

From: [Jefferson Erica](#)
To: [Woodcock Janet](#)
Cc: [Tierney Julia](#); [Safford Melissa](#); [Rebello Heidi](#); [Mulieri Chris](#); [Kimberly Brad](#); [Walsh Sandy](#); [Felberbaum Michael](#)
Subject: RE: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral
Date: Monday, August 23, 2021 3:29:22 PM
Attachments: [image002.png](#)
[image008.png](#)

Hi Dr. Woodcock,

I just wanted to update you on some cool stats Brad just shared from the tweet today. Since we are a data driven agency, I thought you'd appreciate seeing some visuals on the numbers.

- Currently, it's the most popular post we've ever had on Twitter. There is a caveat with this statement given that today's vaccine approval is on its heels.
- All said, it looks like we gained a total of 11K followers across the accounts we posted these on. That's up **636.7%** from the two days prior. That growth is 17.6K overall, including today's vaccine approval social posts.

All in all, we're pleased with the response and the results here. It was also a perfect lead-in to today's vaccine approval, meaning we reached thousands more than we might have had we not picked up some additional followers that were drawn in by the tweet.

Please let us know if you have any follow up questions.
 Erica

Profile	Audience	Net Audience Growth	Published Posts	Impressions	Engagements	Engagement Rate (per Impression)
Reporting Period Aug 21, 2021 – Aug 22, 2021	1,681,379 ↑ 0.7%	10,881 ↑ 636.7%	6 ↓ 71.4%	16,099,564 ↑ 2,076.7%	565,755 ↑ 4,996.9%	3.5% ↑ 134.2%
Compare to Aug 19, 2021 – Aug 20, 2021	1,670,404	1,477	21	739,636	11,100	1.5%
U.S. Food and Drug Ad...	723,928	1,277	1	605,492	49,831	8.2%
@US_FDA	466,953	5,747	3	15,104,509	496,175	3.3%
FDA	465,781	280	1	55,835	2,670	4.8%
fda	24,717	3,577	1	333,728	17,079	5.1%

ANALYTICS

Twitter:



Impressions	23,745,920
Media views	35,707
Total engagements	920,460
Detail expands	579,553
Link clicks	103,494
Likes	89,081
Retweets	54,325
Profile clicks	48,246
Media engagements	35,707
Replies	9,828
Follows	226

Facebook:

U.S. Food and Drug Administration • Favorites • 2d

You are not a horse. You are not a cow. Seriously, y'all. Stop it. — 1 sharing a COVID-19 Update.

Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

Performance for Your Post

338,223 People Reached		
20,349 Reactions, Comments & Shares		
7,725 Like	1,564 On Post	6,161 On Shares
365 Love	108 On Post	257 On Shares
2,189 Haha	616 On Post	1,573 On Shares
456 Wow	38 On Post	418 On Shares
129 Sad	11 On Post	118 On Shares
74 Angry	23 On Post	51 On Shares
5,970 Comments	974 On Post	4,996 On Shares
3,492 Shares	3,492 On Post	0 On Shares
27,906 Post Clicks		
0 Photo Views	7,785 Link Clicks	20,121 Other Clicks

NEGATIVE FEEDBACK

67 Hide Post 17 Hide All Posts
 0 Report as Spam 0 Unlike Page

338,223 People Reached **48,255** Engagements **Boost Post**

2.2K 367 Comments 3,492 Shares

Love Comment Share

LinkedIn:

FDA 466,209 followers • 2d

You are not a horse. You are not a cow. Seriously, y'all. Stop it.

Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

fda.gov • 3 min read

381 • 49 comments

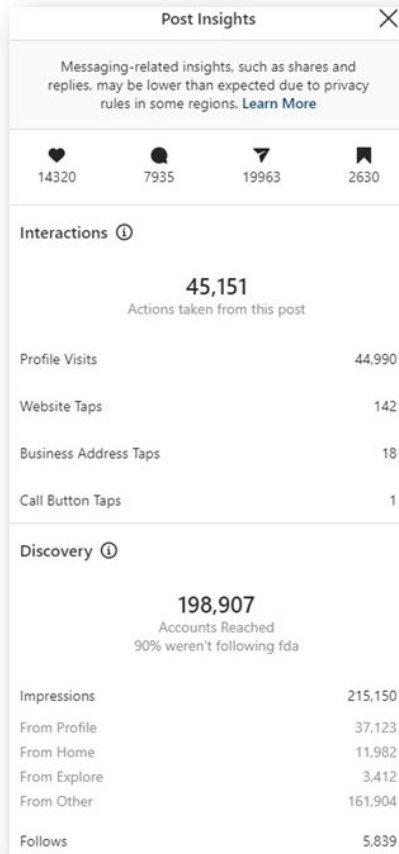
Like Comment

Organic impressions: 45,613 Impressions Hide stats

Organic stats Targeted to: All followers

45,613 Impressions	381 Reactions	5.34% Click-through rate
49 Comments	53 Shares	2,438 Clicks
6.4% Engagement rate		

Instagram:



From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:15 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: RE: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

That was great! Even I saw it! Agree, we need to be creative and accessible! Excellent start! jw

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Sunday, August 22, 2021 11:35 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

Hi Dr. Woodcock,

I hope you are having a great weekend. I know we are all eager for tomorrow.

Separately and as you know, the OEA team and I have been meeting over the past several weeks to discuss ways in which we can more effectively use our social media platforms to share important public health information with consumers. I'm sure you saw some of the news coming out of Mississippi on Friday regarding the use of ivermectin to treat / prevent Covid-19 and the increase in adverse events (poisonings) the state highlighted as a result of its use. I expressed to the team late Friday night that we take the opportunity to remind the public of our own warnings for ivermectin and by early Saturday morning the social media team had posted the following tweet:



Needless to say, the direct, straight-forward and clever (humorous) communication, paired with a follow-on tweet that provided additional answers to common questions about ivermectin, saw the tweet quickly going viral and being shared across multiple social medium platforms (where it was amplified by other influencers) and resulted in additional news coverage by: [NYT](#), [CNN](#), [NBC News](#) and [Rolling Stone](#) to name a few. Notably, the official Today Show Instagram account (3 million followers) also featured an original post on the account. We also took the opportunity to highlight a Consumer Update on ivermectin, that was prepared and distributed earlier this year. I'm pleased to report that as a result of the tweet, the update was accessed 177k times yesterday alone.

By comparison, the tweet currently ranks as our 2nd most popular tweet of all time in terms of the number of people we've reached with the content:

J&J Pause tweet - 20.4M

Not a Horse tweet - 14.5M

Immunocompromised EUA FB - 10.8M

J&J Pause tweet inside original thread - 6.8M

Pfizer4Kidz tweet - 4.5M

As you know, I am committed to identifying unique (for FDA) ways for us to reach the "everyday" American to "brand" FDA. I am grateful the OEA team is enthusiastically supportive of this goal and in particular, I want to recognize Brad, Chris and Sandy, for mobilizing quickly Friday night and Saturday morning to create a unique viral moment at such a critical time for the FDA's image and in our fight against Covid-19. While we won't *always* be able to take this approach (we are still a government entity), we will seek to develop content that allows the agency to feel both accessible and informative in a time of incredible misinformation. We will be meeting with OCC soon to discuss our new recommended approach for social media engagement. We look forward to sharing more about these efforts in the weeks ahead, including an ambition effort to counter much of the vaccine information out there as we prepare to approve Comiraty.

Please let me know if you have any questions in the interim. Thanks for your support on our efforts to evolve FDA's communications with consumers.

Best,
Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov



Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

From: [Jefferson_Erica](#)
To: [Kimberly_Brad](#)
Cc: [Walsh_Sandy](#); [Mulieri_Chris](#); [FDASocialMedia](#); [Felberbaum_Michael](#); [Rebello_Heidi](#); [Hettlage_Daniel](#)
Subject: Re: Well done!
Date: Saturday, August 21, 2021 4:50:33 PM

4:43



Instagram



todayshow



Liked by [kmkhour](#) and **others**

todayshow The FDA is warning people not to take veterinary drugs to treat COVID-19. The federal agency tweeted on Saturday, "You are not a horse. You are not a cow. Seriously, y'all. Stop it." Link in bio for more.

[View all 75 comments](#)



Add a comment...



From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Saturday, August 21, 2021 2:17 PM

To: Jefferson, Erica

Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel

Subject: Re: Well done!

Ha. A couple others using our social words prominently. Not sure how I feel about mediaite categorizing the story as “weird.”

<https://www.mediaite.com/weird/you-are-not-a-horse-fdas-response-to-vaccine-skeptics-taking-livestock-dewormer-as-covid-treatment-goes-viral/>

<https://www.rollingstone.com/politics/politics-news/fda-horse-dewormer-covid-fox-news-1215168/>

<https://www.nbcnews.com/news/us-news/stop-it-fda-warns-people-not-take-veterinary-drugs-treat-n1277371>

<https://www.ctvnews.ca/health/coronavirus/you-are-not-a-cow-fda-begs-americans-to-stop-taking-drug-meant-for-livestock-as-covid-19-remedy-1.5556324>

<https://www.facebook.com/5550296508/posts/10162231881976509/?d=n> (CNN)

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>

Sent: Saturday, August 21, 2021 3:49:39 PM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>

Subject: Re: Well done!

NYT covered:

<https://www.nytimes.com/2021/08/21/world/ivermectin-fda-covid-19-treatment.html>

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Saturday, August 21, 2021 1:09 PM

To: Jefferson, Erica

Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel

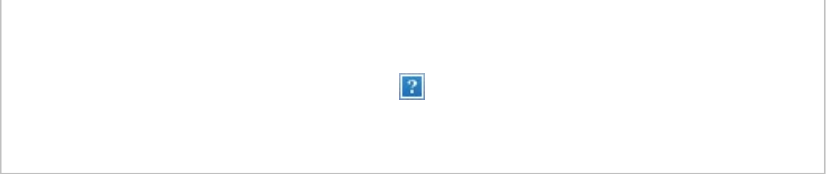
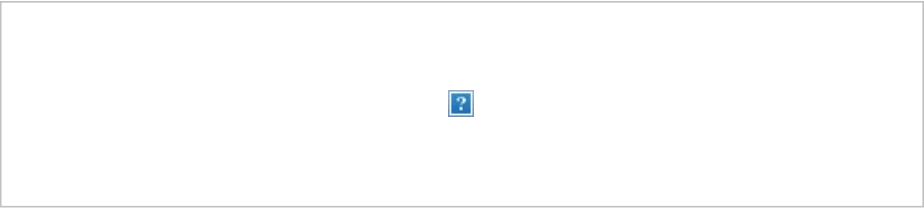
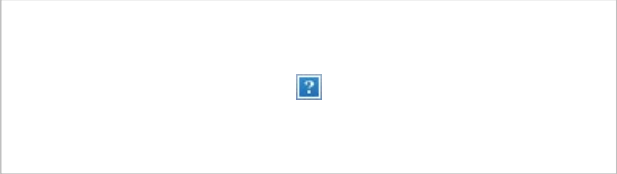
Subject: RE: Well done!

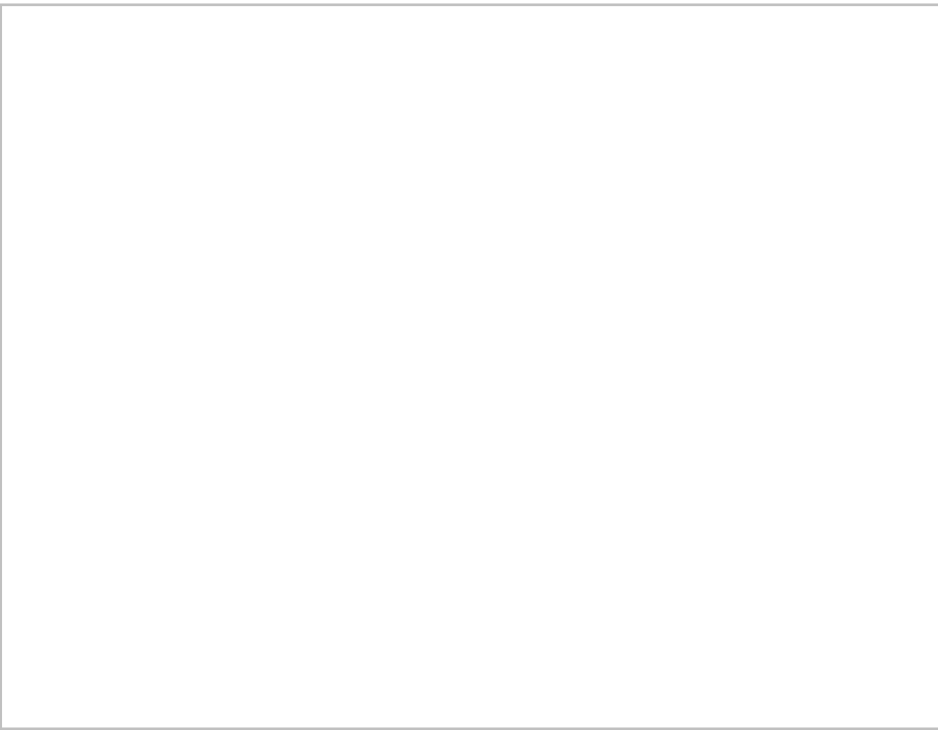
Erica, here's a little bit of info about our posts today.

Far exceeding our baseline average of impressions and engagement across the board. (Cicada-level impressions) Retweeted by huge verified social media influencers and at least one former FDA Commissioner.

Also, if you want to see what people think of our team for doing this: [that's here](#).

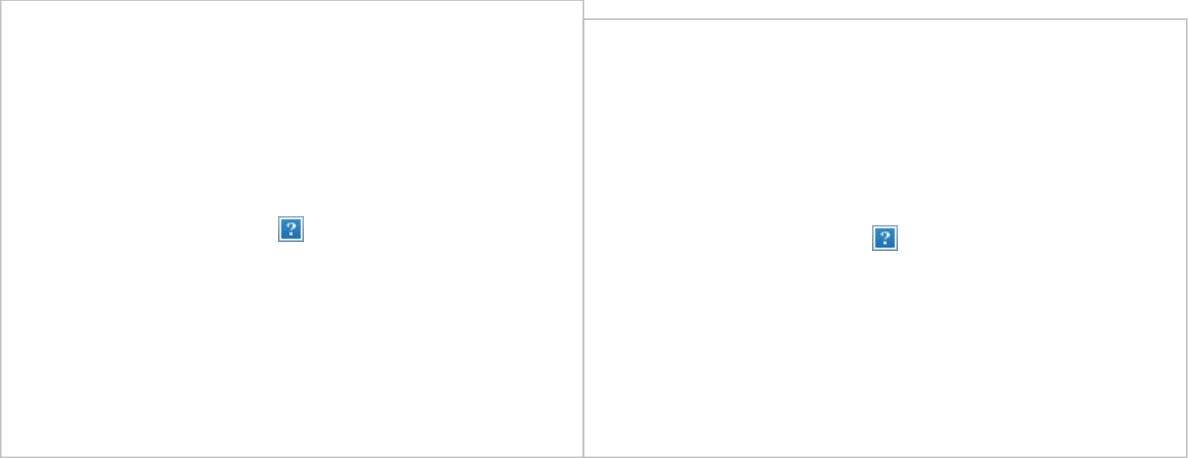
Data below, but first, some of my favorite comments from people:



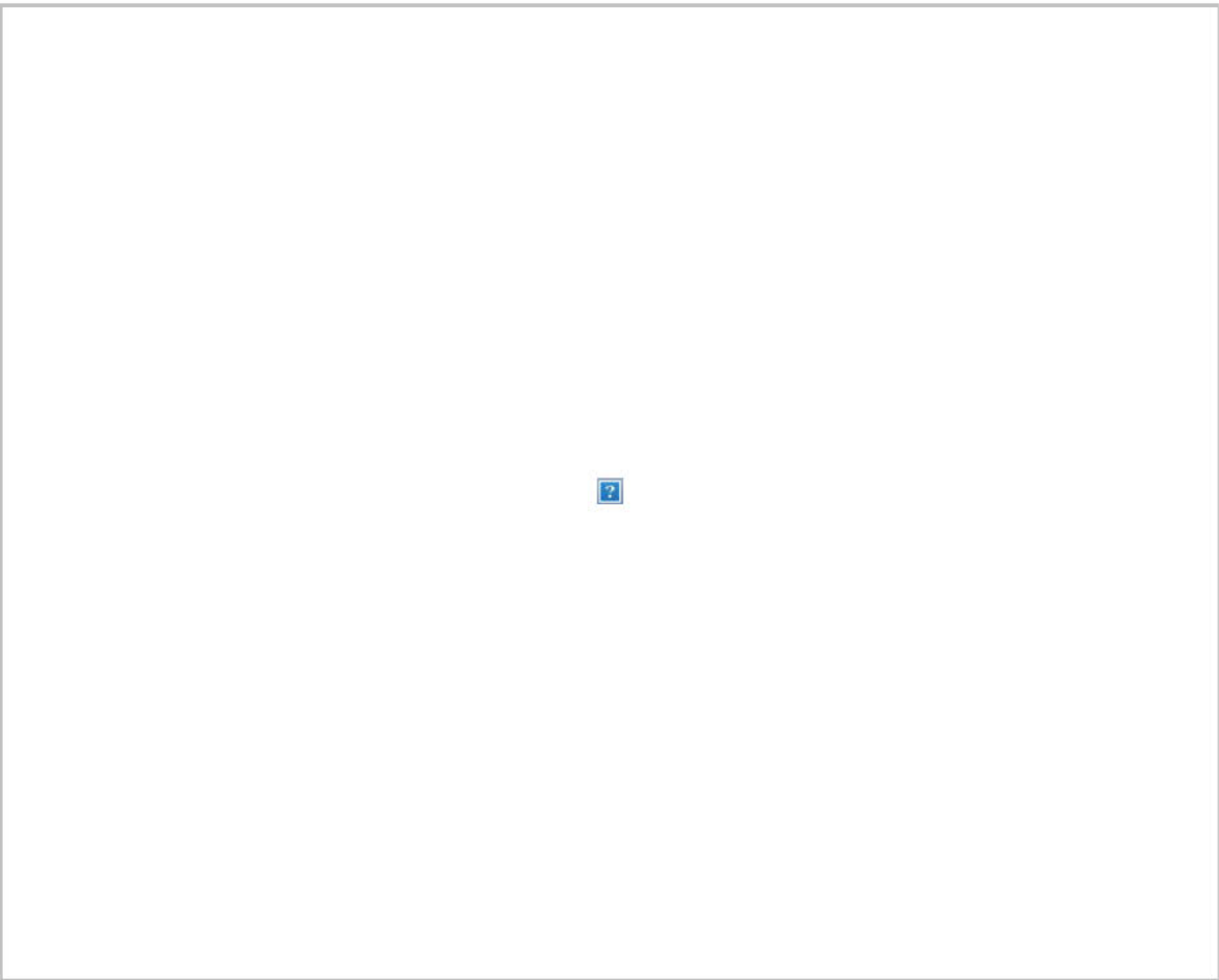


ANALYTICS

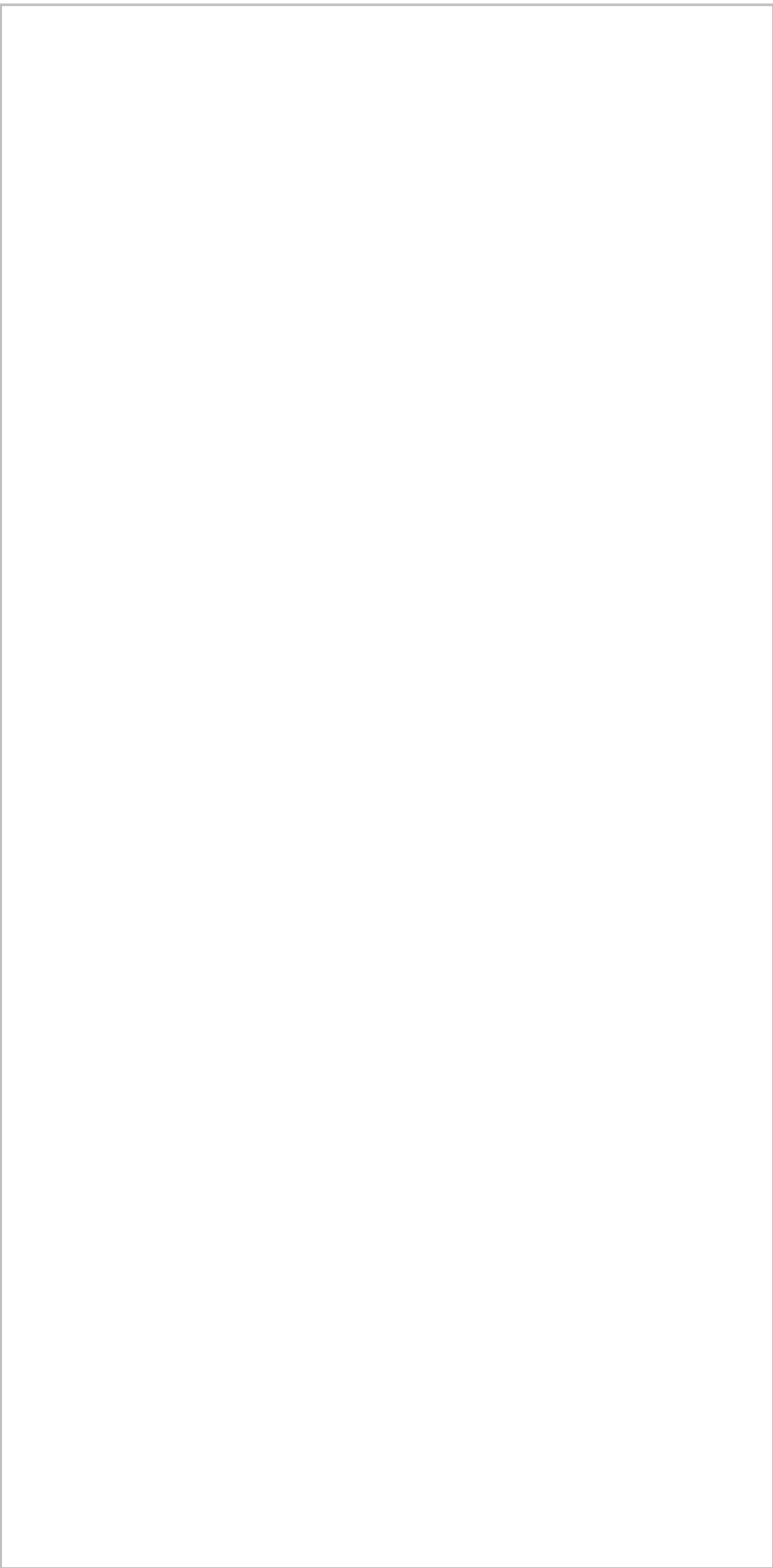
Twitter:



Facebook:



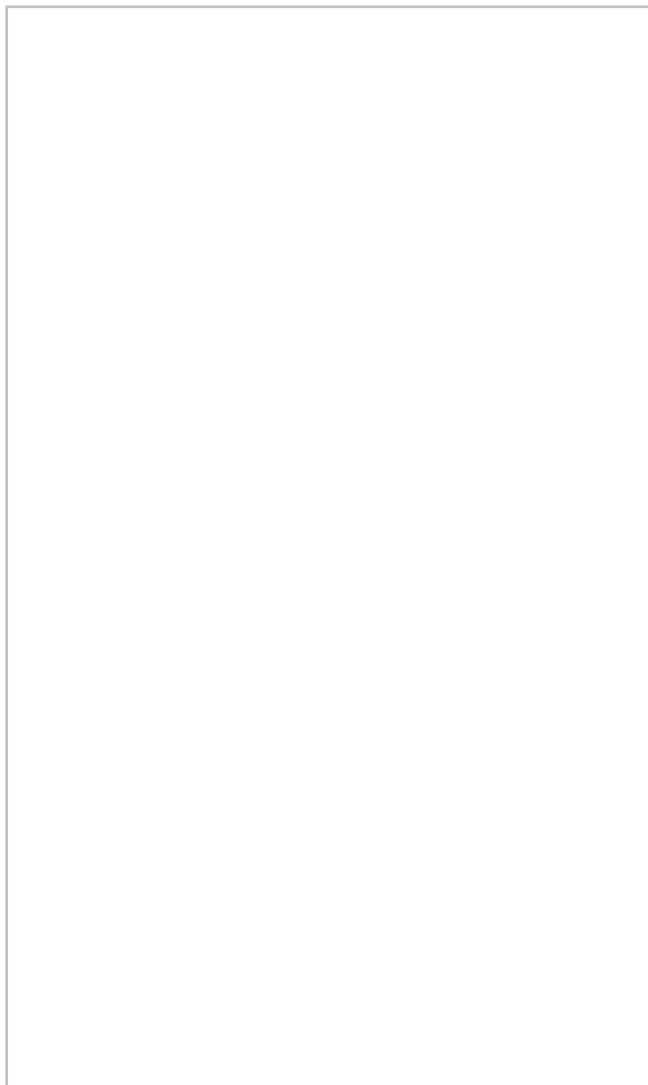
LinkedIn:



Instagram:

A screenshot of a horse Description automatically generated





Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 10:44:52 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Well done!

The numbers are racking up and I laughed out loud.

Thanks for turning the post around. CNN also tweeted a warning as well.

Erica

From: [Kimberly, Brad](#)
To: [Jefferson, Erica](#); [Mulleri, Chris](#); [Tierney, Julia](#); [Felberbaum, Michael](#)
Cc: [Walsh, Sandy](#); [FDASocialMedia](#); [Rebello, Heidi](#); [Hetlage, Daniel](#)
Subject: Re: Well done!
Date: Sunday, August 22, 2021 11:04:21 AM
Attachments: [image002.png](#)
[image003.png](#)

That number undersells it in the screenshot, but there was a significant gain yesterday More on that tomorrow once I get a solid data pull

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Sunday, August 22, 2021 10:48:01 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Mulleri, Chris <Charles.Mulleri@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Thanks, Brad It also looks like we've picked up some new followers Are those numbers compelling for Twitter and IG?

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:40 AM
To: Mulleri, Chris <Charles.Mulleri@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

And for the tweet... as of right now Believe it's our second most popular tweet of all time

 Verizon LTE 

9:38 AM

100% 



Tweet activity

Impressions

14,523,592

times people saw this Tweet on Twitter

Media views

18,129

all views (autoplay and click) of your media are counted across videos, vines, gifs, and images

Total engagements

557,499

times people interacted with this Tweet

Detail expands

334,802

times people viewed the details about this Tweet

Link clicks

65,736

clicks on a URL or Card in this Tweet

Likes	61,730
times people liked this Tweet	
Retweets	38,509
times people retweeted this Tweet	
Profile clicks	31,639
number of clicks on your name, @handle, or profile photo	
Media engagements	18,129
number of clicks on your media counted across videos, vines, gifs, and images	
Replies	6,808
replies to this Tweet	
Follows	146

Brad Kimberly
 Director, Social Media
 Office of External Affairs

From: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:37:13 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Final Consumer Update pageviews for yesterday only: over 177,000

Chris

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:27 AM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Team – this is OUTSTANDING work. So creative and, most importantly, gets FDA's public health message out to the universe. I can't wait to see what else you all have in the works!

Best,
 Julie

Julia C. Tierney, JD (she/her)
 Acting Chief of Staff

U.S. Food and Drug Administration
 (301) 796-8602 (office) (forwarded)
 (240) 907-9331 (cell)
Julia.Tierney@fda.hhs.gov



From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 6:32 PM
To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

Very impressive! Thanks Chris!

From: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Sent: Saturday, August 21, 2021 4:19 PM
To: Kimberly, Brad; Felberbaum, Michael; Jefferson, Erica
Cc: Walsh, Sandy; FDASocialMedia; Rebello, Heidi; Hetlage, Daniel
Subject: RE: Well done!

Google analytics shows over 80,000 pageviews to the CU for today! I will have the final daily total tomorrow morning 30% of today's pageviews came from Twitter 52% of the pageviews came directly from Google

For yesterday and today, the total pageviews for the CU are over 162,000 and counting

Chris

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 6:02 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

JJ Pause tweet - 20 4M
Immunocompromised EUA FB - 10 8M
JJ Pause tweet inside original thread - 6 8M
Not a Horse tweet - 5M
Pfizer4Kidz tweet - 4 5M

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Saturday, August 21, 2021 5:57:38 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

Anything we've put out that compares?

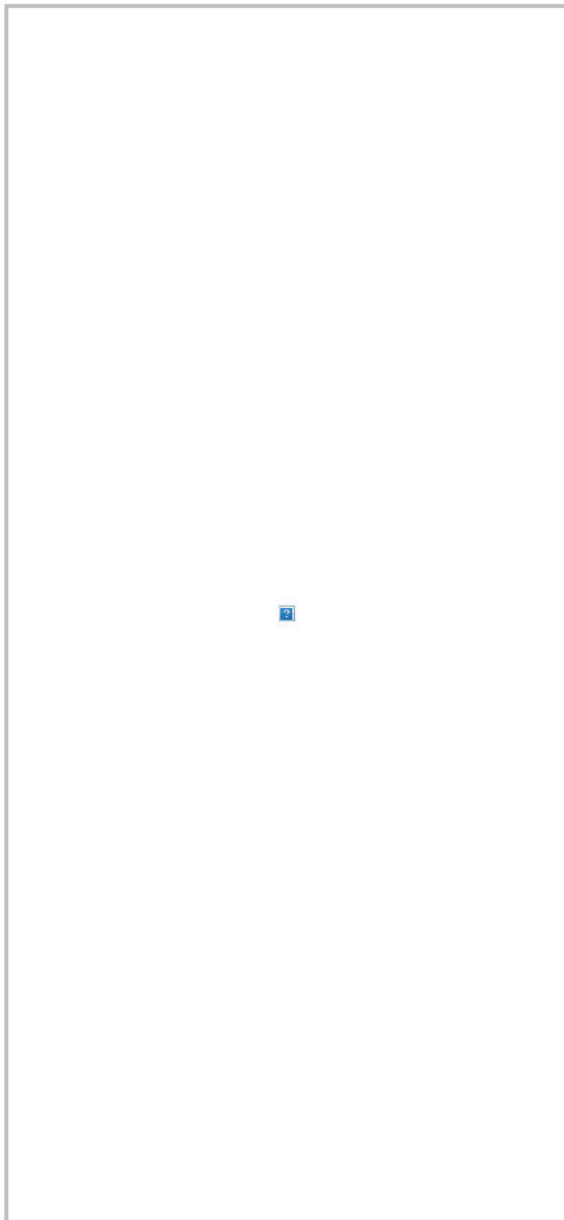
Michael Felberbaum
Assistant Commissioner for Media Affairs (Acting)
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [240-402-9548](tel:240-402-9548) / Cell: [202-906-0229](tel:202-906-0229)
michael.felberbaum@fda.hhs.gov

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 5:56:23 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

So, Twitter impressions at 5M+ at this point Should have mostly final numbers on Monday But you get the idea It went pretty well

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 4:50:30 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!



From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 2:17 PM
To: Jefferson, Erica
Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel
Subject: Re: Well done!

Ha A couple others using our social words prominently Not sure how I feel about mediaite categorizing the story as "weird "

<https://www.mediaite.com/weird/you-are-not-a-horse-fdas-response-to-vaccine-skeptics-taking-livestock-dewormer-as-covid-treatment-goes-viral/>

<https://www.rollingstone.com/politics/politics-news/fda-horse-dewormer-covid-fox-news-1215168/>

<https://www.nbcnews.com/news/us-news/stop-it-fda-warns-people-not-take-veterinary-drugs-treat-n1277371>

<https://www.ctvnews.ca/health/coronavirus/you-are-not-a-cow-fda-begs-americans-to-stop-taking-drug-meant-for-livestock-as-covid-19-remedy-1.5556324>

<https://www.facebook.com/5550296508/posts/10162231881976509/?d=cn> (CNN)

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 3:49:39 PM

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Subject: Re: Well done!

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<https://www.nytimes.com/2021/08/21/world/ivermectin-fda-covid-19-treatment.html>

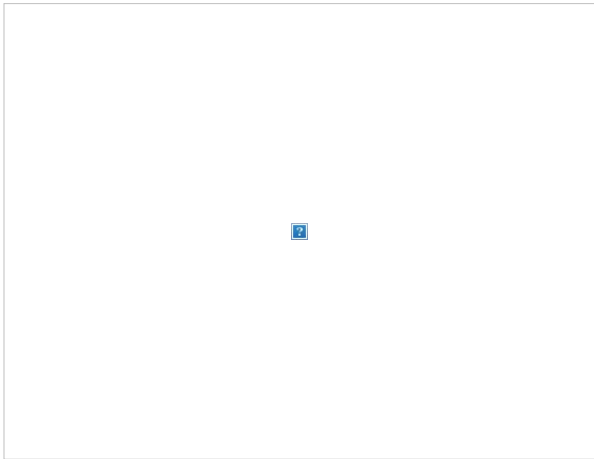
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Also, if you want to see what people think of our team for doing this: [that s here](#)

Data below, but first, some of my favorite comments from people:

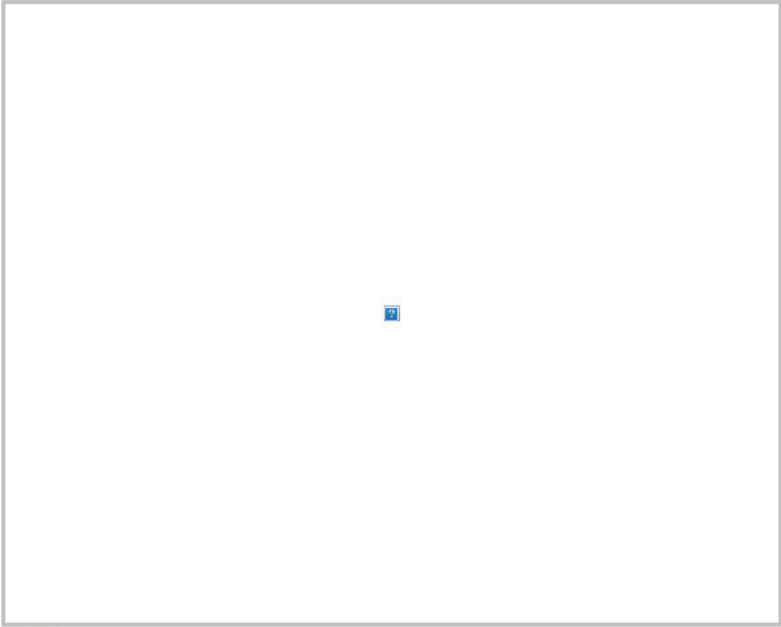


ANALYTICS

Twitter:



Facebook:



LinkedIn:



Instagram:

A screenshot of a horse Description automatically generated



Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | Cell 240-750-9302

brad.kimberly@fda.hhs.gov



From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 10:44 52 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Well done!

The numbers are racking up and I laughed out loud

Thanks for turning the post around CNN also tweeted a warning as well

Erica

From: [Staton, Anna](#)
To: [Walsh, Sandy](#)
Subject: Re: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral
Date: Sunday, August 22, 2021 7:36:35 PM
Attachments: [image004.png](#)

Thanks for sharing! I saw the Tweet and was super impressed. Glad we have data now to backup the direct approach.

Get [Outlook for iOS](#)

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Sunday, August 22, 2021 11:59:39 AM
To: Staton, Anna <Anna.Staton@fda.hhs.gov>
Subject: Fwd: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

FYI we ended up needing to promote the ivermectin CU over the weekend due to some news about its use. Brads edgy Tweet was a hit.

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Sunday, August 22, 2021 11:35:06 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

Hi Dr. Woodcock,

I hope you are having a great weekend. I know we are all eager for tomorrow.

Separately and as you know, the OEA team and I have been meeting over the past several weeks to discuss ways in which we can more effectively use our social media platforms to share important public health information with consumers. I'm sure you saw some of the news coming out of Mississippi on Friday regarding the use of ivermectin to treat / prevent Covid-19 and the increase in adverse events (poisonings) the state highlighted as a result of its use. I expressed to the team late Friday night that we take the opportunity to remind the public of our own warnings for ivermectin and by early Saturday morning the social media team had posted the following tweet:



Needless to say, the direct, straight-forward and clever (humorous) communication, paired with a follow-on tweet that provided additional answers to common questions about ivermectin, saw the tweet quickly going viral and being shared across multiple social medium platforms (where it was amplified by other influencers) and resulted in additional news coverage by: [NYT](#), [CNN](#), [NBC News](#) and [Rolling Stone](#) to name a few. Notably, the official Today Show Instagram account (3 million followers) also featured an original post on the account. We also took the opportunity to highlight a Consumer Update on ivermectin, that was prepared and distributed earlier this year. I'm pleased to report that as a result of the tweet, the update was accessed 177k times yesterday alone.

By comparison, the tweet currently ranks as our 2nd most popular tweet of all time in terms of the number of people we've reached with the content:

J&J Pause tweet - 20.4M

Not a Horse tweet – 14.5M

Immunocompromised EUA FB - 10.8M

J&J Pause tweet inside original thread - 6.8M

Pfizer4Kidz tweet - 4.5M

As you know, I am committed to identifying unique (for FDA) ways for us to reach the “everyday” American to “brand” FDA. I am grateful the OEA team is enthusiastically supportive of this goal and in particular, I want to recognize Brad, Chris and Sandy, for mobilizing quickly Friday night and Saturday morning to create a unique viral moment at such a critical time for the FDA's image and in our fight against Covid-19. While we won't *always* be able to take this approach (we are still a government entity), we will seek to develop content that allows the agency to feel both accessible and informative in a time of incredible misinformation. We will be meeting with OCC soon to discuss our new recommended approach for social media engagement. We look forward to sharing more about these efforts in the weeks ahead, including an ambition effort to counter much of the vaccine information out there as we prepare to approve Comiraty.

Please let me know if you have any questions in the interim. Thanks for your support on our efforts to evolve FDA's communications with consumers.

Best,
Erica

Erica V. Jefferson (she/her)

Associate Commissioner for External Affairs

U.S. Food and Drug Administration

Tel: 240-702-3994

erica.jefferson@fda.hhs.gov



Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

From: [Walsh, Sandy](#)
To: [Staton, Anna](#)
Subject: Fwd: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral
Date: Monday, August 23, 2021 8:22:46 AM

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:17 PM
To: Kimberly, Brad; Mulieri, Chris; Walsh, Sandy; Felberbaum, Michael
Cc: Tierney, Julia
Subject: Fwd: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

☺

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 11:15 AM
To: Jefferson, Erica
Subject: RE: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

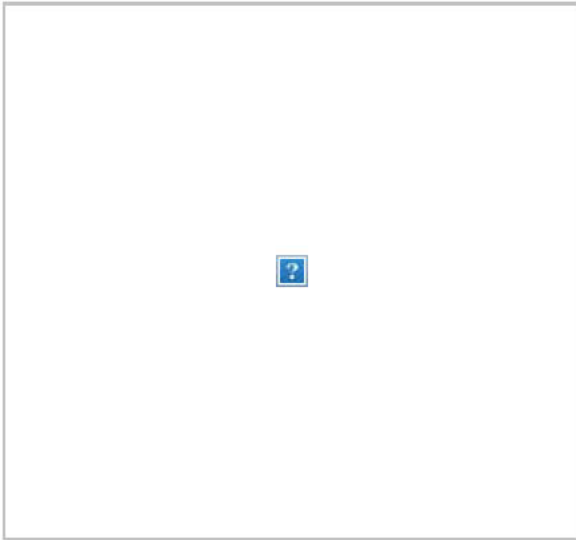
That was great! Even I saw it! Agree, we need to be creative and accessible! Excellent start! jw

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Sunday, August 22, 2021 11:35 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
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to evolve FDA's communications with consumers.

Best,
Erica

Erica V. Jefferson (she/her)

Associate Commissioner for External Affairs

U.S. Food and Drug Administration

Tel: 240-702-3994

erica.jefferson@fda.hhs.gov



Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

Kimberly, Brad

From: Kimberly, Brad
Sent: Monday, August 23, 2021 5:09 PM
To: Thomas, Jacqueline
Subject: RE: Spotlight at all hands on viral tweet

Categories: FOIA

Is the deck 4x3 or 16x9?

Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:07 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Saunders, Shelisha <Shelisha.Saunders@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: Spotlight at all hands on viral tweet

Perfect!

Thank you,
Jacque

Jacqueline Thomas

Executive Assistant to the OEA Associate Commissioner

Operations Staff
Office of External Affairs
U.S. Food and Drug Administration
Work Mobile: (240) 475-7031
Email: Jacqueline.Thomas@fda.hhs.gov



From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:06 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>; Saunders, Shelisha <Shelisha.Saunders@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: Spotlight at all hands on viral tweet

Excellent, thanks!

Jacque – I've added a couple placeholder slides for Brad in the deck.

Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov



Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Monday, August 23, 2021 4:49 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>; Saunders, Shelisha <Shelisha.Saunders@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: Spotlight at all hands on viral tweet

Sure thing. I'll have something to her by then. Thanks for asking me to participate.

Brad Kimberly
Director, Social Media
Web & Digital Services
Office of External Affairs
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Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



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Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Thomas, Jacqueline <Jacqueline.Thomas@fda.hhs.gov>; Saunders, Shelisha <Shelisha.Saunders@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: Spotlight at all hands on viral tweet

Hi Brad,

Would you be interested in presenting a couple slides on the viral tweet and key stats at our all hands on Wednesday morning? It would essentially be the information you've been providing in email for me to share with Dr. W.

I'd like the broader team to have the background/context and see the results.

Let us know. Jacque is working to finalize the presentation by midday tomorrow.

Thanks,
Erica

Erica V. Jefferson (she/her)

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U.S. Food and Drug Administration

Tel: 240-702-3994

erica.jefferson@fda.hhs.gov



Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

Kimberly, Brad

From: Jefferson, Erica
Sent: Monday, August 23, 2021 2:56 PM
To: Kimberly, Brad
Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel
Subject: RE: Well done!

Categories: FOIA

This is great, thanks Brad!

Erica

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Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:44 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Erica, just really quick, I wanted to update you on the Saturday post.

As of right now, it's the most popular post we've ever had on Twitter. I say "right now" because the vax approval is on its heels... much like a horse race.

All said, it looks like we gained about 11K followers across the accounts we posted these on. That's up 636.7% from the two days prior. That growth is 17.6K if you count today with the vaccine approval.





I'd also like to flag the engagement rate, which is much higher across the board... especially when you consider the impressions numbers being so high. Typically, the higher that number, the lower the rate. If we exceed 1% engagement on a post, we're pretty content.

Okay, please let me know if you have any questions.

Brad

Profiles

Review your aggregate profile and page metrics from the reporting period.

Profile	Audience	Net Audience Growth	Published Posts	Impressions	Engagemen
Reporting Period Aug 21, 2021 – Aug 22, 2021	1,681,379 ↗ 0.7%	10,881 ↗ 636.7%	6 ↘ 71.4%	16,099,564 ↗ 2,076.7%	565,75 ↗ 4,996.9
Compare to Aug 19, 2021 – Aug 20, 2021	1,670,404	1,477	21	739,636	11,10
 U.S. Food and Drug Ad...	723,928	1,277	1	605,492	49,83
 @US_FDA	466,953	5,747	3	15,104,509	496,17
 FDA	465,781	280	1	55,835	2,67
 fda	24,717	3,577	1	333,728	17,07

ANALYTICS

Twitter:



Impressions	23,745,920
Media views	35,707
Total engagements	920,460
Detail expands	579,553
Link clicks	103,494
Likes	89,081
Retweets	54,325
Profile clicks	48,246
Media engagements	35,707
Replies	9,828
Follows	226

Facebook:

FDA U.S. Food and Drug Administration

Favorites · 2d ·

You are not a horse. You are not a cow. Seriously, y'all. Stop it. — sharing a COVID-19 Update.

FDA.GOV

Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

338,223 People Reached 48,255 Engagements [Boost Post](#)

2.2K 367 Comments 3,492 Shares

[Love](#) [Comment](#) [Share](#) [FDA](#)

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7,725 Like	1,564 On Post	6,161 On Shares
365 Love	108 On Post	257 On Shares
2,189 Haha	616 On Post	1,573 On Shares
456 Wow	38 On Post	418 On Shares
129 Sad	11 On Post	118 On Shares
74 Angry	23 On Post	51 On Shares
5,970 Comments	974 On Post	4,996 On Shares
3,492 Shares	3,492 On Post	0 On Shares

27,906 Post Clicks

0 Photo Views	7,785 Link Clicks	20,121 Other Clicks
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NEGATIVE FEEDBACK

57 Hide Post	17 Hide All Posts
0 Report as Spam	0 Unlike Page

LinkedIn:



FDA
466,209 followers
2d • 🌐

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Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

fda.gov • 3 min read

👍❤️🗨️ 381 • 49 comments

👍 Like 🗨️ Comment

Organic impressions: 45,613 Impressions Hide stats ^

Organic stats ⓘ
Targeted to: All followers

45,613 Impressions	381 Reactions	5.34% Click-through rate
49 Comments	53 Shares	2,438 Clicks
6.4% Engagement rate		

Instagram:



FDA
Posts



[View Insights](#)

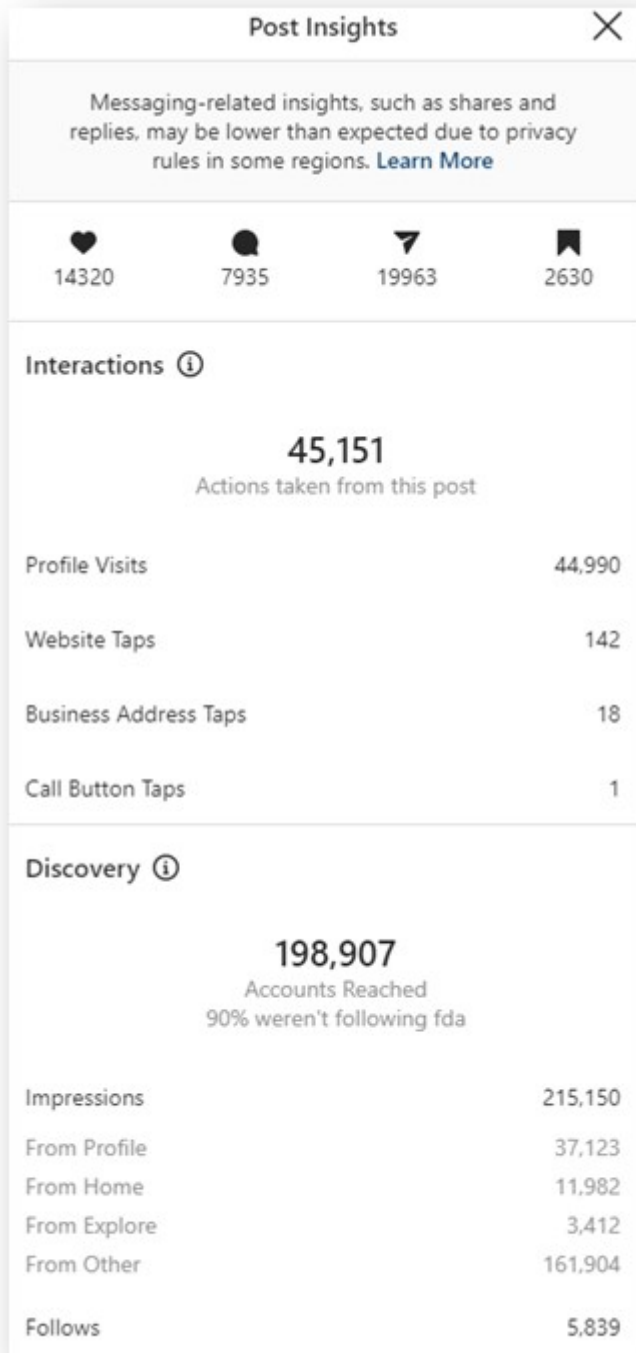
[Promote](#)



602 likes

fda You are not a horse.
Stop it with the #Ivermectin.
It's not authorized for treating #COVID.





Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-1002 | Cell: 240-750-9302

brad.kimberly@fda.hhs.gov





From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>

Sent: Saturday, August 21, 2021 10:44:52 AM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>

Subject: Well done!

The numbers are racking up and I laughed out loud. 😂

Thanks for turning the post around. CNN also tweeted a warning as well.

Erica

Kimberly, Brad

From: Mulieri, Chris
Sent: Monday, August 23, 2021 2:52 PM
To: Kimberly, Brad; Braithwaite, Sonia
Subject: RE: Well done!

Categories: FOIA

Thanks.

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:49 PM
To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Braithwaite, Sonia <Sonia.Braithwaite@fda.hhs.gov>
Subject: FW: Well done!

Chris/Sonia, I still owed Erica that data below... but for your blurb...

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FDA Posts



View Insights

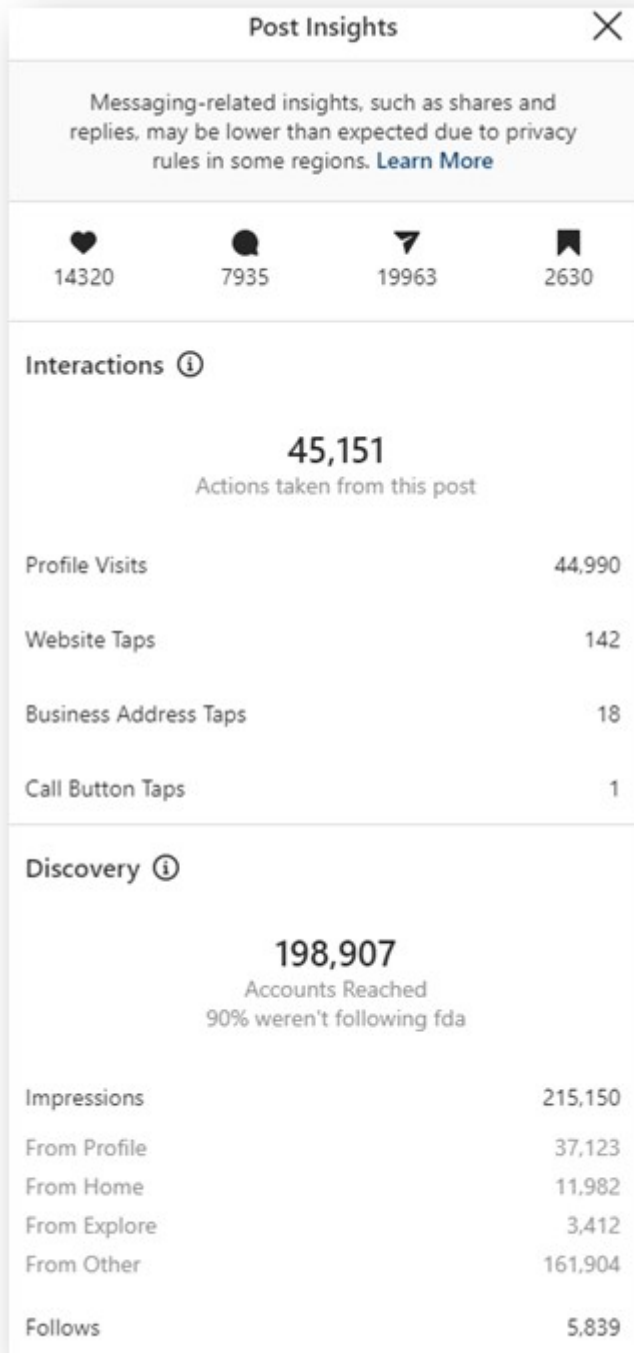
Promote



602 likes

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Erica

Kimberly, Brad

From: Kimberly, Brad
Sent: Monday, August 23, 2021 2:50 PM
To: Mulieri, Chris; Braithwaite, Sonia
Subject: RE: Well done!

Categories: FOIA

Oh... and we utilized existing content from Sandy's team posted on FDA.gov to accomplish the task.

Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



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Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov





From: Kimberly, Brad
Sent: Monday, August 23, 2021 2:44 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Erica, just really quick, I wanted to update you on the Saturday post.

As of right now, it's the most popular post we've ever had on Twitter. I say "right now" because the vax approval is on its heels... much like a horse race.

All said, it looks like we gained about 11K followers across the accounts we posted these on. That's up 636.7% from the two days prior. That growth is 17.6K if you count today with the vaccine approval.

I'd also like to flag the engagement rate, which is much higher across the board... especially when you consider the impressions numbers being so high. Typically, the higher that number, the lower the rate. If we exceed 1% engagement on a post, we're pretty content.

Okay, please let me know if you have any questions.
Brad

Profile	Audience	Net Audience Growth	Published Posts	Impressions	Engagement
Reporting Period Aug 21, 2021 – Aug 22, 2021	1,681,379 ↑ 0.7%	10,881 ↑ 636.7%	6 ↓ 71.4%	16,099,564 ↑ 2,076.7%	565,75 ↑ 4,996.9%
Compare to Aug 19, 2021 – Aug 20, 2021	1,670,404	1,477	21	739,636	11,10
U.S. Food and Drug Ad...	723,928	1,277	1	605,492	49,83
@US_FDA	466,953	5,747	3	15,104,509	496,17
FDA	465,781	280	1	55,835	2,67
fda	24,717	3,577	1	333,728	17,07

ANALYTICS

Twitter:



Impressions	23,745,920
Media views	35,707
Total engagements	920,460
Detail expands	579,553
Link clicks	103,494
Likes	89,081
Retweets	54,325
Profile clicks	48,246
Media engagements	35,707
Replies	9,828
Follows	226

Facebook:

FDA U.S. Food and Drug Administration

Favorites · 2d ·

You are not a horse. You are not a cow. Seriously, y'all. Stop it. — sharing a COVID-19 Update.

FDA.GOV

Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

338,223 People Reached 48,255 Engagements [Boost Post](#)

2.2K 367 Comments 3,492 Shares

[Love](#) [Comment](#) [Share](#) [FDA](#)

Performance for Your Post

338,223 People Reached

20,349 Reactions, Comments & Shares

7,725 Like	1,564 On Post	6,161 On Shares
365 Love	108 On Post	257 On Shares
2,189 Haha	616 On Post	1,573 On Shares
456 Wow	38 On Post	418 On Shares
129 Sad	11 On Post	118 On Shares
74 Angry	23 On Post	51 On Shares
5,970 Comments	974 On Post	4,996 On Shares
3,492 Shares	3,492 On Post	0 On Shares

27,906 Post Clicks

0 Photo Views	7,785 Link Clicks	20,121 Other Clicks
-------------------------	-----------------------------	-------------------------------

NEGATIVE FEEDBACK

57 Hide Post	17 Hide All Posts
0 Report as Spam	0 Unlike Page

LinkedIn:



FDA

466,209 followers

2d • 🌐

You are not a horse. You are not a cow. Seriously, y'all. Stop it.



Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

fda.gov • 3 min read

👍❤️🗨️ 381 • 49 comments

👍 Like 🗨️ Comment

Organic impressions:
45,613 Impressions

Hide stats ^

Organic stats 📊

Targeted to: All followers

45,613 Impressions	381 Reactions	5.34% Click-through rate
49 Comments	53 Shares	2,438 Clicks
6.4% Engagement rate		

Instagram:



FDA Posts



View Insights

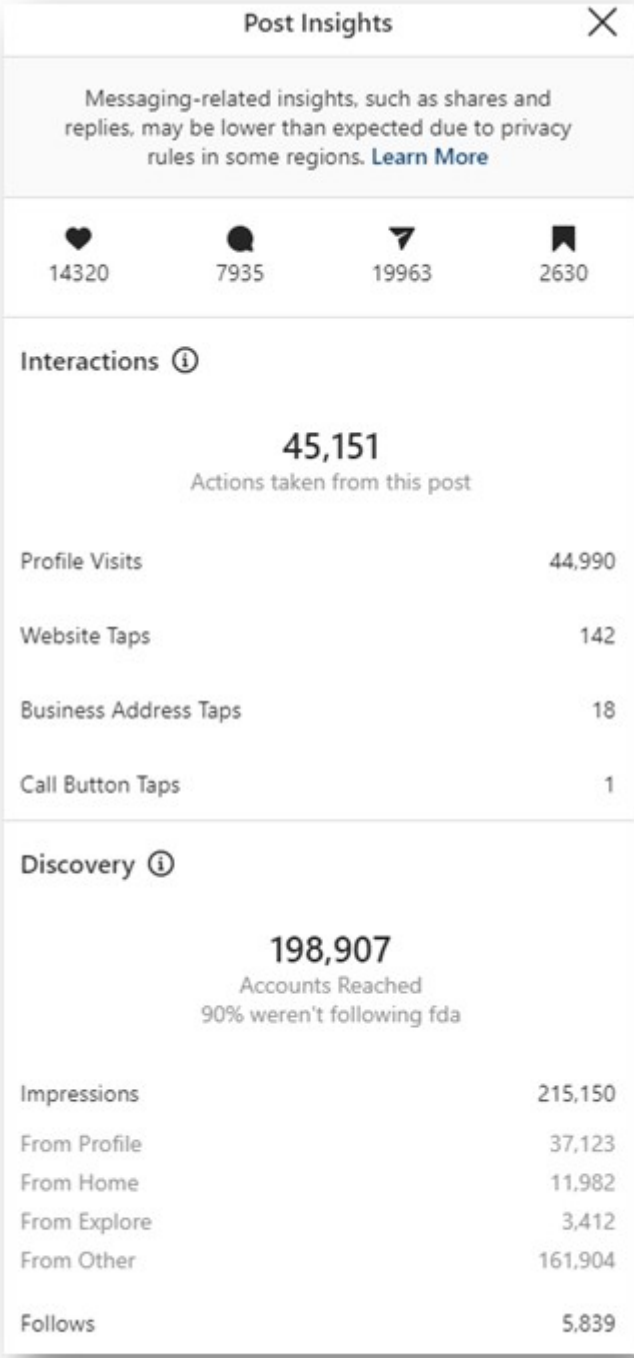
Promote



602 likes

fda You are not a horse.
Stop it with the #Ivermectin.
It's not authorized for treating #COVID.





Brad Kimberly
Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov





From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>

Sent: Saturday, August 21, 2021 10:44:52 AM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>

Subject: Well done!

The numbers are racking up and I laughed out loud. 😂

Thanks for turning the post around. CNN also tweeted a warning as well.

Erica

Kimberly, Brad

From: Kimberly, Brad
Sent: Monday, August 23, 2021 9:32 AM
To: Taiwo, Wumi
Cc: FDASocialMedia
Subject: RE: Well done!

Categories: FOIA

Calculated use of y'all.

Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Taiwo, Wumi <wumi.taiwo@fda.hhs.gov>
Sent: Monday, August 23, 2021 9:31 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: FDASocialMedia <FDASocialMedia@fda.hhs.gov>
Subject: RE: Well done!

Well done! I couldn't help but laugh at the tweet reacting to the infamous use of the word "Ya'll" in Brad's voice. I'm so here for the comments.

Respectfully,

Wumi Taiwo

Public Affairs Specialist, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Cell: 240-743-8918
wumi.taiwo@fda.hhs.gov





From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Sunday, August 22, 2021 11:04 AM

To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>

Subject: Re: Well done!

That number undersells it in the screenshot, but there was a significant gain yesterday. More on that tomorrow once I get a solid data pull.

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>

Sent: Sunday, August 22, 2021 10:48:01 AM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>

Subject: RE: Well done!

Thanks, Brad. It also looks like we've picked up some new followers. Are those numbers compelling for Twitter and IG?

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Sunday, August 22, 2021 9:40 AM

To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>

Subject: Re: Well done!

And for the tweet... as of right now. Believe it's our second most popular tweet of all time.



Tweet activity

Impressions

times people saw this Tweet on Twitter

Media views

all views (autoplay and click) of your media across videos, vines, gifs, and images

Total engagements

times people interacted with this Tweet

Detail expands

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:37:13 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Final Consumer Update pageviews for yesterday only: over 177,000.

Chris

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:27 AM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Team – this is OUTSTANDING work. So creative and, most importantly, gets FDA’s public health message out to the universe. I can’t wait to see what else you all have in the works!

Best,
Julie

Julia C. Tierney, JD (she/her)
Acting Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
(240) 907-9331 (cell)
Julia.Tierney@fda.hhs.gov



From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 6:32 PM
To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

Very impressive! Thanks Chris!

From: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Sent: Saturday, August 21, 2021 4:19 PM
To: Kimberly, Brad; Felberbaum, Michael; Jefferson, Erica
Cc: Walsh, Sandy; FDASocialMedia; Rebello, Heidi; Hetlage, Daniel
Subject: RE: Well done!

Google analytics shows over 80,000 pageviews to the CU for today! I will have the final daily total tomorrow morning. 30% of today's pageviews came from Twitter. 52% of the pageviews came directly from Google.

For yesterday and today, the total pageviews for the CU are over 162,000 and counting.

Chris

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 6:02 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

JJ Pause tweet - 20.4M
Immunocompromised EUA FB - 10.8M
JJ Pause tweet inside original thread - 6.8M
Not a Horse tweet - 5M
Pfizer4Kidz tweet - 4.5M

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Saturday, August 21, 2021 5:57:38 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

Anything we've put out that compares?

Michael Felberbaum
Assistant Commissioner for Media Affairs (Acting)
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [240-402-9548](tel:240-402-9548) / Cell: [202-906-0229](tel:202-906-0229)
michael.felberbaum@fda.hhs.gov

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Sent: Saturday, August 21, 2021 5:56:23 PM

To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>

Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>

Subject: Re: Well done!

So, Twitter impressions at 5M+ at this point. Should have mostly final numbers on Monday. But you get the idea. It went pretty well.

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>

Sent: Saturday, August 21, 2021 4:50:30 PM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>

Subject: Re: Well done!



From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 2:17 PM
To: Jefferson, Erica
Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel
Subject: Re: Well done!

Ha. A couple others using our social words prominently. Not sure how I feel about mediaite categorizing the story as "weird."

<https://www.mediaite.com/weird/you-are-not-a-horse-fdas-response-to-vaccine-skeptics-taking-livestock-dewormer-as-covid-treatment-goes-viral/>

<https://www.rollingstone.com/politics/politics-news/fda-horse-dewormer-covid-fox-news-1215168/>

<https://www.nbcnews.com/news/us-news/stop-it-fda-warns-people-not-take-veterinary-drugs-treat-n1277371>

<https://www.ctvnews.ca/health/coronavirus/you-are-not-a-cow-fda-begs-americans-to-stop-taking-drug-meant-for-livestock-as-covid-19-remedy-1.5556324>

<https://www.facebook.com/5550296508/posts/10162231881976509/?d=n> (CNN)

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 3:49:39 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

NYT covered:

<https://www.nytimes.com/2021/08/21/world/ivermectin-fda-covid-19-treatment.html>

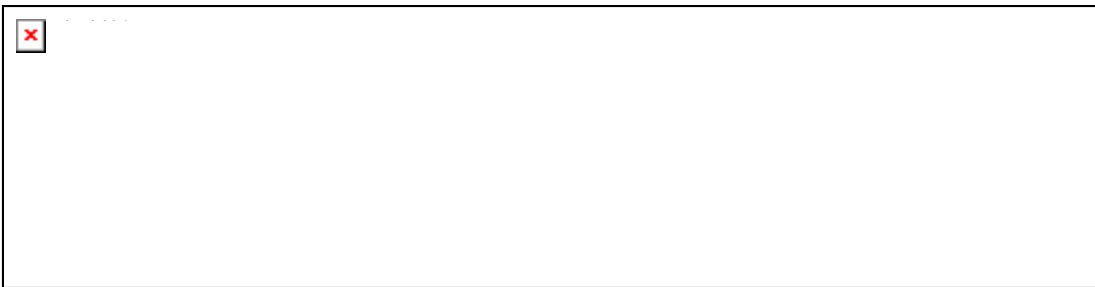
From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 1:09 PM
To: Jefferson, Erica
Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel
Subject: RE: Well done!

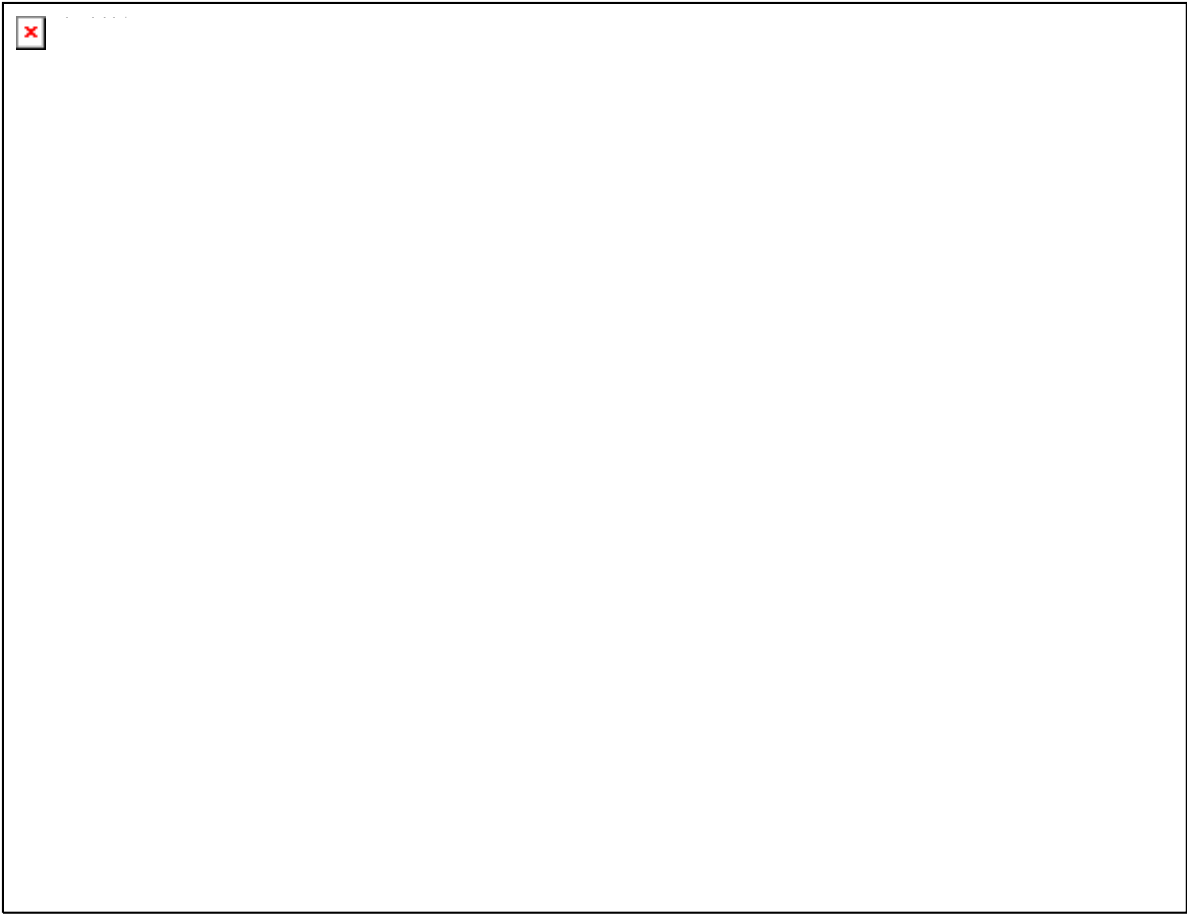
Erica, here's a little bit of info about our posts today.

Far exceeding our baseline average of impressions and engagement across the board. (Cicada-level impressions) Retweeted by huge verified social media influencers and at least one former FDA Commissioner.

Also, if you want to see what people think of our team for doing this: [that's here](#).

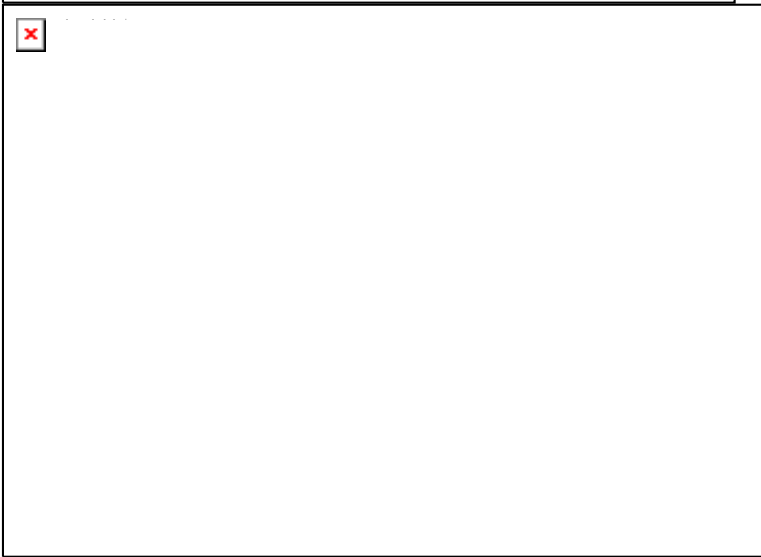
Data below, but first, some of my favorite comments from people:





ANALYTICS

Twitter:



Facebook:



LinkedIn:



Instagram:





Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302

brad.kimberly@fda.hhs.gov





From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>

Sent: Saturday, August 21, 2021 10:44:52 AM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>

Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>

Subject: Well done!

The numbers are racking up and I laughed out loud. 😂

Thanks for turning the post around. CNN also tweeted a warning as well.

Erica

Kimberly, Brad

From: Riley, Karen
Sent: Monday, August 23, 2021 8:29 AM
To: Kimberly, Brad
Subject: Fwd: [EXTERNAL] You are not a horse

Categories: FOIA

Hi Brad, Your Tweet was the kicker for this daily Bloomberg new feed. It was brilliant, by the way. Get [Outlook for iOS](#)

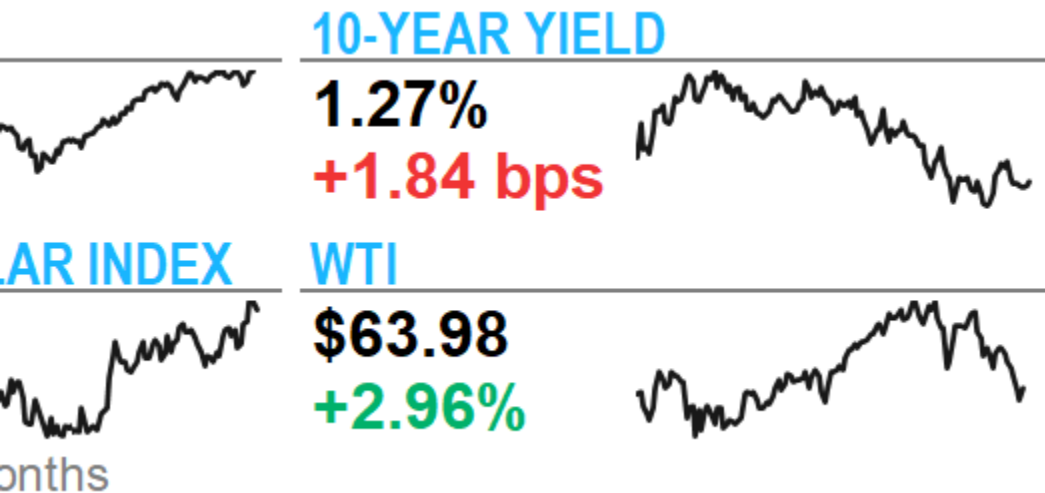
From: The Bloomberg Open <noreply@mail.bloombergbusiness.com>
Sent: Monday, August 23, 2021 7:23:06 AM
To: Riley, Karen <Karen.Riley@fda.hhs.gov>
Subject: [EXTERNAL] You are not a horse

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

The Bloomberg Open

Americas Edition

g drugs meant for horses. Please.



...ch on Friday. Treasuries and the dollar slumped while oil approached \$64 and gold advanced.

...or more. It's been quite a rollercoaster for investors after the token plunged below \$30,000 following a crypto rout in May. Ethereum top

...The president warned of possible terror attacks and may have to push back his deadline for leaving Afghanistan, even as he defended hi

...2020? A \$1.9 trillion budget boost helped the economy roar ahead, with worker shortages and inflation taking off. Now, the big fear is th

...ained momentum after he secured Janet Yellen's endorsement. Keeping him on would reduce uncertainty about the path for monetary po



e swath of the world is yet to receive any inoculation. But the case for boosters on scientific grounds is building. The reason is delta.

m to swiftly block delta on its arrival in the nose and throat, preventing the virus from not only infecting cells and causing illness, but also

ll being worked out. The challenge is how to continue to use them to maximize the most important aspect of public health: preventing inf



...sing restrictions and steadily improving jobs numbers. But now the delta variant is shaking things up. In other virus news:

...y said. Meanwhile, U.S. schools may become unsafe and act as focal points for Covid transmission, an ex-FDA head said. Keep up to the m

measure declaring their drivers were independent contractors, saying it violated the state's constitution. Proposition 22 exempts them from

...made famous in *The Big Short*? Well now he's betting that long-term Treasuries will fall and he's not the only one.

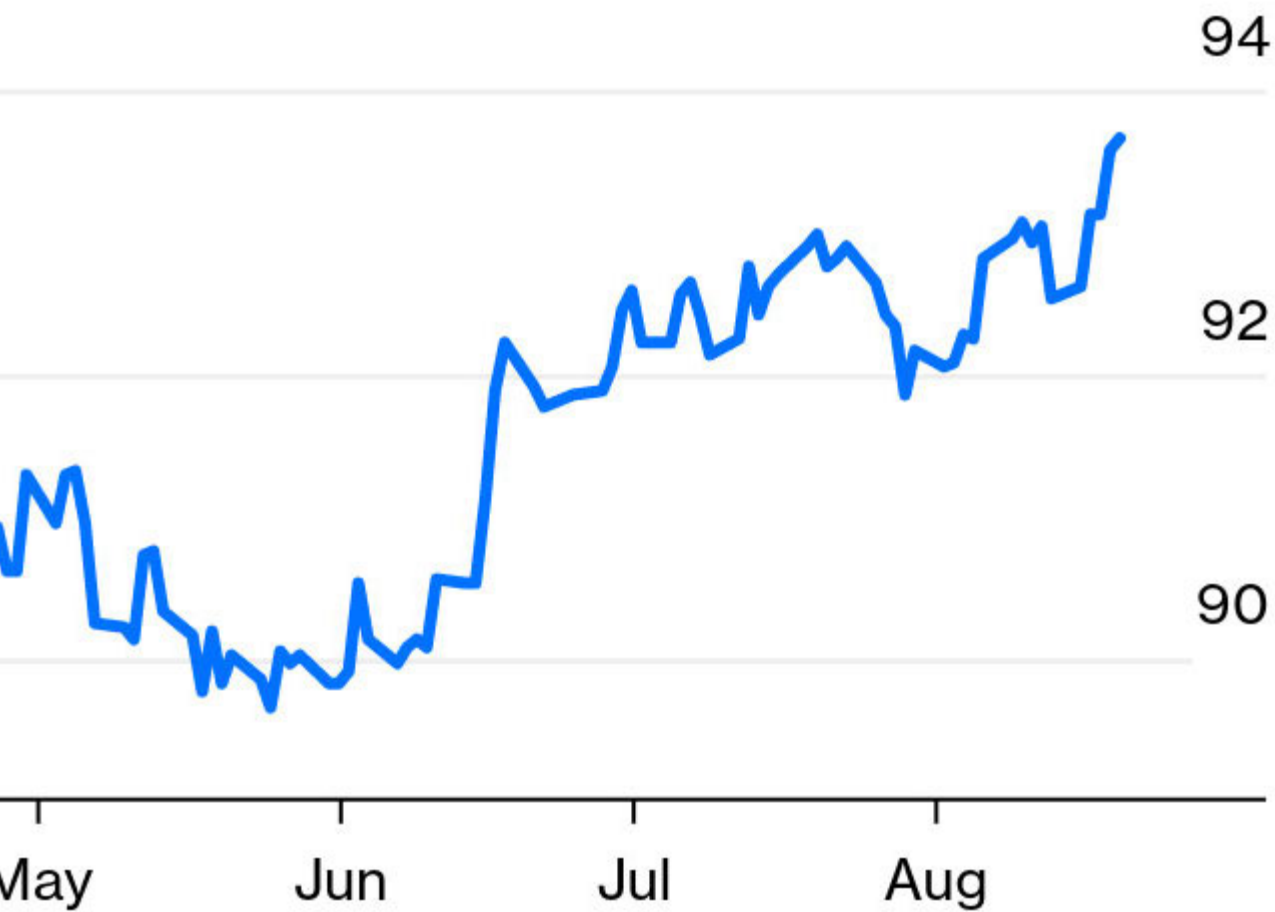
...NHC said. Though downgraded from a hurricane, Henri poured 1.9 inches of rain on Central Park between 10 p.m. and 11 p.m. Saturday, t



end up losing their autonomy, write former BOE Governor Mervyn King and Amberwave Partners's Dan Katz. Once politicians see central

ascend over this quarter may no longer be justified by economic fundamentals. The natural forces of foreign exchange, inflation and inte

nt currency trend so far this year



BloombergOpinion

the agency was reacting to reports from Mississippi of people taking ivermectin, which is often used against parasites in livestock, to treat c

idow and said the picture, which prompted a lawsuit from Johansson, has outperformed other Marvel films. Disney is asking for the suit to be thrown out of money—is being closely watched.

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Bloomberg L.P. 731 Lexington, New York, NY, 10022

Kimberly, Brad

From: Kimberly, Brad
Sent: Sunday, August 22, 2021 5:54 PM
To: Stein, Dayle
Subject: RE: i'm sure you saw this..

Categories: FOIA

Ha, yes. You know what's funny? That was my runner-up photo for Instagram, but I decided on something more standard.

Thanks for flagging. It's been a fun weekend watching people say the words I wrote on TV and TikTok and such.

Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Stein, Dayle <Dayle.Stein@fda.hhs.gov>
Sent: Sunday, August 22, 2021 5:35 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Subject: i'm sure you saw this..

<https://mashable.com/article/covid-ivermectin-fda-vaccines>



d.

Dayle Stein (she/her)

Web Project Coordinator/ORAs Social Media Manager

Office of Regulatory Affairs
Office of Communication and Project Management
U.S. Food and Drug Administration
Tel: 240-402-6486
Mobile: 301-943-5639
[Email: dayle.stein@fda.hhs.gov](mailto:dayle.stein@fda.hhs.gov)

Follow us on Twitter! [@FDA_ORA](https://twitter.com/FDA_ORA)



Kimberly, Brad

From: Wasserman, Jill
Sent: Saturday, August 21, 2021 3:50 PM
To: Kimberly, Brad
Subject: RE: Well done!

Categories: FOIA

Thanks. And bravo to you!

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 3:10 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Subject: FW: Well done!

FYSA

Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 3:09 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Erica, here's a little bit of info about our posts today.

Far exceeding our baseline average of impressions and engagement across the board. (Cicada-level impressions) Retweeted by huge verified social media influencers and at least one former FDA Commissioner.

Also, if you want to see what people think of our team for doing this: [that's here](#).

Data below, but first, some of my favorite comments from people:



Rex Chapman 🦄🇺🇸 @RexChapman · 1h

The FDA for the win...

 **U.S. FDA** ✓ @US_FDA · 6h

You are not a horse. You are not a cow. Serious



Joy Henningsen, MD ✓ @JoyHenningsenMD · 2h

The social media manager at @US_FDA is having a little fun with messaging AND I'M HERE FOR IT 😂

 **U.S. FDA** ✓ @US_FDA · 6h

You are not a horse. You are not a cow. Seriously, y'all. Stop it



MomCat @ufcat · 1m

The @US_FDA using "y'all" in a sentence (correctly, I should add) is the Twitter content I'm here for today.

 **U.S. FDA** ✓ @US_FDA · 6h

You are not a horse. You are not a cow. Seriously, y'all. Stop it.



Blair Strang @StrangVirusLab · 5h

I feel that the FDA have really up'd their social media game.

 **U.S. FDA** ✓ @US_FDA · 6h

You are not a horse. You are not a cow. Seriously, y'all. Stop it.

 **Alan Farley** ✓ @msttrader · 5h ...
but what if you self-identify as a horse or a cow?

 **U.S. FDA** ✓ @US_FDA · 7h
You are not a horse. You are not a cow. Seriously, y'all. Stop it.
[fda.gov/consumers/cons...](https://www.fda.gov/consumers/cons...)
[Show this thread](#)

 3  1  12 

 **U.S. FDA** ✓ @US_FDA ...
Replying to @msttrader

Just say neigh.

9:58 AM · Aug 21, 2021 · Twitter for iPhone

5 Retweets 1 Quote Tweet 25 Likes

ANALYTICS

Twitter:



Impressions	2,279,866
Media views	1,460
Total engagements	107,764
Detail expands	55,371
Likes	17,452
Link clicks	13,062
Retweets	11,805
Profile clicks	6,937
Replies	1,653
Media engagements	1,460
Follows	24

Facebook:

FDA U.S. Food and Drug Administration ✓
 Favorites · 6h ·

You are not a horse. You are not a cow. Seriously, y'all. Stop it. — sharing a COVID-19 Update.

FDA.GOV
Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

154,932 People Reached 19,440 Engagements [Boost Post](#)

958 129 Comments 1,261 Shares

[Like](#) [Comment](#) [Share](#)

Performance for Your Post

154,932 People Reached

6,255 Reactions, Comments & Shares

2,303 Like	661 On Post	1,642 On Shares
100 Love	36 On Post	64 On Shares
797 Haha	256 On Post	541 On Shares
116 Wow	13 On Post	103 On Shares
26 Sad	3 On Post	23 On Shares
22 Angry	11 On Post	11 On Shares
1,641 Comments	399 On Post	1,242 On Shares
1,261 Shares	1,261 On Post	0 On Shares

13,185 Post Clicks

0 Photo Views	3,831 Link Clicks	9,354 Other Clicks
-------------------------	-----------------------------	------------------------------

NEGATIVE FEEDBACK

23 Hide Post	5 Hide All Posts
0 Report as Spam	0 Unlike Page

LinkedIn:



FDA
465,715 followers
6h • 🌐

You are not a horse. You are not a cow. Seriously, y'all. Stop it.



Why You Should Not Use Ivermectin to Treat or Prevent COVID-19

fda.gov • 3 min read

👍❤️👤 112 • 9 comments

Thanks for posting...

Interesting! I like...

I think >

👍 Like 💬 Comment



Add a comment...



Organic impressions:
13,861 Impressions

Hide stats ^

Organic stats ⓘ

Targeted to: All followers

13,861 Impressions	112 Reactions	5.03% Click-through rate
9 Comments	14 Shares	697 Clicks
6% Engagement rate		

Instagram:



FDA
Posts



[View Insights](#)

Promote



602 likes

fda You are not a horse.
Stop it with the [#Ivermectin](#).
It's not authorized for treating [#COVID](#).





Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 10:44:52 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Well done!

The numbers are racking up and I laughed out loud. 😂

Thanks for turning the post around. CNN also tweeted a warning as well.

Erica

Kimberly, Brad

From: Jefferson, Erica
Sent: Saturday, August 21, 2021 3:32 PM
To: Kimberly, Brad
Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel
Subject: Re: Well done!

Categories: FOIA

Brad,

Legendary.

Have a great rest of the weekend!

Erica

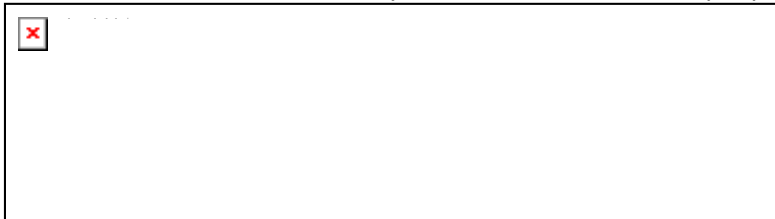
From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 1:09 PM
To: Jefferson, Erica
Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel
Subject: RE: Well done!

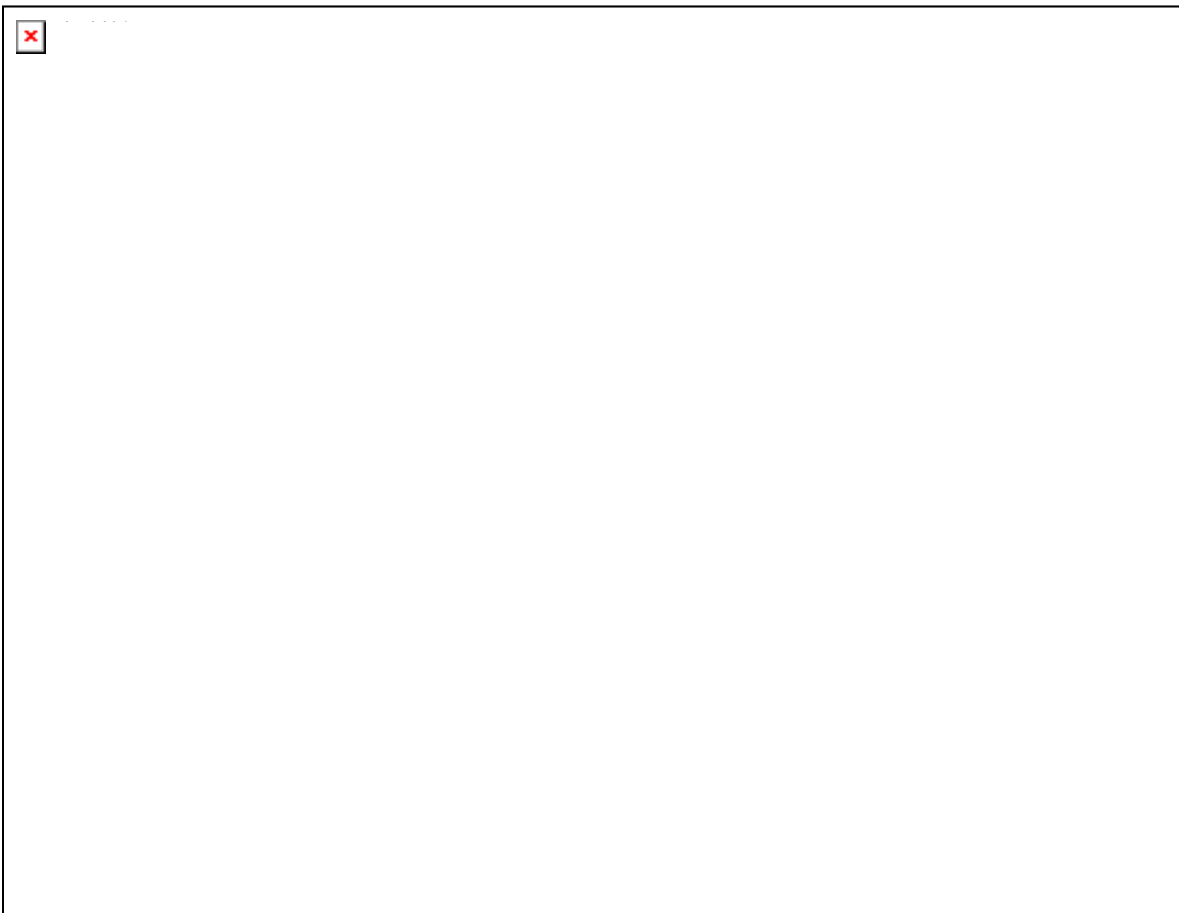
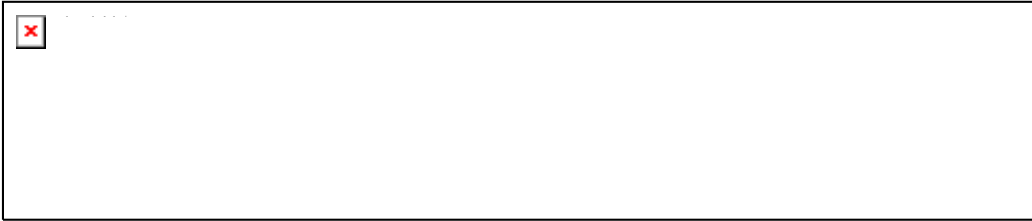
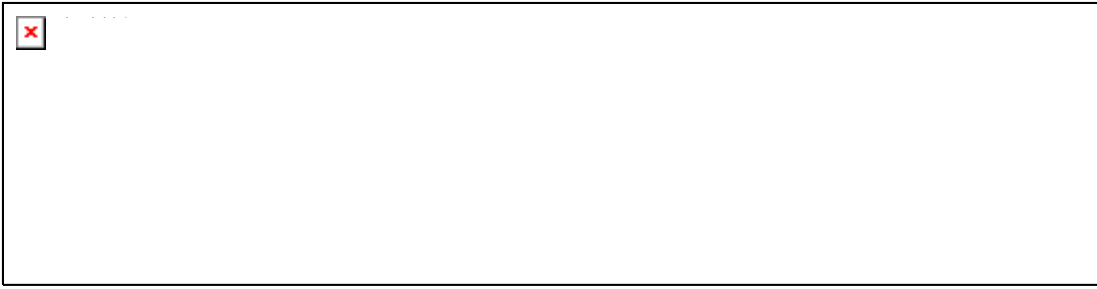
Erica, here's a little bit of info about our posts today.

Far exceeding our baseline average of impressions and engagement across the board. (Cicada-level impressions) Retweeted by huge verified social media influencers and at least one former FDA Commissioner.

Also, if you want to see what people think of our team for doing this: [that's here](#).

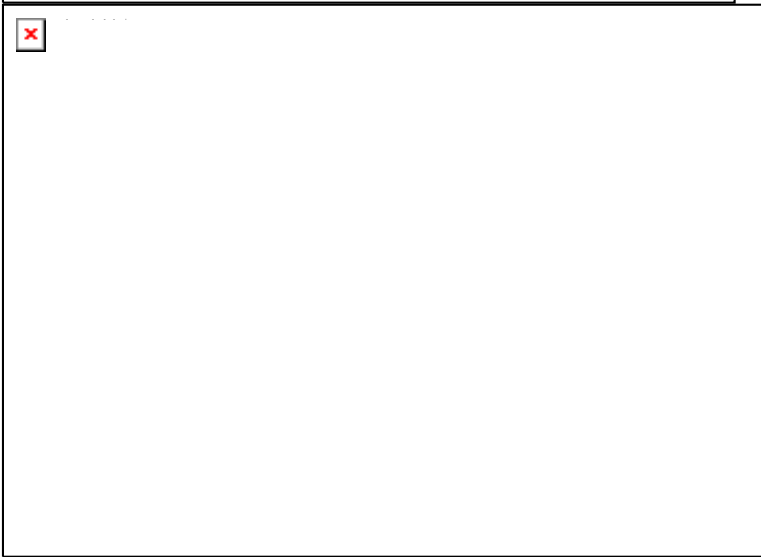
Data below, but first, some of my favorite comments from people:





ANALYTICS

Twitter:



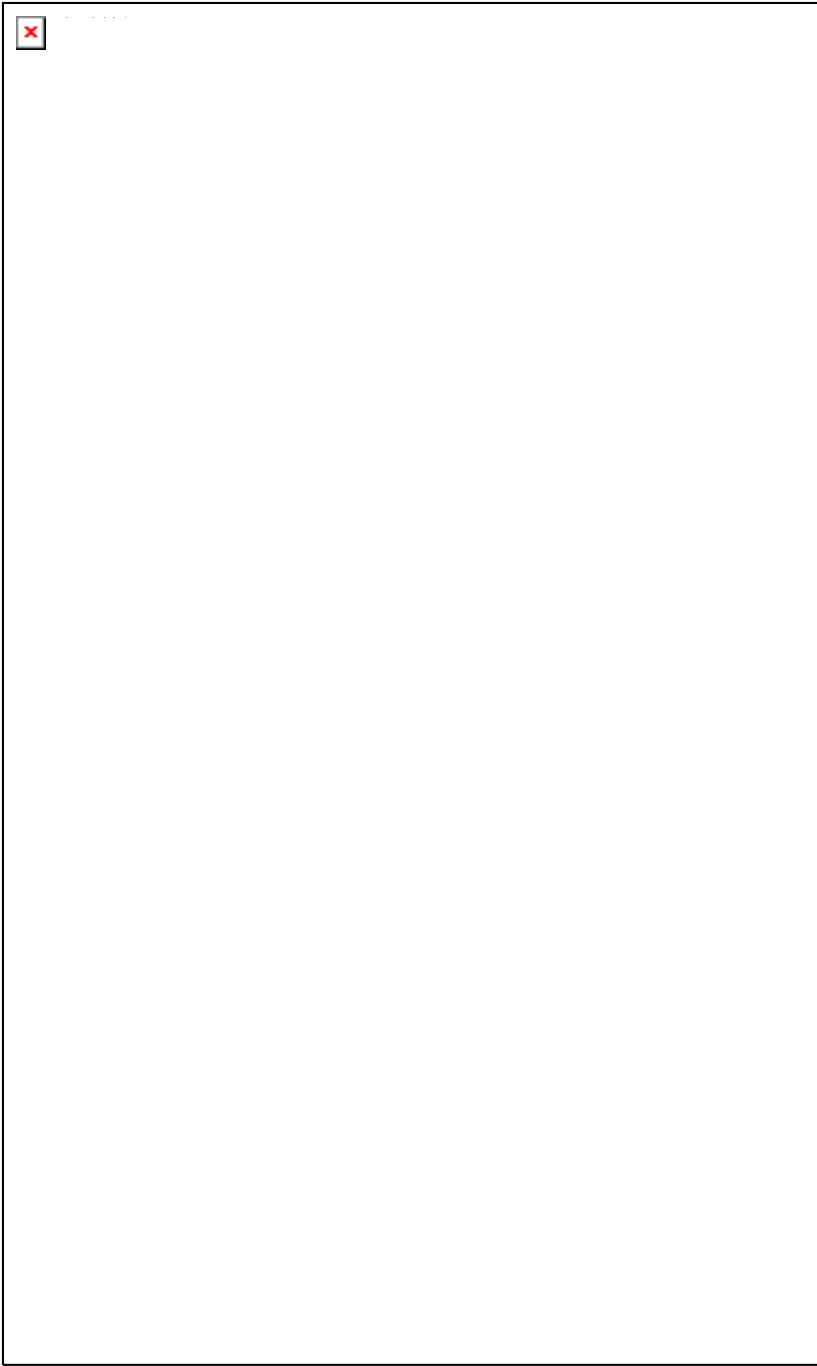
Facebook:



LinkedIn:



Instagram:





Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 10:44:52 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Well done!

The numbers are racking up and I laughed out loud. 😂

Thanks for turning the post around. CNN also tweeted a warning as well.

Erica

Kimberly, Brad

From: Mulieri, Chris
Sent: Saturday, August 21, 2021 11:17 AM
To: Jefferson, Erica; Kimberly, Brad
Cc: Walsh, Sandy
Subject: Re: Well done!

Categories: FOIA

I can pull the CU stats later today.

Chris

Get [Outlook for iOS](#)

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 11:04:46 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Re: Well done!

Sounds great!

Sandy, let's see if we can pull stats on how many times the CU is read today.

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:53 AM
To: Jefferson, Erica
Cc: Mulieri, Chris; Walsh, Sandy
Subject: Re: Well done!

Ha! Thank you. I've been reading some positive stuff. Will send you a roundup later on.

But this was fun...

https://twitter.com/us_fda/status/1429080398999531523?s=21

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 10:44:52 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Well done!

The numbers are racking up and I laughed out loud. 😂

Thanks for turning the post around. CNN also tweeted a warning as well.

Erica

Kimberly, Brad

From: Walsh, Sandy
Sent: Saturday, August 21, 2021 8:00 AM
To: Kimberly, Brad; Mulieri, Chris; Thorpe, Valarie
Subject: Re: Concerns with ivermectin

Categories: FOIA

Thanks also CDC is putting an alert out on ivermectin. Tuesday I think.

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 7:45:38 AM
To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: Re: Concerns with ivermectin

That's totally fine. I was waiting for the CU to hit it again, but I'll pop a thing out today.

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Sent: Saturday, August 21, 2021 12:17:02 AM
To: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: Re: Concerns with ivermectin

Thank you Sandy!

Chris

Get [Outlook for iOS](#)

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Friday, August 20, 2021 9:37:37 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Subject: Concerns with ivermectin

Hi Brad,

Erica reached out to me and Chris tonight saying she was thinking we need to do social again around ivermectin due to news around poison control calls going up.

<https://twitter.com/hyperplanes/status/1428864144128741383?s=20>

We are working on updates to the ivermectin consumer update for next week but they are minor tweaks. But if needed OCC is fine with continuing to point to the CU as published in March for now for messages not to use ivermectin.

Not sure what she has in mind but wanted to flag that she texted us about this topic.

From: [Walsh, Sandy](#)
To: [Kimberly, Brad](#); [Mulieri, Chris](#); [Thorpe, Valarie](#)
Subject: Re: Concerns with ivermectin
Date: Saturday, August 21, 2021 8:06:12 AM
Attachments: [image008.png](#)
[image009.png](#)
[image010.png](#)
[image011.png](#)
[image012.png](#)
[image013.png](#)
[image014.png](#)
[image021.png](#)
[image022.png](#)
[image023.png](#)
[image024.png](#)
[image025.png](#)
[image026.png](#)

Rex Chapman also Tweeted last night about not using ivermectin

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:02:53 AM
To: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: Concerns with ivermectin

We're gettin' crazy over here.

Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:01 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: Re: Concerns with ivermectin

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 7:58:52 AM
To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>;
Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>
Subject: RE: Concerns with ivermectin

https://twitter.com/US_FDA/status/1429050070243192839

 **U.S. FDA** ✓ @US_FDA · 21s ...

You are not a horse. You are not a cow. Seriously, y'all. Stop it.



Why You Should Not Use Ivermectin to Treat or Prevent COVID-19
Using the Drug ivermectin to treat COVID-19 can be dangerous and even lethal. The FDA has not approved the drug for that purpose.
[fda.gov](https://www.fda.gov)

Brad Kimberly

Director, Social Media

Web & Digital Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-1002 | Cell: 240-750-9302
brad.kimberly@fda.hhs.gov



From: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Sent: Saturday, August 21, 2021 12:17 AM
To: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>;

Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>

Subject: Re: Concerns with ivermectin

Thank you Sandy!

Chris

Get [Outlook for iOS](#)

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:37:37 PM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>

Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>

Subject: Concerns with ivermectin

Hi Brad,

Erica reached out to me and Chris tonight saying she was thinking we need to do social again around ivermectin due to news around poison control calls going up.

<https://twitter.com/hyperplanes/status/1428864144128741383?s=20>

We are working on updates to the ivermectin consumer update for next week but they are minor tweaks. But if needed OCC is fine with continuing to point to the CU as published in March for now for messages not to use ivermectin.

Not sure what she has in mind but wanted to flag that she texted us about this topic.

From: [Staton, Anna](#)
To: [Walsh, Sandy](#)
Subject: Re: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral
Date: Sunday, August 22, 2021 7:36:36 PM
Attachments: [image004.png](#)

Thanks for sharing! I saw the Tweet and was super impressed. Glad we have data now to backup the direct approach.

Get [Outlook for iOS](#)

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Sunday, August 22, 2021 11:59:39 AM
To: Staton, Anna <Anna.Staton@fda.hhs.gov>
Subject: Fwd: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

FYI we ended up needing to promote the ivermectin CU over the weekend due to some news about its use. Brads edgy Tweet was a hit.

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Sunday, August 22, 2021 11:35:06 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Sharing: FDA Ivermectin / COVID-19 Tweet Goes Viral

Hi Dr. Woodcock,

I hope you are having a great weekend. I know we are all eager for tomorrow.

Separately and as you know, the OEA team and I have been meeting over the past several weeks to discuss ways in which we can more effectively use our social media platforms to share important public health information with consumers. I'm sure you saw some of the news coming out of Mississippi on Friday regarding the use of ivermectin to treat / prevent Covid-19 and the increase in adverse events (poisonings) the state highlighted as a result of its use. I expressed to the team late Friday night that we take the opportunity to remind the public of our own warnings for ivermectin and by early Saturday morning the social media team had posted the following tweet:



Needless to say, the direct, straight-forward and clever (humorous) communication, paired with a follow-on tweet that provided additional answers to common questions about ivermectin, saw the tweet quickly going viral and being shared across multiple social medium platforms (where it was amplified by other influencers) and resulted in additional news coverage by: [NYT](#), [CNN](#), [NBC News](#) and [Rolling Stone](#) to name a few. Notably, the official Today Show Instagram account (3 million followers) also featured an original post on the account. We also took the opportunity to highlight a Consumer Update on ivermectin, that was prepared and distributed earlier this year. I'm pleased to report that as a result of the tweet, the update was accessed 177k times yesterday alone.

By comparison, the tweet currently ranks as our 2nd most popular tweet of all time in terms of the number of people we've reached with the content:

J&J Pause tweet - 20.4M

Not a Horse tweet – 14.5M

Immunocompromised EUA FB - 10.8M

J&J Pause tweet inside original thread - 6.8M

Pfizer4Kidz tweet - 4.5M

As you know, I am committed to identifying unique (for FDA) ways for us to reach the “everyday” American to “brand” FDA. I am grateful the OEA team is enthusiastically supportive of this goal and in particular, I want to recognize Brad, Chris and Sandy, for mobilizing quickly Friday night and Saturday morning to create a unique viral moment at such a critical time for the FDA's image and in our fight against Covid-19. While we won't *always* be able to take this approach (we are still a government entity), we will seek to develop content that allows the agency to feel both accessible and informative in a time of incredible misinformation. We will be meeting with OCC soon to discuss our new recommended approach for social media engagement. We look forward to sharing more about these efforts in the weeks ahead, including an ambition effort to counter much of the vaccine information out there as we prepare to approve Comiraty.

Please let me know if you have any questions in the interim. Thanks for your support on our efforts to evolve FDA's communications with consumers.

Best,
Erica

Erica V. Jefferson (she/her)

Associate Commissioner for External Affairs

U.S. Food and Drug Administration

Tel: 240-702-3994

erica.jefferson@fda.hhs.gov



Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

From: [Jefferson, Erica](#)
To: [Kimberly, Brad](#)
Cc: [Mulieri, Chris](#); [Walsh, Sandy](#)
Subject: Re: Well done!
Date: Saturday, August 21, 2021 11:04:48 AM

Sounds great!

Sandy, let's see if we can pull stats on how many times the CU is read today.

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:53 AM
To: Jefferson, Erica
Cc: Mulieri, Chris; Walsh, Sandy
Subject: Re: Well done!

Ha! Thank you. I've been reading some positive stuff. Will send you a roundup later on.

But this was fun...

https://twitter.com/us_fda/status/1429080398999531523?s=21

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 10:44:52 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Well done!

The numbers are racking up and I laughed out loud.

Thanks for turning the post around. CNN also tweeted a warning as well.

Erica

From: [Kimberly, Brad](#)
To: [Jefferson, Erica](#); [Mulleri, Chris](#); [Tierney, Julia](#); [Felberbaum, Michael](#)
Cc: [Walsh, Sandy](#); [FDASocialMedia](#); [Rebello, Heidi](#); [Hetlage, Daniel](#)
Subject: Re: Well done!
Date: Sunday, August 22, 2021 11:04:20 AM
Attachments: [image002.png](#)
[image003.png](#)

That number undersells it in the screenshot, but there was a significant gain yesterday More on that tomorrow once I get a solid data pull

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Sunday, August 22, 2021 10:48:01 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Mulleri, Chris <Charles.Mulleri@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Thanks, Brad It also looks like we've picked up some new followers Are those numbers compelling for Twitter and IG?

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:40 AM
To: Mulleri, Chris <Charles.Mulleri@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

And for the tweet... as of right now Believe it's our second most popular tweet of all time

 Verizon LTE 

9:38 AM

100% 



Tweet activity

Impressions

14,523,592

times people saw this Tweet on Twitter

Media views

18,129

all views (autoplay and click) of your media are counted across videos, vines, gifs, and images

Total engagements

557,499

times people interacted with this Tweet

Detail expands

334,802

times people viewed the details about this Tweet

Link clicks

65,736

clicks on a URL or Card in this Tweet

Likes	61,730
times people liked this Tweet	
Retweets	38,509
times people retweeted this Tweet	
Profile clicks	31,639
number of clicks on your name, @handle, or profile photo	
Media engagements	18,129
number of clicks on your media counted across videos, vines, gifs, and images	
Replies	6,808
replies to this Tweet	
Follows	146

Brad Kimberly
 Director, Social Media
 Office of External Affairs

From: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:37:13 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Final Consumer Update pageviews for yesterday only: over 177,000

Chris

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:27 AM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: RE: Well done!

Team – this is OUTSTANDING work. So creative and, most importantly, gets FDA's public health message out to the universe. I can't wait to see what else you all have in the works!

Best,
 Julie

Julia C. Tierney, JD (she/her)
 Acting Chief of Staff

U.S. Food and Drug Administration
 (301) 796-8602 (office) (forwarded)
 (240) 907-9331 (cell)
Julia.Tierney@fda.hhs.gov



From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 6:32 PM
To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

Very impressive! Thanks Chris!

From: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>
Sent: Saturday, August 21, 2021 4:19 PM
To: Kimberly, Brad; Felberbaum, Michael; Jefferson, Erica
Cc: Walsh, Sandy; FDASocialMedia; Rebello, Heidi; Hetlage, Daniel
Subject: RE: Well done!

Google analytics shows over 80,000 pageviews to the CU for today! I will have the final daily total tomorrow morning 30% of today's pageviews came from Twitter 52% of the pageviews came directly from Google

For yesterday and today, the total pageviews for the CU are over 162,000 and counting

Chris

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 6:02 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

JJ Pause tweet - 20 4M
Immunocompromised EUA FB - 10 8M
JJ Pause tweet inside original thread - 6 8M
Not a Horse tweet - 5M
Pfizer4Kidz tweet - 4 5M

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Saturday, August 21, 2021 5:57:38 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

Anything we've put out that compares?

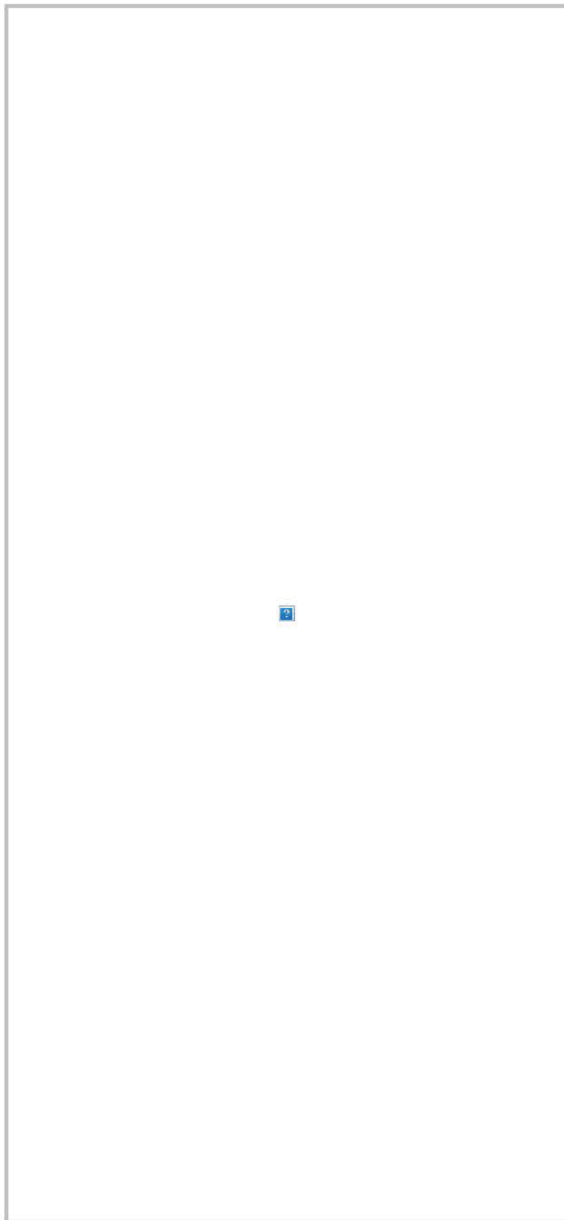
Michael Felberbaum
Assistant Commissioner for Media Affairs (Acting)
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [240-402-9548](tel:240-402-9548) / Cell: [202-906-0229](tel:202-906-0229)
michael.felberbaum@fda.hhs.gov

From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 5:56:23 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

So, Twitter impressions at 5M+ at this point Should have mostly final numbers on Monday But you get the idea It went pretty well

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 4:50:30 PM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!



From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 2:17 PM
To: Jefferson, Erica
Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel
Subject: Re: Well done!

Ha A couple others using our social words prominently Not sure how I feel about mediaite categorizing the story as "weird "

<https://www.mediaite.com/weird/you-are-not-a-horse-fdas-response-to-vaccine-skeptics-taking-livestock-dewormer-as-covid-treatment-goes-viral/>

<https://www.rollingstone.com/politics/politics-news/fda-horse-dewormer-covid-fox-news-1215168/>

<https://www.nbcnews.com/news/us-news/stop-it-fda-warns-people-not-take-veterinary-drugs-treat-n1277371>

<https://www.ctvnews.ca/health/coronavirus/you-are-not-a-cow-fda-begs-americans-to-stop-taking-drug-meant-for-livestock-as-covid-19-remedy-1.5556324>

<https://www.facebook.com/5550296508/posts/10162231881976509/?d=cn> (CNN)

Brad Kimberly
Director, Social Media
Office of External Affairs

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 3:49:39 PM

To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; FDASocialMedia <FDASocialMedia@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hetlage, Daniel <Daniel.Hetlage@fda.hhs.gov>
Subject: Re: Well done!

NYT covered:

<https://www.nytimes.com/2021/08/21/world/ivermectin-fda-covid-19-treatment.html>

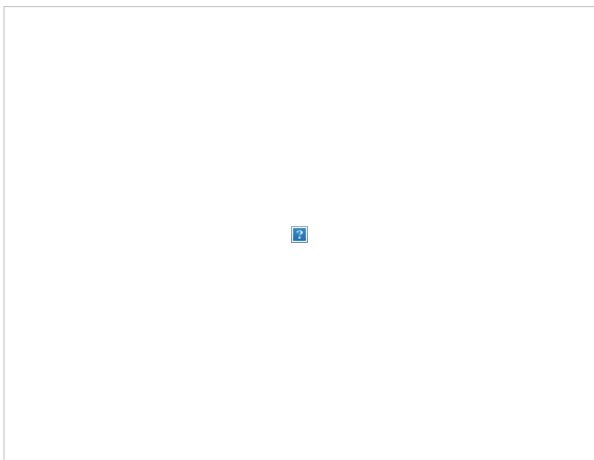
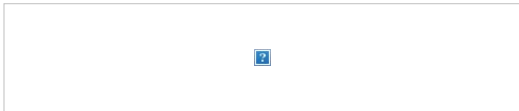
From: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Sent: Saturday, August 21, 2021 1 09 PM
To: Jefferson, Erica
Cc: Walsh, Sandy; Mulieri, Chris; FDASocialMedia; Felberbaum, Michael; Rebello, Heidi; Hetlage, Daniel
Subject: RE: Well done!

Erica, here s a little bit of info about our posts today

Far exceeding our baseline average of impressions and engagement across the board (Cicada-level impressions) Retweeted by huge verified social media influencers and at least one former FDA Commissioner

Also, if you want to see what people think of our team for doing this: [that s here](#)

Data below, but first, some of my favorite comments from people:

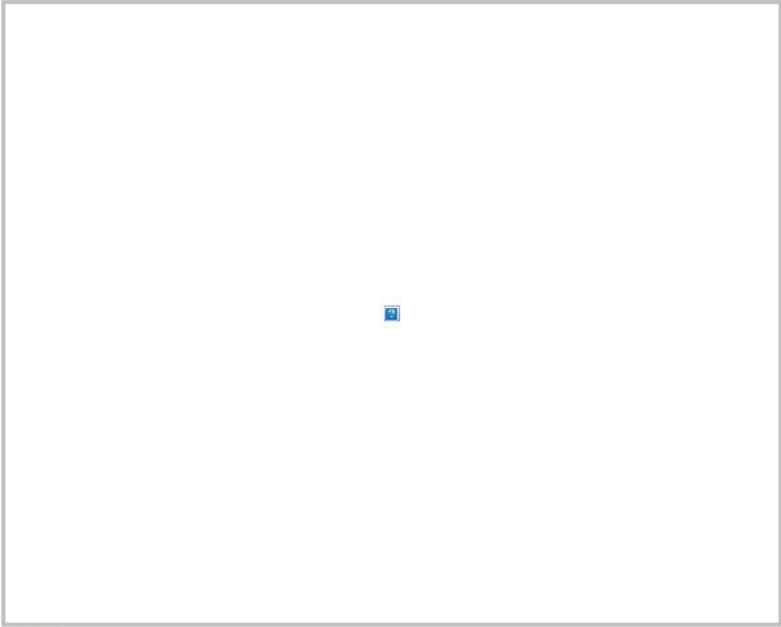


ANALYTICS

Twitter:



Facebook:



LinkedIn:



Instagram:

A screenshot of a horse Description automatically generated



Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-1002 | Cell 240-750-9302

brad.kimberly@fda.hhs.gov



From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Saturday, August 21, 2021 10:44 52 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Subject: Well done!

The numbers are racking up and I laughed out loud

Thanks for turning the post around CNN also tweeted a warning as well

Erica

From: Russ, Wilson [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=209B1BA75C184B17BDA76DBE4A9CF170-WILSON.RUSS]
Sent: 10/1/2021 8:23:19 AM
To: Aveta, Lillian C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3162b13c17584cf9acf2030a899fe855-LAVETA]; Barnes, Marqui [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=840286c9f7564a5f843e16c3256fc9d5-Marqui.Barn]; Bellows, Lisa M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58f5c667583e486b8bae56b3de9e52d4-LISA.BELLOW]; Bigby, Dynna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d1cb0be4fdc4f0d9c40034d921f9386-Dynna.Bigby]; Boston, Candace [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bd7c7e85e854e1eb39879fd2a462a37-Candace.Bos]; Brewster, Max [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f16800c12fa64aea2f39be15c542dfd-Samuel.Brew]; Brubach, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dae6b9c3a9f04ea9b63a2aea21ed6f-April.Bruba]; Burk, Suzann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83015d2cd30a4c62a4e661ac9324f4ee-BurkS]; Clark, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb97d9a579354688aead63213ec8d999-Jacqueline.]; Cooper, Mildred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa838567ff8147ffb5933a8a698133b0-Mildred.Coo]; Cowley, Cullen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20c212dc5e74432f82aa50d79c43adc1-Cullen.Cowl]; Dal Pan, Gerald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=273ac18eca2349d6996990ea22ab1a5b-DALPANG]; Draski, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25cc39114ea487d8bddbb3b6980e5a4-Laura.Drask]; Emergency Operations Staff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=68ae9e70c9484eb5b6d717b5429ed079-Emergency O]; Enders, Sheryl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3386a081484d45a83b6c542c5d1e5c-Sheryl.Ende]; Eshraghi, Jamshid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10ae511a1ff94e12b1885d7af6206fce-Jamshid.Esh]; Forfa, Tracey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b79fc076db4f989001bd369fd3e61b-TFORFA]; Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz_bohn]; Fritsch, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f441249f9466792973f634fbd5eb0-JFritsch]; Gonzalez, Melissa D. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1e306d790c54966afeb6f98a12a5e43-MGONZALE]; Grant, Leonard D [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8eaf148aaacd45b988b85a507e5bb24e-LGRANT]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Hodges, Garland [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f986d2f719b439885be44a0c306f763-Garland.Hod]; Hollinger, Katherine [Katherine.Hollinger@fda.hhs.gov]; Howard Podewitz, John (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c49755ceb15b49bfa1da45c2205fc4a9-HHS-wco7-cd]; Howard, Jasmine M. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7a89e944c9d43a9a44a50e71f0bbc45-JMR]; Hyder, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=766cd44815cc4c7b8404d864895174bd-HyderJ]; Johnson, Anne E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a4df27f9add402a8e8e2d9d224d1c73-ANNE.JOHNSO]; Kelsey, Leigh

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Subject: September 2021 Monthly FOIA Report

Attachments: A.O. Workload Summary.pdf; September FOIA Monthly Report Memo.pdf; Special Interest Report.pdf; Special Interest Report.xlsx

Good morning,

Attached for your information is a copy of the Special Interest Report and the Workload Summary Report for September 2021. In September 2021, FDA received 773 requests. If you have questions about the report, please contact Sarah Kotler at 301-796-8976.

If you don't wish to receive this email, please feel free to contact me so I may take you off the distribution list.

Thank you,

Wilson M. Russ

Government Information Specialist
Office of the Executive Secretariat
Division of Freedom of Information
U.S. Food and Drug Administration
Tel: 301-796-8981
wilson.russ@fda.hhs.gov



Control #	Privacy	Recd Date	Days Open	From	Due Date	Subject	Status
2021-5744	No	09/02/2021	20	CBS	10/01/2021	Reports from inspections referenced on page 13 of the "Summary Basis for Regulatory Action - Comimaty" (https://www.fda.gov/media/151733/download) for facilities involved in the manufacture of Pfizer and BioNTech's COVID-19 vaccine.	Acknowledgment Letter
2021-5749	No	09/02/2021	3	Carlson School of Management, University of Minnesota	10/01/2021	product recall records for Food, Pharmaceutical, and Medical Devices which includes the date in which the firm first became aware of the defective product, along with all other standard recall data (such as description, firm, recall classification, product classification, etc)	Duplicate Request
2021-5750	No	09/02/2021	20	BLOOMBERG	10/01/2021	Hi-- I am looking for any correspondence between Neuralink, a private medical company, and the FDA. In particular, I am looking for waivers to 21 CFR 812.28 requested by Neuralink.	Acknowledgment Letter
2021-5751	No	09/02/2021	20	PROPUBLICA	10/01/2021	I would like any records surrounding the decision to issue warning language on the patient and provider inserts of the Johnson & Johnson/ Janssen Covid-19 vaccine regarding increased risk for Guillain Barre Syndrome. The warning came on July 13, 2021.	Acknowledgment Letter

2021-5752	No	09/02/2021	20	CONSUMER REPORTS	10/01/2021	I'm requesting access to and copies of the following: - A summary list and count of pet food sample analyses conducted by FDA laboratories only, by laboratory classification (e.g., Adverse Findings) and fiscal year, from FY2016 through FY2020. Please include brand and/or company name, and, for all results with Adverse Findings, the column describing a summary description of the findings.	Acknowledgment Letter
2021-5753	No	09/02/2021	15	CONSUMER REPORTS	10/01/2021	I'm requesting access to and copies of the following: - A summary list of any and all recalls conducted over pet food since Jan. 1, 2004, including whether the recall has been terminated.	Closed
2021-5754	No	09/02/2021	18	CONSUMER REPORTS	10/01/2021	2021-2066, 2021-963, 2021-1048, 2021-1426, 2021-1015, 2021-461	Closed
2021-5755	No	09/02/2021	20	Tobacco-Free Alliance	10/01/2021	Please provide any response letters and closeout letters pertaining to 10 warning letters issued by the FDA's Center for Tobacco Products on July 20, 2020.	Acknowledgment Letter

2021-5762	No	09/02/2021	20	Judicial Watch, Inc.	10/01/2021	All emails sent to and from members of the Vaccines and Related Biological Products Advisory Committee regarding adverse events, deaths and/or injuries caused by investigatory vaccines for the prevention or treatment of SARS-CoV-2 and/or COVID-19 currently produced by Pfizer/BioNTech, Moderna and/or Johnson & Johnson.	Acknowledgment Letter
2021-5767	No	09/02/2021	12	UNIVERSITY OF GEORGIA	10/01/2021	Clinical study efficacy data for NDA 207946 supplement 10. Trial investigating use of paliperidone palmitate every 6 months for treatment of schizophrenia.	Withdrawn Closed w/o Charges
2021-5778	No	09/02/2021	20	CONSUMER REPORTS	10/01/2021	- A summary file, preferably in Excel format, of submissions to the FDA's Pet Food Safety Reporting Portal. For context, I'm referring to this: https://www.fda.gov/animal-veterinary/report-problem/pet-food-safety-reporting-portal-frequently-asked-questions	Acknowledgment Letter

2021-5779	No	09/02/2021	20	LOS ANGELES TIMES	10/01/2021	A copy of any and all e-mails, where the e-mail address(es) attached to the below individuals appear in the to, from, cc and/or bcc line(s): Patrizia Cavazzoni, Janet Woodcock, Elizabeth Miller, Martina H. Varnado, Judy McMeekin and Andi Fristedt; and that contain the following word(s) in the e-mail body and/or subject line(s): ivermectin and/or dewormer and/or horse and/or ivermectin-containing products and/or Fred Wagshul and/or Wagshul etc	Acknowledgment Letter
2021-5780	No	09/02/2021	20	POLITICO	10/01/2021	All communications sent or received by the following officials between Jan. 20 and the date this request is processed that include the words/phrases ivermectin, IVM and/or horse paste: - Acting FDA Commissioner Janet Woodcock - Acting FDA chief of staff Julia Tierney - Patrizia Cavazzoni, director of the Center for Drug Evaluation & Research - etc	Partial Response

2021-5781	No	09/02/2021	20	CONSUMER REPORTS	10/01/2021	I'm requesting access to and copies of the following: - A letter and/or email sent Nov. 23, 2018 by FDA pertaining to S. 2434, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018." For context, the letter I'm referring to is mentioned here: https://truthaboutpetfood.com/senator-rand-paul-destroyed-pet-food-safety/	Acknowledgment Letter
2021-5782	No	09/02/2021	20	CONSUMER REPORTS	10/01/2021	I'm requesting access to and copies of the following: - Any and all internal FDA communications related to the document titled, "Guidance for FDA Staff Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Dog and Cat Food Diets Intended to Diagnose, Cure, Mitigate, Treat, or Prevent Diseases." Please limit the date of the search to include communications between Jan. 1, 2011, and Dec. 31, 2012, including but not limited to emails, meeting minutes, documents, and more.	Acknowledgment Letter
2021-5783	No	09/02/2021	20	CONSUMER REPORTS	10/01/2021	The Form 483 and EIR issued over an inspection of Hill's Pet Nutrition. The Inspection ID is: 1079756. The Inspection End Date is: 2/19/2019. The firm location is: 320 Ne Crane St, Topeka, KS 66603-3613 etc	Acknowledgment Letter

2021-5784	No	09/02/2021	20	LOS ANGELES TIMES	10/01/2021	We ask for a log of email(s) sent and/or received by the email address(es) attached to the following people: Patrizia Cavazzoni, Janet Woodcock, Elizabeth Miller, Martina H. Varnado, Judy McMeekin and Andi Fristedt; and that contains the following word(s) in the body and/or subject line of the e-mail: ivermectin and/or dewormer and/or horse and/or ivermectin-containing products and/or Fred Wagshul and/or Wagshul etc	Acknowledgment Letter
2021-5787	No	09/02/2021	9	VATT Institute for Economic Research	10/01/2021	We request the scans of 8 ANDA approval letters. Two of these ANDA were approved by FDA in 2009 (#77328, #78810), one in 2010 (#76968), two in 2011 (#79160 and #90425), and finally three in 2012 (#76255, #200908 and #202389)	Closed
2021-5788	No	09/02/2021	15	CONSUMER REPORTS	10/01/2021	I'm requesting access to and copies of the following: - The Form 483 and EIR issued over an inspection of Nestle Purina Petcare with the Inspection ID of 1084616. The Inspection End Date is: 3/26/2019. The firm address is: 4502 Packers Ave, Saint Joseph, MO 64504-3531 - Any and all records sent in response by Nestle Purina Petcare over that aforementioned inspection	Closed

2021-5789	No	09/02/2021	13	University of Puerto Rico Medical Sciences Campus	10/01/2021	We would like to have access to the ANDA application package for buprenorfine/n aloxone sublingual films generic formulations submitted by Alvogen, Dr Reddys Labs, Mylan and Indivior. Specifically we would like to have access to the pharmacologic al studies used to evidence the bioequivalenc e of these generic formulations to the brand name drug Suboxone.	Withdrawn Closed w/o Charges
2021-5814	No	09/03/2021	17	Carlson School of Management, University of Minnesota	10/04/2021	Date Range: 01/01/2002 - 05/31/21 For a research study we are conducting, we would like to receive product recall records for Food, Pharmaceutica l, and Medical Devices which includes the termination date, along with all other standard recall data (such as description, firm, recall classification, product classification, etc).	Closed
2021-5824	No	09/03/2021	19	BLOOMBER G NEWS	10/04/2021	I am requesting the resignation and/or retirement letters or electronic communicatio n regarding resignation/ret irement filed by Marion Gruber and Phi Krause. Thank you	Acknowledge ment Letter
2021-5840	No	09/03/2021	19	UNIVERSITY OF ILLINOIS AT CHICAGO	10/04/2021	FDA Review of the Lung Transplant sNDA for Prograf (tacrolimus). The sNDA was approved July 16, 2021 and the Letter and Label were posted but the Review was not posted. 07/16/2021 SUPPL-53 Efficacy-New Indication Label (PDF) Letter (PDF)	Acknowledge ment Letter

2021-5847	No	09/03/2021	19	Insider	10/04/2021	Good morning! I am seeking records that will shed light on the exits of FDA officials Marion Gruber and Phil Krause, and the intra-government dispute over whether to administer COVID-19 booster shots. I am seeking any available emails, recordings, and text messages from Marion Gruber, Phil Krause, and Peter Marks sent to/from: - Rochelle Walensky at the CDC - Anthony Fauci at NIAID - ETC	Acknowledgment Letter
2021-5848	No	09/03/2021	11	The Capitol Forum	10/04/2021	All correspondence between the FDA and the company FibroGen, headquartered in San Francisco, California. For reference, Fibrogen submitted a new drug application for its Roxadustat drug for treatment of anemic of chronic kidney disease, which the FDA has initially denied.	Closed
2021-5871	No	09/07/2021	18	Informed Consent Action Network	10/05/2021	All emails sent or received by Marion Gruber between October 1, 2019 and the date of search that include any of the following terms: SARS-CoV, COVID, COVID-19, coronavirus, vaccine, vaccination, booster, Janssen, Moderna, or Pfizer in any portion of the email, including the body, the subject, metadata, sender line, or recipient line of the email, or in any attachment to the email.	Acknowledgment Letter

2021-5872	No	09/07/2021	18	Informed Consent Action Network	10/05/2021	All emails sent or received by Phil Krause between October 1, 2019 and the date of search that include any of the following terms: SARS-CoV, COVID, COVID-19, coronavirus, vaccine, vaccination, booster, Janssen, Moderna, or Pfizer in any portion of the email, including the body, the subject, metadata, sender line, or recipient line of the email, or in any attachment to the email.	Acknowledgment Letter
2021-5873	No	09/07/2021	18	Informed Consent Action Network	10/05/2021	Each and every email communication between October 1, 2019 and the date of search which includes Marion Gruber or her email address on the To, From, Cc or Bcc line and also includes Peter Marks or his email address on the To, From, Cc or Bcc line.	Acknowledgment Letter
2021-5874	No	09/07/2021	18	Informed Consent Action Network	10/05/2021	Each and every email communication between October 1, 2019 and the date of search which includes Phil Krause or his email address on the To, From, Cc or Bcc line and also includes Peter Marks or his email address on the To, From, Cc or Bcc line	Acknowledgment Letter
2021-5880	No	09/07/2021	17	[no person],	10/05/2021	Conducting research looking at colonic ischemia associated with GLP-1 agonists Case ID include: 16992068 17159619 11163267 6472472 12173502 5935207 7890986 16937115 15578135 6187326 13491060	Closed

2021-5881	No	09/07/2021	18	CONSUMER REPORTS	10/05/2021	I'm requesting access to and copies of the following: - Meeting minutes for the Regulatory Meeting held between FDA and Sabra Dipping Co. on 7/9/2015 - The Form 483 issued for Sabra Dipping Co. on 4/28/2015. The firm address is Colonial Heights, VA 23834-5935	Acknowledgment Letter
2021-5882	No	09/07/2021	18	CONSUMER REPORTS	10/05/2021	I'm requesting access to and copies of the following: - The Form 483 and EIR issued in response to an inspection of Sabra Dipping Co. The inspection ID is #1141600. The inspection end date is 5/6/2021. The firm's FEI is: 3008778303. The firm address is: 15900 Sabra Way, South Chesterfield, VA 23834-5935	Acknowledgment Letter
2021-5887	No	09/07/2021	11	UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN	10/05/2021	Drug inspection classification and citation records; Drug recall records	Closed
2021-5892	No	09/07/2021	18	HARVARD UNIVERSITY	10/05/2021	All documents pertaining to Biogen's aducanumab, specifically but not limited to the Biologics License Application submitted in July 2020.	Acknowledgment Letter
2021-5903	No	09/08/2021	17	STAT News	10/06/2021	Please provide any FDA directed inspection and or investigation requests and reports related to Covid-19 rapid tests that include the following parties: Dr Michael Mina, Citibank, LivePerson, Pasaka Capital, Colby College, and the University of California at San Francisco.	Partial Response

2021-5904	No	09/08/2021	17	STAT News	10/06/2021	We are requesting FDA Center for Devices and Radiological Health's directed inspection/investigation request letter directed to Inova Medical Group regarding rapid Covid-19 tests. We request the documents pertaining to the warning letter dated June 10, 2021, the inspection request that led to the investigation of Inova Medical Group's rapid tests from March 15-April 9, 2021.	Acknowledgment Letter
2021-5905	No	09/08/2021	17	STAT News	10/06/2021	We are requesting the entire submission packet submitted by Xiamen Biotime Biotechnology Co., Ltd, for an Emergency Use Authorization (EUA) for its Covid-19 rapid test kits for used in the United States.	Acknowledgment Letter
2021-5906	No	09/08/2021	17	STAT News	10/06/2021	We are requesting the submission packet filed by Inova Medical Group for an Emergency Use Authorization (EUA) for its Inova Medical Group SARS-CoV-2 Antigen Rapid Qualitative Test.	Acknowledgment Letter
2021-5913	No	09/08/2021	17	PROPUBLIC A	10/06/2021	All 483 and EIR reports associated with Respiroics, Inc. Including but not limited to these addresses: 1001 Murry Ridge Ln, Murrysville, PA 15668. 312 Alvin Dr, New Kensington, PA 15068.	Closed

2021-5916	No	09/09/2021	8	BLOOMBERG NEWS	10/07/2021	I am requesting the FDA Form 483 for an inspection of Teva's drug facility in Irvine, California, that ended on or around August 20, 2021. FEI number 2027158. I would prefer the response to this request be sent electronically via email. Thank you	Closed
2021-5918	No	09/09/2021	17	Program on Regulation, Therapeutics, and Law	10/07/2021	Names of all drugs and biologics that were given a breakthrough therapy designation that was subsequently withdrawn or rescinded. Also, the date the breakthrough therapy designation was withdrawn or rescinded.	Acknowledgment Letter
2021-5957	No	09/09/2021	16	Cameron Oakes (freelance)	09/23/2021	All records from the Office of Criminal Investigations (including but not limited to investigative files, emails, unnamed reports, and memos) from 2020 to present surrounding the circulation of counterfeit HIV medications (including but not limited to Descovy, Symtuza, and Biktarvy) in the U.S.	(b) (5)
2021-5961	No	09/09/2021	16	Judicial Watch, Inc.	10/07/2021	MARION GRUBER, PHIL KRAUSE EMAILS 8/1/21-9/3/21	Acknowledgment Letter
2021-5965	No	09/09/2021	16	SIMPSON UNIVERSITY	10/07/2021	All VAERS reports and documentation for individuals (patients) submitting reports prior to May 10, 2021 for children 15 years old and under who received the COVID19 vaccine	Acknowledgment Letter

2021-5966	No	09/09/2021	11	CONSUMER REPORTS	10/07/2021	I'm requesting access to and copies of the following: - Records released in response to the following FOIA request #s, including the original request: 2019-1342	Closed
2021-5967	No	09/09/2021	11	CONSUMER REPORTS	10/07/2021	I'm requesting access to and copies of the following: - Records released in response to the following FOIA requests, including the original request: 2019-10070, 2020-6401, 2021-4009, 2021-4852, 2021-5617 Please send records in a digital format, preferably by email.	Closed
2021-5988	No	09/10/2021	14	THE HEBREW UNIVERSITY OF JERUSALEM	10/08/2021	Seeking information on the FDA records of the original approved labels of the following FDA NDA approved drugs, including also approval-withdrawn drugs: (1) NDA #007529 ("Quinidine Gluconate"); (2); NDA #007529 SUPPL-10 ("Quinidine Gluconate"); (3) NDA #6-320 ("Quinidine Hydrochloride Injection").	Closed
2021-5997	No	09/10/2021	15	NBC NEWS	10/08/2021	Copy of agenda & attendees of closed opioids FDA meeting to be held today Thursday September 9	Acknowledgment Letter
2021-5998	No	09/10/2021	15	NBC NEWS	10/08/2021	An index of the following email fields (not the body of the email itself) sent to and from Donald D Ashley between 01 July 2021 and the day this request is fulfilled: Sender, date/time, subject header, CC/BCC	Acknowledgment Letter

2021-5999	No	09/10/2021	15	NBC NEWS	10/08/2021	All meeting schedules and calendar entries for 9th September 2021 for the following FDA staff members: Donald D. Ashley; Dr Patrizia Cavazzoni; Janet Woodcock; Daniel Burke	Partial Response
2021-6004	No	09/10/2021	15	Amanda Sturgill, Elon University	10/08/2021	References to the following: @alt_fda or alt_fda or AltFDA or AltFDA In email sent by Scott Gottlieb, MD Anna Abram Douglas C. Throckmorton, MD Stacy Cline Amin Brad Kimberley Heidi Rebello Michael Felberbaum Erica Jefferson	Acknowledgment Letter
2021-6007	No	09/13/2021	9	ET Now	10/12/2021	please send USFDA form 483 of lupin goa facility inspection	Closed
2021-6010	No	09/13/2021	14	CNN	10/12/2021	May we please get access to and copies of all communications between Pfizer Inc. and the Food and Drug Administration regarding Johnson & Johnson's Covid-19 vaccine.	Acknowledgment Letter
2021-6021	No	09/13/2021	14	NBC News National	10/12/2021	Any and all email communication from Marion Gruber, Phil Krause, Peter Marks or Janet Woodcock that contains the words "booster" and/or "vaccine" and/or "data".	Acknowledgment Letter
2021-6028	No	09/13/2021	14	Clint Combs	10/12/2021	The official letter of resignation from Marion Gruber. Gruber was the director of Office of Vaccines Research.	Acknowledgment Letter

2021-6045	No	09/14/2021	8	Lindsay Gellman	10/13/2021	1) Any records of communication between FDA and the Utah-based supplement maker Lifevantage Corp. or its representatives, including but not limited to emails, mail correspondence, records of phone calls, meeting notes 2) Any complaints made to FDA that mention or pertain to Lifevantage Corp., its products, or distribution systems such as websites etc	Closed
2021-6074	No	09/14/2021	13	Axios	10/13/2021	Copies of all communications including but not limited to phone calls, emails, text messages, and written memorializations of any conversations or communications to, from, or copying Timothy Stenzel, the Director of the Office of In Vitro Diagnostics and Radiological Health, related to FDA consideration, approval, or authorization of any COVID-19 antigen tests.	Acknowledgment Letter

2021-6075	No	09/14/2021	7	Axios	10/13/2021	Copies of all ethics and financial disclosure paperwork filed by, about, or on behalf of Timothy Stenzel, currently the Director of the Office of In Vitro Diagnostics and Radiological Health at the FDA, including but not limited to: annual personal financial disclosure filings, periodic financial transaction reports, ethics agreements, certifications of ethics agreement complaint, and documentation related to any waivers granted to provisions of 18 U.S.C. 208, 5 CFR 2635.502, Executive Order 13989, or Executive Order 13770.	Closed
2021-6094	No	09/15/2021	12	BLOOMBERG NEWS	10/14/2021	I am requesting individual case reports for each of the following adverse event cases reported in the FAERS public dashboard, pertaining to the drug, Oxbryta	Acknowledgment Letter
2021-6106	No	09/16/2021	12	Reuters News	10/15/2021	I request all notes and correspondence discussing publicly available data in a specific section of the FDA's pharmacology review of application 20-829 for Singulair	(b) (5)

2021-6144	No	09/17/2021	11	CONSUMER REPORTS	10/18/2021	I'm requesting access to and copies of the following: - A copy of this document, which are remarks delivered by FDA's Steven Solomon: https://truthaboutpetfood.com/wp-content/uploads/2019/09/Solomon-speech-2018-8268_CVM-Complete-Response_EN_C.pdf	Acknowledgment Letter
2021-6145	No	09/17/2021	9	CONSUMER REPORTS	10/18/2021	I'm requesting access to and copies of the following: - The most recent "Official Publication" by the Association of American Feed Control Officials. For reference, the publication I'm talking about is described here: https://www.aafco.org/Publications	Closed Denial
2021-6147	No	09/17/2021	11	Quinn Eastman	10/18/2021	All releasable clinical review documents for Xywav (New Drug Application 212690, SUPPL-6) pertaining to the supplementary application for the indication of idiopathic hypersomnia, which was approved by FDA in August 2021.	Acknowledgment Letter
2021-6175	No	09/17/2021	10	POLITICO	10/18/2021	I request all records of communication between Prabhakara Atreya and/or Kathleen Hayes and members of the FDA Vaccines and Related Biological Products Advisory Committee about Covid-19 booster shots. Please include emails, documentation of any phone calls and in-person meetings, as well as lists of participants in any of those calls and meetings.	Acknowledgment Letter

2021-6176	No	09/17/2021	10	POLITICO	10/18/2021	I request all records of communication between Prabhakara Atreya and/or Kathleen Hayes and members of the FDA Vaccines and Related Biological Products Advisory Committee about Covid-19 vaccines for children. Please include emails, documentation of any phone calls and in-person meetings, as well as lists of participants in any of those calls and meetings.	Acknowledgment Letter
2021-6177	No	09/17/2021	10	POLITICO	10/18/2021	I request all records of communication between acting Commissioner Janet Woodcock, CBER Director Peter Marks and CDC Director Rochelle Walensky on the Biden administration's plan to provide booster doses of Covid-19 vaccines. etc	Acknowledgment Letter

2021-6178	No	09/17/2021	10	POLITICO	10/18/2021	I request all records of communication involving Philip Krause and Marion Gruber on the Biden administration's plan to provide booster doses of Covid-19 vaccines. Please include all relevant emails sent or received by Krause or Gruber and others within FDA (including Peter Marks and Janet Woodcock) on this subject, as well as communications between Krause and Gruber. Please include emails, documentation of any phone calls and in-person meetings, as well as lists of participants in any of those calls and meetings.	Acknowledgment Letter
2021-6189	No	09/20/2021	4	University of Massachusetts Amherst	10/19/2021	I would like the full genetic sequence of the attenuated Salmonella typhimurium variant VNP20009 as used in clinical trials NCT00006254, NCT00004216, and NCT00004988. If possible, I would also like the area around the msbB gene deletion to be highlighted. Though if that is not possible the full sequence alone is fine.	Withdrawn Closed w/o Charges
2021-6201	No	09/20/2021	3	Education for All	10/19/2021	483 issued to Lupin Goa India.	Closed
2021-6208	No	09/20/2021	3	ET Now	10/19/2021	Form 483 for Lupin GOA India inspection	Closed

2021-6219	No	09/20/2021	7	Linda Bonvie	10/19/2021	Email and written correspondence both to and from the FDA's Office of Editorial and Creative Services AND the FDA's Web and Digital Services Staff that contain the word "ivermectin."	Closed
2021-6246	No	09/21/2021	3	BloombergQuint	10/20/2021	Request for sharing Lupin Ltd's Goa facility inspection report. The inspection at Goa, India's facility was carried out from September 6, 2021 to September 18, 2021 and closed with seven observations.	Closed
2021-6250	No	09/21/2021	8	Childrens health defense	10/20/2021	We seek all email communications between Marion Gruber, former Director of FDA's Office of vaccine research and Phil Krause, former OVRD Deputy director, who resigned recently. Please disclose all emails, correspondence, or communications of any kind since January 1 2020.	Acknowledgment Letter
2021-6251	No	09/21/2021	5	CONSUMER REPORTS	10/21/2021	I'm requesting access to and copies of the following: - Any and all records released in response to any and all FOIA requests made since Jan. 1, 2017 by "Harrington Films," including the original requests	Closed

2021-6253	No	09/21/2021	8	UNIVERSITY OF FLORIDA	10/20/2021	1. Historical information on medical device recalls associated with all medical devices approved during the period of 1980-2021 (most recent). Please include every item in the recall database.	Acknowledgment Letter
2021-6281	No	09/21/2021	8	POLITICO	10/20/2021	I'd like to request any background materials and decision memos that were created by the FDA in response to the request to create a program for personal drug importation from Canada.	Acknowledgment Letter
2021-6286	No	09/22/2021	1	University of Massachusetts Amherst	10/21/2021	The list of pharmaceutical drugs and their active ingredients combine with demographics data of the reporters that reported the cases of dysgeusia, taste disorder, or that the product taste abnormal. Specifically, the products that taste bitter/metallic or that the reporters have the symptom of metal mouth.	Withdrawn Closed w/o Charges
2021-6310	No	09/22/2021	7	Animal Outlook	10/21/2021	Records re: Blue Ridge Beef (also known as Lea Way Farms), 417 Garden Valley Rd, Statesville, North Carolina 28625	Acknowledgment Letter
2021-6311	No	09/22/2021	7	UNION OF CONCERNED SCIENTISTS	10/21/2021	COMMUNICATIONS RETIREMENT OF DR MARION GRUBER ETC	Acknowledgment Letter
2021-6342	No	09/23/2021	6	America's Frontline Doctors	10/22/2021	All internal FDA communications regarding any control group for the investigational trials for Pfizer BioNTech vaccine from the inception of the trials to the present.	Acknowledgment Letter

2021-6343	No	09/23/2021	6	Albuquerque Neuroscience, Inc.	10/22/2021	Requesting all documents from Clinical Investigator Inspection from 12/16/1986 as well as all information for FDA Disqualification proceedings for NIDPOE issued 5/4/1989 and restriction removal on 7/24/2007 for William K. Summers, MD (Investigator ID # 55878.	Acknowledgment Letter
2021-6380	No	09/24/2021	1	NYCity News Service	10/25/2021	I request all electronic and print submissions reporting products being sold as a therapy for infertility from the following databases - MedWatch, both FDA Form 3500 and Form 3500B - Reporting Unlawful Sales of Medical Products on the Internet - Safety Reporting Portal. Additionally, I request a copy of every Form FDA 483 and Warning Letter issued to companies illegally selling dietary supplements that claim to cure, treat, mitigate, or prevent infertility.	Closed
2021-6386	No	09/24/2021	5	Informa/Natural Products INSIDER	10/25/2021	I am requesting a copy of any technical assistance FDA has provided to Congress on draft or pending legislation in 2021 year to date regarding dietary supplements, including but not limited to the following issues: CBD and mandatory product listing.	Acknowledgment Letter
2021-6401	No	09/27/2021	5	ET Now	10/26/2021	USFDA FORM 483 FOR INDIA HETERO DRUGS INSPECTION	Acknowledgment Letter

2021-6406	No	09/27/2021	4	The Canine Review	10/26/2021	Big Creek Foods (near Atlanta): All available records, including inspection reports, 483's, consumer complaints, inspection notes between 2016-2021 - Simmons Foods, Kingfisher: All available records, including inspection reports, 483's, consumer complaints, inspection notes between 2016-2021 - Glacial Biotics: All available records, including inspection reports, 483's, consumer complaints, inspection notes between 2016-2021	Acknowledgment Letter
2021-6407	No	09/27/2021	4	UNIVERSITY OF ILLINOIS AT URBANA CHAMPAIGN	10/26/2021	I am requesting the recall awareness dates as mentioned in the document https://www.fda.gov/media/71814/download on page 51 under Section 7. Firms Recall Strategy (RES Event Details page) for all Medical Device recalls and Pharmaceutical Drug recalls from Jan 01, 2000 and September 23, 2021, or whatever date ranges this data is available for.	Acknowledgment Letter
2021-6408	No	09/27/2021	4	Physicians for Informed Consent	10/26/2021	Please provide an FDA document that discloses the COVID-19 vaccine ingredient that is redacted on Table 2 (the last ingredient 0.45 mL listed in the table). https://www.fda.gov/media/151733/download Please provide all documents relating to why this ingredient was redacted from the table rather than disclosed to the public.	Acknowledgment Letter

2021-6413	No	09/27/2021	4	Insider, Inc.	10/26/2021	Copies of all customer complaints about Amazon's Fresh grocery, pharmacy, and other food produce that were submitted since September 2018.	Acknowledgment Letter
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From: vinu arumugham (b) (6)
Sent: 8/12/2020 8:46:55 PM
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Subject: Current COVID-19 vaccines are already known to be unsafe; "as safe as they can be" is UNACCEPTABLE.

All,

Regarding:

<https://www.medpagetoday.com/primarycare/vaccines/88030>

https://www.washingtonpost.com/health/coronavirus-vaccine-approval-decider/2020/08/11/7c6fb7a0-d8f1-11ea-930e-d88518c57dcc_story.html

"Our job is to do our best, and to deal with the first wave of vaccines that are coming through and make sure they are as safe as they can be," Marks, a 57-year-old Brooklyn native, told the Post.

"There are no circumstances under which the FDA would allow a vaccine to be released for use by the public if it is not shown to be safe," Hahn said.

NONE of the current vaccines were DESIGNED for safety. No FMEA has been published for ANY them. So they are UNSAFE BY DEFINITION. It is impossible for such vaccines to be "shown to be safe". So, as Hahn said, there are no circumstances under which the FDA can approve ANY these vaccines.

Peter Marks wants to lower the bar with "as safe as they can be". UNACCEPTABLE. They need to be as safe as they SHOULD BE. They are not. We already know that. If ANY of these vaccines are approved, that is politics and money speaking, NOT safety.

[https://omnij.org/Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial](https://omnij.org/Safety_and_immunogenicity_of_the_ChAdOx1_nCoV-19_vaccine_against_SARS-CoV-2:_a_preliminary_report_of_a_phase_1/2,_single-blind,_randomised_controlled_trial)

Regarding,

An mRNA Vaccine against SARS-CoV-2 — Preliminary Report

<https://www.nejm.org/doi/full/10.1056/NEJMoa2022483>

Severe reaction was observed in 3 participants following the second dose.

This is a textbook case of sensitization by first dose. Elicitation by second dose. An IgE mediated hypersensitivity reaction.

This **CANNOT** be dismissed as just a dose issue and that only lower doses will be used. The reason is, upon real world virus exposure, there is no exposure dose control. These participants may develop life-threatening reactions. This has been documented in previous SARS vaccines. It is **CRIMINAL** that this team is glossing over this fundamental safety problem.

In fact, severe COVID-19 is caused by this same mechanism. Coronavirus-like proteins that contaminate vaccines caused allergic sensitization. Upon exposure to the virus the allergic reaction causes severe COVID-19. That is why histamine blockers such as cetirizine and famotidine help in COVID-19.

Immunological mechanisms explaining the role of IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines, Vitamin C, hydroxychloroquine, ivermectin and azithromycin

<https://doi.org/10.5281/zenodo.3748303>

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms

<https://www.researchsquare.com/article/rs-30934/v2>

At a minimum, the team should have measured specific IgE directed at protein(s) encoded in (and contaminating) the vaccine. They report no such thing. They report specific IgG which is not sufficient. They have to break down specific IgG1,2,3,4 subclass levels. They have to report how the severe reaction was treated.

This whole idea of depending on testing alone for safety, is **INCREDIBLY STUPID**.

The U.S. Consumer Product Safety Commission (CPSC) says: **Design is the dominant influence on product safety. Product safety starts in the mind of the product designers.** If all the elements of manufacturing were ranked in order of their potential effect on consumer product safety, the **design function would lead the list.** Additionally, design importantly affects subsequent decisions and practices related to materials, production, testing, processes, labeling, packaging and distribution.

Vaccine safety: Learning from the Boeing 737 MAX disasters

<https://doi.org/10.5281/zenodo.2648251>

Safety engineering dictates that vaccines must be DESIGNED and design FMEA (Failure Modes and Effects Analysis) must be published BEFORE any testing in trials.

It is impossible to establish long term safety in a 3 month trial. YOU HAVE TO **DESIGN FOR SAFETY**, you CANNOT just **TEST FOR IT**.

You have learned NOTHING from the Pandemrix induced narcolepsy disaster.

Pandemrix and Arepanrix vaccine safety analysis and scrutiny fell short

<https://www.bmj.com/content/363/bmj.k4152/tr-14>

Pharmacovigilance is no substitute for good vaccine design

<https://www.bmj.com/content/362/bmj.k3948/tr-11>

No vaccine can be approved without publishing FMEA and **FIXING ALL IDENTIFIED DESIGN ISSUES**.

Thanks,

Vinu

BNT162b1 vaccine development is fundamentally flawed, the trials are invalid and the safety claims are laughable

Lack of Design for Safety

Vaccines must be designed not developed using trial and error as is the case for BNT162b1. Among the first steps during design is publishing design FMEA (Failure Modes and Effects Analysis). This team has **utterly failed** since there is no FMEA published before going into trial. Without FMEA, a proper trial cannot be designed. All failure modes need to be identified. Only then we can test in the trial if the design has successfully avoided the failure modes.

U.S. Consumer Product Safety Commission (CPSC) says:

“**Design** is the dominant influence on product safety. **Product safety starts in the mind of the product designers**. If all the elements of manufacturing were ranked in order of their potential effect on consumer product safety, **the design function would lead the list**. Additionally, **design importantly affects subsequent decisions** and practices related to materials, production, **testing**, processes, labeling, packaging and distribution.”

Vaccine safety: Learning from the Boeing 737 MAX disasters

<https://doi.org/10.5281/zenodo.2648251>

Lack of testing for de novo IgE synthesis directed against vaccine antigens

The vaccination can result in IgE mediated sensitization to the RBD antigen. The Moderna mRNA vaccine failed by doing exactly that. Causing IgE mediated sensitization directed against the vaccine antigen. 3 of 45 recipients therefore predictably suffered severe allergic reaction following the second dose. A textbook case of sensitization followed by elicitation - a type 1 hypersensitivity reaction. You cannot escape by talking about vaccine antigen dose. Vaccine-induced protection is usually short term. IgE is long-term persistent. So recipients can develop severe COVID-19 due to the allergic reaction since vaccine-induced protection has waned. Exactly same failure as the Dengvaxia disaster. You cannot control the RBD antigen dose during a SARS-CoV-2 infection.

www.statnews.com/2020/05/26/moderna-vaccine-candidate-trial-participant-severe-reaction/

Lack of autoimmune serology

You have not performed autoimmune serology to check for vaccine-induced de novo autoimmune disorders.

You excluded individuals with autoimmune disease (AD)? How did you do that? Obesity is AD. Heart disease is AD. Type 2 diabetes is AD. How did you detect subclinical AD?

Vaccines and Biologics injury table based on mechanistic evidence – Feb 2020 Covering over 125 conditions
<https://doi.org/10.5281/zenodo.2582634>

The insanity of completely relying on testing

You are insanely relying on testing alone to check for safety problems. You follow-up for 2 months, you MAY catch problems that show up in two months. You test for 2 years, you MAY catch problem for that duration. How do you catch say vaccine-induced type 1 diabetes that shows up after 15 years? Run a trial for 15 years? You should stop this insanity.

The Biontech/Pfizer vaccine development process is fundamentally flawed, the trials are invalid and the safety claims are laughable.

You need to go back to the drawing board. Per CPSC, your vaccine is **UNSAFE BY DEFINITION** because you lacked a design process.

Obviously, having learned **NOTHING** from the Pandemrix induced narcolepsy disaster, you are proceeding at warp speed to create the next humongous disaster.

Pandemrix and Arepanrix vaccine safety analysis and scrutiny fell short

www.bmj.com/content/363/bmj.k4152/rr-14

Pharmacovigilance is no substitute for good vaccine design

www.bmj.com/content/362/bmj.k3948/rr-11

Vinu

Regarding,

[www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31208-3/fulltext#%20](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31208-3/fulltext#%20)

1. You have a **fundamental design safety flaw**. You will cause IgE mediated sensitization to adenovirus proteins. So otherwise harmless adenovirus infections will now become life-threatening. This is exactly the same problem as COVID-19 where harmless coronavirus (CV) has become life-threatening due to IgE mediated sensitization using dirty, CV protein contaminated, infected animal derived vaccines.

Root cause of COVID-19? Biotechnology's dirty secret: Contamination. Bioinformatics evidence demonstrates that SARS-CoV-2 was created in a laboratory, unlikely to be a bioweapon but most likely a result of sloppy experiments

<https://doi.org/10.5281/zenodo.3766462>

That is why allergy medications such as histamine H1/H2 blockers (cetirizine/famotidine) help in COVID-19.

Immunological mechanisms explaining the role of IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines, Vitamin C, hydroxychloroquine, ivermectin and azithromycin

<https://doi.org/10.5281/zenodo.3748303>

As I have been predicting for 3+ months, there is now evidence that Famotidine (antihistamine, H2-blocker) helps in COVID-19. Study below. The mechanism involved is explained above.

Famotidine Use is Associated with Improved Clinical Outcomes in Hospitalized COVID-19 Patients: A Retrospective Cohort Study

<https://www.medrxiv.org/content/10.1101/2020.05.01.20086694v1>

2. You need to publish EVERY contaminant in your vaccine and design FMEA.

Your dirty, contaminated Wuhan lab created the SARS-CoV-2 virus. Don't expect anyone to believe your vaccines are clean.

3. Why do you think your vaccine will not fail the same way as Dengvaxia did?

Irrational dengue vaccine designs that ignore IgE and IgG4 mediated effects are destined to follow in Dengvaxia's disastrous direction?

<https://doi.org/10.5281/zenodo.1476291>

4. Example of the type of homework you need to do before making ANY claims of vaccine safety.

ERVEBO Ebola vaccine will create a rice allergy epidemic, add to numerous autoimmune diseases, cancer and make Ebola disease even more severe. Design for safety and vaccine safety regulation remain abject failures. Incompetence or indifference?

<https://doi.org/10.5281/zenodo.3595020>

Thanks,

Vinu

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sales.qld@epochtimes.com.au; sales_vic@epochtimes.com.au; sales.wa@epochtimes.com.au;

ad@epochtimes.com.au; ept-malaysia@epochtimes.com; nz@epochtimes.com; office@epochtimes.de; courrierdeslecteurs@epochtimes.fr; service@epochtimes.com.tw; edt@epochtimes.com.hk; (b) (6) xiao@djy.co.jp; swis@indo.net.id; feedback@epochtimes.com.sg; Slater, Jay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2b00a57b0a747a9bc4f2317937a1022-slaterj]; Woo, Jane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f70d0e3a7aa442fb4962b61dde9894b-Woo]; Hess, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Walderhaug, Mark O [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14515448efee47098c38798d5c409b02-MWALDERH]; CBER OCOB Consumer Account [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6d1fb37325043bcbe25183a0aaece3c-CBEROCOD]; DeStefano, Frank (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a799ec222e8741e988566e6141cbf1ba-HHS-fox1-cd]; Thompson, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b2302812fa541759657b0569509577d-HHS-isq8-cd]; Messonnier, Nancy E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3db273e5a524ff690738a633d2c15de-HHS-nar5-cd]; Walker, Tanja Y (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn= (b) (6) Secretary@HHS.gov; Commissioner FDA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn= (b) (6) Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn= (b) (6) directorsincoming@cdc.gov; francis.collins@nih.gov; mrolfes1@cdc.gov; xzd2@cdc.gov; Blanton, Lenee H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9af6c9acc0f6462e9ec15ac743cdcbc7-HHS-acy9-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Katz, Jacqueline M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e8bf32a5224c5faa0b2a8c208b31e0-HHS-jmk9-cd]; Tumpey, Terrence M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21ce7e7681c44913862a0b4829d19df6-HHS-tft9-cd]; Wentworth, David E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c0bcb905b046c28f7e56cd5f2c54f5-HHS-gli9-cd]; sharplessne@nih.hhs.gov; Clark, Thomas A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7654dd7010c34f819e1e2eb29bcc86d1-HHS-tnc4-cd]; Kretsinger, Katrina (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e123d287c55c449d84c4e5dcafb80a33-HHS-kok4-cd]; Linkins, Robert (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ac11517f634867818d7a8882a915a1-HHS-rlx3-cd]; Epperson, Scott (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=884f3347a42048deb11c01980becbc2-HHS-gbq7-cd]; Andes, Linda (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7f7897f96c74f229c4795e534d64f17-HHS-fwf7-cd]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn= (b) (6) rburke@cdc.gov; Walke, Henry (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5177bdc372504f2a81c595838af26e3b-HHS-hfw3-cd]; Yang, Quanhe (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be02c99e79784b699c0ca9056efaf6d4-HHS-qay0-cd]; Dawood, Fatimah S (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58641a45c9ed4bef84ba434e5a685af8-HHS-hgj0-cd]; Braden, Christopher R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b887b037ba8e4940a4ba50173d530c5f-HHS-crb5-cd]; chung@cdc.gov; Chumakov, Konstantin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38b94ccd62474755ae952ea31fa71e6e-Chumakov]; Patel, Manish (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ed9deb67f7548b88a0c7d0afcaeb567-HHS-aul3-cd]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn= (b) (6) Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Birx, Deborah L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2e45952d70d4e2d84d839843f3cda9f-HHS-emg5-cd]; (b) (6) Hepburn, Matt (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=68c7e72407d94642b6e0761db308888-HHS-Matt.He]; Slaoui, Moncef (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=927359946fba418bbe88165cbde8d8ad-HHS-Moncef.]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; katherine.donegan@mhra.gsi.gov.uk; philip.bryan@mhra.gsi.gov.uk; Alasdair.Breckenridge@mhra.gsi.gov.uk; anna.radecka@mhra.gsi.gov.uk; ian.hudson@mhra.gsi.gov.uk; June.Raine@mhra.gsi.gov.uk; dmrc@mhra.gsi.gov.uk; info@mhra.gsi.gov.uk; newscentre@mhra.gsi.gov.uk; RIS.NA@mhra.gsi.gov.uk; whistleblower@mhra.gsi.gov.uk

Subject: Recruit the criminal to investigate his own crime. Genius. The Lancet has now proved that the "conspiracy theorists" are correct.

All,

Regarding:

Scientists to examine possibility Covid leaked from lab as part of investigation into virus origins

<https://www.telegraph.co.uk/global-health/science-and-disease/scientists-examine-possibility-covid-leaked-lab-part-investigation/>

Lancet COVID-19 Commission Statement on the occasion of the 75th session of the UN General Assembly

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31927-9/fulltext#%20](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31927-9/fulltext#%20)

The Lancet has shown us that they don't have an open mind. They already jumped to their conclusion by publishing this piece of garbage, denying lab origin:

Statement in support of the scientists, public health professionals, and medical professionals of China combatting COVID-19

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)30418-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30418-9/fulltext)

So that WAS a lie. Otherwise why is lab origin being "investigated" again now?

Richard Horton already told us that he specializes in publishing garbage:

Skeptical of medical science reports?

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4572812/>

"... Richard Horton, editor of *The Lancet*, wrote that "The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness" (2)."

With the Surgisphere/HCQ fiasco, we know The Lancet is plumbing new depths.

As if that were not bad enough, The Lancet COVID-19 commission appoints the criminal who is at least partly responsible for COVID-19, to "investigate" this crime. Peter Daszak is the insane criminal who used my taxdollars to collect coronaviruses from wild bats in remote areas, transport them thousands of miles and deposited them in leaky, sloppy, Chinese labs located within a city of 11 million.

COVID-19 is proof Daszak's work not only FAILED to PREVENT pandemics, it CREATED one.

We know exactly how SARS-CoV-2 originated.

Root cause of COVID-19? Biotechnology's dirty secret: Contamination. Bioinformatics evidence demonstrates that SARS-CoV-2 was created in a laboratory, unlikely to be a bioweapon but most likely a result of sloppy experiments

<https://doi.org/10.5281/zenodo.3766462>

Coronavirus may have been a 'cell-culture experiment' gone wrong

<https://www.skynews.com.au/details/6158843835001>

SARS-CoV-2 is well adapted for humans. What does this mean for re-emergence?

<https://www.biorxiv.org/content/10.1101/2020.05.01.073262v1>

It grew on human embryonic kidney cells in a Wuhan lab. Is it a surprise that it is well adapted for humans?

So The Lancet and the commission of liars and criminals obviously have zero credibility to start with but they expect us to trust their "investigation". Clowns.

We will rip your pretend science to shreds. Count on it.

Vinu

From: Steve Kirsch [stk@skirsch.com]
Sent: 9/1/2021 9:03:45 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Jessica Rose [REDACTED] (b) (6)]; Mathew Crawford [REDACTED] (b) (6)]
Subject: [EXTERNAL] Vax kills more people than COVID... whoops.
Attachments: ACIP comment 8-30-21.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

See attached comment submitted to ACIP (which of course they didn't read).

I've reached out for comment from FDA people, but no response. 😞

If I'm wrong and someone at FDA can show the error(s) I'm happy to change it.

Otherwise, I'll publish it on TrialSiteNews under my name.

It was fascinating to learn that VAERS is more definitive than the autopsies. The doc explains why.

Your team is really underestimating the power of the VAERS database. Even with all its flaws, it is rich in signal if you know how to use it.

-steve

Comment to ACIP meeting of August 30, 2021 submitted by

Steve Kirsch

Executive Director of the COVID-19 Early Treatment Fund
stk@treatearly.org

September 1, 2021

NOTE:

1. This document is an updated version of the [original August 29, 2021 filing](#).
2. If you are viewing a PDF version of this document, the most up-to-date version is [here](#).

ABOUT ME

I am the founder of the COVID-19 Early Treatment Fund (www.treatearly.org). Our work in [funding early treatments for COVID was featured on 60 Minutes](#).

I have been vaccinated and my entire family has been vaccinated.

However, shortly after I was fully vaccinated, I began to hear stories from my friends that were very troubling. For example, one friend had three relatives who were formerly healthy die after getting the vaccine. Another friend had a heart attack 2 minutes after the injection and is now disabled, apparently for life.

I assembled a team of over 19 doctors and scientists listed at the end of this comment to investigate the available evidence.

OUR FINDINGS

Using the VAERS database and other official government data sources from the US and around the world (covering 35% of the world's population), we found evidence that clearly demonstrates that the current vaccines are significantly more dangerous than has been previously believed.

Our most important findings include:

1. The "real world" fatality data from VAERS does not match the fatality data from the Phase 3 trials. They aren't even close. Using multiple independent methods from independent researchers, we show that it is extremely likely that **over 150,000 Americans** have already been killed (see [Attachment 2](#)). Even with a \$1M reward to academics to spot an error in the analysis, there were no takers. It is urgent to resolve

From: Steve Kirsch [stk@skirsch.com]
Sent: 8/2/2021 2:24:04 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: [EXTERNAL] my latest article. "why people are refusing to get vaccinated"
Attachments: Why so many Americans are refusing to get vaccinated.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

No problem. Attached as PDF. I'll wait to hear from you on any errors before publishing, but it's basically an opinion piece explaining our thinking process. But if there is anything wrong or misleading, i'm happy to fix it before it is published.

I think it will help you to understand why our group feels the way we do, so I think that will be helpful. You might even agree with a few of the points!

-steve

> -----Original Message-----

> From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
> Sent: Monday, August 2, 2021 5:51 AM
> To: Steve Kirsch <stk@skirsch.com>
> Subject: RE: [EXTERNAL] my latest article.. for TSN on Monday "50 reasons why smart people are refusing to get vaccinated"

> I don't think our security will let me access the page. Janet W

> -----Original Message-----

> From: Steve Kirsch <stk@skirsch.com>
> Sent: Sunday, August 1, 2021 8:45 PM
> To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
> Subject: [EXTERNAL] my latest article.. for TSN on Monday "50 reasons why smart people are refusing to get vaccinated"

> CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

> Janet,

> I've been working the last week on an article that explains why people are vaccine hesitant.

> I think you should read the first 20 pages but feel free to read the whole thing. The CDC might find it useful since it shows how they can convince the vaccine hesitant

> The plan is to release this Monday.

> Let me know if you see any mistakes or would like to respond to any points.

> Happy to correct them and insert your responses.

> <https://docs.google.com/document/d/1AD01L3Rm41DExo4q7McBxeeHOq08bcWwerlGu7YJubQ/edit#>

> We are willing to meet with CBER and/or CDC any time.

> If we are wrong, we are happy to correct the info, but so far, all the info we get is confirmatory.

> -steve

Why so many Americans are refusing to get vaccinated

By VaccineTruth

Anthony Fauci says he doesn't understand why so many Americans are refusing to get vaccinated.

Recent news articles have looked at the issue of vaccine hesitancy. A *New York Times* front page article, [Who Are the Unvaccinated in America? There's No One Answer](#), examined why people refuse to be vaccinated. A recent [MIT study found that the people who refuse vaccination are among the most well informed people in America](#).

We wanted to explain to other Americans our reasons for refusing to get vaccinated. Our position is based on facts, scientific evidence, and making reasonable estimates. We are not trying to convince you we are right; we are just offering to share with you **why** we feel the way we do and how we got there. If our conclusions are wrong, please let us know.

Here are some of the most important reasons we are declining to be vaccinated with the current vaccines:

1. **Early treatment is far safer and far more effective than any vaccine:** Early treatment protocols offer up to 99.76% risk reduction, early treatments never kill or maim you, and *you only have to be treated if you get the virus*.
2. **We don't want to die:** For people under 50, the current COVID vaccines kill more people than they save. For example, based upon the numbers in the latest CDC report and data from the Israeli Ministry of Health, we explain below how we calculated that vaccines are 9 times more likely to kill kids under 17 than to save them. We have five different ways to estimate that **over 150,000 people have been killed** so far from the vaccine (doctor surveys, public surveys, pilot death data, VAERS multiplier estimates, official country death data; see [Vaccine Safety FAQ](#) for the details on each of these methods). They all consistently show a death tally of 150,000 or more. Here's [our most recent estimate](#). Our infection fatality rate (IFR) shift analysis is coming in a few days and that should be very convincing.
3. **The vaccines provide no significant benefit anymore:** The vaccines are nearly useless against preventing Delta infections. Data from the UK, Singapore, and Israel all show that the percentage of people vaccinated is the same percentage as the people getting COVID, so it no longer provides protection. As we show below, the latest data out of Israel also shows that vaccination increases the chance of severe disease which is exactly the opposite of what was promised. In addition, the absolute risk reduction is miniscule.
4. **The vaccines are extremely risky because they were never properly tested:** FDA insiders admit that the FDA made a crucial mistake by regulating the vaccines as

From: h.rees@pharmaflowltd.com [h.rees@pharmaflowltd.com]
Sent: 5/14/2021 7:08:08 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: [EXTERNAL] UK Initiative on COVID-19 - brief update
Attachments: BIRD Proceedings final.pdf

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Dear Janet,

Again, sending the attached privately, in case it may or may not be of interest. Also, a link to a recent press release from the Front Line COVID-19 Critical Care Alliance:

<https://covid19criticalcare.com/videos-and-press/flccc-releases/flccc-alliance-statement-on-the-irregular-actions-of-public-health-agencies-and-the-widespread-disinformation-campaign-against-ivermectin/>

If you are curious why I am following this, it's because the 'ROADMAP TO A BETTER FUTURE' has Healthcare professionals, along with patients, front and center of drug development.

In the same way pilots are crucial in developing aircraft (and making sure they are safe for passengers), physicians/doctors/clinicians should undertake an analogous role in medicines (IMHO). Jenner, Banting et al, Fleming, Salk, were all medically qualified – and that is not the case today.

Me thinks the integration of the CPI, GMPs for the 2st Century and the principles of evidence based medicine would be a potent combination, along with a strategic approach to building supply chains to patient markets.

Hope all is still good.

Kind regards,

Hedley

:>)

Sent from my iPhone

On 11 May 2021, at 17:40, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

Thanks! You've been productive. Janet W

From: h.rees@pharmaflowltd.com <h.rees@pharmaflowltd.com>
Sent: Tuesday, May 11, 2021 12:14 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: [EXTERNAL] UK Initiative on COVID-19

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Thanks Janet – good to hear you are driving it – there seems to be a growing body of evidence out there now!

All good here, hope same with you.

Really believing now that COVID has raised public awareness of the crucial importance of the manufacturing supply chain in properly satisfying the needs of patients for safe, effective, high quality (and affordable) drugs. I have covered your work in the final chapter of *What Patients Need to Know About Pharmaceutical Supply Chains*, titled 'ROADMAP TO A BETTER FUTURE'.

Drug Development for Research Scientists is next on the agenda – hopefully you will consider contributing some thoughts, short or long as you like?

Finally, Industrial Pharmacy kindly published a two part article of mine on COVID supply chains in the last fall, see both editions here:

Part 1 <https://www.dropbox.com/s/edbj61w6opl95j2/IP66%20FIP%20Sept%202020.pdf?dl=0>

Part 2 https://www.dropbox.com/s/2v2rfcz1pq8oyue/IP67_2_FIP.pdf?dl=0

That's it from me!

With kind regards,

Hedley

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: 11 May 2021 15:50

To: h.rees@pharmaflowltd.com

Subject: RE: [EXTERNAL] UK Initiative on COVID-19

Thanks, ACTIV at FNIH/NIH at my urging is launching a large simple trial with ivermectin as the first agent. Hope you are well. jw

From: h.rees@pharmaflowltd.com <h.rees@pharmaflowltd.com>

Sent: Tuesday, May 11, 2021 5:53 AM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: [EXTERNAL] UK Initiative on COVID-19

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Janet,

This may be of no interest whatsoever, and this is just an informal observation for you to ignore as you see fit.

As I have been developing patient-physician focussed models of drug development (aligned with the CPI), I happened across this initiative [here](#). The lady behind it is Tess Lawrie. I had a Zoom call with her today and she has some very interesting ideas on building evidence of a drugs' potential in terms of safety, efficacy and quality.

I will leave that with you in case the initiative that Tess is fronting would be useful information within FDA.

With kind regards,

Hedley

Hedley Rees

Managing Consultant PharmaFlow Ltd

T: +44 1656 655664

M: (b) (6)

Author

Book: *Supply Chain Management in the Drug Industry: Delivering Patient Value for Pharmaceuticals and Biologics* (2011) - [Read Me](#)

Book: *FIND IT, FILE IT, FLOG IT: Pharma's Crippling addiction and How to Cure It* (2015) - [Read me](#)

Book: *Taming the BIG PHARMA MONSTER by Speaking Truth to Power* – (2019) - [Read me](#)

Book: *What Patients Need to Know About Pharmaceutical Supply Chains* – (2021) – [Read me](#)

Video: *Supply Chain Management in the Drug Industry: Delivering Patient Value for Pharmaceuticals and Biologics* (2011) – [Watch it](#)

Video: *MEDICINES FOR THE 21st CENTURY: Safe, Better, Cheaper* (2019) – [Watch it](#)

The BIRD Recommendation on the Use of Ivermectin for Covid-19

BIRD

British
Ivermectin
Recommendation
Development



Proceedings and conclusions of the British Ivermectin Recommendation Development meeting held on the 20th February 2021 in Bath, United Kingdom.

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 4/9/2021 8:52:11 AM
To: Tierney, Julia [Julia.Tierney@fda.hhs.gov]; Dupont, Jarilyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce4025bc43cc4505b2f29f2de33b7b36-JDUPONT]
Subject: FW: The FDA News Summary for Thursday, April 09, 2020
Attachments: FDA200409.doc; FDA200409.pdf; STAT Plus - Unprecedented development of Covid.docx; Coronavirus 4-9-2021.docx; BL Risperidone.docx

See first op-ed. Should we be more aggressive on publishing what we are doing in this area — clin trials.gov? jw

From: Staffa, Edward <Edward.Staffa@fda.hhs.gov>

Sent: Friday, April 9, 2021 8:44 AM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Temple, Robert <Robert.Temple@fda.hhs.gov>
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Subject: FW: The FDA News Summary for Thursday, April 09, 2020

Good morning... in the clips today:

CDER/FDA In the News --- NON COVID-19

NYT: “Neither the FDA nor NIH Have Enforced the Law” Intended to Hold Cancer Researchers Who Receive Federal Help Responsible for Timely Reporting of Their Results to The Public. An op-ed in the New York Times says, “In 2016, Joe Biden, then vice president, launched the Cancer Moonshot initiative” and learned that year “of stark failures by NIH and its grantees in managing results from cancer experiments, and he told an audience at a cancer research conference that he was outraged.” The article notes that “researchers using federal funds to conduct cancer trials... were sometimes taking more than a year to report their results to the NIH, as required.” He adds that NIH Director Dr. Francis Collins in 2016 “announced that the agency would begin penalizing researchers for failing to comply with its reporting requirements,” but “in the years since, neither the FDA nor NIH have enforced the law.”

J&J Could Have Warned About Risperidone, Plaintiffs Contend Before U.S. Supreme Court. Bloomberg Law (see attached) reports, “A \$70 million Risperdal [risperidone] award against Johnson & Johnson and unit Janssen Pharmaceuticals Inc. was properly upheld by a Pennsylvania court, because FDA regulations didn't prevent manufacturers from warning about the risk of it causing breast growth in males, a man who alleges childhood use caused him to develop female-like breasts told the U.S. Supreme Court.” According to the article, “Risperdal, an antipsychotic drug, hadn't been approved for children when A.Y. was first prescribed the drug in 2003; it was an ‘off-label’ use.”

Biden Administration and Justice Department Reportedly Slow To Act On Opioid Crisis Despite AG Garland's Pledge. Fox News reports, "Attorney General Merrick Garland pledged to make the opioid crisis still plaguing America a 'high priority' for the Department of Justice (DOJ)," but "Garland and the Biden administration have put the crisis on the backburner." The article adds that "one of President Biden's initial executive orders cut a Trump-era order that made it easier for physicians to prescribe the drug buprenorphine – a transformative treatment used to combat opioid addiction that requires a federal license to prescribe." According to the NIDA, "the US saw a 'significant increase' in opioid overdose-related deaths in 2019, nearing 50,000 deaths due to the drugs."

Dems Will "Likely" Include Provision Requiring Medicare To Negotiate Prices It Pays Drug Companies in Infrastructure Bill, Aide Says. The Washington Times reports "House Democrats are 'likely' to include a controversial provision in the upcoming infrastructure bill that would require Medicare to negotiate down the prices it pays drug companies, a senior Democratic aide told The Washington Times." Proponents "say the measure would lower the prices that Medicare pays for dozens of drugs, creating \$456 billion in savings, according to the Congressional Budget Office." However, "the \$456 billion would come out of the pockets of drug companies, who do not want to be used as a piggy bank to fund Democratic priorities." A 2019 CBO report "estimated that eight fewer drugs would be introduced in the U.S. over the next decade" – roughly "3% fewer than the 300 drugs approved by the FDA, on average, every decade."

FDA Grants Full Approval for Trodelvy For Triple Negative Breast Cancer --- Originally Approved 4/2020 as an Accelerate Approval In April 2020, CDER approved Trodelvy (sacituzumab govitecan-hziy) as an accelerated approval for the treatment of adult patients with metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease. Today, several media outlets report FDA has now granted this drug full approval for that indication. Using the word, "conditional" instead of "accelerated," FiercePharma reports, "Gilead Sciences has turned blockbuster contender Trodelvy's conditional FDA nod in triple-negative breast cancer into a full and better one, taking another step toward making the \$21 billion it shelled out for the drug's developer, Immunomedics, financially worthwhile." BioPharma Dive reports the approval comes "less than a year after the agency cleared use of the drug under an accelerated approval program." The approval "is supported by data from a study that showed the drug could delay disease progression and extend survival." Endpoints News also reports.

Ongoing Coverage... Endpoint News Says Analysts Think Delays of Reviews For JAK Inhibitors May Signal an Upcoming FDA Advisory Committee Yesterday, an article in Reuters focused on FDA's delayed decision about approval of the JAK inhibitor **abrocitinib** (proposed trade name, Cibinqo), discussed some potential safety issues with other drugs in this class and noted, "the FDA could convene a panel to review the safety of JAK inhibitors." Today, Endpoints News reports similarly, noting, "Three-month review delays from the FDA have become the norm in recent days for JAK inhibitors, some of which are seeking label expansions," and, "the pushback of these action dates for AbbVie's Rinvoq [**upadacitinib**], Pfizer's Xeljanz [**tofacitinib**] and abrocitinib, and Eli Lilly's Olumiant [**baricitinib**] may be a sign that the FDA is preparing to hold an advisory committee of outside experts to review the risk/benefit profiles of JAK inhibitors for atopic dermatitis, according to Leerink analyst Geoffrey Porges."

Labeling Error Forces Humana To Recall Nearly 200,000 Bottles of

Acetaminophen. FiercePharma reports a labeling mix-up "has forced one drugmaker to pull nearly 200,000 bottles of a popular pain and fever med." According to the article, "A-S Medication Solutions is recalling 198,350 bottles of extra-strength acetaminophen tablets" that Humana distributed in 100-count bottles in a Health Essentials kit after they "were found to include an incomplete prescription drug label, rather than the required over-the-counter drug facts sheet," according to an FDA notice.

MACPAC To Recommend Changes to How Medicaid Pays for High-Cost Specialty Drugs. Modern Healthcare reports, "The Medicaid and CHIP Payment and Access Commission [MACPAC] is poised to recommend changes to how Medicaid pays for high-cost specialty drugs." Modern Healthcare adds, "At MACPAC's April meeting on Thursday, commissioners signaled they would recommend Congress increase the minimum rebate percentage and additional inflationary rebate on drugs approved by the Food and Drug Administration through the accelerated approval program."

COVID-19 Coverage (possibly more CDER/FDA specific)

Ivermectin As Potential Covid-19 Treatment Back in Media Coverage: Washington Post Says, “Skeptics Call It The ‘New Hydroxychloroquine’ And, “An NIH Trial May Settle Debate” Over Its Use. An article in the Washington Post focused on use of ivermectin as a potential Covid-19 treatment, opens with examples of people who have inappropriately used the veterinary version of this drug in the absence of being able to obtain an off-label prescription for the human version of the drug approved to treat parasitic infection. The article then quotes a virologist saying, “It’s like the new hydroxychloroquine. It would be great if ivermectin did work — it’s been around for years and is cheap. But to my knowledge, there is no data that suggests it’s good for covid-19.” The article then says, “But Pierre Kory, a critical-care physician, is undeterred. Kory, a co-founder of the Front Line Covid-19 Critical Care Alliance, a group of physicians and scientists from several countries, argues that studies from around the world show ivermectin is a “miracle drug” for covid-19 and should be deployed immediately. He opposes waiting for data from large randomized clinical trials to authorize its use, saying too many people are dying of covid-19.” The article links to Kory’s “emotional testimony” before the Senate Homeland Security Committee in December and goes on to say, “Now, the NIH might wade into the controversy. It is planning a randomized clinical trial to explore whether older, already approved drugs can be repurposed to reduce covid-19 symptoms, according to three individuals who spoke on the condition of anonymity because the plans have not been announced. Ivermectin is considered a top candidate for the trial, though the details are not final, the individuals said. Other possibilities are **fluvoxamine**, a decades-old antidepressant, and **famotidine**, the generic name for Pepcid, outside scientists said. The goal would be to get results within months. The outpatient trial would be the latest in a series of studies, conducted with academia and industry, in NIH’s Accelerating Covid-19 Therapeutic Interventions and Vaccines program. The initiative has scrutinized monoclonal antibodies, blood thinners and other agents. Such trials, experts say, are as important in determining what doesn’t work, as what does.” It also says, “A British trial called Recovery has provided important information about older drugs, finding that hydroxychloroquine did not help hospitalized covid-19 patients, while the steroid dexamethasone could be a lifesaver. But the United States has lagged behind in conducting such trials because of the fragmentation of the health-care system and the lack of financial incentive for pharmaceutical companies to continue to do research on old, cheap drugs.” The article also says, “Interest in ivermectin for covid-19 surged last spring after a small Australian study found that the drug inhibited the replication of the coronavirus in laboratory tests. But many scientists warned that it would be impossible for humans to take high enough doses of the drug to produce an antiviral effect.” The article also quotes Dr. Woodcock during a recent webinar on covid-19 treatments sponsored by the American Medical Association, saying, “We don’t have solid evidence right now. We’ve had hints for a long time on ivermectin, but again, we’ve had hints on a lot of these agents and many of them have not panned out.”

Baricitinib Did Not Prevent Progression to Mechanical Ventilation in Patients Hospitalized With COVID-19. Reuters reports, “Eli Lilly and Co and Incyte Corp said their rheumatoid arthritis drug baricitinib (trade name, Olumiant) did not meet the main goal of preventing progression to mechanical ventilation in hospitalized COVID-19 patients under a late-stage study.” According to study data, “patients receiving baricitinib were 2.7% less likely than those receiving standard of care to progress to ventilation, which was not statistically significant.” The article adds that the FDA has granted emergency use authorization for baricitinib in combination with remdesivir for patients with COVID-19 requiring supplemental oxygen. Another Reuters BioPharma Dive FierceBiotech and BioSpace also report.

Johns Hopkins Health Policy Expert, Dr. Marty Makary, Says, “It’s Good” That Fauci Is Now Discussing Natural Immunity from Prior Coronavirus Infections. Fox News reports, “Johns Hopkins health policy expert and Fox News contributor Dr. Marty Makary joined ‘Your World with Neil Cavuto’ on Thursday and responded to White House chief medical adviser Dr. Anthony Fauci calling herd immunity an ‘elusive concept’ while acknowledging herd immunity includes those already infected with COVID-19.” Makary said, “I think it’s good that he’s talking about natural immunity from prior infection now. Because in the past, he clearly did not.” *[Dr. Makary has long maintained a high profile in public media. He’s been in the news a lot recently primarily because of his two recent editorials in the WSJ which both essentially delineate his view that natural immunity to Covid-19 is now likely widespread and should play a more prominent role as a factor for vaccination policies. The February article is titled, We’ll Have Herd Immunity by April].*

Scientists Seeking Antiviral Drugs to Treat COVID-19. Axios reports, “Antiviral drugs can be a key pandemic-fighting tool, but so far there's only one approved in the U.S. for SARS-CoV-2, the virus that causes COVID-19 [remdesivir].” Attributing the comment to Drs. Gottlieb and McClennan from a recent jointly-written commentary, the article says, antivirals matter, “because some people won't get vaccinated, and because there will likely be new variants of the virus, we'll need effective treatments — including antivirals.” The article specifically notes **molnupiravir** as “driving the news,” --- a drug recently discussed in other media coverage (e.g., Bloomberg Businessweek reporting, “Merck's Little Brown Pill Could Transform the Fight Against Covid”] as one potential antiviral Covid-19 treatment. The article provides a lay-person explanation for how antivirals work and discusses what is currently known about the effectiveness of remdesivir. The article also says, “31 other antivirals are being investigated, according to the Milken Institute's COVID-19 tracker,” and quotes an industry exec saying, “A goal for SARS-CoV-2 is to develop an equivalent to Tamiflu, an oral antiviral that can be taken at home after someone is exposed but before symptoms appear.” The article also notes studies under way for the drug, favipiravir (not FDA-approved) and notes the drug is “approved in Japan for treating new flu strains and in Russia and India for COVID-19.” Discussing challenges in developing new antiviral therapies for Covid-19, the article points to plitidepsin, a drug already approved in Australia to treat multiple myeloma, as an possible antiviral for SARS-CoV-2. The article says, “Because they rely on hosts to reproduce, viruses have few proteins of their own that antivirals can act on.”

STAT-Plus: Biopharma Companies Have Turned to New Approaches To Develop COVID-19 Vaccines And Drugs At Record Speeds. STAT Plus (see attached), says, “Business as usual has not been the mantra for companies developing Covid-19 vaccines and drugs.” The authors note, “Instead, biopharma companies and their partners pursued various transformational approaches to get vaccines and treatments to market at unprecedented speeds.” These new approaches included “**adaptive trials, master protocols, real-world evidence**, and other approaches powered by advanced statistical techniques, data science, and analytics using curated datasets.” The article then includes detailed discussions of these areas.

US Suicides Fell Almost 6% Last Year Amid Coronavirus Pandemic, Data Indicate. The AP says, “The number of U.S. suicides fell nearly 6% last year amid the coronavirus pandemic – the largest annual decline in at least four decades, according to preliminary government data.” The piece adds that it is “hard to say exactly why suicide deaths dropped so much, but one factor may be a phenomenon seen in the early stages of wars and national disasters, some experts suggested.” The New York Post and The Hill also report.

One Third of People Recovered From COVID-19 Diagnosed With Psychiatric, Neurological Disorders, Research Suggests. The Los Angeles Times (recently converted to subscription only --- no current OCOMM access --- but will hopefully have soon --- please follow-up with me via email in a day or two if you want access) reports, “New research highlights COVID-19's lingering effects on the brain, finding that in the six months after becoming ill, roughly a third of surviving patients were diagnosed with at least one neurological or psychiatric disorder.” Dr. Avindra Nath, who leads research on the brain and immune system at the National Institute of Neurological Disorders and Stroke, said, “This paper is important because it's the largest data set anyone has looked at. ... In that sense, it's huge.”

Up To 10% Of People with Mild COVID-19 Have Lingering Symptoms Eight Months After Recovery, Study Reveals. Fox News reports, “A study focused on health care workers over the last year found that up to 1 in 10 who experienced a mild case of coronavirus was still dealing with a lingering symptom that negatively impacts their life eight months after their illness resolved.” The most frequently reported “complaints among the study participants were a lingering loss of smell, taste, fatigue and respiratory problems.” The findings were published [4/7] in JAMA.

Vaccines and Other COVID-19 News... see attached above

From: Bulletin Intelligence <FDA@BulletinIntelligence.com>

Sent: Thursday, April 09, 2020 6:05 AM

To: FDA@bulletinintelligence.com

Subject: The FDA News Summary for Thursday, April 09, 2020

This morning's FDA News Summary is attached.

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J&J Could Have Warned About Risperdal, Plaintiff Tells SCOTUS

April 8, 2021, 12:07 PM

- Pennsylvania court upheld award in male breast-growth case
- Janssen sought review; says federal law preempts claims

A \$70 million Risperdal award against Johnson & Johnson and unit Janssen Pharmaceuticals Inc. was properly upheld by a Pennsylvania court, because FDA regulations didn't prevent manufacturers from warning about the risk of it causing breast growth in males, a man who alleges childhood use caused him to develop female-like breasts told the U.S. Supreme Court.

Risperdal, an antipsychotic drug, hadn't been approved for children when A.Y. was first prescribed the drug in 2003; it was an "off-label" use. A.Y. says Janssen didn't warn that Risperdal could cause breast growth in males, and says a warning would have prevented his harm. A Pennsylvania appeals court upheld the jury's \$70 million award, and the state's top court denied review.

Janssen and J&J asked the Supreme Court in January to review the case, saying federal drug labeling law preempts the plaintiffs' claims.

The Food and Drug Administration-approved labeling didn't include a pediatric warning about gynecomastia, the development of breasts in males, until the FDA approved Risperdal for pediatric uses in 2006.

Drug labeling regulations make clear that the FDA alone has the authority to add warnings concerning off-label use, Janssen and J&J said. A.Y.'s claims are preempted because the drugmakers couldn't have complied with any state-imposed duty to add such warnings without violating federal law, they said.

And the "changes being effected" procedure doesn't permit label changes addressing off-label uses, Janssen said. The CBE procedure allows makers of name-brand drugs to enhance label warnings under certain circumstances.

The Supreme Court has already determined that federal law preempts state tort claims regarding on-label uses unless the defendant could have made the sought-after change unilaterally, the companies said.

This case presents a similarly far-reaching issue, whether branded drug manufacturers may assert a preemption defense in state failure-to-warn claims involving off-label uses where FDA regulations prohibit them from imposing warnings concerning risks of such uses, they said.

Up to one-third of all U.S. prescriptions are for off-label uses, they said.

Nothing to See Here

But the Pennsylvania courts properly rejected Janssen's arguments that it was powerless to warn about links between Risperdal and pediatric gynecomastia, A.Y. said Wednesday in opposing review.

Janssen acknowledges it's seeking review on whether federal law "categorically precludes manufacturers from independently implementing off-label warnings," A.Y. said.

The absence of cases addressing this question makes clear that it doesn't merit Supreme Court review, he said.

"A question that affects only cases involving the use of a single drug more than 15 years ago is nowhere near important enough to warrant this Court's intervention, particularly in the absence of any split," he said.

And the decision was correct, he said.

The drugmakers' argument to the contrary relies on a single sentence in an FDA regulation saying that a "specific warning" about an off-label use "may" be required by the FDA. That sentence doesn't restrict what manufacturers may do when the FDA hasn't exercised its authority, he said.

Even if the companies were correct that they couldn't change the "warning" section of the drug label, they had other ways to convey risk information and therefore to comply with their state-law duty, A.Y. said.

For example, they could have added a caution to a different section of the drug label, or could have provided information to doctors through their sales force, A.Y. said.

And the CBE regulation contains no off-label prohibition, he said.

Kirkland & Ellis LLP represents Janssen. Kline & Specter PC, Arnold & Itkin, and Sheller PC represent A.Y.

The case is [[HYPERLINK](https://www.bloomberglaw.com/public/document/JanssenPharmaceuticalsIncetalPetitionersvsAYetalDocketNo201069USF?doc_id=X6KEBUI15F58UQ8Q1OVE2TAV08S?fmt=pdf)

"https://www.bloomberglaw.com/public/document/JanssenPharmaceuticalsIncetalPetitionersvsAYetalDocketNo201069USF?doc_id=X6KEBUI15F58UQ8Q1OVE2TAV08S?fmt=pdf"], U.S., No. 20-1069, opposition 4/7/21.

States Halt J&J Shots Following Adverse Reactions.

The [[HYPERLINK "https://apnews.com/article/north-carolina-coronavirus-pandemic-raleigh-166f5bf453057cd9861d5daf2ae38ad2"](https://apnews.com/article/north-carolina-coronavirus-pandemic-raleigh-166f5bf453057cd9861d5daf2ae38ad2) \t "bipopup"] (4/8, Anderson) reports that “North Carolina health officials said on Thursday that they stopped administering Johnson & Johnson doses at a mass vaccination site in Raleigh and at clinics in Hillsborough and Chapel Hill after at least 26 people experienced adverse reactions, including fainting. Four people were taken to hospitals for further examination, and state and federal health officials are reviewing the matter.” The CDC “noted that reactions like fainting are not uncommon after someone is vaccinated, though it is reviewing reports of adverse reactions in North Carolina and three other states,” including Georgia.

[[HYPERLINK "https://www.usatoday.com/story/news/health/2021/04/08/covid-news-michigan-variants-vaccine-passport/7126994002/"](https://www.usatoday.com/story/news/health/2021/04/08/covid-news-michigan-variants-vaccine-passport/7126994002/) \t "bipopup"] (4/8, Bacon, Ortiz, Aspegren, Rice, 12.7M) reports that “a mass vaccination site in Colorado was shut down after 11 people suffered ‘adverse reactions’ including nausea and dizziness after receiving the one-dose Johnson & Johnson vaccine” on Wednesday. Two people “were transported to a hospital for observation while EMTs treated the other nine people with juice and water, the state health department said.” According to the article, “the issues involved less than 1% of the vaccinations” given at the site.

The [[HYPERLINK "https://www.denverpost.com/2021/04/08/colorado-johnson-johnson-vaccine-investigation/"](https://www.denverpost.com/2021/04/08/colorado-johnson-johnson-vaccine-investigation/) \t "bipopup"] (4/8, Wingerter, 660K) reports that “Colorado public health officials announced Thursday that they found no sign of a problem after” the unexpected reactions following consultation with the CDC. The FDA also “checked with other locations that used vaccines from the same Johnson & Johnson lot, and didn’t find any unusual reactions, according to the state health department.”

The [[HYPERLINK "https://nypost.com/2021/04/08/johnson-johnson-responds-after-reports-of-vaccine-reactions/"](https://nypost.com/2021/04/08/johnson-johnson-responds-after-reports-of-vaccine-reactions/) \t "bipopup"] (4/8, O’Neill, 7.45M) reports, “Johnson & Johnson said Thursday that it is ‘collecting the necessary information’ to review the safety of its COVID-19 vaccine.” The company told FOX 31, “There is no greater priority than the safety and well-being of the people we serve, and we carefully review reports of adverse events in individuals receiving our medicines and vaccines.” J&J “said it would share information about individuals who received the jab with the U.S. Food and Drug Administration and ‘other appropriate health authorities.’”

Among other news outlets providing coverage are [[HYPERLINK](#)

"javascript:playVideoPopup('https://playvideo.bulletinintelligence.com/d73723911e2143b892f3af648fdab38b?pubid=fda'\| "2021040906045515014814154')"

] (4/8, story 4, 2:40, Muir, 6.58M), [[HYPERLINK](#) "javascript:playVideoPopup('https://playvideo.bulletinintelligence.com/2d0f936a55e94f0491143d55f5eacfd1?pubid=fda'\| "2021040906045515014814154')"] (4/8, story 4, 2:40, O’Donnell, 4.01M), [[HYPERLINK](#)

"javascript:playVideoPopup('https://playvideo.bulletinintelligence.com/72ad2fb6075e44769c654ad3e6539da3?pubid=fda'\| "2021040906045515014814154')"

] (4/8, story 5, 2:10, Holt, 5.31M), [[HYPERLINK "https://www.cbsnews.com/news/colorado-north-carolina-johnson-and-johnson-vaccine-reactions/"](https://www.cbsnews.com/news/colorado-north-carolina-johnson-and-johnson-vaccine-reactions/) \t "bipopup"] (4/8, Diaz, 5.39M), the [[HYPERLINK](#)

"https://www.charlotteobserver.com/news/local/article250532089.html" \t "bipopup"] (4/8, Wagner, Johnson, 443K), the [[HYPERLINK "https://www.denverpost.com/2021/04/08/colorado-johnson-johnson-vaccine-investigation/"](https://www.denverpost.com/2021/04/08/colorado-johnson-johnson-vaccine-investigation/) \t "bipopup"] (4/8, Wingerter, 660K), and the [[HYPERLINK](#)

"<https://nypost.com/2021/04/08/second-vaccine-site-paused-after-adverse-reactions-to-johnson-johnson-shots/>" \t "bipopup"] (4/8, Musumeci, 7.45M).

Governments Offer New Guidance After AstraZeneca's Vaccine Was Linked To Blood Clots.

[[HYPERLINK "https://www.axios.com/fda-astrazeneca-coronavirus-vaccines-world-2d4dcc7b-a856-4008-bcb9-63910f7cd786.html"](https://www.axios.com/fda-astrazeneca-coronavirus-vaccines-world-2d4dcc7b-a856-4008-bcb9-63910f7cd786.html) \t "bipopup"] (4/8, Owens, 1.26M) says that on Wednesday, AstraZeneca's coronavirus vaccine "took yet another public relations hit...when the European Medicines Agency announced that the shot has a 'possible' link to rare blood clots." According to Axios, "Even before the link was announced, the U.S. didn't need the AstraZeneca vaccine, based on its existing supply of other shots. But what the Food and Drug Administration decides to do about the vaccine – if the company seeks U.S. authorization – will likely have global ramifications."

The [[HYPERLINK "https://apnews.com/article/europe-united-kingdom-health-coronavirus-pandemic-coronavirus-vaccine-df114b8372aad2e7c53ec2578b484f0"](https://apnews.com/article/europe-united-kingdom-health-coronavirus-pandemic-coronavirus-vaccine-df114b8372aad2e7c53ec2578b484f0) \t "bipopup"] (4/8, Corder) says, "A patchwork of advice was emerging from governments across Europe and farther afield, a day after the European Union's drug regulator said there was a 'possible link' between the AstraZeneca vaccine and a rare clotting disorder while reiterating the vaccine is safe and effective." According to the article, "In Spain, residents now have to be over 60 to get an AstraZeneca coronavirus vaccine. In Belgium, over 55. In the United Kingdom, authorities recommend the shot not be given to adults under 30 where possible, and Australia's government announced similar limits Thursday to AstraZeneca shots for those under 50."

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-astrazeneca/astrazeneca-woes-grow-as-australia-philippines-african-union-curb-covid-19-shots-idUSKBN2BV2BA"](https://www.reuters.com/article/us-health-coronavirus-astrazeneca/astrazeneca-woes-grow-as-australia-philippines-african-union-curb-covid-19-shots-idUSKBN2BV2BA) \t "bipopup"] (4/8, Donovan) reports that the Philippines also "limited use of AstraZeneca's COVID-19 vaccine on Thursday" for those under 60, "while the African Union dropped plans to buy the shot amid global shortages" to instead explore options with J&J. Earlier this week, Italy and South Korea also introduced limits, joining "France, the Netherlands, Germany and others."

[[HYPERLINK "https://www.cnbc.com/2021/04/08/astrazeneca-vaccine-officials-defend-shot-after-ema-mhra-rulings.html"](https://www.cnbc.com/2021/04/08/astrazeneca-vaccine-officials-defend-shot-after-ema-mhra-rulings.html) \t "bipopup"] (4/8, Ellyatt, 7.34M) reports on its website that the British government and UK health officials "have rushed to defend the coronavirus vaccine developed by AstraZeneca and the University of Oxford following concerns over a possible link to blood clots." CNBC says that on Thursday, Matt Hancock, the UK's health secretary, "stressed that the risk of a blood clot after receiving the AstraZeneca Covid vaccination is about the same as on a long-haul flight."

The [[HYPERLINK "https://www.wsj.com/articles/astrazeneca-covid-19-vaccine-restrictions-pile-up-complicating-shot-roll-outs-11617901430"](https://www.wsj.com/articles/astrazeneca-covid-19-vaccine-restrictions-pile-up-complicating-shot-roll-outs-11617901430) \t "bipopup"] (4/8, Hoyle, Legorano, Subscription Publication, 8.41M) reports that the European Medicines Agency has not recommended any age restrictions for the vaccine, and continues to support its use, believing the benefits outweigh any risk.

[[HYPERLINK "https://thehill.com/policy/healthcare/547115-australia-restricting-astrazeneca-vaccine-for-people-under-50"](https://thehill.com/policy/healthcare/547115-australia-restricting-astrazeneca-vaccine-for-people-under-50) \t "bipopup"] (4/8, Schnell, 5.69M) also covers the story.

Florida Sues Federal Government Demanding Cruises Resume Immediately.

The [[HYPERLINK "https://apnews.com/article/miami-lawsuits-florida-ron-desantis-coronavirus-pandemic-f8abaca1f837cc08969eeab4ac52f8c8"](https://apnews.com/article/miami-lawsuits-florida-ron-desantis-coronavirus-pandemic-f8abaca1f837cc08969eeab4ac52f8c8) \t "bipopup"] (4/8, Licon) reports that on Thursday,

Florida Gov. Ron DeSantis (R) announced the state “has filed a lawsuit against the federal government to demand cruise ships be allowed to start sailing immediately.”

According to [[HYPERLINK "https://www.cbsnews.com/news/florida-cruise-industry-de-santis-sues-federal-government/"](https://www.cbsnews.com/news/florida-cruise-industry-de-santis-sues-federal-government/) \t "bipopup"] (4/8, Powell, 5.39M), the lawsuit “names the CDC, Department of Health and Human Services and U.S. government as defendants.”

The [[HYPERLINK "https://www.washingtonpost.com/travel/2021/04/08/florida-desantis-cdc-cruise-lawsuit/"](https://www.washingtonpost.com/travel/2021/04/08/florida-desantis-cdc-cruise-lawsuit/) \t "bipopup"] (4/8, Sampson, 10.52M) says, “The lawsuit comes amid mounting tension between the cruise industry and the CDC, which last week rolled out additional safety instructions for cruise lines, even if passengers are vaccinated.” On Monday, a trade group “called the new requirements ‘unduly burdensome’ and ‘largely unworkable’ and doubled down on its request to sail again by early July.”

[[HYPERLINK "https://cnn.com/2021/04/08/politics/florida-lawsuit-biden-administration-cruise-industry/index.html"](https://cnn.com/2021/04/08/politics/florida-lawsuit-biden-administration-cruise-industry/index.html) \t "bipopup"] (4/8, Stracqualursi, 89.21M) reports, “Florida is asking the court to block the CDC and HHS from enforcing an October ‘conditional sailing’ order, which it suggested is effectively a ban on cruises.”

The [[HYPERLINK "https://www.wsj.com/articles/florida-sues-u-s-health-authorities-to-restart-cruises-11617904047"](https://www.wsj.com/articles/florida-sues-u-s-health-authorities-to-restart-cruises-11617904047) \t "bipopup"] (4/8, Sebastian, Subscription Publication, 8.41M) says neither the CDC nor HHS responded to a request for comment after the announcement of the lawsuit.

Among other outlets covering the story are [[HYPERLINK "https://www.bloomberg.com/news/articles/2021-04-08/desantis-says-florida-suing-federal-government-to-allow-cruises?srnd=premium"](https://www.bloomberg.com/news/articles/2021-04-08/desantis-says-florida-suing-federal-government-to-allow-cruises?srnd=premium) \t "bipopup"] (4/8, Levin, 3.57M), [[HYPERLINK "https://www.newsweek.com/floridas-ron-desantis-sues-federal-government-over-covid-cruise-ship-ban-1582125"](https://www.newsweek.com/floridas-ron-desantis-sues-federal-government-over-covid-cruise-ship-ban-1582125) \t "bipopup"] (4/8, Impelli, 2.67M), [[HYPERLINK "https://www.politico.com/states/florida/story/2021/04/08/florida-sues-biden-administration-over-cruise-restrictions-1371950"](https://www.politico.com/states/florida/story/2021/04/08/florida-sues-biden-administration-over-cruise-restrictions-1371950) \t "bipopup"] (4/8, Fineout, 6.73M), [[HYPERLINK "https://thehill.com/homenews/state-watch/547195-desantis-florida-sue-federal-government-over-cruise-restrictions"](https://thehill.com/homenews/state-watch/547195-desantis-florida-sue-federal-government-over-cruise-restrictions) \t "bipopup"] (4/8, Lonas, 5.69M), the [[HYPERLINK "https://www.ft.com/content/1e114e00-fd2f-4538-b5e7-33ab96a20761?FTCamp=engage/CAP/webapp/Channel_Bulletin//B2B"](https://www.ft.com/content/1e114e00-fd2f-4538-b5e7-33ab96a20761?FTCamp=engage/CAP/webapp/Channel_Bulletin//B2B) \t "bipopup"] (4/8, Fedor, Hancock, Subscription Publication, 1.48M), [[HYPERLINK "https://www.axios.com/desantis-sues-cdc-cruises-resume-67b76ca4-70d4-4928-b7c0-b8e28eb62419.html"](https://www.axios.com/desantis-sues-cdc-cruises-resume-67b76ca4-70d4-4928-b7c0-b8e28eb62419.html) \t "bipopup"] (4/8, Perano, 1.26M), the [[HYPERLINK "https://www.orlandosentinel.com/politics/os-ne-desantis-press-conference-portmiami-20210408-uvtkfabm45dabim3by6jw5fs2y-story.html"](https://www.orlandosentinel.com/politics/os-ne-desantis-press-conference-portmiami-20210408-uvtkfabm45dabim3by6jw5fs2y-story.html) \t "bipopup"] (4/8, Tribou, Lemongello, 599K), the [[HYPERLINK "https://www.palmbeachpost.com/story/news/2021/04/08/desantis-florida-sues-get-cruise-ships-sailing-immediately/7139415002/"](https://www.palmbeachpost.com/story/news/2021/04/08/desantis-florida-sues-get-cruise-ships-sailing-immediately/7139415002/) \t "bipopup"] (4/8, Stapleton, 223K), the [[HYPERLINK "https://www.sun-sentinel.com/business/fl-bz-desantis-suing-cdc-to-reopen-cruise-industry-20210408-irwg5fnhgzbifbpyhtmu6viy4-story.html"](https://www.sun-sentinel.com/business/fl-bz-desantis-suing-cdc-to-reopen-cruise-industry-20210408-irwg5fnhgzbifbpyhtmu6viy4-story.html) \t "bipopup"] (4/8, Hurtibise, 525K), the [[HYPERLINK "http://www.tampabay.com/news/florida-politics/2021/04/08/desantis-sues-cdc-to-get-cruises-restarted-experts-call-it-a-political-stunt/"](http://www.tampabay.com/news/florida-politics/2021/04/08/desantis-sues-cdc-to-get-cruises-restarted-experts-call-it-a-political-stunt/) \t "bipopup"] (4/8, Dolven, 762K), [[HYPERLINK "https://www.foxbusiness.com/politics/desantis-sues-cdc-over-lack-of-cruise-ship-guidance"](https://www.foxbusiness.com/politics/desantis-sues-cdc-over-lack-of-cruise-ship-guidance) \t

"bipopup"] (4/8, Blitzer, 3.06M), and the [[HYPERLINK "https://nypost.com/2021/04/08/florida-sues-feds-to-allow-cruise-ships-to-sail/"](https://nypost.com/2021/04/08/florida-sues-feds-to-allow-cruise-ships-to-sail/) \t "bipopup"] (4/8, Musumeci, 7.45M).

Michigan COVID-19 Cases Surge Close To December Record.

[[HYPERLINK "https://www.bloomberg.com/news/articles/2021-04-08/michigan-cases-surge-to-worst-in-nation-as-variants-multiply?srnd=premium"](https://www.bloomberg.com/news/articles/2021-04-08/michigan-cases-surge-to-worst-in-nation-as-variants-multiply?srnd=premium) \t "bipopup"] (4/8, Querolo, 3.57M) says that on Wednesday, Michigan “reported more than 8,000 infections and 30 deaths” from COVID-19, and over the past week, the state “averaged 470 new cases per 100,000 residents,” which means it’s “on pace for new cases to surpass their December record any day.”

The [[HYPERLINK "https://www.detroitnews.com/story/news/local/michigan/2021/04/08/um-surgeon-plea-whitmer-white-house-covid-19-hospitalizations-surgings/7141718002/"](https://www.detroitnews.com/story/news/local/michigan/2021/04/08/um-surgeon-plea-whitmer-white-house-covid-19-hospitalizations-surgings/7141718002/) \t "bipopup"] (4/8, Bouffard, 1.16M) reports University of Michigan Surgery Department Chairman Dr. Justin Dimick “expressed alarm Thursday over rising COVID-19 infections, begging for intervention from Gov. Gretchen Whitmer, the White House and the Centers for Disease Control and Prevention.”

The [[HYPERLINK "https://www.freep.com/story/news/local/michigan/2021/04/08/university-michigan-postpones-surgical-procedures-coronavirus-covid-19/7140962002/"](https://www.freep.com/story/news/local/michigan/2021/04/08/university-michigan-postpones-surgical-procedures-coronavirus-covid-19/7140962002/) \t "bipopup"] (4/8, Shamus, 2.16M) reports, “Whitmer said earlier this week that the state’s third coronavirus surge isn’t a public policy problem to be solved with COVID-19 health restrictions. Instead, she said Michiganders must double down on mask wearing, social distancing and hand-washing, while getting as many COVID-19 vaccines in arms as possible.” Meanwhile, CDC Director Dr. Rochelle Walensky said, “I would advocate for sort of stronger mitigation strategies...to sort of decrease the community activity and shore up mask wearing.”

[[HYPERLINK "https://www.mlive.com/news/ann-arbor/2021/04/some-surgeries-being-postponed-at-michigan-medicine-as-covid-19-hospitalizations-rise.html"](https://www.mlive.com/news/ann-arbor/2021/04/some-surgeries-being-postponed-at-michigan-medicine-as-covid-19-hospitalizations-rise.html) \t "bipopup"] (4/8, Marowski, 828K) also covers the story.

Lawmakers From Michigan Ask Biden To Increase Vaccine Allocation To The State In Light Of Rising Number Of COVID-19 Cases.

[[HYPERLINK "https://thehill.com/homenews/state-watch/547268-bipartisan-lawmakers-urge-biden-to-send-more-vaccines-to-michigan-amid"](https://thehill.com/homenews/state-watch/547268-bipartisan-lawmakers-urge-biden-to-send-more-vaccines-to-michigan-amid) \t "bipopup"] (4/8, Sullivan, 5.69M) reports Reps. Fred Upton (R-MI) and Debbie Dingell (D-MI) “wrote to President Biden on Thursday urging him to increase the vaccine allocation for” Michigan in the face of a surge in COVID-19 cases. The lawmakers wrote, “The number of new coronavirus cases in Michigan has risen rapidly in recent weeks, which has placed growing stress on the state’s public health infrastructure. ... An increase in vaccine allocation to the state will help save lives and effectively deal with this new outbreak.” To date, however, the Biden Administration has not altered its vaccine allocation formula.

[[HYPERLINK "https://www.statnews.com/2021/04/08/michigan-covid-surge-biden-officials-no-additional-vaccine-doses/"](https://www.statnews.com/2021/04/08/michigan-covid-surge-biden-officials-no-additional-vaccine-doses/) \t "bipopup"] (4/8, Facher, 262K) reports that “on Wednesday, White House officials acknowledged that Michigan’s situation is dire. They gave no indication, though, that they would send additional vaccines there to help quell the surge, when STAT asked.” The article adds that CDC Director Dr. Rochelle Walensky “said the agency was working to expand testing capacity in the state, address outbreaks in Michigan’s jails and prisons, and scale up genomic sequencing.”

The [[HYPERLINK "https://www.detroitnews.com/story/news/politics/2021/04/08/members-congress-urge-white-house-surge-vaccines-michigan/7148096002/"](https://www.detroitnews.com/story/news/politics/2021/04/08/members-congress-urge-white-house-surge-vaccines-michigan/7148096002/) \t "bipopup"] (4/8, Nann Burke, 1.16M) also covers the story.

Russia Demands COVID-19 Vaccines Back After Slovakia Questions Quality.

[[HYPERLINK "https://www.bloomberg.com/news/articles/2021-04-08/russia-demands-vaccine-shots-back-after-slovakia-doubts-quality?srnd=premium"](https://www.bloomberg.com/news/articles/2021-04-08/russia-demands-vaccine-shots-back-after-slovakia-doubts-quality?srnd=premium) \t "bipopup"] (4/8, Laca, Rudnitsky, 3.57M) says, “Slovakia and Russia clashed over the Sputnik V Covid-19 vaccine after the European Union member accused Moscow of delivering shots that were different from those used in a peer-reviewed study.” Russia “rejected the allegations and demanded Bratislava return the 200,000 doses it sent.”

The [[HYPERLINK "https://apnews.com/article/europe-slovakia-coronavirus-pandemic-russia-2c64b760706a5a3993554b7388ef3550"](https://apnews.com/article/europe-slovakia-coronavirus-pandemic-russia-2c64b760706a5a3993554b7388ef3550) \t "bipopup"] (4/8, Janicek) says, “The official Twitter account of the Sputnik V vaccine said Slovakia’s drug regulator ‘in violation of existing contract and in an act of sabotage’ tested Sputnik V ‘in a laboratory which is not part of the EU’s Official Medicines Control Laboratory network.’”

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-slovakia-sputnik-r/russias-sputnik-v-backers-tell-slovakia-to-return-vaccine-doses-arrange-more-tests-idUSKBN2BV280"](https://www.reuters.com/article/us-health-coronavirus-slovakia-sputnik-r/russias-sputnik-v-backers-tell-slovakia-to-return-vaccine-doses-arrange-more-tests-idUSKBN2BV280) \t "bipopup"] (4/8, Ostroukh) also covers this story.

Unaccompanied Immigrant Teenager Reunites With Mother After COVID-19 Hospitalization.

[[HYPERLINK "https://www.nbcnews.com/news/latino/unaccompanied-teen-reunites-her-mother-after-being-hospitalized-covid-n1263356"](https://www.nbcnews.com/news/latino/unaccompanied-teen-reunites-her-mother-after-being-hospitalized-covid-n1263356) \t "bipopup"] (4/8, Acevedo, Boyce, Aguasvivas, 4.91M) reports on a teenager named Cindy who is 17 years old and last month “journeyed from Honduras until she reached the U.S. border from Mexico for a chance to reunite with her mother, who lives in New York.” Cindy “spent three days in a hospital bed on the opposite side of the country, in California, as she battled Covid-19.” The mother, Maria Ana, “said she feared she would never see Cindy again after learning she was hospitalized with Covid-19.” However, “on Wednesday night, Maria Ana flew to San Diego to reunite with her daughter who had just recovered from Covid-19.” NBC adds that “Cindy is among the 13,350 or so unaccompanied children living in the care and custody of the Office of Refugee Resettlement at HHS.” HHS’ Administration for Children and Families is mentioned.

Opinion: People Should Stop Suggesting Individuals Avoiding COVID-19 Vaccine Are Uninformed, Irresponsible.

Robert Kaplan, who has served as associate director of the National Institutes of Health and chief science officer at the US Agency for Healthcare Research and Quality, writes in an opinion piece for the [[HYPERLINK "https://www.wsj.com/articles/stop-taking-shots-at-those-who-fear-them-11617920512"](https://www.wsj.com/articles/stop-taking-shots-at-those-who-fear-them-11617920512) \t "bipopup"] (4/8, Subscription Publication, 8.41M,) that people should cut back on suggesting that individuals who are avoiding the COVID-19 vaccine are uninformed, politically manipulated, or irresponsible. Instead, Kaplan says, common concerns and fears should be addressed informatively and with respect. NIAID Director Anthony Fauci is mentioned.

WSJournal Criticizes YouTube’s COVID-19 Video Removals As Censorship.

The [[HYPERLINK "https://www.wsj.com/articles/youtubes-assault-on-covid-accountability-11617921149"](https://www.wsj.com/articles/youtubes-assault-on-covid-accountability-11617921149) \t "bipopup"] (4/8, Subscription Publication, 8.41M) editorializes that YouTube’s policy removing videos that present misinformation about COVID-19, specifically those featuring officials and advisers, constitutes political censorship.

Columnist: Differences In Societies Between Countries Have Impacted Nations’ COVID-19 Successes, Failures.

In an opinion piece for the [[HYPERLINK "https://www.washingtonpost.com/opinions/global-opinions/a-new-key-to-covid-success-not-states-but-societies/2021/04/08/31142d74-98a7-11eb-a6d0-13d207aad78_story.html"](https://www.washingtonpost.com/opinions/global-opinions/a-new-key-to-covid-success-not-states-but-societies/2021/04/08/31142d74-98a7-11eb-a6d0-13d207aad78_story.html) \t "bipopup"] (4/8, 10.52M,), columnist Fareed Zakaria says “it remains true that the single strongest ingredient to successfully handling the pandemic has been strong and effective governmental institutions, particularly in the public health domain.” However, Zakaria asserts, “it turns out, that’s not enough. In addition to the state, we have to look at society.” He writes that “when looking at cumulative deaths per million among large countries, loose cultures such as Britain, the United States, Brazil and Mexico have been some of the worst performers.” Meanwhile, “tight cultures such as those in East Asia – China, Japan, Taiwan, Singapore, Vietnam – have all maintained very low rates of covid cases, hospitalizations and deaths.”

Walgreens Letting Individuals Waiting For Second Doses Of Pfizer’s COVID-19 Vaccine Reschedule Appointments For Earlier Dates.

The [[HYPERLINK "https://www.chicagotribune.com/coronavirus/vaccine/ct-coronavirus-vaccine-walgreens-second-dose-pfizer-cdc-20210408-fc63tzgfnrcwbkgqch6tl6cidm-story.html"](https://www.chicagotribune.com/coronavirus/vaccine/ct-coronavirus-vaccine-walgreens-second-dose-pfizer-cdc-20210408-fc63tzgfnrcwbkgqch6tl6cidm-story.html) \ | "ed=rss_www.chicagotribune.com/arcio/rss/category/news/" \t "bipopup"] (4/8, Schencker, 2.03M) reports “people who received their first doses of the Pfizer COVID-19 vaccine at Walgreens may try to reschedule their second dose appointments – which were otherwise scheduled for four weeks after the first ones – for slightly earlier dates, a Walgreens spokesman said Thursday.” After 20 days following “the first dose, people may try to reschedule the next shot for an earlier date, said spokesman Jim Cohn.” The CDC has “asked Walgreens to start spacing first and second doses of the Pfizer COVID-19 vaccine three weeks apart instead of four, in line with the agency’s guidance.”

Columnist: Waiving Intellectual Property Rights Not Solution To Vaccine Inequity.

In an opinion piece for the [[HYPERLINK "https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819_story.html"](https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819_story.html) \t "bipopup"] (4/8, 10.52M,), columnist Josh Rogin writes that “Americans will not be safe from covid-19 until the entire world is safe. That basic truth shows why vaccine nationalism is not only immoral but also counterproductive.” Rogin says that “the simplest solutions are rarely the correct ones, and some countries are using the issue to advance their own strategic interests.” Rogin asserts that “the Biden administration must reject the effort by some nations to turn our shared crisis into their opportunity.” He adds, “Vaccine equity is a real problem, but waiving intellectual property rights is not the solution.”

Missouri To Expand COVID-19 Vaccine Eligibility To Residents Aged 16 And Older On Friday.

The [[HYPERLINK "https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/missouri-set-to-expand-vaccine-eligibility-to-everyone-16-and-older/article_7861ebce-ec58-5260-a48c-](https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/missouri-set-to-expand-vaccine-eligibility-to-everyone-16-and-older/article_7861ebce-ec58-5260-a48c-)

4a8c5aeb56e5.html" \t "bipopup"] (4/8, Merrilees, 694K) reports “Missouri is slated to broadly open COVID-19 vaccine eligibility on Friday, allowing health care providers to administer doses to all residents 16 and older.” Overall, “about 4.5 million Missourians will be eligible, according to state estimates.”

Rep. Biggs Reportedly Proposes Legislation Banning Federal Vaccine Passports.

[HYPERLINK "https://thehill.com/homenews/house/547254-exclusive-biggs-offers-bill-banning-federal-vaccine-passports" \t "bipopup"] (4/8, Samuels, 5.69M) reports that Rep. Andy Biggs (R-AZ) “on Thursday introduced a bill that would bar federal government agencies from issuing or requiring so-called ‘vaccine passports,’ according to a copy of the legislation obtained first by” the publication. Biggs said in a statement, “Vaccine passports will not help our nation recover from COVID-19; instead, they will simply impose more Big Brother surveillance on our society.” The No Vaccine Passports Act has 18 co-sponsors, but “faces an uphill battle to passage in the Democratic-controlled House.”

Almost 20% Of US Population Is Fully Vaccinated, But Many Countries May Not Hit That Target This Year.

The [HYPERLINK "https://www.washingtonpost.com/world/percent-of-us-population-vaccinated/2021/04/08/034be0aa-971a-11eb-8f0a-3384cf4fb399_story.html" \t "bipopup"] (4/8, Rauhala, 10.52M) reports that as of Thursday, “just short of 20 percent of the U.S. population was fully vaccinated, giving some 66 million people a strong measure of protection against a disease that has already killed more than 500,000 Americans.” COVAX – “a World Health Organization-backed push for equitable distribution – aims to secure enough doses to cover up to 20 percent of the people in participating countries by the end of 2021, but it may not meet that relatively modest goal, experts warn.” The piece adds that the gap “between the vaccine ‘haves’ and ‘have-nots’ is widening, fueling frustration and potentially extending the pandemic.”

Countries Hitting New Records For COVID-19 Cases And Deaths.

The [HYPERLINK "https://apnews.com/article/countries-worldwide-hit-new-records-coronavirus-cases-deaths-29b18a267f8e972766403f8de0fee415" \t "bipopup"] (4/8) reports that countries are hitting new records for COVID-19 cases and deaths. The piece says, “Brazil this week became just the third country, after the U.S. and Peru, to report a 24-hour tally of COVID-19 deaths that exceeded 4,000.” India reached “a peak of almost 127,000 new cases in 24 hours, and Iran set a new coronavirus infection record for the third straight day, reporting nearly 22,600 new cases.”

Brazil, India Considered “Current Worst Hot Spots” For COVID-19.

[HYPERLINK "https://thehill.com/policy/healthcare/547154-brazil-india-now-seen-as-worst-covid-19-hot-spots" \t "bipopup"] (4/8, Coleman, 5.69M) reports that COVID-19 data identifies “Brazil and India as the current worst hot spots for the virus, as both set records this week for the number of cases or deaths confirmed in a single day.” The piece says, “Brazil has documented the second-most COVID-19 cases and deaths of any country behind the U.S., with more than 13 million and 340,000, respectively.” Meanwhile, “India ranks third in the number of cumulative cases at 12.9 million and fourth for its death toll of more than 166,000, according to Johns Hopkins University.”

Brazil Sets New Record For COVID-19 Deaths As Hospitals Run Low On Supplies.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-brazil/brazil-sets-new-daily-covid-19-death-record-as-hospital-supplies-run-low-idUSKBN2BV38Z"](https://www.reuters.com/article/us-health-coronavirus-brazil/brazil-sets-new-daily-covid-19-death-record-as-hospital-supplies-run-low-idUSKBN2BV38Z) \t "bipopup"] (4/8, Fonseca, Spring) says, "Brazil on Thursday set a new record of 4,249 coronavirus deaths in a day, as overwhelmed hospitals run low on supplies and the country nears record levels of deaths seen in the United States." The piece says three quarters of "private hospitals said they have a week or less of supplies for treating COVID-19, including oxygen, anesthesia and essential drugs for intubation, according to the ANAHP survey of 88 member hospitals across the country."

Several COVID-19 Vaccines Should Provide Effective Defense Against California Variant, Research Suggests.

The [[HYPERLINK "https://www.latimes.com/science/story/2021-04-07/covid-19-vaccines-work-well-against-california-variant"](https://www.latimes.com/science/story/2021-04-07/covid-19-vaccines-work-well-against-california-variant) \t "bipopup"] (4/7, Khan, 3.37M) reports that "as the California coronavirus variant continues to spread across the Golden State and beyond, new research suggests that several vaccines should continue to provide an effective defense against it." The "variant they tested, B.1.429, was a little less susceptible to both the Moderna and the Novavax vaccines, but both shots still generated effective protection, the researchers found." The research's "[[HYPERLINK "https://www.nejm.org/doi/full/10.1056/NEJMc2103740"](https://www.nejm.org/doi/full/10.1056/NEJMc2103740) \t "bipopup"], published Wednesday in the New England Journal of Medicine, offer good reason for Californians to keep rolling up their sleeves as the vaccination campaign picks up steam across the state."

Peruvian Local Government Allowed Secret Burials Of Victims With COVID-19.

The [[HYPERLINK "https://apnews.com/article/latin-america-coronavirus-pandemic-peru-d642e0762796cd490f0ce8d819d3eaea"](https://apnews.com/article/latin-america-coronavirus-pandemic-peru-d642e0762796cd490f0ce8d819d3eaea) \t "bipopup"] (4/8, Briceño) says a "field in Iquitos, a city in Loreto state in the heart of the Peruvian Amazon," may be "the first known case of authorities concealing the fate of dozens of COVID-19 victims, and nobody is able to explain why the clandestine burials were held." The piece adds that family members "told AP that at least 403 people were buried in that field."

UK COVID-19 Infections Declined Almost 60% Amid Vaccinations, Study Finds.

The [[HYPERLINK "https://apnews.com/article/pandemics-england-coronavirus-pandemic-london-coronavirus-vaccine-384f50d678bdc355ecad77aa43b5da1"](https://apnews.com/article/pandemics-england-coronavirus-pandemic-london-coronavirus-vaccine-384f50d678bdc355ecad77aa43b5da1) \t "bipopup"] (4/8, Kirka) says that the UK's COVID-19 "vaccination program is beginning to break the link between infection and serious illness or death, according to the latest results from an ongoing study of the pandemic in England." Researchers found that "COVID-19 infections dropped about 60% in March as national lockdown measures slowed the spread of the virus."

CBP Officials Report Seeing "Exponential Increase" In Counterfeit Mask Seizures In Last Few Months.

[[HYPERLINK "https://www.cnn.com/2021/04/08/us/millions-counterfeit-masks-seized-trnd/index.html"](https://www.cnn.com/2021/04/08/us/millions-counterfeit-masks-seized-trnd/index.html) \t "bipopup"] (4/8, Andrew, 89.21M) reports, "Millions of counterfeit masks have been seized by Customs and Border Protection (CBP) officials since the start of the pandemic," and "the last few months have seen an 'exponential increase' in counterfeit mask seizures, a CBP official told CNN." According to the article, "The counterfeit masks resemble N95 respirators, considered the most effective mask in preventing coronavirus transmission, but don't offer the same level of protection."

Asia Sees Mounting Coronavirus Infections As Vaccine Drives Face Potential Delays Due To Safety Concerns.

[HYPERLINK "<https://www.reuters.com/article/us-health-coronavirus-asia/asias-rising-coronavirus-cases-a-worry-as-vaccine-doubts-cloud-campaigns-idUSKBN2BV138>" \t "bipopup"] (4/8, Birsell) reports, "India, South Korea and Thailand faced mounting coronavirus infections on Thursday, undermining cautious hopes that Asia might be emerging from the worst of the pandemic as worries about safety threatened to delay vaccination drives." According to the article, "India reported a record 126,789 new cases, the third day this week tallies have surged to more than 100,000." Meanwhile, "South Korea reported 700 new cases on Thursday, its highest daily figure since early January."

Germany Mulls Potential Individual Order Of Russian COVID-19 Vaccine.

The [HYPERLINK "<https://apnews.com/article/europe-coronavirus-pandemic-germany-coronavirus-vaccine-europe-bc39b9e4d1a06f32a0fbf774324a5e94>" \t "bipopup"] (4/8, Moulson) reports, "Germany's health minister said Thursday that the European Union doesn't plan to order Russia's Sputnik V coronavirus vaccine but his country will hold talks with Russia on whether an individual order makes sense." The piece says, "In Germany itself, two state governments are pushing ahead with tentative plans to secure doses of the Russian vaccine."

[HYPERLINK "<https://thehill.com/policy/healthcare/public-global-health/547096-eu-wont-order-russia-vaccine-german-minister-says>" \t "bipopup"] (4/8, Schnell, 5.69M) also covers this story.

Scientists Call For Study To Examine Blood Samples In Effort To Figure Out When, How Pandemic Started.

The [HYPERLINK "<https://www.wsj.com/articles/origin-of-covid-19-pandemic-is-sought-in-old-blood-samples-11617874200>" \t "bipopup"] (4/8, McKay, Marcus, Subscription Publication, 8.41M) says that in a March 30 report, scientists called for a study to examine blood samples from Wuhan, China and other places that were taken before the COVID-19 outbreak to determine if the specimens have SARS-CoV-2 antibodies. Their goal is to figure out when and how the pandemic started.

Philippines Suspends Use Of AstraZeneca's COVID-19 Vaccine For Individuals Younger Than 60.

[HYPERLINK "<https://www.reuters.com/article/health-coronavirus-philippines-vaccine/update-1-philippines-suspends-use-of-astrazeneca-vaccine-for-people-under-60-idUSL1N2M10A6>" \t "bipopup"] (4/8, Morales) reports "Philippine health authorities suspended on Thursday the use of AstraZeneca's COVID-19 vaccine for people below 60 years of age to investigate reports of blood clots coming from overseas." The pause "came after the European Medicines Agency recommended to include blood clots as a rare side effect of the AstraZeneca vaccine, Food and Drug Administration chief Rolando Enrique Domingo said in a statement, adding that there were no reports of such adverse side effects in the country."

Opinion: US Should Use UK Strategy To Get First COVID-19 Vaccine Dose To As Many People As Possible.

In an opinion in [HYPERLINK "<https://www.usatoday.com/story/opinion/2021/04/08/covid-surge-deliver-first-vaccine-shots-delay-second-doses-column/7122747002/>" \t "bipopup"] (4/8, 12.7M), contributors Govind Persad, William F. Parker and Ezekiel J. Emanuel write that the US should "adopt

the sensible, evidence-based policy used in the United Kingdom: Vaccinate as many people as possible with just one dose, by delaying the second dose of Pfizer and Moderna vaccines.” They assert that the UK “has vaccinated 46% of the population and effectively avoided a second surge of the highly contagious B.1.1.7 variant,” adding that the US only needs “to vaccinate 40 million more people to reach the U.K. level.” They argue that “trusted communicators” such as NIAID Director “Dr. Anthony Fauci can lead the charge to explain to the public why the guidance has changed in response to new evidence.”

UAE Provides Syria With A Planeload Of Aid To Fight Spread Of COVID-19.

The [[HYPERLINK "https://apnews.com/article/middle-east-lebanon-coronavirus-pandemic-damascus-syria-2029e7878105c611cb6a97380cef1378"](https://apnews.com/article/middle-east-lebanon-coronavirus-pandemic-damascus-syria-2029e7878105c611cb6a97380cef1378) \t "bipopup"] (4/8, Mroue) says, “Syria received a planeload from the United Arab Emirates on Thursday with food items and medical aid to help the war-torn country in its fight against the spread of the coronavirus, Syria’s state media reported.” The piece says the assistance “from the UAE comes as Syria is witnessing a sharp increase in coronavirus cases.”

Hungarian Medical Professionals Question Reopening Amid Spike In COVID-19 Infections, Deaths.

The [[HYPERLINK "https://apnews.com/article/pandemics-europe-budapest-coronavirus-pandemic-hungary-015d6944566217073c341dcd59559582"](https://apnews.com/article/pandemics-europe-budapest-coronavirus-pandemic-hungary-015d6944566217073c341dcd59559582) \t "bipopup"] (4/8, Spike) says that physicians in Hungary “are questioning the government’s decision to lift some lockdown restrictions amid peaking COVID-19 infections and deaths, saying that could lead to an even more dire situation in the Central European nation.” The article adds that the easing of restrictions on Wednesday “coincided with a new daily high of 311 deaths and followed a record number of fatalities last week.”

Tunisia Extends Nighttime Curfew, Tightens Other Restrictions Ahead Of Ramadan.

The [[HYPERLINK "https://apnews.com/article/health-tunisia-middle-east-coronavirus-pandemic-5110ebebef06d5ecbaf2dee3a7a8f3bb"](https://apnews.com/article/health-tunisia-middle-east-coronavirus-pandemic-5110ebebef06d5ecbaf2dee3a7a8f3bb) \t "bipopup"] (4/8) says, “Tunisia is extending its nighttime curfew by three hours and tightening other restrictions ahead of Ramadan following an uptick of COVID-19 infections.” The piece adds that the government also announced “other measures late Wednesday, including a ban on all public and private gatherings, the shuttering of weekly markets, and stronger enforcement of mask-wearing and social distancing.”

Iran Hits New COVID-19 Infection Record For Third Consecutive Day.

The [[HYPERLINK "https://apnews.com/article/pandemics-iran-health-middle-east-coronavirus-pandemic-da55a596e2300f52d3a6a9a06e08cab4"](https://apnews.com/article/pandemics-iran-health-middle-east-coronavirus-pandemic-da55a596e2300f52d3a6a9a06e08cab4) \t "bipopup"] (4/8) says, “Iran hit a new coronavirus infection record on Thursday for the third straight day, reporting 22,586 new cases as the country grapples with a severe spike following the Persian New Year holiday.” The current “case count pushes Iran’s total during the pandemic over 2 million, including 63,884 deaths after health authorities reported 185 new daily fatalities due to COVID-19.”

[[HYPERLINK "https://thehill.com/policy/international/middle-east-north-africa/547128-iran-sets-record-for-coronavirus-cases-for"](https://thehill.com/policy/international/middle-east-north-africa/547128-iran-sets-record-for-coronavirus-cases-for) \t "bipopup"] (4/8, 5.69M) also covers this story.

Cambodia Shuts Down Its Most Popular Tourist Destination For Two Weeks To Curb Spread Of COVID-19.

The [[HYPERLINK "https://apnews.com/article/phnom-penh-asia-pacific-coronavirus-pandemic-cambodia-d7ee69a21616a7db71f73d1901daee3b"](https://apnews.com/article/phnom-penh-asia-pacific-coronavirus-pandemic-cambodia-d7ee69a21616a7db71f73d1901daee3b) \t "bipopup"] (4/8, Cheang) says, “Cambodia is shutting its most popular tourist destination, the centuries-old Angkor temple complex, to visitors for two weeks to help curb the country’s coronavirus outbreak.” This closing is the “latest in a slew of measures the country is taking after the number of coronavirus cases surged in February.”

France Reaches Target Of Administering 10M First Doses Of COVID-19 Vaccine.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-france-vaccine/france-meets-its-target-for-10-million-first-shots-of-covid-vaccine-idUSKBN2BV1YR"](https://www.reuters.com/article/us-health-coronavirus-france-vaccine/france-meets-its-target-for-10-million-first-shots-of-covid-vaccine-idUSKBN2BV1YR) \t "bipopup"] (4/8, Van Overstraeten, Protard) says that on Thursday, Prime Minister Jean Castex said that more than “10 million people in France have now received a first shot of a COVID-19 vaccine, with the government’s target for that number reached a week ahead of schedule.” The piece adds, “France is hoping a ramp-up of its vaccination campaign along with a month-long nationwide lockdown in place since last weekend will help it regain control over the latest outbreak.”

India Claims It Has 43M COVID-19 Vaccine Doses, Denies Shortage.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-india-vaccine/india-says-it-has-millions-of-covid-19-vaccines-in-hand-denies-shortage-idUSKBN2BV1VX"](https://www.reuters.com/article/us-health-coronavirus-india-vaccine/india-says-it-has-millions-of-covid-19-vaccines-in-hand-denies-shortage-idUSKBN2BV1VX) \t "bipopup"] (4/8, Das) says, “India’s health minister said on Thursday the country had more than 43 million COVID-19 vaccine doses in stock or in the pipeline, after many states complained of having to close inoculation centres due to a lack of supplies.” So far, India has “administered more than 90 million doses.”

European Court Accepts Czech Republic’s Position On Mandatory COVID-19 Vaccinations For Children.

[[HYPERLINK "https://www.reuters.com/article/us-eu-court-czech-vaccines/european-court-backs-czech-republics-requirement-to-vaccinate-children-idUSKBN2BV1WY"](https://www.reuters.com/article/us-eu-court-czech-vaccines/european-court-backs-czech-republics-requirement-to-vaccinate-children-idUSKBN2BV1WY) \t "bipopup"] (4/8) says, “The European Court of Human Rights (ECHR) accepts the Czech Republic’s position on mandatory vaccinations for children, it said in a landmark ruling on Thursday that rebuffed parents’ complaints that the government violated their rights.” The piece adds, “The ECHR said it found no violation of the European Convention on Human Rights.”

Swiss Region Offers Privileges To Those Who Participate In Mass COVID-19 Testing.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-swiss/swiss-region-rewards-covid-testing-schools-by-lifting-mask-rule-idUSKBN2BV1IP"](https://www.reuters.com/article/us-health-coronavirus-swiss/swiss-region-rewards-covid-testing-schools-by-lifting-mask-rule-idUSKBN2BV1IP) \t "bipopup"] (4/8) says, “Switzerland is joining nations offering privileges to those conforming with COVID-19 measures, as one region allows fifth- and sixth-grade students to shed masks if their schools have participated in mass testing.” The piece adds that this small move “is emblematic of a broader global debate over whether people who test negative or are vaccinated should enjoy more freedoms.”

Germany’s Vaccination Campaign Extended To Physicians’ Offices.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-germany/germanys-vaccine-rollout-gets-shot-in-the-arm-from-doctors-surgeries-idUSKBN2BV1US"](https://www.reuters.com/article/us-health-coronavirus-germany/germanys-vaccine-rollout-gets-shot-in-the-arm-from-doctors-surgeries-idUSKBN2BV1US) \t "bipopup"] (4/8) says, “Germany’s COVID-19 vaccination drive has picked up speed with more than 650,000 doses administered on Wednesday, data from the Robert Koch Institute (RKI) showed on Thursday, supercharged by extending the rollout to family doctors.” The piece adds that the RKI “said Germany

administered 656,357 doses of COVID-19 vaccines on Wednesday, almost 300,000 more than the number of shots given the previous day,” and “of these, 305,664 were delivered in doctors surgeries.”

Indonesia In Talks With China To Secure More COVID-19 Vaccines After AstraZeneca Delays Deliveries.

[HYPERLINK "<https://www.reuters.com/article/us-health-coronavirus-indonesia-vaccine/indonesia-turns-to-china-for-more-vaccines-after-astrazeneca-delays-idUSKBN2BV0C3>" \t "bipopup"] (4/8, Widiyanto, Rizki) adds, “Indonesia is in talks with China to secure as many as 100 million COVID-19 vaccine doses to plug a gap in deliveries after delays in arrivals of AstraZeneca shots, its health minister said on Thursday.” In addition to “AstraZeneca, Indonesia relies heavily on vaccines produced by China’s Sinovac Biotech for inoculations which began in January.”

Australia Holds National Cabinet Meeting To Devise New COVID-19 Vaccination Program.

[HYPERLINK "<https://www.reuters.com/article/us-health-coronavirus-australia/australian-pm-meets-state-and-territory-leaders-under-pressure-from-vaccine-shift-idUSKBN2BV36E>" \t "bipopup"] (4/8, Kaye) says, “Australia is holding a national cabinet meeting on Friday to devise a new COVID-19 vaccination programme after abruptly changing policy and recommending people under 50 take the Pfizer vaccine not AstraZeneca due to the risks of blood clots.” This “move sees Australia joining countries around the world which have put restrictions on one of the most widely accessible vaccines against the coronavirus over concern about links to very rare blood clots.”

England’s Vaccine Rollout Prevented 10.4K Deaths By Mid-March, Study Indicates.

[HYPERLINK "<https://www.reuters.com/article/us-health-coronavirus-britain-vaccines/vaccine-rollout-in-england-prevented-10400-deaths-by-end-march-study-says-idUSKBN2BV321>" \t "bipopup"] (4/8, Shirbon) says, “England’s fast rollout of COVID-19 vaccines prevented over 10,000 deaths of people aged 60 and older by the end of March, according to an analysis by Public Health England.” England had “a peak in infections, hospitalisations and deaths in January, but the toll would have been even worse without the rapid vaccination programme that began on Dec. 8, according to the study.”

France Says 5,705 People With COVID-19 Are In ICUs.

[HYPERLINK "<https://www.reuters.com/article/us-health-coronavirus-france-infections/france-reports-5705-people-in-intensive-care-units-with-covid-19-idUSKBN2BV2YD>" \t "bipopup"] (4/8, Van Overstraeten, Terzian, Thomas) says, “The French health ministry on Thursday reported the number of people in intensive care units with COVID-19 fell by 24 from Wednesday, to 5,705, the first decrease in eight days.” In addition, France “counted 71,944 deaths in hospitals due to the virus, up 343 from the previous day, while the number of people in hospital for COVID-19 was down by 349 to 30,555.”

Indian PM Rejects Calls To Offer COVID-19 Vaccinations To Younger People Amid Record Surge In Cases.

[HYPERLINK "<https://www.reuters.com/article/us-health-coronavirus-india-cases/indian-pm-rejects-calls-to-widen-vaccine-access-as-infections-hit-record-idUSKBN2BV0E4>" \t "bipopup"] (4/8, Arora, Jadhav) says, “Indian Prime Minister Narendra Modi on Thursday rejected calls from states to offer coronavirus vaccinations to younger people to help contain a record surge in cases.” The vaccinations “are currently limited to those aged over 45 and health and frontline workers.”

Nicaragua Has Slowly Begun Vaccinating People Over 60 Using AstraZeneca COVID-19 Vaccine.

The [[HYPERLINK "https://apnews.com/article/health-nicaragua-coronavirus-pandemic-latin-america-85e335feb2cc915fb3fd1a2f68f7fa32"](https://apnews.com/article/health-nicaragua-coronavirus-pandemic-latin-america-85e335feb2cc915fb3fd1a2f68f7fa32) \t "bipopup"] (4/8) says, “Nicaragua has begun slowly vaccinating people over 60, using an AstraZeneca vaccine made in India.” The piece adds that the country “has only received around 500,000 doses of vaccines for a country of 5 million people.”

COVAX Has Delivered Almost 38.4B COVID-19 Vaccine Doses To Over 100 Countries, Despite Supply Delays.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-vaccines-covax/covax-vaccines-reach-more-than-100-countries-despite-supply-snags-idUSKBN2BV1PK"](https://www.reuters.com/article/us-health-coronavirus-vaccines-covax/covax-vaccines-reach-more-than-100-countries-despite-supply-snags-idUSKBN2BV1PK) \t "bipopup"] (4/8, Nebehay) says, “The COVAX vaccine facility has delivered nearly 38.4 million doses of COVID-19 vaccines to 102 countries and economies across six continents, six weeks after it began to roll out supplies, according to a statement on Thursday.” The piece adds that “there have been some delays” per the GAVI vaccine alliance and World Health Organization.

Canada’s COVID-19 Vaccine Scarcity Highlights Risks Of Foreign Dependence.

[[HYPERLINK "https://www.politico.com/news/2021/04/08/canada-low-covid-vaccine-capacity-480226"](https://www.politico.com/news/2021/04/08/canada-low-covid-vaccine-capacity-480226) \t "bipopup"] (4/8, Blatchford, 6.73M) reports, “The absence of domestic manufacturing forced the Trudeau government from the get-go into a global competition to attract drug producers to the country’s shores.” The article says “Canada has had to rely entirely on over-burdened foreign supply chains for a Covid vaccine rollout that has lagged international peers, including the United States.” Canada has also “announced deals to expand biomanufacturing with domestic companies, including investments of up to C\$173 million with Medicago and C\$25.1 million with Precision NanoSystems Inc.”

Experts Says Italy’s Daily COVID-19 Death Toll Suggests The Country Has Been Vaccinating The Wrong People.

The [[HYPERLINK "https://www.washingtonpost.com/world/europe/italy-vaccines-death-toll/2021/04/08/2d621f12-971a-11eb-8f0a-3384cf4fb399_story.html"](https://www.washingtonpost.com/world/europe/italy-vaccines-death-toll/2021/04/08/2d621f12-971a-11eb-8f0a-3384cf4fb399_story.html) \t "bipopup"] (4/8, Harlan, Noack, 10.52M) reports that “looking at the day-by-day chart tracking Italy’s relentless coronavirus death toll, it would be impossible to tell that the country has been armed since late December with vaccines.” The piece says on Wednesday, “the country reported another 627 victims of the virus, the highest daily figure since early January.” Some experts say that Italy “has been vaccinating too many of the wrong people, overprioritizing young workers and leaving the elderly vulnerable.”

Brazil’s Supreme Court Orders Investigation Of Government’s Handling Of COVID-19 Crisis.

The [[HYPERLINK "https://apnews.com/article/31dec098c1058ca0862b1894270ca90"](https://apnews.com/article/31dec098c1058ca0862b1894270ca90) \t "bipopup"] (4/8, Savarese) says, “A Brazilian Supreme Court justice ordered the Senate on Thursday to investigate the government’s handling of the coronavirus crisis and the full court ruled that churches can be barred from reopening during the pandemic, threatening to further strain tensions between President Jair Bolsonaro and the judiciary.” The piece adds that Bolsonaro “has downplayed the threat of the coronavirus while arguing that the economic and emotional impacts of shutdowns would harm more Brazilians than the pandemic.”

China Urges International Community To Resist “Vaccine Nationalism.”

[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-imf-china/china-repeats-call-to-resist-vaccine-nationalism-pledges-to-keep-monetary-support-idUSKBN2BW0AH" \t "bipopup"] (4/9, Kihara) says, "China urged the international community to resist 'vaccine nationalism' and to coordinate policy to make vaccines accessible for developing countries in order to contain the pandemic and for the sake of the global economy." The piece adds, "The central bank chief also gave an assurance that China would continue to provide necessary monetary support to the economy and refrain from abruptly unwinding stimulus measures."

South Korea Reimposes Bans On Nighttime Entertainment Facilities Amid Fears Over Fourth COVID-19 Wave.

[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-southkorea/south-korea-orders-closure-of-nightclubs-karaoke-bars-amid-concern-over-fourth-covid-19-wave-idUSKBN2BW07Z" \t "bipopup"] (4/8, Shin) says, "South Korea will reimpose a ban on nightclubs, karaoke bars and other nightly entertainment facilities, authorities said on Friday, after the number of new coronavirus cases surged, fanning fears over a potential fourth wave of outbreaks." South Korea's Prime Minister "Chung Sye-kyun announced the curbs, which take effect on Monday for three weeks, after daily new case counts climbed to a three-month high in recent days."

India To Investigate Domestic Instances Of Blood Clot Issues As Possible Side Effects Of COVID-19 Vaccines.

[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-india-vaccines/india-to-review-covid-19-vaccines-after-blood-clot-warning-report-idUSKBN2BW052" \t "bipopup"] (4/9, Babu, Kalia) says, "A government panel of experts is investigating for any domestic cases of blood clotting, even mild ones, as a side effect of the two COVID-19 vaccines being administered in India, financial daily Mint reported on Friday, citing two people aware of the development." The piece adds, "India is currently administering AstraZeneca's COVID-19 vaccine, which is manufactured by the Serum Institute and branded Covishield, and a shot developed by Bharat Biotech called COVAXIN."

Australia Doubles Pfizer COVID-19 Vaccine Order After AstraZeneca's Blood Clotting Worries Upend Rollout.

[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-australia/australia-doubles-pfizer-vaccine-order-as-astra-clotting-worries-upend-rollout-idUSKBN2BV36E" \t "bipopup"] (4/9, Kaye) says, "Australia has doubled its order of the Pfizer Inc COVID-19 vaccine, Prime Minister Scott Morrison said on Friday, as the country raced to overhaul its inoculation plan over concerns about the risks of blood clots with the AstraZeneca Plc vaccine." The piece adds that the "policy change to Pfizer effectively ends plans to have the entire population vaccinated by the end of October."

[HYPERLINK "https://www.bloomberg.com/news/articles/2021-04-09/australia-secures-additional-20-million-pfizer-vaccine-doses?srd=premium" \t "bipopup"] (4/9, Johnson, 3.57M) also covers this story.

Japan To Place Tokyo Under "Quasi-Emergency" State To Combat COVID-19 Surge.

[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-japan/japan-to-add-tokyo-other-areas-to-covid-19-quasi-emergency-state-idUSKBN2BW02Y" \t "bipopup"] (4/8, Takemoto, Kim) says, "Japan aims to place Tokyo under a new, month-long "quasi-emergency" state to combat surging

COVID-19 case numbers, a minister said on Friday, less than a month after the capital and host of the Summer Olympics lifted a broader state of emergency." The piece adds, "Japan has so far seen far fewer COVID-19 than many Western nations – about 490,000 cases and 9,300 deaths to date, according to the health ministry – but concerns about a new wave of infections are rising fast, particularly with the summer hosting of the Olympic Games coming up fast."

The [[HYPERLINK "https://apnews.com/article/yoshihide-suga-tokyo-coronavirus-pandemic-japan-olympic-games-343e6a953bec2e4691774474e436da10"](https://apnews.com/article/yoshihide-suga-tokyo-coronavirus-pandemic-japan-olympic-games-343e6a953bec2e4691774474e436da10) \t "bipopup"] (4/8, Yamaguchi) also covers this story.

Costa Rica Will Use AstraZeneca COVID-19 Vaccine After Assessing Guidance.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-costa-rica/after-weighing-guidance-costa-rica-to-use-astrazeneca-vaccine-idUSKBN2BV36O"](https://www.reuters.com/article/us-health-coronavirus-costa-rica/after-weighing-guidance-costa-rica-to-use-astrazeneca-vaccine-idUSKBN2BV36O) \t "bipopup"] (4/8, Murillo) says, "Costa Rica will use AstraZeneca's COVID-19 vaccine after assessing guidance from the European Medicines Agency (EMA) on the risks of possible side-effects, the health ministry said on Thursday." The country's "authorities will begin distributing 43,000 doses of the vaccine which arrived on Wednesday, the first delivery under an agreement for a million vaccines with the COVAX mechanism of the World Health Organization (WHO)."

Canadian Finance Minister Highlights Need For National Childcare Plan.

[[HYPERLINK "https://www.reuters.com/article/canada-economy-finance/canada-finance-minister-pandemic-an-opportunity-to-bring-in-national-childcare-idUSL1N2M201B"](https://www.reuters.com/article/canada-economy-finance/canada-finance-minister-pandemic-an-opportunity-to-bring-in-national-childcare-idUSL1N2M201B) \t "bipopup"] (4/8, Ljunggren) says, "The COVID-19 pandemic and its damaging impact on women has underlined the need for a national childcare plan, which would also help the economic recovery, [Canada's] Finance Minister Chrystia Freeland said on Thursday." The piece adds, "Since taking up her job in August, Freeland has repeatedly spoken about a 'feminist agenda,' and has said childcare will be part of a stimulus package worth up to C\$100 billion (\$79.6 billion) over three years."

About 119,000 Mississippians Eligible For Lower-Cost ACA Plans Thanks To COVID-19 Stimulus Package.

[[HYPERLINK "https://www.wlbt.com/2021/04/08/thousands-mississippians-eligible-reduced-insurance-rates-under-arp/"](https://www.wlbt.com/2021/04/08/thousands-mississippians-eligible-reduced-insurance-rates-under-arp/) \t "bipopup"] Jackson, MS (4/8, Warren) reports, "For Mississippians who think they can't afford health insurance, Health and Human Services Sec. Xavier Becerra says think again." Because "of the American Rescue Plan, more than 119,000 people in the Magnolia State are now eligible for reduced insurance rates through the federal marketplace, Healthcare.gov." Becerra said, "We're reaching out. We're going to go out there. We have a program which is run by navigators who go out there and know the community...entities and respected leaders who have the confidence of the neighborhoods, and they'll be available to start helping to reach out to some of the community organizations and health clinics." He added, "We want to reach out to those Americans who don't know about this opportunity to get really good healthcare coverage at a low cost. ... President Biden wanted to make sure we didn't miss anyone who qualified."

New COVID-19 Cases Associated With Youth Sports, Daycare Centers Could Hinder School Reopening Efforts.

[HYPERLINK "<https://www.bloomberg.com/news/articles/2021-04-08/biden-s-school-reopening-plans-at-risk-on-sports-tied-outbreaks>" \t "bipopup"] (4/8, Wingrove, 3.57M) reports the COVID-19 “pandemic is erupting anew in youth sports across the U.S., prompting fresh warnings from President Joe Biden’s health advisers and adding a headwind to his push to reopen classrooms.” Certain “states have faced recent outbreaks linked to sporting events and to a variant of the virus from the U.K. called B.1.1.7. Michigan is an epicenter both of the latest surge and the U.K. variant, which is regarded as more transmissible than the original strain of the virus and may be deadlier.” CDC Director Dr. Rochelle Walensky said, “We are hearing reports of clusters of cases associated with daycare centers and youth sports.”

White House Vaccinations Coordinator Touts Progress On COVID-19 Vaccine Rollout.

[HYPERLINK "<https://federalnewsnetwork.com/conversations-on-healthcare/2021/04/white-house-vaccinations-chief-dr-bechara-choucair-on-the-road-to-vaccinating-america/>" \t "bipopup"] (4/8, 220) reports that hosts Mark Masselli and Margaret Flinter spoke with Dr. Bechara Choucair, White House Vaccinations Coordinator. Choucair said, “11 weeks ago, the US was averaging less than one million vaccinations per day. Our current seven-day average is over three million vaccinations per day. This weekend, we reported for the very first time ever four million shots administered in one day. As of today, we have administered over 168 million doses as a country, and for people 65 and older, where we know 80% of the deaths from COVID are occurring, more than 75% of” them “have had at least one shot of the vaccine. That’s up from 8% 11 weeks ago. So, when you look at the numbers, this is really impressive, and I continue to be in awe on how this country is coming together to get us all vaccinated, and getting us past this pandemic.”

CDC Data Show About 25% Of American Adults Have Been Fully Vaccinated Against COVID-19.

[HYPERLINK "<https://www.foxnews.com/health/1-in-4-us-adults-fully-vaccinated-against-covid-19-cdc-data>" \t "bipopup"] (4/8, Hein, 23.99M) reports the latest data from the CDC “appear to reflect that about one in four U.S. adults is now fully vaccinated against COVID-19. According to the agency’s vaccine tracker, about 64.2 million adults aged 18 and older, or 24.9% percent of the population, have received either the one-shot Johnson & Johnson jab or both doses of either the Pfizer and BioNTech or Moderna vaccine.” CDC Director Dr. Rochelle Walensky on Wednesday “said that there is ‘so much reason for so much hope,’ but warned against states letting their guards down prematurely as cases and hospitalizations show recent increases.” The article mentions NIAID Director Dr. Anthony Fauci.

Analysis: This Is Not The First Time The World Has Debated The Issue Of Vaccine Passports.

[HYPERLINK "<https://www.npr.org/sections/goatsandsoda/2021/04/08/985032748/the-vaccine-passport-debate-actually-began-in-1897-over-a-plague-vaccine>" \t "bipopup"] (4/8, Kritz, 3.69M) reports, “This isn’t the first time the world has been engaged in a conversation about ‘vaccine passports.’” Furthermore, “there even is a version of a passport currently in use – the World Health Organization-approved yellow card, which since 1969 has been a document for travelers to certain countries to show proof of vaccination for yellow fever and other shots. Without which they can’t visit those countries.” The piece says the debate over vaccine passports started in 1897 after a vaccine for the plague was developed.

Analysis: Thus Far, Researchers Are Uncertain About Impact Of Vaccines On The COVID-19 Pandemic.

Chris Wilson writes for [[HYPERLINK "https://time.com/5953007/covid-19-mass-vaccination/"](https://time.com/5953007/covid-19-mass-vaccination/) \t "bipopup"] (4/8, 18.1M,) that “after four months and 171 million doses of COVID-19 vaccines administered across the U.S., more than a few of us are eager to know: are the shots working?” To date, “available evidence can half-answer that question: The vaccines are working well for those who can get them.” However, “there’s another part of that question: will mass vaccination hasten the end of the pandemic? On first pass, this might seem to be happening.” Wilson says, “Unfortunately, the researchers I’ve consulted were unanimous in saying that it’s far too soon to attribute the decline in deaths to the vaccine rollout on even a tentative basis. In part, that’s because vaccination rates are still too low to show a connection.”

Analysis Concludes New York’s COVID-19 Vaccine Passport Shows Promise, But Faces Some Challenges.

Geoffrey A. Fowler writes in the [[HYPERLINK "https://www.washingtonpost.com/technology/2021/04/08/vaccine-passport-new-york-excelsior-pass/"](https://www.washingtonpost.com/technology/2021/04/08/vaccine-passport-new-york-excelsior-pass/) \t "bipopup"] (4/8, 10.52M,) that New York recently “became the first state to offer a digital ‘vaccine passport’ – a free app and website you can use to prove you’ve been vaccinated against the coronavirus or gotten a recent negative coronavirus test result.” Thanks to this “new technology, called the Excelsior Pass, New Yorkers can show a screen or a printout with a special code that businesses scan with an app made by the state. A green check mark means you’re allowed inside.” Fowler says, “The good news: For the digitally savvy people who figure it out, using Excelsior Pass doesn’t appear to pose major privacy risks.” However, “I question how effective Excelsior Pass will be at keeping everyone safe. For one, it’s pretty easy to set up a fake pass.”

National Guard Encouraging Americans To Continue Taking Precautions Against COVID-19 Even As Vaccinations Increase.

[[HYPERLINK "https://www.cnbc.com/2021/04/08/national-guard-urges-us-to-follow-health-measures-as-military-races-to-vaccinate-population.html"](https://www.cnbc.com/2021/04/08/national-guard-urges-us-to-follow-health-measures-as-military-races-to-vaccinate-population.html) \t "bipopup"] (4/8, Macias, 7.34M) reports that on Thursday, National Guard leaders urged “people in the U.S. keep adhering to Covid-19 mitigation measures as the military races to vaccinate the population.” U.S. Air Force Col. Russell Kohl, commander of the 131st Medical Group for the Missouri National Guard, said, “We’re excited to follow the [Centers for Disease Control and Prevention] science that tells us what the smart thing is to continue to protect the civilians around us.” The article mentions NIAID Director Dr. Anthony Fauci.

Commentary Says US Will Need “Reliable Access” To COVID-19 Testing Despite Progress On Vaccine Rollout.

Christi A. Grimm, principal deputy inspector general at HHS, and Michael E. Horowitz, inspector general of the Department of Justice, write in a [[HYPERLINK "https://cnn.com/2021/04/08/opinions/lessons-prac-report-improving-covid-19-testing-opinion-grimm-horowitz/index.html"](https://cnn.com/2021/04/08/opinions/lessons-prac-report-improving-covid-19-testing-opinion-grimm-horowitz/index.html) \t "bipopup"] (4/8, 89.21M) op-ed that “even as the number of administered Covid-19 vaccines grows, America’s need for reliable access to Covid-19 testing will extend well into the future.” According to the CDC, preliminary “data suggesting fully-vaccinated people are less likely to spread Covid-19 are promising, but ‘we’re still learning how well Covid-19 vaccines keep people from spreading the disease,’ as well as ‘how effective the vaccines are against variants of the virus.’” Therefore, “it is important that the federal government remains focused on testing.” Grimm and Horowitz go on to discuss how to improve COVID-19 testing.

Commentary Highlights The Pitfalls Of Attempting To Determine A “Magic Number” At Which Herd Immunity Is Achieved.

Kent Sepkowitz, “a CNN medical analyst and a physician and infection control expert at Memorial Sloan Kettering Cancer Center in New York,” writes in a [[HYPERLINK "https://cnn.com/2021/04/08/opinions/covid-19-herd-immunity-vaccine-sepkowitz/index.html"](https://cnn.com/2021/04/08/opinions/covid-19-herd-immunity-vaccine-sepkowitz/index.html) \t "bipopup"] (4/8, 89.21M) op-ed that as more Americans become vaccinated, “the Covid-19 story, which once was nothing more than a tale of enormous tragedy, now has a new plotline: how best to return to normal. A key element of this latter story arc is the poorly understood concept of ‘herd immunity.’” Sepkowitz says “there is no answer,” no “magic number” at which scientists can declare that the US has achieved herd immunity. He adds, “Setting ourselves up for a giant belly flop by forcing public health leaders to produce a magic number will not only make sober experts look like fools, it will further undermine people’s faith in science, thereby slowing our emergence from the long shadow of Covid -19.” He mentions NIAID Director Dr. Anthony Fauci.

Commentary Says Walensky, Fauci Should Not Be Afraid Of Being Candid.

Ramesh Ponnuru writes in [[HYPERLINK "https://www.bloomberg.com/opinion/articles/2021-04-08/fauci-and-cdc-s-walensky-should-be-candid-about-vaccines-now"](https://www.bloomberg.com/opinion/articles/2021-04-08/fauci-and-cdc-s-walensky-should-be-candid-about-vaccines-now) \t "bipopup"] (4/8) that CDC Director Dr. Rochelle Walensky has been providing “confusing” information about the COVID-19 pandemic. He says, “Walensky is not alone in providing whiplash along with Covid guidance.” NIAID Director Dr. Anthony Fauci “notoriously went from discouraging mask use early in 2020 (‘people keep fiddling with the mask and they keep touching their face’) to encouraging it later.” Ponnuru says “these experts deserve some slack. The stakes and the scrutiny have been higher than ever. They have had to convey information about a little-understood virus to tens of millions of people with less scientific literacy than themselves. Errors and miscommunication were inevitable.” Nevertheless, “there is a troubling through line to many of the most damaging episodes of public-health messaging in the pandemic: a fear of candor.”

Federal Officials Ramp Up Vaccine Access For People With Disabilities.

[[HYPERLINK "https://r.bulletinintelligence.com/e796e9f222a846f4897014f489874b61"](https://r.bulletinintelligence.com/e796e9f222a846f4897014f489874b61) \t "bipopup"] (4/9, Diament) reports as COVID-19 vaccine “eligibility opens up to everyone nationwide, federal officials are acknowledging that challenges remain in reaching many people with disabilities who face transportation barriers, difficulty with scheduling appointments or who might struggle to manage a visit to a mass vaccine site, among other issues.” HHS “says the CDC and the Administration for Community Living will provide nearly \$100 million to improve access for people with disabilities and older adults.”

NIH Launches Clinical Trial Investigating Rare Allergic Reactions To COVID Vaccines.

[[HYPERLINK "https://consumer.healthday.com/b-4-8-nih-starts-trial-looking-at-rare-allergic-reactions-to-covid-vaccines-2651383898.html"](https://consumer.healthday.com/b-4-8-nih-starts-trial-looking-at-rare-allergic-reactions-to-covid-vaccines-2651383898.html) \t "bipopup"] (4/8, Reinberg, 11K) reports, “A new clinical trial will investigate whether people who are highly allergic or have what’s known as a mast cell disorder are at higher risk for a sudden allergic reaction to the Moderna or Pfizer COVID-19 vaccines.” NIAID Director Dr. Anthony Fauci stated, “The public understandably has been concerned about reports of rare, severe allergic reactions to the Moderna and Pfizer-BioNTech COVID-19 vaccines. ... The information gathered during this trial will help doctors advise people who are highly allergic or have a mast cell disorder about

the risks and benefits of receiving these two vaccines.” The article adds, “Researchers will also look at the biological mechanism causing the reactions and whether there is a way to predict who is at most risk.”

Fauci Describes Development Of Technology Behind COVID-19 Vaccines.

In an editorial in [[HYPERLINK "http://science.sciencemag.org/cgi/content/short/372/6538/109?rss=1"](http://science.sciencemag.org/cgi/content/short/372/6538/109?rss=1) \t "bipopup"] (4/9, 484K), NIAID Director Dr. Anthony Fauci writes about the “remarkable success story” of the “several highly efficacious” COVID-19 vaccines that were developed “in less than 1 year from the identification of the virus,” which “is unprecedented in the history of vaccinology.” Fauci says that “concern about this truncated timeline has contributed in part to the hesitancy in accepting these vaccines.” However, he adds, “Two activities predate the successful COVID-19 vaccines: the utilization of highly adaptable vaccine platforms such as RNA (among others) and the adaptation of structural biology tools to design agents (immunogens) that powerfully stimulate the immune system.”

“Instagram Generation” Largely Left Out Of COVID-19 Messaging, STAT Finds.

[[HYPERLINK "https://www.statnews.com/2021/04/08/gen-z-hesitant-covid-19-vaccine/"](https://www.statnews.com/2021/04/08/gen-z-hesitant-covid-19-vaccine/) \t "bipopup"] (4/8, Florko, 262K) reports that “useful Covid-19 information isn’t reaching the Instagram generation,” because there is “almost no messaging specifically tailored to them from federal or state public health officials. There’s hardly anything official on Tik Tok. And even the limited efforts to reach them where they are – like Instagram’s links to its ‘Covid-19 information center’-- aren’t working.” STAT adds that it interviewed “more than half a dozen other young people around the country,” and “nearly all said they weren’t opposed to vaccinations – they just couldn’t find information tailored to them.” STAT cites findings of a recent STAT-Harris Poll that found “that lack of information is clearly having an impact.”

Bourla Profiled For COVID-19 Vaccine Development, Willingness To Contribute Financially To Pricing Reforms.

[[HYPERLINK "https://www.economist.com/business/2021/04/08/pfizers-boss-thinks-covid-19-is-reshaping-big-pharma-for-the-better"](https://www.economist.com/business/2021/04/08/pfizers-boss-thinks-covid-19-is-reshaping-big-pharma-for-the-better) \t "bipopup"] (4/8, 2.37M) profiles Pfizer CEO Albert Bourla in light of “the giant American drugmaker’s speedy development (with BioNTech of Germany) of a vaccine against covid-19.” Bourla said, “The impossible can many times become possible.” Concerning the pharmaceutical sector’s public image, Bourla “says that Pfizer does not support the status quo on drug prices in America,” which “are high by global standards, and contribute the lion’s share of profits for the global drugs business.” Bourla also “[insisted] that Pfizer is ‘willing to contribute financially’ to reforms that give ‘access for all’, so long as insurers and government chip in too.” The article adds, “If he can persuade his fellow pharma bosses to support this new social contract, it could be an even bigger feat than those incredible covid-19 shots.”

Newly Vaccinated Mothers Sharing Breast Milk To Help Spread COVID-19 Antibodies To Babies.

The [[HYPERLINK "https://www.nytimes.com/2021/04/08/health/covid-vaccine-breast-milk.html"](https://www.nytimes.com/2021/04/08/health/covid-vaccine-breast-milk.html) \t "bipopup"] (4/8, Murphy, 20.6M) reports that “over the past few weeks, online forums focused on relactation have been swarmed with newly vaccinated mothers” who believe that their antibodies could be passed to babies through breast milk. And researchers agree, noting that “as with so much to do with the coronavirus, more research would be beneficial. But there is no concrete reason for new mothers to hold off on getting vaccinated or to dump out their breast milk, they said.” Meanwhile, there are sti ll

“parenting forums brimming with anecdotes about pediatricians telling mothers to wait to get vaccinated until their baby is older or to dump their milk after vaccination.” The Times says this is “mostly because lactating mothers were not included in [COVID-19] vaccine trials, so researchers have not been able to concretely study risks.”

[[HYPERLINK "https://thehill.com/policy/healthcare/547206-vaccinated-mothers-share-breastmilk-to-help-spread-covid-19-antibodies-to"](https://thehill.com/policy/healthcare/547206-vaccinated-mothers-share-breastmilk-to-help-spread-covid-19-antibodies-to) \t "bipopup"] (4/8, Lonas, 5.69M) reports, “Researchers told the Times that although there is not enough research about how the coronavirus vaccine affects breast milk, there is enough on how vaccines affect it generally that there is no reason to believe it is unsafe.”

UK Officials, Ministers Seeking To Restore Confidence In COVID-19 Vaccine.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-britain-astrazenec/britain-reassures-on-astrazeneca-after-advising-under-30s-take-other-vaccines-idUSKBN2BV2QS"](https://www.reuters.com/article/us-health-coronavirus-britain-astrazenec/britain-reassures-on-astrazeneca-after-advising-under-30s-take-other-vaccines-idUSKBN2BV2QS) \t "bipopup"] (4/8, Smout) reports, “British officials and ministers sought to shore up confidence in AstraZeneca’s COVID-19 vaccine on Thursday, saying advice that most people under 30 should be offered alternative shots was not unusual and would not impact the pace of rollout.” The article adds, “Officials said the suggestion that under-30s should be offered an alternative did not reflect any serious safety concerns, just a ‘vanishingly’ rare possible side effect.” Joint Committee on Vaccination and Immunisation Deputy Chairman Anthony Harnden “said such suggestions were not unusual, pointing out that people of different ages already got different flu shots in Britain.”

French Health Body To Say mRNA Vaccine Should Be Used As Second COVID-19 Vaccine Dose After AstraZeneca.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-france-vaccines-ex/exclusive-french-health-body-to-say-mrna-vaccine-should-be-used-as-second-dose-after-astrazeneca-idUSKBN2BV2W7"](https://www.reuters.com/article/us-health-coronavirus-france-vaccines-ex/exclusive-french-health-body-to-say-mrna-vaccine-should-be-used-as-second-dose-after-astrazeneca-idUSKBN2BV2W7) \t "bipopup"] (4/8, Blamont) reports, “France’s top health body will on Friday say that recipients of a first dose of AstraZeneca’s traditional COVID-19 vaccine who are under 55 should get a second shot with a new-style messenger-RNA vaccine, two sources aware of the plans said on Thursday.” The Haute Autorite de la Sante (HAS) “has now decided to proceed with the plan, the two sources said. Two mRNA vaccines, one from Pfizer and BioNTech and one from Moderna, are approved for use in France.”

Biden Administration Faces Question Of What To Do With 20M AstraZeneca COVID-19 Vaccine Doses.

[[HYPERLINK "https://www.bloomberg.com/news/articles/2021-04-08/biden-s-orphaned-astrazeneca-stockpile-rises-to-20-million-doses?srnd=premium"](https://www.bloomberg.com/news/articles/2021-04-08/biden-s-orphaned-astrazeneca-stockpile-rises-to-20-million-doses?srnd=premium) \t "bipopup"] (4/8, Wingrove, 3.57M) reports, “The U.S. stockpile of the controversial AstraZeneca Plc coronavirus vaccine has grown to more than 20 million doses, according to people familiar with the matter, even as the shot looks increasingly unlikely to factor into President Joe Biden’s domestic vaccination campaign.” AstraZeneca has not yet requested authorization from the FDA “for the two-dose vaccine, and the company faces safety questions abroad and scrutiny from U.S. regulators who’ve already rebuked it for missteps during clinical trials and partial data releases.” The article adds, “Three other vaccines already authorized in the U.S. are going into Americans’ arms at a rate of about 3 million doses per day, with hundreds of millions of additional doses set to be delivered by August,” which “raises the question for Biden” of “what to do with AstraZeneca’s vaccine.”

COVID-19 Survivors May Experience More Intense Side Effects From Vaccine, Studies Suggest.

[[HYPERLINK "https://www.foxnews.com/health/coronavirus-survivors-might-experience-more-intense-covid-19-vaccine-side-effects-experts"](https://www.foxnews.com/health/coronavirus-survivors-might-experience-more-intense-covid-19-vaccine-side-effects-experts)] (4/8, Farber, 23.99M) reports, “Coronavirus survivors who receive the COVID-19 vaccine may experience more intense side effects following the first dose, experts say.” Two small studies “suggested that those who were previously infected with SARS-CoV-2, the novel coronavirus, were more likely to have side effects from the first shot.” One small [[HYPERLINK "https://www.bmj.com/content/372/bmj.n308"](https://www.bmj.com/content/372/bmj.n308)] from researchers with Mount Sinai hospital in New York “found that those who already had the virus developed higher levels of antibodies following their first shot compared to those who were not previously infected.” NIAID Director Dr. Anthony Fauci is quoted.

Planned Parenthood Introduces \$2M Bilingual COVID-19 Vaccine Promotion Campaign.

[[HYPERLINK "https://thehill.com/policy/healthcare/547018-planned-parenthood-introduces-2-million-bilingual-campaign-promoting-covid"](https://thehill.com/policy/healthcare/547018-planned-parenthood-introduces-2-million-bilingual-campaign-promoting-covid)] (4/8, Coleman, 5.69M) reports, “Planned Parenthood introduced a \$2 million bilingual campaign promoting COVID-19 vaccinations on Thursday, with a goal of reaching 1.5 million people by the fall.” According to the article, “The grassroots campaign entitled ‘Protect. Every. Body.’ includes videos and images and utilizes Planned Parenthood’s social media, email lists and website to spread accurate information about the COVID-19 vaccine.” Planned Parenthood Federation of America CEO and President Alexis McGill Johnson stated that the U.S. needs “vaccine administration and education to put an end to this pandemic.”

Moderna Says It Hopes To Provide COVID-19 Vaccine Booster Shots By End Of 2021.

[[HYPERLINK "https://thehill.com/changing-america/well-being/prevention-cures/547143-moderna-says-its-booster-shot-against-covid-19"](https://thehill.com/changing-america/well-being/prevention-cures/547143-moderna-says-its-booster-shot-against-covid-19)] (4/8, Guzman, 5.69M) reports, “Moderna’s Chief Medical Officer Tal Zaks on Wednesday said the company should be able to supply booster shots by the end of 2021, adding that testing shows the boosters provide a confident level of protection against coronavirus variants.” The NIH “began testing a booster shot from Moderna against a variant first found in South Africa that has given scientists some cause for concern compared with other strains.” NIAID Director Dr. Anthony Fauci said, “Out of an abundance of caution, NIAID has continued its partnership with Moderna to evaluate this variant vaccine candidate should there be a need for an updated vaccine.”

Maryland US Attorney’s Office Cracking Down On Websites Selling Fake COVID-19 Vaccines, Cures.

The [[HYPERLINK "https://www.washingtonpost.com/politics/2021/04/08/technology-202-law-enforcement-cracks-down-fake-coronavirus-cures-vaccines/"](https://www.washingtonpost.com/politics/2021/04/08/technology-202-law-enforcement-cracks-down-fake-coronavirus-cures-vaccines/)] (4/8, Zakrzewski, 10.52M) reports, “The Maryland U.S. attorney’s office is cracking down on fraudulent websites pushing fake coronavirus treatments and vaccines.” The office on Wednesday “announced...that it had seized three websites purporting to be the websites of actual biotechnology companies responding to the coronavirus, but actually were stealing people’s personal information and conducting other scams.”

CDC: 85% Less J&J Vaccine Doses Will Be Shipped Next Week.

[[HYPERLINK "https://www.reuters.com/article/us-health-coronavirus-usa-johnson-johnso/us-to-allot-85-fewer-jj-vaccines-to-states-next-week-data-shows-idUSKBN2BV0QO"](https://www.reuters.com/article/us-health-coronavirus-usa-johnson-johnso/us-to-allot-85-fewer-jj-vaccines-to-states-next-week-data-shows-idUSKBN2BV0QO)] (4/8, Kalia)

reports that according to Centers for Disease Control and Prevention data, “the U.S. government will allot nearly 85% less Johnson & Johnson COVID-19 vaccines to states next week. ... Only 785,500 J&J doses will be allocated, compared to 4.95 million doses this week.” The article adds that “a New York Times report last week said that workers at an Emergent BioSolutions facility in Baltimore, which produced both AstraZeneca Plc and J&J doses, mixed up ingredients of the two vaccines, ruining 15 million J&J doses.” However, the article says the Emergent facility “has not yet been authorized by the U.S. Food and Drug Administration.”

Canada’s Surge Comes Amid Slow Vaccine Rollout.

The [[HYPERLINK "https://www.wsj.com/articles/as-the-u-s-vaccinates-millions-for-covid-19-most-canadians-are-still-waiting-11617905495"](https://www.wsj.com/articles/as-the-u-s-vaccinates-millions-for-covid-19-most-canadians-are-still-waiting-11617905495) \t "bipopup"] (4/8, Vieira, Monga, Subscription Publication, 8.41M) reports that Canada has had one of the slowest vaccine rollouts in the developed world, particularly as compared to the US, as it has been hindered by supply chain issues, a lack of coordination, and a surge in new infections as variants rapidly spread throughout the country, forcing authorities to renew lockdown restrictions.

Survey Finds Winston County Ranks Last In Terms Of Residents Vaccinated Against COVID-19 In Alabama.

The [[HYPERLINK "https://apnews.com/article/us-news-race-and-ethnicity-alabama-coronavirus-pandemic-b59fb90cddb6e0299e9d7469724ccb1"](https://apnews.com/article/us-news-race-and-ethnicity-alabama-coronavirus-pandemic-b59fb90cddb6e0299e9d7469724ccb1) \t "bipopup"] (4/8, Reeves) reports Winston County, Alabama “ranks last in terms of people who have been fully vaccinated” against COVID-19. A poll from the Associated Press-NORC Center for Public Affairs Research found “skepticism cut across racial and ethnic lines in the poll, but a pattern is obvious: Both large and small, urban and rural, the counties with the state’s lowest immunization rates all have mostly white populations.” Officials are working to increase COVID-19 vaccinations “among rural white people who think shots are more dangerous than COVID-19.”

California Vaccinators Administer COVID-19 Vaccine To Residents Not Yet Eligible When There Is Excess Supply.

The [[HYPERLINK "https://www.latimes.com/california/story/2021-04-08/parts-of-california-open-up-covid-vaccines-all-adults"](https://www.latimes.com/california/story/2021-04-08/parts-of-california-open-up-covid-vaccines-all-adults) \t "bipopup"] (4/8, Money, 3.37M) reports, “California won’t officially open eligibility for the COVID-19 vaccine to all adults until April 15.” However, periodic excess supply of the vaccine has led “officials to make doses available to all adults, even those not eligible under current rules.” Appointments made through the state’s system will still be prioritized.

Parents Seek Court Order To Force LAUSD To Reopen “To The Greatest Extent Possible.”

The [[HYPERLINK "https://www.latimes.com/california/story/2021-04-08/parents-sue-laUSD-push-wider-reopening-no-covid-tests"](https://www.latimes.com/california/story/2021-04-08/parents-sue-laUSD-push-wider-reopening-no-covid-tests) \t "bipopup"] (4/8, Blume, 3.37M) reports a group of parents is seeking a court order to force the Los Angeles Unified School District (LAUSD) to reopen “to the greatest extent possible” within seven days. In a lawsuit filed Wednesday, the parents ask the court “to prohibit L.A. Unified from using a six-foot distancing standard in classrooms because it effectively prevents the school district ‘from providing in-person instruction to the greatest extent possible.’” The suit “also seeks to prohibit the district from requiring students to take regular coronavirus tests as a condition for returning to campus.”

Pennsylvania AG Warns Of “Dangerous” Market For Fake COVID-19 Vaccination Cards.

[[HYPERLINK "https://thehill.com/policy/healthcare/547183-pennsylvania-attorney-general-warns-of-dangerous-market-for-false"](https://thehill.com/policy/healthcare/547183-pennsylvania-attorney-general-warns-of-dangerous-market-for-false) \t "bipopup"] (4/8, Lonas, 5.69M) reports, “Pennsylvania Attorney General Josh Shapiro (D) is warning the public about the ‘dangerous’ market of people selling fake vaccination cards.” Fakespot founder Saoud Khalifah said “that some cards are being obtained by those who don’t want to get the vaccine and others are getting the cards in order to trick pharmacies into giving them their shot.”

Georgia “Open For Business” Again, Governor Says.

The [[HYPERLINK "https://apnews.com/article/joe-biden-business-georgia-coronavirus-pandemic-atlanta-0f17ce96398b546e28f185b3d82922ed"](https://apnews.com/article/joe-biden-business-georgia-coronavirus-pandemic-atlanta-0f17ce96398b546e28f185b3d82922ed) \t "bipopup"] (4/8, Amy) reports that on Thursday, Gov. Brian Kemp (R) announced “‘Georgia is open for business,’ loosening the restrictions he imposed last year to control the spread of the coronavirus by letting people sit closer together at restaurants and gather in larger crowds.” He “portrays his new executive order as part of an effort to return to ‘normal,’ continuing to emphasize that economic health is as important as freedom from the respiratory illness.” On the other hand, NIAID Director Anthony Fauci said, “We’re really on the brink of a surge. That would be a setback for public health, but that could be a psychological setback, too.”

Nebraska Colleges, Universities Will Not Require Students To Receive COVID-19 Vaccine To Return To School.

The [[HYPERLINK "https://apnews.com/article/4da71742b07bad17912511b25b8bea2e"](https://apnews.com/article/4da71742b07bad17912511b25b8bea2e) \t "bipopup"] (4/8) reports, “Nebraska colleges and universities are encouraging students to get vaccinated for the coronavirus, but they won’t require the shots before students return to campus in the fall.”

California Expects COVID-19 Vaccine Doses To Decrease 15% Next Week.

The [[HYPERLINK "https://www.sfchronicle.com/health/article/California-COVID-vaccine-supply-will-fall-15-16086592.php"](https://www.sfchronicle.com/health/article/California-COVID-vaccine-supply-will-fall-15-16086592.php) \t "bipopup"] (4/8, Ho, 2.44M) reports California expects its COVID-19 vaccine doses to drop 15% next week. This could affect “the state’s plans to reopen June 15, the target date set by Gov. Gavin Newsom to allow almost all sectors of the economy to reopen at or near capacity.”

Kentucky Judge Blocks Another Attempt To Limit Governor’s COVID-19 Powers.

The [[HYPERLINK "https://apnews.com/article/legislature-coronavirus-pandemic-kentucky-laws-0734599614bd68530df8e01d4cefde30"](https://apnews.com/article/legislature-coronavirus-pandemic-kentucky-laws-0734599614bd68530df8e01d4cefde30) \t "bipopup"] (4/8) reports, “A Kentucky judge has temporarily blocked another attempt by Republican lawmakers to restrict Democratic Gov. Andy Beshear’s efforts to combat the coronavirus pandemic.” The judge “extended a temporary injunction Wednesday to apply to a measure passed over the governor’s veto. It specifies which of Beshear’s pandemic-related orders would remain in place should the legislature win its...legal fight with the governor.”

Maryland To Receive 78K Fewer J&J COVID-19 Vaccine Doses Next Week.

The [[HYPERLINK "https://www.baltimoresun.com/coronavirus/bs-md-johnson-and-johnson-vaccine-emergent-maryland-20210408-3b4s5nrcdbee7n5spkcnrhh4qa-story.html"](https://www.baltimoresun.com/coronavirus/bs-md-johnson-and-johnson-vaccine-emergent-maryland-20210408-3b4s5nrcdbee7n5spkcnrhh4qa-story.html) \t "ed=rss_www.baltimoresun.com/arcio/rss/category/latest/" \t "bipopup"] (4/8, Miller, Cohn, 629K) reports, “Maryland health officials expect to see a drastic reduction in the state’s allocation of Johnson

& Johnson's COVID-19 vaccine next week, causing an approximately 33% reduction in the overall first-dose vaccination allotment compared to this week's." On Thursday, Maryland Department of Health spokesman Charles Gischlar said "the state will have 78,000 fewer than expected doses of Johnson & Johnson's single-dose vaccine next week."

NYC Launches Care Program For Patients Suffering From Long COVID.

[[HYPERLINK "https://gothamist.com/news/nyc-launches-care-program-long-haul-covid-patients"](https://gothamist.com/news/nyc-launches-care-program-long-haul-covid-patients) \t "bipopup"] (4/8, Pereira, 122K) reports New York City's Test & Trace program, AfterCare, "is launching an initiative to help patients suffering from COVID-19 symptoms long after coronavirus leaves their system." On Wednesday, Test & Trace Take Care Department Director Dr. Amanda Johnson said the program "will help patients [with long COVID] access physical and mental health care, community support, and financial support."

Detroit Plans To Go Door-To-Door Convincing Residents To Receive COVID-19 Vaccine.

The [[HYPERLINK "https://apnews.com/article/health-michigan-coronavirus-pandemic-detroit-527739ded68d1e4bc3c1ee9bd64baf27"](https://apnews.com/article/health-michigan-coronavirus-pandemic-detroit-527739ded68d1e4bc3c1ee9bd64baf27) \t "bipopup"] (4/8, Williams) reports Detroit officials "are putting together plans to knock on doors across the 139-square-mile city to convince residents to get vaccinated for COVID-19." According to DHHS, only 22% of Detroiters have been inoculated. Officials expect the initial outreach "to last six to seven weeks."

New Mexico Implements New COVID-19 Vaccine Registration Process To Help People Aged 60 And Older.

The [[HYPERLINK "https://apnews.com/article/a8a60d6e718dee2c88bdaf7abddb827e"](https://apnews.com/article/a8a60d6e718dee2c88bdaf7abddb827e) \t "bipopup"] (4/8, Attanasio) reports that on Thursday, the New Mexico Department of Health announced "that people 60 and up can schedule a vaccine appointment without first being offered one by health officials." Under the new policy, they "can register for an appointment online whenever they want." It "effectively gives them first pick at appointments, and" ends "the need for them to have 24/7 access to text messages and emails."

Opinion: Best Vaccine Passport Policy May Be Akin To Florida Governor's Order.

In an opinion piece for [[HYPERLINK "https://www.politico.com/news/magazine/2021/04/08/vaccine-passports-ron-desantis-biden-480216"](https://www.politico.com/news/magazine/2021/04/08/vaccine-passports-ron-desantis-biden-480216) \t "bipopup"] (4/8, 6.73M), senior media writer Jack Shafer says Florida Gov. Ron DeSantis (R) issued "an executive order that bans state and local government from issuing proof-of-vaccination documents, and prohibits...demanding proof of Covid-19 vaccination from individuals." Shafer adds, "Some observers see the 'passport' argument as a new way for conservatives to express skepticism about the whole pandemic response." He concludes, "Rather than rushing headlong into a standardized national system, the best policy may well be something more akin to DeSantis' executive order, slowing the adoption of either private or public [vaccine] passports by discouraging the ground-level market for their use."

Opinion: New York's Revocation Of Nursing Home Immunity Step In Right Direction.

In an opinion piece for the [[HYPERLINK "https://www.nydailynews.com/opinion/ny-oped-finally-holding-nursing-homes-accountable-20210408-h4yu5gmuzbdn3gwz3bc6tbk5ai-story.html"](https://www.nydailynews.com/opinion/ny-oped-finally-holding-nursing-homes-accountable-20210408-h4yu5gmuzbdn3gwz3bc6tbk5ai-story.html) \t "bipopup"] (4/8, 2.51M), Senior Justice Law Firm managing attorney Michael Brevda writes that New York Gov.

Andrew Cuomo (D) “has signed into law legislative language that revokes nursing homes’ immunity from liability for decisions made with respect to the COVID pandemic.” He adds, “This legislation is a silent recognition of prior missteps taken by New York’s lawmakers,” but it “is a step in the right direction.”

More California Counties Expand COVID-19 Vaccine Eligibility To Those Aged 16 And Older.

The [[HYPERLINK "https://apnews.com/article/los-angeles-california-coronavirus-pandemic-3698e89b49b2e7c468baed4ea6eac38c"](https://apnews.com/article/los-angeles-california-coronavirus-pandemic-3698e89b49b2e7c468baed4ea6eac38c) \t "bipopup"] (4/8, Har) reports Santa Clara and Fresno are the latest counties in California to expand COVID-19 vaccine eligibility to residents aged 16 and older a week ahead of schedule.

Pennsylvania Legislators Urge White House To Keep FEMA-Run Mass COVID-19 Vaccine Center Open In Philadelphia.

The [[HYPERLINK "https://www.inquirer.com/health/coronavirus/philadelphia-fema-vaccine-clinic-white-house-20210408.html"](https://www.inquirer.com/health/coronavirus/philadelphia-fema-vaccine-clinic-white-house-20210408.html) \t "bipopup"] (4/8, Laughlin) reports Pennsylvania legislators “urged the White House to keep open Philadelphia’s mass vaccination clinic at the Convention Center, saying the city’s inoculation efforts depend on the tens of thousands of doses administered there every week.” The FEMA-run clinic “is scheduled to end its eight-week pilot April 26.”

CNN’s Sanjay Gupta “Blasts” Georgia’s Decision To Lift Remaining COVID-19 Restrictions.

The [[HYPERLINK "https://dailycaller.com/2021/04/08/sanjay-gupta-jake-tapper-brian-kemp-georgia-reopening-coronavirus-pandemic-restrictions/"](https://dailycaller.com/2021/04/08/sanjay-gupta-jake-tapper-brian-kemp-georgia-reopening-coronavirus-pandemic-restrictions/) \t "bipopup"] (4/8, Gillespie, 375K) reports, “CNN’s Dr. Sanjay Gupta blasted Georgia’s lifting of all remaining restrictions pertaining to the coronavirus pandemic on Thursday” during an appearance on “The Lead With Jake Tapper.” He “expressed his concern over the potential for unnecessary sickness and death, saying ‘so much of this doesn’t need to happen.’”

Columnist: Floridians Are Declaring Victory Over COVID-19 Too Soon.

In a column for the [[HYPERLINK "https://www.miamiherald.com/news/local/news-columns-blogs/fabiola-santiago/article250517504.html"](https://www.miamiherald.com/news/local/news-columns-blogs/fabiola-santiago/article250517504.html) \t "bipopup"] (4/8, 647K), Fabiola Santiago writes, “The next frontier in the mutating coronavirus pandemic has arrived in Ron DeSantis’ wacky Florida.” She adds, “In Fort Lauderdale...a group is staging a ‘mask burning’ party on Las Olas on Saturday.” Santiago concludes that “too many people are shedding their masks and declaring victory over the virus.”

Georgia Health Department Working With State Agencies, Others To Vaccinate Homebound People Against COVID-19.

The [[HYPERLINK "https://www.ajc.com/news/investigations/many-of-georgias-homebound-still-waiting-for-vaccine/XA4Z2SQXMCW7HKNWLLK4ET46A/"](https://www.ajc.com/news/investigations/many-of-georgias-homebound-still-waiting-for-vaccine/XA4Z2SQXMCW7HKNWLLK4ET46A/) \t "bipopup"] (4/8, Hart, 1.46M) reports Georgia’s Department of Public Health “has been working with other state agencies and regional organizations for months to identify homebound people to whom they can offer [the COVID-19] vaccine.” Atlanta Regional Commission Aging and Independent Services Managing Director Becky Kurtz “hopes that new funds the federal government has just awarded states for vaccination outreach can help” inoculate these people. The Atlanta Regional Commission runs the local Area Agency on Aging.

Michigan Ramps Up Efforts To Vaccinate Detroiters, Hamtramck Residents, College Students Against COVID-19.

The [[HYPERLINK "https://www.freep.com/story/news/health/2021/04/08/michigan-vaccinations-detroit-mobile-sites-colleges/7146890002/"](https://www.freep.com/story/news/health/2021/04/08/michigan-vaccinations-detroit-mobile-sites-colleges/7146890002/) \t "bipopup"] (4/8, Boucher, 2.16M) reports Michigan “is ramping up efforts to get COVID-19 vaccines into areas of Detroit and Hamtramck where they are most needed while also trying to inject as many college students as possible before the end of the semester.” The state plans to have “14 mobile clinic visits throughout Detroit and Hamtramck starting Wednesday.” Additionally, local health departments are partnering with 26 colleges and universities.

Nevada County Prepares To Eliminate Mask Requirements, Increase Crowd Capacity.

The [[HYPERLINK "https://apnews.com/article/pandemics-las-vegas-nevada-coronavirus-pandemic-aed548702bdb5b9e4da98dbf47b41a1a"](https://apnews.com/article/pandemics-las-vegas-nevada-coronavirus-pandemic-aed548702bdb5b9e4da98dbf47b41a1a) \t "bipopup"] (4/8) reports Nye County, Nevada “could step ahead of the state and approve lifting mask mandates and business capacity limits enacted as pandemic prevention measures.” The County Commission is slated to vote on April 20. A spokeswoman for Gov. Steve Sisolak (D) said “the Nye County plan will be reviewed...as the state’s COVID-19 Response Task Force prepares to turn over pandemic mitigation control to local authorities beginning May 1.”

Minnesota Prepares For Decline In COVID-19 Vaccine Demand.

The [[HYPERLINK "https://www.startribune.com/minnesota-prepares-for-any-shift-in-covid-19-vaccine-demand/600043642/"](https://www.startribune.com/minnesota-prepares-for-any-shift-in-covid-19-vaccine-demand/600043642/) \t "bipopup"] (4/8, Olson, 855K) reports, “COVID-19 vaccine has been a hot commodity in Minnesota, where more than 3 million shots have been given, but health officials are preparing for any decline in demand that could upset the state’s drive to vaccinate 80% of eligible residents.” State Health Commissioner Jan Malcolm said the state’s “distribution strategy has shifted a bit to earmark more doses for areas that have been underserved or are seeing rising COVID-19 rates, but that the state is ‘a ways away’ from supply exceeding demand.”

Editorial: New York Assembly Needs To Stop “Stalling” And Impeach Governor.

In an editorial, the [[HYPERLINK "https://nypost.com/2021/04/08/team-cuomos-nursing-home-coverup-was-even-worse-than-we-knew/"](https://nypost.com/2021/04/08/team-cuomos-nursing-home-coverup-was-even-worse-than-we-knew/) \t "bipopup"] (4/8, 7.45M) writes, “Gov. Andrew Cuomo’s coverup of nursing-home COVID deaths was even worse than we’d thought: It turns out his Department of Health started collecting the key data a full year ago.” The Post adds, “This (and other Team Cuomo lies along the way) is more than enough to justify impeaching the governor.” It concludes that the Assembly needs to stop “stalling” and “get it done.”

Areas With Heightened Variant Spread Request Additional COVID-19 Vaccine Doses.

According to the [[HYPERLINK "https://www.washingtonpost.com/health/covid-variants-vaccines/2021/04/08/a2eed5b8-97ba-11eb-a6d0-13d207aadb78_story.html"](https://www.washingtonpost.com/health/covid-variants-vaccines/2021/04/08/a2eed5b8-97ba-11eb-a6d0-13d207aadb78_story.html) \t "bipopup"] (4/8, Bernstein, Cha, McCoy, Dupree, 10.52M), “Variants of the coronavirus are increasingly defining the next phase of the pandemic in the United States, taking hold in ever-greater numbers and eliciting pleas for a change in strategy against the outbreak.” The article adds, “One or more of the variants – which also cause more severe disease than the original version of the virus – are racing through the Northeast and the Midwest,” which “has prompted officials in some communities to ask for more vaccine than they would receive under the government’s population-based formula.”

Nebraska Experiencing Increase In Younger People Hospitalized With COVID-19.

The [[HYPERLINK "https://apnews.com/article/health-nebraska-coronavirus-pandemic-7bc9ff05dd2aafff0e91e7d491f1bf90"](https://apnews.com/article/health-nebraska-coronavirus-pandemic-7bc9ff05dd2aafff0e91e7d491f1bf90)] (4/8) reports, “A growing number of younger people are being hospitalized with the coronavirus in Nebraska as more contagious variants of the virus spread in the state.”

Columnist: New COVID-19 Cases Will Probably Be Less Deadly.

In a column for [[HYPERLINK "https://www.bloomberg.com/opinion/articles/2021-04-08/covid-19-is-about-to-become-a-much-less-deadly-disease?srnd=premium"](https://www.bloomberg.com/opinion/articles/2021-04-08/covid-19-is-about-to-become-a-much-less-deadly-disease?srnd=premium)] (4/8), Cathy O’Neil writes, “There’s good reason to believe that [COVID-19] cases won’t translate into deaths the way they have in the past.” She adds, “For one, the vaccination campaign has targeted the most vulnerable. Also, younger people...have been taking up the vaccine more and more.” O’Neil concludes that “the day will come when the case count will no longer matter much, because cases won’t pose much of a threat. I think that day is coming soon.”

More Than 3,600 US Healthcare Workers Died In First Year Of COVID-19 Pandemic, Investigation Finds.

[[HYPERLINK "https://khn.org/news/article/us-health-workers-deaths-covid-lost-on-the-frontline/"](https://khn.org/news/article/us-health-workers-deaths-covid-lost-on-the-frontline/)] (4/8, Jewett, Spencer) reports more than 3,600 healthcare workers in the US “perished in the first year of the pandemic, according to ‘Lost on the Frontline,’ a 12-month investigation by The Guardian and KHN to track such deaths.” The Lost on the Frontline project, “which tracked who died and why, provides a window into the workings – and failings – of the U.S. health system during the covid-19 pandemic.” One of the project’s findings is that two-thirds of the healthcare workers who died “for whom the project has data identified as people of color, revealing the deep inequities tied to race, ethnicity and economic status in America’s health care workforce.”

Meatpacking Workers Face Daily COVID-19 Risks.

[[HYPERLINK "https://www.usatoday.com/in-depth/news/investigations/2021/04/08/meatpacking-workers-still-face-risks-one-year-after-coronavirus/4842584001/"](https://www.usatoday.com/in-depth/news/investigations/2021/04/08/meatpacking-workers-still-face-risks-one-year-after-coronavirus/4842584001/)] (4/8, Axon, Bagenstose, Crowe, Mansfield, 12.7M) says, “Since last April, more than 50,000 [COVID-19] cases have been tied to the meatpacking industry, and at least 248 workers have died, according to tracking by the Midwest Center for Investigative Reporting.” The meatpacking industry “is especially vulnerable to the coronavirus because the same features that allow a steady churn of cheap meat also provide the perfect breeding ground for airborne diseases: a cramped workplace, a culture of underreporting illnesses, and a cadre of rural, immigrant and undocumented workers who often live and work together.”

Nebraska DHHS, Creighton, CHI Health Partner To Expand COVID-19 Variant Testing.

The [[HYPERLINK "https://omaha.com/lifestyles/health-med-fit/with-covid-variants-on-the-rise-in-nebraska-creighton-and-chi-to-begin-expanded-testing/article_65fb3808-9707-11eb-9f4e-4fa0916ec844.html"](https://omaha.com/lifestyles/health-med-fit/with-covid-variants-on-the-rise-in-nebraska-creighton-and-chi-to-begin-expanded-testing/article_65fb3808-9707-11eb-9f4e-4fa0916ec844.html)] (4/8, Anderson, 509K) reports, “To aid in identifying variants, the Nebraska Department of Health and Human Services [DHHS] has contracted with Creighton and clinical partner CHI Health.” Researchers at Creighton “will use genetic sequencing to determine whether

COVID-19-positive test samples collected at CHI's hospitals and clinics were caused by variants of the virus."

Colorado Experiencing Increase In COVID-19 Hospitalizations, Infections.

The [[HYPERLINK "https://apnews.com/article/360655535ccaf01d2f887f2c599d56f5"](https://apnews.com/article/360655535ccaf01d2f887f2c599d56f5) \t "bipopup"] (4/8) reports, "Health officials in Colorado have reported an increase in COVID-19 hospitalizations across the state while infections also suggest wider spread of the virus." State data show "an 8% increase of active coronavirus outbreaks in the past week."

The [[HYPERLINK "https://www.denverpost.com/2021/04/08/colorado-covid-hospitalizations-outbreaks/"](https://www.denverpost.com/2021/04/08/colorado-covid-hospitalizations-outbreaks/) \t "bipopup"] (4/8, Wingerter, 660K) says, "The Colorado Department of Public Health and Environment reported 450 people were hospitalized statewide with confirmed or suspected COVID-19 as of Wednesday afternoon." This many people have not been hospitalized because of COVID-19 since February 19.

Minnesota Estimates 50% To 60% Of New COVID-19 Cases Due To Variants.

The [[HYPERLINK "https://apnews.com/article/health-coronavirus-pandemic-minnesota-c2611f95ea5925df5f4dee0985fd93c0"](https://apnews.com/article/health-coronavirus-pandemic-minnesota-c2611f95ea5925df5f4dee0985fd93c0) \t "bipopup"] (4/8, Ibrahim) says, "Minnesota health officials reported 2,500 new infections on Thursday as more infectious variants of the coronavirus drive case growth across the state." This marks "the highest single-day total since January." On Thursday, state epidemiologist Ruth Lynfield said "that the state estimates 50% to 60% of infections are due to the variants, particularly the variant first detected in Britain."

The [[HYPERLINK "https://www.startribune.com/covid-19-cases-climb-despite-3-million-vaccine-shots-in-minnesota/600043642/"](https://www.startribune.com/covid-19-cases-climb-despite-3-million-vaccine-shots-in-minnesota/600043642/) \t "bipopup"] (4/8, Olson, 855K) says that on Thursday, Minnesota "reported 14 more deaths and 2,535 infections...and a 6.4% positivity rate of diagnostic testing."

South African, Brazilian Coronavirus Variants Identified In Los Angeles County.

The [[HYPERLINK "https://www.latimes.com/california/story/2021-04-08/south-african-brazilian-coronavirus-variants-land-la"](https://www.latimes.com/california/story/2021-04-08/south-african-brazilian-coronavirus-variants-land-la) \t "bipopup"] (4/8, Money, 3.37M) reports, "Two coronavirus variants thought to be more transmissible or resistant to vaccines than their predecessors have been found in Los Angeles County for the first time." Local public health officials used specimen analysis to identify "one case of B.1.351, also referred to as the South African variant, and three cases of P.1, a mutation first identified in Brazil."

Maryland Governor Says Growing COVID-19 Cases Due To Variants.

The [[HYPERLINK "https://www.baltimoresun.com/coronavirus/bs-md-covid-numbers-20210408-ihiaz36ubf3bai74uooo73eq4-story.html"](https://www.baltimoresun.com/coronavirus/bs-md-covid-numbers-20210408-ihiaz36ubf3bai74uooo73eq4-story.html) \t "bipopup"] (4/8, Mann, 629K) says, "As concern about the spread of highly contagious coronavirus variants grows, Maryland reported more than 1,000 new coronavirus cases for the second day in a row, as hospitalizations also crept up, according to state health department data." On WBAL Radio Thursday morning, Gov. Larry Hogan (R) said Maryland has "seen a slight increase in hospitalizations among people in their 20s, 30s and 40s. He attributed the development to the spread of more contagious variations of the virus."

Advocates Concerned Homeless Unable To Access Stimulus Checks.

The [[HYPERLINK "https://www.latimes.com/homeless-housing/story/2021-04-08/how-homeless-people-can-get-a-stimulus-check"](https://www.latimes.com/homeless-housing/story/2021-04-08/how-homeless-people-can-get-a-stimulus-check) \t "bipopup"] (4/8, Oreskes, 3.37M) reports, “With no bank accounts, little access to the internet and a general lack of awareness that the money is available, many homeless people haven’t received the stimulus checks.” Advocates “for homeless people say this money could be potentially transformative for people who lack the savings to put down first and last months’ rent on a lease or have mounting medical bills.”

HUD Funds Can Be Used To Turn Hotels And Motels Into Homeless Shelters.

The [[HYPERLINK "https://www.washingtonpost.com/us-policy/2021/04/08/homeless-hud-marcia-fudge/"](https://www.washingtonpost.com/us-policy/2021/04/08/homeless-hud-marcia-fudge/) \t "bipopup"] (4/8, Jan, 10.52M) reports that on Thursday, HUD Secretary Fudge “unveiled nearly \$5 billion in new grants to states and local governments across the country for rental assistance, the development of affordable housing and other services to help people experiencing or on the verge of homelessness. ... The grants, which must be spent by 2030, can be used to provide temporary or permanent housing, including buying and converting hotels and motels so people who are homeless could have a more private and safe place to live than in congregate shelters, Fudge said.” According to the Post, “The infusion of money to reduce homelessness, part of the \$1.9 trillion coronavirus relief package that President Biden signed in March, is the latest example of how the administration is using the American Rescue Plan to enact a sweeping anti-poverty agenda amid the pandemic.”

Researchers Say Prisons Need To Better Educate Inmates About Vaccines.

The [[HYPERLINK "https://apnews.com/article/connecticut-danbury-prisons-coronavirus-pandemic-971bdd0ce00cee4d1f53a207ea0e8329"](https://apnews.com/article/connecticut-danbury-prisons-coronavirus-pandemic-971bdd0ce00cee4d1f53a207ea0e8329) \t "bipopup"] (4/8) reports, “Inmate advocates and researchers say prison systems need to do more to educate prisoners about...vaccines, as available data and surveys show that many inmates decline or express hesitancy about getting the shots.” Efforts to this end “should include bringing in outside experts and trusted community members, especially people of color, not just passing out flyers and having talks by prison staff, they say.”

Japanese Surgeons Perform World’s First Successful Transplant Of Lung Tissue From Living Donors To Patients With Severe Lung Damage From COVID-19.

The [[HYPERLINK "https://apnews.com/article/japan-lung-transplants-coronavirus-pandemic-16089e2c749a0e24b230fa6bbbbd54b5"](https://apnews.com/article/japan-lung-transplants-coronavirus-pandemic-16089e2c749a0e24b230fa6bbbbd54b5) \t "bipopup"] (4/8, Yamaguchi) reports Japanese surgeons announced “they have successfully performed the world’s first transplant of lung tissue from living donors to a patient with severe lung damage from COVID-19.” Kyoto University Hospital said in a statement that the recipient of the transplant is a woman from the western region of Kansai, and her husband and son both donated parts of their lungs for the operation.

Pioneering Work On mRNA By Researcher Katalin Kariko Highlighted.

The [[HYPERLINK "https://www.nytimes.com/2021/04/08/health/coronavirus-mrna-kariko.html"](https://www.nytimes.com/2021/04/08/health/coronavirus-mrna-kariko.html) \t "bipopup"] (4/8, Kolata, 20.6M) reports that scientists Katalin Kariko “has emerged as one of the heroes of Covid-19 vaccine development.” Kariko’s “work, with her close collaborator, Dr. Drew Weissman of the University of Pennsylvania, laid the foundation for the stunningly successful vaccines made by Pfizer-BioNTech and Moderna.” NIAID Director Dr. Anthony Fauci is familiar with Dr. Kariko’s work, upon which he commented, “She was, in a positive sense, kind of obsessed with the concept of messenger RNA.” Her “ideas about mRNA were definitely unorthodox” and they increasingly “seem to have been

prescient.” Fauci said of the mRNA work, “It’s going to be transforming. ... It is already transforming for Covid-19, but also for other vaccines. HIV – people in the field are already excited. Influenza, malaria.”

CDC Updates Surface Cleaning Guidelines For COVID-19.

The [[HYPERLINK "https://www.nytimes.com/2021/04/08/health/coronavirus-hygiene-cleaning-surfaces.html"](https://www.nytimes.com/2021/04/08/health/coronavirus-hygiene-cleaning-surfaces.html) \t "bipopup"] (4/8, Anthes, 20.6M) reports that the year-long era of obsessive hygiene for surfaces to combat COVID-19 “may have come to an unofficial end this week, when the C.D.C. updated its surface cleaning guidelines and noted that the risk of contracting the virus from touching a contaminated surface was less than 1 in 10,000.” CDC Director Rochelle Walensky said at a White House briefing this week, “People can be affected with the virus that causes Covid-19 through contact with contaminated surfaces and objects. ... However, evidence has demonstrated that the risk by this route of infection of transmission is actually low.” Such an “admission is long overdue, scientists say.” Contracting “the virus from surfaces remains theoretically possible,” one expert said, but he qualified that “it requires many things to go wrong.”

More Online Stores Selling Fake, Stolen COVID-19 Vaccination Cards.

The [[HYPERLINK "https://www.nytimes.com/2021/04/08/technology/vaccine-card-scam.html"](https://www.nytimes.com/2021/04/08/technology/vaccine-card-scam.html) \t "bipopup"] (4/8, Frenkel, 20.6M) reports that with the arrival of COVID-19 vaccines in many countries, the business of selling fake or stolen CDC vaccination cards has emerged at many online stores. Selling these “fake vaccination cards could break federal laws that forbid copying the CDC logo, legal experts said.” Moreover, “if the cards were stolen and filled out with false numbers and dates, they could also violate identity theft laws, they said.” Still, “profiteers have pressed ahead as demand for the cards has grown from anti-vaccine activists and other groups.” Additionally, the cards may attract even more attention with vaccine passports, since some tech companies that are “developing vaccine passports ask people to upload copies of their CDC cards.”

Employers Should Incentivize Workers To Get Vaccinated Against COVID-19, Not Mandate, Professor Says.

[[HYPERLINK "https://www.cnbc.com/2021/04/08/covid-vaccine-mandates-professor-says-incentives-for-staff-are-better.html"](https://www.cnbc.com/2021/04/08/covid-vaccine-mandates-professor-says-incentives-for-staff-are-better.html) \t "bipopup"] (4/8, Stankiewicz, 7.34M) provides coverage of comments by Wharton School professor Nancy Rothbard during an appearance on CNBC’s “Squawk Box” suggesting that employers should opt for incentivizing workers to get vaccinated against COVID-19, rather than mandating it. The piece says that “while many experts believe it’s legal for employers to make vaccines compulsory, business leaders may worry about alienating staff.” On this issue, the management professor said, “Trying really to incentivize people to get vaccinated, I think, is going to be a much more popular route than mandates.” She added, “There are ways to do this more privately, where you may want to take an employee aside and say, ‘Look, have you been vaccinated? ... If you haven’t, then we need to make alternative arrangements,’ for the safety of others.”

The Home Diagnostics Industry Has Grown During The COVID-19 Pandemic.

[[HYPERLINK "https://www.statnews.com/2021/04/08/home-testing-remote-diagnostics-carbon-everly/"](https://www.statnews.com/2021/04/08/home-testing-remote-diagnostics-carbon-everly/) \t "bipopup"] (4/8, Brodwin, 262K) reports the home diagnostics industry has grown during the COVID-19 pandemic. Even after the pandemic ends, at-home testing could save many people from having to make a physical visit to a medical office to receive a diagnosis.

AstraZeneca COVID-19 Vaccine Still Safe For People To Take, Experts Say.

The [[HYPERLINK "https://www.washingtonpost.com/politics/2021/04/08/health-202-astrazeneca-vaccine-is-still-considered-safe-to-take/"](https://www.washingtonpost.com/politics/2021/04/08/health-202-astrazeneca-vaccine-is-still-considered-safe-to-take/)] (4/8, Cunningham, 10.52M) reports, “The available science still indicates the AstraZeneca coronavirus vaccine is safe for people to take, even as regulators investigate a potential red flag,” according to vaccine experts, who are “frustrated by the recent barrage of negative headlines.” Former FDA scientist Luciana Borio said she feels that “in general the press has not been doing a good job.” She said the coverage of AstraZeneca’s COVID-19 vaccine feels “alarmist.” Borio said, “People do not want to take the vaccine in Europe now, and if that’s because of misinformation, then the pandemic’s going to continue to remain very active globally, which means everybody is vulnerable.”

Unprecedented development of Covid-19 vaccines, treatments points to biopharma's future

By Andrew Bolt and Sonal Shah April 8, 2021

[[HYPERLINK "https://www.parsintl.com/publication/stat/"](https://www.parsintl.com/publication/stat/)]

Business as usual has *not* been the mantra for companies developing Covid-19 vaccines and drugs.

Instead, biopharma companies and their partners pursued various transformational approaches to get vaccines and treatments to market at unprecedented speeds. These included adaptive trials, master protocols, real-world evidence, and other approaches powered by advanced statistical techniques, data science, and analytics using curated datasets.

Public agencies have been important catalysts for some of this work. In March 2020, the World Health Organization stood up [[HYPERLINK "https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments"](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments)], a global adaptive trial, in more than 100 countries to evaluate four treatment options for patients with severe Covid-19. In mid-April, the National Institutes of Health and the Foundation for the National Institutes of Health announced the Accelerating Covid-19 Therapeutic Interventions and Vaccines ([[HYPERLINK "https://www.nih.gov/research-training/medical-research-initiatives/activ"](https://www.nih.gov/research-training/medical-research-initiatives/activ)] | ["organizations"](#)]) partnership. This public-private partnership, which includes other health agencies, a number of biopharma companies, and several nonprofit organizations, has developed a collaborative framework for prioritizing and testing vaccine and drug candidates, including a master protocol.

Adaptive trials and master protocols have been around for many years. In an adaptive trial, researchers can modify study design elements and hypotheses based upon prospectively planned interim data analyses. [[HYPERLINK "https://www2.deloitte.com/us/en/insights/industry/life-sciences/master-protocol-clinical-trial-drug-development-process.html"](https://www2.deloitte.com/us/en/insights/industry/life-sciences/master-protocol-clinical-trial-drug-development-process.html)] typically leverage an adaptive approach, using a shared protocol that enables the simultaneous evaluation of multiple treatments for individuals with specific diseases or disease subtypes. Master protocols can help researchers answer scientific questions more quickly, enable continuous learning, and reduce overall drug development cost and time. Despite these benefits, the use of master protocols has been limited outside of oncology.

Much of what we now know about Covid-19 therapies has been learned in master protocols. Using this approach, the RECOVERY trial, for example, showed that [[HYPERLINK "https://www.statnews.com/2020/06/16/major-study-finds-common-steroid-reduces-deaths-among-patients-with-severe-covid-19/"](https://www.statnews.com/2020/06/16/major-study-finds-common-steroid-reduces-deaths-among-patients-with-severe-covid-19/)] deaths of Covid-19 patients on ventilators, which is now used as a standard of care for people with severe Covid-19.

Real-world evidence is becoming increasingly valuable as the health care system gains experience with Covid-19. The [[HYPERLINK "https://friendsofcancerresearch.org/covid19/"](https://friendsofcancerresearch.org/covid19/)], launched by the Reagan-Udall Foundation in collaboration with the Friends of Cancer Research, has [[HYPERLINK "https://friendsofcancerresearch.org/covid19/"](https://friendsofcancerresearch.org/covid19/)] for major data organizations, government and academic researchers, and health systems to collectively use real-world evidence to help answer questions related to the management of Covid-19. The collaboration is also running repeat analyses to compare results using different techniques and data sources.

These approaches, along with enhanced segmentation of disease and patient populations and simulating protocol feasibility, are examples of how companies can accelerate the development of safe and effective vaccines and therapies while improving the quality of research output ([HYPERLINK "https://www.statnews.com/2021/04/08/adaptive-trials-master-protocols-novel-approaches-future-pharm/" \ | "BoltShahTable"]).

To better understand the current adoption of these transformative approaches, their impact, and what is required to scale their applications, colleagues of ours with the Deloitte Center for Health Solutions [HYPERLINK "https://www2.deloitte.com/us/en/insights/industry/life-sciences/future-of-drug-discovery.html" \ t "_blank"] at biopharma companies during the summer of 2020. These conversations showed that approaches such as adaptive trials and master protocols have yet to be scaled more broadly or used in an integrated fashion.

A significant finding was that companies that are further along in their adoption of transformative approaches tended to have portfolios heavily focused on cancer and/or rare diseases. Like Covid-19, the high unmet needs and life-threatening nature of these diseases make companies and stakeholders more willing to consider evidence generated from novel approaches.

Biopharma companies have an opportunity to take the learnings from cancer, rare diseases, and now Covid-19 to scale transformative approaches across their portfolios to other therapeutic areas. They likely can't do it alone, though, and will need to engage stakeholders across the R&D ecosystem: health care organizations, to curate novel real-world datasets; regulators, to shape and pilot new approaches to drug development; payers, to initiate proactive conversations around evidence hurdles; and patient advocacy groups to define endpoints that matter.

Notably, scaling the use of transformative approaches requires expanding the availability of high-quality curated datasets in the therapeutic areas beyond cancer. In a column early in the novel coronavirus pandemic, STAT's Matthew Herper [HYPERLINK "https://www.statnews.com/2020/04/22/people-are-dying-from-coronavirus-because-were-not-fast-enough-at-clinical-research/"] that inadequate technology is part of the reason we were slow to research treatments for Covid-19. Electronic health records are not set up to enable research but to support claims and billing. Imagine — if it existed — how powerful interoperable research-grade data on the impact of existing treatments of Covid-19 patients could be. These real-world clinical datasets could help companies better understand the pathway of disease, which patients respond better to certain treatments, and why.

Biopharma companies need to work collaboratively and transparently within the health care ecosystem to unlock the data necessary to inform these transformative approaches — a process that does not come without challenges. Most health care organizations aren't set up to curate electronic medical records at scale, nor do they have the technical infrastructure and resources to manage datasets once they are curated. Patient privacy and data security must also be maintained, which requires well-defined protocols and controls to govern data access.

Collaboration will likely be key to unlocking the value of transformative approaches that can help bring more precise evidence generation and efficiency to drug development.

Biopharma companies and their stakeholders have been partnering and sharing data sets in unprecedented ways to address the Covid-19 pandemic. Continuing this collaborative mindset long after

the pandemic is behind us can accelerate the development of therapies and preventive measures for other important diseases.

Andrew Bolt is a senior manager in Deloitte Consulting's Life Sciences Strategy practice. Sonal Shah is a senior manager with the Deloitte Center for Health Solutions within Deloitte Services LP and leads the center's life sciences research.

Approach	Benefits
Adaptive trials	Enables continuous learning and adjustments through research phases that help condense development time and decrease the number of patients required to reach endpoints. Adaptive randomization increases the probability of patients being assigned to more efficacious treatment arms or cohorts, adding to patient benefit.
Enhanced segmentation of disease and patient populations	Combines scientific data with real-world data from patient registries, electronic medical records, imaging, and claims data to conduct studies evaluating the natural history of disease to develop more sophisticated and nuanced understanding of a disease, including the identification of distinct subpopulations who have markedly different outcomes.
Master protocols	Adaptive, collaborative, clinical studies that allow for the simultaneous evaluation of multiple treatments for individuals with specific diseases or disease subtypes within the same trial structure can efficiently answer multiple questions in less time.
Real-world evidence for regulatory approval	External control arms built from real-world data can replace establishing traditional control arms in a clinical trial. Real-world evidence can also demonstrate the safety and efficacy of a product used in off-label settings, potentially enabling label expansion.

**Simulating
protocol
feasibility**

Modeling and simulation can assess the impact of protocol decisions (such as inclusion and exclusion criteria) on addressable patient populations, and also predict trial enrollment based on past site performance or the competitive trial landscape.

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
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To: Kessler, David A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=efb6a7c634694533833de5d2f4beaee3-HHS-David.K]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6)]; Bugin, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=735d396f29ce480a88de9e6c2b0f424e-BUGINK]; Teyhen, Deydre (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb1df24e51be4354a15aceb9217c77d2-HHS-Deydre.]; Adam, Stacey J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8de67693eab246c7946108cfd7c6d3dc-HHS-sadam-f]
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Attachments: Draft BIRD Proceedings 25-02-2021 v 1.4.pdf

Another good reason to get ACTIV 6 up and running. (b) (6). jw

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Cc: claire Mock-Muñoz de Luna <claire@e-bmc.co.uk>; Ketan Gajjar <ketan.gajjar@nhs.net>; Andy Bryant <andy.bryant@newcastle.ac.uk>; Tony Tham (b) (6); Scott Mitchell <scott.mitchell@gov.gg>; Tina Peers (b) (6) >
Subject: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment

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Dear Dr. Stein and FDA Colleagues,

We are writing to share with you the evidence to decision framework of the British Ivermectin Recommendation Development (BIRD) Meeting that was held on Saturday 20th February 2021 via Zoom from Bath, United Kingdom. The expert panel of health and allied professionals and other stakeholders included representatives from 16 countries, namely Argentina, Australia, Belgium, Botswana, Canada, France, Hungary, India, Ireland, Japan, Peru, Nigeria, South Africa, The Philippines, United States, United Kingdom. The ethos of the BIRD meeting was that of scientific rigour and transparency in the spirit of international collaboration towards a common goal – that of saving lives.

The recommendation was developed according *The WHO Handbook of Guideline Development (2014)*. BIRD panel conclusions are that ivermectin should be approved immediately for prevention and treatment of covid-19.

The BIRD recommendation on covid-19 prevention and treatment

The British Ivermectin Recommendation Development Panel recommends ivermectin for the prevention and treatment of covid-19 to reduce morbidity and mortality associated with covid-19 infection and to prevent covid-19 infection among those at higher risk.

The BIRD Steering Group has taken heed of the WHO statement on 'Developing global norms for sharing data and results during public health emergencies' that states that 'public disclosure of information of relevance to public health emergencies should not be delayed', and also notes the 'very great risks' that can occur from 'withholding data and results arising from analyses'. We are, therefore, sharing this evidence-to decision framework within just a few days of the BIRD meeting to avoid delay.

Further, due to the urgency related to the communication and dissemination of this recommendation that is aimed at saving thousands of lives daily, please forgive the limitations of the draft proceedings document attached. Information on the process and methods can be found among the annexes. An Executive Summary is being finalised and will be available on Monday.

We look forward to hearing from you soon and would be happy meet with you via teleconference if you think this will be helpful.

Please do not hesitate to contact us with any questions.

Kind regards,

Dr. Tess Lawrie, on behalf of the BIRD Steering Group and Recommendation Development Panel
Evidence-based Medicine Consultancy Ltd
e-bmc.co.uk

The BIRD Recommendations on the Use of Ivermectin for Covid-19

BIRD

British
Ivermectin
Recommendation
Development



Proceedings and conclusions of the British Ivermectin Recommendation Development meeting held on the 20th February 2021 in Bath, United Kingdom.

From: Adam, Stacey (FNIH) [T] [sadam@fnih.org]
Sent: 1/18/2021 8:45:02 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Thanks, Janet,

I appreciate you sharing this with me. I will add to our records for this compound.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (301) 435-8364 | Mobile: (b) (6)

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, January 18, 2021 8:43 AM
To: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: FW: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Sorry if this is duplicative Stacy but these folks tell me they have matching placebo available and I just wanted to make sure you are aware. Will send you another email with more info. jw

From: Andrew Gellman <agellman@ingenus.com>
Sent: Friday, January 15, 2021 6:59 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Dear Dr. Woodcock:

Before I leave my office for the week, I wanted to send a quick note to say thank you for meeting with Mukti, (b) (4) and me. Given your breadth of responsibilities, we were surprised by your approachability and impressed by your knowledge of Ivermectin, particularly its safety profile. We are excited by your interest and fully aligned with identifying a "non-traditional" path to fast track a study. Our clinical team, led by Mukti and also includes (b) (4), can be deployed to support the project as you deem appropriate. The data will speak for itself, but we remain hopeful that a repurposed Ivermectin (b) (4).

We look forward to hearing from you in regard to next steps.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC

(214) 616-0417

From: Andrew Gellman
Sent: Wednesday, January 13, 2021 10:16 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Good Evening Dr. Woodcock:

In preparation for our video conference tomorrow afternoon, attached is the Meeting Agenda. Joining me on the call will be Mukti Gande, our Chief Scientific Officer (b) (4) in the Ivermectin ANDA. I am respectful of your busy schedule, appreciative of the time you've created, so I commit that we will be efficient and incredibly mindful of the clock.

We're really excited to meet with you and share our thoughts.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Andrew Gellman [agellman@ingenus.com]
Sent: 1/22/2021 8:13:12 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Ivermectin Tablets

Dr. Woodcock:

Thank you!

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, January 22, 2021 8:09 PM
To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ivermectin Tablets

I can and will do 1 and 2 and will ask about 3. Jw

From: Andrew Gellman <agellman@ingenus.com>
Date: January 22, 2021 at 8:07:49 PM EST
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ivermectin Tablets
Importance: High

Dear Dr. Woodcock:

We understand your situation and while disappointed, we are happy/excited for you. What a great compliment on your career and even more so, what an exciting time to be heading up the FDA. We wish you success!

In regard to Ivermectin, I have a couple of requests that, without your direct involvement, I'm hoping you can accommodate. I'll detail them below.

1. Can you help us expedite a teleconference with an IND review team/office of infectious disease to facilitate a timely discussion around executing a Pragmatic Study. Our initial (b)(4) () submission was focused on a traditional Phase II Study... the response took 5+ weeks, which while speedy, we can't afford to lose on a second submission.
2. Can you introduce us to Robert Califf at Verily/Alphabet?
3. Can you introduce us to your contact at ACTIV so we can pursue them directly?

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, January 22, 2021 5:58 PM
To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ivermectin Tablets

Unfortunately now I'm in this new role I can't deal with individual companies. But I have connected your name/company with ACTIV and they are working on getting something set up. So I believe the wheels are turning fast even if you can't see the action. Feel free to stay in touch, I can certainly connect you with someone if things become stuck. jw

From: Andrew Gellman <agellman@ingenus.com>
Sent: Thursday, January 21, 2021 8:40 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Ivermectin Tablets

Hello Dr. Woodcock:

I trust you're swamped in your new role. So I apologize in advance, but I wanted to reach out to see if we can get some time on your calendar to continue the discussion on conducting a pragmatic trial for Ivermectin. Since we last spoke, we received a written response to our PIND, which appears to support our desire to pursue a phase II and phase III study. We are encouraged in that regard. Additionally, since the NIH revised their Ivermectin guidance, we're seeing continued uptick in demand, which is also encouraging.

That said, recognizing that your busy, I want you to know that we just need your support and a few doors opened; our team will do the rest. We are experienced and capable, but need an advocate who has your knowledge and connections. With a little help and guidance, we can run a quick trial and then the data will speak for itself.

Please let me know your availability.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, January 15, 2021 7:59 PM
To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

I am working on it! Jw

From: Andrew Gellman <agellman@ingenus.com>
Date: January 15, 2021 at 6:58:40 PM EST
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Dear Dr. Woodcock:

Before I leave my office for the week, I wanted to send a quick note to say thank you for meeting with Mukti, (b) (4) and me. Given your breadth of responsibilities, we were surprised by your approachability and impressed by your knowledge of Ivermectin, particularly its safety profile. We are excited by your interest and fully aligned with identifying a “non-traditional” path to fast track a study. Our clinical team, led by Mukti and also includes (b) (4) (b) (4) can be deployed to support the project as you deem appropriate. The data will speak for itself, but we remain hopeful that a repurposed Ivermectin (b) (4)

We look forward to hearing from you in regard to next steps.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Andrew Gellman
Sent: Wednesday, January 13, 2021 10:16 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Good Evening Dr. Woodcock:

In preparation for our video conference tomorrow afternoon, attached is the Meeting Agenda. Joining me on the call will be Mukti Gande, our Chief Scientific Officer (b) (4) (b) (4) in the Ivermectin ANDA. I am respectful of your busy schedule, appreciative of the time you’ve created, so I commit that we will be efficient and incredibly mindful of the clock.

We’re really excited to meet with you and share our thoughts.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 1/14/2021 11:00:32 AM
To: Bugin, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=735d396f29ce480a88de9e6c2b0f424e-BUGINK]
Subject: RE: Ivermectin Tablets - Plan of Action to repurpose for treatment of SARS CoV-2 virus

No jw

From: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Sent: Thursday, January 14, 2021 11:00 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: Ivermectin Tablets - Plan of Action to repurpose for treatment of SARS CoV-2 virus

Do you need me at this?

Kevin

From: (b) (4) @
Sent: Thursday, January 14, 2021 10:57 AM
To: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Subject: Ivermectin Tablets - Plan of Action to repurpose for treatment of SARS CoV-2 virus

Kevin,

I hope this message finds you well. Will you be present for the 3:00 PM meeting that Ingenus and (b) (4) have with Dr. Woodcock today?

Regards,

(b) (4)

(b) (4)

This communication contains information that may be confidential and/or privileged and is intended only for the individual or entity named above. If you are not the intended recipient of this communication, you are hereby notified that any dissemination, distribution or copying of this communication, and any attachments thereto, is strictly prohibited. Please notify us immediately if you are not the intended recipient at (b) (4) or call

(b) (4)

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 1/18/2021 8:59:01 AM
To: Adam, Stacey (FNIH) [T] [sadam@fnih.org]
Subject: RE: Ingenus, (b) (4) Ivermectin Tablets Meeting Agenda

Great, thanks. I actually think PCORNET is promising. jw

From: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Sent: Monday, January 18, 2021 8:51 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Thanks, Janet,

Once we have a place for this to go, I can reach out and get this company working with us.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (301) 435-8364 | Mobile: (b) (6)

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, January 18, 2021 8:44 AM
To: Adam, Stacey (FNIH) [T] <sadam@fnih.org>
Subject: FW: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Fyi jw

From: Andrew Gellman <agellman@ingenus.com>
Sent: Wednesday, January 13, 2021 10:16 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Good Evening Dr. Woodcock:

In preparation for our video conference tomorrow afternoon, attached is the Meeting Agenda. Joining me on the call will be Mukti Gande, our Chief Scientific Officer (b) (4) in the Ivermectin ANDA. I am respectful of your busy schedule, appreciative of the time you've created, so I commit that we will be efficient and incredibly mindful of the clock.

We're really excited to meet with you and share our thoughts.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 1/15/2021 7:58:39 PM
To: Andrew Gellman [agellman@ingenus.com]
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

I am working on it! Jw

From: Andrew Gellman <agellman@ingenus.com>
Date: January 15, 2021 at 6:58:40 PM EST
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Dear Dr. Woodcock:

Before I leave my office for the week, I wanted to send a quick note to say thank you for meeting with Mukti, (b) (4) and me. Given your breadth of responsibilities, we were surprised by your approachability and impressed by your knowledge of Ivermectin, particularly its safety profile. We are excited by your interest and fully aligned with identifying a "non-traditional" path to fast track a study. Our clinical team, led by Mukti and also includes (b) (4) (b) (4) can be deployed to support the project as you deem appropriate. The data will speak for itself, but we remain hopeful that a repurposed Ivermectin (b) (4)

We look forward to hearing from you in regard to next steps.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Andrew Gellman
Sent: Wednesday, January 13, 2021 10:16 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Good Evening Dr. Woodcock:

In preparation for our video conference tomorrow afternoon, attached is the Meeting Agenda. Joining me on the call will be Mukti Gande, our Chief Scientific Officer (b) (4) (b) (4) in the Ivermectin ANDA. I am respectful of your busy schedule, appreciative of the time you've created, so I commit that we will be efficient and incredibly mindful of the clock.

We're really excited to meet with you and share our thoughts.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 1/24/2021 4:35:59 PM
To: Sharma, Khushboo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0c8e73a04e14d15bb313bf0bc66ded6-SHARMAKH]
Subject: RE: Ivermectin Tablets

Thanks. jw

From: Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>
Sent: Sunday, January 24, 2021 3:39 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ivermectin Tablets

Thanks – I'll get them to the review division.

Khushboo Sharma, MBA, RAC
Deputy Office Director of Operations

Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-1270 Cell: (b) (6)
Khushboo.sharma@fda.hhs.gov



From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, January 24, 2021 11:49 AM
To: Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>
Subject: FW: Ivermectin Tablets
Importance: High

See request #1 below. I have told them I'm recused from any decision-making at FDA. jw

From: Andrew Gellman <agellman@ingenus.com>
Sent: Friday, January 22, 2021 8:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ivermectin Tablets
Importance: High

Dear Dr. Woodcock:

We understand your situation and while disappointed, we are happy/excited for you. What a great compliment on your career and even more so, what an exciting time to be heading up the FDA. We wish you success!

In regard to Ivermectin, I have a couple of requests that, without your direct involvement, I'm hoping you can accommodate. I'll detail them below.

1. Can you help us expedite a teleconference with an IND review team/office of infectious disease to facilitate a timely discussion around executing a Pragmatic Study. Our initial (b) (4) submission was focused on a traditional Phase II Study... the response took 5+ weeks, which while speedy, we can't afford to lose on a second submission.
2. Can you introduce us to Robert Califf at Verily/Alphabet?
3. Can you introduce us to your contact at ACTIV so we can pursue them directly?

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, January 22, 2021 5:58 PM
To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ivermectin Tablets

Unfortunately now I'm in this new role I can't deal with individual companies. But I have connected your name/company with ACTIV and they are working on getting something set up. So I believe the wheels are turning fast even if you can't see the action. Feel free to stay in touch, I can certainly connect you with someone if things become stuck. jw

From: Andrew Gellman <agellman@ingenus.com>
Sent: Thursday, January 21, 2021 8:40 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Ivermectin Tablets

Hello Dr. Woodcock:

I trust you're swamped in your new role. So I apologize in advance, but I wanted to reach out to see if we can get some time on your calendar to continue the discussion on conducting a pragmatic trial for Ivermectin. Since we last spoke, we received a written response to our PIND, which appears to support our desire to pursue a phase II and phase III study. We are encouraged in that regard. Additionally, since the NIH revised their Ivermectin guidance, we're seeing continued uptick in demand, which is also encouraging.

That said, recognizing that you're busy, I want you to know that we just need your support and a few doors opened; our team will do the rest. We are experienced and capable, but need an advocate who has your knowledge and connections. With a little help and guidance, we can run a quick trial and then the data will speak for itself.

Please let me know your availability.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President

Ingenus Pharmaceuticals, LLC

(214) 616-0417

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, January 15, 2021 7:59 PM
To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

I am working on it! Jw

From: Andrew Gellman <agellman@ingenus.com>
Date: January 15, 2021 at 6:58:40 PM EST
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Dear Dr. Woodcock:

Before I leave my office for the week, I wanted to send a quick note to say thank you for meeting with Mukti, (b) (4) and me. Given your breadth of responsibilities, we were surprised by your approachability and impressed by your knowledge of Ivermectin, particularly its safety profile. We are excited by your interest and fully aligned with identifying a "non-traditional" path to fast track a study. Our clinical team, led by Mukti and also includes (b) (4) can be deployed to support the project as you deem appropriate. The data will speak for itself, but we remain hopeful that a repurposed Ivermectin (b) (4)

We look forward to hearing from you in regard to next steps.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Andrew Gellman
Sent: Wednesday, January 13, 2021 10:16 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Good Evening Dr. Woodcock:

In preparation for our video conference tomorrow afternoon, attached is the Meeting Agenda. Joining me on the call will be Mukti Gande, our Chief Scientific Officer (b) (4) in the Ivermectin ANDA. I am respectful of your busy schedule, appreciative of the time you've created, so I commit that we will be efficient and incredibly mindful of the clock.

We're really excited to meet with you and share our thoughts.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 1/28/2021 8:38:37 AM
To: Andrew Gellman [agellman@ingenus.com]
Subject: RE: Ivermectin Tablets

I've been working with ACTIV and forwarded your information. They are trying to stand up a pragmatic trial but are in the very early stages, which is why they have not gotten back. I also forwarded your information to Rob.

Your fastest route may well be thru (b) (4) if they can get a pragmatic trial set up fast. I'm sure ACTIV will get in touch once they have a plan. jw

From: Andrew Gellman <agellman@ingenus.com>
Sent: Wednesday, January 27, 2021 8:23 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ivermectin Tablets

Hello Dr. Woodcock:

I wanted to update you on our progress.

We received a quick response from your agency in regard to the requested PIND live meeting. The ball is in our court now to finalize our construct for the pragmatic study, which we're working on intently. We've engaged with (b) (4)

We've yet to hear, however from Rob Califf at Verily or anyone from the ACTIV platform. At the risk of being a pest, would you to please prompt them again. (b) (4)

I'd like to have a quick discussion with Verily and ACTIV. (b) (4) appears to be well staffed and capable of executing a pragmatic study, but I prefer having options.

As always, I greatly appreciate your help and insights.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, January 24, 2021 1:58 PM
To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ivermectin Tablets

Hope so! jw

From: Andrew Gellman <agellman@ingenus.com>
Sent: Sunday, January 24, 2021 1:45 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ivermectin Tablets

Dr. Woodcock:

I'm sorry to see that you're working on Sunday, but happy to see the prompt response. I appreciate it and will wait to hear from them.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, January 24, 2021 11:50 AM
To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ivermectin Tablets

I have connected with all the parties below. Hopefully they will respond to you. Janet W

From: Andrew Gellman <agellman@ingenus.com>
Sent: Friday, January 22, 2021 8:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ivermectin Tablets
Importance: High

Dear Dr. Woodcock:

We understand your situation and while disappointed, we are happy/excited for you. What a great compliment on your career and even more so, what an exciting time to be heading up the FDA. We wish you success!

In regard to Ivermectin, I have a couple of requests that, without your direct involvement, I'm hoping you can accommodate. I'll detail them below.

1. Can you help us expedite a teleconference with an IND review team/office of infectious disease to facilitate a timely discussion around executing a Pragmatic Study. Our initial (b) (4) submission was focused on a traditional Phase II Study... the response took 5+ weeks, which while speedy, we can't afford to lose on a second submission.
2. Can you introduce us to Robert Califf at Verily/Alphabet?
3. Can you introduce us to your contact at ACTIV so we can pursue them directly?

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AJG

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Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, January 22, 2021 5:58 PM
To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ivermectin Tablets

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From: Andrew Gellman <agellman@ingenus.com>
Sent: Thursday, January 21, 2021 8:40 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Ivermectin Tablets

Hello Dr. Woodcock:

I trust you're swamped in your new role. So I apologize in advance, but I wanted to reach out to see if we can get some time on your calendar to continue the discussion on conducting a pragmatic trial for Ivermectin. Since we last spoke, we received a written response to our PIND, which appears to support our desire to pursue a phase II and phase III study. We are encouraged in that regard. Additionally, since the NIH revised their Ivermectin guidance, we're seeing continued uptick in demand, which is also encouraging.

That said, recognizing that your busy, I want you to know that we just need your support and a few doors opened; our team will do the rest. We are experienced and capable, but need an advocate who has your knowledge and connections. With a little help and guidance, we can run a quick trial and then the data will speak for itself.

Please let me know your availability.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, January 15, 2021 7:59 PM
To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

I am working on it! Jw

From: Andrew Gellman <agellman@ingenus.com>
Date: January 15, 2021 at 6:58:40 PM EST
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Dear Dr. Woodcock:

Before I leave my office for the week, I wanted to send a quick note to say thank you for meeting with Mukti, (b) (4) and me. Given your breadth of responsibilities, we were surprised by your approachability and impressed by your knowledge of Ivermectin, particularly its safety profile. We are excited by your interest and fully aligned with identifying a "non-traditional" path to fast track a study. Our clinical team, led by Mukti and also includes (b) (4) (b) (4) can be deployed to support the project as you deem appropriate. The data will speak for itself, but we remain hopeful that a repurposed Ivermectin (b) (4)

We look forward to hearing from you in regard to next steps.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Andrew Gellman
Sent: Wednesday, January 13, 2021 10:16 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Good Evening Dr. Woodcock:

In preparation for our video conference tomorrow afternoon, attached is the Meeting Agenda. Joining me on the call will be Mukti Gande, our Chief Scientific Officer (b) (4) in the Ivermectin ANDA. I am respectful of your busy schedule, appreciative of the time you've created, so I commit that we will be efficient and incredibly mindful of the clock.

We're really excited to meet with you and share our thoughts.

Respectfully,

AJG

Andrew Gellman
Co-Founder/President
Ingenus Pharmaceuticals, LLC
(214) 616-0417

From: Adam, Stacey (FNIH) [T] [sadam@fnih.org]
Sent: 1/24/2021 3:26:49 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Ivermectin Tablets

Thanks, Janet,

I had waited to reach out to them until we could settle on a path forward, but I will go ahead and send a first email this week.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (301) 435-8364 | Mobile: (b) (6)

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, January 24, 2021 11:48 AM

To: Adam, Stacey (FNIH) [T] <sadam@fnih.org>

Subject: FW: Ivermectin Tablets

Importance: High

Fyi these are the ivermectin people who would like to speak to you. jw

From: Andrew Gellman <agellman@ingenus.com>

Sent: Friday, January 22, 2021 8:07 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: RE: Ivermectin Tablets

Importance: High

Dear Dr. Woodcock:

We understand your situation and while disappointed, we are happy/excited for you. What a great compliment on your career and even more so, what an exciting time to be heading up the FDA. We wish you success!

In regard to Ivermectin, I have a couple of requests that, without your direct involvement, I'm hoping you can accommodate. I'll detail them below.

1. Can you help us expedite a teleconference with an IND review team/office of infectious disease to facilitate a timely discussion around executing a Pragmatic Study. Our initial (b) (4) submission was focused on a traditional Phase II Study... the response took 5+ weeks, which while speedy, we can't afford to lose on a second submission.
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3. Can you introduce us to your contact at ACTIV so we can pursue them directly?

Respectfully,

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Subject: RE: Ivermectin Tablets

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From: Andrew Gellman <agellman@ingenus.com>
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To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
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To: Andrew Gellman <agellman@ingenus.com>
Subject: RE: Ingenus(b) (4) Ivermectin Tablets Meeting Agenda

I am working on it! Jw

From: Andrew Gellman <agellman@ingenus.com>
Date: January 15, 2021 at 6:58:40 PM EST
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

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From: Andrew Gellman
Sent: Wednesday, January 13, 2021 10:16 PM
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Subject: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

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From: Robert Califf [robertcaliff@verily.com]
Sent: 1/25/2021 7:58:02 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: FW: Ivermectin Tablets

thx

On Mon, Jan 25, 2021 at 7:55 AM Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

Am working on them, will try to get them to you this AM. Yesterday got away from me a bit with issues. jw

From: Robert Califf <robertcaliff@verily.com>
Sent: Monday, January 25, 2021 7:54 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: FW: Ivermectin Tablets

ok, we're on it. do you have some bullets for tomorrow? Not a big deal but I really want to give it the best shot to change our pathetic system for evidence generation.

rmc

On Mon, Jan 25, 2021 at 7:49 AM Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

If it is the one I know about it is not illuminating but maybe it's a different one. jw

From: Robert Califf <robertcaliff@verily.com>
Sent: Monday, January 25, 2021 7:26 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: FW: Ivermectin Tablets

I hear there is a paper in press in jama debunking ivermectin based on an adequately powered rct, but i'll contact them.

thx

rmc

On Sun, Jan 24, 2021 at 11:48 AM Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

Rob, these folks make ivermectin and would like to speak to verily. I think they are planning a pragmatic trial. jw

From: Andrew Gellman <agellman@ingenus.com>
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To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: RE: Ivermectin Tablets

Importance: High

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Subject: RE: Ivermectin Tablets

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To: Andrew Gellman <agellman@ingenus.com>

Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

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From: Andrew Gellman <agellman@ingenus.com>

Date: January 15, 2021 at 6:58:40 PM EST

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: RE: Ingenus (b) (4) Ivermectin Tablets Meeting Agenda

Dear Dr. Woodcock:

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Sent: Wednesday, January 13, 2021 10:16 PM

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Subject: Ingenus(b) (4) Ivermectin Tablets Meeting Agenda

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AJG

Andrew Gellman

Co-Founder/President

Ingenus Pharmaceuticals, LLC

(214) 616-0417

From: Tess Lawrie [tess@e-bmc.co.uk]
Sent: 3/16/2021 12:33:04 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Fwd: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment
Attachments: BIRD Proceedings 02-03-2021 v 1.5.2.pdf; BIRD Proceedings Executive Summary.pdf; Guzzo2002 ivm safety.pdf; IVERMECTIN AUTHORIZATION CZECH REPUBLIC.docx

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Janet Woodcock,

I am sharing with you the correspondence that I have had with Peter Stein and colleagues with regard to the use of ivermectin for the treatment and prevention of covid. I am concerned that they have not yet seen the evidence that we sent to them on the 26th February, as the FDA's official position on ivermectin continues to be that there is no evidence to support its use and that ivermectin is intended for animals. The latter is particularly misleading and derogatory, given that ivermectin is widely used in humans around the world, including among the elderly in the US for the treatment of scabies. In addition, the FDA (and NIH) continues to refer to the in vitro Caly study to support the erroneous notion that ivermectin cannot be effective against covid at regular doses - there are at least 22 RCTs and 5 systematic reviews that show that ivermectin could have a significant impact on the pandemic and, in particular, reduce deaths.

I ask you to pay particular attention to the country example of India, which is four times more populous than the US, and where ivermectin is freely distributed in many states.

I attach the documents that I have shared to date with members of your organization and trust that you will read them with soon, so that we can agree to start saving lives with this cheap, safe and effective generic medicine. Honestly, what does the FDA have to lose?

Sincerely,
Tess

Dr. Theresa Lawrie
Evidence-based Medicine Consultancy Ltd
e-bmc.co.uk

Daily new confirmed COVID-19 deaths per million people

Shown is the rolling 7-day average. Limited testing and challenges in the attribution of the cause of death means that the number of confirmed deaths may not be an accurate count of the true number of deaths from COVID-19.

Our World
in Data



Source: Johns Hopkins University CSSE COVID-19 Data

CC BY

Tess

Dr. Theresa Lawrie
Evidence-based Medicine Consultancy Ltd
[e-bmc.co.uk](mailto:tess@e-bmc.co.uk)

Begin forwarded message:

From: Tess Lawrie <tess@e-bmc.co.uk>
Subject: Re: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment
Date: 15 March 2021 at 16:30:33 GMT
To: Tess Lawrie <tess@e-bmc.co.uk>
Cc: "Stein, Peter" <Peter.Stein@fda.hhs.gov>, "Cavazzoni, Patrizia" <Patrizia.Cavazzoni@fda.hhs.gov>, "Farley, John" <John.Farley@fda.hhs.gov>

Dear Dr Stein and Colleagues,

It has been a while since we shared with you the British Ivermectin Recommendation Development (BIRD) meeting recommendation and Evidence-to-Decision Framework. I am therefore writing to enquire where you are in the process of evaluating the evidence we sent on this essential drug for covid-19.

I would also like to share with you a link to the UK-based team's systematic review and meta-analysis on ivermectin for covid-19 that underpins the BIRD recommendation: <https://osf.io/k37ft/>
This manuscript, which is now available on a preprint website, successfully underwent a four-peer review process for a high-impact factor journal. All four reviewers were satisfied that their queries were addressed. Our systematic review is the fifth review of ivermectin for the treatment and prevention of ivermectin (KORY et al 2021 <https://t.co/B3MRnPAw5R>; HILL et al 2021 <https://t.co/r8fQIgbIgu>; COBOS-CAMPOS et al 2021 <https://t.co/EDRx8vyqoe>; BRYANT et al 2021 <https://t.co/ul48ZUsvvy>; NARDELI et al., 2021 - attached). As you know, systematic reviews are considered the highest level of evidence on effects of an intervention. All five systematic review teams are in agreement that the effect that ivermectin could have on reducing mortality and morbidity related to covid-19 is substantial. All reviewers, with the exception of Hill et al, agree that ivermectin could have a significant impact on the pandemic.

In addition, you will have seen from the BIRD Evidence to Decision framework previously shared, that the values, resource, equity, acceptability and feasibility criteria all favour the implementation of ivermectin for covid-19 as soon as possible.

You should know that the World is waiting on your team to act in the global public's interest and approve ivermectin without further delay.

We look forward to some news.

Kind regards,

Tess Lawrie, on behalf of the BIRD Steering Group and recommendation panel

Dr. Theresa Lawrie
Evidence-based Medicine Consultancy Ltd
e-bmc.co.uk

On 5 Mar 2021, at 15:58, Tess Lawrie <tess@e-bmc.co.uk> wrote:

Dear Dr, Stein,

I trust that you are well and thank you for acknowledging receipt of last week's email.

We have since written an executive summary and I attach it here for your information, with an updated BIRD proceedings document. They are still draft documents as endorsements keep flooding in and we intend to publish these with the final document. There are also the results of a public participation survey to be included. Again, please don't hesitate to contact me if you have any queries about the large body of accumulated evidence on ivermectin use for covid-19.

Kind regards,
Tess

Dr. Tess Lawrie, on behalf of the BIRD Steering Group and Recommendation Development Panel

Director
Evidence-based Medicine Consultancy Ltd
e-bmc.co.uk

<BIRD Proceedings 02-03-2021 v 1.5.1.pdf>
<BIRD Proceedings Executive Summary.pdf>

On 26 Feb 2021, at 16:42, Stein, Peter <Peter.Stein@fda.hhs.gov> wrote:

Dear Dr. Lawrie,

Thank you for forwarding this information – it's much appreciated – and clearly reflects your group's thoughtful assessment. We'll certainly review what you've provided.

Sincerely,

Peter Stein

Director, Office of New Drugs, CDER/FDA

From: Tess Lawrie <tess@e-bmc.co.uk>

Sent: Friday, February 26, 2021 10:59 AM

To: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; james.sigg@fda.hhs.gov; Tyler, James <James.Tyler@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; Miller, Elizabeth <Elizabeth.Miller@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Pazdur, Richard <Richard.Pazdur@fda.hhs.gov>; Jeffrey.shuren@fda.hhs.gov; Slikker, William <William.Slikker@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Mitch.zeller@fda.hhs.gov; Stein, Peter <Peter.Stein@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Sally.chloe@fda.hhs.gov
Cc: [claire Mock-Muñoz de Luna <claire@e-bmc.co.uk>](mailto:claire@e-bmc.co.uk); [Ketan Gajjar <ketan.gajjar@nhs.net>](mailto:ketan.gajjar@nhs.net); [Andy Bryant <andy.bryant@newcastle.ac.uk>](mailto:andy.bryant@newcastle.ac.uk); [Tony Tham <tctham1234@gmail.com>](mailto:tctham1234@gmail.com); [Scott Mitchell <scott.mitchell@gov.gg>](mailto:scott.mitchell@gov.gg); [Tina Peers <tina@drtinapeers.com>](mailto:tina@drtinapeers.com)

Subject: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Stein and FDA Colleagues,

We are writing to share with you the evidence to decision framework of the British Ivermectin Recommendation Development (BIRD) Meeting that was held on Saturday 20th February 2021 via Zoom from Bath, United Kingdom. The expert panel of health and allied professionals and other stakeholders included representatives from 16 countries, namely Argentina, Australia, Belgium, Botswana, Canada, France, Hungary, India, Ireland, Japan, Peru, Nigeria, South Africa, The Philippines, United States, United Kingdom. The ethos of the BIRD meeting was that of scientific rigour and transparency in the spirit of international collaboration towards a common goal – that of saving lives.

The recommendation was developed according *The WHO Handbook of Guideline Development (2014)*. BIRD panel conclusions are that ivermectin should be approved immediately for prevention and treatment of covid-19.

The BIRD recommendation on covid-19 prevention and treatment

The British Ivermectin Recommendation Development Panel recommends ivermectin for the prevention and treatment of covid-19 to reduce morbidity and mortality associated with covid-19 infection and to prevent covid-19 infection among those at higher risk.

The BIRD Steering Group has taken heed of the WHO statement on 'Developing global norms for sharing data and results during public health emergencies' that states that 'public disclosure of information of relevance to public health emergencies should not be delayed', and also notes the 'very great risks' that can occur from 'withholding data and results arising from analyses'. We are, therefore, sharing this evidence-to decision framework within just a few days of the BIRD meeting to avoid delay.

Further, due to the urgency related to the communication and dissemination of this recommendation that is aimed at saving thousands of lives daily, please forgive the limitations of the draft proceedings document attached. Information on the process and methods can be found among the annexes. An Executive Summary is being finalised and will be available on Monday.

We look forward to hearing from you soon and would be happy meet with you via teleconference if you think this will be helpful.

Please do not hesitate to contact us with any questions.

Kind regards,

Dr. Tess Lawrie, on behalf of the BIRD Steering Group and Recommendation Development Panel
Evidence-based Medicine Consultancy Ltd
e-bmc.co.uk

IVERMECTIN AUTHORIZATION CZECH REPUBLIC

Information on the authorization of the use of the unregistered medicinal product HUMEVEC (ivermectin)

The State Institute for Drug Control informs about the temporary authorization of the distribution, dispensing and use of the unregistered human medicinal product HUVEMEC 3 mg, tablets, containing the active substance ivermectin.

Information on the temporary authorization of the distribution, dispensing and use of the unregistered human medicinal product HUVEMEC 3 mg, tablets, containing the active substance ivermectin was published on the official notice board of the Ministry of Health.

The full text of the decision is available on the website of the Ministry of Health:

<https://www.mzcr.cz/rozhodnuti-o-docasnem-povoleni-distribuce-vydeje-a-pouzivani-neregistrovaneho-humanniho-leciveho-pripravku-humevec-s-obsahem-lecive-latky-ivermektin/>

Department of coordination of professional activities



MINISTRY OF HEALTH
Palackého náměstí 375/4, 128 01 Prague 2
Str. 1 of 5
Prague, March 3, 2021
No .: MZDR 8603 / 2021-4 / OLZP
* MZDRX01ES9DV *
MZDRX01ES9DV
DECISION

DECISION The Ministry of Health (hereinafter referred to as the "Ministry") as the administrative authority competent pursuant to § 11 letter o) of Act No. 378/2007 Coll., on Medicinal Products and on Amendments to Certain Related Acts (the Medicinal Products Act), as amended (hereinafter referred to as the "Medicinal Products Act") decided the following measure: In order to protect public health in connection with the ongoing global pandemic COVID-19 disease, caused by the spread of SARS-CoV-2 virus, in order to ensure the availability of medicinal products important for the provision of health care Ministry in accordance with § 8 paragraph 6 of the Pharmaceuticals Act.

temporarily allows
distribution, supply and use of the unregistered human medicinal product HUVEMEC 3 mg, tablets, manufactured by Huvepharma, Bulgaria, containing the active substance ivermectin (hereinafter "HUVEMEC medicinal product").

- Number: 5,000 packs of 10x3 mg and 5,000 packs of 30x3 mg
- The dispensing of HUVEMEC medicinal products is subject to a medical prescription.

See discussions, stats, and author profiles for this publication at: <https://www.researchgate.net/publication/11094854>

Safety, Tolerability, and Pharmacokinetics of Escalating High Doses of Ivermectin in Healthy Adult Subjects

Article in *The Journal of Clinical Pharmacology* · November 2002

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Safety, tolerability, and pharmacokinetics of escalating high doses of ivermectin in healthy adult subjects

CA Guzzo, CI Furtek, AG Porras, C Chen, R Tipping, CM Clineschmidt, DG Sciberras, JY Hsieh and KC Lasseter
J Clin Pharmacol 2002 42: 1122

The online version of this article can be found at:
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The BIRD Recommendation on the Use of Ivermectin for Covid-19:

Executive Summary

BIRD

British
Ivermectin
Recommendation
Development



Proceedings and conclusions of the British Ivermectin Recommendation Development meeting held on the 20th February 2021 in Bath, United Kingdom.

The BIRD Recommendation on the Use of Ivermectin for Covid-19

BIRD

British
Ivermectin
Recommendation
Development



Proceedings and conclusions of the British Ivermectin Recommendation Development meeting held on the 20th February 2021 in Bath, United Kingdom.

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 11/17/2020 9:24:35 AM
To: Kilgore, Nicole R CIV USARMY (USA) [nicole.r.kilgore.civ@mail.mil]; Adam, Stacey J (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8de67693eab246c7946108cfd7c6d3dc-HHS-sadam-f]
Subject: FW: Ivermectin and an IND
Attachments: 29593.pdf; COVID-Meta-analysis-Pierre.pdf; Covid-Summary-10-29-2020.pdf; EVMS Critical Care COVID 19 Protocol - 11-3-2020.pdf; FLCCC-Ivermectin-in-the-prophylaxis-and-treatment-of-COVID-19.pdf; FLCCC-IVERMECTIN-Protocol.pdf; FLCCC-IVERMECTIN-Summary.pdf

Potentially more information on Ivermectin use. Janet W

From: Marik, Paul E. <MarikPE@EVMS.EDU>
Sent: Tuesday, November 17, 2020 8:01 AM
To: (b) (6); Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: (b) (6)
Subject: Ivermectin and an IND

Dear Drs. Lieberman and Woodcock:

I was sent this communication below. Two points in response.

1. As this is a FDA approved drug an IND may not be required. Please see the ACTS Vitamin C trial. As the product used (IV Vitamin C) was FDA approved for the treatment of "scurvy" the FDA provided a waiver of an IND.
2. There is now overwhelming evidence that Ivermectin is useful for prophylaxis, postexposure Rx, early symptomatic treatment and late treatment of COVID-19. To ignore this exceedingly safe, effective and cheap medication is immoral. URGENT action is required.

Please see attachments and links below.

Kindly

Paul Marik. MD

U-Tube Channel

<https://www.youtube.com/channel/UCz9Pvn15m4Rv1uY-aBYRVuw>

<https://www.trialsitenews.com/real-world-evidence-i-mask-protocol-ivermectin-key-for-prophylaxis-and-early-treatment-of-covid-19/?fbclid=IwAR33nTE-TJ1fzO87s12DNqWN0cTZ9YBz-m-Nt4haNW0vIKURRJBG6ZO9I1U>

<https://www.trialsitenews.com/why-isnt-ivermectin-being-widely-researched-and-utilized/>

FLCCC

<https://covid19criticalcare.com/>

Here is a happy email exchange w the FDA

Thanks, I will definitely follow up. jw

-----Original Message-----

From: Alexis Lieberman (b) (6) >

Sent: Monday, November 16, 2020 8:15 AM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: Re: Information re Covid treatment

Good morning, Dr Woodcock,

I wanted to follow up about the IND for the Temple/ Einstein ivermectin study. I also learned that the Broward County, Florida study and the Ventura, California study are each also waiting for an IND. While it looks like many trials are occurring in the US for ivermectin use for Covid, I believe only the University of Kentucky has an IND. The others are all waiting. I greatly appreciate your assistance with this!

Alexis Lieberman, MD

On Nov 13, 2020, at 2:11 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

Is this study with an inhaled or oral formulation? Thanks jw

-----Original Message-----

From: Alexis Lieberman <(b) (6)> (b) (6)

Sent: Thursday, November 12, 2020 4:55 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: Re: Information re Covid treatment

Thank you. I understand that part of the reason the drug has not been pursued is that it was considered that there are enough studies already underway. I would like to bring to your attention that the study in Philadelphia that has been listed with clinicaltrials.gov at Albert Einstein Medical Center and Temple University Hospital has not yet begun because the investigators have been waiting for an IND from the FDA for nearly 5 months already. I wonder if there is any way to facilitate them getting the IND rapidly so that their study can begin during the current surge in cases in Philadelphia? Any assistance with this would be greatly appreciated.

Sincerely,

Alexis Lieberman, MD

On Nov 12, 2020, at 10:23 AM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

Thank you. We have considered this drug before, will refer these references to the assessment team for further evaluation. Janet Woodcock

-----Original Message-----

From: Alexis Lieberman <(b) (6)>

Sent: Wednesday, November 11, 2020 5:58 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: Information re Covid treatment

Dear Dr. Woodcock,

As a practicing pediatrician in Philadelphia, I am writing to request that you use your role on the Covid task force to advocate for an immediate, large-scale RCT for ivermectin early in disease. I include summaries of studies done so far on ivermectin that point to its promise.

As you know, Ivermectin is an anti-parasitic drug that is used widely throughout the world and is generally very well-tolerated with only very RARE side effects in those who do not have parasites, primarily limited to allergic reactions. The drug is proposed to prevent the virus from getting into the nucleus of the human cell. While the initial Monash in-vitro study used very high doses and the early Surgisphere study was discredited, since that time, there have been a dozen positive clinical studies. Surely there is enough evidence now to warrant a large-scale, government-funded RCT. This inexpensive, off-patent drug will not make money for any drug company. Therefore, it falls to the government to take steps to fund a trial. I implore you to advocate for this!

STUDIES AND LINKS REGARDING IVERMECTIN:

10/29/30. India: Two doses of ivermectin, given 72 hours apart, prophylactically, was associated with a 73% reduction of COVID-19 infection among healthcare workers for the following one-month, in a case control study of 186 pairs.

<https://www.medrxiv.org/content/10.1101/2020.10.29.20222661v1>

10/26/30: Baghdad, Iraq: A recent study done Baghdad compared COVID patients who took ivermectin or did not. In this, 10% of the non-ivermectin group progressed to severe disease well only 4% of the ivermectin group did. In that same study there was a 27% mortality rate for those who did not take over motion versus 18% and those who did.

<https://www.medrxiv.org/content/10.1101/2020.10.26.20219345v1>

9/28/20: Bangladesh: In this retrospective study, they compared patients who received Ivermectin with those who receive the standard of care. They found that 46% of the standard of care patients required oxygen and 8% went to the

intensive care unit. This was compared to those who did receive ivermectin, in which 9% required oxygen and only 1% went to the intensive care unit. <https://www.trialsitenews.com/mymensingh-medical-college-r.../>

8/28/20: Preventive study from Egypt showing for the first time a large reduction in covid contraction for family members taking prophylactic dose of Ivermectin when there is an infected person in the same household. Household contacts who did not take ivermectin had a 58% rate of contracting Covid, compared to only 7% of those who did take ivermectin.

https://clinicaltrials.gov/.../61/NCT04422561/Prot_SAP_000.pdf

8/26/20: Bangladesh. 400 patients were randomized to either receive ivermectin or placebo. In that study 18% of the placebo patients progressed to clinical deterioration while only 9% of those with ivermectin deteriorated. In that study they also compared percentage of patients who had early clinical improvement within a week, and of those without Ivermectin, 44% improved quickly while of those with Ivermectin, 60% improved quickly.

https://clinicaltrials.gov/.../31/NCT04523831/Prot_ICF_000.pdf

7/8/20 Baghdad, Iraq: This study compared hospitalized patients with mild to moderate symptoms who took ivermectin or did not. Those who did not had a hospital stay of 12 days on average, vs 7% in those who did take ivermectin.

<https://www.medrxiv.org/.../10.../2020.07.07.20145979v1.full.pdf>

6/30/20 Dominican Republic Data:

<https://www.trialsitenews.com/president-of-dominican-repub.../>

6/28/20 Bangladesh Data (mild to moderate cases, comparison with hydroxychloroquine/azithromycin). This study is not statistically significant but showed a trend of recovery in eight days with ivermectin versus nine without.

<https://www.trialsitenews.com/ivermectin-study-reveals-fan.../>

6/10/20 Florida Data (first U.S. data, on hospitalized patients). This is a retrospective intensive care unit study in which those who did not receive ivermectin had a 25% mortality rate while those who did receive ivermectin had a 15% mortality rate. It has since been published in a peer-reviewed journal.

[https://journal.chestnet.org/.../S0012-3692\(20\)34898.../fulltext](https://journal.chestnet.org/.../S0012-3692(20)34898.../fulltext)

5/2/20 Peru Data: areas of the country where ivermectin was used have a lower case rate and lower fatality rate than areas where ivermectin was not used.

<https://www.docdroid.net/J8wuZlb/ivermectin-studyesen-pdf>

3/2020: Australian study that showed that high doses of ivermectin killed the Covid virus in a test tube study.

<https://research.monash.edu/.../the-fda-approved-drug-ivermec...>

The FLCC, a US based group of colleagues with over 200 years of combined experience in Critical Care and Emergency Medicine, as well as long-standing shared interests in developing effective treatments for critical illnesses including sepsis, is a working group devoted to creating a treatment protocol against COVID-19.

They developed an inpatient Covid protocol which has lead to a mortality rate of 4-10%, compared to the world average of 23%.

They have now developed a prophylactic and early outpatient combination treatment protocol for COVID-19 called I-Mask+.

<https://covid19criticalcare.com/.../FLCCC-IVERMECTIN-Protocol...>

This protocol recommends ivermectin, vitamins C and D, Zinc, melatonin and, for adults only, aspirin.

Their rationale is based on multiple studies as well as real-world evidence comparing countries using ivermectin, such as Peru, Brazil and Haiti, to those not using it, such as the Dominican Republic and the US.

Here is the introductory video from FLCC:

<https://vimeo.com/473929788/382c386d60>

Thank you for your consideration,

Alexis Lieberman, MD

Advocare Fairmount Pediatrics

Paul E. Marik MD, FCCP, FCCM|

Eastern Virginia Medical School |

Department of Internal Medicine|

Chief, Pulmonary and Critical Care Medicine|

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✉ marikpe@evms.edu | 🌐 www.evms.edu

Teaching. Discovering. Caring.

IVERMECTIN – A POTENTIAL GLOBAL SOLUTION TO THE COVID-19 PANDEMIC

Recently, a wave of negative results were published from trials on numerous COVID-19 therapies, essentially eliminating any role for remdesivir, hydroxychloroquine, lopinavir/ritonavir, interferon, convalescent plasma, tocilizumab, and mono-clonal antibody therapy.¹⁻⁶ One year on, the only therapy considered “proven” as an effective treatment in COVID-19 are the use of corticosteroids in patients with moderate to severe illness.⁷

Since March 2020, our expert panel, the Front Line COVID-19 Critical Care Alliance (www.flccc.net) led by Professor Paul Marik, has continuously reviewed the rapidly emerging basic science, translational, and clinical data in COVID-19 with the aim of ensuring that our MATH+ Hospital Treatment protocol both continuously evolves and stays current. As of October 28th, 2020, based on the increasing and recently reported data from a number of published and unpublished trials, we have concluded that the drug Ivermectin, an anti-parasitic drug with increasingly well-known anti-viral⁸⁻¹⁶ and anti-inflammatory properties has demonstrated profound activity against COVID-19. Based on these data, we have devised a new prophylaxis and early treatment protocol against COVID-19 which we have named the “**I-MASK+**” protocol which we believe may serve as a global solution to the pandemic. The evidence base in support of this conclusion shows that Ivermectin:

1. Inhibits SARS-CoV-2 replication, leading to absence of nearly all viral material by 48h in infected cell cultures¹⁷
2. Prevents transmission and development of COVID-19 disease in household members of infected patients^{18,19}
3. Hastens recovery and prevents deterioration in patients with mild to moderate disease treated early after symptoms²⁰⁻²⁵
4. Hastens recovery and avoidance of ICU admission and death in hospitalized patients^{25,26}
5. Leads to striking reductions in case-fatality rates in regions with population-wide distribution and use^{27,28}

Equally critical features of Ivermectin supporting its potential role as a global intervention are that it is FDA approved, inexpensive, easily compounded, well-tolerated, and has an excellent safety profile and long history of use.²⁹ Further, the drug has an extended duration of activity, and would require as little as one dose a week as a prophylaxis agent, and from 4-6 doses over two days as a therapeutic agent. The data suggests that as little as one or two doses a week taken by a significant proportion of citizens may lead to population-wide protection and reduced transmission in a manner that is easier to achieve, more effective, and less expensive than the still elusive and widely suspect vaccine.¹⁹

The above listed studies showing the physiologic impacts of Ivermectin therapy in COVID-19 are all referenced below. One study deserves particular attention, posted on the pre-print server Researchgate earlier this month by Dr. Juan Chamie which provides an analysis of large amounts of real-world epidemiologic data in support of Ivermectin as an effective population-wide intervention in Peru.²⁷

The study provides population mortality data among 8 regions in Peru before and after the decision of the Peruvian Ministry of Health to recommend and initiate the widespread distribution of hundreds of thousands of doses of Ivermectin for the treatment of COVID-19 patients. Figure 1 below illustrates a dramatic, temporally associated reduction in case fatality rates in patients over 60 after widespread distribution of ivermectin was initiated, a response seen in multiple regions at different times in the pandemic corresponding to the varying dates of initiation of distribution of Ivermectin. By focusing solely on patients over 60, the analyses remove the potential confounding decreases in mortality that could be caused by an increase of infections in healthier, younger people.

I-MASK+

Prophylaxis & Early Outpatient Treatment Protocol for COVID-19

PROPHYLAXIS PROTOCOL

Ivermectin	<i>Prophylaxis for high risk individuals</i> 0.15-0.2 mg/kg* once weekly <i>Post COVID-19 exposure prophylaxis**</i> 0.2 mg/kg* x1 dose, repeat in 72 hours
Vitamin D3	1,000-3,000 IU/day
Vitamin C	1,000mg twice daily and Quercetin 250 mg/day
Melatonin	6 mg before bedtime (causes drowsiness)
Zinc	100 mg/day
Aspirin	80-100 mg/day (unless contraindicated)

EARLY OUTPATIENT PROTOCOL***

Ivermectin	0.2 mg/kg* daily for two days
Vitamin D3	4,000 IU/day
Vitamin C	2,000mg 2-3 times daily and Quercetin 250 mg twice a day
Melatonin	10 mg before bedtime
Zinc	200 mg/day
Aspirin	325 mg/day (unless contraindicated)

* Example for a person of 60 kg (body weight): 60kg x 0.15mg = 9 mg (1kg = 2.2 lbs)
 ** To use if a household member is COVID-19 positive, or you have prolonged exposure to a COVID-19 positive patient without wearing a mask
 *** For hospitalized patients, see the FLCCC's "MATH+" protocol on www.flccc.net

A summary of the published data supporting the rationale for Ivermectin use in our I-MASK+ protocol can be downloaded from www.flccc.net/flccc-ivermectin-summary
 For updates, references, and information on the **FLCCC Alliance**, the **I-MASK+ Prophylaxis & Early Outpatient Treatment Protocol for COVID-19** and the **MATH+ Hospital Treatment Protocol for COVID-19**, please visit our website.

www.flccc.net

© 2020 FLCCC Alliance · I-MASK+ Protocol v1 · Oct. 31, 2020

DISCLAIMER This protocol is solely for educational purposes and not intended to be a substitute for professional medical advice, diagnosis, or treatment in regards to any patient. Please read our full Disclaimer on www.flccc.net/disclaimer



WEAR MASKS

Must wear cloth, surgical, or N95 mask (without valve) in all indoor spaces with non-household persons.

Must wear a N95 mask (without valve) during prolonged exposure to non-household persons in any confined, poorly ventilated area.



KEEP DISTANCE

Until the end of the Covid-19 crisis, we recommend keeping a minimum distance of approx. 2m / 6 feet in public from people who are not from your own household.



WASH HANDS

We recommend, after a stay during and after outings from home (shopping, subway etc.), a thorough hand cleaning (20-30 sec. with soap), or also to use a hand disinfectant in between.

Review of the Emerging Evidence Supporting the Use of Ivermectin in the Prophylaxis and Treatment of COVID-19

Front Line COVID-19 Critical Care Alliance

Pierre Kory, Associate Professor of Medicine, St. Luke's Aurora Medical Center

G. Umberto Meduri, Professor of Medicine, Univ. of Tennessee Health Science Center, Memphis

Jose Iglesias, DO, Associate Professor of Medicine, Hackensack School of Medicine, Seton Hall

Joseph Varon, MD, Professor of Medicine, University of Texas Health Science Center

Keith Berkowitz, MD, Medical Director, Center for Balanced Health, New York

Howard Kornfeld, MD, Diplomate in Emergency Medicine, Director, Recovery Without Walls

Eivind Vinjevoll, MD, Critical Care and Emergency Department Chief, Volda, Norway

Scott Mitchell, MRCS, Associate Specialist, Princess Elizabeth Hospital, Guernsey

Fred Wagshul, MD, Medical Director, Lung Center of America, Dayton, Ohio

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Dr. Meduri's contribution is the result of work supported with the resources and use of facilities at the Memphis VA Medical Center. The contents of this commentary do not represent the views of the U.S. Department of Veterans Affairs or the United States Government

Conflict of Interest:

The authors have no conflicts of interest to disclose with any material that is present in this manuscript.

Funding: None

Date: November 11, 2020

EVMS

MEDICAL GROUP

EVMS CRITICAL CARE

COVID-19 MANAGEMENT PROTOCOL

Developed and updated by Paul Marik, MD
Chief of Pulmonary and Critical Care Medicine
Eastern Virginia Medical School, Norfolk, VA
November 3rd, 2020

This is our recommended approach to COVID-19 based on the best (and most recent) literature. This is a very dynamic topic; therefore, we will be updating the guideline as new information emerges. Please check on the EVMS website for updated versions of this protocol.

EVMS COVID website: https://www.evms.edu/covid-19/medical_information_resources/
Short url: [evms.edu/covidcare](https://www.evms.edu/covidcare)

Disclaimer: The information provided in this protocol is primarily to provide information to physicians on a protocol that we found to be highly effective in damping down the hyper-inflammatory cytokine “storm” that is the cause of mortality and morbidity in COVID-19. Our guidance should only be used by medical professionals in formulating their approach to COVID-19. Patients should always consult with their physician before starting any medical treatment.

MATH+
HOSPITAL TREATMENT PROTOCOL FOR COVID-19


Intravenous **M**ethylprednisolone
High Dose Intravenous **A**scorbic Acid (Vitamin C)
Thiamine (Vitamin B1)
Low Molecular Weight **H**eparin
+

Statin - Zinc - Vitamin D - Famotidine - Melatonin - Magnesium

FLCCC
A L L I A N C E

Front Line Covid-19
Critical Care Alliance
www.covid19criticalcare.com

BMJ Open Ascorbic Acid, Corticosteroids and Thiamine in Sepsis (ACTS) protocol and statistical analysis plan: a prospective, multicentre, double-blind, randomised, placebo-controlled clinical trial

Ari Moskowitz ^{1,2}, Tuyen Yankama,² Lars W Andersen,^{2,3} David T Huang,^{4,5} Michael W Donnino,^{1,2,6} Anne V Grossestreuer,^{2,6} for the ACTS Clinical Trial Investigators

To cite: Moskowitz A, Yankama T, Andersen LW, *et al.* Ascorbic Acid, Corticosteroids and Thiamine in Sepsis (ACTS) protocol and statistical analysis plan: a prospective, multicentre, double-blind, randomised, placebo-controlled clinical trial. *BMJ Open* 2019;**9**:e034406. doi:10.1136/bmjopen-2019-034406

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2019-034406>).

AM and TY contributed equally.

Received 18 September 2019
Revised 20 November 2019
Accepted 22 November 2019



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For numbered affiliations see end of article.

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amoskowi@bidmc.harvard.edu

ABSTRACT

Introduction Septic shock is a common and highly morbid condition. To date, there is no specific therapy proven to attenuate organ injury in septic shock. Recent studies have suggested a role for the combination of ascorbic acid, corticosteroids and thiamine, although randomised data are lacking.

Methods and analysis The Ascorbic Acid, Corticosteroids, and Thiamine in Sepsis trial is a multi-centre, double-blind, randomised, placebo-controlled clinical trial that aims to determine the impact of ascorbic acid, corticosteroids and thiamine versus placebo on organ injury and mortality in patients with septic shock. Patients are randomised to receive 1500 mg of ascorbic acid, 100 mg of thiamine and 50 mg of hydrocortisone parenterally versus matching placebo every 6 hours for 4 days. Clinical and laboratory data are collected at the time of study enrolment, at 24, 72 and 120 hours. The primary end-point for the trial is change in the Sequential Organ Failure Assessment score between enrolment and 72 hours. Additional key secondary outcomes include the incidence of renal failure and 30-day mortality.

Ethics and dissemination The study was approved by the international review board of each participating study site. Study findings will be disseminated through peer-reviewed publications and conference presentations.

Trial registration number The trial is registered on clinicaltrials.gov (NCT03389555). It was posted on 3 January 2018.

INTRODUCTION

The Ascorbic Acid, Corticosteroids, and Thiamine in Sepsis (ACTS) trial was developed to assess the clinical efficacy and safety of ascorbic acid, hydrocortisone and thiamine in patients with septic shock. The rationale for this trial has previously been published by the trial investigators.¹ In short, there is presently no directed therapy proven to attenuate organ injury in septic shock. Whereas the traditional paradigm of organ injury in sepsis has

Strengths and limitations of this study

- This article describes a multicentre, randomised, blinded clinical trial of ascorbic acid, corticosteroids and thiamine versus placebo in septic shock.
- The described study will be among the earliest completed randomised trials testing the promising combination of ascorbic acid, corticosteroids and thiamine in septic shock, and thus will fill an important knowledge gap.
- The primary outcome for the trial is change in the Sequential Organ Failure Assessment score between enrolment and 72 hours after enrolment which will provide important information regarding the effect of ascorbic acid, corticosteroids and thiamine on the trajectory of organ injury in septic shock.
- 30-day mortality is a secondary outcome for this study, but the trial may be underpowered for this important patient-centred outcome.

focused on impaired oxygen delivery, there is increasing evidence that non-oxygen delivery dependent mechanisms of organ injury may play an important role. In particular, mitochondrial dysfunction has been recognised as a likely contributor to organ injury in many sepsis victims.^{2,3} Ascorbic acid, a potent antioxidant and thiamine, a key co-factor in aerobic respiration, may have roles as mitochondrial resuscitators in septic shock. In observational studies and small clinical trials, both ascorbic acid and thiamine have shown promise as directed therapies for the attenuation of organ injury in sepsis.^{4,5} More recently, a phase II clinical trial of high-dose ascorbic acid in sepsis victims with the acute respiratory distress syndrome found that the intervention was safe and may have improved mortality. Notably however, ascorbic acid did

From: Bugin, Kevin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=735D396F29CE480A88DE9E6C2B0F424E-BUGINK]
Sent: 12/4/2020 12:56:19 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: FW: oral ivermectin tablets

The ever persistent ivermectin.

Kevin

From: (b) (4)
Sent: Friday, December 4, 2020 12:25 PM
To: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Subject: FW: oral ivermectin tablets

Kevin,

I hope that you are well. Just a reminder on the below.

Regards,

(b) (4)

From: (b) (4)
Sent: Sunday, September 6, 2020 8:19 AM
To: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Subject: oral ivermectin tablets

Kevin,

I hope this message finds you well. I am sure that you already aware of (b) (4) oral ivermectin tablets. That said, I didn't want to leave any doubt.

(b) (4)

Regards,

(b) (4)

(b) (4)

(b) (4)

This communication contains information that may be confidential and/or privileged and is intended only for the individual or entity named above. If you are not the intended recipient of this communication, you are hereby notified that any dissemination, distribution or copying of this communication, and any attachments thereto, is strictly prohibited. Please notify us immediately if you are not the intended recipient at (b) (4)@ [REDACTED], or call (b) (4) [REDACTED]

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 8/5/2020 3:33:51 PM
To: Bugin, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=735d396f29ce480a88de9e6c2b0f424e-BUGINK]
Subject: RE: Inhaled Ivermectin

Thanks. wj

From: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Sent: Tuesday, August 4, 2020 8:20 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: Inhaled Ivermectin

FYI. Apparently they have been in contact with NIAID (Ann) but haven't had any luck getting support for additional preclinical work. I suspect folks are skeptical of the dose form.. I recommended they submit to BARDA and we can see what they think. Its definitely too early for OWS.

Kevin

From: (b) (4)
Sent: Monday, August 03, 2020 8:16 PM
To: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Subject: RE: Inhaled Ivermectin

Kevin,

Thank you again for your time today and the (b) (4)

(b) (4)

Ivermectin has a long history of effective use as an anti-parasitic. It has also shown effectiveness against several single-stranded RNA viruses similar to SARS-Cov2. In a Monash University in vitro study it was shown to be effective in clearing SARS-Cov-2 in Vero/SLAM cells within 48 hours. However, based on predictive modeling, IC50 levels needed for viral clearance in the lungs may not be achievable with currently approved oral dosing of Ivermectin. Sufficient local concentrations in the lungs can be achieved using an inhaled form of Ivermectin. (b) (4)

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Regards,

(b) (4)

(b) (4)

(b) (4)

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From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 8/9/2020 7:39:28 PM
To: Kilgore, Nicole R CIV USARMY (USA) [nicole.r.kilgore.civ@mail.mil]
Subject: Cross check: Inhaled Ivermectin
Attachments: Ivermectin Inhalation Proposal 2020-05-21 (FINAL)-1.pdf; 20200713 Nebulized ivermectin supplementary material.pdf; 20200713 Nebulized ivermectin.pdf

I suspect this one is on the list. jw

From: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Sent: Tuesday, August 4, 2020 8:20 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: FW: Inhaled Ivermectin

FYI. Apparently they have been in contact with NIAID (Ann) but haven't had any luck getting support for additional preclinical work. I suspect folks are skeptical of the dose form.. I recommended they submit to BARDA and we can see what they think. Its definitely too early for OWS.

Kevin

From: (b) (4)
Sent: Monday, August 03, 2020 8:16 PM
To: Bugin, Kevin <Kevin.Bugin@fda.hhs.gov>
Subject: RE: Inhaled Ivermectin

Kevin,

Thank you again for your time today and the (b) (4)

Ivermectin has a long history of effective use as an anti-parasitic. It has also shown effectiveness against several single-stranded RNA viruses similar to SARS-Cov2. In a Monash University in vitro study it was shown to be effective in clearing SARS-Cov-2 in Vero/SLAM cells within 48 hours. However, based on predictive modeling, IC50 levels needed for viral clearance in the lungs may not be achievable with currently approved oral dosing of Ivermectin. Sufficient local concentrations in the lungs can be achieved using an inhaled form of Ivermectin. (b) (4)

Regards,

(b) (4)

(b) (4)

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1 **Dose-range finding study of nebulized ivermectin for COVID-19 in a rat model**

2 Carlos Chaccour,^{1,2,3*} Gloria Abizanda,^{4,5} Angel Irigoyen-Barrio,^{6,7} Aina Casellas,^{1,8} Azucena Aldaz,^{5,6}

3 Fernando Martínez-Galán,⁶ Felix Hammann,⁹ Ana Gloria Gil^{6,7}

4

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12 ⁸Departament de Fonaments Clínics, Facultat de Medicina, Universitat de Barcelona, Barcelona, Spain

13 ⁹Department of General Internal Medicine, Clinical Pharmacology and Toxicology, Inselspital, Bern

14 University Hospital, Bern, Switzerland

15

16 Running Head: Dose-ranging nebulized ivermectin

17

18 #Address for correspondence: carlos.chaccour@isglobal.org

19

Ivermectin By Inhalation for Treatment of COVID-19*

1. *Proposal for Ivermectin Inhalation*

As of May 15, 2020, COVID-19, caused by SARS-Cov-2, has infected more than 4.5 million people worldwide and has resulted in more than 300,000 deaths.¹ SARS-Cov-2 is a positive-sense, single-stranded RNA virus.

Ivermectin has a proven and long history of safety and clinical use in several parasitic infections, and billions of doses have been dispensed to date. Ivermectin has also been studied in several viruses, including positive-sense, single-stranded RNA viruses such as Dengue Fever, Zika, Yellow Fever, West Nile, and others.² A recent large-scale Phase III trial with Ivermectin in Dengue Fever was reported from Thailand.

In vitro data suggest that Ivermectin may be effective against SARS-Cov-2, the causative agent for COVID-19³; however, based on initial assessments, achieving lung concentrations following oral administration may not provide the necessary drug level in the lungs for antiviral activity.⁴

The proposed inhalation formulation of Ivermectin uses a Dry Powder Inhaler (DPI), tailoring the respirable particles to Mass Median Aerodynamic Diameters (MMAD) below 3 μm . The particles will be designed using a mixture of crystalline & amorphous Ivermectin to provide immediate dissolution in lung fluids to provide antiviral activity, followed by a sustained action, until virus clearance from lung tissues. A simple capsule-based DPI will be employed to deliver the drug to the lungs and to keep down the cost of development. As explained in greater detail in Section 5 below, a 20 mg capsule for once daily inhalation for seven (7) days is proposed, which

¹ Johns Hopkins University Coronavirus Resource Center. <https://coronavirus.jhu.edu/data>

² Laing R., Gillan V., and Devaney E. Ivermectin – Old Drug, New Tricks? *Trends in Parasitology*, Vol. 33, No. 6, 463-472, 2017.

³ Caly, L., Druce, J.D., Catton, M.G., Jans, D.A., Wagstaff, K.M., The FDA Approved Drug Ivermectin Inhibits the Replication of SARS-CoV-2 *in vitro*, *Antiviral Research*, <https://doi.org/10.1016/j.antiviral.2020.104787>.

⁴ Schmith V.D., Zhou J. and Lohmer L.R.L. The Approved Dose of Ivermectin Alone is not the Ideal Dose for the Treatment of COVID-19. *medRxiv Preprint*, Version Posted April 26, 2020 doi: <https://doi.org/10.1101/2020.04.21.20073262>.