Southington Board of Education

PUBLIC COMMUNICATION

NAME	ADDRESS	TOPIC
Angelica Espada	550 Darling street	Masking/Disabilities
Brian Bradshaw		yielded 3 min
Patricia Tavolozzi	99 Westbrook Rd. Plantsville	masking
Michael Krzyzanski	27 Hitching Post Dr	CRT
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	–
Kristen Ritchie	270 Chesterwood Ter	masks
Steven Boleshiski	191 Queen Street	mask/BOE hypocrisy
Tyler Young	48 Berkley Ave	Mask mandates
Alexandra Grishitsa-Anderson	659 Prospect St	school choice
Colleen Dabkowsk	363 Mulberry St.	Southington Dept. Public Health
yielded to me: Amy Bourdon	35 Pehr Ln. Cheshire 06410	
Viktoria Vagapova	22C Darling Street, Apt. C	masks
Susan Zabchonski	28 Welking St Plantsville	Freedom
Richard Cooper	79 Barbara Ln	Rules
Stacy Jameson	707 West St.	

#1 Angelina

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0

BLA APPROVAL

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

August 23, 2021

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at (b) (4) The final formulated product will be manufactured, filled, labeled and packaged at Pfizer (b) (4) . The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at (b) (4)

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.
We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90°C to -60°C (-130°F to -76°F). The date of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at (b) (4) , the date of manufacture is defined as the date of sterile filtration for the final drug product; at Pfizer (b) (4) , it is defined as the date of the (b) (4) Following the final sterile filtration, (b) (4) , no reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) when stored at (b) (4) We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, or in the manufacturing facilities.

LABELING

We hereby approve the draft content of labeling including Package Insert, submitted under amendment 74, dated August 21, 2021, and the draft carton and container labels submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at monthly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports for Vaccines* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an "**Annual Status Report of Postmarketing Study Requirement/Commitments**" and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion: May 31, 2023

   Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.

   Final Protocol Submission: February 8, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.

   Final Protocol Submission: January 31, 2022

   Study Completion: July 31, 2024

   Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.
Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

   Monitoring Report Submission: October 31, 2022

   Interim Report Submission: October 31, 2023

   Study Completion: June 30, 2025

   Final Report Submission: October 31, 2025

5. Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: January 31, 2022

   Study Completion: March 31, 2024

   Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

   Final Protocol Submission: September 30, 2021

   Study Completion: November 30, 2023

   Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

   We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion: June 30, 2022

   Final Report Submission: December 31, 2022

Please submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if appropriate;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in section 505(o) and 21 CFR 601.70. We remind you that to comply with section 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry."

    Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

    Final Protocol Submission: September 30, 2021

    Study Completion: November 30, 2023

    Final Report Submission: May 31, 2024

12. Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."

    Final Protocol Submission: January 29, 2021

    Study Completion: June 30, 2023

    Final Report Submission: December 31, 2023

13. Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California."

    Final Protocol Submission: March 22, 2021

    Study Completion: December 31, 2022

    Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMC sequential number for each study/clinical trial and the submission number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Study Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

HAROLD KANE SELF INSURANCE COMMITTEE
MINUTES TO MEETING OF MAY 24, 2017

The Harold Kane Self Insurance Committee of the Town of Southington held a meeting on Wednesday May 24, 2017 in the Council Chambers, Town Hall building, 75 Main Street, Southington, Connecticut. Chairman Joe Labieniec called the meeting to order at 5:32 pm.

The following members were present: Zaya Oshana, Sal Dominello, Patricia Queen and Tom Lombardi.
Absent were: Cheryl Lounsbury, John Barry, John Moise and Colleen Clark.

Ex-officio members present: Emilia Portelinha, Sherri DiNello and Terri Buchanan. Absent was Mark Sciota. Also present was Joe Spurgeon from Milliman and Matt Bowker from Anthem.

1. Approval of May 24, 2017 meeting minutes.
Mr. Lombardi made the motion to approve the minutes and Mr. Oshana seconded. Motion passed 5-0.

2. Review FY 2016 - 2017 Self Insurance Budget status.
The members reviewed the April 2017 summary of the Self Insurance Fund. Ms. Portelinha reported that total claims and fees came in $193,000 under budget for the month of April 2017 and $1.0 million under budget year to date. Total HSA/HRA contributions and fees, and Consultant costs totaled $1.2 million. Claims and Fees are 9.6% lower than last year at this time.

Mrs. DiNello informed the HKSIC that due to unanticipated Special Education costs the Board of Education will be short in their FY 2017 Budget. An appropriation request for $450,000 was submitted to the Board of Finance for their May meeting and the Board of Finance tabled this request until their next meeting. She informed the Committee because if the Board of Finance does not approve the additional appropriation, the only recourse she has is to delay the payment of a portion of the Self Insurance employer contribution, or for the Board of Education to request a one-time reduction in their contribution. The Education deficit is currently projected to be $650,000, but may change up or down. Mr. Labieniec requested that Mr. Sciota provide a legal opinion as to whether the HKSIC can forgive some of the Education contribution based on the policy on excess reserves, or would they make the recommendation to the Town Council.

Mr. Spurgeon distributed his Projection vs Actuals report thru April 2017.

3. Presentation of the 2017 Mandates. Mr. Spurgeon stated that because Southington is self-insured we do not have to follow State mandates. We have the option to opt out of these State mandates: 1) Tomosynthesis (3D mammogram) for breast cancer screenings would be preventative. Estimated cost impact is $0.21 per member per month or about $7,300; and 2) Behavioral Health expansion has a very negligible cost impact. Both mandates are low cost.

Federal Mandate – ACA Section 1557 Non-Discrimination Rule is clarification that you cannot discriminate in providing coverage to transgender members. Services must be medically necessary. Mr. Spurgeon explained that if we receive funds from HHS we must accept this mandate. Southington receives the STEPS grant from HHS.

The HKSIC discussed the mandates, and no action was taken.

4. Results of follow-up of Claims Audit Results with Anthem.
Mike Tehan has the responses from Anthem to the final questions. Mr. Lombardi made a presentation to the Town Council and there were no questions or issues.

5. Update on Wellness Program.
Mrs. DiNello and Terri Buchanan updated the HKSIC on the wellness program.

6. Any other business considered proper to come before the committee.

The HKSIC voted to add an Executive Session for Contractual to the Agenda. Mrs. Queen made a motion to go into executive session, and Mr. Oshana seconded. The motion passed unanimously. The HKIC Committee, ex-officio members and Mr. Spurgeon went into executive session at 6:34 pm.

All present came out of executive session at 6:55 pm. No decisions or motions were made while in executive session.

There was some discussion regarding possibly adding a meeting for June 14th to get additional information on several issues.

Motion to adjourn by Mr. Lombardi and seconded by Mr. Oshana. The meeting was adjourned at 6:59 pm.

Respectfully submitted,

Emilia Portelinha
HK Self Insurance Committee

U.S. FOOD & DRUG ADMINISTRATION

August 23, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

10, 2021,[5] June 25, 2021,[6] and August 12, 2021.[7]

On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

COMIRNATY DOES NOT EXIST IN U.S.A.

On August 23, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and to update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.[8]

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[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine.

[7] In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[8] The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct with certain differences that do not impact safety or effectiveness.

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose (with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third dose of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the Pfizer-BioNTech COVID-19 Vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meeting the pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 Vaccine; 67/99 (68%) of the entire group receiving a third vaccination were subsequently considered to have levels of antibodies indicative of a significant response. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar mRNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals or comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was protective. Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binding antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive paper by Hall et al. demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Pfizer-BioNTech COVID-19 vaccine may be effective in this population, and that the known and potential benefits of a third dose of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 12 years of age who have received two doses of the Pfizer-BioNTech COVID-19 Vaccine and who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA when used to provide a two-dose regimen for individuals aged 12 through 15 years, or

to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available[9] alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[10]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[11] to emergency response stakeholders[12] as directed by the U.S.

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[9] Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or that are approved to provide an additional dose to the immunocompromised population described in this EUA.

[10] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[11] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[12] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an

government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[13] and used only to prevent COVID-19 in individuals ages 12 and older; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Product Description

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection) contributes an additional 2.16 mg sodium chloride per dose.

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official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[13] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart. A third dose may be administered at least 28 days following the second dose of the two dose regimen of this vaccine to individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19).

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and

under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 12 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[14]

[14] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
   - Serious adverse events (irrespective of attribution to vaccination);
   - Cases of Multisystem Inflammatory Syndrome in children and adults; and
   - Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

   These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
   - A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
   - A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
   - Newly identified safety concerns in the interval; and
   - Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that

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processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (12 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.

T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
   - Vaccine administration errors whether or not associated with an adverse event
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of Multisystem Inflammatory Syndrome in children and adults
   - Cases of COVID-19 that result in hospitalization or death

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older; and
- 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.

Condition Related to Export

Z. If the Pfizer-BioNTech COVID-19 Vaccine is exported from the United States, conditions C, D, and O through Y do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is now licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 vaccine that was manufactured and labeled in accordance with this emergency use authorization. This authorization thus remains in place with respect to that product for the previously-authorized indication and uses (i.e., for use to prevent COVID-19 in individuals 12 years of age and older with a two-dose regimen, and to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise).

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB, except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

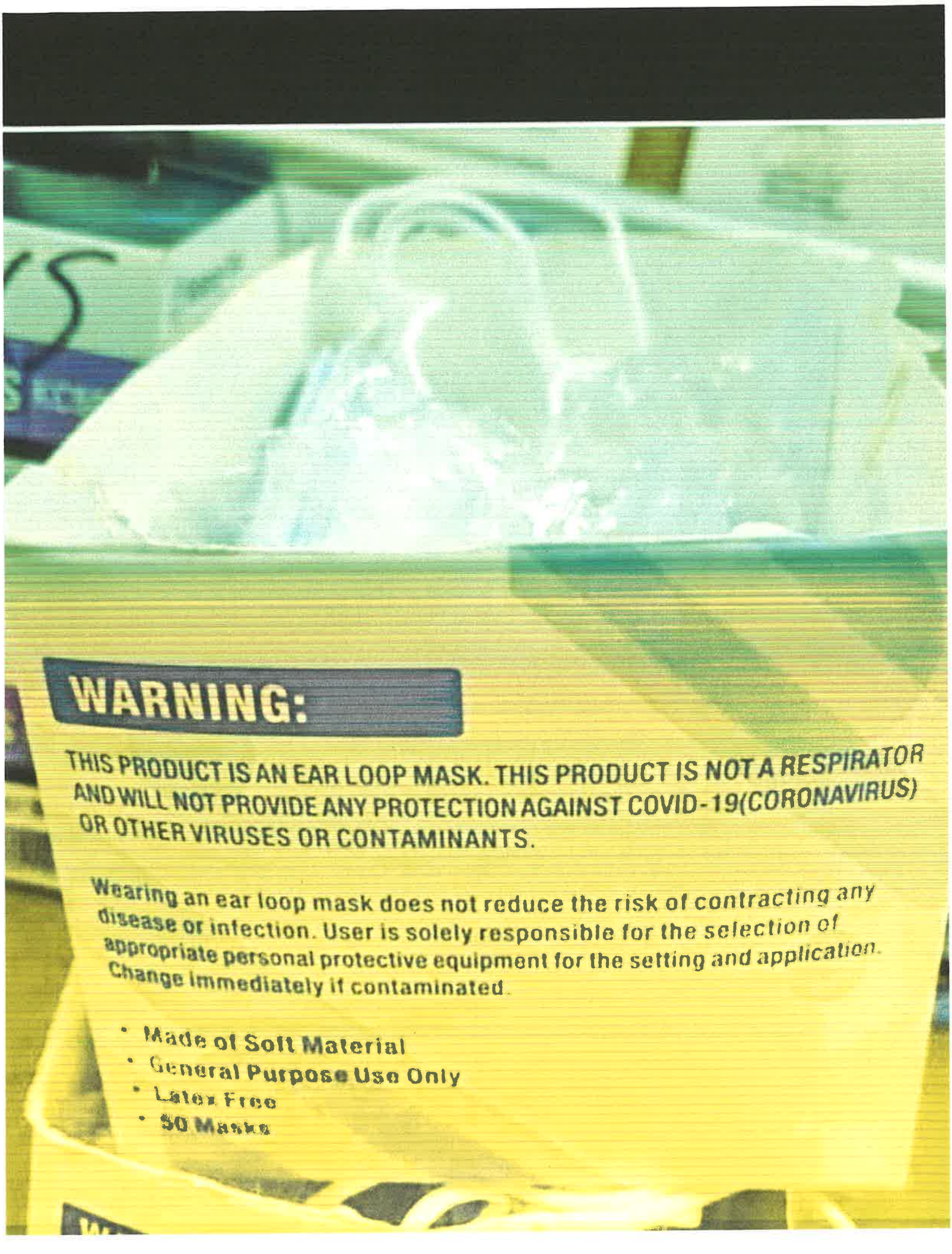
This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures


WARNING:
THIS PRODUCT IS AN EAR LOOP MASK. THIS PRODUCT IS NOT A RESPIRATOR AND WILL NOT PROVIDE ANY PROTECTION AGAINST COVID-19(CORONAVIRUS) OR OTHER VIRUSES OR CONTAMINANTS.
Wearing an ear loop mask does not reduce the risk of contracting any disease or infection. User is solely responsible for the selection of appropriate personal protective equipment for the setting and application. Change immediately if contaminated.
• Made of Soft Material
• General Purpose Use Only
• Latex Free
• 50 Masks

Gmail [redacted]@gmail.com>

21 US code for mask mandates

2 messages

[redacted] Thu, Sep 9, 2021 at 3:34 PM
To: [redacted]@protonmail.com

https://www.law.cornell.edu/uscode/text/21/360bbb-3

UnitedForChoice [redacted] Thu, Sep 9, 2021 at 6:42 PM
Reply-To: [redacted] <[redacted]@protonmail.com>
To: [redacted]

My name is Angelica Espada I live at 550 Darling street. I am running for one of your current positions on this very Board. The purposes of the documents i am about to exhibit for the record is a basis of knowledge and questioning of what YOU, the board members, know about the documentation I am exhibiting.

(I would like to enter, For the record, A memorandum from the FDA dated August 23rd, 2021 addressed to Pfizer Inc attention: Ms.Elisa Harkins regarding an extenuation of the Pfizer Biologic Injection)
(The second piece of documentation entered into the public record is FDA document titled, "BLA Approval" to BioNTech Manufacturing GmbH, Attention: Amit Patel Dated August 23rd, 2021 for the Licensing of a Covid-19 Vaccine)

I would like to inform you that if none of you on the board have viewed any of these documentations (Your attorneys alike) that you are putting individuals, employees, within the school system at risk.
Do the parents know about these documents and have the parents, along with entire school system staff been briefed on the meaning of what these two documents state?
[redacted]
Onto the subject of Children who contend with Intellectual and developmental disabilities specifically children who are on the Autism Spectrum.
Autism as quoted from the CDC often have problems with social, emotional, and communication skills.
They might repeat certain behaviors and might not want change in their daily activities. Many people with ASD also have different ways of learning, paying attention, or reacting to things. Signs of ASD begin during early childhood and typically last throughout a person's life.
Children who suffer from ASD may be blind, wheel chair bound and even apart of the deaf community.
I want to know if IEP's are being implemented INDIVIDUALLY REGARDING MASKING FOR THESE SPECIAL NEEDS CHILDREN? Are you considering implementing resources like teaching sign language to peers. With Masks they are restricting communicative methods by not allowing those students to read lips and restricting their vocabulary.
How is the board implementing Free Appropriate Education to ALL if those specifically in the deaf community who rely on facial expression and social cues start to regress in progress and regress in their ability to communicate? would it not be a hinderance to their education process?
Are parents in Southington aware of the policy changes in the IEP's for those specific students with disabilities and are they requesting PPT's with board members and respected individuals for their specific disabled children? If not, there is a huge problem because again The warning labels on masks admit these surgical masks "WILL NOT PROVIDE ANY PROTECTION AGAINST COVID-19 (CORONAVIRUS) OR OTHER VIRUSES OR CONTAMINANTS."

I know for a fact that the "Pfizer Vaccine that has been being administered over the past few months, is NOT MANDATORY, under ANY LAW within the United States."
So lets talk about...
How was the governor informed about the "Pfizer Approval"?
How was the school board informed about the "Pfizer/BioNTech Apporoval"?
How many employees and teachers did the school system mandate to recieve "A VACCINE"?

------- Original Message -------
On Thursday, September 9th, 2021 at 3:34 PM, [redacted] wrote:

https://www.law.cornell.edu/uscode/text/21/360bbb-3

[redacted]

2) Patricia T

To be read into the record at the Southington Board of Education meeting on Sept 9, 2021:

Many parents have spoken at board of education meetings over the past several months and have sent letters detailing the adverse impact of masking children on a long-term basis. This letter is to recap those communications and reiterate that Parents have an ***unalienable right*** to decide what is best for their children.

- Current State of Connecticut: COVID-19 cases, hospitalizations and deaths among the Connecticut population remain relatively low and at stable levels, due primarily to a high vaccination rate and higher numbers of individuals with natural immunity from previous infections. Also very noteworthy: schools have fared substantially better statistically than the general population throughout the entire pandemic, mainly due to the grace of God sparing children from severe illness.

- There are more than 45 potential adverse impacts of masking young children, including physical symptoms and health impairments, behavioral, psychological, social-emotional, developmental and academic impacts. Parents have provided testimony of their children having to receive medical attention and medication and even hospitalization as a result of having to wear a mask for so many hours per day (the most common testimonies included reference to skin infections, headaches and asthma complications in addition to many other adverse impacts). Parents have also shared with you that school administrators have denied exemptions and accommodations written by our pediatric specialists though these administrators and staff do not have the expertise, credentials or authority to make health decisions for our children.

- A year and a half into the pandemic, there still are no peer-reviewed studies published concluding that mask wearing in schools is effective in reducing viral transmission. It is clear that any potential marginal protection against viruses is completely outweighed by adverse impacts of mask wearing.

- **The World Health Organization's Mask Wearing Guidance** for children recommends that children aged 5 (in Kindergarten) and below never wear masks, and children aged six to eleven only be masked in classrooms if their school is in a locality with widespread transmission and only after consulting with parents, teachers, and medical providers, to weigh the potential impact on learning and psychosocial development. Requiring masks of older aged children should be contingent upon the overall community transmission rate. Most of Connecticut, including Southington, does not meet the WHO's definition of widespread transmission and therefore there should not be a mask mandate for any school ages at this time. Furthermore, children of any age should never wear masks during sports or physical activities. Why is Connecticut ignoring the WHO in regard to this pandemic?

- Ventilation is the number one COVID-19 mitigant per the CDC so that is primarily where federal and state funding should be directed- what has SPS done to improve ventilation in schools?

- Our school guidance recommends the KN95 as the most effective mask but will not provide them for our children in support of the state mandate. SPS's position is that the type of mask is **parent's choice**, so it appears that focus is not on safety, but perhaps on SPS's fear of liability.

- Parents have also voiced concerns about the lack of mask policy and procedures in our schools, a lack of mask breaks, masks being required of children during physical activity and even requiring masks with holes cut in them while playing instruments. Many of these specifics are completely non sensical and absurd.

Thank you for hearing our concerns. It is our hope that this Board, elected by us, will take our concerns to the state level in an effort to restore our parental right to choose for our children.

Signed by more than 100 residents:
Angelo Aldi
Rebecca Alicki
Sara Almeida

Dawn & Steven Anastasio
Mark Anderson
Alexandra Gizhitsa-Anderson
Pranvera Asipi
Mevlan Asipi
Chelsea Bowles
Brian Bradshaw
Deborah Ceruti-Bucci
Dana Charette
Kenneth Colson
Kelly Ann Constantino
Jennifer Couture
Isabeth Criscitello
Gabriel Criscitello
Jacob Criscitello
Rachel Criscitello
Richard Criscitello
Richard Criscitello III
Megan Csuka
Jaimie & Matthew D'Angelo
Colleen Mary Dabkowski
Mike Daley
Alisa DelMonte
Lisa DelToro
Emily Derynoski
Joshua Deziel
Joe Dupuis
Angelica Espada
Lauren Ennen
Jon Flugrad
Samantha Gaffey
Jenna Giacomi
Suzy & Tom Gudja
Elizabeth Hagen
Melissa Lapila Hallgren
Don Hamilton
Kaitlin & Ryan Humble
Sonia Hunt
Eddie Hunt
Eddie Hunt, Jr.
Stacy Jameson
Josh Jillson
Lukasz Jura
Brandon Lee
Britt Elise Lynch
Gina Kaminski
Bryan Kaminski
Jayme & Brian Krisak
Zakaraja Krivca
Zia Krivca
Mike & Halina Kryzanski
Cheryl Leone
Rosemarie Magliochetti

Katherine & Martin Magzag
Christina Mancini
Scott & Sarah Matney
Dianne Marzi
Jackson Matney
Alyssa McAdams
Bryan McAdams
Erica Michalak
Jenn Parrett
Valerie Ragucci
Loriana & Robert Rand
David J Riccio
Rick & Joann Rice
Nick & Elena Rice
Jess Riedel
Kristen & Todd Ritchie
William & Catherine Santarsiero
Michelle & Daniel Santiago
Leona Santopietro
Jeff Smith
Lisa Smith
Stephen Soares
Glenn & Patricia Tavalozzi
Robert Tonon
Richard Toth
Janet Townsley
Jim Townsley
Melissa Tracy
Susan Tracy
James Tracy
John Tracy
Victoria Vagapova
Vadim Vagapov
Marlene Verderame
AnnMarie Vieira
Luke Viera
Robert Wells
Rachael & Jasper Williams
Susan Zabohonski
Janice Zitofsky
State Senator Rob Sampson

#3 Angelina

HAROLD KANE SELF INSURANCE COMMITTEE
MINUTES TO MEETING OF MAY 24, 2017

The Harold Kane Self Insurance Committee of the Town of Southington held a meeting on Wednesday May 24, 2017 in the Council Chambers, Town Hall building, 75 Main Street, Southington, Connecticut. Chairman Joe Labieniec called the meeting to order at 5:32 pm.

The following members were present: Zaya Oshana, Sal Dominello, Patricia Queen and Tom Lombardi.
Absent were: Cheryl Lounsbury, John Barry, John Moise and Colleen Clark.

Ex-officio members present: Emilia Portelinha, Sherri DiNello and Terri Buchanan. Absent was Mark Sciota. Also present was Joe Spurgeon from Milliman and Matt Bowker from Anthem.

1. Approval of May 24, 2017 meeting minutes.
Mr. Lombardi made the motion to approve the minutes and Mr. Oshana seconded. Motion passed 5-0.

2. Review FY 2016 - 2017 Self Insurance Budget status.
The members reviewed the April 2017 summary of the Self Insurance Fund. Ms. Portelinha reported that total claims and fees came in $193,000 under budget for the month of April 2017 and $1.0 million under budget year to date. Total HSA/HRA contributions and fees, and Consultant costs totaled $1.2 million. Claims and Fees are 9.6% lower than last year at this time.

Mrs. DiNello informed the HKSIC that due to unanticipated Special Education costs the Board of Education will be short in their FY 2017 Budget. An appropriation request for $450,000 was submitted to the Board of Finance for their May meeting and the Board of Finance tabled this request until their next meeting. She informed the Committee because if the Board of Finance does not approve the additional appropriation, the only recourse she has is to delay the payment of a portion of the Self Insurance employer contribution, or for the Board of Education to request a one-time reduction in their contribution. The Education deficit is currently projected to be $650,000, but may change up or down. Mr. Labieniec requested that Mr. Sciota provide a legal opinion as to whether the HKSIC can forgive some of the Education contribution based on the policy on excess reserves, or would they make the recommendation to the Town Council.

Mr. Spurgeon distributed his Projection vs Actuals report thru April 2017.

3. Presentation of the 2017 Mandates. Mr. Spurgeon stated that because Southington is self-insured we do not have to follow State mandates. We have the option to opt out of these State mandates: 1) Tomosynthesis (3D mammogram) for breast cancer screenings would be preventative. Estimated cost impact is $0.21 per member per month or about $7,300; and 2) Behavioral Health expansion has a very negligible cost impact. Both mandates are low cost.

Federal Mandate – ACA Section 1557 Non-Discrimination Rule is clarification that you cannot discriminate in providing coverage to transgender members. Services must be medically necessary. Mr. Spurgeon explained that if we receive funds from HHS we must accept this mandate. Southington receives the STEPS grant from HHS.

The HKSIC discussed the mandates, and no action was taken.

4. Results of follow-up of Claims Audit Results with Anthem.
Mike Tehan has the responses from Anthem to the final questions. Mr. Lombardi made a presentation to the Town Council and there were no questions or issues.

5. Update on Wellness Program.
Mrs. DiNello and Terri Buchanan updated the HKSIC on the wellness program.

6. Any other business considered proper to come before the committee.

The HKSIC voted to add an Executive Session for Contractual to the Agenda. Mrs. Queen made a motion to go into executive session, and Mr. Oshana seconded. The motion passed unanimously. The HKIC Committee, ex-officio members and Mr. Spurgeon went into executive session at 6:34 pm.

All present came out of executive session at 6:55 pm. No decisions or motions were made while in executive session.

There was some discussion regarding possibly adding a meeting for June 14th to get additional information on several issues.

Motion to adjourn by Mr. Lombardi and seconded by Mr. Oshana. The meeting was adjourned at 6:59 pm.

Respectfully submitted,

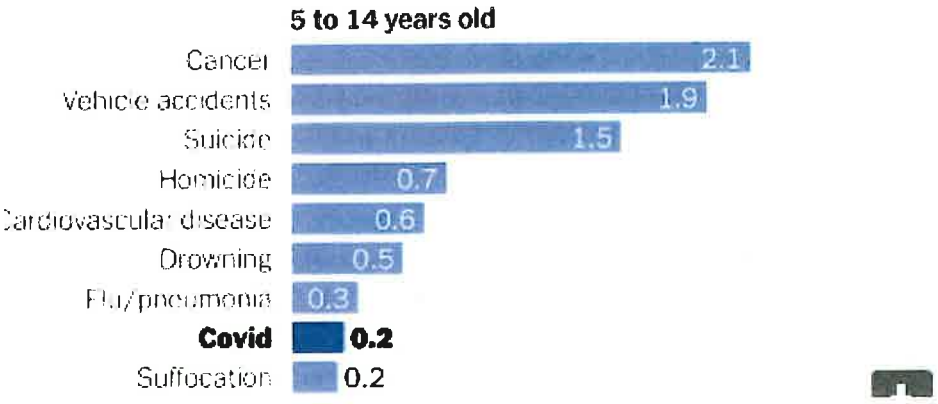
Emilia Portelinha
HK Self Insurance Committee

To the Board of Education, Mr. Madancy, and fellow Southington Citizens,

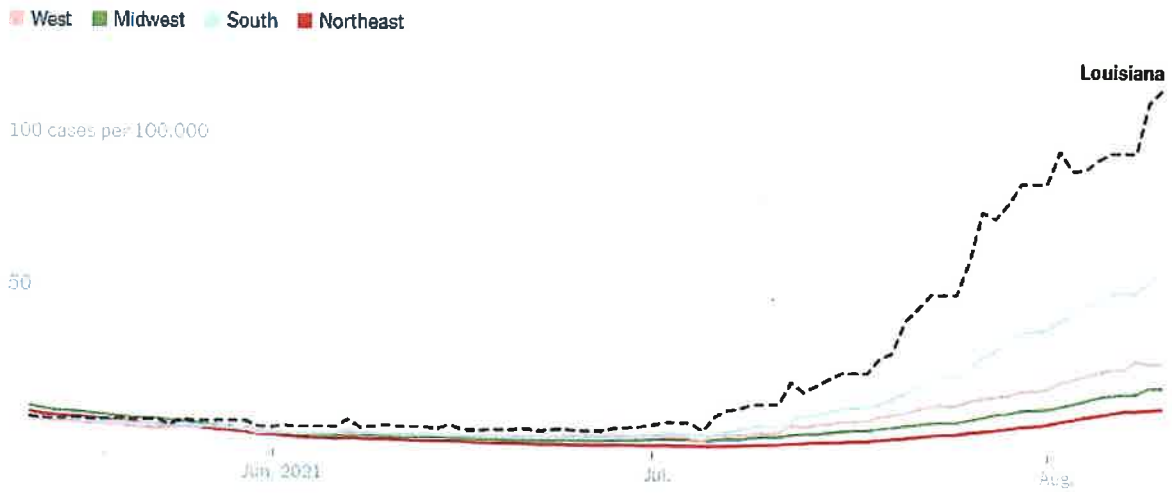
First, let me thank you for doing an amazing job in keeping our schools open last year. Both of my children were able to attend school in person every day, and for that, I couldn't be more grateful.

You may recall, I wrote several letters that you so beautifully read for me last summer, regarding keeping our schools open. For those who don't recall, let me introduce myself. My name is Jillian Echard, and my two children attend Kelley Elementary School. I am also a respected Forensic Scientist, and have spent the last 17 years doing DNA testing for our state's forensic laboratory. I have kept up with a great deal of published information that has been available to us regarding this pandemic, vaccines, and trends, and am fully aware of the benefits of mask wearing, having worn them throughout my career. That being said, I am writing this today as a concerned parent, worried about the social and educational impact masks are having on our elementary age students, and am against them being mandated in our schools.

This chart shows annual deaths among children in the United States, for a year-long period ending in April of 2021. The number is per 100,000. Deaths from the flu and pneumonia are slightly higher than those from Covid, and deaths for vehicle accidents are almost ten times as high. These risks though are ones we've learned to accept in our society, just like we need to learn to accept risks associated with Covid. Even in our worst flu seasons, our children did not wear masks.



Nor do I believe we should be blindly following CDC guidelines that speak for our country as a whole. In the Northeast, we are in a very different situation than most other parts of our country because of our higher vaccination rates. This chart shows over the past 90 days how different regions in the country have been affected by the Delta variant. You can clearly see that the Northeast is the lowest, boasting the highest vaccination rates, while the South has the highest daily changes per capita, due to their vaccination rates being the lowest. Even within our state, our vaccination rates vary wildly. While 64% of the total population of Connecticut is fully vaccinated, some of our larger cities have much lower rates. For example, Hartford only has 41% of their residence fully vaccinated. Southington is 68% fully vaccinated, which even in one of the most vaccinated states, is above the average for that state. How can the CDC recommend that all people in schools, regardless of vaccination status, should wear masks as a blanket statement covering all towns in all states, when there are clearly differences in our country?



I have heard the argument that, yes, children aren't being affected by this virus that much, but they can still spread it to an adult who hasn't been vaccinated. With all due respect, that unvaccinated adult has made it their choice to not be vaccinated. Why, then, is it my child's responsibility, our children's burden, to wear a mask to protect them? Let me make my opinion on this clear: It is not my child's responsibility to protect an unvaccinated adult.

I have heard people say "it's the parents complaining, not the kids", but I know firsthand that not to be true. I kept a positive attitude in front of my children, not complaining or voicing my opinions, for fear they'd just emulate my behavior. But at the end of the school year, with no provocation, my children started to complain that the masks were harder to breathe in. Perhaps it was because their school lacks air conditioning, and this was a result of the rising temperatures in the building. And I have heard countless other parents speak to this as well.

At the beginning of last school year, my sister (also in the Southington School district) asked if my niece, who had just started kindergarten, could benefit from speech therapy. The teacher honestly said that she didn't know, because it's very hard for her to hear what her students are saying with the masks on. After testing occurred, she overwhelmingly qualified for services. However, through a year of speech therapy with both my niece and her therapist in masks, not a single gain was made in any area of concern. These are these children's formative years, and they're being hindered due to these mask policies. Are we really willing to have our children in masks for another school year where there teachers struggle to hear their little, developing voices?

Recently studies have emerged that U.S. elementary school students ended this school year 4-5 months behind where they should have been. No doubt because time and time again, it has been proven that children this age do not learn the way they were made to learn last year. They need interaction, and groups, and play. They need to be heard by their teachers.

A friend's son's teacher, in the Southington school district, with a background in psychology, noted during their parent teacher conference that the masks are affecting our children's ability to empathize, and learn basic social cues. Interested, I then researched this, and found published peer review papers to this point. If we can't tell if someone is sad, or hurt, or angry, how do we know to stop the actions causing these feelings? Masks are impacting our children's emotional development.

But it's not just masking I would like you to take into consideration. It's their entire school experience that has been modified for the better part of one and a half years. Our children missed out on playing with their friends at recess and sitting with their friends at lunch, making new friends, joining after school clubs, participating in a school drama production, attending field trips, browsing through book clubs, sharing their gifts in talent shows, and so much more. There was no Kindergarten readers showcase, no Valentines sing-a-long, no Mother's Day brunch, parents couldn't read books to their children on their birthdays, grandparents couldn't have lunch with their grandchildren, and no doubt countless other experiences I'm not aware of. Sure, missing something here and there isn't the end of the world, but if you add all these experiences up, it amounts to a great deal of the school experience being taken from our children. If this continues for another year, we're taking away half of their elementary school years to partake in these events, form these memories, and enjoy these experiences.

The economy is open. People are traveling, shopping, dining, and socializing with very limited Covid restrictions at this point. The way I see it, it is only our children who continue to suffer. And it's only our children in certain states, seeing that schools around the country, in states far worse than ours, have opened fully without masks. You have the ability to change that, and I beg of you, to consider it. Thank you.

Jillian Echard

Jillian Echard

206 Monarch Dr.

Southington, CT

TERESA COLEGROVE

Subject: FW: Thalberg

From: Stephanie P <sunnydaz1236@yahoo.com>
Sent: Thursday, September 9, 2021 2:56 PM
To: TERESA COLEGROVE <tcolegrove@southingtonschools.org>
Subject: Re: Thalberg

Please read into the record

Please I beg and plead keep our children and staff masked. My son has an aortic Arch which one of his aorta's wraps around his esophagus any small cold causes constricted breathing so imagine covid. It was amazing last year no colds what so ever. Please as a mother who is a hairdresser who wore a mask and a shield. And was capable of working all day like that to make sure I didnt/ don't bring covid home to my children. I'm holding our school system accountable in keeping my children safe as I am.

I see many many teachers and school staff in my chair and they all agree to ensure their safety and the childrens is they need to continue as we did last year with masking. How can we ask a teacher to sit in a room all day in fear wondering who, what, where, and when. It's not, and it's not fair to the parents who have children who have medical conditions to be terrified to send our child to get the proper education they need. Please contact me if you have any questions. Have a great day I understand this is such a stressful time.

Thank you, Stephanie Grennan

1881 West St southington C.T 06489

Thank you, Stephanie Grennan

STEVEN MADANCY

From: Jennifer McPherson <msginger89@hotmail.com>
Sent: Tuesday, September 7, 2021 8:47 PM
To: SBOE
Subject: Input for meeting 9/9/2021

I hope it's not too late to weigh in on this. The email was stuck in my outbox before the August meeting.

Please read into the record during the BOE meeting dated September 9, 2021. Thank you.

I am writing to express my support for children wearing masks in the upcoming school year. We are still in the midst of a global pandemic and are continuing to learn about the virus, including the new variants, but at this point, some is still unknown. For me, children's safety should come first and foremost, before political agendas or "freedom". I'm stunned that we are actually making this an issue. What is the end game here? What if we find out later than children who get the virus could have long-term effects on their growth or learning ability. The point is right now we just don't know. I would ALWAYS err on the side of caution. Our kids won't be damaged physically or psychologically. I think they are probably more confused and scared now because of all the arguing. Parents should be thinking of their health, even if it seems hard. This is hard. But working together, we can and will get through it. Wearing masks might be able to get us through it sooner. The bottom line is, if we are wrong, then all that's happened is that kids had to wear masks; if they are wrong, kids could die.

In terms of CRT, I think that fighting against it only proves why we need it. It doesn't have to be CRT (which I believe is just a FOX "News" talking point that has caught on to outrage people). Just teach us REAL history. I am appalled at the historical events I didn't know and wasn't taught in school. I'm 50 and am just learning things now. Instead of fighting, why don't we ask People of Color what they need from us? Why don't we try to HEAR and actually LISTEN to them when they express the generations of trauma that they have been through. Would you tell someone who was sexually assaulted that it's in the past and to "just get over it" or that they "are exaggerating"? Would you tell a co-worker who loses a parent to just get over it? People are hurting and need support, not push back.

Thank you.
Jenny McPherson
39 Mathews St.
Southington

September 9, 2021

Dear Superintendent Madancy and Members of the Board of Education,

First, I want to thank teachers, staff, and administrators, particularly those at Urbin T. Kelley School, for a successful start to the school year.

I would like to remind you of a **key responsibility *you have* to our school community—ensuring the health of our students**, especially as we are still in a pandemic.

The Centers for Disease Control and Prevention and the American Academy of Pediatrics recommends **universal indoor masking by all students (age 2 and older), staff, teachers, and visitors to K-12 schools, *regardless* of vaccination status**. Even vaccinated individuals can get and spread COVID-19, and while they will be well protected against getting seriously ill, they still may transmit the virus, particularly to those who are unvaccinated.

All children under the age of 12 are unvaccinated. (The COVID-19 vaccine is not indicated for individuals under the age of 12.) Using the Connecticut State Department of Education's number of students in the Southington Public School system for the 2019-2020 school year (most recent data available), **at least, 50% of the student population is NOT ELIGIBLE to receive the COVID-19 vaccine.** They are at risk for contracting, becoming seriously ill, and spreading COVID-19 to each other and the Southington community.

Remember that the 2020-2021 school year proved that kids could go to school and remain safe, even during a global pandemic because of universal **MASKING**. As the National Education Association, another organization supporting universal masking in schools, states, **"America's public schools should be the safest place in every community."** It is up to *you* to *ensure* that *this holds true in Southington Public Schools*!

Thank you for always prioritizing our children, focusing on their health and well-being, and ensuring that all students receive a high-quality education through the Southington Public School system.

Sincerely,

Marissa C Salvo

Marissa Salvo, 8 Yorktown Road, Southington

(Professionally, I'm a pharmacist who has administered the COVID-19 vaccine and trained other healthcare providers to administer the COVID-19 vaccine; all with the hope of improving public health in our community and state.)