Exhibit A

People

Reports

Vaccinator List

Support Shift Signup

Get Vaccinated

Requesting a COVID vaccine exemption for religious reasons

Current Exemption Request Status

If you have submitted a request previously, the status of that request is displayed below:

Requestor: Kaycee Danielle McCoy (kdh6b)

Your request for a religious exemption has **not been approved**. Please see the reviewer's comments below for more info.

Reviewer's comments: Dear Applicant,

Thank you for your request for a religious exemption under the OCH-002-Health Screening Policy. (http://www.healthsystem.virginia.edu/docs/health-system/occupational-health/healthscreeningandmaintenance). At this time your request is **denied**. To qualify for a religious exemption, you must briefly explain the religious principle, tenet or belief and how that religion's principles, tenets or beliefs conflict with or preclude you from receiving a vaccination.

If you have additional information to submit in support of your request, you may email uvahrhealthscreening@virginia.edu.

For information on becoming compliant with OCH-002, please visit Immunize UVA.

Click here to submit a(n) alternate medical exemption request

Human Resources will consider requests for non-medical exemption based on religious principles, tenets or beliefs.

If the request for exemption is approved, you will be marked as compliant for this task. If your request is returned, you must complete the task as assigned or resubmit with valid documentation.

Please describe the religious principle, tenet, or belief for your request

Dear UVA Health System,

I, Kaycee McCoy, assert my right to a religious exemption from vaccination. I am a Christian and have a Christian worldview. I believe in the Bible and the teachings held within it. Christian worldview recognizes that faith and conscience compel an individual to submit to the proper jurisdiction within the rule of law, Divine Law, the word of GOD.

I am objecting to vaccines because I believe in and follow God and the principles laid out in His Word. I deeply believe vaccines violate these principles.

I sincerely believe and hold true that my body is a temple for the Holy Spirit and I shall not defile the temple of God. The principles and teachings that I hold my religious faith are as follows and the vaccines violate these:

1 Corinthians 3:16-17, 6:19-20 (NIV)16?Don't you know that you yourselves are God's temple?and that God's Spirit dwells in your midst?? 17?If anyone destroys God's temple, God will destroy that person; for God's temple is sacred, and you together are that temple.

19?Do you not know that your bodies are temples?of the Holy Spirit, who is in you, whom you have received from God? You are not your own;?20? you were bought at a price.?Therefore honor God with your bodies.

2 Corinthians 7:1 (NIV) Therefore, since we have these promises,?dear friends,?let us purify ourselves from everything that contaminates body and spirit, perfecting holiness?out of reverence for God.

1 Corinthians 8:7 Howbeit?there is?not in every man that knowledge: for some with conscience of the idol unto this hour eat?it?as a thing offered unto an idol; and their conscience being weak is defiled.

I hold the sincere belief according to my Christian faith, that my body is a temple of the Holy Spirit. It is a God-given responsibility and requirement for me to protect my body and the physical integrity of my Body against unclean injections.

The contents of vaccines include, neurotoxins, hazardous substances, attenuated viruses, animal parts, foreign DNA, albumin from human blood, carcinogens and chemical waste that are proven harmful to the human body. Reference: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf

The additives in vaccines are considered contaminants from a biblical standpoint, and the contaminants themselves are often contaminated. Many of the vaccines contain cells, cellular debris, protein and DNA from aborted babies. Vaccines included but not limited to Adenovirus, Polio, Shingles, TB, influenza (http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf)

My sincerely held belief that the blood of man was created by the hand of God and by injecting a vaccine with unnatural components and ingredients corrupts the sanctity of my blood and body as a whole.

The manufactures of COVID-19 vaccines use fetal cell lines in development, confirmation and production. The fetal stem cell lines have been used in the development of the Johnson & Johnson COVID-19 vaccine, and the fetal stem cell lines have been used in the testing of the Moderna and Pfizer Covid 19 vaccines. See James Lawler, MD, You asked we answered: Does the COVID 19-vaccines contain aborted fetal Cells.? Nebraska Medicine, August 4, 2021, https://www.nebraskamed.com/COVID/you-asked-we-answered-do-the-covid-19-vaccines-contain-aborted-fetal-cells

The presence of and use of immortalized human cell lines taken against the will of the person aborted, having been used in the development of vaccinations, violates my sincere and firm beliefs that participation in the vaccination mandate is an indirect engagement and participation in abortion. In the book of Jeremiah 1:5 Before I formed you in the womb I knew you, before you were born. It is against my faith and conscience to sin. According to the Ten Commandments, Deuteronomy 5:17 You shall not murder.

I also hold the sincere belief that the mRNA vaccine violates the creation of man by God. By using an mRNA based vaccine it alters the creation of the human body, a holy temple of God,with an foreign substance forcing our bodies to create a protein that is not found naturally. God created man with the greatest form of defense the immune system as well as our faith in him to protect us. The Lord my God is the only one

well as our faith in him to protect us. The Lord my God is the only one with the ultimate healing power. The act of taking the vaccine is a betrayal of my faith.

My deeply held religious beliefs that innocent life is sacred in conception, to birth to natural death.

The New Testament requires of Christians that we "Render to Caesar the things that are Caesar's, and to God the things that are God's."?(Mark 12:17). When it comes to consuming or injecting things into our bodies, as opposed to make payments to government, compliance with God's law is required.

Again as stated, accepting any such vaccine goes against my sincerely held principles and teachings by the Word of God. The mandated vaccine, containing its numerous additives and its mechanisms for altering my body, is the equivalent of a prohibited "unclean food" that causes harm to my conscience. Vaccines to me are unclean. I believe in the God the Father Almighty Heaven and Creator of Earth. I follow the teachings and principles laid out in His Word, and I sincerely hold beliefs that vaccines violate these principles.

To avoid undue hardship, I am willing to comply with weekly prevalence testing and continue wearing my mask on UVA grounds.

I make this request for the glory of God Almighty and is consistent with my faith.

Please see attached document, signed from my Pastor, attesting these are my sincerely held religious beliefs.

Please describe why this principle, tenet or belief conflicts with or precludes you from receiving a vaccination or immunization.

Dear UVA Health System,
I, Kaycee McCoy, assert my right to a religious exemption from vaccination. I am a Christian and have a Christian worldview. I believe in the Bible and the teachings held within it. Christian worldview recognizes that faith and conscience compel an individual to submit to the proper jurisdiction within the rule of law, Divine Law, the word of GOD.

I am objecting to vaccines because I believe in and follow God and the principles laid out in His Word. I deeply believe vaccines violate these principles.

I sincerely believe and hold true that my body is a temple for the Holy Spirit and I shall not defile the temple of God. The principles and teachings that I hold my religious faith are as follows and the vaccines violate these:

1 Corinthians 3:16-17, 6:19-20 (NIV)16?Don't you know that you yourselves are God's temple?and that God's Spirit dwells in your midst?? 17?If anyone destroys God's temple, God will destroy that person; for God's temple is sacred, and you together are that temple.

19?Do you not know that your bodies are temples?of the Holy Spirit, who is in you, whom you have received from God? You are not your own;?20?

you were bought at a price.?Therefore honor God with your bodies.

2 Corinthians 7:1 (NIV) Therefore, since we have these promises,?dear friends,?let us purify ourselves from everything that contaminates body and spirit, perfecting holiness?out of reverence for God.

1 Corinthians 8:7 Howbeit?there is?not in every man that knowledge: for some with conscience of the idol unto this hour eat?it?as a thing offered unto an idol; and their conscience being weak is defiled.

I hold the sincere belief according to my Christian faith, that my body is a temple of the Holy Spirit. It is a God-given responsibility and requirement for me to protect my body and the physical integrity of my Body against unclean injections.

The contents of vaccines include, neurotoxins, hazardous substances, attenuated viruses, animal parts, foreign DNA, albumin from human blood, carcinogens and chemical waste that are proven harmful to the human body. Reference: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf

The additives in vaccines are considered contaminants from a biblical standpoint, and the contaminants themselves are often contaminated. Many of the vaccines contain cells, cellular debris, protein and DNA from aborted babies. Vaccines included but not limited to Adenovirus, Polio, Shingles, TB, influenza (http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf)

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The presence of and use of immortalized human cell lines taken against the will of the person aborted, having been used in the development of vaccinations, violates my sincere and firm beliefs that participation in the vaccination mandate is an indirect engagement and participation in abortion. In the book of Jeremiah 1:5 Before I formed you in the womb I knew you, before you were born. It is against my faith and conscience to sin. According to the Ten Commandments, Deuteronomy 5:17 You shall not murder.

I also hold the sincere belief that the mRNA vaccine violates the creation of man by God. By using an mRNA based vaccine it alters the creation of the human body, a holy temple of God,with an foreign substance forcing our bodies to create a protein that is not found naturally. God created man with the greatest form of defense the immune system as well as our faith in him to protect us. The Lord my God is the only one with the ultimate healing power. The act of taking the vaccine is a

betrayal of my faith.

My deeply held religious beliefs that innocent life is sacred in conception, to birth to natural death.

The New Testament requires of Christians that we "Render to Caesar the things that are Caesar's, and to God the things that are God's."?(Mark 12:17). When it comes to consuming or injecting things into our bodies, as opposed to make payments to government, compliance with God's law is required.

Again as stated, accepting any such vaccine goes against my sincerely held principles and teachings by the Word of God. The mandated vaccine, containing its numerous additives and its mechanisms for altering my body, is the equivalent of a prohibited "unclean food" that causes harm to my conscience. Vaccines to me are unclean. I believe in the God the Father Almighty Heaven and Creator of Earth. I follow the teachings and principles laid out in His Word, and I sincerely hold beliefs that vaccines violate these principles.

To avoid undue hardship, I am willing to comply with weekly prevalence testing and continue wearing my mask on UVA grounds.

I make this request for the glory of God Almighty and is consistent with my faith.

Please see attached document, signed from my Pastor, attesting these are my sincerely held religious beliefs.

Attach documentation, if applicable

Choose File No file chosen

- UVA exemption letter.pdf [Remove]

If the request for exemption is approved, you will be marked as compliant for this task. If your request is returned, you must complete the task as assigned or resubmit with valid documentation.

Exit

Exhibit B

Emmanuel United Methodist Church

401 North Main Street ✝ P.O. Box 451 ✝ Amherst, VA 24521
Phone (434) 946-7624, office@emmanuelamherst.org
Rev. Nancy C. Johnson, Pastor

September 10, 2021

Dear University of Virginia Health Systems:

Kaycee McCoy is a baptized member and worshiping congregant of Emmanuel United Methodist Church in Amherst, VA. In her own religious exemption letter to UVA, Kaycee has stated her objection to receiving the COVID-19 vaccine based on the fact that fetal cells are used in the creation and testing of the vaccines. As a Christian, Kaycee believes that abortion is a sin, and requiring her to receive the vaccine violates her right to fully exercise and live out her religious beliefs.

I fully support Kaycee's right to this objection based on the exercise of her own personal and faithful convictions. Further, our *United Methodist Book of Discipline* states that "our belief in the sanctity of unborn human life makes us reluctant to approve abortion" (*UM Book of Discipline*, 2008, p. 105). Kaycee's letter includes further Biblical and scientific evidence to support her objection. She has clearly stated her willingness to undergo weekly testing and to wear a mask in the workplace. In my understanding, both our state and federal authorities have announced that this is an appropriate option for employers to offer their employees in order to be in compliance with the vaccine mandate.

Sincerely,

Rev. Nancy C. Johnson

Exhibit C

McCoy, Kaycee Danielle *HS

From: no-reply@hscmail.mcc.virginia.edu
Sent: Thursday, September 30, 2021 9:48 PM
To: kdh6b@virginia.edu
Subject: Vaxtrax Request Processed

Dear Applicant,

Thank you for your request for a religious exemption under the OCH-002-Health Screening Policy. (http://www.healthsystem.virginia.edu/docs/health-system/occupational-health/healthscreeningandmaintenance). At this time your request is **denied**. To qualify for a religious exemption, you must briefly explain the religious principle, tenet or belief and how that religion's principles, tenets or beliefs conflict with or preclude you from receiving a vaccination.

If you have additional information to submit in support of your request, you may email uvahrhealthscreening@virginia.edu.

For information on becoming compliant with OCH-002, please visit Immunize UVA.

Exhibit D

McCoy, Kaycee Danielle *HS

From: McCoy, Kaycee Danielle *HS
Sent: Monday, October 4, 2021 12:32 PM
To: 'uvahrhealthscreening@virginia.edu'
Subject: Denied religious exemption

I am inquiring as to the reasoning why my religious exemption was denied.
I can submit more supporting information, but I also had attached a signed letter from my pastor with my original exemption request.
Was the attachment uploaded correctly?

Thanks,
Kaycee McCoy

Exhibit E

McCoy, Kaycee Danielle *HS

From: AskHR <askhr@virginia.edu>
Sent: Thursday, October 14, 2021 4:12 PM
To: kdh6b@virginia.edu
Subject: COVID Exemption status [ref:_00D36ouwd._5001R1Au0ks:ref]

Hi Kaycee,

Thank you for contacting HR Solutions. I reached out to one of my senior collogues to get clarification on the religious exemption status. Below is the information that we have been asked to communicate with EE's requesting religious exemption.

"The decisions made by the Health System Vaccine Religious Exemption Committee are final unless you have additional information that will support your submission; there is otherwise no appeal process.". If a team member does not receive an approved exemption request, it is important to note that Monday October 18th is the deadline to receive the final dose of the Moderna or Pfizer vaccine series and it is the deadline to receive the single-dose of the Johnson & Johnson vaccine. As of Monday November 1st, the disciplinary process for unvaccinated team members will begin, up to and including termination." Employee relations will not reach out until after you have received a decision from your second submission.`

Regards,

Eric

University of Virginia

ref:_00D36ouwd._5001R1Au0ks:ref

Exhibit F

Gmail Rick Boyer <rickboyerlaw@gmail.com>

Fw: Vaxtrax Request Processed

1 message

pdsuekd@yahoo.com <pdsuekd@yahoo.com> Tue, Nov 9, 2021 at 8:07 PM
Reply-To: "pdsuekd@yahoo.com" <pdsuekd@yahoo.com>
To: Rick Boyer <rickboyerlaw@gmail.com>, Pat McSweeney <patrick@mck-lawyers.com>, Chris Collins <ccollins@vfnlaw.com>, "William J. Olson" <wjo@mindspring.com>

----- Forwarded Message -----
From: Kaycee <pdsuekd@yahoo.com>
To: wjopc@mindspring.com <wjopc@mindspring.com>
Sent: Tuesday, November 9, 2021, 05:28:08 PM EST
Subject: Fw: Vaxtrax Request Processed

Sent from Yahoo Mail on Android

----- Forwarded Message -----
From: "McCoy, Kaycee Danielle *HS" <KDH6B@hscmail.mcc.virginia.edu>
To: "McCoy, Daniel" <Daniel.McCoy@l3harris.com>, "'pdsuekd@yahoo.com'" <pdsuekd@yahoo.com>
Sent: Tue, Nov 9, 2021 at 3:40 PM
Subject: Fw: Vaxtrax Request Processed

Kaycee McCoy, CT (ASCP)^cm
UVA Health Systems
Cytology
434-924-0325

From: no-reply@hscmail.mcc.virginia.edu <no-reply@hscmail.mcc.virginia.edu>
Sent: Tuesday, November 9, 2021 3:29 PM
To: kdh6b@virginia.edu
Subject: Vaxtrax Request Processed

Dear Applicant, Thank you for your request for a religious exemption. Our decision remains the same, denied. Therefore, we will not be accepting further resubmissions.

Exhibit G

UVA Health to Require COVID-19 Vaccination for Team Members Effective Nov. 1

AUGUST 25, 2021

Effective November 1, 2021 for UVA Health Community
(includes Medical Center, SOM, SON, UPG, HS Library, and Community Medicine)

Dear Colleagues,

After seeing a steady decline in positive COVID-19 tests and hospitalizations this spring and early summer, the increasing number of new COVID-19 cases in recent weeks (particularly the highly transmissible delta variant) is a reminder that we must remain committed to protecting the health and well-being of our teams, communities and every patient who entrusts us with their care. In the interest of keeping our environment as safe and healthy as possible, the University of Virginia is working hard to ensure strong vaccination rates across faculty and staff as well as mandating vaccination for students. At UVA Health, we take this commitment — and this responsibility — seriously and will now require all team members without a religious or medical exemption to be vaccinated against COVID-19 by November 1, 2021. Any team member not meeting the vaccination requirement deadline will be subject to disciplinary action up to and including termination.

We firmly believe that a mandatory COVID-19 vaccination program is the most important thing we can do to protect our team members, our patients and our communities. The available vaccines are effective and safe and are proven to prevent against serious infection, hospitalization and death. For any team member who has been reluctant to receive the vaccine,

we want to address any questions or concerns you have. Details about the vaccine requirement and resources for more information are available on (https://hr.virginia.edu/), including instructions for team members (https://hr.virginia.edu/covid-19/hs-covid-19), including instructions for

We do not take this important step lightly. We have some of the world's foremost infectious disease experts and epidemiologists, and their expertise continues to guide UVA Health's strong response to COVID-19 as do the recommendations from major public health and professional organizations — including the American Medical Association, the American Hospital Association, the American Nurses Association, the Virginia Hospital and Healthcare Association and many others — regarding the requirement of healthcare workers to get vaccinated.

Unvaccinated team members should make arrangements to be fully vaccinated at any vaccination site (this is considered paid time for team members). Team members may schedule appointments at a UVA Health vaccination site through VaxTrax (https://www.healthsystem.virginia.edu/auth/login.cfm?referringurl=/vaxtrax&siteUUID=9982EBE6-6F8E-4F08-93414CFBDC0EBF0F). Please note that weekly COVID-19 testing is still required between vaccination doses (Moderna and Pfizer) and for 14 days after the last dose (or the first/only dose with the Johnson & Johnson vaccine). Those who were previously infected with COVID-19 are encouraged to get vaccinated as soon as they have recovered from clinical illness. A detailed timeline about key dates in this process is attached **(see image below)**. Please take some time to read through the attached details and Frequently Asked Questions.

Thank you for your steadfast dedication to UVA Health and the care of our patients. Together, we have an opportunity and responsibility to take this next important step toward protecting our patients, communities and each other.

Sincerely,

K. Craig Kent, MD
Executive Vice President for Health Affairs, University of Virginia Chief Executive Officer, UVA Health

Bobby Chhabra, MD
President, University Physicians Group

Exhibit H

UNIVERSITY of VIRGINIA

SEC-045: COVID-19 Health & Safety Requirements – Vaccination, Testing, Face Masks, Events and Gatherings, and Visitors

Applies To:

Academic Division for the 2021-2022 Academic Year.

Reason for Policy:

The University is committed to providing a safe environment in which to teach, perform research, work, learn, and study. Because coronavirus (COVID-19) can spread quickly and cause widespread illness and death, the University has established requirements for vaccination, testing, face coverings, events and gatherings, and visitors to the University to protect faculty, staff, students, and contractors (vendors who have a contractual relationship with the University) from potential exposure to this disease.

Definition of Terms in Statement:

- Event or Gathering:

  In-person, on- or off-Grounds assembly, meeting, or convening that brings together multiple people from separate households in a single space, indoors or outdoors, at the same time for a common purpose to conduct University business or student activity. Events and gatherings may include meetings, social events, or other extracurricular activities that bring together people for in-person interaction. Events and gatherings do not include University-scheduled classes or labs. Events and gatherings do not include settings in which people are in the same general space at the same time but doing separate activities, like dorms, offices, stores, and restaurants where people may be working, shopping, or eating in the same general area but not gathering together in an organized fashion.

- Expressive Activity:

  A non-commercial activity in which a person intends to convey a lawful message through speech or conduct that is likely to be perceived as such by an observer of the speech or conduct, and includes any lawful public gathering, demonstration, procession, or parade in which the primary purpose is to exercise the rights of free speech or peaceable assembly.

- Face Covering (Face Mask):

  Face coverings/masks are recommended by the Centers for Disease Control & Prevention (CDC) and the Virginia Department of Health primarily to slow the spread of COVID-19 by

reducing spread of the virus from the wearer to others. They are not intended to provide protection from inhalation of small particles or virus aerosols. According to CDC guidance, an effective cloth face covering will:

- Cover both the mouth and the nose;
- Fit snugly but comfortably against the side of the face;
- Include multiple layers of fabric;
- Allow for breathing without restriction; and
- Be able to be laundered and machine-dried without damage or change to shape.

- Fully Vaccinated:

  Fully Vaccinated: Per CDC guidance, people are considered fully vaccinated:
  - 2 weeks after their second dose in a 2-dose series, such as the Pfizer or Moderna vaccines;
  - 2 weeks after a single-dose vaccine, such as Johnson & Johnson's Janssen vaccine; or
  - 2 weeks after the last dose of vaccines that have been authorized for emergency use by the World Health Organization.

- University Property:

  Land or buildings that the University owns or leases and that is under the control of the Board of Visitors. University property also includes premises the University uses for activities of its offices, departments, personnel, or students.

Policy Statement:

To protect faculty, staff, students, contractors, and visitors from potential exposure to COVID-19, the University encourages individuals to follow CDC guidelines and federal, state, and local directives. All faculty, staff, students, and contractors are required to follow COVID-19 risk mitigation measures, as directed by the University.

1. **COVID-19 Vaccination:** All students and Academic Division employees must adhere to the following vaccination requirements, excluding faculty and staff in the School of Medicine, School of Nursing, the University Physicians Group, and the Claude Moore Health System Library who are governed by OCH-002: Occupational Health Screening and Maintenance:

   Students: Beginning July 1, 2021, all students who live, learn, or work in person at the University of Virginia during the 2021-2022 academic year must be fully vaccinated. Students may seek a medical or religious exemption to the vaccination requirement. Students with approved medical or religious exemptions will be subject to pre-arrival and weekly testing requirements and other public health measures such as masking as determined by the University. Students who do not complete pre-arrival testing as well as students who are not vaccinated and not approved for an exemption will not be permitted to come to Grounds after July 1, 2021.

   Faculty and Staff: All full-time and part-time UVA faculty and staff, including those working remotely, must have received their final vaccination dose by January 4, 2022, unless they have a University-approved medical or religious exemption. Faculty and staff with approved medical or religious exemptions will be subject to mandatory saliva PCR testing once each week or as otherwise directed by the University. Unvaccinated faculty and staff must also adhere to other public health measures such as masking as directed by the University. This policy does not apply to faculty and staff in the School of Medicine, School of Nursing, the University Physicians Group, and the Claude Moore Health System Library, who are governed by OCH-002: Occupational Health Screening and Maintenance. Those employees governed by OCH-002 should follow the guidance and deadlines found here. All UVA faculty and staff

who are not vaccinated and not approved for an exemption will be subject to disciplinary action consistent with the University's policies, up to and including unpaid leave or termination.

Contractors: The University expects contract workers who work on Grounds or perform public-facing services on behalf of the University (covered contract workers) to disclose their vaccination status to their employers (i.e., the contracting vendor that employs them). Contracting vendors must certify to the University that covered contract workers are either 1) fully vaccinated; or 2) if not fully vaccinated, require that they adhere to all of the University's public health safety protocols. Covered contract workers who are not vaccinated must follow all University COVID-19 mitigation measures as determined appropriate and directed by the University.

2. **Testing:** Testing requirements apply to all unvaccinated students and Academic Division employees, excluding faculty and staff in the School of Medicine, School of Nursing, the University Physicians Group, and the Claude Moore Health System Library, who are governed by OCH-002: Occupational Health Screening and Maintenance.

   Regular testing of unvaccinated individuals is critical for keeping the University and the local community safe. Unvaccinated students, faculty, and staff are subject to a mandatory COVID-19 PCR test once each week or as otherwise directed by the University.

   Testing exceptions will be granted for faculty and staff who:
   - Are both fully vaccinated with a WHO Emergency Use Listing (EUL) COVID-19 vaccine issued and have uploaded proof of vaccination;
   - Have tested positive for COVID-19 in the last 150 days;
   - Are working remotely 100% of the time; or
   - Are working in a location outside the Charlottesville-Albemarle region.

   Failure to comply with testing requirements may result in disciplinary action in accordance with relevant University policies up to and including unpaid leave or termination.

   Students who do not complete pre-arrival testing will not be permitted to come to Grounds before the beginning of each semester and will be disenrolled. Students who miss their weekly testing requirement will face a series of escalating consequences. Students may also face additional sanctions including referral to the Judiciary Committee, termination of housing contract, registration blocks, and disenrollment and dismissal from the University. The applicable University refund schedule in tuition, housing charges, or any other University fees at the time of dismissal or disenrollment will apply.

3. **Face Masks: Masks are required for all people (students, faculty, staff, contractors, and visitors), both vaccinated and unvaccinated, who enter UVA properties.** This includes University-owned or leased public spaces like academic or administrative buildings, libraries, labs, dining halls, IM/Rec facilities, all UVA Health properties, and public transportation. This does not include dorms or private housing (including common areas within those spaces), or those alone within individual offices.

   Masks are required outdoors for unvaccinated people (students, faculty, staff, contractors, and visitors).

   Exceptions:
   - EATING, DRINKING: Masks are not required when actively eating or drinking.
   - TEACHING: Instructors may remove masks when teaching behind plexiglass barriers as long as they can maintain physical distance of at least six feet from students. Specific course-related exemptions to this policy – including for-credit drama, dance, and

instrumental music activities – will be handled by the schools, in consultation with the Provost's Office.

- AMERICANS WITH DISABILITIES ACT (ADA) ACCOMMODATIONS: Some members of the University community may have pre-existing conditions that preclude them from wearing a mask; the relevant UVA office will evaluate requests for accommodation to determine whether there is a qualifying disability-related condition under ADA and a reasonable accommodation. Students with qualifying disability-related conditions can contact the Student Disability Access Center (SDAC) to seek accommodations related to masking requirements. Employees with qualifying disability-related conditions can seek accommodations related to masking requirements by following the Procedures for Employees with Disabilities to Request Workplace Accommodations.
- INTRAMURAL-RECREATIONAL SPORTS INDOOR AND AQUATIC VENUES: Masks are optional for fully vaccinated students, members, and guests within Intramural-Recreational Sports indoor and aquatic venues when actively exercising on cardio equipment or in a supervised/instructed exercise class. Individuals engaging in these activities without masks must also maintain social distancing and follow specific masking guidelines posted in those venues. Compliance with mask modifications will be actively monitored by IM-Rec Sports student and professional staff.

4. **Events and Gatherings:** To reduce the risk of the potential spread of COVID-19, gatherings and events should be conducted outdoors if possible, and individuals should follow CDC guidelines for safe in-person gatherings and events.

5. **Visitors to the University:** Visitors are allowed on Grounds and must comply with the face mask requirements listed above.

Compliance with Policy:

If a student violates the testing requirement:

- *First Missed Test:* Students who miss one week of testing will receive a warning via email. This warning is not cause for disciplinary action. Because these are just warnings, there is not a process to appeal the warning. Students should ensure that they test weekly so they will not be subject to further sanctions.

- *Second Missed Test:* If students miss a second week of testing, they will receive another warning via email and their school will be notified.

- *Third Missed Test:* Students who miss a third week of testing will have their NetBadge access (or local equivalent) disabled. This means that the student's access to websites, services, and applications protected by NetBadge will be disabled (such as email, SIS, and Collab). Furthermore, students who miss a third week of testing may not access University facilities or participate in University classes, programs, or activities in person until they test. Please note: If you are a graduate teaching assistant, research assistant, or student-worker, losing access to core systems may have an additional impact on your instruction or your ability to fulfill your work responsibilities.

  If a student's NetBadge access has been disabled for failure to comply with the University's COVID-19 testing program, the student can restore NetBadge access by getting tested. Students can view the current testing sites and times at Be SAFE. NetBadge restoration will be processed automatically after testing.

- *Fourth or More Missed Test:* Students who miss four or more weeks of testing will continue to have their NetBadge access (or local equivalent) disabled and be subject to disciplinary

action, including interim suspension, which could result in the forfeit of the entire semester and all associated tuition and fees.

If an **employee** fails to comply with vaccination or testing requirements of this policy, it may result in disciplinary action in accordance with applicable University policies based on employee classification. Details on enforcement procedures for faculty and staff are available here.

If **contract workers** are not in compliance with this policy, the University will request contracting vendors remove the contract workers from the worksite until they are in compliance.

If a **student** violates the rules and requirements around University risk mitigation and public health measures, the violation(s) may result in the following consequences:

- *Minor violations* – will ideally be addressed in the moment by an active bystander (e.g., offering a forgetful student a mask) and/or through an educational discussion (e.g., student meeting with residence life or other staff). The University encourages peer engagement and bystander intervention by faculty, staff, and students in training programs and other communications, consistent with our broader social norming campaign.
- *Serious violations* – will be routed to the University Judiciary Committee (UJC) and also evaluated for immediate interim suspension by the Office of the Dean of Students (ODOS); through this administrative process, ODOS can suspend a student from learning/activities or all enrollment. The interim suspension includes a no-trespass order from Grounds enforceable through the University Police Department. The definition of what is a "serious" violation will be fact-bound, though we expect it will include repeated violations by the same individual or organization and those that constitute a refusal to comply when warned or encouraged.
- *Widespread violations* – will be a factor in determining whether and when to close the University to students and in-person classes and to request that students return home.

If an **employee** fails to comply with the rules and requirements around other risk mitigation and public health measures, it may result in disciplinary action in accordance with relevant University policies.

Effective Term of the Policy: We will continue to monitor 1) public health conditions, (including case counts, hospitalizations, and other conditions); 2) federal, state, local directives; and, 3) CDC and VDH guidelines closely and will adjust this policy as circumstances warrant in order to mitigate the spread of COVID-19.

This policy will remain in effect until federal, state, local, and/or University directives deem that mitigation measures are no longer necessary or recommended to help reduce the spread of COVID-19.

Questions about this policy should be directed to Emergency Management, Environmental Health and Safety, or the Office of the Vice President and Chief Student Affairs Officer.

Effective Date: 09/02/2021 Last Revised Date: 11/08/2021
Policy Type: University
Contact Office: Emergency Management (UVA), Environmental Health and Safety, Vice President and Chief Student Affairs Officer (Office of the)
Oversight Executive: President of the University
Major Category: Safety, Security and Environmental Quality
Next Scheduled Review: 11/30/2021
Approved by, Date: President of the University, 09/02/2021
Revision History: Revised Section 1 Faculty & Staff date for receipt of final vaccination dose 11/8/21; Revised Vaccination and Testing sections 10/28/21; Revised masking exceptions and next scheduled review date 10/22/21; Reviewed and revised next scheduled review date, added definition of University Property 10/1/21; Revised Compliance with Policy/contract workers 9/28/21;

Exhibit I

COMMONWEALTH of VIRGINIA

Office of the Attorney General

Mark R. Herring
Attorney General

202 North Ninth Street
Richmond, Virginia 23219
804-786-2071
Fax 804-786-1991
Virginia Relay Services
800-828-1120
7-1-1

April 26, 2021

The Honorable Mark L. Keam
Member, House of Delegates
Post Office Box 1134
Vienna, Virginia 22183

Dear Delegate Keam:

I am responding to your request for an official advisory opinion in accordance with § 2.2-505 of the Code of Virginia.

Issues Presented

You have asked whether Virginia's public institutions of higher education, as specified in Title 23.1 of the Code of Virginia, may condition in-person attendance on receipt of an approved COVID-19 vaccine during this time of pandemic.

Background

On March 12, 2020, Virginia declared a state of emergency in response to the COVID-19 pandemic. As of the date of this opinion, that state of emergency continues, despite the recent easing of certain surge mitigation measures that were in place as cases peaked over the winter.[1] More than 650,000 cases of COVID-19 have been reported within the Commonwealth and 10,691 Virginians have died as a result.[2] The virus readily spreads through respiratory droplets, particularly where individuals are indoors, in close contact, and in congregate settings.[3]

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[1] *See* Exec. Order No. 51 (March 12, 2020), Declaration of a State of Emergency Due to Novel Coronavirus (COVID-19), https://www.governor.virginia.gov/media/governorvirginiagov/governor-of-virginia/pdf/eo/EO-51-Declaration-of-a-State-of-Emergency-Due-to-Novel-Coronavirus-(COVID-19).pdf; Fifth Amended Exec. Order No. 72 (April 21, 2021), https://www.governor.virginia.gov/media/governorvirginiagov/executive-actions/EO-72-FIFTH-AMENDED-and-Order-of-Public-Health-Emergency-Nine-Easing-of-Commonsense-Surge-Restrictions-Due-to-Novel-Coronavirus-(COVID-19).pdf.

[2] *See* VIRGINIA DEP'T OF HEALTH, *COVID-19 in Virginia: Summary*, https://www.vdh.virginia.gov/coronavirus/covid-19-in-virginia/ (last visited Apr. 26, 2021).

[3] *See* VIRGINIA DEP'T OF HEALTH, *Prevention Tips*, https://www.vdh.virginia.gov/coronavirus/prevention-tips/#spread (last visited Apr. 22, 2021).

More than 5.8 million doses of the COVID-19 vaccine have already been administered in Virginia, with 28.3% of the population fully vaccinated and 42.5% receiving at least one dose.[4] Individuals aged sixteen and over are currently eligible to be vaccinated and there is sufficient supply nationwide for those seeking the vaccine to receive it prior to the start of the next academic year.[5]

Discussion and Relevant Laws

1. The Health Commissioner and General Assembly Possess the Power to Impose a Vaccine Requirement for All Residents.

There is no question that the General Assembly could enact a statute requiring the COVID-19 vaccine for in-person school attendance as a valid exercise of the Commonwealth's police powers.[6] In addition, § 32.1-48 of the Code of Virginia currently grants the Commissioner of Health the power of "requiring immediate immunization of all persons in case of an epidemic of any disease of public health importance for which a vaccine exists other than a person to whose health the administration of a vaccine would be detrimental as certified in writing by a physician licensed to practice medicine in this Commonwealth."[7] As a previous opinion of this Office explained, the "Health Commissioner has the authority, pursuant to § 32.1-43, 'to require quarantine, vaccination or treatment of any individual when he determines any such measure to be necessary to control the spread of any disease of public health importance.'"[8] In the absence of such a mandate, your question stems from the need for colleges and universities to protect their students and employees due to the congregate settings of their campuses.

2. Colleges and Universities May Condition the Attendance of Certain In-Person Events on Having Received an Approved COVID-19 Vaccine.

In my opinion, Virginia's colleges and universities may take steps to protect the health and welfare of their students by conditioning attendance in various activities or settings on the receipt of an approved COVID-19 vaccine.

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[4] *See* VIRGINIA DEP'T OF HEALTH, *COVID-19 Vaccine Summary*, https://www.vdh.virginia.gov/coronavirus/covid-19-vaccine-summary/ (last visited Apr. 26, 2021).

[5] *See* VIRGINIA DEP'T OF HEALTH, *COVID-19 Vaccination Response*, https://www.vdh.virginia.gov/covid-19-vaccine/ (last visited Apr. 22, 2021); THE WHITE HOUSE, *Fact Sheet: President Biden to Announce All Americans to be Eligible for Vaccinations by May 1, Puts the Nation on a Path to Get Closer to Normal by July 4th* (Mar. 11, 2021) (press release), https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/11/fact-sheet-president-biden-to-announce-all-americans-to-be-eligible-for-vaccinations-by-may-1-puts-the-nation-on-a-path-to-get-closer-to-normal-by-july-4th/.

[6] *See* 1959-1960 Op. Va. Att'y Gen. 334 (opining that the enactment of a law mandating vaccination against polio would be a valid exercise of the Commonwealth's police power); *see also* Barsky v. Bd. of Regents, 347 U.S. 442, 449 (1954) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power.").

[7] VA. CODE ANN. § 32.1-48. This and all other citations to the Code of Virginia herein are from the electronic version of the Code on LexisNexis and are current through the 2021 Regular Session of the General Assembly and Acts 2021 Sp. Sess. I, cc. 55, 56, 78, 82, 110, 117, 118, 171, 216, 220 and 243.

[8] 2002 Op. Va. Att'y Gen. 202, 204.

a. No federal law bars Virginia colleges and universities from imposing such a requirement.

With regard to students that attend one of Virginia's state colleges or universities, it remains up to the individual institutions to determine whether requiring students to obtain the COVID-19 vaccination has a real or substantial relation to protecting public health and safety on their campus. Colleges have seen several outbreaks over the course of the pandemic due to the nature of school campuses.[9] In my opinion, a COVID-19 vaccine mandate by a state college or university would be reasonable to control COVID-19 and prevent a campus outbreak.

Currently, there is no federal guidance on the Emergency Use Authorization (EUA) of the COVID-19 vaccine specifically related to colleges and universities. However, the Equal Employment Opportunity Commission (EEOC) has provided detailed guidance that suggests employers can mandate the vaccine for employees even though the vaccine is currently only under an EUA.[10] Additionally, the COVID-19 tests that many colleges and universities have required were authorized under an EUA.[11]

b. An institution's board of visitors may require vaccinations as a condition of in-person attendance.

The General Assembly has vested the various boards of visitors with broad specific and implied discretion in their management of the state's colleges and universities. "[P]arents who send their children to a university have a reasonable expectation that the university will maintain a campus free of foreseeable harm."[12] The Supreme Court of Virginia has recognized that Virginia's higher education institutions have broad authority to implement "rules and regulations includ[ing] policies that promote safety" on their campuses and within residence facilities.[13]

The governing boards of Virginia's higher education institutions are granted the power to set policies and regulations for their respective schools, and are charged with protecting the welfare of their students.[14] In particular, § 23.1-1301(A)(1) grants "[t]he board of visitors of each baccalaureate public

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[9] Lauren Lumpkin, *Rising coronavirus cases at U-Va., VMI and other Virginia colleges spark worry, lead to changes*, WASH. POST (Feb. 19, 2021), https://www.washingtonpost.com/local/education/uva-virginia-colleges-covid-cases/2021/02/19/a1080a66-716e-11eb-93be-c10813e358a2_story.html.

[10] *See* U.S. EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, *What You Should Know About COVID-10 and the ADA, the Rehabilitation Act, and Other EEO Laws* (updated Dec. 16, 2020), https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

[11] *See* U.S. FOOD AND DRUG ADMINISTRATION, *Emergency Use Authorization (EUA) Summary for the Color SARS-CoV-2 RT-LAMP Diagnostic Assay*, https://www.fda.gov/media/138248/download. *See, e.g.*, JAMES MADISON UNIVERSITY, *Stop the Spread: Entry Testing FAQ*, https://www.jmu.edu/stop-the-spread/student-affairs/entry-testing.shtml (requiring entry testing of students); UNIVERSITY OF VIRGINIA, *Pre-Arrival Testing*, https://coronavirus.virginia.edu/testing/pre-arrival-testing (requiring pre-arrival testing of students); VIRGINIA COMMONWEALTH UNIVERSITY, *Testing*, https://together.vcu.edu/faq/testing/ (requiring entry testing of students).

[12] DiGiacinto v. Rector & Visitors of George Mason Univ., 281 Va. 127, 136 (2011).

[13] *Id.*

[14] *See* VA. CODE ANN. § 23.1-1301(A)(1) ("The board of visitors of each baccalaureate public institution of higher education or its designee may . . . [m]ake regulations and policies concerning the institution[.]"); § 23.1-1304(B), (B)(14) ("Educational programs for the governing boards of public institutions of higher education shall include presentations relating to . . . [s]tudent welfare issues, including academic studies; curriculum; residence life; student governance and activities; and the general physical and psychological well-being of undergraduate and graduate students").

institution of higher education or its designee" the power to "[m]ake regulations and policies concerning the institution."[15] Similarly, §§ 23.1-2904 and -2905 grants all the same duties and powers "of governing boards of public institutions of higher education set forth in Chapter 13 (§ 23.1-1300 et seq.)" to the State Board for Community Colleges. Those powers—like corporate powers—consist not only of the ability to address matters that are expressly enumerated in the statute, but also grants the boards of visitors "the implied power to do whatever is reasonably necessary to effectuate the powers expressly granted."[16]

Virginia courts have regularly upheld the General Assembly's broad grant of discretion to the various boards of visitors.[17] For example, the Supreme Court of Virginia rejected a challenge to the decision of the Board of Visitors at George Mason University to restrict weapons on its campus.[18] The Court found that "the General Assembly established 'a corporate body composed of the board of visitors of George Mason University' for the purpose of entrusting to that board the power to direct GMU's affairs," and it specifically noted that "[t]he board of visitors is also tasked with safeguarding the university's property and the people who use it by making 'all needful rules and regulations concerning the University.'"[19]

Accordingly, I conclude that Virginia's state institutions of higher education, as defined in Title 23.1 of the Code of Virginia, may determine that in-person attendance in various activities or settings presents a risk to students or others, and that it may condition attendance upon being vaccinated. While it is my belief that our public colleges and universities may condition in-person attendance on receipt of an approved COVID-19 vaccine during this time of pandemic, it is not without complications and our public colleges and universities should be prepared to provide reasonable accommodations for medical conditions and/or religious objections. Any requirement of an approved COVID-19 vaccine during the pandemic should be formulated to best effectuate the public health and safety of the respective campuses.

Conclusion

Accordingly, for the reasons stated, Virginia's state institutions of higher education, as defined in Title 23.1 of the Code of Virginia, may condition in-person attendance on receipt of an approved COVID-19 vaccine during this time of pandemic.

With kindest regards I am,

Very truly yours,

Mark R. Herring

Mark R. Herring
Attorney General

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[15] Section 23.1-1301 of the Code of Virginia allows a board of visitors to designate its governing powers to another official. Some boards of visitors may have designated various powers to officials like a president. Whether another party within the university has a power, by virtue of a designation or other, is beyond the scope of this opinion.

[16] Batcheller v. Commonwealth, 176 Va. 109, 123 (1940) (citing 13 AM. JUR., CORPORATIONS § 740); *see also* United States v. Bly, 510 F.3d 453, 462-63 (4th Cir. 2007) (applying *Batcheller*).

[17] *See, e.g.*, Goodreau v. Rector, 116 F. Supp. 2d 694, 703 (W.D. Va. 2000) (rejecting the argument that the Board of Visitors of the University of Virginia did not have the power to revoke a degree and finding that the Board's authority over disciplinary matters carried with it the implied power of degree revocation).

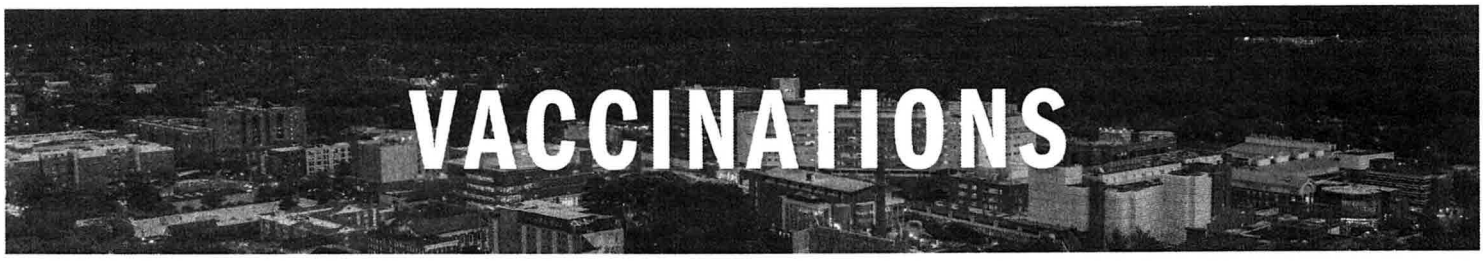
[18] *DiGiacinto*, 281 Va. at 136.

[19] *Id.* (citation omitted).

Exhibit J

UNIVERSITY of VIRGINIA

CORONAVIRUS INFORMATION



VACCINATIONS

EMPLOYEE COVID-19 VACCINE INFORMATION

Vaccination is required for UVA Health team members by November 1, 2021 and for Academic Division employees by January 4, 2022, unless granted a medical or religious exemption. Until these effective dates, faculty and staff members unable to provide proof of vaccination will be subject to mandatory saliva PCR testing at least once each week or as otherwise directed by the University unless they have an exemption because they are working remotely 100% (and documented as such) or tested positive for COVID-19 within 150 days. For details, please see the **HR proof of vaccination webpage** and the **HR COVID Prevalence Testing webpage**.

STUDENT COVID-19 VACCINE REQUIREMENTS

WHAT: Policy Requirements

All students who live, learn, or work in person at the University of Virginia during the 2021-2022 academic year must be fully vaccinated. Students may seek a medical or religious exemption to the vaccination requirement. Students with approved medical or religious exemptions will be subject to pre-arrival and weekly prevalence testing requirements and other public health measures. Students who are not vaccinated and do not qualify for an exemption are not permitted to come to Grounds as of July 1, 2021.

WHY: Rationale for Policy Requirement

According to the **Centers for Disease Control and Prevention (CDC)** and the Food and Drug Administration (FDA), the COVID-19 vaccines are safe and effective; studies have shown they prevent severe illness and death from the virus. Like hundreds of colleges and universities around the country, the University is following this public health guidance and the advice of our medical experts by mandating vaccination for students. This approach will allow us to return to in-person instruction and student residential life and keep our community safe.

- **Can the University mandate vaccines that are currently only subject to Emergency Use Authorizations?**

  Yes. The Virginia Attorney General issued an **official opinion** that Virginia

colleges and universities "may condition in-person attendance on receipt of an approved COVID-19 vaccine" during the time of pandemic to keep their students, faculty, staff, and surrounding communities safe and healthy. As the AG opinion noted, no federal law bars Virginia institutions of higher education from mandating the COVID-19 vaccine. Additionally, the Equal Employment Opportunity Commission (EEOC) has provided guidance that employers may mandate the COVID-19 vaccine even though it is only under an Emergency Use Authorization (EUA).

- **Are faculty and staff required to show proof of vaccination?**

  Yes, all faculty and staff are required to show proof of vaccination before the start of the Fall 2021 semester or participate in weekly prevalence testing. Details of this process are located on the **HR website**.

WHERE: Vaccination Sites, Where can I get vaccinated?

- **Where can I be vaccinated in the United States?**

  Vaccine supply is now plentiful in the United States and authorized for use in individuals above the age of 12. There are several ways to find vaccine providers near you, including **these methods** published by the CDC.

- **Will I have to pay to be vaccinated?**

  No. There is no out-of-pocket cost to get a COVID-19 vaccine in the United

States. If you have health insurance, your insurance company may be billed, but costs will not be passed on to you.

WHO: Defining "Student" for Purposes of the Vaccine Requirement

All students who will live, learn, or work in person at the University of Virginia during the 2021-2022 academic year must be fully vaccinated or have an approved medical or religious exemption on file at Student Health and Wellness.

EMPLOYEES

- **What if I am an employee taking one or more University courses?**
  You are subject to this requirement if you are enrolled in any course that meets in person during the 2021-2022 academic year.

EXECUTIVE FORMAT PROGRAMS

- **What if I am enrolled in an executive-format, degree-granting program and only come to Grounds a few times a year, with the remainder of my course of study occurring online?**
  Students in executive-format, degree-granting programs are subject to this requirement if they come to Grounds in person during the 2021-2022 academic year.

EXECUTIVE EDUCATION

- **I am not a student, but I will attend a short, non-degree executive education program or meeting. Am I subject to this requirement?**

  No. However, we strongly encourage all visitors to Grounds to be vaccinated. Unvaccinated visitors are subject to public health requirements as outlined in **University Policy SEC-045**.

ONLINE PROGRAMS

- **What if my entire course of study occurs online?**

  You are not subject to the vaccine requirement unless you plan to come to Grounds to utilize in-person resources, such as the library or collaboration spaces. However, please note that this is not the case for most UVA students. Consult your program director if you are unsure whether your program is classified as an online program.

Will there be a fully remote/virtual option for students who are enrolled in the fall but are not vaccinated?

No. Only students enrolled in our online programs will have a fully remote/virtual experience. All other programs will resume in-person instruction.

Will there be remote/virtual classes offered for students other than those who are enrolled in online programs?

There may be several remote course offerings, but these will be offered for

single courses rather than entire programs. Most courses will resume in-person instruction.

PREVIOUSLY POSITIVE

- **What if I had COVID-19? Do I still need to be vaccinated?**

  Yes, you can contract COVID-19 more than once. You are still subject to the vaccine requirement.

HOW: Process for Uploading Vaccine Record or Exemption Request Form

- **How do I upload my COVID-19 vaccination record?**

  Students must upload their complete COVID-19 vaccination record to the Student Health and Wellness **Healthy HOOS patient portal** (using NetBadge). Once logged in:

  - Click "Uploads."
  - Choose "COVID-19 Vaccine Immunization Information" for the document you are uploading.
  - Take a photo of your COVID-19 vaccine card and complete the upload process as instructed.

- **How do I request an exemption from the mandatory COVID-19 vaccination?**

  Students may request exemption from the vaccination requirement for medical or religious reasons only. The **medical exemption form** and the

religious exemption form are available on the **Student Health and Wellness website**. Please note that students who are granted exemptions will be required to participate in pre-arrival testing and mandatory weekly prevalence testing, as well as other public health measures.

- Students requesting an exemption for religious reasons will be required to submit a written statement, signed by the student or a parent or legal guardian if the student is a minor (under age 18), explaining how the vaccination requirement conflicts with the student's sincerely-held religious beliefs. A religious exemption is not the same as a philosophical, moral, or conscientious exemption.
- Students requesting a temporary or permanent exemption for medical reasons will be required to submit a statement signed by a health care professional. If approved, the exemption will apply for the period of time designated by the health care professional.

WHEN: Deadlines, Consequences for Non-Compliance

- **When is the deadline for uploading my complete COVID-19 vaccination record or exemption request?**

  Students must upload this documentation via the Student Health and Wellness **HealthyHoos patient portal** (using NetBadge) by July 1, 2021.

- **What are the consequences for non-compliance?**

  All students who plan to live, learn, or work in person at the University during the 2021-2022 academic year must be vaccinated and submit proof of vaccination or request a medical or religious vaccine exemption no later than Thursday, July 1, 2021.

  As of July 1, students are not permitted on Grounds unless they are vaccinated or have a medical or religious exemption request approved by Student Health and Wellness. Students who are still in the process of being vaccinated should upload their documentation as soon as possible and are not permitted on Grounds for any reason until they have done so.

  Failure to have this documentation loaded by early July could result in delays/disruptions to program start dates in August. Beginning in the first week of July, students not in compliance will have their ID cards deactivated and will be unable to access resources on Grounds. Once the documentation is submitted and approved, cards will be reactivated. This reactivation usually occurs within 48 hours of submission.

COMMUNITY UPDATES

MAY 20, 2021 - Message to the University community

APRIL 9, 2021 - Letter to students from Dean of Students Allen W. Groves

APRIL 1, 2021 - Community Update

QUESTIONS?

Domestic - 833-454-6902

International - +1 202 800-2408

covidinformation@virginia.edu

UNIVERSITY of VIRGINIA

2420 Old Ivy Road
P.O. Box 400229
University of Virginia
Charlottesville, VA 22904-4229

PHONE (434) 924-1400
FAX (434) 924-0938
EMAIL University Communications

Exhibit K

Our STN: BL 125742/0 **BLA APPROVAL**

BioNTech Manufacturing GmbH August 23, 2021
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

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)

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 -90ºC to -60ºC (-130ºF to -76ºF). 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

Exhibit L

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.

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.

[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

Exhibit M

WILLIAM J. OLSON
(VA, D.C.)

ROBERT J. OLSON
(VA, D.C.)

JEREMIAH L. MORGAN
(D.C., CA ONLY)

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October 15, 2021

James E. Ryan
President
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president@virginia.edu

Hon. Whitt Clement
Rector of the Board of Visitors
University of Virginia
NW Wing, The Rotunda
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wwwc8n@virginia.edu

Subject: Ms. Kaycee McCoy, 212 Hillcrest Dr., Amherst, Virginia
Employee of University of Virginia Health System
Appeal of Denial of COVID-19 Vaccination Religious Exemption

Dear President Ryan and Rector Clement:

We represent Kaycee McCoy, who is an employee of the University of Virginia Health System, with respect to her religious exemption from the COVID-19 vaccines being mandated for employees.

The deadline for her to submit her religious exemption was September 13, and she filed hers on September 12. For unstated reasons, her religious exemption was denied on September 30. She asked why she was denied, but her question was never answered. She submitted a second letter on October 6, together with a letter signed by her Pastor, and has had no response to that letter. The University of Virginia Health System is requiring that employees take the J&J injection by Monday, October 18, or face termination. Additionally she filed with the EEOC, and had an interview, and the matter is now pending.

On her behalf, we ask you to ensure that her religious exemption is honored. For many reasons, we do not believe that the Virginia Constitution allows state institutions to apply a religious test, to look behind assertions of religious conviction, and certainly does not permit her termination for failure to yield to state control of her religious views.

Not a True Vaccine

It has been said that those persons now objecting to the COVID-19 vaccination have previously not objected to vaccinations. However, the COVID-19 vaccinations are materially different. The earlier vaccinations were largely shown to be safe and effective, while the COVID-19 vaccination has been shown to be unsafe and ineffective.[1]

Many persons, such as pregnant women[2] and those with allergies,[3] should not receive the vaccine for Medical Reasons.It has now been demonstrated that those who had COVID-19 and thus acquired natural immunity have multi-fold better immunity than that achieved from any of the so-called vaccines.[4] However other aspects of the COVID-19 vaccine establish the basis for religious objections to the vaccines.

Experimental Gene Therapy

Prior to the COVID-19 vaccine, all vaccines employed weakened (attenuated) or dead pathogens (*e.g.,* viruses) to trigger an immune response that could later fend off an exposure to the live virus, except for the hepatitis B vaccine which is produced from a recombinant surface antigen of that virus. The three COVID-19 vaccines approved for emergency use in the United States (Johnson & Johnson, Moderna, and Pfizer) use experimental gene therapy — outside of the traditional definition of a vaccine. Indeed, the COVID-19 "vaccines" do not meet the traditional definition of a "vaccine," and some dictionaries have changed the meaning of the word to include gene therapy,[5] to mislead the public to accept this gene therapy as if it were a

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[1] *See* Jon Rappoport, "Massive Fraud in Reporting Vaccine Injuries; Withheld Data, Pretense of 'Safe and Effective,'" *GreenMedinfo* (Aug. 17, 2021).

[2] *See* "WHO warns pregnant women should NOT get Moderna's COVID-19 vaccine because it hasn't been proven safe - but US doctors say it is up to patients," *Daily Mail.com* (Jan. 26, 2021).

[3] *See* "Moderna's and Pfizer's vaccines share the same problem: They're unsafe for people with allergies," *Natural News* (Jan. 26, 2021).

[4] *See* Shawn Fleetwood, "Study: Recovered COVID-19 Patients Possess Robust Immunity To Virus," *The Federalist* (July 26, 2021); "Bombshell" Israeli study finds natural immunity from previous COVID-19 infection vastly superior to vaccination," *Natural News* (Aug. 30, 2021)

[5] *Contrast* traditional definition in"Vaccine, Medical Dictionary with "Vaccine," Merriam-Webster adding alternative definition b: "a preparation of genetic material (such as a strand of synthesized messenger RNA) that is used by the cells of the body to produce an antigenic substance (such as a fragment of virus spike protein)."

standard vaccine, as well as to afford vaccine manufacturers protection from liability. The CDC has even changed the definition of a vaccine in a different manner — to indicate that the COVID-19 vaccine does not provide "immunity" from COVID-19, but only "protection."[6]

These vaccines use a totally new and exotic technology that utilizes cutting edge nanotechnology to introduce into our bodies lipid platforms (*i.e.*, "lipid nanoparticles") or virus-delivery systems (*e.g.*, adenovirus, as is the case with the Johnson & Johnson vaccine) for the purpose of bypassing the innate immune systems that God gave us so that the vaccines contain genetic instructions to produce the SARS CoV-2 spike protein to gain entry into the recipient's nucleus and therein alter the DNA. The mRNA vaccines can permanently alter our inherently fixed and stable human genetic code in such a way that these changes are irrevocable and produce lasting harm to potentially every cell in the body.

These COVID-19 vaccines seek to alter God's creation. The Holy Bible teaches: God created man in his own image: in the image of God, he created them male and female. Genesis 1:26-27. God created every "kind" to procreate after its own "kind." Genesis 1:11, 12, 21, 24, 25. He specifically proscribes the mixing of kinds. Leviticus 19:19; Deuteronomy 22:9.

Use of Aborted Fetal Cells.

Additionally, all COVID-19 vaccines use aborted fetal cell tissue at some stage of their design, testing, development, or manufacture. The Institute for Clinical Systems Improvement (ICSI) in Bloomington, Minnesota states:

> mRNA COVID-19 vaccines do not contain any aborted fetal cells. Fetal cell lines are not the same as fetal tissue. Fetal cell lines are cells that grow in a laboratory. They descend from cells taken from elective abortions in the 1970s and 1980s. Those individual cells from the 1970s and 1980s have since multiplied into many new cells over the past four or five decades, creating fetal cell lines. Current fetal cell lines are thousands of generations removed from the original fetal tissue. [ICSI, "Are the vaccines made with fetal cells?"]
>
> In the Pfizer-BioNTech and Moderna vaccines, no fetal cell lines were used to produce or manufacture the vaccine, and they are not inside the injection you receive from your doctor/nurse. Fetal cells may have been used to test efficacy and/or proof of concept….

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[6] *See* Sharyl Attkisson, "CDC Changes Definition of 'vaccines' to Fit COVID-19 Vaccine Limitations," (Sept. 8, 2021); "CDC changes definitions of "vaccine" and "vaccination" to cover up lie about vaccines being 100% effective," *Natural News* (Sept. 15, 2021).

> The Johnson and Johnson vaccine did use fetal cell cultures, specifically PER.C6 (a retinal cell line that was isolated from a terminated fetus in 1985), in order to produce and manufacture the vaccine.

Use of vaccines based in any way on aborted fetal cell lines violates fundamental Biblical imperatives. "Before I formed you in the womb I knew you." Jeremiah 1:5 (NASB). The thinly veiled excuse that the fetal cells that once belonged to the body of a soul that came from and belongs to God cannot disguise the human blood that stains the creation of SARS CoV-2 in the Wuhan Institute of Virology, research that was supported with the help and funding of the National Institutes of Health and major academic institutions. Without abortions there would be no fetal tissue, no fetal cell lines, through gain of function studies of the bioengineered SARS CoV-2 virus in "humanized mice," and no COVID pandemic. Abortion and its manufactured byproducts are integral to the development of vaccines and their manufacture.

Religious Exemption from Vaccination

Ms. McCoy has sincerely held religious objections to the COVID-19 vaccination. These mandates raise serious issues not present with other vaccines that clearly make compliance with these mandates a religious issue, and refusals to participate are protected under the "Free Exercise of Religion" guaranteed by both the United States and Virginia Constitutions. If the vaccination cannot be required, those who elect to assert their religious liberty cannot be penalized for the exercise of that constitutional right.

Virginia Constituiton Prohibits Religious Discrimination

The refusal to accept mandated vaccinations is a quintessential religious issue, governed in Virginia by Article I, Section 16 of the Virginia Constitution, which protects the "free exercise of religion":

> That **religion or the duty which we owe to our Creator, and the manner of discharging it, can be directed only by reason and conviction**, not by force or violence; and, therefore, all men are equally entitled to the **free exercise of religion**, according to the dictates of conscience; and that it is the mutual duty of all to practice Christian forbearance, love, and charity towards each other. **No man** shall be compelled to frequent or support any religious worship, place, or ministry whatsoever, nor **shall be enforced, restrained, molested, or burthened in his body or goods, nor shall otherwise suffer on account of his religious opinions or belief**; but all men shall be free to profess and by argument to maintain their opinions in matters of religion, and the same shall in nowise diminish, enlarge, or affect their civil capacities. And the General Assembly shall **not prescribe any religious test whatever**.... [Emphasis added.]

Under these provisions, employees need not submit a Religious Exemption application that could be accepted or rejected by government officials through the application of **a religious test**. And mandatory testing of only those who will not accept the vaccination clearly is a burden being imposed on the exercise of a religious right.

The Virginia Supreme Court has set out the different texts of the "free exercise" provisions in Article I, Section 16 of the Virginia Constitution and the First Amendment of the U.S. Constitution, but it does not appear to have distinguished between the free exercise clauses in these constitutions. *See Bowie v. Murphy*, 271 Va. 126, 133, 624 S.E.2d 74 (2006). However, the protection afforded the free exercise of religion by Article I, Section 16 can be viewed to be more robust than the protection afforded under the First Amendment. As Professor A.E. Dick Howard has explained:

> state courts are free to give stricter readings to the religion clauses of state constitutions than might be required even under the First Amendment. So many of the milestones of religious liberty, such as Jefferson's Bill for Religious Liberties and Madison's Memorial and Remonstrance, have sprung from Virginian sources that it is not surprising if the Virginia courts see Virginia's religious guarantees as having a vitality independent of the Federal Constitution. [A.E. Dick Howard, Commentaries on the Constitution of Virginia (Univ. Press of Virginia: 1974) at 303 (emphasis added).]

In *Reid v. Gholson*, the Virginia Supreme Court stated:

> The constitutional guarantees of religious freedom have no deeper roots than in Virginia, where they originated, and nowhere have they been more scrupulously observed. [*Id.*, 229 Va. 179, 187 (1985).]

Therefore, a proper understanding of Article I, Section 16 must be based on a view of the text and its history and tradition of the Virginia Constitution, rather than simply seeking guidance from federal cases analyzing the First Amendment's free exercise guarantee.

The protection of the free exercise of religion described in Thomas Jefferson's Statute of Religious Liberties, and James Madison's Memorial and Remonstrance, were rooted not in the Enlightenment, but rather in the recognition of a separate civil and ecclesiastical jurisdiction during the late Middle Ages and the Protestant Reformation. *See* Robert Louis Wilken, Liberty and the Things of God.

The Original 1776 Text of the Statute of Religious Liberties separated the civil and religious jurisdictions. Those duties "Which We Owe to Our Creator, and the Manner of Discharging [Them] Can Be Directed Only by Reason and Conviction," were expressly defined to constitute "religion." Those duties owed to the state are enforceable by "Force" or "Violence."

In ancient Israel, the jurisdictional division between the authority of the state and the authority of the church was well established in Holy Writ. *See, e.g.,* I Samuel 13 (King Saul was admonished by the Prophet Samuel for offering a religious sacrifice); II Chronicles 19:11 (Jehu counseled King Jehoshaphat: "And, behold, Amariah the chief priest is over you in all matters of the Lord; and Zebadiah the son of Ishmael, the ruler of the house of Judah, for all the king's matters: also the Levites shall be officers before you. Deal courageously, and the Lord shall be with the good."); II Chronicles 26 (King Uzziah was admonished by Azariah the priest for trespassing in the temple to burn incense, and judged with leprosy).

Violations of the jurisdictional division between the authority of the state and the authority of the church were punished in other ancient kingdoms. *See, e.g.*, Daniel 3:10-18 (King Nebuchadnezzar exceeded his authority by ordering that his image be worshiped, and then tried to punish Daniel, Shadrach, Meshach, and Abednego); Daniel 6 (King Darius exceeded his authority to order Daniel not to pray for 30 days).

The jurisdictional division between the authority of the state and the authority of the church is well established in the New Testament. Matthew 28:19-20 (Great Commission); Mark 12:17 ("And Jesus answering said unto them, Render to Caesar the things that are Caesar's, and to God the things that are God's. And they marvelled at him.").

In an 1877 speech entitled, "The History of Freedom in Antiquity," Lord Acton cited the words of Jesus in Mark 12:17 as both: (i) imposing the first limits on the powers of the state, and (ii) birthing of the freedom of individuals:

> … when Christ said: "Render unto Caesar the things that are Caesar's, and unto God the things that are God's" … gave to the civil power, under the protection of **conscience,** a sacredness it had never enjoyed, and **bounds** it had never acknowledged; and they were the repudiation of absolutism and the **inauguration of freedom**. For our Lord not only delivered the precept, but created the force to execute it.… [Lord Acton, "The History of Freedom in Antiquity: An Address Delivered to the Members of the Bridgnorth Institute," Acton Institute (Feb. 26, 1877) (emphasis added).]

The history of the early church in the New Testament also confirm that authority of individuals to resist orders of the state that exceed the state's jurisdiction. *See generally* Acts 4:19 ("Whether it be right in the sight of God to hearken unto you more than unto God, judge ye."); Acts 5:29 ("Then Peter and the other apostles answered and said, We ought to obey God rather than men.").

As Professor A.E. Dick Howard explained the development of the Virginia Declaration of Rights in his Commentaries on the Constitution of Virginia:

> George Mason's original draft stated … "that all Men should enjoy the fullest Toleration in the Exercise of Religion according to the Dictates of Conscience…." [citation omitted.] The emphasis on toleration … could be taken to mean only a limited form of religious liberty: toleration of dissenters in a state where there was an established church. James Madison thought that stronger language was needed and drafted a substitute declaring that "all men are equally entitled to the full and free exercise" of religion… Madison's draft, **substituting the language of entitlement for toleration** sounded more of a **natural right** than did Mason's version. [A.E. Dick Howard, Commentaries on the Constitution of Virginia (Univ. Press of Virginia: 1974) at 290 (emphasis added).]

Section 16 of the Virginia Declaration of Rights, as adopted by Virginia constitutional Convention (June 12, 1776), as modified by James Madison, clearly recognized this jurisdictional division:

> That religion, or the duty which we owe to our Creator, and the manner of discharging it, can be directed only by **reason and conviction**, not by **force or violence**; and therefore all men are equally **entitled** to the **free exercise of religion**, according to the dictates of conscience; and that it is the mutual duty of all to practise Christian forbearance, love, and charity toward each other. [Emphasis added.[7]]

Professor Robert Louis Wilken explains that religious freedom is more robust than mere religious toleration.

> Toleration is forbearance of that which is not approved, a political policy of restraint toward those whose beliefs and practices are objectionable. [R]eligious freedom, or liberty of conscience, [is] a natural right that belongs to all human beings, not an accommodation granted by ruling authorities. [R.L. Wilken, *supra*, at 5.]

Section 16 of the Virginia Declaration of Rights now appears as the first portion of Article I, Section 16, of The Virginia Constitution:

> That religion or the duty which we owe to our Creator, and the manner of discharging it, can be directed only by **reason and conviction**, not by **force or violence**; and, therefore, all men are equally entitled to the **free exercise of**

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[7] Thus, the Virginia Bill of Rights was fundamentally different than other state constitutions, such as the Massachusetts Constitution of 1780 crafted by John Adams.

> **religion**, according to the dictates of **conscience**; and that it is the mutual duty of all to practice Christian forbearance, love, and charity towards each other. [Emphasis added.]

Less than a month later, on July 4, 1776, the Declaration of Independence reaffirmed these truths (July 4, 1776).

> We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, **Liberty and the pursuit of Happiness**.--That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed…. [Emphasis added.]

James Madison's Memorial and Remonstrance Against Religious Assessments (June 20, 1785) reiterated the jurisdictional limitation on the state:

> Because we hold it for a fundamental and undeniable truth, "that **Religion** or **the duty which we owe to our Creator and the manner of discharging it**, can be directed only by **reason and conviction**, not by **force or violence**." **The Religion then of every man must be left to the conviction and conscience of every man**; and it is the right of every man to exercise it as these may dictate. This right is in its nature an **unalienable right**. It is unalienable, because **the opinions of men**, depending only on the evidence contemplated by their own minds **cannot follow the dictates of other men**: It is unalienable also, because what is here a right towards men, is a **duty towards the Creator**. It is the duty of every man to render to the Creator such homage and such only as he believes to be acceptable to him. This duty is **precedent**, both in order of time and in degree of obligation, **to the claims of Civil Society**. Before any man can be considered as a member of Civil Society, he must be considered as a subject of the Governour of the Universe: And if a member of Civil Society, who enters into any subordinate Association, must always do it with a reservation of his duty to the General Authority; much more must every man who becomes a member of any particular Civil Society, do it with a saving of his allegiance to the Universal Sovereign. **We maintain therefore that in matters of Religion, no mans right is abridged by the institution of Civil Society and that Religion is wholly exempt from its cognizance**. True it is, that no other rule exists, by which any question which may divide a Society, can be ultimately determined, but the will of the majority; but it is also true that the majority may trespass on the rights of the minority. [Emphasis added.]

Thomas Jefferson's Virginia Statute for Establishing Religious Freedom (January 19, 1786) embraced the same distinction:

Whereas, **Almighty God hath created the mind free**; that all attempts to influence it by **temporal punishments or burthens**, or by **civil incapacitations** tend only to beget habits of hypocrisy and meanness, and are a departure from the plan of the holy author of our religion, who being Lord, both of body and mind yet chose not to propagate it by coercions on either, as was in his Almighty power to do, that the **impious presumption of legislators and rulers, civil as well as ecclesiastical,** who, being themselves but **fallible and uninspired men** have assumed dominion over the faith of others, **setting up their own opinions and modes of thinking as the only true and infallible, and as such endeavouring to impose them on others,** hath established and maintained false religions over the greatest part of the world and through all time; that **to compel a man to furnish contributions of money for the propagation of opinions which he disbelieves is sinful and tyrannical**; that even the forcing him to support this or that teacher of his own religious persuasion is depriving him of the comfortable liberty of giving his contributions to the particular pastor, whose morals he would make his pattern, and whose powers he feels most persuasive to righteousness, and is withdrawing from the Ministry those temporary rewards, which, proceeding from an approbation of their personal conduct are an additional incitement to earnest and unremitting labours for the instruction of mankind; that our civil rights have no dependence on our religious opinions any more than our opinions in physics or geometry, that therefore the proscribing any citizen as unworthy the public confidence, by laying upon him an incapacity of being called to offices of trust and emolument, unless he profess or renounce this or that religious opinion, is depriving him injuriously of those privileges and advantages, to which, in common with his fellow citizens, he has a natural right, that it tends only to corrupt the principles of that very Religion it is meant to encourage, by bribing with a monopoly of worldly honours and emoluments those who will externally profess and conform to it; that though indeed, these are criminal who do not withstand such temptation, yet neither are those innocent who lay the bait in their way; that **to suffer the civil magistrate to intrude his powers into the field of opinion and to restrain the profession or propagation of principles on supposition of their ill tendency is a dangerous fallacy** which at once destroys all religious liberty because he being of course judge of that tendency will make his opinions the rule of judgment and approve or condemn the sentiments of others only as they shall square with or differ from his own; that **it is time enough for the rightful purposes of civil government, for its officers to interfere when principles break out into overt acts against peace and good order**; and finally, that Truth is great, and will prevail if left to herself, that she is the proper and sufficient antagonist to error, and has nothing to fear from the conflict, unless by human interposition disarmed of her natural weapons free argument and debate, errors ceasing to be dangerous when it is permitted freely to contradict them.… [Emphasis added.]

The First Amendment to the U.S. Constitution, ratified in 1791, provides:

> Congress shall make no law respecting an establishment of **religion**, or prohibiting the **free exercise** thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances. [Emphasis added.]

Although the Virginia Supreme Court has not yet been asked to recognize and honor the jurisdictional principle on which Article I, Section 16 is based, to constrain the power of the state and state subdivisions, that Court has repeatedly and faithfully recognized that jurisdictional principle in other contexts.

In *Reid v. Gholson*, the Virginia Supreme Court explained:

> The constitutional guarantees of religious freedom have no deeper roots than in Virginia, where they originated, and nowhere have they been more scrupulously observed. These principles **prohibit the civil courts from resolving ecclesiastical disputes** which depend upon inquiry into questions of faith or doctrine. [*Id.,* 229 Va. 179, 187, 327 S.E. 2d 107 (1985).]

In *Cha v. Korean Presbyterian Church*, the Virginia Supreme Court ruled:

> It is well established that a civil court may neither interfere in matters of **church governance** nor in **matters of faith and doctrine**.…
>
> It has thus become established that the decisions of religious entities about the **appointment and removal of ministers and persons** in other positions of similar theological significance are **beyond the ken** of civil courts. Rather, such courts must defer to the decisions of religious organizations 'on matters of discipline, faith, internal organization, or ecclesiastical rule, custom or law.'
>
> Indeed, most courts that have considered the question whether the **Free Exercise Clause divests a civil court of subject matter jurisdiction** to consider a pastor's defamation claims against a church and its officials have answered that question in the affirmative. [*Id.*, 262 Va. 604, 611-12, 615, 553 S.E.2d 511, 513-515 (2001) (citation omitted) (emphasis added).]

Most recently, in *Bowie v. Murphy*, the Virginia Supreme Court described the "free exercise" jurisdictional principle, as follows:

> courts **lack subject matter jurisdiction** to resolve issues of **church governance** and disputes over **religious doctrine**. This prohibition arises from the religion

> clauses of the Constitution of the United States and the Constitution of Virginia. [*Id.*, 271 Va. 126, 133, 624 S.E. 2d 74 (2006).]

In *District of Columbia v. Heller*, Justice Scalia set out the rule by which constitutional provisions are to be understood:

> The very enumeration of the right takes out of the hands of government--even the Third Branch of Government--the power to decide on a case-by-case basis whether the right is really worth insisting upon. A constitutional guarantee subject to future judges' assessments of its usefulness is no constitutional guarantee at all. **Constitutional rights are enshrined with the scope they were understood to have when the people adopted them**, whether or not future legislatures or (yes) even future judges think that scope too broad. [*District of Columbia v. Heller*, 554 U.S. 570, 634-35 (2008) (emphasis added).]

The "free exercise" clauses in other state constitutions do not have the same text, history, and tradition, possibly leaving the matter in some doubt in those states, but it is unmistakable that **in Virginia, the government's role is not limited by a duty to "tolerate" the exercise of religion, or to regulate it, but rather the Commonwealth of Virginia has no jurisdiction whatsoever over the "free exercise" of religion due to Article I, Section 16.**

Although the Board of Visitors may believe that the enhancement of "public health" vests in the University government authority over its employees, that view cannot override with the constitutionally protected religious liberties of employees who understand that the COVID-19 vaccine intrudes into areas reserved for their relationship with God — not the state.[8]

As set out above, the COVID-19 vaccine raises serious issues not present with other vaccines that make it particularly fall under the protection of the "Free Exercise of Religion." As the University of Virginia and its Health System is a creature of the Commonwealth, it may not interfere with the Free Exercise of Religion by requiring a COVID-19 vaccination, or by denying Ms. McCoy her right to assert and protect her religious convictions.

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[8] Indeed, there is more support for the principle that health and healing falls under the authority of the Church, rather than the authority of the State. *See, e.g.,* James 5:14-15 (Is any sick among you? let him call for the elders of the church; and let them pray over him, anointing him with oil in the name of the Lord. And the prayer of faith shall save the sick, and the Lord shall raise him up; and if he have committed sins, they shall be forgiven him.) *See also* Leviticus 14:1-7.

Sincerely yours,

/s/ Patrick M. McSweeney

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cc: Wendy Horton, CEO, University of Virginia Health Systems
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Exhibit N

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November 1, 2021

University Counsel
University of Virginia
Charlottesville, Virginia

UniversityCounsel@virginia.edu

Subject: Ms. Kaycee McCoy, 212 Hillcrest Dr., Amherst, Virginia
Employee of University of Virginia Health System
Appeal of Denial of COVID-19 Vaccination Religious Exemption

Gentlemen:

We represent Kaycee McCoy, who is an employee of the University of Virginia Health System, with respect to her religious exemption from the COVID-19 vaccines being mandated for employees. We wrote to the President and Rector on October 15, 2021 on her behalf, and we were directed to send further correspondence to your office at the email address above. Other than that, we have received no further response to our letter.

However, Ms. McCoy advises us that she was notified by her manager that on November 1, 2021 — today — that she would be put on suspension/probation without pay, but she was previously scheduled to be on vacation until November 8, 2021.

For the reasons set out in our letter, and the subsequent letter sent you by Liberty Counsel on October 20, 2021, we ask you to delay any action on her employment status until her religious exemption is ruled upon and we have an opportunity to seek relief on her behalf. Please advise us if this approach is agreed to.

Sincerely yours,

/s/ Patrick M. McSweeney

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