

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>
CC:	MCM Task Force /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49010f8ab3ab4aed868a72c707c08d08-MCM Task Fo <MCMTaskForce@hhs.gov>; Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da <David.Boucher@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>
Subject:	Re: MCM Task Force updates for Tuesday, 4/14
Date:	2020/04/13 21:58:00
Priority:	Normal
Type:	Note

I thought the team invalidated the highlighted item below. Did this come from a news release or from NIAID or our Team? Please triple check. Thanks, Rick

From: "Ventura, Christy (OS/ASPR/BARDA) (CTR)" <Christy.Ventura@hhs.gov>
Date: Monday, April 13, 2020 at 8:22 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>
Cc: MCM Task Force <MCMTaskForce@hhs.gov>
Subject: MCM Task Force updates for Tuesday, 4/14

Rick, Gary, Linda,

Updates for Tuesday for the MCM Task Force are provided here. Please let us know if you have any concerns.

Accomplishments

- USG funded clinical studies
- Therapeutics: 5 (+1) Phase 3 trials (2 BARDA, 2 NIAID, 1 NHLBI)
- Vaccines: 2 Phase 1 trials (1 DoD, 1 NIAID)
- Observational Natural History Study: 2 (NHLBI, DoD)
- NIAID and Biocryst initiated a Phase 1b clinical trial to evaluate galidesivir for treatment of COVID-19

- ACTT Clinical trial to test remdesivir for treatment of COVID-19: 759 (+55) new patients at 67 (+2) sites, including 5 military treatment facilities, in last 24 hrs (target = 700)
- Phase 1 safety trial for mRNA vaccine: 39 (+5) healthy volunteers enrolled (target = 45)
- Human samples are being tested for SARS-CoV-2 at 2 (+1) National Animal Health Laboratory Network labs, 2 additional labs have human sample testing capabilities
- Emergency Use Authorizations granted by FDA: 34 (+1) molecular diagnostic tests, 10 (+1) laboratory-developed tests, 1 antibody test, and 2 repurposed treatments (chloroquine, hydroxychloroquine)

Currently working:

- Continuing to enroll patients in clinical trials to evaluate vaccines and therapeutics for COVID-19
- Accelerating vaccine manufacturing efforts to ensure rapid delivery of vaccines

Thanks

Christy

--

Christy L. Ventura, Ph.D.

Tunnell Government Services

Executive Secretary, SARS-CoV-2 Medical Countermeasures Task Force

Project Manager, CBRN/BARDA/ASPR/HHS

O'Neill 23L05

Office: 202-730-8643

Cell: (b)(6)

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
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Sent Date:	2020/04/13 21:58:06
Delivered Date:	2020/04/13 21:58:00

From:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
To:	Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>
CC:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7bd764440b44b06af644cdcd22e42d6-Oshansky, C <Christine.Oshansky@hhs.gov>; Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da <David.Boucher@hhs.gov>
Subject:	Re: TPs
Date:	2020/03/25 20:59:08
Priority:	Normal
Type:	Note

Thanks Chris. These are great but eerily similar to today's. Except the Moderna number has gone down. Something switched with numbers.

What's status of the NIH RCT for chloroquine? Hydroxychloroquine?

Status of Genentech IL-6 study?

Status of remdesivir manufacturing?

Is the blood collecting today the same as yesterday?

Sent from my iPhone

On Mar 25, 2020, at 8:25 PM, Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov> wrote:

Rick – Please see attached and below. Trying a new format here. TPs are below and on page 1. More details of all other activities are on following pages. Chris

Agencies reporting: BARDA, NIAID, DoD

Agencies not reporting: FDA, CDC, DHS, USDA

- • NIAID multi-center, multi-country, multi-arm adaptive RCT with remdesivir
 - • 28 sites (24 US, 4 global)
 - • 113/440 enrolled (101 US, 12 global)

- Moderna mRNA-1273 vaccine: 19/45 healthy volunteers vaccinated as of 03/25/2020
 - 15 subjects in cohort 1 (25mcg) completed
 - 4 sentinel subjects in cohort 2 (100mcg) vaccinated
 - 4 sentinel subjects in cohort 3 (250mcg) will be vaccinated following completion of cohort 2
- Blood samples are being collected from infected patients in Washington, DC and Hawaii. These blood samples are being provided to scientists and may contain antibody producing cells that can be used to make new therapies. (Note: This study is being supported by NIAID VRC)

Christopher Houchens, PhD
 Director (Acting) Division of CBRN Countermeasures
 Biomedical Advanced Research and Development Authority (BARDA)
 Office of Assistant Secretary for Preparedness and Response (ASPR)
 Department of Health and Human Services (DHHS)
 Office: 202-205-3633
 BB: (b)(6)
 Christopher.houchens@hhs.gov

<MCM Task Force Update_03262020_v3.docx>

Sender:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
Recipient:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7bd764440b44b06af644cdcd22e42d6-Oshansky, C <Christine.Oshansky@hhs.gov>; Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da <David.Boucher@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>
Sent Date:	2020/03/25 20:59:07
Delivered Date:	2020/03/25 20:59:08

From:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
To:	Maffia, Anthony <anthony.maffia@sandoz.com>
Subject:	Tentative: Quick Touchpoint on Hydroxychloroquine Donation
Date:	2020/03/24 13:27:13
Start Date:	2020/03/24 15:00:00
End Date:	2020/03/24 15:30:00
Priority:	Normal
Type:	Schedule.Meeting.Resp.Tent
Location:	Microsoft Teams Meeting: Dialin: 1-862-294-3403 code 789907781#

Unable to join this call, not sure if I am necessary though.

Sender:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
Recipient:	Maffia, Anthony <anthony.maffia@sandoz.com>
Sent Date:	2020/03/24 13:27:12
Delivered Date:	2020/03/24 13:27:13

From: Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>

To: Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>

Subject: FW: Not an over the counter medication

Date: 2020/04/04 18:19:19

Priority: Normal

Type: Note

From: Robert Kadlec <Robert.Kadlec@hhs.gov>
Date: Saturday, April 4, 2020 at 5:03 PM
To: Gary Disbrow <Gary.Disbrow@hhs.gov>
Cc: Bryan Shuy <Bryan.Shuy@hhs.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Robert Walker <Robert.Walker@hhs.gov>
Subject: Re: Not an over the counter medication

Great

Sent from my iPhone

On Apr 4, 2020, at 4:59 PM, Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>wrote:

Just spoke with them. They are in process of submitting. Should come in on Monday. \$12+ M dollar price tag.

Gary L. Disbrow Ph.D.

Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority

BARDA

Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
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Office: 202-260-0899
Mobile: (b)(6)
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email: Gary.Disbrow@HHS.gov

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From: Disbrow, Gary (OS/ASPR/BARDA)
Sent: Saturday, April 4, 2020 4:49 PM
To: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Subject: RE: Not an over the counter medication

Bob and Bryan,

The group has been asked to submit a proposal.

What Michael discussed on the phone and the spread sheet are not representative of what they are proposing. Below is what they are proposing. They need an IND for the high dose IV administration of famotidine. I know they are in the process of working that.

Alchem Laboratories in collaboration with the Northwell (NYC) hospital chain are anticipating launching a 1200+/- patient trial in moderate to severe hospitalized COVID-19 in the next few days.

Three arm, double blind, randomized, 1) historic standard of care (SOC) vs 2) hydroxychloroquine + SOC vs 3) hydroxychloroquine + SOC + high dose famotidine IV.

IRB and FDA allowance to proceed (prelim); formal letters shortly.

Anticipate enrollment and initial dosing this week.

This trial currently has a letter of intent from ASPR.

Gary L. Disbrow Ph.D.

Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority

BARDA

Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
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From: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Sent: Saturday, April 4, 2020 4:44 PM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Subject: RE: Not an over the counter medication

Hi Gary,

Just following-up if we know any more? Thanks, Bryan

From: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Sent: Wednesday, April 1, 2020 1:32 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Subject: Not an over the counter medication

Bob,

The group you discussed last night is not proposing using the OTC Pepcid. They are going to use high dose IV formulation compared to HQC. This study needs to be coordinated with NIH studies for HQC and could cost millions of dollars. See below. They need to submit a full proposal and associated costs. I spoke with ASPR contracting and they do have the band width to stand up a TEP. Our clinical group is maxed out due to the HQC expanded access that will occur across the US. We need assistance for our clinical group.

Alchem Laboratories in collaboration with the Northwell (NYC) hospital chain are anticipating launching a 1200+/- patient trial in moderate to severe hospitalized COVID-19 in the next few days.

Three arm, double blind, randomized, 1) historic standard of care (SOC) vs 2) hydroxychloroquine + SOC vs 3) hydroxychloroquine + SOC + high dose famotidine IV.

IRB and FDA allowance to proceed (prelim); formal letters shortly.

Anticipate enrollment and initial dosing this week.

This trial currently has a letter of intent from ASPR.

We have previously submitted a WP to Dr. Michael Callahan, and he has now requested that we submit to BARDA for consideration to fund.

Gary

Gary L. Disbrow Ph.D.

Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority

BARDA

Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
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Recipient: Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>

Sent Date: 2020/04/04 18:19:19

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>
Subject:	What is the name
Date:	2020/03/24 16:00:04
Priority:	Normal
Type:	Note

Of Janets deputy from CDER? Patrice? I think shes on the swab calls. I just heard her tell the lawyers and hamel that (b)(5) I want to send her an email to get the paper or data. Thanks, Rick

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>
Sent Date:	2020/03/24 16:00:04

From:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
To:	Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>
CC:	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@hhs.gov>
Subject:	Re: Request for BARDA help with DLG International MCM Access and population prioritization for MCM
Date:	2020/04/14 11:49:55
Priority:	Normal
Type:	Note

Linda. That is not even something we can contribute to, let alone lead. SPPR is the policy shop and should lead policy topics such as suggested. Ian Watson is leading SPPR now and they have a full staff for policy and dlq issues.

On Apr 14, 2020, at 11:43 AM, Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov> wrote:

Rick and Gary

SPPR is asking for a BARDA rep to help work up a DLG on population prioritization for CQ/HCQ and possibly broader.

I'll let them know that we can't staff this because of our response mode today. **Holler if otherwise.**

Linda

From: Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>
Sent: Tuesday, April 14, 2020 11:26 AM
To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>
Cc: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>; DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: RE: DLG | International MCM Access

Thanks, Linda. We'd be interested to have whoever at BARDA would be appropriate to discuss how to frame the DLG discussion on population prioritization decisions that would include international access to MCMs, especially when they are limited. Who would be the right person?

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Tuesday, April 14, 2020 11:17 AM
To: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>; Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>
Cc: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>; DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: RE: DLG | International MCM Access

Hi All,

Thank you for the invite. I do not think I can contribute to population prioritization. My expertise is micro and product development with a minor in human resources/HR since joining ASPR.

L

From: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>
Sent: Tuesday, April 14, 2020 11:09 AM
To: Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>; DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: RE: DLG | International MCM Access

I could meet between 11:00 and 12:00 tomorrow. We'll need a rep from the DLG team also. Dan

From: Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>
Sent: Tuesday, April 14, 2020 11:05 AM
To: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>
Subject: RE: DLG | International MCM Access

Thank you, Dan. Could we please schedule a time with you and Linda (and whoever else needs to be on the call) to discuss bringing the issue of population prioritization that includes the international piece to the DLG? Dan and Linda, what is your availability tomorrow between 11-2? Thank you both!

From: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>
Sent: Tuesday, April 14, 2020 9:33 AM
To: Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>

Cc: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>
Subject: RE: DLG | International MCM Access

Thanks all. Let us know if/when you want to consider a DLG on this topic. As noted, it might be similar to other DLGs we've had on related topics. I'm happy to discuss. Dan

From: Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>
Sent: Tuesday, April 14, 2020 8:31 AM
To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>
Subject: RE: DLG | International MCM Access

Hi Linda,

Thank you very much for the quick turnaround on this. This is helpful!

All the best,

Ana

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Monday, April 13, 2020 7:46 PM
To: Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>
Cc: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>
Subject: RE: DLG | International MCM Access

Hi Ana,

We aren't aware of any ongoing discussions in BARDA on this as it's a policy issue. However, a

(b)(5)

Thank you all again. We appreciate SPPR checking in with us on this.

From: Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>
Sent: Monday, April 13, 2020 4:21 PM
To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>

Cc: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>
Subject: RE: DLG | International MCM Access

+ Rachel Wood

From: Ayala, Ana (OS/ASPR/SPPR)
Sent: Monday, April 13, 2020 4:20 PM
To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>
Subject: FW: DLG | International MCM Access

Hi Linda,

Dan Dodgen (copied here) suggested that we reach out to you as one of the starting points as we look into the possibility of having an HHS-internal discussion within the DLG on how international access to COVID-19 MCMs should be handled and balancing that with domestic needs. Some of us have started considering the various complications that could arise as MCMs like Remdesivir become available but in limited numbers, at which point we expect that international stakeholders like WHO and other foreign governments will reach out. Has BARDA started to have conversations internally (or externally with stakeholders) on this issue? We would be interested to hear what BARDA is thinking on the issue.

Many thanks in advance,

Ana

Ana S. Ayala, J.D., LL.M.
Senior Global Health Officer
Office of Global Affairs
U.S. Department of Health and Human Services (HHS)
o: (202) 205-5894 | m: (b)(6)
ana.ayala@hhs.gov

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From: Ayala, Ana (OS/ASPR/SPPR)
Sent: Monday, April 13, 2020 3:04 PM

To: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>
Cc: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>
Subject: RE: DLG | International MCM Access

Thank you, Dan. We haven't had discussions with BARDA on international access to Remdesivir yet. We'll reach out to Linda Lambert to see whether they've begun considering the issue. Regardless, it would be good to have the HHS-internal discussion within DLG to start addressing international access to MCMs in general (does not need to be limited to Remdesivir). Of course, it would make sense to have it as part of a discussion on how various populations will be prioritized when amounts are limited—don't think the DLG could consider the international piece without addressing this first.

If you could please share with us the DLG paper, that would be great. Since Robin and Ruvani helped draft the paper at the early stages, we did not hear on further developments. We'd be particularly interested in how ASPR plans to move forward. Thanks in advance!

Ana

From: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>
Sent: Monday, April 13, 2020 2:26 PM
To: Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>
Cc: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>
Subject: RE: DLG | International MCM Access

Hi Ana, Thanks for your message. As you know, we are currently finalizing a DLG paper regarding the use of HHS-held chloroquine and hydroxychloroquine in international clinical trials. There may be content relevant to your question in the paper, which we hope to finalize today or tomorrow.

Have you spoken with BARDA about the Remdesivir question yet? They have been so engaged in the Remdesivir trials that they may have already given some thought to this issue. I would start with Linda Lambert.

That said, this could be a potential DLG topic if we need broader HHS input and/or consensus. Let's see how BARDA responds. Dan

From: Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>
Sent: Monday, April 13, 2020 2:06 PM
To: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>
Cc: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Weinberger, Collin (OS/OGA) <Collin.Weinberger@hhs.gov>; Wood, Rachel (HHS/OS/OGA) <Rachel.Wood@hhs.gov>
Subject: DLG | International MCM Access

Hi Dan,

Hope you are doing well. We are reaching out with respect to an issue that has begun to come up and which we expect will continue to grow in significance. With advocacy for Remdesivir increasing as a hopeful COVID-19 MCM and considering that the DLG is the coordinating body for high-level policy decisions, we would like to inquire about the possibility of starting an internal HHS conversation about the issue of international access to Remdesivir and our approach with respect to WHO inquiries about accessing it. Has the DLG started discussions on prioritizing populations with respect to Remdesivir or other hopeful MCM candidates? This may be the starting point to consider the potential international aspects of what may be soon coming down the pike.

Many thanks!

Ana

Ana S. Ayala, J.D., LL.M.

Senior Global Health Officer

Office of Global Affairs

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

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Sender:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC> Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>;
Recipient:	Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>
Sent Date:	2020/04/14 11:49:55

From: Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To: Sol Barer <Sol.Barer@tevapharm.com>
Subject: Re: Urgent: COVID-19 ACTG trial
Date: 2020/03/21 23:27:32
Priority: Normal
Type: Note

Thank you Sol,

Very interesting. I will get this into the Task Force and CDC for immediate review to see if we can help. Can you send me CEO contact info and we will talk with him tomorrow. Thank you for catching and moving swiftly. It has been a crazy day...though I say that daily now. Thank you for all that you are doing. Send me name on the PAPR and I will get someone to call him tomorrow. Rick

From: Sol Barer <Sol.Barer@tevapharm.com>
Date: Saturday, March 21, 2020 at 10:56 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: Re: Urgent: COVID-19 ACTG trial

You will hear from Brendan in a very little while. He is trying...very good guy.

(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)
"COVID Czar" of NJ

Also working with

(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

Dr. Sol J. Barer
Chairman of the Board of Directors
TEVA Pharmaceutical industries Ltd.
Tel. (Israel): +972.3.9267683
Tel. (US/Parsippany, NJ) 973-658-1785
sol.barer@tevapharm.com

<https://protect2.fireeye.com/url?k=6cd8ec90-308cf5ec-6cd8ddaf-0cc47adc5fa2-cebc939dd4372c01&u=http://www.tevapharm.com/>

On Mar 21, 2020, at 10:39 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Brendan and Sol,

I hope that you are both well. It was very gratifying to see the news about generous donations that TEVA made to hospitals and the healthcare system. It truly warmed my heart and I know it will be helpful to many people. Thank you again for your leadership and compassion.

Things become more tense here with each passing day. NY is struggling to keep up with the number of patients coming into hospitals across the state. We are searching for solutions 24 hours a day.

(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

Would TEVA be interested/able to consider donating tablets for this study? They will still need to find the azithromycin, but the hydroxychloroquine would be a huge help to get them started on the study.

If you are interested, I can connect you directly to the NIH to arrange logistics and communications.

Thank you both. God Bless you and stay safe.

Rick

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Sender: Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>

Recipient: Sol Barer <Sol.Barer@tevapharm.com>

Sent Date: 2020/03/21 23:27:32

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Charrow, Robert (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro <Robert.Charrow@hhs.gov>
CC:	Josie Briggs <jpbriggs@pcori.org>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>
Subject:	FW: PCORNet trial
Date:	2020/03/23 14:35:44
Priority:	Normal
Type:	Note

Bob,

Per our conversation on 2 trials NIAID is planning for hydroxychloroquine and chloroquine for PREP ACT coverage. Attached is one of the two protocols (2nd coming quickly). The NIAID POC on this is Josie Briggs, copied.

Rick

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Charrow, Robert (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro <Robert.Charrow@hhs.gov>; Josie Briggs <jpbriggs@pcori.org>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>
Sent Date:	2020/03/23 14:35:45
Delivered Date:	2020/03/23 14:35:44

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>
CC:	Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>
Subject:	Re: FDA cleared, Trial to start HCQ +/- Famotidine, Northwell NYC
Date:	2020/04/01 14:35:16
Priority:	Normal
Type:	Note

Bob, help me out. Why would a company send clinical trial proposals to ASPR Next, that focuses on durable equipment? I would suggest they be directed to NIH for a discussion like the one had yesterday with USAID on the many many trials being started and to determine the value for any additional trials. I am not sure ASPR Next is engaged with those trials.

I might have missed something in my fast reads. Can you please clarify the direction to ASPR Next though so I can be aligned? Rick

From: Robert Walker <Robert.Walker@hhs.gov>
Date: Wednesday, April 1, 2020 at 2:03 PM
To: Robert Malone <(b)(6)>
Cc: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Timothy Buchman <Tim.Buchman@hhs.gov>, Michael Callahan <MVCALLAHAN@partners.org>
Subject: RE: FDA cleared, Trial to start HCQ +/- Famotidine, Northwell NYC

Dear Dr. Malone

Thanks for reaching out. I have discussed internally and our recommendation is that you submit a full proposal to ASPRNext. I include their link below. Please let me know if you encounter any problems and I'll see if I can help.

<https://www.phe.gov/ASPRNext/Pages/default.aspx>

Best regards,

Robert Walker, MD

Chief Medical Officer and Director, Division of Clinical Development
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

200 C. St. SW, Room 21J13
Washington, DC 20024
(O) 202-205-7862
(M) (b)(6)

From: Robert Malone <(b)(6)>
Sent: Wednesday, April 1, 2020 1:12 PM
To: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Cc: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Buchman, Tim (OS/ASPR/BARDA) (CTR) <Tim.Buchman@hhs.gov>; Callahan, Michael V., M.D. <MVCALLAHAN@partners.org>
Subject: FDA cleared, Trial to start HCQ +/- Famotidine, Northwell NYC

Dear Dr. Walker (Bob)

I am writing on advice of Tim Buchman.

(b)(3):42 U.S.C. § 247d-6b(d)

IRB and FDA allowance to proceed (prelim); formal letters shortly.

Anticipate enrollment and initial dosing this week.

This trial currently has a letter of intent from ASPR.

We have previously submitted a WP to Dr. Michael Callahan, and he has now requested that we submit to BARDA for consideration to fund.

Protocol etc. available upon request.

Please advise regarding how best to proceed.

Thank you for your time and assistance in advising on this matter.

Best wishes,

Robert Malone, MD, MS
CMO, Alchem Laboratories

iPhone (US) (b)(6)

Office (US) 240.994.3334

<https://protect2.fireeye.com/url?k=7f46254c-23132c9c-7f461473-0cc47a6a52de-5157662168134589&u=http://www.linkedin.com/in/rwmalonemd>

<https://protect2.fireeye.com/url?k=41a93029-1dfc39f9-41a90116-0cc47a6a52de-edb1f81aeddff6481&u=http://www.rwmalonemd.com/>

<https://protect2.fireeye.com/url?k=73e9f66b-2fbcffbb-73e9c754-0cc47a6a52de-5fa92c08d2509a27&u=http://www.alchem.com/>

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>
Sent Date:	2020/04/01 14:35:16

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Lenihan, Keagan (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni <Keagan.Lenihan@fda.hhs.gov>; Hamel, Joseph (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose <Joseph.Hamel@hhs.gov>
Subject:	Re: Donated CQ and HCQ
Date:	2020/04/01 10:00:46
Priority:	Normal
Type:	Note

Keagan,

NIH has the pulse and lead on many different clinical trials that are starting and/or planned to start. I suggest Hilary Marston and/or Elizabeth (Libby) Higgs who provided an update on various trials to USAID yesterday. I would be great if NIH could compile a report of all studies and share a regular update with USG stakeholders.

For the donation supply, I will defer to Joe Hamel and Victor Harper who have a strong hand on those transactions and plans. Joe?

Rick

On 4/1/20, 8:47 AM, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov> wrote:

Hey guys- what is happening with the donated CQ and HCQ? Are those being distributed and how? We following any for clinical trial results? Can you provide an update for me, pls?

Thanks,
KL

Sent from my iPhone

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Lenihan, Keagan (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni <Keagan.Lenihan@fda.hhs.gov>; Hamel, Joseph (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose <Joseph.Hamel@hhs.gov>
Sent Date:	2020/04/01 10:00:46

From: Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To: Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@hhs.gov>
Subject: Re: FOR REVIEW: Policy Options for Release of SNS-Held Chloroquine and Hydroxychloroquine
Date: 2020/04/08 11:56:48
Priority: Normal
Type: Note

Just dig into this. That is why I looped you in. thanks.

From: Gretta Blatner <Gretta.Blatner@hhs.gov>
Date: Wednesday, April 8, 2020 at 11:54 AM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: RE: FOR REVIEW: Policy Options for Release of SNS-Held Chloroquine and Hydroxychloroquine

This is the first I have seen it, I am not copied. I will talk to Dan and Claudia again about being copied.

I can share with the team and collate responses.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, April 8, 2020 11:38 AM
To: Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>
Subject: Fwd: FOR REVIEW: Policy Options for Release of SNS-Held Chloroquine and Hydroxychloroquine

Are you collating this info from across BARDA or who is? Has it been shared with clinical and regulatory teams for review?

Sent from my iPhone

Begin forwarded message:

From: "DLGDESK (HHS/ASPR/OPP)" <DLGDESK@hhs.gov>
Date: April 8, 2020 at 11:07:25 AM EDT
To: "DLGDESK (HHS/ASPR/OPP)" <DLGDESK@hhs.gov>, "Stannard, Paula (HHS/IOS)" <Paula.Stannard@hhs.gov>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "Grigsby, Garrett (HHS/OS/OGA)" <Garrett.Grigsby@hhs.gov>, "Kerr, Lawrence (HHS/OS/OGA)" <Lawrence.Kerr@hhs.gov>, "Chang, William (HHS/OGC)" <William.Chang@hhs.gov>, "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>, "Ray Gorrie, Jennifer (HHS/OGC)" <Jennifer.Ray-Gorrie@hhs.gov>, "Strom, John (HHS/OGC)" <John.Strom@hhs.gov>, "Patel, Anita (CDC/DDID/NCIRD/OD)"

<bop1@cdc.gov>, "Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH)" <kbe0@cdc.gov>, "sh1@fda.hhs.gov" <sh1@fda.hhs.gov>, "Hinton, Denise (FDA/OC)" <Denise.Hinton@fda.hhs.gov>, "Mair, Michael (FDA/OC)" <Michael.Mair@fda.hhs.gov>, "Courtney, Brooke (FDA/OC)" <Brooke.Courtney@fda.hhs.gov>, "Collins, Francis (NIH/OD) [E]" <collinsf@od.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <afauci@niaid.nih.gov>, "Marston, Hilary (NIH/NIAID) [E]" <hilary.marston@nih.gov>, "Shuy, Bryan (OS/ASPR/IO)" <Bryan.Shuy@hhs.gov>, "Yeskey, Kevin (OS/ASPR/IO)" <Kevin.Yeskey@hhs.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Disbrow, Gary (OS/ASPR/BARDA)" <Gary.Disbrow@hhs.gov>, "Lambert, Linda (OS/ASPR/BARDA)" <Linda.Lambert@hhs.gov>, "Adams, Steven A. (ASPR/SNS)" <saal@cdc.gov>, "Gorman, Susan (ASPR/SNS)" <spg4@cdc.gov>

Cc: "Phillips, Sally (OS/ASPR/SPPR)" <Sally.Phillips@hhs.gov>, "DeBord, Kristin (OS/ASPR/SPPR)" <Kristin.DeBord@hhs.gov>, "Dodgen, Daniel (OS/ASPR/SPPR)" <Daniel.Dodgen@HHS.GOV>, "Austin, Meredith (OS/ASPR/IO)" <Meredith.Austin@hhs.gov>, "Sheehy, Janice (FDA/ORA)" <Janice.Sheehy@fda.hhs.gov>, "Shirley, Mayo (FDA/OC)" <Mayo.Shirley@fda.hhs.gov>

Subject: RE: FOR REVIEW: Policy Options for Release of SNS-Held Chloroquine and Hydroxychloroquine

Good morning Disaster Leadership Group Members,

This is a friendly reminder to please provide your edits/comments to the "Release of SNS-Held Chloroquine and Hydroxychloroquine" policy options paper to DLGDESK@hhs.gov by **5:00 PM today**. I've reattached the policy options paper along with the International MCM Sharing Policy Framework for your convenience. Thank you to those who have already responded.

Respectfully,

Dan

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

o. (202) 245-0719

Daniel.Dodgen@HHS.Gov | www.phe.gov

From: DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>

Sent: Tuesday, April 7, 2020 11:48 AM

To: Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Grigsby, Garrett (HHS/OS/OGA) <Garrett.Grigsby@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>;

Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH) <kbe0@cdc.gov>; sh1@fda.hhs.gov; Hinton, Denise (FDA/OC) <Denise.Hinton@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] <afauci@niaid.nih.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Gorman, Susan (ASPR/SNS) <spg4@cdc.gov>
Cc: Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>; Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>;
 (b)(6) Sheehy, Janice (FDA/ORR) <Janice.Sheehy@fda.hhs.gov>;
Blatner@hhs.gov; Shirley, Mayo (FDA/OC) <Mayo.Shirley@fda.hhs.gov>; DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: FOR REVIEW: Policy Options for Release of SNS-Held Chloroquine and Hydroxychloroquine

Dear Disaster Leadership Group Members and Colleagues:

Thank you for your participation in COVID-19 Disaster Leadership Group (DLG) Meetings. We are soliciting feedback to inform a policy recommendation regarding whether or not ASPR should support the release of chloroquine and hydroxychloroquine for clinical trials outside the United States. These two drugs are covered by the Emergency Use Authorizations requested by BARDA and approved by the FDA.

1. **FOR REVIEW:** Please find the attached “**Release of SNS-Held Chloroquine and Hydroxychloroquine**” policy options paper for your review.

Suspense Date: Please offer any edits to the “Release of SNS-Held Chloroquine and Hydroxychloroquine” policy options paper to DLGDESK@HHS.gov **by 5:00 PM on Wednesday April 8, 2020.**

<<File: Release of SNS-Held Chloroquine and Hydroxychloroquine.docx >>

2. **FOR INFORMATION:** Please find the attached “**International MCM Sharing Policy Framework**” document, which is an existing policy framework for any requests to use HHS-held MCMs internationally.

<<File: International MCM Sharing Policy Framework FINAL January 2014.pdf >>

We ask that DLG meeting participants ensure leadership within their respective HHS Staff and Operating Divisions are briefed on these materials, and that you do not forward this material beyond the distribution of this message. Please address any questions related to this request to the DLGDESK Resource Mailbox at DLGDESK@hhs.gov.

Respectfully,

Dan

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

o. (202) 245-0719

Daniel.Dodgen@HHS.Gov | www.phe.gov

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@hhs.gov>
Sent Date:	2020/04/08 11:56:48

From:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
To:	Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7bd764440b44b06af644cdcd22e42d6-Oshansky, C <Christine.Oshansky@hhs.gov>
Subject:	Decades-old drug in two Australian trials related to Covid-19 but experts urge caution Health The Guardian
Date:	2020/03/28 15:31:21
Priority:	Normal
Type:	Note

Two more trials starting up on hcq.

<https://www.theguardian.com/australia-news/2020/mar/24/decades-old-drug-in-two-australian-trials-related-to-covid-19-but-experts-urge-caution>

Sender:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
Recipient:	Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7bd764440b44b06af644cdcd22e42d6-Oshansky, C <Christine.Oshansky@hhs.gov>
Sent Date:	2020/03/28 15:31:21



March 28, 2020

Stephen M. Hahn, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

**Re: Request for Emergency Use Authorization
Use of chloroquine phosphate and hydroxychloroquine sulfate for Treatment of
COVID-19**

Dear Dr. Hahn,

This request for Emergency Use Authorization (EUA) is being submitted for the following drugs to be distributed from the Strategic National Stockpile (SNS) to public health authorities for treatment of COVID-19 during the current public health emergency:

- chloroquine phosphate
- hydroxychloroquine sulfate

We also refer to the Food and Drug Administration (FDA) final guidance entitled, "*Emergency Use Authorization of Medical Products and Related Authorities*" (January 2017).

On February 4, 2020, pursuant to Section 564 of the Federal Food, Drug & Cosmetic (FD&C) Act, the Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On March 27, 2020, on the basis of such determination, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to terms of any authorization issued under that section. On March 10, the Secretary also issued a Declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), effective February 4, 2020 to provide liability immunity for activities related to medical countermeasures against COVID-19.

Chloroquine phosphate and hydroxychloroquine sulfate are not FDA-approved for treatment of COVID-19. Some versions of chloroquine phosphate are approved by FDA for other indications—for suppressive treatment and acute attacks of certain strains of malaria and for the

treatment of extraintestinal amebiasis, but the chloroquine phosphate drug product to be covered by this EUA has not been FDA-approved. Several versions of hydroxychloroquine sulfate are approved by FDA for prophylaxis of and treatment of malaria, treatment of lupus erythematosus, and treatment of rheumatoid arthritis.

Based upon limited in-vitro and anecdotal data, chloroquine phosphate and hydroxychloroquine sulfate are currently recommended for treatment of hospitalized COVID-19 patients in several countries, and a number of national guidelines report incorporating recommendations regarding use of chloroquine phosphate or hydroxychloroquine sulfate in the setting of COVID-19.

This EUA request is for the following uses of chloroquine phosphate and hydroxychloroquine sulfate; product will be distributed by the Strategic National Stockpile:

chloroquine phosphate

that is not approved by FDA for any indication.

Administered by a healthcare provider under a valid prescription to treat the following populations:

- Adults and adolescent patients who weigh 50 kg or more and are hospitalized for COVID-19 infection;
- Patients for whom participation in a clinical trial is not available or feasible.

hydroxychloroquine sulfate

that is approved by FDA for other uses and accompanied by its FDA-approved labeling and authorized Fact Sheets.

Administered by a healthcare provider under a valid prescription to treat the following populations:

- Adult and adolescent patients who weigh 50 kg or more and are hospitalized for COVID-19 infection;
- Patients for whom participation in a clinical trial is not available or feasible.

The request for emergency use of chloroquine and hydroxychloroquine is based on collaborative, USG-interagency effort to rapidly respond to this continuously evolving public health emergency. The breadth and scope of the intended uses of chloroquine or hydroxychloroquine in this public health emergency will continue to be assessed by clinical experts from FDA, National Institutes of Health, BARDA, and Centers for Disease and Control Prevention.

On behalf of the USG interagency group responding to COVID-19, we appreciate FDA's assistance in this effort to combat COVID-19.

If you have any questions or comments regarding this submission, please contact Tremel Faison, Director (acting) of Regulatory and Quality Affairs at Tremel.Faison@hhs.gov or at (b)(6)

(b)(6)

Sincerely,

Rick Bright, Ph.D.

Director

Biomedical Advanced Research and Development Authority (BARDA)

Office of Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services (HHS)

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>; Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da <David.Boucher@hhs.gov>
Subject:	Re: FEMA TPs
Date:	2020/03/25 12:43:33
Priority:	Normal
Type:	Note

???? whoa, now all out of whack. What are these? CQ and HCQ?

From: "Ventura, Christy (OS/ASPR/BARDA) (CTR)" <Christy.Ventura@hhs.gov>
Date: Wednesday, March 25, 2020 at 12:41 PM
To: "Christopher. Houchens" <Christopher.Houchens@hhs.gov>, "Boucher, David (OS/ASPR/BARDA)" <David.Boucher@hhs.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: RE: FEMA TPs

113 (101 in US) enrolled in RCT.
28 (24 in US)

19 enrolled in Moderna

FOUO/PROCUREMENT SENSITIVE

--

Christy L. Ventura, Ph.D.
Tunnell Government Services
Executive Secretary, 2019-nCoV Medical Countermeasures Task Force
Project Manager, CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: 202-730-8643
Cell: (b)(6)

From: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>
Sent: Wednesday, March 25, 2020 12:36 PM
To: Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Subject: FW: FEMA TPs

Do we know?

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 12:35 PM
To: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: Re: FEMA TPs

Today's status of 2 NIH RCT for cq and HCQ?

From: "Christopher. Houchens" <Christopher.Houchens@hhs.gov>
Date: Wednesday, March 25, 2020 at 12:33 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Gretta Blatner <Gretta.Blatner@hhs.gov>, "Boucher, David (OS/ASPR/BARDA)" <David.Boucher@hhs.gov>
Cc: Robert Johnson <Robert.Johnson@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>
Subject: RE: FEMA TPs

This was sent last night and just sent a few minutes ago.

- Moderna vaccine clinical trial hit a critical milestone: 25/45 subjects vaccinated; first cohort is complete

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 12:31 PM
To: Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: Re: FEMA TPs

Please send me the Moderna TP from last night. Quickly, thanks

From: Gretta Blatner <Gretta.Blatner@hhs.gov>
Date: Wednesday, March 25, 2020 at 12:31 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Christopher. Houchens" <Christopher.Houchens@hhs.gov>, "Boucher, David (OS/ASPR/BARDA)" <David.Boucher@hhs.gov>

Cc: Robert Johnson <Robert.Johnson@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>
Subject: RE: FEMA TPs

If you are rewriting, please send for the calendar invite.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 12:30 PM
To: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: Re: FEMA TPs

Thanks, I will rewrite from what we had last night. We all need to talk this afternoon. This process needs help, quickly.

From: "Christopher. Houchens" <Christopher.Houchens@hhs.gov>
Date: Wednesday, March 25, 2020 at 12:28 PM
To: Gretta Blatner <Gretta.Blatner@hhs.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Boucher, David (OS/ASPR/BARDA)" <David.Boucher@hhs.gov>
Cc: Robert Johnson <Robert.Johnson@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>
Subject: RE: FEMA TPs

- • Convalescent plasma: FDA has created a process that allows physicians to obtain plasma from infected patients that have recovered and provide that plasma (which contains antibodies to fight the virus) to treat sick patients.
- • Moderna vaccine update: The first portion of the Moderna Phase 1 vaccine trial is complete and the second portion is underway.
- • Regeneron Treatment protocol update: Regeneron has rapidly enrolled 85 patients (with a target of 400 patients) at 27 US sites in its study of an antibody treatment

From: Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>
Sent: Wednesday, March 25, 2020 12:28 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: RE: FEMA TPs

Please send me these three final TPs and I will update email, text and calendar.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 12:26 PM
To: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: Re: FEMA TPs

Thanks, now can I get one clean list of TPs that only focus on items from the MCM TF? I need in calendar, email (as attachment) and text.

1. • Convalescent plasma
2. • Moderna vaccine update
3. • Regeneron Treatment protocol update

I go live in 6 minutes.

From: "Christopher. Houchens" <Christopher.Houchens@hhs.gov>
Date: Wednesday, March 25, 2020 at 12:24 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Gretta Blatner <Gretta.Blatner@hhs.gov>, "Boucher, David (OS/ASPR/BARDA)" <David.Boucher@hhs.gov>
Cc: Robert Johnson <Robert.Johnson@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>
Subject: RE: FEMA TPs

Moderna mRNA vaccine clinical trial hit a milestone with 25 of 45 subjects vaccinated

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 12:19 PM
To: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: Re: FEMA TPs

What happened to the bullet on the vaccine trial? Why did that get dropped?

From: "Christopher. Houchens" <Christopher.Houchens@hhs.gov>
Date: Wednesday, March 25, 2020 at 12:17 PM

To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Gretta Blatner <Gretta.Blatner@hhs.gov>, "Boucher, David (OS/ASPR/BARDA)" <David.Boucher@hhs.gov>
Cc: Robert Johnson <Robert.Johnson@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>
Subject: RE: FEMA TP's

The information came from Michael Mair at FDA. No WG is working on vents or masks. Plasma being worked by Sample Sharing and Therapeutics

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 12:12 PM
To: Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: FEMA TP's

Where did these TP's originate from in the TF WG? Which WG is working on the ventilators and gas machines? Which WG is working on the mask authorization? Which WG worked on the plasma? I want to know the person and agency who reported those TP's to the TF lead for today. Very quickly please. Thanks Rick

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC < Rick.Bright@hhs.gov >
Recipient:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch < Christy.Ventura@hhs.gov >; Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C < Christopher.Houchens@hhs.gov >; Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da < David.Boucher@hhs.gov >
Sent Date:	2020/03/25 12:43:33

From: Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
To: Seals, Jonathan (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userc998f792 <jonathan.seals@hhs.gov>
Subject: Fwd: URGENT - COVID-19 TREATMENT
Date: 2020/03/22 20:06:31
Priority: Normal
Type: Note

Begin forwarded message:

From: "(b)(6)"
Date: March 22, 2020 at 8:04:37 PM EDT
To: "(b)(6)"
Subject: URGENT - COVID-19 TREATMENT

COVID-19 EXPERIMENTAL TREATMENT

Please share with colleagues.

Photobiomodulation (PBM) may directly treat the respiratory effects of COVID-19.

PBM may also strengthen the immune system and lung functions.

These treatment protocols are attached.

There is strong evidence (attached to each protocol) for PBM treating conditions similar to COVID-19.

This is similar to the possible use of HydroxyChloroquine (with or without Azithromycin) for COVID-19.

<https://www.mediterranee-infection.com/hydroxychloroquine-and-azithromycin-as-a-treatment-of-covid-19/>

<https://www.ncbi.nlm.nih.gov/pubmed/32075365/>

<https://clinicaltrials.gov/ct2/show/NCT04261517>

[1] If you already have a PBM unit.

Please immediately treat patients who are at risk or exhibiting COVID-19 symptoms.

This could be done as an adjunct to prescribing Chloroquine/HydroxyChloroquine.

It is vitally important and timely to collect evidence of PBM's efficacy in treating COVID-19.

[2] If you do not have a PBM unit.

PBM units are available so that patients may be treated, and clinical evidence collected.

There are resources for collecting, analyzing, and disseminating clinical evidence.

<https://protect2.fireeye.com/url?k=9eff8aef-c2aa83fc-9effbbd0-0cc47adb5650-24f50827cc55706a&u=https://www.pcori.org/>

I can arrange for expert advice on collecting PBM/COVID-19 evidence.

Please let me know what support I may provide.

Best regards,

Scot

Hon. Scot Faulkner

PBM Foundation

(b)(6)

(b)(6)

<https://protect2.fireeye.com/url?k=901821f2-cc4d28e1-901810cd-0cc47adb5650-0bb307256008b6d6&u=http://www.congresspbm.com/>

Sender:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
Recipient:	Seals, Jonathan (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userc998f792 <jonathan.seals@hhs.gov>
Sent Date:	2020/03/22 20:06:30
Delivered Date:	2020/03/22 20:06:31



March 28, 2020

Stephen M. Hahn, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

**Re: Request for Emergency Use Authorization
Use of chloroquine phosphate and hydroxychloroquine sulfate for Treatment of
COVID-19**

Dear Dr. Hahn,

This request for Emergency Use Authorization (EUA) is being submitted for the following drugs to be distributed from the Strategic National Stockpile (SNS) to public health authorities for treatment of COVID-19 during the current public health emergency:

- chloroquine phosphate
- hydroxychloroquine sulfate

We also refer to the Food and Drug Administration (FDA) final guidance entitled, "*Emergency Use Authorization of Medical Products and Related Authorities*" (January 2017).

On February 4, 2020, pursuant to Section 564 of the Federal Food, Drug & Cosmetic (FD&C) Act, the Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On March 27, 2020, on the basis of such determination, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 outbreak, pursuant to section 564 of the FD&C Act, subject to terms of any authorization issued under that section. On March 10, the Secretary also issued a Declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), effective February 4, 2020 to provide liability immunity for activities related to medical countermeasures against COVID-19.

Chloroquine phosphate and hydroxychloroquine sulfate are not FDA-approved for treatment of COVID-19. Some versions of chloroquine phosphate are approved by FDA for other indications—for suppressive treatment and acute attacks of certain strains of malaria and for the

treatment of extraintestinal amebiasis, but the chloroquine phosphate drug product to be covered by this EUA has not been FDA-approved. Several versions of hydroxychloroquine sulfate are approved by FDA for prophylaxis of and treatment of malaria, treatment of lupus erythematosus, and treatment of rheumatoid arthritis.

Based upon limited in-vitro and anecdotal data, chloroquine phosphate and hydroxychloroquine sulfate are currently recommended for treatment of hospitalized COVID-19 patients in several countries, and a number of national guidelines report incorporating recommendations regarding use of chloroquine phosphate or hydroxychloroquine sulfate in the setting of COVID-19.

This EUA request is for the following uses of chloroquine phosphate and hydroxychloroquine sulfate; product will be distributed by the Strategic National Stockpile:

chloroquine phosphate

250 mg tablets supplied in blister packs containing ten 250 mg tablets that is not approved by FDA for any indication.

Administered by a healthcare provider under a valid prescription to treat the following populations:

- Adults and adolescent patients who weigh 50 kg or more and are hospitalized for COVID-19 infection;
- Patients for whom participation in a clinical trial is not available or feasible.

hydroxychloroquine sulfate

200 mg tablet that is approved by FDA for other uses and accompanied by its FDA-approved labeling and authorized Fact Sheets.

Administered by a healthcare provider under a valid prescription to treat the following populations:

- Adult and adolescent patients who weigh 50 kg or more and are hospitalized for COVID-19 infection;
- Patients for whom participation in a clinical trial is not available or feasible.

The request for emergency use of chloroquine and hydroxychloroquine is based on collaborative, USG-interagency effort to rapidly respond to this continuously evolving public health emergency. The breadth and scope of the intended uses of chloroquine or hydroxychloroquine in this public health emergency will continue to be assessed by clinical experts from FDA, National Institutes of Health, BARDA, and Centers for Disease and Control Prevention.

On behalf of the USG interagency group responding to COVID-19, we appreciate FDA's assistance in this effort to combat COVID-19.

If you have any questions or comments regarding this submission, please contact Tremel Faison, Director (acting) of Regulatory and Quality Affairs at Tremel.Faison@hhs.gov or at (b)(6)

(b)(6)

Sincerely,

Rick Bright, Ph.D.

Director

Biomedical Advanced Research and Development Authority (BARDA)

Office of Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services (HHS)

Director, Medical Countermeasures Program Support Services
Biomedical Advanced Research and Development Authority (BARDA)
Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: 202-260-1200
Mobile: (b)(6)
email: Linda.Lambert@hhs.gov

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<CQ and HCQ Emergency Use Request Letter request to FDA_final.pdf>
, attachments, and destroy any hard copies.

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.

<CQ and HCQ Emergency Use Request Letter request to FDA_final.pdf>

From: Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To: Brendan O'Grady <Brendan.OGrady@tevapharm.com>
CC: Sol Barer <Sol.Barer@tevapharm.com>
Subject: Re: Urgent: COVID-19 ACTG trial
Date: 2020/03/21 23:28:50
Priority: Normal
Type: Note

Hi Brendan,

THANK YOU. I know you are super busy and I am grateful for your consideration. I let NIH know that we are looking into it now. Tomorrow is fine. Really appreciate it.

Rick

On 3/21/20, 10:56 PM, "Brendan O'Grady" <Brendan.OGrady@tevapharm.com> wrote:

Hi Rick,

I am checking to see what quantities we have on hand still. I probably won't have an update until the morning, but will get back to you as soon as I have something to share.

Thanks,
Brendan

Sent from my iPhone

> On Mar 21, 2020, at 10:39 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

>

> Brendan and Sol,

>

> I hope that you are both well. It was very gratifying to see the news about generous donations that TEVA made to hospitals and the healthcare system. It truly warmed my heart and I know it will be helpful to many people. Thank you again for your leadership and compassion.

>

> Things become more tense here with each passing day. NY is struggling to keep up with the number of patients coming into hospitals across the state. We are searching for solutions 24 hours a day.

>

(b)(5); (b)(3); 42 U.S.C. § 247d-6b(d)

>

> Would TEVA be interested/able to consider donating tablets for this study? They will still need to find the azithromycin, but the hydroxychloroquine would be a huge help to get them started on the study.

>

> If you are interested, I can connect you directly to the NIH to arrange logistics and communications.

>

> Thank you both. God Bless you and stay safe.
>
> Rick
>
>

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Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Brendan O'Grady <Brendan.OGrady@tevapharm.com>; Sol Barer <Sol.Barer@tevapharm.com>
Sent Date:	2020/03/21 23:28:50

From:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
To:	Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>
Subject:	RE: Meeting Report: The potential role of chloroquine in the management of COVID 19
Date:	2020/03/17 19:44:17
Priority:	Normal
Type:	Note

Thank you

From: Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Sent: Tuesday, March 17, 2020 7:14 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: FW: Meeting Report: The potential role of chloroquine in the management of COVID 19

Begin forwarded message:

From: "SALAMI, Kolawole" <salamik@who.int>
Date: March 15, 2020 at 7:05:43 PM EDT
To: Yaseen Arabi <(b)(6)>, Pelfrene Eric <eric.pelfrene@ema.europa.eu>, Jeremy Farrar <J.Farrar@wellcome.ac.uk>, "Erlandson, Karl (OS/ASPR/BARDA)" <Karl.Erlandson@hhs.gov>, "Marston, Hilary (NIH/NIAID) [E]" <hilary.marston@nih.gov>, John Marshall <marshallj@smh.ca>, "sinabavari@comcast.net" <sinabavari@comcast.net>, <(b)(6)>, <(b)(6)>, "philip.E.coyne.30@nd.edu" <philip.E.coyne.30@nd.edu>, <(b)(6)>, <(b)(6)>, <(b)(6)>, <(b)(6)>, Alicia Rosello <Alicia.Rosello@lshtm.ac.uk>, John Marshall <John.Marshall@unityhealth.to>, "pcoyne@nd.edu" <pcoyne@nd.edu>, Julia Tree <Julia.Tree@phe.gov.uk>, William Dowling <william.dowling@cepi.net>, Claire Madelaine <(b)(6)>, "Beigel, John (NIH) [E]" <jbeigel@niaid.nih.gov>, "Thomas R. Fleming" <t Fleming@uw.edu>, "bruno.lina@univ-lyon.fr1" <bruno.lina@univ-lyon.fr1>, "Regine Lehnert (reginelehnert@gmx.de)" <reginelehnert@gmx.de>, "Farley, John (FDA/CDER)" <john.farley@fda.hhs.gov>, "Krause, Philip (FDA/CBER)" <Philip.Krause@fda.hhs.gov>, Monalisa Chatterji <MONALISA.CHATTERJI@gatesfoundation.org>, "fgh@virginia.edu" <fgh@virginia.edu>, "Beigel, John (NIH) [E]" <jbeigel@niaid.nih.gov>, "Michael Kaufmann (US - ADVS)" <michael.c.kaufmann@pwc.com>, "marco.cavaleri@ema.europa.eu" <marco.cavaleri@ema.europa.eu>, "STAHL, Matthias Mario" <stahlm@who.int>, David Vaughn <David.Vaughn@gatesfoundation.org>, Ken Duncan <Ken.Duncan@gatesfoundation.org>, "Higgs, Elizabeth (NIH/NIAID) [E]" <ehiggs@niaid.nih.gov>, "Walker, Robert (OS/ASPR/BARDA)" <Robert.Walker@hhs.gov>, "nickw@tropmedres.ac" <nickw@tropmedres.ac>
Cc: "TANG, Yi" <tangyi@who.int>, "HENA RESTREPO, Ana Maria" <henaorestrepa@who.int>, "PREZIOSI, Marie-pierre" <preziosim@who.int>, "SATHIYAMOORTHY, Vaseeharan" <moorthyv@who.int>, "DIAZ, Janet Victoria" <diazj@who.int>, "MUBANGIZI, Deusdedit" <mubangizid@who.int>, "COOKE, Emer" <cookee@who.int>, "COSTA, Alejandro Javier" <costaa@who.int>, "RIVEROS BALTA, Alina Ximena" <lauriex@who.int>, "GSELL, Pierre"

<gsellp@who.int>, "MIYAZAKI-KRAUSE, Ryoko" <miyazakikrauser@who.int>

Subject: Meeting Report: The potential role of chloroquine in the management of COVID 19

Dear All,

Please find below the key outputs of the consultation on the role of chloroquine in the treatment of COVID 19.

1. • Chloroquine has shown in vitro activity against some viruses, including chikungunya, dengue, and influenzas, but in vivo studies in animal models and randomized controlled trials (RCTs) in humans have been largely disappointing. Chloroquine pre-treatment (prophylaxis) was associated with an enhancement of viral replication and disease with chikungunya in NHPs due to delays in immune responses. Chloroquine treatment of chikungunya infection in humans did not affect viremia or clinical parameters during the acute stage of the disease. However, it reduced levels of C-reactive Protein (CRP) and specific cytokines.
2. • Chloroquine is reasonably active in vitro against SARS-CoV, MERS CoV, and SARS-CoV-2, the causative agent of COVID 19. In vitro studies have shown antiviral activity with an EC₅₀ of 1.0 -1.5 μ molar in Vero cells, but it is unclear how this translates into activity in respiratory epithelial cells and in vivo. BMGF has developed a model of chloroquine penetration into tissues for malaria. This model indicates that the concentration seen in the plasma is similar to that achieved in the lungs, and even when the concentration is below the IC₅₀ in the plasma, there could be the desired reasonable concentration in the lungs. This model is, however, not validated. Chloroquine also has the attraction of being relatively safe, well-tolerated, and cheap to produce. Hence, it is essential to explore further its possibilities as a therapeutic agent for COVID 19.
2. • The selective index of chloroquine and chloroquine diphosphate for SARS-CoV in African Green Monkey kidney cells was low, ranging from 5-13 for a laboratory strain and 2-20 fold for four clinical strains (Barnard, 2006) and this should be a cause for concern. Also, intraperitoneal delivery of chloroquine starting 4 hours before viral challenge did reduce lung titers of SARS-CoV.
3. • A recent in vitro study shows hydroxychloroquine to have greater antiviral activity against SARS CoV-2 in Vero cell lines than chloroquine. However, another recently published RCT study in China with hydroxychloroquine involving 30 COVID 19 patients with mild to moderate symptoms shows no significant reduction in time to clinical improvement or viral clearance in the hydroxychloroquine arm compared to the conventional therapy control group.
4. • An experiment in murine models with SARS-CoV (MA15) in BALB/c mice and MERS-CoV (in the Ad5/hDPP4 mouse model) at the University of Maryland School of Medicine,

involving the daily administration of 40ml/kg and 80 ml/kg dose of chloroquine resulted in protection from weight loss, lung pathology, and clinical symptoms but no reduction in viral titers. Further experiments to delineate the antiviral and immunomodulating effects are ongoing.

5. • A placebo-controlled trial of longer term chloroquine prophylaxis is currently being planned and could commence as early as 2 weeks. The study would involve 20,000 healthcare workers. For this study, CQ will be tested daily as used in the treatment of rheumatoid arthritis. A loading dose of 10 mg base/kg, followed by 100 mg daily will be taken for 3 months or until they are diagnosed with COVID-19. Higher doses would be considered for treatment i.e., 10mg/kg base, followed by 5mg/kg twice daily for seven days. BMGF is also developing a post-exposure prophylaxis clinical trial protocol for hydroxychloroquine that would be made available next week. No prophylactic trials involving chloroquine have been reported from in China.

Conclusions:

- It is expected that there would be some results from animal model studies involving chloroquine in the coming days. However, the decision about the global clinical trial protocol needs to be made ASAP, and WHO would appreciate the possibility of taking this decision from this panel discussion if possible. WHO to contact colleagues from NIH and animal model group to determine the type of animal studies ongoing and the dose of chloroquine being used.
- Both post-exposure prophylaxis and longer term prophylactic use of hydroxychloroquine & chloroquine should be considered.
- BMGF and other global health partners are developing protocols for this prophylactic use. Since WHO also has a prophylaxis protocol, and all must work in unison and avoid duplicate efforts. WHO has proposed a TC involving partners working on prophylaxis to have a common approach. The date and time will be communicated soon by WHO.
- There are more than 20 treatment studies ongoing in China utilizing chloroquine, and it would be better to get these data, provided studies design allows interpretation of data, rather than wait for animal studies from the NIH. WHO is engaging with Chinese colleagues at the mission in Geneva and have received assurances of improved collaboration; however, no data has been shared regarding the chloroquine studies. It should be noted that the RCTs in China are small and may not be powered enough to reach the conclusions that are needed.

- • Animal studies could be useful to conclude that there are no disease enhancement signals, but making firm conclusions about clinical efficacy is uncertain. It should be possible to assess antiviral efficacy in animal models, but the immunomodulatory effects of chloroquine will depend on the pathogenesis of the model.. Current limited evidence from preclinical studies with coronaviruses would not suggest a scenario similar to what was observed with chikungunya. Moreover, it would not be expected that the data from the ongoing animal studies would provide definitive findings before proceeding to clinical evaluation. As the decision should be taken rapidly based on available data, it has been agreed that there is equipoise for the inclusion of chloroquine in clinical trials and to proceed with the evaluation of chloroquine in COVID 19 patients.

Regards,

Kolawole Salami MD MPH M.Sc

Technical Officer,

HQ/EPS Emerging Tech, Research Prioritisation &Support

World Health Organization

Geneva, Switzerland

Tel: +41227915521

Email: salamik@who.int

Sender:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
Recipient:	Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>
Sent Date:	2020/03/17 19:44:17

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>
Subject:	Re: API for hcq
Date:	2020/04/09 08:10:08
Priority:	Normal
Type:	Note

Not at all. Please do. Do you have contact info? Brendan O'Grady is where I would suggest starting. Brendan O'Grady <Brendan.OGrady@tevapharm.com>

From: Hilary Marston <hilary.marston@nih.gov>
Date: Thursday, April 9, 2020 at 8:02 AM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: API for hcq

Do you mind if I reach out to Teva Pharma for 5kg of API to use for inhaled hcq? We have some data indicating it might work better.

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>
Sent Date:	2020/04/09 08:10:18
Delivered Date:	2020/04/09 08:10:08

Withheld pursuant to exemption

(b)(3):41 U.S.C. § 4702

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(3):41 U.S.C. § 4702

of the Freedom of Information Act

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(b)(3):41 U.S.C. § 4702

of the Freedom of Information Act

Purpose

Immediate Emergency COVID 19 Response

The large majority of both active pharmaceutical ingredients and finished drug products for American medicines are created abroad, largely in India and China. In response to the COVID pandemic, India has announced restrictions on the exportation of three antibiotics: acyclovir, metronidazole, and erythromycin.

Although the effect of this action has not yet been felt, it is likely that there will be critical shortages of these drugs in the coming months due to the Indian export restriction. Metronidazole and erythromycin are already considered to be in shortage by the FDA. Further export restriction will only further exacerbate the ability of Americans to gain access to these medicines.

We propose to rapidly develop US sources of active pharmaceutical ingredients of these drug products before worsening shortages become apparent. We will activate currently underutilized capacity in existing US API manufacturing facilities and finished product facilities. We estimate that this should be feasible in a timeframe of approximately 8 weeks.

Severe National Security Weakness

India has blocked exports of both finished drug product and active pharmaceutical ingredient for hydroxychloroquine. As the primary source of American hydroxychloroquine, this will effectively result in a severe shortage in the immediate future. The Indian export ban will dramatically affect the lives of American's with lupus and rheumatoid arthritis, and may cost thousands of Americans lives if the drug continues to show efficacy against COVID 19.

This is a case study that brings into sharp relief the enormous national security implications of having outsourced the large majority of the pharmaceutical supply chain. Insulin is not currently manufactured in the United States. Imagine a scenario where imports of insulin products suddenly halt. Millions of Americans could lose their lives in a matter of weeks.

(b)(3)-41 U.S.C. § 4702

We herein propose a strategy to rapidly reestablish the domestic American pharmaceutical supply chain. Through advanced manufacturing techniques, dynamic resource allocation, and business model innovation, we aim to bring products to market at a dramatically lower cost than existing pharmaceutical manufacturers.

Constant Shortages of Essential Medicines

At the time of writing, the FDA lists over 140 drugs which are currently in shortage within the United States. Over 40 of these medicines are considered “essential” by the World Health Organization.

It is not uncommon for patients in the United States to die for lack of relatively uncomplicated essential medicines. Several pediatric chemotherapy drugs are currently in shortage, and clinical studies have shown increases in morbidity and mortality amongst children with cancer as a consequence. Postponing surgeries and other medical procedures due to a lack of relatively cheap, simple medicines is an everyday occurrence.

We will propose a mechanism by which existing US pharmaceutical infrastructure can be rapidly reactivated to address ongoing shortages of essential medicines.

Broken Pharmaceutical Value Chain Leading to Soaring Costs

The pharmaceutical supply chain includes a wide variety of intermediary players which artificially increase the costs of medicines for American consumers, payers, and the US government. Entities such as API brokers, pharmaceutical wholesalers, and pharmaceutical benefit managers effectively add a tax onto the cost of pharmaceutical products.

In order to make US domestic pharmaceutical production financially viable, we will propose a strategy of radical disintermediation and vertical integration. By managing the supply chain from raw ingredients and intermediates manufacturing all the way through dispensing medications directly to patients, we will radically decrease the cost of medications to patients and the health care system as a whole while relocating manufacturing to the United States.

Solution

Combining API Manufacturing Resources of Multiple Domestic Manufacturers

There remain over 200 active pharmaceutical ingredient manufacturing facilities in the United States. The large majority either have excess capacity that can be quickly repurposed or abandoned capacity that can be revitalized at limited expense.

Combined, the unutilized capacity among existing manufacturers would create the largest domestic pharmaceutical manufacturer in the United States.

We propose contracting with multiple existing manufacturers simultaneously to bring underutilized American manufacturing capacity back online. Through this mechanism, without waiting for new manufacturing sites to be built, staffed, and qualified, America can rapidly rebuild its pharmaceutical manufacturing base.

(b)(3):41 U.S.C. § 4702

Disintermediation

(b)(3):41 U.S.C. § 4702

At present, the pharmaceutical supply chain is extremely complicated and involves many different entities interacting in synchronized fashion in order for a single medicine to reach a patient. These include 1) a raw ingredient / intermediate ingredient manufacturer, 2) an active

pharmaceutical ingredient manufacturer, 3) an API broker, 4) a finished product manufacturer, 5) a drug wholesaler, 6) a third-party logistics / warehouse coordinator, 7) a pharmaceutical benefit manager, and 8) a pharmacy.

(b)(3):41 U.S.C. § 4702

Radical Price Transparency

(b)(3):41 U.S.C. § 4702

Phase 1 – Ultra-rapid response to COVID related shortage

(b)(3):41 U.S.C. § 4702

Phase 2 – Stopping shortages of essential medicines for Americans

At present, there are over 40 medicines which are considered in shortage in the United States which have been deemed essential by the World Health Organization. These medicines are almost entirely produced overseas, leaving the United States extremely vulnerable to supply disruption.

(b)(3):41 U.S.C. § 4702

Phase 3 – Constructing New Capacity and Infrastructure

At present, there is no biologics manufacturing facility within the United States capable of manufacturing insulin drug substance at scale. This is an extraordinary vulnerability, risking the lives of millions of Americans to foreign interests.

After utilizing existing US manufacturing infrastructure to its fullest extent, we would propose the establishment of new API and finished drug product manufacturing sites. This may be accomplished through refurbishment of previously shuttered facility, or through the construction of new facilities.

(b)(3):41 U.S.C. § 4702

Withheld pursuant to exemption

(b)(3):41 U.S.C. § 4702

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(3):41 U.S.C. § 4702

of the Freedom of Information Act

Team



**Alexander Oshmyansky,
MD, PhD**
Founder, CEO

Alex Oshmyansky is a board-certified diagnostic radiologist and serial entrepreneur. He holds a medical degree from Duke University and a PhD (*DPhil. Oxon.*) in mathematics from Oxford University where he was a Marshall Scholar. Alex completed residency and fellowship training at the Harvard Medical School, Brigham and Women's Hospital, and Johns Hopkins Hospital. He also holds an undergraduate degree in biochemistry from the University of Colorado at Boulder where he graduated at the age of 18. Alex is the previous found of medical device startup Altitude Medical, Inc.



**Heidi Nelson-Keherly,
PhD**
Project Director
Executive Vice President,
Preclinical and CMC

Heidi Nelson-Keherly is a 20+ year veteran of working with small and mid-size pharmaceutical and biotech companies to develop their drug programs in support of IND submission. She has managed over 300 drug development programs spanning preclinical lead optimization, pharmacokinetic and safety studies, bioanalysis, process scale up and development, as well as CMC and GMP. During her career, she has been involved with over 1,000 drug development programs. In addition, Heidi was responsible for several multi-therapeutic clinical research sites that participated in over 80 Phase I-IV clinical trials. Heidi holds a PhD in Molecular Biology from the University of Wisconsin.



Scott Silaika, MBA

Project Manager
Vice President, Drug
Development Services

Scott Silaika has over 20 years of commercial leadership experience in drug development, from discovery through commercialization, for both small and large molecules, including medical device and drug combinations. Scott has deep subject matter expertise in the contract development and manufacturing (CDMO) industry, including new chemical entities, 505(b)(2) and generic drug products. Prior to joining, Mr. Silaika held senior commercial development positions at Avara, AbbVie, Aesica, Ricerca and AMRI. He earned his undergraduate degree in Chemical Engineering from Rensselaer Polytechnic Institute and his MBA from the State University of Albany.



Ken Rose

FDA Regulatory and QA/QC
Director, Drug Development and
QA/QC

Ken Rose serves as the Director of Preclinical Development and is responsible for the successful execution, oversight, and completion of preclinical development projects. Ken has over 35 years of experience in the pharmaceutical, agricultural and specialty chemical industries. His experience consists of a broad range of operational, technical and support services responsibilities. Ken is an analytical chemist and has more than 20 years of drug development lab experience as well as more than 10 years' experience managing entire drug development programs, including CMC, GMP, pharmacokinetic studies, safety toxicology studies, bioanalytical methods development and sample analysis to support IND, NDA and BLA submissions.



Dan Rossignol, PhD
Senior Director Regulatory and
Clinical Affairs

Dan is Senior Director, Regulatory and Clinical Services, who brings over 30 year of FDA and EMEA regulatory and clinical drug discovery and development experience. Prior to joining, Dan held Senior Executive management positions at Taisho Pharmaceuticals R&D, Eisai, E.I. Dupont de Nemours, Axovant, PhRMetrix, and Arvelle. Dan was responsible for FDA and EMEA communications, including IND, NDA, ANDA, and BLA submissions and oversaw the clinical and biostatistical services. Dan has received numerous awards and recognitions. In addition, Dan has over 70 issued patents and CIP applications that focus on inflammation and related topics. As a



Joan Breslin, PhD
Regulatory Medical Writer

Joan Breslin is a molecular biologist with over 15 years of academic research experience in a variety of disciplines including cell biology, protein biochemistry, microscopy/morphometric analysis, and statistics. She has authored IND, CTA, NDA, BLA and Orphan Drug Designation submissions. In addition, she has written original articles published in peer-reviewed journals, composed portions of numerous successfully funded grant proposals, and is experienced in editing manuscripts prior to submission. Joan earned her PhD in Anatomy and Cell Biology at the University of Cincinnati College of Medicine and completed her postdoctoral work as a Fellow in Pulmonary Biology at Cincinnati Children's Hospital. Her undergraduate studies at Dickinson College provided rigorous training in composition and expository writing and fostered a lifelong affinity for the written word.



Kirtan Patel, MS

Associate Business Manager

Kirtan Patel is responsible for the project management and project support. Prior to joining, Kirtan served as a Program Director at National Pike Health Center where he helped implement a high-quality management system and fast-track business development by establishing strong partnerships in the local community. Afterwards, Kirtan joined Alight Solutions as an Associate Consultant where he provided an in-depth knowledge on public and private healthcare payers. Kirtan has received his first master's degree in Healthcare Leadership & Management from University of Texas with a certification in Health Information-Technology. In addition, Kirtan is currently pursuing his Master of Business Administration. With a strong leadership and educational background, Kirtan can provide meaningful insight to our clients.



Jim Sergi

Chief Operating Officer

Prior to this role, Jim was the founder and managing partner of Bay Tower Capital, a life sciences merchant bank and the founder and CEO of ProED Communications, a healthcare services and drug development company. Jim has been responsible for over 85 successful NDA/BLA approvals and over 250 medical device approvals. His academic and medical experience includes Director of Experimental Therapeutics at the Cleveland Clinic Cancer Center, Associate Professor of Medical-Surgical Nursing at the Case Western Reserve University and Lecturer for Oncology at Cleveland State University. He has authored over 50 peer reviewed publications and has numerous issued patents. Jim serves as a scientific reviewer for the NIH SBIR/STTR Commercial Readiness Program, as well as a mentor to the NIH/NHLBI and the NIH Larta FeedForward programs. He also serves as a scientific advisor and board member to numerous nonprofits, private equity and venture backed investment firms, including Defta Partners. Jim has an undergraduate degree in nursing from Edinboro University of Pennsylvania and graduate degrees from the University of Akron and Cleveland State University.



Diane Markesich, PhD

Director Preclinical Drug
Discovery & Development

Dr. Markesich has 20 years of experience in pharmaceutical drug discovery and development, encompassing proof of concept and lead optimization, through Phase I human clinical trials. Her work has focused on helping start-up companies meet the demands of the early stages of the commercialization process, through outsourcing of preclinical research and CMC operations and obtaining non-dilutive funding from government and private investment sources. As an industry scientist, she has led target discovery and validation, pharmacodynamics, CMC and IND-enabling programs. Her expertise and broad knowledge base include gastroenterology, immunology, oncology, analgesics and inhaled drug development. Prior to joining, Diane held senior leadership positions with Pulmotect and Lexicon Pharmaceuticals. Dr. Markesich received her PhD in Biochemistry and Cell Biology from Rice University.

Withheld pursuant to exemption

(b)(3):41 U.S.C. § 4702

of the Freedom of Information Act

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of the Freedom of Information Act

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Appendix B: WHO Essential Drugs Currently in Shortage in the US

Essential Drugs in Shortage

Atropine injection
Bupivacaine injection
Lidocaine injection
Calcium Chloride injection
Deferoxamine injection
Dexamethasone injection
Dopamine Injection
Epinephrine Injection
Erythromycin injection
Imipenem and cilastatin injection
Metronidazole Injection
Ondansetron injection
Oxytocin Injection
Potassium chloride injection
Ranitidine injection
Sodium Bicarbonate injection
Sodium chloride injection
Asparaginase injection
Ceftazidime + avibactam injection
Cefazolin Injection
Cefotaxime injection
Diazepam injection
Latanoprost ophthalmic solution
Lorazepam injection
Methotrexate injection
Timolol ophthalmic
Erythromycin ointment
Haloperidol Tablets
Methyldopa tablets
Nystatin suspension
Ranitidine tablets

From: Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>

To: Angelastro, Michael (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=583e910528e7473d9dcdfce9d1a80b83-Angelastro, <Michael.Angelastro@hhs.gov>

Subject: FW: Chloroquine & Hydroxychloroquine Conference Call w/ HHS

Date: 2020/03/27 15:46:36

Priority: Normal

Type: Note

You're on stage buddy. Lead us to a new tomorrow.

From: Joanna Miller <(b)(6)>

Date: Friday, March 27, 2020 at 3:45 PM

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

Cc: (b)(6), (b)(6), "Bartrum, John (OS/ASPR) (CTR)" <John.Bartrum@hhs.gov>, "Hayes, Jonathan (OS/ASPR/IO)" <Jonathan.Hayes@hhs.gov>, (b)(6), Joseph Hamel <Joseph.Hamel@hhs.gov>, Elizabeth Higgs <ehiggs@niaid.nih.gov>

Subject: Re: Chloroquine & Hydroxychloroquine Conference Call w/ HHS

Of course!! Feel free to add him

Sent from my iPhone

On Mar 27, 2020, at 3:05 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>wrote:

Joanna, Thank you for the invitation. Could you please consider inviting Mike Angelastro (Michael.angelastro@hhs.gov) to the meeting? He is the BARDA lead investing in and building out domestic manufacturing capabilities and capacity for drugs, API, etc. He is the braintrust of the future build out and he would be much better than me at explaining this areas for the 4th bullet onj your list.

I am happy to forward the invite to him if you approve. Thanks, Rick

From: Joanna Miller <(b)(6)>

Date: Friday, March 27, 2020 at 2:46 PM

To: (b)(6), <John.Bartrum@hhs.gov>, "John.Bartrum@hhs.gov", <Jonathan.Hayes@hhs.gov>, <Jonathan.Hayes@hhs.gov>, (b)(6), Joseph Hamel <Joseph.Hamel@hhs.gov>, Elizabeth Higgs <EHiggs@niaid.nih.gov>, "Bright, Rick

(OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>

Subject: Chloroquine &Hydroxychloroquine Conference Call w/ HHS

ALL,

Having to push until 4 pm due to a POTUS assignment. So sorry! Let us know if you are able to still dial in.

Participant Dial-In: (b)(6)

Participant Code: (b)(6)

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Angelaastro, Michael (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=583e910528e7473d9dcdfce9d1a80b83-Angelaastro, <Michael.Angelaastro@hhs.gov>
Sent Date:	2020/03/27 15:46:36

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>
CC:	MCM Task Force /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49010f8ab3ab4aed868a72c707c08d08-MCM Task Fo <MCMTaskForce@hhs.gov>
Subject:	Re: MCM Task Force update for 4/8/2020
Date:	2020/04/07 18:02:45
Priority:	Normal
Type:	Note

Great work, as always team. See some thoughts below. Rick

From: "Ventura, Christy (OS/ASPR/BARDA) (CTR)" <Christy.Ventura@hhs.gov>
Date: Tuesday, April 7, 2020 at 5:49 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>
Cc: MCM Task Force <MCMTaskForce@hhs.gov>
Subject: MCM Task Force update for 4/8/2020

Rick, Gary, Linda,

See below for tomorrow's updates for the MCM Task Force. Another item that we will not be reporting out tomorrow but that we are sharing for situational awareness is that NIAID is working with Eli Lilly and Gilead to add baricitinib to the ACTT. Arms are expected to be remdesivir, baricitinib, remdesivir + baricitinib, and placebo, all with SOC.

Here are the updates that we will report tomorrow.

Talking Points for 1200 and 1700 SLBs and 1230 VTC

Accomplishments

- USG funded clinical studies
- Therapeutics: 4 (+1) Phase 3 trials (2 BARDA, 1 NIAID) says 4, but lists 2 BARDA and 1 NIAID, where is the fourth?
- Vaccines: 2 Phase 1 trials (1 DoD, 1 NIAID)
- Observational Natural History Study: 1 DoD

- ACTT Clinical trial to test remdesivir for treatment of COVID-19: 526 (+29) new patients at 58 (+1) sites, including 5 military treatment facilities, in last 24 hrs (target = 700)
- ORCHID Clinical trial to test hydroxychloroquine in COVID-19 patients: 10 patients enrolled (target = 510)
- Two clinical trials to test antibody therapeutics continue Please do not stop reporting the enrollment of these, it is important to find some way to show progress being made on these.
- Emergency Use Authorizations granted by FDA: 28 (+1) molecular diagnostic tests, 5 (+1) laboratory-developed tests, 1 antibody test, and 2 repurposed treatments (chloroquine, hydroxychloroquine)
Please include an update on the drugs pushed out from SNS for the CQ, HCQ EUA.
- 1964 (+42) market research submissions and 185 (+7) CoronaWatch meetings held

Please let us know if you have any concerns.

Thanks
Christy

FOUO/PROCUREMENT SENSITIVE

--

Christy L. Ventura, Ph.D.
Tunnell Government Services
Executive Secretary, SARS-CoV-2 Medical Countermeasures Task Force
Project Manager, CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: 202-730-8643
Cell: (b)(6)

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>; MCM Task Force /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49010f8ab3ab4aed868a72c707c08d08-MCM Task Fo <MCMTaskForce@hhs.gov>
Sent Date:	2020/04/07 18:02:46
Delivered Date:	2020/04/07 18:02:45

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da <David.Boucher@hhs.gov>; MCM Task Force /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49010f8ab3ab4aed868a72c707c08d08-MCM Task Fo <MCMTaskForce@hhs.gov>
CC:	Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7bd764440b44b06af644cdcd22e42d6-Oshansky, C <Christine.Oshansky@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>
Subject:	Re: HCQ CQ clinical studies
Date:	2020/04/02 17:43:57
Priority:	Normal
Type:	Note

awesome

From: David Boucher <David.Boucher@hhs.gov>
Date: Thursday, April 2, 2020 at 5:36 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, MCM Task Force <MCMTaskForce@hhs.gov>
Cc: "Christopher. Houchens" <Christopher.Houchens@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Gretta Blatner <Gretta.Blatner@hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>
Subject: RE: HCQ CQ clinical studies

All the credit goes to Karen Martins (I'll take credit for hiring her though), Bob Walker and Libby Higgs from NIAID. We have a similar slide for the daily S1 briefing. Chris has that right now and I believe you'll see it soon.

*** FOUO – Procurement Sensitive ***

David Boucher, PhD
Chief, Antivirals & Antitoxins
HHS/ASPR/BARDA/CBRN
Cell: (b)(6)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Thursday, April 2, 2020 5:11 PM
To: Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>; MCM Task Force <MCMTaskForce@hhs.gov>
Cc: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Subject: Re: HCQ CQ clinical studies

THIS IS AMAZING! I am grateful for whomever pulled this together. I hope that the CT WG has someone beyond BARDA tracking and updating the information. This is truly a beautiful format that I think works well and will answer many of the data requests we are getting.

We also need something similar for all USG trials ongoing/planned for therapeutics and vaccines. It is a simple format that many can follow and track progress.

Make sure all slides are marked FOUO, Confidential

Please THANK whomever put the elbow grease into this format. Very nice, Rick

From: David Boucher <David.Boucher@hhs.gov>
Date: Thursday, April 2, 2020 at 4:58 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, MCM Task Force <MCMTaskForce@hhs.gov>
Cc: "Christopher. Houchens" <Christopher.Houchens@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Gretta Blatner <Gretta.Blatner@hhs.gov>
Subject: RE: HCQ CQ clinical studies

Rick, I've attached the following two slide decks:

- HCQ and CQ Trials – This compiles HCQ and CQ studies from the COVID-19 clinical trials list that Karen Martins curates as part of her time helping out Bob Walker's Clinical Trials WG. One notable exception in this list is the study that is being assembled by NIAID – the "ACTG" or possibly "DAIDS" study, I believe. From what I gather, they are still in the protocol writing phase of that so not much to report as I understand it. I'll see if I can collect more info on that in the coming days.

- HCQ and CQ Trials Backup Info – There is a tremendous wealth of info in here. I considered distilling it down and incorporating it into the first slide deck, but there's so much good info in these I thought it would be useful to you to have it unfiltered. All thanks goes to Libby Higgs and her group at NIAID who assembled this.

Please let me know if there's any other info that would be helpful. With regard to the studies that are not supported by agencies within the MCM Task Force, there's a lack of visibility here that we probably can't solve in a day, but we can always try to track down info as we see these getting off the ground.

*** FOUO – Procurement Sensitive ***

David Boucher, PhD
Chief, Antivirals & Antitoxins
HHS/ASPR/BARDA/CBRN
Cell: (h)(6)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Thursday, April 2, 2020 12:23 PM
To: MCM Task Force <MCMTaskForce@hhs.gov>
Cc: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>
Subject: HCQ CQ clinical studies

MCM TF:

By COB today, I would like a summary table of ongoing and planned RCT for Chloroquine and hydroxychloroquine +/- other drugs. Both by USG sponsored entities and not sponsored by USG entities. Including for example, BMGF, Univ Minn, WHO global trial, USAID, NIH-DAIDS, PCORI, NYC, etc. Need to know studies, sites, start date, current enrollment (where possible), estimated timeline for any data analysis.

Thanks Rick

Sender:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC < Rick.Bright@hhs.gov >
Recipient:	Boucher, David (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41293945651d475fa0413062a819aac5-Boucher, Da < David.Boucher@hhs.gov >; MCM Task Force /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49010f8ab3ab4aed868a72c707c08d08-MCM Task Fo < MCMTaskForce@hhs.gov >; Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C < Christopher.Houchens@hhs.gov >; Oshansky, Christine (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7bd764440b44b06af644cdcd22e42d6-Oshansky, C < Christine.Oshansky@hhs.gov >;

Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro
<Robert.Johnson@hhs.gov>;
Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga
<Gary.Disbrow@hhs.gov>;
Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr
<Gretta.Blatner@hhs.gov>;
Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li
<Linda.Lambert@hhs.gov>

Sent Date: 2020/04/02 17:43:57

From:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
To:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>
CC:	Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>; MCM Task Force /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49010f8ab3ab4aed868a72c707c08d08-MCM Task Fo <MCMTaskForce@hhs.gov>
Subject:	Re: MCM Task Force update for 4/8/2020
Date:	2020/04/07 22:26:51
Priority:	Normal
Type:	Note

Christy. I caused confusion and Chris corrected me. Please do not report the regen antibody numbers. My mistake. Sorry. Thanks. Rick.

On Apr 7, 2020, at 9:44 PM, Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov> wrote:

All,

Updated talking points are below. I'm awaiting confirmation from Tremel on the number of actual requests vs shipments from the SNS.

Accomplishments

- • USG funded clinical studies
 - • Therapeutics: 4 (+1) Phase 3 trials (2 BARDA, 1 NIAID, 1 NHLBI)
 - • Vaccines: 2 Phase 1 trials (1 DoD, 1 NIAID)
 - • Observational Natural History Study: 1 DoD
- ACTT Clinical trial to test remdesivir for treatment of COVID-19: 526 (+29) new patients at 58 (+1) sites, including 5 military treatment facilities, in last 24 hrs (target = 700)
- ORCHID Clinical trial to test hydroxychloroquine in COVID-19 patients: 10 patients enrolled (target = 510)
- First antibody therapeutic trial: 916 (+86) new patients dosed at 53 (+2) sites
- Second antibody therapeutic trial initiated: 9 (+7) new patients dosed, 11 (+9) sites activated
- Requests for chloroquine/hydroxychloroquine from the SNS
 - 2 clinical trial requests received, 1 fulfilled

- 11 EUA requests received and 2 shipped
- Emergency Use Authorizations granted by FDA: 28 (+1) molecular diagnostic tests, 5 (+1) laboratory-developed tests, 1 antibody test, and 2 repurposed treatments (chloroquine, hydroxychloroquine)
- 1964 (+42) market research submissions and 185 (+7) CoronaWatch meetings held

Christy

FOUO

--

Christy L. Ventura, Ph.D.
Tunnell Government Services
Executive Secretary, SARS-CoV-2 Medical Countermeasures Task Force
Project Manager, CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: 202-730-8643
Cell: (b)(6)

From: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>
Sent: Tuesday, April 7, 2020 6:19 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: MCM Task Force <MCMTaskForce@hhs.gov>
Subject: RE: MCM Task Force update for 4/8/2020

Rick – Thank you for your comments. Regarding your direction to keep reporting out numbers on the Regeneron and Genentech mAb therapeutic studies, I mentioned yesterday that both of those companies have expressed concerns about reporting those numbers (please see attached and below). Please let me know if you have any thoughts regarding the below and how to proceed. Thanks, Chris

There continues to be concern from companies about reporting out any data that is not public even if it is non-attributional as the information could still identify the company (at which point it becomes a notifiable event if it is publicly-traded company). For example, it is publically known that we are supporting two IL-6R mAb therapy studies - one started over a month ago and one stated just last week and reporting higher enrollment numbers will identify the first while lower numbers will identify the second. If the numbers for either do not change for a period of time, and if this information gets released (I know that the Supply Chain Task Force numbers reported each day wind up in the WP the next day), then other stakeholders (investors, companies, regulators, etc) will ask why. However, there is a need to show progress on the MCM TF to our stakeholders and leadership during the daily VTC calls. So my recommendation is that the MCM report out on the following:

1. Total MCM awards and new awards, broken down by TX, VX, and DX
2. Total number of clinical studies and new initiated studies broken down by TX, VX, and DX AND Phase 1, 2, 3
3. Topline clinical study results when publically available.
4. EUAs and approvals by FDA

5. Total number of proposals submitted to portal and TechWatch meetings hosted
6. Any other data that BARDA and our partners feel would demonstrate progress
7. And we will continue to report out numbers for those companies that are OK with us doing so.

Christopher Houchens, PhD
Director (Acting) Division of CBRN Countermeasures
Biomedical Advanced Research and Development Authority (BARDA)
Office of Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services (DHHS)
Office: 202-205-3633
BB: (b)(6)
Christopher.houchens@hhs.gov

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Tuesday, April 7, 2020 6:03 PM
To: Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: MCM Task Force <MCMTaskForce@hhs.gov>
Subject: Re: MCM Task Force update for 4/8/2020

Great work, as always team. See some thoughts below. Rick

From: "Ventura, Christy (OS/ASPR/BARDA) (CTR)" <Christy.Ventura@hhs.gov>
Date: Tuesday, April 7, 2020 at 5:49 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>
Cc: MCM Task Force <MCMTaskForce@hhs.gov>
Subject: MCM Task Force update for 4/8/2020

Rick, Gary, Linda,

See below for tomorrow's updates for the MCM Task Force. Another item that we will not be reporting out tomorrow but that we are sharing for situational awareness is that NIAID is working with Eli Lilly and Gilead to add baricitinib to the ACTT. Arms are expected to be remdesivir, baricitinib, remdesivir + baricitinib, and placebo, all with SOC.

Here are the updates that we will report tomorrow.

Talking Points for 1200 and 1700 SLBs and 1230 VTC

Accomplishments

- USG funded clinical studies
- Therapeutics: 4 (+1) Phase 3 trials (2 BARDA, 1 NIAID) says 4, but lists 2 BARDA and 1 NIAID, where is the fourth?
- Vaccines: 2 Phase 1 trials (1 DoD, 1 NIAID)
- Observational Natural History Study: 1 DoD
- ACTT Clinical trial to test remdesivir for treatment of COVID-19: 526 (+29) new patients at 58 (+1) sites, including 5 military treatment facilities, in last 24 hrs (target = 700)
- ORCHID Clinical trial to test hydroxychloroquine in COVID-19 patients: 10 patients enrolled (target = 510)
- Two clinical trials to test antibody therapeutics continue Please do not stop reporting the enrollment of these, it is important to find some way to show progress being made on these.
- Emergency Use Authorizations granted by FDA: 28 (+1) molecular diagnostic tests, 5 (+1) laboratory-developed tests, 1 antibody test, and 2 repurposed treatments (chloroquine, hydroxychloroquine) Please include an update on the drugs pushed out from SNS for the CQ, HCQ EUA.
- 1964 (+42) market research submissions and 185 (+7) CoronaWatch meetings held

Please let us know if you have any concerns.

Thanks
Christy

FOUO/PROCUREMENT SENSITIVE

--

Christy L. Ventura, Ph.D.
Tunnell Government Services
Executive Secretary, SARS-CoV-2 Medical Countermeasures Task Force
Project Manager, CBRN/BARDA/ASPR/HHS
O'Neill 23L05
Office: 202-730-8643
Cell: (b)(6)

Sender:	Bright, Rick (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC>
	Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>;
	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>;
Recipient:	Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>;
	MCM Task Force /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49010f8ab3ab4aed868a72c707c08d08-MCM Task Fo <MCMTaskForce@hhs.gov>;
	Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>
Sent Date:	2020/04/07 22:26:51

From:	Bright, Rick (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
To:	Hamel, Joseph (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose <Joseph.Hamel@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>
CC:	Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Adams, Peter (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d68d0d59aeb425cbb0ea4a46a2b9365-Adams, Pete <Peter.Adams@hhs.gov>
Subject:	Re: Chloroquine - latest as of 3:00 EDT
Date:	2020/03/20 08:57:47
Priority:	Normal
Type:	Note

Joe, Peter,

Amazing work and great teamwork! Thank you both.

Joe = Awesome Chloroquine King!

From: Joseph Hamel <Joseph.Hamel@hhs.gov>
Date: Friday, March 20, 2020 at 8:10 AM
To: Gary Disbrow <Gary.Disbrow@hhs.gov>
Cc: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Bryan Shuy <Bryan.Shuy@hhs.gov>, "Adams, Peter (OS/ASPR/BARDA)" <Peter.Adams@hhs.gov>
Subject: Re: Chloroquine - latest as of 3:00 EDT

Team effort. Peter was a rockstar as well. One more update coming this morning.

Strategic Innovation and Emerging Technology Manager
Assistant Secretary for Preparedness and Response
Office: [202-969-3852](tel:202-969-3852)
Cell: (b)(6)

On Mar 20, 2020, at 4:11 AM, Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov> wrote:

Nice job, Joe!!

Gary L. Disbrow Ph.D.

Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: 202-260-0899
Mobile: (b)(6)
Fax: 202-205-0873
email: Gary.Disbrow@HHS.gov

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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: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Sent: Thursday, March 19, 2020 3:00 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>
Subject: Chloroquine - latest as of 3:00 EDT

Latest figures enclosed

<<File: Chloroquine Compound Availability 3.docx >>

iPhone friendly version:

NATCO:

What do you have on hand?

INVENTORY STATUS AT NATCO, KOTHUR

Natco has recently dispatched the following to the USA:

250 mg: 3788 bottles of 50's count on 12/18/2019

500 mg: 15612 bottles of 25's count on 03/11/2020 which has been received by Rising Pharma and is ready to be dispatched to customers.

How much can you make and how long does it take?

Natco expects to ship the following product in the next couple weeks:

500mg - 2 additional batches which is approximately 31,000 bottles of 25's count by end March 2020

250mg - 6 additional batches which is approximately 11500 bottles of 50's count between 23rd-26th March 2020

After the current manufacturing campaign, ~95kg of Ipca API remains in Natco's inventory and this represents:

Three batches of 1,00,000 tablets of 250mg strength OR

Three batches of 50,000 tablets of 500mg strength

How can we expedite this?

To meet the unprecedented additional demand, Natco requests the prioritization of review and approval of the PAS - sANDA# 090612 Chloroquine Phosphate Tablets USP, 500 mg and sANDA# 091621 Chloroquine Phosphate Tablets USP, 250 mg. Assuming that this PAS is approved, Natco will be in a better position to address the need of this pandemic demand since we will be able to immediately supply, additional 3 batches of 500mg and 3 batches of 250mg which have been manufactured in our Vizag facility using Natco API and this data is part of the PAS package pending with the FDA.

These batches would represent close to:

250 mg: Approximately 15300 bottles of 50's count

500 mg: Approximately 13340 bottles of 25's count

Zydus:

What do you have on hand?

Zydus currently has sufficient inventory on hand to support our current market share of ~36% (equating to approximately 12.5mn tabs monthly). Below is the inventory snapshot as of today. HYDROXYCHLOROQUINE TAB 200MG (100 CT)- 92,376 bottles on hand, 32,688 in transit from India manufacturing sites

HYDROXYCHLOROQUINE TAB 200MG (500 CT)- 18,300 bottles on hand, 8,844 in transit from India manufacturing sites

Please also note that Zydus has implemented an allocation on our inventory to ensure no speculative purchasing can occur and our customers / patients are protected.

(b)(5); (b)(3); 42 U.S.C. § 247d-6b(d)

How can it be expedited?

Zydus is doing everything it can to expedite the manufacture and shipping of Hydroxychloroquine. We will be shipping all new batches of HCQ via expedited AIR freight instead of via Ocean carriers.

Cardinal Health:

Brand – 33,244 bottles of 100 pills each.

We sell approximately 400 bottles/week normally. Demand has picked up slightly this week.

13,948 – of those bottles will reach 12 mo expiry on 31Mar2020

Authorized Generic – Approx 250,000 bottles of 100 pills each, (but larger orders have come in this week)

No additional information

Amneal Pharmaceuticals:

How much do they have?

60,000 bottles of 100 hydroxychloroquine sulfate 200MG on hand

How much can they make and how fast can they make it?

57,000 bottles ready to ship from India on Tuesday to the US

End of next week they will have 96,000 bottles of 100 tablets

By the 27th of March they will have another 96,000 bottles of 100 Tablets

First week of April, they will have 48,000 bottles

In May, they will have 60,000 bottles ready by May 15th and another 60,000 bottles by May 31st

Translation – about 380,000 bottles of 100 tablets available by end of May

What can we do to expedite?

They need FDA support for immediate approval of facilities in the US to manufacture this compound – recommend they submit CBE zero submission for site change to US with no stability data would be tremendously helpful

May need help with Indian Gvt or Customs interfering with the shipment

Appco Pharma:

How much do they have?

The product in the in-process is about 8 million tablets.

How much can they make?

API on hand can produce about 34 to 35 million tablets.

How long does it take?

Additional API expected to be delivered in next month end which may be equivalent to 15 million tablets. There may be some constraints (we just got some information from our API supplier) in procurement of API if the manufacturing country puts any restrictions in export of the API. We procure API from Fermion, Finland. We request the US government to facilitate the release of material for US use. Our marketing partner, DRL, is holding about 39 million on hand

as on date in different pack configurations and they depleting very faster as there is lot of demand.

How can it be expedited?

We see some constraints from operational perspective because the following reasons:

We have submitted a PAS for approval of testing lab relocation. If this is approved on priority, we should be able to meet the additional requirements without any hindrance in analysis of API and finished products.

We are also in the process of qualification of alternate API from Sanofi, Hungary.

We shall be submitting the PAS in 2nd week of April, 2020 with third month data. We request the agency to permit to submit the application as CBE 30 for the faster review or we can submit the application for the review by this Monday with partial information and supplement with 3rd month stability data by 15th of April. We await for your feedback on this issue.

The ANDA application is transferred to APPCO today from TWI, we shall be communicating with the agency on all these matters from today.

Sandoz

What do you have on hand?

ROUGHLY 56 MILLION TABLETS

How much can you make?

WITH ACTIVE INGREDIENT ON HAND WE COULD PRODUCE ROUGHLY 90 MILLION MORE TABLETS

(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

How can it be expedited?

ADDITIONAL ACTIVE WILL BE THE LIMIT, BUT WE ARE EXPLORING ALTERNATE ACTIVE INGREDIENT SOURCES AND ADDITIONAL MANUFACTURING LINES

Teva

How much do they have?

36,000 bottles of 100 count 200mg tablets in US now

9,000 bottles of 500 count 200 mg tablets in US now

How fast can they make it?

48,000 bottles of 100 count expected end of March - It is made in India with API from Taiwan

96,000 bottles expected end of April (assuming export of API from India not blocked...which is becoming an issue and could be an increased issue following any significant public announcement).

How can we Expedite?

Scaling the tablet compression equipment in Florida to expand from 5 batches per month to 18 batches per month Equipment expected in April and hopefully in use in May (1 batch = approx. 24,000 bottles of 100 count)

Enough API in house for a normal 8 month operation, this will clearly be depleted much sooner now.

API comes from Taiwan, Final product made in India in a TEVA-owned facility, not an Indian company. Bulk then transported to Florida for tableting and packaging

Strategic Innovation and Emerging Technology Manager

Assistant Secretary for Preparedness and Response

Office: [202-969-3852](tel:202-969-3852)

Cell: (b)(6)

Sender:	Bright, Rick (OS/ASPR/BARDA) /o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=53034752F35A4317AA74F46348442D39-BRIGHT, RIC <Rick.Bright@hhs.gov>
Recipient:	Hamel, Joseph (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose <Joseph.Hamel@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Adams, Peter (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d68d0d59aeb425cbb0ea4a46a2b9365-Adams, Pete <Peter.Adams@hhs.gov>
Sent Date:	2020/03/20 08:57:48
Delivered Date:	2020/03/20 08:57:47

From: Brendan O'Grady <Brendan.OGrady@tevapharm.com>

Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group
To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric
<Rick.Bright@hhs.gov>

CC: S Barer <(b)(6)>

Subject: Re:

Date: 2020/03/28 17:58:41

Priority: Normal

Type: Note

Hi Rick,

There are some 2m hydroxychloroquine tablets and a large amount of API stuck in India. The State Department is aware and is working on our behalf to get it out. We hope to see some progress by Monday. If we do not, we'll reach back out. We are not sure the WH is aware of our efforts or not but certainly State, HHS, and others are. Will update you on Monday.

Thanks,
Brendan

Sent from my iPhone

On Mar 28, 2020, at 2:52 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

Thank you. Is the stuff in India in your possession? Is there anything USG can help to get it moved out of there? I can send a note to WH and/or FEMA supply chain task force to try to get it out.

I heard other cos. were having trouble getting any api out of Taiwan because someone bought it all. Was hoping it was you. If there's trouble moving it, I might be able to assist.

(b)(3)-42 U.S.C. § 247d-6b(d)

Thank you both! Rick

On Mar 28, 2020, at 3:36 PM, S Barer <(b)(6)> wrote:

Rick-- Brendan informs me that a I mentioned we brought in the original 16m tons and the product is being distributed -- in addition there are 18 mtons stuck in India. We are expecting a significant shipment from Taiwan in June of API. Brendan is looking at a former Teva facility where we can make the tablets. I'm copying Brendan to correct and/or for direct interface.
Sol

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Sender:	Brendan O'Grady <Brendan.OGrady@tevapharm.com>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; S Barer <(b)(6)>
Sent Date:	2020/03/28 17:58:26
Delivered Date:	2020/03/28 17:58:41

Withheld pursuant to exemption

(b)(5) ; (b)(3):42 U.S.C. § 247d-6b(d)

of the Freedom of Information Act

Withheld pursuant to exemption

(b)(5) ; (b)(3):42 U.S.C. § 247d-6b(d)

of the Freedom of Information Act

Clinical Trials

- **Accomplishments**

- NIAID-sponsored therapeutic RCT activated 47 sites, including 8 ex-US (334 enrolled)
- NIAID-sponsored Phase 1 vax mRNA-1273 trial enrolled 25ug and 100ug dose groups (30/45 total); top dose group to begin April 8 (after monitoring first two dose groups for safety)
- BARDA-supported Sarilumab (Regeneron/Sanofi) trial activated 45 sites, all US (461 enrolled)
- BARDA-supported IL-6 receptor mAb (Genentech) trial scheduled to begin enrollment this week

- **Ongoing tasks**

- First draft HHS Clinical Guidelines drafted, under review
- NIAID-sponsored RCT of hcq&azithro for *treatment* protocol drafted; scientific review complete
- Observational/Natural history studies
 - ✓ Connecting NIH networks (PETAL), VA, DoD to ensure common data elements and analysis
 - ✓ DoD enrolling into EpiCC at military treatment facilities
 - ✓ NIAID INSIGHT study of natural hx of infection pending enrollment; NIAID Immunophenotyping protocol drafted
 - ✓ Studies will be foundation for future host-response clinical trials

- **Next Steps**

- Drafting protocol for adaptive trial of treatments for outpatients at risk for complications (due to age, comorbidity)
- Plan next intervention(s) to be used in NIAID ACTT study
- Develop phase 2/3 Vaccine trial plan/protocol

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(b)(5) ; (b)(3):42 U.S.C. § 247d-6b(d)

of the Freedom of Information Act

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of the Freedom of Information Act

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(b)(5) ; (b)(3):42 U.S.C. § 247d-6b(d)

of the Freedom of Information Act

Withheld pursuant to exemption

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of the Freedom of Information Act

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Withheld pursuant to exemption

(b)(5) ; (b)(3):42 U.S.C. § 247d-6b(d)

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