of packages finished and the amount of labeling issued if discrepancies outside narrow preset limits occur. Limits should be established on the basis of historical operating data. Labeling reconciliation is waived for either cut or roll labeling if a 100% examination for correct labeling is performed.
   (d) All excess labeling bearing a lot or control number must be destroyed.
   (e) Returned labeling should be maintained and stored in a manner to prevent mix-ups.
   (f) Written procedures should describe the control procedures used for the issuance of labeling.
3. There must be written procedures designed to assure that correct labels, labeling, and packaging materials are used. These procedures should incorporate the following features:
   (a) Prevention of mix-ups and cross-contamination by physical or spatial separation of operations on other drug products.
   (b) Identification and handling of filled drug product containers that are set aside and held in unlabeled condition for future labeling operations. Such procedures should be designed to prevent mislabeling individual containers, lots, or portions of lots. It is not necessary to apply identification to each individual container, but the procedure should be adequate to determine the name, strength, quantity of contents, and lot or control number of each container.
   (c) Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.
   (d) Examination of packaging and labeling materials for suitability and correctness before issuing for use and before packaging operations. These examinations must be documented in the batch production record.
   (e) Inspection of the packaging and labeling facility immediately before use to assure that all drug products and labeling materials from the previous operation have been removed. Inspection results must be documented in the batch production record.

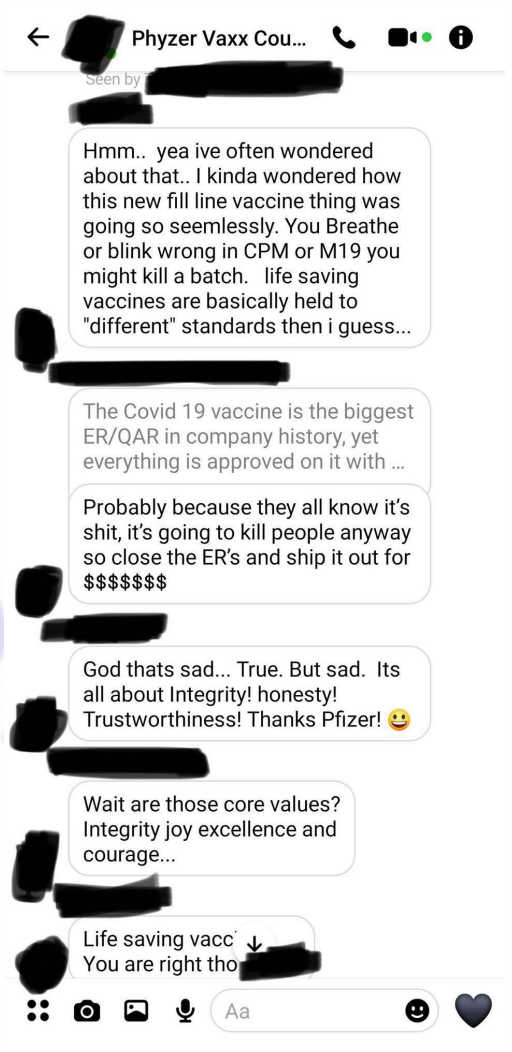

EXIT
SDS


EXIT

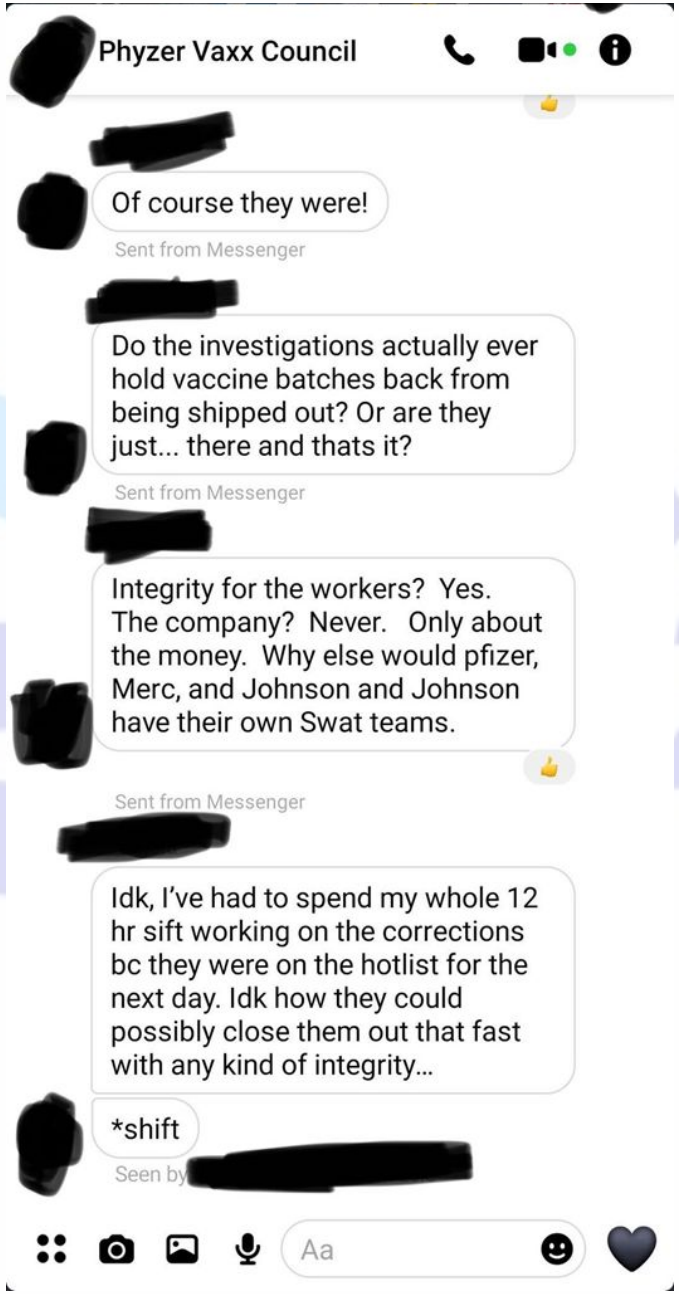

Phyzer Vaxx Council
With full immunity on the vaccines quality was never and isn't an issue. Look what is in the vaccines and that says it all
COVID: Pfizer, Moderna, and Other Vaccine Makers Get Legal Immunity for Some Time - SWFI
The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a PREP Act declaration. The declaration prov
swfinstitute.org
The Covid 19 vaccine is the biggest ER/QAR in company history, yet everything is approved on it with no recourse.
On any other product a simple data entry or lack of signature can shut it down for days and months.
Seen b
Aa

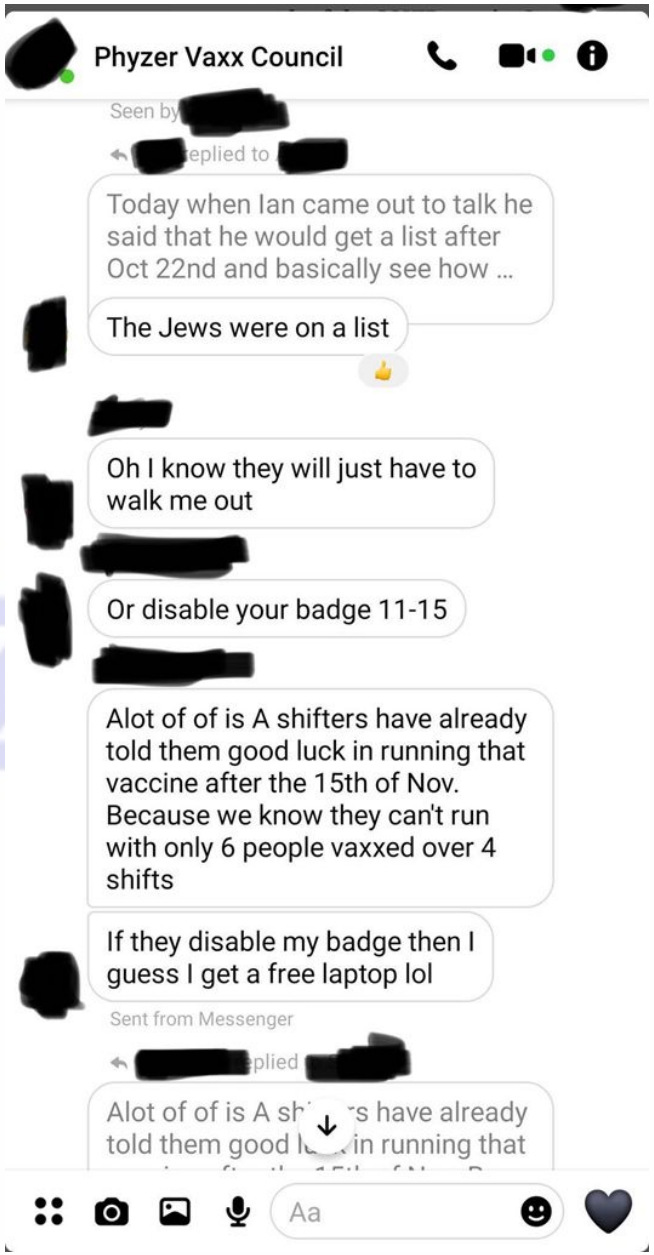

Phyzer Vaxx Cou...
Of course they were!
Sent from Messenger
Do the investigations actually ever hold vaccine batches back from being shipped out? Or are they just... there and thats it?
Integrity for the workers? Yes. The company? Never. Only about the money. Why else would pfizer, Merc, and Johnson and Johnson have their own Swat teams.
Idk, I've had to spend my whole 12 hr sift working on the corrections bc they were on the hotlist for the next day. Idk how they could possibly close them out that fast with any kind of integrity...
*shift
Not to mention the cold storage times. And having to change times to just make it work. Or peeling expired product to relabel it with new dates
2
Seen by
Aa


Phyzer Vaxx Cou...
God thats sad... True. But sad. Its all about Integrity! honesty! Trustworthiness! Thanks Pfizer!
Wait are those core values? Integrity joy excellence and courage...
Life saving vaccine?
You are right tho
Hell idk I just made that up. I knew integrity was one. Its all BS anyways lol.
I can tell you in reviewing those batch records, they are anything but seamless I've never seen so many QARs and MIRs initiated in my entire 20 yrs there.
Seen by
Exactly I was in the ER blitz today and C19 investigations were off the charts
Aa


Phyzer Vaxx Cou...
Seen by
Hmm.. yea ive often wondered about that.. I kinda wondered how this new fill line vaccine thing was going so seemlessly. You Breathe or blink wrong in CPM or M19 you might kill a batch. life saving vaccines are basically held to "different" standards then i guess...
The Covid 19 vaccine is the biggest ER/QAR in company history, yet everything is approved on it with ...
Probably because they all know it's shit, it's going to kill people anyway so close the ER's and ship it out for $$$$$$$
God thats sad... True. But sad. Its all about Integrity! honesty! Trustworthiness! Thanks Pfizer!
Wait are those core values? Integrity joy excellence and courage...
Life saving vacc
You are right tho
Aa


Phyzer Vaxx Cou...
Not to mention the cold storage times. And having to change times to just make it work. Or peeling expired product to relabel it with new dates
2
Seen by
Idk how many times I was locked out of JDE so couldn't put times or pallets in. Not to mention the room time scenario!!! That's a hot mess
And over exposed plates, etc. there's not one batch without major issues attached to it.
Right... Im sure they just wanted it done asap and it didnt matter how. That mindset seems consistent throughout the plant. theyve been riding SP2 To death with the "its never good enough" Attitude. They always want more.
Seen by
No worries carps will be shut down soon
Seen by
Aa


Phyzer Vaxx Council
Of course they were!
Sent from Messenger
Do the investigations actually ever hold vaccine batches back from being shipped out? Or are they just... there and thats it?
Sent from Messenger
Integrity for the workers? Yes. The company? Never. Only about the money. Why else would pfizer, Merc, and Johnson and Johnson have their own Swat teams.
Sent from Messenger
Idk, I've had to spend my whole 12 hr sift working on the corrections bc they were on the hotlist for the next day. Idk how they could possibly close them out that fast with any kind of integrity...
*shift
Seen by
Aa


Phyzer Vaxx Council
Seen by
eplied to
Today when Ian came out to talk he said that he would get a list after Oct 22nd and basically see how ...
The Jews were on a list
Oh I know they will just have to walk me out
Or disable your badge 11-15
Alot of of is A shifters have already told them good luck in running that vaccine after the 15th of Nov. Because we know they can't run with only 6 people vaxxed over 4 shifts
If they disable my badge then I guess I get a free laptop lol
Sent from Messenger
eplied
Alot of of is A sh s have already told them good l in running that
Aa

The Emails

From: Badkar, Advait V <advait.v.badkar@pfizer.com>
Sent: Thursday, February 4, 2021 1:26 PM
To: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>
Subject: FW: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Hi there,

I assume the answer to the question in "**bold**" below is NO. Can you confirm?

Thanks,
Advait

<image007.png>

From: Qureshi, Ambereen <Ambereen.Qureshi@pfizer.com>
Sent: Wednesday, February 3, 2021 8:11 AM
To: Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>
Cc: Barrias, Ana <Ana.Barrias@pfizer.com>
Subject: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Dear Sarah,

I hope that you are well.
I have received an enquiry as follows:

'did Pfizer make use of a cell line from an aborted foetus when carrying out any confirmatory tests for this vaccine?'

We have already confirmed with the customer that no cell lines from an aborted foetus were used in the manufacturing process of the COVID-19 mRNA Vaccine BNT162b2.
Do we have any information to provide in response to her question?

From: Badkar, Advait V <advait.v.badkar@pfizer.com>
Sent: Thursday, February 4, 2021 5:13 PM
To: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>
Subject: Re: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Hi Vanessa. This question came in as an enquiry to our Med Info group. Specifically they are asking " **'did Pfizer make use of a cell line from an aborted foetus when carrying out any confirmatory tests for this vaccine?**

This is AFTER we had already confirmed with the customer that no cell lines from an aborted foetus were used in the manufacturing process of the COVID-19 mRNA Vaccine BNT162b2.

Advait Badkar

On Feb 4, 2021, at 4:52 PM, Gelman, Vanessa <Vanessa.Gelman@pfizer.com> wrote:

Thanks so much – who is this information for? We have been trying as much as possible to not mention the fetal cell lines. So we would really like to stay focused on the first part if possible – this is what we have said most recently for inquiries received via our Board of Directors and through direct emails to Mikael Dolsten…The piece in yellow we have tried really hard to not share unless it's strictly necessary and mission critical.

Human fetal derived cell lines are not used to produce our investigational vaccine, which consists of synthetic and enzymatically produced components. One or more cell lines with an origin that can be traced back to human fetal tissue has been used in laboratory tests associated with the vaccine program.

Preview

COVID19-DOF110

Last edited by: Qureshi, Ambereen on: Jun 24, 2021

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To: Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>; Badkar, Advait V <advait.v.badkar@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Payne, Lara Joan <Lara.Payne@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

No. I would prefer ***we do not use*** the text in yellow.
Is this the same request that came from a subject called *Brian Robinson* who is a member of the public?
I received last night a similar request via Lara Payne, Natalie Zaidman and Robert Enis.
Vanessa

From: Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>
Sent: Friday, February 5, 2021 10:18 AM
To: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>; Badkar, Advait V <advait.v.badkar@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Thank you Vanessa,
Just to be clear, you would like medical information to reply with the text in red below, including the yellow highlighted section?

Thanks again for all your help

Sarah

From: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>
Sent: Thursday, February 4, 2021 5:16 PM
To: Badkar, Advait V <advait.v.badkar@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

A lot of people go to medical information, so I would prefer if possible we respond with what we have consistently said. We wouldn't like to have any inconsistency out there particularly with information that has been shared with policymakers and media.
Vane

From: Badkar, Advait V <advait.v.badkar@pfizer.com>
Sent: Thursday, February 4, 2021 5:13 PM
To: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>
Subject: Re: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

From: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>
Sent: Thursday, February 4, 2021 3:43 PM
To: Badkar, Advait V <advait.v.badkar@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>
Cc: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Hi Advait,

Copying Vanessa Gelman from our Communications group. We have an approved answer to this question, which she probably can provide. HEK293T cells, used for the IVE assay, are ultimately derived from an aborted fetus. On the other hand, the Vatican doctrinal committee has confirmed that they consider it acceptable for Pro-Life believers to be immunized.

Pfizer's official statement couches the answer well and is what should be provided in response to an outside inquiry.

Best,

Phil

Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Payne, Lara Joan <Lara.Payne@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Hello,

Thank you for your efforts with this request. The person asking the question is Susan Roundhill from the UK.
She is a member of the public and made a specific request for this information after already having it confirmed that no cell lines from an aborted foetus were used in the manufacturing process of the COVID-19 mRNA Vaccine BNT162b2.

Kind regards

Ambereen

From: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>
Sent: Friday, 5 February 2021 3:47 PM
To: Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>; Badkar, Advait V <advait.v.badkar@pfizer.com>; Qureshi, Ambereen <Ambereen.Qureshi@pfizer.com>; Barrias, Ana <Ana.Barrias@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Payne, Lara Joan <Lara.Payne@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

I completely understand, but I just want to make sure we are responding to a legitimate request and not to a request that may ignite a FB campaign on this that we may ultimately need to manage.
Vanessa

From: Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>
Sent: Friday, February 5, 2021 10:43 AM
To: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>; Badkar, Advait V <advait.v.badkar@pfizer.com>; Qureshi, Ambereen <Ambereen.Qureshi@pfizer.com>; Barrias, Ana <Ana.Barrias@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Payne, Lara Joan <Lara.Payne@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Hi Vanessa,
We have already provided the answer from the first sentence, and the very specific question came back about cells used in tests, so if we do not provide the text in yellow then we are essentially not answering the question.
I've copied in Ambereen and Ana from MI who received the question to see if they have the name of the individual who asked the question.

Sarah

From: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>

Preview

COVID19-DOF110

Last edited by: Qureshi, Ambereen on: Jun 24, 2021

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<advait.v.badkar@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Payne, Lara Joan <Lara.Payne@pfizer.com>; Mabille-Strele, Claudia <Claudia.Strele@pfizer.com>; Keil, Susanne <Susanne.Keil@pfizer.com>; Larsen, Anders <Anders.Larsen@pfizer.com>; Narciso Tome, Ana Margarida <AnaMargarida.Tome@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Thank you Ambereen.

This may be resulting from a Moderna statement that is saying their vaccine does not make use of a cell line from an aborted foetus.

An appropriate answer from our side will be needed to address the requests that are being received in Medical Information..

Kind regards,

Ana

From: Qureshi, Ambereen <Ambereen.Qureshi@pfizer.com>
Sent: 9 de fevereiro de 2021 10:14
To: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>; Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>; Badkar, Advait V <advait.v.badkar@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Payne, Lara Joan <Lara.Payne@pfizer.com>; Barrias, Ana <Ana.Barrias@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Hello All,

I have now received another request for the same information from another non-HCP called Mhairi Briggs also from the UK.

Would you be able to suggest an appropriate response to non-HCPs as I think that this Is going to be an on-going topic.

Kind regards

Ambereen

From: Qureshi, Ambereen
Sent: Friday, 5 February 2021 5:48 PM
To: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>; Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>; Badkar, Advait V <advait.v.badkar@pfizer.com>; Barrias, Ana <Ana.Barrias@pfizer.com>

Preview

COVID19-DOF110

Last edited by: Qureshi, Ambereen on: Jun 24, 2021

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Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Payne, Lara Joan <Lara.Payne@pfizer.com>; Mabille-Strele, Claudia <Claudia.Strele@pfizer.com>; Keil, Susanne <Susanne.Keil@pfizer.com>; Larsen, Anders <Anders.Larsen@pfizer.com>; Narciso Tome, Ana Margarida <AnaMargarida.Tome@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Thank you everyone for your input.

We are receiving more enquiries of this type asking specifically about the use of fetal cell lines in the 'testing' of the vaccine.
If you conduct a search of the internet, there are numerous sources of information (good and bad) that state that fetal cell lines were used in the testing of some covid-19 vaccines (including ours). Thus, if we are asked a direct question and the information is available in the public domain, I believe that we should provide a clear response.

Suggested wording was provided in the email trail as follows:

Human fetal derived cell lines are not used to produce our investigational vaccine, which consists of synthetic and enzymatically produced components. One or more cell lines with an origin that can be traced back to human fetal tissue has been used in laboratory tests associated with the vaccine program.

In my opinion, this is quite clear, however, I have an alternate proposal which I hope to be able to use in the questions I have had asked from the UK:

In the testing process for COVID-19 mRNA Vaccine BNT162b2, a cell line known as HEK-293 was utilized. This cell line is derived from a single foetal source dating back to 1973 and is used extensively in medical and scientific research. The same foetal cells obtained then, have continued to be grown in the laboratory and are used to test vaccines today. No further sources of foetal cells have been added to this cell line.

Would this be appropriate for me to use in my responses? I have provided the referenced statement in the attached document.
I would appreciate your feedback and suggestions.

Kind regards

From: Gelman, Vanessa <Vanessa.Gelman@pfizer.com>
Sent: Tuesday, 9 February 2021 4:05 PM
To: Barrias, Ana <Ana.Barrias@pfizer.com>; Qureshi, Ambereen <Ambereen.Qureshi@pfizer.com>; Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>; Badkar, Advait V <advait.v.badkar@pfizer.com>
Cc: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>; Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Payne, Lara Joan <Lara.Payne@pfizer.com>; Mabille-Strele, Claudia <Claudia.Strele@pfizer.com>; Keil, Susanne <Susanne.Keil@pfizer.com>; Larsen, Anders <Anders.Larsen@pfizer.com>; Narciso Tome, Ana Margarida <AnaMargarida.Tome@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Thank you so much everyone for keeping us in the loop on this. From the perspective of corporate affairs, we want to avoid having the information on the fetal cells floating out there. As you can all appreciate, we are communicating on this vaccine across multiple fronts and managing issues that arise. In this heated environment of heightened scrutiny on every detail on our vaccine, we would like to avoid creating an opportunity to raise an issue – we believe that the risk of communicating this right now outweighs any potential benefit we could see, particularly with general members of the public who may take this information and use it in ways we may not want it out there. We have not received any questions from policy makers or media on this issue in the last few weeks, so we want to avoid raising this if possible. If you want to expand on the below to explain how our vaccine is made and what mRNA is, that could be an avenue worth exploring to expand on the response.

As much as we can focus on the production side of things, that will help us immensely. This guidance has been consistently shared across the board on inquiries we have received on this sensitive topic.

Vanessa

Human fetal derived cell lines are not used to produce our investigational vaccine, which consists of synthetic and enzymatically produced components

From: Barrias, Ana <Ana.Barrias@pfizer.com>
Sent: Tuesday, February 9, 2021 5:20 AM
To: Qureshi, Ambereen <Ambereen.Qureshi@pfizer.com>; Gelman, Vanessa <Vanessa.Gelman@pfizer.com>; Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>; Badkar, Advait V

From: Dormitzer, Philip Ralph <Philip.Dormitzer@pfizer.com>
Sent: Wednesday, 17 February 2021 6:21 AM
To: Qureshi, Ambereen <Ambereen.Qureshi@pfizer.com>; Gelman, Vanessa <Vanessa.Gelman@pfizer.com>; Barrias, Ana <Ana.Barrias@pfizer.com>; Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>; Badkar, Advait V <advait.v.badkar@pfizer.com>
Cc: Swanson, Kena Anne <Kena.Swanson@pfizer.com>; Payne, Lara Joan <Lara.Payne@pfizer.com>; Mabille-Strele, Claudia <Claudia.Strele@pfizer.com>; Keil, Susanne <Susanne.Keil@pfizer.com>; Larsen, Anders <Anders.Larsen@pfizer.com>; Narciso Tome, Ana Margarida <AnaMargarida.Tome@pfizer.com>
Subject: RE: Medical Information enquiry regarding COVID-19 mRNA Vaccine BNT162b2

Hi Ambereen,

Suggest we stick with the suggested wording from our Communications group. Don't want to have multiple versions circulating, and the statement has been extensively vetted.

Best,

Phil

The Graphene Oxide Emails

From: Van Zyl,Sandra <Sandra.VanZyl@pfizer.com>
Sent: Monday, July 12, 2021 6:11 AM
To: Hays, Steven <Steven.Hays@pfizer.com>
Cc: Weiser, Sarah Elizabeth <Sarah.Weiser@pfizer.com>
Subject: RE: Graphene oxide

Good morning Steve

Trust you had a lovely weekend and doing well!

I just wanted to check if below statement is acceptable regarding 'graphene oxide', please? I see that Sarah is OOO. We received quite a few enquiries on this

Graphene oxide is not used during the manufacturing of the vaccine and the final product does not contain graphene oxide.

We cannot guarantee that minute amounts of substances are not contained in raw materials obtained from our suppliers. To ensure we have a consistent and reliable supply of medications, we must use a network of suppliers and manufacturing sites globally for both active and inactive ingredients.

I appreciate your help!

Kind regards
Sandra

Van Zyl,Sandra

From: Hays, Steven
Sent: 12 July 2021 12:37
To: Van Zyl,Sandra
Cc: Weiser, Sarah Elizabeth
Subject: RE: Graphene oxide

Hi Sandra,

It would obviously be preferred not to add that second sentence ('we cannot guarantee…') but it is our common disclaimer to protect against any ingredients that may be in raw materials that we do not confirm against in any way.

If we have the ability to specifically omit it, we should, but it would likely require some extensive confirmation from GCMC. But I think that is the statement that we should go with for now. Hopefully, our customers would appropriately consider that disclaimer in the right way.

Steve

Biomed Res Int. 2021; 2021: 5518999.
Published online 2021 Jun 10. doi: 10.1155/2021/5518999

PMCID: PMC8213470
PMID: 34222470

Synthesis and Toxicity of Graphene Oxide Nanoparticles: A Literature Review of *In Vitro* and *In Vivo* Studies

Asmaa Rhazouani,[1,2,3] Halima Gamrani,[3] Mounir El Achaby,[4] Khalid Aziz,[5] Lhoucine Gebrati,[6] Md Sahab Uddin,[7,8] and Faissal AZIZ[1,2]

▸ Author information ▸ Article notes ▸ Copyright and License information PMC Disclaimer

Abstract

Go to: ▸

Nanomaterials have been widely used in many fields in the last decades, including electronics, biomedicine, cosmetics, food processing, buildings, and aeronautics. The application of these nanomaterials in the medical field could improve diagnosis, treatment, and prevention techniques. Graphene oxide (GO), an oxidized derivative of graphene, is currently used in biotechnology and medicine for cancer treatment, drug delivery, and cellular imaging. Also, GO is characterized by various physicochemical properties, including nanoscale size, high surface area, and electrical charge. However, the toxic effect of GO on living cells and organs is a limiting factor that limits its use in the medical field. Recently, numerous studies have evaluated the biocompatibility and toxicity of GO *in vivo* and *in vitro*. In general, the severity of this nanomaterial's toxic effects varies according to the administration route, the dose to be administered, the method of GO synthesis, and its physicochemical properties. This review brings together studies on the method of synthesis and structure of GO, characterization techniques, and physicochemical properties. Also, we rely on the toxicity of GO in cellular models and biological systems. Moreover, we mention the general mechanism of its toxicity.

graphene oxid detection in aqueous suspension_497022433

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Robust Magnetized Graphene Oxide Platform for In Situ Peptide Synthesis and FRET-Based Protease Detection

Kim et al, Sensors **2020**, 20 (18), 5275

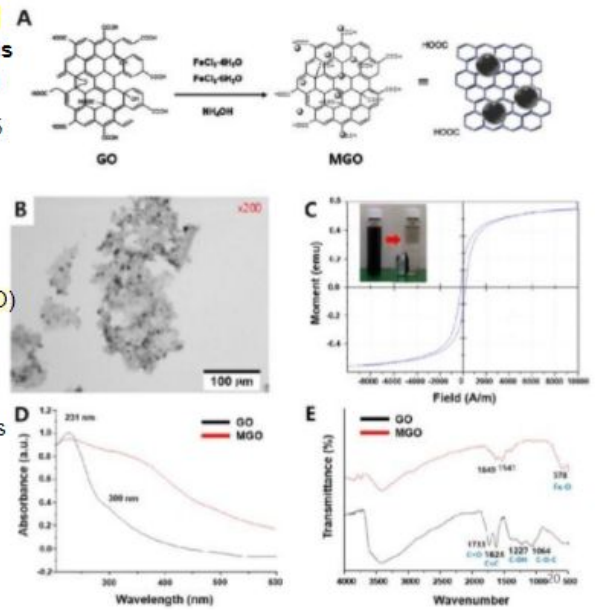

Figure 1. Preparation and characterization of graphene oxide (GO) and magnetic graphene oxide (MGO). (A) Schematic of MGO synthesis procedure. (B) Optical microscopy image of MGO. (C) Magnetic hysteresis loop of MGO. (D) UV / Vis absorption spectra of GO and MGO. (E) FT- IR spectra of GO and MGO.

Comparison of RD1 sample to the light microscope with images of the REDUCED GRAPHENE OXIDE (rGO) standard sample

The optical images of the sheets present in the RD1 sample reveal great similarity with the sheets exfoliated from sonication of the rGO standard sample. Both samples present internally rough translucent sheets, with irregular profiles, folded on themselves and with a tendency to roll up at the edges. The shapes and dimensions of the sheets are highly variable, with both samples presenting sheets in ribbons or bands folded on themselves (ribbons).

The attached ANNEX shows alternate images of STANDARD SAMPLE OF rGO and SAMPLE PROBLEM RD1

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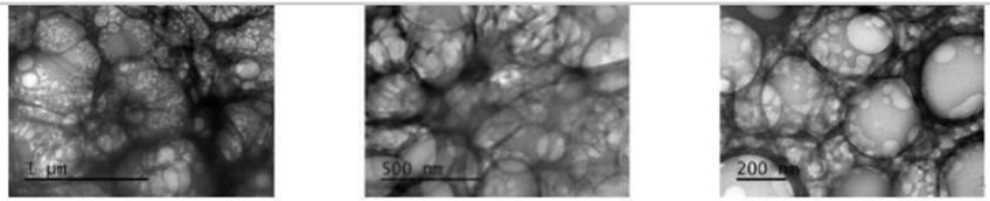
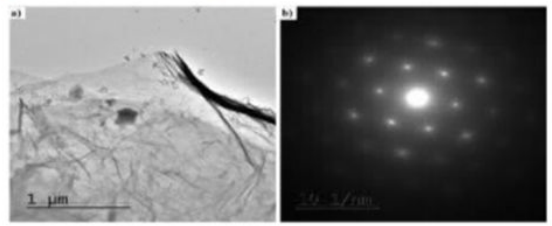


- **Important NOTE:** For a definitive IDENTIFICATION of GRAPHENE by TEM, it is necessary to complement the observation with the structural characterization by obtaining by EDS a characteristic ELECTRON DIFFRACTION STANDARD SAMPLE (as the figure b shown below). The standard sample corresponding to graphite or graphene has a hexagonal symmetry, and generally has several concentric hexagons. **It has not been possible at the moment to obtain this standard sample due to the shortage of sample available for processing, and the chaotic arrangement and density of the folds.**



Matéria (Rio J.) 23 (1) • 2018 • Characterization of graphene nanosheets obtained by a modified Hummer's method. Renata Hack et al.

Optical microscope

CX43 Biological Microscope

10x, 20x (DIC) and 40x (DIC) PLAN Fluor objectives

Eyepiece: 10x

• Condenser set in intermediate position with 3D effect (between light field (BF) and dark field (DF)

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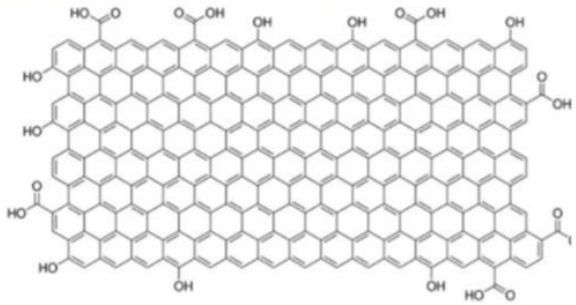
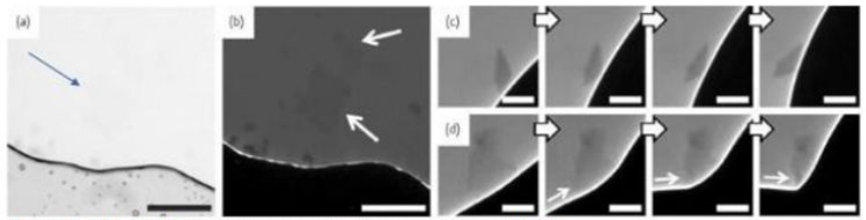
REDUCED GRAPHENE OXIDE STANDARD SAMPLE.



IDENTIFICATION OF GRAPHENE OXIDE AND ITS STRUCTURAL CHARACTERISTICS BY OPTICAL MICROSCOPY

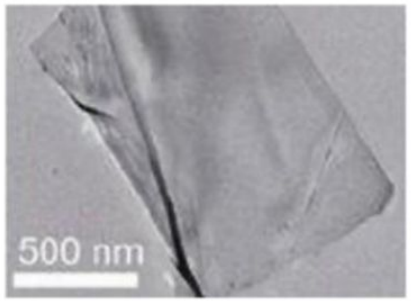
Graphene materials essentially consist of a single atomic layer. This makes absorbance-based light microscope observation difficult, although it is possible to acquire optical images of suspended graphene sheets under brightfield transmitted light (Fig. A). Oxidized graphene (GO) has a much paler color than reduced graphene (rGO).

However, under **reflective illumination**, **high-contrast optical imaging of graphene** and even GO sheets has been reported in literature. Modifying the angle of incidence of the illumination, by means of appropriate adjustment of the condenser (bright field and dark field), this has been the technique used to increase the contrast in sample RD1 of this report and obtain images of the roughness on the surface of the sheets. with 3D effect.



a) Bright field. b-d) Fluorescence extinction microscopy (FQM)
Kim et al, 2010. Seeing graphene-based sheets, Materials Today, Volume 13, 2010, Pages 28-38,

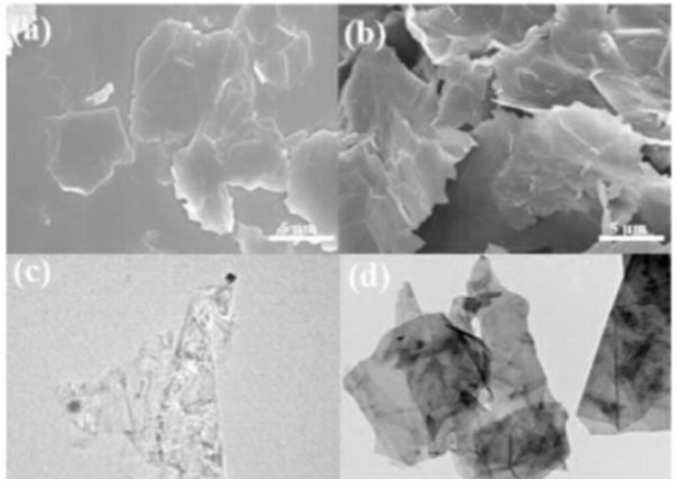
with high yield and high quality. Nano Res. 2, 706-712 (2009).



LITERATURE IMAGES. ELECTRON MICROSCOPY AT LOW MAGNIFICATION ELECTRON SCANNING MICROSCOPY (SEM) (a) and (b) and TRANSMISSION (TEM) (c) and (d)

Effects of Graphene Nanosheets with Different Lateral Sizes as Conductive Additives on the Electrochemical Performance of LiNi0.5Co0.2Mn0.3O2 Cathode Materials for Li Ion Batteries. Figure 2. SEM images of different graphene sheet sizes: (**a**) GN-13 and (**b**) GN-28, and transmission electron microscopy (**TEM**) images of different graphene sheet sizes: (**c**) GN-13 and (**d**) GN -28.

Husu et al. Polymers 2020, 12 (5), 1162



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Robust Magnetized Graphene Oxide Platform for In Situ Peptide Synthesis and FRET-Based Protease Detection

Kim et al, Sensors **2020**, 20 (18), 5275

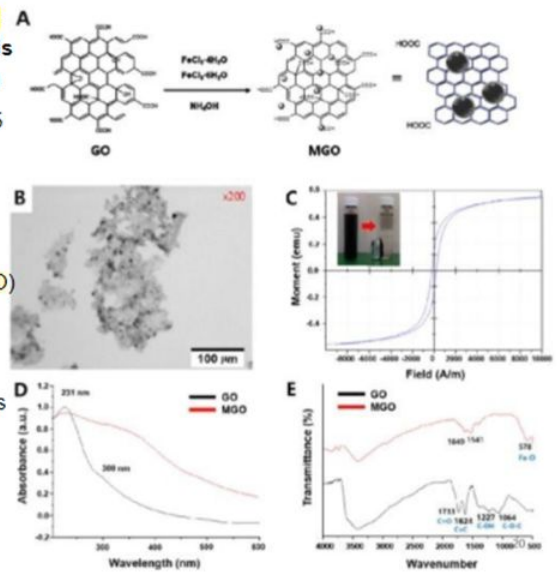

Figure 1. Preparation and characterization of graphene oxide (GO) and magnetic graphene oxide (MGO). (A) Schematic of MGO synthesis procedure. (B) Optical microscopy image of MGO. (C) Magnetic hysteresis loop of MGO. (D) UV / Vis absorption spectra of GO and MGO. (E) FT- IR spectra of GO and MGO.

Comparison of RD1 sample to the light microscope with images of the REDUCED GRAPHENE OXIDE (rGO) standard sample

The optical images of the sheets present in the RD1 sample reveal great similarity with the sheets exfoliated from sonication of the rGO standard sample. Both samples present internally rough translucent sheets, with irregular profiles, folded on themselves and with a tendency to roll up at the edges. The shapes and dimensions of the sheets are highly variable, with both samples presenting sheets in ribbons or bands folded on themselves (ribbons).

The attached ANNEX shows alternate images of STANDARD SAMPLE OF rGO and SAMPLE PROBLEM RD1

Biotrans2021_BookOfAbstracts

graphene oxid detection in aqueous suspension_497022433

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TRANSMISSION ELECTRON MICROSCOPY (TEM)

Electron microscopy (TEM) is commonly used to image graphene nanomaterials. It has become a fairly standard and easy to use instrument that is capable of imaging individual layered graphene sheets.

DESCRIPTION OF THE PREVIOUS IMAGE

(from: Choucair et al, 2009. Gram-scale production of graphene based on solvothermal synthesis and sonication. Nature Nanotechnology 4 (1): 30-3

• Figure 2: "TEM images of the **agglomerated graphene sheets**. The same sample region is viewed at different magnifications and clearly shows the degree of sheet formation and the **tendency of sheets to fuse into overlapping regions**. An inherent sheet-like structure is evident showing **an intricate array of long-range pleats**. Since the images are taken in transmission mode, the relative opacity of the individual sheets is the result of interfacial regions with overlap between individual sheets. The sheets extend in lateral dimensions on micrometer length scales, ranging from 100 nm to more than 1,000 nm. "

RESULTS: Comparison of problem sample (RD1) with a TEM image of literature

SAMPLE RD1 Choucair et al 2009. Nature Nanotechnology 4 (1): 30-3 Fig 2

RESULTS: DESCRIPTION OF THE TEM IMAGES OF THE RD1 PROBLEM SAMPLE

The TEM images of the RD1 sample **in general PRESENT A HIGH SIMILARITY** with images of **graphene oxide** from the literature obtained by the same TEM technique, with similar magnifications. An intricate **matrix** or **mesh of folded translucent flexible sheets** can be observed, with a mixture of darker multilayer agglomerations and lighter colored unfolded monolayers. Darker linear areas appear due to local overlap of sheets and local arrangement of individual sheets

graphene oxid detection in aqueous suspension_497022433

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1. Dilution in 0.9% sterile physiological saline (0.45 ml + 1.2 ml)
2. Polarity fractionation: 1.2 ml hexane + 120 ul of RD1 sample 3. Extraction of hydrophilic phase
4. Extraction and quantification of RNA in the sample
5. Electron and optical microscopy of aqueous phase

Preliminary analysis: extraction and quantification of Rna in the sample

1. RNA extraction: Kit https://www.fishersci.es/shop/products/ambion-purelink-rna-mini-kit-7/10307963
2. Quantification of total UV absorbance in spectrophotometer NanoDrop™ https://www.thermofisher.com/order/catalog/product/ND-2000#/ND-2000
3. Specific quantification of Rna by fluorescence QUBIT2.0: https://www.thermofisher.com/es/es/home/references/newsletters-and-journals/bioprobes-journal-of-cell-biology-applications/bioprobes-issues-2011/bioprobes-64-april-2011/the-qubit-2-0-fluorometer-april- 2011.html

UV absorption spectrum of the aqueous phase of the RD1 sample (Nano-drop team)

Maximum absorption of SAMPLE RD1 (260-270 nm)
- RNA. It presents usual maximums at 260 nm. Total concentration estimated by QUBIT2.0 fluorometry: **6 ng / ul**
- The spectrum reveals the presence of a high quantity of substances or substances other than Rna with maximum absorption in the same region, with a total estimated at **747 ng / ul** (uncalibrated estimate)
- Reduced graphene oxide (RGO) has absorption maxima at 270 nm, **compatible** with the spectrum obtained *(Thema et al, 2013. Journal of Chemistry ID 150536)*
- **The maximum absorption obtained DOES NOT ALLOW TO DISCARD the presence of graphene in the sample. The minimum amount of RNA detected by QUBIT2.0 only explains a residual percentage of the total UV absorption of the sample.**

OBJECTIVE: Microscopic identification of graphene derivatives

METHODOLOGY:
1. Imaging in optical and electron microscopy
2. Comparison with literature images and reduced graphene oxide standard sample

TRANSMISSION ELECTRON MICROSCOPY (TEM)

Electron microscope JEM-2100Plus
Voltage: 200 kV
Resolution 0.14 nm

graphene oxid detection in aqueous suspension_497022433

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- "COMIRNATY™ .Sterile concentrate. COVID-19 mRNA. 6 doses after dilution.
- Discard date / time: PAA165994.LOT / EXP: EY3014 08/2021 "

- Origin and traceability: unknown
- State of conservation: refrigerated
- Maintenance during the study: refrigerated
- Coding of the problem sample to be analyzed: RD1

Preliminary observations of the test sample RD1

Description:
- Sealed vial, with rubber and aluminum cap intact, of 2 ml capacity, containing a 0.45 ml cloudy aqueous suspension.
- RNA extraction and quantification is performed

1

- Presence of uncharacterized nanometric microbiology is observed, visible at 600X in optical microscope

Sample processing

1. Dilution in 0.9% sterile physiological saline (0.45 ml + 1.2 ml)
2. Polarity fractionation: 1.2 ml hexane + 120 ul of RD1 sample 3. Extraction of hydrophilic phase
4. Extraction and quantification of RNA in the sample
5. Electron and optical microscopy of aqueous phase

Preliminary analysis: extraction and quantification of Rna in the sample

1. RNA extraction: Kit https://www.fishersci.es/shop/products/ambion-purelink-rna-mini-kit-7/10307963
2. Quantification of total UV absorbance in spectrophotometer NanoDrop™ https://www.thermofisher.com/order/catalog/product/ND-2000#/ND-2000

Preview

graphene oxid detection in aqueous suspension_497022433

Last edited by: SharePoint App on: Jul 9, 2021

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CONCLUSIONS AND RECOMMENDATIONS

1. Microscopic study of the sample provides **strong evidence for the probable presence of graphene derivatives, although microscopy does not provide conclusive evidence.** The definitive identification of graphene, oxidized graphene (GO) or reduced oxidized graphene (rGO) in the RD1 sample requires the **STRUCTURAL CHARACTERIZATION** through the analysis of specific spectral standard sample comparable to those published in literature and those obtained from the standard sample, obtained with spectroscopic techniques such as XPS, EDS, NMR, FTIR or Raman, among others.

2. The analyzes in this report correspond to **ONE SINGLE SAMPLE, limited in total volume available for processing.** It is therefore necessary to carry out a significant sampling of similar vials to draw conclusions that can be generalized to comparable samples, recording origin, traceability and quality control during storage and transport prior to analysis.

Disclaimer

- **The results and conclusions of this report do not imply any institutional position of the University of Almería**

- Neither the Principal Investigator nor the University of Almería assume any responsibility for the contents and opinions of third parties regarding this report from its possible dissemination on social networks or the media, nor for the conclusions that may be drawn from it that have not been been made explicit in the text.

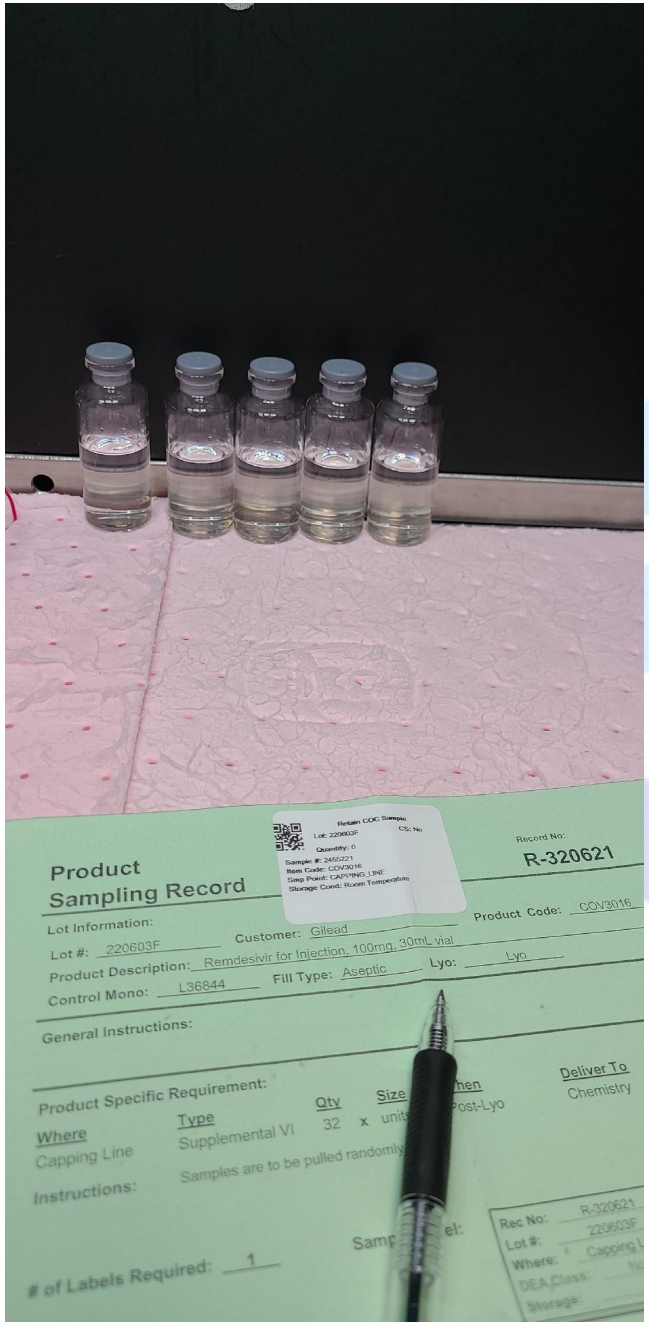
SEE APPENDIX PHOTOGRAPHS OF THE SAMPLE

GRAPHENE OXIDE DETECTION IN AQUEOUS SUSPENSION (COMIRNATY™ (RD1)

OBSERVATIONAL STUDY IN OPTICAL AND ELECTRON MICROSCOPY
Interim report (I)
PHOTOGRAPHS APPENDIX
June 28, 2021

Prof. Dr. Pablo Campra Madrid

Doctor of Chemical Sciences and Bachelor of Biological Sciences



Product
Sampling Record

Record No: R-320621

Lot Information:
Lot #: 220603F
Customer: Gilead
Product Code: COV3016
Product Description: Remdesivir for Injection, 100mg, 30mL vial
Control Mono: L36844
Fill Type: Aseptic
Lyo: Lyo

General Instructions:

Product Specific Requirement:

Where	Type	Qty	Size	When	Deliver To
Capping Line	Supplemental VI	32 x	units	Post-Lyo	Chemistry

Instructions: Samples are to be pulled randomly

# of Labels Required: 1

Revision Date: 15 November 2016

Initiation Date	NA
Product Code	COV3016B
Effective Date	JUL 10 2020
Revision	SR001

REMDESIVIR 100 MG
30R VIAL, 297 CT, BRITESTOCK
PART NUMBER: 103696
STORE BELOW 30° C
MANUFACTURED FOR GILEAD SCIENCES, INC., FOSTER CITY, CA 94404 USA
MANUFACTURED BY HOSPIRA, INC., LAKE FOREST, IL 60045

EXP NA LOT 123456F QTY 297
(17) 000000 (10) 123456F (30) 0297
(I) 103696
COV3016B – SR001 0001

REMDESIVIR 100 MG
30R VIAL, 297 CT, BRITESTOCK
PART NUMBER: 103696
STORE BELOW 30° C
MANUFACTURED FOR GILEAD SCIENCES, INC., FOSTER CITY, CA 94404 USA
MANUFACTURED BY HOSPIRA, INC., LAKE FOREST, IL 60045

EXP NA LOT 123456F QTY 297
(17) 000000 (10) 123456F (30) 0297

3.5" x 10"
gfarrignan
10 Jul 2020

GROUPLEAD

UCT NAME: Remdesivir for Injection, 100mg, 30mL vial
UCT CODE: COV3016B
UMBER: 220653F

DOCUMENT NUMBER: PB001822

T CODE: COV3016B

Inspected as V-COV3016

	(Signature)	(Print Signature)	(Date)
R CENTRE ONE OVED BY / DATE:	J. Sudermann	J. Sudermann	07-10-20
OMER QUALITY OVED BY / DATE:	Kendyll Berggren	Kendyll Berggren	07-10-20
Y CHAIN: VED BY/DATE	Makayla Farmer	Makayla Farmer	07-10-20
CTION PACKAGING VED BY / DATE:	Brian Cunningham	Brian Cunningham	07-14-20
BEL CONTROL VED BY/DATE:	Alison Berger	Alison Berger	07-14-20
UMENTATION ED BY / DATE:	Sharon Rathbone	Sharon Rathbone	07-14-20
ED BY / DATE	Nolan Wheeler Diane Lye	Nolan Wheeler Diane Lye	07-13-20 07-13-20
			07-13-20

REMDESIVIR 100 MG
30R VIAL, 297 CT, BRITESTOCK
PART NUMBER: 103696
STORE BELOW 30° C
MANUFACTURED FOR GILEAD SCIENCES, INC., FOSTER CITY, CA 94404 USA
MANUFACTURED BY HOSPIRA, INC., LAKE FOREST, IL 60045

EXP TBD LOT 220653F QTY 297
(17) 000000 (10) 220653F (30) 0297
(I) 103696
COV3016B – SR001 0036

REMDESIVIR 100 MG
30R VIAL, 297 CT, BRITESTOCK
PART NUMBER: 103696
STORE BELOW 30° C
MANUFACTURED FOR GILEAD SCIENCES, INC., FOSTER CITY, CA 94404 USA
MANUFACTURED BY HOSPIRA, INC., LAKE FOREST, IL 60045

EXP TBD LOT 220653F QTY 297
(17) 000000 (10) 220653F (30) 0297
(I) 103696
COV3016B – SR001 0036

Expiration Date: TBD

RETURNED ACCEPT	% ACCT.

TOTAL EJECTS

Effective 23-Oct-2020 GMT Print Copy Number: 1
Print Request Date: 23-Oct-2020 17:39:17

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced a multi-year agreement with Gilead Sciences, Inc. to manufacture and supply Gilead's investigational antiviral remdesivir, as one of multiple external manufacturing organizations supporting efforts to scale up supply of the investigational treatment for COVID-19. Under the terms of the agreement, Pfizer will provide contract manufacturing services at Pfizer's McPherson, Kansas facility to manufacture and supply remdesivir for Gilead.

In March, Pfizer launched a five-point plan, which called on all members of the innovation ecosystem – from large pharmaceutical companies to the smallest of biotech companies, from government agencies to academic institutions – to commit to work together in addressing the dire COVID-19 crisis.

"From the beginning it was clear that no one company or innovation would be able to bring an end to the COVID-19 crisis. Pfizer's agreement with Gilead is an excellent example of members of the innovation ecosystem working together to deliver medical solutions," said Albert Bourla, Chairman and Chief Executive Officer. "Together, we are more powerful than alone. As one of the largest manufacturers of vaccines, biologics and sterile injectables, it is a privilege to offer our expertise and infrastructure to help fight this pandemic. In that spirit, we are pleased that Gilead is using our manufacturing capacity to help facilitate supply of this medicine to patients as quickly as possible."

Preview

COVID-19 vaccine safety update - ACIP (01.27.2021)

Last edited by: Shen, Wen on: Jul 27, 2021

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† v-safe data as of 1/20/2021, 5:00 AM ET

7

Reactogenicity reported to v-safe

Local and systemic reactions, day 0-7*,†	All vaccines %	Pfizer- BioNTech dose 1 %	Pfizer-BioNtech dose 2 %	Moderna dose 1 %
Pain	70.7	67.7	74.8	70.1
Fatigue	33.4	28.6	50.0	29.7
Headache	29.4	25.6	41.9	26.0
Myalgia	22.8	17.2	41.6	19.6
Chills	11.5	7.0	26.7	9.3
Fever	11.4	7.4	25.2	9.1
Swelling	11.0	6.8	26.7	13.4
Joint pain	10.4	7.1	21.2	8.6
Nausea	8.9	7.0	13.9	7.7

* v-safe data lock point 1/14/2021, 5:00 AM ET

† Reported on at least one health check-in completed on days 0-7 after receipt of vaccine

Target population

Trial populations

BNT162b2:	[illegible]75
mRNA-1273:	[illegible]65
AZD1222:	**18-55 / 56-69 / ≥70**

Non-studied populations

Children

Pregnant women

Immunocompromised subjects

No need to be COVID-19 naïve to get vaccine

545 participants in BNT162b2 trial were COVID-19 convalescent,

and did not show higher AE prevalence

COVID-19 vaccine safety update - VRBPAC (02.26.21)

- VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event
- As a hypothesis-generating system, VAERS identifies potential vaccine safety concerns that can be studied in more robust data systems

U.S. reports to VAERS after COVID-19 vaccines*

Vaccine	N	Non-serious AEs (%)	Serious AEs†§ (%)
Moderna	56,567	54,708 (97)	1,859 (3)
Pfizer-BioNTech	48,196	43,974 (91)	4,222 (9)
Total	**104,763**	**98,682 (94)**	**6,081 (6)**

* Total pre-processed reports received through Feb 16, 2021

† Based on the Code of Federal Regulations if one of the following is reported: death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, congenital anomaly or birth defect

§ Includes 456 reports of death following Moderna COVID-19 vaccine and 510 reports of death following Pfizer-BioNTech COVID-19 vaccine

Preview

ES_HP_JS_LMS_slide_deck_16Mar2021_v6_1_1_final_LMS team

Last edited by: Rouse, Jason C on: Aug 3, 2021

OPEN DOWNLOAD SHARE

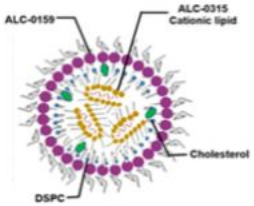
COVID-19 Vaccine Late Migrating Species (LMS) Investigation

Elaine Stephens, Himakshi Patel, and Jason Rouse on Behalf of COVID-19 LMS Team

March 17, 2021
BTxPS LT Science Topic

COVID-19 Vaccine

- **COVID-19 vaccine consists of mRNA encapsulated in a lipid nanoparticle (LNP)**
- LNPs are composed of 4 lipids
  - ALC-0159: Functional PEG-lipid (7%)
    - Forms a hydration layer over LNP and provides a steric barrier to interactions with surfaces or other LNP that may otherwise result in particle fusion during storage.
  - ALC-0315: Functional cationic lipid (57%)
    - Required for the interaction with the endosomal membrane and eventual fusion, and then endosome escape / RNA delivery
  - DSPC: Structural lipid (12%)
    - Provides stable bilayer-forming structure to balance the non-bilayer propensity of the cationic lipid.
  - Cholesterol: Structural lipid (24%)
    - Supports the bilayer structure in the LNP and provides mobility of the lipid components within LNP structure.

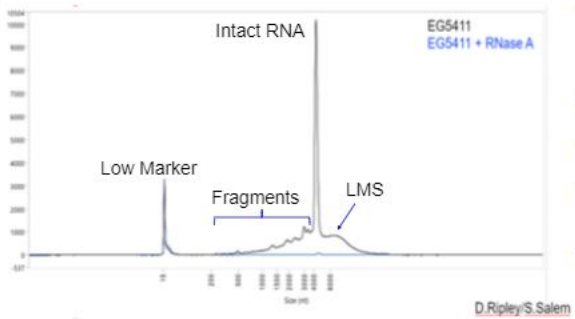


Background

- Integrity of mRNA is evaluated by Fragment Analyzer (FA) for release/stability of DS and DP
- FA is a capillary gel electrophoresis (CGE) method that separates molecules based on their molecular charge, shape and size, similar to traditional slab gel electrophoresis.
  - Smaller RNA (fragments) migrate faster than the main peak
- Analysis of DP engineering run 1 (Lot EG5411, Purrs) by FA showed a significant amount late migrating species (LMS) that was not typically observed

INX100435080,
"Characterization of LMS"

FA of Engineering DP Lot EG5411 (produced w/ Croda 465/1 ALC-0315)



- DP is analyzed following disruption of LNP in detergent and ethanol
- LMS Level: ~25%
- LMS is comprised of RNA
- FA separated species are not recoverable for characterization
- Developed an orthogonal method for separation and characterization of LMS

ES_HP_JS_LMS_slide_deck_16Mar2021_v6_1_1_final_LMS team

1.27-1.28 (Dimer)			0.3	0.3	0.2					0.1		
Total Impurities (LC-CAD)		0.9	1.3	1.4	0.8	0.4	1.1	0.9	0.3	1.1	0.2	0.6
Total Impurity % (Avanti)	5.5	5	5.5	6								

Low <5% Med. 5 to 12% High >12%

RRT From LC/MS	m/z		RRT From LC/CAD
1.18	1121.0417		
1.23	1221.13		1.22
1.25	1321.2182		1.24 or 1.26
1.27	1524.3867	Dimer	1.27
1.26	1526.4024	Dimer	1.26
1.28	1530.4337	Dimer	1.27
1.29	1530.4337	Dimer	

Paul Brown: m/z 1096.9842 elutes with RRT of 1.11

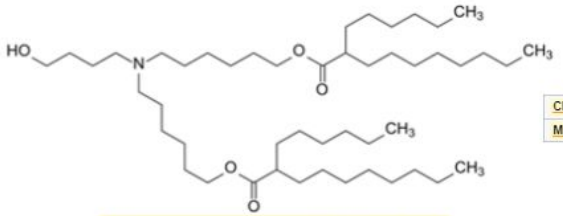
Moderna Experience with "LMS"

- Moderna observes covalent mRNA-cationic lipid impurity/degradant association by RP-HPLC
- Moderna determined that the mRNA-lipid species renders affected mRNA inactive*, impacting potency
- The lipid-RNA species have been isolated for characterization by multiple orthogonal analyses and are analytically indistinguishable from unmodified mRNA. The lipid-RNA species are not mRNA aggregates.
- Stability studies under frozen liquid and accelerated conditions have monitored these impurities
- **Several actions have been undertaken to optimize the manufacturing processes of the cationic lipid component SM-102 & mRNA-1273 LNP leading to a significant reduction in potential lipid-RNA species**
- The applicant should provide a comprehensive summary of the investigations and process changes related to lipid-RNA species
- It should be demonstrated that detection wavelength is suitable for quantification of lipid-RNA species

*Note - ARD never tested the activity of LMS, but it is assumed to be inactive

Pfizer and Moderna Cationic Lipid Structures

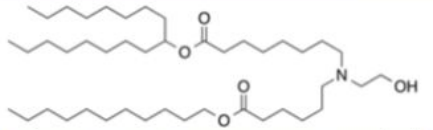
Pfizer
ALC-0315



(((4-Hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate))

Chemical formula	$C_{46}H_{91}NO_5$
Molecular mass	766.290 Da

Moderna
SM-102

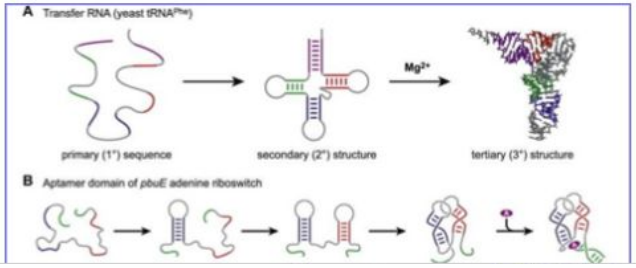


(heptadecan-9-yl 8-{(2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate)

Chemical formula	$C_{44}H_{87}NO_5$
Molecular mass	710.182 Da

RNA Structure, "LMS" Mechanisms, and Lipid Structures

RNA Higher Order Structure



- RNA adopts three levels of structure: (1) primary sequence; (2) secondary structure, in which only Watson-Crick base pairs are present; and (3) tertiary structure, which depends on metal ions such as Mg2+.
- For purine riboswitches, binding of the purine is also required for tertiary stabilization.
- Unlike for proteins, RNA secondary structure elements such as stem-loops (hairpins)

Human reproductive safety data are not available for BNT162 RNA-based COVID-19 vaccines, but there is no suspicion of human teratogenicity based on the intended mechanism of action of the compound. Therefore, the use of a highly effective method of contraception is required (see Appendix 4).

traditional vaccine approaches. This capability is pivotal to enable the most effective response in outbreak scenarios.

Three SARS-CoV-2–RNA lipid nanoparticle (RNA-LNP) vaccines based on a platform of nucleoside-modified messenger RNA (modRNA, BNT162b) may be evaluated in this study. Each vaccine candidate expresses 1 of 3 antigens: the SARS-CoV-2 full-length, P2 mutant, "heads up," prefusion spike glycoprotein (P2 S) (version 9), a trimerized SARS-CoV-2 spike glycoprotein-receptor binding domain (RBD) (version 5), or a membrane-anchored trimerized SARS-CoV-2 RBD. The 3 SARS-CoV-2 vaccine candidates that may be tested in this study are therefore:

- **BNT162b1** (variant RBP020.3): nucleoside-modified messenger RNA (modRNA) with blunted innate immune sensor–activating capacity and augmented expression encoding the RBD.

- **BNT162b2** (variant RBP020.2): nucleoside-modified messenger RNA (modRNA) as above, but encoding P2 S.

- **BNT162b3** (variant RBP020.8): nucleoside-modified messenger RNA (modRNA) as above, but encoding a membrane-anchored RBD.

MEDICAL INFORMATION

07-April-2021

melissa.strickler@pfizer.com

Dear Ms. Strickler,

Thank you for your inquiry about PFIZER-BIONTECH COVID-19 VACCINE.

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent COVID-19 for use in individuals 16 years of age and older.

Your email to Dr Albert Bourla was forwarded to Medical Information for response to your inquiry.

You asked if luciferase is contained in the final vaccine.

Luciferase was used during the early development program in the vaccine candidates to evaluate mRNA expression, but luciferase is not contained in the final Pfizer-BioNTech COVID-19 Vaccine that is used during the Emergency Use Authorization.

(data on file, 129; Pfizer)

Learn More:

What can I do with this information?

This document provides an answer to your question about a Pfizer product but it does not contain all the available information. It does not take the place of talking to your vaccination provider, doctor, or pharmacist. This information is provided for informational purposes only and is not meant to be a substitute for advice provided by a vaccination provider, doctor, or other qualified health care professional. Patients should not use this information for diagnosing a health or fitness problem or disease. You should always talk with a vaccination provider, doctor, or other qualified health care professional about whether a specific treatment or medication is right for you and before starting a new treatment or activity. They are in the best position to advise you about the suitability of a particular treatment as they have access to the details of your medical history, as well as to information on all medical products.

Where can I get more information?

Please refer to the full Fact Sheet for Recipients and Caregivers on important treatment considerations for the Pfizer-BioNTech COVID-19 Vaccine via the following link: https://www.pfizermedicalinformation.com/en-us/patient/pfizer-biontech-covid-19-vaccine or www.cvdvaccine.com. In the event this link does not work, please access the product's Fact Sheet or Prescribing Information at www.pfizer.com.

What should I do if I get any side effects?

The full Fact Sheet for Recipients and Caregivers or Prescribing Information includes a list of possible side effects. If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital. Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away. Report side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to http://vaers.hhs.gov/reportevent.html. Please include "Pfizer BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form. In addition, you can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com, via fax at 1-866-635-8337, or by telephone at 1-800-438-1985

If you did not specifically request this information, please call 1-800-438-1985 to report this to us.

The product prescribing information can be accessed on www.pfizer.com. The website www.pfizermedinfo.com offers a patient portal where patients or caregivers can access information about Pfizer prescription products as well other patient health resources.

Thank you for your interest in Pfizer. To reach Pfizer Medical Information or to report a suspected adverse event or concern about the quality of a Pfizer product, please call 1-800-438-1985.

Sincerely,

STEVEN R HAYS, PharmD, MBA

Pfizer Medical Information

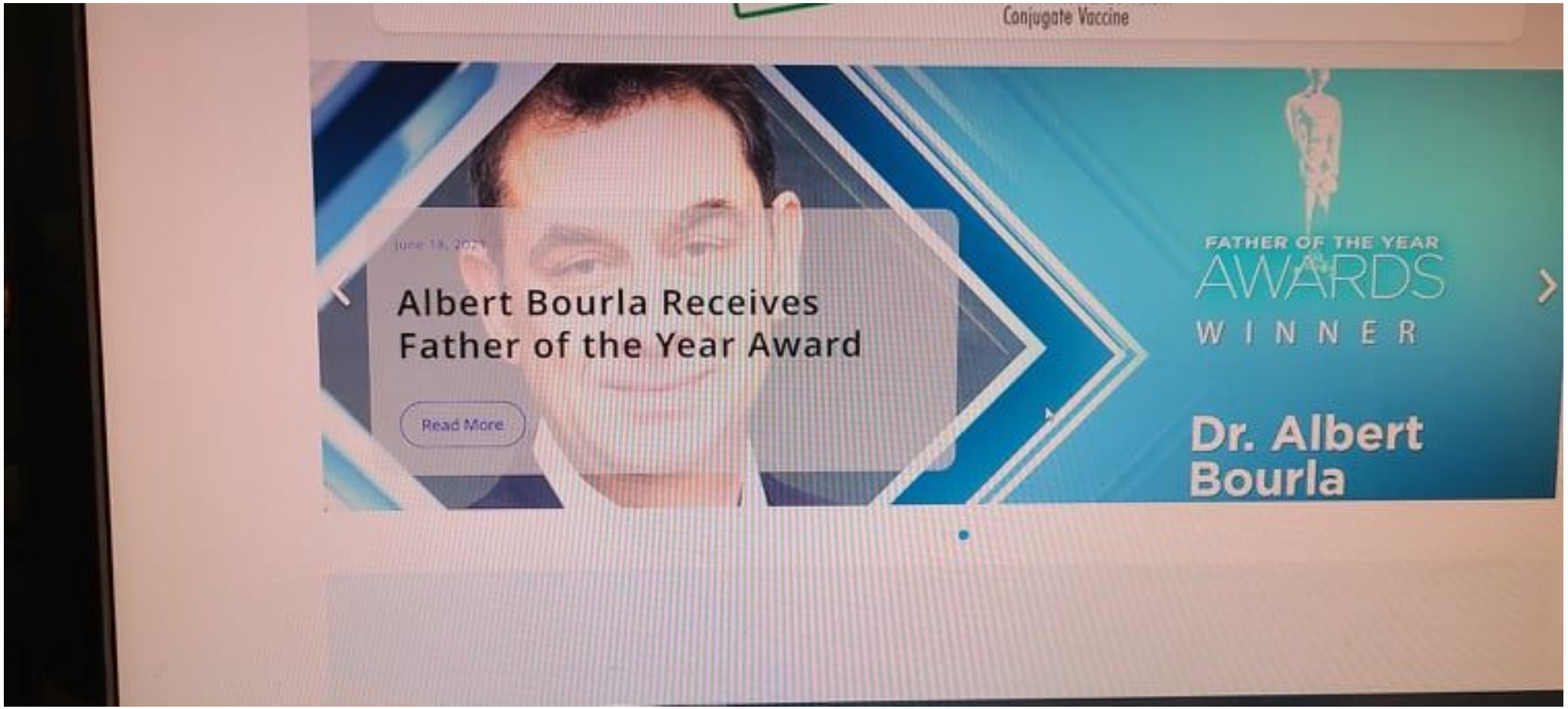
00185619

Worldwide Medical and Safety (WMS) /Global Medical Information Country Business Continuity Supplement

Site/Country: Wuhan / China

Site	Address
Wuhan	Pfizer (Wuhan) Research and Development Co., Ltd (WRDC) Tower B14, Biolake, 666 Gaoxin Avenue, Eastlake Hi-Tech Development Zone, Wuhan 430205, P.R China

This appendix is a supplement to the Global Business Continuity Plan (BCP). It has been developed for country specific operations for the business processes managed within the Global BCP. Recovery Procedures for disruptions are documented in the Global BCP as well. The Country Supplement is intended to document the procedures and responsibilities to guarantee business continuity of the local country, if different than the Global BCP, and the local contacts responsible during an event.


Conjugate Vaccine
Albert Bourla Receives
Father of the Year Award
Read More
FATHER OF THE YEAR
AWARDS
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From: Payal Sahni Becher
Sent: Tuesday, September 21, 2021 9:15 AM
Subject: Next Phase of COVID-19 Vaccination Guidance for U.S. Colleagues and Contractors

Breakthroughs that change patients' lives

Dear Colleagues,

As we see on the news and read in the headlines, highly contagious variants of COVID-19, like Delta, have resulted in many more cases, hospitalizations, and deaths around the world. The science tells us that the variants overwhelmingly attack the unvaccinated with severe infection often requiring hospitalization, while those who are fully vaccinated experience far milder symptoms and do not usually require hospitalizations.

As the global leader in the fight against COVID-19 and the first to receive full FDA approval of our COVID-19 vaccine, COMIRNATY®, in individuals 16 years of age and older, we must do all that we can to support public health and minimize the impact of this pandemic on our colleagues, contractors, families, and the communities we serve.

As a result of our recent vaccination guidance and protocols for U.S. colleagues announced on August 4, 90 percent of U.S. colleagues are now vaccinated with more being scheduled every day. Outside the U.S., in the countries where we can vaccinate, colleagues are also doing their part. Thank you for living our values and setting an example for others to follow.

Today, we are announcing the next phase of our vaccination guidance that – **effective November 15, 2021** – all U.S. colleagues and contractors are **required** to be fully vaccinated unless approved for a medical or religious accommodation from vaccination. **If you are a U.S. colleague and have not yet submitted proof of full vaccination, you will receive a separate message shortly with more details.**

For colleagues outside of the U.S., we understand that some markets still lack availability to vaccinations, and we are working as hard as we can to bring COVID-19 vaccines to your markets. If you do have access to COVID-19 vaccines in your country and have not been vaccinated, we recommend that you do so with any available vaccine as soon as possible. We will look to implement vaccine guidance in your country once we are able to do so.

Guidance for U.S. contractors will be sent separately to the contractor population.

Please continue to visit the COVID-19 information page on PfizerWorld for updated FAQs regarding this new vaccination guidance in the U.S.

Best,

Payal Sahni Becher
Executive Vice President,
Chief Human Resources Officer

am for COVID-19 mRNA Vaccine

As always, I hope this letter finds you and your loved ones staying safe and healthy.

Today is an important and exciting day in our efforts to find medical solutions to fight COVID-19. Along with our partners at BioNTech, we **announced today** that the first participants have been dosed in the U.S. in the Phase 1/2 clinical trial for the BNT162 vaccine program to prevent COVID-19 infection. This trial is part of our co-development program with BioNTech, with human testing already underway in Germany.

The unprecedented, less than four-month timeframe in which our two companies have been able to move from pre-clinical studies to human testing is extraordinary and further demonstrates our commitment to dedicating our best-in-class resources, from the lab to manufacturing and beyond, in the battle against COVID-19.

What makes this program unique – in addition to the speed with which we are advancing it – is that four vaccine candidates are being tested simultaneously, each representing a unique combination of mRNA format and target antigen. Each of the candidates could potentially be tested in three different doses and two different age populations in a single Phase 1/2 study. The design of the trial allows us to move urgently while preserving the highest quality and safety standards, and we are working in collaboration with the FDA to provide real-time data and receive feedback.

Because of the urgent need for a vaccine, we already have begun to invest at risk to actively scale up our manufacturing capacity and distribution infrastructure. Assuming the clinical trials are successful, this will enable us to bring our vaccine candidate to the world faster than we have ever done before. By doing many steps in the process in parallel, rather than sequentially, we have the potential to supply millions of vaccine doses by the end of 2020, subject to technical success and regulatory approvals, then rapidly scale up to produce hundreds of millions of doses in 2021. Our sites in St. Louis, Missouri, Andover, Massachusetts, and Kalamazoo, Michigan, will be the first facilities involved in the manufacturing of the vaccine candidate. As we move into the later stages of development and production, we also plan to engage our teams in Puurs, Belgium, and other sites, as well.

Our purpose – *Breakthroughs that change patients' lives* – is more critical than ever, and I couldn't be prouder of how our colleagues are leveraging our decades of scientific expertise in pioneering vaccine discovery, development and production to respond to this global health crisis.

Thank you to everyone at both companies working on this vitally important program. Your ingenuity, expertise and resolve are exactly what we need to make the seemingly impossible possible.

Stay well.

Albert

From: McPherson <McPherson@pfizer.com>
Sent: Thursday, August 5, 2021 10:47 AM
Subject: Message from Ian MacKellar: Updated Vaccine Guidance and Protocols for U.S. Colleagues

August 5, 2021

McPherson Colleagues,

By now you have likely read the emails sent yesterday from Payal Sahni Becher, Pfizer's Chief Human Resources Officer, regarding Pfizer's updated Vaccination Guidance and Protocols for U.S. Colleagues. If you have not yet done so, I highly recommend you read both and the FAQ document to ensure you understand them.

Our intent is for McPherson to be fully compliant with this guidance but it will take a few days for us to completely understand our local processes. We will dedicate time in our Virtual Townhalls and I will come out to perform cafeteria townhalls next week.

As we have discussed in our townhalls, cases are increasing in different populations than earlier during the pandemic. We are not yet on the other side of this health emergency, which makes our commitment to our patients all the more important. Our priorities remain as they always have been: the health and safety of our colleagues, and the uninterrupted supply of our medicines to the patients who need them.

Finally, I would like to remind you of two important items. First, colleagues should not discuss this guidance with media. Any inquiries must be forwarded to Aquila Harrison. Second, please be reminded of Pfizer's Social Media Policy, particularly when it comes to sharing COVID-19 vaccination information on social media.

Together we achieve,

Ian MacKellar

McPherson Site Lead

Pfizer

Dear Colleagues,

I hope you have been as gratified as I have to see colleagues sharing news and photos of their COVID-19 vaccinations. I realize this may also create questions about when, where and how it is appropriate to share social media posts about your Pfizer-administered vaccinations, if and when you choose to do so. In the spirit of providing this guidance and promoting our culture of JOY for those wanting to celebrate this important milestone, we are sharing appropriate guidance here.

Colleague posts such as these are governed by Pfizer's social media policy guidance under Corporate Policy #407. Under the guidance, all social media posts that reference an approved or investigational Pfizer product must be approved by Legal, as is the case, for example, with Conversation Leaders. Given the intense pride many Pfizer colleagues have about being vaccinated with the Pfizer-BioNTech vaccine, Legal has approved social media posts related to colleague vaccinations so long as colleagues comply with the following guidelines:

- **DO** identify yourself as a Pfizer colleague in any social media post.
    - **CONSIDER** using identifying hashtags, such as #PfizerColleague or #PfizerProud.
- **DO NOT** share opinions about the vaccine or provide medical advice, such as recommending others get it, or not get it.
- **DO** receive their permission before sharing recognizable images of other colleagues, vaccine administrators, or other healthcare professionals.
- **DO** take care to protect your, and others', personal information.
- **DO** follow all adverse event reporting requirements, consistent with Corporate Policy #903. This includes reporting side effects they experience related to a Pfizer product, or that they learn another person has experienced, including information you receive in response to your social media post.
    - **CONSIDER** limiting discussions about vaccine side effects on social media in order to minimize receiving such reports and triggering their reporting obligations.
- **DO NOT** solicit comments or questions from your friends or followers about your vaccination.
- **DO** refer all questions about the vaccine back to the Pfizer website -- one example of an appropriate reply is:"@(their handle) thanks for your question, for more information please visit www.pfizer.com."
- **DO NOT** engage in debates or heated exchanges, including with those that may be "anti-vax."
- **DO** handle all media inquiries in accordance with Corporate Policy #409. If you receive an inquiry from a reporter, contact Pfizer Media Relations.

Beyond our social media guidelines, please be sensitive to the fact that many individuals may not yet be eligible to receive the vaccine so again, please use good judgement. If asked how you qualified to receive the vaccine, consider replying: "@(their handle) thanks for your question, Pfizer has begun to offer the vaccine to its employees, in a phased manner based on risk categories. The vaccination of employees has no impact on Pfizer's ability to meet its supply obligations."

Best,
Sally Susman


CAPTIVE

- This is a sworn testimony. I swear all claims are true due to my experience
- All evidence is not presented due to lack of understanding scientific lingo

For interviews and government officials

MelissaMcAtee1992@yahoo.com