### President Eisenhower's Warning of Misplaced Power



"In the councils of Government we must guard against the acquisition of unwarranted influence ... by the Military / Industrial Complex. The potential for the disastrous rise of misplaced power exists and will persist."

"We must never let the weight of this combination endanger our Liberties or Democratic processes. We should take NOTHING for granted."

"We must be alert to the equal and opposite danger that public policy could, itself, become the captive of a Scientific / Technological Elite."

https://www.youtube.com/watch?v=OyBNmecVtdU





## EVENT 2021: What If The People You Trust Are The People Causing The Problem?

### Richard M Fleming, PhD, MD, JD www.Fleming-Method.com

Potential Conflict of Interest (COI): FMTVDM, The Inflammation and Heart Disease Theory Full Disclosure: <u>seehttps://www.flemingmethod.com/thecase</u> <u>https://www.youtube.com/watch?v=-5Va31X6Rq8</u> <u>https://www.youtube.com/watch?v=GhwgMbIS-e4</u>

## The Impact

## The Worldwide Pandemic has resulted in

devastating loss of life due to failure to treat,

separation of family members from loved ones (hospitalized, nursing homes, family gatherings, etc.)

significant loss of personal liberty with lockdowns, restrictions of personal behaviors, unemployment, economic devastation, fear,

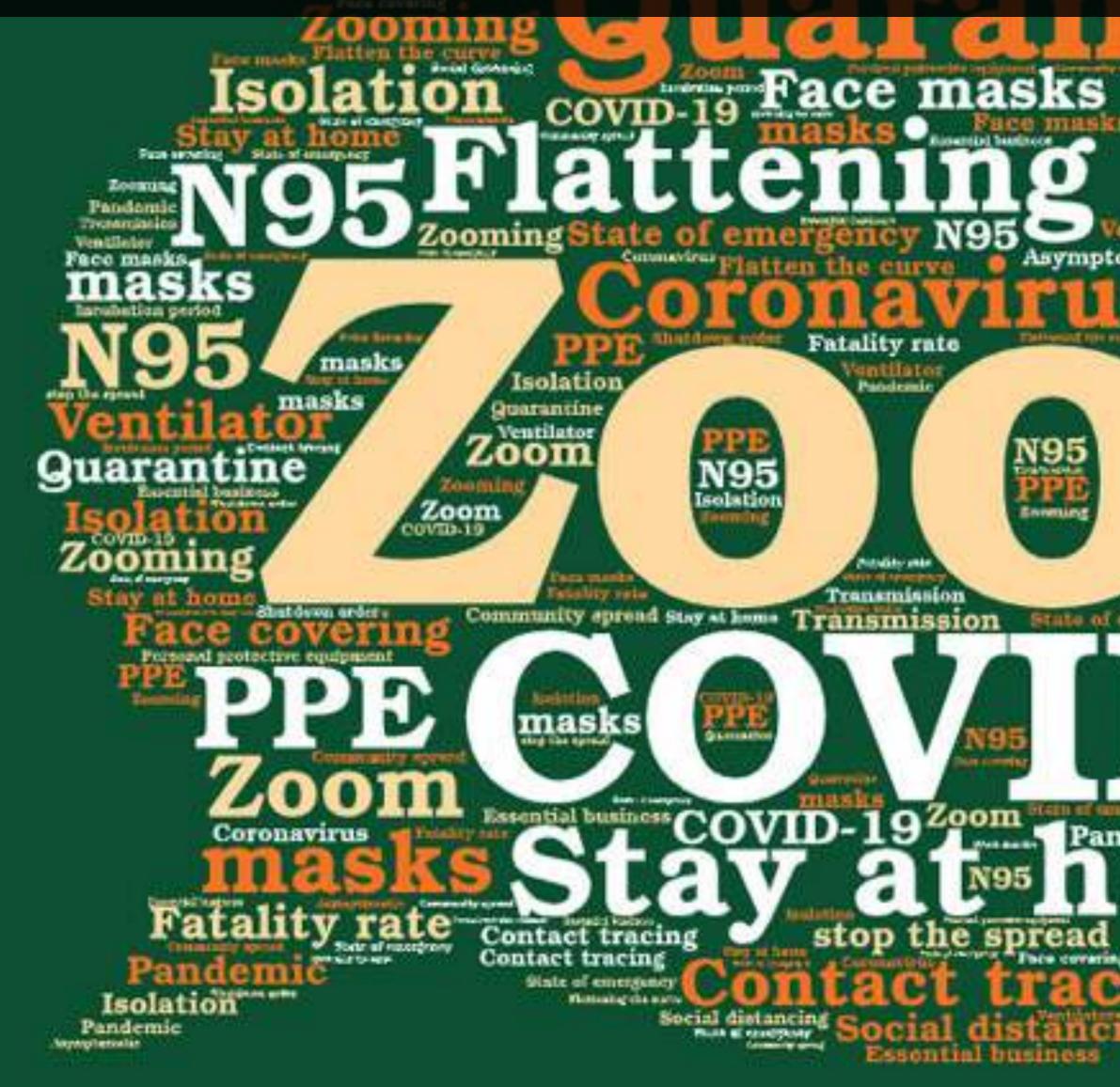
the circumvention of the protective mechanisms designed to protect the American people, and

the initiation of the largest experimental study in the history of mankind.



3

Pandemic popularizes a plethora of words,



demic state Bertial dontronge State of emergency

subgrant pay best the appropriate

N95

Essential

Quarantine TOR WARDEN Asymptomatic Isolation

**Fatality** rate

COVED-19

busin

covm-19- Pandemic lattening the curve Tranumission Notest Lancof Asymptomatic Face masks e covering **OTOMAVITUS** PPE N95 Coronavirus And spinstered Zeom Face masks Enneue masks

Pandemic Isolation Community spread Zoom Shutdown order STALL OF BOLD Zoom Quarantine

State of emergency the state

Shiptdown order

Twend detrong

Then covering





intime period

CAMPBING NOC CAN'T

**I** NEWS**@TheU** 

By Amanda M. Perez -

https://news.miami.edu/stories/2020/09/pandemicpopularizes-a-plethora-of-words,-phrases.html







## Format For This Presentation.

(1) Please turn your cell phones off or place on airplane mode. (2) You do not need to take notes. Please take this opportunity to absorb everything being said. The slides will be available for free on <u>www.Fleming-Method.com</u>. (3) Many of Your Questions will be Covered. (4) Please write down other Questions on the Notecards, to be Answered at the End. (5) Due to Time Limitations Please Do NOT Ask About Specific Cases. There simply is not enough time to do this.

### Questions You Probably Have That We Are Going to Answer.

- (1) What you can do if you get infected with SARS-CoV-2?
- (2) What you can do if you get sick and go to the hospital with COVID?(3) How can you stop forced vaccination of yourself & your children or
- (3) How can you stop forced vaca people close to you?
- (4) What can you do if you've been exposed to someone who has been vaccinated and now you think you have been exposed?
- (5) What can you do if you've been vaccinated?



## TRUTH - Ridiculed, Violently Opposed, Self-Evident.

# All truth passes through three stages. First, it is ridiculed. Second, it is violently opposed. Third, it is accepted as being self-evident. Arthur Schopenhauer





### Galileo Galilei

# All truths are easy to understand once they are discovered; the point is to discover them. Galileo Galilei



## **Replacing Fear with Knowledge.**

### This Presentation is meant to

### inform, educate, & empower you.

### But it is also a call for action on your part.

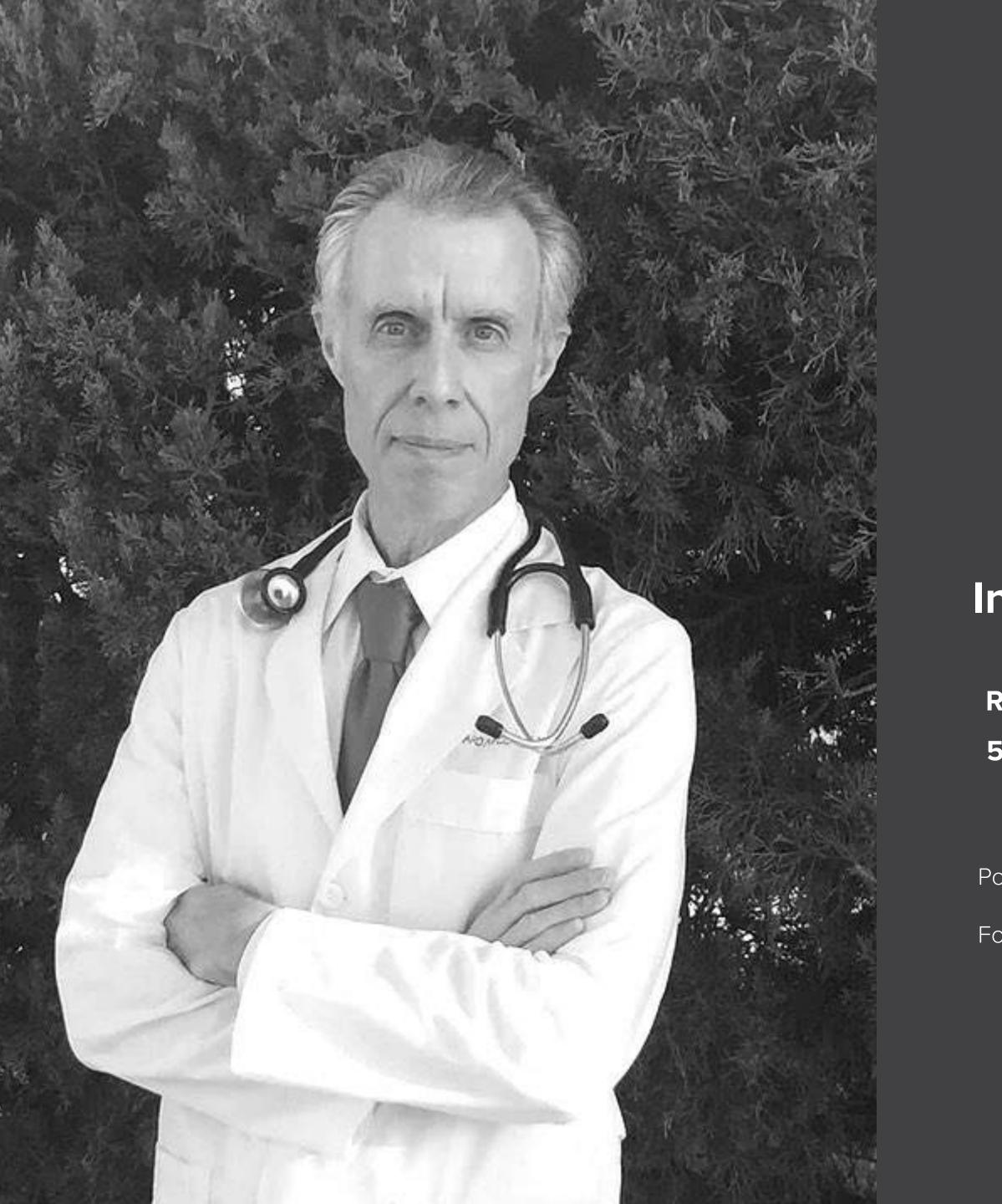
## The Heuristic Method

Question Everything You Hear. Don't take anyon'es word for anything without actual proof; real evidence.

Don't let anyone hide the facts & evidence from you.

It is **your duty** & **responsibility** to yourself, your family, and the world to become informed, educated, and to ACT upon what you learn here today.





# **EVENT 2021**

### Inform, Educate, Empower & HOPE

Richard M. Fleming, PhD, MD, JD 5 June 2021

Potential Conflicts of Interest (COI): FMTVDM, Inflammation and Cardiovascular Disease Theory

For More Information Please go to: <u>www.FlemingMethod.com</u>

## Section 01

## 01 Inform

The SARS-CoV-2 virus & known facts

The Covid-19 disease & published treatments

## 02 Educate

Infectious Diseases

Vaccines efficacy and safety

The Scientific Method

The Difference Between VE, COVID-19 & Death

EUA vs Process vs Risks

## **03 Empower**

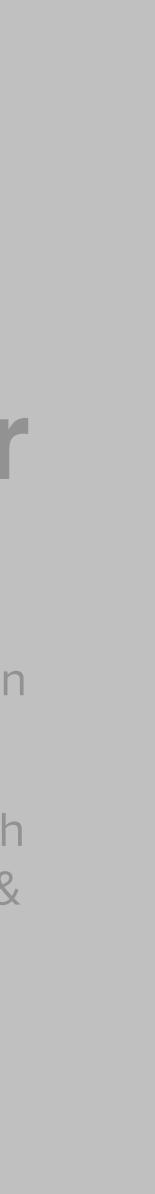
EUA vs Process vs Risks

Stopping the Gain-of-Function Research

Government Interference with Physician-Patient Treatment & **Forced Vaccination** 

Be Heard

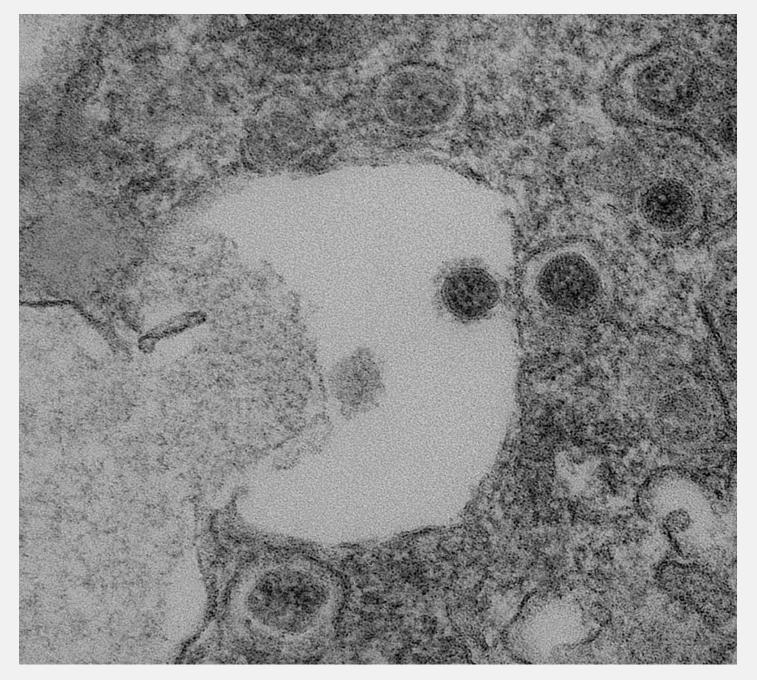
Petition

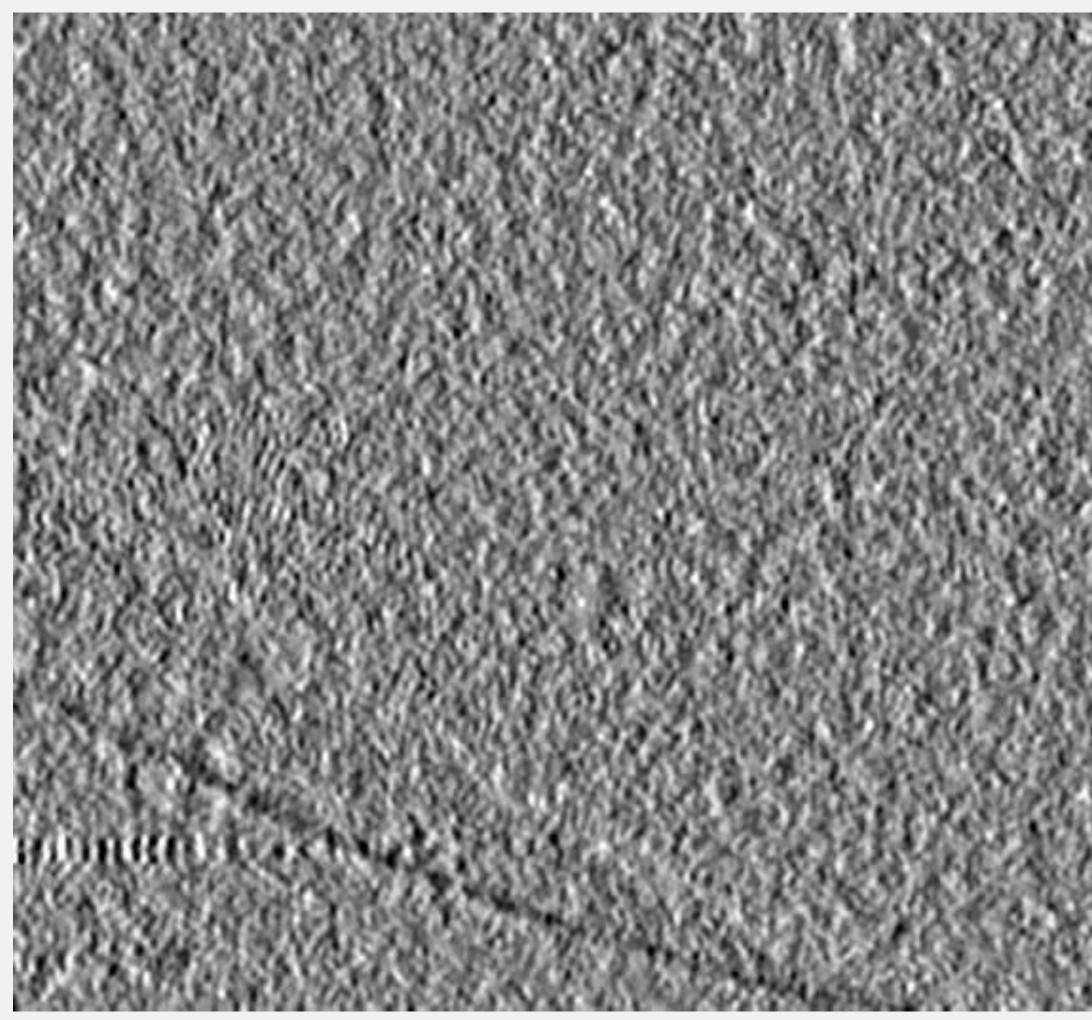


## SARS-CoV-2 versus COVID-19

### The Virus Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) with it's Spike Protein.

The 7th Coronaviridae known to infect people. 80-160 nanometers (10<sup>-9</sup> meters)





Severe acute respiratory syndrome coronavirus 2 isolate Wuhan-Hu-1, complete genome. https://www.ncbi.nlm.nih.gov/nuccore/1798174254



## Where did Sars-CoV-2 Originate?

### **TO ANSWER THAT QUESTION CAN BE FOUND IN THE GAIN-OF-FUNCTION SPIKE PROTEIN.**

Three unique regions not found in other Corona Viruses.

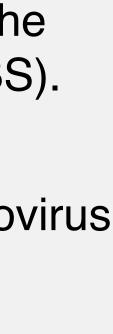
An HIV Pseudovirus glycoprotein 120. 2. A Proline-Arginine-Arginine-Alanine Insert. A Prion-like Domain at the Receptor Binding Site (RBS).

**N-Terminal** Domain

**3.** A Prion-like Domain at the Receptor Binding Site (RBS).

> **1.** An HIV Pseudovirus glycoprotein 120.

**2.** A Proline-Arginine-Arginine-Alanine Insert.





0

## Why understanding Gain of Function is Important

### GOF Reveals that SARS-CoV-2 is Man Made & Paid for by U.S Taxpayers

- U.S. Dept. of Health & Human Services (**HHS**) funds research amplifying the infectious character of **1999O** Coronaviruses.
- In May\* **Ralph Baric** successfully uses reverse genetics (cDNA\*\*) to rescued infectious clone\*\*\* of 2000 0 SARS-CoV Urbani.
- In April Christopher M Curtis, Boyd Young & Ralph Baric file a patent for a recombinant (chimeric) DNA 2002 • means of producing "an infectious, replication defective, coronavirus." Funded by **NIH** Grant GM63228.
  - Dr. Shi **Zhengli** and colleagues increase infectivity by **combining** an **HIV** pseudovirus with SARS-CoV-1.
- Dr. Ralph **Baric** at UNC Chapel Hill receives NIH grant AI23946-08 officially classified as affiliated with 2003 0 NIAID.

Baric works on synthetically **altering Coronaviridae**.

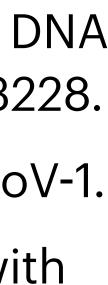
Chinese\*\*\*\* researchers combine HCV, HIV-1, SARS-CoV-1 & SARS-CoV-2. 2006 •

\* U.S. Provisional Application No. 60/206,537, filed May 21, 2000

\*\* Complimentary DNA is Reverse Transcription (mRNA->DNA) frequently using Moloney murine leukemia virus. \*\*\* https://www.pnas.org/content/100/22/12995 \*\*\*\* Huang Q, Cheng Y, Guo Q, Li Q. Preparation of a Chimeric Armored RNA as a Versatile Calibrator for Multiple Virus Assays. Clinchem 2006; 52(7):1446-1448 and Supplement A.









## Why understanding Gain of Function is Important

- was unnecessary?
- H5N1 Asian Avian Influenza Virus (Bird Flu) increasing infectivity.
- success.
  - Ο human cells.
- of **smallpox.** 
  - **Obama Administration halts Gain-of-Function Research**

\* Yang Y...Baric RS, et al. Receptor usage and cell entry of bat coronavirus HKU4 provide insight into bat-to-human transmission of MERS coronavirus. PNAS 2014;111(34):12516-12521. Funded with NIH grants RO1AI089728 & R21AI109094.

2007 NSF Grant IIS-0513650 (Italy, France and Indiana University) study addresses FIRST CRITICAL STEP to control a pandemic - **shut down International Travel**. Given this knowledge why did Fauci tell Trump a Travel Ban

### 2011 O Scientists express Concerns about GoF after Labs in Wisconsin and the Netherlands mutate already lethal

(2015). Rhesus macaques show early treatement with interferon- $\alpha$ 2b and ribavirin critical to treatment

**Baric\*** and Chinese scientists isolate 3 coronaviruses from bats with **HKU4** spike protein - unable to infect

**2014** • CDC accidentally exposes workers to Anthrax; ships deadly flu virus. NIH finds 50-year old forgotten vials











## Why understanding Gain of Function is Important

### **2017** *Gain-of-Function* **Research Ban Lifted**

from the University website.

### **2019** Summer **deletion** of Wuhan Institute of Virology Corona Virus data bank.

## - deleted.

\* Zhengli S, Baric RS, et sl. Two Mutations Were Critical for Bat-to-Human Transmission of Middle East Respiratory Syndrome Coronavirus. J Virol. 2015;89(17):9199-9123. Funded by NIH grants RO1AI089728, RO1AI110700.

\*\* Wuhan City Health Committee (WCHC). Wuhan Municipal Health and Health Commission's briefing on the current pneumonia epidemic situation in our city 2019 [updated 31] December 2019, 14 January 2020]. Available from: http://wjw.wuhan.gov.cn/front/web/showDetail/2019123108989

2015 Or. Zhengli et al "reengineered HKU4 spike aiming to build its capacity to infect human cells." "To this end, we introduced two single mutations...mutations in these motifs in coronavirus spikes have demonstrated **dramatic** effects on viral entry into human cells."

### **A Baric and Zhengli announce they can make a more dangerous, virulent and infectious virus.**

**2018 Zhengli** presents research at Shanghai Jiao Tong University on 14 Nov. 2018 entitled "Studies" on Bat Coronavirus and its cross-species infection." This presentation has since been deleted

**December 31** Wuhan Municipal Health Commission report\*\* discussing COVID-19 pneumonia









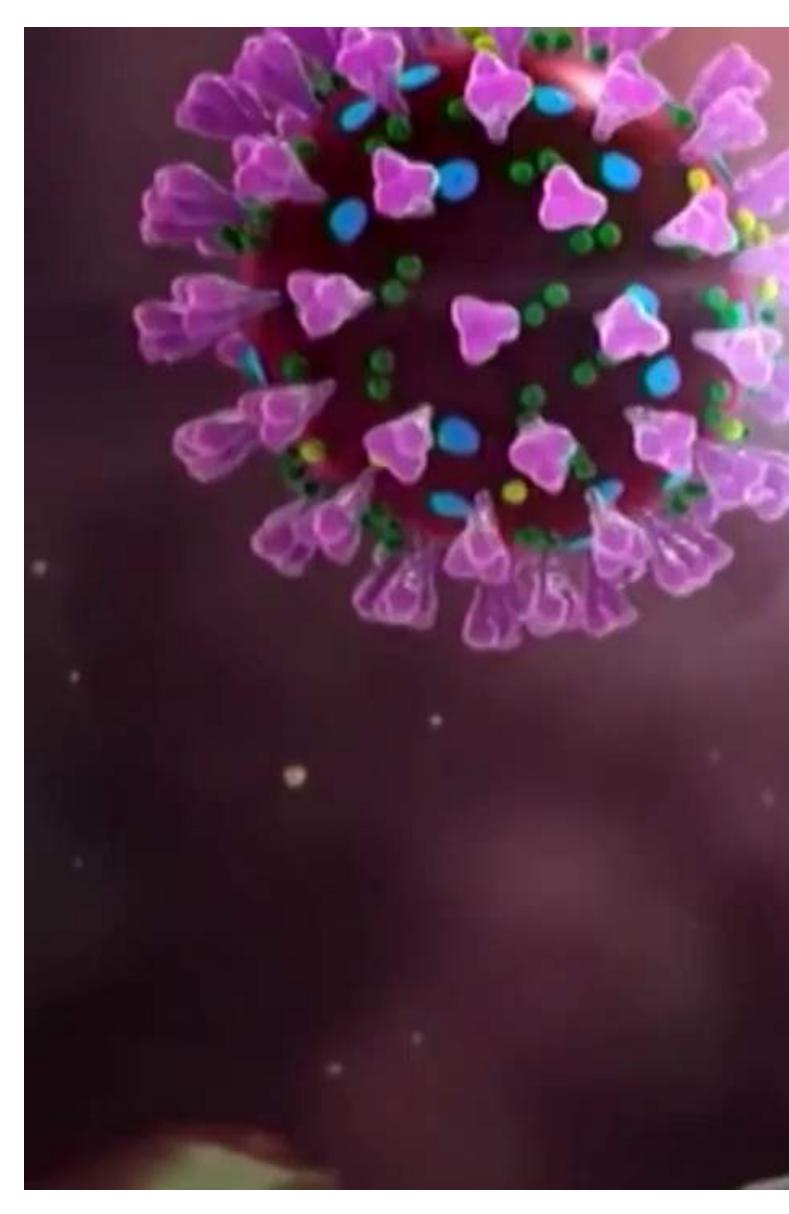




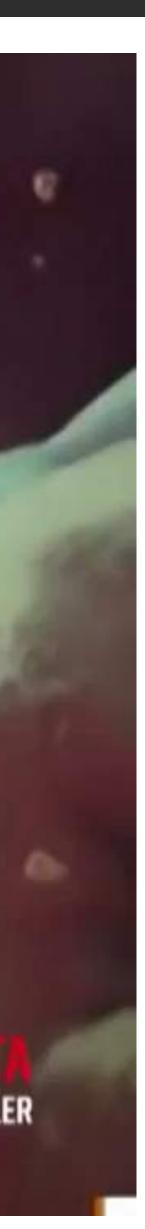
## Italian Media - Daszik-Baric-Zhengli

In 2015, Professor Zhengli works with Professor Baric to construct a hybrid virus.

American & Chinese scientists reengineer SARS virus Spike Protein.



### PRESA SARS CoV-2 IDENTIKIT DI UN KILLER



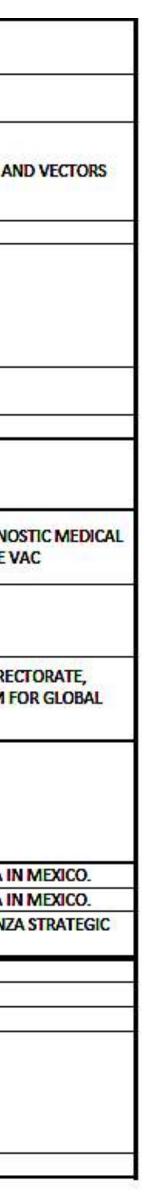
### Multiple Federal Agency Grants to Peter Daszak-EcoHealth

	AGENCY	AWARD ID	YEAR	AMOUNT	TOTAL AMOUNT	RECIPIENT	DESCRIPTION
De	fense Threat Reduction Agency (DOD)	HDTRA115C0041	2015 2016	\$2,217,037.00 \$2,262,641.00		ECOHEALTH ALLIANCE	BASE PERIOD - PSC: AD92 IGF::OT::IGF
De	fense Threat Reduction Agency (DOD)	HDTRA11710037	2017 2018	\$721,249.00 \$883,274.00		ECOHEALTH ALLIANCE	SEROLOGICAL BIOSURVEILLANCE FOR SPILLOVER OF HENIPAVIRUSES AND FILOVIRUSES AT AGRICULTURAL AND HUNTING HUMANANIMAL INTERFACES IN PENINSULAR MALAYSIA
De	fense Threat Reduction Agency (DOD)	HDTRA11910033	2019 2020	\$998,437.00 \$3,990,550.00	\$4 988 987 00	ECOHEALTH ALLIANCE	REDUCING THE THREAT OF RIFT VALLEY FEVER THROUGH ECOLOGY, EPIDEMIOLOGY AND SOCIO-ECONOMICS
De	fense Threat Reduction Agency (DOD)	HDTRA113C0029 *	2013 2014 2015	\$1,371,611.00	\$2,225,134.00	ECOHEALTH ALLIANCE	BASE PERIOD
DO	D	HDTRA11410029 (#1)	2014 2015 2016	\$992,699.00	\$2,942,0 <mark>19.00</mark>	ECOHEALTH ALLIANCE	UNDERSTANDING RIFT VALLEY FEVER IN THE REPUBLIC OF SOUTH AFRICA
8 De	fense Threat Reduction Agency (DOD)	HDTRA11410029 (#2)	2017 2018			ECOHEALTH ALLIANCE	UNDERSTANDING RIFT VALLEY FEVER IN THE REPUBLIC OF SOUTH AFRICA, CHANGE OF ACO TO ONR
De	fense Threat Reduction Agency (DOD)	HDTRA12010016	2020	\$4,912,818.00	\$4,912,818.00	ECOHEALTH ALLIANCE	REDUCING THE THREAT FROM HIGH-RISK PATHOGENS CAUSING FEBRILE ILLNESS IN LIBERIA
De	fence Threat Reduction Agency (DOD)	HDTRA11710064	2017 2018 2019 2020	\$782,330.00 \$2,203,917.00 \$1,995,247.00 \$1,509,531.00	\$6,491,025.00	ECOHEALTH ALLIANCE	UNDERSTANDING THE RISK OF BAT-BORNE ZOONOTIC DISEASE EMERGENCE IN WESTERN ASIA
De	fense Threat Reduction Agency (DOD)	HDTRA12010018	2020	\$4,995,106.00	\$4,995,106.00	ECOHEALTH ALLIANCE	CRIMEAN-CONGO HEMORRHAGIC FEVER: REDUCING AN EMERGING HEALTH THREAT IN TANZANIA.
Un	iformed Services University of the Health Sciences (DOD)	HU00012010031	2020	\$1,360,002.00	\$1,360,002.00	ECOHEALTH ALLIANCE	STRATEGIC COORDINATION TO STRENGTHEN AFRICOM ONE HEALTH AND VETERINARY PROGRAMS FOR GLOBAL HEALTH ENGAGEMENT STRENGTHENING MULTI-SECTORAL APPROACHES TO BIODEFENSE AND BIOSURVEILLANCE IN THE CAUCASUS
De	fense Threat Reduction Agency (DOD)	HDTRA12010029	2020	\$2,956,309.00	\$2,956,309.00	ECOHEALTH ALLIANCE	REDUCING THE THREAT OF MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS AND AVIAN INFLUENZA IN JORDAN&STRENGTHENING REGIONAL DISEASE SURVEILLANCE CAPACITY
Na	tional Institutes of Health (HHS)	<u>R01TW005869</u>	2008 2009 2010 2011 2012	\$697,356.00 \$1,001,985.00 \$763,008.00 \$761,374.00 \$501,437.00	\$3,725,160.00	ECOHEALTH ALLIANCE	THE ECOLOGY, EMERGENCE AND PANDEMIC POTENTIAL OF NIPAH VIRUS IN BANGLADESH
Na	tional Institutes of Health (HHS)	K08AI067549	2007 2009 2010	\$130,950.00 \$180,944.00 \$130,950.00	\$442,844.00	ECOHEALTH ALLIANCE	RISK FOR FUTURE OUTBREAKS OF HENIPAVIRUSES IN SOUTH ASIA
Na	tional Institutes of Health (HHS)	R56TW009502 *	2012	\$300,000.00	\$300,000.00	ECOHEALTH ALLIANCE	COMPARATIVE SPILLOVER DYNAMICS OF AVIAN INFLUENZA IN ENDEMIC COUNTRIES
Na	tional Institute of Allergy and Infectious Diseases (HHS - NIH)	<u>R01AI110964 •</u>	2014 2015 2016 2017 2018 2019	\$666,442.00 \$630,445.00 \$611,090.00 \$597,112.00 \$581,646.00 \$661,980.00	\$3,7 <mark>4</mark> 8,7 <mark>15</mark> .00	ECOHEALTH ALLIANCE	UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE
CD	C OFFICE OF ACQUISITION SERVICES (HHS)	HHSD2002011M41641P	2011 2013 2016	\$59,740.00 \$45,000.00 -\$5,446.00	\$99,294.00	ECOHEALTH ALLIANCE	BUSHMEAT
Na	tional Institutes of Health (HHS)	<u>R01AI079231</u>	2008 2009 2010 2011 2012	\$534,989.00 \$535,156.00 \$480,423.00 \$510,005.00 \$518,980.00		ECOHEALTH ALLIANCE	RISK OF VIRAL EMERGENCE FROM BATS
NI	H NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (HHS)	U01AI151797	2020		\$1,546,744.00	ECOHEALTH ALLIANCE	UNDERSTANDING RISK OF ZOONOTIC VIRUS EMERGENCE IN EID HOTSPOTS OF SOUTHEAST ASIA
De	partment of Health and Human Services (HHS)	<u>U01AI153420</u>	2020	\$580,858.00	\$580,858.00	ECOHEALTH ALLIANCE	STUDY OF NIPAH VIRUS DYNAMICS AND GENETICS IN ITS BAT RESERVOIR AND OF HUMAN EXPOSURE TO NIV ACROSS BANGLADESH TO UNDERSTAND PATTERNS OF HUMAN OUTBREAKS



### Federal Grants Spanning Decades

National Scien	ce Foundation (NSF)	<u>1618919</u>	2016 2017	\$190,223.00 \$309,674.00	\$499,897.00	ECOHEALTH ALLIANCE	ECOHEALTH NET 2.0: A ONE HEALTH APPROACH TO DISEASE ECOLOGY RESEARCH & EDUCATION
NSF		<u>1714394</u>	2017 2020	\$138,000.00 -\$40,250.00	\$97,750.00	N/A REDACTED DUE TO PI	DEVELOPING A QUANTITATIVE MODEL OF ECOHEALTH JUSTICE: A CASE STUDY OF MADISON AND MILWAUKEE, WI
Division of Env	rironmental Biology (NSF)	<u>1015791</u>	2010 2012 2013 2014	\$29,109.00 \$13,948.00 \$14,293.00 \$14,652.00	\$72,002.00	ECOHEALTH ALLIANCE	COLLABORATIVE RESEARCH: THE COMMUNITY ECOLOGY OF VIRAL PATHOGENS - CAUSES AND CONSEQUENCES OF COINFECTION IN HOSTS AND
NSF		1257513	2012	\$22,890.00	\$22,890.00	ECOHEALTH ALLIANCE	US-CHINA ECOLOGY AND EVOLUTION OF INFECTIOUS DISEASES COLLABORATIVE WORKSHOP; KUNMING, CHINA - OCTOBER, 2012
	NVIRONMENTAL BIOLOGY (NSF)	<u>955897</u>	2010 2011 2012 2013 2014	\$99,611.00 \$98,673.00 \$99,919.00 \$98,992.00 \$99,926.00		ECOHEALTH ALLIANCE	ECOHEALTHNET: ECOLOGY ENVIRONMENTAL SCIENCE AND HEALTH RESEARCH NETWORK
NSF		0622391	2006 2008	\$503,291.00 \$428,794.00	\$932,085.00	ECOHEALTH ALLIANCE	PREDICTING SPATIAL VARIATION IN WEST NILE VIRUS TRANSMISSION
NSF		0826779	2008	\$468,673.00	\$468,673.00	ECOHEALTH ALLIANCE	HSD: COLLABORATIVE RESEARCH: HUMAN-RELATED FACTORS AFFECTING EMERGING INFECTIOUS DISEASES
USAID		AID486A1300005	2013 2016	\$1,999,203.00 \$499,944.00	\$2,499,147.00		LAND USE CHANGE & DISEASE EMERGENCE
SCI TECH ACQ	DIV (DHS)	70RSAT19CB0000013	2019	\$566,274.00	\$566,274 <mark>.0</mark> 0	ECOHEALTH ALLIANCE	RAPID EVALUATION OF PATHOGENS TO PREVENT EPIDEMICS IN LIVESTOCK (REPEL) PROJECT TO APPLY BIOLOGICAL-BASED, PATHOGEN AGNO COUNTERMEASURE VACCINE AND DIAGNOSTIC PLATFORMS TO DEVELOP FOREIGN ANIMAL AND EMERGING ZOONOTIC LIVESTOCK DISEASE VA
	H AFFAIRS ACQ DIV (DHS)	HSHQDC16C00113	2016 2017 2018	\$271,272.00 \$327,782.00 \$406,902.00	\$1,005,956.00	ECOHEALTH ALLIANCE	IGF::OT::IGF GROUND TRUTH
SCI TECH ACQ	DIV (DHS)	70RSAT18CB0031001	2017 2018 2019	\$413,761.00 \$246,770.00 \$40,052.00	1	ECOHEALTH ALLIANCE	IGF::CL,CT::IGF_RESEARCH AND DEVELOPMENT SERVICES FOR THE DEPARTMENT OF HOMELAND SECURITY, SCIENCE AND TECHNOLOGY DIRECT CHEMICAL AND BIOLOGICAL DEFENSE DIVISION FOR PURPOSES OF DEVELOPING A WEB-BASED APPLICATION AND EARLY WARNING SYSTEM FOR INFECTIOUS DISEASE BIO-EVENTS THAT THREATEN THE US VIA INTERNATIONAL TRANSPORTATION NETWORKS.
	UISITION DIVISION KANSAS CITY f Commerce (DOC)	DOCWC133F06CN0251	2006 2007 2008 2009 2010	\$256,120.00 \$263,228.00 \$276,685.00 \$220,700.00 \$225,200.00	\$1,241,933.00	ECOHEALTH ALLIANCE	AERIAL SURVEYS OF RIGHT WHALES
- Department of	f Agriculture (USDA)	08-7100-0206-CA	2008	\$143,000.00		ECOHEALTH ALLIANCE	CONDUCT AN AVIAN INFLUENZE SURVEILLANCE PROGRAM TO DETECT THE OCCURRENCE OF HIGHLY PATHOGENIC H5N1 AVIAN INFLUENZA IN
	ant Inspection Service (USDA)	09-7100-0206-CA 0771000237CA	2009	\$100,001.00 \$403,700.00	Burnelburgener	ECOHEALTH ALLIANCE	CONDUCT AN AVIAN INFLUENZE SURVEILLANCE PROGRAM TO DETECT THE OCCURRENCE OF HIGHLY PATHOGENIC H5N1 AVIAN INFLUENZA IN FINANCIAL ASSISTANCE TO PROVIDE THREE WORKSHOPS IN CENTRAL AND SOUTH AMERICA IN SUPPORT OF THE NATIONAL AVIAN INFLUENZA
Department of	f the Interior (DOI)	F12AP01208	2012	\$154,087.00	\$154,087.00	ECOHEALTH ALLIANCE	PLAN. ECO HEALTH ALLIANCE - GEOMYCES DESTUCTANS, IMPLICATIONS FOR THE MIGRATION OF WHITE-NOSE SYNDROME BAT
	life Services (DOI)		2012	\$44,499.00			DEVELOPMENT OF A GREAT APE HEALTH UNIT IN SABAH, MALAYSIA
	life Services (DOI)	F14AP00269	2014	\$29,988.00		ECOHEALTH ALLIANCE	ECOSYSTEM APPROACH FOR BIODIVERSITY MONITORING AND CONSERVATION
8	QUISITION AND GRANTS - RESTON (DOI)	ING04ERSA0526	2004 2005 2006 2007 2008	\$16,000.00 \$15,000.00 \$10,000.00 \$10,000.00 \$10,000.00		ECOHEALTH ALLIANCE	04-2070-0909 MANATEE RESEAR
			2011	-\$22,512.00	-\$22,512.00	ECOHEALTH ALLIANCE	SEABIRD ECOLOGICAL ASSESSMENT NETWORK-SEANET



## Totalling More than \$61 Million

### SUMMARY

### **FEDERAL GRANTS & CONTRACTS**

	AGENCY		-	TOTAL
DoD***	Department of Defense		\$38,949,941.00	2013-2020
HHS **	Health & Human Services		\$13,023,168.00	2007-2020
NSF National Science Foundation			\$2,590,418.00	2006-2020
USAID U.S. Agency for International Development			\$2,499,147.00	2013-2016
DHS Department of Homeland Security			\$2,272,813.00	2016-2019
DoC Department of Commerce			\$1,241,933.00	2006-2010
USDA U.S. Department of Agriculture			\$646,701.00	2007-2009
Dol Department of the Interior			\$267,062.00	2004-2014
<b>GRAND TO</b>	TAL			\$61,491,183.00

\*\* Includes NIH and CDC.

\*\*\* Also provided "Policy Advisor" David Franz. Former Commander for Fort Detrick -Principal U.S. Government Bioware/Biodefense Facility.

## 2001 - Baric Files Patent to Manipulate Genomes

### (12) United States Patent Baric et al.

(54)	DIRECTI	ONAL ASSEMBLY OF LARGE
	VIRAL G	ENOMES AND CHROMOSOMES
(75)	Inventors:	Ralph S. Baric, Haw River, NC (US); Boyd Yount, Hillsborough, NC (US)
(73)	Assignee:	University of North Carolina at Chapel Hill, Chapel Hill, NC (US)
(*)	Notice:	Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.
(21)	Appl. No.:	09/862,847
(22)	Filed:	May 21, 2001
(65)		Prior Publication Data
	US 2002/01	77230 A1 Nov. 28, 2002
	Rel	ated U.S. Application Data
(60)	Provisional	application No. 60/206,537, filed on May 21, rovisional application No. 60/285,320, filed on
(51)	Int. Cl. <sup>7</sup>	C12P 21/06; C12N 7/00
(52)	<b>U.S. Cl.</b>	<b>435/69.1</b> ; 435/235.1; 536/23.72
(58)	Field of S	earch
		536/23.72
(56)		References Cited

### U.S. PATENT DOCUMENTS

5,202,430 A	4/1993	Brian et al	536/23.72
5,916,570 A	6/1999	Kapil	424/222.1

### 

US006593111B2

### (10) Patent No.: US 6,593,111 B2 (45) Date of Patent: Jul. 15, 2003

Lai, Michael M.C. "The making of infectious viral RNA: No size limit in sight," *PNAS*. vol. 97, No. 10, May 9, 2000, pp. 5025–5027.

Almazan et al., "Engineering the largest RNA virus genome as an infectious bacterial artificial chromosome," *Proceedings of the National Academy of Sciences of USA* 97: 5516–5521 (2000).

Thiel et al., "Infectious RNA transcribed in vitro from a cDNA copy of the human coronavirus genome cloned in vaccinia virus," 82: 1273–1281 (2001).

Yount et al., "Strategy for systematic assembly of large RNA and DNa enomes: Transmissible gastroenteritis virus model," 74: 10600–10611 (2000).

International Search Report of PCT/US01/16564 dated Dec. 7, 2002.

Primary Examiner-Hankyel T. Park

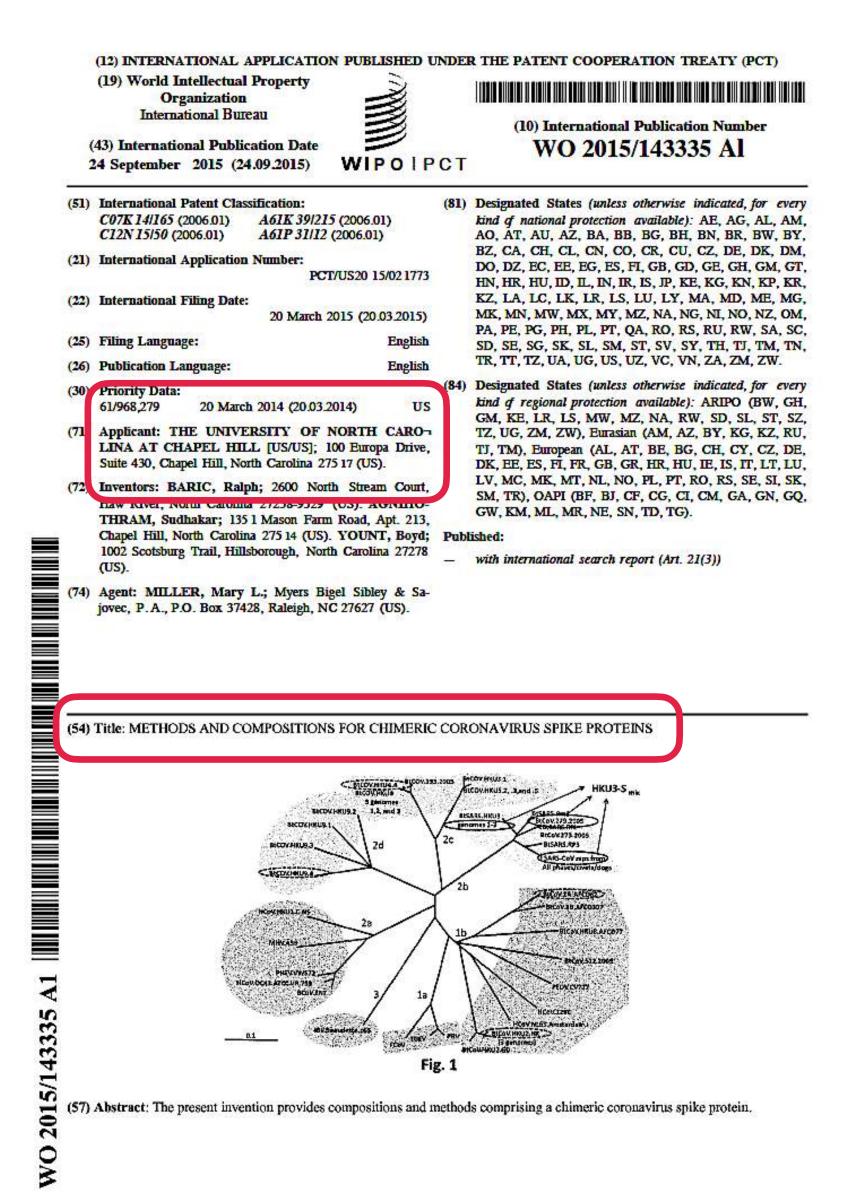
(74) Attorney, Agent, or Firm-Myers Bigel Sibley & Sajovec, P.A.

### (57) ABSTRACT

Full-length, functionally intact genomes or chromosomes are directionally assembled with partial cDNA or DNA subclones of a genome. This approach facilitates the recon-

struction of genomes and chromosomes in vitro for reintroduction into a living host, and allows the selected mutagenesis and genetic manipulation of sequences in vitro prior to reassembly into a full length genome molecule for reintroduction into the same or different host. This approach also provides an alternative to recombination-mediated techniques to manipulate the genomes of higher plants and animals as well as bacteria and viruses.

### 2014 - Ralph Baric Receives International Patent to Alter Spike Protein of Corona Viruses



### Making Chimeric (Gain-of-Function) Corona Virus Spike Proteins.

### Funded by the NIH - Your Tax Dollars

WO 2015/143335

10

PCT/US2015/021773

METHODS AND COMPOSITIONS FOR CHIMERIC CORONAVIRUS SPIKE PROTEINS

STATEMENT OF PRIORITY

5 This application claims the benefit, under 35 U.S.C. § 1 19(e), of U.S. Provisional Application Serial No. 61/968,279, filed March 20, 2014, the disclosure of which is incorporated by reference herein in its entirety.

STATEMENT OF FEDERAL SUPPORT

This invention was made with government support under Grant No. U54AI057157 awarded by the National Institutes of Health. The government has certain rights in the invention.

### Evidence of HIV gp120 Inserts In addition to Zhengli the Statistical Analysis of the Spike Protein

This is the French Virologist who received the **Nobel** in Physiology/Medicine for his discovery of **HIV**. He also a Research at the Paris Pasteur Institute and appointed as University Chair Professor in 2012 at the **Shanghai Jiao University**. This information has since been removed from the University website.

18 RNA fragments matching HIV & SIV (External Informative Elements; EIE).

The SPIKE PROTEIN not only has the **PRRA** insert (4 amino acids; 12 nucleotide bases) but a 590 amino acid (1770 nucleotide bases) insert matching **HIV-1**.

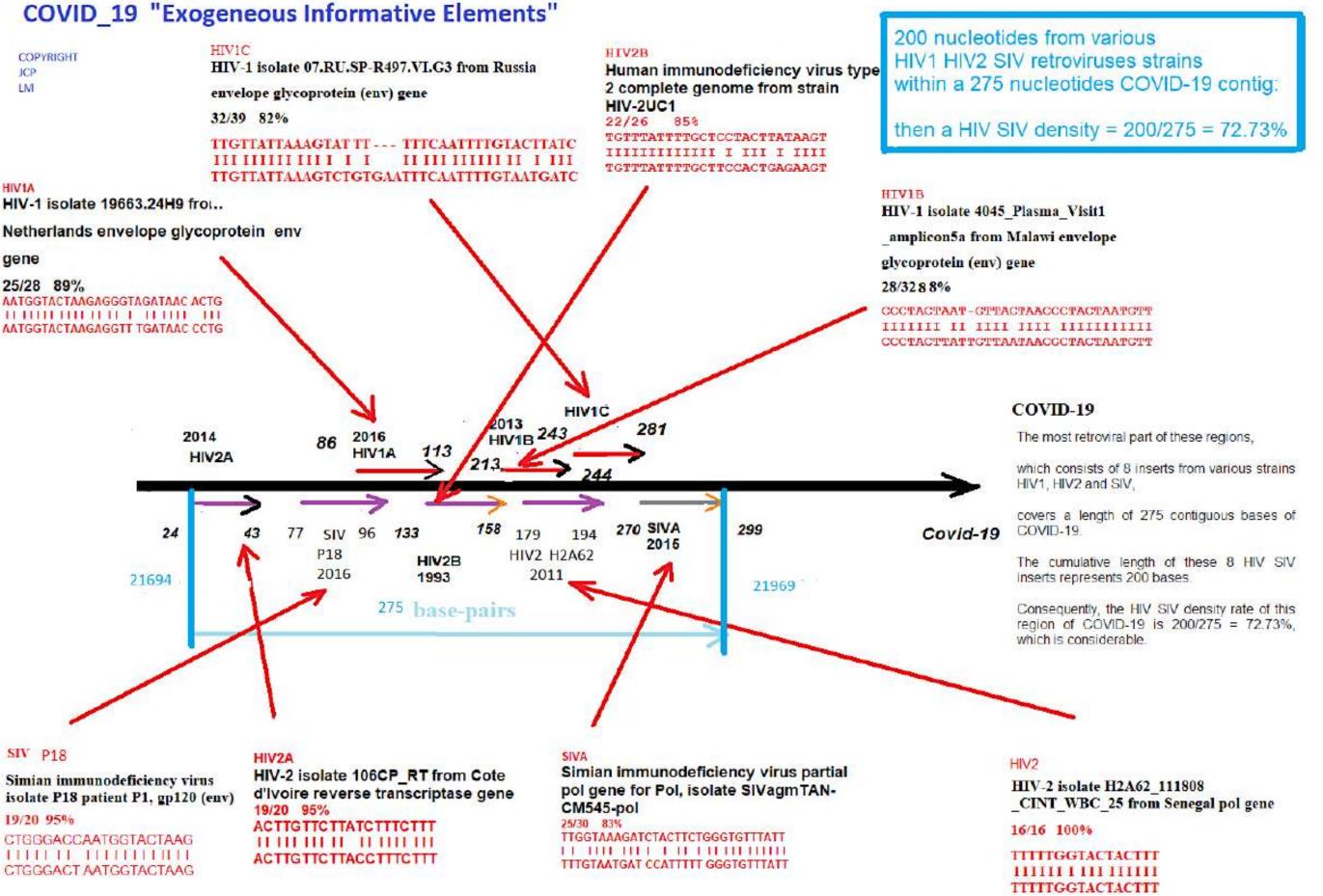
Perez JC, Montagnier L. COVID-19, SARS AND BATS CORONAVIRUSES **GENOMES PECULIAR HOMOLOGOUS RNA SEQUENCES. Intern J Research** 2020;8(7):217-263.

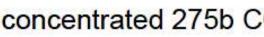
Perez JC, Montagnier L. COVID-19, SARS and Bats Coronaviruses Genomes Unexpected Exogenous RNA Sequences. https://www.researchgate.net/publication/341756383.

So, to summarize: a contiguous region representing 2.49% of the whole COVID-19 genome is 40.99% made up of 12 diverse « EIE » originating from various strains of HIV SIV retroviruses.

Figure 1 – This summary chart demonstrating visually how 200b from various HIV SIV retroviruses strains within a

AATGGTACTAAGAGGGTAGATAAC ACTG AATGGTACTAAGAGGTT TGATAAC CCTG





concentrated 275b COVID-19 contig have a density rate equal to 72.73%.

### Inform The PRRA SPIKE Protein Insert Doesn't Exist in Any Other Corona Virus

Huma Huma Huma

Huma Huma Cive Cive Raco SARS

> Pang Bat Bat

> Bat : Bat Bat Bat

Bat Bat Bat Bat

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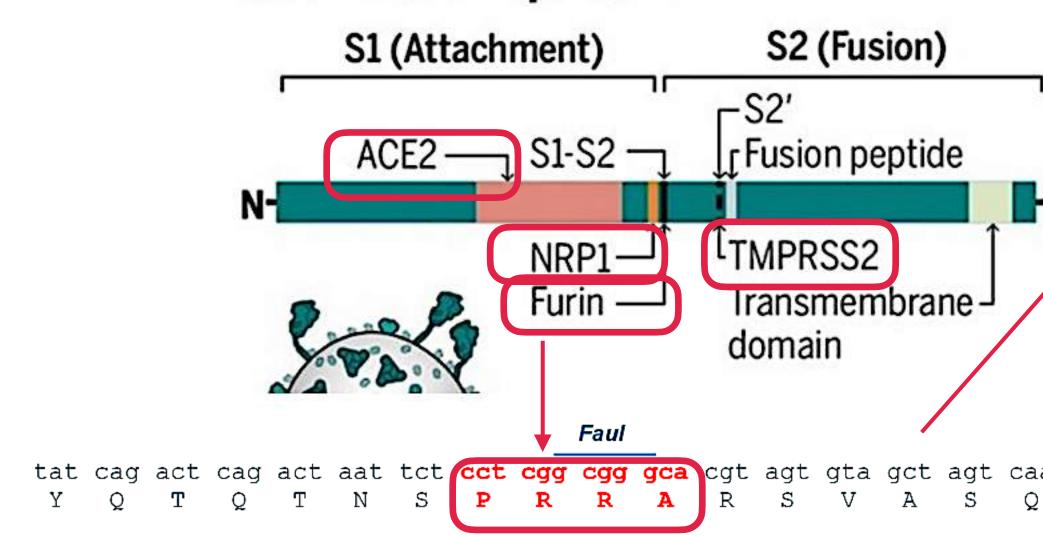
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Bat : Bat :

### What Do We Know About the SPIKE PROTEIN?

S2 is The Unstable Part of the Spike Protein - Where all the Variants are Occuring. S1 on the other hand is where the PRRA (Furin Cleavage Site) Insert Is.



SARS-CoV-2 S protein

Figure 7. Two consecutive Arg residues in the -PRRA- insertion at the S1/S2 junction of SARS-CoV-2 Spike are both coded by a rare codon, CGG. A FauI restriction site, 5'-(N) GCGGG-3', is embedded in the coding sequence of the "inserted" PRRA segment, which may be used as a marker to monitor the preservation of the introduced furin-cleavage site.

\*\*\* Yan LM, Kang S, Guan J, Hu S. Unusual Features of the SARS-CoV-2 Genome Suggesting Sophisticated Laboratory Modification Rather Than Natural Evolution and Delineation of Its Probable Synthetic Route. 1Rule of Law Society & Rule of Law Foundation, New York, NY, USA. 2021

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atc att S Ι

In SARS-Cov	BJ01	655	-	GICASYHTVSLLRSTS		670
In SARS-CoV	CUHK-W1	655	-	GICASYHTVSLLRSTS	-	670
an SARS-CoV	Tor2	655	-	GICASYHTVSLLRSTS	-	670
In SARS-CoV	Frankfurt-1	655	-	GICASYHTVSLLRSTS	-	670
n SARS-CoV	Urbani	655	-	GICASYHTVSLLRSTS	-	670
t SARS-CoV	civet020	655	-	GICASYHTVSSLRSTS	-	670
t SARS-CoV	sz16	655	-	GICASYHTVSSLRSTS	-	670
on dog SAR	S-CoV A030	655	-	GICASYHTVSSLRSTS	-	670
S-CoV-2		669	-	GICASYQTQTNSPRRARSVA	-	688
olin CoV M	P789	n/a	-	GICASYQTQTNSRSVS	-	n/a
SARSr-CoV	RaTG13	669	-	GICASYQTQTNSRSVA	-	684
SARSr-CoV	LYRall	659	-	GICASYHTASLLRNTD	-	674
SARSr-CoV	LYRa3	659	-	GICASYHTASLLRNTG	-	674
SARSr-CoV	RsSHC014	656	-	GICASYHTVSSLRSTS	-	671
SARSr-CoV	Rs4084	656	-	GICASYHTVSSLRSTS	-	671
SARSr-CoV	WIV1	656	-	GICASYHTVSSLRSTS	-	671
SARSI-CoV	Rs3367	656	-	GICASYHTVSSLRSTS	3 <b>1</b> 23	671
SARSr-CoV	Rs7327	656	4	GICASYHTVSSLRSTS	-	671
SARSI-CoV	Rs9401	656	-	GICASYHTVSSLRSTS	-	671
SARST-CoV		655	-	GICASYHTVSSLRSTS	_	670
SARST-CoV		22.22		GICASYHTVSSLRSTS		(179) X (19)
SARSI-CoV				GICASYHTVSSLRSTS		
SARSI-CoV		200.50		GICASYHTASILRSTS		
SARST-CoV				GICASYHTASILRSTG		Sec. 22.
SARSr-CoV	[전장 및 명상 명임]			GICASYHTASTLRGVG		
SARST-CoV		27.7		GICASYHTASLLRSTG		(17) (F-7)
SARST-CoV	영상 전 10 11 12 12 12 12 12 12 12 12 12 12 12 12	22260		GICASYHTASLLRSTG		장 김 영상품건
174767377.799	16B0133			GICASYHTASLLRSTG		
승규의 전화 가장 작품을 통했다.	B15-21	10.000		GICASYHTASLLRSTG		10.000
SARSI-CoV		2.7.2		GICASYHTASTLRSIG		8705974
1740 000 000 000 000 000 000 000 000 000	NT NE CONTRACTOR	STAT. 27.		GICASYHTASTLRSVG		
	Rp/Shaanxi2011			GICASYHTASVLRSTG		
	Rs/HuB2013	1.0		GICASYHTASVLRSTG		
SARSI-COV	말 같은 것이 같은 것은 것이 있는 것이 같이			GICASINIASVLRSTG		
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SARSI-CoV				GICASYHTASHLRSTG		
SARSI-COV		120222		GICASYHTASHLRSTG		2170000
영양 위험은 여름이 잘 가지 않는다.	Rf/SX2013	100000		GICASYHTASLLRSTG		6.2000
	Rf/HeB2013	123312		GICASIHIASLLRSTG		80.9993
	Cp/Yunnan2011	12.02.2		GICASIHIASLLRNTG		0.999180
SARSI-CoV				GICASTHTASELRAIG		S
				GICASIHIASILRSVG		
	Rs4255	10-12-00		GICASIHIASILRSVG		1 M M M M M M
SARSI-CoV	(한 성) (한 1740) 	1.2.2.2.2		그렇고 한 바람이 가지 않는 것 같아. 아니는 것 같아? 정말		1950/19070
SARSI-CoV				GICASYHTASVLRSTG		
SARSI-CoV	2/9	641		GICASYHTASVLRSTG		U.T. (7.973)
SARSE-COV	Rs/GX2013 Rs806	642		GICASYHTASVLRSTG		
				GICASYHTASLLRSTG		
SARST-CoV		12-22-22		GICASYHTASVLRSTG		745660
	Longquan-140			GICASYHTASVLRSTG		
SARSI-CoV				GICASYHTASTLRSVG		
	Rs4247	200 CH 17		GICASYHTASTLRSVG		
	Rs4237	75. TTT		GICASYHTASTLRSVG		1 TO 7 2 2 2 3
SARSr-CoV	A\$6526	641	-	GICASYHTASTLRSVG	-	656

## **The PRRA** (Furin Cleavage Site) Insert is ESSENTIAL for SARS-CoV-2 to Infect People.

### **Molecular Cell**



Short Article

### A Multibasic Cleavage Site in the Spike Protein of SARS-CoV-2 Is Essential for Infection of Human Lung Cells

Markus Hoffmann, 1,\* Hannah Kleine-Weber, 1,2 and Stefan Pöhlmann 1,2,3,\* <sup>1</sup>Deutsches Primatenzentrum – Leibniz Institut f
ür Primatenforschung, G
öttingen, Germany <sup>2</sup>Faculty of Biology and Psychology, University Göttingen, Göttingen, Germany <sup>3</sup>Lead Contact

\*Correspondence: mhoffmann@dpz.eu (M.H.), spoehlmann@dpz.eu (S.P.) https://doi.org/10.1016/j.molcel.2020.04.022

### SUMMARY

The pandemic coronavirus SARS-CoV-2 threatens public health worldwide. The viral spike protein mediates SARS-CoV-2 entry into host cells and harbors a S1/S2 cleavage site containing multiple arginine residues (multibasic) not found in closely related animal coronaviruses. However, the role of this multibasic cleavage site in SARS-CoV-2 infection is unknown. Here, we report that the cellular protease furin cleaves the spike protein at the S1/S2 site and that cleavage is essential for S-protein-mediated cell-cell fusion and entry into human lung cells. Moreover, optimizing the S1/S2 site increased cell-cell, but not virus-cell, fusion, suggesting that the corresponding viral variants might exhibit increased cell-cell spread and potentially altered virulence. Our results suggest that acquisition of a S1/S2 multibasic cleavage site was essential for SARS-CoV-2 infection of humans and identify furin as a potential target for therapeutic intervention.

### INTRODUCTION

It is believed that the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, previously termed nCoV-2019) was introduced into the human population from a poorly characterized an-Imal reservoir in late 2019 (Ge et al., 2013; Wang et al., 2020; Zhou et al., 2020b; Zhu et al., 2020). The epicenter of the subsequent SARS-CoV-2 spread was Wuhan, Hubei province, China, with more than 65,000 cases occurring in this area (WHO, 2020a). However, infections have now been detected in more than 110 countries and massive outbreaks are currently ongoing In the United States, Italy, and Spain (WHO, 2020a, 2020b). Understanding which features of SARS-CoV-2 are essential for Infection of human cells should provide insights into viral transmissibility and pathogenesis and might reveal targets for Intervention.

envelope and facilitates viral entry into target cells. For this, the surface unit S1 binds to a cellular receptor while the transmembrane unit S2 facilitates fusion of the viral membrane with a MERS-CoV and SARS-CoV spread and pathogenesis in the incellular membrane (Hoffmann et al., 2018; Hulswit et al., 2016; fected host (Iwata-Yoshikawa et al., 2019; Simmons et al., Millet and Whittaker, 2018). Membrane fusion depends on Spro- 2005; Zhou et al., 2015). tein cleavage by host cell proteases at the S1/S2 and the S2' site The S1/S2 site in SARS-CoV-2 forms an exposed loop (Figure 1A), which results in S protein activation (Hoffmann et al., (Figure 1B) that harbors multiple arginine residues (multibasic) 2018; Hulswit et al., 2016; Millet and Whittaker, 2018). Cleavage (Walls et al., 2020; Wrapp et al., 2020) that are not found in of the S protein can occur in the constitutive secretory pathway SARS-CoV-related coronaviruses (SARSr-CoV) but are present of infected cells or during viral entry into target cells and is essen- in the human coronaviruses OC43, HKU1, and MERS-CoV

tial for viral infectivity. Therefore, the responsible enzymes constitute potential targets for antiviral intervention.

Our previous work revealed that the activity of the cellular serine protease TMPRSS2, which activates several coronaviruses (Bertram et al., 2013; Gierer et al., 2013; Glowacka et al., 2011; Matsuyama et al., 2010; Shirato et al., 2013, 2016; Shulla et al., 2011), is also required for robust SARS-CoV-2 infection of human lung cells (Hoffmann et al., 2020). However, it is conceivable that the activity of other cellular proteases is also necessary. Thus, the Middle East respiratory syndrome coronavirus spike protein (MERS-S) is activated by a two-step process: MERS-S Is first cleaved by furin at the S1/S2 site in infected cells, which is required for subsequent TMPRSS2-mediated cleavage at the S2' site (Figure 1A) during viral entry into lung cells (Kleine-Weber et al., 2018; Park et al., 2016; Millet and Whittaker, 2014). A cathepsin B/L-dependent auxiliary activation pathway The spike protein of coronaviruses is incorporated into the viral is operative in many TMPRSS2<sup>-</sup> cell lines but seems not to be available in viral target cells in the lung because TMPRSS2dependent activation of the S protein is essential for robust

### 2007 U.S. Government Has Patent Rights to Insertion of Furin Protease Cleavage Sites



### (12) United States Patent Brown

INSERTION OF FURIN PROTEASE CLEAVAGE SITES IN MEMBRANE PROTEINS AND USES THEREOF

(75) Inventor: Dennis T. Brown, Raleigh, NC (US)

- (73) Assignce: Research Development Foundation. Carson City, NV (US)
- (\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.
- (21) Appl. No.: 10/841,787
- May 7, 2004 (22) Filed:

(65) **Prior Publication Data** 

US 2004/0224391 A1 Nov. 11, 2004

### **Related U.S. Application Data**

- (60) Provisional application No. 60/469,126, filed on May 9, 2003.
- (51) Int. Cl.
- A01N 63/00 (2006.01)
- (52) U.S. Cl. ..... 424/93.2; 435/6; 435/463; 435/219; 424/93.6
- 424/185.1, (58) Field of Classification Search 424/204.1, 218.1; 536/23.1
- See application file for complete search history.

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6,562,598	BI	5/2003	Himmelspach et al.
			에 상황하려는 것 같아요. 전 10월 7월 20일 10일 전 10월 10일 전 10일 전 10일 전 10일

(10) Patent No.:	US 7,223,390 B2
(45) Date of Patent:	May 29, 2007

6,566,073 B1 5/2003 Rivera et al.

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Chang et al. Nucleotide sequence of the genome region encoding the 26S mRNA of eastern equine encephaloyelitis virus and the deduced amino acid sequence of the viral structural proteins. Journal of General Virology (1987) vol. 68, No. 8, pp. 2129-2142.\* Kieffer et al., "Proteolytic processing of human zona pellucida proteins," Biol. Reproduction, 66:407-414, 2002.

McKnight et al., "Deduced consensus sequence of sindbis virus strain AR339: mutations contained in laboratory strains which affect cell culture and in vivo phenotypes," J. Virol., 70:1981-1989, 1996. Moehring et al., "Expression of mouse furin in a Chinese hamster cell resistant to pseudomonas exotoxin a and viruses complements the genetic lesion," J. Blol. Chem., 268:2590-2594, 1993.

Phinney et al. "Sindbis virus glycoprotein E1 is divided into two discrete domains at amino acid 129 by disulfide bridge connections," J. Virol., 74:9313-9316, 2000.

Zhang et al., "Mutations that promote furin-independent growth of semliki forest virus affect p62-E1 interactions and membrane fusion," Virology, 327:287-296, 2004.

Zimmer et al., "Proteolytic activation of respiratory syncytial virus fusion protein," J. Biol. Chem., 276:31642-31650, 2001.

Bolt et al., "Cleavage of the respiratory syncytial virus fusion protein is required for its surface expression: role of furin," Virus Res., 68:25-33, 2000.

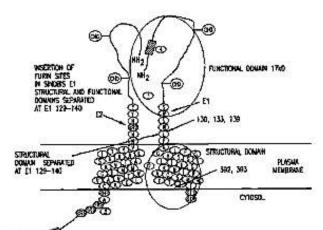
### (Continued)

Primary Examiner-Brenda Brumback Assistant Examiner-Sharon Hurt (74) Attorney, Agent, or Firm-Fulbright & Jaworski LLP

### ABSTRACT (57)

Cleavage site for the protease furin is inserted between domains of a membrane glycoprotein. Upon cleavage by furin in the trans-Golgi network, the protein is separated into individual membrane-free domain that retains its native conformation. This protocol can be used to produce virus membrane protein domains for structural analysis and for trials as vaccines.

### 13 Claims, 3 Drawing Sheets





### Here is the U.S. Patent for Inserting **Furin (PRRA) Protease Cleavage Sites.** Certain Rights may be Owned by U.S. **Government - NIH Grant.**

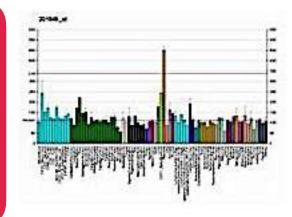
INSERTION OF FURIN PROTEASE CLEAVAGE SITES IN MEMBRANE PROTEINS AND USES THEREOF

CROSS-REFERENCE TO RELATED APPLICATION

This non-provisional patent application claims benefit of provisional patent application U.S. Ser. No. 60/469,126, filed May 9, 2003, now abandoned.

The United States government may own certain rights to this invention pursuant to grant number AI 42775 from the National Institutes of Health.

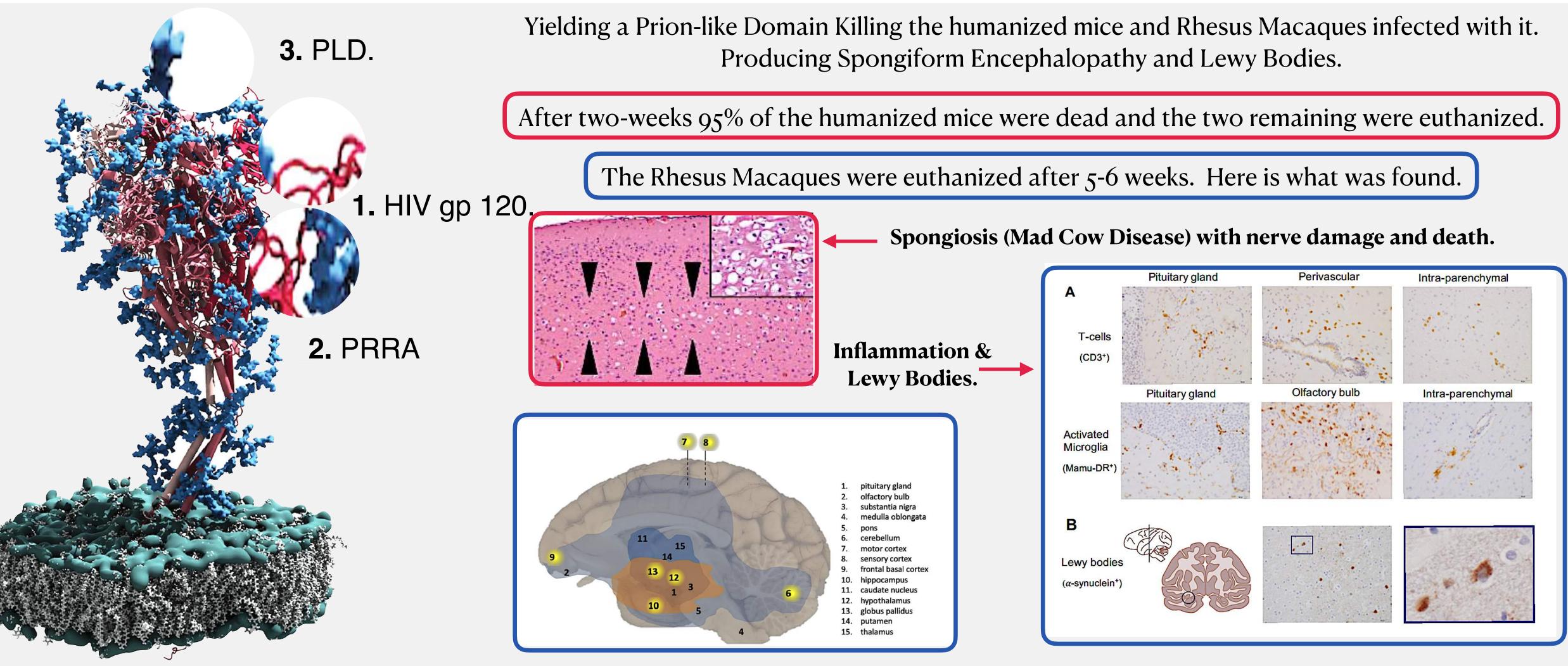
Furin is one of the proteases responsible for the proteolytic cleavage of HIV envelope polyprotein precursor gp160 to gp120 and gp41 prior to viral assembly. This gene is thought to play a role in tumor progression. The use of alternate polyadenylation sites has been found for this gene.



Furin - Wikipedia en.wikipedia.org/wiki/Furin



## Insertions 1 & 2 Produces Prion-Like Domain



Carossino M, et al. Fatal neuroinvasion of SARS-C 1 oV-2 in K18-hACE2 mice is partially dependent on hACE2 expression. https://doi.org/10.1101/2021.01.13.425144 Philippens I, et al. SARS-CoV-2 causes brain inflammation and induces Lewy body 1 formation in macaques. <u>https://doi.org/10.1101/2021.02.23.432474</u>





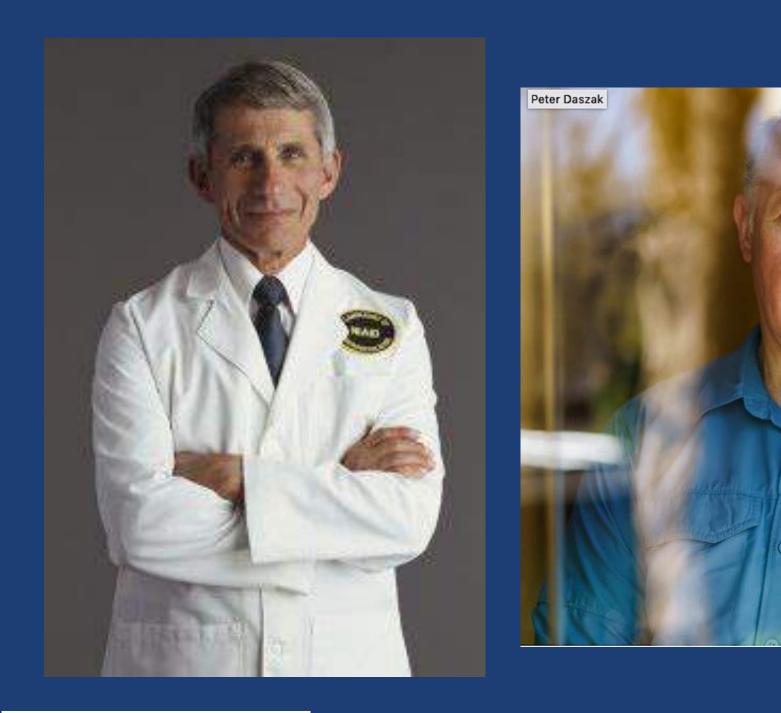
# All Brought to you by the U.S. Federal Government.

### 2002 to 2019 Gain-of Function Research Federal Funding to Peter Daszak (EcoHealth) to Ralph Baric (UNC) and Shi Zhengli (Wuhan Virology Institute)









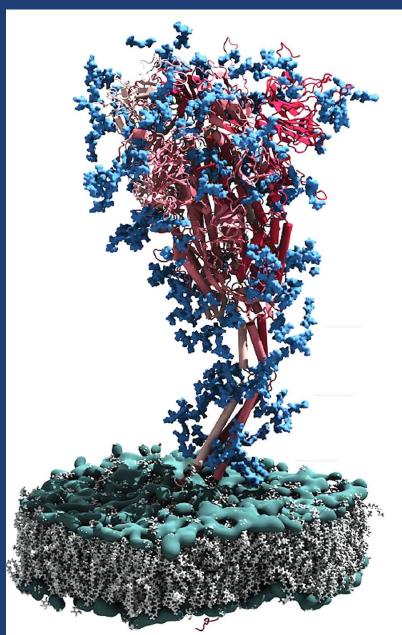
















### What are the Symptoms of SARS-CoV-2 vs COVID-19?



### What you should look for when you are infected.

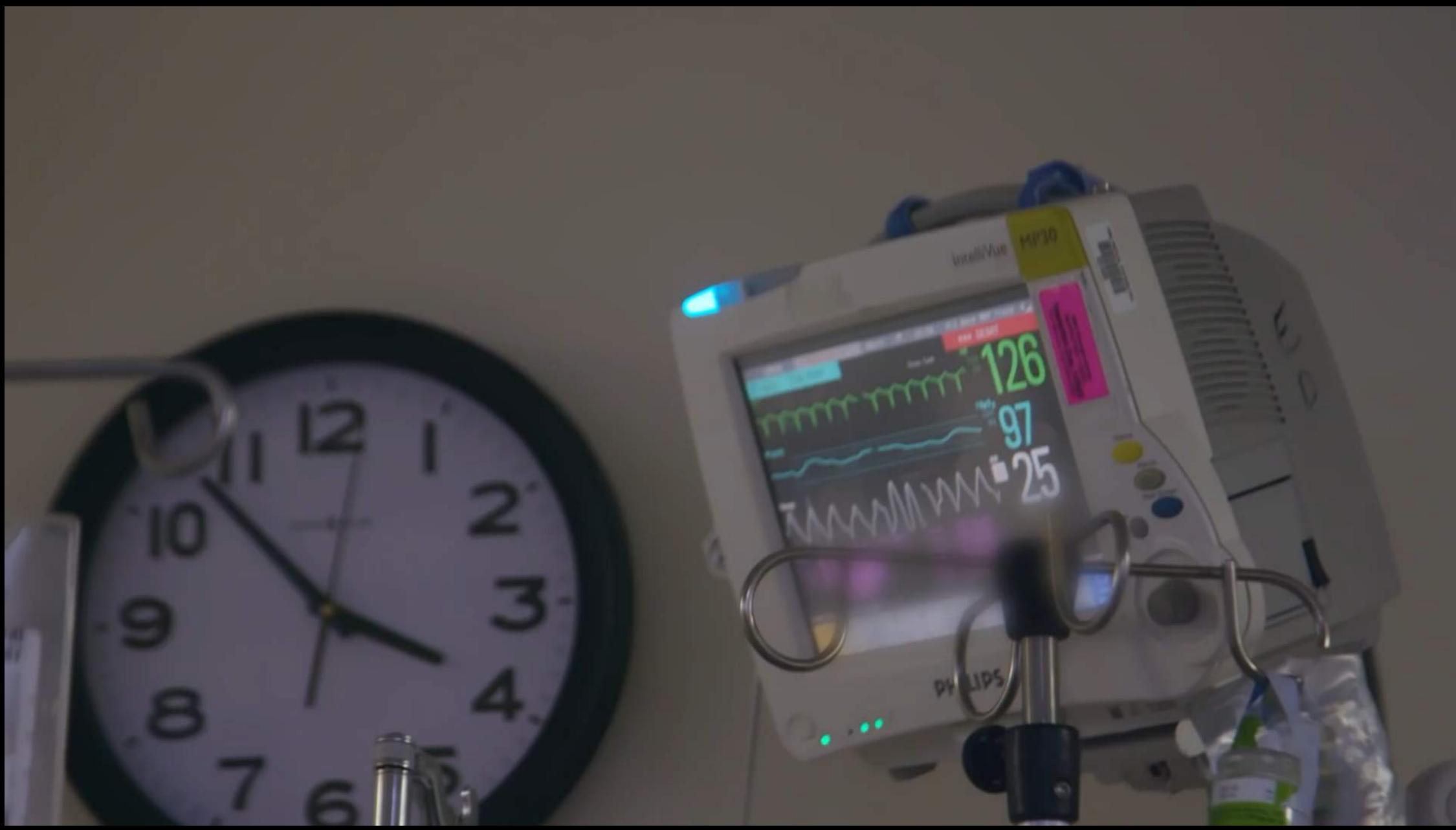
Symptoms may appear 2-14 days after exposure to the virus. People with these symptoms may have COVID-19:

- Fever or chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

How do you know when the infection becomes disease - COVID-19.

Look for emergency warning signs for COVID-19. If someone is showing any of these signs, seek emergency medical care immediately:

Trouble breathing Persistent pain or pressure in the chest New confusion Inability to wake or stay awake Pale, gray, or blue-colored skin, lips, or nail beds, depending on skin tone



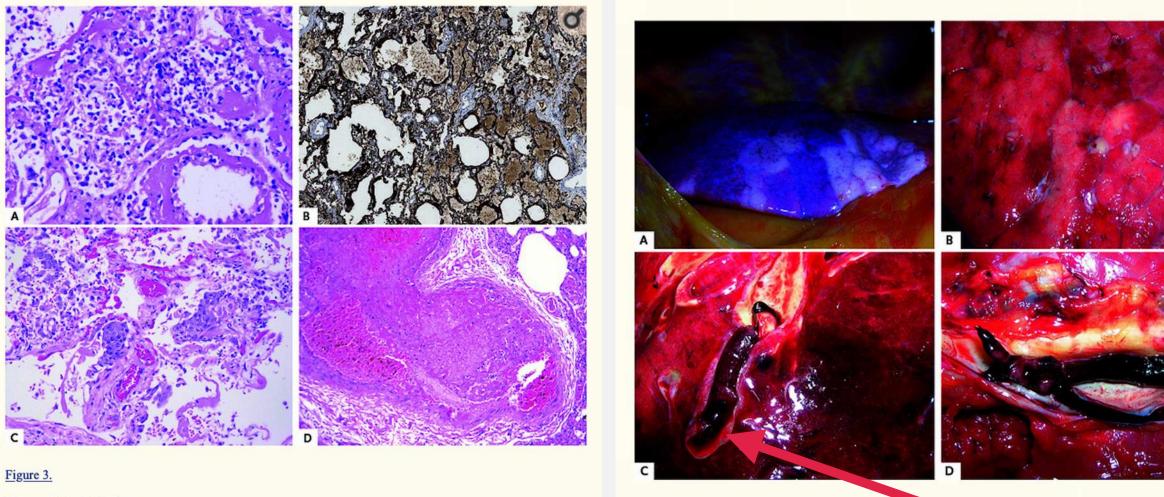
## This is covid



### What is the Difference Between SARS-CoV-2 & COVID-19? The InflammoThrombotic Response (ITR).

### The Disease Co(rona) Vi(rus) D(isease) - 2019

InflammoThrombotic Disease in people who have other InflammoThrombotic Diseases (The Comorbidites) resulting in more InflammoThrombotic Disease. When not treated people died.



A. Diffuse alveolar damage with hyaline membranes (case 4) (hematoxylin-eosin [H&E] stain; original magnification,×50). B. Hyaline membranes (case 4) (cytokeratin AE1/AE3 stain, original magnification×50). C. Squamous metaplasia in the lung (case 5) (H&E stain; original magnification,×100). D. Pulmonary embolism (case 1) (H&E stain; original magnification,×100).

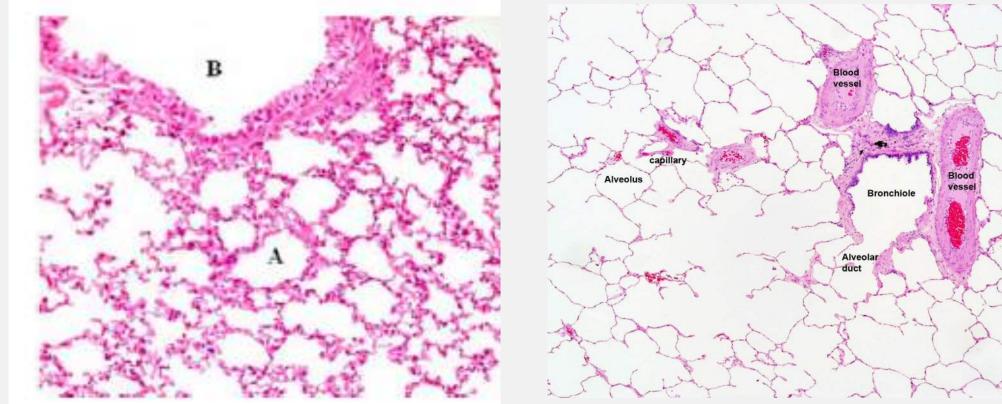
Macroscopic autopsy findings.

A. Patchy aspect of the lung surface (case 1). B. Cutting surface of the lung in case 4. (case 3). D. Deep venous thrombosis (case 5).

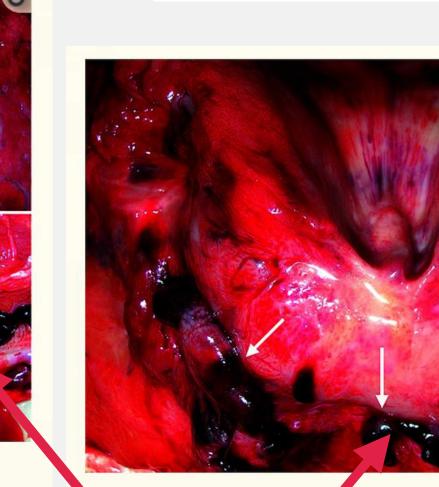
### **Blood Clots in Lungs, Legs, Prostate**

Wichmann D, Sperhake J-P, Lütgehetmann M, et al. Autopsy Findings and Venous Thromboembolism in Patients With COVID-19. A Prospective Cohort Study. Annals of Internal Medicine 2020. 6 May 2020. DOI: 10.7326/M20-2003.

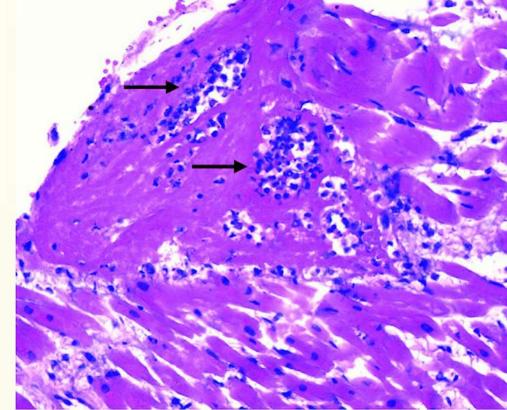
monary embolism



Appendix Figure 2



endix Figure 1. bosis of the prostatic vein (case 1)



Mononuclear infiltrations consisting of lymphocytes (arrows) in the myocardium of the right ventricle (case 3) (hematoxylin-eosin stain; original magnification,×100).

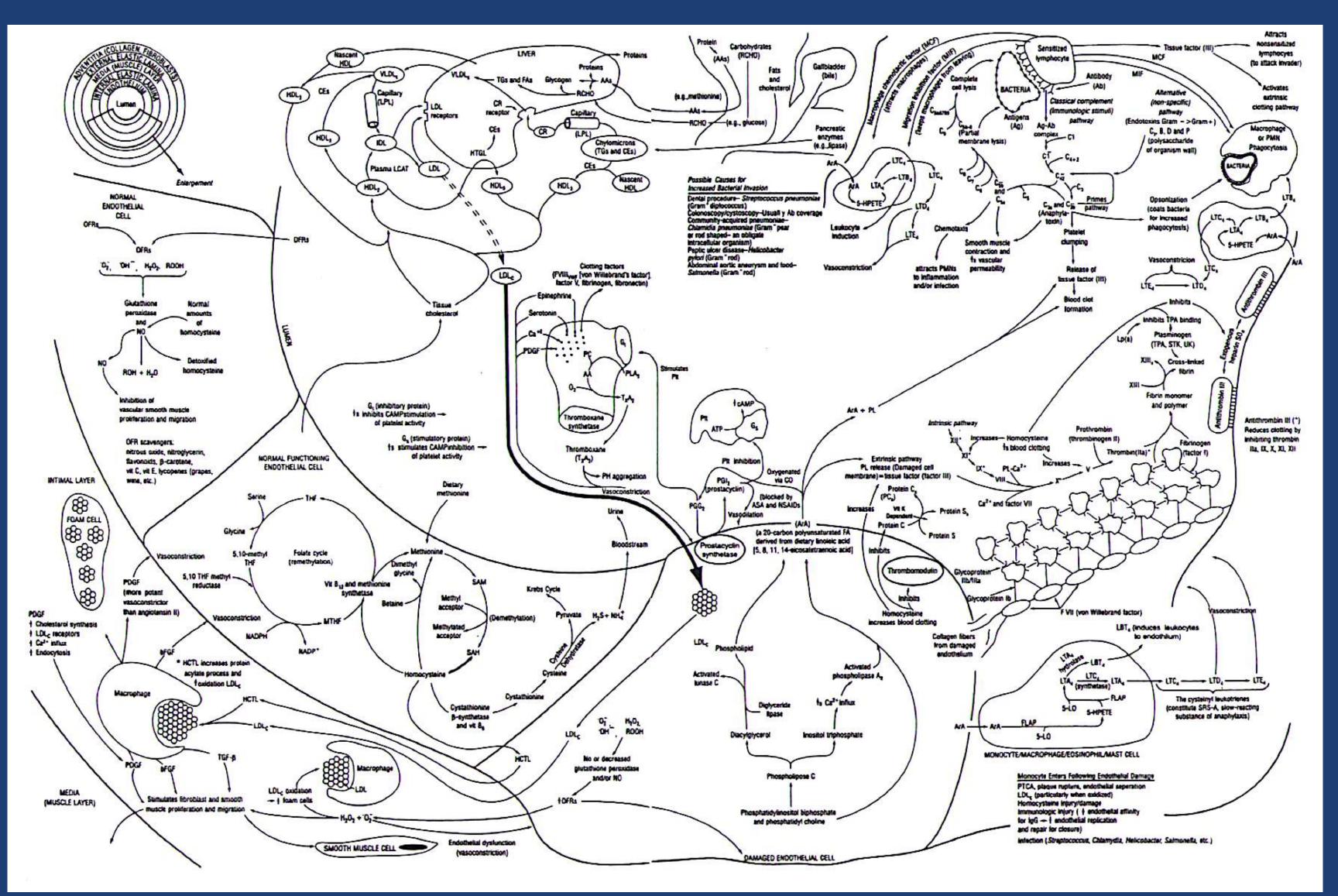








### This Concept of InflammoThrombotic Response (ITR) to Viruses is NOT New!



Fleming RM. Chapter 64. The Pathogenesis of Vascular Disease. Textbook of Angiology. John C. Chang Editor, Springer-Verlag New York, NY. 1999, pp. 787-798. doi:10.1007/978-1-4612-1190-7 64. Infectious Disease -> Fleming (PCN) -> Processing of Food and Decreased Physical Activity -> Hyper Reactive ITR Diseases -> Paving the Way for Infectious Disease to Again Become #1 Cause of Death Killing with ITR.

- 1) LDL cholesterol
- 2) Triglycerides
- 3) Excess Weight
- 4) Homocysteine
- 5) Oxidation
- 6) Lack of Exercise
- 7) Fibrinogen
- 8) Growth Factors
- 9) Cytokines & Leukotrienes
- 10) Complement Cascade
- 11) Infectious Agents
- 12) Direct Physical Trauma



## How is the SARS-CoV-2 Virus Transmitted?

SARS-CoV-2 is spread from person-to-person as many viruses are.

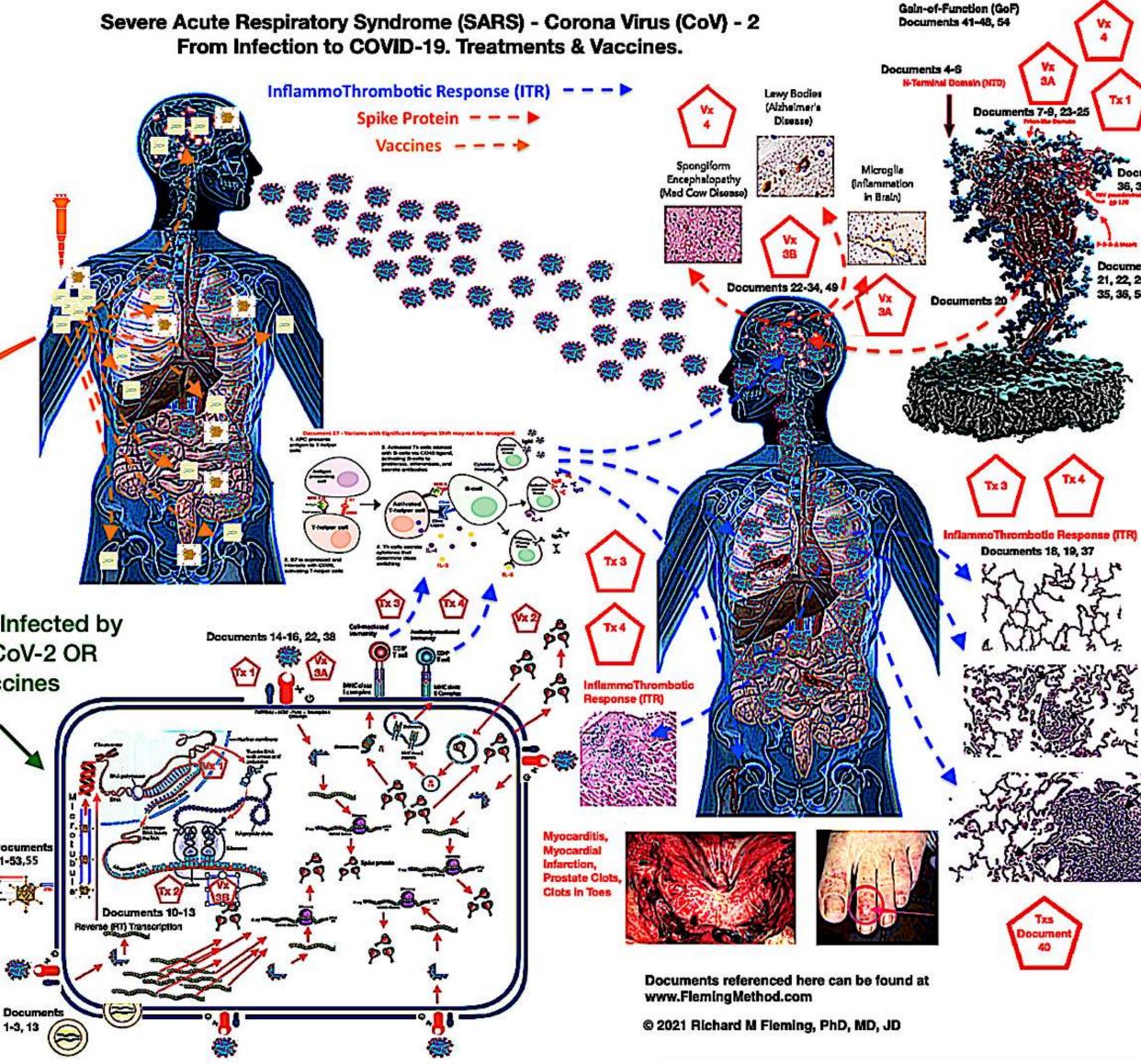
**Respiratory** passage or Gastrointestinal passage.

The following figure shows person-to-person transmission as well as what happens when people are **injected** with a Drug Vaccine.

Our Cells Infected by SARS-CoV-2 OR Vaccines

51-53.5

Docume



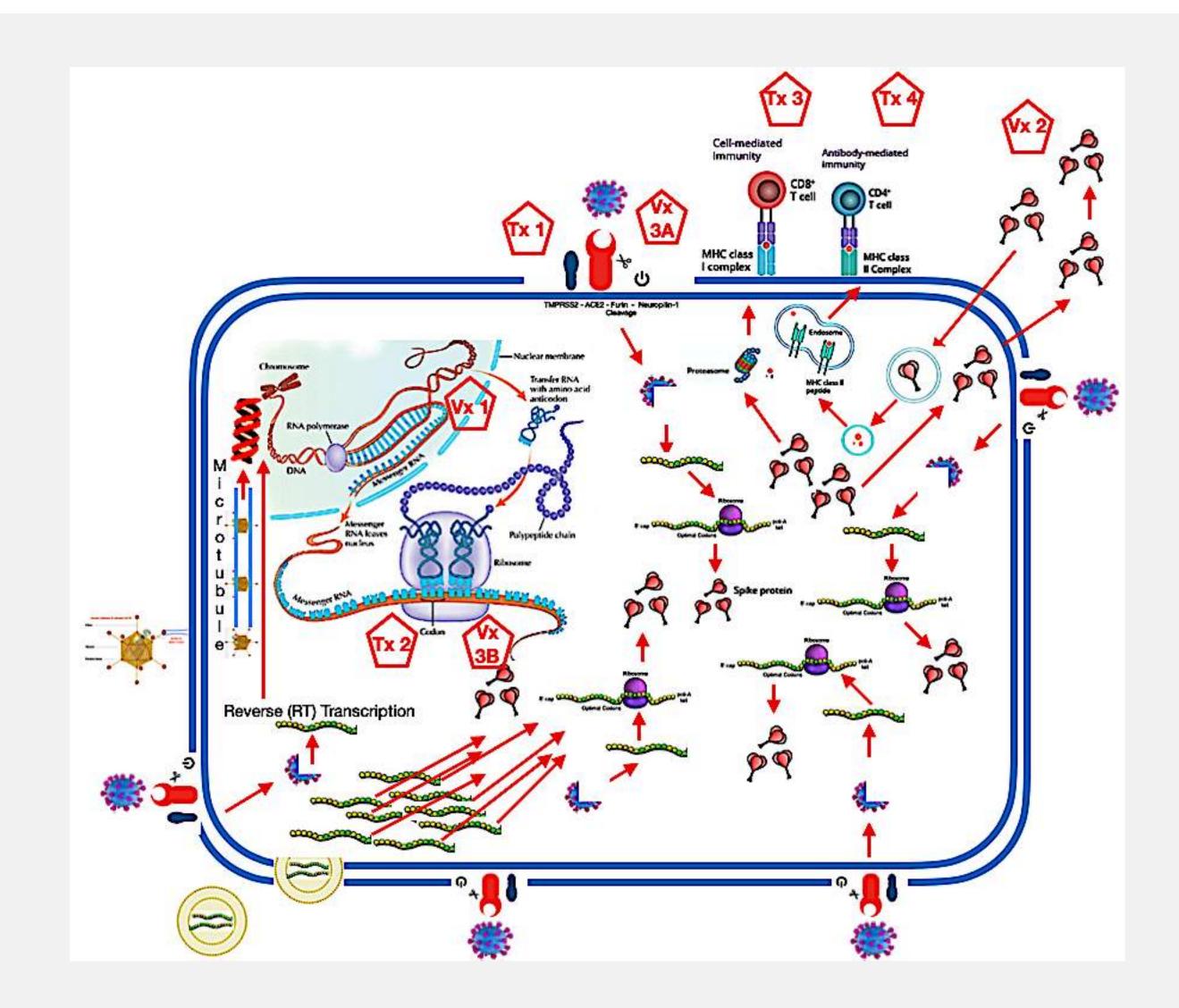


## Treating SARS-CoV-2 & COVID-19

**Treatment Needs to Focus On:** 

- (1) Virus attachment & Entry into the cell.
- (2) Virus replication once inside the cell.
- (3) Reducing Inflammation & Blood Clotting (ITR) associated with the T-Cell (Innate) response to the virus.
- (4) Reducing Inflammation & Blood Clotting (ITR) associated with the B-cell (Delayed Humoral) response to the virus.

As well as Medicines that improve airflow & reduce blood clotting.



## How do we Know What Works? We Measured it! Quantitatively Measured Treatments That Work.

- 1800 Infected People in 7-countries.
- 501 Admitted with COVID-19.
- FMTVDM, Ferritin & IL-6 measured severity and treatment responses.
- Focusing on 10different treatment options in 52-treatment combinations.

Study Site	Continent of Country	Start	Stop	Total Number of Patients	Outpatient HCQ Success	Outpatient Success without Rx	Phase I Patients	Phase II Patients
1	Cuba	4/16/20	4/30/20	56	32	17	7	0
2	India	4/16/20	5/11/20	49	23	17	9	0
3	India	4/16/20	5/20/20	114	39	30	18	27
4	Cuba	4/24/20	4/30/20	32	24	5	3	0
5	Philippines	4/27/20	6/15/20	34	27	1	6	0
6	Philippines	4/29/20	6/8/20	47	22	11	14	0
7	India	4/30/20	5/22/20	58	30	19	9	0
8	S. Africa	5/7/20	5/7/20	5	3	0	2	0
9	Belgium	5/11/20	5/20/20	25	9	5	11	0
10	Germany	5/11/20	6/19/20	145	82	41	22	0
11	Germany	5/14/20	6/1/20	57	22	11	24	0
12	Brazil	5/18/20	6/22/20	142	65	49	28	0
13	Belgium	5/18/20	6/18/20	135	58	38	39	0
14	Belgium	5/18/20	6/19/20	152	60	43	49	0
15	India	5/18/20	6/19/20	95	18	18	59	0
16	Germany	5/19/20	5/27/20	79	49	20	10	0
17	Germany	5/22/20	5/29/20	16	7	0	9	0
18	India	5/22/20	6/19/20	168	90	27	21	30
19	Brazil	7/9/20	8/4/20	94	51	27	0	16
20	Brazil	7/9/20	8/3/20	98	48	25	0	25
21	Philippines	7/9/20	8/5/20	93	36	36	0	21
22	Cuba	7/10/20	7/31/20	40	0	29	0	11
23	Brazil	7/13/20	8/4/20	66	0	35	0	31
Fotals:		4/16/20	8/5/20	1800	795	504	340	161

See application file for complete search history.

# Quantification of Changes in Tissue

### **Measuring Regional Blood Flow & Metabolism**

		US009566037B2
	United States Patent	(10) Patent No.: US 9,566,037 1 (45) Date of Patent: Feb. 14, 20
(54) (71)	FLEMING METHOD FOR TISSUE AND VASCULAR DIFFERENTIATION AND METABOLISM (FMTVDM) USING SAME STATE SINGLE OR SEQUENTIAL QUANTIFICATION COMPARISONS Applicant: Richard Max Fleming, Studio City, CA (US)	<ul> <li>(56) References Cited</li> <li>PUBLICATIONS</li> <li>Fleming-Harrington Redistriution Wash-in washout (FHRW: The platinum Standard for nuclear cardiology, p. 207-250, 20</li> <li>* cited by examiner</li> </ul>
(72)	Inventor: Richard Max Fleming, Studio City, CA (US)	Primary Examiner — Joseph M Santos Rodriguez (57) ABSTRACT
(*)	Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 732 days.	The present invention defines the parameters wher "quantification" of isotope emission may occur and clinically applied and provides a method for detec
(21)	Appl. No.: 13/986,869	abnormal coronary blood flow by "quantifying" emissi of a radiopharmaceutical after stressing the heart ei
(22)	Filed: Jun. 13, 2013	pharmacologically or physiologically under "same sta conditions of stress-stress for detection of ischemic vasc
(65)	<b>Prior Publication Data</b>	(IVD) disease and the ability to differentiate (a) ische heart disease (IHD) due to narrowed coronary lumen
	US 2014/0371579 A1 Dec. 18, 2014 US 2016/0374634 A9 Dec. 29, 2016	subsequent reduced lumen responsiveness to demand more coronary blood flow and (b) vulnerable inflammat plaque (VIP) disease, which reduces lumen responsiver to blood flow demand with potential for sudden rupture
	<b>Related U.S. Application Data</b>	sudden cardiac death. The present invention also provid method of detection of myocyte viability by using
(60)	Provisional application No. 61/658,428, filed on Jun. 12, 2012.	"quantitative" method to differentiate "normal" function cardiac tissue from non-viable "infarcted" cardiac tissue
(51)	Int. Cl. A61B 5/1455 (2006.01) A61B 6/00 (2006.01) A61B 6/03 (2006.01) U.S. Cl. CPC A61B 6/503 (2013.01); A61B 6/037 (2013.01); A61B 6/486 (2013.01); A61B 6/5217 (2013.01)	secondary exposure to isotope emissions. In one embed ment, the nuclear isotope is technetium-99m hexa
(58)	Field of Classification Search CPC A61B 6/503	2-methoxyisobutylisonitrile (sestamibi).

#### 1 Claim, 17 Drawing Sheets

### 

**B2** 2017 \_\_\_\_

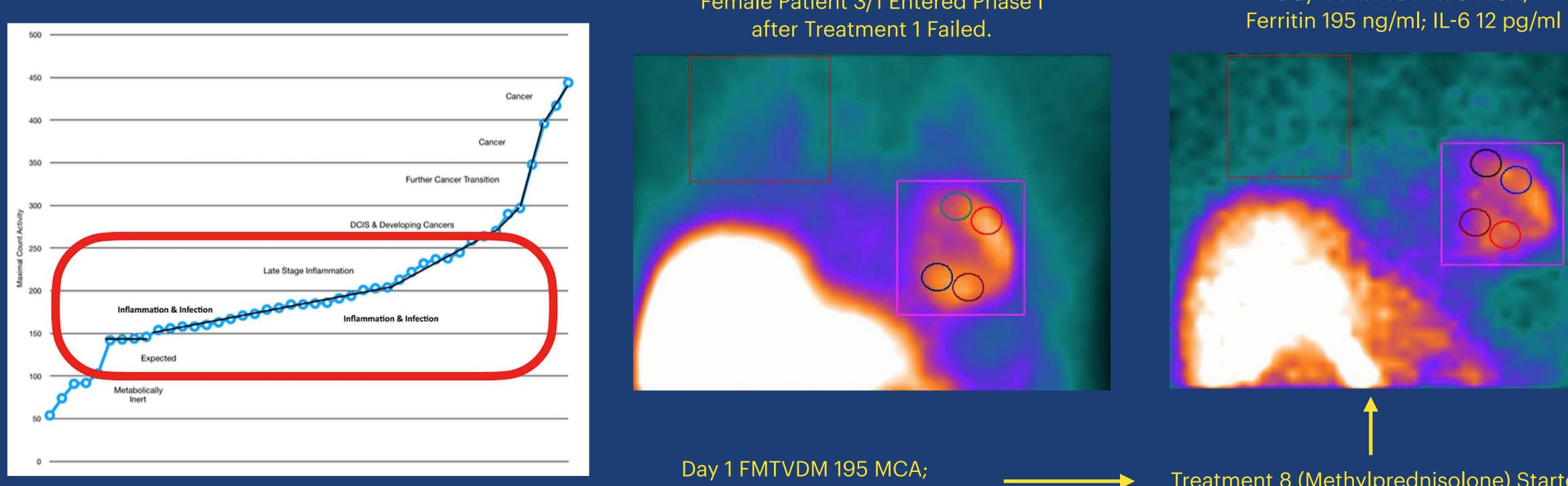
WW) 2011.\*

ereby 1d be cting sions ither tate' cular emic and d for atory eness e and des a the ning e and nefit des a ymic The magand and bođixakis What is claimed is:

1. A method of yielding quantitative diagnosis of bodily pathologies including vascular disease, metabolism and tissue differentiation in a subject comprising the steps of:

- a. either inject a pharmacologic agent or conduct physiologic changes, which produces regional blood flow differences;
- b. inject into the subject's body an isotope;
- c. after determining a time interval, with a computer, acquire one or multiple images at multiple time-points within the time-interval within a determined region of interest (ROI) within the patient;
- d. measure, with the computer, the actual measured radioactive emissions of the injected isotope from the acquired image or images;
- e. create, with the computer, a data array of radioactive emissions of the injected isotope at each time-point;
- f. calculate, with the computer, the total percent gain or loss of the measured radioactive emissions for the time period between each time-point of the data array set and the subsequent data array set;
- g. compare, with the computer, the calculated total percent gain or loss with the expected change resulting from the isotope radioactive decay;
- h. the degree of disease is determined, with the computer, in response to the comparison obtained in "g", this determined degree of disease is a non-linear function defined as the gain, washin, or loss, washout, which includes the differentiating of tissue and metabolism.

## **Measured COVID Severity & Treatment Response?**



level of  $\leq 150$ , Ferritin levels  $\leq 270$  ng/ml for men and  $\leq 160$  ng/ml for women, and an IL-6 level of  $\leq 5$  pg/ml.

### Female Patient 3/1 Entered Phase I

Day 4 FMTVDM 170 MCA;

Ferritin 302 ng/ml; IL-6 45 pg/ml

Treatment 8 (Methylprednisolone) Started

• Successful treatment outcomes were defined using the quantitative measurements of FMTVDM with a reduction of  $\geq 25$ , or a







## Results of Outpatient Response to Treatment

### When Treatment was Started within 3-4 Days of Symptoms

Total	HCQ Pre-hospital Treat- ment Success	HCQ Failures entered Phase I	HCQ Failures entered Phase II	Total Number of Patients Treated with HCQ	Percent Success- ful Treatment	Percent Treat- ment Failure
Treatment 1	225	20	58	303	74.20%	25.70%
Treatment 2	170	17	59	246	69.10%	30.90%
Treatment 3	189	2	2	193	97.90%	2.10%
Treatment 4	211	0	0	211	100%	0.00%

- (1) **100%** Effective [Treatment Regimen 4]
- Primaquine 200 mg by mouth on day 1.
- Clindamycin 150 mg by mouth every 6-hours for 7-days.
- Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.

(2)**97.9%** Effective [Treatment Regimen 3]

- Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.
- Clindamycin 150 mg by mouth every 6-hours for 7-days.

(3) **74.2%** Effective [Treatment Regimen 1]

- Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.
- Azithromycin 500 mg by mouth on day 1, then 250 mg by mouth
- on days 2 through 5.
- (4) **69.1%** Effective [Treatment Regimen 2]
- Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.
- Doxycycline 100 mg by mouth every 12-hours for 10-days.



## **Results of Inpatient Response to Treatment**

99.83% Success Rate When Treatment was Started Immediately Upon Admission.

(1) With prior Aminoquinoline Treatment begin Methylprednisolone 125 mg IV every 6-hours for 3 days; then 125 mg IV every 12-hours for 2 days; then 125 mg IV daily for 2 days; then 60 mg IV daily for 2 days [with each infusion given over 30-minutes]; then Solumedrol dose pack to taper off steroids). (2) With prior Aminoquinoline Treatment begin Tocilizumab 8-mg/kg [IBW; not to exceed 800 mg] not to exceed 800 mg intravenously infused over 1-hour. May be repeated every 8-hours for a maximum of 4-doses; and Interferon  $\alpha$ -2 $\beta$  (5-million units per nebulizer every 12-hours for 7-days). (3) Without prior Aminoquinoline Treatment Primaguine 200 mg by mouth day 1; Clindamycin 150 mg by mouth every 6-hours for 7-days; and Tocilizumab and Interferon- $\alpha 2\beta$  - using the same doses shown in (2) above.





## Inpatients Also Received ... to Improve Immune **Response, Open Airways, and Reduce Blood Clotting.**

Immune Support:

Cobalamin (B12), Pyridoxine (B6), Dehydroepiandrosterone (DHEA), Ascorbic acid (C) 2000, Zinc, and 1,25-dihydroxycholecalciferol (D3). **Respiratory Support:** Atrovent Nebulizer or Inhaler Treatments. **Thrombosis Prophylaxis:** Heparin subcutaneously.

Fleming RM, Fleming MR. FMTVDM Quantitative Nuclear Imaging finds Three Treatments for SARS-CoV-2. Biomed J Sci & Tech Res. 2021;33(4):26041-26083. DOI: 10.26717/BJSTR.2021.33.005443. https://biomedres.us/fulltexts/BJSTR.MS.ID.005443.php

- Folate (B9), Magnesium, Calcium Carbonate,



## **Clinicians Reporting Observed Treatment Success.**

- Dr. Vladimir Zelenko (Family Practice in New York) treatment with hydroxychloroquine, azithromycin and zinc had an 84% reduction in hospitalization. [doi: 10.20944/ preprints202007.0025.v1]
- Dr. Peter A. McCullough (Baylor Dallas) nine studies reveal patients treated with hydroxychloroquine and other drugs like doxycycline had a greater than 60% reduction in death. [https://www.researchgate.net/publication/348946216]
- AAPS Early Treatment Saves Lives [<u>https://aapsonline.org/early-treatment-saves-lives/</u>]
- Dr. Harvey Risch (Yale) Hydroxychloroquine (HCQ) produced a 34% reduction in risk of death, while HCQ and azithromycin produced a 29% reduction in risk of death in hospitalized patients with COVID-19. [https://doi.org/10.1016/j.ijid.2020.06.099]
- Dr. Richard Bartlett (Budesonide Nasal Steroids) reports 100% success rate when started early.
- Dr Eleftheria Atalla (Brown University, R.I.) treatment of critically ill seniors in Long Term Care Facilities with anticoagulants who had elevated markers of inflammation were 84% less likely to die. [Pathogens 2021, 10, 8. <u>https://dx.doi.org/10.3390/pathogens10010008</u>]



## **Treatments Reported to be Beneficial**

### **01 TYPES**

### **Prescription Support:**

- Hydroxychloroquine
- Primaquine
- Ivermectin Maybe
- Clindamycin
- Azithromycin
- Tocilizumab
- Interferon  $\alpha$ -2 $\beta$
- Methylprednisolone
- Remdesivir ???
- Convalescent plasma
- Monoclonal antibodies

### Immune Support:

- Folate
- Magnesium
- Calcium Carbonate
- Cobalamin
- Pyridoxine
- Dehydroepiandrosterone (DHEA)
- Ascorbic acid (C)
- Zinc
- Dihydroxycholecalciferol (D3)

#### **Respiratory Support:**

- Atrovent Nebulizer Treatment
- Budesenide Maybe
- Extracoporeal Membrane Oxygenation (ECMO)
- Ventilators need to be set at 1/2 the standard Tidal Volume.

#### **Thrombosis Prophylaxis:**

• Heparin

### **02 USE CASES**

Trump
 HCQ, Azithromycin,
 Methylprednisolone

### **03** CONTROVERSY

- Access to therapeutics
- Medical community support
- National Guard
- Pharmacy board obstruction
- medical board obstruction
- Cease and desist letters
- Front Line Drs

ort on

Care Providers Are Treating Patients. These People - It Turns Out - Are The Same People Who

Helped Fund and Develop The Drug Vaccines.

Which, We will Talk About in the Next Section.

- What If The People You Trust **Are The People Causing The Problem?**
- The Same People Who Helped Fund and Develop SARS-CoV-2
- Have Also Controlled How Doctors, Nurses, & Other Health



## Section 02

# 01 Inform

The SARS-CoV-2 virus & known facts

The Covid-19 disease & published treatments

## **02 Educate**

**Infectious Diseases** 

**The Scientific Method** 

**COVID-19 & Death** 

**EUA vs Process vs Risks** 

- Vaccines efficacy and safety
- The Difference Between VE,

# **03 Empower**

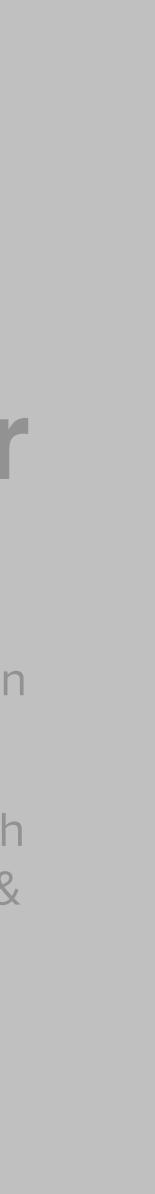
EUA vs Process vs Risks

Stopping the Gain-of-Function Research

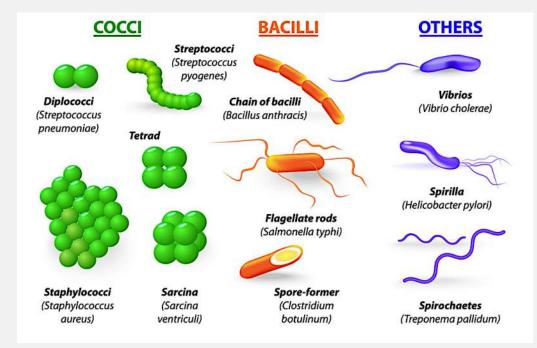
Government Interference with Physician-Patient Treatment & **Forced Vaccination** 

Be Heard

Petition



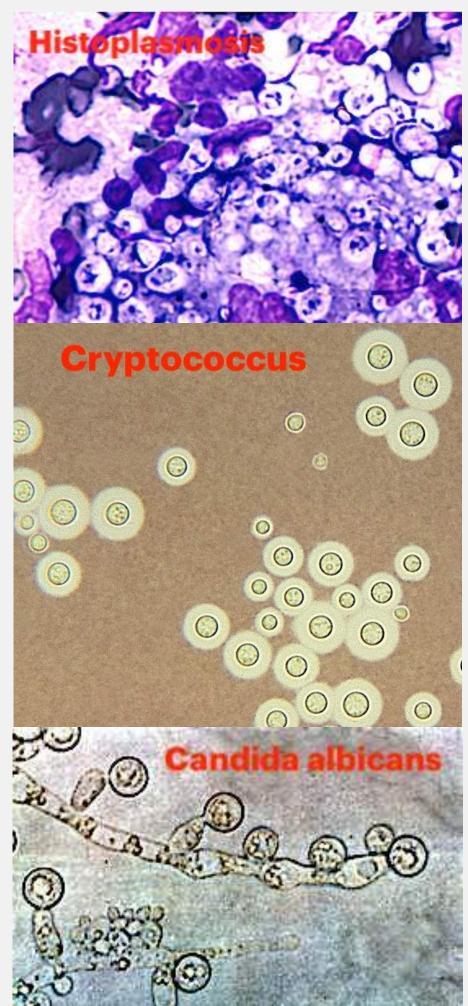
### Bacteria





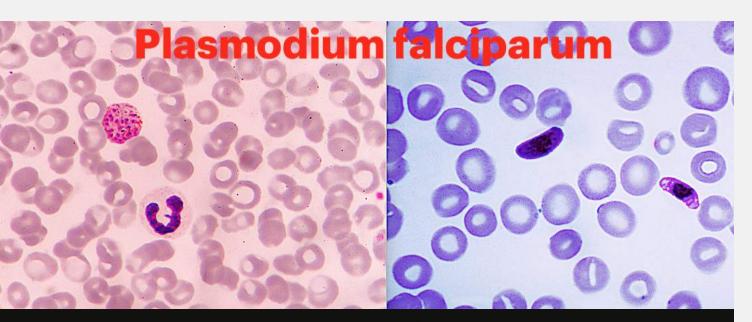


### Fungi/Yeast



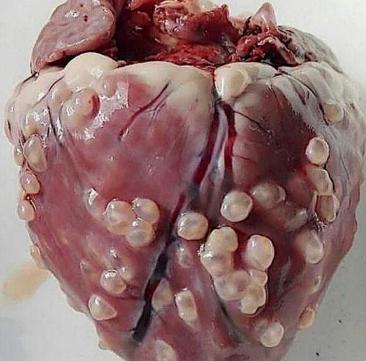


### Parasites

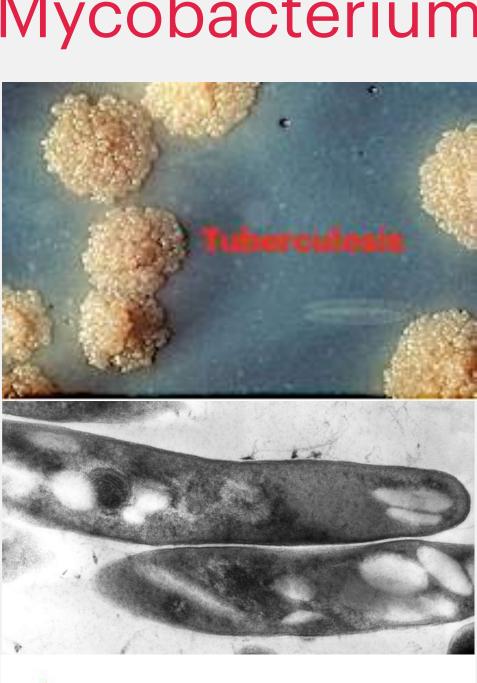




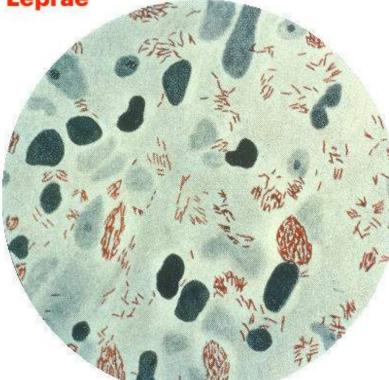




### Mycobacterium



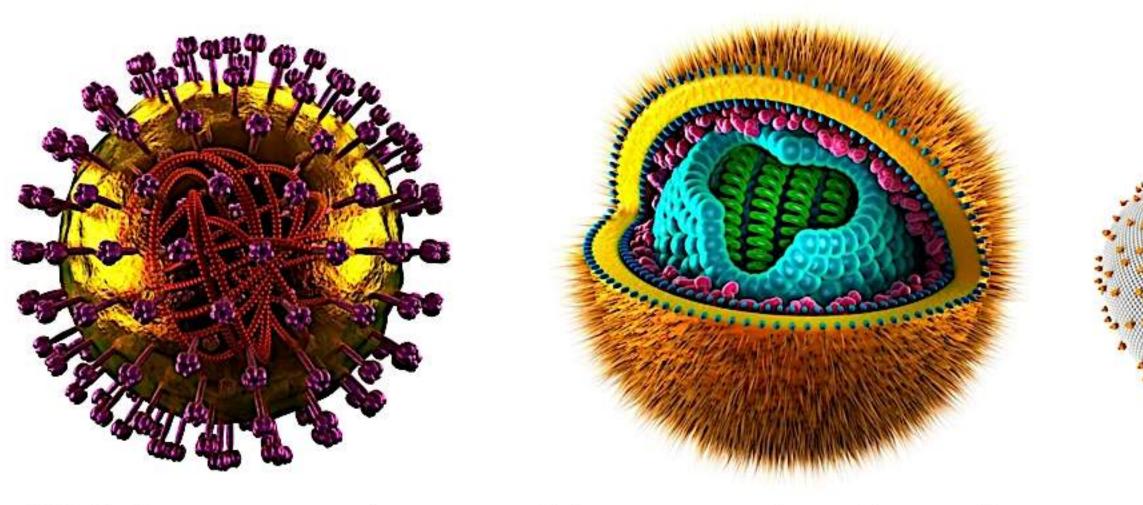






## Viruses

### Unlike the other Infectious Agents Viruses do **NOT** have a Nucleus or Ribosomes, They can't independently reproduce, or make their own energy (mitochondria/chloroplasts).

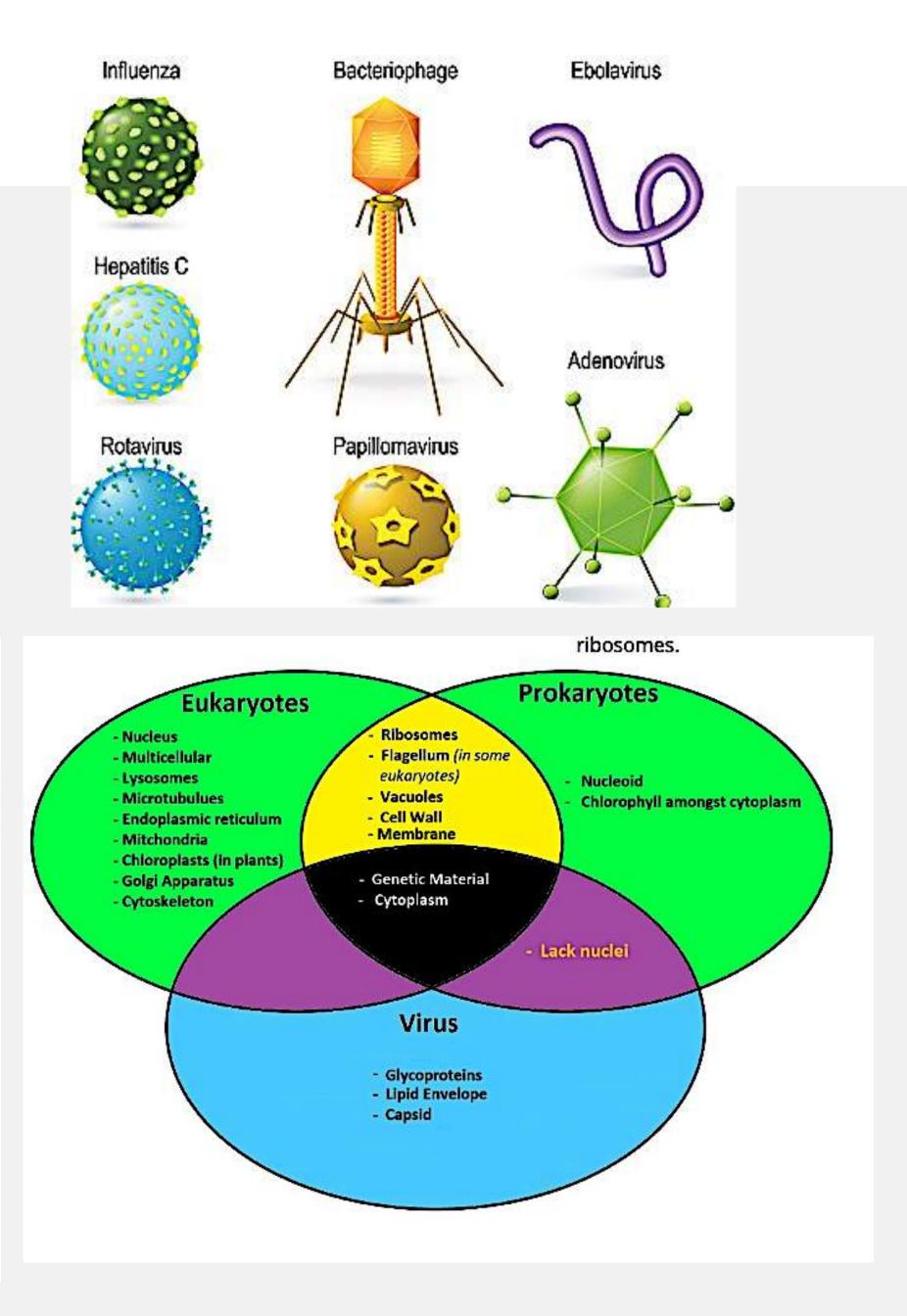


Chickenpox virus

Herpes simplex virus

a dering and a start of the sta

Ebola virus



## **Treating Viruses**

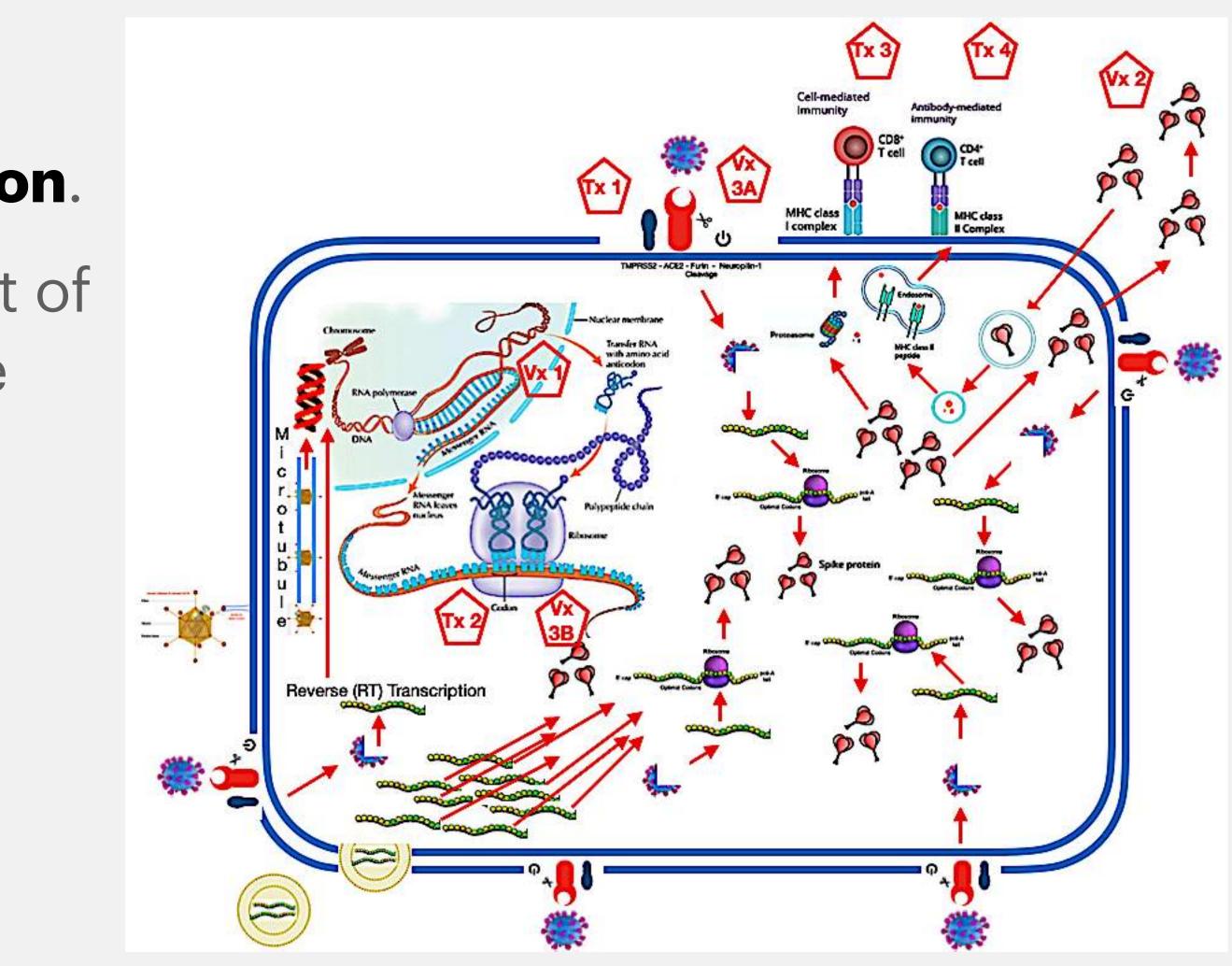
### Must Focus on:

## 1) Viral Attachment and/or Replication.

2) Patient Oxygenation and treatment of Acute Respiratory Distress Syndrome (ARDS) - **ITR**.

3) The Initial Acute Innate T-cell Cytotoxic Response - **ITR**.

4) The Delayed Adaptive Humoral (Antibody) Response - **ITR**.



## **Successful Mechanisms of Action.**

Treatment	Viral Attachment and Replication	Innate T-cell Cytotoxic Response	Oxygenation and ARDS**	Adaptive Humoral (Antibody) Response.	Treatment	Viral Attachment and Replication	Innate T-cell Cytotoxic Response	Oxygenation and ARDS**	Adaptive Humora (Antibody) Respo
1,25-Dihydroxycholecalciferol (Vit. D3)		Improved immune response.		Improved immune response.	Doxycycline	Inhibition of viral protein translation.			
Ascorbic Acid (Vit. C)		Improved immune response.		Ascorbic Acid (Vit. C)	Folate (Vit. B9)		Improved immune response and reduction of inflammatory		Improved immune response and redu inflammatory
Atrovent			$\beta$ –2 bronchodilator to				homocysteine.		homocysteine.
			increase airway diameter and reduce bronchial secretions without the		Hydroxychloroquine	Inhibits viral RNA replication.	Inhibits toll-like receptor 7 (TLR7) to reduce inflammatory response.		Inhibits glycoprote IIb/IIIa thereby in with thrombus for
			increase in heart rate and potential QTc prolongation associated		Hydroxychloroquine	Inhibits viral attachment at ACE2 receptor site.	Reduces the production of pro-inflammatory cytokines.		
	x		with $\beta$ -1 agonists.		Hydroxychloroquine	Enhances entry of zinc			
Azithromycin	Inhibition of viral protein translation.				Hydroxychloroquine	through zinc ionophore. Increases cytosol pH to reduce removal of viral	Increases cellular pH decreasing major		
Clindamycin	Potential inhibitor of viral attachment by inhibiting Transmembrane protease serine 2 (TMPRSS2).					envelope required for replication.	histocompatability complex (MHC) viral antigen presentation to $\beta$ - cells thereby decreasing		
Clindamycin	Inhibition of viral protein translation.	Inhibits cytokine release decreasing tissue necrosis	-	Inhibits cytokine release decreasing tissue necrosis			release of inflammatory cytokines.		
	factor – alpha (TNF- $\alpha$ ) and IL-1 $\beta$ (Interleukin-1		factor – alpha (TNF- $\alpha$ ) and IL-1 $\beta$ (Interleukin-1	Hydroxychloroquine	Enhances production of Type I Interferons.				
		beta).	5	beta).	Interferon α-2β	Interferes with viral replication.	Reduction of IL-6 levels.		Reduction of IL-6
Convalescent Plasma				Provides passive immunity reducing	Losartan***			Potential to decrease ARDS.	
				potential ITR although the increased fibrinogen levels associated with plasma transfusions may	Magnesium		Improved immune response and reduction of QTc prolongation potential.		Improved immune response and redu QTc prolongation potential.
				increase thrombus formation.	Methylprednisolone		-	Stimulates $\beta$ -2 receptors improving airway flow.	
Cyanocobalamin (Vit. B12)		Improved immune		Improved immune	Methylprednisolone			Decreases endothelial leakage producing ARDS.	
		response and reduction of inflammatory		response and reduction of inflammatory	Methylprednisolone		Reduces IL-6 levels.		Reduces IL-6 leve
		homocysteine.		homocysteine.	Oxygen (supplemental) other than ventilator.* [Prone			Reduced inflammatory stretching of alveoli and	



## **Successful Mechanisms of Action.**

Treatment	Viral Attachment and Replication	Innate T-cell Cytotoxic Response	Oxygenation and ARDS**	ť
	Replication	response	mass	1
positioning, BiPAP, V-V ECMO, V-A ECMO, NC, Venti Mask.]			subsequent worsening of ARDS.	
Primaquine	Inhibits entry of Virulent Newcastle Disease (VND) virus.			
Primaquine	Inhibits viral RNA replication and protein translation.			
Pyridoxine (Vit. B6)		Improved immune response and reduction of inflammatory homocysteine.		I r ii h
Remdesivir	Interferes with formation of mRNA via RdRP.****			
Tocilizumab		Blocks IL-6 receptors reducing ITR.		E r
Zinc	May reduce ACE2 receptor activity.			
Zinc	Interferes with RdRP and polyprotein transcription.			
Zinc		Improved immune response.		I r

\* BiPAP = Bilevel Positive Airway Pressure, V-V is vein to vein, V-A is vein to artery, ECMO = extracorporeal membrane oxygenation, NC = nasal cannula, and Venti = Venturi.

\*\* Acute Respiratory Distress Syndrome.

\*\*\* Originally included in study design with prior pre-clinical studies in animals suggesting a possible mechanism of action inhibiting ARDS with H5N1 virus. Excluded from study after IRB review and consideration of concerns for angiotensin-converting-enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs). Included in this table for completeness. \*\*\*\* RdRP = RNA dependent RNA polymerase.

Adaptive Humoral	
(Antibody) Response.	
	-
	ł
Improved immune	Ī
response and reduction of	
inflammatory	
homocysteine.	
	Ì
Blocks IL-6 receptors	
reducing ITR.	-
Improved immune	ľ
response.	

**Absent Treatments** We Are Left with **VACCINES.** 

### **CONTROVERSY & INTERFERENCE** WITH MEDICAL TREATMENTS.

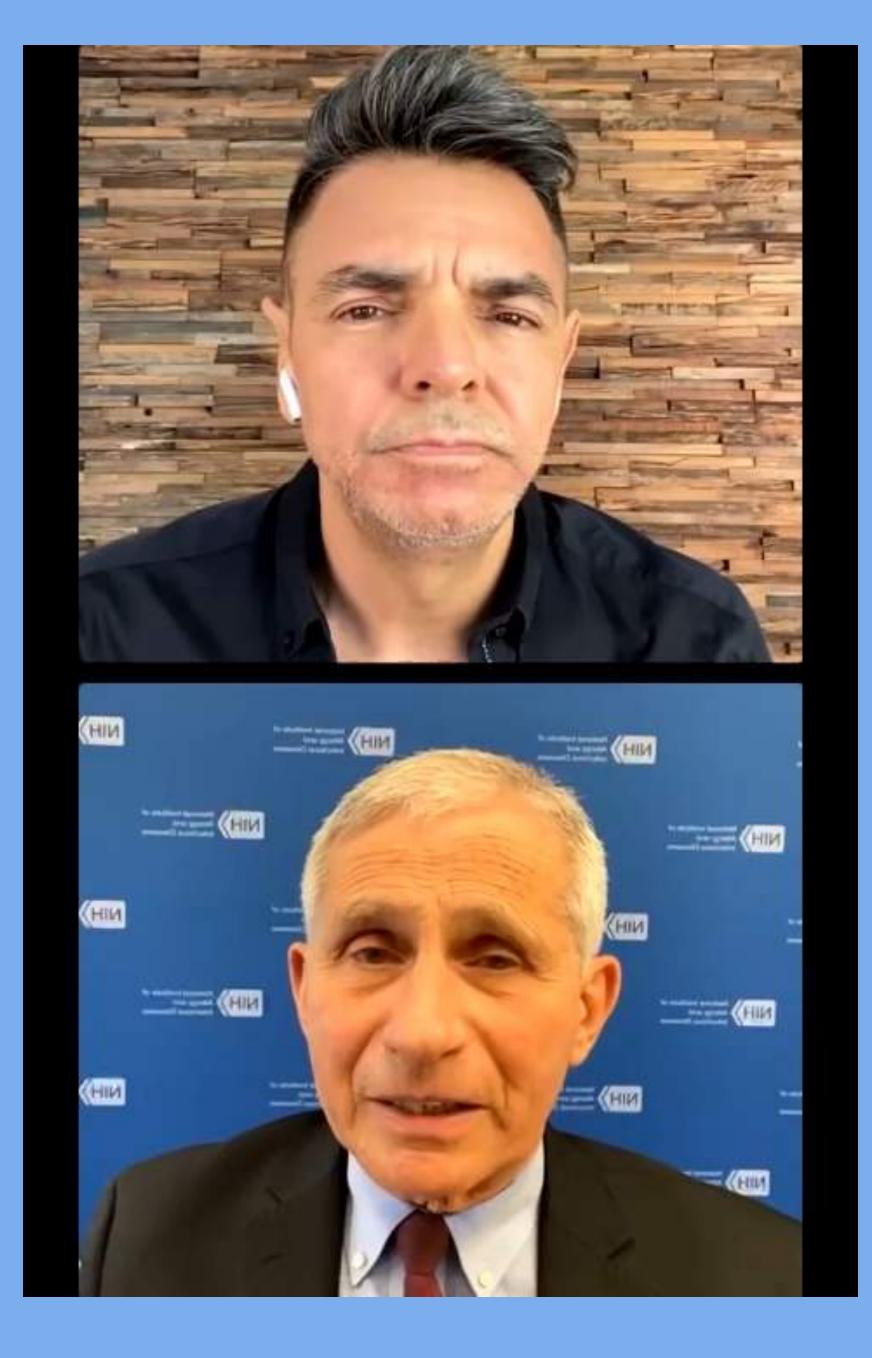
Interference with Physician Decision Making Access to Treatments Lack of Support for Doctors by Peers Pharmacy board obstruction Medical board obstruction



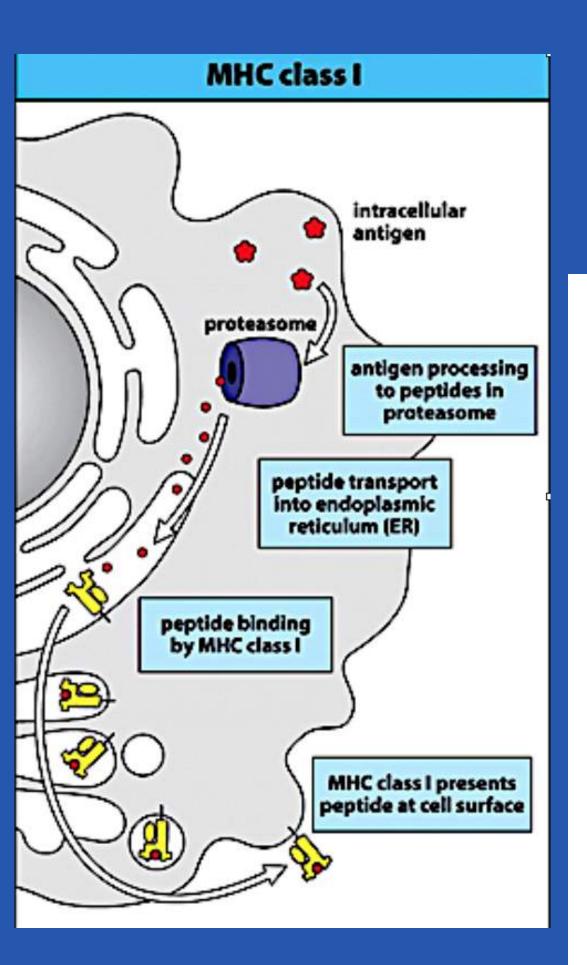
# Vaccines do NOT Prevent you from

## **Becoming Infected**

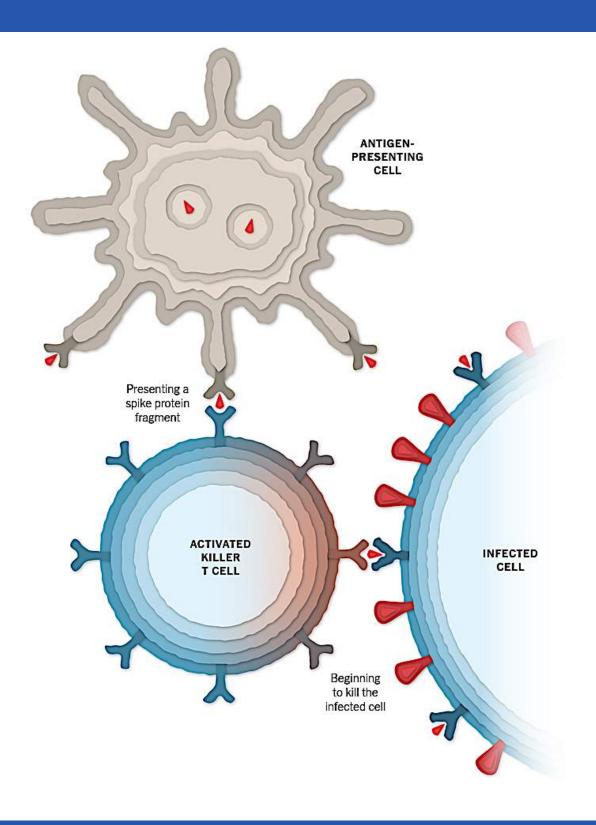
or Spreading the Infection.

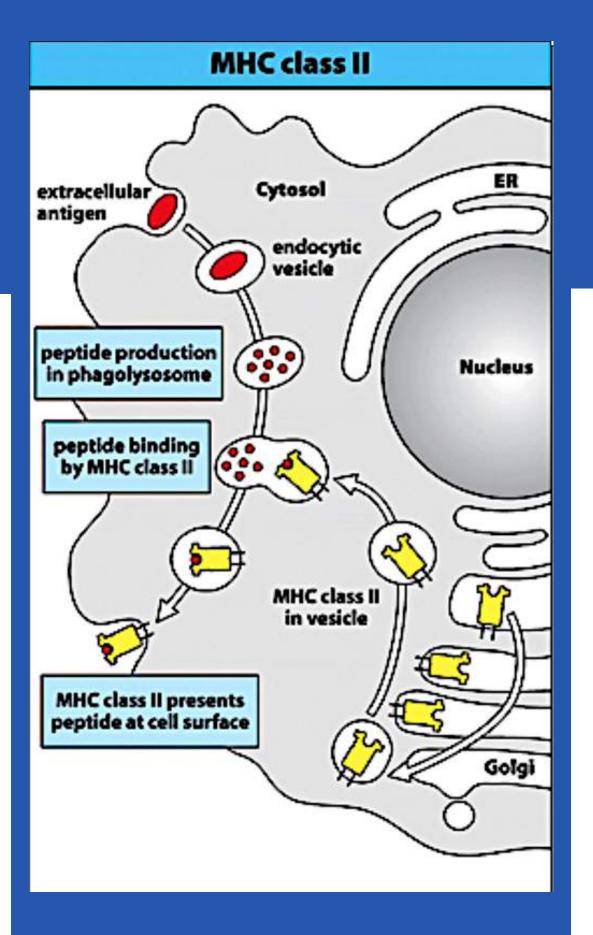


## Vaccines Prepare You for When You Become Infected.

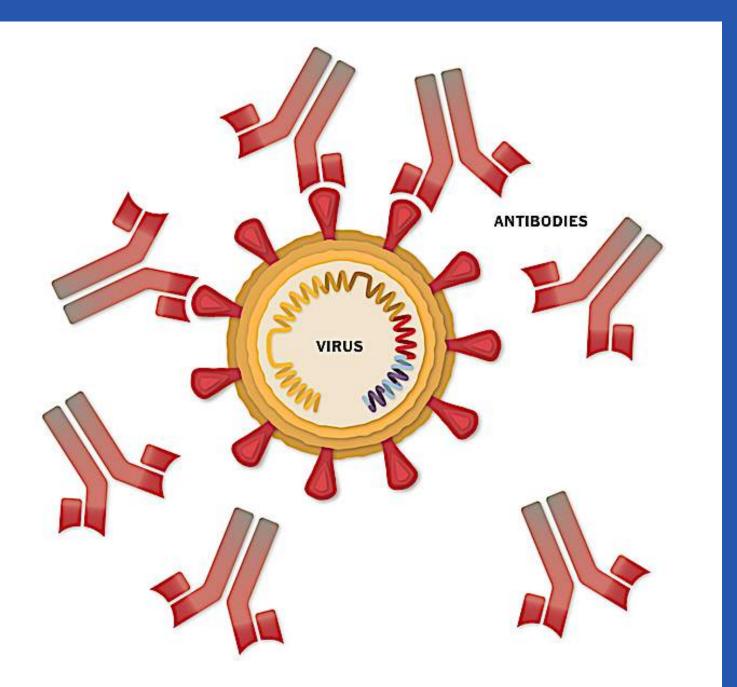


### T-cells MHC-I





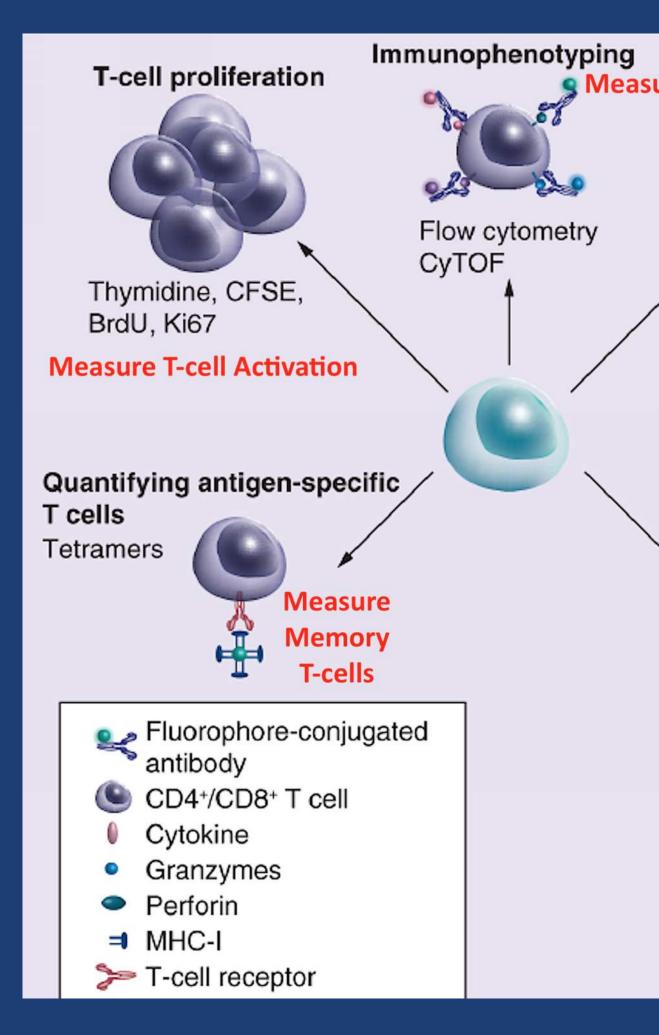
### B-cells MHC-II



## How Do Scientists Know if a Vaccine Works?

### Is There a T-cell Response?

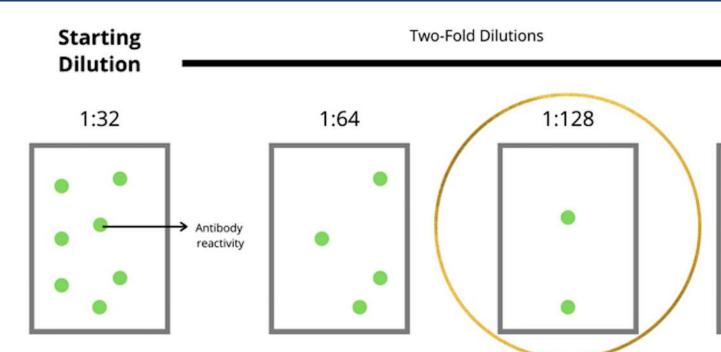
- We measure the immune response to the vaccine?
  - T-cell (cells and cytokines) and
  - B-cell (antibody) responses.





Measure Specific T-cell Responses Cytokine based ELISA CBA, Luminex Cytokine secretion ICS ELISPOT **Measure T-cell Function** Cytotoxic potential <sup>51</sup>Cr release Caspase activation CD107a **Measure Ability of T-cells to Kill APCs** 

Is There a B-cell Response? -Antibody Titers. Diluting blood (1:2, 1:4, 1:8, etc.) Measuring Ag-Ab precipitation.

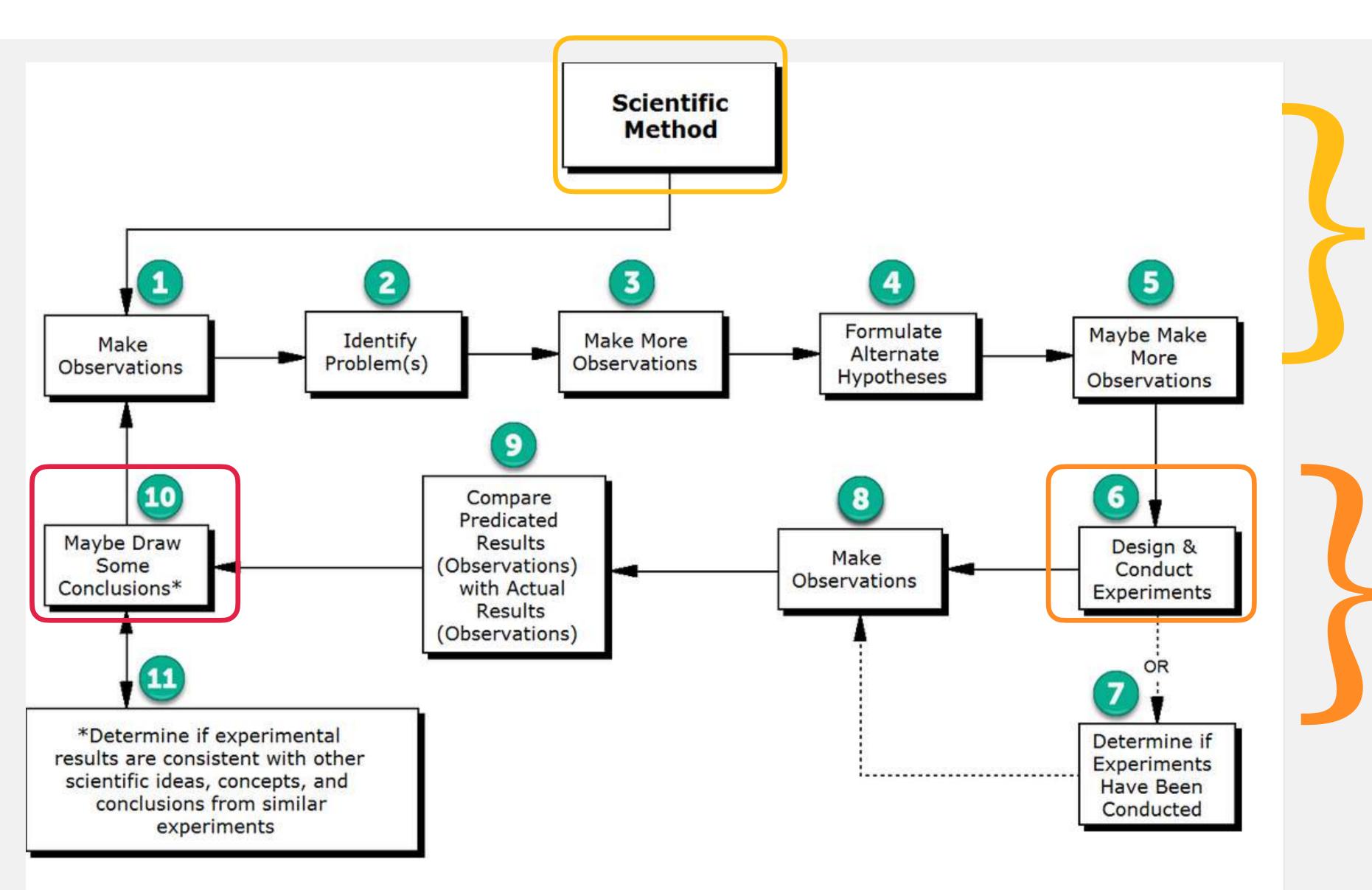


The test sample goes through a series of dilutions. This patient would have an antibody titer of 1:128 because fluorescence, or reactivity, was not observed on the slide at the 1:256 dilution.



# So how do scientists actually know if a drug or biological (vaccine) agent works?

# We Conduct Research Experiments.



Clinical Observations With Limitations

Measured Outcomes Defining Beneficial and Detrimental Treatments

# **Before We Ever Begin Testing People**

We Begin with **Pre-Clinical** Testing.

- When possible **computer** modeling and work on isolated **cell cultures** and **tissue**. 1) At some point you need to know what happens to a living creature.
- **Animal** testing has been an obligatory step **before testing on humans**. 2)
  - EU Directive 2001/83/EC 1)
  - FDA Product Development under the Animal Rule 2)
  - 3)
  - 1947 Nuremburg Code 4)
  - International Covenant on Civil and Political Rights 5)
  - The American Medical Association Code of Medical Ethics **6**)

World Medical Association's "Ethical Principles for Medical Research Involving Human Subjects".

# Phases of Clinical Trials.

Testing of a drug or medical procedure takes time to ensure Efficacy & Safety.

- There are **3 fundamental principles** followed 1) to protect the well-being of the research animals.
  - **Reduce** the number of animals to a 1) minimum
  - 2) **Reduce** or minimize the harm and injury to the animal
  - 3) **Replace** animal experiments with nonanimal studies wherever possible.
- Once you **know enough** from the animal 2) studies to determine RISKS & BENEFITS, **THEN** human research trials are considered.



https://rumble.com/veoy2x-emily-and-jackie-our-most-important-message-yet.html



## Phases of Clinical Trials

Clinical Trials on **Humans** to ensure **Safety** & **Efficacy**.

**Phase I** - Determine **Safety**. If you can't find a **safe dose**, then it doesn't matter if it works. **Small** in **numbers** & **healthy** people. Testing for: **Safety** of Drug & Toxicity Side Effects - Harm, Injury Safe **Dosage** Range - Limits **How** is the drug absorbed, metabolized, distributed and eliminated from the body. (I.e. Pharmacokinetics; Pharmacodynamics)

- Phase II (aka Exploratory Trials) If a Safe Dose is Found Does the Drug Work? Larger numbers of people with the disease. Does the drug work for people you are intending to treat. Testing for:
  - Phase **IIB How well** dose the drug work & for **what disease**(s)?

Phase **IIA** - **How much** (dose) of the **drug** should people receive? What **dose** is safe?

# Phases of Clinical Trials.

- **Phase III** How does the drug <u>compare</u> with that <u>already used</u> for the problem? Testing for:

  - the people the drug is intended to treat. Monitor side effects & risks.
  - **Test different doses** and different ways of giving the drug.
- **Phase IV** Post Marketing Surveillance Studies (aka **Pharmacovigilance**). Testing for:
  - The **long-term effect** of the drug or treatment. Study other impact or use of the drug.

This phase of research occurs when there is compelling evidence of efficacy & safety.

Demonstrate the drug is **Effective & Safe in a larger number of patients** in the target group

Can the drug be used at different stages of the disease being treated - early, late ....

Provide sufficient information about the drug for marketing approval -> FDA.

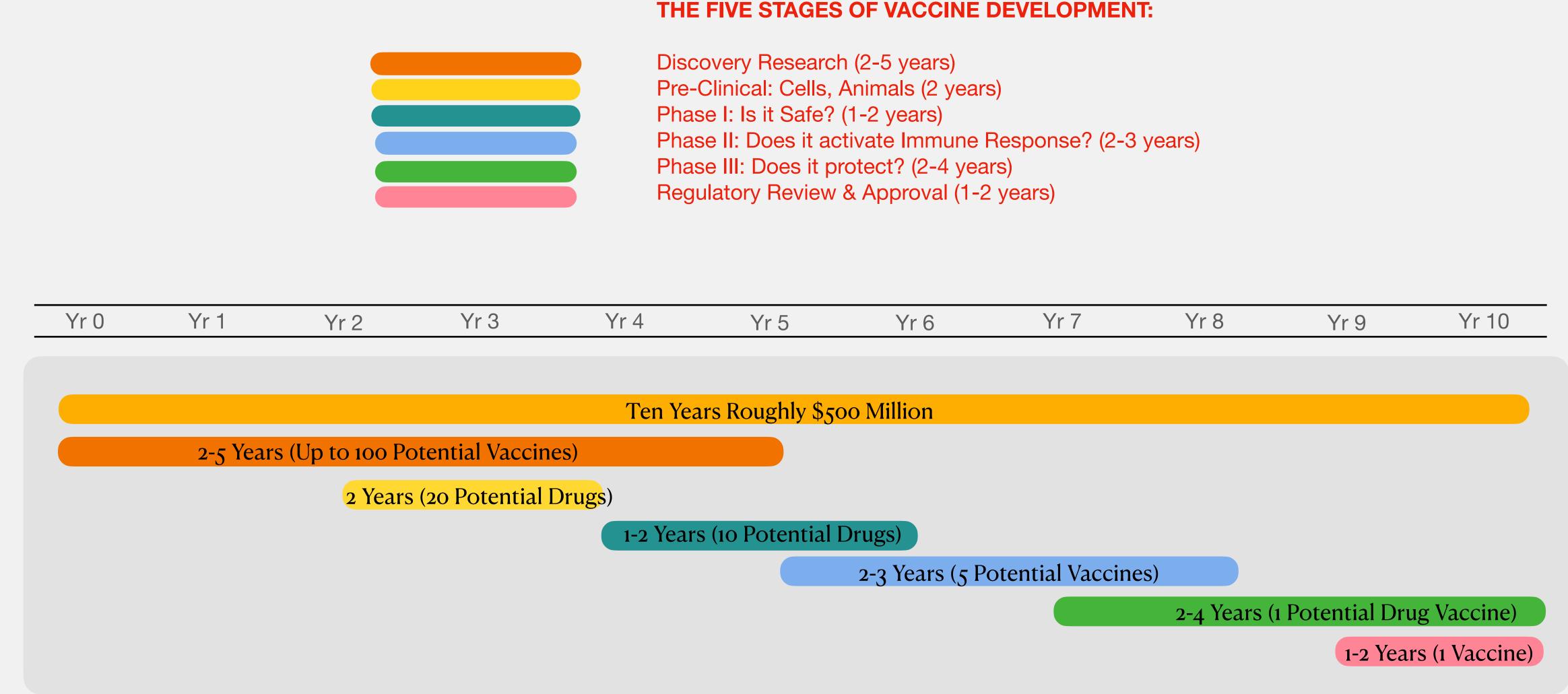
# **Recapping Human Clinical Research Trials**

- **Phase 2 Is it Effective?** 
  - **Phase 3 Is it Better?**

(This is The Slide My Students Wish I Made for Them)

- **Tissue, Computer & Animal Studies Is it Safe Enough to Test in People?** 
  - **Phase I Is it Safe?**

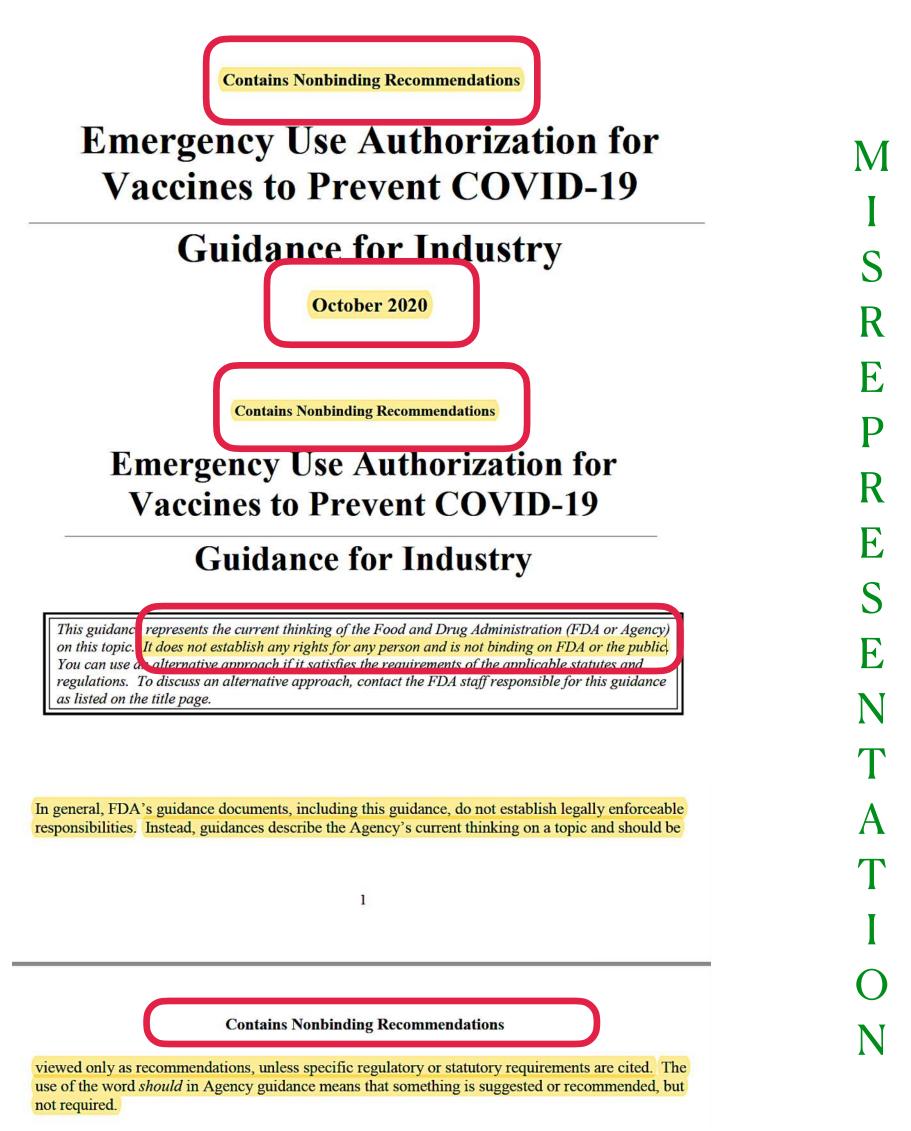
## So How Long Does This Usually Take for Vaccines?



https://www.weforum.org/agenda/2020/06/vaccine-development-barriers-coronavirus/



## EUA Bypass The Scientific Method



### So By Definition The EUA No Longer Exists and the Use of PCR and These Experimental Drug Vaccines Are Therefore No Longer Valid.

### III. CRITERIA AND CONSIDERATIONS FOR THE ISSUANCE OF AN EUA FOR A COVID-19 VACCINE

On February 4, 2020, pursuant to section 564(b)(1)(C) of the FD&C Act (21 U.S.C. 360bbb-3(b)(1)(C)), the Secretary of HHS determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of such determination, on March 27, 2020, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564(b)(1) of the FD&C Act (21 U.S.C. 360bbb-3(b)(1)).<sup>3</sup>

Based on this declaration and determination, FDA may issue an EUA after FDA has determined that the following statutory requirements are met (section 564 of the FD&C Act (21 U.S.C. 360bbb-3)) (Ref. 3):

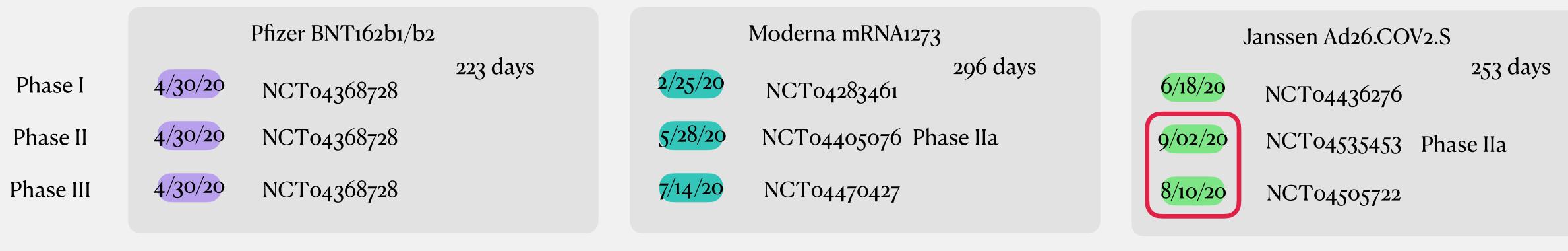
- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition.
- Based on the totality of scientific evidence available, including data from adequate and wellcontrolled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.

 There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

In the case of investigational vaccines being developed for the prevention of COVID-19, any assessment regarding an EUA will be made on a case by case basis considering the target population, the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product.



# The EUA Violation of The Scientific Method



Yr 0	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10



https://www.weforum.org/agenda/2020/06/vaccine-development-barriers-coronavirus/





## The Swine Flu Vaccine



## Let's Take an In-depth Look at These EUAs and See What They Say. www.FlemingMethod.com

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Publications

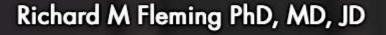
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https://www.flemingmethod.com



COVID-19 EVENT 2021

Fleming Method

### SARS-CoV-2

#### Almost a third of recovered Covid patients return to hospital in five months and one in eight die

Research has found a devastating long-term toll on survivors, with people developing heart problems, diabetes and chronic conditions

By Sarah Knapton, SCIENCE EDITO

The Telegraph

Richard M Fleming PhD, MD, JD

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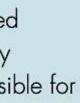
COVID-19 EVENT 2021 Fleming Method About More

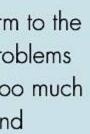
#### DOCUMENTATION

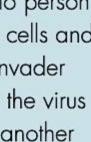
The following diagram shows how SARS-CoV-2 is passed from person to person through respiratory droplets. Once inside the body the virus will invade our cells and reproduce itself. In response to the virus our immune system will attack the invader launching first a response from T-cells designed to kill the cells infected with the virus and later an antibody response designed to kill the virus before it gets into another cell

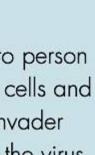
This diagram also shows how too much of a good thing can cause harm to the body. When our VIRAL immune response, either because of other health problems we have (comorbidities) produce too much response OR because there is too much of the virus (e.g. vaccines) in our body; the outcome is INFLAMMATION and BLOOD CLOTTING (InflammoThrombotic Response - ITR) that can kill us (COVID-19).

The document numbers listed on the diagram below match the numbered documents providing links to the research as well as other materials not only explaining these issues but also the Gain-of-Function (GoF) research responsible for the development of this man-made virus.











# Do The Vaccines Reduce Your Risk of COVID

Relative Risk	Absolute Risl
Reduction (RRR/RR)	(AR
The relative decrease in being diagnosed with COVID between those vaccinated and those not.	The actual between those vaccinated vaccin

sk Reduction RR)

al difference se two groups ed vs nonnated. Number Needed to Vaccinate (NNV) =

### 1 ÷ ARR

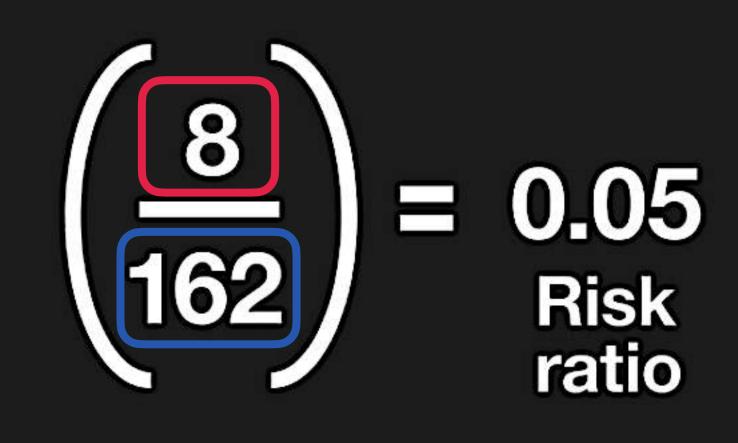
The number of people you need to vaccinate to prevent 1-person from being diagnosed with COVID.

## What Does Vaccine Efficacy (RRR) Really Mean?

### Vaccine Efficacy is 1 minus the Risk Ratio (x 100 for %).

**Risk Ratio**: The number of people diagnosed with COVID after receiving the Vaccine + The number of people diagnosed with COVID who weren't vaccinated.

## Calculating efficacy



### $0.05 \equiv 0.95$ Efficacy



### So How Did They Decide Who Has COVID? Diagnosing COVID-19 in Vaccine Trials = PCR(+) & Symptomatic. Moderna Pfizer Janssen (J&J)

For the primary efficacy endpoint, the case definition for a confirmed COVID-19 case was the presence of at least one of the following symptoms and a positive SARS-CoV-2 NAAT within 4 days of the symptomatic period:

- Fever;
- New or increased cough;
- New or increased shortness of breath:
- Chills:
- New or increased muscle pain;
- New loss of taste or smell;
- Sore throat;
- Diarrhea;
- Vomiting.

For a secondary efficacy endpoint, a second definition, which may be updated as more is learned about COVID-19, included the following additional symptoms defined by CDC (listed at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html)

- Fatigue;
- Headache;
- Nasal congestion or runny nose;
- Nausea.

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)</li>
- Significant acute renal, hepatic, or neurologic dysfunction;

\*Kary Mullis & PCR

- Admission to an ICU;
- Death.

#### Primary Efficacy Endpoint

The primary efficacy endpoint was efficacy of the vaccine to prevent protocol-defined COVID-19 occurring at least 14 days after the second dose in participants with negative SARS-CoV-2 status at baseline (i.e., negative RT-PCR and negative serology against SARS-CoV-2 nucleocapsid on Day 1). The primary analysis was based on the Per-Protocol Set, defined as all randomized, baseline SARS-CoV-2 negative participants who received planned doses per schedule and have no major protocol deviations. For the primary efficacy endpoint, the case definition for a confirmed COVID-19 case was defined as:

- At least TWO of the following systemic symptoms: Fever (≥38°C), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), or
- At least ONE of the following respiratory signs/ symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia; and
- NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR.

#### Secondary Efficacy Endpoints

Secondary endpoints based on the Per-Protocol Set included the VE of mRNA-1273 to prevent the following:

- Severe COVID-19 (as defined below)
- COVID-19 based on a less restrictive definition of disease (defined below) occurring at least 14 days after the second dose of vaccine
- Death due to COVID-19
- COVID-19 occurring at least 14 days after the first dose of vaccine (including cases that occurred after the second dose)

One additional secondary endpoint was based on the Full Analysis Set (FAS): VE of mRNA-1273 to prevent COVID-19 occurring at least 14 days after the second dose, regardless of prior SARS-CoV-2 infection

One of the secondary efficacy endpoints assessed COVID-19 as defined by a less restrictive definition: a positive NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) for SARS-CoV-2 by RT-PCR and one of the following systemic symptoms:

- fever (temperature ≥38°C), or
- chills,
- cough, shortness of breath or difficulty breathing,
- fatigue,
- muscle aches or body aches,
- headache,
- new loss of taste or smell.
- sore throat, nasal congestion or rhinorrhea,
- nausea or vomiting, or diarrhea

Another secondary endpoint assessed cases of severe COVID-19, defined as a case of confirmed COVID-19 plus 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 or Acute Respiratory Distress Syndrome, (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

#### Moderate COVID-19

#### Severe/Critical COVID-19

#### Any 1 of the following new or worsening signs or symptoms:

- Respiratory rate ≥20 breaths/minute
- Abnormal saturation of oxygen (SpO<sub>2</sub>) but still >93% on room air at sea level
- Clinical or radiologic evidence of pneumonia
- Radiologic evidence of deep vein thrombosis
- Shortness of breath or difficulty breathing

#### OR

#### Any 2 of the following new or worsening signs or symptoms:

- Fever (≥38.0°C or ≥100.4°F)
- Heart rate ≥90 beats/minute
- Shaking chills or rigors
- Sore throat
- Couah
- Malaise as evidenced by loss of appetite,
- fatigue, physical weakness, and/or feeling unwell Headache
- Muscle pain (myalgia)
- · Gastrointestinal symptoms (diarrhea, vomiting, nausea, abdominal pain)
- New or changing olfactory or taste disorders
- · Red or bruised looking feet or toes

#### Any one of the following at any time during the course of observation:

- Clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths/minute, heart rate ≥125 beats/ minute, oxygen saturation (SpO₂) ≤93% on room air at sea level, or partial pressure of oxygen/fraction of inspired oxygen (PaO<sub>2</sub>/ FiO<sub>2</sub>) <300 mmHg)
- Respiratory failure (defined as needing) high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation [ECMO])
- Evidence of shock (defined as systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg, or requiring vasopressors)
- Significant acute renal, hepatic, or neurologic dysfunction
- Admission to the ICU
- Death





## Let's Look at Pfizer Vaccine Efficacy.

### The calculated Vaccine Efficacy was 95%. Page 24 of EUA.

Table 6. Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants Without Evidence of Prior SARS-Cov-2 Intection - Evaluable Efficacy Population

	BNT162b2 N <sup>a</sup> = 18198	Placebo N <sup>a</sup> =18325		
	Cases n1 <sup>b</sup>	Cases n1 <sup>b</sup>	Vaccine	Met Predefined
Pre-specified Age Group	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	Efficacy % (95% CI)	Success Criterion*
All participants	2.214 (17411)	162 2.222 (17511)	95.0 (90.3, 97.6) <sup>e</sup>	Yes
16 to 55 years	5 1.234 (9897)	114 1.239 (9955)	95.6 (89.4, 98.6) <sup>f</sup>	NA
> 55 years and older	3 0.980 (7500)	48 0.983 (7543)	93.7 (80.6, 98.8) <sup>f</sup>	NA

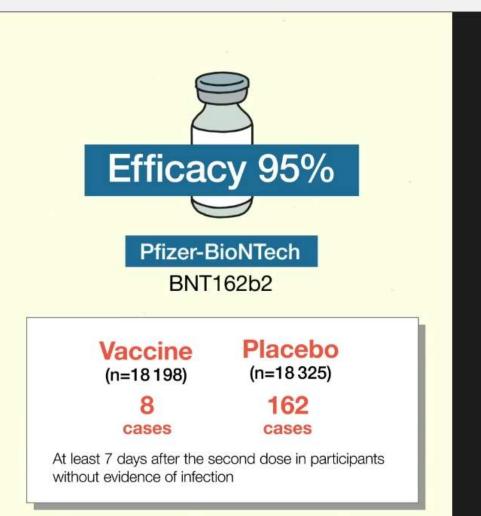
\*Success criterion: the posterior probability that true vaccine efficacy > 30% conditioning on the available data is >99.5% at the final analysis

<sup>a</sup> N = number of participants in the specified group.

<sup>b</sup> n1 = Number of participants meeting the endpoint definition.

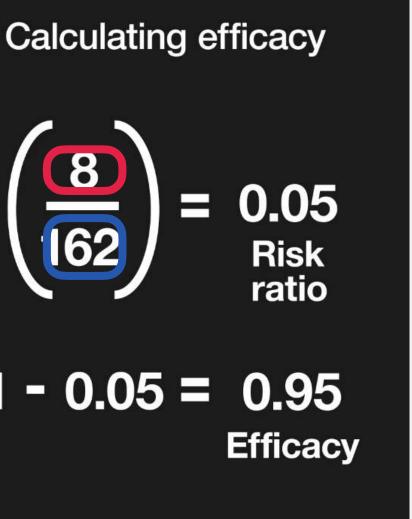
<sup>c</sup> Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period. <sup>d</sup>n2 = Number of participants at risk for the endpoint.

<sup>e</sup> Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. <sup>f</sup> Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.





1 - 0.05 = 0.95



## But the Goal is to Prevent COVID

### Did The Pfizer Vaccine Do Better at Preventing COVID Than Having No Vaccine?

Table 6. Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection - Evaluable Efficacy Population

	BNT162b2	Placebo		
	N <sup>a</sup> = 18198	N <sup>a</sup> =18325		
	Cases	Cases		Met
	n1 <sup>b</sup>	n1 <sup>b</sup>	Vaccine	Predefined
	Surveillance	Surveillance	Efficacy %	Success
Pre-specified Age Group	Time <sup>c</sup> (n2 <sup>d</sup> )	Time <sup>c</sup> (n2 <sup>d</sup> )	(95% CI)	Criterion*
All participants	8	162	95.0	Yes
	2.214 17411	2.222 (17511)	(90.3, 97.6) <sup>e</sup>	
16 to 55 years	5	114	95.6	NA
	1.234 (9897)	1.239 (9955)	(89.4, 98.6) <sup>f</sup>	
> 55 years and older	3	48	93.7	NA
	0.980 (7500)	0.983 (7543)	(80.6, 98.8) <sup>f</sup>	

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

<sup>a</sup> N = number of participants in the specified group.

<sup>b</sup> n1 = Number of participants meeting the endpoint definition.

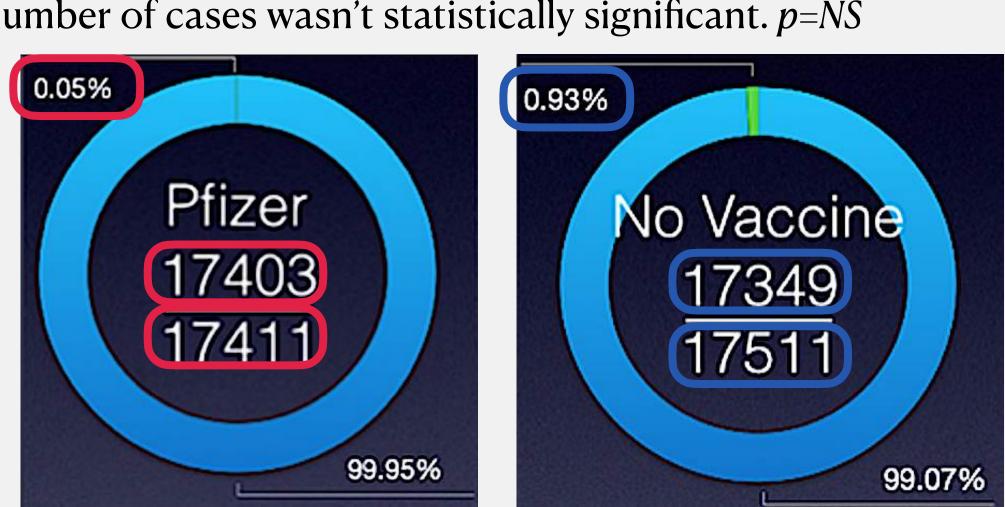
<sup>c</sup> Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period. <sup>d</sup> n2 = Number of participants at risk for the endpoint.

<sup>e</sup> Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.

<sup>f</sup> Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

### Absolute Risk Reduction (ARR) = 0.93%

7 Days after 2<sup>nd</sup> Injection there were fewer cases of COVID but The Difference in the number of cases wasn't statistically significant. *p*=*NS* 



	Observed	Expected	Marginal Row
Pfizer	17403 (17326.25) [0.34]	17249 (17325.75) [0.34]	34652
Nothing	17349 (17425.75) [0.34]	17502 (17425.25) [0.34]	34851
Marginal Column Totals	34752	34751	69503 (Grar

The chi-square statistic is 1.3561. The *p*-value is .244218 *Not* significant at p < .05.

minus 0.05%

The chi-square statistic with Yates correction is 1.3385. The *p*-value is .247304. Not significant at p < .05.

.88%





# **Did the Pfizer Vaccine Reduce COVID Deaths?**

### Going to the Pfizer EUA Documents (page 41 Where We Find this Information.

#### Deaths

A total of six (2 vaccine, 4 placebo) of 43.448 enrolled participants (0.01%) died during the reporting period from April 29, 2020 (first participant, first visit) to November 14, 2020 (cutoff date). Both vaccine recipients were >55 years of age; one experienced a cardiac arrest 62 days after vaccination #2 and died 3 days later, and the other died from arteriosclerosis 3 days after vaccination #1. The placebo recipients died from myocardial infarction (n=1), hemorrhagic stroke (n=1) or unknown causes (n=2); three of the four deaths occurred in the older group (>55 years of age). All deaths represent events that occur in the general population of the age groups where they occurred, at a similar rate.

## There is no statistically significant difference in the numbers of deaths and they represent what is seen in the general population.

1)	Issue	Pfizer	No Vaccine
')	Death	2 of 21621 (0.0%)	4 of 21631 (0.0%)
	MI		1
	Cardiac arrest	1	
5 5 S	ASCAD	1	
s	Hemorrhagic CVS		1
	Unknown		2





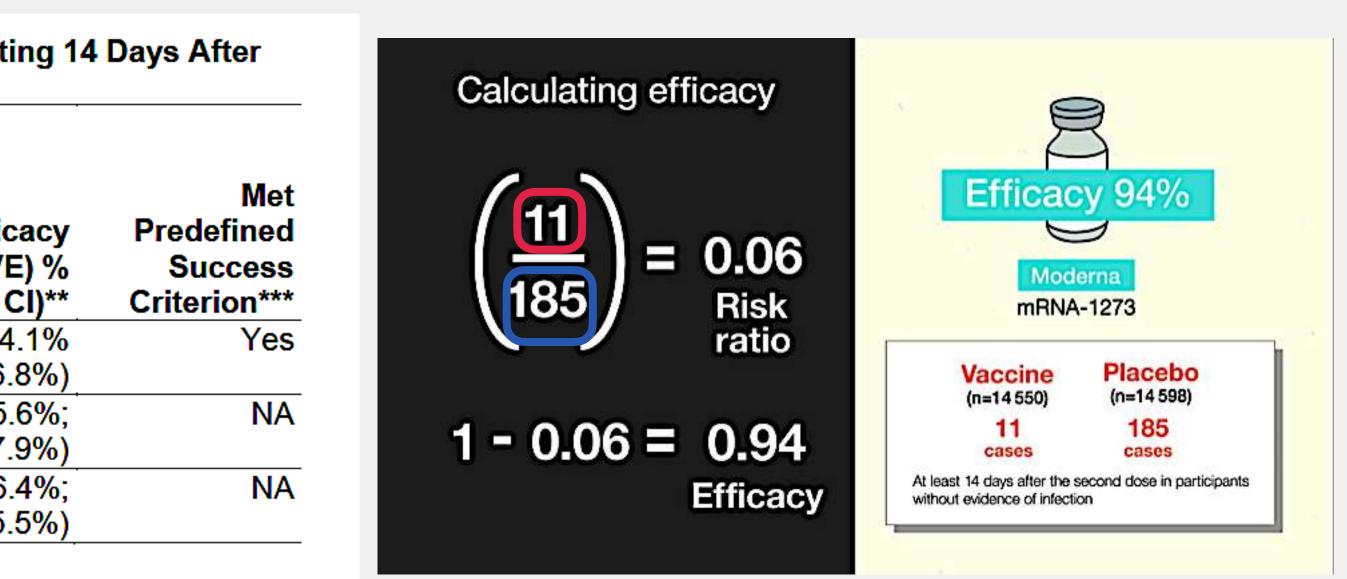


# Let's Look at Moderna Vaccine Efficacy.

## The calculated Vaccine Efficacy was 94%. Page 29 of EUA.

Table 17. Final Scheduled Efficacy Analysis, Primary Endpoint, COVID-19 Starting 14 Days After the Second Dose per Adjudication Committee Assessments, Per-Protocol Set

Primary Endpoint: COVID-19 (per	Vaccine Group N=13934 Cases n (%)	Placebo Group N=13883 Cases n (%)	Vacaina Effia
adjudication	(incluence Rate per	(Incidence Rate per	Vaccine Effic
committee	1,000 person-	1,000 person-	(VE
assessment)	vears)*	vears)*	(95% C
All participants	11 <0.1)	185 (1.3)	94
	3.328	56.510	(89.3%, 96.
18 to <65 years <sup>1</sup>	7/10551 (<0.1)	156/10521 (1.5)	95.
	2.875	64.625	(90.6%, 97.
65 years and older <sup>2</sup>	4/3583 (0.1);	29/3552 (0.8);	86.
	4.595	33.728	(61.4%, 95.



# But the Goal is to Prevent COVID

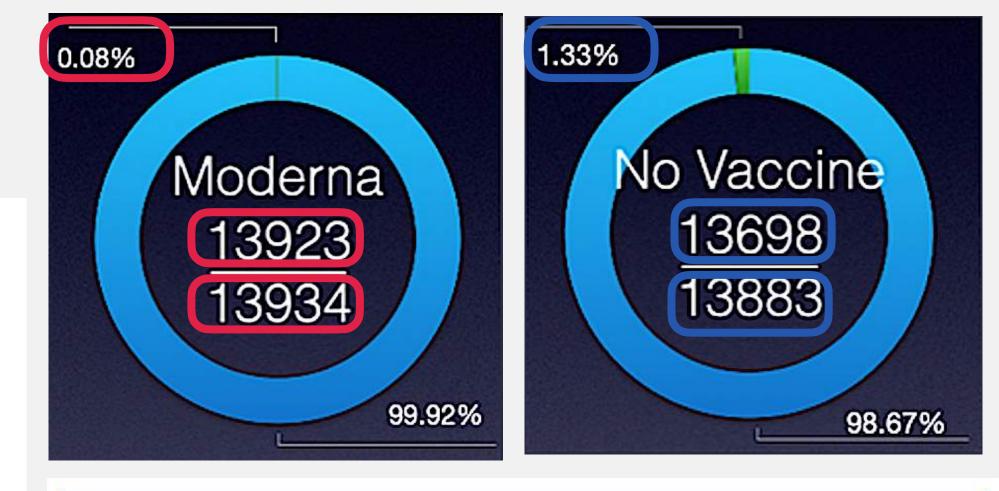
## Did The Moderna Vaccine Do Better at Preventing COVID Than Having No Vaccine?

14 Days after  $2^{nd}$  Injection there were fewer cases of COVID but The Difference in the number of cases wasn't statistically significant. p=NS

Table 17. Final Scheduled Efficacy Analysis, Primary Endpoint, COVID-19 Starting 14 Days After the Second Dose per Adjudication Committee Assessments, Per-Protocol Set

Primary Endpoint:	Vaccine Group N=13934			
COVID-19 (per adjudication committee assessment)	Cases n (%) (Incidence Rate per 1,000 person- years)*	(Incidence Rate per	Vaccine Efficacy (VE) % (95% CI)**	Met Predefined Success Criterion***
All participants	11 < 0.1) 3.328	185(1.3) 56.510	94.1% (89.3%, 96.8%)	Yes
18 to <65 years <sup>1</sup>	7/10551 (<0.1) 2.875	156/10521 (1.5) 64.625	95.6%; (90.6%, 97.9%)	NA
65 years and older <sup>2</sup>	4/3583 (0.1), 4.595	29/3552 (0.8); 33.728	86.4%; (61.4%, 95.5%)	NA

## Absolute Risk Reduction (ARR) = 1.33% minus 0.08% = 1.25%



	Observed	Expected	Marginal Row
Moderna	13923 (13836) [0.55]	13749 (13836) [0.55]	27672
Nothing	13698 (13785) [0.55]	13872 (13785) [0.55]	27570
Marginal Column Totals	27621	27621	55242 (Grand

The chi-square statistic is 2.1923. The *p*-value is .138706 Not significant at *p* < .05.

The chi-square statistic with Yates correction is 2.1671. The *p*-value is .140989. Not significant at p < .05.





# **Did the Moderna Vaccine Reduce COVID Deaths?**

## Going to the Moderna EUA Documents (pages 42-43) We Find this Information.

#### Deaths

As of December 3, 2020, 13 deaths were reported (6 vaccine, 7 placebo). Two deaths in the vaccine group were in participants >75 years of age with pre-existing cardiac disease; one

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Moderna COVID-19 Vaccine VRBPAC Briefing Document

participant died of cardiopulmonary arrest 21 days after dose 1, and one participant died of myocardial infarction 45 days after dose 2. Another two vaccine recipients were found deceased at home, and the cause of these deaths is uncertain: a 70-year-old participant with cardiac disease was found deceased 57 days after dose 2, and a 56-year-old participant with hypertension, chronic back pain being treated with opioid medication died 37 days after dose 1 (The official cause of death was listed as head trauma). One case was a 72-year-old vaccine recipient with Crohn's disease and short bowel syndrome who was hospitalized for thrombocytopenia and acute kidney failure due to obstructive nephrolithiasis 40 days after dose 2 and developed complications resulting in multiorgan failure and death. One vaccine recipient died of suicide 21 days after dose 1. The placebo recipients died from myocardial infarction (n=3), intra-abdominal perforation (n=1), systemic inflammatory response syndrome in the setting of known malignancy (n=1), COVID-19 (n=1), and unknown cause (n=1). These deaths represent events and rates that occur in the general population of individuals in these age groups.

## There is no statistically significant difference in the numbers of deaths and they represent what is seen in the general population.

Issue	Moderna	No Vaccine
Death	6 of 15,184	7 of 15,165
	(0.04%)	(0.05%)
MI	1	3
Cardiac arrest	1	
Thrombocytopenia	1	
and Multiorgan		
failure		
Suicide	1	
Cancer		1
Abdominal		1
Perforation		
Head Trauma	1	
Unknown	1	1







# Let's Look at Janssen Vaccine Efficacy.

Table 14. Vaccine Efficacy of First Occurrence of Moderate to Severe/Critical COVID-19. Including Non-centrally Confirmed Cases, With Onset at Least 14 or at Least 28 Days After Vaccination, by Baseline SARS-CoV-2 Status<sup>a</sup>, Per Protocol Set

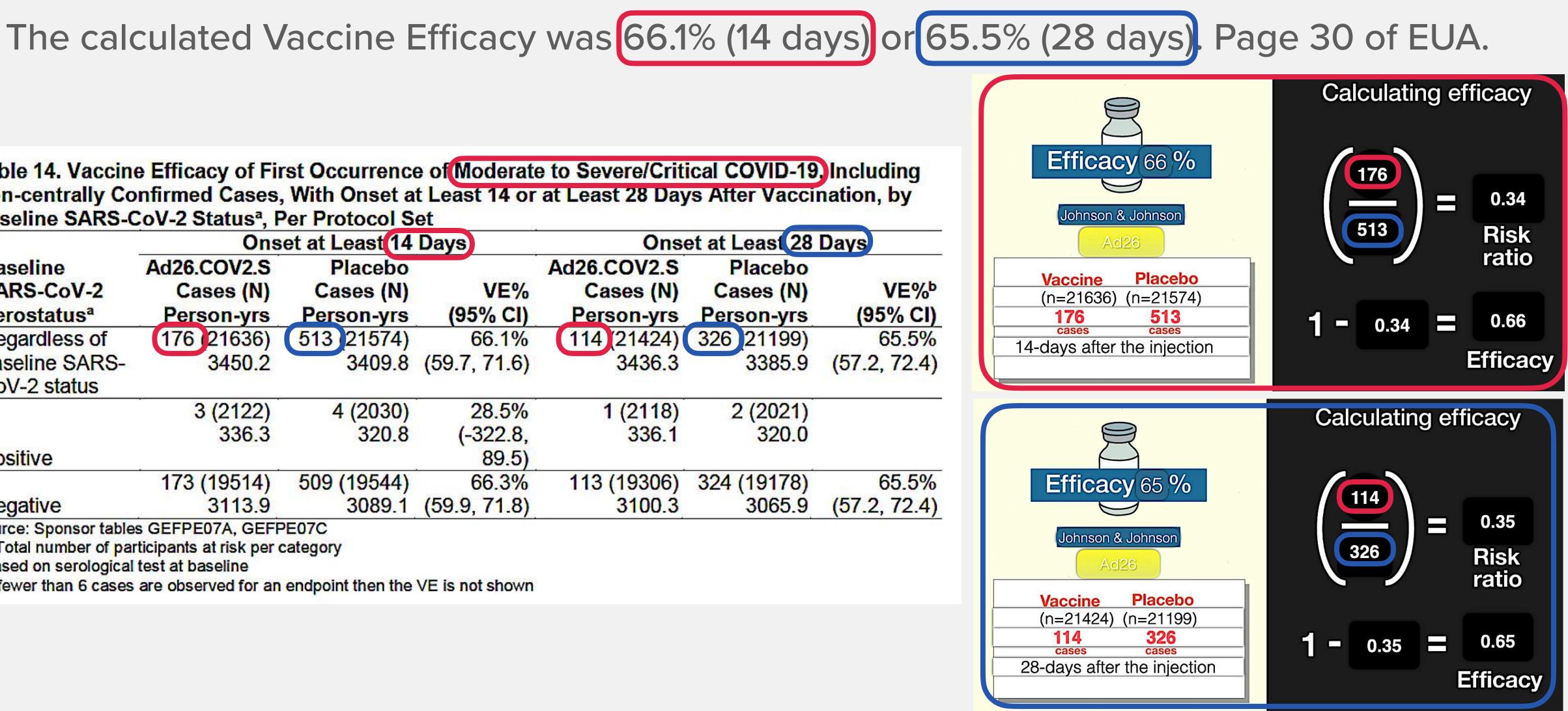
	Ons	Onset at Least 14 Days					
Baseline SARS-CoV-2 Serostatus <sup>a</sup>	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) Person-yrs	Pe		
Regardless of	176 (21636)	513 21574)	66.1%	114 (21424)	32		
baseline SARS- CoV-2 status	3450.2	3409.8	(59.7, 71.6)	3436.3			
	3 (2122) 336.3	4 (2030) 320.8	28.5% (-322.8,	1 (2118) 336.1			
Positive	V		89.5)	a production of the second s			
Negative	173 (19514) 3113.9	509 (19544) 3089.1	66.3% (59.9, 71.8)	113 (19306) 3100.3	324		

Source: Sponsor tables GEFPE07A, GEFPE07C

N=Total number of participants at risk per category

<sup>a</sup> Based on serological test at baseline

<sup>b</sup> If fewer than 6 cases are observed for an endpoint then the VE is not shown



# But the Goal is to Prevent COVID

Did The Janssen Vaccine Do Better at Preventing COVID Than Having No Vaccine? 14 Days after the Injection there were fewer cases of COVID & The Difference in the number of cases was statistically significant.  $p \le 0.05$ 

Table 14. Vaccine Non-centrally Co Baseline SARS-C	onfirmed Cases CoV-2 Status <sup>a</sup> , I	, With Onset a Per Protocol S	t Least 14 or et	at Least 28 Day	s After Vacci	nation, by		ssen 460		accine
Baseline SARS-CoV-2 Serostatus <sup>a</sup> Regardless of baseline SARS- CoV-2 status	Ons Ad26.COV2.S Cases (N) Person-vrs 176 (21636) 3450.2	set at Least 14 Placebo Cases (N) Person-vrs 513 (21574) 3409.8	VE% (95% CI)	Onse Ad26.COV2.S Cases (N) Person-yrs 114 (21424) 3436.3	et at Least 28 Placebo Cases (N) Person-yrs 326 (21199) 3385.9	Days VE% <sup>b</sup> (95% CI) 65.5% (57.2, 72.4)		99.19%		061
Positive	3 (2122) 336.3 173 (19514) 3113.9	4 (2030) 320.8 509 (19544) 3089.1	28.5% (-322.8, 89.5) 66.3% (59.9, 71.8)	1 (2118) 336.1 113 (19306) 3100.3	2 (2021) 320.0 324 (19178) 3065.9	65.5% (57.2, 72.4)	Johnson & Johnson Nothing <i>Marginal Column Totals</i>	Observed 21460 (21290.75) [1.35] 21061 (21230.25) [1.35] 42521	Expected 21121 (21290.25) [1.35] 21399 (21229.75) [1.35] 42520	Marginal Row To 42581 42460 85041 (Grand T

Source: Sponsor tables GEFPE07A, GEFPE07C

N=Total number of participants at risk per category

<sup>a</sup> Based on serological test at baseline

<sup>b</sup> If fewer than 6 cases are observed for an endpoint then the VE is not shown

N.B. On page 6 of the EUA,

The chi-square statistic is 5.3895. The p-value is .020258. Significant a p < .05.

The chi-square statistic with Yates correction is 5.3577. The *p*-value is .020631. Significant at p < .05.

Absolute Risk Reduction (ARR) = 2.38% minus(0.81%)= 1.57%



otais	
Fotal)	



# But the Goal is to Prevent COVID

## Did The Janssen Vaccine CONTINUE to do Better at Preventing COVID Than Having No Vaccine?

28 Days after the Injection there were fewer cases of COVID but The Difference was NO LONGER statistically significant. p=NS

Table 14. Vaccine Efficacy of First Occurrence of Moderate to Severe/Critical COVID-19 Including Non-centrally Confirmed Cases, With Onset at Least 14 or at Least 28 Days After Vaccination, by Baseline SARS-CoV-2 Status<sup>a</sup>, Per Protocol Set

	Ons	et at Least 14	Days	Onset	
Baseline SARS-CoV-2 Serostatus <sup>a</sup>	Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) Person-vrs	Pe
Regardless of	176 (21636)	513 (21574)	66.1%	114 (21424)	326
baseline SARS- CoV-2 status	3450.2	3409.8	(59.7, 71.6)	3436.3	
	3 (2122) 336.3	4 (2030) 320.8	28.5% (-322.8,	1 (2118) 336.1	
Positive			89.5)		
Negative	173 (19514) 3113.9	509 (19544) 3089.1	66.3% (59.9, 71.8)	113 (19306) 3100.3	324

Source: Sponsor tables GEFPE07A, GEFPE07C

N=Total number of participants at risk per category

<sup>a</sup> Based on serological test at baseline

<sup>b</sup> If fewer than 6 cases are observed for an endpoint then the VE is not shown

## Absolute Risk Reduction (ARR) = 1.54% minus (0.53%) =



The chi-square statistic is 2.1916. The p-value is .138761 Not significant at p < .05.

The chi-square statistic with Yates correction is 2.1713. The *p*-value is .140607. Not significant at p < .05.

1.01%



## **But Are These the Table 14 Numbers** The Correct COVID Numbers to Use?

Page 14 Janssen EUA: "Molecular confirmation of SARS-CoV-2 infection (using the Abbott Real Time SARS-CoV-2 RT-PCR assay) by the central laboratory was required to meet the co-primary and secondary efficacy endpoint case definitions."

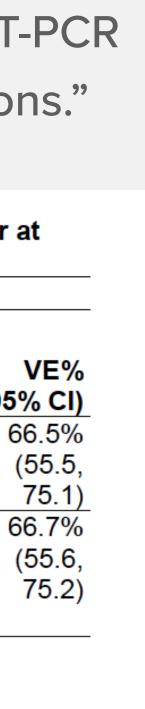
								After Vaccination		l Set, Study		Dnset at Least 1 t at Least 28 Da	
Table 14 Vaccin Non-centrally Co Basenne SARS-	onfirmed Cases	, With Onset a	it Least 14 or let	at Least 28 Day		nation, by		Ad26.COV2.S Cases (N) Person-yrs	Placebo Cases (N) Person-yrs	VE% (95% CI)	Ad26.COV2.S Cases (N) P <u>erson-yrs</u>	Placebo Cases (N) Person-yrs	(95%
Baseline SARS-CoV-2 Serostatus <sup>a</sup> Regardless of	Ad26.COV2.S Cases (N) Person-yrs 176 (21636)	Placebo Cases (N) Person-yrs 513 21574)	VE% (95% CI)			VE% <sup>b</sup> (95% CI) 65.5%	Symptomatic COVID-19, any severity <sup>a</sup>	117 (19514) 3116.5	351 (19544) 3095.9	66.9% (59.1, 73.4)	66 19306) 3102.0	195 (19178) 3070.5	66 (!
baseline SARS- CoV-2 status	3450.2 3 (2122) 336.3	4 (2030) 320.8	(59.7, 71.6) 28.5%	3436.3 1 (2118) 336.1	2 (2021) 320.0	(57.2, 72.4)	FDA harmonized COVID-19	114 (19514) 3116.6	345 (19544) 3096.3	67.2% (59.3, 73.7)	65 (19306) 3102.0	193 (19178) 3070.6	66 (!
Positive Negative Source: Sponsor table	173 (19514) 3113.9	509 (19544) 3089.1	(59.9, 71.8)	113 (19306)	324 (19178) 3065.9	65.5% (57.2, 72.4)	N=Total number o	ables TEFSUM01_A, f participants at risk pe oderate, and severe/cr	er category				

N=Total number of participants at risk per category

<sup>a</sup> Based on serological test at baseline

<sup>b</sup> If fewer than 6 cases are observed for an endpoint then the VE is not shown

## There were 32.2 to 42.1 % fewer COVID cases Confirmed by the Central Lab.



## And Finally When we Remove "Mild" COVID Cases.

Also from page 6 of the Janssen EUA: Note What Happens to these Numbers when the "Mild" Cases of COVID are Removed From the Centrally Confirmed Laboratory?

	Vaccinated (14 days)	Placebo (14 days)	Vaccinated (28 days)	Placebo (28 days)
Table 14(Not Centrally Confirmed)Moderate to Severe	176	513	114	326
Table 15(Centrally Confirmed)Mild - Moderate - Severe	117	351	66	195
EUA page 6 (Centrally Confirmed) Moderate to Severe	116 (65.9%)	348 (67.8%)	66 (57.9%)	193 (59.8%)

There were 32.2 to 42.1 % fewer COVID cases Confirmed by the Central Lab.



# **Did the Janssen Vaccine Reduce COVID Deaths?**

## Going to the Janssen EUA Documents (page 53) We Find this Information.

As of February 5, 2021, a total of 25 deaths were reported in the study (5 vaccine, 20 placebo). These deaths represent events and rates that occur in the general population of individuals in these age groups and include 7 deaths in the placebo group due to COVID-19 infection. Nonfatal serious adverse events, excluding those due to COVID-19, were infrequent and balanced between treatment groups with respect to rates and types of events (0.4% in both groups). A serious event of a hypersensitivity reaction, not classified as anaphylaxis, beginning 2 days following vaccination was likely related to receipt of the vaccine.

#### **COVID-19 Related Deaths**

As of February 5, 2021, there were 7 COVID-19-related deaths reported in the study. All participants had a documented positive SARS-CoV-2 RT-PCR around the time of the event, but not all have been centrally confirmed to date. All 7 deaths occurred in the placebo group and were in study sites in South Africa. All of these participants had one or more comorbidities which placed them at higher risk for severe COVID-19. One death was in a participant PCR positive at baseline, who had onset of illness 10 days after vaccination. These results suggest that the vaccine is efficacious against mortality associated with COVID-19. Outcomes related to an exploratory all-cause mortality endpoint are discussed in a separate section below.

#### Table 19, COVID-19 Related Deaths

Arm	Study Day <sup>c</sup>	Age	Comorbidity
Placebo	15	63	Obesity, Hypertension
Placebo	18ª	52	Obesity, Diabetes
Placebo	31	54	Obesity, Hypertension, Diabetes, Heart failure
Placebo	38	49	Obesity, Hypertension
Placebo	39	68	Obesity
Placebo	49 <sup>b</sup>	60	Obesity
Placebo	55	60	Asthma

' Participant with positive SARS-CoV-2 PCR at baseli

<sup>b</sup> Reported after the primary analysis cutoff date of January 22, 2021

<sup>c</sup> Study day of death

## There is no statistically significant difference in the numbers of deaths and they represent what is seen in the general population.

Page 34. All of the reported COVID deaths were from South Africa with Comorbidities.

No autopsy results are reported and 64% of the cases are reported as either dying from COVID or UNKNOWN causes.

	i
Janssen	No Vaccine
5 of 21424 (0.02%)	20 of 21199 (0.09%)
	1
	1
2	2
1	
	1
	1
2	7
0	7
	5 of 21424 (0.02%) 2 1





# Janssen Vaccine Thromboembolic Events.

## The EUA Documents reveal issues with Thrombotic and Neurologic Consequences beginning with page 7.

Among all adverse events collected through the January 22, 2021 data cutoff, a numerical imbalance was seen in non-serious urticaria events reported in the vaccine group (n=5) compared to placebo group (n=1) within 7 days following vaccination which is possibly related to the vaccine. Numerical imbalances were observed between vaccine and placebo recipients for thromboembolic events (15 versus 10) and tinnitus (6 versus 0). Data at this time are insufficient to determine a causal relationship between these events and the vaccine. There were no other notable patterns or numerical imbalances in the available data as of the cutoff date between treatment groups for specific categories of adverse events that would suggest a causal relationship to Ad26.COV2.S.

Numerical "Imbalances"	Janssen	No Vaccine
Thromboembolic	15	10
Tinnitus	6	0
Non-fatal Urticaris	5	0
Convulsions	4	1

Investigationa		Day of	Resolution		<b>Related</b> (Sponsor	
Product	SAE (PT)	Age/Sex	Onset	Status	Grade	Assessment)
Ad26.COV2.S	Radiculitis brachial	30/M	1	Unresolved	3	Yes (Reassessed a injection site pain)
Ad26.COV2.S	Post-vaccination syndrome	35/M	2	Resolved	3	Yes (Reassessed a reactogenicity)
Ad26.COV2.S	Facial paralysis	62/M	3	Resolving	2	No
Ad26.COV2.S	Vaccination site hypersensitivity	42/M	3	Resolved	3	Likely
Ad26.COV2.S	Facial paralysis	43/M	16	Resolving	2	No
Ad26.COV2.S	Guillain-Barre Syndrome	60/F	16	Unresolved	4	Possibly
Ad26.COV2.S	Pericarditis	68/M	17	Resolved	4	Possibly
Placebo	Deep vein thrombosis	44/M	6	Resolving	4	Indeterminate

50

#### Janssen Ad26.COV2.S (COVID-19) Vaccine VRBPAC Briefing Document

Investigational	ŝ	it. it	Day of	Resolution	\$	<b>Related</b> (Sponsor
Product	SAE (PT)	Age/Sex	Onset	Status	Grade	Assessment)
Placebo	Epstein-Barr infection <sup>a</sup>	69/M	14	Resolved	3	No
Placebo	Atrial flutter <sup>a</sup>	69/M	21	Resolving	3	No

<sup>a</sup> Events occurred the same study participant

as as

## If I've Already Been Infected Should I Get Vaccinated? **INSUFFICIENT DATA**

#### Pfizer EUA page 27

Pfizer-BioNTech COVID-19 Vaccine VRBPAC Briefing Document

NOON 9/
acy % 5% CI) <sup>e</sup>
, 98.1)
, 50.1)
3511.0,
100.0)
7, 99.5)
100.0)
,
2112.1,
100.0)
3, 98.2)
-
9, 98.9)
100.0)
-
9, 98.6)
, 97.9)
100.0)
1

<sup>a</sup> N = number of participants in the specified group

<sup>b.</sup> n1 = Number of participants meeting the endpoint definition.

<sup>c.</sup> Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

<sup>d.</sup> n2 = Number of participants at risk for the endpoint.

e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time. <sup>f.</sup> At risk is defined as having at least one of the Charlson comorbidity index (Appendix B, page <u>52</u>) category or obesity (BMI  $\geq$ 30)  $kg/m^2$ ).

<sup>g.</sup> Obese is defined as BMI ≥30 kg/m<sup>2</sup>.

<sup>h</sup> Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

<sup>1</sup> Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

Moderna EUA page 25

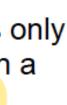
Only 2.2% of participants had evidence of prior infection at study enrollment, and there was only one COVID-19 case starting 14 days after dose 2 reported from this subgroup, which was in a participant in the placebo group. There is insufficient data to conclude on the efficacy of the vaccine in previously infected individuals.

25

#### Janssen EUA page 6

In general, VE among the subgroups (age, comorbidity, race, ethnicity) appears to be similar to the VE in the overall study population. A lower VE estimate was observed for the subgroup of participants 60 years of age and older with comorbidities compared with the overall population, but with an observed trend of increasing VE with narrower confidence intervals as numbers of cases included in the analysis increased (i.e., counting cases from 14 days rather than 28 days and including cases not yet centrally confirmed). There were no COVID-19-related deaths and no COVID-19 cases requiring medical intervention occurring 28 days or more post-vaccination among participants age 60 years or older with medical comorbidities in the vaccine group. The VE results for some other subgroups with small numbers of participants (≥75 years of age, certain racial subgroups) have limited interpretability. Data were insufficient to assess VE in participants with evidence of prior SARS-CoV-2 infection.





# COVID-19 Vaccine Efficacy & Effectiveness

	RRR (RR)	ARR	NNV	Combining Vaccine Efficacy with Different Background Risks of COVID-19.
Pfizer	95%	0.84%	117	0.9%
Moderna	94%	1.2%	76	1.4%
Gamaleya	90%	0.93%	80	1.0%
Janssen	67%	1.2%	84	1.8%
AstraZeneca	67%	1.3%	78	1.9%

Olliaro P, Torreele E, Vaillant M. COVID-19 vaccine efficacy and effectiveness — the elephant (not) in the room. Lancet Microbe 2021; https://doi.org/10.1016/ S2666-5247(21)00069-0



# Why Did I Put You Through All Those Slides? So You & I Could Do the Scientific Review of the EUAs that the FDA Didn't.

1) Based Upon the FDA (EUA) Documents: There is no statistical reduction in COVID rates. There is no statistical reduction in COVID death rates. There is an unacceptable VAERS death and adverse event rates. The vaccine Absolute Risk Reduction (ARR) rate for developing COVID is really only 0.8 to 1.3%. Not the 67 to 95% you've been lead to believe. 2) Why did we go through these slides? To provide you with the answers you need, when someone is trying to force you to get vaccinated. Because the FDA, the Federal Government and the Media failed to do their job. They failed to ask the Scientific Questions that should have been asked.



# **3 Ways to Lower Risk of COVID-19 or Death**

Reduce your overall risk by addressing comorbidities associated with an 1) increased ITR.

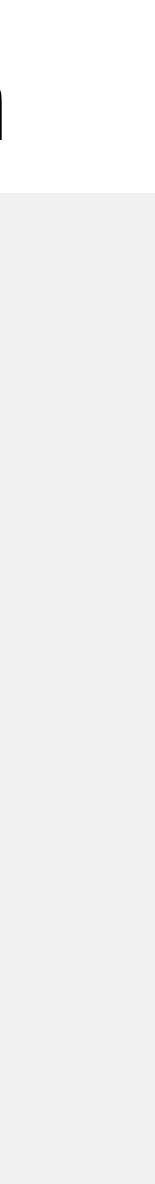
Diet, Lifestyle, control of chronic inflammatory diseases;

**Receive Medical Treatment** for SARS-CoV-2 Infection and/or COVID-19, 2) focusing on:

Reducing Infection & Replication of the Virus, and Reducing the InflammoThrombotic Response (ITR);

Enroll in the Control (non-vaccine) Group of any Drug Vaccine Study outside of 3) South Africa.

- - OR



## Like the iPhone, The Evidence Shows SARS-CoV-2 Was Designed and Paid for by the U.S. & Built in China.



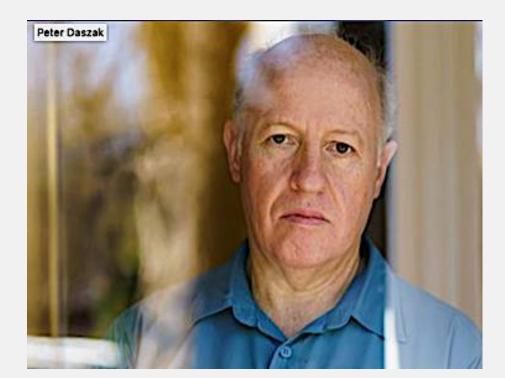
https://rumble.com/vfy3xf-lethal-deception.html

Powered by

Stream Yard

Dr Richard M Flemi...

# What are the Motives of Those Involved?









I'm a very firm believer that a liar is a cheat and a thief and a crook. I don't like liars. I never lie. I always told my own child, "If you murder somebody, tell me. I'll help you hide the body. But don't you lie to me.

— Leona Helmsley —



AZQUOTES



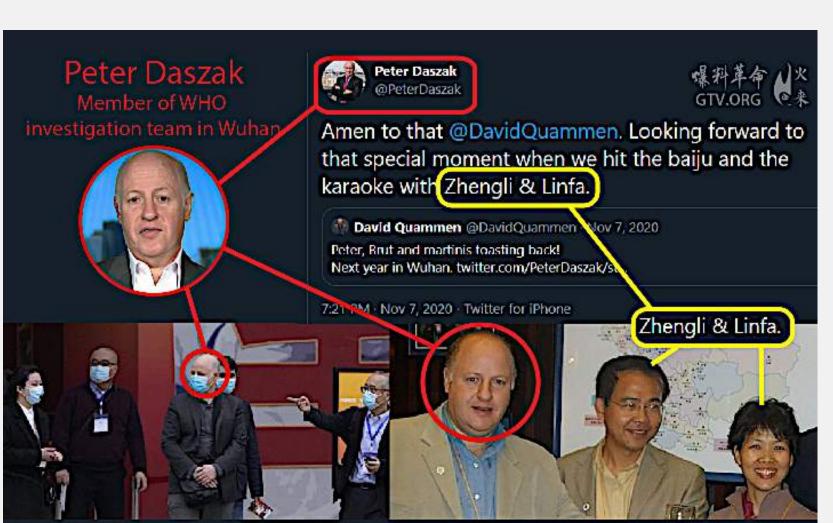
Organization That Funded Wuhan Lab Got Another Taxpayer Bailout In 2021 ( LEAVE A COMMENT )

tients with hydroxychloroqu



on-profit EcoHealth Alliance, which funneled millions of taxpayer dollars in National Institutes of Health grants to the Wuhan Institute of Virology, received yet another taxpayer-funded bailout in February 2021.

The bailout was the second received by EcoHealth since the start of the COVID-19 pandemic. After receiving \$738,861 in a bailout in May 2020, EcoHealth got an additional \$719,570 in February of this year, according to a new report from watchdog group Whitecoat Waste.





#### 

Tweets by @Wizard\_Predicts

Wizard\_Predicts Houston doctor claims to have accessfully treated over 20K

# We Know These People Are Involved in **CRISPR Research Altering Human DNA**

## Like Gain-of-Function (GoF), CRISPR can be used for altruistic purposes or nefarious purposes.

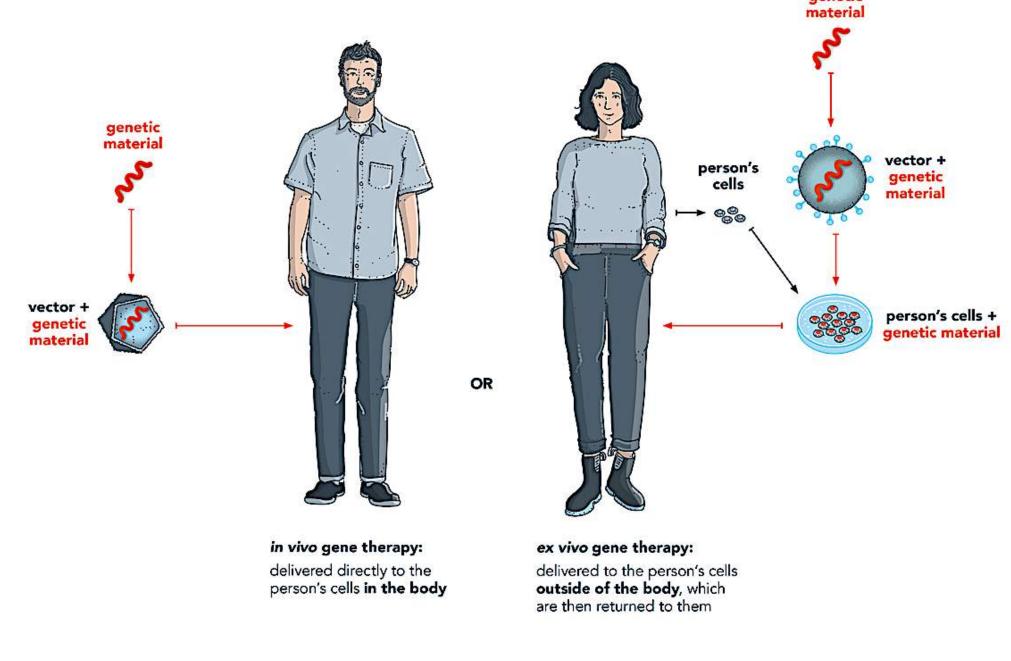
**CRISPR**: Clustered Regularly **Interspaced Short Palindromic** Repeat, is a method for removing segments of DNA or RNA and replacing it with NEW genetic code.

https://www.thegenehome.com/how-does-gene-therapy-work/techniques  $msclkid=038da1e7273418d28b4ec1677222eb34\&utm\_source=bing\&utm\_medium=cpc\&utm\_campaign=Crispr\%20\%20Standard\&utm\_term=crispr\%20gene\%20therapy\&utm\_redium=cpc\&utm\_campaign=Crispr\%20\%20Standard\&utm\_term=crispr\%20gene\%20therapy\&utm\_redium=cpc\&utm\_campaign=Crispr\%20\%20Standard\&utm\_term=crispr\%20gene\%20therapy\&utm\_redium=cpc\&utm\_campaign=Crispr\%20\%20Standard\&utm\_term=crispr\%20gene\%20therapy\&utm\_redium=cpc\&utm\_campaign=Crispr\%20\%20Standard\&utm\_term=crispr\%20gene\%20therapy\&utm\_redium=cpc\&utm\_campaign=Crispr\%20\%20Standard\&utm\_term=crispr\%20gene\%20therapy\&utm\_redium=cpc\&utm\_campaign=Crispr\%20\%20Standard\&utm\_term=crispr\%20gene\%20therapy\&utm\_redium=cpc\&utm\_campaign=Crispr\%20\%20Standard\&utm\_term=crispr\%20gene\%20therapy\&utm\_redium=cpc\&utm\_campaign=Crispr\%20\%20Standard\&utm\_term=crispr\%20gene\%20therapy\&utm\_term=crispr\%20gene$ m\_content=Crispr

### How is genetic material delivered to cells?

For any type of gene therapy to work, whether making a gene inactive or adding/correcting a gene, the genetic material needs to get inside the cells of the person with the disease. Delivery can be either inside the body or outside—either method can be used in both men and women:

- Ex vivo gene therapy refers to the process of genetically altering a person's cells outside of the body and then transplanting them back in<sup>18,19</sup>
- Today, ex vivo gene therapy techniques are most frequently applied to hematopoietic stem cells (HSCs), which are relevant to blood and immunological diseases and genetic diseases that affect tissues and organs easily accessible by blood cells
- In vivo gene therapy refers to direct administration either intravenously, known as systemic administration, or locally to a specific organ of interest (eg, eye, muscle)<sup>19</sup>
  - In vivo delivery has been proven in many areas of research. Some of the currently approved gene therapies deliver genetic material in vivo. Targeted in vivo gene therapy will continue to evolve as scientists continue to experiment with additional methods of gene delivery





# Using CRISPR to Make Synthetic Biology

## **Controlling Human DNA**

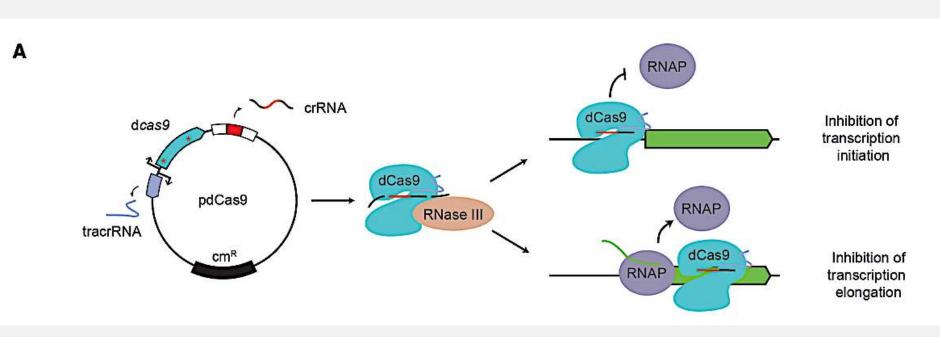
Published online 12 June 2013

Nucleic Acids Research, 2013, Vol. 41, No. 15 7429-7437 doi:10.1093/nar/gkt520

#### **Programmable repression and activation of bacterial** gene expression using an engineered CRISPR-Cas system

David Bikard<sup>1,\*</sup>, Wenyan Jiang<sup>1</sup>, Poulami Samai<sup>1</sup>, Ann Hochschild<sup>2</sup>, Feng Zhang<sup>3,4,5,6</sup> and Luciano A. Marraffini<sup>1,\*</sup>

<sup>1</sup>Laboratory of Bacteriology, The Rockefeller University, 1230 York Avenue, New York, NY 10065, USA, <sup>2</sup>Department of Microbiology and Immunobiology, Harvard Medical School, 4 Blackfan Circle, Boston, MA 02115, USA, <sup>3</sup>Broad Institute of MIT and Harvard, 7 Cambridge Center, Cambridge, MA 02142, USA, <sup>4</sup>McGovern Institute for Brain Research, Massachusetts Institute of Technology, Cambridge, MA 02139, USA, <sup>5</sup>Department of Brain and Cognitive Sciences, Massachusetts Institute of Technology, Cambridge, MA 02139, USA and <sup>6</sup>Department of Biological Engineering, Massachusetts Institute of Technology, Cambridge, MA 02139, USA



ABSTRACT

The ability to artificially control transcription is essential both to the study of gene function and to the construction of synthetic gene networks with desired properties. Cas9 is an RNA-guided doublestranded DNA nuclease that participates in the **CRISPR-Cas immune defense against prokaryotic** viruses. We describe the use of a Cas9 nuclease mutant that retains DNA-binding activity and can be engineered as a programmable transcription repressor by preventing the binding of the RNA polymerase (RNAP) to promoter sequences or as a transcription terminator by blocking the running RNAP. In addition, a fusion between the omega subunit of the RNAP and a Cas9 nuclease mutant directed to bind upstream promoter regions can achieve programmable transcription activation. The simple and efficient modulation of gene expression achieved by this technology is a useful asset for the study of gene networks and for the development of synthetic biology and biotechnological applications.

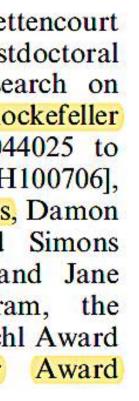
Figure 1. dCas9-mediated repression in E. coli. (A) Plasmid pdCas9 encodes a cas9 mutant containing D10A and H840A substitutions (red asterisks) that abrogate nuclease activity. dCas9 binds to a tracrRNA:precursor crRNA and recruits RNase III to process the precursor and liberate the crRNA. The crRNA directs binding of dCas9 to promoter or open reading frame regions to prevent RNAP binding or elongation, respectively.

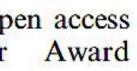
#### FUNDING

Harvey L. Karp Discovery Award and the Bettencourt Schuller Foundation (to D.B.); Helmsley Postdoctoral Fellowship for Basic and Translational Research on Disorders of the Digestive System at The Rockefeller University (to P.S.); NIH grant [R01 GM044025 to A.H.]; NIH Director's Pioneer Award [DP1MH100706], Transformative R01, the Keck, McKnight, Gates, Damon Runyon, Searle Scholars, Klingenstein, and Simons Foundations, Bob Metcalfe, Mike Boylan and Jane Pauley (to F.Z.); Searle Scholars Program, the Rita Allen Scholars Program, an Irma T. Hirschl Award a NIH Director's New Innovator Award and

[1DP2AI104556-01 to L.A.M.]. Funding for open access charge: NIH Director's New Innovator Award [1DP2AI104556-01].

Conflict of interest statement. None declared.





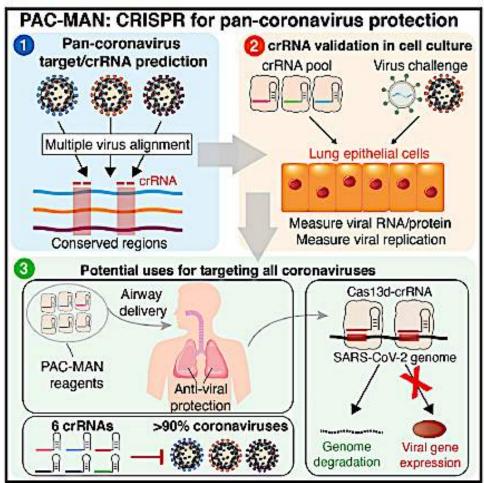
# Prior to LNP There Were Problems Getting CRISPR Into Cells

## Cell

Article

#### Development of CRISPR as an Antiviral Strategy to Combat SARS-CoV-2 and Influenza

#### **Graphical Abstract**



#### Highlights

() Bagetter

- PAC-MAN is a CRISPR-based strategy for RNA-guided viral RNA inhibition and degradation
- Cas13d PAC-MAC is effective at targeting and cleaving SARS-CoV-2 sequences
- Cas13d PAC-MAC can reduce H1N1 IAV load in respiratory epithelial cells
- A group of six crRNAs can target more than 90% of all coronaviruses

## Authors

Timothy R. Abbott, Girija Dhamdhere, Yanxia Liu, ..., Marie F. La Russa, David B. Lewis, Lei S. Qi

#### Correspondence

mlarussa@stanford.edu (M.F.L.R.), dblewis@stanford.edu (D.B.L.), stanley.qi@stanford.edu (LS.Q.)

#### In Brief

A CRISPR-based strategy is developed to target conserved sequences across coronaviruses and other pathogenic viruses

## **CRISPER Limitations overcome with LNP and Nasal Sprays**

#### **Limitations and Future Directions**

The biggest barrier to deploying PAC-MAN clinically is the development of effective and safe in vivo delivery methods. There are several attractive delivery options that could be employed for the in vivo expression of PAC-MAN components. Cas13d and its cognate crRNAs could be delivered in RNA form within chemical polymers or lipid nanoparticles (LNPs) (Hendel et al., 2015; McKinlay et al., 2017; Sago et al., 2018; Xu et al., 2019). DNA-based liposomal delivery strategies, such as lipitoids or the recently developed HEDGES platform, are also attractive (Handumrongkul et al., 2019; Huang et al., 1998). Another strategy would be to deliver a ribonucleoprotein complex containing the Cas13d protein assembled with crRNAs (Amirkhanov and Stepanov, 2019; Xu et al., 2019). Other work successfully used engineered amphiphilic peptides to deliver Cas9-guide RNA complexes to airway epithelia, which provides a promising approach for delivering PAC-MAN Cas13d complexes (Krishnamurthy et al., 2019). In addition, recent advances in gene therapy delivery strategies optimized for cystic fibrosis that can deliver mRNA or plasmid DNA, such as self-assembled peptide-poloxamine nanoparticles, may also be an option (Guan et al., 2019). We anticipate that one of the above-mentioned strategies can potentially be administered to patients or healthy populations via a nebulizer system or nasal spray as an antiviral strategy.

Abbott et al., 2020, Cell 181, 865-876 May 14, 2020 © 2020 Elsevier Inc. https://doi.org/10.1016/j.cell.2020.04.020



#### ACKNOWLEDGMENTS

The authors thank all members from the Stanley Qi lab and David Lewis lab for facilitating experiments and useful discussions. The authors thank the researchers who generated and contributed the SARS-CoV-2 sequence data to GISAID (https://www.gisaid.org/). The authors would also like to thank Dr. Elodie Ghedin (NYU) for her advice on targeting influenza with Cas13 and insights about influenza replication. The project is supported by a contract grant from Defense Advanced Research Projects Agency (DARPA) (HR001119C0060). L.S.Q. is also supported by the Li Ka Shing Foundation.

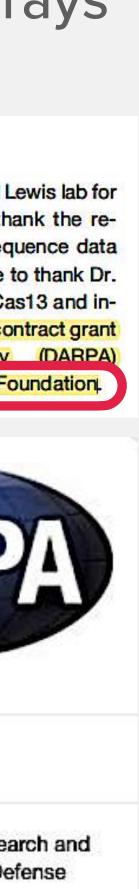
DARPA

Agency of the U.S. Department of Defense responsible for the development of new technologies

DARPA

darpa.mil

The Defense Advanced Research Projects Agency is a research and development agency of the United States Department of Defense responsible fo... en.wikipedia.org



# A Perspective from Tal Zaks Moderna CEO 2017

## Vision The Software of Life and manipulation of human DNA





# Perspective of Bill Gates Microsoft CEO Feb 2020

## Vision

**Intentional Pandemic** disrupting economies, healthcare & cause more than 10 Million excess deaths. **Introducing GENE Drives passed on to** your children.







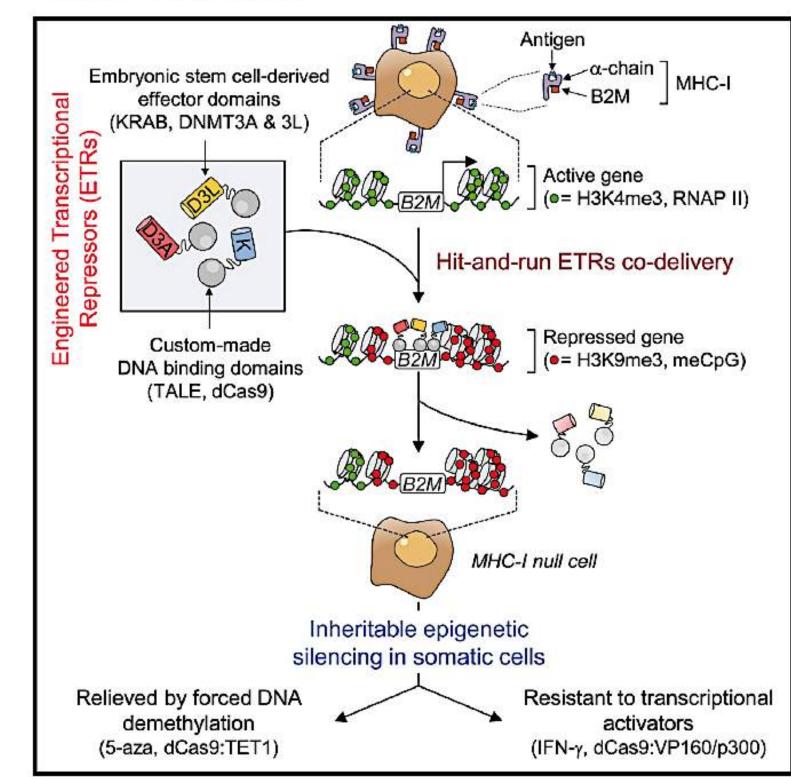
# **Silencing DNA Resistant to Immune Recognition**



Cell 167, 219-232, September 22, 2016

## Inheritable Silencing of Endogenous Genes by Hitand-Run Targeted Epigenetic Editing

#### **Graphical Abstract**



#### Authors

Angelo Amabile, Alessandro Migliara, Paola Capasso, Mauro Biffi, Davide Cittaro, Luigi Naldini, Angelo Lombardo

#### Correspondence

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#### In Brief

Transient co-expression of engineered transcriptional repressors (ETRs) allows for stable and highly specific epigenetic silencing of endogenous genes, which is amenable to multiplexing and can be reverted by targeted DNA demethylation.

## Resource

#### SUMMARY

**Resistant to your Immune system.** 

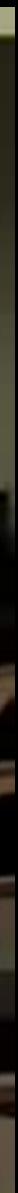
Gene silencing is instrumental to interrogate gene function and holds promise for therapeutic applications. Here, we repurpose the endogenous retroviruses' silencing machinery of embryonic stem cells to stably silence three highly expressed genes in somatic cells by epigenetics. This was achieved by transiently expressing combinations of engineered transcriptional repressors that bind to and synergize at the target locus to instruct repressive histone marks and de novo DNA methylation, thus ensuring long-term memory of the repressive epigenetic state. Silencing was highly specific, as shown by genome-wide analyses, sharply confined to the targeted locus without spreading to nearby genes, resistant to activation induced by cytokine stimulation, and relieved only by targeted DNA demethylation. We demonstrate the portability of this technology by multiplex gene silencing, adopting different DNA binding platforms and interrogating thousands of genomic loci in different cell types, including primary T lymphocytes. Targeted epigenome editing might have broad application in research and medicine.



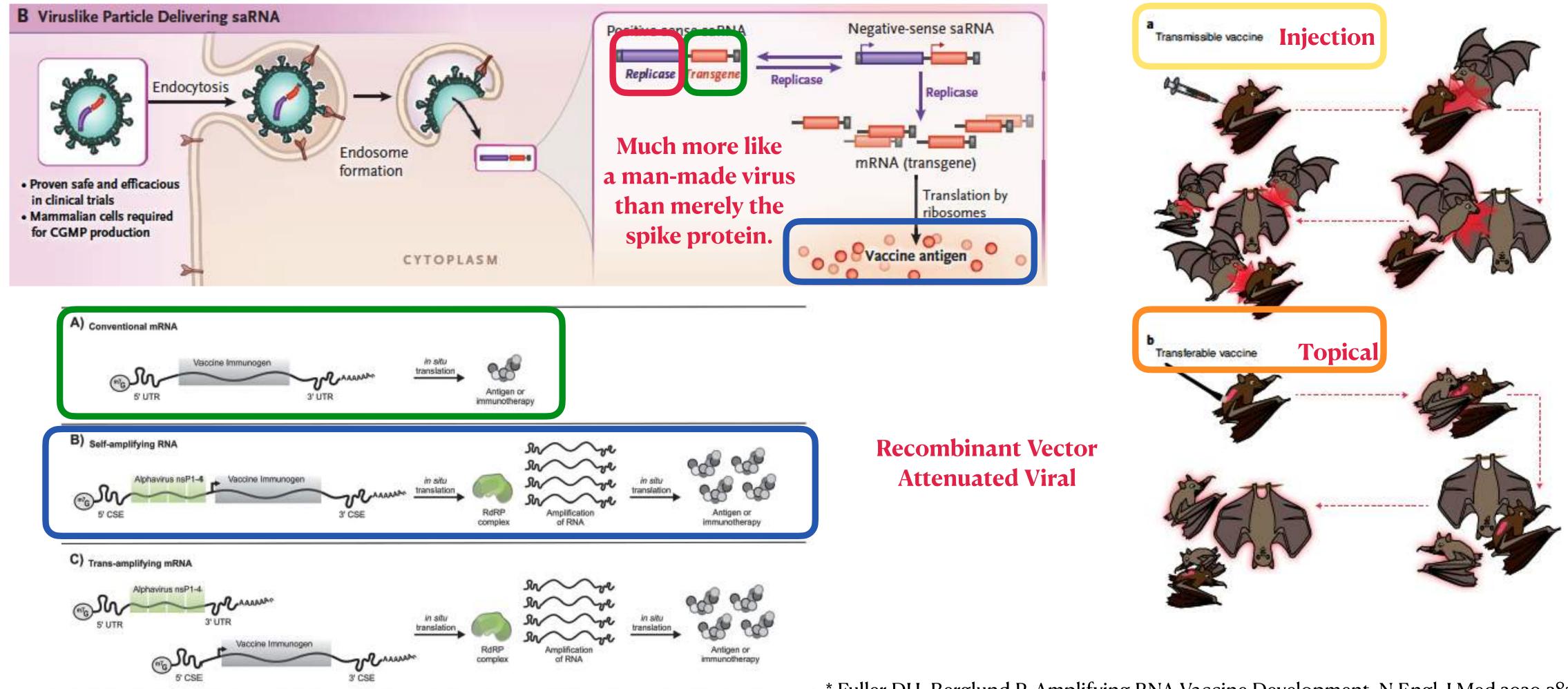
# Gates-DOD-Viruses-GOD Gene



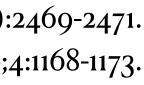
# الالتد فالتابية والمحالية 09:19:02



# The Question of Shedding. Self Amplifying mRNA Vaccines (SAM)\* & Transmissible Vaccines\*\*



\* Fuller DH, Berglund P. Amplifying RNA Vaccine Development. N Engl J Med 2020 382(25):2469-2471. \*\* Nuismer SL, Bull JJ. Self-disseminating vaccines to suppress zoonoses. Nature Ecology & Evolution 2020;4:1168-1173.



# Is This New?

## It Dates Back to At Least 2000

Vol. 74, No. 3

0022-538X/00/\$04.00±0 Copyright @ 2000, American Society for Microbiology. All Rights Reserved.

#### Horizontal Transmissible Protection against Myxomatosis and Rabbit Hemorrhagic Disease by Using a Recombinant Myxoma Virus

JUAN BÁRCENA,1 MÓNICA MORALES,1 BELÉN VÁZQUEZ,1 JOSÉ A. BOGA,2 FRANCISCO PARRA,2 JAVIER LUCIENTES,3 ALBERT PAGÈS-MANTÉ,4 JOSÉ M. SÁNCHEZ-VIZCAÍNO,1 RAFAEL BLASCO,<sup>1</sup> AND JUAN M. TORRES<sup>18</sup>

Centro de Investigación en Sanidad Animal (CISA-INIA), Valdeolmos, 28130 Madrid,<sup>1</sup> Departamento de Bioquímica y Biología Molecular, Instituto Universitario de Biotecnología de Asturias (CSIC), Universidad de Oviedo, 33006 Oviedo,<sup>2</sup> Departamento de Patología Animal, Facultad de Veterinaria, Universidad de Zaragoza, Zaragoza,<sup>3</sup> and Laboratorios Hipra S.A. Amer., 1710 Girona,<sup>4</sup> Spain

Received 1 July 1999/Accepted 1 November 1999

We have developed a new strategy for immunization of wild rabbit populations against myxomatosis and rabbit hemorrhagic disease (RHD) that uses recombinant viruses based on a naturally attenuated field strain of myxoma virus (MV). The recombinant viruses expressed the RHDV major capsid protein (VP60) including a linear epitope tag from the transmissible gastroenteritis virus (TGEV) nucleoprotein. Following inoculation, the recombinant viruses induced specific antibody responses against MV, RHDV, and the TGEV tag. Immunization of wild rabbits by the subcutaneous and oral routes conferred protection against virulent RHDV and MV challenges. The recombinant viruses showed a limited horizontal transmission capacity, either by direct contact or in a flea-mediated process, promoting immunization of contact uninoculated animals.

## Is There Any Evidence This is Being Used with SARS-CoV-2?

Gene Therapy (2021) 28:117-129 https://doi.org/10.1038/s41434-020-00204-y

**REVIEW ARTICLE** 



#### Self-amplifying RNA vaccines for infectious diseases

Kristie Bloom <sup>1</sup> · Fiona van den Berg <sup>1</sup> · Patrick Arbuthnot<sup>1</sup>

Received: 19 June 2020 / Revised: 29 September 2020 / Accepted: 8 October 2020 / Published online: 22 October 2020 © The Author(s), under exclusive licence to Springer Nature Limited 2020

Infectious disease	Replicon	Immuno gen	Delivery	Animal	Year (reference
Clinical studies					
Rabies		Characteria C	CNE	Human	2019 (NCT04062669)
COVID-19	VEE	Spike protein	LNP	Human	2020 (ISRCTNI 7072692)
Preclinical studies					
RSV	SFV	F glycoprotein	Naked	Miceb	2001 [80]
	VEE-SINV	F glycoprotein	LNP	Mice, rats <sup>b</sup>	2012 [81]
	VEE-SINV	F glycoprotein	CNE	Mice	2014 [68]
Influenza	SFV	NP	Naked	Mice	1994 [79]
	SFV	HA	Naked	Miceh	2001 [80]
	VEE-SINV	HA	LNP Chinese NCA	Mice	2013 [14]
	CSFV VEE-SINV	HA/NP HA	Chitosan NGA CNE	Mice, rabbit Mice <sup>b</sup> , ferret <sup>b</sup>	2014 [71]
	VEE-SINV	NP	LNP	Mice	2015 [125] 2015 [126]
	VEE-SINV	M1/NP	LNP	Miceb	2016 [85]
	VEE	HA	MDNP	Miceb	2016 [127]
	CSFV	HA/NP	CPP PEI	Pigs	2017 [128]
	CSFV	NP	Cationic lipid	Mice	2018 [129]
		HA	PEI	Miceb	2018 [12]
	VEE	HA	Neutral LPP	Mice	2019 [55]
	-	HA	MLNP	Mice	2019 [54]
	Trans-amplifying	HA	Naked	Miceb	2020 [62]
	VEE	HA	pABOL	Miceb	2020 [50]
Coronavirus	VEE	Spike protein	LNP	Mice	2020 [86]
LIV	SFV	prM-E	Naked	Miceb	2001 [80]
TBEV	TBEV	∆ TBEV capsid	Gene gun	Miceh	2004 [130]
	TBEV	A TREV capsid	Gene min	Miceb	2005 [131]
HIV	VEE-SINV	Env	LNP	Mice	2012 [81]
	VEE-SINV	Env	Electroporation	Mice	2013 [132]
	VEE-SINV	Env	CNE	Rabbit	2014 [68]
	VEE-SINV	Env	CNE	NHP	2015 [121]
	SFV	Gag/Pol mosaic	PEI	Mice	2019 [123]
	VEE	cOD-GT8 Env	LNP Exterior LNP	Mice	2019 [120]
CMV	VEE-SINV	gB/pp65-IE1	CNE	NHP	2019 [58] 2014 [68]
Ebola	VEE	Glycoprotein	MDNP	Miceb	2016 [127]
Toxoplasma gondii	VEE	Multimer <sup>a</sup>	MDNP	Miceb	2016 [127]
To when the second	SEV	NTPase-II	LNP	Miceb	2017 [133]
GAS	VEE-SINV	SLOdm	CNE	Miceb	2017 [134]
GBS	VEE-SINV	BP-2a	CNE	Miceh	2017 [134]
Zika	VEE	prM-E	MDNP	Mice	2017 [91]
	VEE	prM-E	NLC	Mice <sup>b</sup> , guinea pigs	2018 [90]
	VEE	prM-E	Naked	Miceb	2019 [89]
VEE	VEE	Attenuated VEE	CNE	Miceb	2019 [88]
Rabies	VEE-SINV	Glycoprotein G	CNE	Rats	2020 [92]
	VEE-SINV	Glycoprotein G	Liposome, nanoparticle, CNE	Mice	2020 [59]

Table 1 Clinical and preclinical synthetic saRNA vaccine studies for infectious diseases

BP-2a GBS pilus 2a backbone protein, CMV cytomegalovirus, CSFV classical swine fever virus, CNE cationic nanoemulsion, Env envelope, GAS group A streptococci, GBS group B streptococci, gB glycoprotein B, HA haemagglutinin, HIV human immunodeficiency virus, LIV louping ill virus, LNP lipid nanoparticle, LPP lipopolyplexes, M1 matrix protein 1, MLNP manosylated LNP, MDNP modified dendrimer nanoparticle, NGA nanogel alginate, NHP nonhuman primate, NLC nanostructured lipid carrier, NP nucleoprotein, pABOL poly(CBA-co-4-amino-1-butanol (ABOL)), PEI polyethylenimine, Pol polymerase, prM-E premembrane and envelope glycoproteins, RSV respiratory syncytial virus, SFV Semliki forest virus, SINV Sindbis virus, SLOdm double-mutated GAS Streptolysin-O, TBEV tick-borne encephalitis virus, VEE Venezuelan equine encephalitis virus, VEE-SINV alphavirus chimera based on the VEE and SINV replicons.

<sup>a</sup>Multimer comprised of granule protein 6 (GRA6), rhoptry protein 2A (ROP2A), rhoptry protein 18 (ROP18), surface antigen 1 (SAG1), surface antigen 2A (SAG2A), and apical membrane antigen 1 (AMA1).

<sup>b</sup>Vaccination conferred protection.

## What If The People You Trust Are The People Causing The Problem?

<b>NIH</b> Director's Blo	
Search The Blog	I'll h
NIH.gov Blog Home Director's Album	7
CRISPR-Based Anti-Viral Therapy Could One Day Foil the Flu—and COVID-19	
Posted on March 16th, 2021 by Dr. Francis Collins	
Hard Hard Hard Hard Hard Hard Hard Hard	
Europe Europe	
Cast Ball	
Donald Bliss/NIH	

CRISPR gene-editing technology has tremendous potential for making non-heritable DNA changes that can treat or even cure a wide range of devastating disorders, from HIV to muscular dystrophy Now, a recent animal study shows that another CRISPR system—targeting viral RNA instead of human DNA—could work as an inhaled antiviral therapeutic that can be preprogrammed to seek out and foil potentially almost any flu strain and many other respiratory viruses, including SARS-CoV-2, the coronavirus that causes COVID-19.

How can that be? Other CRISPR gene-editing systems rely on a sequence-specific guide RNA to direct a scissorlike, bacterial enzyme (Cas9) to just the right spot in the genome to cut out, replace, or repair disease-causing mutations. This new anti-viral CRISPR system also relies on guide RNA. But the guide instead directs a different bacterial enzyme, called Cas13a, to the right spot in the viral genome to bind and cleave viral RNA and stop viruses from replicating in lung cells.

## elp you hide the body (the evidence).



I'm a very firm believer that a liar is a cheat and a thief and a crook. I don't like liars. I never lie. I always told my own child, "If you murder somebody, tell me. I'll help you hide the body. But don't you lie to me.

— Leona Helmsley —

AZQUOTES



## Gain-of-Function, CRISPR, LNP, Nasal, SAM, Transmissible/Transferable Biologics.

# Section 03

# 01 Inform

The SARS-CoV-2 virus & known facts

The Covid-19 disease & published treatments

# 02 Educate

Infectious Diseases

Vaccines efficacy and safety

The Scientific Method

The Difference Between VE, COVID-19 & Death

EUA vs Process vs Risks

# **03 Empower**

**EUA vs Process vs Risks** 

**Stopping the Gain-of-Function** Research

**Government Interference with Physician-Patient Treatment & Forced Vaccination** 

**Be Heard** 

Petition



## Blindly Following Makes it Easy to Be Manipulated By Those in Power. **During his 1947 Nuremberg Trial Göring Said The Following.**

... it is the leaders of the country who determine the policy and it is always a simple matter to drag the people along, whether it is a democracy or a fascist dictatorship or a Parliament or a Communist dictatorship.

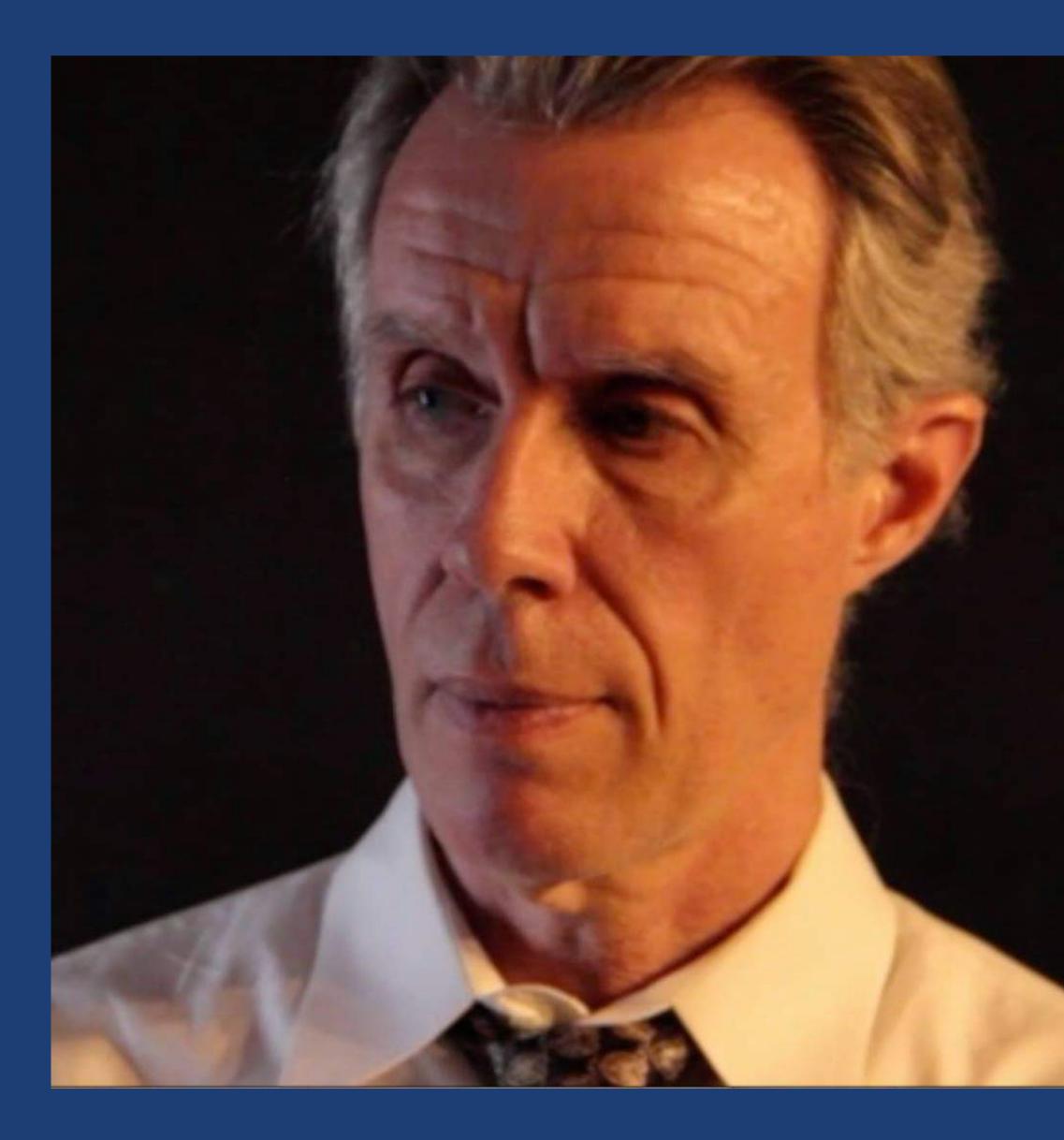


...voice or no voice, the people can always be brought to the bidding of the leaders. That is easy. All you have to do is tell them they are being attacked and denounce the pacifists for lack of patriotism and exposing the country to danger. It works the same way in any country.

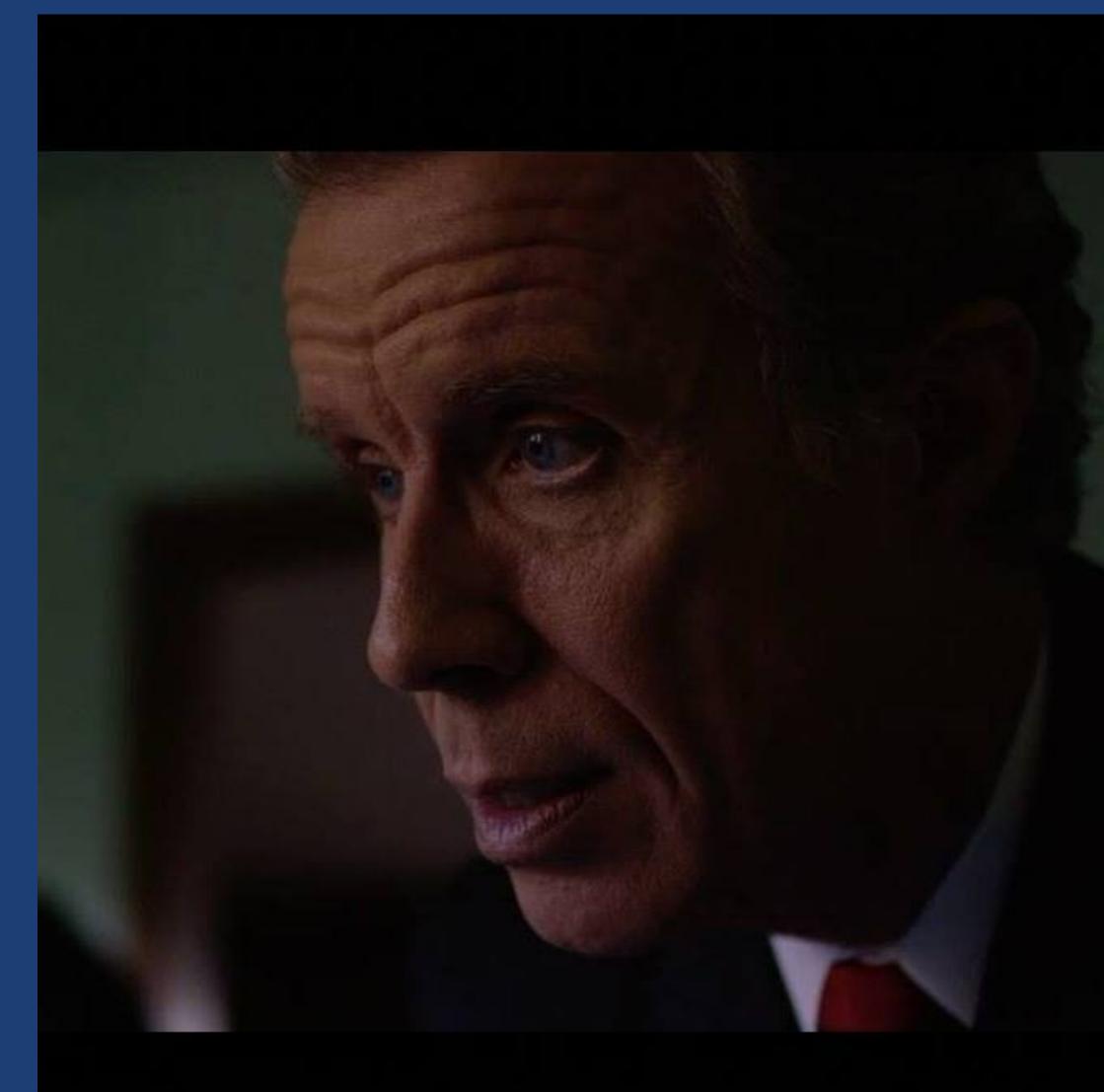




## Carpe Diem Quam Minimum Credula Postero!



Empower





## What If The People You Trust Are The People Causing The Problem? Vaccines - a Little Hope. Treatment & Holding Those Accountable - Real Hope.



#### Empower

# Lockdowns: A Response to Fear





# Masks: A Response to Fear

India Today

## The age of fear: How Covid has impacted our mental health

Suhani Singh - Thursday



https://www.msn.com/en-in/health/wellness/the-age-of-fear-how-covid-has-impacted-our-mental-health/ar-AAKu39Q https://www.dukehealth.org/blog/wear-face-mask-protect-eachother#:~:text=%20Wear%20a%20Face%20Mask%20to%20Protect%20Each,the%20virus%20cannot%20live%20for%20more...%20More%20 https://www.dailymail.co.uk/news/article-8166105/New-York-hospitals-set-refrigerated-trailers-used-makeshift-morgues.html





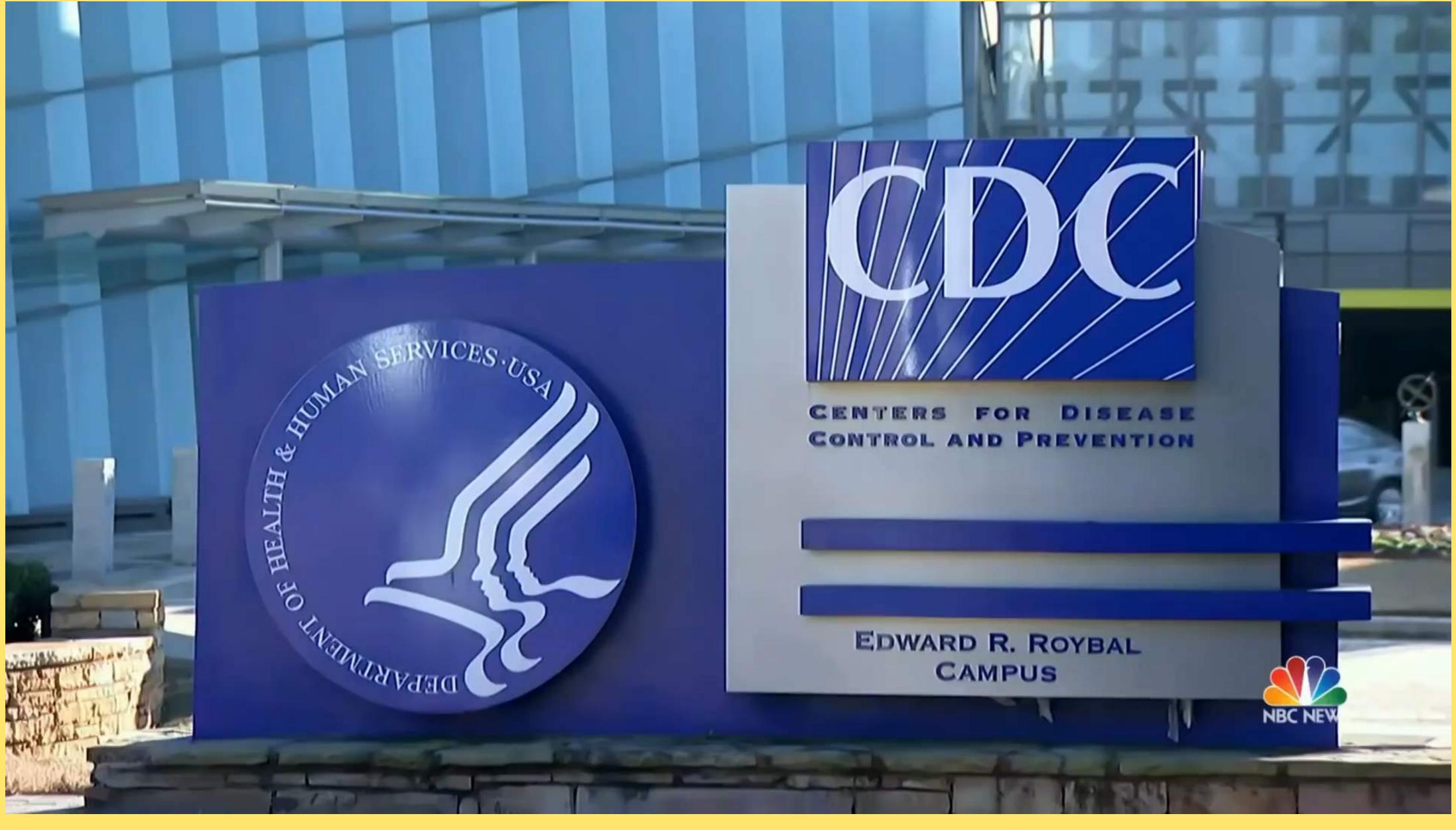
A line of refrigerated trucks that are being used as morgues sit outside Bellevue Hospital Center in Manhattan on Sunday







Empower

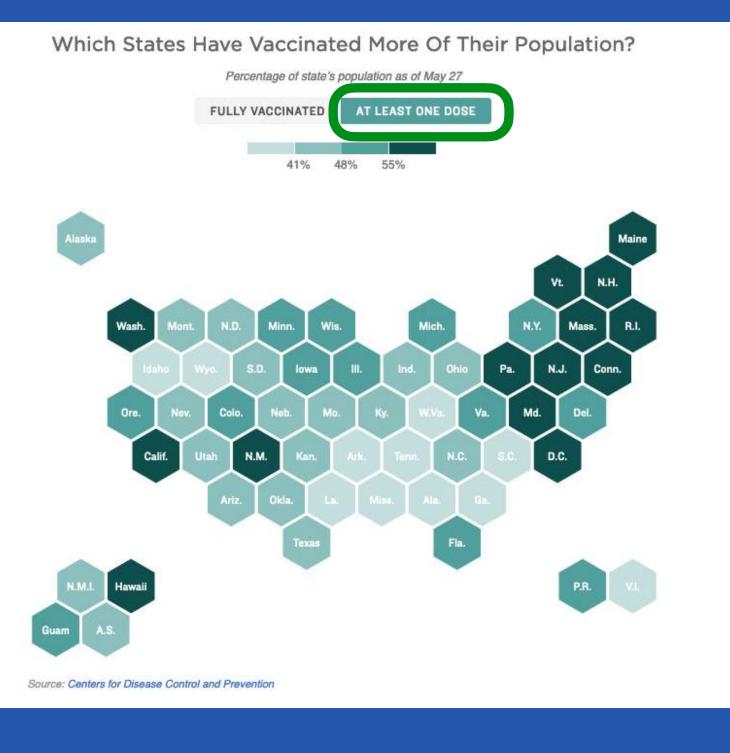


https://www.youtube.com/watch?v=4vcdJ2Zsc8U&t=13s

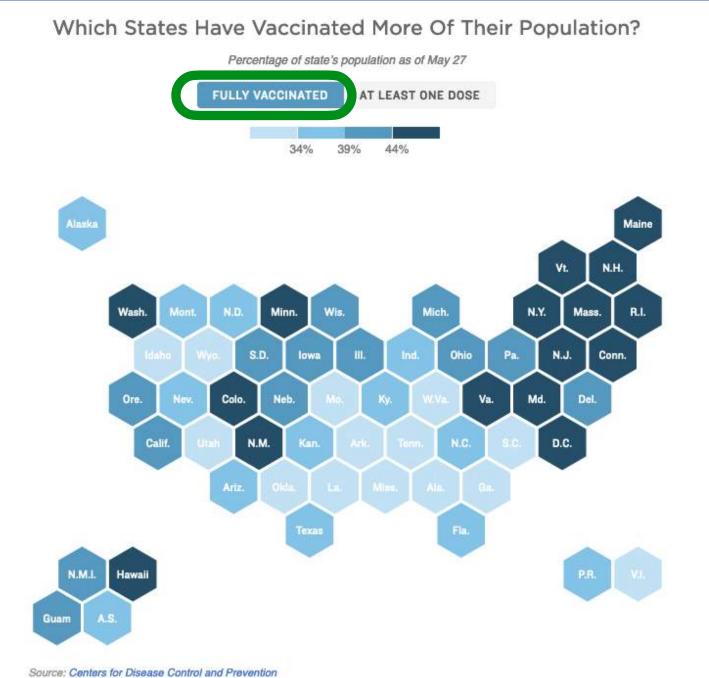
## Fauci & Masks



## Vaccinations: A Response to Fear & Hope

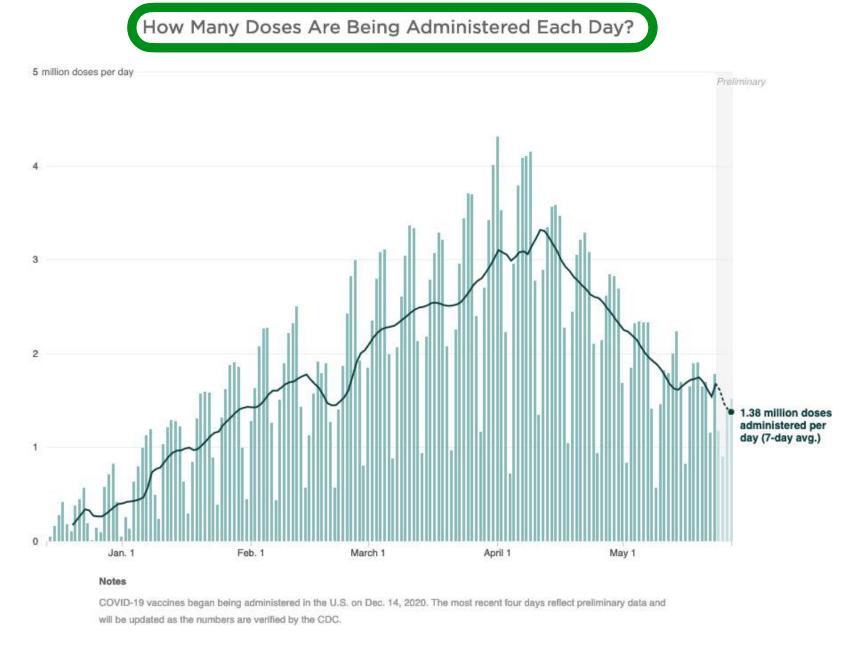


## The More Fear The More Vaccinations



## The People Who Have Been Vaccinated are not the Enemy and Many of Them are Now Fearful of What Might Be Happening to Them and Those They Love.

https://www.npr.org/sections/health-shots/2021/01/28/960901166/how-is-the-covid-19-vaccination-campaign-going-in-your-state



Source: Centers for Disease Control and Prevention (as of May 27)



#### Empower

# Hope Shattered by Reality

## https://vaers.hhs.gov/index.html

As of 19 April 2021 the Centers for Disease Control (CDC) reported on its Vaccine Adverse Event Reporting System (VAERS) 68,347 Adverse Events Including 2,602 Deaths 8,285 Serious Injuries

As of 23 April 2021 the Centers for As of 7 May 2021 the Centers for Disease Control (CDC) reported on its Vaccine Adverse Event Reporting System (VAERS) 118,902 Adverse Case Events Including 3,544 Deaths 12,619 Serious Injuries

https://www.lifesitenews.com/news/latest-vaers-data-show-reports-of-blood-clotting-disorders-after-all-three-emergency-use-authorization-vaccines https://childrenshealthdefense.org/defender/vaers-significant-jump-reported-injuries-deaths-after-covid-vaccine/ https://childrenshealthdefense.org/defender/vaers-cdc-data-reported-deaths-covid-vaccines-kids-12-now-eligible/

Disease Control (CDC) reported on its Vaccine Adverse Event Reporting System (VAERS) 192,954 Adverse Case Events Including 4,057 Deaths **17,190 Serious Injuries** 



# Deaths Reports in VAERS as of May 28, 2021

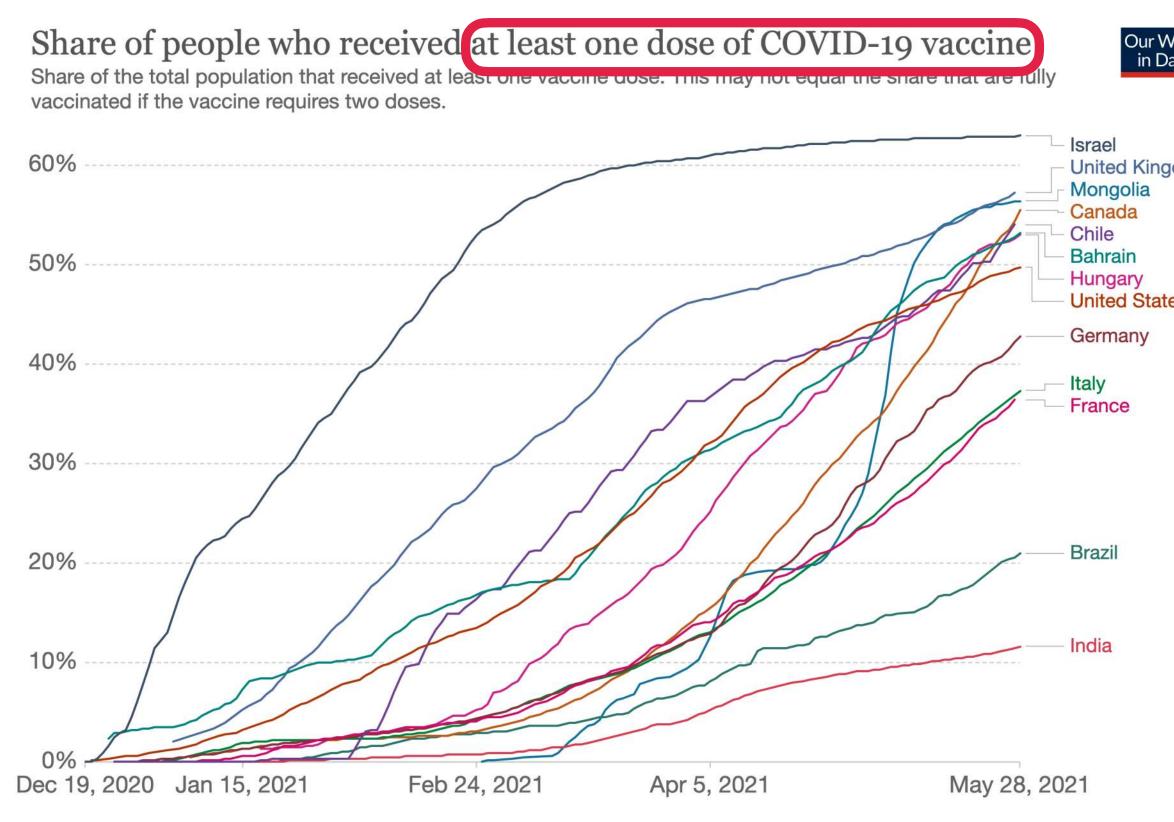
2020 total excludes 16 deaths after COVID vaccination included in last column



https://www.revolver.news/2021/06/REVOLVER-PART-ONE-COVID-VAERS-DEATHS-COVER-UP/



### European Database (EudraVigilance) 22 May 2021



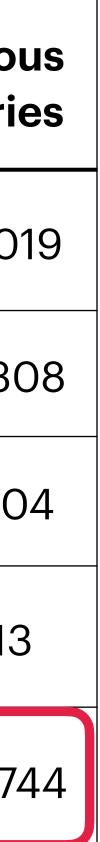
Source: Official data collated by Our World in Data

### https://ourworldindata.org/covid-vaccinations

World Data	22 May 2021	Reported Cases	Deaths	All Multiple Symptoms	Serio Injuri
tes	AstraZeneca	237,648	2,489	655,534	372,0
165	Pfizer BioNTech	191,215	5,961	452,779	186,30
	Moderna	29,616	3,365	72,596	38,70
	Janssen	4,997	369	15,281	7,713
C BY	Total	463,476	12,184	1,196,190	604,74

CC

https://www.globalresearch.ca/12184-dead-1196190-injuries-europe





## Crimes Against Humanity.



### crime a-gainst hu-man-i-ty

noun

 a deliberate act, typically as part of a systematic campaign, that causes human suffering or death on a large scale:

"he was handed over to the International Criminal Court in The Hague to face charges of crimes against humanity"

Powered by Oxford Dictionaries



### Discovery of a rich gene pool of bat SARS-related coronaviruses provides new insights into the origin of SARS coronavirus

"... we successfully cultured an additional novel SARSr-CoV Rs4874 from a single fecal sample... we constructed a group of infectious bacterial artificial chromosome (BAC) clones with the backbone of WIV1 and variants of S genes from 8 different bat SARSr-CoVs. Only the infectious clones for Rs4231 and Rs7327 led to cytopathic effects in Vero E6 cells after transfection..."

Peter Daszak, Zheng-Li Shi and others November 30, 2017



## Immediate Call to Action Items - STOP:

- (1) Gain-of-Function Research;
- (2) Interference of Physician Treatment of Patients;
- (3) Promotion and Coercion of Experimental Vaccines;
- (4) Experimenting on People without Informed Consent; and
  - (5) Hold Those Responsible Criminally Accountable.

### Violations of The Biological Weapons Convention (BWC) Treaty

### The Biological Weapons Convention (BWC) At A Glance

FACT SHEETS & BRIEFS

Last Reviewed: March 2020

Contact: Daryl Kimball, Executive Director, (202) 463-8270 x107

The Biological Weapons Convention (BWC) is a legally binding treaty that outlaws biological arms. After being discussed and negotiated in the United Nations' disarmament forum starting in 1969, the BWC opened for signature on April 10, 1972, and entered into force on March 26, 1975. It currently has 183 statesparties, including Palestine, and four signatories (Egypt, Haiti, Somalia, Syria, and Tanzania). Ten states have neither signed nor ratified the BWC (Chad, Comoros, Djibouti, Eritrea, Israel, Kiribati, Micronesia, Namibia, South Sudan and Tuvalu).

### **Terms of the Treaty**

The BWC bans:

- The development, stockpiling, acquisition, retention, and production of:
- Biological agents and toxins "of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;"
- Weapons, equipment, and delivery vehicles "designed to use such agents or toxins for hostile purposes or in armed conflict."
- The transfer of or assistance with acquiring the agents, toxins, weapons, equipment, and delivery vehicles described above.

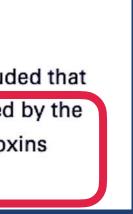
The convention further requires states-parties to destroy or divert to peaceful purposes the "agents, toxins, weapons, equipment, and means of delivery" described above within nine months of the convention's entry into force. The BWC does not ban the use of biological and toxin weapons but reaffirms the 1925 Geneva Protocol, which prohibits such use. It also does not ban biodefense programs.

The BWC bans biological agents that have NO justification for prophylactic, protective or other "peaceful" purposes.

Seventh Review Conference

The seventh BWC review conference was held in December 2011. The Final Declaration document concluded that "under all circumstances the use of bacteriological (biological) and toxin weapons is effectively prohibited by the Convention and affirms the determination of States parties to condemn any use of biological agents or toxins other than for peaceful purposes, by anyone at any time."

> "under all circumstances ... biological and toxic weapons ... effectively prohibited ... condemn any use...





## Violation of The 1947 Nuremberg Code

BRITISH MEDICAL JOURNAL No 7070 Volume 313: Page 1448, 7 December 1996.

### Introduction

The judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects in a new code that is now accepted worldwide.

This judgment established a new standard of ethical medical behaviour for the post World War II human rights era. Amongst other requirements, this document enunciates the requirement of *voluntary informed consent* of the human subject. The principle of voluntary informed consent protects the right of the individual to control his own body.

This code also recognizes that the risk must be weighed against the expected benefit, and that unnecessary pain and suffering must be avoided.

This code recognizes that doctors should avoid actions that injure human patients.

The principles established by this code for medical practice now have been extended into general codes of medical ethics.

### The Nuremberg Code (1947)

### Permissible Medical Experiments

The great weight of the evidence before us to effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments wield results for the good of society that are upprocurable by other

methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is

Human Medical experimentation must be conducted by trained personnel based upon animal studies and following informed consent.

a personal duty and responsibility which may not be delegated to another with impunity.

- The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
- The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment.
- The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
- No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
- 6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
- Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.
- The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
- During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
- 10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

For more information see Nuremberg Doctor's Trial, BMJ 1996;313(7070):1445-75.



## The 1947 Nuremberg Code

OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS



VOLUME 11 "THE MEDICAL CASE" "THE MILCH CASE" THE GREAT WEIGHT OF THE EVIDENCE BEFORE US IS TO THE EFFECT THAT CERTAIN TYPES OF MEDICAL EXPERIMENTS ON HUMAN BEINGS, WHEN KEPT WITHIN REASONABLY WELL-DEFINED BOUNDS, CONFERM TO THE ETHICS OF THE MEDICAL PROFESSION GENERALLY.

THE PROTAGONISTS OF THE PRACTICE OF HUI IAN EXPERIMENTATION JUSTIFY THEIR VIEWS ON THE BASIS THAT SUCH EXPERIMENTS YIELD RESULTS FOR THE GOOD OF SOCIETY THAT ARE UNPROCURABLE BY OTHER METHODS OR MEANS OF STUDY. ALL AGREE, HOWEVER, THAT CERTAIN BASIC PRINCIPLES MUST BE OBSERVED IN ORDER TO SATISFY MORAL, ETHICAL AND LEGAL

CONTRACT INC

THE VOLUNTARY CONSENT OF THE HUMAN SUBJECT IS ABSOLUTELY ESSENTIAL. THIS MEANS THAT THE PERSON INVOLVED SHOULD HAVE LEGAL CAPACITY TO GIVE CONSENT; SHOULD BE SO SITUATED AS TO BE ABLE TO EXERCISE FREE POWER OF CHOICE, WITHOUT THE INTERVENTION OF ANY ELEMENT OF FORCE, FRAUD, DECEIT, -DURESS, OVER-REACHING, OR OTHER ULTERIOR FORM OF CONSTRAINT OR COERCION; AND SHOULD HAVE SUFFICIENT KNOWLEDGE AND COMPREHENSION OF THE ELEMENTS OF THE SUBJECT MATTER INVOLVED AS TO ENABLE HIM TO MAKE AN UNDERSTANDING & ENLIGHTENED DECISION.

## Violation Declaration of Helsinki

A Set of Ethical Principles for Conducting Human Research. Article 8: Respect for Individual. Articles 20, 21, 22: Informed Consent. Article 27: Conflicts of Interest. Articles 2, 3, 10: Investigators Duty is to Patient. Articles 16, 17: Careful Assessment of Risks & Benefits.

- Established International **Research Ethics** June **1964** in Helsinki, Finland.
- Article 11: Responsibility for Thorough Scientific Knowledge of Research.

## Unethical Human Experimentation in the U.S.

Numerous experiments which were performed on human test subjects in the United States are considered unethical, because they were illegally performed or they were performed without the knowledge, consent, or informed consent of the test subjects. Such tests were performed throughout American history, but most of them were performed during the 20th century. The experiments included the exposure of humans to many chemical and biological weapons (including infections with deadly or debilitating diseases), human radiation experiments, injections of toxic and radioactive chemicals, surgical experiments, interrogation and torture experiments, tests which involved mind-altering substances, and a wide variety of other experiments. Many of these tests were performed on children,<sup>[1]</sup> the sick, and mentally disabled individuals, often under the guise of "medical treatment". In many of the studies, a large portion of the subjects were poor, racial minorities, or prisoners.

Many of these experiments violated US law. Some others were sponsored by government agencies or rogue elements thereof, including the Centers for Disease Control, the <u>United States military</u>, and the <u>Central Intelligence Agency</u>, or they were sponsored by private corporations which were involved in military activities.<sup>[2][3][4]</sup> The human research programs were usually highly secretive and performed without the knowledge or authorization of Congress, and in many cases information about them was not released until many years after the studies had been performed.

The ethical, professional, and legal implications of this in the United States medical and scientific community were quite significant, and led to many institutions and policies that attempted to ensure that future human subject research in the United States would be ethical and legal. Public outrage in the late 20th century over the discovery of government experiments on human subjects led to numerous congressional investigations and hearings, including the Church Committee and Rockefeller Commission, both of 1975, and the 1994 Advisory Committee on Human Radiation Experiments, among others.

In 1987 the United States Supreme Court ruled in United States v. Stanley, 483 U.S. 669, that a U.S. serviceman who was given LSD without his consent, as part of military experiments, could not sue the U.S. Army for damages. Stanley was later awarded over \$400,000 in 1996, two years after Congress passed a private claims bill in reaction to the case.<sup>[187]</sup> Dissenting the original verdict in U.S. v. Stanley, Justice Sandra Day O'Connor stated:

No judicially crafted rule should insulate from liability the involuntary and unknowing human experimentation alleged to have occurred in this case. Indeed, as Justice Brennan observes, the United States played an instrumental role in the <u>criminal prosecution</u> of Nazi scientists who <u>experimented with human subjects</u> during the Second World War, and the standards that the Nuremberg Military Tribunals developed to judge the behavior of the defendants stated that the 'voluntary consent of the human subject is absolutely essential ... to satisfy moral, ethical, and legal concepts.' If this principle is violated, the very least that society can do is to see that the victims are compensated, as best they can be, by the perpetrators.

https://en.wikipedia.org/wiki/Unethical\_human\_experimentation\_in\_the\_United\_States



### Violation of The International Covenant on Civil and Political Rights (ICCPR) Treaty on Human Experimentation.

International Covenant on Civil and Political Rights

Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, entry into force 23 March 1976, in accordance with Article 49

Article 7

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.



### Physician Violation The American Medical Association (AMA) Code of Medical Ethics

Informed Consent | American Medical Association

https://www.ama-assn.org/delivering-care/ethics/informed-consent

### **Code of Medical Ethics Opinion 2.1.1**

Informed consent to medical treatment is fundamental in both ethics and law.

Patients have the right to receive information and ask questions about

recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.

### CME course: Informed consent and decision making

This e-learning module will help physicians identify the standard process of informed consent and how to handle situations when patients cannot give informed consent.

Go to Course

### PACKAGE INSERTS

The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:

- (a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.
- (b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:
  - (i) The diagnosis (when known)
  - (ii) The nature and purpose of recommended interventions
  - (iii) The burdens, <mark>risks,</mark> and expected benefits of all options, including forgoing treatment
- (c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the

Patient Informed Consent is Fundamental to both Medicine and Law.

Informed Consent is between the patient and physician.

Informed Consent requires patients being made aware of the purpose, risks & benefits of a test or treatment.

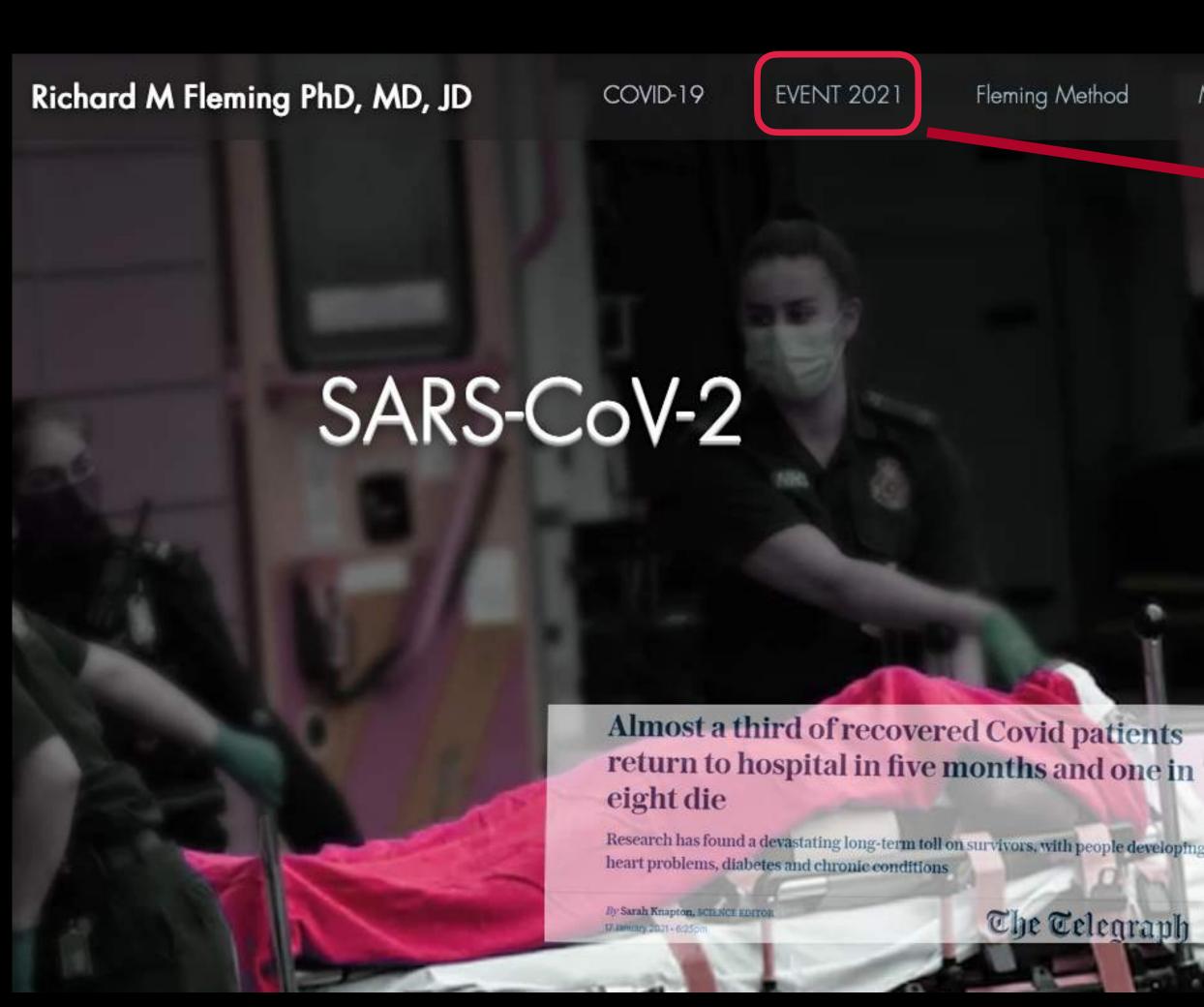


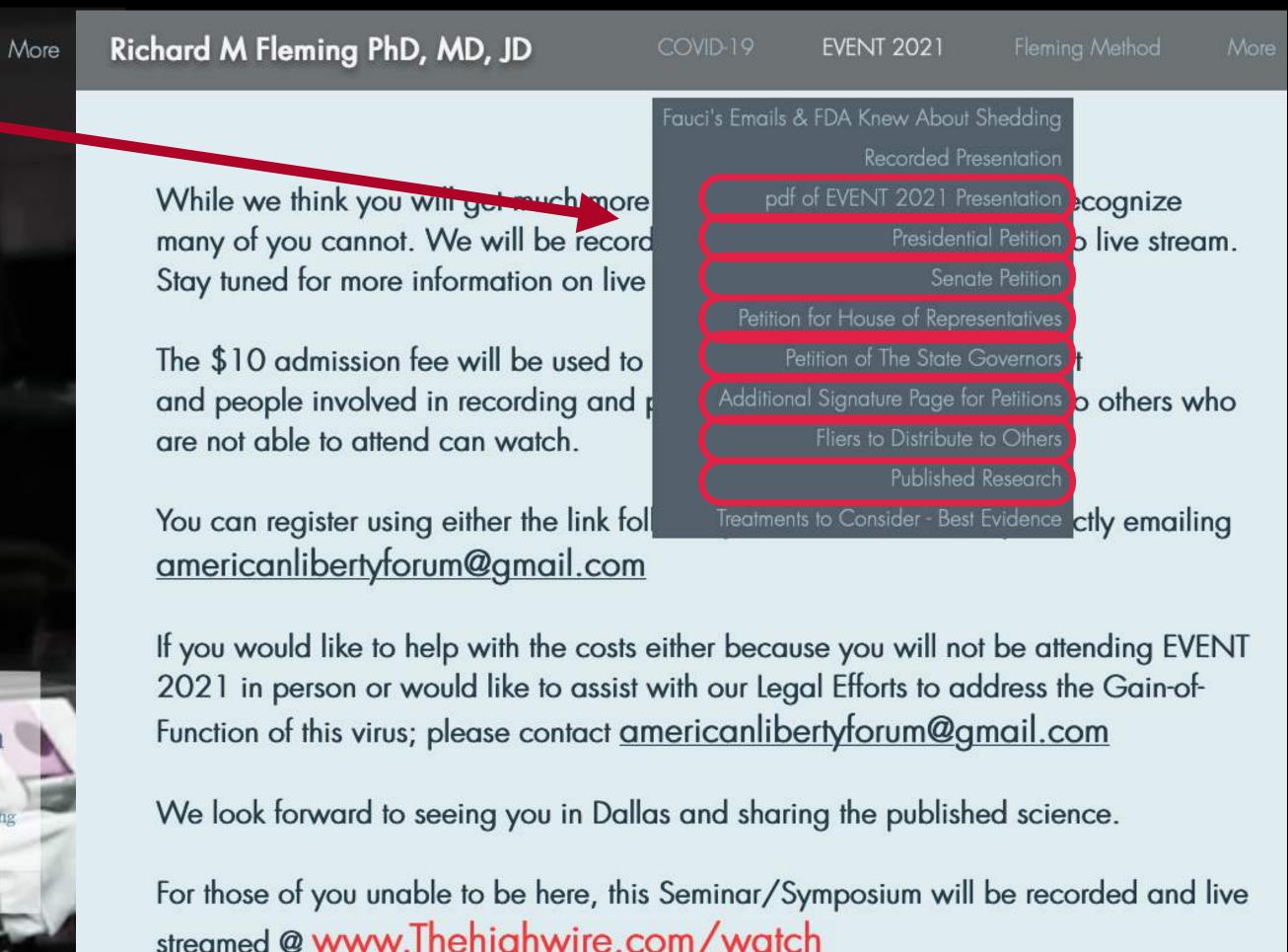
## This Time

This time there will be no hiding of evidence from the jury (the people) & There will be no pulling the wool over the jury's (people's) eyes.

## Action Items on www.FlemingMethod.com

### **Download and Act Upon.**





streamed @ www.Thehighwire.com/watch

### From There You Can Download & Share

### Notice to Cease and Desist

This document serves as an order to CEASE AND DESIST harassment, which is an UNLAWFUL ACTION as outlined below. Whoever chooses to knowingly and willingly engage in unlawful behavior is committing a CRIMINAL OFFENSE and is subject to any punishments afforded by well established law.

Unlawful Mask Mandates and Vaccine Verification

While some states may mandate the wearing of masks or vaccine verification, there is no law in place requiring them. Denying entry or access to services for those without a face covering or requiring proof of SARS-CoV-2 vaccination is in direct violation of state law and is discriminatory, unlawful and unconstitutional.

Individuals without a face covering or vaccine verification cannot be considered a direct threat, unless they have been deemed to be contagious by a treating physician with full access to their medical history, and are therefore legally entitled to full access at all places of public accommodation. A person that complies with all lawful conditions at places of public accommodation cannot be considered as trespassing.

Behavior meant to create a hostile or unsafe environment toward those without a face covering or vaccine verification is regarded as harassment, which is a criminal offense.

> Harassment is a gross misdemeanor punishable by up to a year of jail time.

----- This document is supported by Richard M Fleming, PhD, MD, JD ------

For more information on SARS-CoV-2 & COVID-19 go to: www.FlemingMethod.com

The following types of actions toward individuals without a face covering or vaccine verification are regarded as harassment:

(1) Subjecting someone to physical restraint such as blocking their entry or restraining their free movement.

(2) Deprivation of rights under color of law (18 U.S.C. § 242).

(3) Being unlawfully detained by police when there is no evidence of trespass. Such action by law enforcement is considered a false report and restraining these individuals against their will is false imprisonment. Every public officer who shall knowingly and willingly make any false or misleading statement in any official report or statement, under circumstances not otherwise prohibited by law, shall be guilty of a gross misdemeanor.

(4) Threatening someone so as to create concern for his or her physical or mental health safety, such as calling or purporting to call law enforcement under the guise of a trespass violation is assault.

The Office of the Sheriff is the chief law-enforcement agency in the County with duty to keep peace and uphold the LAW in accordance with Federal and State Constitutions. In the execution of their duties, the Sheriff may arrest and commit to prison all persons who break the peace, attempt to break the law, and all persons guilty of these public offenses.

A public offense is any conduct that is in violation of the United States Constitution, the State Constitution, and well-established law, and is punishable to the fullest extent the law will allow.

Harassment, false reporting, false imprisonment, and assault are violations of law established under Federal and State Constitutions.

----- This document is supported by Richard M Fleming, PhD, MD, JD ------

For more information on SARS-CoV-2 & COVID-19 go to: www.FlemingMethod.com

### Harassment

### Sheriff

### Civil Rights Act 1964 Titles I & II

Public accommodations are prohibited from unlawful discrimination and must allow free and equal access to all goods, services, facilities, privileges and accommodations as the general public.

### Title U.S.C. 42 § 2000

(a) All persons shall be entitled to the full and equal enjoyment of the goods, services, facilities, privileges, advantages, and accommodations of any place of public accommodation, as defined in this section, without discrimination or segregation on the ground of race, color, religion, or national origin.

(b) Establishments affecting interstate commerce or supported in their activities by State action as places of public accommodation; lodgings; facilities principally engaged in selling food for consumption on the premises; gasoline stations; places of exhibition or entertainment; other covered establishments.

A Private Business is a Public Accommodation that is open to the general public & engaged in commerce. A private business cannot lawfully deny you service if they are open to the general public while they are engaging in commerce.

They are breaking well-established law if they discriminate against you. The only places that are not a public accommodation are churches, temples, synagogues, private membership association, or a 501(C)(3) nonprofit.

A grocery store is a private entity that provides goods and services to the general public and is therefore lawfully defined in Federal and State laws as a place of "Public Accommodation". The legal, federal definition of a public accommodation: Public accommodation means a private entity that owns, leases (or leases to), or operates a place of public accommodation.

----- This document is supported by Richard M Fleming, PhD, MD, JD ------

For more information on SARS-CoV-2 & COVID-19 go to: www.FlemingMethod.com



## You Can Download, Sign and Send to

By affixing our signatures below, we respectfully petition both Governor Abbott of the State of Texas, and the Texas State Legislature to take the following actions on behalf of the Citizens of the State of Texas pursuant to the 10<sup>th</sup> Amendment of the U.S. Constitution as ratified on 15 December 1791.

Whereas: The Spike Protein of SARS-CoV-2 virus is the direct result of Gain-of-Function (GoF) research on Corona Viruses; and

Whereas: this Gain-of-Function research was funded by Texan and U.S. taxpayers via Federal Agencies, including but not limited to, the NIH, NIAID, DOD, HHS, NSF, and the USAID; and

Whereas: these Federal Agencies have paid monies to multiple Universities, Public and Private Corporations for Gain-of-Function research, in addition to and including but not limited to, Peter Daszak of EcoHealth, who subsequently funneled these monies including but not limited to, Professor Ralph Baric at the University of North Carolina - Chapel Hill, and Professor Shi Zhengli at the Wuhan Institute of Virology; and

Whereas: this has resulted in a pandemic that has cost more American lives than any war in U.S. history including WWII, The Civil War, or all other U.S. Wars combined; and

Whereas: The EUA documents filed by Pfizer, Moderna, and Janssen all demonstrate that the use of these Experimental Drug/Vaccines that include either the mRNA or dsDNA of the Spike Protein produced by this Gain-of-Function Research, do NOT statistically reduce the incidence of COVID-19; and

Whereas: by definition this Spike Protein is pursuant to the terms and conditions of the Biological Weapons Convention Treaty Treaty; and

Whereas: the failure to require and provide written Informed Consent to individuals being given an Experimental Drug, which these Vaccines are by definition; is a violation of (1) The 1947 Nuremberg Code, (2) The International Covenant on Civil and Political Rights (ICCPR) Treaty, (3) The 1964 Declaration of Helsinki, and (4) The American Medical Association (AMA) Code of Ethics.

We respectfully and formally request: That Governor Abbott and the Texas legislature pass legislation and/or executive action that protect consumers from businesses denying entry to consumers who don't have vaccine or mask pursuant to the 10<sup>th</sup> Amendment to the U.S. Constitution.

We respectfully and formally request: That Governor Abbott and the legislature provide an exemption from any vaccine documents including vaccine passports for consumers and citizens of the State of Texas pursuant to the 10<sup>th</sup> Amendment to the U.S. Constitution.

We respectfully and formally request: That Governor Abbott and the legislature pass legislation protecting consumers from any and types of discrimination if a consumer decides not to wear a mask or take a vaccine. In other words, no business, company, or entity can force its employees or consumers to take a vaccine or wear a mask pursuant to the 10<sup>th</sup> Amendment to the U.S. Constitution.

(BWCT) is a violation of the Biological Weapons Convention

Signatories

o Your Governor
Richard M Fleming, PhD, MD, JD 5 June 2021
Date:

### You Can Download, Sign and Send to President Biden & The Congress of the USA

By affixing our signatures below, we respectfully petition both The President of the United States, Joseph Robinette Biden, Jr. and the Congress of the United States to take the following actions on behalf of the Citizens of the United States of American pursuant to Article I and Article II of the U.S. Constitution as ratified on 21 June 1788, and in accordance with the Amendments to the U.S. Constitution.

Whereas: The Spike Protein of SARS-CoV-2 virus is the direct result of Gain-of-Function (GoF) research on Corona Viruses; and

Whereas: this Gain-of-Function research was funded by U.S. taxpayers via Federal Agencies, including but not limited to, the NIH, NIAID, DOD, HHS, NSF, and the USAID; and

Whereas: these Federal Agencies have paid monies to multiple Universities, Public and Private Corporations for Gain-of-Function research, in addition to and including but not limited to, Peter Daszak of EcoHealth, who subsequently funneled these monies including but not limited to, Professor Ralph Baric at the University of North Carolina - Chapel Hill, and Professor Shi Zhengli at the Wuhan Institute of Virology; and

Whereas: the Constitution of the United States of America does not empower the Senate or the Executive Branch of the U.S. Federal Government with the power or authority to regulate medical care; and

Whereas: physicians have been prevented from practicing medical care of patients as they and their patients deem medically appropriate, following actions taken by the Federal Government including but not limited to Administrative agencies including the NIH, NIAID, CDC, PHS, FDA, and HHS; and

Whereas: this has resulted in a pandemic that has cost more American lives than any war in U.S. history including WWII, The Civil War, or all other U.S. Wars combined; and

Whereas: The EUA documents filed by Pfizer, Moderna, and Janssen all demonstrate that the use of these Experimental Drug/Vaccines that include either the mRNA or dsDNA of the Spike Protein produced by this Gain-of-Function Research, do NOT statistically reduce the incidence of COVID-19, or deaths from COVID-19, and

Whereas: by definition this Spike Protein is pursuant to the terms and conditions of the Biological Weapons Convention Treaty (BWCT) a direct violation of the Biological Weapons Convention Treaty; and

Whereas: the failure to provide the required written Informed Consent to individuals being given these Experimental Drug Vaccine (Biological Agents), make the injection of these Experimental Drug Vaccines (Biological Agents) by definition; a violation of (1) The 1947 Nuremberg Code, (2) The International Covenant on Civil and Political Rights (ICCPR) Treaty, (3) The 1964 Declaration of Helsinki, and (4) The American Medical Association (AMA) Code of Ethics.

We hereby respectfully and formally request: That the President and Congress of the United States of American begin the immediate investigation of those involved in Gain-of-Function research, and that the investigation specifically include the investigation of those individuals and agencies responsible for the investment and development of the SARS-CoV-2 virus. That these individuals be held legally and criminally accountable for their actions in violation with including but not limited to U.S.

Statutory violations as well as violations of the BWC Treaty, the ICCPR Treaty, and The Declaration of Helsinki.

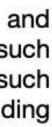
We hereby respectfully and formally request: Legislative and Executive action to ban the funding and development of such Gain-of-Function research, and the immediate cessation of such research currently being conducted and a return of such funding to the agencies or individuals that dispensed said funding.

We hereby respectfully and formally request: Legislative and Executive action to ban any Federal interference with the practice of medicine and to refrain from any further interference with the practice of medicine.

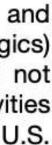
We hereby respectfully and formally request: Legislative and Executive action to ban any mask or drug vaccine (biologics) mandates or requirements of U.S. citizens including but not limited to travel, entry into places of business, or other activities consistent with the practices and principles of the U.S. Constitution and Amendments to the Constitution.

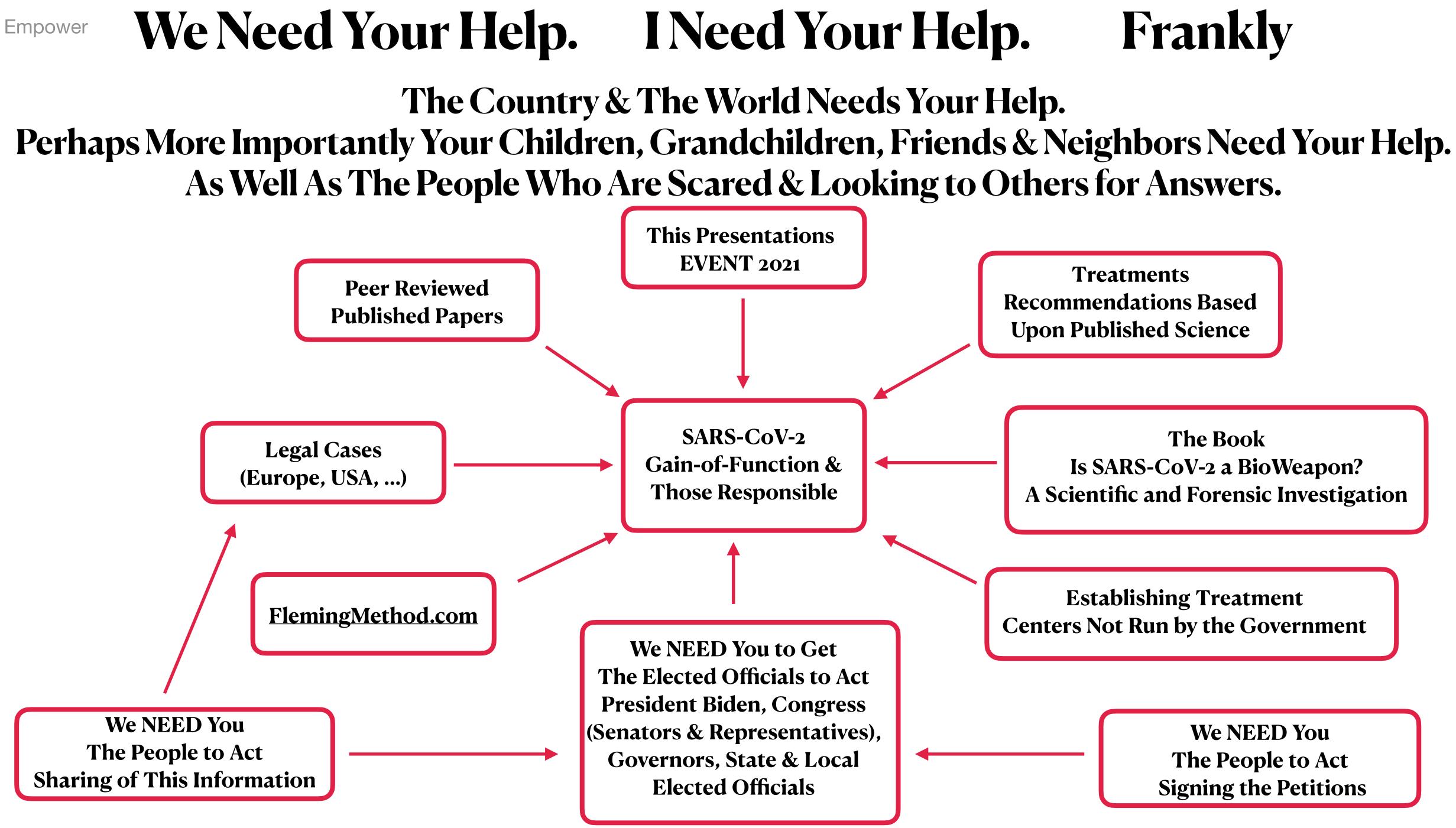
SignatoriesStateDate								
Richard M Fleming, PhD, MD, JD								
		TEX/	AS 5 June 202 <sup>-</sup>					
NAME	YOUR STATE	Date:	DATE					
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		Date:						
		Date:						











### Help Us Prove Hermann Wilhelm Göring Wrong! **Because the Alternative is to Prove He was Right.**





### What We Do Together Will Determine What Happens Next





## Section 04

### 04 Hope From The Best **Available Research Results.**

**The Prevention** 

**Treatment of SARS-CoV-2 Infection** 

**Treatment of COVID-19 ITR Disease** 

**Treatment of Those Who Are Experiencing** 

- **Adverse Effects Following Vaccination with Biologics.**

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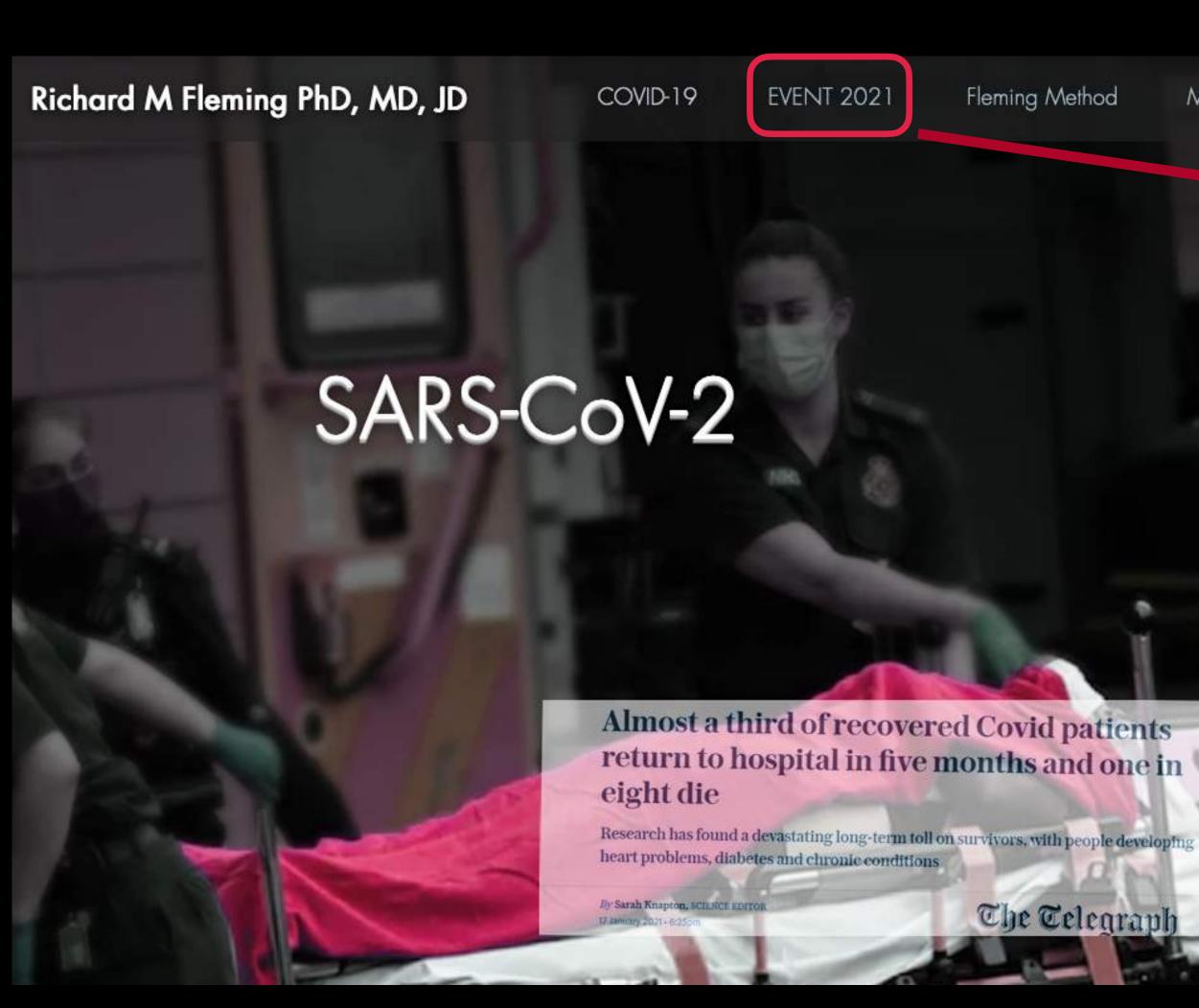
### HOPE: Best Available Evidence Treatments



### **Richard Urso MD**

Dr. Li-Meng Yan

### Treatments to Consider www.FlemingMethod.com



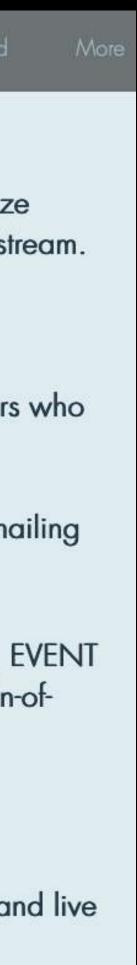
### **Download and Act Upon.**

More	Richard M Fleming PhD, MD, JD	COVID-19	EVENT 2021	Fleming Method
		Fauci's Emails	& FDA Knew About	Shedding
			Recorded Pre	esentation
	While we think you will get much more	рс	lf of EVENT 2021 Pre	esentation ecognize
	many of you cannot. We will be record		Presidenti	al Petition <mark>o live stre</mark>
	Stay tuned for more information on live		Sena	te Petition
		Petitic	on for House of Repre	sentatives
	The \$10 admission fee will be used to		Petition of The State (	Governors <b>†</b>
1	and people involved in recording and	Additio	nal Signature Page fo	r Petitions o others
	are not able to attend can watch.		Fliers to Distribute	to Others
			Published	Research
	You can register using either the link fol	Treatme	nts to Consider - Best	Evidence ctly emai
	americanlibertyforum@gmail.com			
	If you would like to help with the costs of	111 March 11	and the second second second second	

2021 in person or would like to assist with our Legal Efforts to address the Gain-of-Function of this virus; please contact americanlibertyforum@gmail.com

We look forward to seeing you in Dallas and sharing the published science.

For those of you unable to be here, this Seminar/Symposium will be recorded and live streamed @ www.Thehighwire.com/watch



## You Can Download The Following & Give to Doctors

5 June 2021

### Treatments to Consider Based Upon the Best Available Evidence Research Results.

PROPOSED TREATMENT APPROACHES FOR PROPHYLAXIS, SARS-COV-2, COVID-19, AND POST-VACCINATION; FOR YOU TO DISCUSS WITH YOUR PHYSICIAN. THIS IS NOT A SERVICE, THE SALE, BUYING, OR MARKETING OF A PRODUCT, OR THE PRACTICING OF MEDICINE.

This document has been assembled following repeated requests for such information. Given the discordant dissemination of information and misinformation, it is clear that clinicians are receiving little guidance in the treatment of individuals infected with SARS-CoV-2; who have developed the InflammoThrombotic Response (ITR) disease of COVID-19; or who have undergone injection of a vaccine containing genetic material encoding the gain-of-function spike protein.

Consequently, pursuant to those requests, and the need to provide some level of guidance. I have assembled based upon the best available evidence research results. the following proposed treatment options to be considered by your doctor to address these various health problems and concerns1.

Also included are potential options for treatment of Individuals infected with SARS-CoV-2 or have been injected with SARS-CoV-2 Vaccines, based upon mechanisms of action and the best available evidence research results.

> These best available evidence research results and understood mechanisms of action are to be followed only under the care and supervision of your physician.

> Nothing within this material should be considered as my providing you with medical care, a service, sale or advertisement of a product or medical advice.

> I have no relationship to any of the companies that make any of these drug products.

> Any care or treatment provided to you is the responsibility of your personal physician, as well as yourself, and should follow informed consent. There is no expressed U.S. Constitutional authority under Article I or II, for the Federal Government to direct, govern, or otherwise be involved in your personal Health Care. https://constitutioncenter.org/interactiveconstitution/full-text

The fundamental expressed concerns people appear to have as a result of becoming infected with SARS-CoV-2 or having been vaccinated include:

- (CRISPR).
- resulting in further disease.
- like diseases and sequela.

5 June 2021

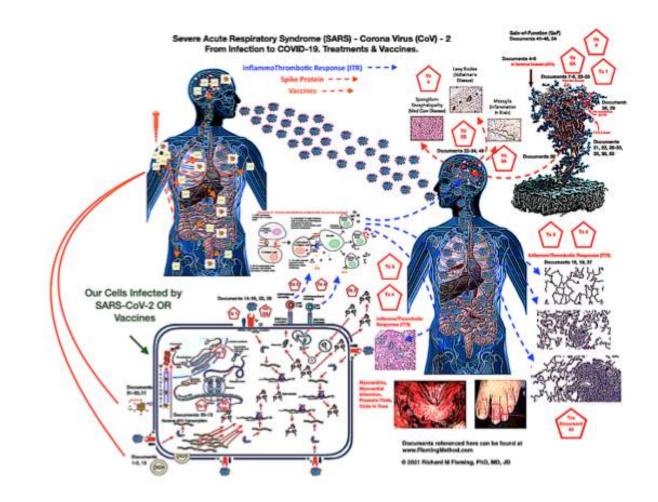
(1) The possible insertion of the genetic code sequence(s) found within the Drug Vaccines through Reverse Transcription (RT) into human DNA, potentially made possible as a result of either the RT capacities present within the SARS-CoV-2 virus itself (spike protein, nucleocapsid, envelope, or other genetic sequences); the Long Interspersed Nuclear Elements (LINE-1) found within approximately 18% of the human genome; or RT facilitated in CD-4 cells and platelets as previously demonstrated with Human Immunodeficiency Viruses (HIV); raise increased concerns about the potential of genetic material being inserted into the human genome, or replacing components of the human genome; particularly when coupled with Clustered Regularly Interspaced Short Palindromic Repeats

(2) The circulation of the spike protein within the body, from the virus or drug vaccine with induced production of SARS-CoV-2 spike proteins, as well as other genetic material; needs to be neutralized to reduce the dissemination of this genetic material as well as prion-like domains found near the receptor binding domain (RBD) of the spike protein; either within the individual infected or injected, to minimize the InflammoThrombotic Response (ITR) resulting in the disease COVID-19; the potential development of amyloidal and prion diseases, occurring within the brain resulting from the prion-like domain at the Receptor Binding Site (RBS) of the spike protein as seen in animal models; and to minimize the shedding of this genetic and protein material that could be transmitted to others,

(3) The need to reduce, inhibit or prevent the viral or other non-native individual genetic material from being re-expressed at a later time - as seen with many viral diseases - through transcription and translation of viral or genetic material inserted into the human DNA through the above noted RT process, and

(4) The immediate and long treatment of potentially damaged human DNA, including but not limited to the potential short and long-term neurologic, cardiac, and prion5 June 2021

OVERVIEW OF THE SARS-CoV-2 PROCESS IN INFECTED AND VACCINATED PEOPLE INCLUDING THE INFLAMMOTHROMBOTIC RESPONSE (ITR) DISEASE COVID-19. https://www.flemingmethod.com/documentation



### CURRENTLY SUGGESTED TREATMENTS BASED UPON BEST AVAILABLE EVIDENCE RESEARCH RESULTS PROPHYLAXIS FOR PEOPLE CONCERNED ABOUT SARS-CoV-2

As someone who has practiced clinically I am not a believer in the use of medications for prophylaxis when there is no disease yet to be treated. Just as treating an abnormal blood test without the presence of a disease to be treated makes it impossible to measure a treatment benefit - given no disease to measure - or treatment failure; the only potential measureable outcome is that of potential risks or complications resulting from the treatment. E.g. prophylaxis of cancer by having chemotherapy when there is no measureable evidence of cancer.

That being said, the following steps based upon best available evidence research results have been shown to reduce the development and progression of InflammoThrombotic Response (ITR) Diseases; including but not limited to aging, coronary artery disease, cancer, strokes, hypertension, diabetes, and obesity.





<sup>&</sup>lt;sup>1</sup> This does not represent a "service."

## You Can Download The Following & Give to Doctors

5 June 2021

Modification of diet and lifestyle, to reduce risk factors for these chronic inflammatory diseases, as I and others have previously published and discussed [https://www.youtube.com/watch?v=OE6cnZFOBJ8] have been shown to reduce the risk of associated comorbidities associated with SARS-CoV-2 & COVID-19.

In addition, it has been the standard of care, that patients with respiratory problems, particularly those with compromised airway flow and reductions in acceptable oxygen levels within the arteries (viz. oxygen saturation), have received bronchodilator treatments and steroids when deemed medically appropriate.

Many researchers and clinicians would additionally advocate for sufficient dietary supplementation of vitamins and minerals to maximize overall immune response particularly under "stressful" conditions.

Examples of these best available evidence research results include:

### RESPIRATORY SUPPORT

Ipratropium bromide (Atrovent) inhaler treatment every 4-hours.

Inhalers 2-puffs every 4 hours. Nebulizer 500 mcg every 4 hours (adults). Dose to be reduced accordingly for children.

### THROMBOSIS REDUCTION

- 1) Either heparin 5000 units subcutaneously every 12 hours OR
- 2) Aspirin 325 mg tablets (once or twice daily as tolerated), OR
- 3) Equivalent given specifics of person.

### IMMUNE SUPPORT

- 1) Folate (B9) 3 mg by mouth daily
- 2) Magnesium 400 mg by mouth daily
- 3) Calcium Carbonate 400 mg by mouth daily
- 4) Cobalamin (B12) 3 mg by mouth daily
- 5) Pyridoxine (B6) 30 mg by mouth daily
- 6) Dehydroepiandrosterone (DHEA) 50 mg by mouth twice daily
- 7) Ascorbic acid (C) 2000 mg by mouth daily
- 8) Zinc 10 mg by mouth daily, and
- 9) 1,25-dihydroxycholecalciferol (D3) 1500 IU by mouth daily.

Based upon best available evidence research results, viruses have been treated by focusing on viral attachment and replication. Given the InflammoThrombotic Response (ITR) to SARS-CoV-2, and the best available evidence research results, patients infected with the virus with adverse outcomes are developing ITRs. Currently suggested treatments based upon best available evidence research results include the following.

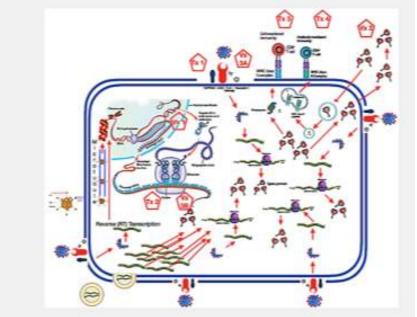
Yes Treatment of SARS-CoV-2 & COVID-19 are Treatable by Using a Combination of Medicines to address

- (1) Virus attachment & Entry into the cell. (2) Virus replication once inside the cell.
- (3) Reducing Inflammation & Blood Clotting
- associated with the T-Cell (Innate)
- response to the virus.
- (4) Reducing Inflammation & Blood Clotting associated with the B-cell (Delayed Humoral) response to the virus.

It is also important to use Medicines that improve airflow in and out of the lungs, as well as Medications to reduce blood clotting, and assist controlled immune response.

5 June 2021

### Is SARS-CoV-2 & COVID-19 Treatable?



- CONTINUED -

### CURRENTLY SUGGESTED TREATMENTS BASED UPON BEST AVAILABLE EVIDENCE RESEARCH RESULTS FOR PEOPLE INFECTED BY SARS-CoV-2 WHO ARE NOT HOSPITALIZED

### When Treatment was Started within 3-4 Days of Symptoms.

### (1) 100% Effective

Primaguine 200 mg by mouth on day 1.

Clindamycin 150 mg by mouth every 6-hours for 7-days.

Hydroxychloroguine 200 mg by mouth every 8-hours for 10-days.

### (2) 97.9% Effective

Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.

Clindamycin 150 mg by mouth every 6-hours for 7-days.

(3) 74.2% Effective

Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.

Azithromycin 500 mg by mouth on day 1, then 250 mg by mouth on days 2 through 5.

(4) 69.1% Effective

Hydroxychloroquine 200 mg by mouth every 8-hours for 10-days.

Doxycycline 100 mg by mouth every 12-hours for 10-days.

### CURRENTLY SUGGESTED TREATMENTS BASED UPON BEST AVAILABLE EVIDENCE RESEARCH RESULTS FOR PEOPLE INFECTED BY SARS-CoV-2 WHO ARE HOSPITALIZED WITH COVID-19 (ITR to Virus)

(1) With prior Aminoquinoline Treatment begin

Methylprednisolone 125 mg IV every 6-hours for 3 days;

then 125 mg IV every 12-hours for 2 days;

then 125 mg IV daily for 2 days;

then 60 mg IV daily for 2 days [with each infusion given over 30-minutes];

then Solumedrol dose pack to taper off steroids).

(2) With prior Aminoquinoline Treatment begin

Tocilizumab 8-mg/kg [IBW; not to exceed 800 mg] not to exceed 800 mg intravenously infused over 1-hour. May be repeated every 8-hours for a maximum of 4-doses; and

Interferon  $\alpha$ -2 $\beta$  (5-million units per nebulizer every 12-hours for 7-days).

(3) Without prior Aminoquinoline Treatment

Primaguine 200 mg by mouth day 1;

Clindamycin 150 mg by mouth every 6-hours for 7-days; and

Tocilizumab and Interferon- $\alpha 2\beta$  - using the same doses shown in (2) above.







## You Can Download The Following & Give to Doctors

5 June 2021

### CURRENTLY SUGGESTED TREATMENTS BASED UPON BEST AVAILABLE EVIDENCE RESEARCH RESULTS FROM PHYSICIANS REPORTING CLINICALLY SUCCESSFUL TREATMENTS

### **Clinicians** Reporting Treatment Success.

- Dr. Vladimir Zelenko (Family Practice in New York) treatment with hydroxychloroquine, azithromycin and zinc had an 84% reduction in hospitalization. [doi: 10.20944/ preprints202007.0025.v1 ]
- Dr. Peter A. McCullough (Baylor Dallas) nine studies reveal patients treated with hydroxychloroquine and other drugs like doxycycline had a greater than 60% reduction in death. [https://www.researchgate.net/publication/348946216]
- AAPS Early Treatment Saves Lives [https://aapsonline.org/early-treatment-saves-lives/]
- Dr. Harvey Risch (Yale) Hydroxychloroquine (HCQ) produced a 34% reduction in risk of death, while HCQ and azithromycin produced a 29% reduction in risk of death in hospitalized patients with COVID-19. [https://doi.org/10.1016/j.ijid.2020.06.099 ]
- Dr. Richard Bartlett (Budesonide Nasal Steroids) reports 100% success rate when started early.
- Dr Eleftheria Atalla (Brown University, R.I.) treatment of critically ill seniors in Long Term Care Facilities with anticoagulants who had elevated markers of inflammation were 84% less likely to die. [Pathogens 2021, 10, 8. https://dx.doi.org/10.3390/pathogens10010008]

### CURRENT POTENTIAL TREATMENTS CONSIDERATIONS BASED UPON BEST AVAILABLE EVIDENCE RESEARCH RESULTS - FOCUSING ON SPECIFIC COMPONENTS - FOR PEOPLE WHO HAVE BEEN VACCINATED

Based upon the best available evidence currently being collected, the fundamental goals for treating potential complications from drug vaccine delivery of genetic material, includes first blocking the Nuclear Protein Complex (NPC), to minimize continued entry and re-entry of this genetic material into the cellular nuclear region where reverse transcription (RT) could occur; protecting the native human DNA.

The next step is to remove any circulation spike proteins, minimizing the potential harm they might cause including InflammoThrombotic Response (ITR) disease and Prion diseases. The next logical step would be to interfere with any reuptake of spike protein by host cells that could serve as potential new sources of prions, mRNA or DNA, with potential RT, or any other potential sources of SARS-CoV-2 genetic material or any other genetic or non-genetic material circulating from the injected drug vaccines.

The fourth goal is to minimize any potential damage caused by the prion-like domains (PLDs) including reducing the potential longer term neurologic, cardiac, and other organ tissue damage.

This sequence of steps will hopefully reduce the genetic load introduced into the body by these drug vaccines. By interfering with the entry and re-entry of this genetic material through the NPC through this series of steps, this will hopefully provide adequate time for sufficient glycosylase enzyme removal of genetic bases or nucleotide excision - repair mechanisms - of any damaged DNA; through continued encouragement of transcription of the viral - and other - genetic material, increasing the potential for these DNA repairs to occur.

In essence, by reducing the active viral or spike protein load through these steps, the increased transcription required for maintenance of the genetic code or protein products, will increase the potential for DNA excision repair and exhaust or at a minimum fatigue the viral genetic load.

Step 1: Stop the Reverse Transcriptase (RT) - Block the Nuclear Protein Complex (NPC)

(A) Ivermectin 0.2-0.4 mg/kg body weight by mouth (PO) every two weeks.

Step 2: Remove Spike Protein in circulation hat could cause ITR or prion-like initiated amyloid or equivalent plaquing

(A) Casirivimab 1200 mg & Imdevimab 1200 mg provided intravenously together as a single infusion over a minimum of 60-minutes.

Step 3A Reduce further uptake of Spike protein by cells hroughout the body including transmission across the Blood Brain Barrier (BBB).

(A) Primaguine 200 mg orally given once – Targets ACE2 receptor.

(B) Clindamycin 150 mg orally every 6-hours for 7-days - Targets transmembrane protease serine 2 (TMPRSS2) receptor.

(C) Hydroxychloroquine 200 mg orally twice a week – Targets ACE2 receptor.

Step 3B Reduce further translation of mRNA to spike protein.

(A) The Primaguine from 3A also inhibits viral protein translation (production of spike protein from mRNA).

(B) The Clindamycin from 3A also inhibits viral protein translation; reduces ITR by reducing tissue necrosis factor – alpha (TNF- $\alpha$ ) and interleukin-1 beta (IL-1β).

(C) The Hydroxychloroquine from 3A enhances zinc entry through the zinc ionophore; enhances the production of type 1 interferons, interferes with ribosomal translation of the spike protein, reduces interleukin-6 (IL-6) levels;

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increases cellular pH thereby decreasing viral antigen (mRNA or spike protein) major histocompatability complex (MHC) presentation of the spike protein to B-cells reducing antibody formation and ITR.

(D) Zinc 10 mg orally (po) daily. While this may also interfere with the ACE2 receptor, it also interferes with RNA dependent RNA polymerase (RdRP).

(E) Ascorbic Acid (Vitamin C) 2000 mg orally (po) daily to reduce ITR.

(F) 1,25-dihydroxycholecalciferol (Vitamin D3) 1500 IU orally (po) daily to reduce ITR.

Step 4: Address potential amyloid production and neurologic sequlae resulting from prion-like domains on spike protein.

(A) Treat ApoE through dietary and lifestyle factors; HMG CoA-reductase inhibitors or Probucol [An ATP-binding transporter A1 (ABCA1)]. (B) Niacin (Vitamin B3) 15 mg twice daily.

FURTHER INFORMATION WILL BE MADE AVAILABLE BASED UPON BEST AVAILABLE EVIDENCE RESEARCH RESULTS.

Richard M Fleming, PhD, MD, JD

### Sites in Europe will soon begin providing these treatments & using FMTVDM to measure results.







### We Cannot Blame Others If We Fail To Act!





### **Books With More Information For Medical Professionals & The General Public.**



• https://www.amazon.com/Dr-Richard-M-Fleming/e/B08NGY2YZK?ref=sr\_ntt\_srch\_lnk\_1&qid=1609337190&sr=1-1



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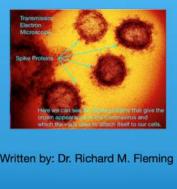
CoVid-19

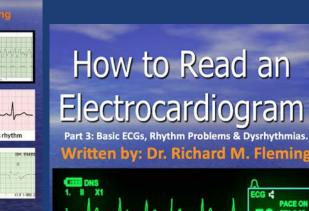
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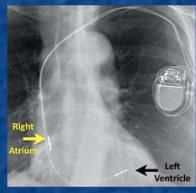
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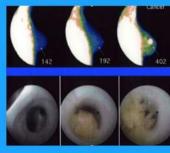
### Basic **Pacemakers**

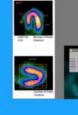


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### FMTVDM

Guessing & Knowing











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