From: S Barer <s(b)(6)

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

Subject: Re: C9F091C1-2B68-42CD-AFF2-E59972177D2B.pdf

Date: 2020/03/30 11:07:06

Priority: Normal

Type: Note

Rick-- please find attached regarding a new vaccine approach from a company I Chair. Probably more than you want given pressures on your time. Please let me know of any comments/reactions etc. and thanks for looking at this. (meanwhile more encouraging phone calls on hydroxychloroquine)
Sol

Summary:

NexImmune has developed a proprietary nanotechnology platform that utilizes "**a**rtificial **a**ntigen **p**resenting **c**ells" or "aAPC" to bypass the antigen processing and presentation immune functions of natural dendritic cells. The aAPC are used to directly activate and expand (viral) antigen-specific T cells through classic Signal 1 and Signal 2 mechanisms. The critical role of CD8+ T cells in effective viral clearance has been strongly established.

For this BARDA application, AIM101 is proposed for use as a rapid, early intervention therapy in epidemics or pandemics such as COVID-19. The injectable aAPCs utilized in AIM101 can be rapidly loaded with **multiple virus-specific antigens** (as peptides) that elicit the specific *in vivo* activation and expansion of antigen-specific $CD8^+$ T cells directed toward virally infected cells or tissues.

The promise of AIM101 technology is grounded in five mechanistic properties:

1. • aAPCs have the ability to target and activate very low frequency T cell populations within naïve and memory repertoire
2. • aAPCs overcome low T cell activation thresholds to expand targeted T cell populations via natural mechanisms without any genetic engineering

3. • Activated T cells effectively kill virally infected cells, and initiate a robust immune response including B cell activation with subsequent antibody and complement response (cell-mediated immunity initiates humoral immunity)
4. • Only infected cells express the targeted viral epitopes, ensuring target-specific recognition, engagement and killing – healthy cells and tissue remain intact
5. • Use of multiple COVID virus-specific antigens generates a robust T cell response against multiple viral targets – minimizes potential for escape through viral mutation and maximizes therapeutic potential

An analog modality of the AIM technology is currently being evaluated in Phase I/II clinical trials for treatment of various hematological malignancies. As such, the FDA-cleared INDs can easily be cross-referenced to expedite the development and submission of a new IND to support the AIM 101 product proposed. We anticipate IND submission in 3Q2021.

PLEASE SEE ATTACHED FOR PRESENTATION AND DETAILS

On Sat, Mar 28, 2020 at 12:23 PM Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>wrote:

You are my hero. Will keep all confidential until you signal, while I quietly educate myself in parallel.

For the vaccine, please direct them to https://protect2.fireeye.com/url?k=3aebf004-66bef917-3aebc13b-0cc47adb5650-b515fdfe1189cc37&u=http://www.medicalcountermeasures.gov/ and have them also send me information/data via email that I will get into the hands of the vaccine working group quickly.

From: Sol Barer <(b)(6)>
Date: Saturday, March 28, 2020 at 12:18 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: Re: C9F091C1-2B68-42CD-AFF2-E59972177D2B.pdf

-All 16 metric tons. India bottleneck now but people working on it. I will find out.

-Also very confidentially Celgene drug Otezla showing powerful anecdotal activity. Quite expensive and Amgen has it. They were informed but still early. Gates will run a trial. Would

work as an immunomodulator- (one of my drugs!). Will keep you informed. There is a successor conpound ready for clinic that friends are trying to get to scale up etc. Please keep confidential.

- a company i Chair has an approach to a modular vaccine- can just add antigens to artificial nanoparticle for viral mutation. Entering clinic for oncology but readily adaptable --but early. That company actually needs funding for this (Neximmune). Can i present this to you in some written form?

On Sat, Mar 28, 2020, 12:07 PM Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>wrote:

Thank you. This is very helpful.

Btw, did TEVA acquire and successfully transport API from Taiwan to US? Do they need collaboration in US to finish/tablet?

From: Sol Barer <(b)(6)>
Date: Saturday, March 28, 2020 at 11:44 AM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: C9F091C1-2B68-42CD-AFF2-E59972177D2B.pdf

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Sender:	S Barer (b)(6)
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/03/30 11:03:09
Delivered Date:	2020/03/30 11:07:06

From:	Houchens, Christopher (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7AC94A574BD04528B7C91BBD61893975-HOUCHENS, C <Christopher.Houchens@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@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 22:01:47
Priority:	Normal
Type:	Note

Adding Gretta here.

From: Houchens, Christopher (OS/ASPR/BARDA)
Sent: Wednesday, March 25, 2020 9:31 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Subject: RE: TPs

Rick – One edit to my clarifying response to the very last issue. Chris

(b)(5)

From: Houchens, Christopher (OS/ASPR/BARDA)
Sent: Wednesday, March 25, 2020 9:28 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA)

<Christine.Oshansky@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Subject: RE: TPs

Rick,

(b)(5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 8:59 PM
To: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>
Cc: Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Subject: Re: TPs

(b)(5)

(b)(5)

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

(b)(5)

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:	Houchens, Christopher (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7AC94A574BD04528B7C91BBD61893975-HOUCHENS, C <Christopher.Houchens@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@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>; 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>
Sent Date:	2020/03/25 22:01:44
Delivered Date:	2020/03/25 22:01:47

To the editor,

Recently Caly et al. reported *in vitro* activity of ivermectin against SARS-CoV-2 following a single addition to Vero-hSLAM cells, and suggest that these data "demonstrate that ivermectin is worthy of further consideration as a possible SARS-CoV-2 antiviral" [1]. In isolation, these *in vitro* data are robust and encouraging but the report does not include a correlation of the in vitro findings with clinically achievable plasma and, more relevantly, lung concentrations that would permit the determination of whether the macrocyclic lactones (and specifically in this case ivermectin) are genuine therapeutic options.

Caly et al bathed Vero-hSLAM cells with ivermectin at a concentration of 5μM from 2 hours post-infection SARS-CoV-2 isolate Australia/VIC01/2020 until the conclusion of the experiment. SARS-CoV-2 RNA was determined by RT-PCR at Days 0 to 3 in both supernatant and cell pellet experiments. The authors noted 93 to 99.8% reduction in viral RNA for ivermectin versus DMSO control at 24h in supernatant (released virions) and cell associated viral RNA (total virus) respectively. They also describe by 48 hours a ~5000-fold reduction of viral RNA and maintenance of effect at 72 hours. Additional experiments were conducted with serial dilutions of ivermectin to establish the concentration-response profile, and the authors describe ivermectin as a potent inhibitor of SARS-CoV-2, with an IC_{50} determined to be approximately 2 μM under these conditions.

We sought to examine the clinical relevance of the concentrations evaluated in these *in vitro* experiments to those that may be achieved with ivermectin dosing in practice, in order to assist in prioritizing ongoing efforts with finding therapeutics that may be effective in COVID-19.

Ivermectin is one of humanity's most important medicines [2] and is extensively used for 5 neglected tropical diseases at single oral doses of 150 to 200 µg/kg, resulting in the mean peak plasma concentrations of approximately 30 to 47 ng/mL [3]. In Phase I studies, doses up to 2000 µg/kg [4] have been administered in a fasted state or up to 600 µg/kg following a standard high-fat meal. Smit et al [5] report that ivermectin 600 µg/kg administered orally resulted in a maximum median concentrations (Cmax) in plasma of 118.9 ng/mL (p5-p95: 45.2–455.1ng/mL), with relatively rapid clearance and a half-life of approximately 3 to 5 hours.

Similar to Yao et al. who proposed the potential for hydroxychloroquine for treating COVID-19,[6] we applied a physiologic-based pharmacokinetic (PBPK) model of ivermectin using the Simcyp platform to explore the plasma and lung concentrations relative to the IC_{50} values against SARS-CoV-2 determined *in vitro*. The ivermectin PBPK model was initially developed to facilitate drug development for parasitic diseases including onchocerciasis and is a full model that allows prediction of tissue drug concentrations. The model has been independently verified. The predicted *versus* observed plasma profiles for ivermectin across clinical studies in the Mectizan NDA were well aligned, [7] indicating the base model is well defined. Furthermore, the PBPK model was able to predict ivermectin exposures in plasma, adipose and skin to within 1.3-fold of observed data in patients infected with *Onchocerca volvulus* [8]

Simulations were performed using the Simcyp Simulator Version 19 Release 1. Ten virtual trials of 10 subjects aged 18-75 years (50 % female) were simulated using the Sim-NEurCaucasion

population. In the simulation, high dose ivermectin (600 µg/kg) was administered orally, daily for 3 days and the virtual study carried on to 9 days. Dosing was in the Fed state and fraction unbound was 0.07 (plasma) and 0.13 (lung). Simulations for mean systemic plasma and lung tissue concentrations are shown in Figure 1.

Pharmacodynamic response is generally achieved by ensuring an appropriate duration of exposure above the minimum therapeutic concentration at the site of action. Even with most generous assumptions for clinical translation, the *in vitro* IC50 is >9-fold and >21-fold higher than the day 3 plasma and lung tissue simulated Cmax respectively, following a high dose ivermectin regimen of 600 µg/kg dose daily for 3 days. [5] This dose scenario, which ignores consistent exposure, exceeds the highest regulatory approved dose of ivermectin, being a 200 µg/kg single dose for the treatment of Strongyloidiasis.[3]

Caly et al. cite the importance of regulatory approval of ivermectin as a key part of the rationale for further evaluation against SARS-CoV-2. However, the rigorous data review and reassurance of a stringent regulatory authority review only applies to currently approved doses – clinical pharmacology and toxicology margins (including pre-and post-natal and carcinogenicity studies) would, therefore, need to be recalculated. In reality, the resultant unravelling of the supporting package of data could result in lengthy delays while supporting data are revised and re-run.

It is understandable that, faced with a devastating pandemic and a medical and societal imperative, there is great enthusiasm for promising news of treatments. Picking and supporting the best therapies and preventions to tackle the COVID-19 pandemic head on is one of the scientific community's most urgent priorities. To assist this process, the clinical pharmacological relevance of *in vitro* or *in vivo* findings should be included. *In vitro* promise leads to clinical

failure in the vast majority of cases, and in the volatile environment of the current pandemic, it is critical that we are sensitive to the implications of our communication and apply our resources to compounds most likely to succeed. A small window exists for the current data to have relevance for humans: we need to confirm the effective concentrations, assess if the class of macrocyclic lactones has similar target interactions, and understand the relevance of the concentrations used *in vitro* against SARS-CoV-2 to those likely to be achieved at the site of action, within a dose range considered to be well tolerated. Alternative routes could also be considered, although these present new formulation and safety challenges. Modelling and simulation approaches integrate *in vitro* findings with the *in vivo* situation and may serve to prioritize existing drugs that are candidates for repurposing.

Authors:

Karen Yeo PhD, David Wesche MD, PhD, Lisa Almond PhD, Michael Dodds, PhD, Patrick F Smith PharmD, Mark Sullivan BSc, Craig R. Rayner PharmD,

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Conflict of interest statement:

KY, DW, LA, MD, PS and CR work for Certara, a consulting firm in integrated drug development and have directly consulted with a variety of not-for-profit global health organizations, biotechnology and pharmaceutical companies and governments with an interest in medical countermeasures against respiratory virus infections. MS works for Medicines Development for Global Health and the Kirby Institute and has no conflicts of interest to declare.

Funding information: No funding was provided to write this short communication.

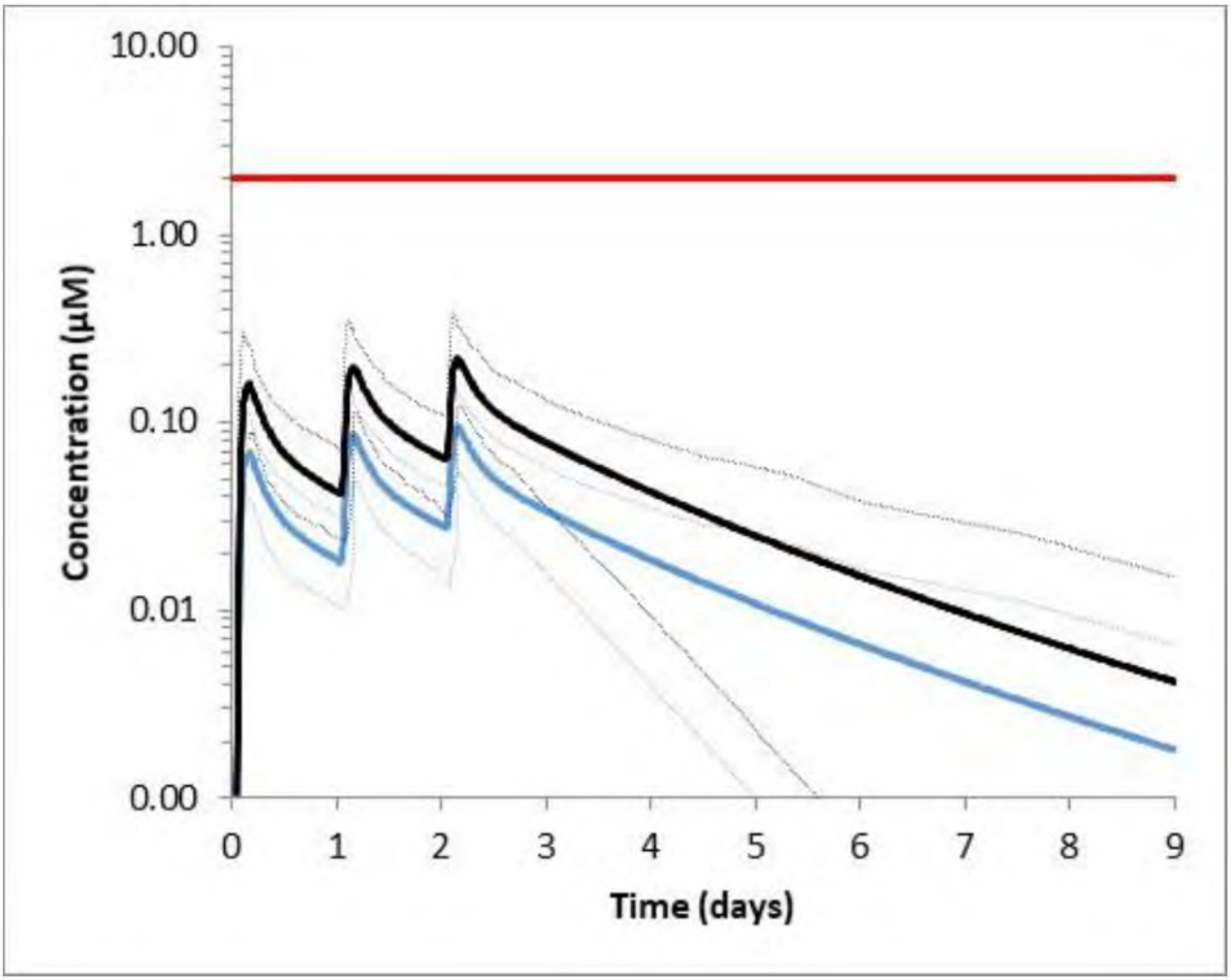
References

1. Caly, L., et al., *The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro.* Antiviral research, 2020. **https://doi.org/10.1016/j.antiviral.2020.104787**.
2. Crump, A. and S. Omura, *Ivermectin, 'wonder drug' from Japan: the human use perspective.* Proc Jpn Acad Ser B Phys Biol Sci, 2011. **87**(2): p. 13-28.
3. Merck, *Stromectol USPI.* https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/050742s026lbl.pdf, 2009.
4. Guzzo, C.A., et al., *Safety, tolerability, and pharmacokinetics of escalating high doses of ivermectin in healthy adult subjects.* J Clin Pharmacol, 2002. **42**(10): p. 1122-33.
5. Smit, M.R., et al., *Pharmacokinetics-Pharmacodynamics of High-Dose Ivermectin with Dihydroartemisinin-Piperaquine on Mosquitocidal Activity and QT-Prolongation (IVERMAL).* Clin Pharmacol Ther, 2019. **105**(2): p. 388-401.
6. Yao, X., et al., *In Vitro Antiviral Activity and Projection of Optimized Dosing Design of Hydroxychloroquine for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2).* Clin Infect Dis, 2020.

7. Merck, *Mectizan NDA 050742*. 1996.

8. Baraka, O.Z., et al., *Ivermectin distribution in the plasma and tissues of patients infected with Onchocerca volvulus*. Eur J Clin Pharmacol, 1996. **50**(5): p. 407-10.

Figure 1: Simulated mean concentration-time profile of ivermectin in plasma (black line) and lung tissue (blue line) following 600 µg/kg dose daily for 3 days. The 5th and 95th percentiles are also shown. The red-line is the IC_{50} (2µM) against SARS-CoV-2 determined *in vitro* by Caly et al. [1]


10.00
1.00
0.10
0.01
0.00
Concentration (µM)
0
1
2
3
4
5
6
7
8
9
Time (days)

From:	Gianetti, Denise (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E1CCC952FD6C4120858031215B2B66F3-GIANETTI, S <Denise.Gianetti@hhs.gov>
To:	OS - ASPR - BARDA - ALL /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0714db244354ae682406ec39719058d-BARDAALL-Ne <BARDAALL@hhs.gov>
Subject:	Recent BARDA Announcements
Date:	2020/04/17 18:49:35
Priority:	Normal
Type:	Note

Dear Colleagues,

Below please find the most recent announcements published over the last two weeks highlighting BARDA's response to the COVID-19 pandemic.

4/6 - **BARDA is partnering with OraSure Technologies Inc. to develop first rapid at-home COVID-19 diagnostic test**

OraSure Web Announcement

The announcement says in part: "BARDA and OraSure Technology, Inc. are working together on the development of a point-of-care (POC) test for SARS-CoV-2 that could bring testing closer to the patient. OraSure's rapid, point-of-care test will be available for use both in clinical settings and at home. This test could become the first for use at home in the United States."

4/6 - **HHS accepts donations of medicine to Strategic National Stockpile as possible treatments for COVID-19 patients**

Donations of Medicine to SNS

The announcement says in part "FDA issues emergency use authorization for donated hydroxychloroquine sulfate, chloroquine phosphate. The U.S. Department of Health and Human Services (HHS) today accepted 30 million doses of hydroxychloroquine sulfate donated by Sandoz, the Novartis generics and biosimilars division, and one million doses of chloroquine phosphate donated by Bayer Pharmaceuticals, for possible use in treating patients hospitalized with COVID-19 or for use in clinical trials. These and other companies may donate additional doses, and companies have ramped up production to provide additional supplies of the medication to the commercial market."

4/7 - **BARDA and Genentech collaborate to accelerate clinical trial of a novel COVID-19 therapeutic treatment**

Genentech Web Announcement

The announcement says in part "BARDA expanded an existing partnership with Genentech, part of Roche Group and headquartered in South San Francisco, to accelerate a Phase 3 clinical trial of Actemra® (tocilizumab) as a potential treatment of patients with severe cases of COVID-19. Currently, Actemra® is approved by the U.S. Food and Drug Administration and in more than 100 countries to treat rheumatoid arthritis or other inflammatory conditions."

4/7 - **HHS, Department of Defense, and Grifols Collaborate to Develop Plasma-based Treatment for COVID-19**

Grifols Web Announcement

The announcement says in part, "BARDA and the U.S. Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (DoD-JPEO-CBRND) will collaborate with Grifols to make available potentially life-saving COVID-19 treatments that use convalescent plasma or hyperimmune globulin."

4/7 - **BARDA leverages CIADM Partner for Development of Plasma-based Therapeutic Treatment for COVID-19**

BARDA Leverages CIADM Partner

The announcement says in part, "BARDA is partnering with the Center for Innovation in Advanced Development and Manufacturing (CIADM) at Emergent Biosolutions to develop COVID-19 Human Immune Globulin (HIG) for clinical evaluation as a potential therapeutic for COVID-19. BARDA's funding will support the collection of plasma and the manufacture of the therapeutic for clinical evaluation in COVID-19 patients later this year."

4/8 - **HHS supports Nanomix, Inc. to develop a rapid mobile diagnostic test to detect presence of current or past COVID-19 infection in patients**

Nanomix Web Announcement

The announcement says in part, "BARDA has partnered with Nanomix, Inc. on the development of a COVID-19 rapid mobile test to diagnose COVID-19 infections with results in as little as 15 minutes. The test detects the presence of SARS-CoV-2 antigen in nasal and throat swabs. As part of the contract, a serological test will also be developed that can detect antibodies of SARS-CoV-2 in the blood, for indication of current or past COVID-19 infection."

4/13 - **HHS/BARDA supports DiaSorin, Inc. to develop a fully automated serology test to detect novel coronavirus infections**

DiaSorin Web Announcement

The announcement says in part, "BARDA is collaborating again with DiaSorin, this time to develop a clinical laboratory test to identify people who have been infected with the SARS-CoV-2 virus but have recovered. Known as a serology assay, the test detects the presence of IgG antibodies specific to the virus in a person's blood. Having certain levels of these immuno-protective antibodies indicates that the person is convalescent (recovering or recovered from COVID-19)."

4/13 - **HHS facilitates development of immunotherapies for COVID-19 patients**

Immunotherapies for COVID-19 Patients

The announcement says in part, "In the race to identify and provide safe, effective treatments for hospitalized patients with COVID-19, the U.S. Department of Health and Human Services (HHS) will collaborate with multiple non-government organizations on the development of convalescent plasma and hyperimmune globulin immunotherapies. These treatments would use antibodies against SARS-CoV-2 from COVID-19 survivors and are intended to stimulate the immune systems of people currently ill from the virus."

4/14 – **BARDA and Vela Diagnostics USA, Inc. entered into a public-private partnership to develop a rapid diagnostic test for the COVID-19 pandemic**

Vela Diagnostics Web Announcement

The announcement says in part, "BARDA and Vela Diagnostics USA, Inc. are entering into a partnership to develop a rapid diagnostic test for use on two instrument platforms to aid in the detection of COVID-19 infections. Diagnostics on multiple platforms are needed to test as many people as possible and identify those who are infected in order to slow the pandemic."

4/15 – **BARDA and American Red Cross collaborate on convalescent plasma for therapeutic use in COVID-19 infected patients**
American Red Cross Web Announcement
The announcement says in part, "BARDA and the American Red Cross (ARC) are collaborating on systems and procedures to recruit donors who have recovered from COVID-19. Through this collaboration the ARC will prepare procedures for the collection of plasma for investigational use in treating patients infected with COVID-19."

4/15 – **BARDA and Sanofi prepare for studies of COVID-19 vaccine**
Sanofi Web Announcement
The announcement says in part, "BARDA and Sanofi Pasteur, the vaccines global business unit of Sanofi, are expanding their collaboration to develop a SARS-CoV-2 vaccine. The previously announced research for a COVID-19 vaccine using a recombinant DNA platform will accelerate into non-clinical studies and a Phase 1 clinical trial to demonstrate initial safety and efficacy of the vaccine candidate."

4/16 – **BARDA supports Hememics Biotechnologies, Inc. to develop a rapid antigen and antibody diagnostic to identify current or past SARS-CoV-2 infections in 60 seconds**
Hememics Web Announcement
The announcement says in part, "BARDA is collaborating with Hememics Biotechnologies, Inc. on the development of a rapid, Bluetooth-connected SARS-CoV-2 diagnostic test. The test is being designed to detect SARS-CoV-2 antigen from nasal swab samples and associated antibodies in 60 seconds or less through a finger-prick."

Thank you
Denise

Denise Gianetti
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O: 202.205.5592
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Denise.Gianetti@hhs.gov

in this e-mail is intended to constitute contractual direction or to impact the current negotiated 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.

Sender:	Gianetti, Denise (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E1CCC952FD6C4120858031215B2B66F3-GIANETTI, S <Denise.Gianetti@hhs.gov>
Recipient:	OS - ASPR - BARDA - ALL /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0714db244354ae682406ec39719058d-BARDAALL-Ne <BARDAALL@hhs.gov>
Sent Date:	2020/04/17 18:49:32
Delivered Date:	2020/04/17 18:49:35

Weekly Briefing (Week of 3/30/2020)

To: HHS/BARDA COVID-19 Response Team
Rick Bright (OS/ASPR/BARDA), Michael Angelastro (OS/ASPR/BARDA), Robert Johnson (OS/ASPR/BARDA), James Harris ((OS/ASPR/BARDA), Monica Watson (HHS/ASPR), Carol Lavrich (OS/ASPR/BARDA)

From: Eric Edwards, MD, PhD on Behalf of the Phlow MCM/Essential Medicine Response Team (Phlow, Civica, Ampac, M4All)

RE: Phlow Corp. Situational Analysis

Objective: Per Pre-award Directive, Operationalize and Mobilize Program Management Infrastructure; Secure and preserve a Stockpile and Strategic Reserve Key Essential Medicines and Associated Ingredients Required to Treat COVID-19 Hospitalized Patients; Ramp-up Surge Manufacturing Capacity for MCM/Essential Medicines for the COVID-19 Response all in accordance with CLIN0001, CLIN0002, and CLIN0003

Dear BARDA Team-

Please see below information as well as concerns and requested direction at the end of this briefing. This update is to provide information on how Phlow is executing against the Pre-Award provided to Phlow by BARDA in the letter dated March 21, 2020.

Summary: Tasks this week were divided into three key areas:

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

B)

C)

Detail:

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

(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

B) Phlow has responded to the Request for Information for Inventory and Manufacturing Capacity relating specifically to Finished Generic Medicines and Active Pharmaceutical Ingredients. Phlow made the strategic decision to encourage manufacturers to respond directly to ASPR instead of going through Phlow for those that had FDA or ASPR reach out directly to them. Other manufacturers were not aware of the RFI and Phlow included these in their response. Below is a summary of Phlow's activities to support the RFI Effort this week:

(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

Please don't hesitate to reach out with any additional concerns or questions.

From:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>
Subject:	Reuter's re HCQ and CQ - FDA and ASPR and concerns
Date:	2020/04/19 07:35:07
Priority:	Normal
Type:	Note

Sent from my iPhone

Begin forwarded message:

From: "Walker, Robert (OS/ASPR/BARDA)" <Robert.Walker@hhs.gov>
Date: April 18, 2020 at 5:08:27 PM EDT
To: "Faison, Tremel (OS/ASPR/BARDA)" <Tremel.Faison@hhs.gov>, "Mason, Robin (OS/ASPR/BARDA)" <Robin.Mason@hhs.gov>
Cc: "Lambert, Linda (OS/ASPR/BARDA)" <Linda.Lambert@hhs.gov>
Subject: Fwd: not sure if you saw this

FYI.

Begin forwarded message:

From: "Kozak, Marina (OS/ASPR/BARDA)" <Marina.Kozak@hhs.gov>
Date: April 18, 2020 at 4:34:00 PM EDT
To: "Walker, Robert (OS/ASPR/BARDA)" <Robert.Walker@hhs.gov>
Subject: not sure if you saw this

https://www.reuters.com/article/us-health-coronavirus-bayer-chloroquine/exclusive-bayers-chloroquine-donation-to-u-s-raises-concern-about-fda-standards-in-pandemic-idUSKBN21Y2LO

Sender:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>;

	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>
Sent Date:	2020/04/19 07:35:04
Delivered Date:	2020/04/19 07:35:07

From:	Narasimhan, Vas <vas.narasimhan@novartis.com>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	Fwd: COVID-19 Collaboration Inquiry from Novartis
Date:	2020/04/02 07:29:31
Priority:	Normal
Type:	Note

Dear Rick

As a follow-up to below, I wanted to give you a heads up we will be making three announcements today and in the coming days on COVID-19 Pivotal Studies:

— Initiation of a Pivotal RCT of Jakafi/Jakavi with our partner Incyte in hospitalized COVID-19 patients (FDA sign-off pending). Of note, we have seen now the initial data from China on this medicine.
— Initiation of a Pivotal RCT of Hydroxychloroquine in hospitalized COVID-19 patients (FDA sign-off received)
— Initiation of a Pivotal RCT of Canakinumab in hospitalized COVID-19 patients (FDA sign-off pending)

We will continue to follow-up with our BARDA contacts. I would welcome a brief call with you to discuss how we might be able to partner if of interest.

Best regards
Vas

From: Narasimhan, Vas
Sent: Tuesday, March 31, 2020 10:50:37 AM
To: rick.bright@hhs.gov <rick.bright@hhs.gov>
Cc: Leeds, Jennifer <jennifer.leeds@novartis.com>; Bradner, James <james.bradner@novartis.com>; Tsai, John <john.tsai@novartis.com>; Casserly, Dan <dan.casserly@novartis.com>
Subject: COVID-19 Collaboration Inquiry from Novartis

Dear Rick

We previously met/worked together when I was at Novartis Vaccines and we collaborated on a range of efforts for pandemic preparedness. I am currently CEO of Novartis and was hoping our teams could connect with BARDA to assess whether there are ways for us to partner on the COVID-19 response. Thank you and BARDA for your tremendous leadership on the pandemic response – I only here consistent praise for the efficiency with which BARDA is operating. We hope our commitment to donate Hydroxychloroquine to the strategic national stockpile demonstrates our deep commitment to support the US Government in its pandemic response.

Our core areas of focus currently include

1. **Clinical Research and Supply of Existing Novartis Medicines**

A. Hydroxychloroquine

- Phase 3 Clinical Trial (Protocol submitted to FDA): Randomized, double-blind, placebo-controlled, multicenter three-arm parallel study to evaluate the clinical response, safety and tolerability of oral hydroxychloroquine in patients with moderate and severe COVID-19 pneumonia. The study will enroll patients who require hospitalization and will receive, in addition to best available standard of care, hydroxychloroquine, hydroxychloroquine in combination with azithromycin, or placebo. Study Duration: 28 days. Sample size: ~442 patients. Countries: USA; FPFV: April 20th
- Scaling supply capacity to meet US and Global Needs

B. Canakinumab (Ilaris) – Anti-IL1b Mab

- Phase 3 Clinical Trial (Protocol Submitted to FDA): Randomized, multi-center study to assess the efficacy and safety of canakinumab on COVID-19 pneumonia and cytokine release syndrome (CAN-COVID). Patients randomized 2:1 canakinumab to placebo. Study Duration: 126 days (18 weeks) after initial canakinumab dose. Sample size: 450 patients in 40 sites. Countries: USA, United Kingdom, France, Germany, Spain, Switzerland; FPFV: April 30

C. Jakavi (Ruxolitinib): Based on results in China and Italy from Investigator studies in severe patients, we are preparing with our partner Incyte to pursue phase 3 studies

2. **Research into Novel Anti-Viral Agents:** Advancing two drug discovery efforts: (1) Covalent compound screen against **SARS-CoV-2 main protease** (in collaboration with Berkeley), and (2) targeting of SARS-CoV-2 ORFs and known genes with **glue-degraders**

Dr. Jennifer Leeds would be our lead interface with BARDA on these efforts (cc'd). If there would be interest on collaborations on these areas, if you could connect us to the right person on your team we would appreciate it for an initial discussion.

With best regards,
Vas

Sender:	Narasimhan, Vas <vas.narasimhan@novartis.com>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/04/02 07:28:59
Delivered Date:	2020/04/02 07:29:31

From:	Anna Edney (BLOOMBERG/ NEWSROOM:) <aedney@bloomberg.net>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	Bloomberg News inquiry
Date:	2020/04/22 16:18:50
Priority:	Normal
Type:	Note

Hi again. I see the New York Times story on your departure. Can you confirm that you left BARDA over differences over hydroxychloroquine? Please give me a call if you can (b)(6)

Thank you
Anna

Anna Edney
Health reporter
Bloomberg News
@annaedney
aedney@bloomberg.net
202-807-2136 (office)
(b)(6) (cell)

Sender:	Anna Edney (BLOOMBERG/ NEWSROOM:) <aedney@bloomberg.net>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/04/22 16:17:39
Delivered Date:	2020/04/22 16:18:50
Message Flags:	Unread

Weekly Briefing (Week of 3/23/2020)

To: HHS/BARDA COVID-19 Response Team
Rick Bright (OS/ASPR/BARDA), Michael Angelastro (OS/ASPR/BARDA), Robert Johnson (OS/ASPR/BARDA), James Harris ((OS/ASPR/BARDA), Monica Watson (HHS/ASPR), Carol Lavrich (OS/ASPR/BARDA)

From: Eric Edwards, MD, PhD on Behalf of the Phlow MCM/Essential Medicine Response Team (Phlow, Civica, Ampac, M4All)

RE: Phlow Corp. Situational Analysis

Objective: Per Pre-award Directive, Operationalize and Mobilize Program Management Infrastructure; Secure and preserve a Stockpile and Strategic Reserve Key Essential Medicines and Associated Ingredients Required to Treat COVID-19 Hospitalized Patients; Ramp-up Surge Manufacturing Capacity for MCM/Essential Medicines for the COVID-19 Response all in accordance with CLIN0001, CLIN0002, and CLIN0003

Dear BARDA Team-

(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

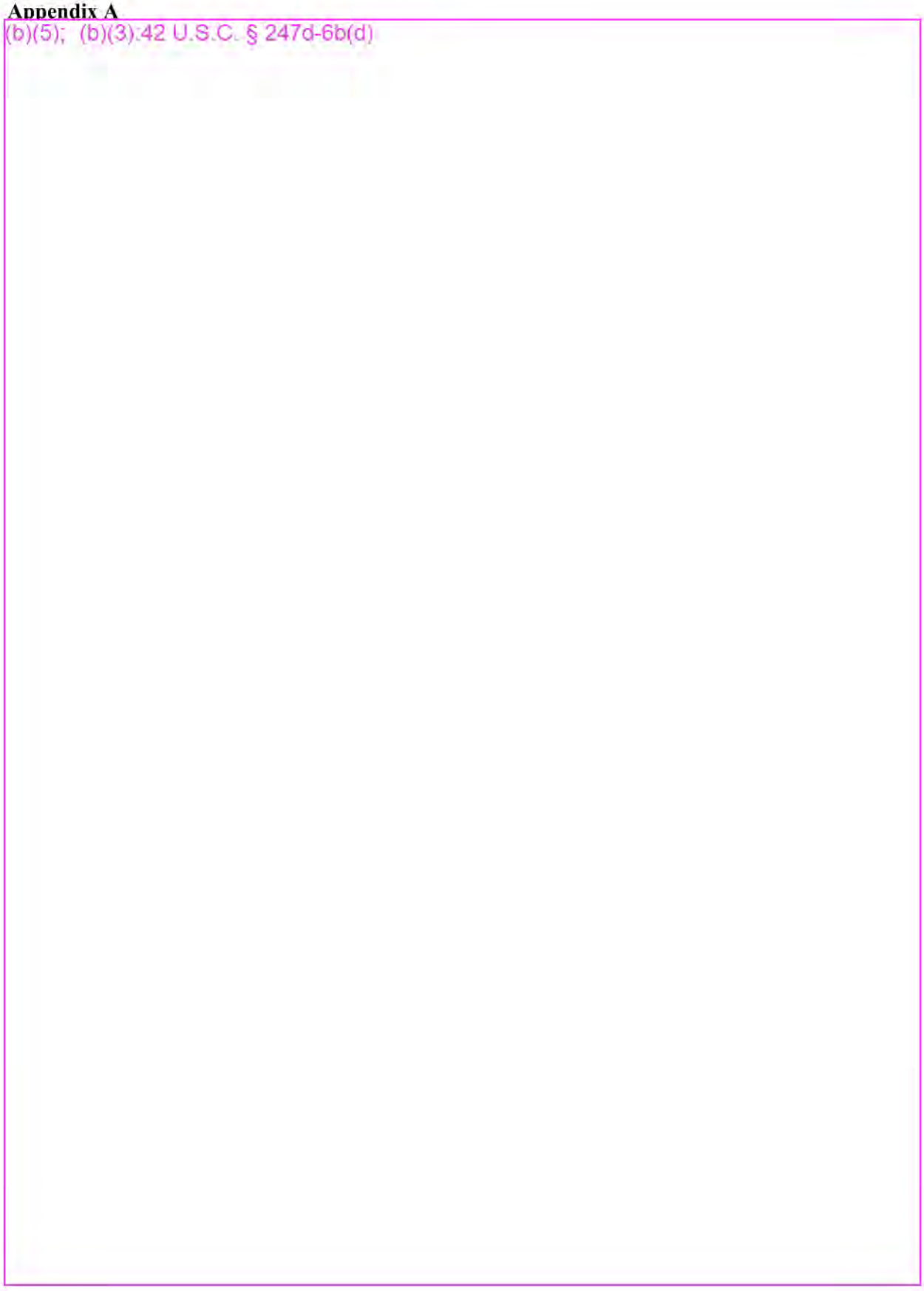
(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

Please don't hesitate to reach out with any additional concerns or questions.

Appendix A

(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)



(b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

Shield. Shelter. Save. Sustain.

HHS COVID-19 Top Highlights

March 31, 2020

Top Updates

- A top priority continues to be allocating ventilators through the SNS to medical hotspots as quickly as possible that have an urgent 72-hour need
  - Ventilators have been delivered to: NY (2,400), NYC (2,000), NJ (200), MD (120), FL (200), GA (150), IL (300), LA (CA) county (170), AK (60), OR (140), and WA (500), NJ (300)
  - Ventilators being processed for: Chicago (150), MI (400), and LA (150)
  - 9,404 ventilators remain in in the SNS
- CBTS Transition Plan: No later than 10Apr20, all existing federally supported CBTS will have either transitioned to fully state led, managed, and supported CBTS or will have permanently closed. This will include the demobilization of all USPHS officers directly supporting the CBTS, the final disposition of all federal supplies associated with the USPHS ordering physician and stop orders of all federally supported agreements and/or contracts.
- FDA authorized emergency use of chloroquine and hydroxychloroquine to treat COVID-19 patients who cannot be enrolled in a clinical trial

What Have We Done

- Community Based Testing:
  - 30 sites are live, 1 is opening today (CO Memorial Hospital), 2 are on hold
  - Screening/Testing Throughput:
    - Overall: 37,762 people have been screened and 31,817 have been tested
  - Tests Processed: 15,992 tests processed; 2,975 positive results (18.6%)
- Airbridge Flight #2, a USG and healthcare distributor partnership, arrived in Chicago on 30Mar20; cargo included 15.16M latex gloves with distribution through industry chain and 50% to “hotspots”
- NY: Phase 1 of the Javits ACS is operational and treating patients with 1,000 beds
- The USNS Comfort will begin operations today. The crew onboard will provide critically needed medical surge capacity to NYC by caring for New Yorkers who do not have COVID-19 but require urgent medical care
- USNS Mercy is operational and receiving patients in Los Angeles
- 3 DOD Field Hospitals are Deploy-Ready and planned sites are Texas (Dallas), Louisiana (New Orleans), and Washington. There will be approximately 200 medical personnel at each location
- Confirmed that the US Navy EMF can accept the mission in Louisiana

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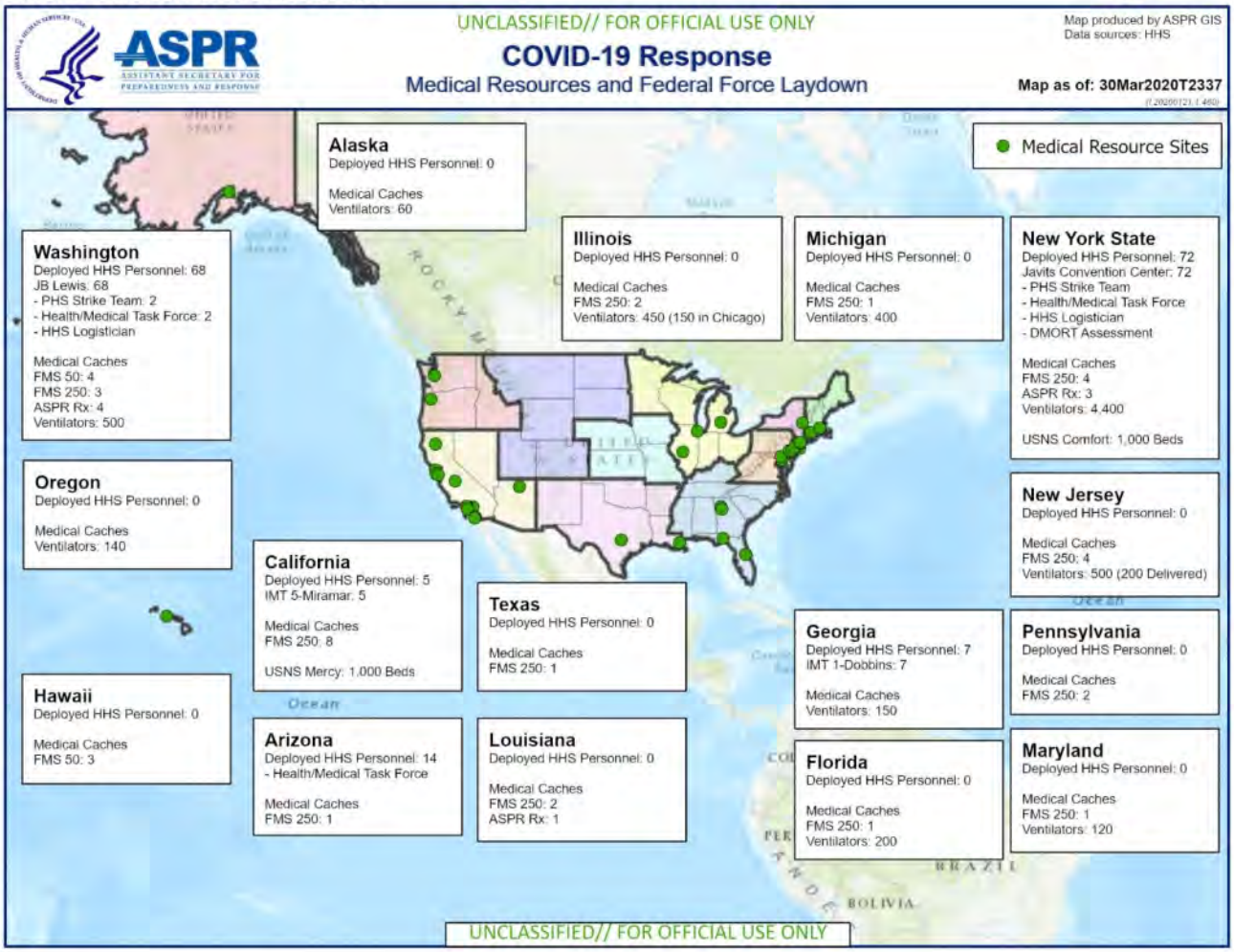


What We Are Doing

- Reviewing/processing urgent ventilator requests as they are received – received requests from MA and OH that are not within the 72-hour window. Attempting to get more details from WA.
- All 32 250 Bed and 10 50 Bed FMS have been allocated. HHS and FEMA are in the process of procuring 100 more FMS.
    - A MA for 19 has been accepted by HHS and deliver time is between 2-3 weeks
    - A second MA for 81 is in process
- ASPR and FEMA are working closely to receive and rapidly distribute recent donations of 30M doses of hydroxychloroquine sulfate from Sandoz/Novartis and 1M doses of chloroquine phosphate from Bayer Pharmaceuticals.
- Dialysis network has concerns about transportation with the growing number of positive cases. HHS advised the network that the process for reporting any public health/healthcare related transportation issues is the same for COVID-19 as for any other disaster and should be made through the local/state ESF-8 desk. Requests that cannot be handled locally will be moved up to the federal level.
- Requests currently being processed include 250 ambulances for New York City and 85 refrigerated storage units

Shield. Shelter. Save. Sustain.

- Deploying 57 person DMORT team to New York City for 24-hour operations – will arrive Wednesday April 1st
- Location determined for PHS Strike Teams and HMTFs in Washington – they will be going to Yakima, WA, to support FMS operations. Travel will comment Thursday April 2nd.
- NY: Construction of phase 2 at the Javits ACS begins today for 2,000 beds for increased acuity care
- WA: Initial operations to begin today to staff ACS Century Link Field Event Center in Seattle with 275 personnel from 62nd Medical Brigade plus augment units. Fully operational by 07Apr20
- LA: A 3,000-bed ACS is being established at the New Orleans Convention Center and will be operational by 02Apr20

US CASE COUNTS & OUTBREAK UPDATES

- 163,524 *[+21,487]* cases and 2,893 *[+478]* deaths
- 1,904 U.S. healthcare workers COVID positive (67 travel related, 394 contact with known case, 1,443 under investigation) and 3 deaths
  **new numbers are received each day from CDC at 0730ET*
- **Domestic outbreaks, widespread***:*
  - 50 states + DC, Guam, PR, USVI, and CNMI have cases
  - 10 states have over 1,000 cases and 14 states have over 2,000. New York has 67,131 cases (including 38,087 in NYC (57% of the state total))
- **International outbreaks, widespread:**
  - There were over 58,000 new cases and over 3,200 new deaths in the last 24 hours. Europe accounted for 54% of the reported cases.

From:	Josie Briggs <jpbriggs@pcori.org>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
CC:	Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>; Kimberly DiGioia <kdigioia@pcori.org>; Lauren Cohen <lauren.w.cohen@duke.edu>
Subject:	Health Care Worker HCQ Prophlaxis trial
Date:	2020/03/28 07:47:16
Priority:	Normal
Type:	Note

Greetings Rick,
An update and a request. We are moving forward at breakneck speed to implement a HCQ Pre-exposure Prophylaxis trial for health care workers. The broad strokes of the approach are outlined in the attached powerpoint. Thanks to BARDA, the outreach to Sandoz was prompt and immediate – and the Duke clinical research pharmacy is going to receive the drug in the first week of April. We hope to have the registry phase open in the first week in April and the trial actually enrolling by the third week of April. Our trial network has been amazing in pulling this quite large – and we think really definitive – trial together very quickly.

One remaining problem however is access to nasopharyngeal swabs. I am sure you are encountering this problem on many fronts. Again, our need will be acute in about two or three weeks.
Thanks,
Josie Briggs
Josephine P. BriggsMD
Interim Executive Director
Patient Centered Outcomes Research Institute

Sender:	Josie Briggs <jpbriggs@pcori.org>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>; Kimberly DiGioia <kdigioia@pcori.org>; Lauren Cohen <lauren.w.cohen@duke.edu>
Sent Date:	2020/03/28 07:46:41
Delivered Date:	2020/03/28 07:47:16

From:	Anna Edney (BLOOMBERG/ NEWSROOM:) <aedney@bloomberg.net>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	Bloomberg News request
Date:	2020/04/21 15:42:51
Priority:	Normal
Type:	Note

Hi. I'm reaching out given the news about your departure at BARDA today. If this email still works, could you let me know why you're leaving? Is it true you're going to NIH?

I'm hoping to chat for a few minutes if you have time. I'd like to ask you about the hydroxychloroquine EUA as well. Feel free to call my cell (b)(6) (b)(6)

Thank you
Anna

Anna Edney
Health reporter
Bloomberg News
@annaedney
aedney@bloomberg.net
202-807-2136 (office)
(b)(6) (cell)

Sender:	Anna Edney (BLOOMBERG/ NEWSROOM:) <aedney@bloomberg.net>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/04/21 15:42:46
Delivered Date:	2020/04/21 15:42:51
Message Flags:	Unread

From:	Kane, Elleen (OS/ASPR/OEA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=USER25DBD6C7 <Elleen.Kane@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>
CC:	Billet, Courtney (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb5c51123f2f41b98b61a37383994a8d-courtney.bi <billetc@niaid.nih.gov>; Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@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: Novartis, Mylan and Teva to supply tens of millions of chloroquine tablets to fight COVID-19 | FiercePharma
Date:	2020/03/28 17:37:47
Priority:	Normal
Type:	Note

We drafted the news release around the products for which FDA provided an EUA. Happy to include others if appropriate. Draft is attached with Teva included.

-----Original Message-----
From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Saturday, March 28, 2020 5:17 PM
To: Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Subject: Re: Novartis, Mylan and Teva to supply tens of millions of chloroquine tablets to fight COVID-19 | FiercePharma

Not sure, but Elleen is drafting a PR about hcq donations to USG to support clinical studies, includes Sandoz and bayer and we suggested it also include Teva for their generosity.

Elleen, do you need any information to include a mention of Teva in the PR?

On 3/28/20, 5:08 PM, "Marston, Hilary (NIH/NIAID) [E]" <hilary.marston@nih.gov> wrote:

Yes do you need the letter documenting the donation? (we are very grateful for the help from BARDA securing the donation)

On 3/28/20, 5:05 PM, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov> wrote:

Elleen, teva is donating drug for planned nih studies. Perhaps a separate agreement with nih directly.

https://www.fiercepharma.com/pharma/new-commitments-mylan-and-teva-move-to-supply-tens-millions-hydroxychloroquine-tablets-to

Sender:	Kane, Elleen (OS/ASPR/OEA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=USER25DBD6C7 <Elleen.Kane@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Billet, Courtney (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb5c51123f2f41b98b61a37383994a8d-courtney.bi <billetc@niaid.nih.gov>; Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@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:	2020/03/28 17:37:46
Delivered Date:	2020/03/28 17:37:47

BARDA COVID-19 Acquisitions Report - Brief Report - Active

2020-04-16 9:50:32 -04:00
Last Refreshed

Organization Name	Project Name	Product Category	Acquisition Vehicle	Obligated Amount	Date of Action	Award or Reprogramming	Project Status
(b)(4); (b)(5)							

BARDA COVID-19 Acquisitions Report - Brief Report - Pending

2020-04-16 9:50:32 -04:00
Last Refreshed

Organization Name	Project Name	Product Category	Acquisition Vehicle	Obligated Amount	Date of Action	Award or Reprogramming	Project Status
(b)(4); (b)(5)							

BARDA COVID-19 Acquisitions Report - Obligated and Active

2020-04-16 9:50:32 -04:00
Last Refreshed

(b)(4); (b)(5)

BARDA COVID-19 Acquisitions Report - Appropriation vs Obligation

2020-04-16 9:50:32 -04:00
Last Refreshed

(b)(4); (b)(5)

Senior Leadership Brief COVID-19

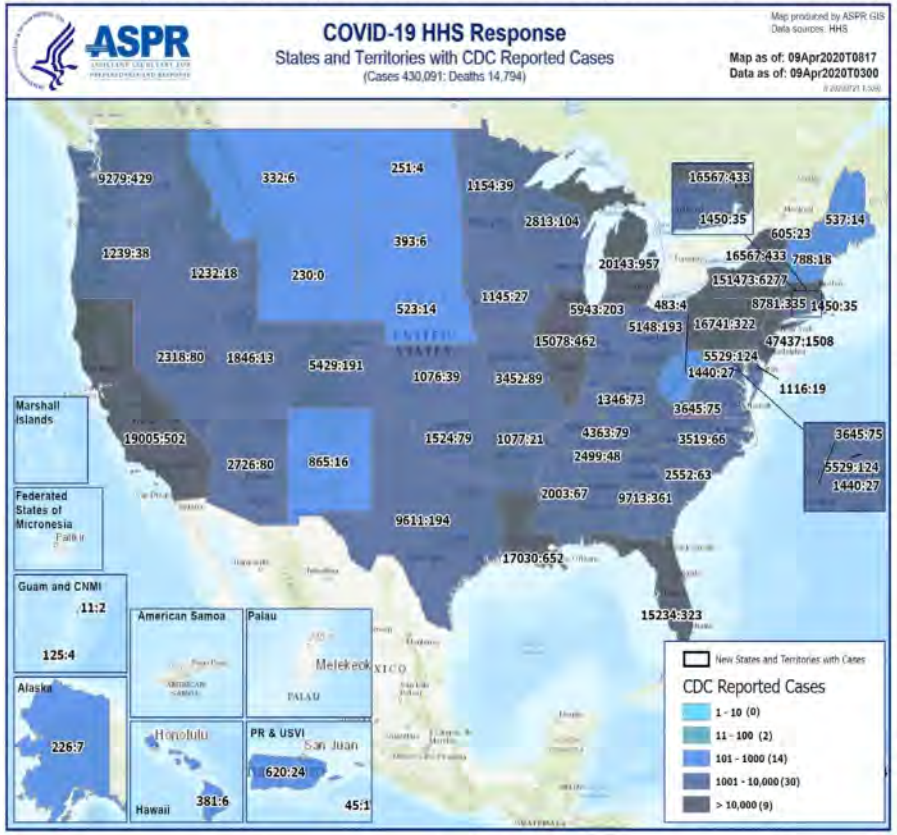
April 9, 2020 12:00 p.m. ET

For the most up to date COVID-19 data: https://geohealth.hhs.gov/arcgis/home/

Current Situation: FEMA, HHS, and our federal partners are working with state, local, tribal and territorial governments to execute a whole-of-America response to the COVID-19 pandemic. The federal government is coordinating the deployment of PPE and ventilators from multiple sources including the SNS, donations, and vendor procurements. These shipments are being sent nationwide with prioritization given to areas in greatest need. **CDC Update:** CDC confirmed and presumptive U.S. cases of COVID-19: 430,091 (+32,518) across 50 states and D.C., Guam, PR, CNMI, and USVI; Deaths: 14,794 (+1,900); Combined CDC and WHO reported global cases: 1,353,361 (+73,639); global deaths: 79,235 (+6,621); Countries and areas with cases: 211 (+1) *(HHS Update, April 9, 2020, 7:30 a.m. ET)* **Testing:** 2,068,067 (+109,823) cumulative as of April 9 (includes samples tested by State/Local Public Health Laboratories, Commercial Laboratories, Hospital Laboratories, CDC, and VA)

Operational Task Forces

Medical Counter-Measure (MCM) Development	• Requests for chloroquine/hydroxychloroquine from the SNS: 11 Emergency Use Authorizations (EUA) requests received and 11 (+6) shipped *(MCM TF Update, April 9, 2020, 9:25 a.m. ET)* • Clinical trial to test remdesivir for treatment: 560 (+34) new patients (target: 700) at 61 (+3) sites *(MCM TF Update, April 9, 2020, 9:25 a.m. ET)*
Health Care Resilience (HCR)	• Finalized performance indicators of decontamination system for N95 masks; hosting decontamination system informational webinar April 9 with Regions and States *(HCR TF Update, April 9, 2020, 10:10 a.m. ET)* • Supplies (PPE, Abbott testing system) for Maryland Nursing Home pilot expected to ship April 10 *(HCR TF Update, April 9, 2020, 10:10 a.m. ET)*
Lab Diagnostics	• International Reagent Resource has 5,000 Abbott ID Now test in inventory to support requests from registered public health labs *(LD TF Update, April 9, 2020, 10:27 a.m. ET)* • Coordinating with HHS and Abbott on replenishment plan for state public health labs that received the Abbott ID Now machines and tests *(LD TF Update, April 9, 2020, 10:27 a.m. ET)*
Community Based Testing Sites (CBTS)	• 77,344 cumulative tested since March 23 at CBTS locations *(CBTS TF Update, April 9, 2020, 10:08 a.m. ET)* • Emergency resupply of PPE and swabs arrived at CBTS locations April 8 *(CBTS TF Update, April 9, 2020, 10:08 a.m. ET)*
Supply Chain Stabilization	• 21 total Airbridge flights complete; 49 remaining flights scheduled *(SC TF Update, April 9, 2020, 10:01 a.m. ET)* • Airbridge flights #19, #20, and #21 landed in Chicago on April 8; total cargo was 34,385,299 gloves; 8,730,450 protective masks; 195,450 gowns *(SC TF Update, April 9, 2020, 10:01 a.m. ET)* • Received authorization for Defense Production Act (DPA) Title 3 to increase N95 mask production *(DPA Update, April 9, 2020, 11:00 a.m ET)*
Community Mitigation Measures	• Collaborating with Data and Analysis Task Force to help integrate information about community mitigation models into NRCC modeling activities *(CMM TF Update, April 9, 2020, 10:00 a.m. ET)*
Continuity of Operations and Essential Services	• 8 Wireless Emergency Alert (WEA) messages sent by local authorities; 7 were reminders of protective measures; 1 requested PPE from the public *(COOP TF Update, April 9, 2020, 9:45 a.m. ET)*
Data and Analysis	• State data for 55 (+2) states/territories integrated into the HHS GeoHealth Common Operating Picture to support decision making *(DA TF Update, April 9, 2020, 9:40 a.m. ET)* • Provided Medical Countermeasure Task Force with supply and demand analysis to compare projections of patients with ventilator needs over time vs the availability of certain drug development production *(DA TF Update, April 9, 2020, 9:40 a.m. ET)*



Key Updates/Actions

All 50 states, the District of Columbia, 5 territories, and 25 tribal nations are working directly with FEMA under the nationwide emergency declaration for COVID-19 *(FEMA Update, April 8, 2020, 3:15 p.m. ET)*

FEMA HQ: National Watch Center Steady State; NRCC Level I (6:00 a.m. ET to 12:00 a.m. ET); Level 1: Region I, IX; Level 2: Regions II, III, IV, V, VI, VII, VIII, X; COVID-19 Major Declarations: 52 (+1) (VT) *(FEMA Update, April 9, 2020, 2:11 a.m. ET)*

HHS: SOC at Level I (24/7) co-located with FEMA; CDC EOC activated, ACF OHSEPR at Level I *(FEMA National SITREP, March 21, 2020, 6:00 a.m. ET and HHS Update, March 20, 2020, 2:14 p.m. ET)*

Department of Homeland Security: 2,800 (+19) FEMA employees deployed to support COVID-19 Response; IMAT-A teams deployed to 26 states, territories, and DC; LNOs deployed to 37 states and territories *(FEMA Update, April 9, 2020, 10:00 a.m. ET)*

Health and Medical Lifeline

Public Health

Federal Assistance

• USACE received 27 mission assignments (MA): 3 national MAs, 2 EM Dec MAs (AZ, WI), and 10 MAs to design/build ACS in NY (8 sites), PA (5 sites), IL (4 sites), CA (3 sites), OR (3 sites), VA (3 sites), FL (2 sites), CO (2 sites), NM (2 sites), TN (1 site), ID (1 site), WA (1 site), MD (1 site), MO (2 sites), NJ, MI, IA, KS, NV, and the Navajo Nation; 17 contracts awarded with a total projected bed capacity of 15,587; completed 828 out of 869 requested ACS assessments; 2,078 (+58) USACE personnel supporting *(ESF-3 Update, April 9, 2020, 8:27 a.m. ET)*

Medical Equipment

• HHS announced first contract with corporation for ventilator production rated under the DPA *(CISA Update, April 9, 2020, 5:48 a.m. ET)*

Medical Care

Hospital Capacity

• NYC: Javits Center 155 (+51)/1000 (+335) beds filled; 0 (-1)/84 (+39) beds with ventilators filled; 7 (+2)/48 ICU beds filled; 207 (+70) patients seen *(DoD Update, April 9, 2020, 10:05 a.m. ET)*

• NYC: USNS Comfort 60 (+10)/500 (-420) beds filled; 16(+9)/52 beds with ventilator filled; 16 (-9)/80 ICU beds filled; 76 (+12) patients seen *(DoD Update, April 9, 2020, 10:05 a.m. ET)*

• NYC: Refrigerated trailers to support mortuary operations continue to arrive in NYC; 63 received and 10 deployed *(CISA Update, April 9, 2020, 5:48 a.m. ET)*

• CA: USNS Mercy currently with 13 (+1)/1000 (+80) beds filled; 0 (-1)/70 beds with ventilator filled; 6 (-1)/80 ICU beds filled; 32 (+2) patients seen *(DoD Update, April 9, 2020, 10:05 a.m. ET)*

• LA: Ernest N. Morial Convention Center in New Orleans; 3 (+1)/204 beds filled; 3 (+1) patients seen *(DoD Update, April 9, 2020, 10:05 a.m. ET)*

Other Domestic Lifelines

Safety & Security

• At least 42 states, D.C., 4 territories, and 31 (+7) tribes issued shelter-in-place orders *(FEMA Tribal Update, April 8, 2020, 8:19 p.m. ET)*

• Customs and Border Protection reports 50,000+ U.S. citizens have been repatriated on 485 flights from 94 countries; 72 additional repatriation flights with 9,385 passengers are currently scheduled *(DHS Update, April 9, 2020, 8:53 a.m. ET)*

• USCG tracking 1 remaining cruise ship (Pacific Princess) to arrive in US port with 125 passengers (approx. 40 U.S. citizens) and 368 crew. *(DHS Update, April 9, 2020, 8:53 a.m. ET)*

Food, Water, & Shelter

• Southern Baptist Disaster Relief partnered with local organizations to provide food distribution in 7 states (AZ,CO,KY,LA,NM,TN,VT) *(ESF-6 Update, April 8, 2020, 10:25 a.m. ET)*

• PA: National Guard is assembling approximately 3,000 food boxes for families in need *(NGB Update, April 9, 2020, 6:51 a.m. ET)*

Ventilators

Region Number	Delivered	Processing	Total
01	**150**		**150**
Connecticut	50		**50**
Massachusetts	100		**100**
02	**5750**		**5750**
New Jersey	1350		**1350**
New York	2000		**2000**
New York City	2400		**2400**
03	**120**	**150**	**270**
Delaware		50	**50**
Maryland	120	100	**220**
04	**350**		**350**
Florida	200		**200**
Georgia	150		**150**
05	**1300**		**1300**
Chicago	300		**300**
Illinois	300		**300**
Michigan	700		**700**
06	**350**	**20**	**370**
BOP		20	**20**
Louisiana	350		**350**
09	**170**	**30**	**200**
Guam		30	**30**
LA County (CA)	170		**170**
10	**700**		**700**
Alaska	60		**60**
Oregon	140		**140**
Washington	500		**500**
Total	**8890**	**200**	**9090**

Product groups	Gloves			N95s			Surgical Gowns			Surgical Masks		
FEMA Region	In Transit	Delivered	Total	In Transit	Delivered	Total	In Transit	Delivered	Total	In Transit	Delivered	Total
⊟ II												
New York		1,499,298	**1,499,298**	313,380	5,709,420	**6,022,800**		301,639	**301,639**		2,536,890	**2,536,890**
⊟ III												
District of Columbia		384,660	**384,660**		132,478	**132,478**		55,657	**55,657**		314,600	**314,600**
⊟ IX												
California		1,821,422	**1,821,422**	59,400	1,587,120	**1,646,520**		412,017	**412,017**		3,788,009	**3,788,009**
⊟ V												
Michigan		618,930	**618,930**		362,420	**362,420**		121,703	**121,703**		740,018	**740,018**
⊟ VI												
Louisiana		483,464	**483,464**		258,242	**258,242**		83,633	**83,633**		494,800	**494,800**
⊟ X												
Washington		240,376	**240,376**		494,780	**494,780**		109,264	**109,264**		794,428	**794,428**

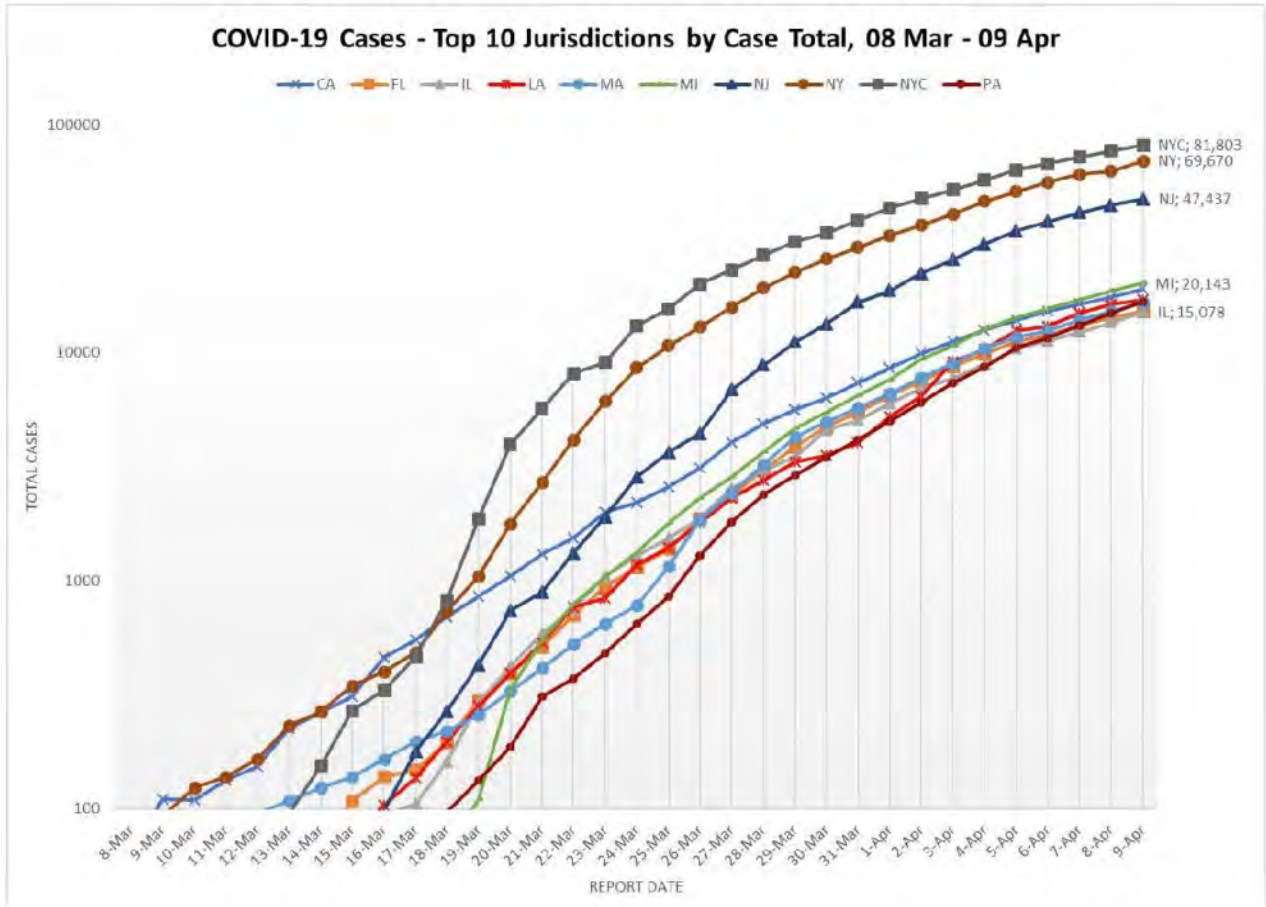
Table includes SNS and Logistics Supply Chain Management System as of 6pm on April 8

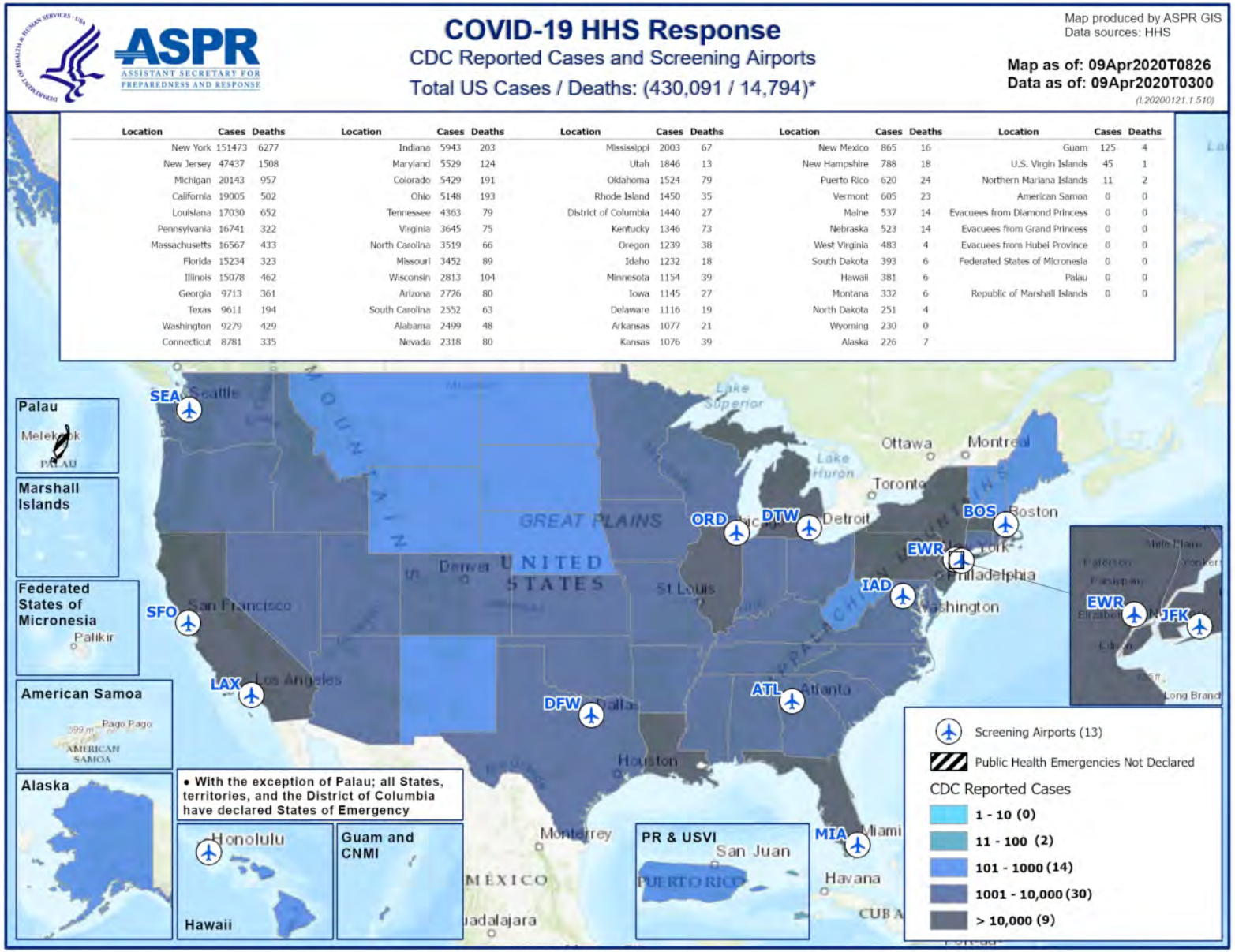
FEMA

Senior Leadership Brief COVID-19

April 9, 2020 12:00 p.m. ET

For the most up to date COVID-19 data: https://geohealth.hhs.gov/arcgis/home/





Location	Cases	Deaths	Location	Cases	Deaths	Location	Cases	Deaths	Location	Cases	Deaths	Location	Cases	Deaths
New York	151473	6277	Indiana	5943	203	Mississippi	2003	67	New Mexico	865	16	Guam	125	4
New Jersey	47437	1508	Maryland	5529	124	Utah	1846	13	New Hampshire	788	18	U.S. Virgin Islands	45	1
Michigan	20143	957	Colorado	5429	191	Oklahoma	1524	79	Puerto Rico	620	24	Northern Mariana Islands	11	2
California	19005	502	Ohio	5148	193	Rhode Island	1450	35	Vermont	605	23	American Samoa	0	0
Louisiana	17030	652	Tennessee	4363	79	District of Columbia	1440	27	Maine	537	14	Evacuees from Diamond Princess	0	0
Pennsylvania	16741	322	Virginia	3645	75	Kentucky	1346	73	Nebraska	523	14	Evacuees from Grand Princess	0	0
Massachusetts	16567	433	North Carolina	3519	66	Oregon	1239	38	West Virginia	483	4	Evacuees from Hubei Province	0	0
Florida	15234	323	Missouri	3452	89	Idaho	1232	18	South Dakota	393	6	Federated States of Micronesia	0	0
Illinois	15078	462	Wisconsin	2813	104	Minnesota	1154	39	Hawaii	381	6	Palau	0	0
Georgia	9713	361	Arizona	2726	80	Iowa	1145	27	Montana	332	6	Republic of Marshall Islands	0	0
Texas	9611	194	South Carolina	2552	63	Delaware	1116	19	North Dakota	251	4			
Washington	9279	429	Alabama	2499	48	Arkansas	1077	21	Wyoming	230	0			
Connecticut	8781	335	Nevada	2318	80	Kansas	1076	39	Alaska	226	7			

ASPR
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

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USG COVID-19 Response

USG Medical Resources, Force Laydown and County Hotspots

Map produced by ASPR GIS
Data sources: CDC, DoD, HHS, FEMA, USACE

Map as of: 08Apr2020T2212

USG Total

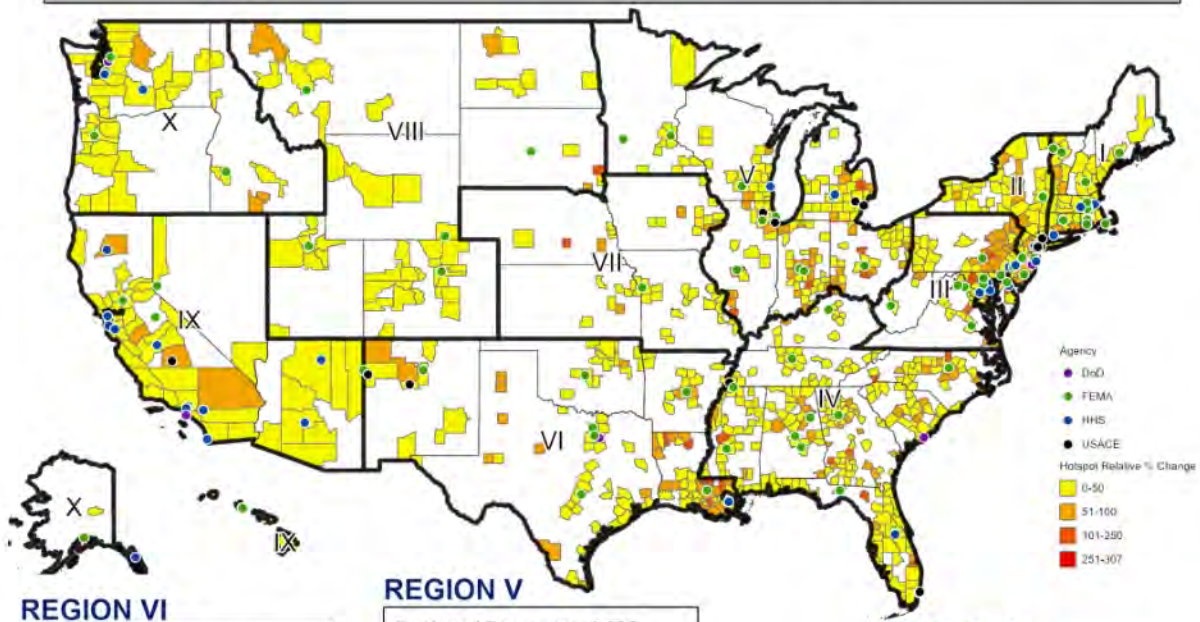
Deployed Personnel: 19,870
- CDC: 99
- HHS: 438
- DoD: 16,651
- FEMA: 2,781

Equipment / Supplies
- FMS 250 (32)
- FMS 50 (9)
- ASPR Rx (8)
- DoD Field Hospital (2)

ACS (51)
- Total Beds: 24,350
  - ASPR Beds: 8,200
  - DoD Beds: 534
  - USACE: 15,616

Ventilators (9,340)

USNS Medical Ship (2)



REGION X

Deployed Personnel: 1,417
- HHS: 136
- DoD: 1,132
- FEMA: 149

Equipment / Supplies
- FMS 250 (2)
- FMS 50 (2)
- ASPR Rx (4)
- DoD Field Hospital (1)

ACS (3)
- Total Beds: 850
  - ASPR Beds: 600
  - DoD Beds: 250

Ventilators (560)

REGION IX

Deployed Personnel: 2,755
- HHS: 37
- DoD: 2,534
- FEMA: 184

Equipment / Supplies
- FMS 250 (8)
- FMS 50 (5)

ACS (13)
- Total Beds: 2,496
  - ASPR Beds: 2,250
  - USACE Beds: 246

Ventilators (200)

USNS Mercy: 1,000 Beds

REGION VIII

Deployed Personnel: 387
- HHS: 9
- DoD: 265
- FEMA: 113

ACS (1)
- Total Beds: 2,000
  - USACE Beds: 2,000

Ventilators (100)

REGION VII

Deployed Personnel: 98
- FEMA: 98

REGION VI

Deployed Personnel: 597
- HHS: 4
- DoD: 448
- FEMA: 145

Equipment / Supplies
- FMS 250 (3)
- FMS 50 (1)
- ASPR Rx (1)

ACS (5)
- Total Beds: 1,050
  - ASPR Beds: 800
  - USACE Beds: 250

Ventilators (370)

REGION V

Deployed Personnel: 3,925
- HHS: 69
- DoD: 3,708
- FEMA: 148

Equipment / Supplies
- FMS 250 (4)

ACS (8)
- Total Beds: 7,061
  - ASPR Beds: 750
  - USACE Beds: 6,311

Ventilators (1,350)

REGION IV

Deployed Personnel: 1,652
- HHS: 29
- DoD: 1,453
- FEMA: 170

Equipment / Supplies
- FMS 250 (1)

ACS (4)
- Total Beds: 1,947
  - ASPR Beds: 250
  - USACE Beds: 1,697

Ventilators (350)

REGION I

Deployed Personnel: 2,067
- HHS: 2
- DoD: 1,877
- FEMA: 188

Equipment / Supplies
- FMS 250 (3)

ACS (1)
- ASPR Beds: 750

Ventilators (250)

REGION II

Deployed Personnel: 4,365
- HHS: 141
- DoD: 3,970
- FEMA: 254

Equipment / Supplies
- FMS 250 (8)
- ASPR Rx (3)
- DoD Field Hospital (1)

ACS (10)
- Total Beds: 8,396
  - ASPR Beds: 2,000
  - DoD Beds: 284
  - USACE Beds: 5,112

Ventilators (5,890)
- DoD Ventilators (300)

DoD Mortuary Affairs Team (1)

USNS Comfort: 1,000 Beds

REGION III

Deployed Personnel: 2,607
- HHS: 11
- DoD: 1,264
- FEMA: 1,332

Equipment / Supplies
- FMS 250 (3)
- FMS 50 (1)

ACS (4)
- Total Beds: 800
  - ASPR Beds: 800

Ventilators (270)

NBEOC Service Desk Processing - Coronavirus (COVID-19) - April 8, 2020 – 1:00 Pm EDT

Private sector RFIs continue to be inquiries regarding FEMA seizing or blocking shipments of supplies

NBEOC Actions Today

- Coordinating updates to "How to Help" at FEMA.gov
- Building/coordinating scripting and protocols in response to non-FEMA issues or frivolous inquiries

TOTAL TICKETS- 4719 PROCESSED

TYPES OF INQURIES

3132 (66%) Offers of Support
1332 (28%) Requests for Information
202 (4%) NBEOC Membership Request
36 (1%) Status Update
17 (1%) Meeting Request

NBEOC Service Desk / NBEOC Offers of Support Totals by Component and Disposition since Jan. 30

NBEOC Disposition	Donations/Volunteer	Manufacturing/Retooling	Sale/Contract	Unspecified	T:
Laboratory Diagnostic Task Force	0	0	3	0	3
Community Based Testing Sites Task ...	0	0	1	1	2
Supply Chain Task Force	0	57	3	0	59
Healthcare Resilience Task Force	1	0	0	0	1
Medical Countermeasures Task Force	0	1	1	0	2
Data Management Task Force	0	0	2	0	2
Procurement	0	0	1	0	1
Other - add comment	0	1	2	0	3
None	409	890	1,753	97	3,059
Total:	**410**	**949**	**1,766**	**98**	3,132

3,132 total issues — Issue Count by Components 4 / NBEOC Disposition 9

NBEOC Service Desk / NBEOC Offers Total by Offer Category since Jan. 30

COVID-19 Offer Categories	Donations/Volunteer	Manufacturing/Retooling	Sale/Contract	Unspecified	T:
Facilities	3	25	177	1	205
Logistics	3	39	50	6	93
Medical Supplies	28	196	238	21	476
N-95 Respirators	6	35	155	5	200
Other Non-Medical	17	118	300	4	432
Other PPE	56	245	371	13	665
Professional Services	14	83	386	10	492
Surgical Masks	6	106	73	4	187
Ventilators	6	73	101	4	179
None	285	230	191	51	705
Total:	**410**	**949**	**1,766**	**98**	3,132

3,132 total issues — Issue Count by Components 4 / COVID-19 Offer Categories 10

COVID-19 BARDA Overview

Date: April 10, 2020

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Policy Options: Allocation of HHS-Held Chloroquine and Hydroxychloroquine for International Clinical Trials

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treatment withdrawal is contemplated. Until improved blood or urine biomarkers have been developed, repeat biopsy will remain a useful tool for the clinic.

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1. Malvar A, Alberton V, Lococo B, *et al*. Kidney biopsy-based management of maintenance immunosuppression is safe and may ameliorate flare rate in lupus nephritis. *Kidney Int*. 2019
2. De Rosa M, Azzato F, Toblli JE, *et al*. A prospective observational cohort study highlights kidney biopsy findings of lupus nephritis patients in remission who flare following withdrawal of maintenance therapy. *Kidney Int*. 2018;**94**:788–794.
3. Arriens C, Chen S, Karp DR, *et al*. Prognostic significance of repeat biopsy in lupus nephritis. Histopathologic worsening and a short time between biopsies is associated with significantly increased risk for end stage renal disease and death. *Clin Immunol*. 2017;**185**:3–9.

Oral presentations

O1 HYDROXYCHLOROQUINE BLOOD LEVELS AND RISK OF THROMBOTIC EVENTS IN SYSTEMIC LUPUS ERYTHEMATOUS

Maximillian F Konig, Jessica Li, Michelle Petri. *Medicine, Rheumatology, Johns Hopkins University School of Medicine, Baltimore, USA*

10.1136/lupus-2020-eurolupus.15

Background Hydroxychloroquine (HCQ) has a primary role in the treatment of systemic lupus erythematous (SLE). Beyond its pleiotropic immunomodulatory effects on TLR and type 1 interferon signaling, HCQ use has been found to be protective for thrombosis in SLE. Optimal dosing of HCQ in SLE is unknown. The longitudinal measurement of HCQ blood levels may provide an opportunity to individualize weight-based dosing strategies and reduce risk of toxicity. We examined the association of HCQ blood levels with thrombotic events in a longitudinal SLE cohort.

Methods 812 SLE patients with HCQ level measured prior to the thrombosis were included: 93% female, 43% African-American, 46% Caucasian. HCQ blood levels were quantified by liquid chromatography-tandem mass spectrometry. Mean HCQ blood levels (± SD) over all cohort visits prior to occurrence of thrombosis were calculated for each patient. Thromboses were defined as venous (DVT/PE or other venous) or arterial thrombosis (stroke, myocardial infarction, digital gangrene or other arterial).

Results Thrombosis had occurred during prospective follow up in 44 patients (5.4%), venous in 3.0% and arterial in 2.5%. Lupus anticoagulant was strongly associated with a history of any thrombosis (OR 3.25, P<0.0001), venous thrombosis (OR 3.53, P<0.0001), and arterial thrombosis (OR 3.08, P<0.0001). A prospective analysis shows that for any thrombosis and for venous thrombosis, the HCQ blood level was significantly lower. Higher prescribed doses of HCQ (as opposed to HCQ blood levels) were also associated with decreased odds of any thrombosis and venous thrombosis in a separate cross-sectional analysis (OR 0.88, P=0.04 and OR 0.83, P=0.009, respectively for each 1 mg/kg increase in prescribed HCQ).

Conclusions HCQ blood levels are inversely associated with risk of any thrombosis and of venous thrombosis in patients with SLE in a prospective analysis. Reduction of HCQ dosing, as suggested by the American Academy of Ophthalmologists, could reduce or eliminate the benefit of hydroxychloroquine to prevent thrombosis.

Acknowledgements The Hopkins Lupus Cohort is supported by NIH Grant RO1 AR 69572.

O2 EFFECT OF TREATMENT ON ANTIPHOSPHOLIPID ANTIBODIES IN SLE

[1]Michelle Petri, [2]Laurence S Magder, [1]Daniel W Goldman. *[1]Medicine, Rheumatology, Johns Hopkins University School of Medicine, Baltimore; [2]Dept. Epidemiology, University of Maryland, School of Medicine, Baltimore, USA*

10.1136/lupus-2020-eurolupus.16

Background Unlike primary antiphospholipid syndrome patients, most SLE patients with antiphospholipid antibodies are on one or more treatments for their SLE that might affect levels of their antiphospholipid antibodies. We examined the effect of prednisone and hydroxychloroquine on antiphospholipid antibodies in an SLE longitudinal cohort.

Methods 943 SLE patients, who were tested for each anticardiolipin isotype (aCL IgG, IgM and IgA; INOVA) and lupus anticoagulant (LAC; dRVVT with further confirmatory testing) for at least 10 quarterly clinic visits, were included. We compared visits positive for antiphospholipid antibodies (aCL>20 and aCL>40; dRVVT>45) to visits negative for antiphospholipid antibodies, with respect to treatment, using conditional logistic regression and conditioning on the patient.

Results Prednisone treatment significantly reduced the levels of aCL IgG isotypes (aCL IgG>40 and some prednisone but less than 10 mg/day, OR 0.61 95% CI 0.46–0.80 p=0.0004), but not aCL IgM, IgA, or LAC. Hydroxychloroquine treatment significantly reduced aCL IgG (aCL IgG>40, OR 0.35 95% CI 0.22–0.55 p<0.0001), aCL IgM (aCL IgM>40, OR 0.56 95% CI 0.36–0.87 p=0.010) and LAC (OR 0.71 95% CI 0.58–0.86 p=0.007) but not aCL IgA.

Conclusions Prednisone does not reduce IgM or IgA isotypes of anticardiolipin, or LAC. These results explain why prednisone does not reduce thrombosis in SLE. Hydroxychloroquine, on the other hand, significantly reduces all antiphospholipid types except for the IgA isotype of anticardiolipin. This may explain why IgA isotypes are more common in SLE. It may also explain why hydroxychloroquine leads to only a 50% reduction in thrombosis, as IgA isotypes do confer some risk of thrombosis.

Acknowledgements The Hopkins Lupus Cohort is supported by NIH Grant RO1 AR 69572.

O3 CHANGES IN GUT MICROBIOTA AFTER SYNBIOTIC SUPPLEMENTATION IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

[1,2,3]Alvina Widhani, [1,2]Samsuridjal Djauzi, [4]Fransiscus D Suyatna, [5]Beti Ernawati Dewi, [4]Melva Louisa, [5]Andi Yasmon, [6]Susan Rahayu. *[1]Allergy and Clinical Immunology Division, Dept. of Internal Medicine, Faculty of Medicine, Universitas Indonesia, Jakarta; [2]Dr. Cipto Mangunkusumo National General Hospital, Jakarta; [3]Doctoral Program in Biomedical Science, Faculty of Medicine, Universitas Indonesia, Jakarta; [4]Dept. of Pharmacology and Therapeutic, Faculty of Medicine, Universitas Indonesia, Jakarta; [5]Dept. of Microbiology, Faculty of Medicine, Universitas Indonesia, Jakarta; [6]Molecular Biology Unit, Integrated Laboratory, Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia*

10.1136/lupus-2020-eurolupus.17

Background Systemic lupus erythematosus (SLE) is a chronic multiorgan autoimmune disease with high morbidity. The pathogenesis is multifactorial. Gut dysbiosis plays a role in the pathogenesis of systemic lupus erythematosus (SLE). It can cause systemic inflammation.

Methods We conducted a randomized, double-blind, placebo-controlled trial to investigate whether synbiotic supplementation could improve gut microbiota composition and function in patients with SLE.

Results Forty six SLE patients were randomised to two groups: the synbiotic group received synbiotic capsule (*Lactobacillus helveticus* R0052 60%, *Bifidobacterium infantis* R0033 20%, *Bifidobacterium bifidum* R0071 20% and 80 mg fructo-oligosaccharides) for 60 days and placebo group. In the synbiotic-supplemented group, 21 patients completed the intervention. In the placebo group, one was excluded from the final analysis because she needed antibiotic treatment for 33 days. We analysed 16s rRNA microbiome data from 89 faecal samples of the 46 patients. We found increases in the *Firmicutes* to *Bacteroidetes* ratio, butyrate metabolism and nitrotoluene degradation after synbiotic supplementation. We also found a decrease in potentially pathogenic species and an increase in beneficial species.

Conclusion Synbiotic supplementation affect the composition and functions of gut microbiota in patients with systemic lupus erythematosus.

04 BARICITINIB-INDUCED CHANGES IN STAT-ASSOCIATED GENE EXPRESSION IN SYSTEMIC LUPUS ERYTHEMATOSUS

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10.1136/lupus-2020-eurolupus.18

Background Baricitinib, an oral selective Janus kinase (JAK)1 and 2 inhibitor, resulted in significant clinical improvements in patients with active systemic lupus erythematosus (SLE) receiving standard background therapy in the phase 2 study JAHH (NCT02708095). Baricitinib may impact key cytokines implicated in the pathogenesis of SLE through effects on the JAK/signal transducer and activator of transcription (STAT) signaling pathway. The impact of baricitinib on STAT-related gene expression and associations with clinical response in SLE were evaluated.

Methods 314 patients were randomized 1:1:1 to receive once-daily placebo, baricitinib 2-mg, or baricitinib 4-mg for 24 weeks in JAHH. Patients were ≥18 years of age, had a

Abstract 04 Table 1 Number of STAT –related genes whose variation has statistically significant association to SLEDAI-2K variation

STAT	Week	Number of downstream genes	Number of downstream genes with FDR < 0.1	Number of downstream genes with P < 0.05
STAT1	2	135	30	45
STAT1	4	135	0	5
STAT1	12	135	0	2
STAT1	24	135	0	1
STAT2	2	38	11	13
STAT2	4	38	0	2
STAT2	12	38	0	0
STAT2	24	38	0	0
STAT4	2	6	0	1
STAT4	4	6	0	0
STAT4	12	6	0	0
STAT4	24	6	0	0

Spearmen rank coefficient correlations between variation in SLEDAI-2K (from baseline) and variation in log2 expression (from baseline) of genes were computed at weeks 2, 4, 12, and 24 with baricitinib 4-mg treatment and tested for statistically significant differences from zero. Genes analyzed were downstream of *STAT1*, *STAT2*, or *STAT4* as selected from the MetaCore Database. The number of selected downstream genes for each STAT is shown, along with the number of statistically significant genes.
FDR=false discovery rate; SLEDAI-2K=Systemic Lupus Erythematosus Disease Activity Index-2000; STAT=signal transducer and activator of transcription

Iloprost for the Treatment of COVID-19

April 7, 2020
Daniel J. Sussman, Ph.D.
VisionGate, Inc.

Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), now known as Covid-19, is causing a world-wide pandemic. Therapeutics are urgently needed to prevent the onset of severe disease and to reduce the risk of death of severely ill patients. Potentially effective therapeutic strategies include the use of anti-inflammatory drugs that can mitigate severe disease. The following report presents evidence that iloprost could be an effective drug to treat infected patients and potentially act to prophylactically prevent infection.

COVID-19 and Pulmonary Function

Statistics from the Chinese Centers for Disease Control and Prevention encompassing 72, 314 cases reported that 81% were of a mild nature with an overall case fatality rate of 2.3%, and a sub-group of 5% presented with respiratory failure, septic shock and multi-organ dysfunction (China CDC Weekly) Half of the cases presenting with severe symptoms resulted in fatality. The overall death rate in the U.S. due to coronavirus is currently approximately 3%, however a lack of testing may overestimate this death rate. Siddiqi and Mehra (2020), physicians at Harvard Medical School, have proposed the following staging: Stage 1 (mild) – This stage involves the initial viral inoculation and early establishment of the disease where the virus multiplies and establishes residence in the host, primarily focusing on the respiratory system. Stage 2 (moderate) – Pulmonary involvement (IIa) is prevalent with viral multiplication and localized inflammation in the lung. Patients develop a viral pneumonia, with cough, fever and possibly hypoxia. Stage 3 (severe) – Patients develop extra-pulmonary systemic hyperinflammatory syndrome, also referred to as a cytokine storm. Inflammatory cytokines and biomarkers such as interleukin (IL)-2, IL-6, IL-7, granulocyte-colony stimulating factor, macrophage inflammatory protein 1-α, tumor necrosis factor-α, C-reactive protein, ferritin, and D-dimer are significantly elevated in these patients.

Treatment of COVID-19 With Anti-Inflammatory Agents

A number of agents to treat COVID-19 disease are currently being tested in clinical trials. Several small trials employing hydroxyquinine have given mixed results, with one showing promising results (Gautret et al., 2020) and others showing no benefit (Chen et al., 2020; Molina et al., 2020). No benefit was found in a randomized clinical trial of 199 patients treated with the antiviral agents lopinavir–ritonavir (Cao et al., 2020). Siddiqi and Mehra (2020) have suggested the possible benefit of treating COVID-19 patients with anti-inflammatory agents.

Patients infected by previous coronaviruses, severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS), exhibited rapid virus replication, inflammatory cell infiltration, and cytokine storm which led to acute lung injury and acute respiratory distress syndrome (ARDS) (Channappanavar et al., 2017; Chousterman et al., 2017). As described above, Inflammation of the lungs is prevalent in COVID-19 patients, with severe cases exhibiting cytokine storm (Huang et al., 2020; Conti et al., 2020). In one study of 123 COVID-19 patients, all of them had lymphocytopenia (one of the diagnostic criteria used in China) where the remaining lymphocytes were activated (Wan et al., 2020). The percentage of CD8 + T cell reduction were 28.43% and 61.9% in mild and severe group respectively, and the NK cell reduction were 34.31% and 47.62% respectively in mild and severe groups.

A review of our current knowledge of anti-inflammation treatment in COVID-19 patients was published by Zhang et al. (2020). The rationale for the use of anti-inflammatory agents is to help with lung function and to prevent the lung damage that is caused by a cytokine storm. There are a variety of anti-inflammatory medications, including non-steroidal anti-inflammatory drugs, glucocorticoids, chloroquine/hydroxychloroquine, immunosuppressants, and inflammatory cytokines antagonists. Some of these, such as glucocorticoids are not recommended in the early stage of infection as they might amplify viral replication. As described in detail in the review (Zhang et al., 2020), clinical trials have shown no efficacy in treating COVID-19 patients with glucocorticoids. Clinical trials are underway with immunosuppressants and cytokine antagonists.

Iloprost, Inflammation, and COVID-19 Treatment

Iloprost, a synthetic analogue of prostacyclin PGI2, is an excellent candidate for the treatment of COVID-19. Iloprost has been in use for many years as an effective therapeutic agent for the treatment of moderate to severe pulmonary hypertension. Perhaps the best evidence that iloprost will be an effective treatment of COVID-19 is a recently proposed Phase II clinical trial for the treatment of ARDS (Haeberle et al., 2020). In addition to its anti-inflammatory properties described below, through target-based virtual ligand screening, iloprost has been identified as a molecule with potential to block the binding of the virus to its cellular receptor (Wu et al., 2020).

Iloprost has been shown to reduce pulmonary inflammation in a number of small and large animal studies. These studies include a pressure-induced model of lung injury (Birukova et al.,2010), ischemia-reperfusion (IR) injury (Kawashima et al., 2003; Yasa et al., 2008; Erer et al., 2014 and 2016); and porcine models of ARDS (Dembinski et al., 2005; Witter et al., 2005a and 2005b). A study with human patients demonstrated that iloprost improved gas exchange in patients with pulmonary hypertension and ARDS (Sawheny et al., 2013).

There are several mechanisms by which iloprost has been shown to reduce pulmonary inflammation, including the cyclooxygenase-2 (COX-2) system with involvement of lipoxin A4 (Scully et al., 2012), Ras-related protein 1 (RAP-1) (Burkova, 2009), and IL-1β (Crutchley et al., 1994; Della Bella et al., 1997; Zor et al., 2010; Lammi et al., 2016), a critical component of lung inflammation during viral infection (Kim et al., 2015). iloprost/prostacyclin suppresses inflammation through other pathways. Iloprost has been shown to possess anti-inflammatory and immunomodulating actions *in vitro* (Jores et al., 1997; Medsger et al., 1999; Czeslick et al.,

2003; Zhou et al., 2007) and *in vivo* (Jaffar et al.; 2002; Di Renzo et al.; 2005; Zhou et al., 2007; Leibbrandt et al., 2008). Mechanisms by which iloprost reduces inflammation include its activity in reducing TNF-□ production by T cells and the number of T regulatory cells, as well as in increasing IL-2 and RANKL (D'Amelio et al., 2010). In addition, iloprost has been shown to inhibit production of intracellular tumour necrosis factor TNF-α and interleukin IL-6 in human monocytes (Czeslick et al., 2003).

In conclusion, iloprost has been shown to be effective at treating COVID-19 because it has been shown to be effective at inhibiting many of the pro-inflammatory molecules that result in cytokine storm. In addition, qt least theoretical, iloprost has the potential to block infection.

Advantages of Iloprost Over Other Drugs for Treatment of COVID-19

Unlike the other agents listed above, iloprost works through multiple pathways to inhibit pulmonary inflammation. In addition, Iloprost causes dilation of narrowed blood vessels in the lungs, decreasing pulmonary blood pressure and improving lung function. Iloprost has been used successfully for many years to treat Pulmonary hypertension and Reynaud's syndrome and has minimal side effects.

Advantage of Oral Iloprost Vs. Inhaled Iloprost

The advantages of oral iloprost of the inhaled formulation (Ventavis) are based on dosing and serum levels. The half-life of inhaled iloprost is 20 to 30 minutes. Following inhalation of iloprost (5 mcg) patients with pulmonary hypertension have iloprost peak serum levels of approximately 150 pg/mL, with Iloprost generally not detectable in the plasma 30 minutes to 1 hour after inhalation (https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021779s006lbl.pdf). In contrast, oral iloprost is similar to infused iloprost with steady-state levels of 260 pg/mL (Hildebrand, 1997).

The recommended dose of inhaled iloprost is as follows: "Ventavis should be taken 6 to 9 times per day (no more than once every 2 hours) during waking hours, according to individual need and tolerability. The maximum daily dose evaluated in clinical studies was 45 mcg (5 mcg 9 times per day)." As a result of this dosing, lung and serum levels of inhaled iloprost drops to zero as the patient sleeps.

There are other dosing problems with inhaled medications that do not occur with oral delivery. These problems include shallow breathing in patients with respiratory disease (Kallet et al., 2007), sub-optimal use of inhalers (Price et al., 2013; Lavorini, 2013), and uneven distribution in the lungs with reduced deposition in distal regions (Berridge et al., 2000).

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Zor HM, İmren YV, Ereer D, Oktar L, Bayram H, Benson AA. Protective effects of iloprost on cardiopulmonary bypass induced lung injury. Gazi Medical Journal 21(2):58-63, June 2010

From:	Josie Briggs <jpbriggs@pcori.org>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; adrian.hernandez <adrian.hernandez@duke.edu>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>
CC:	Kim Marschhauser <kmarschhauser@pcori.org>; Sarah Daugherty <sdaugherty@pcori.org>; Vidya Raghavan <srividya.raghavan@duke.edu>; Tyrus Rorick <tyrus.rorick@duke.edu>; Donna L Parker <donna.l.parker@duke.edu>
Subject:	RE: PCORNet trial
Date:	2020/03/23 13:03:07
Priority:	Normal
Type:	Note

Answer coming soon.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 12:49 PM
To: adrian.hernandez <adrian.hernandez@duke.edu>; Josie Briggs <jpbriggs@pcori.org>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Cc: Kim Marschhauser <kmarschhauser@pcori.org>; Sarah Daugherty <sdaugherty@pcori.org>; Vidya Raghavan <srividya.raghavan@duke.edu>; Tyrus Rorick <tyrus.rorick@duke.edu>; Donna L Parker <donna.l.parker@duke.edu>
Subject: Re: PCORNet trial

Thanks, and same number for CQ or only seeking HCQ?

From: "Adrian Hernandez, M.D." <adrian.hernandez@duke.edu>
Date: Monday, March 23, 2020 at 12:17 PM
To: Josie Briggs <jpbriggs@pcori.org>, Hilary Marston <hilary.marston@nih.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Cc: Kim Marschhauser <kmarschhauser@pcori.org>, Sarah Daugherty <sdaugherty@pcori.org>, Vidya Raghavan <srividya.raghavan@duke.edu>, Tyrus Rorick <tyrus.rorick@duke.edu>, Donna L Parker <donna.l.parker@duke.edu>
Subject: Re: PCORNet trial

Josie

Here's the info

(b)(5)

(b)(5)

adrian

From: Josie Briggs <jpbriggs@pcori.org>
Date: Monday, March 23, 2020 at 12:04 PM
To: "Marston, Hilary (NIH/NIAID) [E]" <hilary.marston@nih.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Cc: Kim Marschhauser <kmarschhauser@pcori.org>, Sarah Daugherty <sdaugherty@pcori.org>, "Adrian Hernandez, M.D." <adrian.hernandez@duke.edu>
Subject: RE: PCORNet trial

Hilary – Thank you. This is excellent.
Rick – Glad to meet virtually. We should have a clear proposal about the doses and numbers for our prophylaxis in Health Care Worker study by later today.

(b)(5)

Needless to say – timeliness is critical for us.

Josie Briggs

Josephine P. BriggsMD
Interim Executive Director
Patient Centered Outcomes Research Institute

From: Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Sent: Monday, March 23, 2020 10:46 AM
To: Josie Briggs <jpbriggs@pcori.org>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Subject: PCORNet trial

Dr. Briggs,

I want to connect you with Dr. Rick Bright, Director of BARDA, who has been reaching out to various companies interested in donating hcq and cq for clinical trial purposes. He is aware of the PCORNet innovative trial design planning and wanted to discuss supply possibilities. Dr. Woodcock also reached out to him directly on this topic.

Best of luck and please let me know if I can be of help.

Hilary

Sender:	Josie Briggs <jpbriggs@pcori.org>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; adrian.hernandez <adrian.hernandez@duke.edu>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>; Kim Marschhauser <kmarschhauser@pcori.org>; Sarah Daugherty <sdaugherty@pcori.org>; Vidya Raghavan <srividya.raghavan@duke.edu>; Tyrus Rorick <tyrus.rorick@duke.edu>; Donna L Parker <donna.l.parker@duke.edu>
Sent Date:	2020/03/23 13:01:37
Delivered Date:	2020/03/23 13:03:07

AGENDA

COVID-19

Joint HHS / FEMA Interagency VTC

4-16-2020 at 12:30 p.m. ET

Call-in Number: 1-800-320-4330; Muted PIN: 963852#

Closed captioning available.

(Complete connection instructions provided below.)

BLUF:

Situation Update Centers for Disease Control and Prevention

(b)(5)

Lines of Effort

- **Medical Countermeasures (BARDA)**

(b)(5)

- **Data Analytics**

(b)(5)

-

HHS/FEMA Regional Priorities/Concerns

(b)(5)

Interagency Support

(b)(5)

AGENDA

Objective

- To discuss COVID-19 and related Federal response operations

Opening Comments HHS / FEMA

Situation Update Centers for Disease Control and Prevention

(b)(5)

Lines of Effort

(b)(5)

(b)(5)

HHS/FEMA Regional Priorities/Concerns

(b)(5)

Interagency Support

(b)(5)

(b)(5)

WH National Security Council (NSC)

-

Closing Comments

- FEMA / HHS

From:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
CC:	Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>; 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>; 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>; Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@hhs.gov>
Subject:	Rick - FDA requesting need your signature by 7:30pm tonight
Date:	2020/03/28 18:02:13
Importance:	High
Priority:	Urgent
Type:	Note

Rick - Attached are the updated FACT SHEETS and draft FDA response to BARDA's request for an EUA. FDA OC is asking for BARDA/your signature by 7:30pm tonight.

RQA is proofing the proposed final version of BARDA's letter as the submitter of the EUA request. Will send when ready.

Linda

From: Lambert, Linda (OS/ASPR/BARDA)
Sent: Saturday, March 28, 2020 8:41 AM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>
Subject: IMPT - Rick - attacked DRAFT letter requesting EUA for you to sign

Rick Please let Tremel know if you need edits. Expect need to send this early today.

Sent from my iPhone

Begin forwarded message:

From: "Faison, Tremel (OS/ASPR/BARDA)" <Tremel.Faison@hhs.gov>
Date: March 28, 2020 at 8:17:01 AM EDT
To: "Lambert, Linda (OS/ASPR/BARDA)" <Linda.Lambert@hhs.gov>, "Walker, Robert (OS/ASPR/BARDA)" <Robert.Walker@hhs.gov>
Subject: RE: I'll be on the 9am interagency call - can stay until 10am - talk before hand on how to facilitate?

This is the letter for Rick's signature. FDA has reviewed.

Please let me know how you would like to proceed.

Tremel

From: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
Sent: Saturday, March 28, 2020 7:05 AM
To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Subject: RE: I'll be on the 9am interagency call - can stay until 10am - talk before hand on how to facilitate?

OK. Sil and Susan made comments that they think are important. I am looking at now. I'm up and can talk anytime.

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Saturday, March 28, 2020 6:43 AM
To: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Cc: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
Subject: I'll be on the 9am interagency call - can stay until 10am - talk before hand on how to facilitate?

I'm free now or until 9

Linda C. Lambert, PhD
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

From: Lambert, Linda (OS/ASPR/BARDA)
Sent: Friday, March 27, 2020 9:04 PM
To: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Cc: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
Subject: Re: Follow up: URGENT request for your agency's participants for the EUA access plan for CQ and HCQ

Received. Same time as Ricks briefing meeting.
: (

Sent from my iPhone

On Mar 27, 2020, at 8:07 PM, Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>wrote:

You both should already have received this a while ago. Will you please confirm---for 9 AM tomorrow.

Bob

From: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
Sent: Friday, March 27, 2020 8:07 PM
To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Subject: Re: Follow up: URGENT request for your agency's participants for the EUA access plan for CQ and HCQ

Bob and I discussed. He is going to send out meeting announcement for tomorrow am.

Tremel

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Friday, March 27, 2020 7:21 PM
To: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
Subject: Re: Follow up: URGENT request for your agency's participants for the EUA access plan for CQ and HCQ

Dear Bob and Tremel
Will you send out a hollow up alerting that the call will likely be tomorrow?

Sent from my iPhone

On Mar 27, 2020, at 5:48 PM, Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>wrote:

Dear All

Thank you very much for agreeing to serve on the interagency EUA working group for chloroquine/hydroxychloroquine. As I think you are aware, there is urgency to initiating this EUA as quickly as possible, and FDA is currently asking for agreement by 7 AM ET on Saturday, March 28.

I plan to assemble this group at a time to be determined but targeting 9 PM (tonight) to ensure we are all in agreement with the terms of the Letter of Authorization, including the indicated population, the text of the fact sheets, and the plan forward. Of course, the timing for assembling this group will depend on when we receive the documents from our FDA colleagues, and acknowledging that we need an appropriate amount of time to review and consider what they've prepared before coming together to discuss.

Please stand by for more information. As soon as I receive any further information I will be sure to pass it along to all of you. If you are not available tonight on short notice to review and discuss, please advise so we can plan accordingly.

Best,
Bob

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Thursday, March 26, 2020 1:38 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Farley, John (FDA/CDER) <John.Farley@fda.hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Lane, Cliff (NIH/NIAID) [E] <clane@niaid.nih.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) <(b)(6)>; Birnkrant, Debra B (FDA/CDER) <Debra.Birnkrant@fda.hhs.gov>; Beigel, John (NIH) [E] <jbeigel@niaid.nih.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>;

Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>
Cc: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Subject: Follow up: URGENT request for your agency's participants for the EUA access plan for CQ and HCQ - by 4pm today.
Importance: High

FOUO, Confidential, Pre-Decisional

Dear All,

(b)(5)

(b)(5)

If we have missed including anyone – please let Tremel Faison, Robert Walker and me know. Please also note the additional questions are posed in Rick's email below for the teams.

As we all know, concerns have been raised about the use of these drugs. Given the unprecedented nature of COVID-19, it is imperative that we work together more than ever. We need to ensure that as interagency partners while we move forward rapidly we also do so with the utmost consideration for patient safety.

Again, send us the names of your agency's participants by 4pm today. BARDA will coordinate the interagency calls.

Finally – we are very appreciative of our FDA colleagues and the work that they have done in very short order to draft the EUA and some of the regulatory documents.

Thank you very much in advance,

Linda

Linda C. Lambert, PhD
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

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 6:00 PM
To: Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Farley, John (FDA/CDER) <John.Farley@fda.hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Lane, Cliff (NIH/NIAID) [E] <clane@niaid.nih.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) <(b)(6)>; Birnkrant, Debra B (FDA/CDER) <Debra.Birnkrant@fda.hhs.gov>; Beigel, John (NIH) [E] <jbeigel@niaid.nih.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Subject: Re: URGENT Questions on planned study

Apologies for the resend, I accidentally omitted Joe Hamel. He has a critical role. Thanks. Rick

FOUO, Confidential, Pre-Decisional

Dear All,

(b)(5)

(b)(5)

Thank you all for your critical and urgent contributions to these collaborative efforts.

Rick

From: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Date: Monday, March 23, 2020 at 9:09 PM
To: "Amin, Stacy (FDA/OC)" <Stacy.Amin@fda.hhs.gov>
Cc: Janet Woodcock <Janet.Woodcock@fda.hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>, Robert Walker <Robert.Walker@hhs.gov>, Tremel Faison <Tremel.Faison@hhs.gov>, "Farley, John (FDA/CDER)" <John.Farley@fda.hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Hilary Marston <hilary.marston@nih.gov>, Cliff Lane <clane@niaid.nih.gov>, Anita Patel <bop1@cdc.gov>, Timothy Uyeki <tmu0@cdc.gov>, "Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA)" <matthew.j.hepburn.civ@mail.mil>, Debra Birnkrant <Debra.Birnkrant@fda.hhs.gov>, John Beigel <jbeigel@niaid.nih.gov>, Elizabeth Higgs <ehiggs@niaid.nih.gov>, "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>
Subject: URGENT Questions on planned study

Hi Stacy,

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

(b)(5)

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

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

Rick
Rick A. Bright, PhD

Director, BARDA
Deputy Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services

Sender:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>; 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>; 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>; Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@hhs.gov>
Sent Date:	2020/03/28 18:02:08
Delivered Date:	2020/03/28 18:02:13
From:	Faison, Tremel (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BBAB0BCEB1342FBBEDBBCC94DEEB80F-FAISON, TRE <Tremel.Faison@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: Documents
Date:	2020/03/28 16:57:48
Priority:	Normal
Type:	Note

We need signature from Rick by 7:30. I am sending the new LoA to Sil to see if she wants to make any modifications.

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Saturday, March 28, 2020 4:55 PM
To: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Cc: Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>; Farley, John (FDA/CDER) <John.Farley@fda.hhs.gov>; Gormley, Andrea (Vincent) (FDA/CDER) <Andrea.Vincent@fda.hhs.gov>; Leissa, Brad G (FDA/CDER) <Brad.Leissa@fda.hhs.gov>; Sadove, Elizabeth (FDA/OC)

<Elizabeth.Sadove@fda.hhs.gov>
Subject: Documents

Hi

(b)(5)

Thank you,

Jacqueline

Sender:	Faison, Tremel (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BBAB0BCEB1342FBBEDBBCC94DEEB80F-FAISON, TRE <Tremel.Faison@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>
Sent Date:	2020/03/28 16:57:46
Delivered Date:	2020/03/28 16:57:48

From:	Goldberg, Alan (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B807C301181D4EFAAF3449A8AF8AA5C2-GOLDBERG, A <Alan.Goldberg@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	Re: J&J on the today show
Date:	2020/03/30 11:18:21
Priority:	Normal
Type:	Note

Noted from several sources that BARDA is managing the Hydroxychloroquine EUA. Times noted that BARDA was established 13 years ago and that in "its first year of operations, It estimated that 70,000 ventilators would be needed." Nickie Laurie is quoted re: project Aura. The article then chronicles an unfortunate chain of events regarding the company awarded the contract.
In no way is BARDA blamed for the corporate problems. The company is noted as asking to be released from the contract as it was not sufficiently profitable.

I'd send the article but my HHS laptop isn't interfaced with my scanner.

Sent from my iPhone

On Mar 30, 2020, at 10:11 AM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>wrote:

Thanks Alan, can you please. Send the story if you can still find it? Many thanks, Rick

---

From: Alan Goldberg <Alan.Goldberg@hhs.gov>
Date: Monday, March 30, 2020 at 9:18 AM
To: Gary Disbrow <Gary.Disbrow@hhs.gov>
Cc: BARDA ALL <BARDAALL@hhs.gov>
Subject: Re: J&J on the today show

Shout out to BARDA as well in New York Times

Sent from my iPhone

On Mar 30, 2020, at 8:22 AM, Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>wrote:

Johnson and Johnson on today show. CEO mentioned partnership with BARDA.

Congrats to all involved!

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

Sender:	Goldberg, Alan (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B807C301181D4EFAAF3449A8AF8AA5C2-GOLDBERG, A <Alan.Goldberg@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/03/30 11:18:20
Delivered Date:	2020/03/30 11:18:21

From:	(b)(6)
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	Re: BARDA stockpile of HCQ?
Date:	2020/04/01 02:49:20
Priority:	Normal
Type:	Note

Dear Rick,

Resending in case my email went o spam over the weekend. Any chance UNC Hospitals would qualify to receive some of the (b)(3):42 Sandoz hydroxychloroquine tablets now in the stockpile?

Thank you
Michelle

M. Michelle Berrey, MD, MPH
(b)(6)

On Mar 30, 2020, at 3:25 PM, Michelle Berrey <(b)(6) wrote:

Dear Rick,

I hope you are doing well and staying safe during these trying times. I am working with a young researcher at UNC Chapel Hill to develop a protocol for outpatients with SARS-CoV2 by nasal swab. We are trying to get some hydroxychloroquine OR chloroquine, both now on the EUA list:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics

We are desperately trying to identify a source of CTM, and are aware that BARDA has (or is soon to receive) drug to be available for EINDs. Is this drug also available for a small outpatient trial?

Thank you in advance for any guidance.

Warm regards,
Michelle

M. Michelle Berrey, MD, MPH
(b)(6)

Sender:	Michelle Berrey <(b)(6)>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/04/01 02:48:56
Delivered Date:	2020/04/01 02:49:20

From:	Christine Baeder <Christine.Baeder@tevapharm.com>
To:	Charrow, Robert (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro <Robert.Charrow@hhs.gov>
CC:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	RE: FDA PHL Request: hydroxychloroquine API- TEVA
Date:	2020/03/20 13:11:20
Priority:	Normal
Type:	Note

Thank you for quick turnaround

Best regards,

cid:image001.png@01CB4876.00748C50

Christine Baeder
SVP, Chief Operating Officer US Gx
Tel: 1-215-591-8913 **Cell:** (b)(6)
Christine.Baeder@tevapharm.com https://protect2.fireeye.com/url?k=97be92ef-cbeb9b3f-97bea3d0-0cc47a6a52de-4e3dd1760aff599e&u=http://www.tevapharm.com/

From: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Sent: Friday, March 20, 2020 1:08 PM
To: Christine Baeder <Christine.Baeder@tevapharm.com>
Cc: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: RE: FDA PHL Request: hydroxychloroquine API- TEVA

We have a call into her and have emailed her. Bob

From: Christine Baeder <Christine.Baeder@tevapharm.com>
Sent: Friday, March 20, 2020 1:03 PM
To: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Cc: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: FW: FDA PHL Request: hydroxychloroquine API- TEVA

Bob,

Thank you for your help. Here is the contact we discussed.

Per our discussion

Best regards,

Christine Baeder
SVP, Chief Operating Officer US Gx
Tel: 1-215-591-8913 **Cell:** (b)(6)
Christine.Baeder@tevapharm.com https://protect2.fireeye.com/url?k=735fd56c-2f0adcbc-735fe453-0cc47a6a52de-c857eb8098c30a73&u=https://protect2.fireeye.com/url?k=4ebf322c-12eb1b07-4ebf0313-0cc47a6d17cc-2354539208ea13ee&u=http://www.tevapharm.com/

cid:image001.png@01CB4876.00748C50

From: Heather Conner-Garofalo <Heather.Conner-Garofalo@tevapharm.com>
Sent: Friday, March 20, 2020 12:46 PM
To: Christine Baeder <Christine.Baeder@tevapharm.com>
Cc: Daniel Hoey <Daniel.Hoey@tevapharm.com>; Matthew Roberts <Matthew.Roberts06@tevauk.com>; Chris Lagullo <Chris.Lagullo@tevapharm.com>
Subject: RE: FDA PHL Request: hydroxychloroquine API

Hi Christine,

An e-mail is fine, does not need to be formal. Just that they are asking us to import the API and the person's name and contact information.

If HHS prefers to speak with the FDA officer, her information is as follows:

Tonya O. Corbin
Compliance Officer
DNEI-Philadelphia
Office of Regulatory Affairs
U.S. Food and Drug Administration
Tel: 215-717-3715
Tonya.corbin@fda.hhs.gov

cid:image002.jpg@01D2E03F.8FA9FF50

Officer Corbin is not holding anything up, she is merely responding to my request for guidance as to which ACE-ITDS codes to transmit and what to list in our end use letter.

Thank you,

Heather

From: Christine Baeder
Sent: Friday, March 20, 2020 12:16 PM
To: Heather Conner-Garofalo
Cc: Daniel Hoey; Matthew Roberts; Chris Lagullo
Subject: RE: FDA PHL Request: hydroxychloroquine API

Heather,

We do not have anything in writing.. If you tell me what you need I will call and ask them to give us a letter. Can you draft what you need and I can forward and ask them to put on the correct letterhead?

Or provide contact information and I can ask HHS to reach out to the appropriate contact at FDA directly?

Best regards,


cid:image001.png@01CB4876.00748C50

Christine Baeder
SVP, Chief Operating Officer US Gx
Tel: 1-215-591-8913 **Cell:** (b)(6)
Christine.Baeder@tevapharm.com https://protect2.fireeye.com/url?k=adad9a72-f1f893a2-adadab4d-0cc47a6a52de-9a365731a4eb49ae&u=https://protect2.fireeye.com/url?k=202f7e4e-7c7b5765-202f4f71-0cc47a6d17cc-2d6428040a2c1204&u=http://www.tevapharm.com/

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Sender:	Christine Baeder <Christine.Baeder@tevapharm.com>
Recipient:	Charrow, Robert (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro <Robert.Charrow@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/03/20 13:10:02
Delivered Date:	2020/03/20 13:11:20

From:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9BB949CACA464329823CA3CF77654A06-VENTURA, CH <Christy.Ventura@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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:	MCM Task Force updates for Wednesday
Date:	2020/04/21 18:35:48
Priority:	Normal
Type:	Note

The MCM Task Force updates for Wednesday are shown here. We learned today that the FEMA Daily Operational Briefing and the FEMA-HHS Senior Leader Brief is made available to the public through a govdelivery.com distribution list, so we are changing some of the reporting moving forward. Please let us know if you have any concerns.

Accomplishments

- Emergency Use Authorizations granted by FDA: 38 (+1) molecular diagnostic tests, 17 (+1) laboratory-developed tests, 4 (+3) antibody tests, and 2 repurposed treatments (chloroquine, hydroxychloroquine)
- Requests for chloroquine/hydroxychloroquine from the SNS
    - 4 clinical trial requests received, 2 (+1) fulfilled
    - 26 (+3) EUA requests received, 23 (+0) shipped
- 2402 (+29) market research submissions and 225 (+0) CoronaWatch meetings held

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
- Continuing to identify lead antibody treatment candidates for further development and manufacturing

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:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9BB949CACA464329823CA3CF77654A06-VENTURA, CH <Christy.Ventura@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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:	2020/04/21 18:35:47
Delivered Date:	2020/04/21 18:35:48
Message Flags:	Unread

From:	Hamel, Joseph (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96D2C1602DFA45E5A5E21452A098B96D-HAMEL, JOSE <Joseph.Hamel@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>
Subject:	Full list enclosed as of 1:50 PM EDT
Date:	2020/03/20 13:52:52
Priority:	Normal
Type:	Note

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

From: Hamel, Joseph (OS/ASPR/IO)
Sent: Friday, March 20, 2020 10:40 AM
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: Latest as of this morning

<< File: Chloroquine Compound Availability 4.docx >>

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

From: Hamel, Joseph (OS/ASPR/IO)
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:

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

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

Sender:	Hamel, Joseph (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96D2C1602DFA45E5A5E21452A098B96D-HAMEL, JOSE <Joseph.Hamel@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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 13:52:50
Delivered Date:	2020/03/20 13:52:52

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

From:	Faison, Tremel (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BBAB0BCEB1342FBBEDBBCC94DEEB80F-FAISON, TRE <Tremel.Faison@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature
Date:	2020/03/28 21:43:19
Priority:	Normal
Type:	Note

Revised. T

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Saturday, March 28, 2020 9:24 PM
To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
Subject: RE: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

I see on page 1, but in header of pages 2 and 3 is march 27

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Saturday, March 28, 2020 9:22 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
Subject: Re: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

Rick
Version we sent is dated March 28. Do you see that?
L

Sent from my iPhone

On Mar 28, 2020, at 9:07 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>wrote:

Linda/Tremel, the version I sign will need to have the header date updates to March 28. Just send that version to me. When ASPR approves, I will sign that version and send back to you. Thanks, Rick

---

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Saturday, March 28, 2020 8:42 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Kadlec, Robert (OS/ASPR/IO)

<Robert.Kadlec@hhs.gov>
Cc: Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Subject: RE: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

Dear Dr. Kadlec and Rick,

Please find attached a revised request letter for the EUA. Per the request to modify from Joe/John, (b)(5)

Linda

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Saturday, March 28, 2020 8:18 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Subject: Re: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

Email error. Apologies. Retrying and Resending Rick.

On Mar 28, 2020, at 7:43 PM, Rick Bright (b)(6) wrote:

Dr. Kadlec,

As directed by the department, HHS agencies CDC, ASPR, FDA, BARDA, and NIH have worked rapidly to develop an EUA protocol for hydroxychloroquine and chloroquine per the direction.

The attached letter has been drafted by HHS and OGC and is ready for signature and transmission.

I seek your final review and concurrence to sign and submit. Once received, this will be transmitted to FDA and they will submit a response letter.

I await your concurrence to proceed.

Thank you. Rick

On Mar 28, 2020, at 7:31 PM, Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>wrote:

Dear Rick,

(b)(5)

Thank you,
Linda ASPRLinda C. Lambert, PhD

Sender:	Faison, Tremel (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2BBAB0BCEB1342FBBEDBBCC94DEEB80F-FAISON, TRE <Tremel.Faison@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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:	2020/03/28 21:43:18
Delivered Date:	2020/03/28 21:43:19

Organization Name
Search

BARDA COVID-19 Acquisitions Report - Brief Report - Active

2020-04-24 8:32:18 -04:00
Last Refreshed

Organization Name	Project Name	Product Category	Acquisition Vehicle	Obligated Amount	Date of Action	Award or Reprogramming	Project Status

(b)(4); (b)(5)

BARDA COVID-19 Acquisitions Report - Brief Report - Pending

2020-04-24 8:32:18 -04:00
Last Refreshed

Organization Name	Project Name	Product Category	Acquisition Vehicle	Obligated Amount	Date of Action	Award or Reprogramming	Project Status
(b)(4); (b)(5)							

BARDA COVID-19 Acquisitions Report - Obligated and Active

2020-04-24 8:32:18 -04:00
Last Refreshed

(b)(4); (b)(5)

BARDA COVID-19 Acquisitions Report - Appropriation vs Obligation

2020-04-24 8:32:18 -04:00
Last Refreshed

(b)(4); (b)(5)

BARDA COVID-19 Acquisitions Report - Location Information

2020-04-24 8:32:18 -04:00
Last Refreshed

Organization Name	Project Name	Product Category	Obligated Amount	Date of Action	City	State / Province	Country

(b)(4); (b)(5)

From:	Hamel, Joseph (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96D2C1602DFA45E5A5E21452A098B96D-HAMEL, JOSE <Joseph.Hamel@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>; 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: Latest as of this morning
Date:	2020/03/20 10:45:41
Priority:	Normal
Type:	Note

Yep – just sent to the group that was on the 10:00 invite to cover our bases for now. Will confirm with Bryan.

Thank you again!!

Best,
Joe

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

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Friday, March 20, 2020 10:44 AM
To: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Cc: 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: Re: Latest as of this morning

Thanks for the update joe. I think the broader group was asking for your summary. Not sure who is included, might need to check with Bryan. Thanks. Rick.

On Mar 20, 2020, at 10:39 AM, Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>wrote:

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

From: Hamel, Joseph (OS/ASPR/IO)
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:

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

Strategic Innovation and Emerging Technology Manager

Assistant Secretary for Preparedness and Response
Office: 202-969-3852
Cell: (b)(6)

<Chloroquine Compound Availability 4.docx>

Sender:	Hamel, Joseph (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96D2C1602DFA45E5A5E21452A098B96D-HAMEL, JOSE <Joseph.Hamel@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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 10:45:40
Delivered Date:	2020/03/20 10:45:41
Message Flags:	Unread

From:	Walker, Robert (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A02E128C60F4A7195532A1545AF9556-WALKER, ROB <Robert.Walker@hhs.gov>
To:	Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>
CC:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@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:	Re: Donated CQ and HCQ
Date:	2020/04/03 07:01:34
Priority:	Normal
Type:	Note

Robert

(b)(5)

Bob

> On Apr 3, 2020, at 6:15 AM, Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov> wrote:
>
> Bob,
>

(b)(5)

>
> Robert Johnson, Ph.D.
> Director, Influenza and Emerging Infectious Diseases Division
> Biomedical Advanced Research and Development Authority
> BARDA
> Assistant Secretary for Preparedness and Response ASPR
> Department of Health and Human Services
> 330 Independence Avenue, S.W. Room 640 G
> Washington, D.C. 20201
> Office: 202-401-4680
> Cell: 202-701-5646
> email: Robert.Johnson@HHS.gov
>
> Legally Privileged - This e-mail transmission and any documents attached to it may contain information that is legally privileged. If you are not the intended recipient, or a person responsible for delivering this transmission to the intended recipient, you are hereby notified that any disclosure, copying, distribution, or use of this transmission is strictly prohibited. If you have received this transmission in

error, please immediately notify the sender and destroy the original transmission, 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
>
>
> -----Original Message-----
> From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
> Sent: Wednesday, April 1, 2020 10:02 AM
> To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
> Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
> Subject: FW: Donated CQ and HCQ
>
> Bob, Robert, any thoughts on this inquiry?
>
> On 4/1/20, 8:47 AM, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov> wrote:
>
(b)(5)

>
> Thanks,
> KL
>
> Sent from my iPhone
>

Sender:	Walker, Robert (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A02E128C60F4A7195532A1545AF9556-WALKER, ROB <Robert.Walker@hhs.gov>
Recipient:	Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@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:	2020/04/03 07:01:33
Delivered Date:	2020/04/03 07:01:34

TEVA TO DONATE POTENTIAL COVID-19 TREATMENT, HYDROXYCHLOROQUINE SULFATE TABLETS TO HOSPITALS NATIONWIDE

Teva will donate 6 Million tablets through wholesalers to hospitals by March 31, and more than 10 Million within a month

TEL AVIV, Israel & PARSIPPANY, N.J.--(BUSINESS WIRE)-- Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) announced today the immediate donation of more than 6 million doses of hydroxychloroquine sulfate tablets through wholesalers to hospitals across the U.S. to meet the urgent demand for the medicine as an investigational target to treat COVID-19. The company is also looking at additional ways to address the global need.

"We are committed to helping to supply as many tablets as possible as demand for this treatment accelerates at no cost," said Brendan O'Grady, Teva Executive Vice President, North America Commercial. "Immediately upon learning of the potential benefit of hyroxychloroquine, Teva began to assess supply and to urgently acquire additional ingredients to make more product while arranging for all of what we had to be distributed immediately."

Additional production of hydroxychloroquine sulfate tablets is also being assessed and subsequently ramped up with materials that are being sent to Teva from our ingredient supplier. Teva will ship 6 Million tablets through wholesalers to hospitals by March 31, and more than 10 Million within a month.

Hydroxychloroquine sulfate tablets manufactured by Teva are approved by U.S. Food and Drug Administration (FDA) for the treatment of malaria, lupus erythematosus and rheumatoid arthritis. Although the product is not currently approved for use in the treatment of COVID-19, it is currently under investigation for efficacy against the coronavirus and has been requested by US government officials to be made available for use immediately. The Company is also reviewing supply of both hydroxychloroquine and chloroquine globally to determine whether there are additional supply and access opportunities for patients.

Teva is also actively looking across its expansive range of products to determine if the company can help to provide any other products that may be relevant in addressing acute and substantial need during the COVID-19 crisis.

ABOUT TEVA

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) has been developing and producing medicines to improve people's lives for more than a century. We are a global leader in generic and specialty medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Around 200 million people around the world take a Teva medicine every day, and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics, we have significant innovative research and operations supporting our growing portfolio of specialty and biopharmaceutical products. Learn more at www.tevapharm.com.

FORWARD LOOKING STATEMENT

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown, that could cause our future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences are discussed in our Quarterly Reports on Form 10-Q for the first, second and third quarter of 2019 and in our Annual Report on Form 10-K for the year ended December 31, 2018, including in the sections captioned "Risk Factors." Forward-looking statements speak only as of the date on which they are made, and we assume no obligation to update or revise any forward-looking statements or other information contained herein, whether as a result of new information, future events or otherwise. You are cautioned not to put undue reliance on these forward-looking statements.

# # #

BARDA COVID-19 Acquisitions Report - Brief Report - Active

2020-04-21 17:08:58 -04:00
Last Refreshed

Organization Name	Project Name	Product Category	Acquisition Vehicle	Obligated Amount	Date of Action	Award or Reprogramming	Project Status
(b)(4); (b)(5)							

BARDA COVID-19 Acquisitions Report - Brief Report - Pending

2020-04-21 17:08:58 -04:00
Last Refreshed

Organization Name	Project Name	Product Category	Acquisition Vehicle	Obligated Amount	Date of Action	Award or Reprogramming	Project Status
(b)(4); (b)(5)							

BARDA COVID-19 Acquisitions Report - Obligated and Active

2020-04-21 17:08:58 -04:00

Last Refreshed

(b)(4); (b)(5)

BARDA COVID-19 Acquisitions Report - Appropriation vs Obligation

2020-04-21 17:08:58 -04:00

Last Refreshed

(b)(4); (b)(5)

BARDA COVID-19 Acquisitions Report - Location Information

2020-04-21 17:08:58 -04:00
Last Refreshed

Organization Name	Project Name	Product Category	Obligated Amount	Date of Action	City	State / Province	Country

(b)(5)

From: (b)(6)

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

Subject: Re: Zinc-- getting a lot of calls on this--is this something we should gear up for?

Date: 2020/03/30 18:45:55

Priority: Normal

Type: Note

various anecdotal claims; mechanism in general vis a vis coronaviruses; that hydroxychloroquine works via this mechanism; apparently starting to get into short supply. I've emailed Brendan regarding supply etc. just in case. I have no opinion on this but on't want to be caught short.

On Mon, Mar 30, 2020 at 6:30 PM Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>wrote:

I have not heard about this one yet, But I have been in a top secret room all day. Have you seen any data or anecdotal news? OR just an uptake in supply?

From: S Barer <(b)(6)
Sent: Monday, March 30, 2020 5:27 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: Zinc-- getting a lot of calls on this--is this something we should gear up for?

--

--

may not review, copy or distribute this message. If you receive this in error, please notify the sender by reply e-mail and delete this message. Thank you

Sender:	S Barer <(b)(6)
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/03/30 18:44:47
Delivered Date:	2020/03/30 18:45:55

From:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@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>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>
CC:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>
Subject:	FYSA - Final Policy Options Paper on Allocation of HHS-Held Chloroquine and Hydroxychloroquine for International Clinical Trials
Date:	2020/04/14 13:12:52
Priority:	Normal
Type:	Note

From: Dodgen, Daniel (OS/ASPR/SPPR) <Daniel.Dodgen@HHS.GOV>
Sent: Tuesday, April 14, 2020 1:03 PM
To: Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>; DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: Policy Options Paper on Allocation of HHS-Held Chloroquine and Hydroxychloroquine for International Clinical Trials

Good afternoon Linda and Sally,

The DLG has solicited input on a policy options paper title "Allocation of HHS-Held Chloroquine and Hydroxychloroquine for International Clinical Trials." The policy paper attached has been reviewed by a limited paper DLG including CDC, SNS, NIH, FDA, BARDA, and OGC. It can be considered final and forwarded to ASPR/HHS leadership for consideration.

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:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@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>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>
Sent Date:	2020/04/14 13:12:51
Delivered Date:	2020/04/14 13:12:52

Policy Options: Allocation of HHS-Held Chloroquine and Hydroxychloroquine for International Clinical Trials

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Policy Options: Release of SNS-Held Chloroquine and Hydroxychloroquine for International Clinical Trials

(b)(5)

(b)(5)

(b)(5)

From:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9BB949CACA464329823CA3CF77654A06-VENTURA, CH <Christy.Ventura@hhs.gov>
To:	Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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 21:44:24
Priority:	Normal
Type:	Note

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 you 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

(b)(5)

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 baracitinib 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

(b)(5)

- (b)(5)
-
-
-
-

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:	Ventura, Christy (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9BB949CACA464329823CA3CF77654A06-VENTURA, CH <Christy.Ventura@hhs.gov>
Recipient:	Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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 21:44:21
Delivered Date:	2020/04/07 21:44:24

From:	Houchens, Christopher (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7AC94A574BD04528B7C91BBD61893975-HOUCHENS, C <Christopher.Houchens@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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 21:30:37
Priority:	Normal
Type:	Note

Rick – One edit to my clarifying response to the very last issue. Chris

(b)(5)

From: Houchens, Christopher (OS/ASPR/BARDA)
Sent: Wednesday, March 25, 2020 9:28 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Subject: RE: TPs

Rick,

(b)(5)

(b)(5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 8:59 PM
To: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>
Cc: Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Boucher, David (OS/ASPR/BARDA) <David.Boucher@hhs.gov>
Subject: Re: TPs

Thanks Chris. These are great but eerily similar to todays. 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

(b)(5)

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:	Houchens, Christopher (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7AC94A574BD04528B7C91BBD61893975-HOUCHENS, C <Christopher.Houchens@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>; 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>
Sent Date:	2020/03/25 21:30:36
Delivered Date:	2020/03/25 21:30:37

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

Sandoz

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

Teva

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

Operational Task Forces	
Community Based Testing Sites (CBTS)	Accomplishments in last 24 hours 1. Please be succinct, but use plain language and ensure appropriate contextualization 2. Currently Working 1. Describe actions currently underway. Be sure to include any barriers or limiting factors. 2.
Community Mitigation	Accomplishments in last 24 hours 1. Please be succinct, but use plain language and ensure appropriate contextualization 2. Currently Working 1. Describe actions currently underway. Be sure to include any barriers or limiting factors. 2.
Continuity of Operations and	Accomplishments in last 24 hours 1. Please be succinct, but use plain language and ensure appropriate contextualization 2. Currently Working 1. Describe actions currently underway. Be sure to include any barriers or limiting factors. 2.
Data and Analysis	Accomplishments in last 24 hours 1. Please be succinct, but use plain language and ensure appropriate contextualization 2. Currently Working 1. Describe actions currently underway. Be sure to include any barriers or limiting factors. 2.
Healthcare Resilience	Accomplishments in last 24 hours 1. Please be succinct, but use plain language and ensure appropriate contextualization 2. Currently Working 1. Describe actions currently underway. Be sure to include any barriers or limiting factors. 2.
Laboratory Diagnostics	
Medical Countermeasure (MCM)	**Accomplishments** (b)(5) **Currently working:**

	(b)(5)	
Supply Chain		

From:	Charrow, Robert (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=00531138AF454CE3AC0B5885BEAD345F-CHARROW, RO <Robert.Charrow@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	RE: Sandoz/Novartis Donation of HydroxyChloroquine
Date:	2020/03/23 13:53:22
Priority:	Normal
Type:	Note

Please call ASAP

Robert P. Charrow
General Counsel
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
(202) 690-7741
(b)(6) cell)
Email: Robert.Charrow@hhs.gov

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 1:52 PM
To: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Subject: Re: Sandoz/Novartis Donation of HydroxyChloroquine

Bob, (not sure who needs to be on the string, apologies if too many or too few)

(b)(5)

Thanks Rick
Rick A. Bright, PhD
Director, BARDA
Deputy Assistant Secretary for Preparedness and Response

Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services

+1 202 260 8535 (Office)

From: "Charrow, Robert (HHS/OGC)" <Robert.Charrow@hhs.gov>
Date: Saturday, March 21, 2020 at 4:51 PM
To: Joseph Hamel <Joseph.Hamel@hhs.gov>, "Maffia, Anthony" <anthony.maffia@sandoz.com>
Cc: "Lenihan, Keagan (FDA/OC)" <Keagan.Lenihan@fda.hhs.gov>, "Amin, Stacy (FDA/OC)" <Stacy.Amin@fda.hhs.gov>, "Adams, Steven A. (ASPR/SNS)" <saa1@cdc.gov>, Robert Kadlec <Robert.Kadlec@hhs.gov>, Bryan Shuy <Bryan.Shuy@hhs.gov>, "Franklin, Joseph (FDA/OC)" <Joseph.Franklin@fda.hhs.gov>, "Roberts, Rosemary (FDA/CDER)" <Rosemary.Roberts@fda.hhs.gov>, "Guram, Jeet (FDA/OC)" <Jeet.Guram@fda.hhs.gov>, "Cavazzoni, Patrizia (FDA/CDER)" <Patrizia.Cavazzoni@fda.hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Gorman, Susan (ASPR/SNS)" <spg4@cdc.gov>, "Ottem, Ronald (Ron) (ASPR/SNS)" <rco9@cdc.gov>, "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>
Subject: Re: Sandoz/Novartis Donation of HydroxyChloroquine

(b)(5)

Bob Charrow
General Counsel
HHS
Cell (b)(6)

On: 21 March 2020 16:00,
"Hamel, Joseph (OS/ASPR/IO)" <Joseph.Hamel@hhs.gov>wrote:

All,

(b)(5)

Anthony, above, has point at Sandoz/Novartis.

Bob Charrow,
Can you send Anthony and his Team a donation agreement?

Team FDA,
Can you please reach out to Anthony to run down regulatory/compliance/acceptance questions?

Anthony,
Please have your team contact Steve Adams, Sue Gorman and Ron Ottem above with pickup locations in NC and PA, and approximate weights and dimensions.

Thank you for reaching out on this, and we very much appreciate your willingness to help in this fight.

Best,
Joe Hamel

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

Sender:	Charrow, Robert (HHS/OGC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=00531138AF454CE3AC0B5885BEAD345F-CHARROW, RO <Robert.Charrow@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/03/23 13:53:21
Delivered Date:	2020/03/23 13:53:22

From:	S Barer <(b)(6)
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	Fwd: new HCQ trial in COVID = encouraging w/ big caveats
Date:	2020/03/30 19:01:08
Priority:	Normal
Type:	Note

---------- Forwarded message ---------
From: **Umer Raffat** <umer.raffat@evercoreisi.com>
Date: Mon, Mar 30, 2020, 6:58 PM
Subject: new HCQ trial in COVID = encouraging w/ big caveats
To: <(b)(5) >

EVERCORE ISI 30 March 2020

Health Care

new HCQ trial in COVID = encouraging w/ big caveats

A new trial of hydroxychloroquine just reported – and it reads encouraging (but with caveats – of course).

Unlike other recent Chinese/French trials, this trial design reads pretty decent (it was randomized and double blind) … however, the

way in which results were reported (and omitted) makes it hard to draw definitive conclusions.

The interesting thing about the key results of this trial: author focuses on "significantly" better clinical improvement (fever, cough, chest CT scan, progression to severe disease). Recall the recent French trials have only focused on viral load going negative with HCQ. With that said,

First, let's start w/ the trial design:

- It was a RANDOMIZED trial (<that's good … recall many recent Chinese trials were NOT randomized)
- It was double blinded (<although the paper didn't confirm that)
- N = 62 (across 2 arms: HCQ vs pbo)
- Mild-moderate pts
- HCQ dose = 400 mg/day

Next, what were the limitations of this trial?

- The trial design as per clinicaltrials.gov was supposed to have 3 arms … HCQ 200 mg/day vs HCQ 400 mg/day vs pbo. However, the paper only mentions 2 arms: HCQ 400 mg/day vs pbo. It's not clear if the 200 mg/day arm was dropped. For our purposes, I have to flag it – but not sure what to make of it

- The key outcome measure was supposed to be time to viral nucleic acid going negative … and somehow, paper made ZERO mention of this viral load endpoint

- BTW, they also didn't report time from symptom onset to first dose (which would be a key factor for antiviral effect)

- Instead, paper solely focused on clinical improvement endpoints

- No full disclosure given on why only 62 pts made it to the study (and 80 were excluded out of 142). Presumably some were excluded because they were severe (the trial was meant for mild-mod), but we'd like to see far more color on the big # of exclusion

So what's the data on clinical improvement?

See this image below – it sums it all up. Clinical improvement looks quite good.

But again, I was hoping to see other endpoints where it probably wasn't as encouraging – that would complete the picture.

(Btw, if you can't see images in my emails, pls let me know – it's an easy fix – you just have to click "display images" in your Outlook window where you're reading this)

	Hydroxy-chloroquine	Control	
N	31	31	62
Fever @ day 0	22	17	
Fever recovery time	2.2	3.2	-1.0
Cough @ day 0	22	15	
Cough remission time	2	3.1	-1.1
Progression to severe illness	0	4	
Chest CT scan:			
Significant improvement	61%	16%	
Moderate improvement	19%	39%	
Total improvement	81%	55%	

Picture 1

Click Here for the Report

Umer Raffat

212-888-3905

Umer.Raffat@evercoreisi.com

Important Disclosures

Important disclosures, including company-specific disclosures and recommendation history, are available on https://protect2.fireeye.com/url?k=8f51c4e3-d304cdf0-8f51f5dc-0cc47adb5650-f94c6609bef9015b&u=https://evercoreisi.mediasterling.com/disclosure.

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Sender:	S Barer <(b)(6) >
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/03/30 19:00:43
Delivered Date:	2020/03/30 19:01:08

From:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
To:	Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>; Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@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: Rick - please review - this is the process we will propose to the ASPR I/O for requests for CQ and HCQ for clinical trials
Date:	2020/03/31 09:50:54
Priority:	Normal
Type:	Note

Dear Robert

Thank you for the very helpful follow up.

(b)(5)

Linda

Linda C. Lambert, PhD
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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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: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Sent: Monday, March 30, 2020 10:03 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Subject: RE: Rick - please review - this is the process we will propose to the ASPR I/O for requests for CQ and HCQ for clinical trials

Linda,

Hi. Two follow-on items:

(b)(5)

Thanks.

Robert

Robert Johnson, Ph.D.
Director, Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G

Washington, D.C. 20201
Office: 202-401-4680
Cell: (b)(6)
email: Robert.Johnson@HHS.gov

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 30, 2020 7:48 PM
To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Subject: RE: Rick - please review - this is the process we will propose to the ASPR I/O for requests for CQ and HCQ for clinical trials

Linda, I am out of the loop on this. Have you reviewed this plan with the interagency clinical WG? Have you discussed it with ASPR IO and SNS? If all are in alignment, please make the decision and proceed.

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Monday, March 30, 2020 5:14 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Subject: Rick - please review - this is the process we will propose to the ASPR I/O for requests for CQ and HCQ for clinical trials
Importance: High

Rick,

Below is the proposed process for requests that come in for clinical trials with CQ and HCQ.
Robert is very supportive.

ARE YOU OK with this?

==========

(b)(5)

==========

Sender:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
Recipient:	Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>;

	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>
Sent Date:	2020/03/31 09:50:53
Delivered Date:	2020/03/31 09:50:54

From:	Kadlec, Robert (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB <Robert.Kadlec@hhs.gov>
To:	Bartrum, John (OS/ASPR) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb2cc9052221421c8d5b7fd480f25bbe-Bartrum, Jo <John.Bartrum@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>; Hamel, Joseph (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose <Joseph.Hamel@hhs.gov>
Subject:	RE: HOT — Fwd: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature
Date:	2020/03/28 23:05:45
Priority:	Normal
Type:	Note

I approve this package please send

From: Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>
Sent: Saturday, March 28, 2020 9:12 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Subject: HOT — Fwd: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

The package for your review and signature.

Begin forwarded message:

From: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Date: March 28, 2020 at 9:08:49 PM EDT
To: "Bartrum, John (OS/ASPR) (CTR)" <John.Bartrum@hhs.gov>, "Hamel, Joseph (OS/ASPR/IO)" <Joseph.Hamel@hhs.gov>
Cc: "Shuy, Bryan (OS/ASPR/IO)" <Bryan.Shuy@hhs.gov>
Subject: FW: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

Making sure you see this was resent by linda under separate email and that someone can get to the Boss for approval. FDA is getting anxious. THANK YOU.

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Saturday, March 28, 2020 8:42 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Subject: RE: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

Dear Dr. Kadlec and Rick,

(b)(5)

Linda

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Saturday, March 28, 2020 8:18 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Subject: Re: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

Email error. Apologies. Retrying and Resending Rick.

On Mar 28, 2020, at 7:43 PM, Rick Bright <rabright1@yahoo.com>wrote:

Dr. Kadlec,

As directed by the department, HHS agencies CDC, ASPR, FDA, BARDA, and NIH have worked rapidly to develop an EUA protocol for hydroxychloroquine and chloroquine per the direction.

The attached letter has been drafted by HHS and OGC and is ready for signature and transmission.

I seek your final review and concurrence to sign and submit. Once received, this will be transmitted to FDA and they will submit a response letter.

I await your concurrence to proceed.

Thank you. Rick

On Mar 28, 2020, at 7:31 PM, Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>wrote:

Dear Rick,
Attached is the EUA request letter for the EUA. FDA will review and issue a letter of acceptance for the EUA.
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.
Please review, sign and send to Tremel Faison who will transmit this to the FDA.
Thank you,
Linda ASPRLinda C. Lambert, PhD

Sender:	Kadlec, Robert (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB <Robert.Kadlec@hhs.gov>
Recipient:	Bartrum, John (OS/ASPR) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb2cc9052221421c8d5b7fd480f25bbe-Bartrum, Jo <John.Bartrum@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@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:	2020/03/28 23:05:44
Delivered Date:	2020/03/28 23:05:45

From:	Petillo, Jay (OS/ASPR/MFHC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=59CE6133DFA14F6D96B9662B7CFDEBC5-PETILLO, JA <Jay.Petillo@HHS.GOV>
To:	Kadlec, Robert (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob <Robert.Kadlec@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>
CC:	Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Yeh, Bai (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=902f9845be5e49f88cb7b2798a8c6e83-Yeh, Bai (H <Bai.Yeh@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a96c8cefe54e86a9eccf3b4763431c-Acheampong, <Otuo.Acheampong@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong, <Kimberly.Armstrong@hhs.gov>; Daniels, Miles (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa4ad4decfc84cd59d4b24599425a375-Daniels, Mi <Miles.Daniels@hhs.gov>; Eldridge, Schuyler (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=102f8b9575fe4272b3a14d43a5cf3f1a-Eldridge, S <schuyler.eldridge@hhs.gov>
Subject:	NTE $22M for therapeutic clinical trials BK Approved 4-13
Date:	2020/04/13 16:37:29
Priority:	Normal
Type:	Note

Received.

(b)(5)

This email is documentation of required approvals.

Jay

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Monday, April 13, 2020 4:35 PM
To: Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA)

<Rick.Bright@hhs.gov>; Yeh, Bai (OS/ASPR/BARDA) <Bai.Yeh@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) <Otuo.Acheampong@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Daniels, Miles (OS/ASPR/MFHC) <Miles.Daniels@hhs.gov>; Eldridge, Schuyler (OS/ASPR/MFHC) <schuyler.eldridge@hhs.gov>
Subject: RE: Funding Requests

Approved
Kadlec Sends

From: Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>
Sent: Monday, April 13, 2020 3:22 PM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Yeh, Bai (OS/ASPR/BARDA) <Bai.Yeh@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) <Otuo.Acheampong@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Daniels, Miles (OS/ASPR/MFHC) <Miles.Daniels@hhs.gov>; Eldridge, Schuyler (OS/ASPR/MFHC) <schuyler.eldridge@hhs.gov>
Subject: RE: Funding Requests

Sir

(b)(5)

Jay

From: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Sent: Monday, April 13, 2020 2:52 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Yeh, Bai (OS/ASPR/BARDA) <Bai.Yeh@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) <Otuo.Acheampong@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>
Subject: Funding Requests

Bob, Bryan and Jay,

(b)(5)

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

Sender:	Petillo, Jay (OS/ASPR/MFHC) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=59CE6133DFA14F6D96B9662B7CFDEBC5-PETILLO, JA <Jay.Petillo@HHS.GOV>
Recipient:	Kadlec, Robert (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob <Robert.Kadlec@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>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Yeh, Bai (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=902f9845be5e49f88cb7b2798a8c6e83-Yeh, Bai (H <Bai.Yeh@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a96c8cefe54e86a9eccf3b4763431c-Acheampong, <Otuo.Acheampong@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong, <Kimberly.Armstrong@hhs.gov>; Daniels, Miles (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa4ad4decfc84cd59d4b24599425a375-Daniels, Mi <Miles.Daniels@hhs.gov>; Eldridge, Schuyler (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=102f8b9575fe4272b3a14d43a5cf3f1a-Eldridge, S <schuyler.eldridge@hhs.gov>
Sent Date:	2020/04/13 16:37:28
Delivered Date:	2020/04/13 16:37:29

From:	Trueman, Laura (HHS/IEA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99DCBA4C6EA342C08D58F63E37D997E7-TRUEMAN, LA <Laura.Trueman@hhs.gov>
To:	Trueman, Laura (HHS/IEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcba4c6ea342c08d58f63e37d997e7-Trueman, La <Laura.Trueman@hhs.gov>
Subject:	HHS COVID-19 Update, 4-7-2020
Date:	2020/04/07 20:01:32
Priority:	Normal
Type:	Note

Dear Colleague:
At this evening's Task Force press conference, CMS Administrator Seema Verma gave updates on the financial relief going to healthcare providers in two forms. First, she indicated that in just over a week, CMS has delivered $33.5 billion dollars to providers on the frontlines in advance payments. CMS received over 25,000 requests from healthcare providers and have approved over 17,000 for advance payments. These are loans, helping providers with immediate cash flow. Second, Administrator Verma updated on HHS's intent to release a first tranche - $30 billion – of the $100 billion dollar CARES Act Provider Fund. These are grants. More information regarding how the $30 billion will be allocated, distributed, and application instructions will be coming.

CMS Updates:
Clinician Letter: CMS posted a letter to clinicians that outlines a summary of actions CMS has taken to ensure clinicians have maximum flexibility to reduce unnecessary barriers to providing patient care during the unprecedented outbreak of COVID-19. The summary includes information about telehealth and virtual visits, accelerated and advanced payments, and recent waiver information.

Recommendations on Non-Essential Medical Services: CMS recently updated recommendations to postpone non-essential surgeries and other procedures to conserve critical healthcare resources and limit exposure of patients and staff to COVID-19. Developed in collaboration with medical societies and associations, the recommendations outline a tiered approach for state and local officials, clinicians, and delivery systems to consider in prioritizing services and care to those who require emergent or urgent attention to save a life, manage severe disease, or avoid further harms from an underlying condition.

Increased Waiver Flexibility: CMS has approved Medicaid Disaster Amendments that bring disaster relief to Arizona, Alabama, and Minnesota to ensure that states have the tools they need to combat COVID-19 through a wide variety of state plan flexibilities. CMS also authorized amendments to ensure emergency flexibilities in programs that care for the elderly and people with disabilities, including most recently in Arizona, North Carolina, and South Dakota. All told, CMS has approved 49 emergency waivers, which now includes Michigan, Maine, Nevada, and the U.S. Virgin Islands, 21 State Amendments, and 3 Medicaid Disaster Amendments in record time. All of the emergency waiver actions can be found on CMS Federal Disaster Resources webpage.

2021 Medicare Advantage and Part D Rates: Yesterday CMS posted their 2021 Medicare Advantage and Part D Rates with a 1.08% increase in the effective growth rate between the Advance Notice and Final Rate Announcement. CMS remains committed to implementing the policies that matter most for

ensuring continuous and predictable payments across the health care system and ensuring care can be provided where it is needed. While the Rate Announcement does not catalog CMS' actions related to the COVID-19 outbreak, CMS has created an overview of actions related to the outbreak for MA organizations, PACE organizations, and Part D sponsors.

Testing and Treatment

Purchase of Point in Care Testing: The Federal government announced that it is purchasing the ID NOW COVID-19 rapid point-of-care test, developed by Abbott Diagnostics Scarborough Inc., for state, territorial and tribal public health labs. The ID NOW COVID-19 test is performed on the ID NOW device. This test allows for medical diagnostic testing at the time and place of patient care, provides COVID-19 results in under 13 minutes and expands the capacity for coronavirus testing. HHS is providing these tests and devices to public health labs (PHLs) in every state and territory, and Washington, D.C. To ensure that remote and rural populations are also being reached, the Indian Health Service will receive tests and devices to distribute to tribal PHLs.

Hydroxychloroquine Tablets: The FDA approved an Abbreviated New Drug Application (ANDA) for Hydroxychloroquine Sulfate Tablets USP, 200 mg. for the treatment of: (1) Uncomplicated malaria due to P. falciparum, P. malariae, P. ovale, and P. vivax. (2) Chronic discoid lupus erythematosus and systemic lupus erythematosus in adults and (3) Treatment of acute and chronic rheumatoid arthritis in adults. Side effects of hydroxychloroquine include irreversible retinal damage, cardiac effects (including cardiomyopathy and QT prolongation), worsening of psoriasis and porphyria, proximal myopathy and neuropathy, neuropsychiatric events, and hypoglycemia. The FDA recently posted information regarding shortages of hydroxychloroquine and chloroquine to its drug shortages webpage due to a significant surge in demand. The agency is working with manufacturers to assess their supplies and is actively evaluating market demand for patients dependent on hydroxychloroquine and chloroquine for treatment of malaria, lupus and rheumatoid arthritis.

PPE and Supplies

Updated PPE Burn Rate Calculator: CDC updated their Burn Rate Calculator that is a spreadsheet-based model that will help healthcare facilities plan and optimize the use of PPE for response to coronavirus disease 2019 (COVID-19). Non-healthcare facilities such as correctional facilities may also find this tool useful.

Tracking and Monitoring Cases: The Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) is supporting the nation's COVID-19 response by introducing a new COVID-19 Patient Impact and Hospital Capacity Module within NHSN's Patient Safety Component. The Module enables hospitals to report daily counts of patients with suspected and confirmed COVID-19 diagnoses and current use and availability of hospital beds and mechanical ventilators. NHSN, in turn, will enable state and local health departments to gain immediate access to the COVID-19 data for hospitals in their jurisdictions.

Expanding Availability of Electronic Thermometers: The FDA issued guidance on clinical electronic thermometers that immediately went into effect. Fever is a common symptom of COVID-19 and clinical electronic thermometers are an important screening and diagnostic tool to assist in the identification of those individuals who may be infected with COVID-19. The policy set forth in the guidance may help expand the availability of clinical electronic thermometers to address this public health emergency.

Expanding Availability of Remote Ophthalmic Devices: the FDA issued a guidance for remote ophthalmic assessment and monitoring devices. These devices include visual acuity charts, visual field devices, general use ophthalmic cameras, and tonometers. The guidance will help expand the capability of remote ophthalmic assessment and monitoring devices to facilitate patient care while reducing patient and healthcare provider contact and exposure to COVID-19 during this pandemic.

Availability of Infusion Pumps: The FDA issued guidance on infusion pumps and accessories that immediately went into effect. The guidance aims to help ensure the availability of infusion pumps and accessories for patients who require continuous infusion of medications, nutrition, and other fluids and help foster technologies, such as remote capabilities, that maintain a safer physical distance between the health care provider and the patient.

Expanding Availability of Cardiopulmonary Bypass Devices The FDA issued an updated policy to help expand the availability of cardiopulmonary bypass devices used in extracorporeal membrane oxygenation (ECMO) therapy to address this public health emergency.

Conservation Strategies for Medical Gloves: This Letter to Health Care Providers refers specifically to potential shortages relating to surgeons' gloves and patient examination gloves. The following conservation strategies are recommended for use by health care organizations and personnel and are categorized for a range of needs and supply levels and are intended to assist health care organizations as they determine procedures during the COVID-19 pandemic.

3-D Printing of Medical Supplies: FDA released an FAQ document for entities who 3D print devices, accessories, components, and/or parts during the COVID-19 emergency. The FAQs address which PPE supplies can be made via 3-D printing, recommendations and guidance from the FDA on the uses for 3-D printed PPE and other resources.

EPA to Donate PPE: The Environmental Protection Agency identified approximately 225,000 pieces of PPE that they will donate to state and local responders fighting COVID-19 across the country.

ASPR Resources for Supply Chain, Fatality Management, and Emergency Departments: ASPR has a site where resources can be uploaded to include plans, tools, templates, and other immediately implementable resources to help with COVID-19 preparedness, response, recovery, and mitigation efforts. The resources are for peers to share COVID-19 best or promising practices, plans, tools, or templates on fatality management, emergency departments, and supply chain.

Information for Specific Populations and Facilities

What Errands are Essential? CDC released information on the essential errands related to grocery shopping, take-out, banking, getting gas, and doctor visits. As communities across the United States take steps to slow the spread of COVID-19 by limiting close contact, people are facing new challenges and questions about how to meet basic household needs, such as buying groceries and medicine, and completing banking activities. The information provides advice about how to meet these household needs in a safe and healthy manner.

Additional Information on Social Distancing, Quarantine, and Isolation: CDC updated their information on Social Distancing, Quarantine, and Isolation. The information defines each term and provides guidance for individuals in case they feel sick.

Report on COVID-19 in Children: CDC published their first report that looks at COVID-19 Illness in Children in the United States in the MMWR. Topline findings include that while some children with COVID-19 may have mild illness and may not show symptoms, they can still spread the disease to others. The limited data suggest that young infants (<1 year of age) may be at higher risk of severe illness with COVID-19 compared with older children, but more information is needed to understand factors contributing to severe outcomes. The report also indicates that children with underlying health conditions are more likely to be hospitalized. Though children with COVID-19 infection may have mild disease, they can still spread COVID-19. It's important that people of all ages follow recommendations from CDC and state and local public health authorities to help prevent the spread of COVID-19.

Guidance for Healthcare Facilities Facing Staffing Shortages: CDC released information on Strategies to Mitigate Healthcare Personnel Staffing Shortages with recommendations for contingency and crisis capacity recommendations for consideration.

Protecting Healthcare Workers Psychological Health and Wellbeing: The resilience of our Nation's healthcare system depends on our healthcare workforce's ability to report for duty. Critical supplies, equipment, and surge capacity rely on dedicated, trained health professionals and support staff to provide care. This document provides recommendations to help healthcare facilities protect their workers' psychological health and well-being. The recommendations are categorized under tips to prepare the workforce before the surge takes place and supporting them effectively during the surge.

Updated Information on Management of Persons with Confirmed COVID-19: CDC updated their Interim Clinical Guidance for Management of Patients with Confirmed COVID-19 to include additional information on asymptomatic and pre-symptomatic patients, reinfection, non-steroidal drugs, possibility of infection with other viruses, additional laboratory and imaging findings, updated information from WHO and new resources on therapeutic options for patients with COVID-19.

Information for Pharmacy Staff: CDC released information on Considerations for Pharmacies during the COVID-19 Pandemic which advises pharmacy staff on strategies to minimize their risk of exposure to the virus and how to reduce the risk for customers during COVID-19.

Updated Information for Alternative Care Sites: CDC updated their Infection Control and Prevention in Alternative Care Sites guidance to align with the level of care categories to include general (non-acute) and acute care.

Guidance for Water Systems in Buildings: CDC released 8 steps that building managers should take to ensure the safety of their building water system and devices after a prolonged shutdown.

Faith-Based Organizations Eligible to Receive SBA Loans: The Small Business Administration has clarified that faith-based organizations and congregations are eligible to receive loans through the Paycheck Protection Program and the Economic Injury Disaster Loans loan programs for COVID recovery, regardless of whether they provide secular social services, and without restrictions based on their religious identity or activities, to the extent they meet the eligibility criteria outlined in the CARES Act. The SBA released an FAQ document that further outlines the details of the program and how faith-based organizations can qualify for and apply for the loans.

World Health Day: Secretary Azar released the following statement on World Health Day: The United States has worked to focus global health priorities and the efforts of the World Health Organization on infectious outbreaks that can cross borders. Now, we face a pandemic that has spread to almost every country on earth, costing lives, disrupting societies, and stalling economies. On World Health Day, we rededicate ourselves, as an international community and as individual nations, to fighting this pandemic with science-based public health policies. Working together, we will defeat this invisible enemy and our countries will emerge from this crisis stronger for it—knowing that preparing for such crises must always be one of our top global health priorities.

Stay hopeful and commited to flattening the curve. If you have questions, follow up with Gary Beck, HHS's Director of External Affairs at gary.beck@hhs.gov.

Laura

Laura C. Trueman
Director, Office of Intergovernmental and External Affairs
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington D.C. 20201
Laura.Trueman@hhs.gov
202-690-6060 (main office)

Sender:	Trueman, Laura (HHS/IEA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99DCBA4C6EA342C08D58F63E37D997E7-TRUEMAN, LA <Laura.Trueman@hhs.gov>
Recipient:	Trueman, Laura (HHS/IEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcba4c6ea342c08d58f63e37d997e7-Trueman, La <Laura.Trueman@hhs.gov>
Sent Date:	2020/04/07 20:01:29
Delivered Date:	2020/04/07 20:01:32

From:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	Fwd: Susan - short turn around -needed (sorry) can you look at this final draft request from BARDA to FDA for CQ and HCQ EUA?
Date:	2020/03/28 18:50:12
Priority:	Normal
Type:	Note

Sent from my iPhone

Begin forwarded message:

From: "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>
Date: March 28, 2020 at 6:40:02 PM EDT
To: "Lambert, Linda (OS/ASPR/BARDA)" <Linda.Lambert@hhs.gov>
Subject: RE: Susan - short turn around -needed (sorry) can you look at this final draft request from BARDA to FDA for CQ and HCQ EUA?

Hi Linda,

Please see attached edits.

Stay safe!

Susan

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Saturday, March 28, 2020 6:10 PM
To: Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Subject: Susan - short turn around -needed (sorry) can you look at this final draft request from BARDA to FDA for CQ and HCQ EUA?
Importance: High

Final review of BARDA's request is ongoing.
It was built off of the FDA's written response.

I'd like Rick to know that you took a look at it.
Any deal breakers please advise.

FDA wants us to request with Rick's signature no later than 7:30pm tonight.
L

From: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
Sent: Saturday, March 28, 2020 6:07 PM
To: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Subject: RE: can you send me the current draft of the BARDA request memo FDA wants us to sign? I want to run it by Susan Sherman quickly.

<<File: BARDA Emergency Use Request Letter. final draft.docx >>

From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Saturday, March 28, 2020 6:05 PM
To: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>
Subject: can you send me the current draft of the BARDA request memo FDA wants us to sign? I want to run it by Susan Sherman quickly.

Linda C. Lambert, PhD
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

Sender:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>

Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/03/28 18:50:10
Delivered Date:	2020/03/28 18:50:12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of the Assistant Secretary for
Preparedness & Response
Biomedical Advanced Research &
Development Authority (BARDA)
Washington, D.C. 20201

(b)(5)

Page 183

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Page 184

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

April 5, 2020

Famotidine Plus Hydroxychloroquine Proposed Clinical Trial
Talking Points

(b)(5)

April 5, 2020

(b)(5)

From:	Hamel, Joseph (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96D2C1602DFA45E5A5E21452A098B96D-HAMEL, JOSE <Joseph.Hamel@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>
Subject:	Chloroquine Update
Date:	2020/03/19 12:30:59
Importance:	High
Priority:	Urgent
Type:	Note

All,

Consolidated update to cut down on emails – here's what we know as of 12:30

iPhone friendly version follows:

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

(b)(4); (b)(5); (b)(3):42 U.S.C. § 247d-6b(d)

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

Sender:	Hamel, Joseph (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96D2C1602DFA45E5A5E21452A098B96D-HAMEL, JOSE <Joseph.Hamel@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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:	2020/03/19 12:30:58
Delivered Date:	2020/03/19 12:30:59

From:	Kadlec, Robert (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB <Robert.Kadlec@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>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Ford-Barnes, Arwenthia (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes <Arwenthia.FordBarnes@hhs.gov>
CC:	Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	RE: Update on HCQ for the Detroit study
Date:	2020/04/04 12:38:40
Priority:	Normal
Type:	Note

Thanks Linda great news and work Best Bob

-----Original Message-----
From: Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>
Sent: Saturday, April 4, 2020 12:29 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Ford-Barnes, Arwenthia (OS/ASPR/IO) <Arwenthia.FordBarnes@hhs.gov>
Cc: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: Update on HCQ for the Detroit study

Dr. Kadlec,

The interagency COVID-19 clinical working group reviewed the details re the proposed study below for Detroit, and approved it this morning.

Since we already had your approval below, the request to release the drug from the SNS was just sent by Dr. Walker.

We expect additional requests.

After the working group reviews these requests and makes a recommendation to approve or not approve, we will send that to you for your consideration and ultimate decision.

Please let us know if you have any questions and thank you sir for your leadership.

Linda
>>
>> -----Original Message-----
>> From: Ottem, Ronald (Ron) (ASPR/SNS) <rco9@cdc.gov>
>> Sent: Friday, April 3, 2020 8:13 AM
>> To: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Khaldun, Joneigh (DHHS) <KhaldunJ@michigan.gov>
>> Cc: Zervos, Marcus <MZERVOS1@hfhs.org>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Mabry, Shirley (ASPR/SNS) <aiq8@cdc.gov>; john.j.bartrum.mil@mail.mil
>> Subject: RE: Is there any interest in setting up a clinical trial with Hydroxychloroquine?
>>
>> + Sue Gorman
>>
>> -----Original Message-----
>> From: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
>> Sent: Friday, April 3, 2020 8:09 AM
>> To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Khaldun, Joneigh (DHHS) <KhaldunJ@michigan.gov>
>> Cc: Zervos, Marcus <MZERVOS1@hfhs.org>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Ottem, Ronald (Ron) (ASPR/SNS) <rco9@cdc.gov>; Mabry, Shirley (ASPR/SNS) <aiq8@cdc.gov>; john.j.bartrum.mil@mail.mil
>> Subject: RE: Is there any interest in setting up a clinical trial with Hydroxychloroquine?
>>
>> Thanks Sir!
>>
>> I know Robert W reached out to Marcus on this very topic.
>>
>> Robert,
>>
>> Once you get all the approvals you need for the study, let us know ship to: location. Adding Ron and Shirley from SNS for vis.
>>
>> Best,
>> Joe
>>
>> Strategic Innovation and Emerging Technology Manager Assistant Secretary for Preparedness and Response
>> Office: 202-969-3852
>> Cell: (b)(6)
>>
>>
>>
>>
>> -----Original Message-----
>> From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
>> Sent: Friday, April 3, 2020 7:50 AM

>> To: Khaldun, Joneigh (DHHS) <KhaldunJ@michigan.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
>> Cc: Zervos, Marcus <MZERVOS1@hfhs.org>
>> Subject: RE: Is there any interest in setting up a clinical trial with Hydroxychloroquine?
>>
>> Thanks for your note Dr. Khaldun I am copying Joe Hamel who can help arrange this. Best Bob
>>
>> -----Original Message-----
>> From: Khaldun, Joneigh (DHHS) <KhaldunJ@michigan.gov>
>> Sent: Thursday, April 2, 2020 10:54 PM
>> To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
>> Cc: Zervos, Marcus <MZERVOS1@hfhs.org>
>> Subject: RE: Is there any interest in setting up a clinical trial with Hydroxychloroquine?
>>
>> Hi there,
>> Following up again here. Dr Zervos is copied here- he's already convened a group of Detroit researchers that are ready to move on clinical studies in Detroit. He needs 80,000 200mg tablets. Hoping you can connect here. Let me know how I can help.
>> Thanks!
>>
>> Joneigh S. Khaldun, MD, MPH, FACEP
>> Chief Medical Executive
>> Chief Deputy Director for Health
>> Michigan Department of Health and Human Services
>> Office: 517-284-4730
>> khaldunj@michigan.gov
>>
>>
>>
>>
>> -----Original Message-----
>> From: Kadlec, Robert (OS/ASPR/IO)
>> Sent: Monday, March 30, 2020 8:22 PM
>> To: khaldunj@michigan.gov
>> Subject: Is there any interest in setting up a clinical trial with Hydroxychloroquine?
>>
>> Dr Khaldun wanted to find out if you would be interested or know a clinician researcher or institute I Detroit that would be willing to sponsor a Clinical study to evaluate the potentially efficacy of Hydroxychloroquine. Please let me know we have quantities of the drug that we can provide to enable such a study.
>> Best.
>> Bob Kadlec ASPR
>>
>> Sent from my iPhone
>>

Sender:	Kadlec, Robert (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB <Robert.Kadlec@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>;

	Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Ford-Barnes, Arwenthia (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes <Arwenthia.FordBarnes@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/04/04 12:38:39
Delivered Date:	2020/04/04 12:38:40

From:	Lee, Scott (OS/ASPR/EMMO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=USERF6879348 <Scott.Lee@hhs.gov>
To:	Cockrill, Jennifer (OS/ASPR/EMMO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8e59c35b5914108bd63bb8489c0a486-Cockrill, J <Jennifer.Cockrill@hhs.gov>
CC:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Childs, Brian (NIH/OD/ORF) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5b805a8bd1431bbcf130cab72f48bb-brian.child <childsb@mail.nih.gov>
Subject:	Re: Study you should be aware of if exposed
Date:	2020/04/06 16:17:04
Priority:	Normal
Type:	Note

Jen,

Not sure who can enroll folks into clinical trail. Rick Bright or RADM Childs are likely good candidates to answer your ask.

CAPT Scott Lee
Federal Health Coordinating Official
HHS/ASPR

(913) 210-0179
(816) 591-0390

From: Jennifer Cockrill <Jennifer.Cockrill@hhs.gov>
Date: Monday, April 6, 2020 at 1:55 PM
To: Scott Lee <Scott.Lee@hhs.gov>
Subject: RE: Study you should be aware of if exposed

Does the ASPR CMO have the ability to prescribe remdesivir? Or the connections to enroll us into the clinical trials?

From: Lee, Scott (OS/ASPR/EMMO) <Scott.Lee@hhs.gov>
Sent: Monday, April 6, 2020 9:56 AM
To: DFOR Regional Operations Branch <ASPR.DFOR.RegionalOps@hhs.gov>
Subject: Study you should be aware of if exposed

This was posted on Teams earlier. I am forwarding to all -- might be worth your time if you are still out and about at risk with potential to get exposed.

From:	Sol Barer <Sol.Barer@tevapharm.com>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	Re: Are you doing ok? Anything I can do to help?
Date:	2020/03/25 06:53:52
Priority:	Normal
Type:	Note

Rick- thanks for everything you do. If there is any help you need I am here.
Gd bless.
Sol

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
www.tevapharm.com

> On Mar 25, 2020, at 2:25 AM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:
>
> Good evening/morning, Sol. All is well, very busy as the train pulls through NYC. Thank you again for connecting me with Garry, he is talking with our teams now. Also, Brendan is fantastic and helping the NIH greatly with drug supply to support the much-needed RCT. Mixed data from China on potential benefit of HCQ...or none. Truly warrants a trial, but wish it would've started 2 months ago.
>
> Couldn't sleep tonight. Many things need to get started quickly. Time is running out for people to be able to get into factories to work, borders closing from shipping supplies, case counts rising.
>
> We will get this done! It makes me feel good to get your notes. You are a great man and I feel blessed to know you.
>
> Have a nice morning. Rick
>
> On 3/24/20, 9:34 PM, "Sol Barer" <Sol.Barer@tevapharm.com> wrote:
>
> All the best
> Sol
>
> 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
> www.tevapharm.com

>
> This message is intended solely for the designated recipient(s). It may contain confidential or proprietary information and may be subject to attorney-client privilege or other confidentiality protections. If you are not a designated recipient you may not review, copy or distribute this message. If you receive this in error, please notify the sender by reply e-mail and delete this message. Thank you.
>
>
>

This message is intended solely for the designated recipient(s). It may contain confidential or proprietary information and may be subject to attorney-client privilege or other confidentiality protections. If you are not a designated recipient you may not review, copy or distribute this message. If you receive this in error, please notify the sender by reply e-mail and delete this message. Thank you.

Sender:	Sol Barer <Sol.Barer@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>
Sent Date:	2020/03/25 06:53:36
Delivered Date:	2020/03/25 06:53:52

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PURCHASE/SERVICE/STOCK REQUISITION

REQUISITION NUMBER	BPA AND CALL NO.		OFFICE CODE/SYMBOL

TO	REQUEST FOR		
OS/ASPR	☐ PURCHASE ☒ SERVICE ☐ STOCK ISSUE ☐ RENTAL/LEASE		
REQUESTING ORGANIZATION	CUSTODIAL AREA	DATE	OBJECT CLASS
OS/ASPR/BARDA/DCD	O'Neill Building	02/06/2020	25103
FOR REFERENCE CALL	EXTENSION		APPROPRIATION
Marcy Beth Grace Ph.D.	202-205-9802		75-2024-0140
DELIVER TO	CAN		DATE REQUIRED
DHHS/ASPR/BARDA 330 Independence Avenue, SW., Room G-644	199COV2		March 24, 2020

ITEM NO.	DESCRIPTION (INCLUDE STOCK NUMBER, MODEL/PART NO., ETC.)	QUANTITY REQUIRED	UNIT OF ISSUE	COST UNIT	COST TOTAL
1	Simplified Contracting Mechanism Expanded Use nationwide emergency access IND for Chloroquine or hydroxychloroquine	1	job	$750,000.00	$750,000.00
					$0.00
	remote access with Oracle				$0.00
	HHSO1002014000031				$0.00
					$0.00
	PPD DEVELOPMENT, LP				$0.00
	929 N FRONT ST WILMINGTON NC Zip Code: 284013331				$0.00
					$0.00
	COVID-19 chloroquine/ hydroxychloroquine trial				$0.00
					$0.00
					$0.00

* I certify that the property/services requested are required for Government business.and are not available from excess or current assets.	FUNDS AVAILABLE *(Signature/Title)*	DATE	TOTAL	
		03/24/2020		$750,000.00

(b)(6)

Marcy B. Grace -S

Digitally signed by Marcy B. Grace -S
Date: 2020.03.24 10:25:14 -04'00'

Marcy Beth Grace, PhD; COR III; Project Officer	DATE 03/24/2020	**RECEIVING OFFICIAL** - I certify that the quantities indicated in the "Quantity Required" column above have been received in total or as annotated.	
RECOMMEND APPROVAL *(Signature/Title)**	DATE	RECEIVING OFFICIAL *(Signature/Title)*	DATE
Robert Johnson, Director, BARDA IEIDD			
APPROVED BY *(Signature/Title)*	DATE	ORDER NO. *(PO, DO, FEDSTRIP, etc.)*	ORDER DATE
PROPERTY MANAGEMENT OFFICER *(Signature)**	DATE	VOUCHER NO.	VOUCHER DATE

REQUISITION NUMBER	BPA AND CALL NO.	TO	DATE
			03/24/20

DESCRIPTION *(Include Stock No., Model/Part No., etc.)*

Summary of the COVID-19 plan:

1. Issue a $750,000 time and materials purchase order to PPD using simplified acquisition procedures. Under a time and materials contract, the Government has flexibility to direct the contractor so long as our direction is within scope, and the contractor bills fully loaded hourly rates (hourly rate plus fringe/overhead/profit) and their materials (travel, supplies, subcontractors, other direct costs).

2. Sole source a follow-on cost-reimbursement contract to PPD. We would work on contract award while PPD is performing under the T&M purchase order. This contract would include details of the study

From:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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:	Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@hhs.gov>
Subject:	FW: FOR REVIEW: Policy Options for Allocation of HHS-Held Chloroquine and Hydroxychloroquine for International Clinical Trials
Date:	2020/04/14 11:11:44
Priority:	Normal
Type:	Note

Rick, Gary
DLG members asked to indicate if they agree with the below prioriziation – should the USG be asked for HCQ or HQ for international clinical trials. We have not received any international requests through the SNS to date.
I've worked on this with SPPR and am comfortable with the priority below.
Any questions or concerns?
Linda

From: DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Sent: Monday, April 13, 2020 4:55 PM
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>; Austin, Meredith (OS/ASPR/IO) <Meredith.Austin@hhs.gov>; Sheehy, Janice (FDA/ORA)

<Janice.Sheehy@fda.hhs.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.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 Allocation of HHS-Held Chloroquine and Hydroxychloroquine for International Clinical Trials

Dear Disaster Leadership Group (DLG) Members:
Thank you for your feedback informing the policy options paper titled "Allocation of HHS-Held Chloroquine and Hydroxychloroquine for International Clinical Trials." We have updated the document to include rankings for the three policy options. Please let us know if you disagree with the ranked order or have any additional concerns by **Tuesday, April 14th at 12:00 pm**. The ranked options are listed below:

1. Donate a pre-determined percentage* of HHS-held hydroxychloroquine and chloroquine to the World Health Organization (WHO) for use in their international clinical trials (SOLIDARITY) conducted under an IND authorized by FDA. WHO would review and make determinations on the requests in accordance with any existing donation agreements.
2. Reserve a pre-determined percentage* of HHS-held hydroxychloroquine and chloroquine for use in clinical trials, both domestic and international, that are under an IND authorized by FDA as required by the donation agreements and allocate reserved product based on ISMPG review and recommendation as requests are received.
3. Refer request to WHO or other international clinical trial supporters to determine if the requestor could be part of existing clinical trials.

***Note:** SNS indicated that 10% of the U.S. stockpile is available for clinical trials, whether domestic or international.
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: Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>

Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>
Sent Date:	2020/04/14 11:11:42
Delivered Date:	2020/04/14 11:11:44

From:	Kadlec, Robert (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB <Robert.Kadlec@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>
CC:	Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Petillo, Jay (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59ce6133dfa14f6d96b9662b7cfdebc5-Petillo, Ja <Jay.Petillo@HHS.GOV>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Yeh, Bai (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=902f9845be5e49f88cb7b2798a8c6e83-Yeh, Bai (H <Bai.Yeh@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a96c8cefe54e86a9eccf3b4763431c-Acheampong, <Otuo.Acheampong@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong, <Kimberly.Armstrong@hhs.gov>
Subject:	Re: Funding Requests
Date:	2020/04/13 17:28:27
Priority:	Normal
Type:	Note

Ok. Thanks.

Sent from my iPhone

On Apr 13, 2020, at 5:18 PM, Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>wrote:

Bob,

No, the arms are limited to those below. They do not have the bandwidth to support an adaptive trial design.

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
Washington, D.C. 20201
Office: 202-260-0899
Mobile (b)(6)
Fax: 202-205-0873
email: Gary.Disbrow@HHS.gov

From: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Sent: Monday, April 13, 2020 4:34 PM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Yeh, Bai (OS/ASPR/BARDA) <Bai.Yeh@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) <Otuo.Acheampong@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>
Subject: RE: Funding Requests

Approved with one question doe sthis permit insertion of additional candidate therapeutics that may be identified going forward? Best Bob
Kadlec sends.

From: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Sent: Monday, April 13, 2020 2:52 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Yeh, Bai (OS/ASPR/BARDA) <Bai.Yeh@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) <Otuo.Acheampong@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>
Subject: Funding Requests

Bob, Bryan and Jay,

Funding request to support a clinical trial to evaluate famotidine.

Contract number: BAA (New)
Funding source: COVID-19 supplemental 2 (Therapeutics)
Contractor: Alchem Laboratories
Location: Alachua, FL

BARDA is seeking approval to request fund for a multi-site, randomized, double-blind, multi-arm historical control, comparative trial of the safety and efficacy of hydroxychloroquine and combination of hydroxychloroquine and famotidine for treatment of moderate to severe COVID-19 disease in hospitalized adults for **$20,747,018.00.**

Study will help evaluate the clinical efficacy of COVID-19 treatments consisting of standard of care (SOC) combined with pharmaceutical antiviral management using hydroxychloroquine or SOC with hydroxychloroquine and high-dose intravenous famotidine in hospitalized patients meeting nucleic acid diagnostic and radiologic criteria for COVID-19 disease.

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

Sender:	Kadlec, Robert (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB <Robert.Kadlec@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>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Petillo, Jay (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59ce6133dfa14f6d96b9662b7cfdebc5-Petillo, Ja <Jay.Petillo@HHS.GOV>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Yeh, Bai (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=902f9845be5e49f88cb7b2798a8c6e83-Yeh, Bai (H <Bai.Yeh@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a96c8cefe54e86a9eccf3b4763431c-Acheampong, <Otuo.Acheampong@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong, <Kimberly.Armstrong@hhs.gov>
Sent Date:	2020/04/13 17:28:26
Delivered Date:	2020/04/13 17:28:27

From:	Walker, Robert (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A02E128C60F4A7195532A1545AF9556-WALKER, ROB <Robert.Walker@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong, <Kimberly.Armstrong@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7bd764440b44b06af644cdcd22e42d6-Oshansky, C <Christine.Oshansky@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>
Subject:	RE: 2nd Gilead Remdesivir trial halted in China
Date:	2020/04/15 19:10:19
Priority:	Normal
Type:	Note

The last call minutes with Gilead are attached fyi.

Enrollment = 73 (target = 328) and Gilead did not indicate a plan to close the study on the April 10 call. In fact, Gilead agreed that it made sense to continue the study since the pressure to publish in the mild/moderate population was not so great as in the severe patients.

In late February the study had enrolled 56, and by March 13 the peak of 73 had been reached. Around that time the study was amended to remove the exclusion for previous receipt of Kaletra, and consideration was given to expanding to more sites outside of Wuhan proper because of lack of cases, but this was not implemented. Despite the change to eligibility there was no impact on enrollment.

The HHS team asked repeatedly and the answer from Gilead was consistent week-to-week, there were few new cases.

Bob

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, April 15, 2020 5:58 PM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Cc: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA)

<Christine.Oshansky@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Subject: Re: 2nd Gilead Remdesivir trial halted in China

There were plenty of cases when the trials started. And there have been weekly calls between hhs and Gilead on the trials. So wondering what we can learn from the "lack" of enrollment. First, is it true? And what was enrollment? Then, why didn't either trial enroll? Wrong site? Inclusion/exclusion criteria? Concurrent treatments? Etc.

There were a lot of cases, just wondering about the back story.

Thanks. Rick.

On Apr 15, 2020, at 5:39 PM, Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>wrote:

Rick,

What do you mean deeper. There are no additional cases so they halted the trial.

Gary L. Disbrow Ph.D.
Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority
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Assistant Secretary for Preparedness and Response ASPR
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Office: 202-260-0899
Mobile (b)(6)
Fax: 202-205-0873
email: Gary.Disbrow@HHS.gov

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, April 15, 2020 5:36 PM
To: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA)

<Gary.Disbrow@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) <Kimberly.Armstrong@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Subject: 2nd Gilead Remdesivir trial halted in China

Any deeper info on this from the weekly calls with Gilead on these trials?

https://www.fiercebiotech.com/biotech/gilead-shares-slip-as-a-second-remdesivir-covid-19-trial-halted-china?mkt_tok=eyJpIjoiTmpCaVpXSm1aR0kzTURoaSIsInQiOiJqK3lhNVN4NkI4bUwxNU80d0N1XC9kMWpYSVRJVmpuK0lMeXlYdmxrTW1NNGlxODRVSGZLYUIzN3lGTU40eDFwd2NaM3ZNSGhDVnF4MnZGUWJlMDZwZlRhV1NvYU9BSWF4K3N1Z2ZVUCt2b0pOaStobDZUTHc2aWlFa2FmbkNpcisifQ%3D%3D&mrkid=638766

Sender:	Walker, Robert (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A02E128C60F4A7195532A1545AF9556-WALKER, ROB <Robert.Walker@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li <Linda.Lambert@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong, <Kimberly.Armstrong@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7bd764440b44b06af644cdcd22e42d6-Oshansky, C <Christine.Oshansky@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>
Sent Date:	2020/04/15 19:10:18
Delivered Date:	2020/04/15 19:10:19

From:	Lauren Cohen <lauren.w.cohen@duke.edu>
To:	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>
CC:	Adrian Hernandez, M.D. <adrian.hernandez@duke.edu>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	RE: Health Care Worker HCQ Prophlaxis trial
Date:	2020/03/28 11:32:36
Priority:	Normal
Type:	Note

Thank you, Josie and all.

I will connect Hilary with key team members in my next email to make sure everyone has the information needed.

Lauren

From: Josie Briggs <jpbriggs@pcori.org>
Sent: Saturday, March 28, 2020 11:10 AM
To: Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; Lauren Cohen <lauren.w.cohen@duke.edu>
Cc: Adrian Hernandez, M.D. <adrian.hernandez@duke.edu>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: RE: Health Care Worker HCQ Prophlaxis trial

Central shipping and then shipping to study sites is fine with us – or shipping directly to the site our Duke coordinating center will name. Either is workable Lauren Cohen is cced on this email – and she can help coordinate.
Josie Briggs

From: Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>
Sent: Saturday, March 28, 2020 10:13 AM
To: Josie Briggs <jpbriggs@pcori.org>
Cc: adrian.hernandez <adrian.hernandez@duke.edu>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: Re: Health Care Worker HCQ Prophlaxis trial

Josie we're working on this with Rick (for you and other studies). What is the address for this delivery? We have a central address in Rockville and could receive all for various studies (can ship from there for you if that's okay). Let us know.

From: Josie Briggs <jpbriggs@pcori.org>
Date: Saturday, March 28, 2020 at 7:47 AM
To: Rick Bright <Rick.Bright@hhs.gov>
Cc: Hilary Marston <hilary.marston@nih.gov>, Kimberly DiGioia <kdigioia@pcori.org>, Lauren Cohen <lauren.w.cohen@duke.edu>
Subject: Health Care Worker HCQ Prophlaxis trial

Greetings Rick,
An update and a request. We are moving forward at breakneck speed to implement a HCQ Pre-exposure Prophylaxis trial for health care workers. The broad strokes of the approach are outlined in the attached powerpoint. Thanks to BARDA, the outreach to Sandoz was prompt and immediate – and the Duke clinical research pharmacy is going to receive the drug in the first week of April. We hope to have the registry phase open in the first week in April and the trial actually enrolling by the third week of April. Our trial network has been amazing in pulling this quite large – and we think really definitive – trial together very quickly.

One remaining problem however is access to nasopharyngeal swabs. I am sure you are encountering this problem on many fronts. Again, our need will be acute in about two or three weeks.
Thanks,
Josie Briggs
Josephine P. BriggsMD
Interim Executive Director
Patient Centered Outcomes Research Institute

Sender:	Lauren Cohen <lauren.w.cohen@duke.edu>
Recipient:	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>; Adrian Hernandez, M.D. <adrian.hernandez@duke.edu>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/03/28 11:32:24
Delivered Date:	2020/03/28 11:32:36

From:	Cook, Sara <CookS@cbsnews.com>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	CBS Q on your reassignment
Date:	2020/04/22 16:30:24
Priority:	Normal
Type:	Note

Hi Dr. Bright,

I saw the NYT piece with your statement about having been sidelined for pressing for rigorous vetting of possible coronavirus treatments, particularly ahead of making chloroquine and hydroxychloroquine widely available for use. Can we receive this statement as well? Additionally, I saw that you are planning to request that the HHS IG look into "the manner in which this administration has politicized the work of BARDA and has pressured me and other conscientious scientists to fund companies with political connections and efforts that lack scientific merit." Have you officially raised this with the Inspector General?

We heard from a source that there was a power struggle with Secretary Azar trying to assert more of a role in the drug/vaccine process--is this something you saw in your experience?

Thank you,
Sara

Sara Cook
White House Producer
CBS News
(b)(6)
cooks@cbsnews.com

Sender:	Cook, Sara <CookS@cbsnews.com>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/04/22 16:29:00
Delivered Date:	2020/04/22 16:30:24
Message Flags:	Unread

From:	Vaught, Andrea (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=22132FB08EF6407AB9FA3C698000AD44-VAUGHT, AND <Andrea.Vaught@hhs.gov>
To:	OS - ASPR - BARDA nCoVAdmin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8160f63f8c1b460aa34b410eec44c5d1-BARDAnCoVAd <BARDAnCoVAdmin@hhs.gov>; BARDA SARS2 IMT Comms /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc2f0a7acd3a4ba2906aaf7d39e65a1a-BARDASARS2I <BARDASARS2IMTComms@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@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>; Blatner, Gretta (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr <Gretta.Blatner@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af00dcf720cb429f8e2accbe06ee32ff-Donis, Rube <Ruben.Donis@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7bd764440b44b06af644cdcd22e42d6-Oshansky, C <Christine.Oshansky@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c83127c6669486888ec57ccc0d09c28-Donabedian, <armen.donabedian@hhs.gov>; Armstrong, Kimberly (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong, <Kimberly.Armstrong@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4654f8f0c0f4623b9e47465e9e1037a-Wallace, Ro <Rodney.Wallace@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Sciarretta, Kimberly (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df0aa767616f40de93add716f2df7f7a-Sciarretta, <Kimberly.Sciarretta@hhs.gov>; Angelastro, Michael (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=583e910528e7473d9dcdfce9d1a80b83-Angelastro, <Michael.Angelastro@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>; Little, James (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user6914ecde <James.Little@hhs.gov>; Acheampong, Otuo (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a96c8cefe54e86a9eccf3b4763431c-Acheampong, <Otuo.Acheampong@hhs.gov>; Kane, Elleen (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user25dbd6c7 <Elleen.Kane@hhs.gov>; Jarrett, Elizabeth (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b3d14cf1823486e90e4cd0814351ce9-Jarrett, El <Elizabeth.Jarrett@HHS.GOV>; Benford, Joffrey (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=475b27f64a8345d98908051b5f96d1d4-Benford, Jo <Joffrey.Benford@hhs.gov>; Harris, James (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=72bc577bb4a94dd29acaef880f4411e2-Harris, Jam <James.Harris2@hhs.gov>; McCord, Matthew (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d70d652bf2940ceb6066aa5ed985c13-Matthew McC <Matthew.McCord@hhs.gov>; Manan, Enrique (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a97d7188e2e545c4b718608948bef5dd-Manan, Enri <Enrique.Manan@hhs.gov>; Hill, Rosemary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4588f1a5786d4cd68fdcdd1aea2c4180-Hill, Rosem <Rosemary.Hill@hhs.gov>; Howell, David (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b005ab75d4234af08485940cfc761d7f-David Howel <David.Howell@hhs.gov>
Subject:	Notification: New Award / Modification by Schmidt, Jeff
Date:	2020/04/14 14:00:19
Priority:	Normal
Type:	Note

Organization/Company Name: Alchem Laboratories Corp
Contract IAA, or OTA Number: 75A50120C00078
TO#/Mod #/CLIN: N/A
Type of Contract/Agreement Action: New Award
Acquisition Vehicle: Firm-Fixed Price
Project Name: Trial of the safety and efficacy of hydroxychloroquine and the combination of hydroxychloroquine and famotidine for the treatment of moderate to severe COVID-19 disease in hospitalized adults
Project Category: Clinical
Obligated Amount: $20747018
Date of Contract Award/Modification: 2020-04-14
Funding Used: 199C002
Period of Performance: 2020-04-14 to 2020-09-30
CO: Schmidt, Jeff
COR: Grace, Marcy

Sender:	Vaught, Andrea (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=22132FB08EF6407AB9FA3C698000AD44-VAUGHT, AND <Andrea.Vaught@hhs.gov>
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<Rodney.Wallace@hhs.gov>;
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<Kimberly.Sciarretta@hhs.gov>;
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<Michael.Angelastro@hhs.gov>;
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre
<Tremel.Faison@hhs.gov>;
Little, James (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user6914ecde <James.Little@hhs.gov>;
Acheampong, Otuo (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group
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<Otuo.Acheampong@hhs.gov>;
Kane, Elleen (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user25dbd6c7 <Elleen.Kane@hhs.gov>;
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=9b3d14cf1823486e90e4cd0814351ce9-Jarrett, El
<Elizabeth.Jarrett@HHS.GOV>;
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=475b27f64a8345d98908051b5f96d1d4-Benford, Jo
<Joffrey.Benford@hhs.gov>;
Harris, James (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=72bc577bb4a94dd29acaef880f4411e2-Harris, Jam
<James.Harris2@hhs.gov>;
McCord, Matthew (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d70d652bf2940ceb6066aa5ed985c13-Matthew McC
<Matthew.McCord@hhs.gov>;
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a97d7188e2e545c4b718608948bef5dd-Manan, Enri
<Enrique.Manan@hhs.gov>;
Hill, Rosemary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4588f1a5786d4cd68fdcdd1aea2c4180-Hill, Rosem
<Rosemary.Hill@hhs.gov>;
Howell, David (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b005ab75d4234af08485940cfc761d7f-David Howel
<David.Howell@hhs.gov>

Sent Date:	2020/04/14 14:00:17
Delivered Date:	2020/04/14 14:00:19

From:	Hamel, Joseph (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96D2C1602DFA45E5A5E21452A098B96D-HAMEL, JOSE <Joseph.Hamel@hhs.gov>
To:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
CC:	Wolf, Laura (OS/ASPR/SIIM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c <Laura.Wolf@hhs.gov>; Harper, Victor (OS/ASPR/ORM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user0bdee7e8 <Victor.Harper@hhs.gov>; Adams, Steven A. (ASPR/SNS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f98462fe8d124743a437c7a80b3f60dd-Adams, Stev <saa1@cdc.gov>; Polowczyk, John P (MIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9601fb487104533a91fbf61381d884e-john.p.polo <john.p.polowczyk.mil@mail.mil>; Falcon, Jessica (OS/ASPR/SIIM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2f34b1b5a874e108d1dedfa20a01eb7-Falcon, Jes <Jessica.Falcon@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>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>
Subject:	RE: URGENT: CQ and HCQ donations
Date:	2020/03/23 13:26:38
Priority:	Normal
Type:	Note

On it.

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

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 1:21 PM
To: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Cc: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Polowczyk, John P (MIL) <john.p.polowczyk.mil@mail.mil>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; 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>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: Re: URGENT: CQ and HCQ donations

Joe. Thank you. Please pull the Mylan thread if you have time. I saw the press release but no details. Trying to connect donors to needs for USG trials. Thank you.

On Mar 23, 2020, at 12:57 PM, Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>wrote:

Thank you Rick!

I'm not sure anyone's set up a tracker on this yet, as they've been coming in piece meal. If you need me to pull the Mylan thread, I'm happy to.

Talk soon!

Best,
Joe

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

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 12:56 PM
To: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Polowczyk, John P (MIL) <john.p.polowczyk.mil@mail.mil>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@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>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: Re: URGENT: CQ and HCQ donations

Awesome, thank you Joe. This is exactly what I was looking for…contact for Sandoz/Novartis. I thought that Mylan also made a donation announcement, but not sure where that arrow landed. I will reach out to the POC you provided.

Does anyone know if there is a database set up yet to track the various donations? If not, I can send a request to the data fusion cell, but trying not to duplicate effort if already in play.

Joe, thank you for the rapid response and all you are doing to save lives. Truly grateful. Rick

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From: Joseph Hamel <Joseph.Hamel@hhs.gov>
Date: Monday, March 23, 2020 at 12:29 PM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Laura Wolf <Laura.Wolf@hhs.gov>, "Harper, Victor (OS/ASPR/ORM)" <Victor.Harper@hhs.gov>, "Adams, Steven A. (ASPR/SNS)" <saa1@cdc.gov>, "Polowczyk, John P (MIL)" <john.p.polowczyk.mil@mail.mil>, "Falcon, Jessica (OS/ASPR/SIIM)" <Jessica.Falcon@hhs.gov>
Cc: "Christopher. Houchens" <Christopher.Houchens@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>, Bryan Shuy <Bryan.Shuy@hhs.gov>
Subject: RE: URGENT: CQ and HCQ donations

Rick,

I know you're in contact with TEVA, and the only other one other than Bayer that I know is donating now is Sandoz/Novartis (you were on the traffic with them and Charrow this weekend). POC at Sandoz/Novartis is Anthony, below:

Anthony Maffia, III
Vice President, Regulatory Affairs, North America
T +1-609-627-6944
M +1(b)(6)
F +1-609-395-2792
anthony.maffia@sandoz.com

Best,
Joe

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

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 12:14 PM
To: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Adams, Steven A.

(ASPR/SNS) <saa1@cdc.gov>; Polowczyk, John P (MIL) <john.p.polowczyk.mil@mail.mil>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@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>
Subject: URGENT: CQ and HCQ donations
Importance: High

Joe/SNS/Supply Chain,

(b)(5)

If you do not have the information, please connect me. Very urgent need, thanks, Rick

Sender:	Hamel, Joseph (OS/ASPR/IO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96D2C1602DFA45E5A5E21452A098B96D-HAMEL, JOSE <Joseph.Hamel@hhs.gov>
Recipient:	Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c <Laura.Wolf@hhs.gov>; Harper, Victor (OS/ASPR/ORM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user0bdee7e8 <Victor.Harper@hhs.gov>; Adams, Steven A. (ASPR/SNS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f98462fe8d124743a437c7a80b3f60dd-Adams, Stev <saa1@cdc.gov>; Polowczyk, John P (MIL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9601fb487104533a91fbf61381d884e-john.p.polo <john.p.polowczyk.mil@mail.mil>; Falcon, Jessica (OS/ASPR/SIIM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2f34b1b5a874e108d1dedfa20a01eb7-Falcon, Jes <Jessica.Falcon@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>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>
Sent Date:	2020/03/23 13:26:37
Delivered Date:	2020/03/23 13:26:38

From:	Tegeris, John (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD48E9EB139645DF8B45EA8439820E7F-TEGERIS, JO <john.tegeris@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>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>
Subject:	RE: UPDATE: Eastman Kodak Company Inquiry: capability to manufacture chloroquine and hydroxychloroquine...
Date:	2020/03/23 20:10:11
Priority:	Normal
Type:	Note

Will do. Will call Kristen then connect to Joe. Thanks, Gary.

From: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Sent: Monday, March 23, 2020 2:53 PM
To: Tegeris, John (OS/ASPR/BARDA) (CTR) <john.tegeris@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Subject: RE: UPDATE: Eastman Kodak Company Inquiry: capability to manufacture chloroquine and hydroxychloroquine...

John,

Please loop in Joe Hamel for you call. He is off and running with the Chloroquine actions and has already assisted shipment that arrives today. He is collecting information from companies that can manufacture the product.

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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Office: 202-260-0899
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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: Tegeris, John (OS/ASPR/BARDA) (CTR) <john.tegeris@hhs.gov>
Sent: Monday, March 23, 2020 2:51 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Tegeris, John (OS/ASPR/BARDA) (CTR) <john.tegeris@hhs.gov>
Subject: FW: UPDATE: Eastman Kodak Company Inquiry: capability to manufacture chloroquine and hydroxychloroquine...

...for your awareness from Kodac...please see email from Kristin forwarded below...have plans to chat with her tomorrow morning, so if there is anything of interest to share with her then, standing by to learn more...many thanks

---

From: Tegeris, John (OS/ASPR/BARDA) (CTR) <john.tegeris@hhs.gov>
Sent: Monday, March 23, 2020 2:49 PM
To: Williams, Kristin Calabrese <kristin.williams@kodak.com>; Tegeris, John (OS/ASPR/BARDA) (CTR) <john.tegeris@hhs.gov>
Subject: UPDATE: Eastman Kodak Company Inquiry: capability to manufacture chloroquine and hydroxychloroquine...

Hi Kristin,

Thanks for reaching out. If we can chat tomorrow morning around 8:30am ET, that would be helpful to advance the discussion. Challenging times for sure. Hope you are hanging in there, too. Drinking water from a fire hose is the new normal here at BARDA. My cell is (b)(6) to call me when you can (8-9am ET window works well most days). Thanks for your interest in working with BARDA and the USG for the COVID-19 response.

Best Wishes,
John

From: Williams, Kristin Calabrese <kristin.williams@kodak.com>
Sent: Saturday, March 21, 2020 8:33 PM
To: Tegeris, John (OS/ASPR/BARDA) (CTR) <john.tegeris@hhs.gov>
Subject: Eastman Kodak Company Inquiry

John,

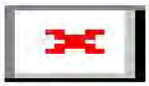
Please allow me to introduce myself—my name is Kristin Williams, and I head up Government Relations at Eastman Kodak Company. I received your name from Mary Kosinkski with PhRMA.

Kodak has a specialty chemicals business based in Rochester, New York, and we have the capability to manufacture **chloroquine and hydroxychloroquine**. We are trying to reach out to HHS in order to determine how we can support the effort. Kodak would need a waiver from the FDA's cGMP requirements.

If you could provide any guidance, I'd appreciate your feedback. Please hang in there during these challenging times.

Many thanks,
Kristin Williams

Kristin Calabrese Williams
Vice President, Public Affairs &Chief Privacy Officer
Eastman Kodak Company
kristin.williams@kodak.com | (b)(6)
www.kodak.com



Sender:	Tegeris, John (OS/ASPR/BARDA) (CTR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD48E9EB139645DF8B45EA8439820E7F-TEGERIS, JO <john.tegeris@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>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>
Sent Date:	2020/03/23 20:10:10
Delivered Date:	2020/03/23 20:10:11

From:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
To:	Hayes, Jonathan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona <Jonathan.Hayes@hhs.gov>
CC:	Bartrum, John (OS/ASPR) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb2cc9052221421c8d5b7fd480f25bbe-Bartrum, Jo <John.Bartrum@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose <Joseph.Hamel@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user161a2a33 <Susan.Sherman@HHS.GOV>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Subject:	Re: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature
Date:	2020/03/29 16:53:34
Priority:	Normal
Type:	Note

Dear John,

Request letter was sent and FDA issued authorization. I will forward email from BARDA's Tremel Faison from 12:03am this morning.

Linda

Sent from my iPhone

On Mar 29, 2020, at 4:45 PM, Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>wrote:

Confirming this will not come through today? Task for Monday?

We expect Dr. Kadlec back in the ASPR Suite at FEMA a little after 5pm.

FYSA

From: Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>
Sent: Saturday, March 28, 2020 8:26 PM
To: Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Cc: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: RE: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

Tremel &Joe – when you have the package coordinated and final – please resend as requested.

Thanks – John

Note – I dropped off Dr. Kadlec until it is completed and ready for his review.

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Saturday, March 28, 2020 8:14 PM
To: Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>
Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Subject: Re: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

John, I'm connecting you and Joe to Tremel and Linda who've worked on the document and Susan who's reviewing for legal.

Please work with them to address any questions.

Thanks. Rick.

On Mar 28, 2020, at 8:09 PM, Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>wrote:

Rick,

My understanding is this document may not include a couple key edits requested by Joe that may impact our procurement option.

Please work with Joe to resolve and send a summary the changes with the revised document for Dr. Kadlec's review.

Thanks,

John

John J. Bartrum, BG, USAF, MSC
COVID-19 ESF-8 (Med) Deputy Commander
Rm 8NW-2007, Cell (b)(6)

From: Rick Bright <Rick.Bright@hhs.gov>
Sent: Saturday, March 28, 2020 7:43 PM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Yeskey, Kevin (OS/ASPR/IO) <Kevin.Yeskey@hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>
Subject: Re: Letter to FDA to request EUA for chloroquine and hydroxycloroquine - for signature

Dr. Kadlec,

As directed by the department, HHS agencies CDC, ASPR, FDA, BARDA, and NIH have worked rapidly to develop an EUA protocol for hydroxychloroquine and chloroquine per the direction.

The attached letter has been drafted by HHS and OGC and is ready for signature and transmission.

I seek your final review and concurrence to sign and submit. Once received, this will be transmitted to FDA and they will submit a response letter.

I await your concurrence to proceed.

Thank you. Rick

On Mar 28, 2020, at 7:31 PM, Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>wrote:

Dear Rick,
Attached is the EUA request letter for the EUA. FDA will review and issue a letter of acceptance for the EUA.

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.
Please review, sign and send to Tremel Faison who will transmit this to the FDA.
Thank you,
Linda

Linda C. Lambert, PhD
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

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

Sender:	Lambert, Linda (OS/ASPR/BARDA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CE6824B6A92A4A4E893EA7B54E17EB3C-LAMBERT, LI <Linda.Lambert@hhs.gov>
Recipient:	Hayes, Jonathan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona <Jonathan.Hayes@hhs.gov>; Bartrum, John (OS/ASPR) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb2cc9052221421c8d5b7fd480f25bbe-Bartrum, Jo <John.Bartrum@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2bbab0bceb1342fbbedbbcc94deeb80f-Faison, Tre <Tremel.Faison@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose <Joseph.Hamel@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Sherman, Susan (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user161a2a33 <Susan.Sherman@HHS.GOV>; Bright, Rick (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric <Rick.Bright@hhs.gov>
Sent Date:	2020/03/29 16:53:33
Delivered Date:	2020/03/29 16:53:34