OWS Board Update

Vaccine (Vx) and Therapeutic (Tx) Workstreams

JULY 2ND, 2020

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DEPARTMENT OF HEALTH & HUMAN SERVICES
USA


OPERATION
WARP SPEED


DEPARTMENT OF DEFENSE
UNITED STATES OF AMERICA

Thank you!

From:	Oakley, Caitlin B. (OS/ASPA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E5EE4C35534C4AF9BDAC46789C034790-OAKLEY, CAI <Caitlin.Oakley@HHS.GOV>
To:	Kane, Elleen (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user25dbd6c7 <Elleen.Kane@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Michael, Gretchen (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0632b4526d6447b5af26552afde05c33-Michael, Gr <Gretchen.Michael@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00e638c4ddf64006bcc009e8032dd700-Waters, Cic <Cicely.Waters@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona <Jonathan.Hayes@hhs.gov>; Sellman, Suzanne (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bfe40dc98b54fc7989a00075a9c8ab7-Sellman, Su <Suzanne.Sellman@hhs.gov>; Bialek, Stephanie M. (ASPR/SNS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7d77e22d4bd40b6a0b205df4d8a2f58-stephanie.b <ilq8@cdc.gov>
CC:	McKeogh, Katherine (OS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c652f2c415b44dff8369dd7f4596f030-McKeogh, Ka <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya <Ryan.Murphy1@hhs.gov>; Stimson, Brian (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338aa495176d4c92bb314f8f3f51d118-Stimson, Br <Brian.Stimson@hhs.gov>; Barry, Daniel J (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3e449ce0 <daniel.barry@hhs.gov>
Subject:	RE: For ASPR Review--more info: price of remdesivir
Date:	2020/04/07 18:32:27
Priority:	Normal
Type:	Note

(b)(5) Thank you.

From: Oakley, Caitlin B. (OS/ASPA)
Sent: Tuesday, April 7, 2020 6:32 PM
To: Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Sellman, Suzanne (OS/ASPR/OEA) <Suzanne.Sellman@hhs.gov>; Bialek, Stephanie M. (ASPR/SNS) <ilq8@cdc.gov>
Cc: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Barry, Daniel J

(HHS/OGC) <daniel.barry@hhs.gov>
Subject: RE: For ASPR Review--more info: price of remdesivir

Ok. Can ASPR please draft a reactive statement for NY Times?

Need this group to clear it. Thank you.

Caitlin B. Oakley
Deputy Assistant Secretary, National Spokesperson
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
caitlin.oakley@hhs.gov

From: Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>
Sent: Tuesday, April 7, 2020 6:31 PM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Sellman, Suzanne (OS/ASPR/OEA) <Suzanne.Sellman@hhs.gov>; Bialek, Stephanie M. (ASPR/SNS) <ilq8@cdc.gov>
Cc: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>
Subject: RE: For ASPR Review--more info: price of remdesivir

No.

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Sent: Tuesday, April 7, 2020 6:30 PM
To: Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Sellman, Suzanne (OS/ASPR/OEA) <Suzanne.Sellman@hhs.gov>; Bialek, Stephanie M. (ASPR/SNS) <ilq8@cdc.gov>
Cc: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>
Subject: RE: For ASPR Review--more info: price of remdesivir

Did they receive donations?

From: Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>
Sent: Tuesday, April 7, 2020 6:30 PM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>;

Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Sellman, Suzanne (OS/ASPR/OEA) <Suzanne.Sellman@hhs.gov>; Bialek, Stephanie M. (ASPR/SNS) <ilq8@cdc.gov>
Cc: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>
Subject: RE: For ASPR Review--more info: price of remdesivir

Neither the SNS nor BARDA has purchased remdesivir from Gilead.

From: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Sent: Tuesday, April 7, 2020 6:26 PM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Sellman, Suzanne (OS/ASPR/OEA) <Suzanne.Sellman@hhs.gov>; Bialek, Stephanie M. (ASPR/SNS) <ilq8@cdc.gov>
Cc: McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>
Subject: For ASPR Review--more info: price of remdesivir

Team ASPR—See below. More info from the reporter…

Any guidance on what happened with this?

Happy to chat on this. I'm at (b)(6)

Thanks.

DRAFT PRE-DECISIONAL DELIBERATIVE

From: Thomas, Katie <katie.thomas@nytimes.com>
Sent: Tuesday, April 7, 2020 6:03 PM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Subject: Re: Deadline q: price of remdesivir

Hi,

Gilead gave me a response, which unfortunately only confuses matters a bit more. Wondering if you can tell me what the story is with regards to procuring remdesivir doses, whether they were actually acquired, etc? And I have until tomorrow now as I try to sort this out.

This is what they told me:

It appears as if two distinct discussions around procuring remdesivir may have been conflated. In February and March 2020, Gilead and HHS discussed making certain amounts of our very limited supply available to HHS for use by the government for various purposes, including

supplying military needs. HHS's desire was to purchase quantities of between 2,000 and 7,500 patient courses. Instead of charging the government for these amounts, Gilead committed to donating them. At no time has Gilead sold remdesivir to the government. Under the remdesivir clinical supply agreement entered into several years ago during the Ebola breakout, the government had the ability to purchase remdesivir for use to treat Ebola outside of clinical trials. It did not do so. Gilead has had no discussion with the government about remuneration to Gilead for supplying remdesivir to treat patients infected with COVID-19.

By the way, I noticed that Navarro has mentioned this price point and doses another time, in late February:
https://protect2.fireeye.com/url?k=3b195864-674d4118-3b19695b-0cc47adc5fa2-bac7302cd6980ca9&u=https://www.hughhewitt.com/white-house-trade-advisor-peter-navarro-on-the-admins-coronavirus-response/

"If somebody gets Corona, and they're moderately to severely infected, there's, first of all, there's a drug called Remdesivir. It's made by Gilead. What we've done there are a number of things. First of all, we've secured the 4,500 doses that they have. In addition, as a cost of almost $200 million, we're moving to secure the other 90,000 doses they have in involved material."

(if you do the math there, it's about $2,200 a dose)

Katie Thomas
Staff Writer, New York Times
(b)(6)
Twitter: @katie_thomas

On Tue, Apr 7, 2020 at 3:56 PM Thomas, Katie <katie.thomas@nytimes.com>wrote:
thanks!

Katie Thomas
Staff Writer, New York Times
(b)(6)
Twitter: @katie_thomas

On Tue, Apr 7, 2020 at 3:55 PM Oakley, Caitlin B. (OS/ASPA)
<Caitlin.Oakley@hhs.gov>wrote:
Hi Katie—Checking on this!

Caitlin B. Oakley
Deputy Assistant Secretary, National Spokesperson
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
caitlin.oakley@hhs.gov

From: Thomas, Katie <katie.thomas@nytimes.com>
Sent: Tuesday, April 7, 2020 4:46 PM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Subject: Deadline q: price of remdesivir

Hi Caitlin,

I'm working on a deadline story (ASAP) about the price of remdesivir

In the leaked memo from Navarro:
https://www.axios.com/exclusive-navarro-deaths-coronavirus-memos-january-da3f08fb-dce1-4f69-89b5-ea048f8382a9.html

It says that HHS paid Gilead $2,200 per dose for 4,500 doses of remdesivir, and that it was imperative that they secure 90,000 more doses for a total cost of $198 million

Wondering if HHS can comment on what it has paid for remdesivir, and if that additional order for 90,000 additional doses was placed. If not, what is the total amount of remdesivir that has been ordered and at what price?

I'm sorry for the quick turnaround but just got the story and we are trying to put it out quickly. If my timing changes I'll try to give you as much of a heads up as I can.

Katie

Katie Thomas
Staff Writer, New York Times
(b)(6)
Twitter: @katie_thomas

Sender:	Oakley, Caitlin B. (OS/ASPA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E5EE4C35534C4AF9BDAC46789C034790-OAKLEY, CAI <Caitlin.Oakley@HHS.GOV>
Recipient:	Kane, Elleen (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user25dbd6c7 <Elleen.Kane@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Michael, Gretchen (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0632b4526d6447b5af26552afde05c33-Michael, Gr <Gretchen.Michael@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00e638c4ddf64006bcc009e8032dd700-Waters, Cic <Cicely.Waters@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona <Jonathan.Hayes@hhs.gov>; Sellman, Suzanne (OS/ASPR/OEA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bfe40dc98b54fc7989a00075a9c8ab7-Sellman, Su

	<Suzanne.Sellman@hhs.gov>; Bialek, Stephanie M. (ASPR/SNS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7d77e22d4bd40b6a0b205df4d8a2f58-stephanie.b <ilq8@cdc.gov>; McKeogh, Katherine (OS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c652f2c415b44dff8369dd7f4596f030-McKeogh, Ka <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=314e69c69a844b47bdd9f74bc60a8d44-Murphy, Rya <Ryan.Murphy1@hhs.gov>; Stimson, Brian (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338aa495176d4c92bb314f8f3f51d118-Stimson, Br <Brian.Stimson@hhs.gov>; Barry, Daniel J (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3e449ce0 <daniel.barry@hhs.gov>
Sent Date:	2020/04/07 18:32:26
Delivered Date:	2020/04/07 18:32:27

Sender:	Chandrasekera, Ruvani (OS/ASPR/SPPR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=678D9FF8E02D477AB5D0516BD3659A34-CHANDRASEKE <Ruvani.Chandrasekera@hhs.gov>
Recipient:	Mantoan, Patricia (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user0ebe3257 <Patricia.Mantoan@HHS.GOV>; Albrecht, Mark (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e115b1de167b4ebe8307fe50864592fc-Albrecht, M <Mark.Albrecht@hhs.gov>; Ford, Kenya S. (CDC/OCOO/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19abf444c4644ba4b98f32d69346b089-Ford, Kenya <kdf6@cdc.gov>; Godin, Jacquelyn (NIH/OD) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ef166d22710401ea386330709579d0e-jacquelyn.g <jacquelyn.godin@nih.gov>; Sherman, Susan (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user161a2a33 <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userdee6c80e <Jennifer.Ray-Gorrie@hhs.gov>; CDC IMS 2019 NCOV Response International Task Force <eocevent223@cdc.gov>; Kerr, Lawrence (HHS/OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ce9de2e7497472bb758f8fd6e262c86-Kerr, Lawre <Lawrence.Kerr@hhs.gov>; Sadove, Elizabeth (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae67103141a7491b98842bd017e466d7-elizabeth.s <Elizabeth.Sadove@fda.hhs.gov>; Courtney, Brooke (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=435939b5eab748a989b326804d3437be-brooke.cour <Brooke.Courtney@fda.hhs.gov>; Mair, Michael (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3e2b23223bc4a1abecf698a4122f6c3-michael.mai <Michael.Mair@fda.hhs.gov>; AvilesMendoza, Guillermo (OS/OASH) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0364bceaec8465ea5ac8efd7c1e2f3d-Aviles-Mond <Guillermo.Aviles-Mendoza@hhs.gov>; Barry, Daniel J (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3e449ce0 <daniel.barry@hhs.gov>; Vinter, Serena (CDC/DDPHSIS/CGH/OD) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ff7ab2691b6428cbe5cce9e66373bb6-serena.vint <uvv3@cdc.gov>; Weir, Charles (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user24f49da6 <Charles.Weir@hhs.gov>; Peerbolte, Stacy (OS/ASPR/EMMO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07f40bb90b3c473088149d741edccc76-Peerbolte, <Stacy.Peerbolte@hhs.gov>; Phung, Hai Lien (ASPR/SNS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=291075dceb7e422db9f0c0dc58639fb5-hailien.phu <vvt3@cdc.gov>; Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars <hilary.marston@nih.gov>; Christl, Thomas (OS/ASPR/SIIM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4ff7673b404ee289efb5329c319e90-Christl, Th <Thomas.Christl@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose <Joseph.Hamel@hhs.gov>; Lamana, Joseph (OS/ASPR/EMMO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userdc0ca36a <Joseph.Lamana@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d421d3e0f6474bc3857583cfc5870d69-Moudy, Robi <Robin.Moudy@hhs.gov>; Ayala, Ana (OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80a408be55b14221a42c2b91002d6bf7-Ayala, Ana <Ana.Ayala@hhs.gov>; Tewell, Adam (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group

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<Adam.Tewell@hhs.gov>;
Fitzgerald, Denis (OS/ASPR/EMMO) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=usere4967f9b <Denis.Fitzgerald@hhs.gov>;
Horahan, Kevin (OS/ASPR/EMMO) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user09957bb0 <Kevin.Horahan@hhs.gov>;
Harper, Victor (OS/ASPR/ORM) /o=ExchangeLabs/ou=Exchange Administrative Group
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Ashton, Dustun (OS/ASPR/EMMO) /o=ExchangeLabs/ou=Exchange Administrative Group
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Evans, Pamela (OS/ASPR/EMMO) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=userac4ac959 <Pamela.Evans@hhs.gov>;
Vincent, Erik (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=09e0bad3f82749018db7f112a4e1ba6a-Vincent, Er
<Erik.Vincent@hhs.gov>;
Adams, Steven A. (ASPR/SNS) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f98462fe8d124743a437c7a80b3f60dd-Adams, Stev
<saa1@cdc.gov>;
Gorman, Susan (ASPR/SNS) /o=ExchangeLabs/ou=Exchange Administrative Group
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<spg4@cdc.gov>;
Carpenter, Robert (ASPR/SNS) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f14ae003e1df4fb8b6bbd30e6c2a077c-Carpenter,
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Dillard, Lisa (ASPR/SNS) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a66e8ebd21a84da8b2cc54d5ac6ec8c7-Dillard, Li
<lsw9@cdc.gov>;
Dolinsky, David (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a1c0737560da438e9ea5444b550ab62f-Dolinsky, D
<David.Dolinsky@hhs.gov>;
Arthur, Ray (CDC/DDPHSIS/CGH/DGHP) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=855f8ca30adc4a59906fd6647ac8371d-Arthur, Ray
<rca8@cdc.gov>;
Degrange, Elizabeth (HHS/OASH) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6311a56c8d504cd1b0301ce0fa2fe646-Degrange, E
<Elizabeth.Degrange@hhs.gov>;
Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob
<Robert.Walker@hhs.gov>;
Lambert, Linda (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce6824b6a92a4a4e893ea7b54e17eb3c-Lambert, Li
<Linda.Lambert@hhs.gov>;
Weinberger, Collin (OS/OGA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=641554fc7843407585827af5898d9c26-Weinberger,
<Collin.Weinberger@hhs.gov>;
<eocevent209@cdc.gov>;
Lawrence, Theresa (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=281df890cadd49ea9e8622a68fd9b726-Lawrence, T
<Theresa.Lawrence@HHS.GOV>;
Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga
<Gary.Disbrow@hhs.gov>;
Dodgen, Daniel (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c23f0d7c1d634508918e1c87cf50c48c-Dodgen, Dan
<Daniel.Dodgen@HHS.GOV>;
George, Kysa <Kysa.George@fema.dhs.gov>;
Schwartz, Benjamin J CAPT USN NAVHOSP BREMERTON WA (USA)
<benjamin.j.schwartz3.mil@mail.mil>;
Moniz, Charles R Lt Col USAF DLA LOGISTICS OPERATIONS (USA) <Charles.Moniz@dla.mil>;
Abbott, Christopher J. EOP/WHO <Christopher.J.Abbott2@who.eop.gov>;
Neuhauser, Melinda (CDC/DDID/NCEZID/DHQP) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9d14e9c3a57048018057da3866678bac-melinda.neu
<ikf5@cdc.gov>;
Marston, Hilary (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=93be476c17024bbcbc5b44add01fe6a8-hilary.mars
<hilary.marston@nih.gov>;

	Beigel, John (NIH) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45af28983cfa4300b0217b591151861c-john.beigel <jbeigel@niaid.nih.gov>; Lane, Cliff (NIH/NIAID) [E] /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11a174ee688e426392d98ba9cd5e1945-cliff.lane. <clane@niaid.nih.gov>; Thomas, Jason (CDC/DDPHSS/CSELS/DHIS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8e9919902434ceaae788e25db1f8d22-Thomas, Mat <dvz5@cdc.gov>; Imbriale, Samuel (OS/ASPR/SIIM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere7e54524 <Samuel.Imbriale@hhs.gov>; Greene, Jonathan (OS/ASPR/EMMO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b692a4d6cff4afabbeea99d35336ece-Greene, Jon <Jonathan.Greene@hhs.gov>; DLGDESK (HHS/ASPR/OPP) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f1f856fe64345d3ac04f5afd847622b-DLGDESK.OS@ <DLGDESK@hhs.gov>; Smith, Timothy D. (fema.dhs.os) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8223228af8e843d6b88803f73d5abbbd-Timothy.D.S <Timothy.Smith5@fema.dhs.gov>
Sent Date:	2020/04/20 09:52:17
Delivered Date:	2020/04/20 09:52:20

Page 030

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Page 031

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

Page 032

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

TAIWAN BIOTECH CO., LTD.

22, CHIEH SHOU ROAD, TAOYUAN, TAIWAN, R.O.C.

CERTIFICATE OF ANALYSIS

Product : Hydroquine Film Coated Tablets 200 mg

Lot No. : 6 P C 2 3 8 9

Mfg. Date : 2019. 10. 23 Exp. Date : 2021. 10.

Item	Specification	Analysis Result
(b)(3):42 U.S.C. § 247d-6b(d)		

TAIWAN BIOTECH CO., LTD.

22, CHIEH SHOU ROAD, TAOYUAN, TAIWAN, R.O.C.

CERTIFICATE OF ANALYSIS

Product : Hydroquine Film Coated Tablets 200 mg

Lot No. : 6 P C 2 3 8 9

Mfg. Date : 2019. 10. 23 Exp. Date : 2021. 10.

Item	Specification	Analysis Result
(b)(3):42 U.S.C. § 247d-6b(d)		

Conclusions: It meets requirements of the specification

Deputy Manager of Quality Control Department : Yu-Shiang Hung

信東生技股份有限公司
TAIWAN BIOTECH CO., LTD.
22, CHIEH-SHOU ROAD, TAOYUAN, TAIWAN, R.O.C.

March 31st, 2020

To whom it may concern:

With the recent emergency use authorization (EUA) by the FDA this weekend and the report of widespread global shortage of hydroxychloroqine, Taiwan Biotech Co. (TBC) currently manufactures the finished drug hydroxychloroquine. TBC is currently in a unique position to offer hydroxychloroquine for importation to the United States. We have one million doses of hydroxychloroquine reserved to ship to the United States with the capability of having much greater quantities available by mid-April.

Use of hydroxychloroquine for treatment of SARS-CoV-2 via EUA has contributed to global shortage of the drug. Many are affected by this shortage in addition to patients battling SARS-CoV-2 who lack access to the drug, but also patients who rely on hydroxychloroquine for management of lupus (SLE) and rheumatoid arthritis (RA).

We would like to play a role in supporting the United States through the SARS-CoV-2 crisis and drug shortage crisis for SLE and RA patients. We would like to offer the immediate delivery of 1 million tabs to the US Federal Government in the battle against the viral crisis. If the government is not in need of the hydroxychloroquine supply, we would like guidance on offering the supply to US pharmacy wholesalers to prevent the further interruption to the supply chain on which SLE and RA patients so desperately depend.

Sincerely,

B. J. Huang

B. J. Huang

Vice President,

International Business and Development Division

Taiwan Biotech Co. Ltd

E-mail : bjhung@sintong.com

Website : http://www.taiwanbiotech.com.tw

From:	Ken Nelson <knelson@bardydx.com>
To:	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>
CC:	Gust Bardy <gbardy@bardydx.com>
Subject:	RE: Follow Up - BardyDx & BARDA - COVID-19 Remote Patient Monitoring & Hydroxychloroquine Clinical Studies
Date:	2020/05/06 09:55:58
Priority:	Normal
Type:	Note

Gary,

No problem, and thanks for getting back to me. We were actually able to get a call set up on May 14th with 9 members of BARDA and are looking forward to that conversation.

Thanks again for your help,

Ken

From: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Sent: Wednesday, May 6, 2020 4:56 AM
To: Ken Nelson <knelson@bardydx.com>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Subject: RE: Follow Up - BardyDx &BARDA - COVID-19 Remote Patient Monitoring &Hydroxychloroquine Clinical Studies

Ken,

Apologies for the delayed response, these are very busy times. If you have not already submitted your ideas to the MCM portal, please do so. The link is copied below. This will allow a discussion with your company. We are experiencing high volumes of submissions under the market research portal but we are moving them quickly through the process. I thank you for your interest is potentially partnering with BARDA.

I hope you, your family and those in your company are staying safe.

The federal government established a single point of entry for product developers to submit their research on 2019 novel coronavirus medical countermeasures If you are interested in partnering with with BARDA and PHEMCE partners about medical countermeasures against COVID-19, submit your ideas via the BARDA 2019 Novel Coronavirus Market Research Initiative. This is for market research only and a submission is not a submission to the solicitations listed below for potential funding. This does allow for a conversation and potential TechWatch.

For additional questions about the Market Research Initiative, please contact: TechWatchInbox@hhs.gov.

Regards,

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: Ken Nelson <knelson@bardydx.com>
Sent: Friday, May 1, 2020 11:03 AM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Subject: Follow Up - BardyDx &BARDA - COVID-19 Remote Patient Monitoring &Hydroxychloroquine Clinical Studies
Importance: High

Gary,

A few days ago, on April 29th we presented to multiple individuals at BARDA and HHS via the BARDA/ MedTech Innovator COVID-19 Solutions Event for about 3 hours. As a follow up to those presentations, we are trying to determine the appropriate people at BARDA to follow up with to further explore the potential use of our BardyDx CAM Patch in some of the COVID-19 clinical studies that BARDA is funding and collaborating with others on, especially ones related to monitoring QT intervals for COVID-19 patients taking Hydroxychloroquine (HCQ), Azithromycin (Z-Pak), or any other experimental or investigational drugs that may prolong QT intervals and/ or lead to other potentially lethal cardiac arrhythmias. The

BardyDx CAM Patch is the only external cardiac monitoring patch clinically validated to monitor QT intervals.

Any help with directing me to the right individuals at BARDA would be greatly appreciated so that we can get a follow up call scheduled to discuss in more detail.

In the mean time, below is a very high level summary of BardyDx, our CAM Patch, and the COVID-19 related educational resources for mailing directly to patients and for home applications with remote patient monitoring, based on the rapid shift to telehealth in the current COVID-19 environment.

BardyDx Overview &Summary of COVID-19 Remote Patient Monitoring Solutions

- • ***Company*** - Bardy Diagnostics, Inc. ("BardyDx") is an innovator in digital health and remote patient monitoring, with a focus on providing the highest fidelity rhythm strips and most diagnostically-accurate and patient-friendly cardiac patch monitors in the industry.
- • ***Product*** – Our BardyDx CAM Patch is a single use and disposable, non-invasive, P-wave centric™ ambulatory cardiac monitor and arrhythmia detection device, that is uniquely designed to accurately monitor QT intervals and detect any other cardiac arrhythmias. CAM records every heart beat continuously for up to 14 Days.
- • ***COVID-19 Solution*** –
    - • Monitoring QT intervals for COVID-19 patients taking Hydroxychloroquine (HCQ), Azithromycin (Z-Pak), or any other experimental or investigational drugs that may prolong QT intervals and/ or lead to other potentially lethal cardiac arrhythmias.
    - • The BardyDx CAM Patch is the only external cardiac monitoring patch clinically validated to monitor QT intervals.
- • ***Current COVID-19 Studies*** – CAM Patch is currently being used in significant clinical studies of COVID-19 patients including one at Walter Reed, several at UW Medicine in Seattle, and others at leading institutions across the country.
- • ***Proprietary*** – The CAM Patch's proprietary design includes patented circuit board design and signal processing with 60+ U.S. patents issued and more pending to help protect it.
- • ***Clinical Evidence*** - In addition, 3 separate head to head clinical studies have been done providing clinical evidence to help back up the superior rhythm fidelity and detection accuracy, with 2 peer reviewed and published in the American Heart Journal.

- • **Monitor Life-Threatening QT Prolongation In COVID-19 Patients** Using Hydroxychloroquine (HCQ), Azithromycin (Z-Pak), or Other Drugs (e.g., Remdesivir) Via BardyDx CAM Patch.
    - • There are 3 key ECG monitoring facts regarding proper QT monitoring with COVID-19:
        - • First, proper QT interval monitoring should include the ability to record low amplitude, low frequency content at the tail end of the T wave. The CAM Patch is designed for this very function.
        - • Second, the BardyDx CAM Patch has been clinically validated in a peer-reviewed clinical trial demonstrating excellent correlation with standard QT measurement tools.
            - • A head-to-head clinical study published in the *American Heart Journal* comparing the CAM Patch and a traditional multi-vector (3 lead) Holter monitor provides clinical evidence that the CAM Patch ECG

intervals PR, QRS and QT correlated well with the traditional 3-channel Holter ECG intervals having correlation coefficients of 0.93, 0.86, and 0.94 respectively.

- • Third, it has been reported in studies that COVID-19 may generate a myocarditis or cardiomyopathy leading to other arrhythmias if the patient receives a Z-pak or HCQ.

Sources:

1. • ACC Clinical Bulletin on COVID-19 Clinical Guidance for Cardiovascular Care Team
2. • Wang D, Hu B, Hu C, et al.Clinical Characteristics of 138 Hospitalized Patients with2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. JAMA. Published online February 07, 2020. doi:10.1001/jama.2020.1585
3. • Chun-Yu Chen, Feng-Lin Wang &Chih-Chuan Lin (2006) Chronic Hydroxychloroquine Use Associated with QT Prolongation and Refractory Ventricular Arrhythmia, Clinical Toxicology, 44:2, 173-175, DOI: 10.1080/15563650500514558
4. • Smith WM., et al. Comparison of diagnostic value using a small, single channel, P-wave centric sternal ECG monitoring patch with a standard 3-lead Holter system over 24 hours. American Heart Journal. March 2017 (See Figure 3-c)
5. • https://www.prnewswire.com/news-releases/bardy-diagnostics-announces-use-of-the-carnation-ambulatory-monitor-patch-to-measure-qt-segments-in-covid-19-patients-using-hydroxychloroquine-301029840.html

We are all fighting the COVID-19 pandemic together, and in order to help with transitioning the care of both research and non-research patients in need of cardiac monitoring to telehealth, we wanted to make you aware of the following options to consider, along with associated educational resources (available at https://protect2.fireeye.com/url?k=6b6e93fa-373b9ae9-6b6ea2c5-0cc47adb5650-45d5299295bb228c&u=https://protect2.fireeye.com/url?k=02f92029-5ead3955-02f91116-0cc47adc5fa2-e66e1f9b29fa0b0e&u=https://www.bardydx.com/patients along with a patient home application video):

1. • New Mail To Patient / Home Application Offering for CAM Patches &Patient Education Resources
2. • One Time Use (Disposable) BardyDx CAM Patches
3. • Monitor Life-Threatening QT Interval Prolongation and related arrhythmias in COVID-19 Patients With BardyDx CAM Patches
    a. • COVID-19 patients using hydroxychloroquine, Azithromycin or other drugs (e.g., Remdesivir)

- • **Mail To Patient/ Home Application Resources**
    - • Please to visit https://protect2.fireeye.com/url?k=36f600ce-6aa309dd-36f631f1-0cc47adb5650-d63d32b0d36bdd31&u=https://protect2.fireeye.com/url?k=f924621b-a5707b67-f9245324-0cc47adc5fa2-db5090d36ce53c52&u=https://www.bardydx.com/patients to learn more and view the home application video.

Thanks and we look forward to next steps,

Ken

Kenneth W. Nelson III
Chief Commercial Officer
knelson@bardydx.com

Bardy Diagnostics, Inc.
+1-844-77P-WAVE | +1-844-777-9283
316 Occidental Ave South, Suite 310
Seattle, WA 98104
https://protect2.fireeye.com/url?k=6f81dfc7-33d4d6d4-6f81eef8-0cc47adb5650-bb9ac5d854c52ccc&u=https://protect2.fireeye.com/url?k=2dad2024-71f93958-2dad111b-0cc47adc5fa2-12adc0da1d592919&u=http://www.bardydx.com/

Sender:	Ken Nelson <knelson@bardydx.com>
Recipient:	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Gust Bardy <gbardy@bardydx.com>
Sent Date:	2020/05/06 09:55:33
Delivered Date:	2020/05/06 09:55:58

From:	Diana Brainard <Diana.Brainard@gilead.com>
To:	Merdad Parsey <merdad.parsey@gilead.com>; Anderson, Michael <Michael.Anderson@ucsf.edu>
CC:	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob <Robert.Kadlec@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>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Mair, Michael (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3e2b23223bc4a1abecf698a4122f6c3-michael.mai <Michael.Mair@fda.hhs.gov>
Subject:	RE: [EXTERNAL] Re: Avaialbility of REMDESIVIR in San Fran
Date:	2020/03/08 12:41:48
Priority:	Normal
Type:	Note

Dear Dr. Anderson,

I am available if you'd like to speak over the phone today. We have some limited experience with RDV in the setting of Ebola where we have treated a very small number of children. As Merdad mentioned, the efficacy and safety have not been established.

Please feel free to reach out: (b)(6)

Kind regards,
Diana

Diana M Brainard, MD
Senior Vice President
Therapeutic Area Head, Virology
Gilead Sciences, Inc.
Tel: (b)(6)

From: Merdad Parsey <merdad.parsey@gilead.com>
Sent: Sunday, March 08, 2020 8:49 AM

To: Anderson, Michael <Michael.Anderson@ucsf.edu>; Diana Brainard <Diana.Brainard@gilead.com>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>
Subject: Re: [EXTERNAL] Re: Avaialbility of REMDESIVIR in San Fran

Drs Anderson and Disbrow
Thanks for bringing me in the loop. As Gary mentioned, from a trial standpoint and our data to date, we do not have pediatric data nor eligibility for any of the studies. I'm happy to discuss compassionate use for anyone who may get infected, although as you can imagine, the number of patients with underlying comorbidities around the world is very high and our drug supply does not enable us to preposition drug in case of infection. We are generally able to respond quickly to compassionate use requests.

We would value working with you should a patient become infected and establishing a protocol in advance either in collaboration with NIAID or directly with us. This would be preferred to compassionate use since we do not have data for the safety and efficacy of remdesevir in adults or children. In particular, dosing in children has not been established, and we do have data that liver function abnormalities may be an adverse event at higher exposures. Given none of the children have been infected, we do have time to establish a protocol. I don't know if the NIAID team has considered including children or if the FDA would allow us to investigate this agent in children at this time.
I'm copying Diana Brainard who leads our virology group. I'm happy to speak on the phone later today.

Merdad

On Mar 8, 2020, at 8:34 AM, Anderson, Michael <Michael.Anderson@ucsf.edu>wrote:

Will do

Dr Parsey...can I call you?

==========
Michael Anderson, MD, MBA, FAAP, FCCM, FAARC
President, UCSF Benioff Children's Hospitals
Professor and Vice Chair for Children's Health, UCSF
Cell: (b)(6)
O: 415-476-6744

Assistant: joseph.genser@ucsf.edu OR (b)(6)

From: "Disbrow, Gary (OS/ASPR/BARDA)" <Gary.Disbrow@hhs.gov>
Date: Sunday, March 8, 2020 at 8:21 AM
To: Michael R Anderson <Michael.Anderson@ucsf.edu>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
Cc: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Johnson, Robert (OS/ASPR/BARDA)" <Robert.Johnson@hhs.gov>, "Shuy, Bryan (OS/ASPR/IO)" <Bryan.Shuy@hhs.gov>, Merdad Parsey <merdad.parsey@gilead.com>, "Walker, Robert (OS/ASPR/BARDA)" <Robert.Walker@hhs.gov>, "Mair, Michael (FDA/OC)" <Michael.Mair@fda.hhs.gov>
Subject: RE: Avaialbility of REMDESIVIR in San Fran

Michael,

RCT is for adults only. Would need to discuss with Gilead if they have any data from treatment of pediatric patients with Ebola to potentially identify a pediatric dose of other than weight based.

Please call Dr. Parsey to obtain additional information on potential use of drug in pediatric patients.

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

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: Anderson, Michael <Michael.Anderson@ucsf.edu>
Sent: Sunday, March 8, 2020 10:52 AM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Merdad Parsey <merdad.parsey@gilead.com>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Anderson, Michael <Michael.Anderson@ucsf.edu>
Subject: Re: Avaialbility of REMDESIVIR in San Fran

Thanks team.

My plans for the next 24 hrs

1. • Make sure my onc team is in the loop
2. • Our command center is open and awaiting more data on the 9 make-a-wish children. We have two children's campuses in SF and Oakland. Likewise other peds beds exist in the Bay…
3. • Dr Parsey—please feel free to contact me w questions. Once we have a more clear picture on the clinical issues, will decide if enrollment is appropriate
4. • Awaiting other input/counsel

Mike
Cell: (b)(6)

==========

Michael Anderson, MD, MBA, FAAP, FCCM, FAARC
President, UCSF Benioff Children's Hospitals
Professor and Vice Chair for Children's Health, UCSF
Cell: (b)(6)
O: 415-476-6744

Assistant: joseph.genser@ucsf.edu OR (b)(6)

From: "Disbrow, Gary (OS/ASPR/BARDA)" <Gary.Disbrow@hhs.gov>
Date: Sunday, March 8, 2020 at 7:42 AM
To: Michael R Anderson <Michael.Anderson@ucsf.edu>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
Cc: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Johnson, Robert (OS/ASPR/BARDA)" <Robert.Johnson@hhs.gov>, "Shuy, Bryan (OS/ASPR/IO)" <Bryan.Shuy@hhs.gov>, Merdad Parsey <merdad.parsey@gilead.com>, "Walker, Robert (OS/ASPR/BARDA)" <Robert.Walker@hhs.gov>, "Mair, Michael (FDA/OC)" <Michael.Mair@fda.hhs.gov>
Subject: RE: Avaialbility of REMDESIVIR in San Fran

Michael,

Thanks for the quick call and discussion. Providing information for Chief Medical Officer for Gilead, Dr. Merdad Parsey. I will also check with NIAID to determine if RCT is established in Oakland, if not and if it takes too much time to expand, a treating clinician could request product under an investigator initiated emergency IND.

Merdad Parsey, MD PhD
Chief Medical Officer
Gilead Sciences, Inc.
(M) (b)(6)

Also, the company is allowed to preposition drug in advance, if needed.

Providing an FDA contact who could assist if there are questions about eIND paperwork. Michael Mair in the email above could help connect to the review division.

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

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: Anderson, Michael <Michael.Anderson@ucsf.edu>
Sent: Sunday, March 8, 2020 10:18 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: 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>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: Re: Avaialbility of REMDESIVIR in San Fran

Ready to help any way we can

==========

Michael R Anderson MD MBA FAAP FCCM
President, UCSF Benioff Children's Hospitals
Professor of Pediatrics
Cell (b)(6)

Sent from my iPhone

On Mar 8, 2020, at 7:17 AM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>wrote:

BARDA Team please note there are 9 high risk children (Make a Wish Foundation) with advanced stage cancer. Please request from GILEAD 10 courses for compassionate use to be available immediately. These children have high potential mortality rates if exposed/infected to this virus. Please advise and keep me informed on any and all developments If you need a POC I have copied Mike Anderson at UCSF Peds hospital.

Sender:	Diana Brainard <Diana.Brainard@gilead.com>
Recipient:	Merdad Parsey <merdad.parsey@gilead.com>; Anderson, Michael <Michael.Anderson@ucsf.edu>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob <Robert.Kadlec@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>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Mair, Michael (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3e2b23223bc4a1abecf698a4122f6c3-michael.mai <Michael.Mair@fda.hhs.gov>
Sent Date:	2020/03/08 12:40:28
Delivered Date:	2020/03/08 12:41:48

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GILEAD
Creating Possible

An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences

April 4, 2020

Over the course of the past week, Gilead has been working in consultation with regulatory authorities to establish additional expanded access programs for remdesivir, our investigational medicine for COVID-19. The programs enable hospitals or physicians to apply for emergency use of remdesivir for multiple severely ill patients at a time. These are patients who cannot take part in clinical trials and where the word "emergency" is all too real for them, their families and the healthcare providers advocating on their behalf.

We know the desperate urgency of reaching these patients and believe that the expanded access program will help to accelerate the process. New U.S. sites have been initiated and we are adding more on an ongoing basis. We are also making progress in Europe. Yesterday, the European Medicines Agency announced that it has provided EU member states with recommendations on implementing expanded access programs for remdesivir in their countries.

In addition to the expanded access programs, we continue to provide remdesivir on an individual compassionate use basis for children and pregnant women. More than 1,700 patients have now been treated through these programs.

Remdesivir is still an investigational medicine and has not been approved by regulatory authorities anywhere in the world. The safety and efficacy are not yet known, so while we feel the greatest sense of urgency in our work with remdesivir, we must take the responsible, ethical approach of determining whether it is indeed a safe, effective treatment. This is why multiple clinical trials for remdesivir are underway, involving thousands of patients with COVID-19 across the world.

We know from the heartbreaking letters we receive, the images we see in the news and the all-too-bleak statistics that the urgency to find broad, effective solutions becomes more intense each day. In the ways we believe it is appropriate for Gilead to play a role today - primarily through clinical trials, as well as expanded access and compassionate use - we are doing everything it takes to meet our significant responsibility with remdesivir.

Supply and Donation of Remdesivir

A critical part of Gilead's responsibility today is ensuring sufficient supply of remdesivir. To provide product for trials, compassionate use and expanded access, we needed to effectively start from ground zero in ramping up our supplies. The progress we have made on this to date is thanks to the actions we have been taking since January to rapidly expand production and increase supply.

As soon as we knew that remdesivir may have potential in treating the novel coronavirus, our teams began to establish a supply chain for large-scale production. Then, as now, there were many unknowns including how long the outbreak would last, at what scale and whether remdesivir is a safe and effective treatment for COVID-19. We made the decision to invest and scale up regardless, because if remdesivir was going to be needed for patients, we had to be ready.

We knew there would be challenges in producing the amounts we would ideally want to deliver in a short timeframe. One of these challenges is the length of time it takes to produce remdesivir. It is a linear process that requires specialized chemistry and multiple chemical reactions, some of which can take several weeks to complete. It also calls for scarce raw materials as well as sterile manufacturing capabilities with limited global capacity, which are needed to make finished vials ready for administration to patients.

Working within these parameters, our teams have found multiple ways of accelerating production. These include process improvements that cut production times. As a result, we have reduced the end-to-end manufacturing timeline from approximately one year, to around six months. We have repurposed some of our own facilities to focus on remdesivir and we have also increased our network of external manufacturing partners around the world.

In the space of two months, we have significantly increased our available supply of remdesivir using the inventory of active pharmaceutical ingredients we already had on hand. Our existing supply, including finished product ready for distribution as well as investigational medicine in the final stages of production, amounts to 1.5 million individual doses. Depending on the optimal duration of treatment, which is something we are studying in clinical trials, this supply could equate to well over 140,000 treatment courses for patients.

Our efforts to increase supply continue with a strong sense of urgency. There is a long way to go and a lot of work to be done but I'm pleased that, despite the challenges we have been able to get supply levels to where they are today in a very short space of time - through the resourcefulness of our teams, creative approaches and collaboration.

Gilead is providing the entirety of this existing supply at no cost, to treat patients with the most severe symptoms of COVID-19. The 1.5 million individual doses are available for compassionate use, expanded access and clinical trials and will be donated for broader distribution following any potential future regulatory authorizations. These doses are for treating patients with severe symptoms, through daily intravenous infusions in a hospital setting. Having a potential treatment in our hands comes with significant responsibility. Providing our existing supplies at no charge is the right thing to do, to facilitate access to patients as quickly as possible and in recognition of the public emergency posed by this pandemic.

Looking Forward

While we are working with the utmost sense of urgency on the immediate needs before us, we are also looking forward. Over the next weeks and months, we will be able to further increase our supplies of remdesivir as raw materials with long lead times become available for manufacture. We have set an ambitious goal of producing more than 500,000 treatment courses by October and more than 1 million treatment courses by the end of this year.

To help us meet and exceed this goal, we are building a geographically diverse consortium of pharmaceutical and chemical manufacturers to expand global capacity for raw materials and production. This collaboration will allow us to achieve far more than any of us could have done working alone. The international nature of the supply chain for remdesivir reminds us that it is essential for countries to work together to create enough supply for the world.

These are intense, ongoing efforts and while they continue, we must await the data from the clinical trials before we know whether remdesivir is a safe and effective treatment.

In the meantime, in the face of many unknowns and the exceptional circumstance of this pandemic, we are finding every means possible to meet our responsibilities with remdesivir today, and to be prepared for meeting the needs of patients in the future.

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of the Freedom of Information Act

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of the Freedom of Information Act

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(b)(5)

of the Freedom of Information Act

From: Ricke, Darrell - 0449 - MITLL <darrell.ricke@ll.mit.edu>

To: Robert Malone <[redacted]>;
vinu arumugham <vaccine.safety@aol.com>;
Sestili, Piero <piero.sestili@uniurb.it>;
<def2004@cumc.columbia.edu>;
<jconigliaro@northwell.edu>;
<ddm1@cumc.columbia.edu>;
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<mo2130@cumc.columbia.edu>;
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<dtuveson@cshl.edu>;
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<dwl1@cumc.columbia.edu>;
<tcw21@cumc.columbia.edu>;
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mvcallahan@mgh.harvard.edu /o=ExchangeLabs/ou=Exchange Administrative Group
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<bryan_roth@med.unc.edu>;
<Victor.Francone@quinnipiac.edu>;
<Norbert.Herzog@quinnipiac.edu>;
<Maurice.Fremont-Smith@quinnipiac.edu>;
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Lawrence Steinman <steiny@stanford.edu>;
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Matzinger, Polly <pcm@helix.nih.gov>;
<pconti@unich.it>;
Kadlec, Robert (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob
<Robert.Kadlec@hhs.gov>;
HHS Secretary (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e3fce8f00194d8d94fc91094888d811-HHS Secreta
<secretary@hhs.gov>;
Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga
<Gary.Disbrow@hhs.gov>;
Christine Laine <claine@acponline.org>;
<fgodlee@bmj.com>;
<howard.bauchner@jamanetwork.org>;
<richard.horton@lancet.com>;
<erubin@hsph.harvard.edu>

Subject: Re: Use mast cell stabilizers, histamine H1/H2 blockers in COVID-19

Date: 2020/07/08 08:28:35

Priority: Normal

Type: Note.SMIME.MultipartSigned

All,

The following preprint on Kawasaki Disease and Multisystem Inflammatory Syndrome in Children: An Antibody-Induced Mast Cell Activation Hypothesis is posted here: https://www.ll.mit.edu/r-d/publications/kawasaki-disease-and-multisystem-inflammatory-syndrome-children-antibody-induced is now in press: J Pediatrics &Pediatr Med. 2020; 4(2): 1-7 (attached draft).

I would be interested in contributing to the proposed efforts.

Sincerely,

Darrell

Darrell O. Ricke, Ph.D.
Group 49 Biological and Chemical Technologies
Lincoln Laboratory, Massachusetts Institute of Technology
244 Wood Street
Lexington, MA 02421-6426

Phone: 781-981-8323 (voice messages only)
Work cell: (b)(6)
E-mail: Darrell.Ricke@ll.mit.edu

From: Robert Malone (b)(6)
Date: Tuesday, July 7, 2020 at 6:12 PM
To: vinu arumugham <vaccine.safety@aol.com>
Cc: "Sestili, Piero" <piero.sestili@uniurb.it>, "def2004@cumc.columbia.edu" <def2004@cumc.columbia.edu>, "jconigliaro@northwell.edu" <jconigliaro@northwell.edu>, "ddm1@cumc.columbia.edu" <ddm1@cumc.columbia.edu>, "ag3786@cumc.columbia.edu" <ag3786@cumc.columbia.edu>, "mo2130@cumc.columbia.edu" <mo2130@cumc.columbia.edu>, "jl1333@cumc.columbia.edu" <jl1333@cumc.columbia.edu>, "dtuveson@cshl.edu" <dtuveson@cshl.edu>, "zj7@cumc.columbia.edu" <zj7@cumc.columbia.edu>, "wt62@cumc.columbia.edu" <wt62@cumc.columbia.edu>, "dwl1@cumc.columbia.edu" <dwl1@cumc.columbia.edu>, "tcw21@cumc.columbia.edu" <tcw21@cumc.columbia.edu>, "kjtracey@northwell.edu" <kjtracey@northwell.edu>, "mvcallahan@mgh.harvard.edu" <mvcallahan@mgh.harvard.edu>, "ja660@cumc.columbia.edu" <ja660@cumc.columbia.edu>, "janowitz@cshl.edu" <janowitz@cshl.edu>, "djp65@cam.ac.uk" <djp65@cam.ac.uk>, "Ricke, Darrell - 0449 - MITLL" <darrell.ricke@ll.mit.edu>, "yongfeng@email.unc.edu" <yongfeng@email.unc.edu>, "xphuang@unc.edu" <xphuang@unc.edu>, "kris.white@mssm.edu" <kris.white@mssm.edu>,

"elena.morenodelolmo@mssm.edu" <elena.morenodelolmo@mssm.edu>, "Assaf_Alon@hms.harvard.edu" <Assaf_Alon@hms.harvard.edu>, "Andrew_Kruse@hms.harvard.edu" <Andrew_Kruse@hms.harvard.edu>, "anthony.mittermaier@mcgill.ca" <anthony.mittermaier@mcgill.ca>, "Julianne.Hall@quinnipiac.edu" <Julianne.Hall@quinnipiac.edu>, "Robert.Bona@quinnipiac.edu" <Robert.Bona@quinnipiac.edu>, "h.clark@ucl.ac.uk" <h.clark@ucl.ac.uk>, "bryan_roth@med.unc.edu" <bryan_roth@med.unc.edu>, "Victor.Francone@quinnipiac.edu" <Victor.Francone@quinnipiac.edu>, "Norbert.Herzog@quinnipiac.edu" <Norbert.Herzog@quinnipiac.edu>, "Maurice.Fremont-Smith@quinnipiac.edu" <Maurice.Fremont-Smith@quinnipiac.edu>, "marikpe@evms.edu" <marikpe@evms.edu>, "Commins, Scott P" <scommins@email.unc.edu>, Lawrence Steinman <steiny@stanford.edu>, "ngkounis@otenet.gr" <ngkounis@otenet.gr>, "Matzinger, Polly" <pcm@helix.nih.gov>, "pconti@unich.it" <pconti@unich.it>, "Robert.Kadlec@hhs.gov" <Robert.Kadlec@hhs.gov>, "Secretary@HHS.gov" <Secretary@hhs.gov>, "Gary.Disbrow@hhs.gov" <Gary.Disbrow@hhs.gov>, Christine Laine <claine@acponline.org>, "fgodlee@bmj.com" <fgodlee@bmj.com>, "howard.bauchner@jamanetwork.org" <howard.bauchner@jamanetwork.org>, "richard.horton@lancet.com" <richard.horton@lancet.com>, "erubin@hsph.harvard.edu" <erubin@hsph.harvard.edu>
Subject: Re: Use mast cell stabilizers, histamine H1/H2 blockers in COVID-19

you may not be aware that this is now posted?

On Tue, Jul 7, 2020 at 5:42 PM vinu arumugham <vaccine.safety@aol.com>wrote:

Prof. Sestili,

Thank you for your quick response and suggestion.

All,

As Prof. Sestili has suggested, I agree that we should coauthor a paper (or perhaps an open letter like this one?) requesting that authorities rapidly consider and promote the clinical exploitation of medications that address inappropriate mast cell activation and the resulting immune cascade in COVID-19 (these include mast cell stabilizers, histamine H1/H2 blockers, leukotriene antagonists and leukotriene receptor antagonists, Vitamin C, etc.)

We have been able to correctly predict the beneficial effects of these medications since late January 2020 because the mechanism was understood. Hundreds of thousands of lives could have been saved if these medications had been used. If we do not act now, hundreds of thousands more lives will be lost.

Many authors have described the mechanism and role of mast cell dysregulation in severe COVID-19:

Repositioning Chromones for Early Anti-inflammatory Treatment of COVID-19

https://doi.org/10.3389/fphar.2020.00854

COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms
https://www.researchsquare.com/article/rs-30934/v2

Mast Cells Contribute to Coronavirus-Induced Inflammation: New Anti-Inflammatory Strategy
https://pubmed.ncbi.nlm.nih.gov/32013309/

Immunological mechanisms explaining the role of IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines, Vitamin C, hydroxychloroquine, ivermectin and azithromycin
https://doi.org/10.5281/zenodo.3748303

As I wrote in my comment posted in the Annals of Internal Medicine,

Understanding mechanisms is better than demanding clinical trials in the middle of a pandemic

Please see comments section:

https://protect2.fireeye.com/url?k=d9b16216-85e57b6a-d9b15329-0cc47adc5fa2-91c17008eb66e06a&u=https://annals.org/aim/fullarticle/2764199/use-hydroxychloroquine-chloroquine-during-covid-19-pandemic-what-every-clinician

Please respond if you would like to be a coauthor and please share any other ideas to make this happen. Please include coworkers who may be interested.

Thanks,

Vinu

On 7/7/20 12:11 AM, Sestili, Piero wrote:
Dear Vinu,

I wrote a paper in March proposing mast cell stabilizers to treat COVID-19 soon after its early clinical presentation.
I am elated to see that many colleagues around the world independently formulated similar thoughts and that evidences are accumulating strengthening this hypothesis.

We could collectively prepare a paper coauthorized by all of us (I see that you have a wide list where Prof. Conti, Prof Kritas and their coworkers could be included) pushing authorities to rapidly consider and promote the clinical exploitation of MCS against COVID.

Here is the DOI of my article
https://doi.org/10.3389/fphar.2020.00854

Please, if you think it might be useful, forward this message to your MCS mail list.

Truly yours and thanks for your relevant effort, ciao

Piero Sestili
Full Professor in Pharmacology,
University of Urbino, Italy

Il giorno mar 7 lug 2020 alle 02:46 vinu arumugham <vaccine.safety@aol.com>ha scritto:

www.bmj.com/content/368/bmj.m1252/rr-1

-------- Forwarded Message --------

Subject: Kawasaki disease and COVID-19 are iatrogenic diseases; Try mast cell stabilizers, H1/H2 blockers

Date: Thu, 14 May 2020 09:42:05 -0700

From: vinu arumugham <vaccine.safety@aol.com>

To: nchoueit@montefiore.org <nchoueit@montefiore.org>, Brett.Giroir@hhs.gov <Brett.Giroir@hhs.gov>, ufficiostampa@asst-pg23.it <ufficiostampa@asst-pg23.it>, ldantiga@hpg23.it <ldantiga@hpg23.it>, letters@nytimes.com <letters@nytimes.com>, nytnews@nytimes.com <nytnews@nytimes.com>, inytletters@nytimes.com <inytletters@nytimes.com>, editorial@nytimes.com <editorial@nytimes.com>, corrections@nytimes.com <corrections@nytimes.com>, books@nytimes.com <books@nytimes.com>, magazine@nytimes.com <magazine@nytimes.com>, travelmail@nytimes.com <travelmail@nytimes.com>, edu@nytimes.com <edu@nytimes.com>, eileen.murphy@nytimes.com <eileen.murphy@nytimes.com>, danielle.rhoades-ha@nytimes.com <danielle.rhoades-ha@nytimes.com>, booking@nytimes.com <booking@nytimes.com>, bizday@nytimes.com <bizday@nytimes.com>, foreign@nytimes.com <foreign@nytimes.com>, sports@nytimes.com <sports@nytimes.com>, washington@nytimes.com <washington@nytimes.com>, national@nytimes.com <national@nytimes.com>, thearts@nytimes.com <thearts@nytimes.com>, metropolitan@nytimes.com <metropolitan@nytimes.com>, tips@nytimes.com <tips@nytimes.com>, public@nytimes.com <public@nytimes.com>, sarah.mervosh@nytimes.com <sarah.mervosh@nytimes.com>, pam.belluck@nytimes.com <pam.belluck@nytimes.com>, reed.abelson@nytimes.com <reed.abelson@nytimes.com>, (b)(5) <(b)(6)>, n.walsh@medpagetoday.com <n.walsh@medpagetoday.com>, tips@medpagetoday.com <tips@medpagetoday.com>, c.bankhead@medpagetoday.com <c.bankhead@medpagetoday.com>, (b)(5) <(b)(6)>, c.phend@medpagetoday.com <c.phend@medpagetoday.com>, m.walker@medpagetoday.com <m.walker@medpagetoday.com>, ehlavinka@medpagetoday.com <ehlavinka@medpagetoday.com>, iingram@medpagetoday.com <iingram@medpagetoday.com>, k.fiore@medpagetoday.com <k.fiore@medpagetoday.com>, n.lou@medpagetoday.com <n.lou@medpagetoday.com>, Press.Office@exec.ny.gov, r.viner@ucl.ac.uk <r.viner@ucl.ac.uk>, e.whittaker@imperial.ac.uk <e.whittaker@imperial.ac.uk>, m.levin@imperial.ac.uk <m.levin@imperial.ac.uk>, JPIDS.EditorialOffice@oup.com <JPIDS.EditorialOffice@oup.com>, gerberj@email.chop.edu

gerberj@email.chop.edu, sarah.parker@ucdenver.edu, greemd@chp.edu, ravi.jhaveri@northwestern.edu, samir.shah@cchmc.org, ashane@emory.edu, ilan.youngster@childrens.harvard.edu, storch@wustl.edu, jsbradley@ucsd.edu, penelope.bryant@mcri.edu.au, chchiu@adm.cgmh.org.tw, lara.danziger-isakov@cchmc.org, dhunstad@wustl.edu, Huskins.Charles@mayo.edu, mlaufer@medicine.umaryland.edu, latania_logan@rush.edu, fernando.p.polack@vanderbilt.edu, Adam.Ratner@nyulangone.org, jennifer_read@nih.gov, jr3@ualberta.ca, Lrubin@lij.edu, Ls5@cumc.columbia.edu, mike.sharland@stgeorges.nhs.uk, bill.steinbach@duke.edu, ptamma1@jhmi.edu, ttan@northwestern.edu, jvallejo@bcm.edu, a.warris@abdn.ac.uk, CGIDRadmin@seattlechildrens.org, danielle.zerr@seattlechildrens.org

Kawasaki disease (KD) and COVID-19 are iatrogenic diseases; Try mast cell stabilizers, H1/H2 blockers.

KD shock syndrome is same mechanism as influenza and dengue shock syndrome covered below ("slow rolling anaphylaxis").

https://twitter.com/ArumughamVinu/status/1259659169046474753?s=20

One can also expect peripheral blood eosinophilia. Have you checked? RCPCH case definition does not include it.

That would be consistent with the body's (iatrogenically induced) anti-parasite response against SARS-CoV-2, instead of just an antiviral response. Consider IgE/IgG4 responses against heat shock proteins.

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

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

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

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

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

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

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

My comment posted in the Annals of Internal Medicine:

Please see comments section:

https://protect2.fireeye.com/url?k=1691f284-4ac5ebf8-1691c3bb-0cc47adc5fa2-bb6cf91271dd0e97&u=https://annals.org/aim/fullarticle/2764199/use-hydroxychloroquine-chloroquine-during-covid-19-pandemic-what-every-clinician

Understanding mechanisms is better than demanding clinical trials in the middle of a pandemic

Hydroxychloroquine and azithromycin use in COVID-19 have been dismissed as "unproven" or "anecdotal", by the medical establishment. But the benefit of ventilators in COVID-19 is equally unproven. Why the clamor for ventilators? And now there are reports that ventilators are not helping.
https://www.npr.org/sections/health-shots/2020/04/02/826105278/ventilators-are-no-panacea-for-critically-ill-covid-19-patients

Running protein sequence analysis with the SARS-CoV-2, MERS, SARS viruses, there is a strong similarity to a pig spike protein (coronavirus infected pig). Accession number QGV12786 vs. QHD43416.1 for SARS-CoV-2.

Since vaccines contain porcine proteins derived from pigs infected with any number of diseases, one could develop IgE mediated sensitization to coronavirus spike proteins. We have entire, viable porcine circoviruses in the rotavirus vaccines, for example.
https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf

Upon infection with any of these viruses, the concurrent allergic reaction can increase disease severity. In such cases, antihistamines and other allergy treatments such as mast cell stabilizers may help reduce infection severity.
This is similar to influenza vaccine induced allergy to the influenza virus, increasing the severity of subsequent influenza infection as described here:
Influenza vaccines and dengue-like disease
https://www.bmj.com/content/360/bmj.k1378/rr-15

There have been reports that elevated ferritin and IL-6 levels are predictors of fatality in COVID-19.
https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30628-0/fulltext

There is an increase in mast cell density during infections:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4435071/

IgE mediated mast cell degranulation results in increased ferritin levels as well as histamine levels.

Ferritin Particles Accumulate in Human Mast Cell Secretory Granules and Are Released upon FcεRI-mediated Activation
https://protect2.fireeye.com/url?k=19d2f71a-4586ee66-19d2c625-0cc47adc5fa2-74fbd81851f5df7f&u=https://www.jacionline.org/article/S0091-6749(17)32622-2/fulltext

Histamine promotes release of IL-6.

Histamine Promotes the Release of Interleukin-6 via the H1R/p38 and NF-κB Pathways in Nasal Fibroblasts
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4214978/

Also, neutrophils recruited to the lung during infection can release histamine.

Neutrophil histamine contributes to inflammation in mycoplasma pneumonia.
https://www.ncbi.nlm.nih.gov/pubmed/17158962

The antihistamine effect of Vitamin C IV seems to help.

Antihistamine effect of supplemental ascorbic acid and neutrophil chemotaxis
https://www.ncbi.nlm.nih.gov/pubmed/1578094

https://www.nutraingredients.com/Article/2020/03/25/Hospital-turns-to-high-dose-vitamin-C-to-fight-coronavirus

Also, azithromycin reduces histamine induced inflammation.

The anti-inflammatory effects of erythromycin, clarithromycin, azithromycin and roxithromycin on histamine-induced otitis media with effusion in guinea pigs.
https://www.ncbi.nlm.nih.gov/pubmed/29888693

Hydroxychloroquine helps in allergic asthma.

Hydroxychloroquine improves airflow and lowers circulating IgE levels in subjects with moderate symptomatic asthma.
https://www.ncbi.nlm.nih.gov/pubmed/9723661

Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial
https://www.sciencedirect.com/science/article/pii/S0924857920300996
https://protect2.fireeye.com/url?k=2bbd2335-77e93a49-2bbd120a-0cc47adc5fa2-b1c304165a4ec544&u=https://www.mediterranee-infection.com/covid-19/

So there are many indicators pointing to the role of mast cell degranulation/histamine release being a major component of COVID-19.
Antihistamines, mast cell stabilizers, Vitamin C, hydroxychloroquine, azithromycin may all address different aspects of this same problem.
Focusing on only the antiviral actions of hydroxychloroquine or azithromycin, will lead us into blind alleys.

--
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https://protect2.fireeye.com/url?k=a9892aa5-f5dd33d9-a9891b9a-0cc47adc5fa2-f9118219fee9d633&u=http://www.rwmalonemd.com/

"Tread lightly, take only pictures, leave only footprints, kill only time"

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A Multi-site, Randomized, Double-Blind, Multi-Arm Historical Control, Comparative Trial of the Safety and Efficacy of Hydroxychloroquine, and the Combination of Hydroxychloroquine and Famotidine for the Treatment of COVID-19 in Hospitalized Adults

Protocol: xx-xxx

Sponsor:

PROTOCOL VERSION: April 1, 2020

Proprietary and Confidential

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Janowitz, Tobias <janowitz@cshl.edu>;
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mvcallahan@mgh.harvard.edu /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20f0e9a3ebeb4ef99d30a96386fb2627-Guest_945f5 <mvcallahan@mgh.harvard.edu>;
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HHS Secretary (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e3fce8f00194d8d94fc91094888d811-HHS Secreta <secretary@hhs.gov>;
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<fgodlee@bmj.com>;
<howard.bauchner@jamanetwork.org>;
<richard.horton@lancet.com>;
<erubin@hsph.harvard.edu>

Subject: Re: [EXTERNAL] RE: Use mast cell stabilizers, histamine H1/H2 blockers in COVID-19

Date: 2020/07/08 15:03:00

Priority: Normal

Type: Note

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On 7/8/20, 2:55 PM, "Landry, Donald W." <dwl1@cumc.columbia.edu> wrote:

External Email. Use Caution.

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Don Landry

-----Original Message-----
From: Janowitz, Tobias <janowitz@cshl.edu>
Sent: Wednesday, July 8, 2020 2:41 PM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; 'Marik, Paul E.' <MarikPE@EVMS.EDU>; Ricke, Darrell - 0449 - MITLL <darrell.ricke@ll.mit.edu>; Robert Malone <[redacted]>; vinu arumugham <vaccine.safety@aol.com>; Sestili, Piero <piero.sestili@uniurb.it>; Freedberg, Daniel E. <def2004@cumc.columbia.edu>; jconigliaro@northwell.edu; Markowitz, David D. <ddm1@cumc.columbia.edu>; Gupta, Aakriti <ag3786@cumc.columbia.edu>; O'Donnell, Max R. <mo2130@cumc.columbia.edu>; Li, Jianhua <jl1333@cumc.columbia.edu>; Tuveson, David <dtuveson@cshl.edu>; Jin, Zhezhen <zj7@cumc.columbia.edu>; Turner, William C. <wt62@cumc.columbia.edu>; Landry, Donald W. <dwl1@cumc.columbia.edu>; Wang, Timothy C. <tcw21@cumc.columbia.edu>; kjtracey@northwell.edu; mvcallahan@mgh.harvard.edu; Abrams, Julian A. <ja660@cumc.columbia.edu>; djp65@cam.ac.uk; yongfeng@email.unc.edu; xphuang@unc.edu; kris.white@mssm.edu; elena.morenodelolmo@mssm.edu; Assaf_Alon@hms.harvard.edu; Andrew_Kruse@hms.harvard.edu; anthony.mittermaier@mcgill.ca; Julianne.Hall@quinnipiac.edu; Robert.Bona@quinnipiac.edu; h.clark@ucl.ac.uk; bryan_roth@med.unc.edu; Victor.Francone@quinnipiac.edu; Norbert.Herzog@quinnipiac.edu; Maurice.Fremont-

Smith@quinnipiac.edu; Commins, Scott P <scommins@email.unc.edu>; Lawrence Steinman <steiny@stanford.edu>; ngkounis@otenet.gr; Matzinger, Polly <pcm@helix.nih.gov>; pconti@unich.it; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; HHS Secretary (HHS/IOS) <secretary@hhs.gov>; Christine Laine <claine@acponline.org>; fgodlee@bmj.com; howard.bauchner@jamanetwork.org; richard.horton@lancet.com; erubin@hsph.harvard.edu
Subject: Re: Use mast cell stabilizers, histamine H1/H2 blockers in COVID-19

I would also like to unsubscribe from this list.

Regards,

Tobias

From: "Disbrow, Gary (OS/ASPR/BARDA)" <Gary.Disbrow@hhs.gov>
Date: Wednesday, July 8, 2020 at 2:38 PM
To: "'Marik, Paul E.'" <MarikPE@EVMS.EDU>, "Ricke, Darrell - 0449 - MITLL" <darrell.ricke@ll.mit.edu>, Robert Malone <[redacted]>, vinu arumugham <vaccine.safety@aol.com>, "Sestili, Piero" <piero.sestili@uniurb.it>, "def2004@cumc.columbia.edu" <def2004@cumc.columbia.edu>, "jconigliaro@northwell.edu" <jconigliaro@northwell.edu>, "ddm1@cumc.columbia.edu" <ddm1@cumc.columbia.edu>, "ag3786@cumc.columbia.edu" <ag3786@cumc.columbia.edu>, "mo2130@cumc.columbia.edu" <mo2130@cumc.columbia.edu>, "jl1333@cumc.columbia.edu" <jl1333@cumc.columbia.edu>, "Tuveson, David" <dtuveson@cshl.edu>, "zj7@cumc.columbia.edu" <zj7@cumc.columbia.edu>, "wt62@cumc.columbia.edu" <wt62@cumc.columbia.edu>, "dwl1@cumc.columbia.edu" <dwl1@cumc.columbia.edu>, "tcw21@cumc.columbia.edu" <tcw21@cumc.columbia.edu>, "kjtracey@northwell.edu" <kjtracey@northwell.edu>, "mvcallahan@mgh.harvard.edu" <mvcallahan@mgh.harvard.edu>, "ja660@cumc.columbia.edu" <ja660@cumc.columbia.edu>, "Janowitz, Tobias" <janowitz@cshl.edu>, "djp65@cam.ac.uk" <djp65@cam.ac.uk>, "yongfeng@email.unc.edu" <yongfeng@email.unc.edu>, "xphuang@unc.edu" <xphuang@unc.edu>, "kris.white@mssm.edu" <kris.white@mssm.edu>, "elena.morenodelolmo@mssm.edu" <elena.morenodelolmo@mssm.edu>, "Assaf_Alon@hms.harvard.edu" <Assaf_Alon@hms.harvard.edu>, "Andrew_Kruse@hms.harvard.edu" <Andrew_Kruse@hms.harvard.edu>, "anthony.mittermaier@mcgill.ca" <anthony.mittermaier@mcgill.ca>, "Julianne.Hall@quinnipiac.edu" <Julianne.Hall@quinnipiac.edu>, "Robert.Bona@quinnipiac.edu" <Robert.Bona@quinnipiac.edu>, "h.clark@ucl.ac.uk" <h.clark@ucl.ac.uk>, "bryan_roth@med.unc.edu" <bryan_roth@med.unc.edu>, "Victor.Francone@quinnipiac.edu" <Victor.Francone@quinnipiac.edu>, "Norbert.Herzog@quinnipiac.edu" <Norbert.Herzog@quinnipiac.edu>, "Maurice.Fremont-Smith@quinnipiac.edu" <Maurice.Fremont-Smith@quinnipiac.edu>, "Commins, Scott P" <scommins@email.unc.edu>, Lawrence Steinman <steiny@stanford.edu>, "ngkounis@otenet.gr" <ngkounis@otenet.gr>, "Matzinger, Polly" <pcm@helix.nih.gov>, "pconti@unich.it" <pconti@unich.it>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>, "HHS Secretary (HHS/IOS)" <secretary@hhs.gov>, Christine Laine <claine@acponline.org>, "fgodlee@bmj.com" <fgodlee@bmj.com>, "howard.bauchner@jamanetwork.org" <howard.bauchner@jamanetwork.org>, "richard.horton@lancet.com" <richard.horton@lancet.com>, "erubin@hsph.harvard.edu" <erubin@hsph.harvard.edu>
Subject: RE: Use mast cell stabilizers, histamine H1/H2 blockers in COVID-19

Please remove me from this email distribution list.

Regards

Gary

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Biomedical Advanced Research and Development Authority
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Assistant Secretary for Preparedness and Response ASPR
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email: Gary.Disbrow@HHS.gov<mailto:Gary.Disbrow@HHS.gov>

From: Marik, Paul E. <MarikPE@EVMS.EDU>
Sent: Wednesday, July 8, 2020 8:40 AM
To: Ricke, Darrell - 0449 - MITLL <darrell.ricke@ll.mit.edu>; Robert Malone <(b)(6)>; vinu arumugham <vaccine.safety@aol.com>; Sestili, Piero <piero.sestili@uniurb.it>; def2004@cumc.columbia.edu; jconigliaro@northwell.edu; ddm1@cumc.columbia.edu; ag3786@cumc.columbia.edu; mo2130@cumc.columbia.edu; jl1333@cumc.columbia.edu; dtuveson@cshl.edu; zj7@cumc.columbia.edu; wt62@cumc.columbia.edu; dwl1@cumc.columbia.edu; tcw21@cumc.columbia.edu; kjtracey@northwell.edu; mvcallahan@mgh.harvard.edu; ja660@cumc.columbia.edu; janowitz@cshl.edu; djp65@cam.ac.uk; yongfeng@email.unc.edu; xphuang@unc.edu; kris.white@mssm.edu; elena.morenodelolmo@mssm.edu; Assaf_Alon@hms.harvard.edu; Andrew_Kruse@hms.harvard.edu; anthony.mittermaier@mcgill.ca; Julianne.Hall@quinnipiac.edu; Robert.Bona@quinnipiac.edu; h.clark@ucl.ac.uk; bryan_roth@med.unc.edu; Victor.Francone@quinnipiac.edu; Norbert.Herzog@quinnipiac.edu; Maurice.Fremont-Smith@quinnipiac.edu; Commins, Scott P <scommins@email.unc.edu>; Lawrence Steinman <steiny@stanford.edu>; ngkounis@otenet.gr; Matzinger, Polly <pcm@helix.nih.gov>; pconti@unich.it; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; HHS Secretary (HHS/IOS) <secretary@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Christine Laine <claine@acponline.org>; fgodlee@bmj.com; howard.bauchner@jamanetwork.org; richard.horton@lancet.com; erubin@hsph.harvard.edu
Subject: RE: Use mast cell stabilizers, histamine H1/H2 blockers in COVID-19

To add to the discussion it has been known for a long time that Vitamin C stabilizes mast cells and,

inhibits histamine synthesis and inactives histamine.

PM

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https://protect2.fireeye.com/url?k=198b731b-45df6a67-198b4224-0cc47adc5fa2-104b02046eeb6eea&u=https://urldefense.proofpoint.com/v2/url?u=https-3A__protect2.fireeye.com_url-3Fk-3Daf60a9f4-2Df335a024-2Daf6098cb-2D0cc47a6a52de-2D11162424aad75683-26u-3Dhttp-3A__www.evms.edu_&d=DwIGaQ&c=G2MiLlal7SXE3PeSnG8W6_JBU6FcdVjSsBSbw6gcR0U&r=22kP0O04-cxbq2uHLN567gn_jmYZt5B29PSwWt9O8Hk&m=hkDX7i7ai2mPodTtSVes5gVtelXtrKGRMFqirZi6U_o&s=eOyBQfxU_xEjv10CE5vZiZr6Dg_yHJsVHSpjnCCJDtI&e=
|<https://protect2.fireeye.com/url?k=33bfe32c-6febfa50-33bfd213-0cc47adc5fa2-de3a6e35c2e11507&u=https://urldefense.proofpoint.com/v2/url?u=https-3A__protect2.fireeye.com_url-3Fk-3D456a8f77-2D193f86a7-2D456abe48-2D0cc47a6a52de-2D2a48786653d90e0b-26u-3Dhttp-3A__www.evms.edu-257c_&d=DwMGaQ&c=mkpgQs82XaCKIwNV8b32dmVOmERqJe4bBOtF0CetP9Y&r=6BEXLUmDIROBW3umLQEgX7YxisEG8VjS1tJ0oxmu_lk&m=f_IaRuzze9NBCIPdMzJCrb-e8IgWakoRNvkw5IZR_bQ&s=HsgHWSDc56o6HYznVALb7C88k0O98NgiCJOKeGARaXo&e=>

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From: Ricke, Darrell - 0449 - MITLL <darrell.ricke@ll.mit.edu<mailto:darrell.ricke@ll.mit.edu>>
Sent: Wednesday, July 8, 2020 8:27 AM
To: Robert Malone <(b)(6)<mailto:rwmalonemd@gmail.com>>; vinu arumugham <vaccine.safety@aol.com<mailto:vaccine.safety@aol.com>>; Sestili, Piero <piero.sestili@uniurb.it<mailto:piero.sestili@uniurb.it>>; def2004@cumc.columbia.edu<mailto:def2004@cumc.columbia.edu>; jconigliaro@northwell.edu<mailto:jconigliaro@northwell.edu>; ddm1@cumc.columbia.edu<mailto:ddm1@cumc.columbia.edu>; ag3786@cumc.columbia.edu<mailto:ag3786@cumc.columbia.edu>; mo2130@cumc.columbia.edu<mailto:mo2130@cumc.columbia.edu>; jl1333@cumc.columbia.edu<mailto:jl1333@cumc.columbia.edu>; dtuveson@cshl.edu<mailto:dtuveson@cshl.edu>; zj7@cumc.columbia.edu<mailto:zj7@cumc.columbia.edu>; wt62@cumc.columbia.edu<mailto:wt62@cumc.columbia.edu>; dwl1@cumc.columbia.edu<mailto:dwl1@cumc.columbia.edu>; tcw21@cumc.columbia.edu<mailto:tcw21@cumc.columbia.edu>; kjtracey@northwell.edu<mailto:kjtracey@northwell.edu>; mvcallahan@mgh.harvard.edu<mailto:mvcallahan@mgh.harvard.edu>; ja660@cumc.columbia.edu<mailto:ja660@cumc.columbia.edu>; janowitz@cshl.edu<mailto:janowitz@cshl.edu>; djp65@cam.ac.uk<mailto:djp65@cam.ac.uk>; yongfeng@email.unc.edu<mailto:yongfeng@email.unc.edu>; xphuang@unc.edu<mailto:xphuang@unc.edu>; kris.white@mssm.edu<mailto:kris.white@mssm.edu>;

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erubin@hsph.harvard.edu<mailto:erubin@hsph.harvard.edu>
Subject: Re: Use mast cell stabilizers, histamine H1/H2 blockers in COVID-19

All,

The following preprint on Kawasaki Disease and Multisystem Inflammatory Syndrome in Children: An Antibody-Induced Mast Cell Activation Hypothesis is posted here:
https://urldefense.proofpoint.com/v2/url?u=https-3A__www.ll.mit.edu_r-2Dd_publications_kawasaki-2Ddisease-2Dand-2Dmultisystem-2Dinflammatory-2Dsyndrome-2Dchildren-2Dantibody-2Dinduced&d=DwIGaQ&c=G2MiLlal7SXE3PeSnG8W6_JBU6FcdVjSsBSbw6gcR0U&r=22kP0O04-cxbq2uHLN567gn_jmYZt5B29PSwWt9O8Hk&m=hkDX7i7ai2mPodTtSVes5gVtelXtrKGRMFqirZi6U_o&s=sBIIx1ji43B4i1e9C3ai9zTRAWbxTbHEDb3p2AGDUqo&e=
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is now in press: J Pediatrics & Pediatr Med. 2020; 4(2): 1-7 (attached draft).

I would be interested in contributing to the proposed efforts.

Sincerely,

Darrell

Darrell O. Ricke, Ph.D.
Group 49 Biological and Chemical Technologies
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Lexington, MA 02421-6426

Phone: 781-981-8323 (voice messages only)
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From: Robert Malone (b)(6) <mailto:(b)(6)>>
Date: Tuesday, July 7, 2020 at 6:12 PM
To: vinu arumugham <vaccine.safety@aol.com<mailto:vaccine.safety@aol.com>>
Cc: "Sestili, Piero" <piero.sestili@uniurb.it<mailto:piero.sestili@uniurb.it>>,
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<anthony.mittermaier@mcgill.ca<mailto:anthony.mittermaier@mcgill.ca>>,
"Julianne.Hall@quinnipiac.edu<mailto:Julianne.Hall@quinnipiac.edu>"
<Julianne.Hall@quinnipiac.edu<mailto:Julianne.Hall@quinnipiac.edu>>,
"Robert.Bona@quinnipiac.edu<mailto:Robert.Bona@quinnipiac.edu>"
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"bryan_roth@med.unc.edu<mailto:bryan_roth@med.unc.edu>"
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<Victor.Francone@quinnipiac.edu<mailto:Victor.Francone@quinnipiac.edu>>,
"Norbert.Herzog@quinnipiac.edu<mailto:Norbert.Herzog@quinnipiac.edu>"
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<erubin@hsph.harvard.edu<mailto:erubin@hsph.harvard.edu>>
Subject: Re: Use mast cell stabilizers, histamine H1/H2 blockers in COVID-19

you may not be aware that this is now posted?

On Tue, Jul 7, 2020 at 5:42 PM vinu arumugham
<vaccine.safety@aol.com<mailto:vaccine.safety@aol.com>> wrote:

Prof. Sestili,

Thank you for your quick response and suggestion.

All,

As Prof. Sestili has suggested, I agree that we should coauthor a paper (or perhaps an open letter like this one<https://urldefense.proofpoint.com/v2/url?u=https-3A__academic.oup.com_cid_article_doi_10.1093_cid_ciaa939_5867798&d=DwMGaQ&c=mkpgQs82XaCKIwNV8b32dmVOmERqJe4bBOtF0CetP9Y&r=6BEXLUmDIROBW3umLQEgX7YxisEG8VjS1tJ0oxmu_lk&m=f_IaRuzze9NBCIPdMzJCrb-e8IgWakoRNvkw5IZR_bQ&s=MYgdONPADt-JwIncB1Vw5AnbwEquKEL1Qxinmhextcw&e=>?) requesting that authorities rapidly consider and promote the clinical exploitation of medications that address inappropriate mast cell activation and the resulting immune cascade in COVID-19 (these include mast cell stabilizers, histamine H1/H2 blockers, leukotriene antagonists and leukotriene receptor antagonists, Vitamin C, etc.)

We have been able to correctly predict the beneficial effects of these medications since late January 2020 because the mechanism was understood. Hundreds of thousands of lives could have been saved if these medications had been used. If we do not act now, hundreds of thousands more lives will be lost.

Many authors have described the mechanism and role of mast cell dysregulation in severe COVID-19:

Repositioning Chromones for Early Anti-inflammatory Treatment of COVID-19

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COVID-19: Famotidine, Histamine, Mast Cells, and Mechanisms
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Mast Cells Contribute to Coronavirus-Induced Inflammation: New Anti-Inflammatory Strategy
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Immunological mechanisms explaining the role of IgE, mast cells, histamine, elevating ferritin, IL-6, D-dimer, VEGF levels in COVID-19 and dengue, potential treatments such as mast cell stabilizers, antihistamines, Vitamin C, hydroxychloroquine, ivermectin and azithromycin
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As I wrote in my comment posted in the Annals of Internal Medicine,

Understanding mechanisms is better than demanding clinical trials in the middle of a pandemic

Please see comments section:

https://protect2.fireeye.com/url?k=2484ebde-78d0f2a2-2484dae1-0cc47adc5fa2-bee3b784d9212345&u=https://urldefense.proofpoint.com/v2/url?u=https-3A__protect2.fireeye.com_url-3Fk-3De18ec594-2Dbddbcc44-2De18ef4ab-2D0cc47a6a52de-2D44d3aa827e434ccc-26u-3Dhttps-3A__annals.org_aim_fullarticle_2764199_use-2Dhydroxychloroquine-2Dchloroquine-2Dduring-2Dcovid-2D19-2Dpandemic-2Dwhat-2Devery-2Dclinician&d=DwIGaQ&c=G2MiLlal7SXE3PeSnG8W6_JBU6FcdVjSsBSbw6gcR0U&r=22kP0O04-cxbq2uHLN567gn_jmYZt5B29PSwWt9O8Hk&m=hkDX7i7ai2mPodTtSVes5gVtelXtrKGRMFqirZi6U_o&s=Fxen-UZuKpsxodmB4gXAwTEhE7MA6bPMiOFd0bCpTAc&e=
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Please respond if you would like to be a coauthor and please share any other ideas to make this happen. Please include coworkers who may be interested.

Thanks,

Vinu

On 7/7/20 12:11 AM, Sestili, Piero wrote:
Dear Vinu,

I wrote a paper in March proposing mast cell stabilizers to treat COVID-19 soon after its early clinical presentation.
I am elated to see that many colleagues around the world independently formulated similar thoughts and

that evidences are accumulating strengthening this hypothesis.

We could collectively prepare a paper coauthorized by all of us (I see that you have a wide list where Prof. Conti, Prof Kritas and their coworkers could be included) pushing authorities to rapidly consider and promote the clinical exploitation of MCS against COVID.

Here is the DOI of my article
https://urldefense.proofpoint.com/v2/url?u=https-3A__doi.org_10.3389_fphar.2020.00854&d=DwIGaQ&c=G2MiLlal7SXE3PeSnG8W6_JBU6FcdVjSsBSbw6gcR0U&r=22kP0O04-cxbq2uHLN567gn_jmYZt5B29PSwWt9O8Hk&m=hkDX7i7ai2mPodTtSVes5gVtelXtrKGRMFqirZi6U_o&s=F505tdPeS9p3B4QQ3TuXmZT3nBrEiTmVOvA2LtaTNQY&e=
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Please, if you think it might be useful, forward this message to your MCS mail list.

Truly yours and thanks for your relevant effort, ciao

Piero Sestili
Full Professor in Pharmacology,
University of Urbino, Italy

Il giorno mar 7 lug 2020 alle 02:46 vinu arumugham <vaccine.safety@aol.com<mailto:vaccine.safety@aol.com>> ha scritto:

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-------- Forwarded Message --------
Subject:

Kawasaki disease and COVID-19 are iatrogenic diseases; Try mast cell stabilizers, H1/H2 blockers

Date:

Thu, 14 May 2020 09:42:05 -0700

From:

vinu arumugham <vaccine.safety@aol.com><mailto:vaccine.safety@aol.com>

To:

nchoueit@montefiore.org<mailto:nchoueit@montefiore.org>
<nchoueit@montefiore.org><mailto:nchoueit@montefiore.org>,
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<a.warris@abdn.ac.uk><mailto:a.warris@abdn.ac.uk>, CGIDRadmin@seattlechildrens.org<mailto:CGIDRadmin@seattlechildrens.org>
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<danielle.zerr@seattlechildrens.org><mailto:danielle.zerr@seattlechildrens.org>

Kawasaki disease (KD) and COVID-19 are iatrogenic diseases; Try mast cell stabilizers, H1/H2 blockers.

KD shock syndrome is same mechanism as influenza and dengue shock syndrome covered below ("slow rolling anaphylaxis").

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e8IgWakoRNvkw5IZR_bQ&s=pnGu5AyahOEN7R2OQ5ZswzoWK8DdK5VPJFPtfmgTLUo&e=>

One can also expect peripheral blood eosinophilia. Have you checked? RCPCH case definition does not include it.

That would be consistent with the body's (iatrogenically induced) anti-parasite response against SARS-CoV-2, instead of just an antiviral response. Consider IgE/IgG4 responses against heat shock proteins.

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

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3A__doi.org_10.5281_zenodo.3748303&d=DwIGaQ&c=G2MiLlal7SXE3PeSnG8W6_JBU6FcdVjSsBS
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As I have been predicting for 3+ months, there is now evidence that Famotidine (antihistamine, H2-blocker) helps in COVID-19. Study below. The mechanism involved is explained above.

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

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3A__www.medrxiv.org_content_10.1101_2020.05.01.20086694v1&d=DwIGaQ&c=G2MiLlal7SXE3Pe
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e8IgWakoRNvkw5IZR_bQ&s=SdocmnvkWuC9GxFjSeluKdp2X3478rCrePpVHDAdRX0&e=>

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

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My comment posted in the Annals of Internal Medicine:

Please see comments section:

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955ddadbb69cc620&u=https://urldefense.proofpoint.com/v2/url?u=https-3A__protect2.fireeye.com_url-
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3A__annals.org_aim_fullarticle_2764199_use-2Dhydroxychloroquine-2Dchloroquine-2Dduring-
2Dcovid-2D19-2Dpandemic-2Dwhat-2Devery-
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e8IgWakoRNvkw5IZR_bQ&s=QrwjMplMCw-gYAwRoZoBxzxIFDIdGJmefJnVOFKD99A&e=>

Understanding mechanisms is better than demanding clinical trials in the middle of a pandemic

Hydroxychloroquine and azithromycin use in COVID-19 have been dismissed as "unproven" or "anecdotal", by the medical establishment. But the benefit of ventilators in COVID-19 is equally unproven. Why the clamor for ventilators? And now there are reports that ventilators are not helping.
https://urldefense.proofpoint.com/v2/url?u=https-3A__www.npr.org_sections_health-
2Dshots_2020_04_02_826105278_ventilators-2Dare-2Dno-2Dpanacea-2Dfor-2Dcritically-2Dill-
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<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.npr.org_sections_health-
2Dshots_2020_04_02_826105278_ventilators-2Dare-2Dno-2Dpanacea-2Dfor-2Dcritically-2Dill-
2Dcovid-2D19-
2Dpatients&d=DwMGaQ&c=mkpgQs82XaCKIwNV8b32dmVOmERqJe4bBOtF0CetP9Y&r=6BEXLU
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e8IgWakoRNvkw5IZR_bQ&s=ns_rDtrq5q1sozVBGVyfFAeePW4EpuKhWO1UUB8HYMM&e=>

Running protein sequence analysis with the SARS-CoV-2, MERS, SARS viruses, there is a strong similarity to a pig spike protein (coronavirus infected pig). Accession number QGV12786 vs. QHD43416.1 for SARS-CoV-2.

Since vaccines contain porcine proteins derived from pigs infected with any number of diseases, one could develop IgE mediated sensitization to coronavirus spike proteins. We have entire, viable porcine circoviruses in the rotavirus vaccines, for example.

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<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.cdc.gov_vaccines_pubs_pinkbook_downloads_appendices_b_excipient-2Dtable-2D2.pdf&d=DwMGaQ&c=mkpgQs82XaCKIwNV8b32dmVOmERqJe4bBOtF0CetP9Y&r=6BEXLUmDIROBW3umLQEgX7YxisEG8VjS1tJ0oxmu_lk&m=f_IaRuzze9NBCIPdMzJCrb-e8IgWakoRNvkw5IZR_bQ&s=TFHoxIH57zLMFMv8B1cU3L7N-aeSGInUothbCDoARbQ&e=>

Upon infection with any of these viruses, the concurrent allergic reaction can increase disease severity. In such cases, antihistamines and other allergy treatments such as mast cell stabilizers may help reduce infection severity.

This is similar to influenza vaccine induced allergy to the influenza virus, increasing the severity of subsequent influenza infection as described here:

Influenza vaccines and dengue-like disease

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There have been reports that elevated ferritin and IL-6 levels are predictors of fatality in COVID-19.

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There is an increase in mast cell density during infections:

https://urldefense.proofpoint.com/v2/url?u=https-3A__www.ncbi.nlm.nih.gov_pmc_articles_PMC4435071_&d=DwIGaQ&c=G2MiLlal7SXE3PeSnG8W6_JBU6FcdVjSsBSbw6gcR0U&r=22kP0O04-cxbq2uHLN567gn_jmYZt5B29PSwWt9O8Hk&m=hkDX7i7ai2mPodTtSVes5gVtelXtrKGRMFqirZi6U_o&s=F2o6e0t3LvlYcRt5jr7Xzc8fQtlPqXRwiZggFCD7QYM&e=
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sEb0eDhAMxtzrEzT3L6il6_7wkpQjEw&e=>

IgE mediated mast cell degranulation results in increased ferritin levels as well as histamine levels.

Ferritin Particles Accumulate in Human Mast Cell Secretory Granules and Are Released upon FcεRI-mediated Activation
https://protect2.fireeye.com/url?k=388d2877-64d9310b-388d1948-0cc47adc5fa2-39166b882133b206&u=https://urldefense.proofpoint.com/v2/url?u=https-3A__protect2.fireeye.com_url-3Fk-3Da8f577aa-2Df4a07e7a-2Da8f54695-2D0cc47a6a52de-2D0c20b4f854efc630-26u-3Dhttps-3A__www.jacionline.org_article_S0091-2D6749-2817-2932622-2D2_fulltext&d=DwIGaQ&c=G2MiLlal7SXE3PeSnG8W6_JBU6FcdVjSsBSbw6gcR0U&r=22kP0O04-cxbq2uHLN567gn_jmYZt5B29PSwWt9O8Hk&m=hkDX7i7ai2mPodTtSVes5gVtelXtrKGRMFqirZi6U_o&s=QqA624rnsoU24Dqx9N2Iu_8mKklRCedFU9u6HTVjFgg&e=
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Histamine promotes release of IL-6.

Histamine Promotes the Release of Interleukin-6 via the H1R/p38 and NF-κB Pathways in Nasal Fibroblasts
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<https://urldefense.proofpoint.com/v2/url?u=https-3A__www.ncbi.nlm.nih.gov_pmc_articles_PMC4214978_&d=DwMGaQ&c=mkpgQs82XaCKIwNV8b32dmVOmERqJe4bBOtF0CetP9Y&r=6BEXLUmDIROBW3umLQEgX7YxisEG8VjS1tJ0oxmu_lk&m=f_IaRuzze9NBCIPdMzJCrb-e8IgWakoRNvkw5IZR_bQ&s=wsLUIe3V45G_Ra2-A-21xEpUGFdR6ngbytk5APv67NU&e=>

Also, neutrophils recruited to the lung during infection can release histamine.

Neutrophil histamine contributes to inflammation in mycoplasma pneumonia.
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The antihistamine effect of Vitamin C IV seems to help.

Antihistamine effect of supplemental ascorbic acid and neutrophil chemotaxis
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Also, azithromycin reduces histamine induced inflammation.

The anti-inflammatory effects of erythromycin, clarithromycin, azithromycin and roxithromycin on histamine-induced otitis media with effusion in guinea pigs.
https://urldefense.proofpoint.com/v2/url?u=https-3A__www.ncbi.nlm.nih.gov_pubmed_29888693&d=DwIGaQ&c=G2MiLlal7SXE3PeSnG8W6_JBU6FcdVjSsBSbw6gcR0U&r=22kP0O04-cxbq2uHLN567gn_jmYZt5B29PSwWt9O8Hk&m=hkDX7i7ai2mPodTtSVes5gVtelXtrKGRMFqirZi6U_o&s=fDXb-YRe6rsmzpxcXQuG5itp8h4wSjBjCf9mXbTuWfs&e=
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Hydroxychloroquine helps in allergic asthma.

Hydroxychloroquine improves airflow and lowers circulating IgE levels in subjects with moderate symptomatic asthma.
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Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial
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So there are many indicators pointing to the role of mast cell degranulation/histamine release being a major component of COVID-19.
Antihistamines, mast cell stabilizers, Vitamin C, hydroxychloroquine, azithromycin may all address different aspects of this same problem.
Focusing on only the antiviral actions of hydroxychloroquine or azithromycin, will lead us into blind alleys.

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Prof. Piero Sestili
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Dipartimento di Scienze Biomolecolari,
Università degli Studi di Urbino Carlo Bo
Via "I Maggetti" 26 61029 URBINO (PU)
Phone +[redacted]

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"Tread lightly, take only pictures, leave only footprints, kill only time"

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Landry, Donald W. <dwl1@cumc.columbia.edu>;
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Wang, Timothy C. <tcw21@cumc.columbia.edu>;
mvcallahan@mgh.harvard.edu /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20f0e9a3ebeb4ef99d30a96386fb2627-Guest_945f5 <mvcallahan@mgh.harvard.edu>;
Abrams, Julian A. <ja660@cumc.columbia.edu>;
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<Andrew_Kruse@hms.harvard.edu>;
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	<Julianne.Hall@quinnipiac.edu>; <Robert.Bona@quinnipiac.edu>; <h.clark@ucl.ac.uk>; <bryan_roth@med.unc.edu>; <Victor.Francone@quinnipiac.edu>; <Norbert.Herzog@quinnipiac.edu>; <Maurice.Fremont-Smith@quinnipiac.edu>; Commins, Scott P <scommins@email.unc.edu>; Lawrence Steinman <steiny@stanford.edu>; <ngkounis@otenet.gr>; Matzinger, Polly <pcm@helix.nih.gov>; <pconti@unich.it>; Kadlec, Robert (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob <Robert.Kadlec@hhs.gov>; HHS Secretary (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e3fce8f00194d8d94fc91094888d811-HHS Secreta <secretary@hhs.gov>; Christine Laine <claine@acponline.org>; <fgodlee@bmj.com>; <howard.bauchner@jamanetwork.org>; <richard.horton@lancet.com>; <erubin@hsph.harvard.edu>
Sent Date:	2020/07/08 15:00:17
Delivered Date:	2020/07/08 15:03:00

From:	Merdad Parsey <merdad.parsey@gilead.com>
To:	Anderson, Michael <Michael.Anderson@ucsf.edu>; Diana Brainard <Diana.Brainard@gilead.com>
CC:	Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob <Robert.Kadlec@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>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Mair, Michael (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3e2b23223bc4a1abecf698a4122f6c3-michael.mai <Michael.Mair@fda.hhs.gov>
Subject:	Re: [EXTERNAL] Re: Avaialbility of REMDESIVIR in San Fran
Date:	2020/03/08 11:49:54
Priority:	Normal
Type:	Note

Drs Anderson and Disbrow
Thanks for bringing me in the loop. As Gary mentioned, from a trial standpoint and our data to date, we do not have pediatric data nor eligibility for any of the studies. I'm happy to discuss compassionate use for anyone who may get infected, although as you can imagine, the number of patients with underlying comorbidities around the world is very high and our drug supply does not enable us to preposition drug in case of infection. We are generally able to respond quickly to compassionate use requests.

We would value working with you should a patient become infected and establishing a protocol in advance either in collaboration with NIAID or directly with us. This would be preferred to compassionate use since we do not have data for the safety and efficacy of remdesevir in adults or children. In particular, dosing in children has not been established, and we do have data that liver function abnormalities may be an adverse event at higher exposures. Given none of the children have been infected, we do have time to establish a protocol. I don't know if the NIAID team has considered including children or if the FDA would allow us to investigate this agent in children at this time.
I'm copying Diana Brainard who leads our virology group. I'm happy to speak on the phone later today.

Merdad

On Mar 8, 2020, at 8:34 AM, Anderson, Michael <Michael.Anderson@ucsf.edu> wrote:

Will do

Dr Parsey…can I call you?

==========

Michael Anderson, MD, MBA, FAAP, FCCM, FAARC
President, UCSF Benioff Children's Hospitals
Professor and Vice Chair for Children's Health, UCSF
Cell: (b)(6)
O: 415-476-6744

Assistant: joseph.genser@ucsf.edu<mailto:joseph.genser@ucsf.edu> OR (510) 428-3051

From: "Disbrow, Gary (OS/ASPR/BARDA)" <Gary.Disbrow@hhs.gov>
Date: Sunday, March 8, 2020 at 8:21 AM
To: Michael R Anderson <Michael.Anderson@ucsf.edu>, "Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov>
Cc: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Johnson, Robert (OS/ASPR/BARDA)" <Robert.Johnson@hhs.gov>, "Shuy, Bryan (OS/ASPR/IO)" <Bryan.Shuy@hhs.gov>, Merdad Parsey <merdad.parsey@gilead.com>, "Walker, Robert (OS/ASPR/BARDA)" <Robert.Walker@hhs.gov>, "Mair, Michael (FDA/OC)" <Michael.Mair@fda.hhs.gov>
Subject: RE: Avaialbility of REMDESIVIR in San Fran

Michael,

RCT is for adults only. Would need to discuss with Gilead if they have any data from treatment of pediatric patients with Ebola to potentially identify a pediatric dose of other than weight based.

Please call Dr. Parsey to obtain additional information on potential use of drug in pediatric patients.

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
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330 Independence Avenue, S.W. Room 640 G
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email: Gary.Disbrow@HHS.gov<mailto:Gary.Disbrow@HHS.gov>

From: Anderson, Michael <Michael.Anderson@ucsf.edu>
Sent: Sunday, March 8, 2020 10:52 AM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Cc: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Merdad Parsey <merdad.parsey@gilead.com>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Anderson, Michael <Michael.Anderson@ucsf.edu>
Subject: Re: Avaialbility of REMDESIVIR in San Fran

Thanks team.

My plans for the next 24 hrs

1. Make sure my onc team is in the loop
2. Our command center is open and awaiting more data on the 9 make-a-wish children. We have two children's campuses in SF and Oakland. Likewise other peds beds exist in the Bay…
3. Dr Parsey—please feel free to contact me w questions. Once we have a more clear picture on the clinical issues, will decide if enrollment is appropriate
4. Awaiting other input/counsel

Mike
Cell: (b)(6)

==========

Michael Anderson, MD, MBA, FAAP, FCCM, FAARC
President, UCSF Benioff Children's Hospitals
Professor and Vice Chair for Children's Health, UCSF
Cell: (b)(6)
O: 415-476-6744

Assistant: joseph.genser@ucsf.edu<mailto:joseph.genser@ucsf.edu> OR (b)(6)

From: "Disbrow, Gary (OS/ASPR/BARDA)"
<Gary.Disbrow@hhs.gov<mailto:Gary.Disbrow@hhs.gov>>
Date: Sunday, March 8, 2020 at 7:42 AM
To: Michael R Anderson <Michael.Anderson@ucsf.edu<mailto:Michael.Anderson@ucsf.edu>>,
"Kadlec, Robert (OS/ASPR/IO)" <Robert.Kadlec@hhs.gov<mailto:Robert.Kadlec@hhs.gov>>
Cc: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov<mailto:Rick.Bright@hhs.gov>>,
"Johnson, Robert (OS/ASPR/BARDA)" <Robert.Johnson@hhs.gov<mailto:Robert.Johnson@hhs.gov>>,
"Shuy, Bryan (OS/ASPR/IO)" <Bryan.Shuy@hhs.gov<mailto:Bryan.Shuy@hhs.gov>>, Merdad Parsey
<merdad.parsey@gilead.com<mailto:merdad.parsey@gilead.com>>, "Walker, Robert
(OS/ASPR/BARDA)" <Robert.Walker@hhs.gov<mailto:Robert.Walker@hhs.gov>>, "Mair, Michael
(FDA/OC)" <Michael.Mair@fda.hhs.gov<mailto:Michael.Mair@fda.hhs.gov>>
Subject: RE: Avaialbility of REMDESIVIR in San Fran

Michael,

Thanks for the quick call and discussion. Providing information for Chief Medical Officer for Gilead, Dr. Merdad Parsey. I will also check with NIAID to determine if RCT is established in Oakland, if not and if it takes too much time to expand, a treating clinician could request product under an investigator initiated emergency IND.

Merdad Parsey, MD PhD

Chief Medical Officer

Gilead Sciences, Inc.

(M)(b)(6)

Also, the company is allowed to preposition drug in advance, if needed.

Providing an FDA contact who could assist if there are questions about eIND paperwork. Michael Mair in the email above could help connect to the review division.

Gary

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
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<mailto:Gary.Disbrow@HHS.gov>

From: Anderson, Michael <Michael.Anderson@ucsf.edu<mailto:Michael.Anderson@ucsf.edu>>
Sent: Sunday, March 8, 2020 10:18 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov<mailto:Robert.Kadlec@hhs.gov>>
Cc: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov<mailto:Rick.Bright@hhs.gov>>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov<mailto:Gary.Disbrow@hhs.gov>>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov<mailto:Robert.Johnson@hhs.gov>>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov<mailto:Bryan.Shuy@hhs.gov>>
Subject: Re: Avaialbility of REMDESIVIR in San Fran

Ready to help any way we can
==========
Michael R Anderson MD MBA FAAP FCCM
President, UCSF Benioff Children's Hospitals
Professor of Pediatrics
Cell (b)(6)

Sent from my iPhone

On Mar 8, 2020, at 7:17 AM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov<mailto:Robert.Kadlec@hhs.gov>> wrote:
BARDA Team please note there are 9 high risk children (Make a Wish Foundation) with advanced stage cancer. Please request from GILEAD 10 courses for compassionate use to be available immediately. These children have high potential mortality rates if exposed/infected to this virus. Please advise and keep me informed on any and all developments If you need a POC I have copied Mike Anderson at UCSF Peds hospital.

Sender:	Merdad Parsey <merdad.parsey@gilead.com>
Recipient:	Anderson, Michael <Michael.Anderson@ucsf.edu>; Diana Brainard <Diana.Brainard@gilead.com>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob <Robert.Kadlec@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>; Shuy, Bryan (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan <Bryan.Shuy@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@hhs.gov>; Mair, Michael (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3e2b23223bc4a1abecf698a4122f6c3-michael.mai <Michael.Mair@fda.hhs.gov>
Sent Date:	2020/03/08 11:48:39
Delivered Date:	2020/03/08 11:49:54

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Withheld pursuant to exemption

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GILEAD

Gilead Sciences Initiates Two Phase 3 Studies of Investigational Antiviral Remdesivir for the Treatment of COVID-19

February 26, 2020

-- U.S. FDA Grants Investigational New Drug Authorization to Study Remdesivir for the Treatment of COVID-19 --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 26, 2020-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced the initiation of two Phase 3 clinical studies to evaluate the safety and efficacy of remdesivir in adults diagnosed with COVID-19 (novel coronavirus). These randomized, open-label, multicenter studies will enroll approximately 1,000 patients at medical centers primarily across Asian countries, as well as other countries globally with high numbers of diagnosed cases, beginning in March. The studies will assess two dosing durations of remdesivir, administered intravenously. The initiation of these studies follows the U.S. Food and Drug Administration's (FDA) rapid review and acceptance of Gilead's investigational new drug (IND) filing for remdesivir for the treatment of COVID-19.

The new clinical studies expand the ongoing research into remdesivir, which includes two clinical trials in China's Hubei province led by the China-Japan Friendship Hospital as well as the recently initiated clinical trial in the United States led by the National Institute of Allergy and Infectious Diseases (NIAID). Gilead has donated drug and provided scientific input for these studies, with results from those in China expected in April.

"Gilead's primary focus is on rapidly determining the safety and efficacy of remdesivir as a potential treatment for COVID-19, and this complementary array of studies helps to give us a more expansive breadth of data globally on the drug's profile in a short amount of time. The speed with which remdesivir has moved into clinical development for this coronavirus reflects the pressing need for treatment options and the shared commitment of industry, governments, global health organizations and healthcare providers to respond to this public health threat with the highest urgency," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences.

The Gilead studies will evaluate two dosing durations of remdesivir. One study will randomize approximately 400 patients with severe clinical manifestations of COVID-19 to receive either five or 10 days of remdesivir. The second study will randomize approximately 600 patients with moderate clinical manifestations of disease to receive five or 10 days of remdesivir or standard of care alone. The primary endpoint of both studies is clinical improvement, as described below.

Remdesivir is not yet licensed or approved anywhere globally and has not been demonstrated to be safe or effective for any use. Working with government agencies, non-governmental organizations and local regulatory authorities, Gilead is providing remdesivir to qualified patients with COVID-19 on a compassionate use basis for emergency treatment outside of ongoing clinical studies.

For more information on Gilead's response to the coronavirus outbreak please visit the company's dedicated page: https://www.gilead.com/purpose/advancing-global-health/covid-19

About Remdesivir

Remdesivir is an investigational nucleotide analog with broad-spectrum antiviral activity both in vitro and in vivo in animal models against multiple emerging viral pathogens including Ebola, Marburg, MERS and SARS. Remdesivir has been studied in healthy volunteers and in people with Ebola virus infection. Individual compassionate use cases are not sufficient to determine the safety and efficacy of remdesivir in treating COVID-19, which can only be determined through prospective clinical trials.

About Gilead-Sponsored New Remdesivir Clinical Trials

The first of two studies will evaluate the safety and efficacy of both a 5-day and a 10-day dosing regimen of remdesivir administered intravenously in patients with severe manifestations of COVID-19. Approximately 400 participants will be randomized in a 1:1 ratio to receive remdesivir 200 mg on day one, followed by remdesivir 100 mg each day until day 5 or 10, in addition to standard of care. The primary objective of this study is to evaluate the effect of remdesivir, as measured by the normalization of fever and oxygen saturation [T < 36.6 C armpit, < 37.2 C oral, < 37.8 C rectal; and Sp02 > 94%, sustained for at least 24 hours through Day 14].

The second study will evaluate the safety and efficacy of a 5-day and a 10-day dosing regimen of remdesivir administered intravenously in patients with moderate manifestations of COVID-19, compared with standard of care. Approximately 600 participants will be randomized in a 1:1:1 ratio to receive remdesivir 200 mg on day one, followed by remdesivir 100 mg in addition to standard of care each day until day 5 or 10, compared with standard of care alone. The primary objective of this study is to evaluate the effect of remdesivir, as measured by the proportion of participants in each group discharged by day 14.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

Forward Looking Statement

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility of unfavorable results from clinical trials involving remdesivir and the possibility that we may be unable to complete one or more of such trials in the currently anticipated timelines or at all. Further, it is possible that Gilead may make a strategic decision to discontinue development of remdesivir. As a result, remdesivir may never be successfully commercialized. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could

cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

View source version on businesswire.com: https://www.businesswire.com/news/home/20200226005955/en/

Sonia Choi, Media
(b)(6)

Douglas Maffei, Ph.D., Investors
(b)(6)

Source: Gilead Sciences, Inc.

Sonia Choi, Media
(b)(6)

Douglas Maffei, Ph.D., Investors
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COVID-19 MEDICAL COUNTERMEASURE UPDATE

(FOUO, Procurement Sensitive, Pre-Decisional)

April 5, 2020

Brief to HHS Secretary Azar and HHS COVID-19 Advisory Panel, including NIH, FDA, CDC, ASPR, ASFR Leadership

FOUO- FOR OFFICIAL USE ONLY- PRE-DECISIONAL

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of the Freedom of Information Act

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From:	Disbrow, Gary (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0FD5845DEFDA4DC0BB45F8FAC629CF09-DISBROW, GA>
To:	Libert, Thomas (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a4deb4ea6eb4132b0611663952365c8-Libert, Tho <Thomas.Libert@hhs.gov>; Merkeley, Tyler (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf1f9626f <Tyler.Merkeley@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Howell, David (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b005ab75d4234af08485940cfc761d7f-David Howel <David.Howell@hhs.gov>
CC:	Dubay, Johanna (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67e2379a38194477959edf8ebd791fe2-Dubay, Joha <Johanna.Dubay@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4654f8f0c0f4623b9e47465e9e1037a-Wallace, Ro <Rodney.Wallace@hhs.gov>
Subject:	RE: CV3 Spendplan Questions from OMB
Date:	2020/04/23 17:43:12
Priority:	Normal
Type:	Note

Tom,

1. (b)(5)
2.

Common human coronaviruses, including types 229E, NL63, OC43, and HKU1, usually cause mild to moderate upper-respiratory tract illnesses, like the common cold.

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
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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Fax: 202-205-0873
email: Gary.Disbrow@HHS.gov

From: Libert, Thomas (OS/ASPR/MFHC) <Thomas.Libert@hhs.gov>
Sent: Thursday, April 23, 2020 5:01 PM
To: Merkeley, Tyler (OS/ASPR/BARDA) <Tyler.Merkeley@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Howell, David (OS/ASPR/SPPR) <David.Howell@hhs.gov>
Cc: Dubay, Johanna (OS/ASPR/MFHC) <Johanna.Dubay@hhs.gov>
Subject: Re: CV3 Spendplan Questions from OMB

Two follow-up Qs from ASFR

1. (b)(5)
2.

From: Merkeley, Tyler (OS/ASPR/BARDA) <Tyler.Merkeley@hhs.gov>
Sent: Thursday, April 23, 2020 9:45 AM
To: Libert, Thomas (OS/ASPR/MFHC) <Thomas.Libert@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Howell, David (OS/ASPR/SPPR) <David.Howell@hhs.gov>
Cc: Dubay, Johanna (OS/ASPR/MFHC) <Johanna.Dubay@hhs.gov>
Subject: RE: CV3 Spendplan Questions from OMB

Tom
Sorry for the delay, please find our final comments

We responded to most of OMB questions, by providing comments under their questions vs changing the document.
Please let us know if you have any questions
Thanks
Tyler

TYLER G. MERKELEY
Biomedical Advanced Research and Development Authority (BARDA)
Office of Assistant Secretary of Preparedness and Response (ASPR)
U.S. Department of Health &Human Services (HHS)

O'Neill Building
200 C Street SW
Washington, DC 20024

C (b)(6) | O 202.260.0315 | F 202.205.8442 Connect on LinkedIn

MedicalCounterMeasures.gov
DRIVe.HHS.gov

From: Libert, Thomas (OS/ASPR/MFHC) <Thomas.Libert@hhs.gov>
Sent: Tuesday, April 21, 2020 3:15 PM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) <Christopher.Houchens@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Merkeley, Tyler (OS/ASPR/BARDA) <Tyler.Merkeley@hhs.gov>; Howell, David (OS/ASPR/SPPR) <David.Howell@hhs.gov>
Cc: Dubay, Johanna (OS/ASPR/MFHC) <Johanna.Dubay@hhs.gov>
Subject: CV3 Spendplan Questions from OMB

BARDA-

OMB sent questions on the ASPR's CV3 spend plan. We are requesting responses by 4pm, Wednesday, 4/22. Please let us know if you have questions or concerns.

Thank you,
Tom

Sender:	Disbrow, Gary (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0FD5845DEFDA4DC0BB45F8FAC629CF09-DISBROW, GA>
Recipient:	Libert, Thomas (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a4deb4ea6eb4132b0611663952365c8-Libert, Tho <Thomas.Libert@hhs.gov>; Merkeley, Tyler (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=userf1f9626f <Tyler.Merkeley@hhs.gov>; Houchens, Christopher (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac94a574bd04528b7c91bbd61893975-Houchens, C <Christopher.Houchens@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Howell, David (OS/ASPR/SPPR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b005ab75d4234af08485940cfc761d7f-David Howel <David.Howell@hhs.gov>; Dubay, Johanna (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67e2379a38194477959edf8ebd791fe2-Dubay, Joha <Johanna.Dubay@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga <Gary.Disbrow@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4654f8f0c0f4623b9e47465e9e1037a-Wallace, Ro <Rodney.Wallace@hhs.gov>
Sent Date:	2020/04/23 17:43:11
Delivered Date:	2020/04/23 17:43:12

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of the Freedom of Information Act

From:	Disbrow, Gary (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0FD5845DEFDA4DC0BB45F8FAC629CF09-DISBROW, GA>
To:	Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@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>; Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>
Subject:	RE: NEJM Remdesivir
Date:	2020/04/12 11:16:00
Priority:	Normal
Type:	Note

(b)(5)

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: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Sent: Sunday, April 12, 2020 11:16 AM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Cc: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Subject: RE: NEJM Remdesivir

Gary
Please clarify---send him the attached internal BARDA clinical consensus? Or the information we learned from John Farley unofficially? OR both?

Bob

<< File: Remdesivir EAP - NEJM Summary and Limitations 4-11-2020.docx >>

From: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Sent: Sunday, April 12, 2020 11:12 AM
To: Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Subject: FW: NEJM Remdesivir

Bob,

Can you respond to Dr. Kadlec and please remove Michael Callahan and James Lowler and mark as FOUO FOR INTERNAT USG USE ONLY

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: Sunday, April 12, 2020 9:47 AM
To: Redd, John (OS/ASPR/SPPR) <John.Redd@hhs.gov>; Hunt, Richard (OS/ASPR/EMMO) <Richard.Hunt@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>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; mvcallahan@mgh.harvard.edu; Lawler, James V <james.lawler@unmc.edu>
Subject: NEJM Remdesivir

Here is the NEJM about compassionate use of Remdesivir. I would benefit from what you all think about the data

https://www.nejm.org/doi/pdf/10.1056/NEJMoa2007016?articleTools=true

Bob

Sender:	Disbrow, Gary (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0FD5845DEFDA4DC0BB45F8FAC629CF09-DISBROW, GA>
Recipient:	Walker, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a02e128c60f4a7195532a1545af9556-Walker, Rob <Robert.Walker@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:	2020/04/12 11:16:46
Delivered Date:	2020/04/12 11:16:00

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Withheld pursuant to exemption

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of the Freedom of Information Act

From:	Disbrow, Gary (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0FD5845DEFDA4DC0BB45F8FAC629CF09-DISBROW, GA>
To:	Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Byrne, Patrick (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f35f48b1788b435e9a8471516dfaf600-Byrne, Patr <Patrick.Byrne@hhs.gov>; Figlio, Joseph (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3f14f4ea <Joseph.Figlio@hhs.gov>; Kovacs, Gerald (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5143eb64ef3340a8bb08213be15f063e-Kovacs, Ger <Gerald.Kovacs@hhs.gov>
CC:	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>; Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>
Subject:	RE: budget and planning question
Date:	2020/05/24 07:58:43
Priority:	Normal
Type:	Note

We can add lines or change the description in a line item to capture this but assign it to SNS or CDC

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
Mobile: (b)(6)
Fax: 202-205-0873
email: Gary.Disbrow@HHS.gov

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

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From: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Sent: Sunday, May 24, 2020 7:56 AM
To: Byrne, Patrick (OS/ASPR/BARDA) (CTR) <Patrick.Byrne@hhs.gov>; Figlio, Joseph (OS/ASPR/BARDA) <Joseph.Figlio@hhs.gov>; Kovacs, Gerald (OS/ASPR/BARDA) (CTR) <Gerald.Kovacs@hhs.gov>
Cc: Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) <armen.donabedian@hhs.gov>; Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Subject: RE: budget and planning question

Pat,

Thanks and understood. Not to beat a dead horse, but I want to be sure I understand what is and is not covered under the existing budget.

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-
-

If you confirm the above, I'll update the budget tab accordingly.

Thanks.

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
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email: Robert.Johnson@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: Byrne, Patrick (OS/ASPR/BARDA) (CTR) <Patrick.Byrne@hhs.gov>
Sent: Sunday, May 24, 2020 7:47 AM
To: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Figlio, Joseph (OS/ASPR/BARDA) <Joseph.Figlio@hhs.gov>; Kovacs, Gerald (OS/ASPR/BARDA) (CTR) <Gerald.Kovacs@hhs.gov>
Cc: Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) <armen.donabedian@hhs.gov>; Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Subject: Re: budget and planning question

Robert,

Lots of versions floated around yesterday. Bottom line: The budget estimate accounts for the supplies and services needed to execute a kitting operation. What is needed is a kitting decision and who should perform that mission.

- (b)(5)

Pat

From: Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Sent: Sunday, May 24, 2020 6:52 AM
To: Byrne, Patrick (OS/ASPR/BARDA) (CTR) <Patrick.Byrne@hhs.gov>; Figlio, Joseph (OS/ASPR/BARDA) <Joseph.Figlio@hhs.gov>; Kovacs, Gerald (OS/ASPR/BARDA) (CTR) <Gerald.Kovacs@hhs.gov>
Cc: Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Donabedian, Armen (OS/ASPR/BARDA) <armen.donabedian@hhs.gov>; Ventura, Christy (OS/ASPR/BARDA) (CTR) <Christy.Ventura@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>
Subject: budget and planning question

Pat, Joe and Gerry,

(b)(5)

Gary has to present today, so can we get a response as soon as possible?

Thanks.

Robert
Operation Warp Speed Global Budget Template - Vaccines May23_NIAID&BARDA_v3.xlsx
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: [redacted]
email: Robert.Johnson@HHS.gov

Sender:	Disbrow, Gary (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0FD5845DEFDA4DC0BB45F8FAC629CF09-DISBROW, GA>
Recipient:	Johnson, Robert (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>; Byrne, Patrick (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f35f48b1788b435e9a8471516dfaf600-Byrne, Patr <Patrick.Byrne@hhs.gov>; Figlio, Joseph (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3f14f4ea <Joseph.Figlio@hhs.gov>; Kovacs, Gerald (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5143eb64ef3340a8bb08213be15f063e-Kovacs, Ger <Gerald.Kovacs@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>; Ventura, Christy (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bb949caca464329823ca3cf77654a06-Ventura, Ch <Christy.Ventura@hhs.gov>
Sent Date:	2020/05/24 07:58:42
Delivered Date:	2020/05/24 07:58:43

From:	Disbrow, Gary (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0FD5845DEFDA4DC0BB45F8FAC629CF09-DISBROW, GA>
To:	Petillo, Jay (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59ce6133dfa14f6d96b9662b7cfdebc5-Petillo, Ja <Jay.Petillo@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: NSC Questions re: Remdesivir COAs
Date:	2020/03/11 15:57:00
Priority:	Normal
Type:	Note

Jay,

There is supposed to be a call with NSC and OMB. HHS OGC has the lead. I have provided some draft responses to Brian Stimson, Bryan and Bob. Still waiting for information on a call from HHS OGC.

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: Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>
Sent: Wednesday, March 11, 2020 3:55 PM
To: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>
Subject: FW: NSC Questions re: Remdesivir COAs

Confirming you have visibility on this.

From: Goyle, Suraj (OS/ASFR) <Suraj.Goyle@hhs.gov>
Sent: Wednesday, March 11, 2020 3:42 PM
To: Petillo, Jay (OS/ASPR/MFHC) <Jay.Petillo@HHS.GOV>; Dubay, Johanna (OS/ASPR/MFHC) <Johanna.Dubay@hhs.gov>; Eisemann, Darla (OS/ASPR/MFHC) <Darla.Eisemann@hhs.gov>; Libert, Thomas (OS/ASPR/MFHC) <Thomas.Libert@hhs.gov>
Cc: Cabezas, Miriam (HHS/ASFR) <Miriam.Cabezas@hhs.gov>; Cormier, Justin (HHS/ASFR) <Justin.Cormier@hhs.gov>
Subject: NSC Questions re: Remdesivir COAs

ASPR colleagues,

NSC sent the below questions for HHS response related to the Remdesivir COAs. Gary D. and Bryan S. were copied on the incoming request. We are sending at the staff level as well.

- (b)(5)
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-
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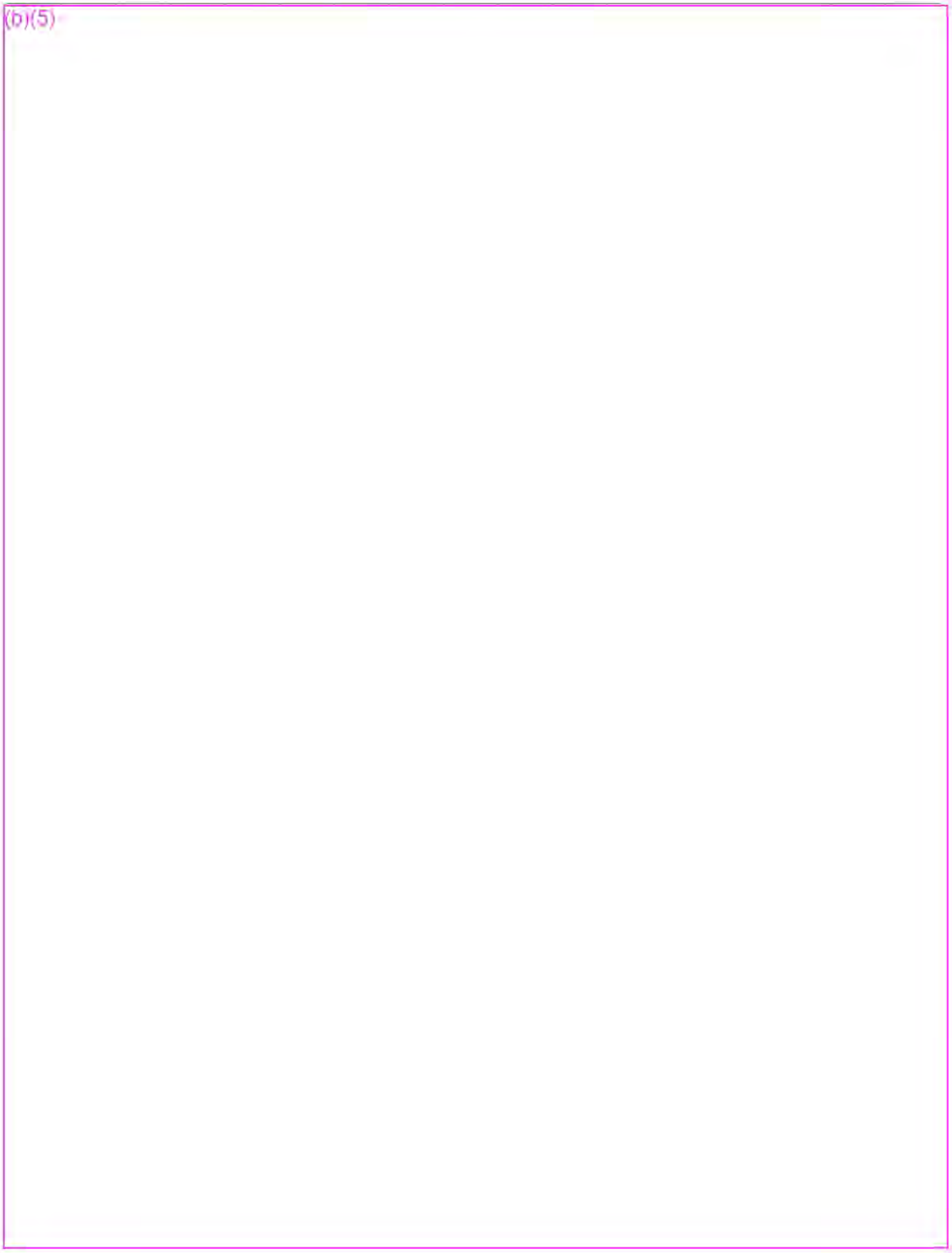
Thank you,
Suraj

Suraj Goyle
U.S. Department of Health and Human Services
Office of the Secretary | ASFR | Office of Budget
(202) 841-8701

Sender:	Disbrow, Gary (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0FD5845DEFDA4DC0BB45F8FAC629CF09-DISBROW, GA>
Recipient:	Petillo, Jay (OS/ASPR/MFHC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59ce6133dfa14f6d96b9662b7cfdebc5-Petillo, Ja <Jay.Petillo@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:	2020/03/11 15:57:27
Delivered Date:	2020/03/11 15:57:00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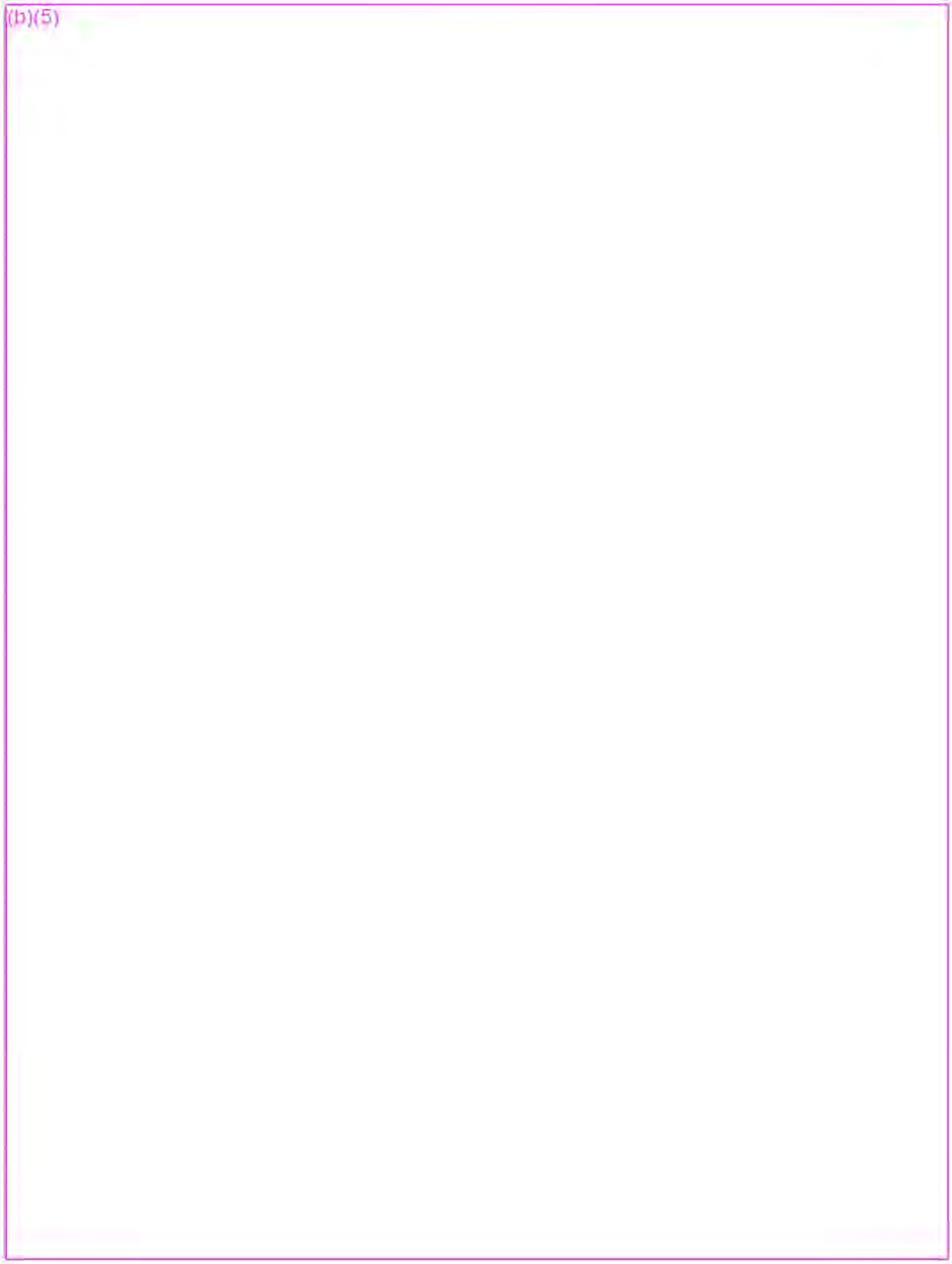
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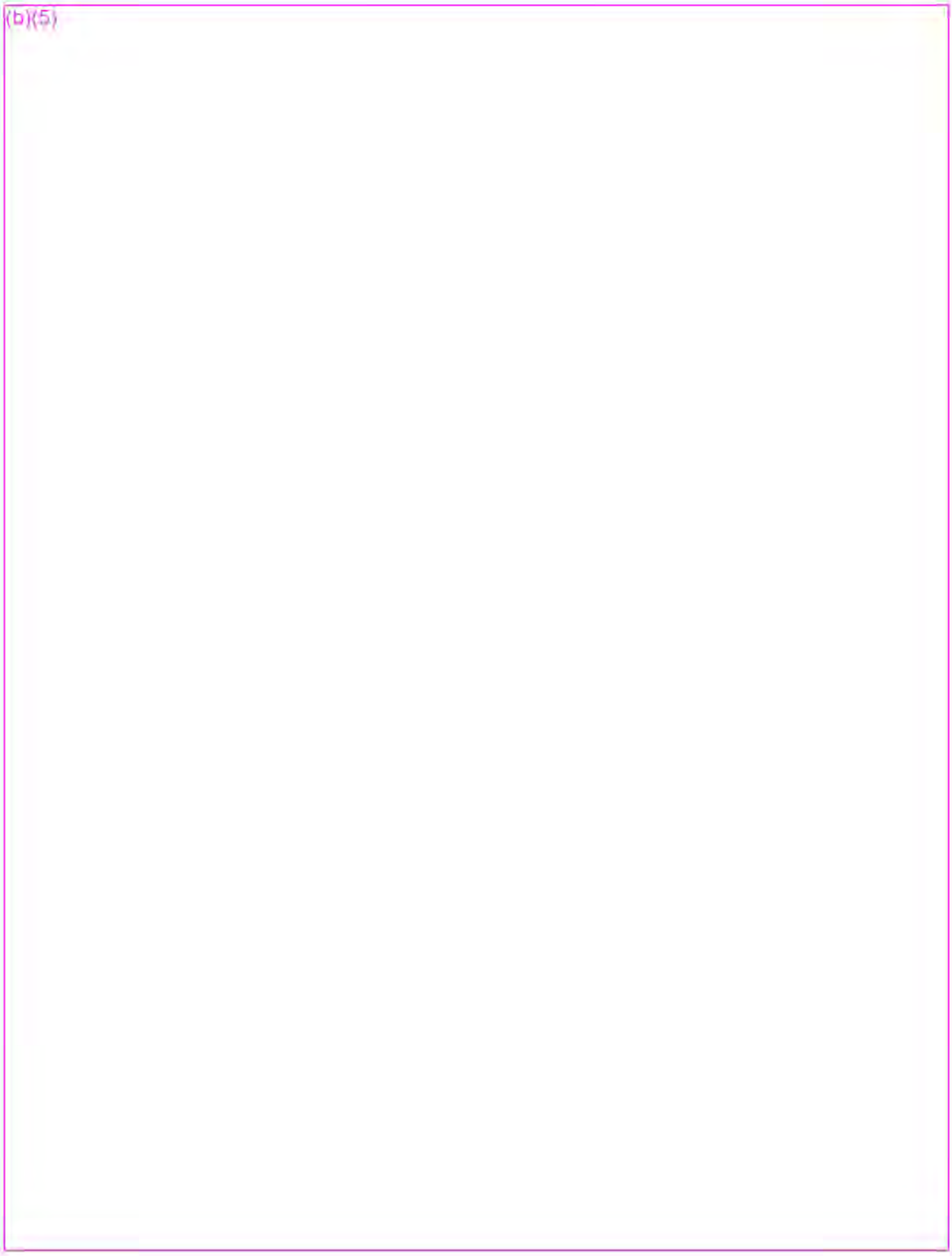
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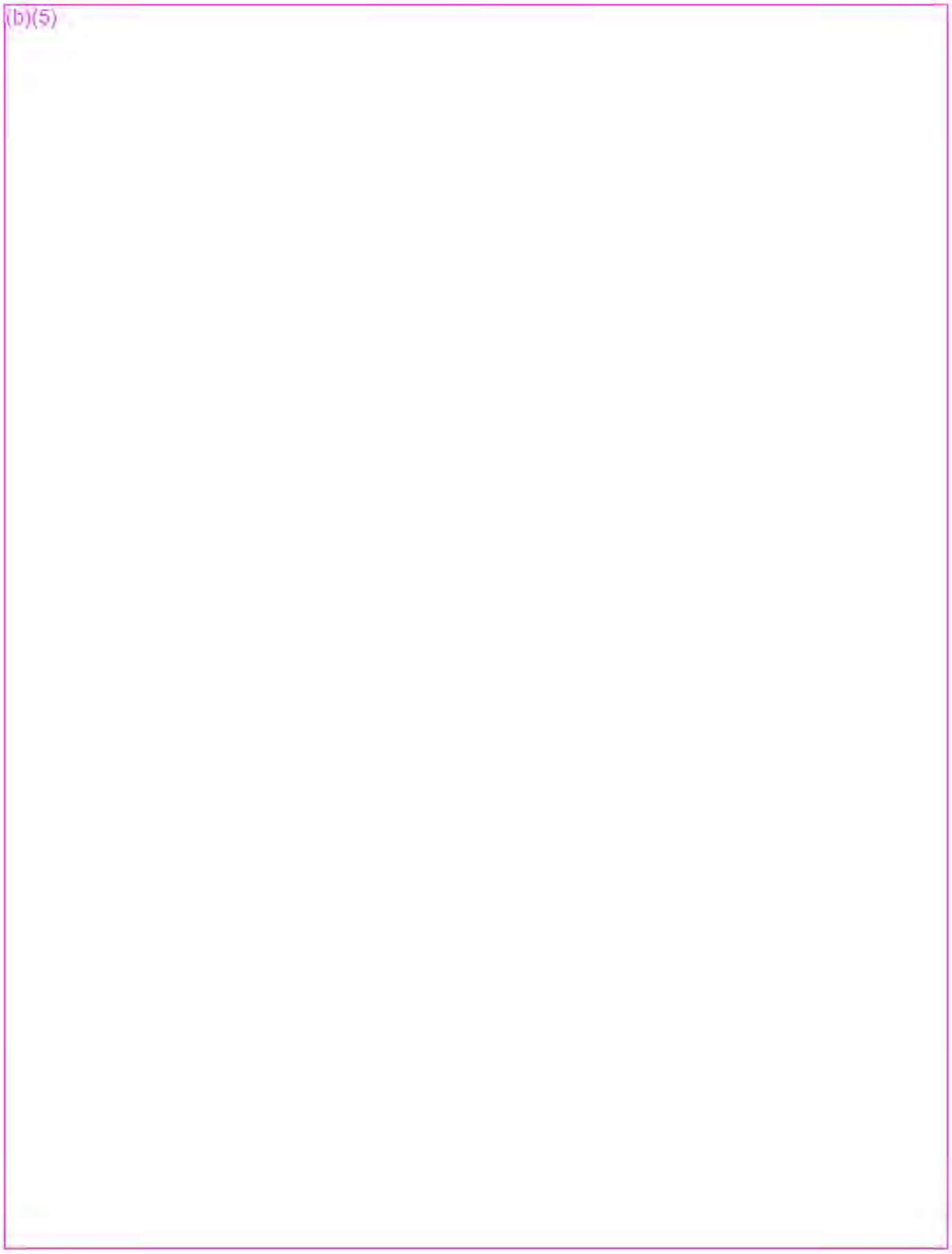
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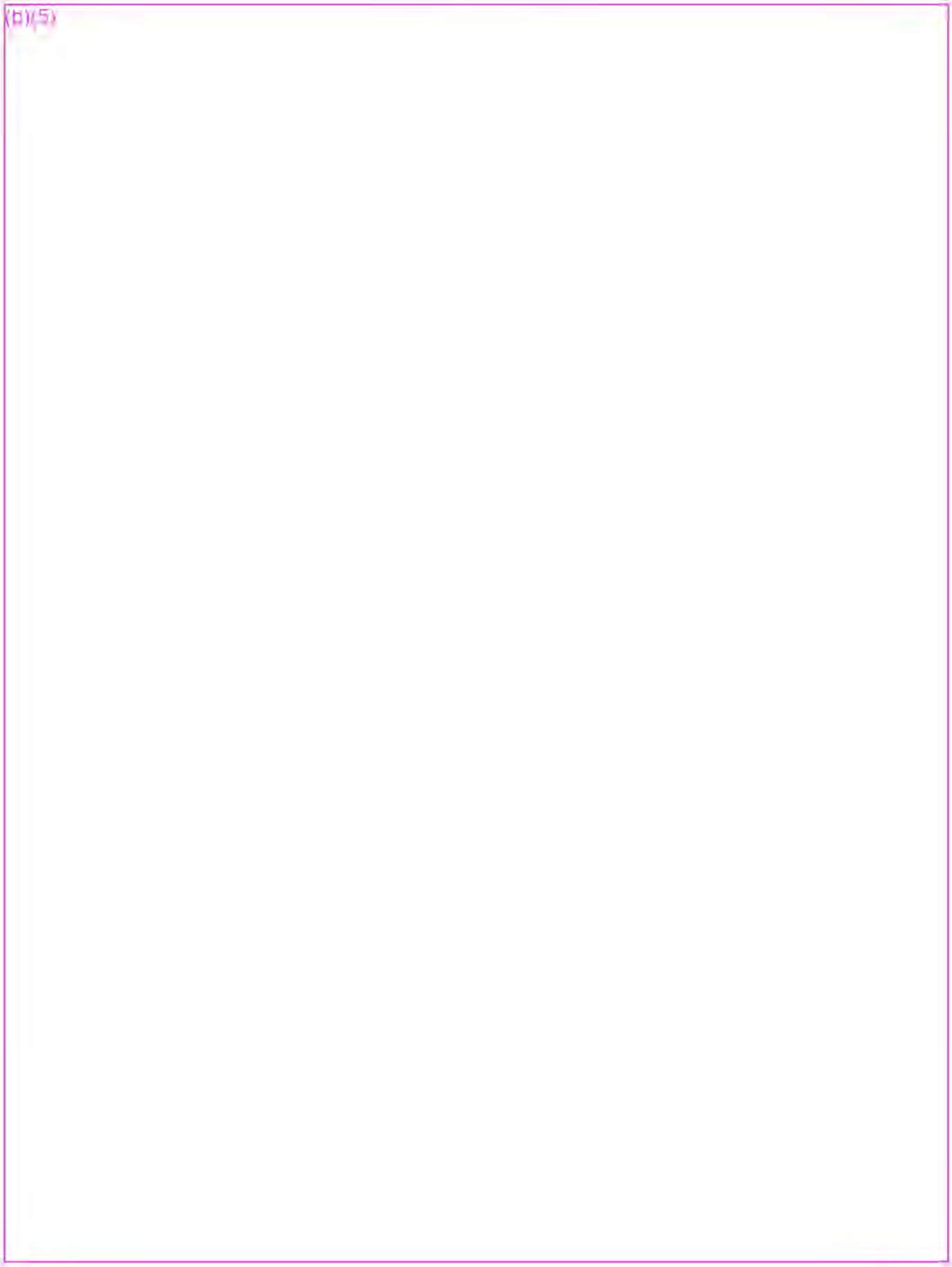
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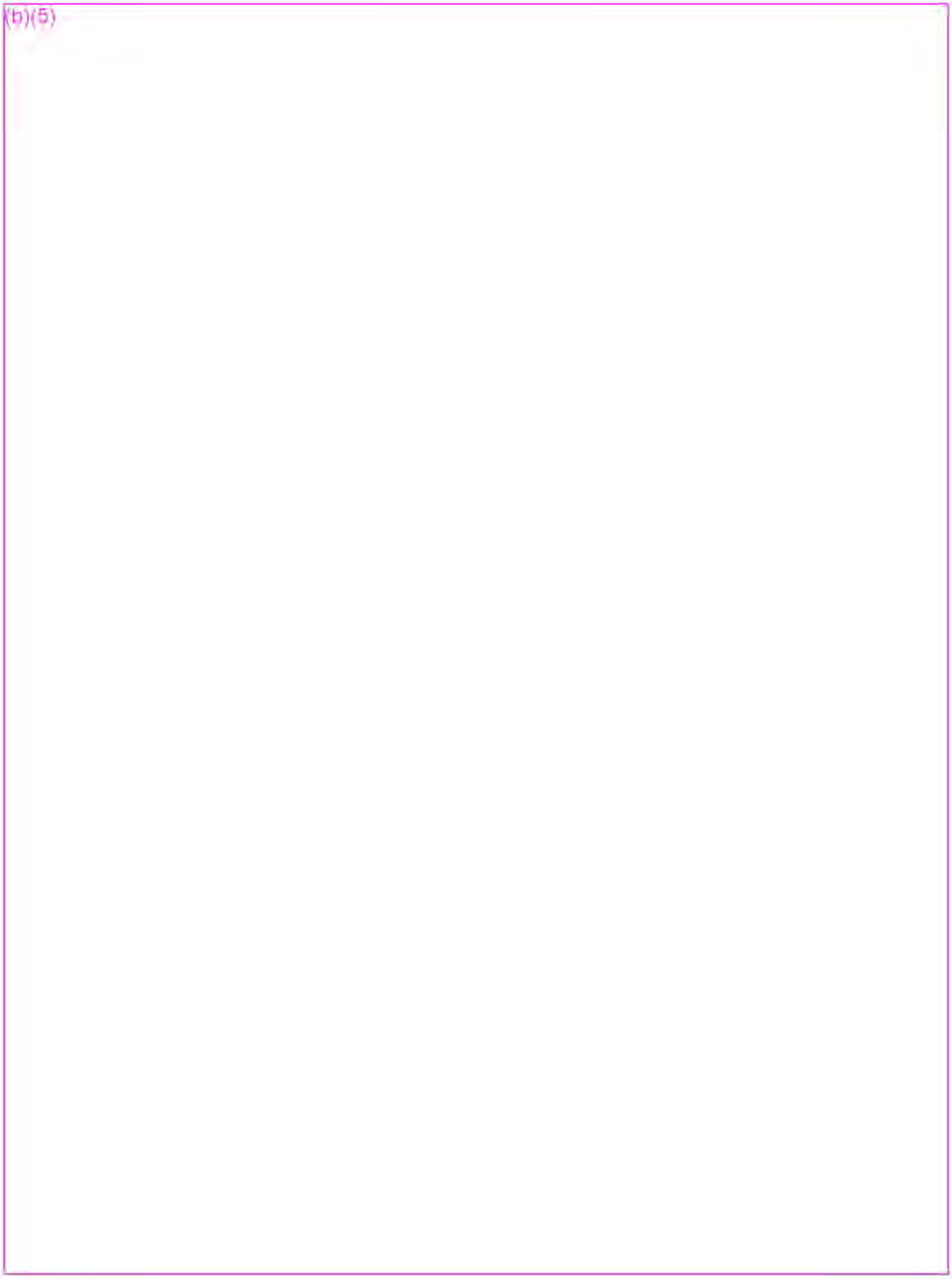
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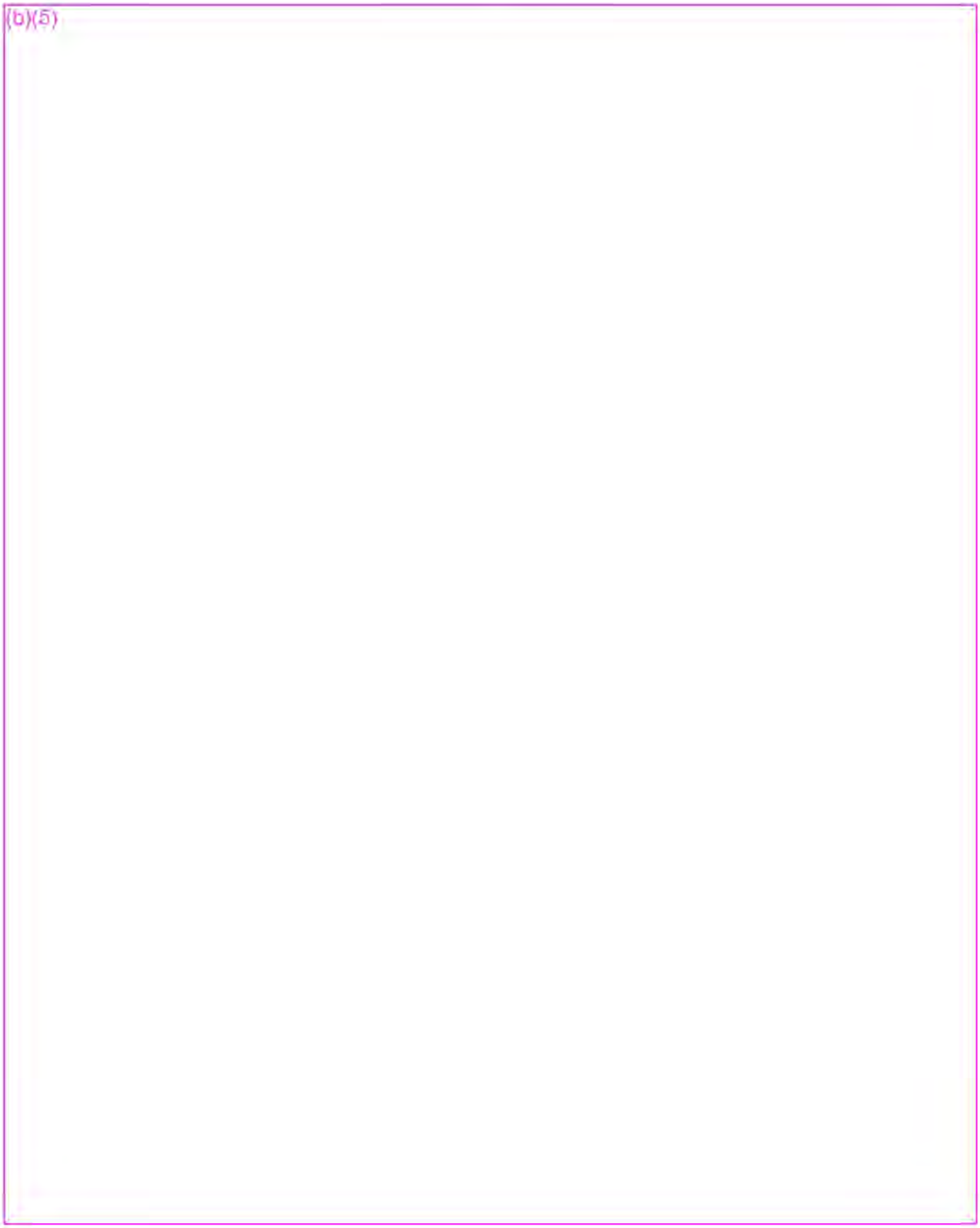
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Page 375

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DEPARTMENT OF

HEALTH AND HUMAN SERVICES

PURCHASE/SERVICE/STOCK REQUISITION

BPA and Call No. _____

REQUISITION NUMBER	
OFFICE CODE/SYMBOL	

TO	REQUEST FOR		
BARDA Procurement	☐ PURCHASE	☑ SERVICE	☐ STOCK ISSUE ☐ RENTAL/LEASE

REQUESTING ORGANIZATION	CUSTODIAL AREA	DATE	OBJECT CLASS
ASPR/BARDA/IEIDD		04/28/2020	25102

FOR REFERENCE CALL	EXTENSION	APPROPRIATION
B. Bunny Yeh	202-205-1584	75-20-0140

DELIVER TO	CAN
HHS/ASPR/BARDA/IEIDD 200 C Street, SW Washington, DC 20024	1992004
	DATE REQUIRED: 05/08/2020

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

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	$3,305,198.87
	Budget Analyst			

(b)(6)

B. Bunny Yeh, COR, IEIDD

	DATE		
	05/04/2020	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
(b)(6) Digitally signed by Robert A. Johnson -S Date: 2020.05.05 05:06:41 -04'00'			
Robert Johnson, Dir., IEIDD			
APPROVED BY *(Signature/Title)** Gary L. Disbrow -S Digitally signed by Gary L. Disbrow -S DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2000012425, cn=Gary L. Disbrow -S Date: 2020.05.05 08:43:10 -04'00'	DATE	ORDER NO. *(PO, DO, FEDSTRIP, ETC.)*	ORDER DATE
PROPERTY MANAGEMENT OFFICER *(Signature)**	DATE	VOUCHER NO.	VOUCHER DATE

HHS-393 (6/90) EF

Request for Requisition of Good or Services: ASPR Standard Form

Project Name: Funding request for storage/stability of vaccine bulk lots and final containers
Project Officer: B. Bunny Yeh
Requesting Office: BARDA
Contracting Office (if applicable): PSC ☐ BARDA ☒
Contracting Officer (if applicable): Ryan Marion
Vendor Name (if applicable): Sanofi Pasteur
Contract Number (if applicable): HHSO100201600006I
Requested Date of Award: TBD
Period of Performance: 08/22/2020 to 08/21/2021

Type of Activity: New Contract w/393 ☐ Contract Mod w/ 393 ☒ PSC-59 ☐ IAA ☐ Other ☐
Attached Documents (Check all that apply): SOW ☐ IGCE ☐ JOFOC ☐ Source List ☐

Amount: $3,305,198.92
CAN(s) and Cost Allocation (if applicable): 1992004
Spend Plan Line(s):
Current Balance(s) before request:
Object Class: 25102
If New/Not Budgeted Activity,
Justification:
Offset (Spend Plan Line(s)):
Details:

Description:

HHS, through the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR) has purchased vaccine bulk lots from PSC. The vaccines are being stored in cGMP facilities within United States under environmental conditions that are appropriate for vaccine storage. Periodic testing of vaccine samples is being performed suing validated analytical approaches to monitor the stability of these vaccines. The testing is being performed by the manufacturer's Quality Control Department. The results generated from the stability are critical for pandemic preparedness.

Only for commitments over $100,000
RPE Budget Team Recommendation: Approve ☐ Disapprove ☐
Comments:

Allotment Holder Approval: _____ Disapproval: _____ Date: _____

Only for commitments over $1,000,000
Approve ☒ Disapprove ☐
Comments:

Director of BARDA signature Gary L. Disbrow -S Digitally signed by Gary L. Disbrow -S DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2000012425, cn=Gary L. Disbrow -S Date: 2020.05.05 08:43:45 -04'00' Date _____

TO: Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

THROUGH: Bryan Shuy
Deputy Assistant Secretary
Chief of Staff

Jay Petillo, MPP John J. Petillo -S Digitally signed by John J. Petillo -S Date: 2020.03.08 14:07:25 -04:00
Acting Deputy Assistant Secretary
Acting Director, Office of Management Finance and Human Capital
Director, Division of Finance

FROM: Rick A. Bright, PhD
Director, Biomedical Advanced Research and Development Authority
Deputy Assistant Secretary for Preparedness and Response

SUBJECT: March 2020: The Biomedical Advanced Research and Development Authority's Funding Actions for Below $10 Million – **DECISION**

ISSUE

The Biomedical Advanced Research and Development Authority (BARDA) seeks approval to provide additional funding to ten existing contracts and award two new contracts using funds from the Division of Chemical, Biological, Radiological, and Nuclear (CBRN) Medical Countermeasures' Advanced Research and Development (ARD) program. BARDA also seeks approval to provide additional funding to three existing contracts using Project BioShield (PBS) funds, and funding to four existing contracts using Pandemic Influenza (PI) funds. The actions are those planned for FY 2020, however COVID-19 response will take priority. If time permits, these actions will be executed.

BACKGROUND

Funding Action One: ARD

BARDA is seeking approval to award a new contract to University of Pennsylvania (Philadelphia, Pennsylvania) to support the development of its lung-on-chip technologies, to examine chlorine-induced respiratory complications and to predict the toxicity of inhaled chlorine gas in human lungs. This particular technology may be able to mimic living human tissue under the relevant chemical threat exposure conditions and allow for the measuring of an

array of biological responses to chlorine gas and potential other inhalation insults, thus providing a rapid and high throughput screening system for potential treatments. This may also reduce the need for animal testing in the development of some medical countermeasures. BARDA is seeking $5.5 million to support these activities.

Funding Action Two: ARD

BARDA is seeking approval to provide additional funds to Public Health Vaccines (Cambridge, Massachusetts) to continue support of its portfolio of vaccines against Marburg virus. This funding would support the development of clinical immunology assays that will be needed for the development of their vaccine against Marburg virus in clinical trials and nonclinical studies. BARDA is seeking $2.7 million to support these activities.

Funding Action Three: ARD

BARDA requests approval to provide additional funding to Chimerix, Inc. (Durham, North Carolina) to support continued development of Brincindofovir (BCV), an antiviral drug for the treatment of smallpox. Funding will support New Drug Application (NDA) enabling activities and submission of NDAs for BCV for the treatment of smallpox in two dosage forms. BARDA is seeking $7 million to support these activities.

Funding Action Four: ARD

BARDA requests approval to award a new contract to support development of a Botulinum monoclonal antibody (mAb) cocktail. Currently, the only FDA-approved Botulinum antitoxin available in the SNS is the Heptavalent Botulinum Antitoxin (hBAT), manufactured by Emergent Biosolutions. hBAT is an equine-derived polyclonal product. The horse herd has matured and is no longer a viable source of new material for the stockpile. Funding requested here will support identification of monoclonal antibodies against all seven BoNT serotypes and down-selection of a final cocktail that retains efficacy against all. BARDA is seeking $4 million to support these activities.

Funding Action Five: ARD

BARDA is seeking approval to provide additional funding to Cytovale, Inc. (San Francisco, California) who is developing a novel sepsis diagnostic and seeking FDA clearance. The rapid sepsis diagnostic can rapidly quantify immune activation through measuring the biophysical properties of cells and provide information on the risk of sepsis. This diagnostic will be able to aid in the early diagnosis of sepsis in patients presenting with signs or suspicion of infection in the Emergency Department, providing a sample-to-answer in less than five minutes. The current funding request will support the execution of analytical and clinical validation studies, secure the supply chain, and initiate Good Manufacturing Practice scale up processes. BARDA is seeking $3.3 million to support these activities.

Funding Action Six: ARD

BARDA is seeking additional funding for the University of Maryland (Baltimore, Maryland) to build the capability to test available blood product components (plasma, platelets, whole blood) in a rabbit model of acute radiation syndrome (ARS). This capability will allow BARDA to assess the use of blood products in both medical management and to test blood product components under advanced development at BARDA, including Cellphire Inc.'s (Rockville, Maryland) Thrombosomes®, for efficacy against ARS. BARDA is seeking $5.1 million to support this activity.

Funding Action Seven: ARD

BARDA is seeking approval to provide funds to the U.S. Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND) (Aberdeen, Maryland) to further fund an existing Other Transactional Agreement (OTA) JPEO-CBRND has with Cepheid, Inc. (Sunnyvale, California). The funding will support Cepheid in developing and obtaining FDA Emergency Use Authorization (EUA) of an assay for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2); support further development of the assay to a pan-coronavirus assay that detects and differentiates known human coronaviruses and detects novel or emerging coronaviruses; and, allows Cepheid to complete studies in order to achieve FDA clearance and other regulatory approvals as necessary, of the pan-coronavirus assay. All assays will be designed for use on the widely-placed automated Cepheid GeneXpert® platform, be compatible with the smaller portable Cepheid OMNI, and provide results within 30 minutes. BARDA is seeking $5 million to support these activities.

Funding Action Eight: ARD

BARDA is seeking approval to provide additional funding to Inflammatix Inc. (Burlingame, California) for continued, development of an FDA Clinical Laboratory Improvement Amendments (CLIA)-waivable point of care (POC) platform to determine whether a patient has an acute infection, and if so, whether it is due to a virus or bacteria. The POC platform will be appropriate for use across outpatient and inpatient settings, will inform appropriate use of antibiotics, and identify septic patients in 20-30 minutes. Funding will support design of the instrument and a consumable cartridge; analytical validation for the assays; and, transfer to manufacturing of units to be used in clinical trials. BARDA is seeking a total of $7.5 million dollars to fund this effort.

Funding Action Nine: ARD

BARDA is seeking approval to provide additional funding to SRI International, (Menlo Park, California) to develop an Anthrax Lethal Factor (LF) POC diagnostic. In just 15 minutes, healthcare providers may be able to diagnose anthrax infections with this easy-to-use lateral flow anthrax test by analyzing blood from a finger-stick blood. The funding will support all verification and validation preparations for testing, including manufacturing of 10,000 assays and consumables, performance of verification and validation studies, and the filing of a 510(k) package and pre-EUA package for use with capillary blood samples. BARDA is seeking $5.3 for these activities.

Funding Action Ten: ARD

BARDA is seeking approval to provide additional funds to First Light Diagnostics (FLD), (Bedford, Massachusetts). FLD is developing a rapid bacterial identification and phenotypic antimicrobial susceptibility diagnostic system for use in a physician's office lab (large practice), emergency departments, and small hospital labs. With these additional funds, FLD will initiate clinical studies at three sites to measure analytical performance of the LF anthrax assay, and additionally provide a rate adjustment for three past fiscal years (2016-2018) at the recommendation of Defense Finance and Accounting Services. BARDA is seeking $6.4 million for these activities, of which $0.9 million are to be funds from prior fiscal years.

Funding Action Eleven: ARD

BARDA is seeking approval to provide additional funds to Janssen Research & Development, LLC (HHSO100201800012C), Raritan NJ to continue development of Thrombopoietin mimetic (TPOm) to address acute radiation syndrome and chemical injury. This will be done under the existing Janssen Other Transaction Authority (OTA). Under the ARS indication, the requested funding will support establishment of Bioassay as requested by FDA, complete non-clinical biomarker analysis, manufacturing support for a Phase 2 clinical study and execution of the Phase 2a clinical study. This funding will also include completion of animal model development for Sulfur Mustard and proof of concept efficacy testing of two Janssen assets. The total funding request is $5.8 million.

Funding Action Twelve: ARD

BARDA is seeking additional funding for Novartis Pharmaceuticals Corporation, Inc. (East Hanover, New Jersey) to continue development of eltrombopag as a medical countermeasure for the treatment of acute radiation syndrome (ARS). This will allow support for studies to assess the pharmacodynamics and pharmacokinetics (PK/PD) and support a clinical study to determine the relative bioavailability of varying doses of crushed eltrombopag tablets as an alternative route of administration to tablets. BARDA is seeking a total of $3.18 million to support these activities.

Funding Action Thirteen: PBS

BARDA is seeking approval to provide additional funding to ASELL LLC (Owings Mills, Maryland) to continue development of a high-throughput test that predicts medically important absorbed doses of radiation after a nuclear incident. The test uses a small blood sample and is a direct measure of radiation absorption. If cleared by the FDA, this test will give patient-specific absorbed dose information to better assist with patient clinical management. BARDA is seeking a total of $7.2 million to support the validation activities in preparation for FDA pre-EUA submission and potential 510(k) filing.

Funding Action Fourteen: PBS

BARDA is seeking approval to provide additional funds to SRI International (Menlo Park, California) for late stage development of a rapid POC biodosimetry test for estimating radiation

exposure. This test is needed to assist in patient management following an improvised nuclear device detonation or nuclear incident. The SRI test will analyze a patient's blood from a finger-stick sample and determine if a casualty has absorbed more than 2 Gray of ionizing radiation and therefore needs prompt medical care, or can evacuate. Additional funds are need to support FDA pre-submission meeting and feedback activities, including down-selection to the best candidate marker, integration of this new marker into the diagnostic, and verification testing of the resulting diagnostic system. BARDA is seeking $7.8 million to support these activities.

Funding Action Fifteen: PBS

BARDA is seeking approval to provide additional funding to DxTerity Diagnostics Inc. (Rancho Dominguez, California) to continue development of the REDI-Dx ® Biodosimetry Test system, an in vitro diagnostic test intended for the quantitative estimation of a casualty's absorbed ionizing radiation dose following detonation of an improvised nuclear device or nuclear explosion. The REDI-Dx test uses a small blood sample to measure dose dependent gene expression in response to ionizing radiation absorption. If cleared by the FDA, this test will give patient-specific absorbed dose information to better inform post-irradiation clinical management. BARDA is seeking $2.5 million to finalize analysis of animal study data and the preparation for a pre-EUA package for FDA submission.

Funding Action Sixteen: Pandemic Influenza

BARDA is seeking approval to provide additional funding to Aardvark Medical, LLC. (Ross, California) for continued development of a next generation device, Clearinse CTS™, a portable, compact and disposable nasal wash system indicated for the collection, storage, and transport of respiratory viral specimens. A portion of the collected specimen may be used immediately for rapid testing, while the remainder is stabilized with an integrated transfer medium and sealed for shipment or storage. The stabilized portion can be used later by laboratories for POC testing using traditional lateral flow assays or the newer molecular assays, as well as for culture identification, speciation, and antiviral drug resistance testing. Funding will support testing of the device in Clinical Trials, including collection, shipping, and testing of specimens collected from the wash head with commercially available molecular assays. A portion of the funding will support an influenza clinical trial with four different groups of subjects. BARDA is seeking $2.8 million to support these activities.

Funding Action Seventeen: Pandemic Influenza

BARDA is seeking approval to provide Cue Health Inc, (San Diego, California) additional funding to support continued development of their in-home, over-the-counter molecular Influenza A/B diagnostic test. The Cue instrument and cartridge platform developed in this program are part of a new class of rapid, small, POC molecular diagnostic platforms that will become game changers, when available, for responses to emerging infectious diseases. The funds will support completion of analytical validation studies, clinical studies, and two separate FDA 510(k) submissions for CLIA POC and Home Use testing. BARDA is seeking $7.8 million to support these activities.

Funding Action Eighteen: Pandemic Influenza

BARDA is seeking approval for additional funds for Sanofi Pasteur (Swiftwater, Pennsylvania) to continue storage and stability testing of pre-pandemic vaccines in the National Pre-Pandemic Vaccine Stockpile. Sanofi holds H5N1 and H7N9 Pre-pandemic vaccine manufactured between 2005 and 2018 in their facility must continue testing for stability. The stockpiled products for Sanofi consists of 129 lots of H5N1; 20 lots of H7N9; and 280,000 Final Containers (H5N1 and H7N9). BARDA is seeking $3.3 million to support these activities.

Funding Action Nineteen: Pandemic Influenza

BARDA is seeking approval for additional funds for GlaxoSmithKline (Marietta, Pennsylvania) to continue storage and stability testing of pre-pandemic vaccines and adjuvant in the National Pre-Pandemic Vaccine Stockpile. GSK holds H5N1 and H7N9 Pre-pandemic as well as AS03 adjuvant manufactured between 2006 and 2019 in their facility must continue testing for stability. The stockpiled products for GSK consist of 72 lots of H5N1; 17 lots of H7N9; and three lots of adjuvant; 2,600,000 Final Containers (AS03 and H7N9). BARDA is seeking $3.1 million to support these activities.

Table 1: BARDA Funding Action

Program Area	Company	Contract #	Product	Funds Needed for Option/ Award	Approved	Need More Information
Chemical MCMs (ARD)	University of Pennsylvania	New	Lung-on-chip technologies to examine chlorine-induced respiratory complications and to predict the toxicity of inhaled chlorine gas in human lungs.	$5.5 million		
Viral Hemorrhagic Fever Vaccine MCMs (ARD)	Public Health Vaccines	HHSO100201900022C	Development of clinical immunology assays that will be needed for the continued development of a vaccine against *Marburg virus*.	$2.7 million		
Smallpox MCMs (ARD)	Chimerix, Inc.	HHSO100201100013C	Development of Brincindofovir, an antiviral drug for the treatment of smallpox.	$7 million		
Botulism Therapeutic MCMs (ARD)	TBD	New	Support identification of monoclonal antibodies against all seven botulism serotypes and down-selection of a final cocktail that retains efficacy against all.	$4 million		

Program Area	Company	Contract #	Product	Funds Needed for Option/ Award	Approved	Need More Information
Sepsis Diagnostic and Detection MCMs (ARD)	Cytovale, Inc.	75A50119C00072	Early diagnosis of sepsis in patients presenting with signs or suspicion of infection in the Emergency Department with a sample to answer in <5min.	$3.3 million		
Rad/Nuc Therapeutics (ARD)	University of Maryland, Baltimore	HHSO100201500009I	Build the capability to test available blood products in a rabbit model of acute radiation syndrome.	$5.1 million		
Diagnostic and Detection MCMs (ARD)	Cepheid, Inc.	IPIAA20OS254451 (OTA)	Point of care diagnostic for rapid coronavirus detection, including EUA and studies to achieve FDA clearance.	$5 million		
Diagnostic and Detection MCMs (ARD)	Inflammatix Inc.	75A50119C00034	A point of care (POC) platform to determine whether a patient has an acute infection and if so, is it bacterial or viral.	$7.5 million		
Diagnostic and Detection MCMs (ARD)	SRI International	HHSO100201600007C	Anthrax Point of Care POC diagnostic.	$5.3 million		
Diagnostic and Detection MCMs (ARD)	First Light Diagnostics	HHSO100201500022C	A rapid bacterial identification and phenotypic antimicrobial susceptibility diagnostic system.	$6.4 million		
RadNuc and Chem MCMs (ARD)	Janssen	HHSO100201800012C	Continue development of Thrombopoietin mimetic (TPOm) to address acute radiation syndrome and chemical injury. T	$5.8 million		
Rad/Nuc Therapeutic MCMs (ARD)	Novartis, Inc.	HHSO100201700026C	Development of eltrombopag as a medical countermeasure for the treatment of acute radiation syndrome.	$3.18 million		
Rad/Nuc MCMs (PBS)	ASELL LLC.	HHSO100201700022C	A high-throughput test that predicts absorbed dose of radiation after a nuclear incident.	$7.2 million		
Diagnostic and Detection MCMs (PBS)	SRI International	HHSO100201700030C	A rapid POC radiation exposure test.	$7.8 million		

Program Area	Company	Contract #	Product	Funds Needed for Option/ Award	Approved	Need More Information
Diagnostic and Detection MCMs (PBS)	DxTerity Diagnostics Inc.	HHSO100201600034C	REDI-Dx Test system, an in vitro diagnostic test intended for the quantitative estimation of a casualty's absorbed ionizing radiation dose following detonation of an improvised nuclear device or nuclear explosion.	$2.5 million		
Pandemic Influenza Diagnostic and Detection MCMs (PI)	Aardvark Medical, Inc	HHSO100201800039C	Clearinse CTS™, a portable, compact and disposable nasal wash system is indicated for the collection, storage, and transport of respiratory viral specimens.	$2.8 million		
Pandemic Influenza Diagnostic and Detection MCMs (PI)	Cue Health, Inc.	HHSO100201800016C	An in-home over-the-counter molecular Influenza A/B diagnostic.	$7.8 million		
Pre-pandemic Vaccine Stockpile (PI)	Sanofi Pasteur, Inc.	HHSO100201600006I	Continued storage-testing of pre-pandemic vaccine in National Pre-Pandemic Vaccine Stockpile	$3.3 million		
Pre-pandemic Vaccine Stockpile (PI)	GlaxoSmithKline, LLC	HHSO100201600004I	Continued storage-testing of pre-pandemic vaccine and adjuvant in National Pre-Pandemic Vaccine Stockpile	$3.1 million		
TOTAL				$95.3 million		

RECOMMENDATION

I recommend you approve the financing of BARDA's 12 ARD, three PBS, and four PI funding actions as outlined in Table 1, subject to the availability of funds. These actions are subject to a 10 percent variance.

Gary L. Disbrow -S Digitally signed by Gary L. Disbrow -S
Date: 2020.03.04 10:29:27 -05:00

Rick A. Bright, PhD
Director, Biomedical Advanced Research and Development Authority
Deputy Assistant Secretary for Preparedness and Response

DECISION

Approved _____ Disapproved _____ Need More Information _____

Robert P. Kadlec -S Digitally signed by Robert P. Kadlec -S
Date: 2020.03.11 19:33:26 -04:00

Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response

Date