UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

CHILDREN'S HEALTH DEFENSE,
a California Nonprofit corporation,

COMFORT GEOFFREY, individually and as parent and legal guardian of S.G., and W.G., minor children,

LEONARD ROBERTS, individually and as parent and legal guardian of A.R., a minor child,

MARIA PARRILLO, individually, and as parent and legal guardian of I.P., a minor child,

JENNIFER MORRISSEY, individually and as parent and legal guardian of G.M., a minor child,

DENISE SEDJIAN, individually and as parent and legal guardian of K.C., B.C., and B.C., minor children,

MARIA HUBER, individually and as parent and legal guardian of C.H., and E.H., minor children, and

JESSICA ZARECZKY, individually and as parent and legal guardian of L.B., minor child,

Plaintiffs,

v.

THE CITY OF PHILADELPHIA, THE CITY OF PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH, AND CHERYL BETTIGOLE, M.D., M.P.H., in her official capacity as Health Commissioner for the City of Philadelphia Department of Public Health

Defendants.

Case No. 23-cv-4228

EXHIBITS TO COMPLAINT FOR DECLARATORY RELIEF

EXHIBIT INDEX	
EXHIBIT#	**DESCRIPTION**
1	City of Philadelphia, Department of Public Health, Regulations Governing the Immunization and Treatment of Newborns, Children and Adolescents
2	City of Philadelphia, Department of Public Health, Emergency Regulation for the Control and Prevention of COVID-19 Supplementing the Regulation Governing the Immunization and Treatment of Newborns, Children, and Adolescents (Vaccine Information Statements)
3	NVICP Vaccine Injury Table
4	U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement for COVID-19 Vaccine issued 10/19/2023
5	Fact Sheet for Recipients and Caregivers about Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) which has Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in Individuals 6 Months through 11 Years of Age
6	Fact Sheet for Recipients and Caregivers about Moderna COVID-19 Vaccine (2023-2024 Formula) which has Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in Individuals 6 Months through 11 Years of Age
7	U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Vaccine Information Statement for MMR Vaccine (Measles, Mumps, and Rubella)

Exhibit 1

City of Philadelphia

Department of Public Health

Regulations Governing the Immunization and Treatment of Newborns, Children and Adolescents

Approved:

BOARD OF HEALTH	**July 18, 2007**
LAW DEPARTMENT	**July 19, 2007**
RECORDS DEPARTMENT	**Aug. 27, 2007**
AMENDED:	**April 6, 2009**

CITY OF PHILADELPHIA
DEPARTMENT OF PUBLIC HEALTH

Regulations Governing the Immunization and Treatment of Newborns, Children and Adolescents

Table of Contents

1. DEFINITIONS

In these Regulations, the following definitions apply:

(a) *Advisory Committee on Immunization Practices (ACIP).* The Committee appointed by the Centers for Disease Control and Prevention (CDC) to develop written recommendations for the routine administration of vaccines to the pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

(b) *Authorized user.* Any person or entity authorized to provide or receive information from an immunization registry, which may include health care providers, parents and guardians, schools and child care facilities, managed care organizations, and local government health departments and their agents.

(c) *Board.* The Board of Health of the City of Philadelphia.

(d) *Coverage rate.* The percent of a given population immune to a specific communicable disease, or combination of diseases, as a result of vaccination or disease history.

(e) *Child care group setting.* A home or facility in which four or more children who are not related to the operator receive child care.

(f) *Department.* The Department of Public Health of the City of Philadelphia, the Commissioner of the said Department, or any designated representative thereof.

(g) *Health care facility.* A facility providing health services, including, but not limited to, a general, chronic disease, or other type of hospital; a private medical practice; a home health care agency; a hospice; a long-term care nursing facility, a cancer treatment center; an ambulatory surgical facility; a birth center; and an inpatient drug and alcohol treatment facility, regardless of whether such health care facility is operated for profit, nonprofit or by an agency of the government.

(h) *Health care provider.* An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth of Pennsylvania licensing agency or board.

(i) *Immunization status.* The number of dosages of specific vaccine antigens and their respective dates of administration, which are used to determine adequacy of immunization.

(j) *Medical record.* An account compiled by physicians and other health professionals including a patient's medical history; present illness; findings on physical examination; details of treatment; reports of diagnostic tests; findings and conclusions from special examinations; findings and diagnoses of consultants; diagnoses of the responsible physician; notes on treatment, including medication, surgical operations, radiation, and physical therapy; and progress notes by physicians, nurses and other health professionals.

(k) *Record of immunization.* A written document, such as a physician record or other document of similar reliability, reflecting the date and type of immunization.

(l) *School.* Public, private and parochial schools in Philadelphia, including special education, special classes, vocational programs, intermediate units and home education programs.

2. IMMUNIZATION REQUIREMENTS FOR ATTENDING SCHOOL

(a) *Required for School Entry Into Kindergarten or First Grade.* The following immunizations, whether administered as single vaccines or as components of U.S. Food and Drug Administration-approved combination vaccines, given in compliance with the minimum intervals and schedules required for each component vaccine, are required for entry into school and attendance at the kindergarten or first grade level:

(1) *Hepatitis B.* Three properly spaced doses of hepatitis B vaccine or a history of hepatitis B immunity proved by laboratory testing.

(2) *Diphtheria.* Four or more properly spaced doses of diphtheria toxoid, which may be administered as a single antigen vaccine, in combination with tetanus toxoid or in combination with tetanus toxoid and pertussis vaccine. One dose must have been administered on or after the fourth birthday.

(3) *Tetanus.* Four or more properly spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine, in combination with diphtheria toxoid or in combination with diphtheria toxoid and pertussis vaccine. One dose must have been administered on or after the fourth birthday.

(4) *Pertussis.* Four properly spaced doses of pertussis vaccine in combination with diphtheria and tetanus toxoids, or a physician's documentation of a medical contraindication to pertussis vaccine. One dose shall be administered on or after the fourth birthday.

(5) *Poliomyelitis.* Three or more properly spaced doses of any combination of oral polio vaccine or enhanced inactivated polio vaccine.

(6) *Measles (rubeola), Mumps, Rubella (german measles).* Two properly spaced doses of live attenuated vaccine, as the combination vaccine Measles, Mumps, Rubella (MMR) or as Measles, Mumps, Rubella, Varicella (MMRV), according to the routine recommended schedule, or a history of measles, mumps, and rubella immunity proved by serological evidence. The first dose of vaccine must have been given no sooner than 12 months of age, and the second dose at 4-6 years of age, with a minimum interval of 28 days between doses. Immunization with single antigen vaccines for measles, mumps, and rubella is also acceptable, provided two doses of each were administered at appropriate intervals.

(7) V*aricella (chickenpox).* One of the following:

(i) Two doses of varicella vaccine, administered as the single antigen Varicella (V) or as the combination vaccine Measles, Mumps, Rubella Varicella (MMRV). The first dose of vaccine must have been given no sooner than 12 months of age, and the second dose at 4-6 years of age, with a minimum interval of 3 months between doses.

(ii) A history of chickenpox immunity proved by laboratory testing or a written statement of history of chickenpox disease from a health care provider.

(b) *Required for School Attendance.* The following immunizations, whether administered as single vaccines or as components of U.S. Food and Drug Administration approved combination vaccines, given in compliance with the minimum intervals and schedules required for each component vaccine, are required as a condition for attending school at grade levels 2 through 12:

(1) *Diphtheria.* Three or more properly spaced doses of diphtheria toxoid, which may be administered as a single antigen vaccine, in combination with tetanus toxoid or in combination with tetanus toxoid and pertussis vaccine.

(2) *Tetanus.* Three or more properly spaced doses of tetanus toxoid, which may be administered as a single antigen vaccine, in combination with diphtheria toxoid or in combination with diphtheria toxoid and pertussis vaccine.

(3) *Poliomyelitis.* Three or more properly spaced doses of either oral polio vaccine or enhanced inactivated polio vaccine. If a child received any

doses of inactivated polio vaccine administered prior to 1988, a fourth dose of inactivated polio vaccine is required.

(4) *Measles (rubeola).* Two properly spaced doses of live attenuated measles vaccine, given as a single antigen vaccine, or as a combination vaccine Measles, Mumps, Rubella (MMR) or Measles, Mumps, Rubella, Varicella (MMRV), according to the routine recommended schedule, or a history of measles proved by serological evidence. The first dose of vaccine must have been given no sooner than 12 months of age, and the second dose at least 28 days following the first dose.

(5) *German measles (rubella).* One dose of live attenuated rubella vaccine administered as a single antigen vaccine, or as a combination vaccine Measles, Mumps, Rubella (MMR) or Measles, Mumps, Rubella, Varicella (MMRV), or a history of rubella proved by serological evidence.

(6) *Mumps.* One dose of live attenuated mumps vaccine, administered as a single antigen vaccine, or as a combination vaccine Measles, Mumps, Rubella (MMR) or Measles, Mumps, Rubella, Varicella (MMRV), or a history of mumps proved by serological evidence, or a physician diagnosis of mumps disease indicated by a written record signed by the physician or the physician's designee.

(7) V*aricella (chickenpox).* One of the following:

(i) One dose of varicella vaccine, administered at 12 months of age or older.

(ii) A history of chickenpox immunity proved by laboratory testing or a written statement of history of chickenpox disease from a health care provider or parent.

(c) *Required for School Entry into Sixth Grade.* In addition to the requirements listed as a condition of attending school at grade levels 2 through 12, the following immunizations, whether administered as single vaccines or as components of U.S. Food and Drug Administration-approved combination vaccines, given in compliance with the minimum intervals and schedules required, are required for entry at the sixth grade level:

(1) *Meningococcal.* One dose of meningococcal conjugate vaccine quadrivalent (MCV4).

(2) *Pertussis, tetanus, diphtheria.* One dose of pertussis vaccine administered in combination with tetanus and diphtheria toxoids (Tdap). This dose must have been administered on or after the 10th birthday.

Students having received a Td-containing vaccine within two years prior to entering sixth grade should not receive the booster dose of Tdap until two years have elapsed. Students who are not eligible to receive Tdap on this basis shall not be denied entry to 6th grade, but must receive the booster dose of Tdap when this two-year period has elapsed.

(3) V*aricella (chickenpox).* One of the following:

(i) Two doses of varicella vaccine, administered as the single antigen Varicella (V) or as the combination vaccine Measles, Mumps, Rubella-Varicella (MMRV). The first dose of vaccine must have been given no sooner than 12 months of age, and the second dose prior to entry to 6th grade, with a minimum interval of 3 months between doses, provided, however, that if the first dose is administered at the time of entry to 6th grade, the child shall not be denied entry to school, but shall receive the second dose after expiration of the minimum interval.

(ii) A history of chickenpox immunity proved by laboratory testing or a written statement of history of chickenpox disease from a healthcare provider or parent.

(d) *Exemption from Immunization Requirements for School Entry or Attendance.*

(1) Medical exemption. Children need not be immunized if a physician or the physician's designee provides a written statement that immunization may be detrimental to the health of the child. Such a statement must comply with the list of valid vaccine contraindications as established by the Advisory Committee for Immunization Practices (ACIP). When the physician determines that immunization is no longer detrimental to the health of the child, the child shall be immunized according to this regulation.

(2) Religious exemption. Children need not be immunized if the parent, guardian or emancipated child objects in writing to the immunization on the grounds of prohibition based on religious belief or on the basis of a strong moral or ethical conviction similar to a religious belief.

(3) Exclusion of exempt students in situations of disease epidemic. In the event the Department declares that there is an epidemic of a vaccine-preventable disease, any child who is enrolled in a public, private, or parochial school and who has been exempt from one or more immunization requirement for any of the causes authorized herein shall be temporarily excluded from attendance at the school. An enrollee so

temporarily excluded shall be authorized to return to school upon the lifting of the epidemic declaration by the Department.

3. IMMUNIZATION REQUIREMENTS FOR CHILD CARE SETTINGS

(a) *Vaccination requirements.* Each child enrolled in a child care group setting shall be immunized in accordance with the most current standards established by the Advisory Committee on Immunization Practices (ACIP), as presented in their *Recommended Childhood and Adolescent Immunization Schedule.*

(b) *Caregiver responsibilities.* For each child enrolled in a child care group setting, the person in charge of the group setting shall ensure that a record of immunization is provided for each child enrolled in the child care group setting by a health care provider, or designee, setting forth the vaccines the child has received and their dates of administration (month, day and year). The person in charge of the group setting shall ensure that the records are updated on a regular basis. The immunization status of each enrolled child shall be available for review by the Department, upon request.

(1) The caregiver at a child care group setting may not accept or retain a child 2 months of age or older at the setting, for more than 60 days, without verification of satisfaction of a child's age-appropriate immunization requirements, or the caregiver has received written documentation of satisfaction of one of the exemptions set forth in section 3(c).

(2) Verifications of immunization status shall also specify any vaccination not given due to medical condition of the child and shall state whether the condition is temporary or permanent.

(3) If the caregiver receives a written verification explaining that timely vaccination did not occur due to a temporary medical condition, the caregiver shall exclude the child from the child care group setting after an additional 30 days unless the caregiver receives, within that 30-day period, written verification from a health care provider that the child was vaccinated or that the temporary medical condition still exists. If the caregiver receives a written verification that vaccination has not occurred because the temporary condition persists, the caregiver shall require the presentation of a new verification at 30-day intervals. If a verification is not received as required, the caregiver shall exclude the child from the child care group setting and not readmit the child until the caregiver receives a verification that meets the requirements of this section.

(4) The caregiver shall retain the written verification or objection referenced in paragraph (b) for 60 days following the termination of the child's attendance.

(c) *Exemptions.* Immunization requirements for child care settings do not apply with respect to:

(1) Children who are known by the caregiver to attend a kindergarten, elementary school or high school in Philadelphia.

(2) A caregiver who does not serve as a caregiver for at least 40 hours during any one-month period.

4. MEDICAL EVALUATION, IMMUNIZATION, AND TREATMENT OF MINORS

(a) *Minor's Consent to Examination and Treatment.* A person between the ages of 11 and 18 may give consent, without the approval or consent of another person, for medical and other health examination, treatment and services to determine the presence of or to treat a sexually transmitted disease and any other disease, infection or condition reportable pursuant to the Disease Prevention and Control Law of 1955 and the regulations adopted thereunder, provided such person is capable of providing informed consent. The health care provider may not be sued or held liable for implementing appropriate diagnostic measures or administering appropriate treatment to the minor if the minor has consented to such procedures or treatment.

(b) *Minor's Consent to* Immunization. A person between the ages of 11 and 18 may authorize his or her own immunization, without the approval or consent of another person, to prevent occurrence of a reportable disease, infection, or condition, provided such person is capable of providing informed consent. A parent or guardian does not need to be present at the time the vaccine is administered. Written consent by the minor is not required, but documentation that the vaccine information statement (VIS) was provided to the vaccine recipient, and the publication date of the VIS, is required. The health care provider may not be sued or held liable for providing such immunization to the minor if the minor has consented to such procedures or treatment.

5. RESPONSIBILITY AND AUTHORITY FOR REPORTING IMMUNIZATION INFORMATION ON NEWBORNS, CHILDREN, AND ADOLESCENTS

(a) *Responsibility for Reporting Immunization Information.* Any health care provider who treats or examines a newborn, child, or other person below the age of 19, and any head, superintendent or other person in charge of a health care facility that treats such persons, who has knowledge of administration of any immunization included in the current Advisory Committee on Immunization Practices/American Academy of Pediatricians (ACIP/AAP) *Recommended Childhood and Adolescent Immunization Schedule* that are routinely administered to persons less than 19 years of age shall make a report of the immunization to the Department. The

report shall be submitted in a content and manner as specified below and in accordance with additional parameters as may be established by the Department.

(b) *Timing and Method of Reporting.* Reports of immunizations shall be made within 30 days of vaccine administration to the Department's Division of Disease Control, by mail to: Immunization Program, Division of Disease Control, Department of Public Health, 500 S. Broad Street, Philadelphia, PA 19146; or through secure transfer of electronic data in a manner as established by the department.

(c) *Content of Reports.* All reports shall include the following information:

(1) Child's name (first, middle and last);

(2) Child's date of birth;

(3) Child's sex;

(4) Name of the child's legal guardian;

(5) Address of the child's legal guardian;

(6) Type of immunization;

(7) Date of vaccine administration (month, day, year);

(8) Name of the immunization provider;

(9) Any additional information as the Department may require in connection with a particular type of immunization or case.

6. IMMUNIZATION REGISTRY

(a) *Authority to Obtain Medical Information on Immunizations.* The Health Commissioner, or designated representative, has the authority to obtain and store medical information, including photocopies of medical records and medical summaries, regarding immunizations governed by this Regulation without a signed authorization release from the patient or patient's representative.

(b) *KIDS Immunization Registry.* Reported data shall be housed in the KIDS Immunization Registry at the Department. The KIDS Immunization Registry shall provide authorized users with immunization histories, vaccination forecasting tools, and reporting capabilities.

(c) *Access to the Immunization Registry.* Access to immunization information reported to the Department and maintained in the Immunization Registry shall be

limited to authorized users as defined in this regulation. Immunization information shall not be available for records marked to indicate a parent or legal guardian's decision not to participate in the KIDS Registry.

(1) Authorized users of the Immunization Registry must be approved by the Department and shall be authorized only as permitted by law.

(2) Authorized users of the Immunization Registry must agree to and sign the KIDS Registry Security and Confidentiality Agreement.

(3) Patient information in the Immunization Registry shall be accessed by an authorized user only to ascertain and monitor immunization status of newborns, children and adolescents for which the authorized user has professional responsibility and in accordance with the data use and confidentiality policies of the KIDS Registry.

(d) *Maintaining Immunization Data.*

(1) The Department may choose, at its discretion, to maintain immunization data on newborns, children, and adolescents beyond their nineteenth birthday. Such records will be maintained for purpose of documenting prior immunization status and for assisting medical management of individuals in adulthood.

(2) The Department may choose, at its discretion, to maintain immunization data for adults in the Immunization Registry. Recording adult immunizations in the Registry will be applied when necessary in order to effectively carry out those programs of the Department designed to prevent and control disease and to monitor vaccine coverage rates

Exhibit 2

CITY OF PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH	BOARD OF HEALTH: May 14, 2021 LAW DEPARTMENT: May 14, 2021 RECORDS DEPARTMENT:

EMERGENCY REGULATION FOR
THE CONTROL AND PREVENTION OF COVID-19
SUPPLEMENTING THE REGULATION GOVERNING THE IMMUNIZATION AND TREATMENT OF NEWBORNS, CHILDREN, AND ADOLESCENTS
(VACCINE INFORMATION STATEMENTS)

WHEREAS, the Pennsylvania Disease Control and Prevention Act of 1955, 1956, April 23, P.L. 1510, 35 P.S. § 52.1 *et seq.*, (the "DCPA") and Chapter 6-200 of The Philadelphia Code authorize the Board of Health to establish lists of reportable diseases and conditions, and further provide that the Board and the Department of Public Health are responsible for implementing appropriate disease control and prevention measures in order to limit the spread of disease in an epidemic emergency; and

WHEREAS, on March 6, 2020, in response to the 2019 novel coronavirus disease, COVID-19, the Governor of Pennsylvania issued a Proclamation of Disaster Emergency, and on March 11, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, or global epidemic; and

WHEREAS, on March 12, 2020, the Board added COVID-19 to the City's list of reportable and quarantinable diseases; and

WHEREAS, there have been more than 16,000 COVID-19 hospitalizations and 3,500 COVID-19 deaths in Philadelphia since the beginning of the pandemic; and

WHEREAS, on January 20, 2021, the Philadelphia Board of Health approved a "Consolidated and Restated Supplemental Emergency Regulation Governing the Control and Prevention of COVID-19 (Consolidated Safer at Home Restrictions and Delegation of Authority)," which expressly authorized the Health Commissioner to issue such additional orders as the Health Commissioner determines are necessary or appropriate control or prevention measures to limit the spread of COVID-19; and

WHEREAS, safe, highly effective COVID-19 vaccines are now widely available in the United States; and

WHEREAS, administration of a COVID-19 vaccine is a medically accepted form of prophylactic treatment that dramatically reduces the likelihood of experiencing a symptomatic SARS-CoV-2 infection, and recent studies show that available COVID-19 vaccines also reduce asymptomatic infection and transmission; and

WHEREAS, broad distribution and uptake of COVID-19 vaccines is essential to ending the COVID-19 pandemic; and

WHEREAS, Section 4 of the Board of Health's *Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents* authorizes minors 11 and older who are able to give informed consent to consent to receive a vaccine for a reportable disease, such as COVID-19, and requires that they be provided with a Vaccine Information Statement ("VIS") for such vaccine; and

WHEREAS, similarly, Pennsylvania's Minors' Consent to Medical Care Act, 35 P.S. § 10103, and the Pennsylvania Code, 28 Pa. Code § 27.97, authorize minors to give consent for medical and health services to treat reportable diseases, such as COVID-19; and

WHEREAS, a VIS is a document produced by the U.S. Centers for Disease Control and Prevention (the "CDC") that provides information to vaccine recipients about the vaccine they are receiving, but a VIS is not available for any of the COVID-19 vaccines currently authorized under an Emergency Use Authorization ("EUA") issued by the U.S. Food and Drug Administration (the "FDA"); and

WHEREAS, an FDA-issued COVID-19 Fact Sheet for Recipients and Caregivers contains information similar to the information provided by a VIS and the CDC has identified it as the appropriate substitute for a VIS with respect to COVID-19 vaccines currently authorized for emergency use by the FDA; and

WHEREAS, at least one COVID-19 vaccine has been authorized under an EUA for people sixteen years of age and older since December 2020; and

WHEREAS, on April 21, 2021, the Health Commissioner issued an Emergency Order Concerning COVID-19 Vaccine Information Statements, which clarified that an FDA-issued COVID-19 Fact Sheet for Recipients and Caregivers is an appropriate substitute for a VIS for purposes of Section 4 of the Board of Health's *Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents*; and

WHEREAS, on May 10, 2021, the FDA authorized a COVID vaccine for use in people twelve years of age or older pursuant to an EUA; and

WHEREAS, the Board of Health hereby reaffirms, consistent with Section 4 of its *Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents*, that minors eleven (11) years of age and older are typically capable of providing informed consent on their own behalf to be vaccinated for a reportable disease, subject to a vaccine provider's individual determination that the minor is able to and does provide such informed consent, and the Board hereby clarifies that an FDA-issued COVID-19 Fact Sheet for Recipients and Caregivers is an appropriate substitute for a VIS; and

NOW, THEREFORE, the Board of Health hereby adopts the following emergency regulation, effective upon delivery to the Department of Records, while the remaining procedures and formalities of Section 8-407 are followed to promulgate this as a formal regulation:

Section 1. Temporary Emergency Supplement to Board of Health Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents

With respect to a minor eleven (11) years of age or older, the Emergency Use Authorization Fact Sheet for Recipients and Caregivers for a COVID-19 vaccine authorized by the U.S. Food and Drug Administration for use in persons of the age of the vaccine recipient, if and when such an authorization exists, may be provided for the purposes of Section 4 of the Board of Health's *Regulations Governing the Immunization and Treatment of Newborns, Children, and Adolescents*, when a Vaccine Information Statement does not exist for the COVID-19 vaccine being administered.

Section 2. Interaction With April 21, 2021 Emergency Order Concerning COVID-19 Vaccine Information Statements

This regulation approves of and supersedes the April 21, 2021 Emergency Order Concerning COVID-19 Vaccine Information Statements. The Health Commissioner remains authorized to issue emergency orders as appropriate to control the spread of COVID-19 consisent with the authority provided by the Board's Consolidated and Restated Supplemental Emergency Regulation Governing the Control and Prevention of COVID-19 (Consolidated Safer at Home Restrictions and Delegation of Authority).

Section 3. Effective Date and Duration

This regulation shall be effective immediately upon filing with the Department of Records and shall remain in effect indefinitely, until rescinded, superseded, or amended by further regulation.

Exhibit 3

Vaccine Injury Table

Applies Only to Petitions for Compensation Filed under the National Vaccine Injury Compensation Program on or after January 3, 2022

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660, 100 Stat. 3779 (42 U.S.C. 300aa-1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa-14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the qualifications and aids to interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (*e.g.,* DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis	≤4 hours.
	B. Brachial Neuritis	2-28 days (not less than 2 days and not more than 28 days).
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (*e.g.,* DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	≤72 hours.
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
III. Vaccines containing measles, mumps, and rubella virus or any of its components (*e.g.*, MMR, MM, MMRV)	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	5-15 days (not less than 5 days and not more than 15 days).
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
IV. Vaccines containing rubella virus (*e.g.*, MMR, MMRV)	A. Chronic arthritis	7-42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus (*e.g.*, MMR, MM, MMRV)	A. Thrombocytopenic purpura	7-30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient	
	- Vaccine-strain virus identified	Not applicable.
	- If strain determination is not done or if laboratory testing is inconclusive	≤12 months.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio	
	- in a non-immunodeficient recipient	≤30 days.
	- in an immunodeficient recipient	≤6 months.
	- in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection	

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
	- in a non-immunodeficient recipient	≤30 days.
	- in an immunodeficient recipient	≤6 months.
	- in a vaccine associated community case	Not applicable.
VII. Vaccines containing polio inactivated virus (*e.g.*, IPV)	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
IX. Haemophilus influenzae type b (Hib) vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
X. Varicella vaccines	A. Anaphylaxis	≤4 hours.
	B. Disseminated varicella vaccine-strain viral disease	
	-Vaccine-strain virus identified	Not applicable.
	- If strain determination is not done or if laboratory testing is inconclusive	7-42 days (not less than 7 days and not more than 42 days).
	C. Varicella vaccine-strain viral reactivation	Not applicable.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
	D. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	E. Vasovagal syncope	≤1 hour.
XI. Rotavirus vaccines	A. Intussusception	1-21 days (not less than 1 day and not more than 21 days).
XII. Pneumococcal conjugate vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
XIII. Hepatitis A vaccines	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
XIV. Seasonal influenza vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
	D. Guillain-Barré Syndrome	3-42 days (not less than 3 days and not more than 42 days).
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVI. Human papillomavirus (HPV) vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration	A. Shoulder Injury Related to Vaccine Administration	≤48 hours.

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
to children and/or pregnant women, after publication by the Secretary of a notice of coverage	B. Vasovagal syncope	≤1 hour.

(b) ***Provisions that apply to all conditions listed.***

(1) Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed in paragraph (a) of this section (and defined in paragraphs (c) and (d) of this section) qualifies as a Table injury under paragraph (a) except when the definition in paragraph (c) requires exclusion.

(2) In determining whether or not an injury is a condition set forth in paragraph (a) of this section, the Court shall consider the entire medical record.

(3) An idiopathic condition that meets the definition of an illness, disability, injury, or condition set forth in paragraph (c) of this section shall be considered to be a condition set forth in paragraph (a) of this section.

(c) ***Qualifications and aids to interpretation.*** The following qualifications and aids to interpretation shall apply to, define and describe the scope of, and be read in conjunction with paragraphs (a), (b), and (d) of this section:

(1) ***Anaphylaxis.*** Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequela. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) ***Encephalopathy.*** A vaccine recipient shall be considered to have suffered an encephalopathy if an injury meeting the description below of an acute encephalopathy occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) ***Acute encephalopathy.***

(A) For children less than 18 months of age who present:

(1) Without a seizure, an acute encephalopathy is indicated by a significantly decreased level of consciousness that lasts at least 24 hours.

(2) Following a seizure, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that lasts at least 24 hours and cannot be attributed to a postictal state - from a seizure or a medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists at least 24 hours and is characterized by at least two of the following:

(1) A significant change in mental status that is not medication related (such as a confusional state, delirium, or psychosis);

(2) A significantly decreased level of consciousness which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) The following clinical features in themselves do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia.

(D) Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy and in the absence of other evidence of an acute encephalopathy seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy.

(ii) ***Exclusionary criteria for encephalopathy.*** Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by:

(A) An underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, prenatal or perinatal central nervous system (CNS) injury); or

(B) An acute event shown to be unrelated to the vaccine such as a head trauma, stroke, transient ischemic attack, complicated migraine, drug use (illicit or prescribed) or an infectious disease.

(3) ***Encephalitis.*** A vaccine recipient shall be considered to have suffered encephalitis if an injury meeting the description below of acute encephalitis occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) ***Acute encephalitis.*** Encephalitis is indicated by evidence of neurologic dysfunction, as described in paragraph (c)(3)(i)(A) of this section, plus evidence of an inflammatory process in the brain, as described in paragraph (c)(3)(i)(B) of this section.

(A) Evidence of neurologic dysfunction consists of either:

(1) One of the following neurologic findings referable to the CNS: Focal cortical signs (such as aphasia, alexia, agraphia, cortical blindness); cranial nerve abnormalities; visual field defects; abnormal presence of primitive reflexes (such as Babinski's sign or sucking reflex); or cerebellar dysfunction (such as ataxia, dysmetria, or nystagmus); or

(2) An acute encephalopathy as set forth in paragraph (c)(2)(i) of this section.

(B) Evidence of an inflammatory process in the brain (central nervous system or CNS inflammation) must include cerebrospinal fluid (CSF) pleocytosis (>5 white blood cells (WBC)/mm^3 in children >2 months of age and adults; >15 WBC/mm3 in children <2 months of age); or at least two of the following:

(1) Fever (temperature ≥ 100.4 degrees Fahrenheit);

(2) Electroencephalogram findings consistent with encephalitis, such as diffuse or multifocal nonspecific background slowing and periodic discharges; or

(3) Neuroimaging findings consistent with encephalitis, which include, but are not limited to brain/spine magnetic resonance imaging (MRI) displaying diffuse or multifocal areas of hyperintense signal on T2-weighted, diffusion-weighted image, or fluid-attenuation inversion recovery sequences.

(ii) ***Exclusionary criteria for encephalitis.*** Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in the Table if it is shown that the encephalitis was caused by:

(A) An underlying malignancy that led to a paraneoplastic encephalitis;

(B) An infectious disease associated with encephalitis, including a bacterial, parasitic, fungal or viral illness (such as herpes viruses, adenovirus, enterovirus, West Nile Virus, or human immunodeficiency virus), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing; or

(C) Acute disseminated encephalomyelitis (ADEM). Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal, or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen but is a minor component); or

(D) Other conditions or abnormalities that would explain the vaccine recipient's symptoms.

(4) ***Intussusception.***

(i) For purposes of paragraph (a) of this section, intussusception means the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is

characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered to be a Table intussusception:

(A) Onset that occurs with or after the third dose of a vaccine containing rotavirus;

(B) Onset within 14 days after an infectious disease associated with intussusception, including viral disease (such as those secondary to non-enteric or enteric adenovirus, or other enteric viruses such as Enterovirus), enteric bacteria (such as Campylobacter jejuni), or enteric parasites (such as Ascaris lumbricoides), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;

(C) Onset in a person with a preexisting condition identified as the lead point for intussusception such as intestinal masses and cystic structures (such as polyps, tumors, Meckel's diverticulum, lymphoma, or duplication cysts);

(D) Onset in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Scholein purpura, hematoma, or hemangioma); or

(E) Onset in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease).

(5) ***Chronic arthritis.*** Chronic arthritis is defined as persistent joint swelling with at least twoadditional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months.

(i) Chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation recorded within 30 days after the onset of objective signs ofacute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination; and

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) ofthe persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) The following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile idiopathic arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/determatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease,

infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders, and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's Syndrome, blood disorders, or arthralgia (joint pain), or joint stiffness without swelling.

(6) ***Brachial neuritis.*** This term is defined as dysfunction limited to the upper extremity nerve plexus (*i.e.,* its trunks, divisions, or cords). A deep, steady, often severe aching pain inthe shoulder and upper arm usually heralds onset of the condition. The pain is typically followed in days or weeks by weakness in the affected upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. Atrophy of the affected muscles may occur. The neuritis, or plexopathy, may be present on the same side or on the side opposite the injection. It is sometimes bilateral, affecting both upper extremities. A vaccine recipient shall be considered to have suffered brachial neuritis as a Table injury if such recipient manifests all of the following:

(i) Pain in the affected arm and shoulder is a presenting symptom and occurs within thespecified time-frame;

(ii) Weakness;

(A) Clinical diagnosis in the absence of nerve conduction and electromyographic studiesrequires weakness in muscles supplied by more than one peripheral nerve.

(B) Nerve conduction studies (NCS) and electromyographic (EMG) studies localizing theinjury to the brachial plexus are required before the diagnosis can be made if weakness islimited to muscles supplied by a single peripheral nerve.

(iii) Motor, sensory, and reflex findings on physical examination and the results of NCSand EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and

(iv) No other condition or abnormality is present that would explain the vaccine recipient'ssymptoms.

(7) ***Thrombocytopenic purpura.*** This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm^3 with normal red and white blood cell indices. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with othercauses such as hypersplenism, autoimmune disorders (including alloantibodies from previoustransfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. Thrombocytopenic purpura does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, asobserved with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, human immunodeficiency virus, adenovirus, and dengue virus. An antecedent viral infection may bedemonstrated by clinical signs and symptoms and need

not be confirmed by culture or serologic testing. However, if culture or serologic testing is performed, and the viral illness isattributed to the vaccine-strain measles virus, the presumption of causation will remain in effect. Bone marrow examination, if performed, must reveal a normal or an increased numberof megakaryocytes in an otherwise normal marrow.

(8) ***Vaccine-strain measles viral disease.*** This term is defined as a measles illness that involves the skin and/or another organ (such as the brain or lungs). Measles virus must be isolated from the affected organ or histopathologic findings characteristic for the disease must be present. Measles viral strain determination may be performed by methods such as polymerase chain reaction test and vaccine-specific monoclonal antibody. If strain determination reveals wild-type measles virus or another, non-vaccine-strain virus, the disease shall not be considered to be a condition set forth in the Table. If strain determinationis not done or if the strain cannot be identified, onset of illness in any organ must occur within 12 months after vaccination.

(9) ***Vaccine-strain polio viral infection.*** This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(10) ***Shoulder injury related to vaccine administration (SIRVA).*** SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (*e.g.* tendons,ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known).
A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms,examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time-frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which theintramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms(*e.g.* NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies,or any other neuropathy).

(11) ***Disseminated varicella vaccine-strain viral disease.*** Disseminated varicella vaccine-strain viral disease is defined as a varicella illness that involves the skin beyond the dermatome in which the vaccination was given and/or disease caused by vaccine-strain varicella in another organ. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. If there is involvement of an organ beyond the skin, and no virus was identified in that organ, the involvement of all organs must occur as part of the same, discrete illness. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table. If strain determinationis not done or if the strain cannot be identified, onset of illness in any organ must occur 7- 42days after vaccination.

(12) ***Varicella vaccine-strain viral reactivation disease.*** Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster with or without concurrent disease in an organ other than the skin. Zoster, or shingles, is a painful, unilateral,pruritic rash appearing in one or more sensory dermatomes. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormallaboratory values. There must be laboratory confirmation that the vaccine-strain of the varicella virus is present in the skin or in any other involved organ, for example by oligonucleotide or polymerase chain reaction. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be consideredto be a condition set forth in the Table.

(13) ***Vasovagal syncope.*** Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequela. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurssimultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent syncope occurring after the applicable time period are not considered to be sequela of an episode of syncope meeting the Table requirements.

(14) ***Immunodeficient recipient.*** Immunodeficient recipient is defined as an individual withan identified defect in the immunological system which impairs the body's ability to fight infections. The identified defect may be due to an inherited disorder (such as severe combined immunodeficiency resulting in absent T lymphocytes), or an acquired disorder (such as acquired immunodeficiency syndrome resulting from decreased CD4 cell counts). The identified defect must be demonstrated in the medical records, either preceding or postdating vaccination.

(15) ***Guillain-Barré Syndrome (GBS).***

(i) GBS is an acute monophasic peripheral neuropathy that encompasses a spectrum of

fourclinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.

(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which hasthe pathologic and electrodiagnostic features of focal demyelination of motor and sensoryperipheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy(AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects thesensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis ofAIDP, AMAN, and AMSAN requires:

(A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;

(B) A monophasic illness pattern;

(C) An interval between onset and nadir of weakness between 12 hours and 28 days;

(D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at thenadir of symptoms, or subsequent improvement without significant relapse; however,death may occur without a clinical plateau); and,

(E) The absence of an identified more likely alternative diagnosis.

(iii) Fisher Syndrome (FS), also known as Miller Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDPmay be seen with limb weakness. The diagnosis of FS requires:

(A) Bilateral ophthalmoparesis;

(B) Bilateral reduced or absent tendon reflexes;

(C) Ataxia;

(D) The absence of limb weakness (the presence of limb weakness suggests a diagnosisof AIDP, AMAN, or AMSAN);

(E) A monophasic illness pattern;

(F) An interval between onset and nadir of weakness between 12 hours and 28 days;

(G) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significantrelapse; however, death may occur without a clinical plateau);

(H) No alteration in consciousness;

(I) No corticospinal track signs; and

(J) The absence of an identified more likely alternative diagnosis.

(iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with a total CSF white blood cell count below 50 cells per microliter. Both CSF and electrophysiologic studies are frequently normal in the first week of illnessin otherwise typical cases of GBS.

(v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosisfor the weakness.

(vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, criticalillness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.

(d) ***Glossary for purposes of paragraph (c) of this section -***

(1) ***Chronic encephalopathy.***

(i) A chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy or encephalitis, persists for at least 6 months from the first symptom or manifestation of onsetor of significant aggravation of an acute encephalopathy or encephalitis.

(ii) Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis shall not be presumed tohave suffered residual neurologic damage from that event; any subsequent chronic

encephalopathy shall not be presumed to be a sequela of the acute encephalopathy or encephalitis.

(2) ***Injected*** refers to the intramuscular, intradermal, or subcutaneous needle administrationof a vaccine.

(3) ***Sequela*** means a condition or event which was actually caused by a condition listed in theVaccine Injury Table.

(4) ***Significantly decreased level of consciousness*** is indicated by the presence of one or more of the following clinical signs:

(i) Decreased or absent response to environment (responds, if at all, only to loud voice orpainful stimuli);

(ii) Decreased or absent eye contact (does not fix gaze upon family members or otherindividuals); or

(iii) Inconsistent or absent responses to external stimuli (does not recognize familiar peopleor things).

(5) ***Seizure*** includes myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures, but not absence (petit mal), or pseudo seizures. Jerking movementsor staring episodes alone are not necessarily an indication of seizure activity.

(e) ***Coverage provisions.***

(1) Except as provided in paragraph (e)(2), (3), (4), (5), (6), (7), or (8) of this section, this section applies only to petitions for compensation under the program filed with the UnitedStates Court of Federal Claims on or after February 21, 2017

(2) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, and X of the Table) are includedin the Table as of August 6, 1997.

(3) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22,1998.

(4) Pneumococcal conjugate vaccines (Item XII of the Table) are included in the Table as ofDecember 18, 1999.

(5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1,2004.

(6) Trivalent influenza vaccines (Included in item XIV of the Table) are included on the Table as of July 1, 2005. All other seasonal influenza vaccines (Item XIV of the Table) areincluded on the Table as of November 12, 2013.

(7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of theTable) are included on the Table as of February 1, 2007.

(8) Other new vaccines (Item XVII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the Federal Register to announcethe effective date of such a tax.

[82 FR 6299, Jan. 19, 2017, as amended at 86 FR 68427, Dec. 2, 2021]

Exhibit 4

VACCINE INFORMATION STATEMENT

COVID-19 Vaccine:

What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

COVID-19 vaccine can prevent **COVID-19** disease. Vaccination can help reduce the severity of COVID-19 disease if you get sick.

COVID-19 is caused by a coronavirus called SARS-CoV-2 that spreads easily from person to person. COVID-19 can cause mild to moderate illness lasting only a few days, or severe illness requiring hospitalization, intensive care, or a ventilator to help with breathing. COVID-19 can result in death.

If an infected person has symptoms, they may appear 2 to 14 days after exposure to the virus. Anyone can have mild to severe symptoms.

- Possible symptoms include fever or chills, cough, shortness of breath or difficulty breathing, fatigue (tiredness), muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, or diarrhea.
- More serious symptoms can include trouble breathing, persistent pain or pressure in the chest, new confusion, inability to wake or stay awake, or pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone.

Older adults and people with certain underlying medical conditions (like heart or lung disease or diabetes) are more likely to get very sick from COVID-19.

2. COVID-19 vaccine

Updated (2023–2024 Formula) COVID-19 vaccine is recommended for everyone 6 months of age and older.

COVID-19 vaccines for infants and children 6 months through 11 years of age are available under Emergency Use Authorization from the U. S. Food and Drug Administration (FDA). Please refer to the Fact Sheets for Recipients and Caregivers for more information.

For people 12 years of age and older, updated COVID-19 vaccines, manufactured by ModernaTX, Inc. or Pfizer, Inc., are approved by FDA.

- **Everyone 12 years and older** should get 1 dose of an FDA-approved, updated 2023–2024 COVID-19 vaccine. If you have received a COVID-19 vaccine recently, you should wait at least 8 weeks after your most recent dose to get the updated 2023–2024 COVID-19 vaccine.
- **Certain people who have medical conditions or are taking medications that affect the immune system** may get additional doses of COVID-19 vaccine. Your health care provider can advise you.

Some people 12 years of age and older might get a different COVID-19 vaccine called Novavax COVID-19 Vaccine, Adjuvanted (2023–2024 Formula) instead. This vaccine is available under Emergency Use Authorization from FDA. Please refer to the Fact Sheet for Recipients and Caregivers for more information.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of COVID-19 vaccine** or an ingredient in the COVID-19 vaccine, or has any **severe, life-threatening allergies**
- Has had **myocarditis** (inflammation of the heart muscle) or **pericarditis** (inflammation of the lining outside of the heart)
- Has had **multisystem inflammatory syndrome** (called MIS-C in children and MIS-A in adults)
- Has a **weakened immune system**

In some cases, your health care provider may decide to postpone COVID-19 vaccination until a future visit.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover. People with current COVID-19 infection should wait to get vaccinated until they have recovered from their illness and discontinued isolation.

Pregnant people with COVID-19 are at increased risk for severe illness. COVID-19 vaccination is recommended for people who are pregnant, breastfeeding, or trying to get pregnant now, or who might become pregnant in the future.

COVID-19 vaccine may be given at the same time as other vaccines.

4. Risks of a vaccine reaction

- Pain, swelling, or redness where the shot is given, fever, tiredness (fatigue), headache, chills, muscle pain, joint pain, nausea, vomiting, and swollen lymph nodes can happen after COVID-19 vaccination.
- Myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) have been seen rarely after COVID-19 vaccination. This risk has been observed most commonly in males 12 through 39 years of age. The chance of this occurring is low.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

Seek medical attention right away if the vaccinated person experiences chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after COVID-19 vaccination. These could be symptoms of myocarditis or pericarditis.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. Countermeasures Injury Compensation Program

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit the program's website at **www.hrsa.gov/cicp**, or call **1-855-266-2427**.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for COVID-19 Fact Sheets, package inserts, and additional information at **www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's COVID-19 vaccines website at **www.cdc.gov/coronavirus**.

Exhibit 5

FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT PFIZER-BIONTECH COVID-19 VACCINE (2023-2024 FORMULA) WHICH HAS EMERGENCY USE AUTHORIZATION (EUA) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 6 MONTHS THROUGH 11 YEARS OF AGE

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) to prevent coronavirus disease 2019 (COVID-19), which is caused by the virus SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula), hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see https://www.covidvaxoption.com/.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make the Pfizer-BioNTech COVID-19 Vaccine available during the COVID-19 pandemic (for more details about an EUA please see "**WHAT IS AN EMERGENCY USE AUTHORIZATION?**" at the end of this document). The Pfizer-BioNTech COVID-19 Vaccine is not an FDA-approved vaccine in the United States. Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine.

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through close contact with another person who has the virus.

It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine for use in individuals 6 months through 11 years of age to prevent COVID-19[1]. The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine under an EUA.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

[1] The Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

WHAT SHOULD YOU MENTION TO THE VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects the immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine is given as an injection into the muscle.

Individuals 6 months through 4 years of age

- **Unvaccinated individuals:** Three doses of Pfizer-BioNTech COVID-19 Vaccine are administered over at least 11 weeks. The first 2 doses are administered 3 weeks apart. The third dose is administered at least 8 weeks after the second dose.
- **Individuals who have received 1 dose of the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent)[2] or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent[3]:** Two doses of Pfizer-BioNTech COVID-19 Vaccine are administered. The first dose of Pfizer-BioNTech COVID-19 Vaccine is administered 3 weeks after the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent and the second dose at least 8 weeks later.
- **Individuals who have received 2 to 4 doses of the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) or the Pfizer BioNTech COVID-19 Vaccine, Bivalent:** A single dose of Pfizer-BioNTech COVID-19 Vaccine is administered at least 8 weeks after the last previous dose of Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

[2] The Original monovalent Pfizer-BioNTech COVID-19 Vaccine encodes the spike protein of only the Original SARS-CoV-2, no longer authorized for use in the U.S.

[3] The Pfizer-BioNTech COVID-19 Vaccine, Bivalent encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2, no longer authorized for use in the U.S.

Individuals 5 through 11 years of age

- **Unvaccinated individuals:** A single dose of Pfizer-BioNTech COVID-19 Vaccine.
- **Individuals who have received 1 or more doses of a monovalent COVID-19 vaccine[4] or a bivalent COVID-19 vaccine[5]:** A single dose of Pfizer-BioNTech COVID-19 Vaccine is administered at least 2 months after the last previous dose of any monovalent COVID-19 vaccine or bivalent COVID-19 vaccine.

Immunocompromised individuals 6 months through 11 years of age

Additional doses of Pfizer-BioNTech COVID-19 Vaccine may be administered. For more information, talk to your child's healthcare provider.

WHO SHOULD NOT GET PFIZER-BIONTECH COVID-19 VACCINE?

A person should not get Pfizer-BioNTech COVID-19 Vaccine if they had:

- a severe allergic reaction after a previous dose of any Pfizer-BioNTech COVID-19 vaccine
- a severe allergic reaction to any ingredient in these vaccines.

WHAT ARE THE INGREDIENTS IN THIS VACCINE?

Pfizer-BioNTech COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol), tromethamine, tromethamine hydrochloride, and sucrose. Pfizer-BioNTech COVID-19 Vaccine may also contain sodium chloride.

HAS THIS VACCINE BEEN USED BEFORE?

Millions of individuals 6 months of age and older have received a Pfizer-BioNTech COVID-19 vaccine under EUA.

In a clinical trial, approximately 1,200 individuals 6 months through 23 months of age, approximately 1,800 individuals 2 through 4 years of age, and approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent). In another clinical trial, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent).

In clinical trials, 60 individuals 6 months through 4 years of age, 113 individuals 5 through 11 years of age, 107 individuals 12 through 17 years of age, 103 individuals 18 through 55 years of age, and 106 individuals greater than 55 years of age received a dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

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[4] Monovalent refers to a COVID-19 vaccine that encodes the spike protein of only the Original SARS-CoV-2.

[5] Bivalent refers to a COVID-19 vaccine that encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2.

The Pfizer-BioNTech COVID-19 Vaccine is made in the same way as the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

WHAT ARE THE BENEFITS OF PFIZER-BIONTECH COVID-19 VACCINE?
FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine to provide protection against COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF PFIZER-BIONTECH COVID-19 VACCINE?
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose. For this reason, the vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines. Myocarditis and pericarditis following Pfizer-BioNTech COVID-19 vaccines have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after your child receives a dose of the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported with Pfizer-BioNTech COVID-19 vaccines include:

- Severe allergic reactions
- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site pain/tenderness
- Tiredness
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Injection site swelling
- Injection site redness
- Nausea
- Feeling unwell
- Swollen lymph nodes (lymphadenopathy)
- Decreased appetite
- Diarrhea
- Vomiting
- Arm pain
- Fainting in association with injection of the vaccine
- Dizziness
- Irritability

These may not be all the possible side effects. Serious and unexpected side effects may occur. The possible side effects are still being studied.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

WHAT IF I DECIDE NOT TO HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE?
Under the EUA, there is an option to accept or refuse receiving this vaccine. Should you decide for your child not to receive this vaccine, it will not change the standard medical care.

ARE THERE OTHER VACCINES FOR PREVENTING COVID-19 BESIDES THE PFIZER-BIONTECH COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under EUA, including vaccines that encode the spike protein of the SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

CAN MY CHILD RECEIVE PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not been submitted to FDA on administration of Pfizer-BioNTech COVID-19 Vaccine at the same time as other vaccines. If you are considering having your child receive Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child's healthcare provider.

WHAT IF MY CHILD IS IMMUNOCOMPROMISED?
Immunocompromised individuals 6 months through 11 years of age may receive additional doses of Pfizer-BioNTech COVID-19 Vaccine (see **HOW IS THE VACCINE GIVEN?** above).

Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised; therefore, your child should continue to maintain physical precautions to help prevent COVID-19. Your child's close contacts should be vaccinated as appropriate.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?
If your child is pregnant or breastfeeding, discuss the options with your child's healthcare provider.

WILL THIS VACCINE GIVE MY CHILD COVID-19?
No. This vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?
- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The FDA has made Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA-approved product.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be

effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used under EUA during the COVID-19 pandemic.

The EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

BIONTECH
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

Pfizer
Manufactured by
Pfizer Inc., New York, NY 10001

LAB-1572-2.7a

Revised: 11 September 2023

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

GDTI: *0886983000585*

Exhibit 6

FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT MODERNA COVID-19 VACCINE (2023-2024 FORMULA) WHICH HAS EMERGENCY USE AUTHORIZATION (EUA) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 6 MONTHS THROUGH 11 YEARS OF AGE

Your child is being offered Moderna COVID-19 Vaccine (2023-2023 Formula)[1] to prevent coronavirus disease 2019 (COVID-19), which is caused by the virus SARS-CoV-2. This fact sheet contains information to help you understand the risks and benefits of Moderna COVID-19 Vaccine (2023-2024 Formula), hereafter referred to as Moderna COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make Moderna COVID-19 Vaccine available during the COVID-19 pandemic (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). Moderna COVID-19 Vaccine is not an FDA-approved vaccine for ages 6 months through 11 years of age in the United States. Read this Fact Sheet for information about Moderna COVID-19 Vaccine.

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through close contact with another person who has the virus.

It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness leading to death. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS MODERNA COVID-19 VACCINE?

Moderna COVID-19 Vaccine is a vaccine for use in individuals 6 months through 11 years of age to prevent COVID-19. The FDA has authorized the emergency use of Moderna COVID-19 Vaccine under an EUA.

Moderna COVID-19 Vaccine may not protect everyone.

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[1] Moderna COVID-19 Vaccine (2023-2024 Formula) encodes the spike protein of the Omicron XBB.1.5 SARS-CoV-2.

WHAT SHOULD YOU MENTION TO THE VACCCINATION PROVIDER BEFORE YOUR CHILD GETS MODERNA COVID-19 VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

Moderna COVID-19 Vaccine is given as an injection into the muscle.

Individuals 6 months through 4 years of age:

- **Unvaccinated individuals:** Two doses of Moderna COVID-19 Vaccine are administered. The second dose is administered 1 month after the first.
- **Individuals who have received one dose of Moderna COVID-19 Vaccine (Original monovalent)[2] or Moderna COVID-19 Vaccine, Bivalent:[3]** A single dose of Moderna COVID-19 Vaccine is administered 1 month after Moderna COVID-19 Vaccine (Original monovalent) or Moderna COVID-19 Vaccine, Bivalent.
- **Individuals who have received two or more doses of Moderna COVID-19 Vaccine (Original monovalent) or Moderna COVID-19 Vaccine, Bivalent:** A single dose of Moderna COVID-19 Vaccine is administered at least 2 months after the last previous dose of Moderna COVID-19 Vaccine (Original monovalent) or Moderna COVID-19 Vaccine, Bivalent.

Individuals 5 years through 11 years of age:

- **Unvaccinated individuals:** A single dose of Moderna COVID-19 Vaccine.
- **Individuals who have received one or more doses of a monovalent COVID-19 vaccine[4] or a bivalent COVID-19 vaccine:[5]** A single dose of Moderna COVID-19 Vaccine is administered at least 2 months after the last previous dose of any monovalent COVID-19 vaccine or bivalent COVID-19 vaccine.

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[2] Original monovalent Moderna COVID-19 Vaccine encodes the spike protein of only the Original SARS-CoV-2, no longer authorized for use in the U.S.

[3] Moderna COVID-19 Vaccine, Bivalent encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2, no longer authorized for use in the U.S.

[4] Monovalent refers to a COVID-19 vaccine that encodes the spike protein of only the Original SARS-CoV-2.

[5] Bivalent refers to a COVID-19 vaccine that encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2.

Immunocompromised individuals 6 months through 11 years of age:
Additional doses of Moderna COVID-19 Vaccine may be administered. For more information, talk to your child's healthcare provider.

WHO SHOULD NOT GET MODERNA COVID-19 VACCINE?
Your child should not get Moderna COVID-19 Vaccine if your child had:

- a severe allergic reaction after a previous dose of any Moderna COVID-19 vaccine.
- a severe allergic reaction to any ingredient in these vaccines.

WHAT ARE THE INGREDIENTS IN THIS VACCINE?
Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate trihydrate, and sucrose.

HAS THIS VACCINE BEEN USED BEFORE?
Millions of individuals 6 months of age and older have received a Moderna COVID-19 vaccine under EUA. In clinical trials, approximately 5,000 individuals 6 months through 5 years of age, 4,000 individuals 6 years through 11 years of age, and 30,000 individuals 12 years of age and older have received at least 1 dose of Moderna COVID-19 Vaccine (Original monovalent).

The Moderna COVID-19 Vaccine is made in the same way as the Moderna COVID-19 Vaccine (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

WHAT ARE THE BENEFITS OF MODERNA COVID-19 VACCINE?
FDA has authorized Moderna COVID-19 Vaccine to provide protection against COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF MODERNA COVID-19 VACCINE?
There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose. For this reason, the vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines. Myocarditis and pericarditis following Moderna COVID-19 vaccines have occurred most commonly in young adult males 18 years through 24 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very

low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after your child receives a dose of the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported in clinical trials with Moderna COVID-19 vaccines include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection or in the groin, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, fever, rash, irritability/crying, sleepiness, and loss of appetite

Side effects that have been reported during post-authorization use include:

- Severe allergic reactions
- Urticaria (itchy rash/hives)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all the possible side effects. Serious and unexpected side effects may occur. The possible side effects are still being studied.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child or do not go away.

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine (2023-2024 Formula) EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

WHAT IF I DECIDE NOT TO HAVE MY CHILD GET MODERNA COVID-19 VACCINE?
Under the EUA, there is an option to accept or refuse receiving this vaccine. Should you decide for your child not to receive this vaccine, it will not change the standard medical care.

ARE THERE OTHER VACCINES FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under EUA, including vaccines that encode the spike protein of the SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

CAN MY CHILD RECEIVE MODERNA COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of Moderna COVID-19 Vaccine at the same time as other vaccines. If you are considering having your child receive Moderna COVID-19 Vaccine with other vaccines, discuss your options with your child's healthcare provider.

WHAT IF MY CHILD IS IMMUNOCOMPROMISED?
Immunocompromised individuals 6 months through 11 years of age may receive additional doses of Moderna COVID-19 Vaccine (see **HOW IS THE VACCINE GIVEN?** above).

Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised; therefore, your child should continue to maintain physical precautions to help prevent COVID-19. Your child's close contacts should be vaccinated as appropriate.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?
If your child is pregnant or breastfeeding, discuss the options with your child's healthcare provider.

WILL THIS VACCINE GIVE MY CHILD COVID-19?
No. This vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

WHERE WILL VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The FDA has made Moderna COVID-19 Vaccine available under an emergency access mechanism call an EUA. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA-approved product.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used under EUA during the COVID-19 pandemic.

The EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

Moderna US, Inc.
Princeton, NJ 08540

Patent(s): www.modernatx.com/patents
Revised: September/11/2023

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

GDTI: 0886983000615

Exhibit 7

VACCINE INFORMATION STATEMENT

MMR Vaccine (Measles, Mumps, and Rubella): *What You Need to Know*

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

MMR vaccine can prevent **measles, mumps,** and **rubella.**

- **MEASLES (M)** causes fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body. It can lead to seizures (often associated with fever), ear infections, diarrhea, and pneumonia. Rarely, measles can cause brain damage or death.
- **MUMPS (M)** causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears. It can lead to deafness, swelling of the brain and/or spinal cord covering, painful swelling of the testicles or ovaries, and, very rarely, death.
- **RUBELLA (R)** causes fever, sore throat, rash, headache, and eye irritation. It can cause arthritis in up to half of teenage and adult women. If a person gets rubella while they are pregnant, they could have a miscarriage or the baby could be born with serious birth defects.

Most people who are vaccinated with MMR will be protected for life. Vaccines and high rates of vaccination have made these diseases much less common in the United States.

2. MMR vaccine

Children need 2 doses of MMR vaccine, usually:

- First dose at age 12 through 15 months
- Second dose at age 4 through 6 years

Infants who will be traveling outside the United States when they are between 6 and 11 months of age should get a dose of MMR vaccine before travel. These children should still get 2 additional doses at the recommended ages for long-lasting protection.

Older children, adolescents, and **adults** also need 1 or 2 doses of MMR vaccine if they are not already immune to measles, mumps, and rubella. Your health care provider can help you determine how many doses you need.

A third dose of MMR might be recommended for certain people in mumps outbreak situations.

MMR vaccine may be given at the same time as other vaccines. Children 12 months through 12 years of age might receive MMR vaccine together with varicella vaccine in a single shot, known as MMRV. Your health care provider can give you more information.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of MMR or MMRV vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant** or thinks they might be pregnant—pregnant people should not get MMR vaccine
- Has a **weakened immune system**, or has a **parent, brother, or sister with a history of hereditary or congenital immune system problems**
- Has ever had a **condition that makes him or her bruise or bleed easily**
- Has recently **had a blood transfusion or received other blood products**
- Has **tuberculosis**
- Has **gotten any other vaccines in the past 4 weeks**

In some cases, your health care provider may decide to postpone MMR vaccination until a future visit.

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People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting MMR vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Sore arm from the injection or redness where the shot is given, fever, and a mild rash can happen after MMR vaccination.
- Swelling of the glands in the cheeks or neck or temporary pain and stiffness in the joints (mostly in teenage or adult women) sometimes occur after MMR vaccination.
- More serious reactions happen rarely. These can include seizures (often associated with fever) or temporary low platelet count that can cause unusual bleeding or bruising.
- In people with serious immune system problems, this vaccine may cause an infection that may be life-threatening. People with serious immune system problems should not get MMR vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**.