FYI- House Approps released a new covid supp today
Only includes an additional $1.5m for FDA to do vaccine advisory committees. After I review the whole thing will keep you posted of any other relevant items.
Thx
Chairman Pallone would still like for you to brief his Members so they have a chance to ask you questions; if he raises it today you can say...
Two other FYSAs:  
HHS-ASL colleagues may join the call in listen-only mode.
Dr. Mark's will brief the staff of the Members on the call, along with the staff of every member of the E&C, HELP. and Appropriations Committees, Monday at 8:30am.
2020-12-12 15:58:49 UTC: Messages -> [4 recipients]

From: Stephen Hahn
To: Anna Abram, Keagan Lenihan, Andrew Tantillo, Maren McBride
Date: Sat, 12 Dec 2020 10:58:49 -0500

Thx.
House leaders expect to vote on the unreleased COVID-19 aid bill and $1.4 trillion omnibus spending package Sunday, according to an announcement from Hoyer's office.
I'll let
You know if we get text
I am told a new CR and the Omni/COVID supp will post tonight before midnight.
I'll keep you posted when I see it
Want me to check in with McConnell team?
Liked “I am told a new CR and the Omni/COVID supp will post tonight before midnight.”
Sure if you want!
House voting on a CR through tomorrow at 6:30 and it supposed to be last votes of night so I'm guessing they won't vote
on the supp/Omni till then.
Senate passed CR
2020-12-21 03:56:15 UTC: Messages -> [4 recipients]

From: Keagan Lenihan
To: Anna Abram, Andrew Tantillo, Maren McBride, Stephen Hahn
Date: Sun, 20 Dec 2020 22:56:15 -0500

Thx. Great news.
From: Maren McBride
To: Anna Abram, Keagan Lenihan, Andrew Tantillo, Stephen Hahn
Date: Mon, 21 Dec 2020 14:24:05 -0500

FYI- bill posted. 42M increase in boll
Bill
And 55M for COVID supp
House will vote tonight on the supp and OMNI
Great news.

From: Keagan Lenihan
To: Anna Abram, Andrew Tantillo, Maren McBride, Stephen Hahn
Date: Mon, 21 Dec 2020 15:57:19 -0500
2020-12-21 21:20:39 UTC: Messages -> [4 recipients]

From: Stephen Hahn
To: Anna Abram, Keagan Lenihan, Andrew Tantillo, Maren McBride
Date: Mon, 21 Dec 2020 16:20:39 -0500

Liked "House will vote tonight on the supp and OMNI"
House passed supp/omni
Supposed pass
Senate tonight
2020-12-22 02:45:47 UTC: Messages -> [4 recipients]

From: Stephen Hahn
To: Anna Abram, Keagan Lenihan, Andrew Tantillo, Maren McBride
Date: Mon, 21 Dec 2020 21:45:47 -0500

Liked "Supposed pass Senate tonight"
House and Senate both passed week long CR tonight and senate should pass Omni/ supp in a bit
In good shape!
Thx, Maren.
From: Maren McBride
To: Anna Abram, Keagan Lenihan, Andrew Tantillo, Stephen Hahn
Date: Mon, 21 Dec 2020 23:46:16 -0500

Senate just passed the Omni and supp
<table>
<thead>
<tr>
<th>From:</th>
<th>Keagan Lenihan</th>
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<tbody>
<tr>
<td>To:</td>
<td>Anna Abram, Andrew Tantillo, Maren McBride, Stephen Hahn</td>
</tr>
<tr>
<td>Date:</td>
<td>Mon, 21 Dec 2020 23:46:41 -0500</td>
</tr>
</tbody>
</table>

Great news
Maren, thanks to you and our OCA team for the great work on this front!
Agreed! Appreciate all the hard work.
Maren
So terrific. Thank you
Liked â€œMaren, thanks to you and our OCA team for the great work on this front! â€œ
From: Maren McBride
To: Anna Abram, Keagan Lenihan, Andrew Tantillo, Stephen Hahn
Date: Tue, 22 Dec 2020 09:25:34 -0500

Liked “Agreed! Appreciate all the hard work.”
From: Maren McBride
To: Anna Abram, Keagan Lenihan, Andrew Tantillo, Stephen Hahn
Date: Tue, 22 Dec 2020 09:25:39 -0500

Likes "Maren
So terrific, Thank you "
Thanks all!
The president signed the Omni and COVID supp in case you didn't see...
From: Keagan Lenihan  
To: Anna Abram, Andrew Tantillo, Maren McBride, Stephen Hahn  
Date: Sun, 27 Dec 2020 20:56:18 -0500  

Thx
Liked “The president signed the Omni and COVID supp in case you didn't see”
2020-10-01 02:08:41 UTC: (b)(6) Messages -> [6 recipients]

From: (b)(6) messages" 
To: (b)(6) messages", Ron Johnson (b)(6) messages">, (b)(6) messages">, (b)(6) messages">, (b)(6) messages">
Date: Wed, 30 Sep 2020 22:08:41 -0400

https://www.medrxiv.org/content/10.1101/2020.09.30.20204693v1
28 minute Senate Hearing on early Covid-19 treatment. Please share with the American people.
2020-11-20 03:38:37 UTC: Messages -> [6 recipients]

From: messages, Ron Johnson
To: messages, Mark Meadows
messages, Stephen Hahn
Date: Thu, 19 Nov 2020 22:38:37 -0500

https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.google.com%2Furl%3Fq%3Dhttps%3A%2F%2Fyoutu.be%2Fftq6ImRIKgQ%26source%3Dg

FDA-OC_FOIL_2020-6423_002605
From: (b)(6) messages"
To: (b)(6) messages", Ron Johnson
  (b)(6) messages", Mark Meadows
  (b)(6) messages", Stephen Hahn
  (b)(6) messages">

https://twitter.com/zev_dr/status/1331470564691734528?s=21
Dr. Vladimir (Zev) Zelenko  
Board Certified Family Practitioner  
Office: 845-782-0000

November 23, 2020

Dear President Trump:

I humbly offer the following observations:

1. Based on my front-line experience, it is essential to start treatment against Covid-19 immediately upon clinical diagnosis of the infection and not to wait for confirmatory testing. There is a very narrow window of opportunity to eliminate the virus before pulmonary complications begin. Delaying treatment is the essence of the problem. My treatment regime is attached and please know that as of today it has saved thousands of patients without serious complications or negative side effects. Hundreds of top doctors across the world have embraced prehospital treatment of Covid-19 in high risk patients.

2. Based on my front-line experience, the emphasis must be on preemptive treatment for high-risk patients in the outpatient setting - primary care and urgent care settings. It makes no sense to wait until a patient is admitted to a hospital and put on a ventilator.
High-risk patients are those over the age of 45, those with underlying health conditions or compromised immune systems, and anyone with symptoms and shortness of breath.

In addition, we should consider immediate prophylactic treatment of very high-risk individuals.

Very high-risk individuals are front-line health care providers, nursing home residents, police officers, etc.

3. Based on my direct observations, the risk of side effects to this treatment regime is exaggerated. The theoretical risk of heart arrhythmia (QT prolongation) is 1 in a 10000. However, the actual risk of death from Covid-19 in the high-risk population is between 5 to 10%. The risk versus benefit analysis overwhelmingly favors treatment. And in my clinical experience, I have seen no negative side effects.

4. This is World War III (virus vs humanity). Under these circumstances, we don’t have the luxury of operating as we do in peacetime for studies and research. Millions will die and the economy will collapse while we wait.
Dear Mr. President:

I humbly request the following:

1. We need an executive order to override any state obstacles and to (a) allow all physicians to prescribe the above regime without the fear of liability or retribution; and (b) permit pharmacies to dispense this medication without the fear of liability or retribution.

2. The pharmacies need an immediate supply of sufficient medicine to dispense the above regime to at least 150 million people. Please do everything in your power to achieve this.

4. The Task Force, CDC, FDA, NIH should all issue strong recommendations to physicians to treat their patents early and aggressively based on clinical diagnosis, without the delay caused by confirmatory testing.

5. Any bureaucratic/man made obstacles that interfere with doctors’ ability to treat their patients with these well known, field tested, inexpensive and life saving medications in my humble opinion is inexcusable and should be treated as a crime against humanity.

With much respect,

Dr. Vladimir (Zev) Zelenko
Zelenko Protocol Plus\textsuperscript{12}

Clinical Suspicion of Covid-19 Treatment Algorithm
Risk Stratify Patients and Treat Immediately Based on Clinical Suspicion

![Clinical Risk Stratification Diagram]

Treatment options based on clinical judgement and patient presentation
If patient is symptomatic more than 7 days, and/or appears toxic, and/or has very high risk for complications

1 https://doi.org/10.1016/j.ijantimicag.2020.106214

2 Special thanks to Dr. Roland Derwand, Dr. Martin Scholz, Senator Ron Johnson, Mayor Rudy Giuliani, Dr. Roger Sehault, Dr. Didier Raoult, Dr. Harvey Risch, Dr. James Todaro, Greg Rigano, Esq, Gary Greenstein, Esq.
Previous tweet has been deleted. Will try again.
From: (b)(6) messages"
To: (b)(6) messages", Ron Johnson (b)(6) messages", Mark Meadows (b)(6) messages", Stephen Hahn (b)(6) messages">

https://twitter.com/zev_dr/status/1331815608070103040?s=21
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With much respect,

Dr. Vladimir (Zev) Zelenko
Zelenko Protocol Plus¹²

Clinical Suspicion of Covid-19 Treatment Algorithm
Risk Stratify Patients and Treat Immediately Based on Clinical Suspicion

Low Risk
Less than 45 years old
No comorbidities
No Shortness of Breath

High Risk
More than 45 years old
Less than 45 years old with comorbidities
Any age if Short of Breath

Treatment options based on clinical judgement and patient presentation
If patient is symptomatic more than 7 days, and/or appears toxic, and/or has very high risk for complications

Budesonide 1mg/2cc nebulizer twice a day x 7 days and/or
Dexamethasone 8mg once a day x 7 days and/or
Ivermectin 6mg twice a day x 1 day and/or
Eliquis 5mg twice a day x 7 days
Consider home IV fluids and/or home Oxygen

¹ https://doi.org/10.1016/j.ijantimicag.2020.106214
² Special thanks to Dr. Roland Derwand, Dr. Martin Scholz, Senator Ron Johnson, Mayor Rudy Giuliani, Dr. Roger Seheult, Dr. Didier Raoult, Dr. Harvey Risch, Dr. James Todaro, Greg Rigano, Esq, Gary Greenstein, Esq.
2020-11-27 11:56:12 UTC: Messages -> [6 recipients]

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<td>Fri, 27 Nov 2020 06:56:12 -0500</td>
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</table>

Thx Ron u are doing the lords work
Messages -> [6 recipients]

From: (b)(6) messages"
To: (b)(6) messages", Ron Johnson
(b)(6) messages", Mark Meadows
(b)(6) messages", Stephen Hahn
(b)(6) messages">

Date: Wed, 30 Dec 2020 06:18:48 -0500

From: Ron Johnson
To: Stephen Hahn
Date: Thu, 01 Oct 2020 07:00:22 -0400

https://www.medrxiv.org/content/10.1101/2020.09.30.20204693v1
Will this have any impact?
From: Stephen Hahn
To: Ron Johnson
Date: Sat, 03 Oct 2020 09:50:26 -0400

(b)(6)
From: Ron Johnson  
To: Stephen Hahn  
Date: Sat, 03 Oct 2020 09:54:14 -0400  

Thanks: (b)(6)
Let me know if I can help
From: Ron Johnson
To: Stephen Hahn
Date: Sat, 03 Oct 2020 10:05:03 -0400

How about approving HCQ?
From: Ron Johnson
To: Stephen Hahn
Date: Tue, 06 Oct 2020 09:10:02 -0400

From: Ron Johnson
To: Stephen Hahn
Date: Tue, 06 Oct 2020 09:10:17 -0400

https://pjmedia.com/columns/stacey-lennox/2020/10/05/why-is-fauci-wringing-his-hands-over-covid-cases-detected-by-prc-tests-n1004333
Is FDA or CDC addressing the super sensitivity of the PCR test? Sounds like we are significantly over stating the number of cases that are contagious.
It depends upon what you mean by addressing. Happy to speak.
Hope you are well and keeping safe
Patrick
ImmunityBio, NantKwest Announce First Patient Dosed in Phase 1 Clinical Trial of Second-Generation COVID-19 Vaccine Candidate Delivering Both Spike and Nucleocapsid of SARS-CoV-2

First patient receives ImmunityBio’s second-generation hAd5 COVID vaccine, delivering both outer S (spike) protein and inner N (nucleocapsid) leading to potential long-term T cell and antibody immunity to the SARS-CoV-2 virus

October 21, 2020 05:06 PM Eastern Daylight Time

CULVER CITY, Calif. & EL SEGUNDO, Calif.--(BUSINESS WIRE). ImmunityBio, a privately-held immunotherapy company, and NantKwest, Inc. (NASDAQ: NK), a clinical-stage, natural killer cell-based therapeutics company, today announced that the first patient has been dosed in the Phase 1 clinical trial of hAd5-COVID-19, a novel COVID-19 vaccine candidate that targets the inner nucleocapsid (N) and the outer spike (S) protein, engineered to activate both T cells and antibodies against the coronavirus (SARS-CoV-2). This is a novel COVID vaccine that uses a second-generation adenovirus that delivers multiple proteins of the SARS-CoV-2 with the potential for long-term immunity through memory T cells. The Phase 1 trial, which is being conducted at the Hoag Hospital in Newport Beach, California, is currently enrolling healthy adult subjects up to age 55 with the goal of examining the safety and reactogenicity of two doses of the vaccine candidate.

“Our vaccine candidate, hAd5-COVID-19, targets both the nucleocapsid protein on the interior of the virus particle and the spike protein on the virus’ surface,” said Dr. Patrick Soon-Shiong, Chairman and CEO of ImmunityBio and NantKwest. “We believe this dual targeting is a key advantage that may lead to the
stimulation of both T-cell-mediated and antibody-mediated immunity to SARS-CoV-2, which is an important differentiator from other vaccine candidates that only target the spike protein."

Dr. Soon-Shiong continued, “A successful vaccine may require the stimulation of both T-cell-mediated and antibody-mediated immunity, particularly since studies have shown that patients with SARS-CoV infection have long-term T cell memory to the nucleocapsid protein. We believe that our approach, which is based on many years of experience in cancer research, could provide a robust and effective vaccine that harnesses the full potential of the immune system as an important new tool to combat the coronavirus and we look forward to advancing hAd5-COVID-19, as well as our oral, inhalational and intranasal candidates."

About the ImmunityBio hAd5-COVID-19 Vaccine Candidate

NantKwest and ImmunityBio’s hAd5-COVID-19 vaccine candidate is a uniquely engineered, second-generation human adenovirus serotype 5 vaccine that has been designed to deliver both the spike protein and nucleocapsid protein by dual constructs of SARS-CoV-2 to potentially generate both B and T cell memory to the COVID-19 antigens and long-term immunity to the virus. Most of the COVID-19 vaccines in late-stage clinical trials deliver only the monovalent spike protein on the surface of the virus to generate blocking antibodies.

Modified to enhance the safety of the vector and immunogenicity of the COVID insert, ImmunityBio’s novel human adenovirus vector has demonstrated preliminary safety in over 125 patients in 13 Phase I and 2 trials to date. Clinical studies performed by the National Cancer Institute have demonstrated that this novel Ad5 vector induces antigen-specific T-cell immunity in patients, even in the presence of pre-existing adenoviral immunity.

About the Phase I Clinical Trial

NantKwest and ImmunityBio are currently enrolling 35 healthy adults aged 18 to 55 years old in the Phase 1 study for the hAd5-COVID-19 vaccine candidate (NCT04591717). hAd5-COVID-19 will be administered as both a prime and boost using the same vector platform to enable sustained protection against SARS-CoV-2. The study’s main objective is to examine the safety and reactogenicity of two doses of the vaccine. The companies are also pursuing development for oral, inhalational, and intranasal administration of hAd5.

For more information about the trial or to enroll in it, please contact clinicalresearch@hoa.org.

About ImmunityBio and NantKwest Joint Collaboration Agreement

Under the terms of a definitive agreement announced on August 24, 2020, ImmunityBio, Inc. and its affiliate NantKwest, Inc. agreed to share equally the costs of development, manufacturing, marketing and commercialization of the products each is developing related to COVID-19, including the hAd5 vaccine candidate. Should a product be commercialized successfully, the companies have agreed to a 60-40 percentage split of net profits, with the larger share going to the company that developed the product. The agreement also details the structure of shared governance of the joint collaboration.

About the Hoag Center for Research and Education
The Hoag Center for Research and Education (HCRE) is a strategic and operational platform that selects, oversees and conducts government, industry, and foundation sponsored research trials translating early stage research and development into bedside patient care. HCRE’s aim is to provide the most advanced device technology, biopharmaceutical treatments, medical software and artificial intelligence health applications to the patients in our community and beyond. HCRE leadership procures, allocates and oversees the resources and regulatory requirements demanded of clinical trials, including patient safety and outcomes. Through nimble collaboration and efficient patient enrollment, HCRE conducts more than 150 trials annually. Trials span the entire spectrum of Hoag’s institute programs, including Cancer, Neurosciences, Women’s, Heart and Vascular, as well as individual investigator-initiated trials. Examples include anti-cancer vaccine therapy trials, Phase 1 cancer therapeutics, advanced cardiac and radiology interventional tools, applications of virtual and augmented reality tools for patient education and neuromodulation, cutting edge molecular imaging targets, Alzheimer’s detection and targeted biotherapeutics.

Since March, Hoag has participated in more than 20 COVID-19 clinical trials, providing patient access to cutting-edge therapies and innovative treatment including options that have documented improved outcomes, including decreased mortality and decreased length of stay for hospitalized COVID-19 patients.

About ImmunityBio

ImmunityBio, Inc. is a late-clinical-stage immunotherapy company developing next-generation therapies that drive immunogenic mechanisms for defeating cancers and infectious diseases. The company’s immunotherapy platform activates both the innate (natural killer cell and macrophage) and adaptive (T cell) immune systems to create long-term “immunological memory.” This novel approach is designed to eliminate the need for high-dose chemotherapy, improve upon the outcomes of current CAR T-cell therapies, and extend beyond checkpoint inhibitors.

ImmunityBio’s platform is based on the foundation of three separate modalities: antibody cytokine fusion proteins, synthetic immunomodulators, and second-generation human adenovirus (hAd5) vaccine technologies.

Anktiva™ (ImmunityBio’s lead cytokine infusion protein) is a novel interleukin-15 (IL-15) superagonist complex and has received Breakthrough Therapy and Fast Track Designations from the U.S. Food and Drug Administration (FDA) for BCG-unresponsive CIS non-muscle invasive bladder cancer (NMIBC). The company is also in Phase 2 or 3 trials for indications such as first- and second-line lung cancer, triple-negative breast cancer, metastatic pancreatic cancer, recurrent glioblastoma, and soft tissue sarcoma in combination with the company’s synthetic immune modulator (aldoxorubicin).

ImmunityBio is also developing therapies, including vaccines, for the prevention and treatment of HIV, influenza, and the coronavirus SARS-CoV-2 with its second-generation human adenovirus (hAd5) vaccine technologies.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements concerning or implying that ImmunityBio will be successful in improving the treatment of various diseases, including, but not limited to the novel coronavirus and cancer. Risks and uncertainties related to this endeavor include, but are not
limited to, the company’s beliefs regarding the success, cost, and timing of its development activities and clinical trials.

Forward-looking statements are based on management’s current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. These forward-looking statements speak only as of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

About NantKwest

NantKwest (NASDAQ: NK) is an innovative, clinical-stage, immunotherapy company focused on harnessing the power of the innate immune system to treat cancer and infectious diseases. NantKwest is the leading producer of clinical dose forms of off-the-shelf natural killer (NK) cell therapies. The activated NK cell platform is designed to destroy cancer and virally-infected cells. The safety of these optimized, activated NK cells—as well as their activity against a broad range of cancers—has been tested in phase I clinical trials in Canada and Europe, as well as in multiple phase I and II clinical trials in the United States. By leveraging an integrated and extensive genomics and transcriptomics discovery and development engine, together with a pipeline of multiple, clinical-stage, immuno-oncology programs, NantKwest’s goal is to transform medicine by bringing novel NK cell-based therapies to routine clinical care. NantKwest is a member of the NantWorks ecosystem of companies. For more information, please visit www.nantkwest.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements concerning or implying that NantKwest will be successful in improving the treatment of cancer or other critical illnesses, including COVID-19. Risks and uncertainties related to these endeavors include, but are not limited to, obtaining FDA approval of NantKwest’s NK cells and MSC as well as other therapeutics and manufacturing challenges.

Forward-looking statements are based on management’s current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements.

These and other risks regarding NantKwest’s business are described in detail in its Securities and Exchange Commission filings, including in NantKwest’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020. These forward-looking statements speak only as of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.
Thx Patrick
Doing well
You?
Feel for you as I watch how tough it is in DC. Proud that all are following science!!!
From: Stephen Hahn  
To: Patrick Soon-Siong  
Date: Wed, 21 Oct 2020 18:48:00 -0400

Thx Patrick
From: Patrick Soon-Siong
To: Stephen Hahn
Date: Thu, 22 Oct 2020 12:54:45 -0400

A good lay description of our scientific approach to the Covid Vaccine and how we took our experience to drive T cells.

(b)(4)
Here is the lay description for the public audience
From: Patrick Soon-Siong
To: Stephen Hahn
Date: Thu, 22 Oct 2020 12:55:26 -0400

Amazing paper confirms our attack of N
Hi Stephen,

Hope all is well.
Patrick Soon Shiong
Great news. Thx for the update. Hope you are well
NEW THIS MORNING

FDA CHIEF ON VACCINE DECISION

ADVISORY PANEL SET TO VOTE ON PFIZER EMERGENCY APPROVAL

FEDS TODAY SET TO EXECUTE FIRST OF 5 INMATES BEFORE BIDEN INAUGUR
<table>
<thead>
<tr>
<th>From:</th>
<th>Denise Hinton</th>
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<tr>
<td>To:</td>
<td>Stephen Hahn</td>
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<tr>
<td>Date:</td>
<td>Thu, 10 Dec 2020 07:16:00 -0500</td>
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</tbody>
</table>

Great job. #FDAStrong
From: Stephen Hahn
To: Denise Hinton
Date: Thu, 10 Dec 2020 07:18:20 -0500

Thank you
Thank you for taking time to give remarks - our officers greatly appreciate your leadership and support.
From: Stephen Hahn
To: Denise Hinton
Date: Tue, 15 Dec 2020 14:21:09 -0500

You are very welcome
Hi - it's signed - sending to OCET/CBER then off to the company - will let you know when receipt confirmed.
<table>
<thead>
<tr>
<th>From:</th>
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<tr>
<td>To:</td>
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<tr>
<td>Date:</td>
<td>Fri, 18 Dec 2020 19:11:38-0500</td>
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</table>

Excellent and thx
Thank you! Find time to enjoy your family this weekend.
You too
Thank you
You may have heard the Moderna news. I just got a call from our team.
We met after VRBPAC and we made the decision to move forward with the EUA. Teams working in shifts to get the needed work done. We told the sponsor and given them the ok to preposition vaccine at clinical sites now. Vaccine can be administered after EUA issued. Redfield and CDC notified and they are coordinating with OWS. We've also notified OWS of the decision to move forward.
We are issuing a proactive statement subject to comms clearance from HHS and WH
<table>
<thead>
<tr>
<th>From:</th>
<th>Alex M Azar</th>
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<tr>
<td>To:</td>
<td>Stephen Hahn</td>
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<tr>
<td>Date:</td>
<td>Thu, 10 Dec 2020 21:29:40 -0500</td>
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</tbody>
</table>

What do you think timing of announcement could look like?
We were hoping tonight or tomorrow AM
Oh my. That's wonderful!
From: Stephen Hahn
To: Alex M Azar
Date: Thu, 10 Dec 2020 21:31:29 -0500

... announcement about our intention to issue and prepositioning.
That way vaccine could be given when EUA is issued
Mr. Secretary, know you are busy and happy to talk. Increasingly confident about getting EUA out the door tonight. Wanted you to have situational awareness.
EUA going out between 8 and 9 this evening. Technical briefing for the press by us in the AM. WH aware. Thx
When will Ellume be announced. With VP now.
It's been announced
Do you want me to send you the link?
From: Stephen Hahn
To: Alex M Azar
Date: Tue, 15 Dec 2020 12:20:11 -0500

Perfect. Thank you.
From: Stephen Hahn
To: Alex M Azar
Date: Thu, 17 Dec 2020 20:13:14 -0500

I wanted to let you know that we have informed Moderna that we will rapidly work toward finalization and issuance of an emergency use authorization. Our teams are working to finalize the EUA now and we're on track for tomorrow. We have notified the CDC and OWS, so they can execute their plans.
From: Alex M Azar
To: Stephen Hahn
Date: Thu, 17 Dec 2020 20:14:25 -0500

Excellent news. Thank you. Any estimate on timing tomorrow?
We’re trying to shave off a couple of hours.
**From:** Stephen Hahn  
**To:** Alex M Azar  
**Date:** Fri, 18 Dec 2020 19:04:57 -0500

EUA being signed now. Will be public in the next 60 minutes
Moderna, of course
Thanks for letting me know. Congratulations.
From: Stephen Hahn
To: Alex M Azar
Date: Fri, 18 Dec 2020 19:31:20 -0500

Congratulations to you Sir
Now that you are through the regulatory decisions, think how you can appropriately be out there encouraging people to get vaccines.
Absolutely. Very important and I’ll talk to our media team
Sen. Steve Daines participates in Pfizer COVID-19 vaccine trial, tests positive for antibodies


Explore the Fox News apps that are right for you at http://www.foxnews.com/apps-products/index.html.
Really well done. Are you feeling ok?
Great interview! Thanks so much. Is there really a chance people could get shots before 12/14? What's your best guess for earliest vaccinations? Just for planning/scripting.
<table>
<thead>
<tr>
<th>From:</th>
<th>Stephen Hahn</th>
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<tr>
<td>To:</td>
<td>Josh Margolis</td>
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<tr>
<td>Date:</td>
<td>Thu, 03 Dec 2020 10:19:03 -0500</td>
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Yes there is real chance
That's deep background please
From: Josh Margolis  
To: Stephen Hahn  
Date: Mon, 07 Dec 2020 17:00:07 -0500  

Is this story accurate? No fingerprints.
I'm free whenever you can talk. Sorry about that.
Let me know if you can talk for 5 minutes today.
W/ the panel's decision, any updated sense of timing for EUA?
Good morning. What do you think, today, tomorrow? Just for planning.
This is crazy.

White House orders FDA chief to authorize Pfizer-BioNTech vaccine Friday or submit his resignation
I'm sure you're too busy to pay attention to TV at night. But our special aired last night and you were a big part of it. https://abc.com/shows/abc-news-specials/episode-guide/2020-12/14-the-shot-race-for-the-vaccine-a-special-edition-of-2020

We're also putting up some additional material online today or tomorrow focusing on you and FDA.

Can't thank you enough.
Thank you Josh. Glad we could get this done
Congratulations on getting through the last month. Don't know how you did it. After you take a nap, let's talk a little. I have some thoughts about taking a deep look.
Hello Dr Hahn — Sanjay here. I imagine everyone is emailing or texting you. Not sure if you saw my reporting, but I emphasized the role of the data scientists and described the complexities of raw data analysis. Would love to chat for a moment and here how things are going.
Hello—Sanjay here. Just wanted to make sure you had my text and phone number.
We’re talking tomorrow?
That was great! Covered a lot of ground. I know how busy you are, and always appreciate your time.
Hello Sir — Wonder if you can give me a quick confirmation on the EUA? Just yes or now?
Yes
Wanted to wish you congratulations. Big day. Hope you get to take a breath.
Thank you Sanjay. It was a big day and our teams did a great job.
Hope all is well! I can only imagine how busy you have been. As you may know, we are planning on creating a film around the pandemic. To give people a real idea of what happened over the last year, and what still needs to happen going forward. Confidentially speaking, doctors Fauci and Birx are already on board. We have several other people that have been involved with the response as well. I know our production team has contacted your office, but no definitive word back yet. Just wanted to encourage you to participate if you were inclined. I will be overseeing the interviews and production. We know each other, and I hope that gives you some inspiration to join us. I would love for you to be a part of it.
From: Gus Perna
To: Stephen Hahn
Date: Tue, 22 Dec 2020 09:13:02 -0500

Steve, thank you for your note.
From: [redacted] messages
To: [redacted] messages, Mark Meadows [redacted] messages, Ron Johnson [redacted] messages, Stephen Hahn [redacted] messages
Date: Thu, 28 Jan 2021 14:02:31 -0500

From: Stephen Hahn  
To: Keagan Lenihan  
Date: Sat, 16 May 2020 09:03:52 -0400

Alex. Can you find out what is happening at fda on the following

I'm sorry to bring this matter to your attention, but I thought it was worth your consideration based in

was awarded a FEMA contract in early May for the delivery of PPE masks from its FDA approved
manufacturing facilities in China. Per the rapid delivery contract began immediately importing millions of
the contracted masks from China to over the past two weeks. On May 7, the FDA issued a list called "Appendix A"
which comprises the FDA/US GOV approved importers of PPE from China has submitted all the required FDA
certifications to be placed on Appendix A for over two weeks now, but no response and still not on the Appendix A.

This morning, FEMA notified that it could not take delivery on the 6MM+ already imported masks until it sees the
name added to the Appendix A list. So a now has of approved masks that are sitting in a warehouse
awaiting delivery to the FEMA approved drop sites by May 31, 2020 is now in jeopardy of not
meeting the FEMA contract shipping deadline and as a small business has already fronted to meet this
order. If this doesn't get resolved - and FDA doesn't file the paperwork soon is going to be forced to sell all of
this PPE back to China to recoup these "fronted" expenses resulting from simply trying to fulfill the very FEMA contract
they were awarded (contract attached).

Any insight or suggestions would be much appreciated. Thanks.
From: Stephen Hahn
To: Keagan Lenihan
Date: Sun, 14 Jun 2020 21:18:18 -0400

Make sure there is a line on the press release about (b)(5)
Keep me up to date on when the CBER teleconference with the exosome company will occur today? It most occur today
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<thead>
<tr>
<th>From:</th>
<th>Stephen Hahn</th>
<th>To:</th>
<th>Keagan Lenihan</th>
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<tbody>
<tr>
<td>Date:</td>
<td>Mon, 15 Jun 2020 07:45:37 -0400</td>
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Must not most
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 15 Jun 2020 10:28:27 -0400

(b)(5)
I believe that is the plan.
Today and tomorrow
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 15 Jun 2020 10:30:38 -0400

I want to
Understood.
From: Keagan Lenihan
To: Stephen Hahn
Date: Mon, 15 Jun 2020 10:37:20 -0400

Do you want Janice to set up time?
From: Stephen Hahn
To: Keagan Lenihan
Date: Mon, 15 Jun 2020 10:38:37 -0400

I think Peter and I can call today after the touch base call with Peter primarily providing the update.
I heard you talking, but then Heidi from DPC called to discuss EUA rescission and missed the end. Sorry.
Understand why.
2020-06-16 14:45:56 UTC: (b)(6) Messages -> (b)(6) Messages

From: Stephen Hahn
To: Keagan Lenihan
Date: Tue, 16 Jun 2020 10:45:56 -0400

Agreed
From: Stephen Hahn
To: Keagan Lenihan
Date: Tue, 16 Jun 2020 10:46:33 -0400
Let's discuss the LDT issue
Can you make sure Peter is on the exosome call (4pm) and then have him call the Congressman? I've had multiple calls with the congressman over the last 3 days and he is in a good place.
He has the company’s permission to hear CCI
THX
The Congressman feels that the company has all of the data needed to answer the questions and Peter needs to be transparent about ongoing deficiencies that need to be addressed.
From: Keagan Lenihan
To: Stephen Hahn
Date: Tue, 16 Jun 2020 15:41:56 -0400

CMS wants a meeting about payment for COVID drugs. It is scheduled during Brooke/Fleming discussion tomorrow. Do AMA will be in CMS meeting and I believe Redfield as well.
2020-06-17 16:54:48 UTC: [messages] (b)(6)

From: Keagan Lenihan
To: Stephen Hahn
Date: Wed, 17 Jun 2020 12:54:48 -0400

Did you [messages] (b)(5) Stephanie wants to start working with their staff
About half. May I have a little more time?
2020-06-17 17:01:09 UTC: (b)(6) Messages -> (b)(6) Messages

From: Keagan Lenihan (b)(6) messages>
To: Stephen Hahn (b)(6) messages>
Date: Wed, 17 Jun 2020 13:01:09 -0400

Yes
Where are we with leaning in on the (b)(5)?
From: Keagan Lenihan
To: Stephen Hahn
Date: Thu, 18 Jun 2020 08:49:22 -0400

We got the right folks connected from CDC with JW and PM yesterday
Great
Hi Commissioner- Sen. Lankford would like to invite you to video tape a conversation w him that would appear on his podcast - the Breakdown- in September to discuss COVID vaccine development. If you're interested, I can run all the traps and report back.
Definitely
FYI- House Approps released a new covid supp today
Only includes an additional $1.5m for FDA to do vaccine advisory committees. After I review the whole thing will keep you posted of any other relevant items.
Thx
Thought the press conference went great! Reminder the Member call is at 12:00 today. We sent materials last night to Frank/Janice/Jakea.

Pls let us know if you need anything or would like to talk in advance.
From: Andrew Tantillo [messages]
To: Stephen Hahn [messages], Ann K. Abram [messages], Maren McBride [messages], Keagan Lenihan [messages]
Date: Sat, 12 Dec 2020 10:52:49 -0500

Chairman Pallone would still like for you to brief his Members so they have a chance to ask you questions; if he raises it today you can say...
Two other FYSAs:

HHS-ASL colleagues may join the call in listen-only mode.

Dr. Mark's will brief the staff of the Members on the call, along with the staff of every member of the E&C, HELP. and Appropriations Committees, Monday at 8:30am.
Thx.
House leaders expect to vote on the unreleased COVID-19 aid bill and $1.4 trillion omnibus spending package Sunday, according to an announcement from Hoyer's office.
I'll let
You know if we get text
2020-12-20 23:00:18 UTC: Messages -> [4 recipients]

From: Maren McBride (b)(6) messages>
To: Stephen Hahn (b)(6) messages>, Ann K. Abram (b)(6) messages>, Andrew Tantillo (b)(6) messages>, Keagan Lenihan (b)(6) messages>
Date: Sun, 20 Dec 2020 18:00:18 -0500

I am told a new CR and the Omni/COVID supp will post tonight before midnight
I'll keep you posted when I see it
Liked “I am told a new CR and the Omni/COVID supp will post tonight before midnight”
House voting on a CR through tomorrow at 6:30 and it supposed to be last votes of night so I'm guessing they won't vote on the supp/Omni till then
FYI- bill posted. 42M increase in boll
Bill
And 55M for COVID supp
House will vote tonight on the supp and OMNI
Great news.
From: Maren McBride
To: Stephen Hahn, Andrew Tantillo, Keagan Lenihan, Ann K. Abram
Date: Mon, 21 Dec 2020 21:24:13 -0500

House passed supp/omni
Supposed pass
Senate tonight
2020-12-22 02:45:54 UTC: (b)(6) Messages -> [4 recipients]

From: Stephen Hahn
To: Ann K. Abram, Andrew Tantillo, Maren McBride, Keagan Lenihan
Date: Mon, 21 Dec 2020 21:45:54 -0500

Liked “Supposed pass Senate tonight”
From: Maren McBride
To: Stephen Hahn, Ann K. Abram, Andrew Tantillo, Keagan Lenihan
Date: Mon, 21 Dec 2020 22:54:36 -0500

House and Senate both passed week long CR tonight and senate should pass Omni/ supp in a bit
In good shape!
Thx, Maren.
Senate just passed the Omni and supp
Great news
So no shutdowns and fully funded agency as soon as pres signs!
<table>
<thead>
<tr>
<th>From</th>
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<tr>
<td>Date</td>
<td>Mon, 21 Dec 2020 23:48:08 -0500</td>
<td>(b)(6) messages*</td>
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Wonderful. Thank you, Maren!
Maren, thanks to you and our OCA team for the great work on this front!
Agreed! Appreciate all the hard work.
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</table>

Maren
So terrific. Thank you
Liked Maren, thanks to you and our OCA team for the great work on this front! 💜
2020-12-22 14:25:40 UTC: [(b)(6)] Messages -> [4 recipients]

From: Maren McBride
To: Stephen Hahn, Ann K. Abram, Andrew Tantillo, Keagan Lenihan
Date: Tue, 22 Dec 2020 09:25:40 -0500

Liked “Agreed! Appreciate all the hard work.”
2020-12-22 14:25:51 UTC: Messages -> [4 recipients]

From: Maren McBride
To: Stephen Hahn, Ann K. Abram, Andrew Tantillo, Keagan Lenihan
Date: Tue, 22 Dec 2020 09:25:51 -0500

Liked “Maren
So terrific. Thank you ”
Thanks all!
The president signed the Omni and COVID supp in case you didn't see
Thx
2020-12-28 01:56:40 UTC: Messages -> [4 recipients]

From: Stephen Hahn
To: Ann K. Abram, Andrew Tantillo, Maren McBride, Keagan Lenihan
Date: Sun, 27 Dec 2020 20:56:40 -0500

Liked “The president signed the Omni and COVID supp in case you didn't see”