

Description: <https://capitol.texas.gov/tlodocs/86R/schedules/html/C6102020120709301.HTM>
Witness List: <https://capitol.texas.gov/tlodocs/86R/witlistmtg/html/C6102020120709301.HTM>
Video: https://tlcsenate.granicus.com/MediaPlayer.php?view_id=46&clip_id=15241

SPOTLIGHT COMMENTS

- Senator Louis Kolkhorst, Chair - Absolutely Cycle threshold is critical – with enough cycles, they will find minuscule amounts and show a false positive.
- Senator Charles Perry, Vice-Chair - “Be Bold and Courageous!”

TESTIMONY COMMENTS:

1. 10:54 **John Hellerstedt, (also providing written testimony) (Department of State Health Services), Austin,**
 - a. 12:20 – some people have no symptoms at all
 - b. Slide 3 COVID timeline – we began planning forward in late 2019 became aware of the threat the novel virus –
 - c. 13:55:00 which means that no existing population had any immunity to it. Rather than taking time to spread it hit all at once.
 - d. By Jan 7 China had identified the virus
 - e. On Jan 21 CDC confirmed the first case in WA state –
 - f. On Jan 23 DSHS pushed the COVID website and prepared #TexasDSHS social media campaigns.
 - g. On Dec 31 Stop Medical Operations Center (SMOC) we were studying the disease and planning for the arrival in TX – daily call, website, hotline, coordination daily activities
 - h. On March 4, first positive case in TX
 - i. On March 13, Gov. Abbott blank tape
 - j. ??? announces first death – blank tape
 - k. On March 19, DSHS declared a public health disaster
 - l. On March 26, DSHS and Dept of Emergency Management developed a command center.
 - m. It is documented to be in all 254 states
 - n. To date lab confirmed 1,249, 323 cases, fatality 22,594 and hospital count 8,790 as of Dec 7 – Primary goal is to have critical bed available
 - o. 17:15:00 Slide 4 – charts of cases – in a steep peak of number of cases what followed is the number of hospital cases...when a person become infected, incubate, symptoms, get tested and then need hospitalization.
 - p. 18:39:00 the number of cases is higher but the number of hospitalizations has decreed – the number testing have increased.

- q. Better ability to track data with numerator and denominator to track both the positive test and negative test.
- r. 20:45:00 The direction is more important than the accuracy
- s. 22:15:00 many hospitalizations end up in ICU which is also used for car wrecks, strokes, heart attacks etc. that existed before COVID
- t. 23:10:00 if we need to expand the ICU that we expand within the hospital. If the have the “staff and stuff” we can expand.
- u. 24:00 A lot of the hot spots have become regional and can become very critical requiring transfer of patients from there to other parts of the state. Where we have setup care type settings, we learned what really provides value and better able to provide relief to the hospitals
- v. 24:50 Slide 6 Trends for hospitalizations – Mid November until now shows an increase. We have thousands of people staffed.
- w. Stopped at 22:20

THERAPEUTICS

1. 1:29:17 Larry Schlesinger, Professor/President/CEO

(Texas Biomedical Research Institute), San Antonio, TX

- a. 1:30:03 Public Policy voice for healthcare and bioscience industry –
- b. Infectious disease physician and active scientist focused on air born infections having worked closely with the NIH and Bill and Melinda Gates Foundation through several infectious disease threats
- c. 1:30:14 Texas BioMedical Research Institutes is a Independent biomedical dedicated on irradiation infectious diseases.
- d. The only non-profit institutions in the nation working exclusively on infectious diseases.
- e. Three take-aways 1) Science is cumulative, 2) Sciences are collaborative, and 3) infection disease, R&D and education must change from reactive to proactive with more investment of resources.
- f. 1:31:50 – Economist predict 2050 infectious disease will become the leading cause of death with impact on world economies.
- g. 1:32:10 – what took months to years to discover a new virus took two weeks with virus... This is allowing us to deliver science to market faster.
- h. 1:32:47 it was the preclinical data created from Texas BioMed’s validated animal models last March that propelled the clinical trials for the monoclonal antibodies cocktail therapy created by Regeneron and given to the President as well as the Pfizer vaccine being reviewed by the FDA.
- i. 1:33:15 The institute has robust partnership with Regeneron and Pfizer, Novax ... over 30 in total.

- j. 1:33:35 I am confident in the process, I believe the FDA is fully examining the data in a comprehensive and independent fashion to insure that any interventions ... of the 2 vaccines under consideration... monoclonal antibodies... have the rigor
- k. 1:39:58 I trust my colleges at the NIH, CDC and FDA
- l. 1:34:07 I am excited at the vaccine being review and their distribution to those who need it
- m. 1:34:15 **However there are still many unknowns regarding the vaccine's effects.** ... Research must continue. We must be prepared for unanticipated challenges with the vaccine as they roll out.

NOTE:



- n. 1:35:10 – We must answer the questions to this pandemic to get ahead of the next one. HIV, TB, Malaria, Sepsis still cause millions of deaths each year.
 - o. 1:35:50 Education is essential
 - p. 1:36:35 We must wash our hands, wear our masks and social distance
-
- 2. 1:37:37 Kolkhorst takes about has SAR and MERS burned out so quickly
 - 3. 1:39:00 – Kolkhorst asks Are we going to have to wear masts forever.



- a. Dr -- Flu vaccine 40% efficacy – vaccine to get back to “normalcy” – roll out toward the majority of the population. MERS is 30% fatality.
- b. 500 new therapies for COVID – 300 in clinical trials

NOTE:

11/16/20 • BIG PHARMA > VIEWS

Pfizer Vaccine 90% Effective Claim Unsubstantiated by Peer-Review Journals and World Health Organization

Can the public afford to trust vaccine companies who deliberately withhold information and data and have preyed on the public's desperation to escape lockdowns, while, at the same time, reaping the rewards from the stock market that has responded to a premature and unsupported announcement?

Pfizer was conspicuous, given its position as one of the largest drug companies in the world, in excluding itself from the U.S. government [Operation Warp Speed](#). The downside for Pfizer was that it didn't benefit from the U.S. government (= taxpayer) funding support that the likes of [Moderna](#), [Johnson & Johnson](#) and [Astra-Zeneca](#) have been privy to. But don't feel too bad, [BioNTech](#) received funding from the German government. The plus side for Pfizer was that it didn't need to be dictated to by others, and it didn't need to data share or have its data analysed by a shared, [Operation Warp Speed](#) data monitoring committee. Remember this as you read on.

4. 1:41:47 – Senator Miles asks about side effects –
 - a. Dr -- Pfizer trials of 30K to 40K – side effects reports are local response, pain in the arm. Others – fever, feeling tired – **we don't know about long lasting effects – had 2 months of safety data**. Efficacy and how long it last is unknown – non effective or lasting.
5. 1:43:50 Senator Perry– “Does your facility consider the conversations consider that we knew about therapeutics early on – like HCQ and other therapeutics, vitamins – do you see an intention of prevention through vaccine rather than treatment with therapeutics? We must be cautious when we are against therapeutics that are working – the agenda took a more active role against therapeutics.
 - a. 1:46:05 DR – the bedrock of biomedical institute – always aware of the information out there monitoring – we are on the bedrock of scientific exploration. We were not involved in HCQ studies, we did some with therapeutics. At the end of the day we evaluate to the public as to what is fact of fiction. I am very concerned about facts – where we are headed. 15 more trials on vaccines and more therapies. We have to evaluate the science.

NOTE:

Antiviral Drugs That Are Approved or Under Evaluation for the Treatment of COVID-19

Last Updated: November 3, 2020

Summary Recommendations

Remdesivir is the only Food and Drug Administration-approved drug for the treatment of COVID-19. In this section, the COVID-19 Treatment Guidelines Panel (the Panel) provides recommendations for using antiviral drugs to treat COVID-19 based on the available data. **As in the management of any disease, treatment decisions ultimately reside with the patient and their health care provider.** For more information on these antiviral agents, see [Table 2](#).

6. 1:48:00 Perry— do you have a responsibility to have therapeutics to be proven out. Of a study of 30K to 40K number of people – how many would have been in a responsible sample – a standard normal sample population.
 - a. 1:50:00 DR -- The scientific has been sequential and not parallel. Phase 3 of 30K to 40K is normal study. No corners cut on the size of trials. **The animal models produced, the Pfizer protect 100% of the animals** – predictive of human responses.
7. 1:51:57 Perry – what is herd immunity –
 - a. Dr -- answer 70% exposure. If efficacy is in the 90% to 90% we will break transmission. “People need to take the vaccine.”
8. 1:52:00 – Perry - Where do you get your funding to do research – from vaccine manufacturers ?
 - a. Dr -- Majority grants **NIH / Bill and Melinda Gates Foundation**, endowment and philanthropic - private funding.
9. 1:53:40 – Kolkhorst – therapeutics – she knows several examples of off label use that works – zinc. I am frustrated by the lack of knowledge of things that are working – pharmaceuticals – we guess on the flu vaccine each year – she mentions Tamaflu – 70% is in the elderly – wants some therapy instead of just being sent home to come back once you get really bad.
 - a. Dr – there is practical side – do no harm – rest on data – the body’s immune system goes haywire – We are rolling out vaccine while still trying to understand the virus. 300 drugs in clinical trials.
10. 1:59:17 Kolkhorst asked about number of deaths from various diseases
 - a. Dr --COVID has killed 300K - Malaria kills about 500K– what is the number 1 killer - TB. HIV 1 M die each year.
11. 2:00:00 **Dr Matt Leveno Medical Director Parkland MICU and COVID TCU (UT Southwester** - Comments on current COVID treatment.
 - a. Pts come in with pneumonia, low O2.
 - i. Three categories –
 - ii. 1- low O2 support needed – nasal cannula – Remdesivir and a steroid

- iii. 2- higher level of O2 support – high flow nasal cannula with higher concentration – O2 via facemasks or high flow nasal cannula, Remdesivir and steroids–
 - iv. 3 – require mechanical ventilation to provide the act of breathing- can take weeks to get off or death.
 - b. Perry - Have seen people in their 30's and 40's who progress to ventilation and death.
 - i. Dr – Yes It's unlike any other disease I've ever worked with.
12. 2:08:45 Perry– is there something that you are required to report that the state with minimum effort be able to access and compile the co-morbidity. Data to describe what is a co-morbidity.
- a. Dr – medium BMI is 30% - high blood pressure, 44% diabetes, age is 58 – unpredictability.
13. 2:13:08 Kolkhorst – before someone gets to the hospital – have you seen what is successful in the early stages of COVID and what can be helpful from being admitted as cat 1,2,3.
- a. 2:13:40 – Dr – we are now going outside his expertise. I provide critical care – Anecdotally many had been on HCQ – in terms of commonly discussed – outpatient strategies – I am unfamiliar. Kolkhorst – you mentioned steroid use – what steroid are you administering – Decadron - Is Remdesivir still limited?
14. Kolkhorst 2:15:45 – what about convalescent plasma –
- a. Dr --most pts would have already received that therapy, not at the critical care.
15. Perry – 2:16:30 – have you seen an instance of patients who received HCQ – would your treatment change if they had received various therapeutics.
- a. Dr -- People who have been on antibiotics might influence my decision making.
16. 2:18:18 – Perry have you seen pts who had received other therapeutics.
- a. Dr. yes – he has seen pts who received other therapeutics.
17. 2:18:50 Kolkhorst – what are you seeing regarding influenza =
- a. 2:19:15 **Dr - What type of volume are we seeing with influenza? Zero hospitalizations as of right now.**
18. Perry 2:20:00 is the lack of flu due to everyone who has the flu is being diagnosed as COVID.
- a. Dr – flu and COVID testing should be able to distinguish between the two. Unlike COVID, flu contagious from symptomatic people – COVID can be transmitted by asymptomatic people.
- 19. 2:22:30 James J McCarthy Chief Physician Executive (Memorial Hermann Health System) Houston, TX**
- a. 1st case in Houston - March 4 – initial response was need of PPE and testing.
 - b. High level of anxiety by healthcare providers.
 - c. Universal masking – had difficulty identifying patients –
 - d. **Reprocessed N95 masks with hydrogen peroxide to sterilize masks.**
 - e. On April 4, we started with convalescent plasma – treated 1800 to date – very challenging to administer first 10 were under emergency use authorization - next 1300 was under the Mayo protocol for data collection.
 - i. **Requires a tremendous amount of work – it takes 20 patients interviewed to 1 to get one plasma donation under emergency use authorization.**
 - ii. **Socio demographic disadvantage population are hotspots of Hispanic and African American higher incidence.**
 - f. May 14 – Remdesivir – heavily limited early on now have plenty. When given early reduces the duration and severity of illness.

20. 2:27:40 – Kolkhorst asks about steroids – most pts in hospitals require oxygen. What O2 level is the condition considered a problem –
- Dr – nervous in low 90’s – need oxygen.
 - Hyper coagulation – testing for d-dimer’s – put pts on anti-coagulations –
 - Pts are being sent home on oxygen – something only historically done for lung or heart conditions.
 - July – had over 1000 pts in hospitals – the recovery trial and the use of steroids – gave us better guidance.
 - Some trials show that steroids can make people worse.** Pts numbers dropped to 200 which is has remained constant. Now have rolled out for monoclonal antibodies – and distribution program ready to go for vaccinated healthcare workers.
 - NOVEMBER 100% increase of volume of in patients in 30 days – now at 400 COVID pts. Have tested 140,000, treated 22K, over 1000 die in facilities.
 - Good news cumulative medical knowledge – mortality in medically vulnerable – **we are still worried with provider fatigue.**
 - But we have demonstrated that we can keep our staff safe.
21. 2:34:30 – Kolkhorst - what is the ICU census.
- Dr—will check on ICU census –
 - Kolkhorst Have you curtailed elective surgeries?
 - 2:35:35 Senator Kolkhorst - What you seeing in influenza rates –
 - Dr—Exceptionally little not aware of any influenza – later confirms -
6 admissions for flu in October
22. 2:36:15 Perry –have you heard of intestinal complications of COVID –
- Dr – we do see GI problems – fever, malaise, loss of smell.
23. 2:37:00 Perry –Have you seen anything with pregnancies – I have been reported that there have been 6 young pregnant women experience clotting issues – has the Dr seen this?
- Dr – we see significant levels of COVID in pregnant women – 100% of women are tested for COVID.
24. 2:38:00 Perry Have new babies tested positive at birth and show positive –
- Dr – Yes - not sure if it was pre or post-delivery.
25. 2:38:45Perry – Would heart ablation considered elective – would delay be a problem.
- Dr – yes delay could be a problem.
26. 2:39:44 Miles – Are we working on how we are going to get the vaccine to hot spots in District 13.
- Dr – working to have distribution in all clinics who have storage capacity – for the -80 degree storage.
27. 2:42:15 Kolkhorst – are ya’ll using therapeutics
- Dr – no
 - Kolkhorst - Have you seen in therapeutics that have come to the hospital.
 - Dr -- Steroids are really on good for those dropping O2 below 90%. The infusion of the monoclonal antibodies may help.
28. **2:44:20 – Kolkhorst does call out for written testimony – for best practices!!!!**

- a. 2:45:50 – Kolkhorst asks about putting people on stomachs – supine position =
Dr – proning is being used helps getting the back of the lungs to get more oxygen helps prevents people getting ventilation.

VACCINES - 2:47:50 –

1. 2:49:45 **Imelda Garcia, Associate Commissioner, Laboratory and Infectious Disease Services** (also providing written testimony) (Texas Department of State Health Services), Austin, TX
 - a. Vaccine Distribution Plan – plans may change before the vaccine arrives
 - b. Slide 11 – Assumptions of COVID Vaccine planning – CDC out 4 Key Assumptions:
 - i. 1. Expect limited doses but supply will increase in 2021. Additional vaccines likely approved in 2021
 - ii. 2. 2:50:45 The Initial supply could be approved in one of two ways. It could be fully licensed as a vaccine or more likely it will be licensed for Emergency Use Authorization (EUA).
 - A. Vaccines under an EUA CANNOT MANDATED
 - B. **“IN TEXAS RECEIVING THE COVID 19 VACCINE IS COMPLETELY VOLUNTARY AND WE WANT TO MAKE SURE EVERYON KNOWS THAT – BECAUSE IT IS LICENSED UNDER AN EUA – IT CANNOT BE MANDATED BY ANYONE.”**
 - iii. 3. 2:51:20 Cold chain storage
 1. Refrigerated
 2. Frozen
 3. Ultra code – -80 degree Celsius
 - iv. 4. 2:51:40 :Two doses from the same manufacturer separated by either 21 or 22 days will be required for the individual to **attain immunity from most of the COVID 19 vaccines.**

NOTE: Click On images for links to articles


Statements associating immunity to receiving the vaccine are FALSE.


Surgeon General Jerome Adams says people still need to wear masks and socially distance after they've been vaccinated because it doesn't prevent infection just severe illness

- Surgeon General Jerome Adams appeared on GMA on Monday as the first vaccines were rolled out across the US
- He said that Pfizer vaccine protects people against severe disease but not from getting infected
- It means that after people have been vaccinated, they still need to be careful
- The government says it'll roll out 100million vaccinations by March
- But that's only a third of the country and many are unwilling to take the vaccine
- The first doses are being administered across the country on Monday morning
- Intensive care nurse Sandra Lindsay received the first Pfizer shot in the U.S. at the Long Island Jewish Medical Center in Queens just before 9.30am

By JENNIFER SMITH FOR DAILYMAIL.COM

PUBLISHED: 08:57 EST, 14 December 2020 | UPDATED: 13:38 EST, 14 December 2020

Are there other vaccines that can help prevent me from getting COVID-19? 

There are currently no available vaccines that will prevent COVID-19. However, [multiple agencies and groups in the United States](#)  are working together to make sure that a safe and effective COVID-19 vaccine is available as quickly as possible.

A flu vaccine will not protect you from getting COVID-19, but it can prevent you from getting influenza (flu) at the same time as COVID-19. This can keep you from having a more severe illness. While it's not possible to say with certainty what will happen in the winter, CDC believes it's likely that flu viruses and the virus that causes COVID-19 will both be spreading during that time. That means that getting a flu vaccine is more important than ever.

- c. 2:52:15 Vaccine Life Cycle
 - i. While Operation Warp Speed has tried to accelerate the process to being the COVID vaccine to market... each of the steps must be made for FDA to meet along the way.
 - ii. Even after FDA approves or Authorizes – the CDC will give additional information as to who the vaccines will be giving to.
 - iii. Even after we have vaccine approval - we will continue to monitor for safety concerns even after the vaccines are out there.
- d. 2:53:17 Operation Warp Speed has many components –
 - i. The six vaccine candidates are all under Federal contract prior to FDA approval
 - ii. Five of the Six require a two dose series – only one is a single dose but they are testing with a two dose as well



-
- iii. Timing various depending on which brand you get.
 - iv. Storage and handling requirements –
 - v. It does create complexity for distribution and practitioner handling and distribution.
 - vi. Hyper scrip

DESCRIPTION

COMMITTEE: Health & Human Services
TIME & DATE: 9:30 AM, Monday, December 7, 2020
PLACE: E1.012 (Hearing Room)
CHAIR: Senator Lois Kolthorst

The Senate Committee on Health and Human Services will meet on Monday, December 7 to hear invited testimony on the following topics:

- **COVID-19:** Examine clinical best practices, including therapeutics, for treating COVID-19 patients at each stage of the disease. Monitor the status of vaccine development and distribution.
- **COVID-19:** Analyze the procedures for collecting, modeling, and reporting data on COVID-19 tests, cases, hospitalizations, and fatalities. Examine the role of state agencies, local governments, and private entities.

Capitol access is limited to legislators and staff only. Testimony will be limited to invited testimony. Invited testimony will be conducted via video-conference. The public may view the livestream of the hearing at <https://senate.texas.gov/av-live.php>

WITNESS LIST

Health & Human Services
December 7, 2020 9:30 AM

COVID-19

ON:

Basit, Mujeeb Associate Director of Clinical Informatics Center at UTSW (also providing written testimony) (University of Texas Southwestern), Dallas, TX

Public Boerwinkle, Eric Dean (also providing written testimony) (UTHealth School of Health), Houston, TX

Services (also Epley, Eric Executive Director/CEO (also providing written testimony) (SW Texas Regional Advisory Council), San Antonio, TX

TX Garcia, Imelda Associate Commissioner, Laboratory and Infectious Disease providing written testimony) (Texas Department of State Health Services), Austin,

State Gruber, David Associate Commissioner (also providing written testimony) (Texas Department of State Health Services), Austin, TX

Southwestern Hellerstedt, John Commissioner (also providing written testimony) (Department of Health Services), Austin, TX

Officer Leveno, Matt Medical Director Parkland MICU and COVID TCU (UT Medical School and Parkland), Dallas, TX

Houston McCarthy, James J Chief Physician Executive (Memorial Hermann Health System), Houston, TX

District), Moran, Brett SVP, Associate Chief Medical Officer, Chief Medical Information Officer (also providing written testimony) (Parkland Health & Hospital System), Dallas, TX

Health Department), Houston, TX

Diagnostocs), Persse, David Chief Medical Officer (also providing written testimony) (City of Roberts Jr., George T. Chief Executive Officer (Northeast Texas Public Health Tyler, TX

San Sabol, Christine Senior Director, Medical Operations & Regulations (Quest Laguna Niguel, CA

Public Shah, Umair Executive Director (also providing written testimony) (Harris County Health), Houston, TX

written Thomas, Georgia AVP Quality, Patient Safety and Regulatory (also providing testimony) (Memorial Hermann Health System), Houston, TX

Walters, Faith Vaccines US Medical Affairs/ Field Medical Lead (Pfizer Vaccines), Collegeville, PA

Registering, but not testifying:
ON:

Benz, Allison Executive Director (Texas State Board of Pharmacy), Austin, TX
Bredt, Robert Medical Director (Texas Medical Board), Pflugerville, TX



Freshour, Scott M. General Counsel (Texas Medical Board), Austin, TX
Hill, Chris County Judge (Collin County), McKinney, TX
Kidd, Nim Chief (TDEM), Austin, TX
Shuford, Jennifer Chief State Epidemiologist (Department of State Health Services),

TX