Are Unvaccinated Children and Adults a Threat to National Security?

December 11, 2021

Presented by: **Karen Kingston**

MiFiGHT

Public Health Emergency

Public Health and Medical Emergency Support for a Nation Prepared

Determination that a Public Health Emergency Exists

As a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV), on this date and after consultation with public health officials as necessary, I, Alex M. Azar II, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby determine that a public health emergency exists and has existed since January 27, 2020, nationwide.

01/31/2020 — Date

/s/ — Alex M. Azar II

https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
October 29, 2021

Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19–Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity — Nine States, January–September 2021

TABLE 2. Adjusted odds ratios* of laboratory-confirmed COVID-19 among hospitalizations in adults with COVID-19–like illness comparing unvaccinated adults with a SARS-CoV-2 infection occurring 90–179 days before the index test date and adults who were fully vaccinated 90–179 days before the index test date without a previous documented SARS-CoV-2 infection — nine states, January–September 2021

Outcome	Total no.	No. (row %) of SARS-CoV-2 positive test results	Adjusted odds ratio (95% CI)
All adults (aged ≥18 years), any COVID-19 mRNA vaccine			
Any mRNA vaccine			
Fully vaccinated† without previous documented infection	6,328	324 (5.1) %	Ref
Unvaccinated with a previous SARS-CoV-2 infection	1,020	89 (8.7) %	5.49 (2.75–10.99)

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7044e1-H.pdf

TABLE 2. Adjusted odds ratios* of laboratory-confirmed COVID-19 among hospitalizations in adults with COVID-19–like illness comparing unvaccinated adults with a SARS-CoV-2 infection occurring 90–179 days before the index test date and adults who were fully vaccinated 90–179 days before the index test date without a previous documented SARS-CoV-2 infection — nine states, January–September 2021

By time relative to SARS-CoV-2 B.1.617.2 (Delta) variant predominance			
Before Delta predominance (January–June 2021)			
Fully vaccinated† without previous documented infection	1,115	18 (1.6)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	831	70 (8.4)	6.11 (2.83–13.16)
During Delta predominance (June–September 2021)**			
Fully vaccinated† without previous documented infection	5,213	306 (5.9)	Ref
Unvaccinated with a previous SARS-CoV-2 infection	189	19 (10.1)	7.55 (3.45–16.52)

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7044e1-H.pdf

Pfizer Phase 3 Primary Efficacy Outcome was *ONLY* 7 DAYS Post 2-Dose

(Data from Table 7) Efficacy of BNT162b2 Against CONFIRMED COVID-19 from 7 DAYS After Dose 2 in Participants with and without Evidence of Prior SARS-CoV-2 Infection, pg. 24

Table 7. Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants With and Without Evidence of Prior SARS-CoV-2 Infection, Evaluable Efficacy Population

Pre-specified Age Group	BNT162b2 N[a] = 19965 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a] =20172 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)	Met Predefined Success Criterion*
All participants	9 2.332 (18559)	169 2.345 (18708)	94.6 (89.9, 97.3)[e]	Yes
16 to 55 years	6 1.309 (10653)	120 1.317 (10738)	95.0 (88.7, 98.2)[f]	NA
>55 years	3 1.022 (7892)	49 1.028 (7956)	93.8 (80.9, 98.8)[f]	NA

*Success criterion: the posterior probability that true vaccine efficacy >30% conditioning on the available data is >99.5% at the final analysis

[a] N = number of participants in the specified group.

https://www.fda.gov/media/144416/download

Pfizer Phase 3 Primary Efficacy Outcome was *ONLY* 7 DAYS Post 2-Dose

U.S. Phase 2/3 Trials were conducted in the US, Brazil, Argentina, S. Africa, Germany and Turkey
US = 6,653 OUS = 36,998 % US = 6,653/43,651 = 15% of subjects were in the US

(Data from Table 7) Efficacy of BNT162b2 Against CONFIRMED COVID-19 from 7 DAYS After Dose 2 in Participants with and without Evidence of Prior SARS-CoV-2 Infection, pg. 24

Study Group	N-Value	Number Infected (RT-PCR+)	Infection Risk (IFR)	Reduction in Infection Risk	Vaccine Efficacy = Confidence Interval
Placebo	18,559	169	.910%		
PFE Vaccine	18,708	9	.048%	0.862%	95%
Total	37,307				

https://www.fda.gov/media/144416/download

CONCLUSION: The Pfizer BNT162b Reduces Risk of Infection by less than 1% for up to 7 DAYS Post 7-Days Second Dose Compared to Placebo.

BMJ INVESTIGATION

Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial

After Jackson left the company problems persisted at Ventavia, this employee said. In several cases Ventavia lacked enough employees to swab all trial participants who reported covid-like symptoms, to test for infection. Laboratory confirmed symptomatic covid-19 was the trial's primary endpoint, the employee noted. (An FDA review memorandum released in August this year states that across the full trial swabs were not taken from 477 people with suspected cases of symptomatic covid-19.)

"I don't think it was good clean data," the employee said of the data Ventavia generated for the Pfizer trial. "It's a crazy mess."

A second employee also described an environment at Ventavia unlike any she had experienced in her 20 years doing research. She told *The BMJ* that, shortly after Ventavia fired Jackson, Pfizer was notified of problems at Ventavia with the vaccine trial and that an audit took place.

https://www.bmj.com/content/bmj/375/bmj.n2635.full.pdf

Symptomatic but "NOT CONFIRMED" COVID-19 within 7 DAYS After Dose 1 or 2, pg. 41

Suspected COVID-19 Cases

Among 3,410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1,594 occurred in the vaccine group vs. 1816 in the placebo group. Suspected COVID-19 cases that occurred within 7 days after any vaccination were 409 in the vaccine group vs. 287 in the placebo group. It is possible that the imbalance in suspected COVID-19 cases occurring in the 7 days postvaccination represents vaccine reactogenicity with symptoms that overlap with those of COVID-19. Overall though, these data do not raise a concern that protocol-specified reporting of suspected, but unconfirmed COVID-19 cases could have masked clinically significant adverse events that would not have otherwise been detected.

https://www.fda.gov/media/144416/download

For another secondary endpoint, the case definition for a severe COVID-19 case was a confirmed COVID-19 case with at least one of the following:

- Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO2 ≤93% on room air at sea level, or PaO2/FiO2 <300 mm Hg);
- Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO);
- Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors)
- Significant acute renal, hepatic, or neurologic dysfunction;
- Admission to an ICU;
- Death.

14

https://www.fda.gov/media/144416/download

FDA/CBER Plans for Monitoring COVID-19 Vaccine Safety & Effectiveness

Presented by: Steve Anderson, PhD, MPP – Dir. Office of Biostats & Epidemiology, CBER
October 22, 2020 – Vaccines & Related Biological Products Advisory Committee (VRBPAC)Meeting

FDA Safety Surveillance of COVID-19 Vaccines :
DRAFT Working list of possible adverse event outcomes
Subject to change

Center for Biologics Evaluation and Research

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

https://www.fda.gov/media/143557/download?fbclid=IwAR1SooRjTDuhBPqM4TiD3O7vYgX4eAp3CCqB7SzCk04CMve_OzgtMNPfNkc

Center for Biologics Evaluation and Research

Vaccines and Related Biological Products Advisory Committee Meeting
June 10, 2021

Licensure and Emergency Use Authorization of Vaccines to Prevent COVID-19 for Use in Pediatric Populations

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2.1.1. Clinical endpoint efficacy trials

The incidence and severity of COVID-19 disease in pediatric populations, especially in younger age groups, are generally lower than in adults. Depending on epidemiologic trends, an adequately powered clinical endpoint efficacy trial with sufficient case accrual across pediatric age groups may be very difficult, if not infeasible, to conduct. Furthermore, in considering the balance of benefits and risks to support licensure or emergency use authorization of COVID-19 vaccines for use in pediatric populations, it could be argued that the lower burden of disease in pediatric populations might warrant more stringent success criteria than for adults, at least for placebo-controlled trials. A very high VE point estimate, with a narrow confidence interval, observed in studies in adults might also warrant more stringent success criteria in pediatric trials to ensure that the vaccine is as effective in pediatric populations as it is in adult populations. Conversely, an argument could be made that demonstration of very high VE in adults could allow for a less stringent success criterion for the VE confidence interval lower bound in pediatric trials (and thus a smaller number of primary endpoint cases needed), provided that the VE point estimate is similar to that observed in adults. The choice of primary endpoint may also inform appropriately stringent success criteria for placebo-controlled pediatric trials, as data demonstrating prevention of infection (rather than prevention of disease, or prevention of severe disease) may be less likely for children vs. adults.

https://www.fda.gov/media/149935/download

Solicited reactogenicity data in adolescents 16-17 years of age are not available for the reporting period. Reactogenicity data from a total of 100 adolescents 12 through 15 years of age enrolled in C4591001 Phase 2/3 were provided in the EUA submission. However, the Sponsor did not request inclusion of this age group in the EUA because the available data, including number of participants and follow-up duration, were

insufficient to support favorable a benefit-risk determination at this time. Therefore, the reactogenicity data for participants 12 through 15 years of age are not presented in this document.

https://www.fda.gov/media/144416/download

Pfizer/COMIRNATY Post-FDA Approval Studies

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

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

Final Report Submission: May 31, 2024

https://www.fda.gov/media/151710/download

"A major problem with protein-based therapeutics is their immunogenicity, that is, their tendency to trigger an unwanted immune response against themselves... Such antibodies can cause complications that can be life threatening."

https://www.fda.gov/vaccines-blood-biologics/biologics-research-projects/immunogenicity-protein-based-therapeutics

Harnessing the immune system's full potential to fight human disease

BIONTECH

This NEVER should have happened to Maddie!

Albert Bourla, Anthony Fauci, Francis Collins, Rochelle Walensky, & FDA EUA Panel Members CONSPIRED to COMMITT AGGRAVATED ASSAULT and MURDER of CHILDREN with a BIOWEAPON.

5 EUA AMENDMENT REQUEST FOR THE PFIZER-BIONTECH COVID-19 VACCINE FOR USE IN CHILDREN 5-11 YEARS OF AGE

Vaccine formulation

To provide a vaccine with an improved stability profile, the Pfizer-BioNTech COVID-19 Vaccine for use in children 5-11 years of age uses tromethamine (Tris) buffer instead of the phosphate-buffered saline (PBS) as used in the previous formulation and excludes sodium chloride and potassium chloride. The packaged vials for the new formulation are stored frozen at -90°C to -60°C. The frozen vials may be thawed and stored at refrigerator at 2°C to 8°C for up to 10 weeks.

https://www.fda.gov/media/153447/download

Vaccines and Related Biological Products Advisory Committee Meeting
September 17, 2021

FDA Briefing Document

Application for licensure of a booster dose for COMIRNATY (COVID-19 Vaccine, mRNA)

Although not independently verified by FDA, the post hoc analysis appears to indicate that the incidence of SARS-CoV-2 during the analysis period among 18,727 study participants originally randomized to BNT162b2 (mean of 9.8 months post-Dose 2 at the beginning of the analysis period) was 70.3 cases per 1,000 person-years, compared with an incidence of 51.6 cases per 1,000 person-years among 17,748 study participants originally randomized to placebo and crossed over to BNT162b2 (mean of 4.7 months post-Dose 2 at the beginning of the analysis period). An additional analysis appears to indicate that incidence of COVID-19 generally increased in each group of study participants with increasing time post-Dose 2 at the start of the analysis period. Only 3 severe COVID-19 cases were reported during the analysis period, all of which occurred among study participants originally randomized to BNT162b2. https://www.fda.gov/media/152176/download

Effectiveness of mRNA COVID-19 Vaccines Against the Delta Variant Among 5.6M Medicare Beneficiaries 65 Years and Older

Weekly update of September 28, 2021

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Project Salus

JAIC

https://www.humetrix.com/powerpoint-vaccine.html

Salus Platform for COVID-19 Analyses

Project Salus

VE Study Attributes

Cohort

20M Medicare beneficiaries nationwide with 16M individuals 65 years and older

Exposure

5.6M fully vaccinated with 2.7M Pfizer and 2.9M Moderna

Period of study

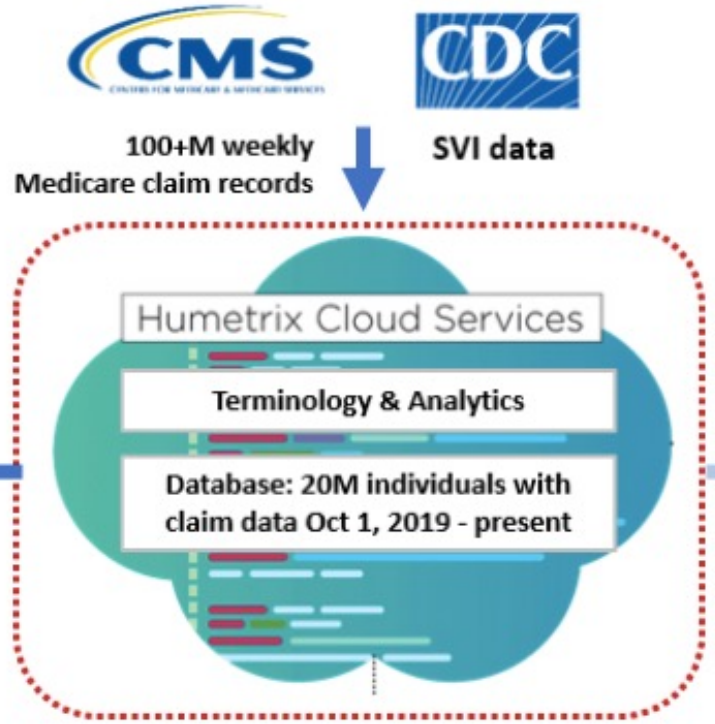
January - August 21 2021

Breakthrough Key Metrics

161K Breakthrough cases

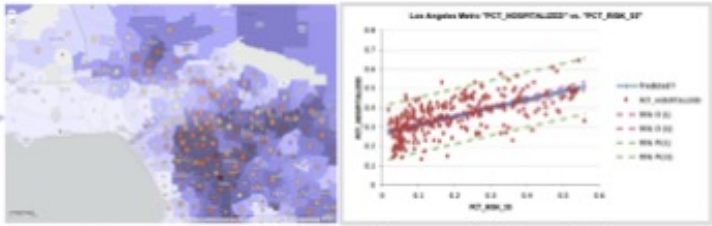
33K Breakthrough hospitalizations

10.4K requiring ICU admissions



Other Platform Applications

Nationwide Mapping of COVID-19 Outcomes
Hospitalizations, ICU, Ventilator Rx, Deaths



Disease Risk Models with Population Risk Profiling: Severe COVID-19 risk with Validation with Hospitalization Rates

Vaccination Mapping overlaid on severe COVID-19 risk

humetrix

** Medicare data and Humetrix software are hosted in a secure government enclave of the Department of Defense*

Executive Summary

Project Salus

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Basic questions which require data-driven answers

- Is vaccine effectiveness (VE) **waning** over time?
- Is VE **reduced** for the **Delta variant**?
- Does the need vary by **sub-population**?

Project Salus provides answers to these questions

- **VE of both mRNA vaccines appears to wane over time in this large 5.6M US-based 65 & over vaccinated cohort**
- **Risk of breakthrough hospitalization increases with time elapsed since mRNA vaccination with odds ratio increasing to 2.5 at 6 months post vaccination**
- **VE against Delta breakthrough hospitalization (62%) exceeds VE against Delta infection (41%)**
- **Prior COVID-19 infection has a major protective effect against breakthrough hospitalization**
- **Older age groups** (75-84 & 85 and older) **experienced further reduction in vaccine protection against hospitalization**
- **Hospitalization rate (21% vs 32%) and death rate (4% vs 12%) of breakthrough infections lower than rates observed in Covid-19 cases in pre-vaccination pandemic phase in 2020**

Graphic adapted from CDC Presentation ACIP Meeting August 30, 2021
Oliver, S. Framework for Booster Doses of COVID-19 Vaccines

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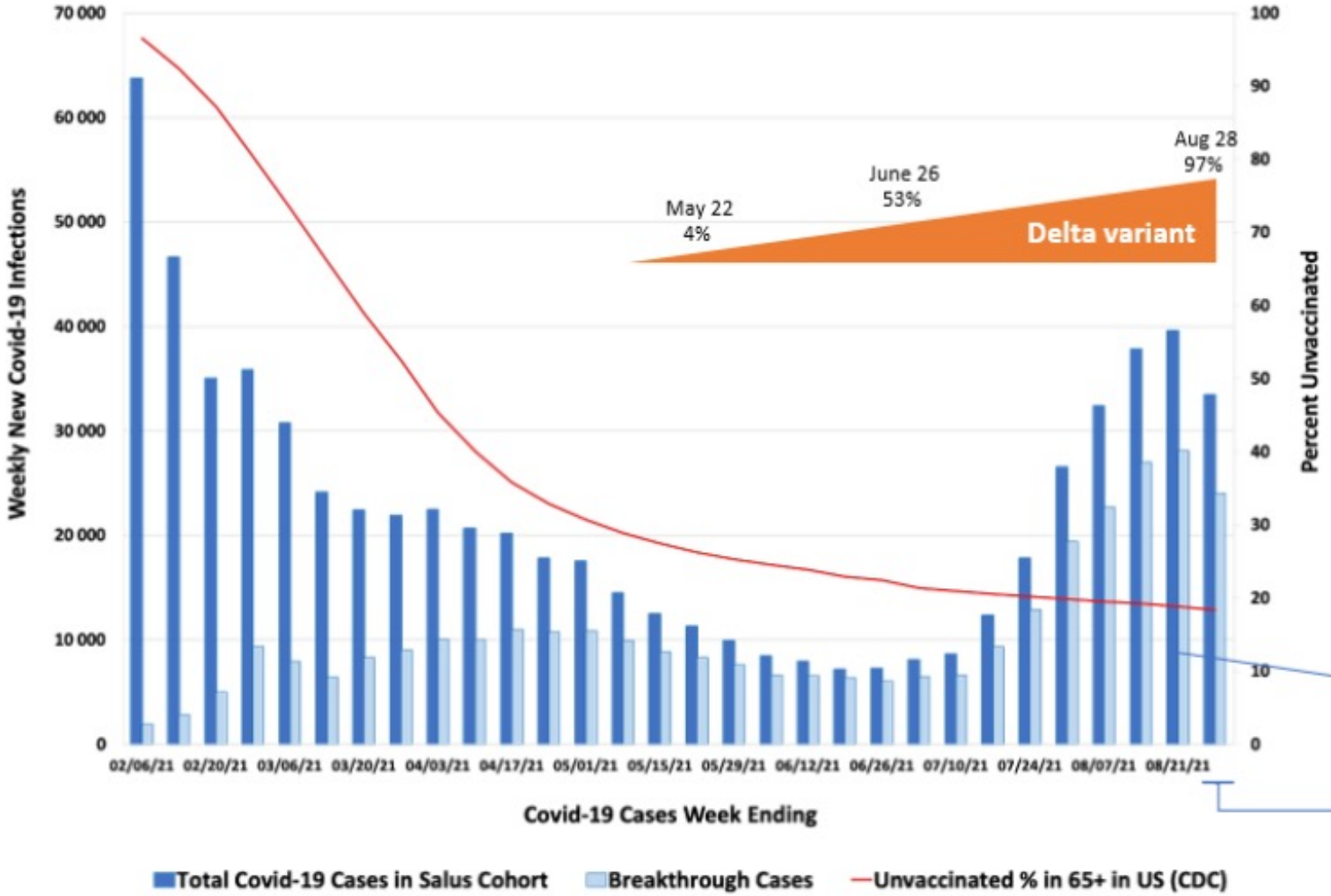
Project Salus

Total & Breakthrough Cases in the 65 Years and Older Salus Cohort



- **As Delta variant became predominant, COVID-19 cases increased five-fold** in the >=65 population
- In this 80% vaccinated >=65 population, an estimated **71% of COVID-19 cases occurred in fully vaccinated individuals**

Breakthrough cases = 71% of total Covid-19 cases in cohort

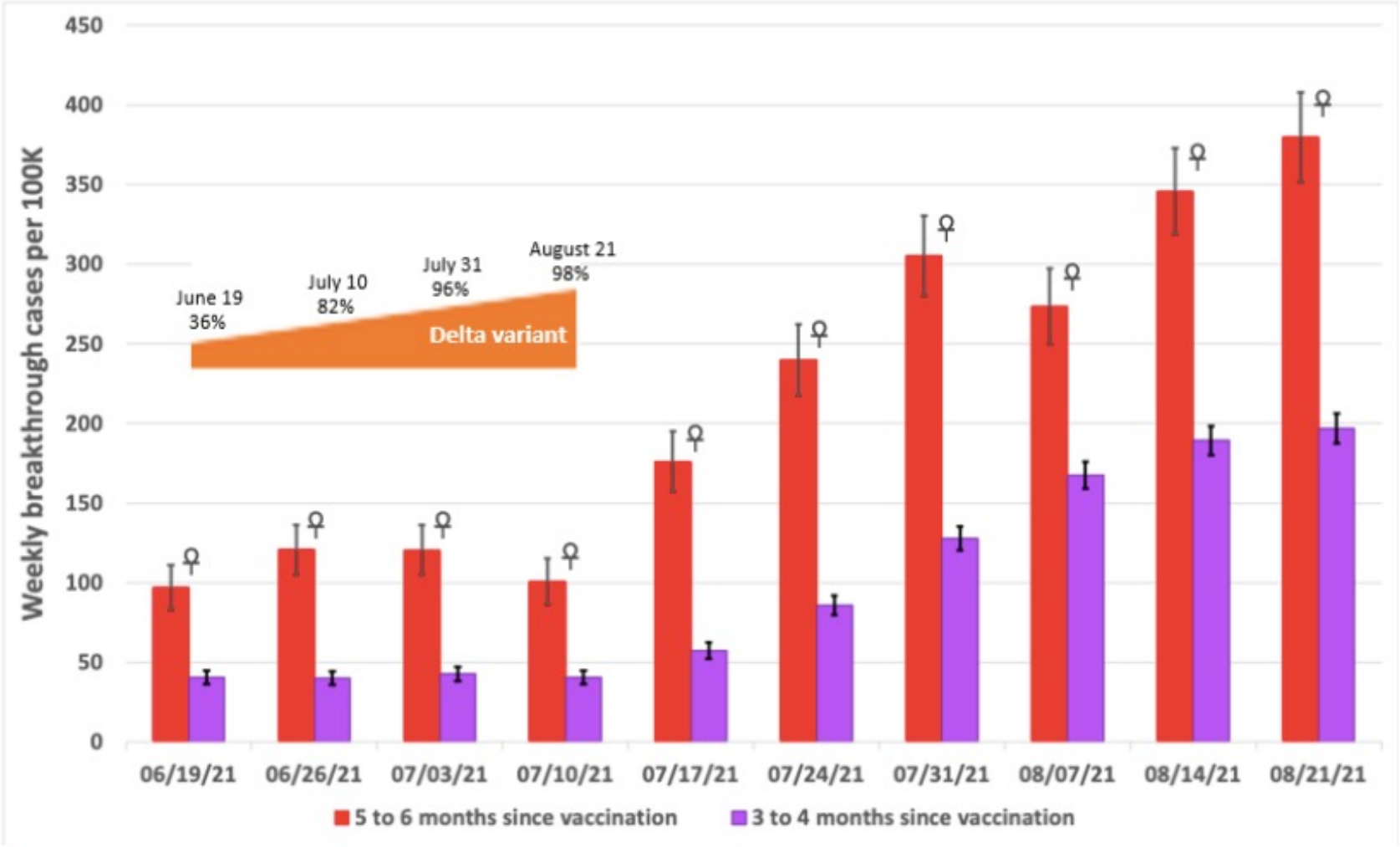
Week ending 08/28/21, data incomplete due to lag in claims processing

humetrix

*CDC data: % of SARS-CoV-2 genomes sequenced

Project Salus

Is mRNA Vaccine Effectiveness Against Delta Breakthrough Infection Waning Over Time in 65 Years and Older Salus Cohort?



- **Breakthrough infection rates 5-6 months post vaccination are twice as high as 3-4 months post vaccination**

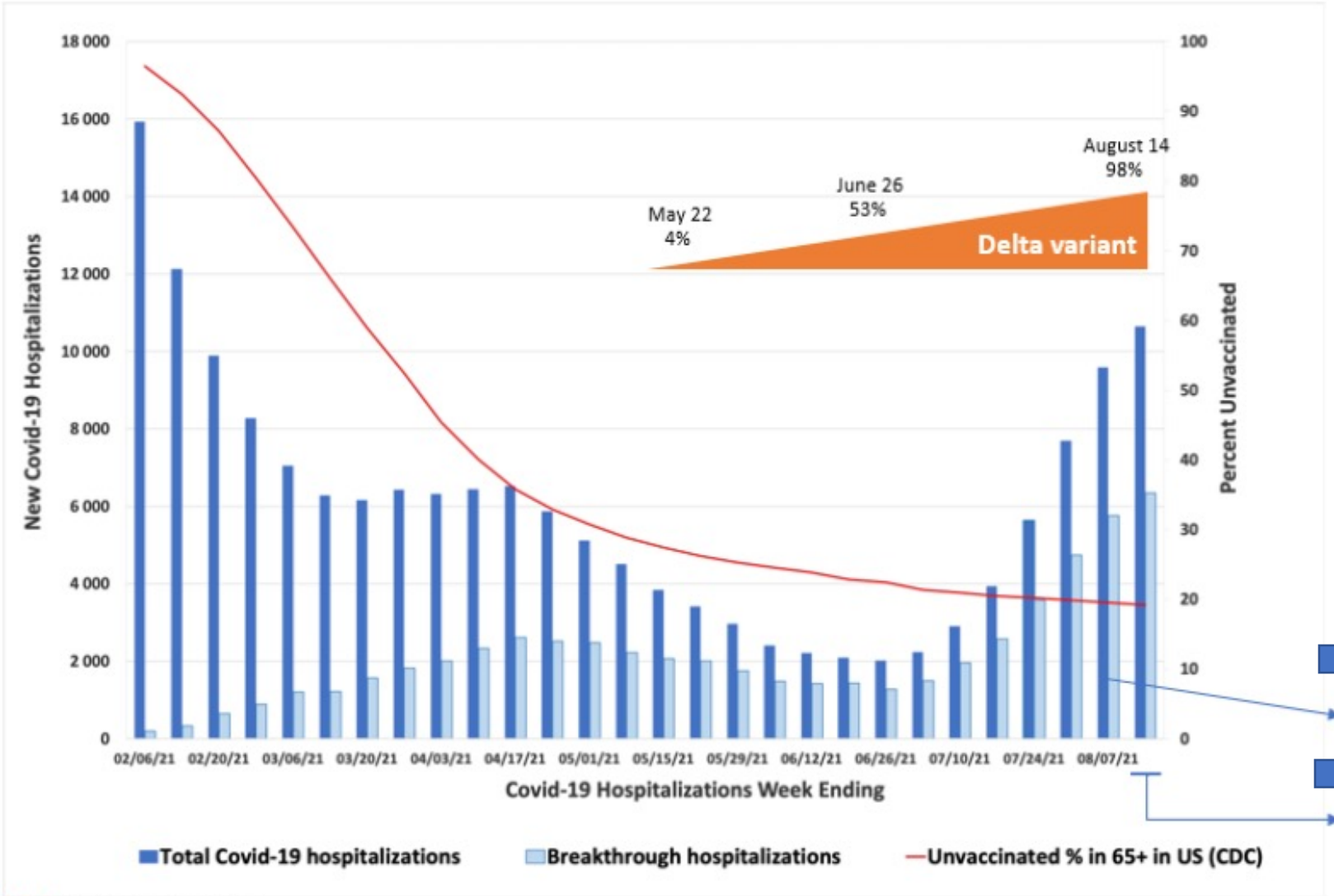
95% CI

♀ Breakthrough infection rates 5-6 months since vaccination > 3-4 months since vaccination
P < 0.001

humetrix

Project Salus

Total & Breakthrough Hospitalizations in the 65 Years and Older Cohort



- **As Delta variant surged to over 50% in June, COVID-19 hospitalizations more than doubled, reversing the prior trend of decreasing hospitalizations since April**
- In this 80% vaccinated 65+ population, an estimated **60% of COVID-19 hospitalizations occurred in fully vaccinated individuals in the week ending August 7th**

60% of COVID-19 hospitalizations are in vaccinated individuals

On 08/14/21, data incomplete due to lag in claims processing

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WSJ | OPINION

OPINION | COMMENTARY

The Science Suggests a Wuhan Lab Leak

By Steven Quay and Richard Muller

June 6, 2021 11:59 am ET

The Covid-19 pathogen has a genetic footprint that has never been observed in a natural coronavirus.

Although the **double CGG is suppressed naturally, the opposite is true in laboratory** work. The **insertion sequence of choice is the double CGG**. That's because it is readily available and convenient, and scientists have a great deal of experience inserting it. An additional advantage of **the double CGG sequence** compared with the other 35 possible choices: It **creates a useful beacon that permits the scientists to track the inse**rtion in the laboratory. **Now the damning fact**. **It was this exact sequence that appears in CoV-2**. Proponents of zoonotic origin must explain why the novel coronavirus, when it mutated or recombined, happened to pick its least favorite combination, the double CGG. Why did it replicate the choice the lab's gain-of-function researchers would have made?

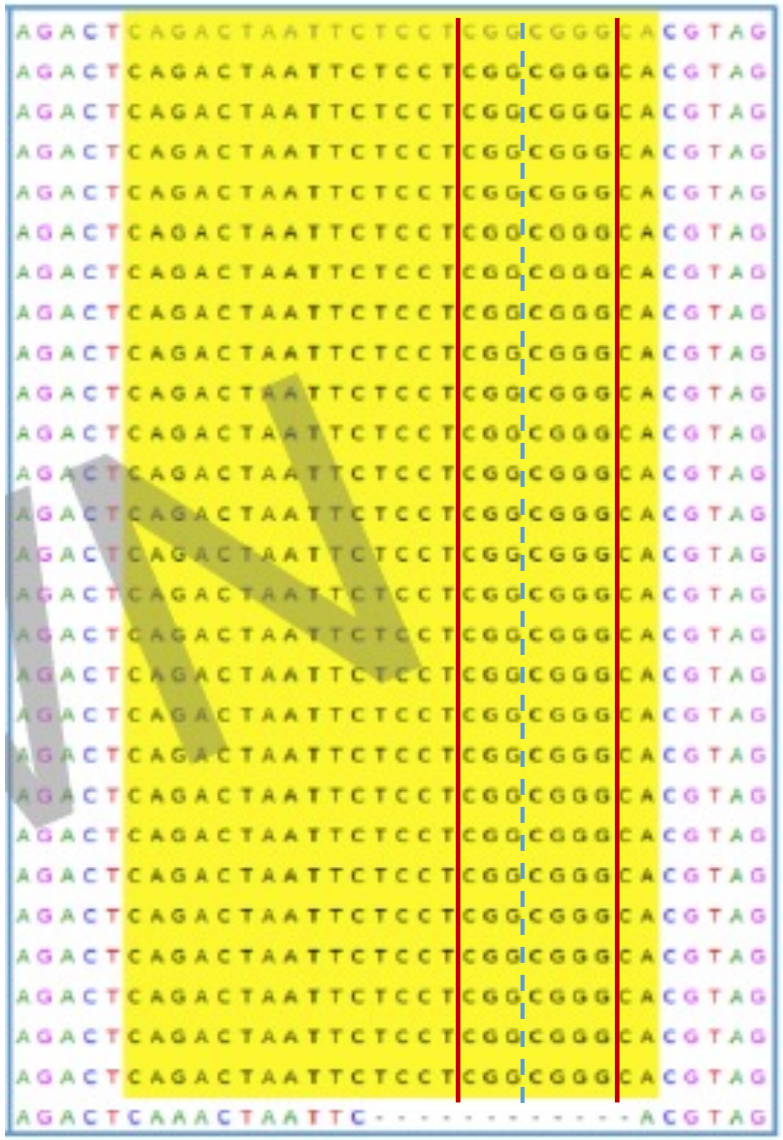
When the lab's Shi Zhengli and colleagues published a paper in February 2020 with the virus's partial genome, they omitted any mention of the special sequence that supercharges the virus or the rare double CGG section. Yet the fingerprint is easily identified in the data that accompanied the paper.

https://www.wsj.com/articles/the-science-suggests-a-wuhan-lab-leak-11622995184

Uncanny similarity of unique inserts in the 2019-nCoV spike protein to HIV-1 gp120 and Gag

Prashant Pradhan[$1,2], Ashutosh Kumar Pandey[$1], Akhilesh Mishra[$1], Parul Gupta[1], Praveen

Insert 4



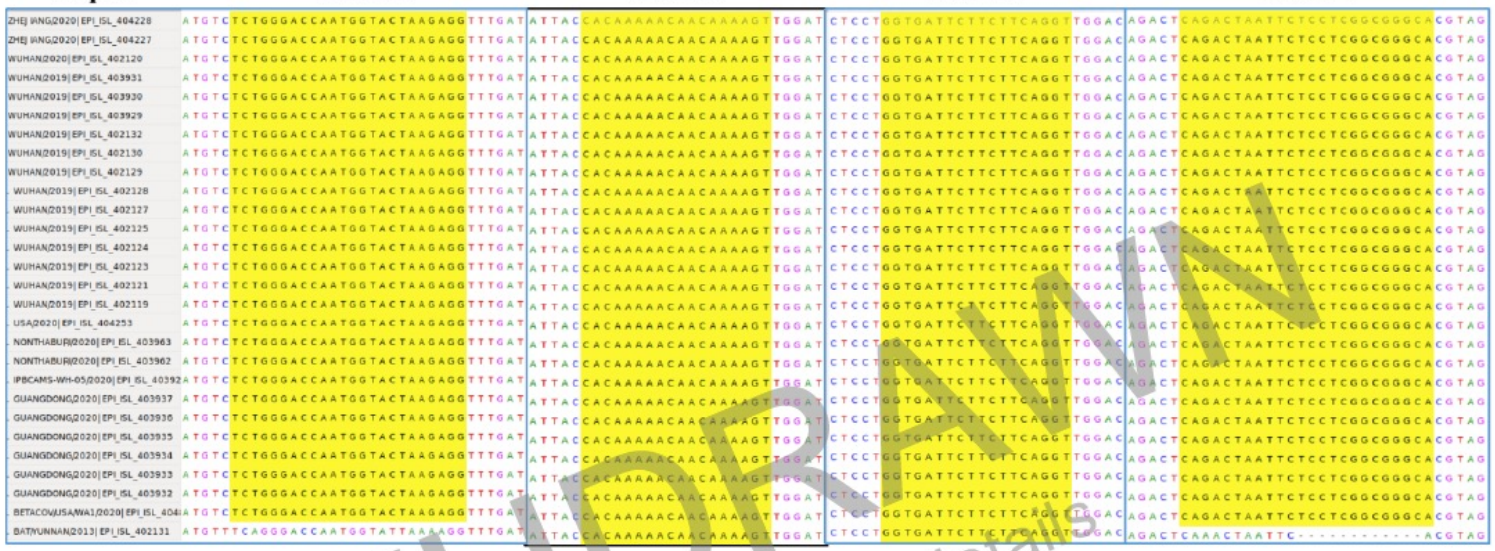


Fig.S2: All four inserts are present in the aligned 28 Wuhan 2019-nCoV virus genomes obtained from GISAID. The gap in the Bat-SARS Like CoV in the last row shows that insert 1 and 4 is very unique to Wuhan 2019-nCoV.

https://www.biorxiv.org/content/10.1101/2020.01.30.927871v1.full.pdf

3. Chemistry, Manufacturing and Controls (CMC)

a. Product Quality

COMIRNATY Manufacturing Overview

The mRNA in COMIRNATY is a single-stranded, 5'-capped mRNA encoding the full-length SARS-CoV-2 spike glycoprotein derived from the Wuhan-Hu-1 isolate (GenBank MN908947.3 and GenBank QHD43416.1). The antigen-coding RNA sequence is codon-optimized and contains two proline mutations ((b) (4)), which ensures an antigenically optimal trimerized pre-fusion confirmation (S-2P). The RNA also contains common structural elements, including 5'-cap, 5'-UTR, 3'-UTR, and poly(A) tail, all of which are designed for mediating high RNA stability and translation efficiency. During RNA transcription, (b) (4) is replaced with the (b) (4) . This nucleoside substitution has been demonstrated to enhance translation of *in vitro* transcribed mRNA while reducing its reactogenicity.

https://www.fda.gov/media/151733/download

JOURNAL OF VIROLOGY, Oct. 2004, p. 10628–10635 Vol. 78, No. 19
0022-538X/04/$08.00+0 DOI: 10.1128/JVI.78.19.10628–10635.2004

Retroviruses Pseudotyped with the Severe Acute Respiratory Syndrome Coronavirus Spike Protein Efficiently Infect Cells Expressing Angiotensin-Converting Enzyme 2

Michael J. Moore,[1] Tatyana Dorfman,[1] Wenhui Li,[1] Swee Kee Wong,[1] Yanhan Li,[2] Jens H. Kuhn,[1,3] James Coderre,[4] Natalya Vasilieva,[5] Zhongchao Han,[2] Thomas C. Greenough,[4] Michael Farzan,[1]* and Hyeryun Choe[5]*

Partners AIDS Research Center, Brigham and Women's Hospital, and Department of Medicine (Microbiology and Molecular Genetics),[1] and Perlmutter Laboratory, Children's Hospital, and Department of Pediatrics,[5] Harvard Medical School, Boston, and Program in Molecular Medicine, University of Massachusetts Medical School, Worcester,[4] Massachusetts; State Key Laboratory of Experimental Hematology, Institute of Hematology and Hospital of Blood Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College, Tianjin, China[2]; and Department of Biology, Chemistry, Pharmacy, Freie Universität Berlin, Berlin, Germany[3]

Infection of receptor-bearing cells by coronaviruses is mediated by their spike (S) proteins. The coronavirus (SARS-CoV) that causes severe acute respiratory syndrome **(SARS) infects cells expressing the receptor angiotensin-converting enzyme 2 (ACE2)**. Here we show that **codon optimization of the SARS-CoV S-protein gene substantially enhanced S-protein expression**. We also found that two retroviruses, **simian immunodeficiency virus (SIV) and murine leukemia virus, both expressing green fluorescent protein and pseudotyped with SARS-CoV S protein or S-protein variants, efficiently infected HEK293T cells stably expressing ACE2. Infection mediated by an S-protein variant whose cytoplasmic domain had been truncated and altered to include a fragment of the cytoplasmic tail of the human immunodeficiency virus type 1 envelope glycoprotein was, in both cases, substantially more efficient than that mediated by wild-type S protein. Using S-protein-pseudotyped SIV, we found that the enzymatic activity of ACE2 made no contribution to S-protein-mediated infection.** Finally, we show that a soluble and catalytically inactive form of ACE2 potently blocked infection by S-protein-pseudotyped retrovirus and by SARS-CoV. These results permit studies of SARS-CoV entry inhibitors without the use of live virus and suggest a candidate therapy for SARS.

T	Act	Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC
Interaction of HIV envelope with cell surface receptors										
1	ZIA	AI000883-20			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2020	NIAID	NIAID	$1,001,661
Role of HIV Envelope Proteins in Viral Replication and HIV Pathogenesis										
1	ZIA	AI000887-20			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2020	NIAID	NIAID	$1,001,661
Interaction of HIV envelope with cell surface receptors										
1	ZIA	AI000883-19			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2019	NIAID	NIAID	$1,069,830
Role of HIV Envelope Proteins in Viral Replication and HIV Pathogenesis										
1	ZIA	AI000887-19			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2019	NIAID	NIAID	$1,069,830
Interaction of HIV envelope with cell surface receptors										
1	ZIA	AI000883-18			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2018	NIAID	NIAID	$984,045
Role of HIV Envelope Proteins in Viral Replication and HIV Pathogenesis										
1	ZIA	AI000887-18			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2018	NIAID	NIAID	$984,045
Interaction of HIV envelope with cell surface receptors										
1	ZIA	AI000883-17			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2017	NIAID	NIAID	$1,117,501
Role of HIV Envelope Proteins in Viral Replication and HIV Pathogenesis										
1	ZIA	AI000887-17			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2017	NIAID	NIAID	$921,475
Interaction of HIV envelope with cell surface receptors										
1	ZIA	AI000883-16			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2016	NIAID	NIAID	$744,742
Role of HIV Envelope Proteins in Viral Replication and HIV Pathogenesis										
1	ZIA	AI000887-16			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2016	NIAID	NIAID	$744,742
Interaction of HIV envelope with cell surface receptors										
1	ZIA	AI000883-15			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2015	NIAID	NIAID	$853,062
Role of HIV Envelope Proteins in Viral Replication and HIV Pathogenesis										
1	ZIA	AI000887-15			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2015	NIAID	NIAID	$853,062
Role of Viral Reservoirs in the Pathogenesis of HIV Disease										
1	ZIA	AI000851-15			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2015	NIAID	NIAID	$1,384,173
Therapeutic Strategies for the Management of HCV/HIV co- infection										
1	ZIA	AI000390-31			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2014	NIAID	NIAID	$689,091
Interaction of HIV envelope with cell surface receptors										
1	ZIA	AI000883-14			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2014	NIAID	NIAID	$612,656
Role of HIV Envelope Proteins in Viral Replication and HIV Pathogenesis										
1	ZIA	AI000887-14			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2014	NIAID	NIAID	$501,264
Role of Viral Reservoirs in the Pathogenesis of HIV Disease										
1	ZIA	AI000851-14			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2014	NIAID	NIAID	$966,899
Role of B Lymphocytes In HIV Infection And Pathogenesis										
1	ZIA	AI000825-17			FAUCI, ANTHONY S.	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	2014	NIAID	NIAID	$772,682

miFiGHT

2014 -2020

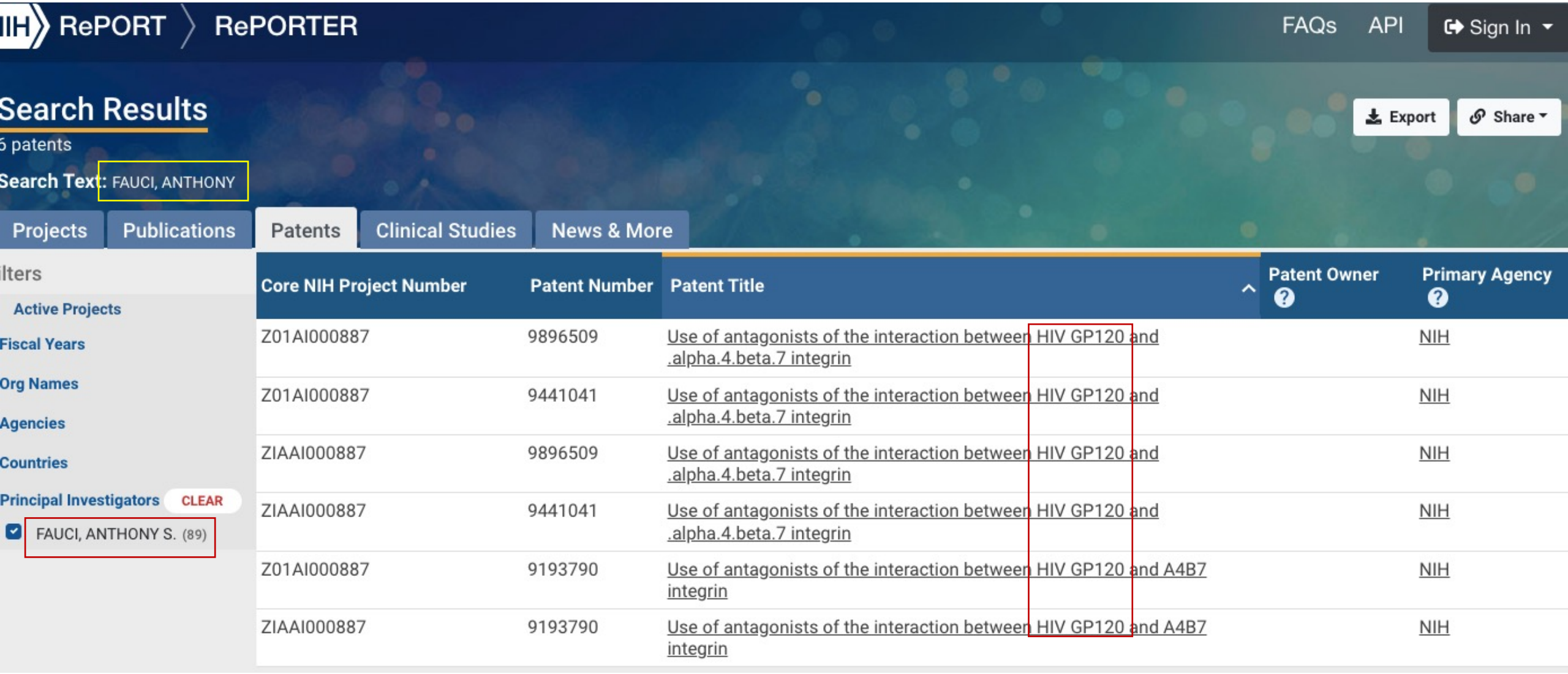
NIAID GRANTS

HIV ENVELOPE (GP120)

ANTHONY FAUCI

$	1,001,661
$	1,069,830
$	984,045
$	1,175,501
$	921,475
$	744,742
$	853,062
$	1,384,173
$	689,091
$	612,656
$	501,264
$	966,899
$	772,682
$	11,677,081

https://reporter.nih.gov/search/3_Ch3YpiTEum9wv2qeurbA/projects?PI=2403678



https://reporter.nih.gov/search/3_Ch3YpiTEum9wv2qeurbA/patents?PI=2403678&sort_field=patent_title&sort_order=asc

NIH SPONSORED AND HAS OWNER$HIP OF VACCINE NANOTECHNOLOGY FOR A BIOWEAPON

(12) **United States Patent**
von Andrian et al.

(10) **Patent No.: US 9,539,210 B2**
(45) **Date of Patent: Jan. 10, 2017**

(54) **VACCINE NANOTECHNOLOGY**

(58) **Field of Classification Search**

STATEMENT OF GOVERNMENT SUPPORT

This invention was made with government support under Grant Nos. CA119349, AI069259, AI072252, EB003647, HL056949 and AI061663 awarded by the National Institutes of Health. The government has certain rights in the invention.

https://patentimages.storage.googleapis.com/29/d1/ca/18013ced0621f0/US9539210.pdf

Y is polyalkylene glycol or polyalkylene oxide. In some embodiments, X is PLGA, PLA or PGA. In some embodiments, Z is absent.

In some aspects, a composition comprising a nanocarrier comprising an immunostimulatory agent is provided. In some embodiments, the composition further comprises an antigen and/or a targeting moiety. In some embodiments, at least one of the antigen, targeting moiety, and immunostimulatory agent is conjugated to a water soluble, non-adhesive polymer. In some embodiments, at least one of the antigen, targeting moiety, and immunostimulatory agent is conjugated to a biodegradable polymer. In some embodiments, at least one of the antigen, targeting moiety, and immunostimulatory agent is conjugated to a biocompatible polymer. In some embodiments, the biocompatible polymer is a conjugate of a water soluble, non-adhesive polymer conjugated to a biodegradable polymer. In some embodiments, the antigen is a B cell antigen. In some embodiments, the B cell antigen is not a T cell antigen. In some embodiments, the nanocarrier further comprises a T cell antigen. In some embodiments, the antigen is a T cell antigen.

In some aspects, a composition comprising a nanocarrier comprising a small molecule, an immunostimulatory agent, and a T cell antigen is provided.

In some embodiments, the small molecule is a toxin. In some embodiments, the toxin is from a chemical weapon, an agent of biowarfare, or a hazardous environmental agent.

November 10, 2021
11:07 PM PST
Last Updated 6 days ago

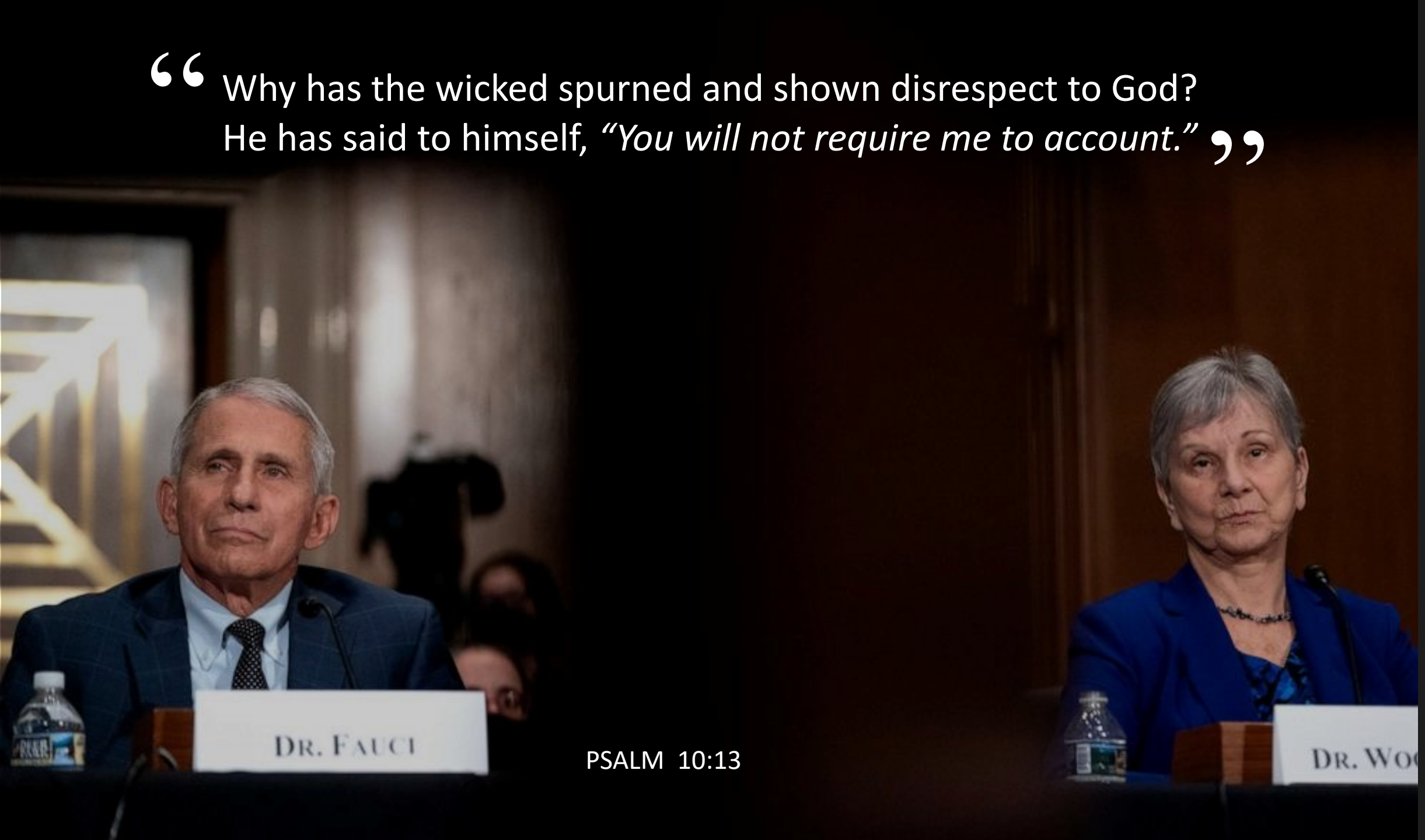
Healthcare & Pharmaceuticals

Moderna COVID-19 vaccine patent dispute headed to court, U.S. NIH head says

3 minute read

By Julie Steenhuysen

CHICAGO, Nov 10 (Reuters) - U.S. National Institutes of Health scientists played "a major role" in developing Moderna Inc's (MRNA.O) COVID-19 vaccine and the agency intends to defend its claim as co-owner of patents on the shot, NIH


“ Why has the wicked spurned and shown disrespect to God?
He has said to himself, *“You will not require me to account.”* ”
DR. FAUCI
PSALM 10:13

Public Health Emergency

Public Health and Medical Emergency Support for a Nation Prepared

Renewal of Determination That A Public Health Emergency Exists

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Xavier Becerra, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective October 18, 2021, the January 31, 2020, determination by former Secretary Alex M. Azar II, that he previously renewed on April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, and that I renewed on April 15, 2021 and July 19, 2021, that a public health emergency exists and has existed since January 27, 2020, nationwide.

October 15, 2021

Date

/s/

Xavier Becerra

https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx