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TAMEST NATURAL HAZARDS SUMMIT

Responding to and Mitigating the Impacts

PART I: VIRTUAL SUMMIT
10.19.2021

#NATURALHAZARDSSUMMIT

Theme Two:

EMERGENCY RESPONSE AND RECOVERY

Moderated by:

CHANDRA FRANKLIN WOMACK, P.E.

Owner and Chief Executive Officer, Aran & Franklin

Board Chair, Texas Windstorm Insurance Association

Panel:

Disparate Impacts of Natural Disasters and Disease

ROBERT D. BULLARD, PH.D.

Distinguished Professor

Texas Southern University

LOREN HOPKINS, PH.D.

Chief Environmental Science Officer

City of Houston

PETER HOTEZ, M.D., PH.D. (NAM)

Dean, National School of Tropical Medicine

Baylor College of Medicine

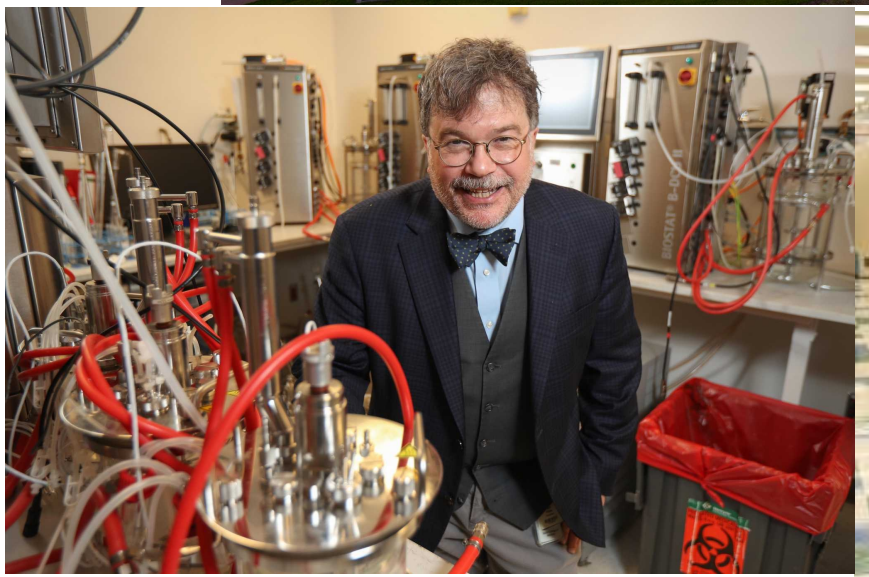
The Rise of Emerging Infections in Texas

@PeterHotez

Peter Hotez MD PhD
Professor, Departments of Pediatrics, Molecular Virology & Microbiology
Dean, National School of Tropical Medicine
Co-Director Texas Children's Hospital Center for Vaccine Development
Texas Children's Hospital Chair in Tropical Pediatrics

Texas Children's Center for Vaccine Development
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

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Review

The antipoverty vaccines

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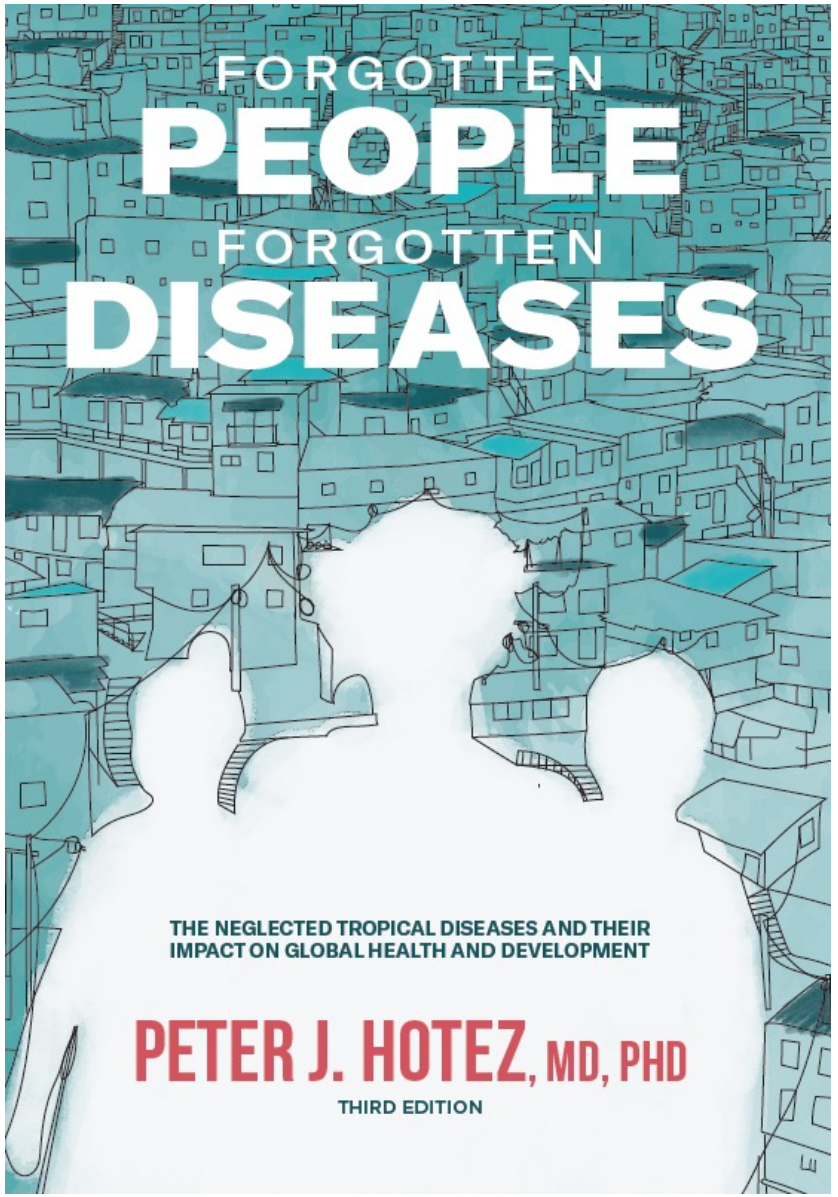
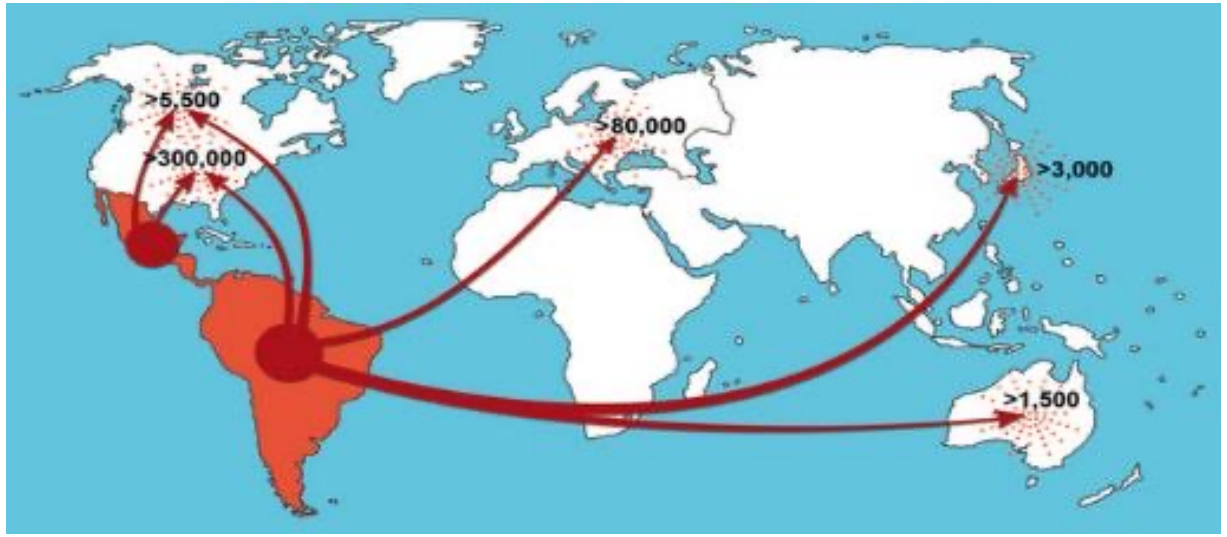
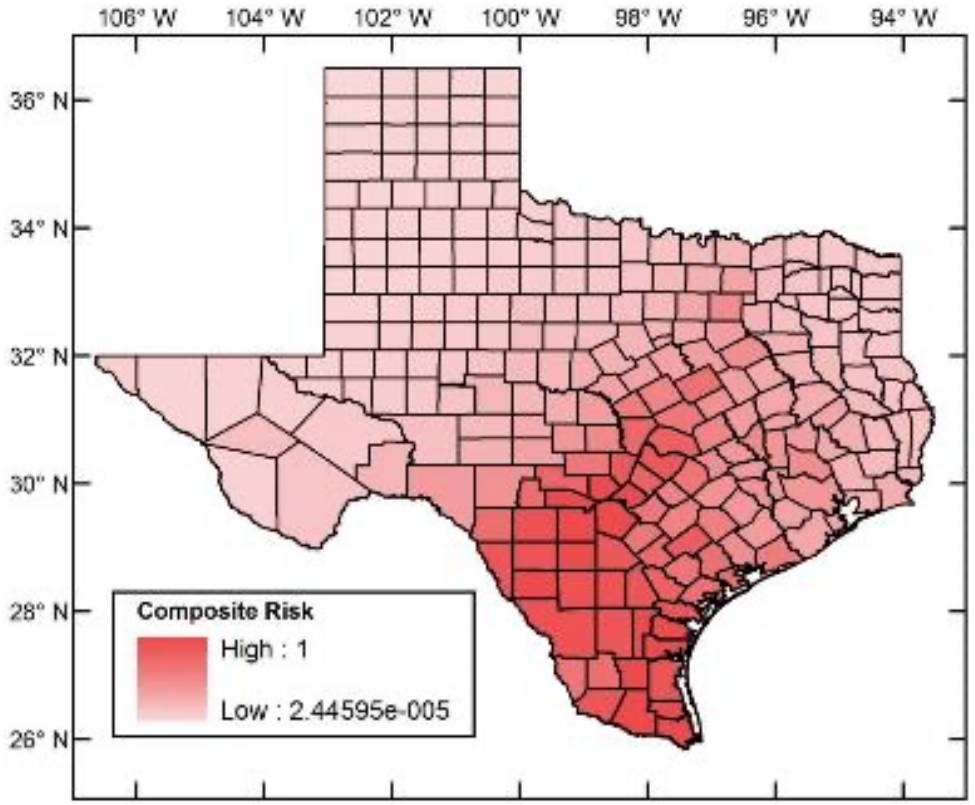
Keywords: Neglected tropical diseases; Antipoverty vaccines; Amebiasis; Buruli ulcer; Chagas disease; Chlamydia infections; Hookworm; Leishmaniasis; Leprosy; Leptospirosis; Schistosomiasis; Treponematoses



Global Burden of Chagas Disease



6.5 million cases worldwide
Endemic in Latin America
High Risk of infection in Central and South Texas
20,000 annual deaths
$1.2 billion economic losses



Nature Volume: 465, Pages: S6–S9 Date published: (24 June 2010)
Sarkar et al. 2010. *PLoS NTDs*

New 21st Century Drivers

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

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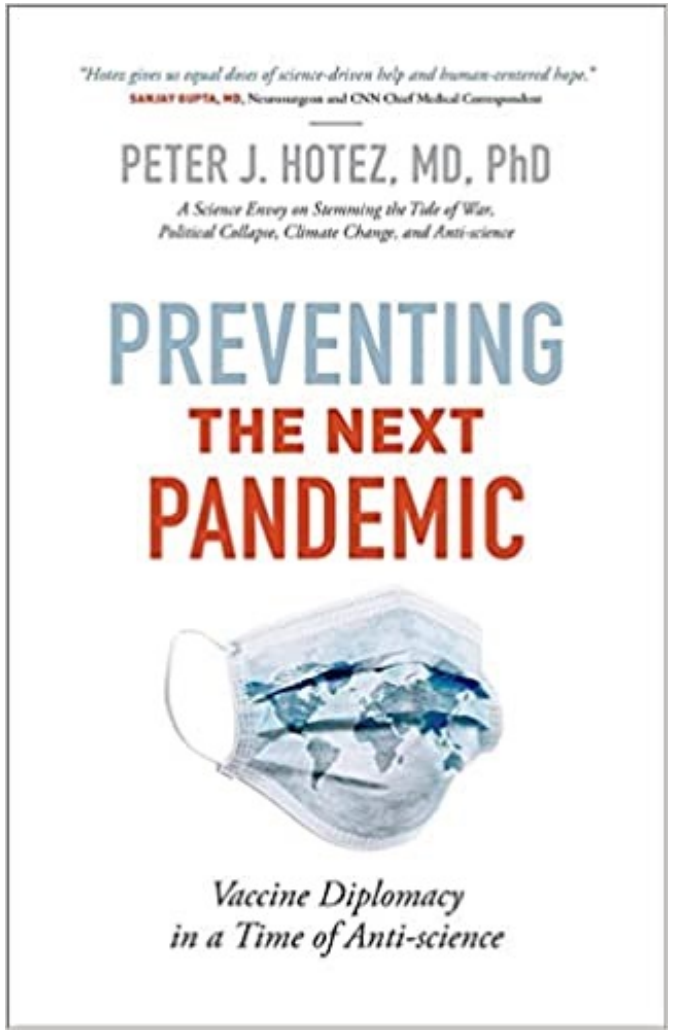
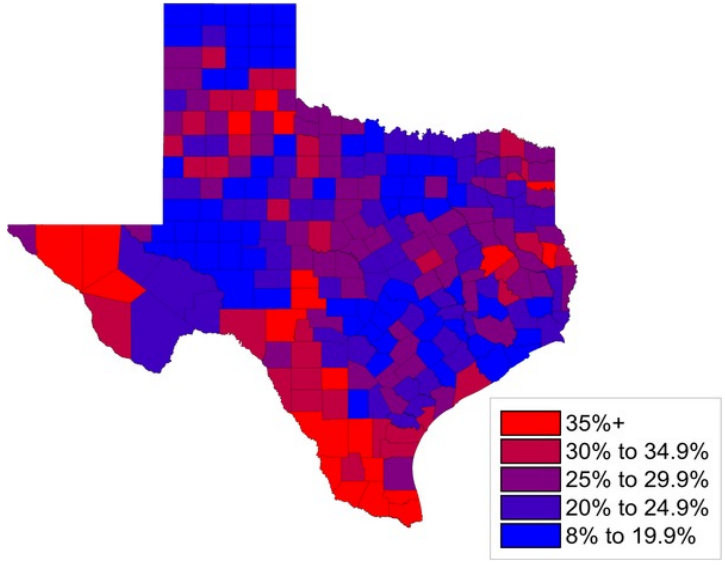


POVERTY IN TEXAS

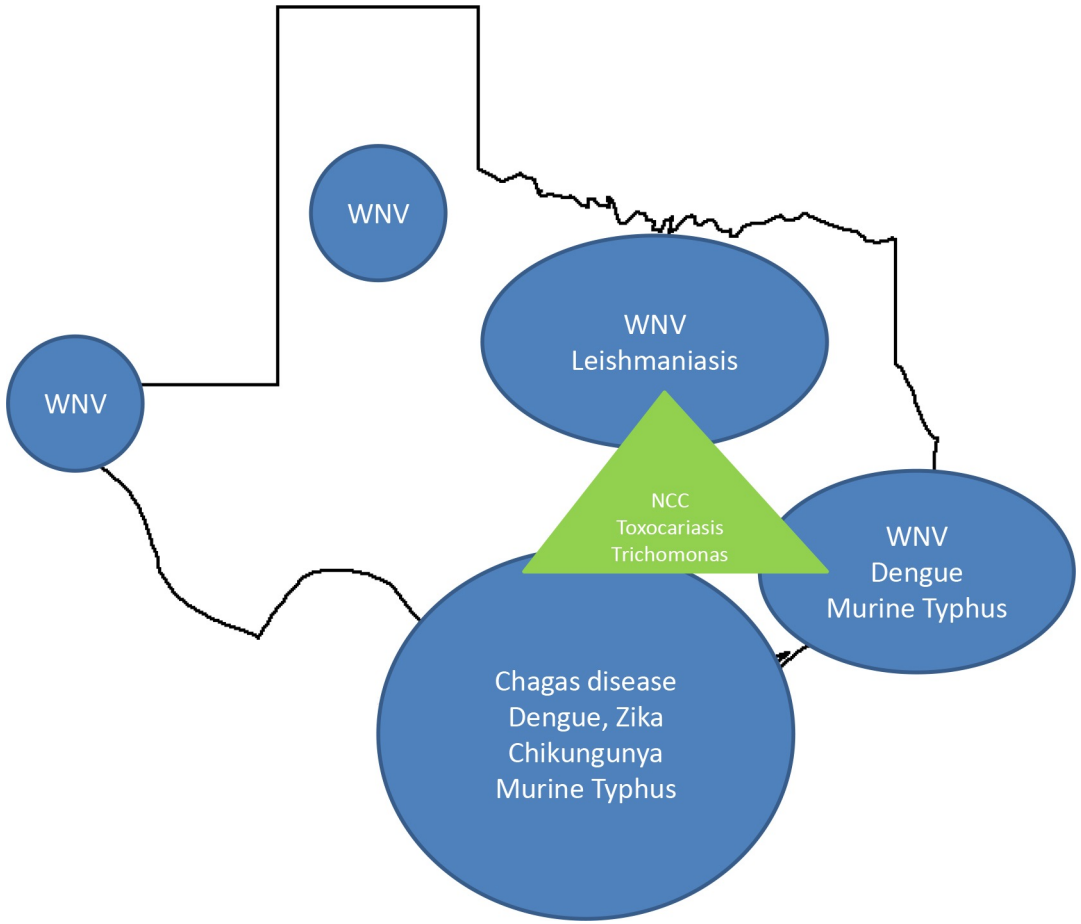
Hotez PJ (2017) The Rise of Neglected Tropical Diseases in the 'New Texas'

South Texas "Colonias" Shaghayegh Tajvidi.

Fifth Ward, Houston Texas
Anna Grove

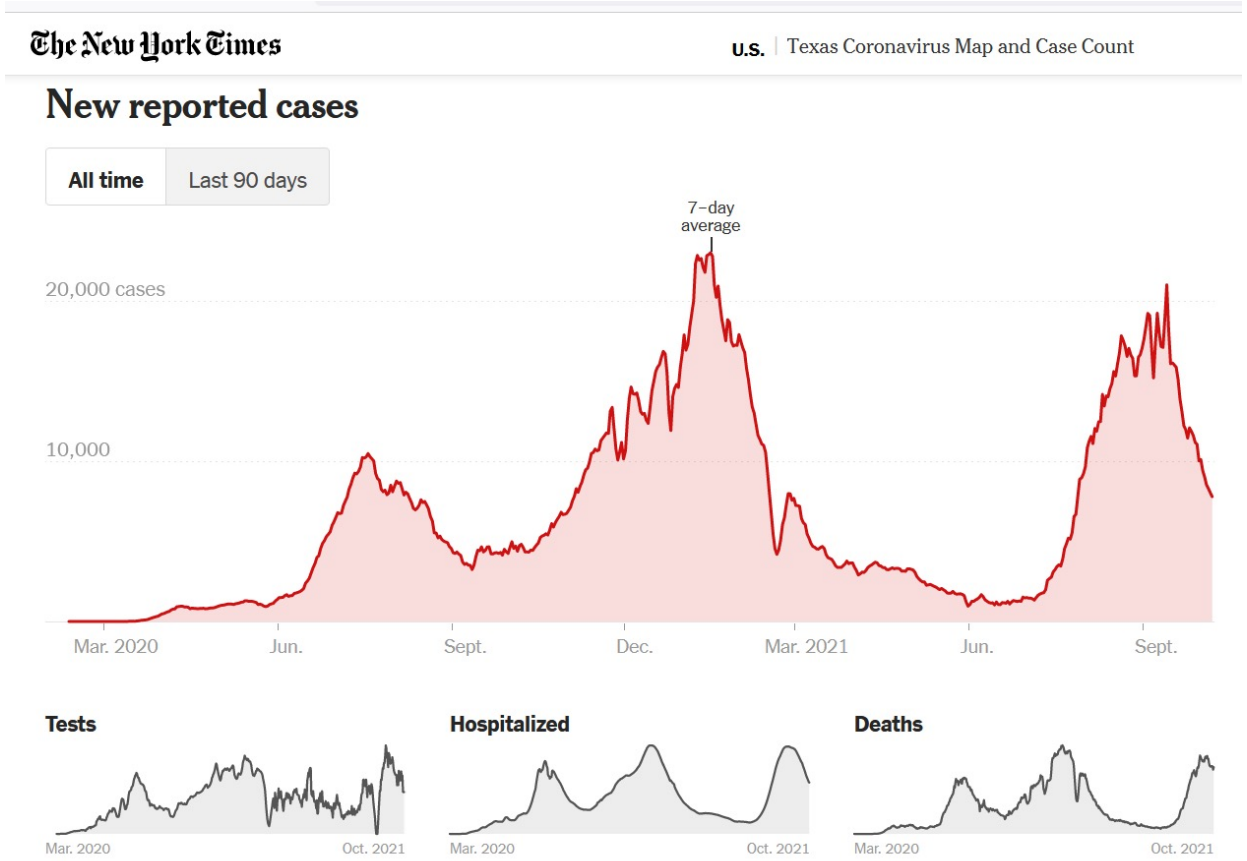


Texas: The Confluence of Poverty, Climate Change, Urbanization

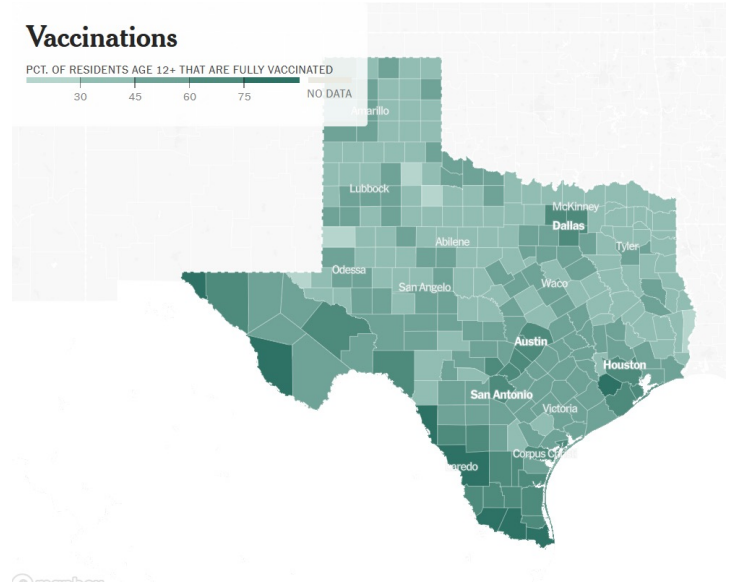


Delta in Texas: October 2021

https://www.nytimes.com/interactive/2021/us/texas-covid-cases.html

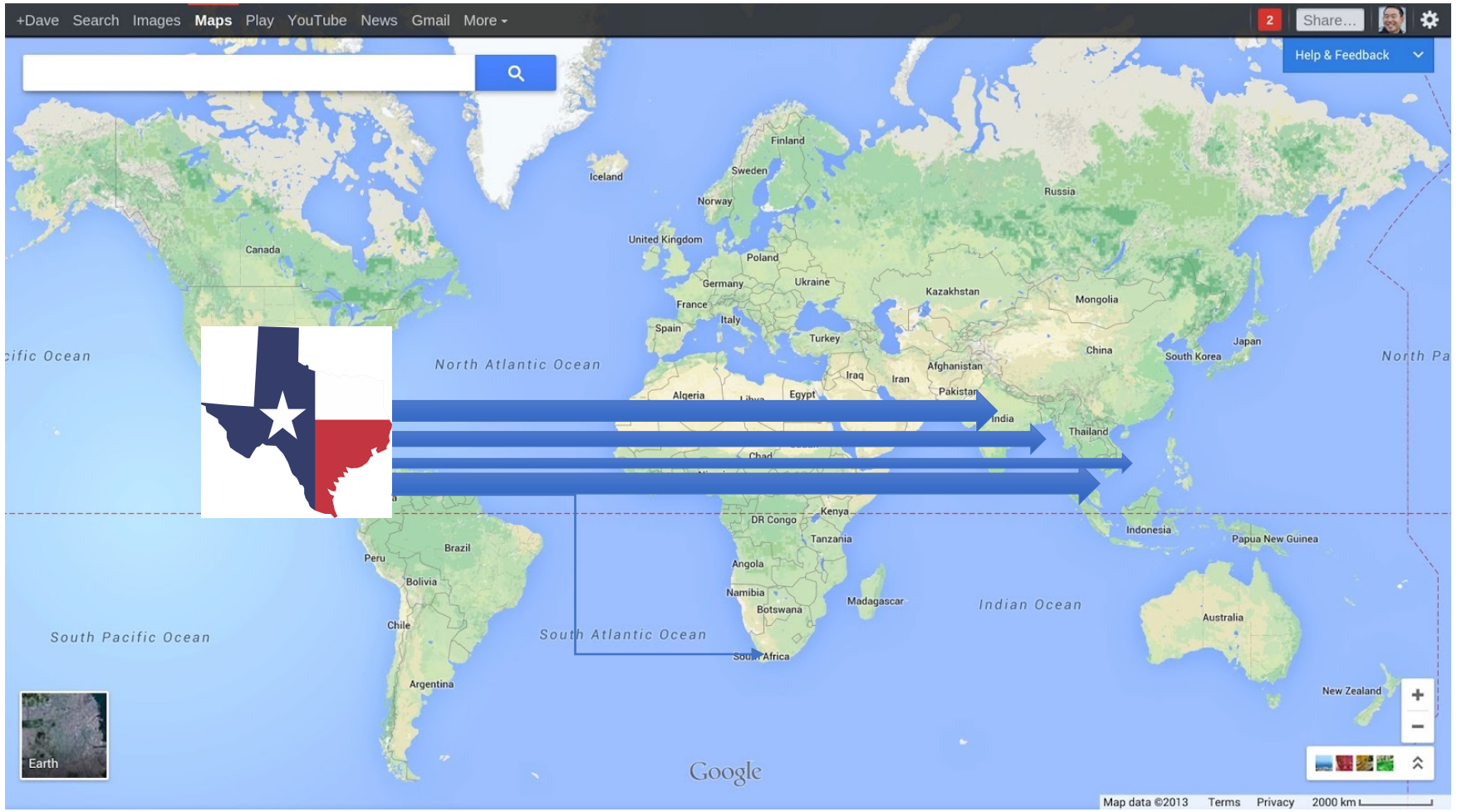


- >4 million reported cases
- One-half the state infected?
- 70,000 deaths



Technology Transer:

India (Corbevax), Indonesia, S Africa



Corbevax Biological E

- The vaccine and its production cell bank were developed at Texas Children's CVD.
- It was licensed non-exclusively to BioE
- Bio E is scaling up production and clinical testing 100 million doses/month
- Completed Phase 1 and 2 – in five sites in India; Phase 3 in India

INDIAN EXPRESS N. D. 5/6/2021

SIMPLY PUT

How Corbevax is different

India has placed an advance order for 300 million doses of Corbevax. How does this Covid-19 vaccine work, and how does it differ from others? What could the order mean for India's vaccination programme?

PRABHA RAGHAVAN
NEW DELHI, JUNE 4

INDIA HAS placed an advance order to block 300 million doses of a new Covid-19 vaccine, Corbevax, from Hyderabad-based company Biological E. What is this vaccine, and why is it important for India?

How it works

Corbevax is a "recombinant protein subunit" vaccine, which means it is made up of a specific part of SARS-CoV-2 — the spike protein on the virus's surface.

The spike protein allows the virus to enter the cells in the body so that it can replicate and cause disease. However, when this protein alone is given to the body, it is not expected to be harmful as the rest of the virus is absent. The body is expected to develop an immune response against the injected spike protein. Therefore, when the real virus attempts to infect the body, it will already have an immune response ready that will make it unlikely for the person to fall severely ill.

Although this technology has been used for decades to make hepatitis B vaccines, Corbevax will be among the first Covid-19 vaccines to use this platform. Novavax has also developed a protein-based vaccine, which is still waiting for emergency use authorisation from various regulators.

How it was made

While it is indigenously produced, Corbevax's beginnings can be traced to the Baylor College of Medicine's National School of Tropical Medicine. The School had been working on recombinant protein vaccines for coronaviruses SARS and MERS for a decade.

"We knew all the techniques required to produce a recombinant protein (vaccine) for coronaviruses at high levels of efficiency and integrity," said Dr Peter Hotez, Professor and Dean at the School.

When the genetic sequence for SARS-CoV-2 was made available in February 2020, researchers at the School pulled out the sequence for the gene for the spike protein, and worked on cloning and engineering it. The gene was then put into yeast, so that it could manufacture and release copies of the protein. "It's actually similar to the production of beer. Instead of releasing alcohol, in this case, the yeast is releasing the recombinant protein," Dr Hotez said.

After this, the protein was purified to remove any remnants of the yeast "to make it pristine". Then, the vaccine was formulated using an adjuvant to better stimulate the immune response.

Most of these ingredients are cheap and easy to find.

THE MANUFACTURER

BIOLOGICAL E, headquartered in Hyderabad, was founded by Dr D V K Raju in 1953 as a biological products company that pioneered the production of heparin in India. By 1962, it forayed into the vaccines space, producing DPT vaccines on a large-scale. Today, it is among the major vaccine makers in India and, by its own claim, the "largest" tetanus vaccine producer in the world.

It has seven WHO-prequalified shots, including a five-in-one vaccine against diphtheria, tetanus, pertussis, hepatitis B and haemophilus influenza type-b infections. Its vaccines are supplied to over 100 countries and it has supplied more than two billion doses in the last 10 years alone.

Since 2013, the company has been under the management of Mahima Datla — the third generation of the founding family. During her time as managing director, the company has received WHO prequalification of its Japanese encephalitis, DTwP and Td as well as measles and rubella vaccines and also commenced commercial operations in the US.

In August, BCM transferred its production cell bank for this vaccine to Biological E, so that the Hyderabad-based company could take the candidate through trials. The vaccine has received approval for phase 3 trials, which the government expects will be over by July.

Biological E is also expected to scale up production for the world.

How it's different

Other Covid-19 vaccines approved so far are either mRNA vaccines (Pfizer and Moderna), viral vector vaccines (AstraZeneca-Oxford/Covishield, Johnson & Johnson and Sputnik V) or inactivated vaccines (Covaxin, Sinovac-CoronaVac and Sinopharm's SARS-CoV-2 Vaccine–Vero Cell).

Inactivated vaccines, which include killed particles of the whole SARS-CoV-2 virus, attempt to target the entire structure of the virus. On the other hand, Corbevax, like the mRNA and viral vector Covid-19 vaccines, targets only the spike protein, but in a different way.

Viral vector and mRNA and vaccines use a code to induce our cells to make the spike proteins against which the body have to build immunity. "In this case (Corbevax), we're actually giving the protein," said Dr Hotez.

Like most other Covid-19 vaccines, Corbevax is administered in two doses. However, as it is made using a low-cost platform, it is also expected to be among the cheapest available in the country.

Why it matters

This is the first time the Indian government has placed an order for a vaccine that has not received emergency use authorisation, paying Rs 1,500 crore in advance to block an order that could vaccinate 15 crore Indian citizens. The Centre has provided major pre-clinical and clinical trial support towards the vaccine's development, including a grant-in-aid of Rs 100 crore from the Department of Biotechnology.

A major reason for India placing such a big order is the difficulties it is facing in enhancing vaccine supplies. While the US, UK and the EU had made advance payments and at-risk investments into vaccines like Pfizer, AstraZeneca and Moderna, India waited until after its first two vaccines were approved before placing limited orders. Even after the government eased regulatory requirements for foreign vaccines, it did not receive a speedy response from companies like Pfizer and Moderna, their supplies already blocked through orders from other countries. India is currently in negotiations for a limited supply of Pfizer's vaccine, and expecting to secure up to two billion doses of Covid vaccines by December this year. Given the ease with which it can be mass produced, Corbevax could make up a sizeable portion of this expected supply.

TexasMonthly

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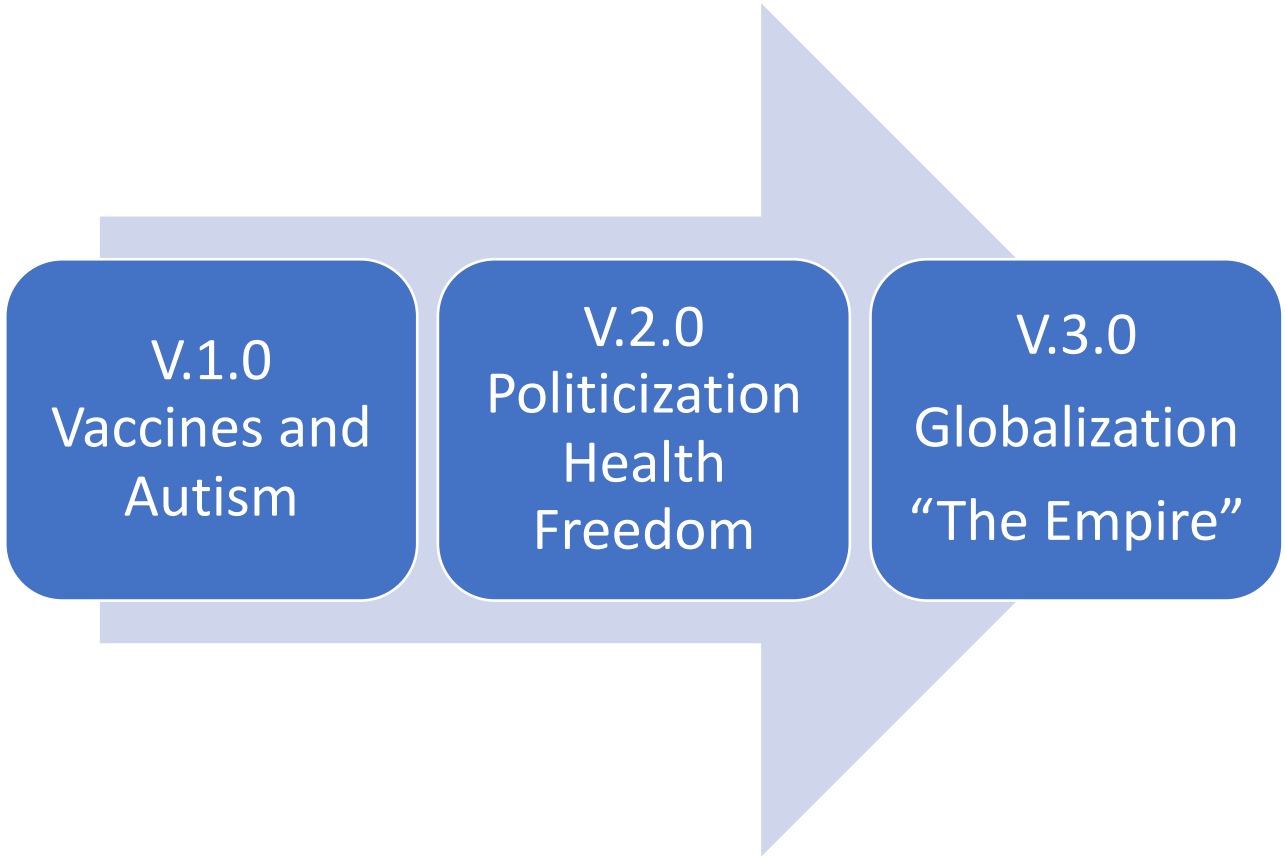
The Coronavirus Pandemic READ OUR COVERAGE

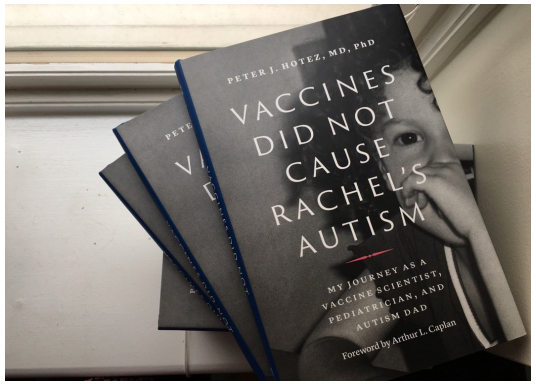
HEALTH

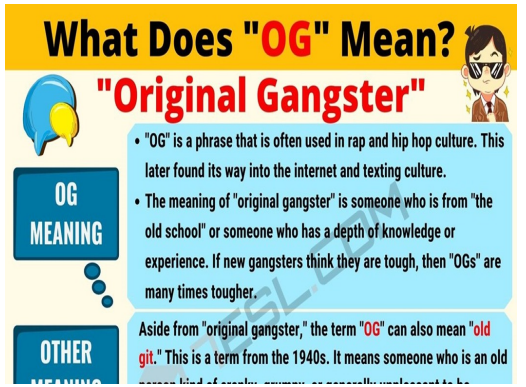
Can This Houston-Born COVID Vaccine Save the Developing World?

Antivaccine-Antiscience Ecosystems and Empires



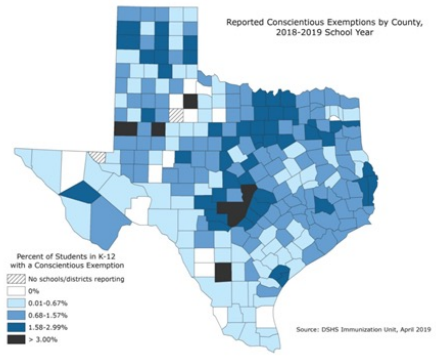
Vaccine Scientist, Pediatrician, Parent of Adult Daughter with Autism, and the "OG Villain"





V.2.0 Expansion of "Health Freedom" to Texas

TEXAS NON-MEDICAL EXEMPTIONS (2003-2020)



Source: Tex. Dep't St. Health Serv., *Vaccination Coverage Levels in Texas Schools* (May4,2020).
https://www.dshs.texas.gov/immunize/coverage/schools/.

nature

Vol 592 | 29 April 2021 | 661

A personal take on science and society

World view

By Peter Hotez

COVID vaccines: time to confront anti-vax aggression

Defeating the coronavirus will need high-level action against new destructive forces.

Nearly one billion COVID-19 vaccine doses have been delivered in less than six months, but anti-vaccine disinformation and targeted attacks on scientists are undermining progress. These threats must be confronted directly, and the authority and expertise of the health community alone aren't enough to do this.

Even before the pandemic, I had a front-row seat to all of this. I have co-led efforts to develop vaccines in programmes, including a COVID-19 vaccine currently being tested in India. I also have an adult daughter with autism; my 2018 book, *Vaccines Did Not Cause Rachel's Autism*, became a dog whistle for anti-vaccine activists.

The World Health Organization recognized vaccine hesitancy as a top threat to global health before the pandemic. As COVID-19 vaccines moved through devel-

> "Accurate, targeted counter-messaging from the global health community is important but insufficient."

to destabilize the United States and other democratic countries. The administration of US President Joe Biden has warned Russian media groups to halt their anti-vaccine aggression, and announced sanctions tied to disinformation and other behaviour, but we need much more.

The United States hosts the world's largest and best-organized anti-vaccine groups. According to the London-based Center for Countering Digital Hate, these are influential groups, not a spontaneous grass-roots movement. Many far-right extremist groups that spread false information about last year's US presidential election are doing the same about vaccines. Anti-vaccine groups also target Black communities; an anti-vaccine documentary released in March vilifies COVID-19 vaccine testing among African Americans, calling it "medical racism".

Global anti-vaccine messaging around the adenovirus vaccines means that more people will die and the pandemic will be prolonged. Extremely rare but life-threatening blood clots caused the United States to pause roll-out of the Johnson & Johnson vaccine, and many European nations