

Exhibit 2

From: Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP /CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT>
Sent: Monday, January 13, 2020 2:43 PM
To: Disbrow, Gary (OS/ASPR/BARDA)
Subject: Re: Wuhan, China outbreak - GHSI teleconference

That's what I meant to imply. Very closely involved. No commitments without NEW \$\$.

Sent from my iPhone

On Jan 13, 2020, at 12:38 PM, Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov> wrote:

We don't have money. That is not a reason to not get involved. I would manage much like we did for Zika. Actively engaged but no commitment without funds.

Gary L Disbrow, PhD
ASPR DAS and
Director, MCM Programs
BARDA

On Jan 13, 2020, at 3:36 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

I'm with you. Let's not lean forward yet. Unless some nee \$\$\$ is suddenly available outside Of our budget. Let nih spin up for now. Stay fully involved but don't offer up unless \$\$\$\$. Is this okay with you?

On Jan 13, 2020, at 12:33 PM, Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov> wrote:

Do you want to lean forward on developing MCMs? I am waiting for this to be highlighted as a test case for development of antibody based therapeutic.

My suggesting is to sit tight but can express a higher interest if that is what you want

Gary L Disbrow, PhD
ASPR DAS and
Director, MCM Programs
BARDA

On Jan 13, 2020, at 3:30 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Yes. USG.

But Barda needs to push as we have a unique bend on the need for actual viruses and detailed, sequential sequences. But yes, push from USG. You are correct.

On Jan 13, 2020, at 12:23 PM,
Disbrow, Gary (OS/ASPR/BARDA)
<Gary.Disbrow@hhs.gov> wrote:

Rick
Assume you mean USG when you say we and not specifically BARDA?

Gary L Disbrow, PhD
ASPR DAS and
Director, MCM Programs
BARDA

On Jan 13, 2020, at 3:11 PM, Bright, Rick (OS/ASPR/BARDA)
<Rick.Bright@hhs.gov> wrote:

We need to get virus samples to USG colleagues ASAP. Sequences alone are insufficient for potential mcm development and assessment. We cannot let this fact get lost in the uphoria of a few publicly released sequences. For national security, we need more. Thanks. Rick.

On Jan
13,
2020,
at
12:05
PM,
Disbro

Exhibit 3

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Saturday, January 18, 2020 3:02 PM
To: Bright, Rick (OS/ASPR/BARDA)
Cc: Yeskey, Kevin (OS/ASPR/IO); Phillips, Sally (OS/ASPR/SPPR); Shuy, Bryan (OS/ASPR/IO)
Subject: Re: NCoV DLG?

Rick I think there is value to your point to level set and an informational DLG is appropriate. Not sure if that is a time sensitive urgency.

Sent from my iPhone

On Jan 18, 2020, at 2:46 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Rgr.

On Jan 18, 2020, at 1:36 PM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov> wrote:

Let's discuss Tuesday. PCC activities marire. Don't know if we HHS has outstanding policy issues to resolve.

Sent from my iPhone

On Jan 18, 2020, at 12:55 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

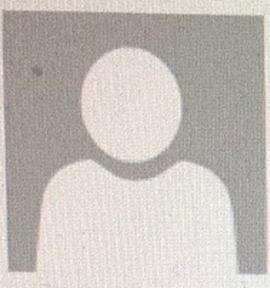
Bob, Kevin, Sally, Bryan,

Given all of the various components, data, news, etc (CDC travel guidance, airport screening...), it may be worth considering for ASPR/SPPR to pull together a DLG to align all USG parties on the situational aspects (CDC, DoD), Epi (CDC), virology (CDC, NIH), International aspects/sample sharing (OGA), research agenda (NIH), potential MCM pipeline (NIH, ASPR/BARDA), etc. The news seems to be evolving quickly and a basic foundational level setting and planning may be timely.

Rick

Exhibit 4

Reply Reply All Forward



Mon 1/20/2020 2:09 PM

Bright, Rick (OS/ASPR/BARDA)

Re: possible therapeutic - nCoV

To Johnson, Robert (OS/ASPR/BARDA)

Cc Donis, Ruben (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA)

On Jan 20, 2020, at 1:21 PM, Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov> wrote:

Ruben and Rick,

Hi. I have been monitoring the e-mails but trying not to clog the inbox, as Ruben has this well in hand. I agree that at this point, we need to increase the staff involvement, and bringing Kim in for this request makes sense.

Is the ASPR (and hopefully through him) the S1, aware of just how *BARDA's hands are tied due to lack of EID funding, and the precious time being lost?* Hopefully this issue is being worked on?

Thanks.

Robert

Robert Johnson, Ph.D.
Director, Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
220 Independence Avenue, S.W. Room 610 C

Exhibit 6

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Sent: Tuesday, January 21, 2020 7:01 PM
To: Bright, Rick (OS/ASPR/BARDA)
Subject: Re: FYI, Homeland Security just called me looking for masks for their airport screeners.

Will do

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov
Desk: [202-260-0666](tel:202-260-0666)
Cell: [202-823-2011](tel:202-823-2011)

On: 21 January 2020 19:59,
"Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov> wrote:

Thanks Laura,

Can you please reach out to Mike Bowen below? He is a great partner and a really good source for helpful information that might be of use to the overall picture. Thanks, Rick

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Sent: Tuesday, January 21, 2020 7:52 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>
Cc: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; ssa1@cdc.gov; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>
Subject: Re: FYI, Homeland Security just called me looking for masks for their airport screeners.

Thanks, Rick- we are tracking and have begun to coordinate with fda, niosh, and manufacturers today. More to follow tomorrow. Thinking about masks, gowns (inc those in shortage), gloves, and eye protection.

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov
Desk: [202-260-0666](tel:202-260-0666)
Cell: [202-823-2011](tel:202-823-2011)

On: 21 January 2020 19:39,
"Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov> wrote:

Thanks Rick alerted Jessica for whom Laura works for appreciate the heads up. Best. Bob

Sent from my iPhone

On Jan 21, 2020, at 7:34 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Bob, Bryan, Cicely, Laura, Steve,

FYSA, note below from one of the only US mask makers. Apparently DHS is making calls. Thought Laura and/or SNS might be tracking this topic.

Cicely, would you us to direct these inquiries through you for response, or would this be handled by CIP? I can connect you if that is helpful.

Rick

From: Mike Bowen <mike@prestigeam.com>

Sent: Tuesday, January 21, 2020 4:35 PM

To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>

Subject: FYI, Homeland Security just called me looking for masks for their airport screeners.

Importance: High

Is this virus going to be problematic?

Mike Bowen

Phone: 817-898-0037

Fax: 817-886-2733

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7201 Iron Horse Blvd.

North Richland Hills, TX 76180

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Exhibit 7

From: Mike Bowen <mike@prestigeam.com>
Sent: Thursday, January 23, 2020 11:27 AM
To: 'Wolf, Laura (OS/ASPR/SIIM)'
Cc: 'Falcon, Jessica (OS/ASPR/SIIM)'; 'Disbrow, Gary (OS/ASPR/BARDA)'; 'Wallace, Rodney (OS/ASPR/BARDA)'; 'Bright, Rick (OS/ASPR/BARDA)'
Subject: RE: Four unused N95 Respirator manufacturing Lines

Dr. Wolf,

The reason for my email was merely to let the government know that I could help in a dire pandemic emergency. My 220,000 square foot Texas factory used to make 87% of the US surgical mask and hospital N95 respirator supply (it's Kimberly Clark's former factory – that we used to run). We are the last major domestic mask company. Most of the masks sold in the US are made outside of the USA on machines that we designed and built in Texas in the nineties. For the past 14 years, I've been warning hospitals that their imported masks are subject to foreign confiscation during a severe pandemic. I've been mostly ignored. In fact, the Veterans Administration and all military hospitals rely on imported masks that BARDA fears may not exist. This shouldn't be.

As you can imagine, my phones are ringing now, so I don't "need" government business. I'm just letting you know that I can help you preserve our infrastructure if things ever get really bad. I'm a patriot first, businessman second. See <https://protect2.fireeye.com/url?k=c706c556-9b53cc86-c706f469-0cc47a6a52de-bb38d4e456fd2fd7&u=http://www.securemasksupply.org/> for more information about the fragile US mask supply.

I can meet on Friday, as you proposed. However, my mission of letting you know that I'm here has been accomplished, so unless you have questions, a conference call may not be necessary.

Thank you for serving our country.

Mike Bowen

Phone: 817-898-0037

Fax: 817-886-2733

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From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Sent: Wednesday, January 22, 2020 4:54 PM
To: Mike Bowen <mike@prestigeam.com>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>
Subject: Re: Four unused N95 Respirator manufacturing Lines

Hi mike-

Happy to discuss further. I don't believe we as an government are anywhere near answering those questions for you yet, but let's walk through each one to understand scope and key decision makers/points on the federal and private sector side. I'm dealing with a sick kiddo and that may spill over into tomorrow, so let's plan on a Friday morning conversation. I will suggest 1030am Eastern?

Thanks!

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.sgov.gov
Desk: [202-260-0666](tel:202-260-0666)
Cell: [202-823-2011](tel:202-823-2011)

On: 22 January 2020 17:23, "Mike Bowen" <mike@prestigeam.com> wrote:

Rick,

I have not been contacted. I can make myself available anytime on Thursday or Friday.

Mike Bowen

Phone: 817-898-0037
Fax: 817-886-2733

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From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, January 22, 2020 3:12 PM
To: Mike Bowen <mike@prestigeam.com>
Cc: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>
Subject: Re: Four unused N95 Respirator manufacturing Lines

Mike. Thank you for reaching out to me about this important resource and plan. I forwarded your information to our aspr critical infrastructure team yesterday and hope that someone has already connected with you. Via this email, I am connecting you all directly in hope of expediting a conversation. I'm connecting you to both Jessica Falcon and Laura Wolfe.

Thank you for all that you are doing. Your leadership in this area remains an important resource for our nation and public health.

Please keep me looped in as appropriate.

Best regards, Rick.

On Jan 22, 2020, at 2:10 PM, Mike Bowen <mike@prestigeam.com> wrote:

Rick,

We still have four like-new N95 manufacturing lines that we got in the Safelife/Triomed acquisition a few years ago. To activate them, we'd need more people, raw materials, emergency NIOSH approval and large, non-cancelable orders. Reactivating these machines would be very difficult and very expensive but could be achieved in a dire situation and with government help.

This is NOT something we would ever wish to do and we have NO plans to do it on our own. I'm simply letting you know that in a dire situation, it *could* be done.

Rick, I hope that your and my predictions about the foreign made US mask supply don't come true.

Mike Bowen

Phone: 817-898-0037

Fax: 817-886-2733

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Exhibit 8

On 1/23/20, 4:06 PM, "Michael, Gretchen (OS/ASPR/OEA)" <Gretchen.Michael@hhs.gov> wrote:

2019 Novel Coronavirus (2019-nCoV) Media Key Points January 23, 2020

MAIN KEY MESSAGES

- This is a rapidly changing situation and we are still learning about the new coronavirus (2019-nCoV) discovered in China. We are monitoring the situation closely and anticipate updating our recommendations and guidance as needed.
- Outbreaks like this – when a new virus is emerging to infect people – are always concerning. Some people might be worried about this virus and how it may impact Americans.
 - o While this situation poses a very serious public health threat, CDC believes the immediate risk to the U.S. public is low at this time.
 - o However, the situation is evolving, and the risk will depend on how well the virus spreads and how sick it makes people.
- CDC has activated its Emergency Operations Center and begun using public health measures, including enhanced entry screening, as part of our aggressive public health response strategy.
- We fully expect that in the coming days and weeks, we will see more cases of this new coronavirus here in the United States and globally.

SITUATION UPDATE

- Although Chinese officials have closed transport within and out of Wuhan, CDC will continue to conduct enhanced entry screening at five designated airports – New York JFK, San Francisco, Los Angeles LAX, Chicago O’Hare, and Atlanta Hartsfield-Jackson. We are currently evaluating the extent and duration of this enhanced screening.
 - Next week CDC will begin regular reporting of laboratory results on our website.
 - o As of today, no new cases with novel coronavirus have been detected in the United States since our announcement on Tuesday.
 - Again, it’s likely that we will see more cases in the United States.
 - o We must also prepare for potential person to person spread here since we have seen instances of this in Asia.
- CDC will continue to lean in on public health response efforts to protect Americans. We are working closely with state and local health departments and have teams on standby to deploy if needed.

WHAT YOU CAN DO

- While the immediate risk of this new virus to the American public is believed to be low at this time, there are simple daily precautions that everyone should always take.
 - o It’s currently flu and respiratory disease season and CDC recommends getting vaccinated, taking everyday preventive actions to stop the spread of germs, and taking flu antivirals if prescribed.

- Right now, CDC recommends travelers avoid all nonessential travel to Wuhan, China. We also recommend people traveling to China practice certain health precautions like avoiding contact with people who are sick and practicing good hand hygiene.

Gretchen B. Michael
Director of Communications
Office of the Assistant Secretary for Preparedness and Response
Phone: 202-205-8114
Cell: 571-839-7617

200 C Street, SW
O'Neill House Office Building
Room 12J07
Washington, DC 20204

Exhibit 9

From: Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>
Sent: Saturday, January 25, 2020 8:53 PM
To: Bright, Rick (OS/ASPR/BARDA)
Cc: CIP Supply Chain; Adams, Steven A. (CDC/SNS/DSNS); Wolf, Laura (OS/ASPR/SIIM); Phillips, Sally (OS/ASPR/SPPR); Disbrow, Gary (OS/ASPR/BARDA); Hassell, David (Chris) (OS/ASPR/IO); Johnson, Robert (OS/ASPR/BARDA); Seiler, Brittney (OS/ASPR/SIIM)
Subject: Re: Supply of Surgical Masks to the Government Logistics Department of the Government of Hong Kong Special Administrative Region of the People's Republic of China

Thank you and we will be sure the concerns around this are included within the items the task force tracks.

I have included Brittney Seiler as she is working on the task force request this weekend.

Thank you
Jessica

Sent from my iPhone

On Jan 25, 2020, at 8:44 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Disseminating in case Laura is still down with sick child. The mask situation seems to be of concern and we have been receiving warnings for over a week. Important to keep this at the top of the heap of various issues. Thanks, Rick

From: Mike Bowen <mike@prestigeam.com>
Date: Saturday, January 25, 2020 at 8:35 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Laura Wolf <Laura.wolf@dhs.sgov.gov>
Subject: Fwd: Supply of Surgical Masks to the Government Logistics Department of the Government of Hong Kong Special Administrative Region of the People's Republic of China

Laura and Rick,

I'm getting lots of requests from China and Hong Kong. See below.

We'll soon learn if China will continue to export masks to the USA. As much as 50% of masks come from China. If the supply stops, US hospital will run out of masks. No way to prevent it.

We are gearing up (on our own) as much as we can risk. To go all out, we'd need a government partner. Not asking for one - just stating a fact.

We'll give you some numbers as soon as possible.

Mike Bowen

Sent from my iPhone

Begin forwarded message:

From: Elizabeth Givens <info@prestigeameritech.com>
Date: January 25, 2020 at 10:33:07 AM CST
To: Mike Bowen <mike@prestigeam.com>
Subject: Fwd: **Supply of Surgical Masks to the Government Logistics Department of the Government of Hong Kong Special Administrative Region of the People's Republic of China**

See below.

Begin forwarded message:

From: "Kelvin YC CHEUK" <ssob@gld.gov.hk>
Subject: **Supply of Surgical Masks to the Government Logistics Department of the Government of Hong Kong Special Administrative Region of the People's Republic of China**
Date: January 25, 2020 at 2:17:47 AM CST
To: info@prestigeameritech.com
Cc: "Tina CW LEUNG" <cp@gld.gov.hk>, "CN LO" <psop1@gld.gov.hk>

Dear Sir / Madam,

The Government Logistics Department is looking for supply of regular size surgical masks to meet our imminent needs. The specifications and requirements are detailed in the **Annex**. You may wish to note that our estimated requirements are over ten million pieces.

If your company is able to supply regular size surgical masks meeting our requirements, we would be most grateful if you could provide further information by completing Proforma A attached for our consideration.

Please note that this is an enquiry only and should not be construed as a firm commitment of order. Orders (if any) for the goods will be placed

after a written acceptance of your offer, and the terms and conditions of the contract (if any) are yet to be confirmed. A copy of our prevailing standard terms and conditions for goods contracts is attached for reference.

Besides, we are also looking for supply of small size surgical masks and N95/FFP2/P2 mouth masks. The respective specifications and requirements are attached hereunder:

If your company is able to supply any of above items, we would be most grateful if you could provide the required information by completing Proforma B attached for our consideration.

We would appreciate it if you could let us have your reply by return email as early as possible and preferably before 9:00 a.m. on 29 January 2020 (Hong Kong time). For enquiries, please feel free contact me at (852) 9236 2371 / 2231 5250.

Best regards,
Kelvin CHEUK
Senior Supplies Officer B
Government Logistics Department
The Government of the Hong Kong Special
Administrative Region
Tel: (852) 2231 5279

<Annex.doc>

<Proforma A.rtf>

<GLD-TERMS-1 (Oct 2019) (Eng) (1).doc>

<Specifications of surgical masks (small size).pdf>

<Specifications of N95 masks (regular size and small size).pdf>

<Proforma B.rtf>

Exhibit 13

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Monday, January 27, 2020 6:59 AM
To: Bright, Rick (OS/ASPR/BARDA)
Cc: Disbrow, Gary (OS/ASPR/BARDA); Johnson, Robert (OS/ASPR/BARDA)
Subject: Re: [DRAFT] Input for briefing memo for HHS Health Attache on WHO Info Session on coronavirus - January 27, 2020

8 am call with Minister Ma. AMA was going to raise it as #1 issue but CDC spoke up to reverse order of discussion points and told him that we don't need the samples now that it is in the US. When they dropped off the pre-brief we said there is strong disagreement and that BARDA, NIH, and FDA have expressed the urgent need for a panel of viruses for MCM development.

Sent from my iPhone

On Jan 27, 2020, at 7:51 AM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Omg. You are kidding me? In what meetings? Let's raise it at the 9 am mtg.

On Jan 27, 2020, at 7:49 AM, Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov> wrote:

Minus Tiffany.

Rick we have to talk. CDC just told the Secretary for his call with Minister Ma that samples from China are not needed and to de-prioritize it on the upcoming call. We fought back and I think he is still going to raise it but we need BARDA, NIH, and FDA to speak up.

The USG needs requirement is clear but CDC leadership is not saying that.

Sent from my iPhone

On Jan 27, 2020, at 7:45 AM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Tiffany,

We can send you the paper. But it is clear that China has virus that has been isolated, grown and evaluated. But not shared. We need access to the virus ASAP. Extremely critical to initiate medical countermeasure development. We urgently need assistance in access to virus.

I'll let Gary respond to the rest of the inquiry.

Thanks. Rick.

Exhibit 14

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Monday, January 27, 2020 7:00 AM
To: Bright, Rick (OS/ASPR/BARDA)
Subject: Re: Fysa NCoV paper

Bob was on the call but didn't speak up

Sent from my iPhone

On Jan 27, 2020, at 7:52 AM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

I Can't believe this!!!!

I understand even a request to WHO hasn't been submitted. Is that true?

On Jan 27, 2020, at 7:50 AM, Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov> wrote:

No one has officially asked China for samples as of this morning. That's a problem.

Sent from my iPhone

On Jan 27, 2020, at 7:48 AM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Larry,

See the paper below. It seems very clear from this paper that labs in China have had the virus isolated, propagated and evaluated for a while. We cannot emphasize enough the critical need to access virus to initiated mcm development.

Have we exhausted all pathways to accessing this virus?

Thanks. Rick.

Begin forwarded message:

From: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Date: January 27, 2020 at 5:07:32 AM EST
To: "Donis, Ruben (OS/ASPR/BARDA)" <Ruben.Donis@hhs.gov>, "Johnson, Robert (OS/ASPR/BARDA)" <Robert.Johnson@hhs.gov>,

"Disbrow, Gary (OS/ASPR/BARDA)"
<Gary.Disbrow@hhs.gov>, "Bright, Rick
(OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>,
"Blatner, Gretta (OS/ASPR/BARDA)"
<Gretta.Blatner@hhs.gov>, "Lambert, Linda
(OS/ASPR/BARDA)" <Linda.Lambert@hhs.gov>,
"Johnson, Robert (OS/ASPR/BARDA)"
<Robert.Johnson@hhs.gov>, "Houchens,
Christopher (OS/ASPR/BARDA)"
<Christopher.Houchens@hhs.gov>, "Armstrong,
Kimberly (OS/ASPR/BARDA)"
<Kimberly.Armstrong@hhs.gov>, "Walker, Robert
(OS/ASPR/BARDA)" <Robert.Walker@hhs.gov>,
"Wallace, Rodney (OS/ASPR/BARDA)"
<Rodney.Wallace@hhs.gov>, "Donabedian, Armen
(OS/ASPR/BARDA)"
<armen.donabedian@hhs.gov>, "Erlandson, Karl
(OS/ASPR/BARDA)" <Karl.Erlandson@hhs.gov>,
"Humes, Rosemary (OS/ASPR/BARDA)"
<Rosemary.Humes@hhs.gov>, "Seals, Jonathan
(OS/ASPR/BARDA)" <jonathan.seals@hhs.gov>,
"Vaught, Andrea (OS/ASPR/BARDA) (CTR)"
<Andrea.Vaught@hhs.gov>
Subject: Fysa NCoV paper

<https://www.biorxiv.org/content/10.1101/2020.01.22.914952v2.full.pdf>

<2020.01.22.914952v2.full.pdf>

Exhibit 15

From: Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP /CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT>
Sent: Tuesday, January 28, 2020 4:17 PM
To: Kerr, Lawrence (HHS/OS/OGA)
Subject: Re: Morning

Cool. I'll ask Bob to see if he can get us in there. Barda isn't at the same level as an opdiv or staffdiv so obvious group to cut if shrinking the table. But we have a significant role.

In the meantime if you need any info or tps from ya, don't hesitate to ask. Thank you. Rick

> On Jan 28, 2020, at 4:54 PM, Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov> wrote:

>

> Decision by Brian/Judy but still no clue what happened yesterday that caused it. All Staff and Opdivs are limited to one. When I told Brian Shuy that this morning that he would have to present for BARDA too, he didn't look thrilled. I suggested that to Gary at the PCC that you and/or Bob ask Brian and Judy to add you because of the on-going work on MCM distinct from NIH.

>

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

> From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>

> Sent: Tuesday, January 28, 2020 4:47 PM

> To: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>

> Subject: Morning

>

> Heard they cut the s1 briefs to small group and clipped barda. Any insights?

Exhibit 16

From: Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP /CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT>
Sent: Wednesday, January 29, 2020 3:37 PM
To: Disbrow, Gary (HHS/ASPR) (Gary.Disbrow@hhs.gov)
Subject: FW: Need today an update on our supply chain analysis at risk during this outbreak

FYSA

-----Original Message-----

From: Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>
Sent: Wednesday, January 29, 2020 4:31 PM
To: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>; Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Ford-Barnes, Arwenhithia (OS/ASPR/IO) <Arwenhithia.FordBarnes@hhs.gov>; Cooper, Kevin (OS/ASPR/ORM) <Kevin.Cooper@hhs.gov>
Subject: RE: Need today an update on our supply chain analysis at risk during this outbreak

A storyboard is in the works. In the interest of time, below is an update of what is known at this time and what the focus of analysis will be going forward. SNS will have some additional information routed shortly.

Identified Medical Supply Chain Focus Areas:

- CDC, based on their PPE and other guidance, identified top priority product areas for data collection and analysis to drive Supply Chain Task Force work. In the absence of a vaccine or specific treatment, these products include:
 - o PPE: N95 masks, surgical masks, gloves, gowns, face shields, and respirators
 - o IV Antimicrobials
 - o Ventilators and ancillaries

Ongoing Actions for analysis:

- WHO Pandemic Supply Chain Network is conducting a survey with approximately 30 major manufacturers and logistics companies. The timeline is lengthier than we would like (3 weeks), and we will be working directly with domestic manufacturers on product information.
- We are working closely with private sector and FDA for data, and with FEMA, SNS, and Information Management for analysis. Some private sector associations and Information Sharing & Analysis Centers (ISACs) including the International Safety Equipment Association (ISEA), Health Industry Distributors Association (HIDA), and Healthcare Ready are conducting internal surveys with membership with information shared as they able.
- We have strategic level analysis ongoing for overall reliance on China and concerns about transportation issues or prevention of exports.
- We are setting up a policy decision points team to identify policy questions that may need to be made before or as we analyze data, including government purchases, changes to more restrictive PPE guidance, release of the stockpile, or blocking exports.
- We will be working closely with the Hospital Resilience Task Force on identifying demand challenges and considerations.

Concerns/ Additional Analysis:

- Supply & Raw Materials: Raw materials have been identified as a concern for PPE. Global production of the primary inputs (plastics & polymers) needed to make masks is dominated by China and Chinese companies.
- Exports: Taiwan announced (January 24, 2020) it will ban all mask exports for 30 days (until February 23).
 - o Major private label N95 mask producer, Makrite Industries, is a Taiwan-based firm with most of its plants in China. It produces private labels for multiple major lines (Cardinal Health, CVS, Medline, etc).
- Workforce & Manufacturing: Major US companies' Chinese mask manufacturing plants appear to be clustered in certain major cities, largely in provinces on or near China's East Coast, which do not directly neighbor Hubei Province. These areas are, however, seeing incremental increases in 2019-nCoV cases.
- Demand: Major companies such as Honeywell and 3M are reporting increased global face mask demand.

Jessica Falcon

Deputy Assistant Secretary

Director, Office of Security, Intelligence, and Information Management Office of the Asst. Secretary for Preparedness and Response (ASPR) U.S. Department of Health and Human Services Jessica.Falcon@hhs.gov 202-401-4055 (Office)

-----Original Message-----

From: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>

Sent: Wednesday, January 29, 2020 2:16 PM

To: Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>

Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>; Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Ford-Barnes, Arwenithia (OS/ASPR/IO) <Arwenithia.FordBarnes@hhs.gov>

Subject: Re: Need today an update on our supply chain analysis at risk during this outbreak

Can we do a story board one page slide to hc as sector and separate one to SNS supply chains/cip? I know it will be a condensing effort extraordinaire, but think it will help

Sent from my iPhone

> On Jan 29, 2020, at 1:58 PM, Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov> wrote:

>

> CIP is drafting a summary of the concerns and where the task force is in analysis. In addition to a summary, Dr. Laura Wolf is available for a conversation at any point today.

>

> Jessica Falcon

> Deputy Assistant Secretary

> Director, Office of Security, Intelligence, and Information Management
> Office of the Asst. Secretary for Preparedness and Response (ASPR)
> U.S. Department of Health and Human Services Jessica.Falcon@hhs.gov
> 202-401-4055 (Office)
>
>
>
>
>
> -----Original Message-----
> From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
> Sent: Wednesday, January 29, 2020 1:05 PM
> To: Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; Dodgen,
> Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>; Yeskey, Kevin
> (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Shuy, Bryan (OS/ASPR/IO)
> <Bryan.Shuy@hhs.gov>; Phillips, Sally (OS/ASPR/SPPR)
> <Sally.Phillips@hhs.gov>; Bright, Rick (OS/ASPR/BARDA)
> <Rick.Bright@hhs.gov>
> Cc: Ford-Barnes, Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov>
> Subject: Need today an update on our supply chain analysis at risk
> during this outbreak
>
>
>
> Sent from my iPhone

Exhibit 18

From: Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>
Sent: Monday, February 03, 2020 7:38 PM
To: Bright, Rick (OS/ASPR/BARDA)
Cc: Blatner, Gretta (OS/ASPR/BARDA); Michael, Gretchen (OS/ASPR/OEA)
Subject: Re: New York Times doing a story about the US mask supply.

Thanks for the heads up. Right now the message on supplies is the subject of debate.

On Feb 3, 2020, at 8:04 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

FYSA, in case we see a media request on Masks/PPE. We can gear up some basic TPs if you think this will be cleared.

Rick

From: Mike Bowen <mike@prestigeam.com>
Sent: Monday, February 03, 2020 6:48 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Subject: New York Times doing a story about the US mask supply.
Importance: High

The New York Times just called me. Rick, please do an interview with reporter Knvul Sheike when he contacts you by email. Now is the time to make the president aware of this little known national security risk. If we let this opportunity go by, the US mask supply will forever remain under foreign control. Trump reads the news. I'm going to make as much news as I can, while I can.

Mike Bowen

Phone: 817-898-0037
Fax: 817-886-2733

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North Richland Hills, TX 76180

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Exhibit 19

From: Mike Bowen <mike@prestigeam.com>
Sent: Wednesday, February 05, 2020 5:32 PM
To: 'Bright, Rick (OS/ASPR/BARDA)'
Subject: RE: Prepare for a call from the White House. (Personal)

Rick,

I'm also telling people that you and Robin Robinson are exemplary public servants. I know that you're doing what's in your power. And, without Robin and your encouragement, I'd have quit long ago. Please ask your associates to convey the gravity of this national security issue to the White House. I'm pretty sure you'll get the chance.

Mike Bowen

Phone: 817-898-0037
Fax: 817-886-2733

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From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, February 5, 2020 5:22 PM
To: 'Mike Bowen' <mike@prestigeam.com>
Cc: Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Subject: RE: Prepare for a call from the White House.

Mike, I am making sure that the appropriate ASPR office is aware of this development. Laura Wolf, Jessica Falcon and Dr. Sally Phillips are leading supply chain issues for ASPR and are likely already engaged.

Thank you again. Rick

From: Mike Bowen <mike@prestigeam.com>
Sent: Wednesday, February 05, 2020 6:16 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: Prepare for a call from the White House.
Importance: High

Rick,

I'm pretty sure that my mask supply message will be heard by President Trump this week. I'm getting a ton of press and I'm passing out your email address and saying that you're the guy who knows that I'm telling the truth. Thanks to a Trump insider reading yesterday's Wired.com article, the ball is screaming toward your court.

I'm handing you the power to fix the US mask supply. Please don't let American down.

Mike Bowen

Phone: 817-898-0037

Fax: 817-886-2733

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Exhibit 21

2.9.20

**MEMORANDUM TO THE TASK FORCE
THROUGH COS AND NSA
FROM PETER NAVARRO
RE: REQUEST FOR IMMEDIATE ACTION**

We face a significant probability of a serious pandemic coronavirus event in the U.S. that may extend well into 2021. In the course of analyzing issues related to the supply chain, I have identified three actions for consideration by the Task Force that should be IMMEDIATELY undertaken. Funding must likewise be identified IMMEDIATELY.

1. Halt the Export of N-95 Masks, Ramp Up U.S. Production

China produces about half of the world's N-95 masks – the mask likely most effective against coronavirus. China has nationalized foreign companies (like America's 3M) and is prohibiting N-95 mask exports. According to HHS, China is seeking to buy equipment in a U.S. factory and export it to China. Other countries are, or are considering, a similar export ban on masks.

The U.S. has four small companies that produce masks but depends on the rest of the world for about 90% of its supplies.¹ Currently, U.S. companies are ramping up but they are exporting much of their production. The U.S. therefore faces the real prospect of a severe mask shortage!

RECOMMENDATIONS

- Halt of the export of all N-95 masks.
- Provide immediate purchase guarantees for all U.S. supplies at maximum production capacity (\$10 million estimate)
- Prohibit the sale of U.S. N-95 factory equipment to China
- Over the longer run, enforce Buy American provisions for N-95 masks

2. Buy All Existing U.S. Doses of Remdesivir and BULK MATERIALS

Remdesivir was originally developed to treat Ebola cases. Currently, it has the highest probability of an existing drug for being efficacious for treating coronavirus (2019-nCoV).

Gilead has 4,500 doses on hand at a cost of \$2,200 per dose. It also has sufficient bulk material to produce an additional 100,000 doses at the rate of 5,000 per week by the end of February.

¹ <https://www.nytimes.com/2020/02/06/business/coronavirus-face-masks.html>

RECOMMENDATIONS:

- Immediately purchase the existing 4,500 doses
- Secure the right of first refusal for all doses coming out of the factory
- Enter into a contract to buy all 100,000 additional doses as they are produced. (\$220 million)
- Immediately work with Gilead to on-shore ALL STEPS of the Remdesivir supply chain, including chemical-based intermediate production steps that are currently being performed in Canada, to ensure an uninterrupted U.S. supply.

3. "Manhattan Project" Vaccine Development

There is currently no vaccine to protect against coronavirus. If we start this week to fast track vaccine development with appropriate funding, we can likely have a vaccine to clinical trials within 7 months and a workable vaccine by October or November, with a production capacity of 150 million doses by the end of the year IF we act NOW.

We don't yet know what type of vaccine would be safe and effective. Therefore, it is critical the USG invest in multiple shots on goal to ensure that at least one vaccine is realized.

Efforts should be prioritized to focus on US-based vaccine companies with extensive experience with being licensed by the FDA or with significant human safety data. Funding should be flexible to allow for movement from a less optimal candidate to a more favorable one as the science develops.

RECOMMENDATIONS

- Identify 4-5 US-based companies with the experience, infrastructure, skilled labor and resources to most quickly develop a vaccine
- Identify funding for vaccine development (\$1B to \$3B)
- Place developer contracts within next one to two weeks to incentivize them to 1) prioritize nCoV vaccine development 2) identify and prepare US-based facilities for large scale vaccine production 3) secure sufficient raw materials for large scale production
- Work closely with HHS and FDA to identify critical pathways to accelerate the development and evaluation of the vaccine for human use

I cannot stress how important it is to leave this meeting with a firm decision to immediately advance all three recommendations.

Inaction at this point risks losing our Remdesivir drug supply, our N-95 production capabilities, and any head start we may have on a vaccine for next year.

Exhibit 22

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Monday, February 10, 2020 6:31 AM
To: Bright, Rick (OS/ASPR/BARDA)
Subject: Re: update

Thanks Rick

Sent from my iPhone

On Feb 10, 2020, at 7:28 AM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Confidential, Close hold

Bob,

Following the exploratory discussion with Navarro on Saturday, we met again on Sunday to discuss a few topics on supply chain, potential issues, potential options. Curious about potential challenges with sourcing required materials to make components of MCMs, and pathways that some MCMs take around the world from starting materials to final product form. I explained the 2007-2008 pathway that was put in place for Tamiflu to illustrate the complexity yet the potential for some production systems to be moved completely into US, along with some of the limitations and challenges to sustain such capacity when established.

Mask supply chain. Are there and number of US mask producers, source for raw materials, import/export flow, options for surge. This is an area that ASPR CIP is already leaning forward to collect specific details. I will connect with Laura Wolf to get a status on some of these areas.

Remdesivir antiviral. US inventory and potential timelines for resupply if needed. Source of raw materials. Potential costs for the drug based on experience. Is it produced in US or elsewhere?

Vaccine options. Are there US companies/facilities with capability/interest to develop vaccine candidates. Potential timelines to get started and for development. Any options for acceleration, innovation, surge.

I understand that he plans to meet with FDA soon to discuss manufacturing infrastructure, innovation.

Exhibit 26

2.14.20

MEMO TO COVID-19 TASK FORCE

THROUGH COS, NSA

FROM PETER NAVARRO

RE: RAMP UP PRODUCTION OF ANCILLARY SUPPLIES

We face an urgent need to administer large quantities of vaccine once produced. An estimated 850M needles and syringes are required to deliver vaccine.

Our current inventory of these supplies is limited and, under current capabilities, it would take up to two years to produce this amount of specialized safety needles. We may find ourselves in a situation where we have enough vaccine but no way to deliver all of it.

Recommendations

- Direct OSHA and CDC to take steps to liberalize the current policies to allow for the use of non-specialized needles to administer vaccines. Current delivery is with specialized needles with safety caps that have limited production capacity. This one change would significantly increase available inventory.
- Provide HHS Strategic National Stockpile with immediate funding to place orders to ramp up US production to full capacity for needles and syringes needed to deliver a vaccine. We need to immediately determine budget needs and allocate accordingly.
- Direct HHS BARDA to initiate a program to identify all alternate vaccine delivery methods and ramp up production. Other delivery possibilities include jet injectors and similar devices, some of which are already approved to deliver influenza vaccines.

Exhibit 27

2.14.20

MEMO TO COVID-19 TASK FORCE

THROUGH COS, NSA

FROM PETER NAVARRO

RE: EXPAND REMDESIVIR PRODUCTION TO INCLUDE A US-BASED PRODUCTION FACILITY

Remdesivir is currently the most promising treatment option for people infected with nCoV. All upstream production is done in Canada and only the final production step is done in the US.

In the case of a full blown crisis in the hemisphere, it will be easier for Canada to find a final filling step and keep upstream production in Canada than it will be for the US to transfer the production of the starting materials into the US.

Failure to onshore this upstream production capacity will put the US at a significant disadvantage to access additional drug supply after the initial 100,000 doses are exhausted.

REMEMBER: In 2009, during H1N1, Canada withheld vaccines from the U.S. until their national need was satisfied.

Recommendations

- Direct HHS to immediately work with Gilead to identify a US-based production facility and begin a transfer process to produce all steps of Remdesivir in the US.
- Direct HHS to identify all chemical ingredients for Remdesivir and identify a US-based source for the chemical ingredient production.
- Determine the level of, and identify funding for, starting this process immediately.

This is a heavy but important lift.

Exhibit 28

2.14.20

MEMO TO COVID-19 TASK FORCE
THROUGH COS, NSA
FROM PETER NAVARRO
RE: STATUS OF N-95 FACE MASK SUPPLY

This memo follows up a request to immediately secure the N-95 face mask supply. Key questions that need to be answered:

- What is the US inventory and production capacity? We need to designate an agency to assess this and report an answer within 7 days. Not rocket science.
- Has the export of N-95 been halted? If not, why not? We are facing shortages of raw materials that suggest a constrained supply. We should not be exporting any more masks.
- Have orders been placed with US producers to ramp up to full capacity? This is absolutely critical to maintaining the viability of US manufacturing in this space. If these orders are not placed, we will continue to see masks go offshore.

Let's move this in Trump time. These masks are the frontline defense for our health care professionals and we can't waste time.

Exhibit 30

From: Steven Adams <saa1@cdc.gov>
Date: Thursday, March 12, 2020 at 10:10 PM
To: Rick Bright <Rick.Bright@hhs.gov>
Cc: Laura Wolf <Laura.Wolf@hhs.gov>, "Kevin.Cooper@hhs.gov" <Kevin.Cooper@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>, Jessica Falcon <Jessica.Falcon@hhs.gov>, Sally Phillips <Sally.Phillips@hhs.gov>
Subject: Re: Needles/Syringes for COVID-19 response

Rick, we don't yet have full access but we've been asked to acquire critical PPE (500M n-95s, 1B surgical masks, gowns, gloves, etc...) that will likely exceed the supplemental. It has also been suggested we acquire additional high priority items like test kits. To be clear, I'm agnostic about which priorities we're addressing but we won't be able to cover everything already identified as a critical priority.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Thursday, March 12, 2020 10:02:57 PM
To: Adams, Steven A. (CDC/SNS/DSNS) <saa1@cdc.gov>
Cc: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Cooper, Kevin (OS/ASPR/ORM) <Kevin.Cooper@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>
Subject: Re: Needles/Syringes for COVID-19 response

Laura and Jessica, was this Seems a high priority for the supply chain TF. Is it already on the agenda?

On Mar 12, 2020, at 9:08 PM, Adams, Steven A. (CDC/SNS/DSNS) <saa1@cdc.gov> wrote:

Thanks for raising Rick. I agree completely but the challenge may be finding the funding.

Steve

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Thursday, March 12, 2020 8:19:22 PM
To: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Cooper, Kevin (OS/ASPR/ORM) <Kevin.Cooper@hhs.gov>; Adams, Steven A. (CDC/SNS/DSNS) <saa1@cdc.gov>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; Phillips, Sally

(OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>

Subject: Needles/Syringes for COVID-19 response

Laura, Steve and Kevin,

Not to add more to the busy list, But, we are hearing rumblings about the US inventory of needles and syringes (critical ancillary supplies for vaccine and some therapeutics administration) are heading to other countries. There is limited inventory in the supply chain, it could take 2+ years to make enough to satisfy the US vaccine needs for a pandemic. We need to hold on to all that we have and look at surging supplies now from producers.

Efforts to halt the export should be considered now. The easiest way may be for the SNS to place some orders with US-based manufacturers to 1) buy the current inventory and 2) ramp up production of more. One nice thing is that BARDA has some existing IDIQ contracts that SNS can easily use to place orders. We are happy to make these available to you for consideration in lieu of writing new contracts.

I believe this warrants urgent attention so we are not chasing things down when we need them later and they are all procured by other countries.

Let the team copied above know if you have questions about accessing the IDIQ contracts.

Thanks Rick

Exhibit 39

From: Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP /CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT>
Sent: Friday, March 13, 2020 3:44 PM
To: Navarro, Peter K. EOP/WHO
Cc: Miller, Joanna R. EOP/WHO
Subject: Re: Bloomberg: New coronavirus test 10 times faster is approved, company says

Peter, Joanna,

I'm buried. Lots of hell breaking lose that we're juggling. Sorry I can't come by today. Rick

On Mar 13, 2020, at 10:49 AM, Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov> wrote:

[Let's get rick in at 2::45](#)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Friday, March 13, 2020 8:28 AM
To: Navarro, Peter K. EOP/WHO <Peter.K.Navarro@who.eop.gov>
Subject: Re: Bloomberg: New coronavirus test 10 times faster is approved, company says

Able to come by today any time after 2:30.

From: "Navarro, Peter K. EOP/WHO" <Peter.K.Navarro@who.eop.gov>
Date: Friday, March 13, 2020 at 8:24 AM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: Re: Bloomberg: New coronavirus test 10 times faster is approved, company says

Let's huddle today or tomorrow

Sent from my iPhone

On Mar 13, 2020, at 7:22 AM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Done last night. Also discussed media and swab issues with FDA. Several options reviewed and being released to reduce stress on global supply chain.

We need to reduce our vulnerability of accessing these critical materials from outside the US. These little things that no one thinks about are killing us.

Lead the way!

New coronavirus test 10 times faster is approved, company says

Roche Holding AG said it won emergency approval from the U.S. government for a highly automated coronavirus test, potentially speeding up the ability to test patients by a factor of 10.

Read in Bloomberg: [>>https://apple.news/AKvqqCIDARUyJ_8fFyvaO4w<<](https://apple.news/AKvqqCIDARUyJ_8fFyvaO4w);

Shared from [Apple News](#)

Sent from my iPhone

Exhibit 41

From: Bright, Rick (OS/ASPR/BARDA) <rick.bright@hhs.gov>
Sent: Saturday, March 14, 2020 11:00 PM
To: Navarro, Peter K. EOP/WHO
Cc: Abbott, Christopher J. EOP/WHO
Subject: Operation SWAB - Rolling

Peter,

Attached are high level bullets about the SWAB shortage issue and path to resolution. Chris might need to customize them for your style. You did something miraculous tonight to break through the wall and bureaucratic barrier that was stalling shipment from Italy to US. Four days of bureaucracy that you broke down in 5 minutes.

First problem: Why do we buy our critical supplies such as swabs from Italy instead of US producers such as Puritan?

Second problem: In a global crisis, global supplies quickly become global shortages

Solution: Incentivize expansion of US produced ancillary medical supplies. Buy American to sustain the US capacity.

Things are moving VERY rapidly now between the FDA, DoD and the company in Italy. From the email traffic, planes could be on ground loading tomorrow night or Monday at latest. You broke through...again. Awesome!

Exhibit 53

Message (1/1)

Tell me what you want to do...

Reply Reply Forward More - Respond

Meeting

Chloroquine
Team Email
Reply & Delete

To Manager
Done
Create New

Quick Steps

Move

Rules -
OneNote
Actions -

Move

Assign Policy -
Mark Unread
Tags

Categorize
Follow Up -

Translate

Find
Related -
Select -

Editing

Zoom
Zoom

Send to OneNote
OneNote

Wed 3/18/2020 3:56 PM

Shuy, Bryan (OS/ASPR/IO)

Re: Chloroquine for COVID19

ert (OS/ASPR/BARDA)

OS/ASPR/BARDA); Hamel, Joseph (OS/ASPR/IO); Hassell, David (Chris) (OS/ASPR/IO); Disbrow, Gary (OS/ASPR/BARDA)

is part of a tracked conversation. Click here to find all related messages or to open the original flagged message.

From: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Sent: Tuesday, March 17, 2020 1:22 PM
To: Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Braxton, Makoto (OS/ASPR/ORM) <Makoto.Braxton@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Ottem, Ronald (Ron) (ASPR/SNS) <rco9@cdc.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>
Cc: Hernandez, Cameron (OS/ASPR/ORM) <Cameron.Hernandez@hhs.gov>; Callahan, Michael (OS/ASPR/IO) (CTR) <Michael.Callahan@hhs.gov>
Subject: Chloroquine for COVID19
Importance: High

All,

We were approached by a group about a promising compound (chloroquine) that is making waves in the European and Chinese critical care community – see enclosed pub, more coming. Used for malaria, but has shown antiviral properties, and appears to work. Not a blockbuster drug for this fight, but a good drug.

Bayer just reached out and is willing to give this away to the SNS for free, and we can activate our current infrastructure to get this out the door to those that need it.

Susan and Makoto,

Can ASPR accept this as a donation given the current national emergency, and if not, is there an external group or contractual agreement by which this can be done?

Chris,
Bayer is sending me more data on this from a safety/efficacy/tox perspective and I'll need your team to take a look and make sure it's legit. Short term use safe according to Bayer.

Bryan,

Assuming BARDA signs off that this can work, we'll need help from the task force to have the FDA commissioner grant an import exception and issue an emergency request that will go to the Pakistani authorities. We'll also need a plane so it doesn't take 7 days to import. I can work on that if you say go.

1M pills available immediately to treat 35K patients, 2M pills can be made available shortly thereafter. The EUA package is being put together now. This can be a BIG immediate win.

Best,
Joe

Taskbar: Chrome, Edge, Outlook, Word, PowerPoint, Excel, System tray (Volume, Network, Battery, Time: 11:22 PM 4/27/2020)

Exhibit 54

File Message Tell me what you want to do...

Ignore Delete Reply Reply All Forward More Meeting

Chloroquine To Manager
Team Email Done
Reply & Delete Create New

Move Rules OneNote Actions

Assign Mark Categorize Follow Translate Find Related Select

Policy Unread Tags Up

Zoom Send to OneNote

Delete Respond Quick Steps Move Editing Zoom OneNote

Wed 3/18/2020 2:08 PM

Bright, Rick (OS/ASPR/BARDA)

Fwd: Resochin (chloroquine phosphate) and COVID19

To: Shuy, Bryan (OS/ASPR/IO)

Cc: Johnson, Robert (OS/ASPR/BARDA)

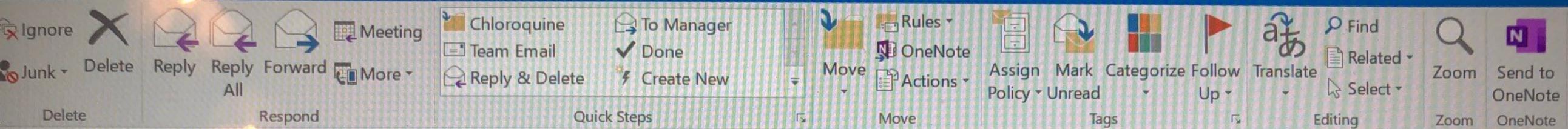
From: Houchens, Christopher (OS/ASPR/BARDA)**Sent:** Tuesday, March 17, 2020 7:16 PM**To:** Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>**Cc:** Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>**Subject:** RE: Resochin (chloroquine phosphate) and COVID19

Rick – Robert forwarded me your email regarding chloroquine. Joe Hamel also asked me to review the same set of data provided by Bayer. It is my understanding that SNS would like to make a donation to the SNS. I asked Kim and Bob to review the data provided and their overall opinion is that there are safety liabilities associated with the drug and accepting the donation could send a signal that we are not concerned about the risk. One could also argue that the potential benefit outweighs the risk, especially when we have few/no options. Below are the comments from Kim and Bob. Please let me know if and how you would like for me to respond to Joe Hamel.

Chris

- Bottom-line upfront, I do not believe we should accept the donation until we have an understanding on the clinical utility of the drug. Accepting the donation could lead to widespread use that is not supported by any clinical data.
- Attached is a summary of the clinical trials that are associated with chloroquine use; not a single study has posted any data for peer-review. The attached Gao publication says chloroquine works without providing supporting data. The Cell Research paper shows in vitro activity, which is supported by data we have seen from other researchers. The most important publication (besides Meghan's write-up) is the one attached to Joe Hamel's original email.
- The Touret article actually says to use caution when thinking about chloroquine for widespread use because the chikungunya clinical trial showed that those treated with chloroquine were harmed. In addition, despite having activity against influenza and dengue in vitro, randomized controlled clinical trials failed to show any benefit in the prevention of influenza infection or treatment of dengue. Chloroquine has a long history of showing in vitro inhibition that doesn't translate into animal models or clinical benefit.
- Despite 16 clinical trials in China we have only media reports or short notes saying the data is good, no actual data. We need to be very careful about the message it sends the public about accepting a donation of a drug with questionable utility at this point.

File Message Tell me what you want to do...



Wed 3/18/2020 2:08 PM

Bright, Rick (OS/ASPR/BARDA)

Fwd: Resochin (chloroquine phosphate) and COVID19

To: Shuy, Bryan (OS/ASPR/IO)

Cc: Johnson, Robert (OS/ASPR/BARDA)

were harmed. In addition, despite having activity against influenza and dengue in vitro, randomized controlled clinical trials failed to show any benefit in the prevention of influenza infection or treatment of dengue. Chloroquine has a long history of showing in vitro inhibition that doesn't translate into animal models or clinical benefit.

- Despite 16 clinical trials in China we have only media reports or short notes saying the data is good, no actual data. We need to be very careful about the message it sends the public about accepting a donation of a drug with questionable utility at this point.
- Let's wait for the data to be shared and make an informed decision.
- A couple points to add: Chloroquine is contraindicated in people with G6PD deficiency, where it can cause life-threatening hemolytic anemia, and chloroquine crosses the placenta. So while considered safe in much of what we're reading, when large numbers of the population are exposed these adverse reactions can be expected to feature more prominently.
- The DMID government team and non-government investigators have repeatedly rejected studying chloroquine in the ongoing RCT due to lack of compelling data.
- The WHO agreed to add chloroquine as an arm in their master protocol mainly because they deemed it "unlikely to be harmful." I'm attaching the 1 page summary that was distributed to the WHO consultation attendees.
- I do believe that BARDA's standard for accepting a donation and dispensing a product should be higher than in vitro activity and unlikely to harm. I endorse working with WHO to aggressively pursue the Chinese investigators to share their data.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>

Sent: Tuesday, March 17, 2020 5:48 PM

To: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>

Subject: FW: Resochin (chloroquine phosphate) and COVID19

Team, Have you already seen these items? I need a quick consideration from you on this topic. Information I have received indicates a potential to rapidly reduce viral load and reduce viral shedding and thus potentially transmission. I would greatly appreciate your serious consideration and thoughts tonight.

Thanks Rick

Exhibit 55

File Message Tell me what you want to do...

Ignore Delete Reply Reply Forward Meeting
All More -

Chloroquine To Manager
Team Email Done
Reply & Delete Create New

Rules -
OneNote
Actions -

Assign Mark Categorize Follow
Policy - Unread - Up -

Translate

Find
Related -
Select -

Zoom
Send to
OneNote

Delete Respond Quick Steps Move Tags Editing Zoom OneNote

Wed 3/18/2020 8:42 AM

Johnson, Robert (OS/ASPR/BARDA)

RE: Resochin (chloroquine phosphate) and COVID19

To: Bright, Rick (OS/ASPR/BARDA)

Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the contractor must disregard that portion of the communication and contact the Contracting Officer for direction.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>

Sent: Wednesday, March 18, 2020 8:37 AM

To: Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>

Cc: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>

Subject: Re: Resochin (chloroquine phosphate) and COVID19

Thanks, Kim. I'll meet with Robert on this topic this morning to map out next steps. Lots of moving pieces.

Robert will provide guidance after I talk with him. Thanks.

On Mar 18, 2020, at 8:18 AM, Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov> wrote:

Rick,
FDA is well represented on both the Therapeutics Working Group and the Clinical Working Group. Both working groups have discussed chloroquine as a group, and as outlined by Chris, the consensus is to wait for clinical data on the numerous clinical trials that are ongoing before making recommendations on the use of chloroquine for COVID-19. Currently, there is no data available to support that chloroquine provides clinical benefit in the treatment or prevention of COVID-19.

I will reach out to CDER today to get their opinion on the Bayer donation under the PHEMCE MOU, and I will keep Bob Walker and Tremel in the loop on these communications.

Thanks,
Kim

Exhibit 58

From: Bright, Rick (OS/ASPR/BARDA) <rick.bright@hhs.gov>
Sent: Monday, March 23, 2020 5:44 PM
To: Kadlec, Robert (OS/ASPR/IO); Sherman, Susan (HHS/OGC)
Cc: Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Johnson, Robert (OS/ASPR/BARDA)
Subject: Re: chloroquine IND

Received. We are trying to get background as none of us know the plan.

I will reach out to Stacy Amin who seems to have the string start below.

Our clinical and regulatory teams are alerted, but scrambling to understand the requirement.

Do you know who we can contact to get caught up to speed?

Thank you. Rick

From: Robert Kadlec <Robert.Kadlec@hhs.gov>
Date: Monday, March 23, 2020 at 5:40 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>
Cc: Gary Disbrow <Gary.Disbrow@hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>
Subject: RE: chloroquine IND

Rick Bob Charrow asked that BARDA lead this. Please identify a team to support.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 5:37 PM
To: Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Subject: Re: chloroquine IND

Thanks Susan, can you please call me. I am not sure who has the background on this, BARDA does not yet and are playing catch up with little to no details. Is Stacy Amin the Lead? Who has talked with Oracle? Where is the drug coming from? Has FDA cleared?

Please call 202-674-5129. Thanks Rick

From: "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>
Date: Monday, March 23, 2020 at 5:32 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>

Cc: Robert Kadlec <Robert.Kadlec@hhs.gov>

Subject: Fwd: chloroquine IND

Hi Rick,

See below. Please do not hesitate let me know if you envision any problem with BARDA being the IND sponsor that can be facilitated by OGC.

Susan

Begin forwarded message:

From: "Charrow, Robert (HHS/OGC)" <Robert.Charrow@hhs.gov>
Date: March 23, 2020 at 5:18:31 PM EDT
To: "Amin, Stacy (FDA/OC)" <Stacy.Amin@fda.hhs.gov>, "Lankford, David (NIH/OD) [E]" <lankford@od31tm1.od.nih.gov>, "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>, "Chang, William (HHS/OGC)" <William.Chang@hhs.gov>, "Franklin, Joseph (FDA/OC)" <Joseph.Franklin@fda.hhs.gov>
Subject: RE: chloroquine IND

NIH would provide the IRB

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Monday, March 23, 2020 5:15 PM
To: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Lankford, David (NIH/OD) [E] <lankford@od31tm1.od.nih.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>
Subject: chloroquine IND
Importance: High

I spoke to Bob and he spoke to Kadlec, etc. Can we please start moving forward on BARDA sponsoring the chloroquine IND and NIH providing the IND? The President is announcing this tonight and I believe the WH would like it set up by tomorrow with data to flow into the Oracle platform.

What needs to be done and what requirements do we think can be waived or use enforcement discretion? Joe could you provide that list for FDA, Susan for BARDA, and David for NIH?

Bob please correct me if I'm getting ahead of anything. And Will I ultimately defer to you how you would like to handle for NIH and ASPR—just trying to get the ball rolling.

Best,
Stacy

Stacy Cline Amin
Chief Counsel
Food and Drug Administration
Deputy General Counsel
Department of Health and Human Services

Exhibit 59

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 23, 2020 at 10:54:40 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Johnson, Robert (OS) <Robert.Johnson@hhs.gov>, Walker, Robert (OS) <Robert.Walker@hhs.gov>, Faison, Tremel (OS) <Tremel.Faison@hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Marston, Hilary D (NIH) <hilary.marston@nih.gov>, Lane, Henry C (NIH) <clane@niaid.nih.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, Uyeki, Timothy M (CDC) <tmu0@cdc.gov>, Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) <matthew.j.hepburn.civ@mail.mil>, Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>, Beigel, John H (NIH) <jbeigel@niaid.nih.gov>, Higgs, Elizabeth S (NIH) <ehiggs@niaid.nih.gov>, Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: Re: URGENT Questions on planned study

Thank you Stacy. This is already much more info than we had and very helpful. We are eager to talk with you and Amy tomorrow morning. Dr Bob Walker will take the lead to coordinate.

Given the limited information we have on both the drug and the innovative data system, I'm sure we'd all lean heavily towards a pilot over a national roll out. Many variables to get right in an already hectic setting across the nation.

Thank you for all you are doing.

Rick

Sent from my iPhone

On Mar 23, 2020, at 10:33 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

Hi Rick, adding our Principal Deputy Commissioner, Amy Abernethy, who is leading this effort for FDA. Also including my team in FDA OGC.

Happy to talk at your earliest convenience. Could you suggest a time? My understanding is there are two potential candidates for a chloroquine trial. One is the Bayer donation of 1.5 million doses + 2 million more on the way. Another is attached.

I have heard there are WH discussions tomorrow morning to consider path forward and whether a BARDA trial should be national or piloted to NY first.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>

Sent: Monday, March 23, 2020 9:09 PM

To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Walker, Robert (OS) <Robert.Walker@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Lambert, Linda (OS) <Linda.Lambert@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Lane, Henry C (NIH) <clane@niaid.nih.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) <matthew.j.hepburn.civ@mail.mil>; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Beigel, John H (NIH) <jbeigel@niaid.nih.gov>; Higgs, Elizabeth S (NIH) <ehiggs@niaid.nih.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>

Subject: URGENT Questions on planned study

Hi Stacy,

I hope that you are doing well, given the extremely busy pace that everyone is working. I hope that you are able to assist us with an urgent matter.

HHS has been tasked to conduct what we understand to be a nationwide emergency access IND for Chloroquine or hydroxychloroquine. The HHS COVID19 clinical and regulatory teams urgently need to talk with you to understand the information that you have about this study and a potential combination with an experimental database system from Oracle.

The details available enable us to proceed are very sketchy and the directive is to move quickly. We understand that you might have helpful information from various conversations you have had with Oracle, the drug supplier and other entities planning the trial. In order to coordinate

this USG/HHS-lead study, it will be very helpful if you can update us on any background information, either by email or a conference call.

Dr. Bob Walker is copied with the HHS team above. He can assist in coordinating a call at your earliest convenience.

Thank you for taking the time to assist in clarifying this task and a path forward.

Rick

Rick A. Bright, PhD

Director, BARDA

Deputy Assistant Secretary for Preparedness and Response

Office of the Assistant Secretary for Preparedness and Response

US Department of Health and Human Services

<mime-attachment>

Exhibit 60

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Sunday, April 05, 2020 12:05 PM
To: Giroir, Brett (HHS/OASH)
Cc: Gaynor, Pete (fema.dhs.gov); Adams, Steven A. (ASPR/SNS); Polowczyk, John P (MIL); Farmer, William (OS/ASPR/SPPR); Bright, Rick (OS/ASPR/BARDA)
Subject: Re: [Non-DoD Source] RE: Hydroxychloroquine

Agree

Sent from my iPhone

> On Apr 5, 2020, at 11:49 AM, Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov> wrote:

>

> NOPE

> Needs to go to pharmacies as well.

> The EUA matters not ---

> The drug is approved any therefore can be prescribed as per doctor's

> orders That is a FINAL ANSWER

>

> And pharmacies need it for ON LABEL use as well

>

>

> Brett P. Giroir, MD

> ADM, US Public Health Service

> Assistant Secretary for Health (ASH)

> 200 Independence Avenue, SW

> Washington, DC 20201

> Office Phone: 202-690-7694

>

>

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

> From: Gaynor, Pete <pete.gaynor@fema.dhs.gov>

> Sent: Sunday, April 5, 2020 11:32 AM

> To: Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Polowczyk, John P

> (MIL) <john.p.polowczyk.mil@mail.mil>; Farmer, William (OS/ASPR/SPPR)

> <William.Farmer@hhs.gov>

> Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Giroir, Brett

> (HHS/OASH) <Brett.Giroir@hhs.gov>; Bright, Rick (OS/ASPR/BARDA)

> <Rick.Bright@hhs.gov>

> Subject: RE: [Non-DoD Source] RE: Hydroxychloroquine

>

> So....hospitals only for the 2m doses distro?

>

> Pete Gaynor

> Administrator

> Office: (202) 212-5516 | Mobile: (202) 812-8623

> Pete.Gaynor@fema.dhs.gov

>
> -----Original Message-----
> From: Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>
> Sent: Sunday, April 5, 2020 11:30 AM
> To: Polowczyk, John P (MIL) <john.p.polowczyk.mil@mail.mil>; Farmer,
> William (OS/ASPR/SPPR) <William.Farmer@hhs.gov>
> Cc: Gaynor, Pete <pete.gaynor@fema.dhs.gov>; Kadlec, Robert
> <Robert.kadlec@hhs.gov>; Giroir, Brett (HHS/OASH)
> <Brett.Giroir@hhs.gov>; Bright, Rick (OS/ASPR/BARDA)
> <Rick.Bright@hhs.gov>
> Subject: RE: [Non-DoD Source] RE: Hydroxychloriquine
>
> All, just want to assure everyone is aware that the EUA for hydroxychloroquine and chloroquine (attached)
appears to limit use to the treatment of hospitalized patients. I'm told that PREP Act liability protection would
likely not apply to non-hospital use.

>
> Steve

>
> -----Original Message-----
> From: Polowczyk, John P RADM USN JS J4 (USA)
> <john.p.polowczyk.mil@mail.mil>
> Sent: Sunday, April 5, 2020 10:07 AM
> To: Farmer, William (OS/ASPR/SPPR) <William.Farmer@hhs.gov>
> Cc: Gaynor, Pete (fema.dhs.gov) <pete.gaynor@fema.dhs.gov>; Kadlec,
> Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Giroir, Brett (HHS/OASH)
> <Brett.Giroir@hhs.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>
> Subject: RE: [Non-DoD Source] RE: Hydroxychloriquine

>
> Bob,

>
> Distro to Hospitals and retail pharmacies and geography:

>
> NYC area - 100K to hospitals, 150K to retail Detroit - 50K to
> hospitals, 100K to retail Chicago - 50K to hospitals, 100K to retail
> NO - 20K hospitals - 50K retail

>
> Total hospitals - 220K hospitals, 400K retail. Total 620K first shipments. Ill get you the distributors.

>
>
> V/r John

>
> -----Original Message-----
> From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
> Sent: Sunday, April 5, 2020 8:17 AM
> To: Polowczyk, John P RADM USN JS J4 (USA)
> <john.p.polowczyk.mil@mail.mil>; Gaynor, Pete (fema.dhs.gov)
> <pete.gaynor@fema.dhs.gov>
> Cc: Giroir, Brett P ADM USPHS (USA) <brett.giroir@hhs.gov>
> Subject: RE: [Non-DoD Source] RE: Hydroxychloriquine

>
> All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

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>
> Additional data the 200K & *)K destined for institutions (hospitals)
> conducting clinical trials so none likely is going to retail drug
> stores

>
>
>
> From: Polowczyk, John P RADM USN JS J4 (USA)
> <john.p.polowczyk.mil@mail.mil>
> Sent: Sunday, April 5, 2020 7:39 AM
> To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Gaynor, Pete
> (fema.dhs.gov) <pete.gaynor@fema.dhs.gov>
> Cc: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
> Subject: Re: [Non-DoD Source] RE: Hydroxychloriquine

>
>
>
> Sir

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>
>
> I have way to get this done distribution wise. Where is it and who is the poc?

>
> Vr John

>
>
>
>
> From: "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov <
> Caution-mailto:Robert.Kadlec@hhs.gov > >
> Date: Saturday, April 4, 2020 at 9:55:45 PM
> To: "Gaynor, Pete (fema.dhs.gov)" <pete.gaynor@fema.dhs.gov <
> Caution-mailto:pete.gaynor@fema.dhs.gov > >
> Cc: "Giroir, Brett P ADM USPHS (USA)" <brett.giroir@hhs.gov <
> Caution-mailto:brett.giroir@hhs.gov > >, "Polowczyk, John P RADM USN
> JS J4 (USA)" <john.p.polowczyk.mil@mail.mil <
> Caution-mailto:john.p.polowczyk.mil@mail.mil > >
> Subject: [Non-DoD Source] RE: Hydroxychloriquine

> All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

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> Copy all

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>
>
> From: Gaynor, Pete <pete.gaynor@fema.dhs.gov <
> Caution-mailto:pete.gaynor@fema.dhs.gov > >
> Sent: Saturday, April 4, 2020 9:55 PM
> To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov <
> Caution-mailto:Robert.Kadlec@hhs.gov > >
> Cc: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov <
> Caution-mailto:Brett.Giroir@hhs.gov > >; Polowczyk, John P (MIL)
> <john.p.polowczyk.mil@mail.mil <
> Caution-mailto:john.p.polowczyk.mil@mail.mil > >
> Subject: Re: Hydroxychloriquine

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>
> Hahn asked to distribute to hospitals and the drug stores.

>
>
>
> Pete Gaynor
>
> FEMA Administrator
>
> 202-812-8623

> _____
>
> From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov <
> Caution-Caution-mailto:Robert.Kadlec@hhs.gov <
> Caution-mailto:Robert.Kadlec@hhs.gov %3c
> Caution-Caution-mailto:Robert.Kadlec@hhs.gov > > >
> Sent: Saturday, April 4, 2020 9:08:50 PM
> To: Gaynor, Pete <pete.gaynor@fema.dhs.gov <
> Caution-Caution-mailto:pete.gaynor@fema.dhs.gov <
> Caution-mailto:pete.gaynor@fema.dhs.gov %3c
> Caution-Caution-mailto:pete.gaynor@fema.dhs.gov > > >
> Cc: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov <
> Caution-Caution-mailto:Brett.Giroir@hhs.gov <

> Caution-mailto:Brett.Giroir@hhs.gov %3c
> Caution-Caution-mailto:Brett.Giroir@hhs.gov >>>; Polowczyk, John P
> (MIL) <john.p.polowczyk.mil@mail.mil <
> Caution-Caution-mailto:john.p.polowczyk.mil@mail.mil <
> Caution-mailto:john.p.polowczyk.mil@mail.mil %3c
> Caution-Caution-mailto:john.p.polowczyk.mil@mail.mil >>>
> Subject: Re: Hydroxychloriquine
>
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>
> We can get more but discussed hospitalized patients. You are indicating outpatients right?
>
> Sent from my iPhone
>
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>
>
>
> On Apr 4, 2020, at 9:01 PM, Gaynor, Pete <pete.gaynor@fema.dhs.gov < Caution-Caution-
mailto:pete.gaynor@fema.dhs.gov < Caution-mailto:pete.gaynor@fema.dhs.gov %3c Caution-Caution-
mailto:pete.gaynor@fema.dhs.gov >>> wrote:
>
>
>
> Hahn called me. Me and Adm P are on it. More to follow in am.
>
>
>
> Pete Gaynor
>
> FEMA Administrator
>
> 202-812-8623
>
>
>
> _____
>
> From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov < Caution-Caution-mailto:Brett.Giroir@hhs.gov
< Caution-mailto:Brett.Giroir@hhs.gov %3c Caution-Caution-mailto:Brett.Giroir@hhs.gov >>>
> Sent: Saturday, April 4, 2020 8:59:22 PM
> To: Gaynor, Pete <pete.gaynor@fema.dhs.gov < Caution-Caution-mailto:pete.gaynor@fema.dhs.gov <
Caution-mailto:pete.gaynor@fema.dhs.gov %3c Caution-Caution-mailto:pete.gaynor@fema.dhs.gov >>>;
Kadlec, Robert <Robert.kadlec@hhs.gov < Caution-Caution-mailto:Robert.kadlec@hhs.gov < Caution-
mailto:Robert.kadlec@hhs.gov %3c Caution-Caution-mailto:Robert.kadlec@hhs.gov >>>; Polowczyk, John
P (MIL) <john.p.polowczyk.mil@mail.mil < Caution-Caution-mailto:john.p.polowczyk.mil@mail.mil <
Caution-mailto:john.p.polowczyk.mil@mail.mil %3c Caution-Caution-mailto:john.p.polowczyk.mil@mail.mil
>>>>
> Subject: Hydroxychloriquine
>
>
>

- > WH call. Really want to flood Ny and NJ with treatment courses.
- > Hospitals have it. Sick out patients don't. And can't get. So go
- > through distribution channels as we discussed. If we have 29 million
- > perhaps send a few million ASAP? WH wants follow up in A M
- >
- > I think this is fine. We can get a lot more of this. Right Bob? Millions per week?
- >
- > Sent from my iPhone
- >