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The Twin Pillars of Global Vaccine Partnerships: Addressing Equity & Hesitancy

@PeterHotez

Peter Hotez MD PhD

Texas Children's Hospital Endowed
Chair in Tropical Pediatrics

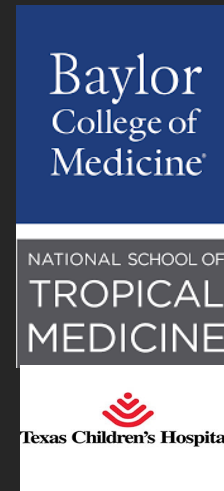
Dean, National School of Tropical Medicine
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Senior Fellow, James A Baker III
Institute for Public Policy, Rice University

Texas Children's CVD

NATIONAL SCHOOL OF TROPICAL MEDICINE, BAYLOR COLLEGE OF MEDICINE

- Portfolio of Global Health & Neglected Disease Vaccines
- Schistosomiasis
- Hookworm
- Chagas Disease
- Leishmaniasis
- Coronavirus Infections
 - SARS CoV
 - SARS CoV2
 - MERS



Antipoverty Vaccines



Available online at www.sciencedirect.com

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Vaccine 24 (2006) 5787–5799

Vaccine

www.elsevier.com/locate/vaccine

Review

The antipoverty vaccines

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^b Department of Pediatrics, State University of New York at Stony Brook, Stony Brook, NY 11794, United States

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Received 19 April 2006; received in revised form 8 May 2006; accepted 9 May 2006

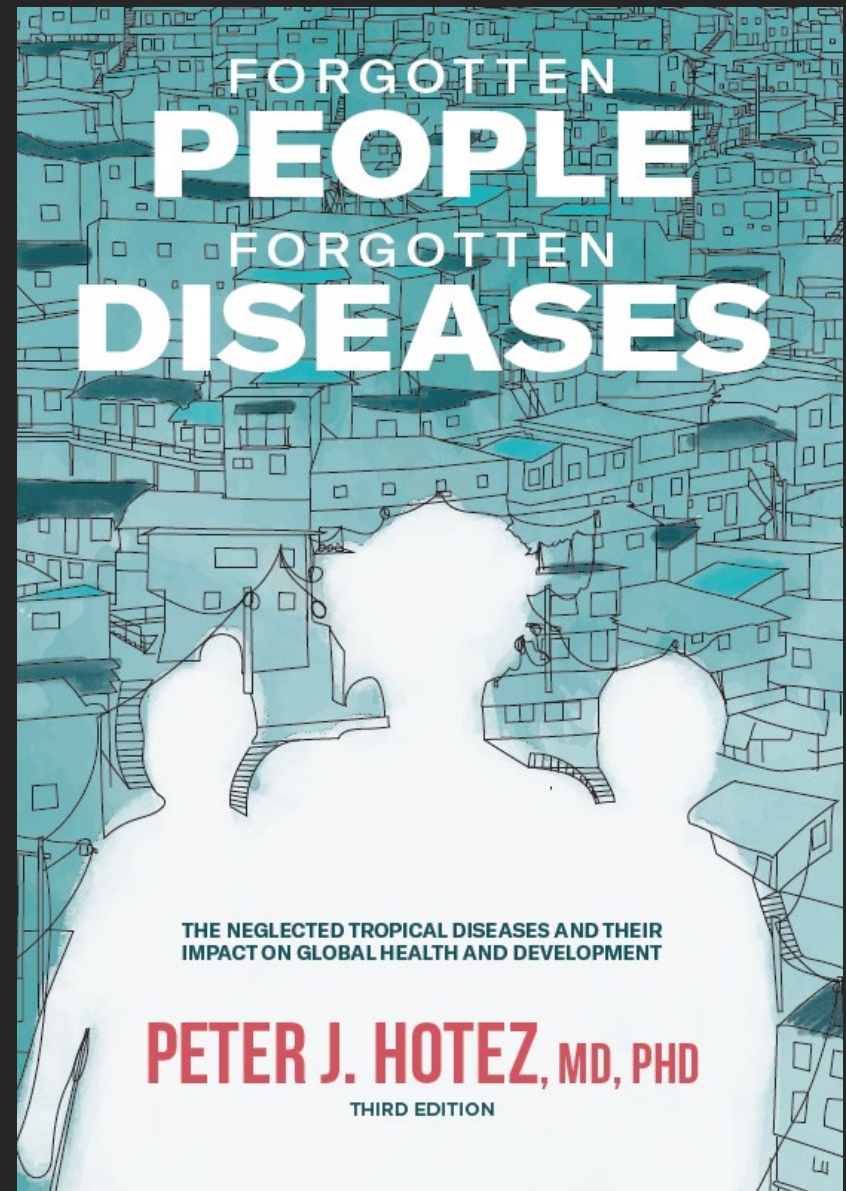
Available online 17 May 2006

Abstract

The neglected tropical diseases represent a group of parasitic and bacterial diseases, occurring primarily in rural areas or impoverished urban areas of developing countries. Because of their chronic and stigmatizing character and their impact on child development, pregnancy outcomes, and worker productivity, the neglected tropical diseases are considered poverty-promoting conditions. Through the activities of public–private partnerships, first or second-generation recombinant vaccines for three of these conditions—hookworm, leishmaniasis, and schistosomiasis, have undergone early development and clinical testing. However, through the acquisition of extensive bioinformatics information or animal model testing for several other neglected tropical diseases pathogens, it is possible to consider new generation vaccines as well for amebiasis, Buruli ulcer, Chagas disease, Chlamydia infections (including trachoma), leprosy, leptospirosis, and the treponematoses. Early development of such antipoverty vaccines will require the establishment of product development public–private partnerships and partnerships with innovative developing countries where these diseases are endemic.

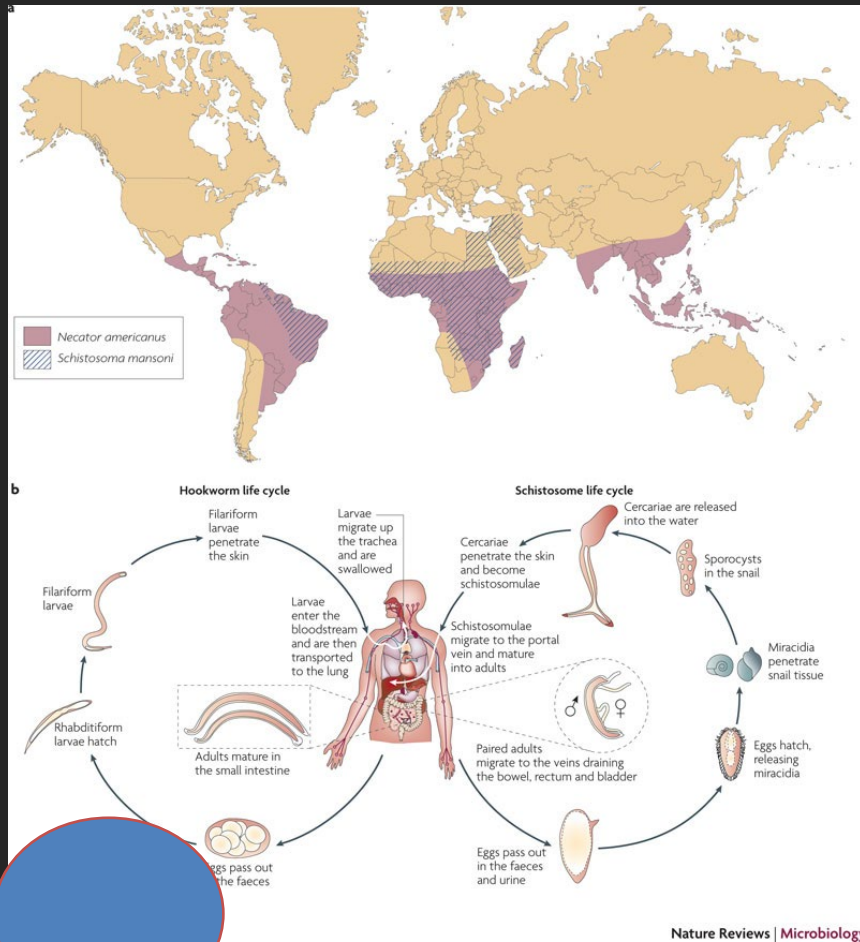
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Keywords: Neglected tropical diseases; Antipoverty vaccines; Amebiasis; Buruli ulcer; Chagas disease; Chlamydia infections; Hookworm; Leishmaniasis; Leprosy; Leptospirosis; Schistosomiasis; Treponematoses



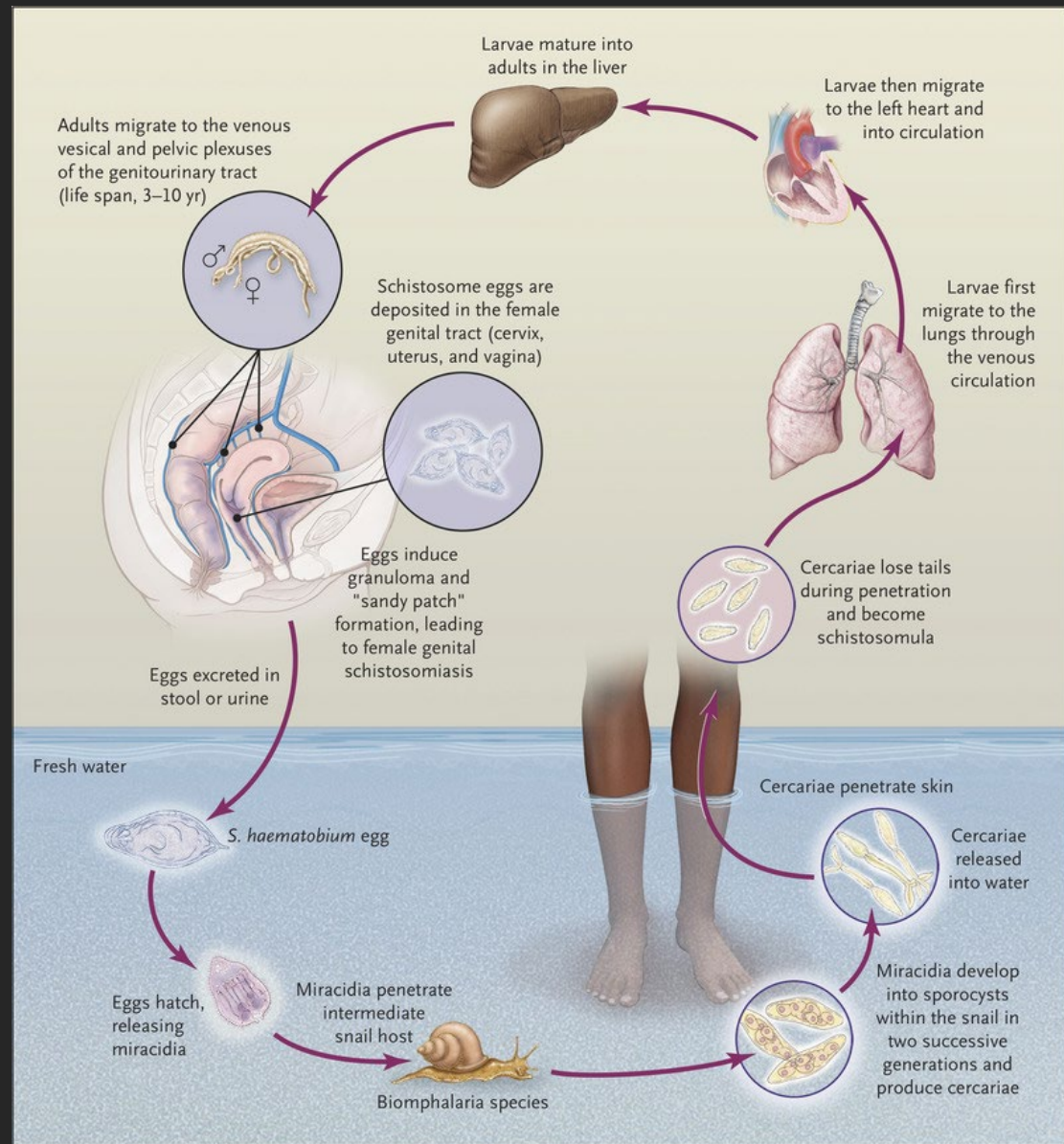
Vaccine Targeting Hookworm and Schistosomiasis Co-Infections

A MULTIVALENT
VACCINE TARGETING
HOOKWORM + SCHISTO



Female Genital Schistosomiasis

- 40 million Girls and Women in Africa
- Pain, bleeding, stigma, depression
- 2-3 OR in acquiring HIV/AIDS



Developing Country Vaccine Manufacturers Network



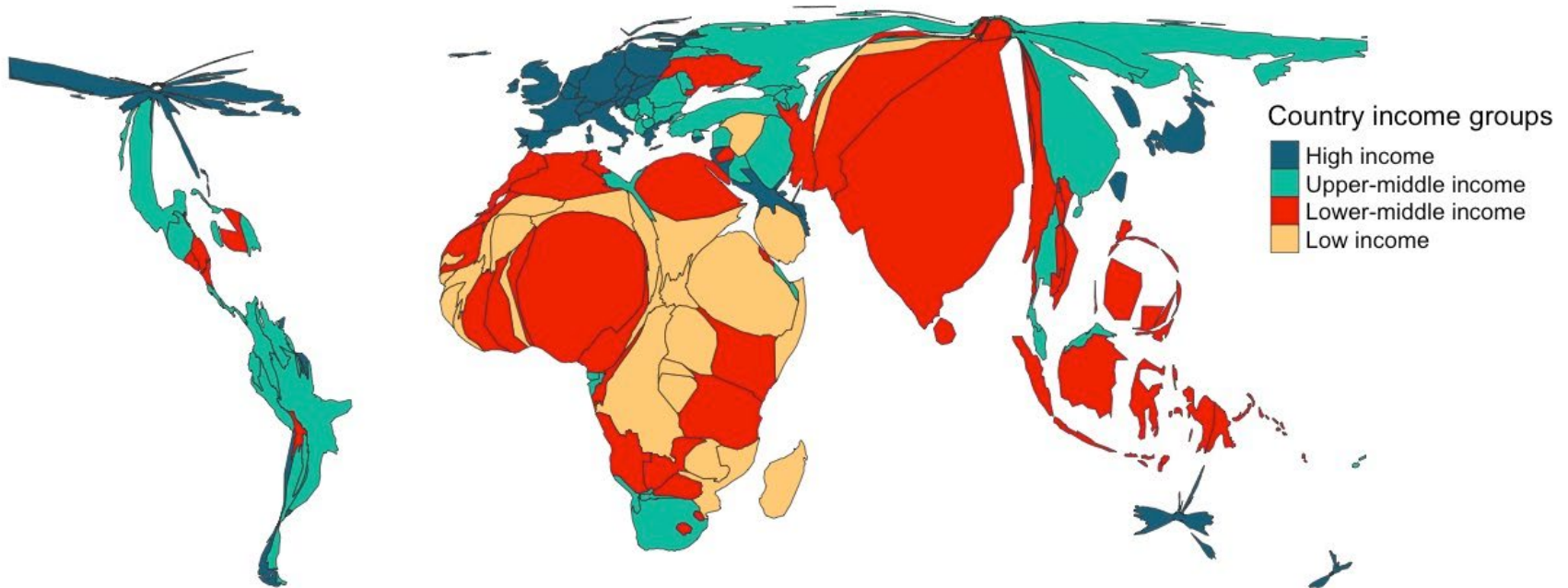
- Bangladesh
 - China
 - India
 - Indonesia
 - Thailand
 - Vietnam
-
- Argentina
 - Brazil
 - Cuba



COVID-19 Vaccinations

The unvaccinated population

Land mass scaled to reflect absolute number of unvaccinated (transformed EPSG 3410 equal-area projection)



Source: Schellekens (2021); OWID; WPP. Updated: 2022-01-13. Latest: pandem-ic.com.

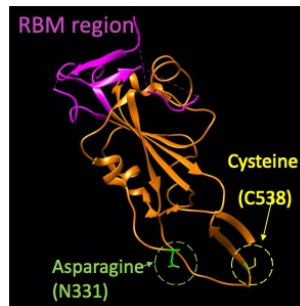
CORBEVAX (Biological E)



Engineering and Cloning Strategy

Selection of SARS CoV-2 RBD 219-N1C1 Construct (residues 331–549)

RBD219-WT	NITNLCPFGEVFNATRFASVYAWNRRKISNCVADYSVLVNSASFSTFKCYGVSPTKLNDL	60
RBD219-N1	ITNLCPFGEVFNATRFASVYAWNRRKISNCVADYSVLVNSASFSTFKCYGVSPTKLNDL	59
RBD219-N1C1	ITNLCPFGEVFNATRFASVYAWNRRKISNCVADYSVLVNSASFSTFKCYGVSPTKLNDL	59
RBD219-WT	CFTNVYADSFVIRGDEVQRQIAPGQTGKIADYNYKLDDFTGCVIAWNSNNLDSKVGNNY	120
RBD219-N1	CFTNVYADSFVIRGDEVQRQIAPGQTGKIADYNYKLDDFTGCVIAWNSNNLDSKVGNNY	119
RBD219-N1C1	CFTNVYADSFVIRGDEVQRQIAPGQTGKIADYNYKLDDFTGCVIAWNSNNLDSKVGNNY	119
RBD219-WT	YLYRLFRKSNLKPFFERDISTEIQAGSTPCNGVEGFNCYFPLQSYGFQPTNGVGYPYRV	180
RBD219-N1	YLYRLFRKSNLKPFFERDISTEIQAGSTPCNGVEGFNCYFPLQSYGFQPTNGVGYPYRV	179
RBD219-N1C1	YLYRLFRKSNLKPFFERDISTEIQAGSTPCNGVEGFNCYFPLQSYGFQPTNGVGYPYRV	179
RBD219-WT	VVLSFELLHAPATVCGPKKSTNLVKNKAVNFNFNGLTGT	219
RBD219-N1	VVLSFELLHAPATVCGPKKSTNLVKNKAVNFNFNGLTGT	218
RBD219-N1C1	VVLSFELLHAPATVCGPKKSTNLVKNKAVNFNFNGLTGT	218





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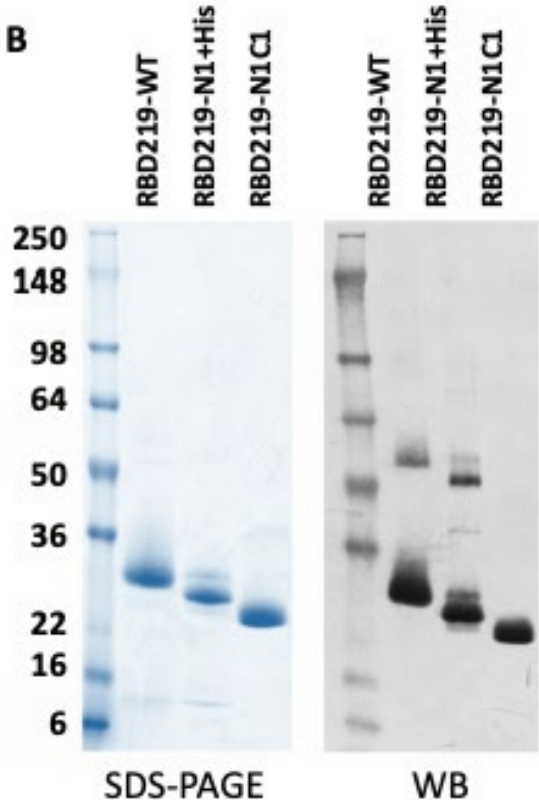


Genetic modification to design a stable yeast-expressed recombinant SARS-CoV-2 receptor binding domain as a COVID-19 vaccine candidate

Wen-Hsiang Chen^{a,b}, Junfei Wei^a, Rakhi Tyagi Kundu^a, Rakesh Adhikari^a, Zhuyun Liu^a, Jungsoo Lee^a, Leroy Versteeg^a, Cristina Poveda^a, Brian Keegan^a, Maria Jose Villar^a, Ana C. de Araujo Leao^a, Joanne Altieri Rivera^a, Portia M. Gillespie^a, Jeroen Pollet^{a,b}, Ulrich Strych^{a,b}, Bin Zhan^{a,b}, Peter J. Hotez^{a,b,c,d,*}, Maria Elena Bottazzi^{a,b,c,d,*}



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7955913/>



Process Development and Scale-up Strategy

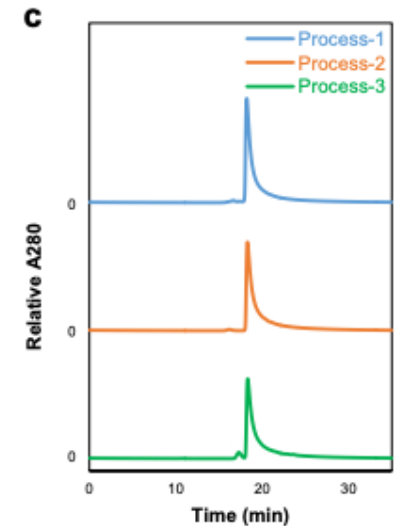
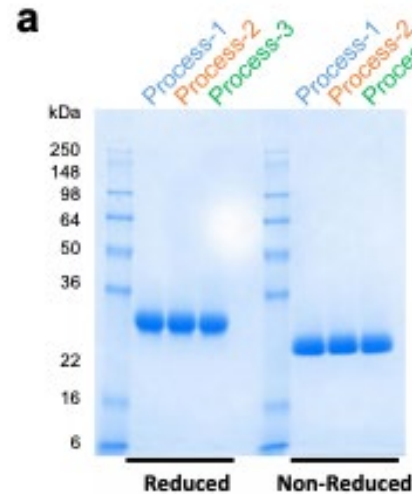
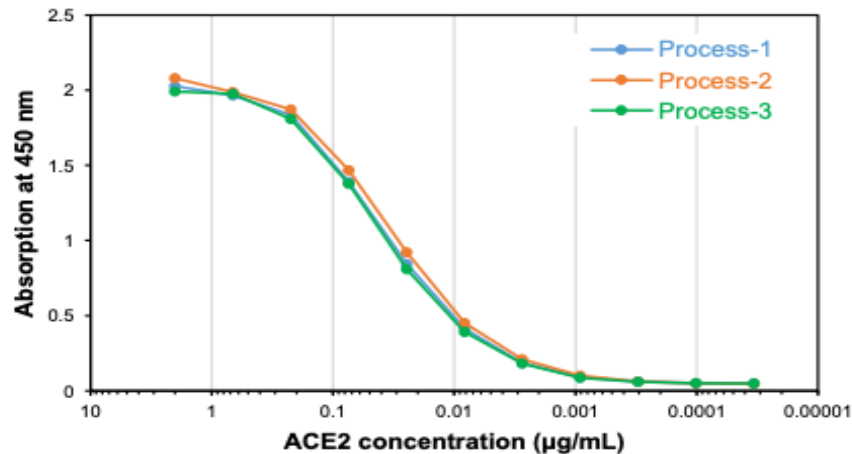
Applied Microbiology and Biotechnology (2021) 105:4153–4165
<https://doi.org/10.1007/s00253-021-11281-3>

BIOTECHNOLOGICAL PRODUCTS AND PROCESS ENGINEERING



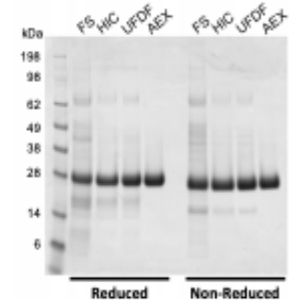
Process development and scale-up optimization of the SARS-CoV-2 receptor binding domain–based vaccine candidate, RBD219-N1C1

Jungsoon Lee^{1,2} • Zhuyun Liu^{1,2} • Wen-Hsiang Chen^{1,2} • Junfei Wei^{1,2} • Rakhi Kundu^{1,2} • Rakesh Adhikari^{1,2} • Joanne Altieri Rivera^{1,2} • Portia M. Gillespie^{1,2} • Ulrich Strych^{1,2} • Bin Zhan^{1,2} • Peter J. Hotez^{1,2,3,4,5} • Maria Elena Bottazzi^{1,2,3,4}



b Process-2

	Yield (mg)	Step Recovery (%)	Overall Recovery (%)	Purity, Non-Reduced (%)
FS	345.0 ± 7.1			77.0 ± 0.4
HIC	154.4 ± 0.0	45 ± 1	45 ± 1	95.2 ± 0.9
UFDF	173.6 ± 5.7	113 ± 4	50 ± 3	94.6 ± 1.2
AEX	134.9 ± 1.8	78 ± 4	39 ± 0	95.1 ± 0.4



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8102132>

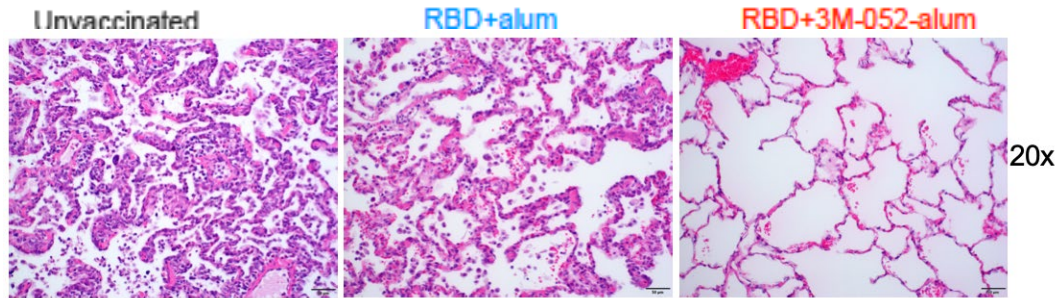
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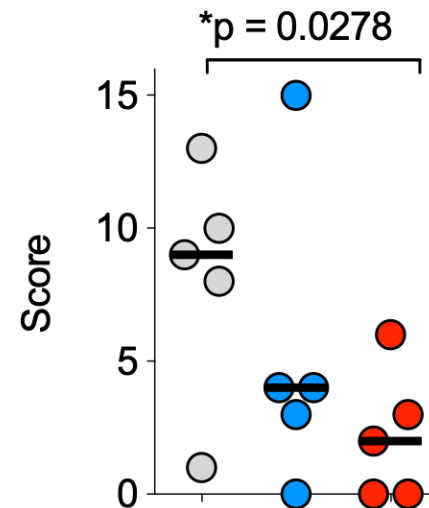
Safety and Efficacy in a NHP Model

RBD formulated with 3M-052+alum promotes significant **reduced lung pathology** after respiratory challenge with SARS CoV-2



Hematoxylin and eosin-stained sections of lung lobes from representative animals in the study at (20x) magnifications. Scale bars = 50μM.

Total pathology score



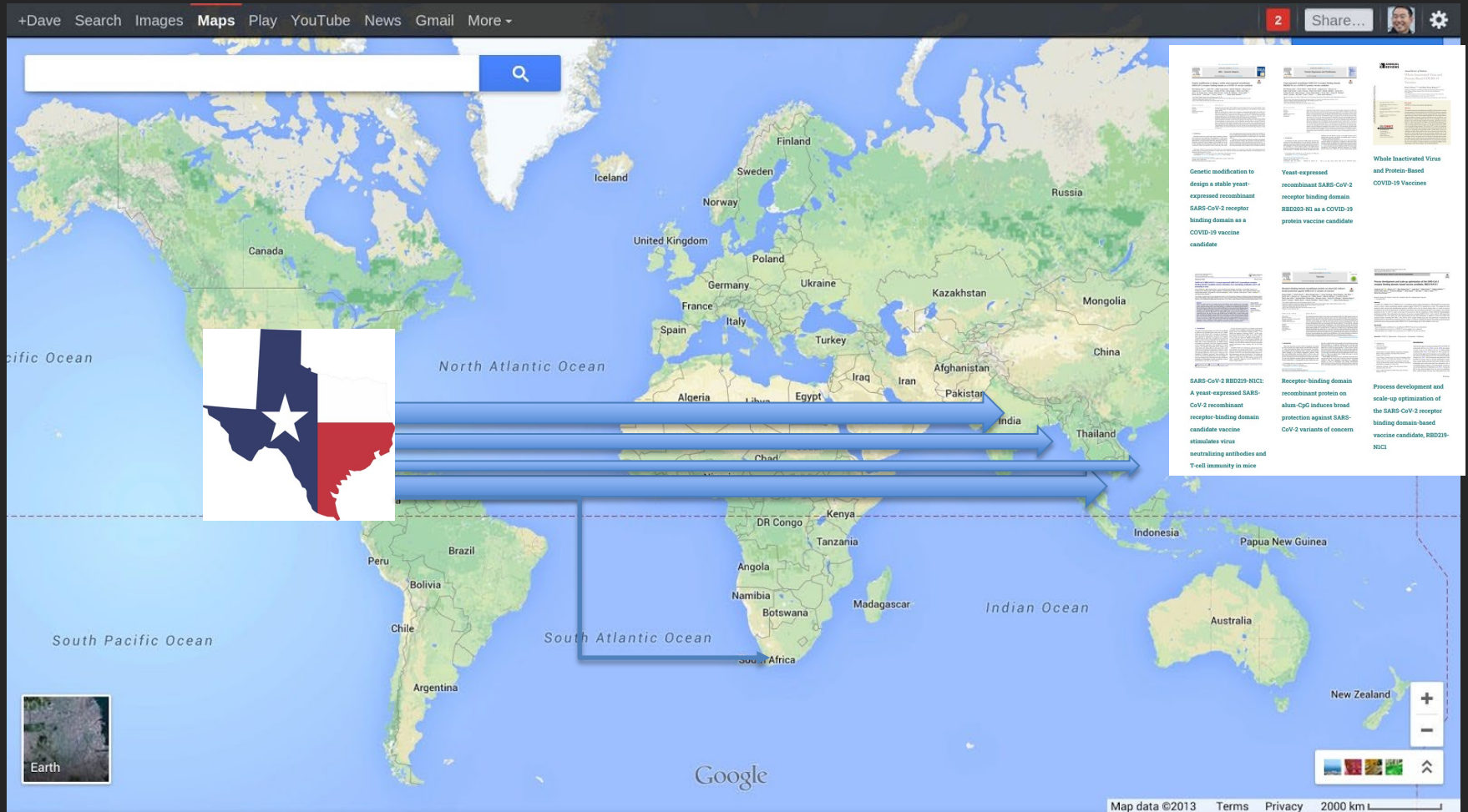
Total and average pathology scores quantified as explained in methods.



<http://immunology.sciencemag.org/lookup/doi/10.1126/sciimmunol.abj1031>

Technology Transfer:

India (Corbevax), Indonesia (IndoVac), Bangladesh, S Africa



CORBEVAX Phase 1 and Phase 2

eBioMedicine

Part of THE LANCET *Discovery Science*

ARTICLES | [VOLUME 83, 104217, SEPTEMBER 01, 2022](#)

Evaluation of safety and immunogenicity of receptor-binding domain-based COVID-19 vaccine (Corbevax) to select the optimum formulation in open-label, multicentre, and randomised phase-1/2 and phase-2 clinical trials

[Subhash Thuluva](#)   • [Vikram Paradkar](#) • [Subba Reddy Gunneri](#) • [Vijay Yerroju](#) • [Rammohan Mogulla](#) • [Kishore Turaga](#) • et al. [Show all authors](#)

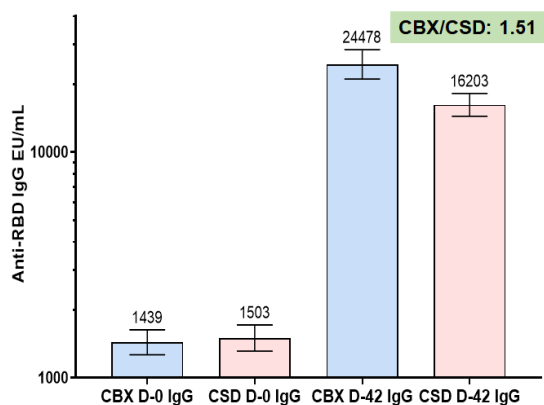
Open Access • Published: August 12, 2022 • DOI: <https://doi.org/10.1016/j.ebiom.2022.104217> •



Immunogenic superiority and safety of Biological E's CORBEVAX™ vaccine compared to COVISHIELD™ (ChAdOx1 nCoV-19) vaccine studied in a phase III, single blind, multicenter, randomized clinical trial

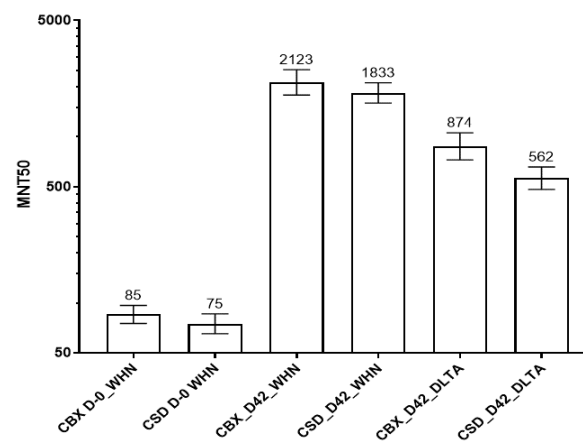
Anti-RBD IgG concentration

Anti-RBD IgG EU/mL: BECT-074 Phase III study



nAb titers against Wuhan and Delta strains

MicroNeutralization Titers BECT-074 Phase III study



Vaccine Arm & Number of subjects	Day-0 Testing		Day-42 testing		Ratio of Corbevax to Covishield	% SCR
	GMC ; EU/mL	95% CI	GMC, EU/mL	95% CI		
Corbevax N=304	1439	1268 -1633	24478	21075 -28431	1.51	91%
Covishield N=307	1503	1316 – 1716	16203	14428 – 18196		88%

	# of Subjects	MNT Titres GMT (95% CI)
CX-day-0	303	85 (75 – 96)
D-day-0	307	75 (65 - 86)
Corbevax-day-42	301-Wuhan 95% SCR	2123 (1801 – 2514)
	301-Delta	874 (724 – 1055)
Covishield - day-42	304-Wuhan 94% SCR	1833 (1632 - 2089)
	304-Delta	562 (482 – 657)

ELSEVIER

Available online 31 October 2022

In Press, Corrected Proof (?)



Subhash Thuluva^a, **Vikram Paradkar**^a, **Subash Reddy Chinnappa**^a, **Vijay Venkata**^a, **Ramesh Babu Reddy Manjula**^a,
Pothakamuri Venkata Suneetha^a, **Kishore Turag**^a, **Adabala**^a, **Aditya Sri Javadi**^a, **Guruprasad Meda**^a,
Aymaan Zaheer^b, **Amit Awasthi**^b, **Manish Narai**

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Highlights

- Limited data available on safety and immunogenicity of sub unit COVID-19 vaccines in children from large phase-3 trials.
- We demonstrated the safety and immunogenicity of RBD based sub unit covid-19 vaccine (CORBEVAX™) in pediatric population.
- CORBEVAX™ was found to be safe and tolerable when compared to placebo group.
- The nAbs elicited in pediatric age cohorts were non-inferior to the adult cohort in terms of ratio of GMT's.

Times of India

March 15, 2022



<https://timesofindia.indiatimes.com/city/mumbai/in-photos-covid-vaccination-for-12-14-years-of-age-group-begins-in-mumbai-and-thane/photostory/90263346.cms>

Indovac (BioFarma) Indonesia



A Second Chance for Equity

Comment

nature
REVIEWS

MICROBIOLOGY

<https://doi.org/10.1038/s41579-022-00824-8>

SARS-CoV-2 variants offer a second chance to fix vaccine inequities

Peter J. Hotez

 Check for updates

Global COVID-19 vaccine equity remains aspirational for much of the world. But the emergence of rapidly evolving SARS-CoV-2 variants provides new opportunities to correct past public policies, support local vaccine production and combat rising anti-vaccine aggression.

Omicron RBD-escape subvariants, will the death rate increase further? The key to prevent this from happening is to look at lessons learned during the first years of the pandemic, when LMICs were denied access to mRNA vaccines in adequate amounts. The countries could not afford them, and vaccine donations came too little, too late. Beyond the tragic losses in life that ensued, this situation bred resentment among LMIC populations⁴. Anti-vaccine activists from the United States and elsewhere also piled on to promote widespread vaccine hesitancy and refusal⁵.

This time around, we cannot afford to repeat the missteps of 2020–2022. We must ensure a rapid turnaround of next-generation boosters

WHO Immunization Agenda 2030

IMPLEMENTING THE IMMUNIZATION AGENDA 2030:

A Framework for Action through Coordinated Planning, Monitoring & Evaluation, Ownership & Accountability, and Communications & Advocacy



 **IA2030 IMMUNIZATION AGENDA 2030**

by 2030,
the Immunization
Agenda aims to

Reduce by
50%
the number of
children
missing out
on all vaccines

Achieve
90%
coverage
for essential
vaccines given
in childhood
and adolescence

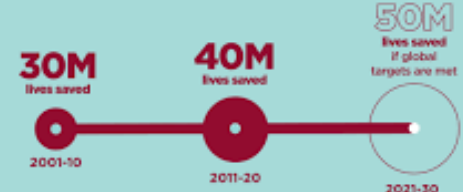
Introduce
500
new vaccines
in low and
middle-income
countries

#VaccinesWork

IMMUNIZATION AGENDA 2030



the impact of
childhood vaccination
is increasing



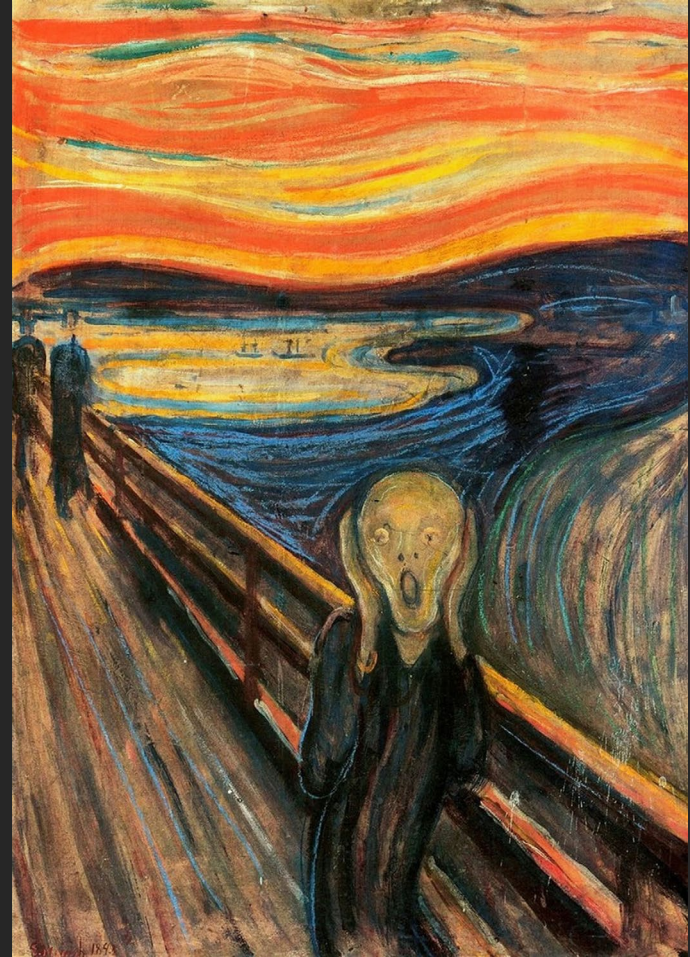
#VaccinesWork

IMMUNIZATION AGENDA 2030



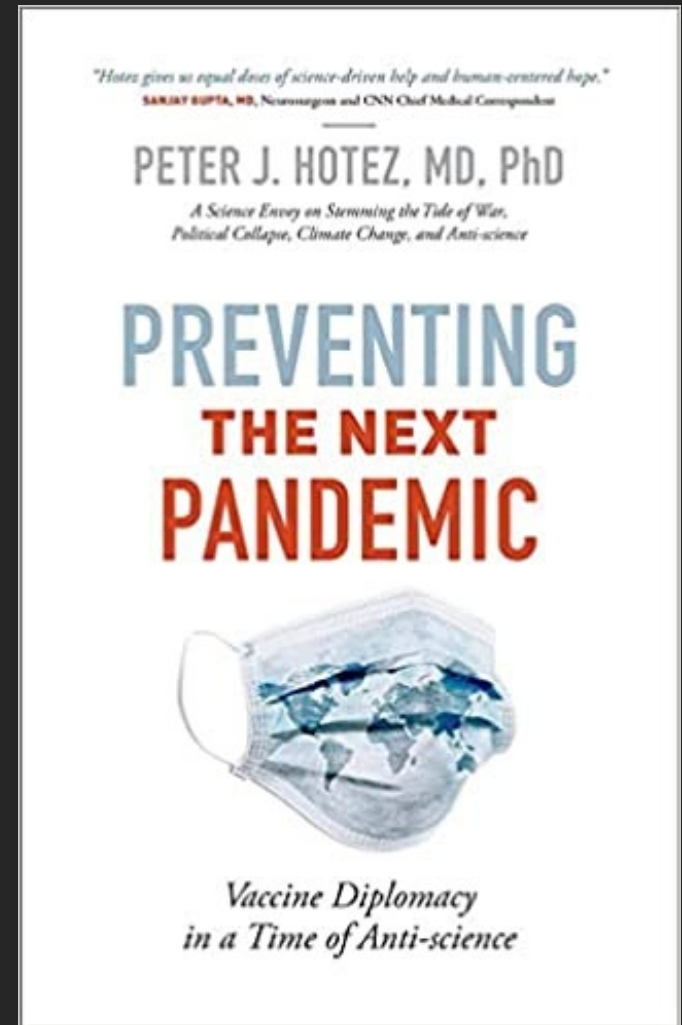
The Concern

- We don't bounce back
- A new rise in US and global antivaccine activism
- Something new and ominous has happened

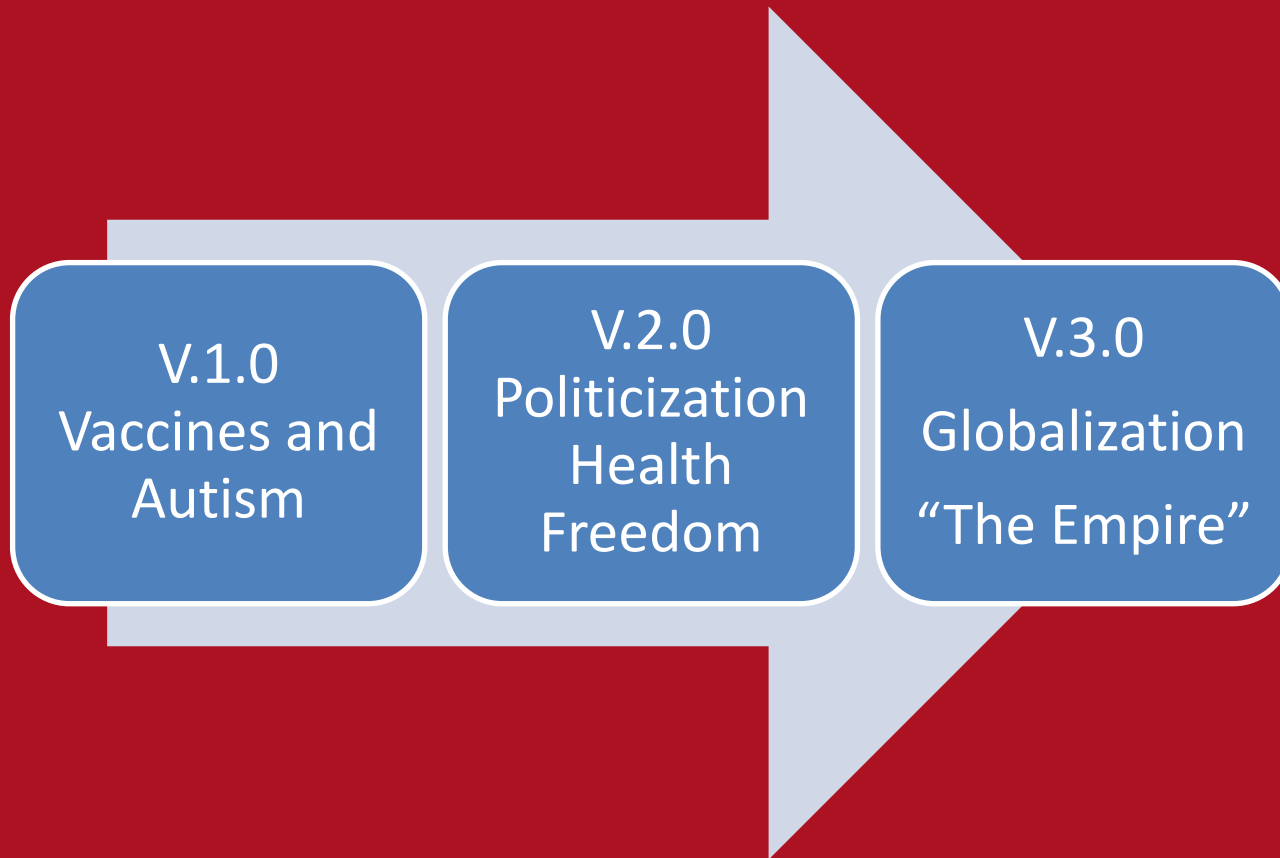


New 21st Century Drivers

- Poverty
- War
- Political Instability
- Urbanization
- Deforestation
- Climate Change
- **Anti-Science**

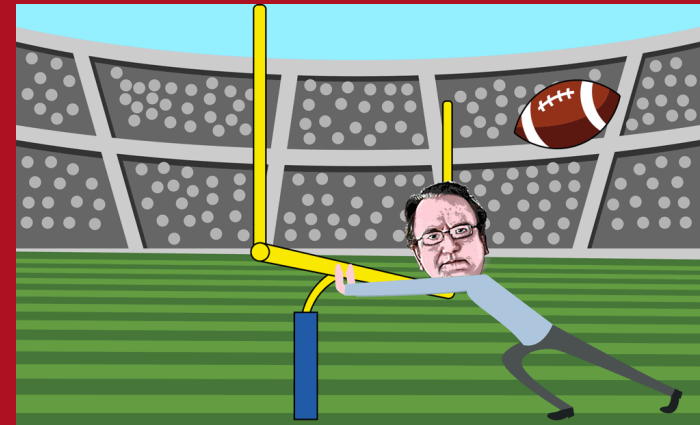
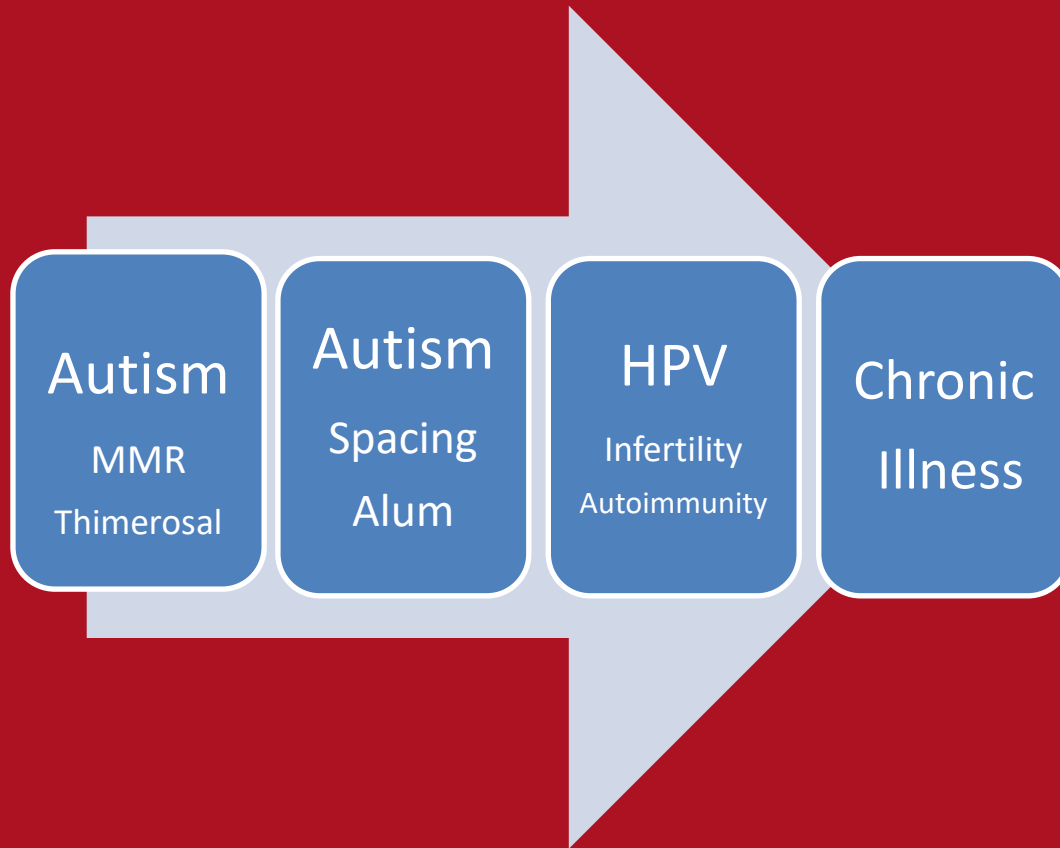


Antivaccine-Antiscience Ecosystems and Empires

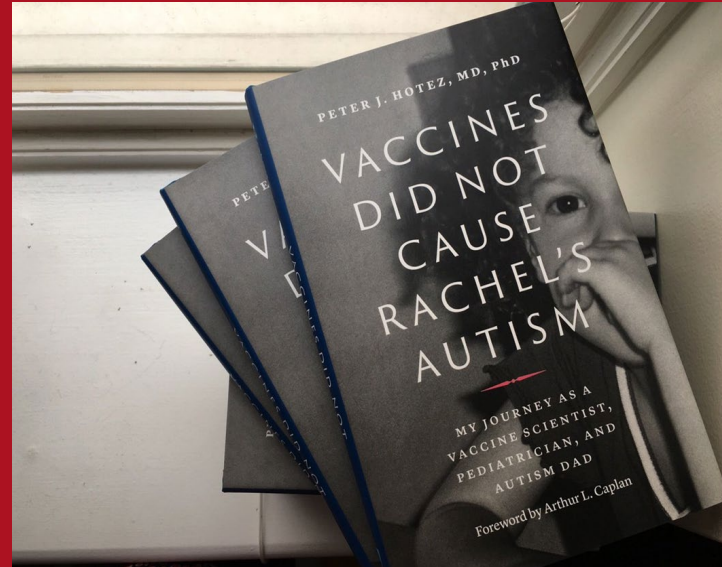


V.1.0: Vaccines and Autism

“Moving Goalposts”



Vaccine Scientist, Pediatrician, Parent of Adult Daughter with Autism, and the “OG Villain”



What Does "OG" Mean?

"Original Gangster"

OG MEANING

- "OG" is a phrase that is often used in rap and hip hop culture. This later found its way into the internet.
- The meaning of "original gangster" or someone who is "old school" or someone who has a lot of experience. If new gangsters come along, they are many times tougher.

OTHER MEANING

Aside from "original gangster," "OG" can also mean "old" or "original." This is a term from the 1990s that was used to describe a person who was "old" or "original."

VILLAIN

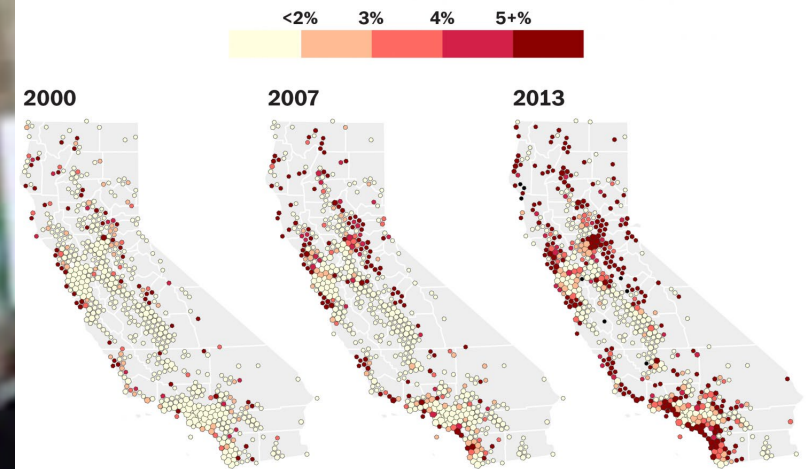
"the" "s" are "old" "is an old

V.2.0: Origins of the Health Freedom Movement in Orange CA



The spread of anti-vax sentiment in California

Share of public school kindergartners with personal belief exemptions to vaccination requirements



WASHINGTONPOST.COM/WONKBLOG

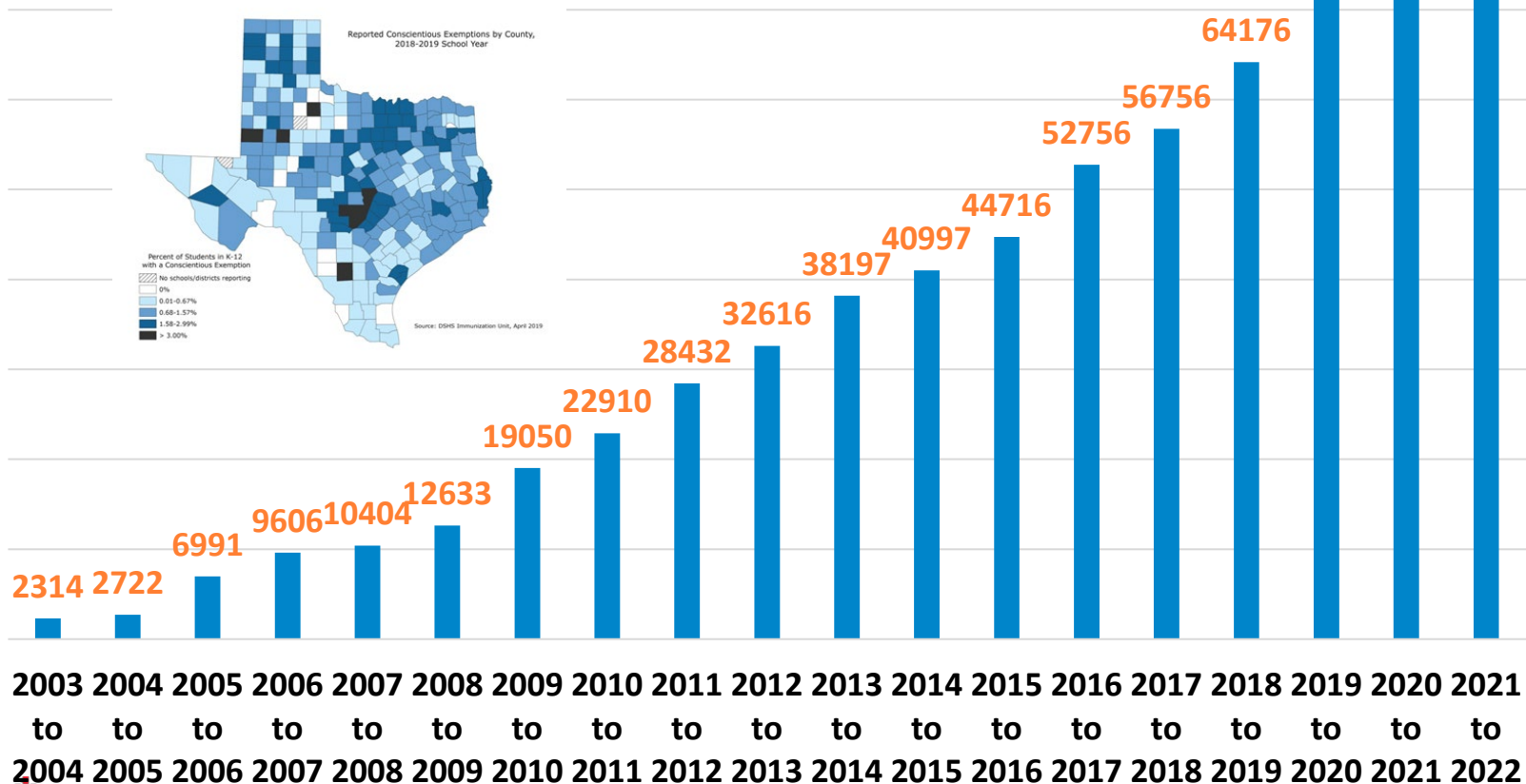
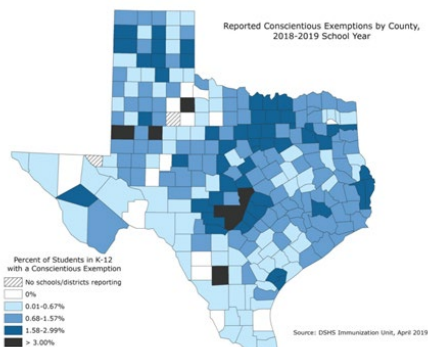
Source: California Department of Public Health



Expansion of Health Freedom to Texas

Non-Medical Exemptions 2003-2022

Figure 1. Percent of Students in Kindergarten through 12th Grade with a Conscientious Exemption on file for at least one vaccine



Texas Antivax Protests April 2019



<https://www.timesofisrael.com/anti-vaxxers-using-holocaust-era-yellow-stars-to-promote-their-agenda/>

PLOS GLOBAL PUBLIC HEALTH

 OPEN ACCESS

OPINION

The great Texas COVID tragedy

Peter J. Hotez 

Published: October 20, 2022 • <https://doi.org/10.1371/journal.pgph.0001173>

Article



Authors

Metrics

Comments

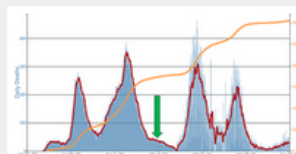
Media Coverage

References

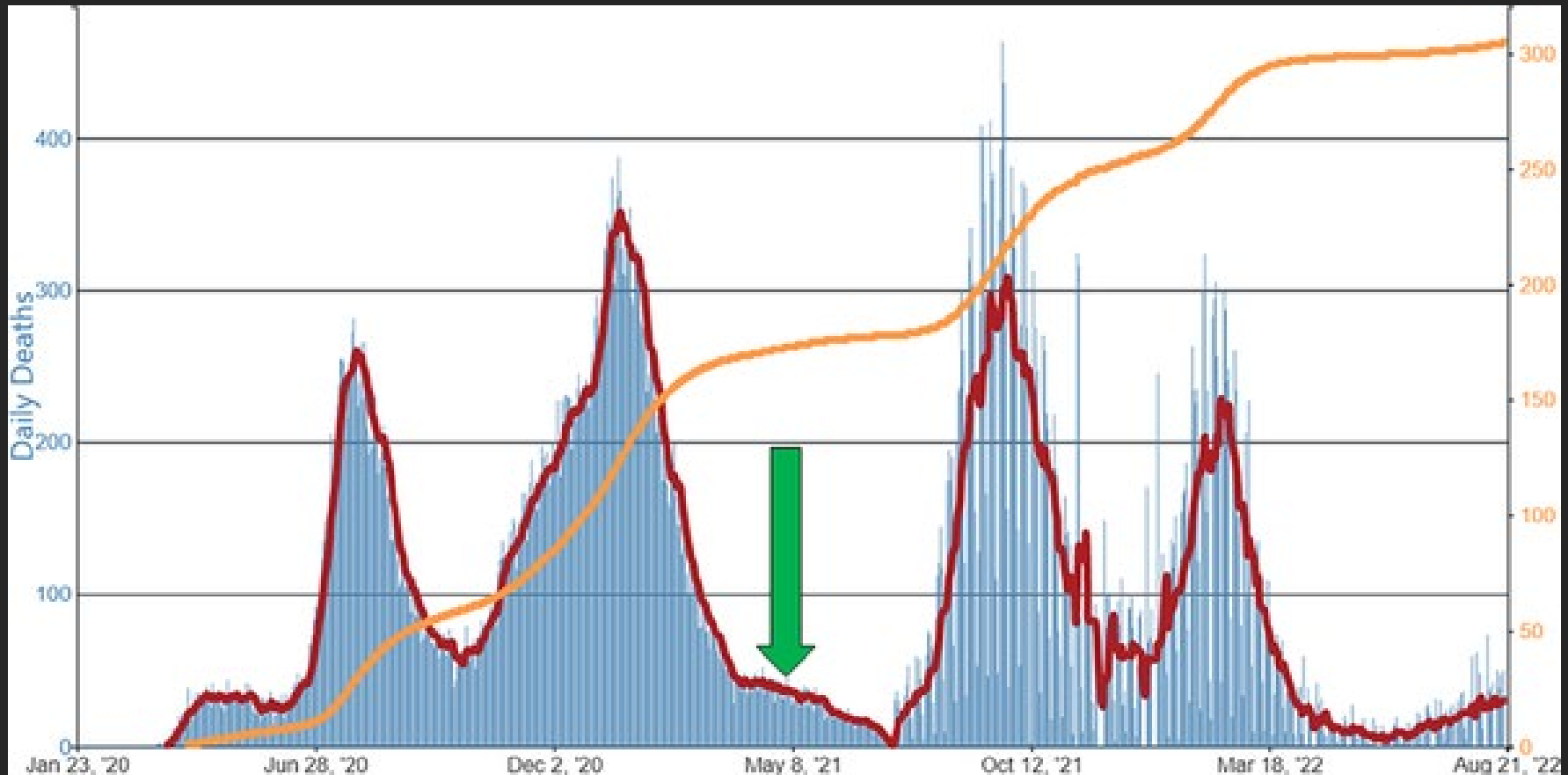
Reader Comments

Figures

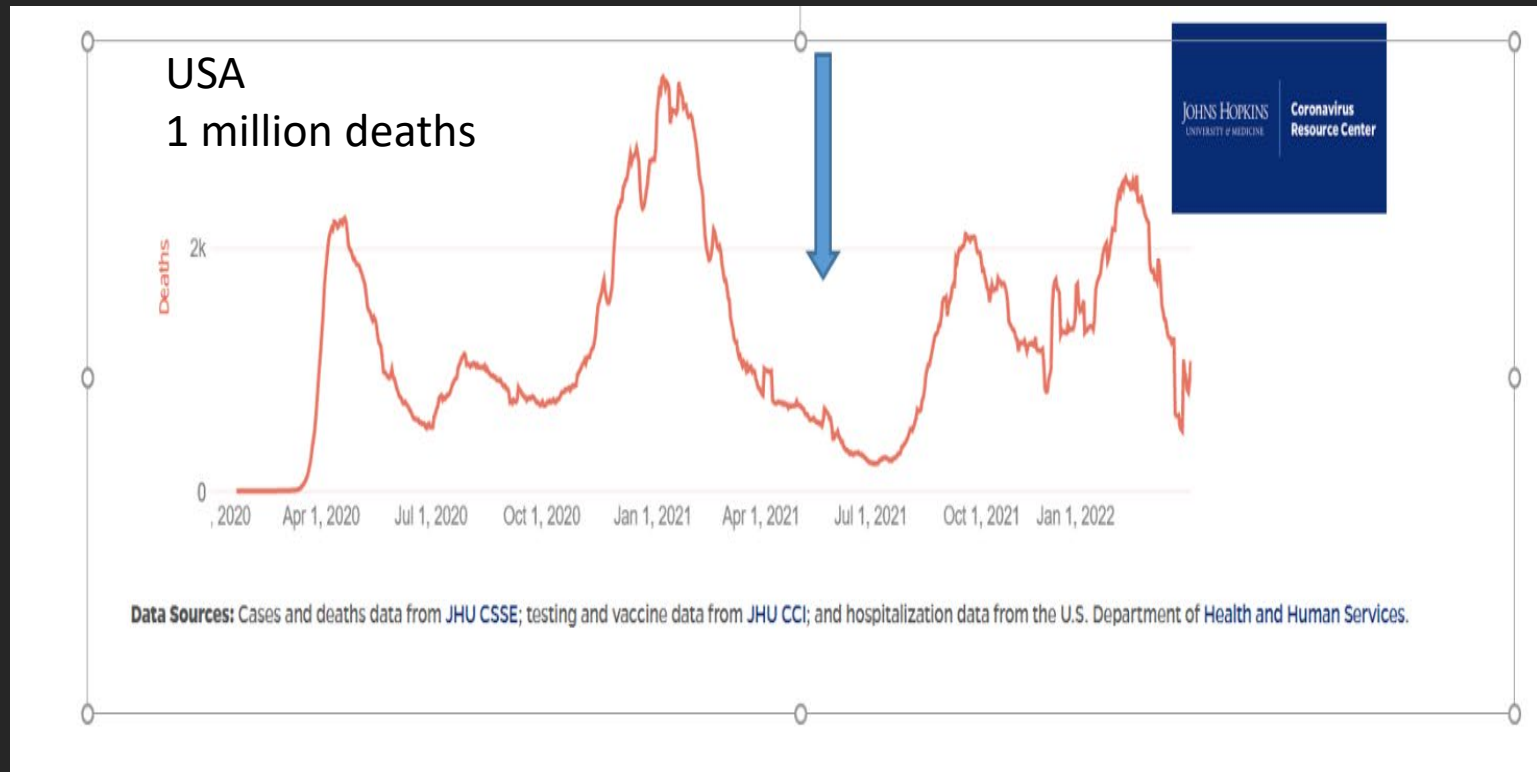
Figures



Daily Trends in Number of COVID-19 Deaths in Texas Reported to the CDC, per 100,000 population, 2020–2022



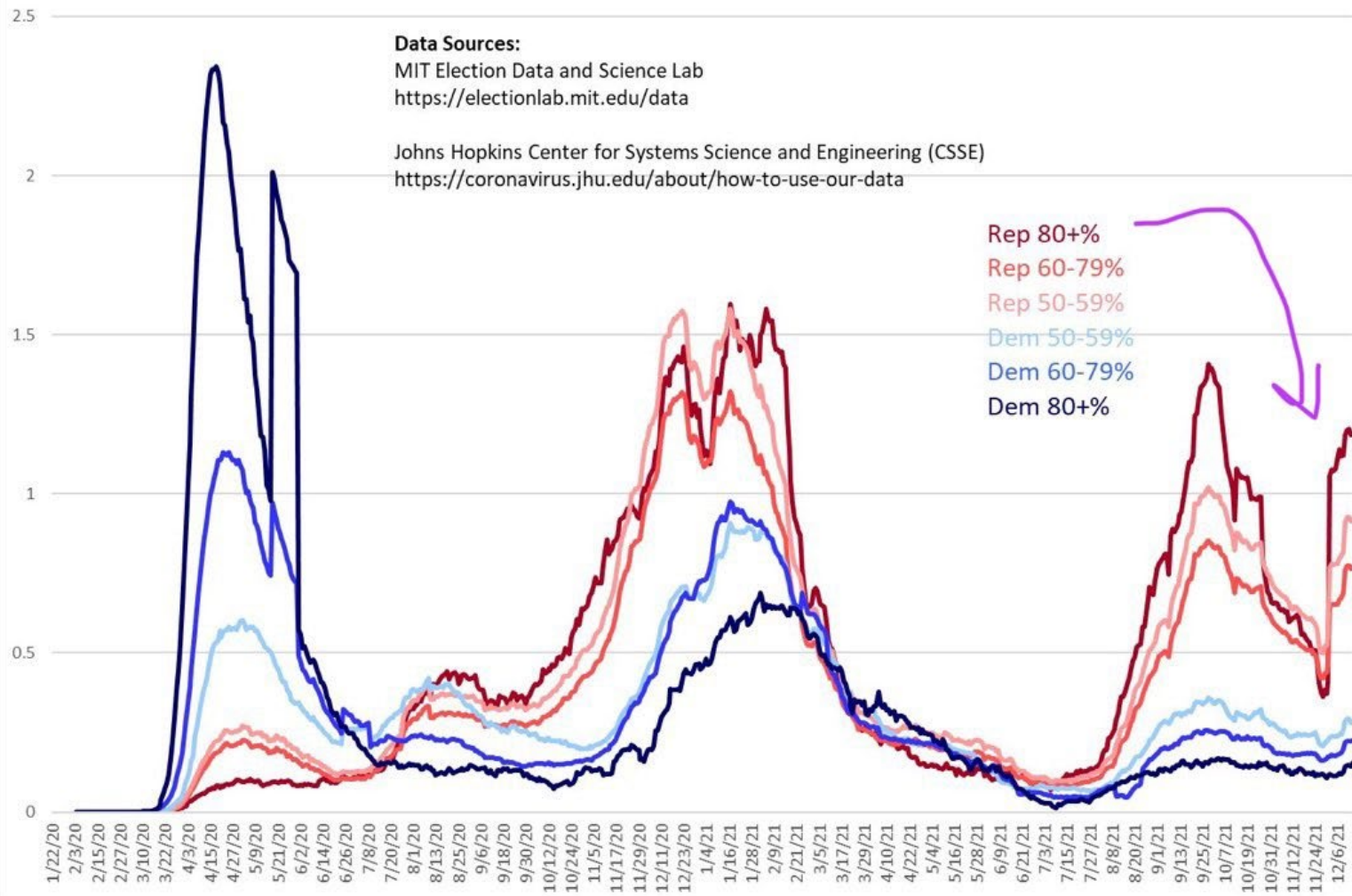
Antiscience Kills: 200,000 Americans Needlessly Lost



USA: Up to 40% of Deaths after COVID-19 Vaccines
Widely Available After May 1, 2021

Red COVID Deaths

COVID Death Incidence Rate per 100,000 Population by 2020 Presidential Vote
(14-day moving average)



V.3.0: Globalization of American Anti-Science Western Europe, Canada, African Nations

nature reviews immunology

COMMENT

 Check for updates

Will anti-vaccine activism in the USA reverse global goals?

Peter J. Hotez

In the time of the COVID-19 pandemic, anti-vaccine activism in the USA accelerated, amplified and formed an alliance with political groups and even extremists. An organized, well-funded and empowered anti-science movement now threatens to spill over and threaten all childhood immunizations in the USA and globally.