ESTADO LIBRE ASOCIADO DE PUERTO RICO
TRIBUNAL DE APELACIONES
REGIÓN JUDICIAL DE SAN JUAN

LOURDES AMADEO OCASIO, por sí y en representación de sus hijos (A.M.A) y (M.M.A), Y OTROS **PARTE RECURRENTE** **VS.** **PEDRO PIERLUISI URRUTIA, EN SU CAPACIDAD COMO GOBERNADOR DE PUERTO RICO Y OTROS** **PARTE RECURRIDA**	**TA NÚM: KLAN202100796** **CIVIL NÚM: SJ 2021CV04779 (907)** **SOBRE: SENTENCIA DECLARATORIA, INTERDICTO, LIBERTAD DE EXPRESIÓN RELIGIOSA, DAÑOS**

MOCIÓN EN AUXILIO DE JURISDICCIÓN
SOLICITANDO PARALIZACIÓN DE MANDATOS DE VACUNACIÓN

AL HONORABLE TRIBUNAL:

COMPARECE la parte peticionaria, por conducto de la representación legal que suscribe, y muy respetuosamente **EXPONE, ALEGA** Y **SOLICITA:**

PREÁMBULO

Los productos utilizados como vacunas, al igual que otros productos de uso médico, conllevan un proceso de experimentación, observación, análisis, validación y aprobación. Los medicamentos y las vacunas son productos con licencia o productos experimentales. No hay un área gris entre ellos en la ley Federal. Ya sea que la investigación se realice o no explícitamente, el uso de productos experimentales (incluidos los emitidos con una Autorización de Uso de Emergencia, EUA) caen bajo el Código de Nuremberg y bajo la ley Federal que regula los medicamentos experimentales. Estos criterios y procesos son de medular importancia para que no se causen daños a los individuos que usen los productos experimentales, y se pueda proveer de consentimiento informado antes de su uso. Según dispuesto en el 21 CFR Subchapter D Part 312, "*an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.*" Las vacunas son consideradas un subconjunto de medicamentos por la FDA[1]. Y el uso de vacunas autorizadas de uso de emergencia sin licencia es, por lo tanto, por definición, experimental.

[1] https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC7152379/

Recientemente, en National Federation of Independent Business, et al., a *v. D*epartment of Labor, Occupational Safety and Health Administration, *et al.* Ohio, et al., 595 U. S. ____ (2022), enero 13 de 2022, el Tribunal Supremo Federal, emitió una decisión en la que paralizó y anuló, el Mandato del Presidente a que OSHA regule y requiera el uso de vacunas autorizadas en lugares donde laboraran más de 100 empleados. El núcleo de la decisión de la Corte es que, en una sociedad democrática, el Congreso es la institución que hace las leyes. El pueblo elige a los miembros del Congreso y les otorga la autoridad para promulgar leyes en nombre del pueblo. El papel del poder ejecutivo es llevar a cabo o ejecutar esas leyes. El Congreso puede establecer agencias, como OSHA, con poderes delegados para administrar áreas particulares de la ley, pero esas agencias deben operar dentro de los parámetros de esta autoridad asignada.

El Hon. Juez Neil Gorsuch indicó en su opinión concurrente "*[i]f administrative agencies seek to regulate the daily lives and liberties of millions of Americans ... they must at least be able to trace that power* ***to a clear grant of authority from Congress***". El Congreso, señaló la Corte, ha aprobado varias leyes relacionadas con COVID-19, incluidos múltiples paquetes de alivio de COVID. El Congreso claramente podría haber optado por legislar un mandato nacional. Pero no fue así.

Similar situación ha ocurrido en Puerto Rico, al no existir una legislación especial al respecto.

En Puerto Rico, como se indicó, solo existe una ley especial para vacunación. Por su parte, la mal utilizada Ley de Seguridad Pública – en la que han querido amparar la Órdenes Ejecutivas – en ningún momento crea o delega poderes al Ejecutivo o sus agencias para implantar el uso de productos, medicamentos, drogas o vacunas a la población. La naturaleza de las Órdenes Ejecutivas, al amparo de la Ley de Seguridad Pública, no se sostienen, toda vez que el Departamento de Salud no es parte de esa sombrilla, y los aspectos de Salud Pública se atienden bajo la Ley Orgánica del Departamento de Salud. *Véanse,* argumentos expuestos en la Demanda y recurso de Apelación.

Los peticionarios solicitan que este tribunal pueda ampararse en el estado de Derecho vigente y proteja a nuestros niños y maestros, sus derechos, dignidad e intimidad, de ser objeto de persecución del Estado, al querer imponerse el uso de estos productos que han demostrado que NO PROVEEN INMUNIDAD, NO EVITAN CONTAGIOS, ENFERMEDAD NI PROPAGACIÓN. Ahora, bajo la nueva consigna de que pueden disminuir los síntomas. Esto lo discutiremos adelante.

De otra parte, y un asunto que fue totalmente ignorado por el TPI, **es el asunto de responsabilidad e indemnización ante la posibilidad de reacciones adversas por el uso de estos productos.** Debemos llamar la atención, que en la petición de Amicus Curia se han presentado un sin número de estudios y datos sobre la incidencia de estas reacciones adversas en individuos jóvenes. Por ejemplo, los casos de

Miocarditis y pericarditis aumentaron sustancialmente en la población joven, sobrepasando incluso la probabilidad de fallecimiento. *Véase* SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis, Tracy Beth Høeg MD, PhD1; Allison Krug, MPH2; Josh Stevenson; John Mandrola, MD4, doi/10.1101/2021.08.30.21262866.

A su vez, al Vaccine Adverse Event Reporting System (VAERS) se han reportado cientos de miles de reacciones adversas y miles de fallecimientos, lo cual, son datos que no pueden continuar siendo ignorados al momento de tomar decisiones de Salud Pública. COVID vaccination and age-stratified all-cause mortality risk, Spiro P. Pantazatos and Hervé Seligmann, octubre 2021[13]. Los reportes se realizan al Vaccine Adverse Event Reporting System. Vemos más de **11,500 fallecimientos reportados**, y más de 518,000 reportes, a julio 23 de 2021,[14] y a diciembre de 2021, más de 900,000 reacciones adversas y más de 20,000 fallecimientos. Un análisis de junio de 2021[15] de los informes de muerte de la vacuna: VAERS COVID-19 dirigido por Scott Mclachlan de la Universidad de Londres, descubrió que "*contrary to claims that most of these reports are made by lay-people and are hence clinically unreliable*," los empleados de los servicios de salud fueron los reporteros en al menos el 67 por ciento de las veces, y "*there were only 14 percent of the cases for which a vaccine reaction could be ruled out as a contributing factor in their death.*"

Esto nos lleva a la importante pregunta de: ¿qué hago o qué alternativas existen si yo o algún dependiente, tiene o sufre una reacción adversa por el uso de alguno de estos productos contra el SARS-CoV-2? Como se explica en la Demanda y en el Recurso de Apelación, al no ser vacunas aprobadas, se pierde la protección bajo el National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), 42 USC § 300 aa, la cual, provee inmunidad a los manufactureros de vacunas, pero crea un Fondo de Compensación al cual las víctimas de reacciones adversas o muertes pueden reclamar. Para poder reclamar a dicho fondo, la vacuna tiene que haber sido aprobada por el FDA y existir en un *protocolo aprobado*. Como se ha señalado, los productos actuales que se están obligados a utilizar por las Órdenes emitidas **no están autorizadas y del individuo tener una reacción adversa o muerte, la persona o sus familiares no pueden reclamar al Fondo de Compensación a víctimas.**

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[13] DOI:10.13140/RG.2.2.28257.43366

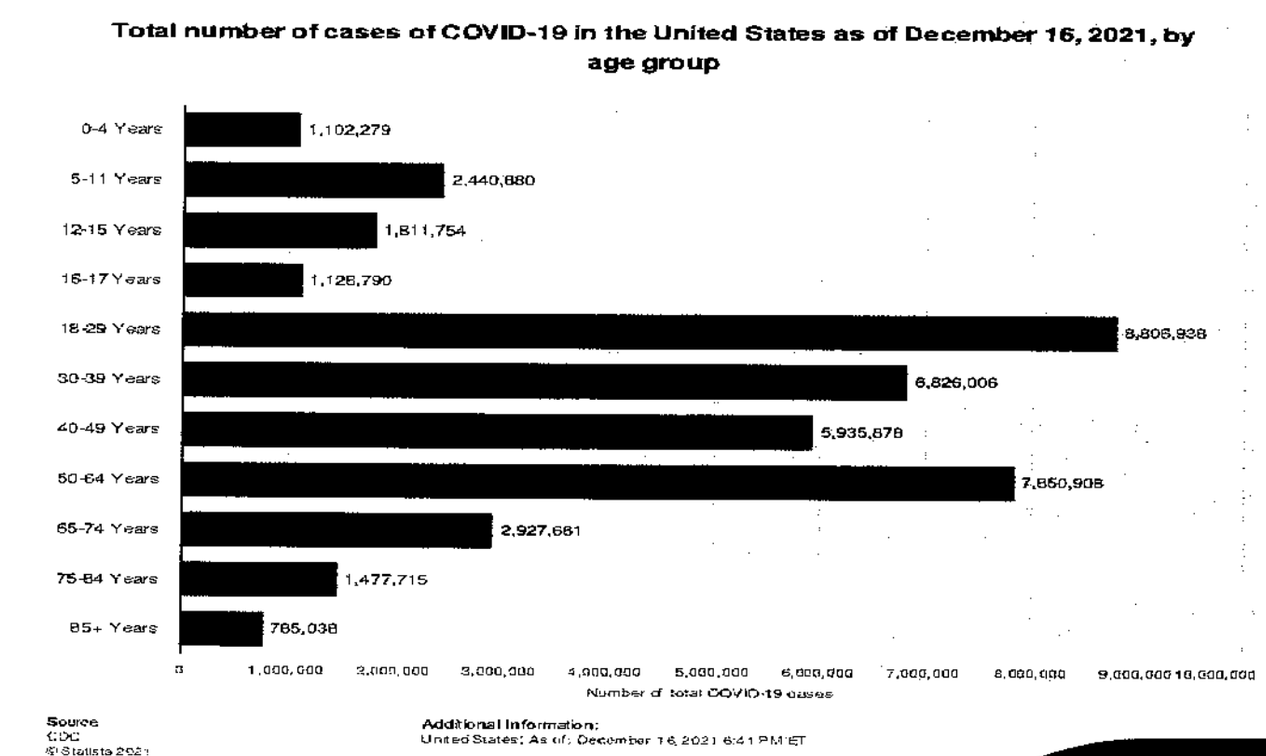
[14] Mortality (openvaers.com) https://openvaers.com/index.php Open VAERS es una Plataforma donde se presentan los datos del VAERS ya filtrados por categorías.

[15] Los revisores clínicamente capacitados han realizado un análisis detallado de una muestra de las muertes tempranas reportadas en VAERS (250 de las 1644 muertes registradas hasta abril de 2021). Análisis de los informes de muertes por vacunas COVID-19 de la base de datos provisional del Sistema de notificación de eventos adversos a las vacunas (VAERS): Resultados y análisis DO - 10.13140/RG.2.2.26987.26402

Las compensaciones en casos de reacciones adversas o severas que ha otorgado el Vaccine Compensation Program, bajo el US Court of Federal Claims han llegado a ser millonarias, y atienden todo tipo de daño y partidas, como tratamiento, cuidado, ingresos dejados de percibir, etc. *Véase* Anejo I. La única opción que existe actualmente es el *Countermeasures Injury Compensation Program* **(CICP)**, que solamente cubre partidas limitadas, y no ha adjudicado ningún caso de reacciones adversas. Esto se explica en el recurso de Apelación.

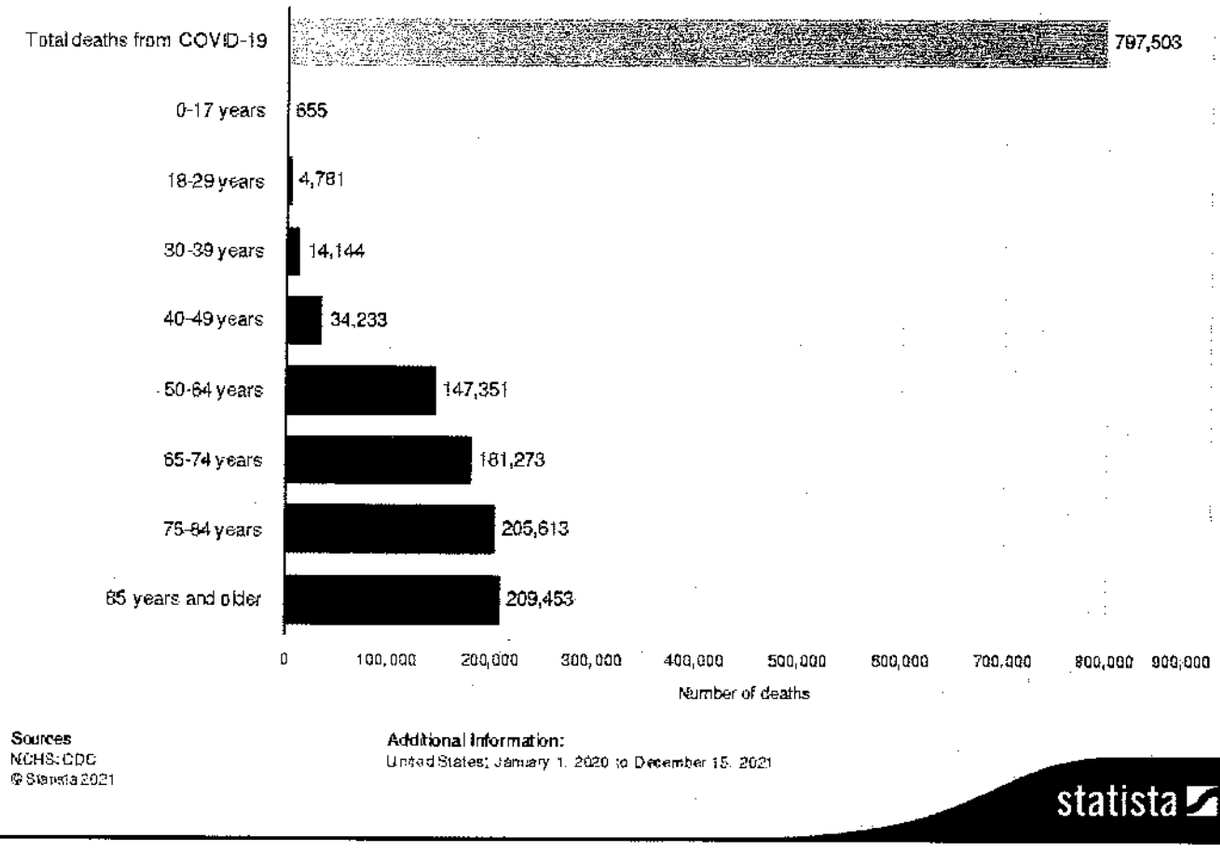
Por tanto, ponemos en riesgo a nuestros niños y a los empleados que se sometan a estas órdenes, al no tener un andamiaje legal que les indemnice o pueda atender sus tratamientos en caso de una reacción adversa. Claro, el Gobierno le miente al país en sus argumentos al indicar que los productos son seguros y efectivos, determinaciones que se reserva al F.D.A. y sus dependencias una vez termine de estudiar los productos. De hecho, las EUA de los productos advierten que no se pueden promocionar como que evitan contagios o enfermedad ni como que son efectivas. Anejamos a la presente una hoja de propaganda del Departamento de Salud, en la que inducen a error para viciar el consentimiento informado de los padres al indicar que los productos **evitan contagios, enfermarse gravemente, evitar contagiar a otras personas**. *Véase* II.

Es un hecho que las escuelas estuvieron abiertas durante todo el semestre y no hubo problemas o situaciones que lamentar, además de que no hubo cierres de escuelas por brotes, y donde se encontraron casos, se siguieron protocolos. Pero hay que cuestionar, por qué Puerto Rico es la única jurisdicción donde se han establecido estos mandatos. En la población joven y escolar no tenemos problemas de mortalidad ni casos significativos severos. Esto son datos que no pueden continuar siendo ignorados. A nivel nacional,



la cantidad de fallecimientos reportados como asociado a la enfermedad de COVID-19, en las edades menores a los 17 años, son unas 655. Esto **representa un 0.0002%** entre **los contagiados.**

Number of coronavirus disease 2019 (COVID-19) deaths in the U.S. as of December 15, 2021, by age*



A nivel nacional y local se ha constatado que la mayoría de los casos de hospitalizaciones no llegan o se presentan por causa de COVID-19, **sino por traumas y otras emergencias**, que al recibirse y hacerse pruebas al SARS-CoV-2 (realmente al material genético del virus), se catalogan como casos de COVID-19, independientemente estén enfermos o no, y la norma es que no se confirman con cultivos de laboratorio. Esto infla los números sin que la población pueda obtener la información correcta. Citamos a varios miembros directivos del CDC al respecto.

La directora de los Centros para el Control y la Prevención de Enfermedades (CDC), la doctora Rochelle Walensky, dijo a MSNBC el 29 de diciembre pasado que el número de hospitalizaciones de niños con COVID-19 ha aumentado en los últimos días, pero señaló que muchas de ellas no están relacionadas con el virus. "*Many of them are actually coming in for another reason. But they happen to be tested when they come in and they're found incidentally to have COVID*". Walensky también señaló que el alto número de hospitalizaciones infantiles es "*common for this time of year*," añadiendo que los niños "*more often don't require intensive care unit treatment.*"

El asesor en COVID-19 de la Casa Blanca, Anthony Fauci, dijo en diciembre que los hospitales ahora están sobre contando los casos de COVID-19 en niños porque se les hace una prueba automática cuando son admitidos, haciéndose eco de una narrativa que ha sido repetida por algunos escépticos durante meses. Cuando se le preguntó durante una entrevista de MSNBC sobre el aumento de las hospitalizaciones, Fauci dijo que "*quantitatively, you're having so many more people, including children, who are getting infected.*" "*Even though hospitalization among children is much, much lower on a percentage basis than hospitalizations for adults, particularly elderly individuals*," Fauci, el 29 de diciembre de 2021, indicó a través de la cadena de comunicaciones: "*when you have such a large volume of infections among children, even with a low level of rate of infection, you're going to still see a lot more children who get hospitalized.*" Fauci luego dijo que "*if you look at the children who are hospitalized, many of them are hospitalized with COVID(SARS-CoV-2) as opposed to because of COVID*," Continuaron sus declaraciones indicando que "*If a child goes in the hospital, they automatically get tested for COVID. And they get counted as a COVID-hospitalized individual*," Fauci comentó. "*When in fact, they may go in for a broken leg or appendicitis or something like that. So, it's overcounting the number of children who are, quote, 'hospitalized with COVID,' as opposed to because of COVID.*"

De otra parte, el CDC reportó que, para el 10 de diciembre de 2021, la mayoría de los 43 casos de COVID-19 causados por la variante de Omicron identificados en los Estados Unidos habían sido en personas que estaban completamente vacunadas, y un tercio de ellos habían recibido una dosis de refuerzo.

Posteriormente, el gobierno y el CDC han reportado que la mayoría de los casos se atribuyen a la variante de Omicron. Las "vacunas" no están diseñadas para las variantes. La transmisión del virus se ha dado incluso entre el personal de salud vacunado. *Véase* Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam by Nguyen Van Vinh Chau, Nghiem My Ngoc, OUCRU COVID-19 Research Group :: SSRN, octubre 11 de 2021. Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021, Kasen K. Riemersma, DVM.

El diseño de las vacunas que se distribuyen en Puerto Rico y los Estados Unidos se realizó para exclusivamente producir anticuerpos a la proteína espiga (Spike Protein) del virus original, y no al capsoide (envolvimiento) ni al resto de las proteínas del virus. Por lo que, a la proteína S_0 original continuar mutando, disminuyó cualquier protección que se alegaba podía proveer la vacuna, además de menguar rápidamente su cantidad de anticuerpos[16] ante los cambios de la proteína espiga. Se indica que al tener

[16] Spike-antibody waning after second dose of BNT162b2 or ChAdOx1, https://doi.org/10.1016/s0140-6736(21)01642-1

por ejemplo un Omicron con más de 25 mutaciones, la proteína S_{26} del virus actual, presenta un escenario distinto, en el cual, las vacunas han demostrado su ineficacia. Agraciadamente, las mutaciones han convertido al virus en uno más inofensivo.

Todos estos factores parecen ser obviados por el Gobierno, pero claramente llevan a cuestionar las motivaciones y necesidad de querer imponer unos productos invasivos al cuerpo de niños, jóvenes y el personal docente y no docente del sector de la Educación.

Esto nos lleva a otro argumento importante. Por qué se requieren solamente pruebas, según las Órdenes emitidas, a los empleados **no** vacunados y a los estudiantes de más de 12 años que no se hayan vacunado. Los números publicados a nivel internacional, nacional y locales afirman que los contagios actualmente pueden ocurrir en toda la población, independientemente del estado de vacunación. De igual forma, en los casos reportados con fallecimientos, se encuentran personas con la tercera dosis puesta.[17]

Esta presión indebida tiene el único fin de coaccionar y forzar a que los estudiantes y los empleados utilicen los productos. Esto es un acto irresponsable, ilegal y totalmente innecesario. Es un discrimen, con el agravante de que se impone como un requisito para poder ejercer derechos fundamentales y vitales como lo son el estudiar y trabajar. Cabe señalar, que se le impone hacer pruebas semanales a individuos presuntamente saludables, **y a su propio costo**. Si el estado, sin justificación alguna, pretende trastocar el orden y los derechos de estas personas, no puede imponerles cargas económicas y controlar sus vidas, teniendo en la actualidad que esperar horas o días para poder realizarse pruebas, las cuales están bajo autorizaciones de emergencias, y que no se pueden utilizar para diagnosticar por sí mismas.

Este Honorable Tribunal debe entender que las Órdenes Ejecutivas no son conforme a derecho. Se utilizaron para controlar a la población e imponer requisitos que laceran las libertades individuales de los puertorriqueños. Se manipulan los hechos para imponer requisitos en actividades esenciales, y fomentan el discrimen. Incluso empleados y padres que aceptaron el uso de estos productos, ahora ven como se les mintió y se les continúa obligando a usar los productos, aun cuando no crean inmunidad, ni evitan enfermedad ni contagios.

Los peticionarios, dentro de la espada y la pared en que se encuentran, tienen que suplicar a este Tribunal que paralice toda Orden Ejecutiva y Administrativa que exija como requisito el vacunarse o tener que hacerse pruebas semanales para acudir a estudiar, o ir a trabajar a una escuela o universidad.

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[17] Los recurrentes no reconocen que los reportes de "muertes por COVID" sean necesariamente atribuibles al contagio con SARS-CoV-2. No se informa el resto de las comorbilidades, y variantes, o incluso la falta de tratamiento adecuado antes atribuir la causa, por una mera prueba de PCR o similar. Se debe de informar la causa principal del certificado de defunción y analizar los casos de manera más responsable, ya que esta es la información para crear pánico, o tomar decisiones.

POR TODO LO CUAL, se solicita muy respetuosamente a este Honorable Tribunal que en tanto resuelva el recurso de Apelación incoado, emita una Orden en Auxilio de Jurisdicción, en **la que paralice toda Orden o Mandato** emitido por el Gobernador, el Departamento de Salud, de Educación, o cualquier dependencia del Poder Ejecutiva, y a sí evitar que se continué causando daño a las partes comparecientes, y poner en riesgo la salud física y emocional, tanto de los estudiantes, sus familias y empleados:

A. Vacunación

(1) Dejar sin efecto el requisito de uso de vacunas contra el "Covid-19" a los estudiantes como requisito para asistir a las escuelas;

(2) Dejar sin efecto el requisito de uso de vacunas contra el "Covid-19" a los estudiantes como requisito para asistir a las universidades, o instituciones técnicas o graduadas, o en cualquier otro centro de estudio;

B. Pruebas

(3) Dejar siu efecto el requisito de uso de pruebas para detectar presencia de SARS-CoV-2, a los estudiantes no vacunados como requisito para asistir a las escuelas, universidades, o instituciones técnicas o graduadas, o en cualquier otro centro de estudio, salvo no presente síntomas o se recomienda por un profesional de la salud que haya evaluado al individuo;

(4) Dejar sin efecto el requisito de uso de pruebas para detectar presencia de SARS-CoV-2, a los empleados no vacunados como requisito para asistir a las escuelas, universidades, o instituciones técnicas o graduadas, o en cualquier otro centro de estudio, salvo no presente síntomas o se recomienda por un profesional de la salud que haya evaluado al individuo;

C. En la alternativa a que no prohíba el mandato de realizarse pruebas

(5) Ordene la realización de las pruebas a todo estudiante o empleado indistintamente su estado de vacunación;

(6) Ordene que toda prueba que no sea recomendada por un un profesional de la salud que haya evaluado al individuo, sea pagada y facilitada por el Gobierno o alguna entidad que este designe.

En San Juan, Puerto Rico a 18 de enero de 2022.

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Anejo I

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 12-630V

Filed: March 6, 2017

[redacted]	*	UNPUBLISHED
	*	
Petitioner,	*	Case No. 12-630 V
	*	
v.	*	Chief Special Master Dorsey
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Damages Award; Neuromyelitis Optica ("NMO"); Human Papilloma Virus ("HPV") Vaccine; Proffer.
	*	
Respondent.	*	

Anne Carrion Toale, Maglio, Christopher & Toale, Sarasota, FL, for petitioner.
Gordon Elliot Shemin, U.S. Department of Justice, Washington, D.C., for respondent.

DECISION AWARDING DAMAGES[1]

On September 24, 2012, [redacted] filed a petition for compensation under the National Vaccine Injury Compensation Program ("the Program"),[2] as the legal representative of her then-minor [redacted] in which she alleged that the Gardasil ("HPV") and FluMist ("influenza") vaccinations [redacted] received on September 28, 2011, caused her to develop multiple sclerosis ("MS"). Petition at 3, ¶11. After the filing of the petition, it was discovered that [redacted] actually suffers from a rare autoimmune disorder known as neuromyelitis optica ("NMO") or Devic's Syndrome, rather than MS. See Petitioner's ("Pet'r's") Exhibit ("Ex.") 6 at 13.

On November 13, 2015, the undersigned issued a decision finding that petitioner was entitled to compensation. During the time in which this case was being adjudicated, [redacted]

[1] Because this decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa.

turned 18 years old and was made the petitioner in her case. On May 31, 2016, the undersigned awarded [redacted] interim damages for past pain and suffering in the amount of $250,000.00.[3]

On March 3, 2017, respondent filed a Proffer on Award of Compensation ("Proffer"). In the Proffer, respondent represented that petitioner agrees with the proffered award. Based on the record as a whole, the undersigned finds that petitioner is entitled to an award as stated in the Proffer.

Pursuant to the terms stated in the attached Proffer, the undersigned awards petitioner:

(1) A lump sum payment of $1,283,828.14, representing compensation for life care expenses expected to be incurred during the first year after judgment ($305,186.22), lost earnings ($968,386.45), and past unreimbursable expenses ($10,255.47), in the form of a check made payable to petitioner, [redacted]

(2) A lump sum payment in the amount of $7,584.74, representing compensation for satisfaction of the State of Indiana Medicaid lien, in the form of a check made payable to petitioner, [redacted] and

Anthem BCBS, Inc.
Attn: Anel Mendez
21555 Oxnard Street
Mail Drop AC-10C
Woodland Hills, CA 91367
[redacted]

(3) An amount sufficient to purchase the annuity contract described in section II.C. of the Proffer.

Proffer at 5.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** herewith.[4]

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[3] Respondent filed a motion for review of this decision on June 30, 2016, and the decision was affirmed by Judge Wolski on December 7, 2017. The final judgment awarding interim damages was entered on January 18, 2017. Because petitioner has already received the maximum amount of pain and suffering damages permitted by the statute, pain and suffering damages are not awarded in this decision.

[4] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

[redacted] and [redacted] as parents and natural guardians of their [redacted] [redacted], Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	No. 12-403V Special Master Christian J. Moran Filed: December 19, 2016 Stipulation; influenza ("flu"); acute hemorrhagic leukoencephalomyelitis ("AHLE").

Anne Carrion Toale, Maglio Christopher and Toale, PA, Sarasota, FL, for Petitioner.
Claudia B. Gangi, U.S. Dep't of Justice, Washington, DC, for Respondent.

UNPUBLISHED DECISION[1]

On December 15, 2016, the parties filed a joint stipulation concerning the petition for compensation filed b[redacted] and [redacted] as parents and natural guardians of their [redacted] [redacted] on June 22, 2012. In their petition, petitioners allege that the influenza ("flu") vaccine, which is contained in the Vaccine Injury Table, 42 C.F.R. §100.3(a), and which [redacted] received on September 9, 2009, caused her to suffer a stroke and develop acute hemorrhagic leukoencephalomyelitis ("AHLE"). Petitioners further allege that [redacted] experienced residual effects of this injury for more than six months. Petitioners

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

represent that there has been no prior award or settlement of a civil action for damages on behalf of [redacted] as a result of her condition.

Respondent denies that [redacted] suffered a stroke or developed AHLE as a result of her immunization and denies that the flu vaccine caused her any other injury.

Nevertheless, the parties agree to the joint stipulation, attached hereto. The undersigned finds said stipulation reasonable and adopts it as the decision of the Court in awarding damages, on the terms set forth therein.

Damages awarded in that stipulation include:

a. **A lump sum of $617,027.40, which amount represents compensation for first year life care expenses ($206,402.40) and trust seed funds ($410,625.00), in the form of a check payable to Counsel Trust Company, as trustee of the grantor reversionary trust established for the benefit of** [redacted]

b. **A lump sum of $1,089,257.36, which amount represents compensation for lost future earnings ($839,257.36) and pain and suffering ($250,000.00), in the form of a check payable to petitioners as guardian(s)/conservator(s) of the estate of** [redacted] **for the benefit of** [redacted] **No payments shall be made until petitioners provide respondent with documentation establishing that they have been appointed as guardian(s)/conservator(s) of** [redacted]**s estate;**

c. **A lump sum payment of $4,779.49, which amount represents compensation for past reimbursable expenses, in the form of a check payable to petitioners,** [redacted] **and** [redacted] [redacted] **and**

d. **A lump sum of $50,728.71, which amount represents reimbursement of a lien for services rendered on behalf of** [redacted] **in the form of a check payable jointly to petitioners and**

Recovery Section
P.O. Box 8486
Harrisburg, PA 17105-8486
Attn: Barbara Witmer
CIS No: 990624514

Petitioners agree to endorse this payment to the Commonwealth of Pennsylvania.

e. **An amount sufficient to purchase the annuity contract described in paragraph 10 of the stipulation, paid to the life insurance company from which the annuity will be purchased (the "Life Insurance Company").**

In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment in case 12-403V according to this decision and the attached stipulation.[2]

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

[2] Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by each party filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-119V
Filed: November 20, 2017
UNPUBLISHED

[redacted] on behalf of [redacted] a minor child,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU); Damages Decision Based on Proffer; Measles Mumps Rubella (MMR) Vaccine; Encephalopathy

Diana Lynn Stadelnikas, Maglio Christopher & Toale, PA, Sarasota, FL, for petitioner.
Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.

DECISION AWARDING DAMAGES[1]

Dorsey, Chief Special Master:

On January 27, 2016, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,[2] (the "Vaccine Act"). Petitioner alleges that [redacted] was diagnosed with encephalopathy following receipt of Hepatitis A, Haemophilus influenza type B, measles, mumps and rubella (MMR), Prevnar, and varicella vaccinations on February 13, 2013. Petition at 2. The case was assigned to the Special Processing Unit of the Office of Special Masters.

On July 18, 2016, a ruling on entitlement was issued, finding petitioner entitled to compensation for [redacted]s encephalopathy injury. On November 17, 2017, respondent filed a proffer on award of compensation ("Proffer"). Respondent proffers that, based upon her review of the evidence of record, petitioner should be awarded:

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[1] Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

A. A lump sum in the amount of $1,191,475.29 paid to Regions Bank, as Trustee of the Grantor Reversionary Trust for the benefit of [redacted]

B. A lump sum in the amount of $1,043,951.66 paid to the court-appointed guardian(s)/conservator(s) of the estate of [redacted] for the benefit of [redacted].

C. A lump sum payment of $278,476.84, representing compensation for satisfaction of the State of Oklahoma Medicaid lien; and

D. An amount sufficient to purchase the annuity contract described above in section II.D.

In the Proffer, respondent represented that petitioner agrees with the proffered award. Based on the record as a whole, the undersigned finds that petitioner is entitled to an award as stated in the Proffer.

Pursuant to the terms stated in the attached Proffer, **the undersigned awards petitioner:**

A. A lump sum in the amount of $1,191,475.29 paid to Regions Bank, as Trustee of the Grantor Reversionary Trust for the benefit of [redacted]

B. A lump sum in the amount of $1,043,951.66 paid to the court-appointed guardian(s)/conservator(s) of the estate of [redacted] **for the benefit of** [redacted]

C. A lump sum payment of $278,476.84, representing compensation for satisfaction of the State of Oklahoma Medicaid lien payable jointly to petitioner and

Oklahoma Health Care Authority
P.O. Box 18497
Oklahoma City, Oklahoma 73154
Attn: Susan L. Eads
c/o Legal Unit
OHCA Case No: 502137

Petitioner agrees to endorse this payment to the State of Oklahoma.; and

D. An amount sufficient to purchase the annuity contract described in Proffer Section II.D.

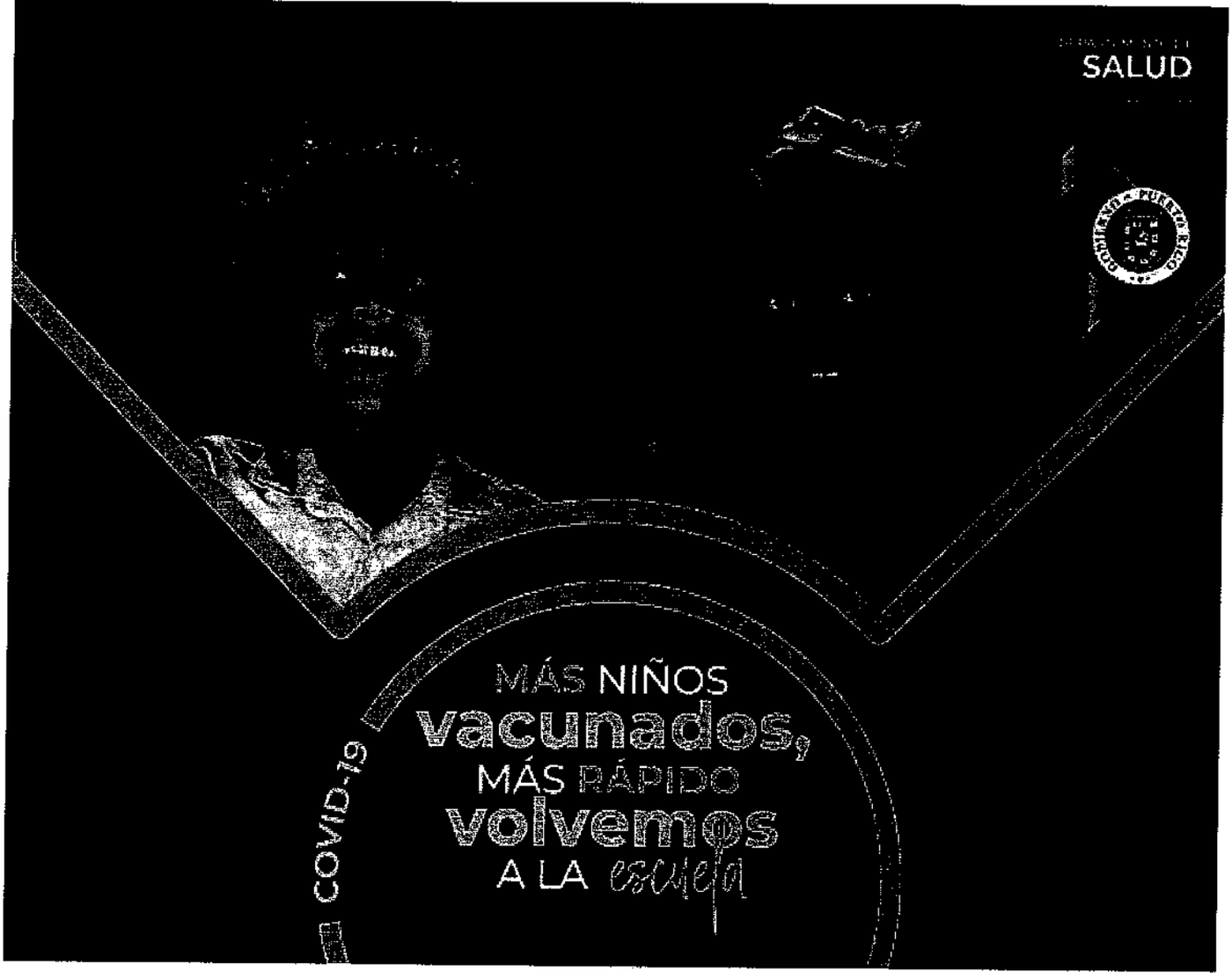
This amount represents compensation for all damages that would be available under § 300aa-15(a).

The clerk of the court is directed to enter judgment in accordance with this decision.[3]

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

[3] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.



El Departamento de Salud continúa trabajando para detener el Covid -19. Llegó el momento de vacunar a los niños y sus beneficios superan los riesgos, porque evita:

- Infectarse por el virus.
- Enfermarse gravemente.
- Contagiar a otras personas.
- Complicaciones de salud a corto y largo plazo.

A la hora de vacunar a tus hijos sigue estos pasos y recomendaciones:

- Comunícate con su pediatra para aclarar dudas y suministrarle la vacuna.
- Si su pediatra no es proveedor, haz una cita en un centro elegible.
- Una vez vacunado, monitorea a tu hijo.
- Es importante regresar a los 21 días para completar la vacunación.

Centros de vacunación elegibles

Aibonito
Hospital Menonita
787-735-0384 / 8001
Ext. 1424 / 1438

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- Dorado 787-796-3183
- Luquillo 787-889-1077
- Toa Baja 787-261-0400

Barranquitas
SIM Barranquitas
787-869-5900

Bayamón
Bayamón Health Center
787-479-2539

SIM Bayamón
787-869-5900

Caguas
Centro de Neumología Pediátrica
787-743-1917

Grupo Pediátrico de Caguas
787-746-2021

Cidra
CDT Luis Aramburu
787-434-1700
Ext. 1920 / 1903

Comerío
SIM Comerío
787-869-5900

Corozal
SIM Corozal
787-869-5900

Florida
Florida Medical Plaza
787-822-2170

Naranjito
SIM Naranjito
787-869-5900

Orocovis
SIM Orocovis
787-869-5900

Ponce
Hospital San Lucas
787-844-2080

Escuela de Medicina de Ponce
787-840-2575 Ext. 5843

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- Caguas 787-746-1039
- Carolina 787-769-2038
- Hatillo 787-544-7265
- Ponce 787-843-4835
- San Juan 787-522-3601

San Germán
Hospital La Concepción
787-892-1860

San Juan
Hospital Auxilio Mutuo
787-758-2000 / 787-242-4867

Recinto de Ciencias Médicas
787-758-2525 Ext. Ext. 2535

Hospital San Jorge
787-727-1000
Ext. 4189 / 4190

Hospital Ashford
787-727-2160 Ext. 6525

Plaza Las Américas
(Segundo Nivel)
VacuKids

Toa Alta
SIM Toa Alta 2
787-869-5900

Walmart
- Barceloneta 787-970-8107
- Bayamón 787-740-0730
- Caguas 787-286-8460
- Canóvanas 787-957-2715
- Carolina 787-701-1045
- Cayey 787-738-7240
- Fajardo 787-801-0500
- Guayama 787-866-2060
- Hatillo 787-544-4855
- Humacao 787-852-9620
- Isabela 787-830-3004
- Manatí 787-621-0487
- Mayagüez 787-265-1090
- Toa Baja 787-641-5650
- Ponce 787-709-4036, 787-651-0482
- Santa Isabel 787-971-1010
- San Juan 787-641-5606

Para cita online, accede:

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cvs.com | costco.com | walgreens.com

DEPARTAMENTO DE SALUD

ProtegeteVacunate.pr.gov | 787-709-4610

Spike-antibody waning after second dose of BNT162b2 or ChAdOx1

Vaccines based on the spike glycoprotein of SARS-CoV-2 are being rolled out globally to control transmission and limit morbidity and mortality due to COVID-19. Current evidence indicates strong immunogenicity and high short-term efficacy for BNT162b2 (Pfizer–BioNTech) and ChAdOx1 nCoV-19 (Oxford–AstraZeneca).[1–3] Both vaccines are delivered through a prime-boost strategy, and many countries, including the UK, have used dose intervals longer than 3–4 weeks, expecting to maximise first-dose coverage and immunogenicity. With continued high global incidence, and potential for more transmissible SARS-CoV-2 variants, data on longer-term vaccine efficacy and antibody dynamics in infection-naive individuals are essential for clarifying the need for further booster doses.

To identify early indications of waning antibody levels to the spike protein (S-antibody) after complete two-dose vaccination, we did a cross-sectional analysis of fully vaccinated adults (aged ≥18 years) who submitted capillary blood samples for Virus Watch, a longitudinal community cohort study in England and Wales.[4] The study received ethical approval from the Hampstead NHS Health Research Authority Ethics Committee (20/HRA/2320). Sera were tested using Elecsys Anti-SARS-CoV-2 S and N electro-chemiluminescent immunoassays (Roche Diagnostics, Basel, Switzerland); the S assay targets total antibodies to the S1 subunit of the spike protein (range 0·4–25 000 units per mL [U/mL]), whereas the N assay targets total antibodies to the full-length nucleocapsid protein, which we took as a proxy for previous SARS-CoV-2 infection (specificity 99·8% [99·3–100]).[5] Serological results were linked with demographic and clinical information collected at enrolment and with weekly self-reported vaccination status.

605 adults submitted a valid sample on June 14–15, 2021. 321 (53%) of 605 participants were women, and the median age was 63 years (IQR 58–67). Of 605 participants, 186 (31%) were categorised as clinically vulnerable, 117 (19%) as clinically extremely vulnerable, and 302 (50%) as not clinically vulnerable (additional participant characteristics and definitions of clinical vulnerability are available in the appendix). Participants contributed a single sample, taken 14–154 days after their second vaccine dose (median 42 days [IQR 30–53]). 197 (33%) of 605 samples were from BNT162b2 vaccinees and 405 (67%) samples were from ChAdOx1 vaccinees; vaccine type was missing for three (<1%) participants. The median interval between first and second doses was 77 days (IQR 70–78).

Participants with previous infection (N-seropositive; n=47) had a median S-antibody level of 9091 U/mL (IQR 3143 to 16 135), with 2·5-fold lower median levels for ChAdOx1 (median 5179 [IQR 2432·5 to 9513·5]) than BNT162b2 (median 13 025 [9091 to ≥25 000]). N-seronegative individuals had seven-fold lower average S-antibody levels than N-seropositive individuals (median 1257 U/mL [616 to 3526]) and six-fold lower median levels were seen after ChAdOx1 (median 864 [IQR 481 to 1395]) compared to BNT162b2 (median 5311 [3133 to 8829]) within this infection-naive group.

We examined the distribution of S-antibody levels for confirmed N-seronegative samples 14–20 days, 21–41 days, 42–55 days, 56–69 days, and 70 days or more after second vaccination to infer the general trend in antibody levels with time, stratified by vaccine type, with p values derived from non-parametric tests for trend. We excluded two individuals with shorter dose intervals of 21–28 days (and assumed those missing first dose date had a longer dose interval) as this has been demonstrated (in part, through preliminary data) to be less immunogenic than longer intervals for both ChAdOx1 and BNT162b2,[6,7] giving a total of 552 individuals included in the analysis.

A significant trend of declining S-antibody levels was seen with time for both ChAdOx1 (p<0·001) and BNT162b2 (p<0·001; figure; appendix), with levels reducing by about five-fold for ChAdOx1, and by about two-fold for BNT162b2, between 21–41 days and 70 days or more after the second dose. This trend remained consistent when results were stratified by sex, age, and clinical vulnerability (appendix). For BNT162b2, S-antibody levels reduced from a median of 7506 U/mL (IQR 4925–11 950) at 21–41 days, to 3320 U/mL (1566–4433) at 70 or more days. For ChAdOx1, S-antibody levels reduced from a median of 1201 U/mL (IQR 609–1865) at 0–20 days to 190 U/mL (67–644) at 70 or more days.

Across both vaccine types, women had higher initial S-antibody levels than men at 21–42 days after complete

Published Online July 15, 2021 https://doi.org/10.1016/S0140-6736(21)01642-1

See Online for appendix

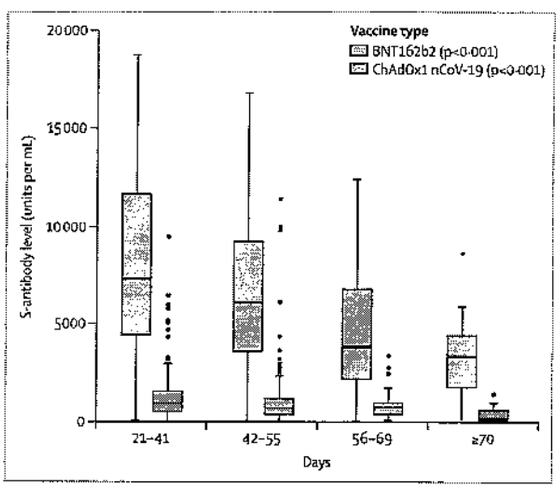

Figure: Levels of antibody against the spike glycoprotein of SARS-CoV-2 (S-antibody) at defined timepoints after second dose of vaccination (with extended dose intervals) in individuals with no previous infection, stratified by vaccine type
p values derived from non-parametric tests for trend for each vaccine subgroup are given in parenthesis in the key.

vaccination; also ending with higher levels at 70 days or more (appendix). Similarly, those aged 18–64 years had higher levels at 21–42 days compared to those aged 65 years and older, with correspondingly higher levels at 70 or more days (appendix).

For BNT162b2 vaccinees, some disparity was noted by clinical vulnerability status in peak antibody levels at 21–41 days, although this pattern was not observed with ChAdOx1 (appendix). At 70 days or more, the pattern of disparities was different, with higher antibody levels in vulnerable groups for BNT162b2 and the reverse for ChAdOx1. These data suggest substantial underlying heterogeneity within clinical vulnerability groupings and are also limited by small numbers in the clinically extremely vulnerable strata. However, the trend for declining S-antibody levels with time remains consistent, and the low levels in clinically vulnerable ChAdOx1 vaccinees at 70 days or more might be cause for concern.

Our data suggest waning of S-antibody levels in infection-naive individuals over a 3–10-week period after a second dose of either ChAdOx1 or BNT162b2. These data are consistent with the decline in Spike-antibody and neutralising antibody levels observed after infection, although memory B-cell populations appear to be maintained.[8,9] As such, the clinical implications of waning antibody levels post-vaccination are not yet clear, and it remains crucial to establish S-antibody thresholds associated with protection against clinical outcomes.

Although trends were consistent after stratification by key variables that are likely to affect the immune response, there might be residual confounding due to age and dosing interval as small numbers precluded more precise strata. These findings are also limited by the cross-sectional nature of the data. This analysis should be repeated with a larger number of participants to allow better adjustment for potential confounding, and with longitudinal follow-up of antibody dynamics in individuals over 6–12 months to establish plateau levels, or time to seroreversion.

Higher antibody levels are possibly associated with greater protection against variants that can partially evade immunity, which could explain the observed higher efficacy (partly preliminary) of BNT162b2 compared to ChAdOx1 against the Delta variant (B.1.617.2).[10,11] Disparity in peak antibody levels between vaccine types, and to a lesser extent between population groups, might therefore be important if antibody levels in some groups drop below (as yet undefined) thresholds of protection earlier than in others. There is, however, accumulating evidence suggesting the importance of T-cell-mediated immunity, particularly in individuals with weak or absent antibody responses,[12] so it is possible that T-cell responses compensate to some extent as antibody responses wane.

In the context of recent advice in support of booster vaccinations from the UK's Joint Committee on Vaccination and Immunisation,[13] and given the potentially rapid S-antibody decline suggested by these data, heterologous regimens, which preliminary data suggest elicit stronger antibody and T-cell responses,[14,15] might provide more durable immunity and greater protection against emerging variants. However, the ultimate effect of different dose intervals and various heterologous combinations on clinical outcomes remain important unanswered questions. Principally, the ethical basis for universal booster dose deployment in high-income settings should be carefully considered in the context of widening global vaccine inequities. Data on disparities in peak antibody levels and rates of decline might therefore inform targeted and equitable booster deployment.

ACH serves on the UK New and Emerging Respiratory Virus Threats Advisory Group.

All other authors declare no competing interests. The research costs for the study have been supported by the Medical Research Council Grant awarded to University College London. The study also received US$15 000 of Facebook advertising credit to support a pilot social media recruitment campaign on Aug 18, 2020. Virus Watch received funding via the UK Government Department of Health and Social Care's Vaccine Evaluation Programme to provide monthly Thriva antibody tests to adult participants. This work was supported by the Wellcome Trust through a Wellcome Clinical Research Career Development Fellowship to RWA. Author contributions and members of the Virus Watch Collaborative are listed in the appendix.

*Madhumita Shrotri, Annalan M D Navaratnam, Vincent Nguyen, Thomas Byrne, Cyril Geismar, Ellen Fragaszy, Sarah Beale, Wing Lam Erica Fong, Parth Patel, Jana Kovar, Andrew C Hayward, *Robert W Aldridge, on behalf of the Virus Watch Collaborative*

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Institute of Health Informatics, University College London, WC1E 6BT London, UK

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