From: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Sent: 3/26/2020 4:00:44 PM
To: Corrigan-Curay, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cff7c455d5d24bc69c1239a23041a596-Jacqu.Corri]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: EUA

Thanks Jacqueline. I believe Dr Walker will be reporting out. He's got the most information. Thank you. Rick

Sent from my iPhone

On Mar 26, 2020, at 3:42 PM, Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov> wrote:

Hi Rick

(b) (5)

Best,
Jacqueline

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 26, 2020 2:46 PM
To: Bright, Rick (OS) <Rick.Bright@hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Subject: EUA

Rick, connecting you with Jacqueline Whois our lead on the EUA. Jw

From: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Sent: 3/26/2020 12:55:48 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: BARDA and Regeneron

Thanks.

On Mar 26, 2020, at 12:12 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

I'll call you at 2:30. jw

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Thursday, March 26, 2020 11:57 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: BARDA and Regeneron

Yes, are you available anytime betwee 1:40 to 2:35? (b) (6)

From: Janet Woodcock <Janet.Woodcock@fda.hhs.gov>
Date: Thursday, March 26, 2020 at 10:17 AM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: FW: BARDA and Regeneron

Can we discuss? Do you have a minute sometime today? jw

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:50 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: BARDA and Regeneron

John's time is more precious than ours. Is this something you would like to handle? Happy to join or help in any way
Patrizia

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 25, 2020 at 6:37:15 PM EDT
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: BARDA and Regeneron

(b) (5)

Thanks,
KL

From: Howard, Jeff D. Jr. EOP/OVP (b) (6)
Sent: 3/25/2020 2:56:53 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
CC: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

Thank you.

Sent from my iPhone

> On Mar 25, 2020, at 2:53 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:
>
>

From: Hamel, Joseph (OS/ASPR/IO) [Joseph.Hamel@hhs.gov]
Sent: 3/26/2020 7:53:25 AM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
CC: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Walker, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d03cc33ba5c4f15bd581b757dc9daa4-HHS-Robert.]; Faison, Tremel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4945bc9afa3c4d34a274cb286e2f2a09-HHS-Tremel.]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffbd5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Uyeki, Timothy M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f106bd981def4bfeb945e86b266662b2-HHS-tmu0-cd]; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6) ; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]; Beigel, John H (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db2bc96f962b4661b0494e9fa6ca6bcf-HHS-jbeigel]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Harper, Victor G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d572fe7d36f44ffe86101e5cbef9c957-HHS-Victor.]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]
Subject: Re: Nationwide Access Plan

(b) (5)

Strategic Innovation and Emerging Technology Manager

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

On Mar 25, 2020, at 10:06 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

Renaming this email thread since (b) (5)

(b) (5)

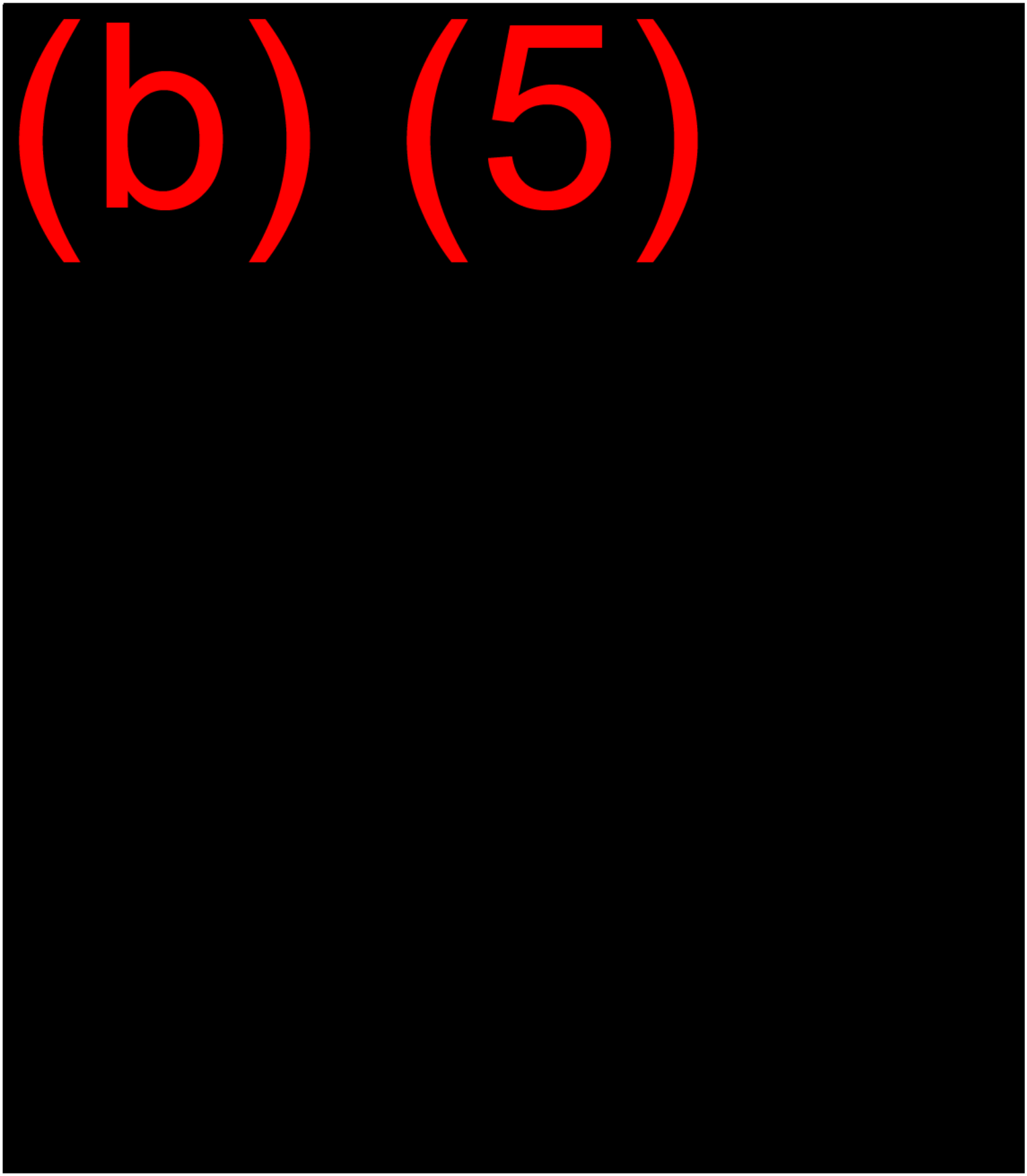
From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 6:00 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Walker, Robert (OS) <Robert.Walker@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Lambert, Linda (OS) <Linda.Lambert@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Marston, Hilary D (NIH) (b) (6); Lane, Henry C (NIH) (b) (6); Patel, Anita (CDC) <bop1@cdc.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6); Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Beigel, John H (NIH) (b) (6); Higgs, Elizabeth S (NIH) (b) (6); Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Harper, Victor G (OS) <Victor.Harper@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Hamel, Joseph (OS) <Joseph.Hamel@hhs.gov>
Subject: Re: URGENT Questions on planned study

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

FOUO, Confidential, Pre-Decisional

Dear All,

(b) (5)



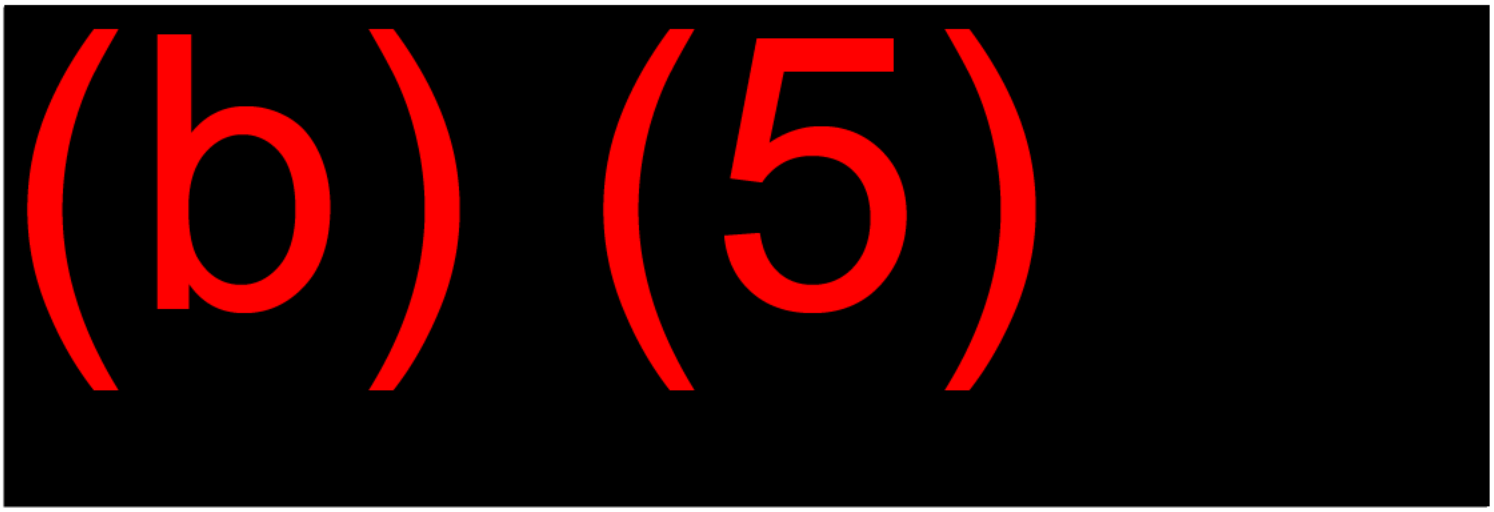
Thank you all for your critical and urgent contributions to these collaborative efforts.

Rick

From: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Date: Monday, March 23, 2020 at 9:09 PM
To: "Amin, Stacy (FDA/OC)" <Stacy.Amin@fda.hhs.gov>
Cc: Janet Woodcock <Janet.Woodcock@fda.hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>, Robert Walker <Robert.Walker@hhs.gov>, Tremel Faison <Tremel.Faison@hhs.gov>, "Farley, John (FDA/CDER)" <John.Farley@fda.hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Hilary Marston (b) (6) Cliff Lane (b) (6), Anita Patel <bop1@cdc.gov>, Timothy Uyeki <tmu0@cdc.gov>, "Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA)" (b) (6), Debra Birnkrant <Debra.Birnkrant@fda.hhs.gov>, John Beigel (b) (6), Elizabeth Higgs (b) (6), "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>
Subject: URGENT Questions on planned study

Hi Stacy,

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



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

Rick
Rick A. Bright, PhD
Director, BARDA
Deputy Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services

From: Patel, Anita (CDC/DDID/NCIRD/OD) [bop1@cdc.gov]
Sent: 3/26/2020 12:52:10 AM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Walker, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d03cc33ba5c4f15bd581b757dc9daa4-HHS-Robert.]; Faison, Tremel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4945bc9afa3c4d34a274cb286e2f2a09-HHS-Tremel.]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffbd5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Uyeki, Timothy M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f106bd981def4bfeb945e86b266662b2-HHS-tmu0-cd]; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6) ; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]; Beigel, John H (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db2bc96f962b4661b0494e9fa6ca6bcf-HHS-jbeigel]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Harper, Victor G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d572fe7d36f44ffe86101e5cbef9c957-HHS-Victor.]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Hamel, Joseph (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b90f78a9c02426eb8d62bd1ad9117b8-HHS-Joseph.]; Budnitz, Dan (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=169fded3348548418a7c5e05fa74ba6f-HHS-zyq6-cd]; Yu, Yon C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a354f2cb95a4943bceda08697422dd2-HHS-fkb8-cd]; Chatham Stephens, Kevin M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99b4f0e8f5e44ad9a21e67bb1738d77b-HHS-xdc4-cd]
CC: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]
Subject: RE: Nationwide Access Plan

+ yon, dan, and kevin from CDC.

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:06 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Walker, Robert (OS/ASPR/BARDA) <Robert.Walker@hhs.gov>; Faison, Tremel (OS/ASPR/BARDA) <Tremel.Faison@hhs.gov>; Farley, John (FDA/CDER) <John.Farley@fda.hhs.gov>; Lambert, Linda (OS/ASPR/BARDA) <Linda.Lambert@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] (b) (6); Lane, Cliff (NIH/NIAID) [E] (b) (6); Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6); Birnkrant, Debra B (FDA/CDER) <Debra.Birnkrant@fda.hhs.gov>; Beigel, John (NIH) [E] (b) (6); Higgs, Elizabeth (NIH/NIAID) [E] (b) (6); Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Harper, Victor (OS/ASPR/ORM) <Victor.Harper@hhs.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Cc: Guram, Jeet (FDA/OC) <Jeet.Guram@fda.hhs.gov>; Franklin, Joseph (FDA/OC) <Joseph.Franklin@fda.hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
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Renaming this email thread since (b) (5)

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Subject: Re: URGENT Questions on planned study

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FOUO, Confidential, Pre-Decisional

Dear All,

(b) (5)

(b) (5)

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Rick

From: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Date: Monday, March 23, 2020 at 9:09 PM
To: "Amin, Stacy (FDA/OC)" <Stacy.Amin@fda.hhs.gov>
Cc: Janet Woodcock <Janet.Woodcock@fda.hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>, Robert Walker <Robert.Walker@hhs.gov>, Tremel Faison <Tremel.Faison@hhs.gov>, "Farley, John (FDA/CDER)" <John.Farley@fda.hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Hilary Marston (b) (6) Cliff Lane (b) (6), Anita Patel <bop1@cdc.gov>, Timothy Uyeki <tmu0@cdc.gov>, "Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA)" (b) (6), Debra Birnkrant <Debra.Birnkrant@fda.hhs.gov>, John Beigel (b) (6), Elizabeth Higgs (b) (6), "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>
Subject: URGENT Questions on planned study

Hi Stacy,

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

(b) (5)

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

Rick
Rick A. Bright, PhD
Director, BARDA
Deputy Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services

From: Hamel, Joseph (OS/ASPR/IO) [Joseph.Hamel@hhs.gov]
Sent: 3/19/2020 2:41:27 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Zadecky, Leo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8adc6be4e8ec4f05a6061549feb10ce8-Leo.Zadecky]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Adams, Peter (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93840333b622413cbcda581d938c65f8-HHS-Peter.A]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]
Subject: RE: Chloroquine

Will do!

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

-----Original Message-----
From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Thursday, March 19, 2020 2:31 PM
To: Roberts, Rosemary (FDA/CDER) <Rosemary.Roberts@fda.hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia (FDA/CDER) <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo (FDA/CDER) <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E (FDA/CDER) <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C (FDA/CDER) <Douglas.Throckmorton@fda.hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>
Subject: Re: Chloroquine

+ Joe Hamel and Peter Adams.

Joe, Peter, can you please (b) (5) Thanks, Rick

On 3/19/20, 2:09 PM, "Roberts, Rosemary" <Rosemary.Roberts@fda.hhs.gov> wrote:

Mr. Harrison,

(b) (4)

Rosemary Roberts
2019 n-CoV FDA IMG Operations/Drug Lead
FDA/CDER/OCD

-----Original Message-----
From: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 7:28 PM
To: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Subject: FW: Chloroquine

Mr. Harrison,

In response to your request:

Manufacturers with product currently available (in alphabetical order):
•Chloroquine phosphate tablets, 150 mg and 300 mg
oNatco Pharma (distributed by Rising Pharmaceuticals)
Glenda Bryant (US Agent) glenda.bryant@syneoshealth.com (b) (6)
•Hydroxychloroquine sulfate tablets, 200 mg
oAlkaloida Chemical Co (distributed by Sun Pharmaceutical)
Praveen Devakadaksham (US Agent)– Praveen.devakadaksham@sunpharma.com (b) (6)
oAmneal Pharmaceuticals (distributed by Amneal Pharmaceuticals)
Janie Gwinn – Janie.gwinn@amneal.com or Candis Edwards – cedwards@amneal.com (b) (6)
oConcordia Pharmaceuticals (distributed by Concordia (Plaquenil®) and Prasco Laboratories)
Wayne Vallee (US Agent) – wayne.vallee@cardinalhealth.com (b) (6)
oSandoz (distributed by Sandoz)
Lara Hansen – lara.hansen@sandoz.com (b) (6)
oTeva Pharmaceuticals (distributed by Actavis Pharma)
Joe DeVito – Joseph.DeVito@tevapharm.com (b) (6)
(b) (4) (distributed by Dr. Reddy's Laboratories)
(b) (4) (b) (6)
oZydus Pharmaceuticals (distributed by Northstar Rx, Zydus Pharmaceuticals)
Srinivas Gurram – Gsrinivas@zydususa.com (b) (6)

Please let us know if any questions.

Rosemary Roberts
2019 n-CoV FDA IMG Operations/Drug Lead
FDA/CDER/OCD

-----Original Message-----
From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:48 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>
Subject: RE: Chloroquine

(b) (5)

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:44 PM
To: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Subject: RE: Chloroquine

(b) (5)

-----Original Message-----
From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Sent: Wednesday, March 18, 2020 5:37 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Subject: Re: Chloroquine

+FDA

Brian Harrison
Chief of Staff
U.S. Department of Health and Human Services
(b) (6)
brian.harrison@hhs.gov

> On Mar 18, 2020, at 5:35 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:
>
> Patrizia- connecting you with HHS leadership to (b) (5)
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: Janet.Woodcock@fda.hhs.gov [Janet.Woodcock@fda.hhs.gov]
Sent: 3/25/2020 5:09:16 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Howard, Jeff D. Jr. EOP/OVP (b) (6)
Subject: Re: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

(b) (5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 25, 2020 at 5:02:24 PM EDT
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Howard, Jeff D. Jr. EOP/OVP (b) (6)
Subject: Re: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

From: Janet.Woodcock@fda.hhs.gov [Janet.Woodcock@fda.hhs.gov]
Sent: 3/25/2020 6:22:38 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
Subject: Re: URGENT Questions on planned study

(b) (5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 25, 2020 at 5:57:52 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Walker, Robert (OS) <Robert.Walker@hhs.gov>, Faison, Tremel (OS) <Tremel.Faison@hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Marston, Hilary D (NIH) (b) (6), Lane, Henry C (NIH) (b) (6), Patel, Anita (CDC) <bop1@cdc.gov>, Uyeki, Timothy M (CDC) <tmu0@cdc.gov>, Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6), Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>, Beigel, John H (NIH) (b) (6), Higgs, Elizabeth S (NIH) (b) (6), Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Harper, Victor G (OS) <Victor.Harper@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Johnson, Robert (OS) <Robert.Johnson@hhs.gov>
Subject: Re: URGENT Questions on planned study
Importance: High

(b) (5)

(b) (5)

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(b) (5)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

From: Higgs, Elizabeth S (NIH) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0AC36DD643C04994B3161BAF825CBFC3-HHS-EHIGGS-]
Sent: 3/18/2020 12:26:02 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Uyeki, Timothy M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f106bd981def4bfeb945e86b266662b2-HHS-tmu0-cd]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcfcc02744b3a6-HHS-carrie.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Auchincloss, Hugh (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab02b9d7c8514b538a08bab4a6659fba-HHS-auchinc]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]
Subject: Re: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
Attachments: SARS-CoV-2 Prophylaxis summary slides v3 for WHO.PDF

Colleagues,

(b) (5)

Kind regards,
Libby

Elizabeth S. Higgs, MD, DTMH, MIA

Global Health Science Advisor
Division of Clinical Research
National Institute of Allergy and Infectious Diseases
NIH, HHS, USG
(b) (6)

From: Anand.Shah@fda.hhs.gov
When: 12:00 PM - 12:45 PM March 18, 2020
Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
Location: (b) (6) ; (b) (6)

-----Original Appointment-----
From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:55 AM
To: Shah, Anand; Bright, Rick (OS/ASPR/BARDA); Fauci, Anthony (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Cavazzoni, Patrizia (FDA/CDER); Guram, Jeet; Farley, John (FDA/CDER); Roberts, Rosemary (FDA/CDER); Amin, Stacy (FDA/OC); Davis, May M. EOP/WHO; Raza, Mark (FDA/OC); Edmonds, Amanda (FDA/OC); Beers, Donald (FDA/OC); Zembower, Jenna (FDA/OC); Uyeki, Timothy M. (CDC/DDID/NCIRD/ID); Lenihan, Keagan (FDA/OC); Wolinetz, Carrie (NIH/OD) [E]; Shuy, Bryan (OS/ASPR/IO); Disbrow, Gary (OS/ASPR/BARDA); Auchincloss, Hugh (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]
Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
When: Wednesday, March 18, 2020 12:00 PM-12:45 PM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6) ; (b) (6)

Participants on this call:

FDA
Anand Shah, Office of the Commissioner, Deputy Commissioner for Medical & Scientific Affairs
Keagan Lenihan, Office of the Commissioner, Chief of Staff
Jeet Guram, Office of the Commissioner, Senior Advisor
Janet Woodcock, CDER, Director
Patrizia Cavazzoni, CDER, Deputy Director for Operations
John Farley, CDER Office of Infectious Diseases, Director
Rosemary Roberts, CDER Counter-Terrorism and Emergency Coordination Staff, Director
Stacy Amin, Office of the Chief Counsel, Chief Counsel
Mark Raza, Office of the Chief Counsel, Deputy Chief Counsel
Amanda Edmonds, Office of the Chief Counsel, Deputy Chief Counsel for Program Review for Biologics and Drugs

ASPR/BARDA
Rick Bright, Deputy Assistant Secretary for Preparedness and Response (ASPR) & Director of the Biomedical Advances Research and Development Authority (BARDA)
Brian Shuy, ASPR Deputy Assistant Secretary and Chief of Staff
Gary Disbrow, Acting Deputy Director of BARDA

NIH
Anthony Fauci, NIAID, Director

Hugh Auchincloss, NIAID, Principal Deputy Director
Carrie Wolinetz, Acting Chief of Staff
Hilary Marston, Office of the Chief of Staff, Medical Officer/Policy Advisor

CDC
Timothy Uyeki, National Center for Immunization and Respiratory Diseases

White House
May Davis, Associate White House Counsel

Bayer has been in touch with FDA on the offer to donate Resochin (branded chloroquine phosphate).

(b) (5)

Thank you

Best,
Anand

-- Do not delete or change any of the following text. --

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+1-877-465-7975 US Toll Free
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Need help? Go to http://help.webex.com

From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/23/2020 4:25:59 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Flanagan, Keith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15dcaab5c1ea4007adbc43e9acd413a6-Keith.Flana]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: By 6pm - Clinical trials underway for chloroquine
Attachments: Re: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

(b) (5)

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 23, 2020 4:22 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: By 6pm - Clinical trials underway for chloroquine

(b) (5)

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 4:19 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: By 6pm - Clinical trials underway for chloroquine

(b) (5)

Let me know if you have any questions – and just to clarify, (b) (5) [redacted] Thanks so much.

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
(b) (6) [redacted] | jeet.guram@fda.hhs.gov

From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/19/2020 11:50:15 AM
To: Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Zadecky, Leo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8adc6be4e8ec4f05a6061549feb10ce8-Leo.Zadecky]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Hamel, Joseph (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b90f78a9c02426eb8d62bd1ad9117b8-HHS-Joseph.]; Adams, Peter (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93840333b622413cbcda581d938c65f8-HHS-Peter.A]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: RE: Chloroquine

(b) (5)

-----Original Message-----
From: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Sent: Thursday, March 19, 2020 11:09 AM
To: Bright, Rick (OS) <Rick.Bright@hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Hamel, Joseph (OS) <Joseph.Hamel@hhs.gov>; Adams, Peter (OS) <Peter.Adams@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Chloroquine

(b) (4)

(b) (4)

-----Original Message-----
From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Thursday, March 19, 2020 10:49 AM
To: Roberts, Rosemary (FDA/CDER) <Rosemary.Roberts@fda.hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia (FDA/CDER) <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo (FDA/CDER) <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E (FDA/CDER) <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C (FDA/CDER) <Douglas.Throckmorton@fda.hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: Re: Chloroquine

ALCON,

(b) (5)

Christine Baeder
SVP, Chief Operating Officer US Gx
Tel: 1-215-591-8913 Cell: (b) (6)
Christine.Baeder@tevapharm.com (b) (4)

(b) (4)

On 3/18/20, 7:28 PM, "Roberts, Rosemary" <Rosemary.Roberts@fda.hhs.gov> wrote:

> Mr. Harrison,
>
> In response to your request:
>
> Manufacturers with product currently available (in alphabetical order):
> •Chloroquine phosphate tablets, 150 mg and 300 mg
> oNatco Pharma (distributed by Rising Pharmaceuticals)
> Glenda Bryant (US Agent) glenda.bryant@syneoshealth.com (b) (6)
> •Hydroxychloroquine sulfate tablets, 200 mg
> oAlkaloida Chemical Co (distributed by Sun Pharmaceutical)
> Praveen Devakadaksham (US Agent)– Praveen.devakadaksham@sunpharma.com (b) (6)
> oAmneal Pharmaceuticals (distributed by Amneal Pharmaceuticals)
> Janie Gwinn – Janie.gwinn@amneal.com or Candis Edwards – cedwards@amneal.com (b) (6)
> oConcordia Pharmaceuticals (distributed by Concordia (Plaquenil®) and Prasco Laboratories)
> Wayne Vallee (US Agent) – wayne.vallee@cardinalhealth.com (b) (6)
> oSandoz (distributed by Sandoz)
> Lara Hansen – lara.hansen@sandoz.com (b) (6)
> oTeva Pharmaceuticals (distributed by Actavis Pharma)

Joe DeVito – Joseph.DeVito@tevapharm.com (b) (6)
(b) (4) (distributed by Dr. Reddy's Laboratories)
(b) (4) (b) (6)
oZydus Pharmaceuticals (distributed by Northstar Rx, Zydus Pharmaceuticals)
Srinivas Gurram – Gsrinivas@zydususa.com (b) (6)

Please let us know if any questions.

Rosemary Roberts
2019 n-CoV FDA IMG Operations/Drug Lead
FDA/CDER/OCD

-----Original Message-----
From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:48 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>
Subject: RE: Chloroquine

(b) (5)

Patrizia

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:44 PM
To: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Subject: RE: Chloroquine

(b) (5)

-----Original Message-----
From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Sent: Wednesday, March 18, 2020 5:37 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Subject: Re: Chloroquine

+FDA

Brian Harrison
Chief of Staff
U.S. Department of Health and Human Services
(b) (6)
brian.harrison@hhs.gov

> On Mar 18, 2020, at 5:35 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:
>
(b) (5)
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/19/2020 1:03:26 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Ashley, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40241a76230349cbb195ab1721092196-Donald.Ashl]
Subject: RE: Hydroxy Chloroquine
Attachments: RE: Chloroquine

Stacy

(b) (5)

Patrizia

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Thursday, March 19, 2020 12:45 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: Hydroxy Chloroquine

(b) (5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 19, 2020 at 12:32:13 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Cc: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Hydroxy Chloroquine

(b) (5), (b) (4)

From: "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>
Date: Thursday, March 19, 2020 at 12:24 PM
To: "Charrow, Robert (HHS/OGC)" <Robert.Charrow@hhs.gov>
Cc: "Charrow, Robert (HHS/OGC)" <Robert.Charrow@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Bryan Shuy

<Bryan.Shuy@hhs.gov>, "Lenihan, Keagan (FDA/OC)" <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Hydroxy Chloroquine

(b) (5) [redacted]

From: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Date: March 19, 2020 at 12:20:40 PM EDT
To: christine.baeder@tevapharma.com <christine.baeder@tevapharma.com>
Cc: Charrow, Robert (OS) <Robert.Charrow@hhs.gov>, Harrison, Brian (OS) <Brian.Harrison@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Hydroxy Chloroquine

Christine,

Just got off phone with FedEx; they can move material on their planes direct from [redacted] to U.S. once you obtain export license. I've copied FDA on this in the event that you need documentation from them. Keep us posted on the export license. Thanks so much, Bob

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

From: Hamel, Joseph (OS) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4B90F78A9C02426EB8D62BD1AD9117B8-HHS-JOSEPH.]
Sent: 3/23/2020 3:10:58 PM
To: Maffia, Anthony [anthony.maffia@sandoz.com]
CC: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Houchens, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffd780651964b4b999a0a9865886b23-HHS-Christo]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]
Subject: RE: Quick request for support

Anthony,

Thank you for reaching out. There's a NIH PCORI trial about to launch. Adding the BARDA and FDA team to get this over the finish line.

Best,
Joe

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

From: Maffia, Anthony <anthony.maffia@sandoz.com>
Sent: Monday, March 23, 2020 2:08 PM
To: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Subject: Quick request for support

Joe,

Given the COVID-19 pandemic worldwide and the need to access potential treatments, Novartis is urgently developing a clinical protocol to assess the utility of hydroxychloroquine with and without azithromycin in COVID-19 positive patients who have been hospitalized. To facilitate the execution of the study and to maximize the robustness of the results, we propose to collaborate with the Aids Clinical Trials Group (ACTG) to execute the protocol within their trial network. We believe this partnership will accelerate addressing this urgent unmet medical need and address critical gaps in our scientific knowledge.

We request a rapid approval to move quickly to engage with ACTG and execute the study with all due haste. Any push you or members of your team could give as we move ahead would be great.

We are in contact with FDA of course and we will also be reaching out as we move ahead.

Best
A

Anthony Maffia, III
Vice President, Regulatory Affairs, North America

T 609-627-6944
(b) (6)
F 609-395-2792
anthony.maffia@sandoz.com

"If you believe you can, or believe you can't, you are right."-Henry Ford

Sandoz Inc.
Regulatory Affairs
100 College Road West
Princeton, NJ 08540
USA

From: Amin, Stacy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB3764B7438648838C22881A06FC6AFB-STACY.AMIN]
Sent: 3/23/2020 10:32:41 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Walker, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d03cc33ba5c4f15bd581b757dc9daa4-HHS-Robert.]; Faison, Tremel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4945bc9afa3c4d34a274cb286e2f2a09-HHS-Tremel.]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffbd5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Uyeki, Timothy M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f106bd981def4bfeb945e86b266662b2-HHS-tmu0-cd]; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6) ; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]; Beigel, John H (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db2bc96f962b4661b0494e9fa6ca6bcf-HHS-jbeigel]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Flamberg, Gemma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbcd7049351f49009ec2ebc1efbd5513-Gemma.Flamb]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
Subject: RE: URGENT Questions on planned study
Attachments: RE: Quick request for support

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

Happy to talk at your earliest convenience. Could you suggest a time? (b) (5)

(b) (5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 9:09 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Walker, Robert (OS) <Robert.Walker@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Lambert, Linda (OS) <Linda.Lambert@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Marston, Hilary D (NIH) (b) (6); Lane, Henry C (NIH) (b) (6); Patel, Anita (CDC) <bop1@cdc.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6); Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Beigel, John H (NIH) (b) (6); Higgs, Elizabeth S (NIH) (b) (6); Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>
Subject: URGENT Questions on planned study

Hi Stacy,

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

(b) (5)

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

Rick
Rick A. Bright, PhD
Director, BARDA
Deputy Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services

From: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) [tmu0@cdc.gov]
Sent: 3/19/2020 12:33:42 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Davis, May M. EOP/WHO (b) (6) ; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcfcc02744b3a6-HHS-carrie.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Auchincloss, Hugh (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab02b9d7c8514b538a08bab4a6659fba-HHS-auchinc]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Lankford, David W (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d9ca5f75534cd8a2f3d22c3beb2e0b-HHS-Lankfor]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]
CC: Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Pillai, Satish K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e43838cb79744d390db5bd55b132650-HHS-vig8-cd]
Subject: RE: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

Thanks

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Thursday, March 19, 2020 12:30 PM
To: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Cavazzoni, Patrizia (FDA/CDER) <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6); Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Guram, Jeet (FDA/OC) <Jeet.Guram@fda.hhs.gov>; Farley, John (FDA/CDER) <John.Farley@fda.hhs.gov>; Roberts, Rosemary (FDA/CDER) <Rosemary.Roberts@fda.hhs.gov>; Davis, May M. EOP/WHO (b) (6); Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda (FDA/OC) <Amanda.Edmonds@fda.hhs.gov>; Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>; Zembower, Jenna (FDA/OC) <Jenna.Zembower@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Wolinetz, Carrie (NIH/OD) [E] (b) (6); Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Auchincloss, Hugh (NIH/NIAID) [E] (b) (6); Marston, Hilary (NIH/NIAID) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6); Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Higgs, Elizabeth (NIH/NIAID) [E] (b) (6)
Cc: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Pillai, Satish K. (CDC/DDID/NCEZID/DPEI) <vig8@cdc.gov>
Subject: RE: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

(b) (5)

Thank you.

From: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>
Date: March 19, 2020 at 12:19:51 PM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Fauci, Anthony S (NIH) (b) (6), Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Davis, May M. EOP/WHO (b) (6), Raza, Mark <Mark.Raza@fda.hhs.gov>, Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Wolinetz, Carrie D (NIH) (b) (6), Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Auchincloss, Hugh (NIH) (b) (6), Marston, Hilary D (NIH) (b) (6) Lankford, David W (NIH) (b) (6), Mair, Michael <Michael.Mair@fda.hhs.gov>, Higgs, Elizabeth S (NIH) (b) (6)
Cc: Patel, Anita (CDC) <bop1@cdc.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>
Subject: RE: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

I attached (b) (5)

Thanks,
Tim

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Thursday, March 19, 2020 11:10 AM
To: Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6); Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Guram, Jeet (FDA/OC) <Jeet.Guram@fda.hhs.gov>; Farley, John (FDA/CDER) <John.Farley@fda.hhs.gov>; Roberts, Rosemary (FDA/CDER) <Rosemary.Roberts@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Davis, May

M. EOP/WHO (b) (6) ; Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda (FDA/OC) <Amanda.Edmonds@fda.hhs.gov>; Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>; Zembower, Jenna (FDA/OC) <Jenna.Zembower@fda.hhs.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Wolinetz, Carrie (NIH/OD) [E] (b) (6) ; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Auchincloss, Hugh (NIH/NIAID) [E] (b) (6) Marston, Hilary (NIH/NIAID) [E] (b) (6) ; Lankford, David (NIH/OD) [E] (b) (6) Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>
Subject: RE: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

Let's all try this alternate number, I will dal in as leader

Dial In Number Local/Toll Number (b) (6) Freephone/Toll Free Number (b) (6) Passcodes Leader: (b) (6) Participant: (b) (6)

-----Original Appointment-----
From: Zembower, Jenna **On Behalf Of** Shah, Anand
Sent: Wednesday, March 18, 2020 3:27 PM
To: Shah, Anand; Bright, Rick (OS); Fauci, Anthony S (NIH); Woodcock, Janet; Cavazzoni, Patrizia; Guram, Jeet; Farley, John; Roberts, Rosemary; Amin, Stacy; Davis, May M. EOP/WHO; Raza, Mark; Edmonds, Amanda; Beers, Donald; Zembower, Jenna; Uyeki, Timothy M (CDC); Lenihan, Keagan; Wolinetz, Carrie D (NIH); Shuy, Bryan (OS); Disbrow, Gary (OS); Auchincloss, Hugh (NIH); Marston, Hilary D (NIH); Lankford, David W (NIH); Mair, Michael
Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
When: Thursday, March 19, 2020 11:00 AM-11:45 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6) ,,, (b) (6)

POC for Scheduling: Jenna Zembower (Office of the Commissioner, FDA)

Agenda

(b) (5)

Participants on this call:

FDA

- Anand Shah, Office of the Commissioner, Deputy Commissioner for Medical & Scientific Affairs
- Keagan Lenihan, Office of the Commissioner, Chief of Staff
- Jeet Guram, Office of the Commissioner, Senior Advisor
- Michael Mair, Acting Assistant Commissioner for Counterterrorism Policy, Office of the Chief Scientist
- Janet Woodcock, CDER, Director
- Patrizia Cavazzoni, CDER, Deputy Director for Operations
- John Farley, CDER Office of Infectious Diseases, Director
- Rosemary Roberts, CDER Counter-Terrorism and Emergency Coordination Staff, Director
- Stacy Amin, Office of the Chief Counsel, Chief Counsel
- Mark Raza, Office of the Chief Counsel, Deputy Chief Counsel
- Amanda Edmonds, Office of the Chief Counsel, Deputy Chief Counsel for Program Review for Biologics and Drugs

ASPR/BARDA

- Rick Bright, Deputy Assistant Secretary for Preparedness and Response (ASPR) & Director of the Biomedical Advances Research and Development Authority (BARDA)
- Brian Shuy, ASPR Deputy Assistant Secretary and Chief of Staff
- Gary Disbrow, Acting Deputy Director of BARDA

NIH

- Anthony Fauci, NIAID, Director
- Hugh Auchincloss, NIAID, Principal Deputy Director
- Carrie Wolinetz, Acting Chief of Staff
- Hilary Marston, Office of the Chief of Staff, Medical Officer/Policy Advisor

CDC

- Timothy Uyeki, National Center for Immunization and Respiratory Diseases

White House

- May Davis, Associate White House Counsel

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A systematic review on the efficacy and safety of chloroquine for the treatment of COVID-19

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ABSTRACT

Purpose: COVID-19 (coronavirus disease 2019) is a public health emergency of international concern. As of this time, there is no known effective pharmaceutical treatment, although it is much needed for patient contracting the severe form of the disease. The aim of this systematic review was to summarize the evidence regarding chloroquine for the treatment of COVID-19.
Methods: PubMed, EMBASE, and three trial Registries were searched for studies on the use of chloroquine in patients with COVID-19.
Results: We included six articles (one narrative letter, one in-vitro study, one editorial, expert consensus paper, two national guideline documents) and 23 ongoing clinical trials in China. Chloroquine seems to be effective in limiting the replication of SARS-CoV-2 (virus causing COVID-19) in vitro.
Conclusions: There is rationale, pre-clinical evidence of effectiveness and evidence of safety from long-time clinical use for other indications to justify clinical research on chloroquine in patients with COVID-19. However, clinical use should either adhere to the Monitored Emergency Use of Unregistered Interventions (MEURI) framework or be ethically approved as a trial as stated by the World Health Organization. Safety data and data from high-quality clinical trials are urgently needed.

1. Introduction

COVID-19 (Coronavirus Disease-2019) is a public health emergency of international concern. Patients contracting the severe form of the disease constitute approximately 15% of the cases [1]. As of this time there is no known specific, effective, proven, pharmacological treatment. In-vitro studies have suggested that chloroquine, an immunomodulant drug traditionally used to treat malaria, is effective in reducing viral replication in other infections, including the SARS-associated coronavirus (CoV) and MERS-CoV [2–4].

Chloroquine has been used worldwide for more than 70 years, and it is part of the World Health Organization (WHO) model list of essential medicines. It is also cheap and has an established clinical safety profile [3]. However, the efficacy and safety of chloroquine for treatment of SARS-CoV-2 (the new virus causing COVID-19) pneumonia remains unclear.

2. Methods

We performed a systematic review of the PubMed and EMBASE databases from inception to 1-March-2020 to find articles providing information on the efficacy and safety of chloroquine and chloroquine-related formulations in patients with SARS-CoV-2 pneumonia and articles describing related in-vitro studies. As much of the data on COVID-19 are coming from Asia, no language restrictions were imposed (see detailed search strategy in Supplement 1). The search was expanded using a snowballing method applied to the references of retrieved papers. We also searched the Chinese Clinical Trial Registry, Clinicatrial.gov and the International Clinical Trials Registry Platform (WHO ICTRP) to identify ongoing trials. Two authors (AC, MI) independently screened the databases and the trial registries and extracted relevant information (MI, GI). Discrepancies and doubts about relevance of the sources were solved by consensus with two more authors (AG, SE). We did not register the systematic review protocol because we anticipated the very limited available evidence on the topic and due to the urgency of the matter.

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0883-9441/

Table 1
Characteristics of clinical trials studying the efficacy and safety of Chloroquine or related formulation in patients with new coronavirus.pneumonia (COVID-19).

ID	Recruiting Status	Number of centers and Study design	Country	Population (n patients)	Intervention Group(s)	Comparison Group(s)	Primary Outcomes
ChiCTR2000030417	Not yet recruiting	Single Center RCT	China	COVID-19 pneumonia (n = 30)	Chloroquine phosphate aerosolized inhalation solution	Water for injection atomized inhalation combined	Temperature normal for more than 3 days, respiratory symptoms, pulmonary imaging, test negativization
ChiCTR2000030054	Pending approval	Single Center RCT	China	Mild and common COVID-19 pneumonia (n = 100)	Hydroxychloroquine sulfate group: Hydroxychloroquine sulfate 0.2 g BID × 14 days Chloroquine phosphate group: First dose of chloroquine phosphate 1 g × 2 days, then 0.5 g × 12 days	Standard treatment	Clinical recovery time
ChiCTR2000030031	Recruiting	Single Center RCT	China	Mild and common COVID-19 pneumonia (n = 120)	2 tablets Chloroquine phosphate BID	2 tablets placebo BID	Time of conversion to be negative of novel coronavirus nucleic acid
ChiCTR2000029992	Pending approval	Single Center RCT	China	Severe COVID-19 pneumonia (n = 100)	Chloroquine phosphate group: Chloroquine phosphate 1.0 g × 2 days, then 0.5 g × 12 day from the third day Hydroxychloroquine sulfate group: Hydroxychloroquine sulfate 0.2 g BID x 14 days	Standard treatment	Clinical recovery time; Changes in viral load of upper and lower respiratory tract samples compared with the baseline
ChiCTR2000029988	Recruiting	Single Center RCT	China	Severe COVID-19 pneumonia (n = 80)	Chloroquine phosphate	Standard treatment	Time to Clinical Recovery
ChiCTR2000029975	Pending approval	Single CenterSingle-arm clinical trial	China	COVID-19 pneumonia (n = 10)	150 mg chloroquine phosphate dissolved in 5 ml of normal saline, q12h, inhaled by atomization for one week	No comparison group	Viral negative-transforming time; 30-day cause-specific mortality; Co-infections; Time from severe and critical patients to clinical improvement
ChiCTR2000029939	Recruiting	Single Center RCT	China	COVID-19 pneumonia (n = 100)	Chloroquine phosphate	Standard treatment	Length of hospital stay
ChiCTR2000029935	Recruiting	Single CenterSingle-arm clinical trial	China	COVID-19 pneumonia (n = 100)	Chloroquine phosphate	No comparison group	Length of hospital stay
ChiCTR2000029899	Recruiting	Single Center RCT	China	Mild and Common COVID-19 pneumonia (n = 100)	Hydroxychloroquine: Day1: first dose: 6 tablets (0.1 g/table), second dose: 6 tablets (0.1 g/table) after 6 h; Day 2–10: 2 tablets/day (0.1 g/table)	Phosphate chloroquine: Day1–3: 500 mg BID; Day4–10: 250 mg BID	Time to Clinical Recovery
ChiCTR2000029898	Recruiting	Single Center RCT	China	Severe COVID-19 pneumonia (n = 100)	Hydroxychloroquine Day1: first dose: 6 tablets (0.1 g/tablet), second dose: 6 tablets (0.1 g/tablet) after 6 h; Day2–10: 2 tablets/day (0.1 g/tablet)	Phosphate Chloroquine Day1–3: 500 mg BID; Day4–10: 250 mg BID	Time to Clinical Improvement
ChiCTR2000029868	Recruiting	Multi-Center RCT	China	COVID-19 pneumonia (n = 200)	Oral hydroxychloroquine sulfate tablets	Standard treament	Viral nucleic acid test
ChiCTR2000029837	Pending approval	Single Center RCT	China	Mild and common COVID-19 pneumonia (n = 120)	2 tablets Chloroquine phosphate BID	2 tablets placebo BID	Negative conversion rate of COVID-19 nucleic acid
ChiCTR2000029826	Pending approval	Single Center RCT	China	Critically ill COVID-19 pneumonia (n = 45)	2 tablets Chloroquine phosphate BID	2 tablets placebo BID	Mortality rate
ChiCTR2000029803	Pending approval	Single Center RCT	China	Close contacts with suspected or confirmed cases, and positive test of COVID-19 nucleic acid (n = 320)	Group A1: Hydroxychloroquine, small dose; Group A2: Hydroxychloroquine, high dose	Group B1: Abidol hydrochloride low dose; Group B2: Abidol hydrochloride high dose	Progression to suspected or confirmed disease within 24 days
ChiCTR2000029762	Recruiting	Single Center RCT	China	COVID-19 pneumonia (n = 60)	Hydroxychloroquine tablet	Standard treatment	Negative conversion rate of COVID-19 nucleic acid; lung inflammation absorption ratio
ChiCTR2000029761	Recruiting	Multi-Center RCT	China	Common COVID-19	Low-dose group: Low-dose hydroxychloroquine;	Standard treatment	Negative conversion rate of COVID-19 nucleic acid; lung

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Table 1 (*continued*)

ID	Recruiting Status	Number of centers and Study design	Country	Population (n patients)	Intervention Group(s)	Comparison Group(s)	Primary Outcomes
				pneumonia (n = 240)	Medium-dose group: Medium-dose hydroxychloroquine; High-dose group: High-dose hydroxychloroquine		inflammation absorption ratio
ChiCTR2000029741	Recruiting	Multi-Center RCT	China	Mild and common COVID-19 pneumonia (n = 112)	Chloroquine phosphate	Lopinavir/Ritonavir	All-cause mortality at day 28; length of stay; oxygen index during treatment; blood cell count; inflammation serum factors; coagulation indicators
ChiCTR2000029740	Recruiting	Single Center RCT	China	COVID-19 pneumonia (n = 78)	Oral intake hydroxycholoroquine 0.2 g BID	Standard treatment	Negative conversion rate of COVID-19 nucleic acid; prognosis; oxygen index; respiratory rate; lung radiography; temperature; count of lymphocyte; temperature; other infections
ChiCTR2000029609	Pending approval	Multi-Center Non-randomized controlled trial	China	COVID-19 pneumonia (n = 205)	Mild-moderate Chloroquine group: oral Chloroquine phosphate; Mild-moderate combination group: Chloroquine phosphate plus Lopinavir/ritonavir; Severe Chloroquine group: oral Chloroquine phosphate	Mild-moderate Lopinavir/Ritonavir group: oral Lopinavir/Ritonavir; Severe Lopinavir/Ritonavir group: oral Lopinavir/ritonavir	Negative conversion rate of COVID-19 nucleic acid
ChiCTR2000029559	Recruiting	Single center RCT	China	COVID-19 pneumonia (n = 300)	Group 1: Hydroxychloroquine 0.1 g oral BID; Group 2: Hydroxychloroquine 0.2 g oral BID	Placebo control group: Starch pill oral BID	Negative conversion rate of COVID-19 nucleic acid; T cell recovery time
ChiCTR2000029542	Recruiting	Single center prospective cohort study	China	COVID-19 pneumonia (n = 20)	Oral chloroquine 0.5 g BID for 10 days	Standard treatment	Negative conversion rate of COVID-19 nucleic acid; 30-day cause specific mortality
NCT04286503	Not yet recruiting	Multi-center RCT	China	Critically ill COVID-19 pneumonia (n = 520)	Carrimycin	lopinavir/ritonavir or Arbidol or Chloroquine phosphate	Fever to normal time; pulmonary inflammation resolution time at 30 day; negative conversion of COVID-19 nucleic acid at the end of treatment
NCT04261517	Not yet recruiting	Single center RCT	China	COVID-19 pneumonia (n = 30)	Hydroxychloroquine 400 mg/day for 5 days	Standard treatment	Mortality rate at day 14; Virological clearance rate of throat swabs, sputum, or lower respiratory tract secretions at day 3,5,7

For data entry, we used the definitions and the information provided by the investigators in the trial registries, if available. The number of patients in the Population columns refers to the reported sample size. In the 'Primary outcomes column' we reported only the primary outcomes, as described by the investigators; BID: twice per day; RCT: Randomized controlled trial.

3. Results

The initial search identified 234 sources (156 from PubMed, 73 EMBASE and 5 from other sources). Following screening of titles and abstracts and removing duplicates, we evaluated eight articles in full text. Among these, we found six relevant articles (one narrative letter, one research letter, one editorial, one expert consensus paper in Chinese, one national guideline document in Dutch and one in Italian) [3,5–9]. Twenty-three trials were found in the trial registries (Table 1).

4. Discussion

The research letter, written by a group of Chinese researchers, studied the effect of chloroquine in vitro, using Vero E6 cells infected by SARS-CoV-2 at a multiplicity of infection (MOI) of 0.05. The study demonstrated that chloroquine was highly effective in reducing viral replication, with an Effective Concentration $(EC)_{90}$ of 6.90 μM that can be easily achievable with standard dosing, due to its favourable penetration in tissues, including in the lung [6]. The authors described that chloroquine is known to block virus infection by increasing endosomial ph and by interfering with the glycosylation of cellular receptor of SARS-CoV. The authors also speculated on the possibility that the known immunomodulant effect of the drug may enhance the antiviral effect in vivo [6].

A narrative letter by Chinese authors reported that a news briefing from the State Council of China had indicated that "Chloroquine phosphate… had demonstrated marked efficacy and acceptable safety in treating COVID-19 associated pneumonia in multicentre clinical trials conducted in China" [5]. The authors also stated that these findings came from "more than 100 patients" included in the trials [5]. We sought for evidence of such data in the trial registries we reviewed and found none.

The Editorial written by French researchers, underlined the in-vitro efficacy of chloroquine in other viral infections, especially SARS (whose disappearance resulted in limited further research). They also discussed the potentially favourable risk-benefit balance, the high safety, and the low expenditure of such treatment in the context of the current COVID-19 outbreak [3]. Since cases were reported in 85 countries so far (5th March 2020), the low cost of chloroquine is a major benefit for both the highly stressed healthcare systems of involved high-income countries and the underfunded heathcare systems of middle- and low-income counties [10].

The expert consensus was published on 20th February by a multicentre collaboration group of the Department of Science and

Technology of Guangdong Province and Health Commission of Guangdong Province paper and related specifically to the use of chloroquine phosphate [7]. No information was provided on the method used to achieve consensus [7]. Based on in vitro evidence and still unpublished clinical experience, the panel recommended chloroquine phosphate tablet, at a dose of 500 mg twice per day for 10 days, for patients diagnosed as mild, moderate and severe cases of SARS-CoV-2 pneumonia, provided that there were no contraindications to the drug. The panel recommended using several precautions, including blood testing to rule out the development of anemia, thrombocytopenia or leukopenia as well as serum electrolyte disturbances and/or hepatic and renal function dysfunction. Also recommended were routine electrocardiography to rule out the development of QT interval prolongation or bradycardia and patient interviews to seek the appearance of visual and/or mental disturbance/deterioration. The panel recommended avoiding concurrent administration of other drugs known to prolong the QT interval (i.e. chinolones, macrolides, ondansetron) as well as various antiarrhythmic, antidepressant and antipsychotic drugs [7].

The Dutch Center of Disease control (CDC), in a public document on its website, suggested to treat severe infections requiring admission to the hospital and oxygen therapy or admitted to the ICU with chloroquine, [8]. However, the document also stated that treating patients only with optimal supportive care is still a reasonable option, due to lack of supportive evidence. The suggested regimen in adults consists of 600 mg of chloroquine base (6 tablets A-CQ 100 mg) followed by 300 mg after 12 h on day 1, then 300 mg × 2/die per os on days 2–5 days. This document also underlined 1) the needs for stopping the treatment at day 5 to reduce the risk of side effects, considering the long half-life of the drug (30 h); 2) the need to differentiate between regimens based on chloroquine phosphate and chloroquine base since 500 mg of the first correspond to 300 mg of the second [8].

Another guideline document by the Italian Society of Infectious and Tropical disease (Lombardy section) recommend the use of chlorochine 500 mg × 2/die or hydroxychloroquine 200 mg die for 10 days, although the treatment may vary from 5 to 20 days according to clinical severity. The suggested target population ranged from patients with mild respiratory symptoms and comorbidities to patients with severe respiratory failure [9].

Our search also identified ongoing 23 trials, all in China (Table 1). The trials varied in study design, severity of the disease in the target population and in dosing and duration of the treatment. Indeed, the trial registrations varied also in quality of the reported information. That so many such studies are being conducted in parallel suggests that that the scientific community is making a huge effort to clarify this question, but this effort is probably insufficiently coordinated. In support of this observation, the Chinese authorities have recently issued a directive to regulate and coordinate clinical trials studying potential pharmacological treatments for COVID-19 [11]. The results of these trials will be the first available on humans, since studies published to date on the characteristics and management of patients with COVID-19 did not report data about chloroquine use [1,12–15]. Of note, the WHO published a generic protocol for randomized clinical trials to investigate the clinical efficacy and safety of drugs in hospitalized patients with COVID-19 (i.e. a "master template" for researching drugs in this setting) [16].

The vital ethical issue is whether administration of chloroquine in the setting of COVID-19 is experimental, and therefore requires ethical trial approval, or off-label (i.e. ethically justifiable as the best available treatment). Additional information on chloroquine will soon be released in the context of the evolving outbreak. Timely release of this information can be of importance due to the growing number of infected patients, and the absence of licensed specific drugs. Meanwhile, the recommendations for "Clinical management of severe acute respiratory infection when novel coronavirus (2019-nCoV) infection is suspected", published by the WHO, confirm that there is currently no evidence from RCTs to inform on specific drug treatment of COVID-19 and that unlicensed treatments should be administered only in the context of ethically-approved clinical trials or the Monitored Emergency Use of Unregistered Interventions Framework (MEURI), under strict monitoring [17]. The WHO therefore seems to view chloroquine as experimental. The authors tend to agree with this viewpoint. But even off-label use of chloroquine may be accompanied by several concerns; the first is patient safety. Such use should be accompanied by close monitoring. An epidemic is hardly the ideal setting to do this. The ethical approach to off-label drug use also differs between countries, raising questions regarding equity. Finally, chloroquine remains a pivotal drug in the treatment of Malaria in many places in the world. Off label drug use can create major drug shortages [18].

5. Conclusion

There is sufficient pre-clinical rationale and evidence regarding the effectiveness of chloroquine for treatment of COVID-19 as well as evidence of safety from long-time use in clinical practice for other indications [3] to justify clinical research on the topic. The current circumstances justify prioritization of ethical review of study proposals above other, less pressing, research topics (i.e. fast track institutional ethical review). Although the use of chloroquine may be supported by expert opinion, clinical use of this drug in patients with COVID-19 should adhere to the MEURI framework or after ethical approval as a trial as stated by the WHO. Data from high-quality, coordinated, clinical trials coming from different locations worldwide are urgently needed.

Authors' contribution

AC conceived the content, retrieved the data, wrote the manuscript and approved the final version. MI retrieved the data, wrote the manuscript and approved the final version. GI retrieved the data, wrote the manuscript and approved the final version. AG conceived the content, helped in data extraction, revised the manuscript critically and approved the final version. SE conceived the content, helped in data extraction, wrote the manuscript and approved the final version.

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None.

Declaration of Competing Interest

AC, GI, MI, AG, SE declare to have no competing interests.

Acknowledgment

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcrc.2020.03.005.

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From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/18/2020 1:15:56 PM
To: Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Uyeki, Timothy M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f106bd981def4bfeb945e86b266662b2-HHS-tmu0-cd]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcfcc02744b3a6-HHS-carrie.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Auchincloss, Hugh (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab02b9d7c8514b538a08bab4a6659fba-HHS-auchinc]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]
Subject: RE: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
Attachments: Cortegniani et al_Review of Chloroquine in COVID-19_JCritCare_Mar132020.pdf

Review paper from Italy
Parizia

From: Higgs, Elizabeth (NIH/NIAID) [E] (b) (6)
Sent: Wednesday, March 18, 2020 12:26 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Higgs, Elizabeth S (NIH) (b) (6); Bright, Rick (OS) <Rick.Bright@hhs.gov>; Fauci, Anthony S (NIH) (b) (6); Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Guram, Jeet

<Jeet.Guram@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Davis, May M. EOP/WHO (b) (6); Raza, Mark <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Wolinetz, Carrie D (NIH) (b) (6); Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Auchincloss, Hugh (NIH) (b) (6); Marston, Hilary D (NIH) (b) (6)
Subject: Re: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

Colleagues,
(b) (5)
Kind regards,
Libby

Elizabeth S. Higgs, MD, DTMH, MIA
Global Health Science Advisor
Division of Clinical Research
National Institute of Allergy and Infectious Diseases
NIH, HHS, USG
(b) (6)

From: Anand.Shah@fda.hhs.gov
When: 12:00 PM - 12:45 PM March 18, 2020
Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
Location: (b) (6); (b) (6)

-----Original Appointment-----
From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:55 AM
To: Shah, Anand; Bright, Rick (OS/ASPR/BARDA); Fauci, Anthony (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Cavazzoni, Patrizia (FDA/CDER); Guram, Jeet; Farley, John (FDA/CDER); Roberts, Rosemary (FDA/CDER); Amin, Stacy (FDA/OC); Davis, May M. EOP/WHO; Raza, Mark (FDA/OC); Edmonds, Amanda (FDA/OC); Beers, Donald (FDA/OC); Zembower, Jenna (FDA/OC); Uyeki, Timothy M. (CDC/DDID/NCIRD/ID); Lenihan, Keagan (FDA/OC); Wolinetz, Carrie (NIH/OD) [E]; Shuy, Bryan (OS/ASPR/IO); Disbrow, Gary (OS/ASPR/BARDA); Auchincloss, Hugh (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]
Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
When: Wednesday, March 18, 2020 12:00 PM-12:45 PM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6); (b) (6)

Participants on this call:

FDA

Anand Shah, Office of the Commissioner, Deputy Commissioner for Medical & Scientific Affairs
Keagan Lenihan, Office of the Commissioner, Chief of Staff
Jeet Guram, Office of the Commissioner, Senior Advisor
Janet Woodcock, CDER, Director
Patrizia Cavazzoni, CDER, Deputy Director for Operations
John Farley, CDER Office of Infectious Diseases, Director
Rosemary Roberts, CDER Counter-Terrorism and Emergency Coordination Staff, Director
Stacy Amin, Office of the Chief Counsel, Chief Counsel
Mark Raza, Office of the Chief Counsel, Deputy Chief Counsel
Amanda Edmonds, Office of the Chief Counsel, Deputy Chief Counsel for Program Review for Biologics and Drugs

ASPR/BARDA
Rick Bright, Deputy Assistant Secretary for Preparedness and Response (ASPR) & Director of the Biomedical Advances Research and Development Authority (BARDA)
Brian Shuy, ASPR Deputy Assistant Secretary and Chief of Staff
Gary Disbrow, Acting Deputy Director of BARDA

NIH
Anthony Fauci, NIAID, Director
Hugh Auchincloss, NIAID, Principal Deputy Director
Carrie Wolinetz, Acting Chief of Staff
Hilary Marston, Office of the Chief of Staff, Medical Officer/Policy Advisor

CDC
Timothy Uyeki, National Center for Immunization and Respiratory Diseases

White House
May Davis, Associate White House Counsel

(b) (5)

Thank you

Best,
Anand

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From: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) [tmu0@cdc.gov]
Sent: 3/19/2020 12:19:38 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcfcc02744b3a6-HHS-carrie.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Auchincloss, Hugh (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab02b9d7c8514b538a08bab4a6659fba-HHS-auchinc]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Lankford, David W (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d9ca5f75534cd8a2f3d22c3beb2e0b-HHS-Lankfor]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]
CC: Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Pillai, Satish K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e43838cb79744d390db5bd55b132650-HHS-vig8-cd]
Subject: RE: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
Attachments: Information for Clinicians on COVID-19 Therapies 03192020_v2.docx

(b) (5)

It is planned for posting on the CDC webpages.
Thanks,

Tim

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Thursday, March 19, 2020 11:10 AM
To: Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6); Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Guram, Jeet (FDA/OC) <Jeet.Guram@fda.hhs.gov>; Farley, John (FDA/CDER) <John.Farley@fda.hhs.gov>; Roberts, Rosemary (FDA/CDER) <Rosemary.Roberts@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Davis, May M. EOP/WHO (b) (6); Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda (FDA/OC) <Amanda.Edmonds@fda.hhs.gov>; Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>; Zembower, Jenna (FDA/OC) <Jenna.Zembower@fda.hhs.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Wolinetz, Carrie (NIH/OD) [E] (b) (6); Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Auchincloss, Hugh (NIH/NIAID) [E] (b) (6); Marston, Hilary (NIH/NIAID) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6); Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>
Subject: RE: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

Let's all try this alternate number, I will dal in as leader

Dial In Number Local/Toll Number (b) (6) Freephone/Toll Free Number (b) (6) Passcodes Leader: (b) (6) Participant: (b) (6)

-----Original Appointment-----
From: Zembower, Jenna **On Behalf Of** Shah, Anand
Sent: Wednesday, March 18, 2020 3:27 PM
To: Shah, Anand; Bright, Rick (OS); Fauci, Anthony S (NIH); Woodcock, Janet; Cavazzoni, Patrizia; Guram, Jeet; Farley, John; Roberts, Rosemary; Amin, Stacy; Davis, May M. EOP/WHO; Raza, Mark; Edmonds, Amanda; Beers, Donald; Zembower, Jenna; Uyeki, Timothy M (CDC); Lenihan, Keagan; Wolinetz, Carrie D (NIH); Shuy, Bryan (OS); Disbrow, Gary (OS); Auchincloss, Hugh (NIH); Marston, Hilary D (NIH); Lankford, David W (NIH); Mair, Michael
Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
When: Thursday, March 19, 2020 11:00 AM-11:45 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6),,(b) (6)

POC for Scheduling: Jenna Zembower (Office of the Commissioner, FDA)

Agenda

(b) (5)

Participants on this call:

FDA

- Anand Shah, Office of the Commissioner, Deputy Commissioner for Medical & Scientific Affairs
- Keagan Lenihan, Office of the Commissioner, Chief of Staff
- Jeet Guram, Office of the Commissioner, Senior Advisor
- Michael Mair, Acting Assistant Commissioner for Counterterrorism Policy, Office of the Chief Scientist

- Janet Woodcock, CDER, Director
- Patrizia Cavazzoni, CDER, Deputy Director for Operations
- John Farley, CDER Office of Infectious Diseases, Director
- Rosemary Roberts, CDER Counter-Terrorism and Emergency Coordination Staff, Director
- Stacy Amin, Office of the Chief Counsel, Chief Counsel
- Mark Raza, Office of the Chief Counsel, Deputy Chief Counsel
- Amanda Edmonds, Office of the Chief Counsel, Deputy Chief Counsel for Program Review for Biologics and Drugs

ASPR/BARDA
- Rick Bright, Deputy Assistant Secretary for Preparedness and Response (ASPR) & Director of the Biomedical Advances Research and Development Authority (BARDA)
- Brian Shuy, ASPR Deputy Assistant Secretary and Chief of Staff
- Gary Disbrow, Acting Deputy Director of BARDA

NIH
- Anthony Fauci, NIAID, Director
- Hugh Auchincloss, NIAID, Principal Deputy Director
- Carrie Wolinetz, Acting Chief of Staff
- Hilary Marston, Office of the Chief of Staff, Medical Officer/Policy Advisor

CDC
- Timothy Uyeki, National Center for Immunization and Respiratory Diseases

White House
- May Davis, Associate White House Counsel

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Meeting number (access code): (b) (6)
Meeting password: (b) (6)

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+1-877-465-7975 US Toll Free
Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

Need help? Go to http://help.webex.com

From: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Sent: 3/17/2020 2:09:23 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: Can you contact me? Need some advice. Time good for you? jw

Yes.

On Mar 17, 2020, at 2:05 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

Just lost my window so can call at around 4? Thanks!!jw

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Tuesday, March 17, 2020 1:54 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Can you contact me? Need some advice. Time good for you? jw

Now is good. What number? My cell is (b) (6) . Or any time between 4 and 6pm today I can walk away from any other meeting.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 1:51 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Subject: Can you contact me? Need some advice. Time good for you? jw

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/18/2020 10:08:14 AM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]
Subject: Int Call - FDA / BARDA / NIH (chloroquine)

Importance: High

Dear Rick and Tony -

(b) (5)

Would you both, or a designee, be available for a call at 12:00pm today (Wednesday, March 18th) (b) (5) An invitation will be forthcoming, please let me know if you have any questions.

Thank you

Best,
Anand

Anand Shah, MD
Deputy Commissioner for Medical and Scientific Affairs
U.S. Food and Drug Administration

PRE-DECISIONAL, CONFIDENTIAL

From: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Sent: 3/17/2020 4:05:15 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: I'm back.

Sorry I missed too. Free now. (b) (6)

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From: Amin, Stacy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB3764B7438648838C22881A06FC6AFB-STACY.AMIN]
Sent: 3/11/2020 8:59:39 PM
To: (b) (6)
CC: Williams, James H. EOP/WHO (b) (6); Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; (b) (6); Sinclair, Michael R. EOP/NSC (b) (6); Cavanaugh, Brian J. EOP/NSC (b) (6); Barry, Daniel J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a27773dc40564218b76dc8ec50ceb0d5-HHS-daniel.]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: For Review: Proposed Medical Supply Chain EO
Attachments: FOUO - Proposed Medical Supply Chain EO FDA Comments.docx

Hello, attached are (b) (5)

Seth – could you possibly add me to the distribution list please? I have been getting them forwarded.

Thank you.

From: Jonas, Seth H. EOP/NSC (b) (6)
Date: March 10, 2020 at 10:46:03 PM EDT
To: (b) (6) Nazak Nikakhtar <Nazak.Nikakhtar@trade.gov>, (b) (6) Williams, James H. EOP/WHO (b) (6), Stanich.Ted@epa.gov <Stanich.Ted@epa.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, (b) (6) Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Phillips, Sally (OS) <Sally.Phillips@hhs.gov>, Storch, Thomas H. EOP/NSC (b) (6), Kan, Derek T. EOP/OMB (b) (6), Watson, Ian D. EOP/OSTP (b) (6), McCommas, Brendan N. EOP/WHO (b) (6), Abbott, Christopher J. EOP/WHO (b) (6), Gerrish, Jeffrey D. EOP/USTR (b) (6), john.mashburn@va.gov <john.mashburn@va.gov>, DeBacker, Devin A. EOP/WHO (b) (6), William.C.Hughes@usdoj.gov <William.C.Hughes@usdoj.gov>, fenwickpa@state.gov <fenwickpa@state.gov>, Lin, Merry S. EOP/WHO (b) (6) Sinclair, Michael R. EOP/NSC (b) (6), Ferro, Phil J. EOP/NSC (b) (6)
Cc: Cavanaugh, Brian J. EOP/NSC (b) (6) @
Subject: For Review: Proposed Medical Supply Chain EO

Message sent on behalf of Brian J. Cavanaugh, Special Assistant to the President and Senior Director for Resilience Policy


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From: Jonas, Seth H. EOP/NSC (b) (6)
Sent: 3/10/2020 10:45:48 PM
To: (b) (6) Nazak Nikakhtar [Nazak.Nikakhtar@trade.gov]; (b) (6); Williams, James H. EOP/WHO (b) (6); Stanich.Ted@epa.gov; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; joel.doolin@fema.dhs.gov; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Storch, Thomas H. EOP/NSC (b) (6); Kan, Derek T. EOP/OMB (b) (6); Watson, Ian D. EOP/OSTP (b) (6); McCommas, Brendan N. EOP/WHO (b) (6); Abbott, Christopher J. EOP/WHO (b) (6); Gerrish, Jeffrey D. EOP/USTR (b) (6); john.mashburn@va.gov; DeBacker, Devin A. EOP/WHO (b) (6); William.C.Hughes@usdoj.gov; (b) (6) Lin, Merry S. EOP/WHO (b) (6); Sinclair, Michael R. EOP/NSC (b) (6); Ferro, Phil J. EOP/NSC (b) (6)
CC: Cavanaugh, Brian J. EOP/NSC (b) (6)
Subject: For Review: Proposed Medical Supply Chain EO
Attachments: FOUO - Proposed Medical Supply Chain EO.docx

Message sent on behalf of Brian J. Cavanaugh, Special Assistant to the President and Senior Director for Resilience Policy

# # #

Dear Restricted Supply Chain PCC Principals,

As discussed at the PCC today, attached please find (b) (5) (b) (5) Please remember that the attached document is deliberative, pre-decisional, executive-privileged material. Please handle accordingly and please do not distribute further.

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From: Jonas, Seth H. EOP/NSC (b) (6)
Sent: 3/8/2020 10:55:12 PM
To: McCommas, Brendan N. EOP/WHO (b) (6); Abbott, Christopher J. EOP/WHO (b) (6); Storch, Thomas H. EOP/NSC (b) (6); DeBacker, Devin A. EOP/WHO (b) (6); Kan, Derek T. EOP/OMB (b) (6); Williams, James H. EOP/WHO (b) (6); Watson, Ian D. EOP/OSTP (b) (6); Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; John.Mashburn@va.gov; (b) (6); Nazak Nikakhtar [Nazak.Nikakhtar@trade.gov]; Stanich.Ted@epa.gov; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Gerrish, Jeffrey D. EOP/USTR (b) (6); (b) (6)
CC: Butterfield, Nicholas W. EOP/WHO (b) (6); Cavanaugh, Brian J. EOP/NSC (b) (6)
Subject: Snap restricted PCC on supply chain
Attachments: FOUO - Proposed COVID Supply Chain EO.docx

Importance: High

Message sent on behalf of Brian J. Cavanaugh, Special Assistant to the President and Senior Director for Resilience Policy

# # #

Dear Colleagues,

(b) (5)

The meeting will be held tomorrow, 03/09/2020, from 1500-1630, in EEOB 374 (SMS Large).

Please complete WAVES by 1200-noon at the following URL:
https://events.whitehouse.gov/?rid=FCDWQ77WY7

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/25/2020 5:09:07 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Howard, Jeff D. Jr. EOP/OVP (b) (6)
Subject: Re: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

(b) (5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 25, 2020 at 5:02:24 PM EDT
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Howard, Jeff D. Jr. EOP/OVP(b) (6)
Subject: Re: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

(b) (5)

From: Janet Woodcock <Janet.Woodcock@fda.hhs.gov>
Date: Wednesday, March 25, 2020 at 3:34 PM
To: Jeff Shuren <Jeff.Shuren@fda.hhs.gov>, "Howard, Jeff D. Jr. EOP/OVP" (b) (6), "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: RE: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

We will take a look at this. Seems like a long shot. jw

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 2:51 PM
To: Howard, Jeff D. Jr. EOP/OVP (b) (6); Bright, Rick (OS) <Rick.Bright@hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Fwd: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

(b) (5)

Jeff

From: Howard, Jeff D. Jr. EOP/OVP (b) (6)
Date: March 25, 2020 at 1:29:46 PM EDT
To: Bright, Rick (OS) <Rick.Bright@hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

Gentlemen,

(b) (5)

Jeff Howard, MD, MBA, MPH
Office of the Vice President

From: Frederic Bourke <fabourke@immunolight.com>
Sent: Wednesday, March 25, 2020 8:35 AM
To: Howard, Jeff D. Jr. EOP/OVP (b) (6)
Subject: [EXTERNAL] Fwd:

Jeff this should give you a quick overview of what we are proposing. Thanks so much for your time

Sent from my iPhone

Begin forwarded message:

From: harold <hwalder@immunolight.com>
Date: March 24, 2020 at 9:12:05 AM MDT
To: Rick Bourke <fabourke@immunolight.com>

Harold

Harold Walder
President
Immunolight, LLC
hwalder@immunolight.com
Immunolight.com

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/26/2020 9:37:33 AM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
Subject: (b) (5)

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/25/2020 8:25:21 AM
To: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Subject: RE: Quick call when you get a minute

(b) (5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Wednesday, March 25, 2020 12:12 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Quick call when you get a minute

(b) (5)

(b) (5) Thank you for all you do. You are amazing...always. Rick

On Mar 24, 2020, at 10:29 AM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

Spoke with your folks this am. jw

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 2:48 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Quick call when you get a minute

(b) (5) ...thanks, (b) (6)

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/24/2020 7:26:52 AM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
Subject: Re: URGENT Questions on planned study

Rick(b) (5) Happy to talk. Jw

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 23, 2020 at 10:54:40 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Johnson, Robert (OS) <Robert.Johnson@hhs.gov>, Walker, Robert (OS) <Robert.Walker@hhs.gov>, Faison, Tremel (OS) <Tremel.Faison@hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Marston, Hilary D (NIH) (b) (6), Lane, Henry C (NIH) (b) (6), Patel, Anita (CDC) <bop1@cdc.gov>, Uyeki, Timothy M (CDC) <tmu0@cdc.gov>, Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6), Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>, Beigel, John H (NIH) (b) (6), Higgs, Elizabeth S (NIH) (b) (6), Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: Re: URGENT Questions on planned study

Thank you Stacy. (b) (5)

(b) (5)

Thank you for all you are doing.

Rick

Sent from my iPhone

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

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

Happy to talk at your earliest convenience. Could you suggest a time? (b) (5)

(b) (5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 9:09 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Walker, Robert (OS) <Robert.Walker@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Lambert, Linda (OS) <Linda.Lambert@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Marston, Hilary D (NIH) (b) (6); Lane, Henry C (NIH) (b) (6); Patel, Anita (CDC) <bop1@cdc.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6); Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Beigel, John H (NIH) (b) (6); Higgs, Elizabeth S (NIH) (b) (6); Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>
Subject: URGENT Questions on planned study

Hi Stacy,

(b) (5)

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

Rick
Rick A. Bright, PhD
Director, BARDA
Deputy Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services

<mime-attachment>

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/23/2020 10:54:09 AM
To: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]; Josie Briggs [jbriggs@pcori.org]
Subject: RE: Can I connect you to PCORI/PCORNET

Thanks very much Rick! jw

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 10:46 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Can I connect you to PCORI/PCORNET

(b) (5)

And HANG IN THERE, STAY SAFE. WE NEED YOU! Rick

From: Janet Woodcock <Janet.Woodcock@fda.hhs.gov>
Date: Monday, March 23, 2020 at 10:26 AM
To: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: Can I connect you to PCORI/PCORNET

(b) (5)

Information Package - Resochin® (chloroquine phosphate) 250mg tablets

Bayer Pharmaceuticals

Date: 17 Mar 2020

Please note that this information package is intended to provide a general overview of summary level information on safety, known efficacy in the use of Chloroquine (Resochin®) as a potential "Therapeutic / Investigational Agent" in Symptomatic Patients infected with SARS-CoV-2 / COVID-19 Disease of coronavirus, and Chinese guidelines on dosing for the treatment on COVID-19.

1. What is Chloroquine?

Chloroquine was discovered in 1934 by Bayer scientists in Germany and shown to have promising activity against the pathogen causing Malaria (*Plasmodium spp.*) It only came into clinical use both in the treatment and prophylaxis of Malaria after the second world war and subsequently was shown to also possess clinical efficacy in rheumatoid arthritis, including juvenile rheumatoid arthritis as well as in systemic lupus erythematosus. In addition, it was shown to be useful in certain forms of resistant amoebiasis. The use of Chloroquine in Malaria has constantly declined over the past decades due to increasing resistance of Plasmodium, but it still has clinical utility in areas where chloroquine resistance rates are low. Chloroquine is listed in the WHO *Model List of Essential Medicines, 21st edition 2019,* for the treatment and chemoprevention/prophylaxis of Malaria (caused by *Plasmodium vivax*).

Chloroquine (as phosphate salt) has been marketed by Bayer in many countries under the tradename **Resochin®.**

2. What are the clinical indications of Resochin® and safety profile for these indications?

The clinical indications of Resochin® are:

- Prophylaxis and treatment of the four malarial Plasmodium species that are pathogenic to humans, with the exception of chloroquine-resistant strains.
- Extraintestinal amoebiasis when nitroimidazole products are ineffective or cannot be used.
- Chronic polyarthritis (rheumatoid arthritis, RA), including juvenile rheumatoid arthritis.
- Systemic lupus erythematosus.

Typical Adverse Events
Resochin® is generally well tolerated when used at regular doses (250 - 500 mg once-daily for treatment or 500 mg once a week for prophylaxis) over short periods of time. When used over extended periods of time (> 5 years), e.g. in the treatment of RA, it has been shown to cause permanent damage to the eye (irreversible retinopathy) and therefore the total cumulative lifetime dose should not exceed 1 g per KG bodyweight). Cardiac toxicity has also been observed, typically at very high doses well above the therapeutic dose (acute intentional and unintentional overdose). This can result in cardiac arrhythmias, which can be life-threatening).[1]

Contraindications
- Hypersensitivity to chloroquine or any of the excipients or to other 4-aminoquinolones
- Retinopathy or impairment of the visual field
- Disorders of the hematopoietic system
- Glucose-6-phosphate dehydrogenase deficiency (favism; symptom: hemolytic anemia)
- Myasthenia gravis
- Pregnancy and breastfeeding (exceptions: malarial therapy and short-term prophylaxis)

QT prolongation
Resochin may increase the QT interval in acute overdose and at the recommended doses.

Chloroquine should be used with caution in patients with congenital or documented acquired QT prolongation and/or known risk factors for prolongation of the QT interval such as:
- cardiac disease e.g. heart failure, myocardial infarction
- proarrhythmic conditions e.g. bradycardia (< 50 bpm)
- a history of ventricular dysrhythmias
- uncorrected hypokalemia and/or hypomagnesemia
- and during concomitant administration with QT interval prolonging agents (see section 4.5 'Interaction with other medicinal products and other forms of interaction') as this may lead to an increased risk for ventricular arrhythmias, sometimes with fatal outcome.

At high therapeutic doses of chloroquine a cardiac risk for arrhythmia cannot be excluded, especially in case of co-morbidities. Therefore, the recommended dose should not be exceeded. If signs of cardiac arrhythmia occur during treatment with chloroquine, treatment should be stopped and an ECG should be performed.

Cardiotoxicity
Chloroquine may induce cardiotoxicity in acute overdose and at therapeutic dose. In acute overdose, chloroquine may induce acute heart failure and serious cardiac arrhythmias. At therapeutic dose, cardiomyopathy and various degrees of atrioventricular block were reported. Cardiomyopathy was mainly reported in patients with long term use, though it occurred after a few months' therapy in a few patients.

Cardiomyopathy may lead to heart failure, sometimes with fatal outcome. If signs and symptoms of cardiomyopathy occur during treatment with chloroquine, treatment should be stopped.

Hepatic impairment
Since chloroquine is known to accumulate in the liver, patients with impaired liver function may require an adjustment of the dose.

Renal impairment
Chloroquine is partially excreted by the kidneys. Therefore, patients with severely impaired kidney function may require a reduction of the dose.

End-stage renal disease (ESRD)
The use of Resochin in patients with renal failure with a creatinine clearance below 10 mL/min, i.e. ESRD, is not recommended due to a lack of data.

Nervous system
Epileptics sufferers receiving treatment with Resochin require regular medical check-ups.

Metabolic disorders
Caution is necessary in patients with porphyria, as the use of chloroquine could lead to deterioration of symptoms.

Skin disorders
Caution is also necessary in patients with psoriasis, as the use of chloroquine could lead to
deterioration of symptoms.

Hypoglycaemia
Chloroquine has been shown to cause severe hypoglycaemia including loss of consciousness
that could be life threatening in patients treated with and without antidiabetic medications.
Patients treated with chloroquine should be warned about the risk of hypoglycaemia and the
associated clinical signs and symptoms. Patients presenting with clinical symptoms suggestive of hypoglycaemia during treatment with chloroquine should have their blood
glucose level checked and treatment reviewed as necessary.

Retinopathy
An ophthalmological examination must be carried out before the start of long-term therapy and repeated at 3-month intervals during treatment to check for possible adverse ocular effects. At the first sign of retinopathy (loss of the ability to perceive red), treatment must be discontinued. The primary recommended methods for retinopathy screening are automated visual fields and spectral domain optical coherence tomography (SD-OCT). If color vision testing is the only available screening method for retinopathy, chloroquine should only be administered in children who are able to perform the color vision test. Irreversible visual impairment resulting from chloroquine-induced retinopathy is a well documented complication of

long-term, high-dosage therapy. Retinal monitoring is recommended for long-term chloroquine recipients. Cumulative total doses of chloroquine 1 g base/kg body weight or 50-100 g total dose (base) have been associated with retinal damage. Retinopathy has rarely, if ever, resulted from doses recommended for malaria prophylaxis. It would be of significant concern only for those on long-term (>5 years) chloroquine prophylaxis.

Complete blood cell count
The blood cell count (red blood cells, white blood cells and platelets) must be checked before
initiating long-term treatment, and then at 2-month intervals.

Long-term prophylaxis in women of childbearing age
Female patients who are taking Resochin for the long-term prophylaxis of malaria should
ensure that they use adequate contraception methods during this time and avoid pregnancy for
3 months after stopping prophylaxis treatment.

Long-term treatments in children
Resochin should not be administered to children for long-term malarial prophylaxis.
A precaution should be taken while taking Resochin regarding the cumulative dose during long-term use indications

Interaction with other medicinal products and other forms of interaction
Drugs that affect Chloroquine:
Antacids and kaolin can reduce the absorption of chloroquine and it is recommended that these drugs are taken at least 4 hours apart.

Concomitant administration of phenylbutazone increases the likelihood of the development of exfoliative dermatitis.

Concomitant administration of probenecid increases the risk of sensitization.

Simultaneous administration of corticosteroid derivatives can accentuate myopathies or cardiomyopathies.

Resochin should not be taken concomitantly with substances with known potential for hepatotoxic reactions (such as isoniazid, amiodarone, carbamezipine, phenytoin, phenothiazides and ketoconazole) or MAO inhibitors (such as phenelzine, tranylcypromide, isocarboxazid and selegiline).

Cimetidine can reduce the excretion of chloroquine.

The concurrent use of mefloquine and buproprion may increase the risk of seizures.

An acute dystonic reaction has been observed after simultaneous administration of chloroquine and metronidazole.

Concurrent use with penicillamine may increase the potential for serious hematological and/or renal adverse events associated with penicillamine as well as skin reactions.

Combination of chloroquine and pyrimethamine/sulphadoxine distinctly increases the risk of skin reactions.

Effects of Chloroquine on other drugs:

Chloroquine has been reported to reduce the antibody response to human diploid-cell rabies vaccine (HDCV). However, the immune response to other vaccines used in routine immunization (tetanus, diphtheria, measles, poliomyelitis, typhoid and BCG) has not been found to be altered. If coadministration is unavoidable the Centers for Disease Control and Prevention, (Department of Health and Human Services, US) recommend that HDCV be administered intramuscularly, not intradermally, for pre-exposure rabies prophylaxis, since inadequate protection against rabies may result with intradermal administration of the vaccine, whilst intramuscular administration is likely to provide a sufficient margin of efficacy in these individuals.

Prolonged co-administration with digoxin can lead to glycoside intoxication via elevated plasma digoxin concentrations.

The action of folic acid antagonists (methotrexate) is potentiated by chloroquine.

Chloroquine antagonizes the effect of neostigmine and pyridostigmine.

Concurrent use with cyclosporin may cause a sudden increase in cyclosporin plasma concentrations.

Chloroquine may reduce the gastrointestinal absorption of ampicillin. Therefore, it is recommended that administration of ampicillin should occur at least two hours after chloroquine administration.

Drugs known to prolong QT interval / with potential to induce cardiac arrhythmia
Chloroquine should be used with caution in patients receiving drugs known to prolong the QT interval e.g. Class IA and III antiarrhythmics, tricyclic antidepressants, antipsychotics, some anti-infectives due to increased risk of ventricular arrhythmia.

Pregnancy
Chloroquine crosses the placental barrier and can provoke organ damage in the fetus. For this
reason chloroquine is contra-indicated throughout pregnancy (exception: malaria). Data on adverse outcomes following exposure to chloroquine during the first trimester are
particularly limited. The drug should only be used if absolutely necessary in pregnancy. The
risk: benefit ratio should be considered when advising pregnant women, as the risks of
malaria in pregnancy may outweigh any harmful effects of chemotherapy. Thus, if malaria is

a possibility, after evaluation of the risks and benefits a decision will as a rule be taken in
favor of the administration of Resochin, as the malarial infection itself is harmful to the fetus.

Lactation
2-4% of the ingested chloroquine dose passes into maternal milk. Although there are no
known cases of infants being harmed by milk containing chloroquine, breastfeeding should be
discontinued during the administration of Resochin as a precaution.

Women of childbearing potential / Contraception
The possibility of pregnancy must be ruled out before therapy with chloroquine is started for indications other than malaria. An effective form of contraception must be used throughout the course of the treatment and for at least 3 months after the end of the treatment. For malaria prophylaxis with chloroquine an effective form of contraception must be used for the duration of the prophylaxis and for 3 months afterwards.

Effects on ability to drive or use machines
On account of the potential side effects of chloroquine on the central nervous system (headache, dizziness, somnolence, states of confusion) and on vision (visual disturbances, retinopathy), the ability to drive and to operate machinery may be impaired.

Undesirable effects
The majority of the adverse drug effects observed after administration of Resochin are dose dependent, and occur above all at plasma concentrations in excess of 250 µg/L.

Acute overdose
Acute chloroquine intoxication (after severe overdosages of 2-5 g) can cause death within 1-3h as a result of a paralyzing effect on the cardiovascular system and on respiration. The prodromal stage is characterized by headache, visual disturbances, and heart rhythm disturbances. A fall in blood pressure may be followed by a shock state with loss of consciousness and convulsions. As a result of respiratory and cardiac arrest death may occur. Acute chloroquine overdose may cause QRS widening and QT prolongation, Torsade de pointes, ventricular arrhythmias, ventricular fibrillation and ventricular tachycardia.

Chronic overdose
Chronic overdose may lead to potentially fatal cardiomyopathy. If signs of a toxic cardiac effect are detected, treatment should be discontinued. The toxic cardiac effect may be reversible if recognized early.

Chronic overdose may lead to complete heart block (CAVB).

Management of Overdose in Man
There is no known antidote. Immediate elimination of the toxin by gastric lavage must be attempted. Respiratory and circulatory assistance (adrenaline) must then be

introduced at an early stage. The convulsions must be suppressed with benzodiazepines (diazepam), phenobarbital, and if necessary with peripheral muscle relaxants and artificial ventilation. Hemodialysis is inappropriate.

Pronounced hypokalemia requires correction.

3. What is the current knowledge on the (potential) utility of Chloroquine as a treatment for clinically symptomatic patients infected with SARS-CoV-2 (the Coronavirus type that causes COVID-19)?

There is only limited information and published data available on the utility of Chloroquine as a treatment for clinically symptomatic patients infected with SARS-CoV-2 at this point in time. However, in the current situation of the COVID-19 outbreak in China and its continuing spread in many parts of the world, Chloroquine has to be considered as one of the few options currently at hand for a potential causal treatment of patients with moderate to severe pneumonia.

The potential of Chloroquine as a therapeutic agent is based primarily on a recent pre-clinical study from Chinese scientists from Wuhan, published in January in *Cell Research* (1) The study tested several compounds with known anti-viral activity as well as Chloroquine and Remdesivir (a novel antiviral agent in development for the treatment of Ebola infection) in a standard *in vitro* assay using so called Vero E6 cells which were infected with SARS-CoV-2.

In this cell culture infection model, Chloroquine and Remdesivir were the only compounds which turned out to be highly active against SARSCoV-2. Chloroquine was shown to be effective at concentrations (so called EC_{90} values) which are well within the range of clinically achievable exposure levels at recommended malaria doses. It was also mentioned that the clinical experience and knowledge of its adverse event profile from decades of clinical use would be an advantage of Chloroquine over the “experimental compound” Remdesivir (for which, obviously, much less data and experience is currently at hand).

Overall, the results from this pre-clinical study resulted in the recommendation that both Chloroquine as well as Remdesivir should be further investigated in clinical studies in patients.

Subsequently, several clinical trials were set up in China. A total of 20 clinical trials are currently registered on the WHO International Clinical Trials Registry Platform (ICTRP) as of 05 March 2020 and no results have been posted yet. It is hoped that results from these studies will be reported in the near future, both on the registry website as well as in peer-reviewed scientific journals.

However, there have been some early hints of Chloroquine utility. Notably, on the occasion of the Chinese National Press Conference on 17 February 2020, which was also quoted by a short article by Gao et al. in the scientific journal *BioScienceTrends* (2), it was mentioned that “results from more than 100 patients have demonstrated

that chloroquine phosphate is superior to the control treatment in inhibiting the exacerbation of pneumonia, improving lung imaging findings, promoting a virus negative conversion, and shortening the disease course", but no specific detail results were mentioned. It was also noted that "severe adverse reactions to chloroquine phosphate were not noted in the aforementioned patients". The article continues in stating that "given these findings, a conference was held on February 15, 2020; and participants including experts from government and regulatory authorities and organizers of clinical trials reached an agreement that chloroquine phosphate has potent activity against COVID-19. The drug was recommended for inclusion in the next version of the Guidelines for the Prevention, Diagnosis, and Treatment of Pneumonia Caused by COVID-19 issued by the National Health Commission of the People's Republic of China"(3).

No further or more detailed data or results from the other ongoing clinical trials have been reported to date, but it is not unreasonable to expect further demand for Chloroquine, when and if these encouraging hints of Chloroquine utility materialize, even though it is currently seen as unlikely that regulatory approvals for clinical use in patients suffering from COVID-19 disease would be granted.

References

1) Manli Wang, Ruiyuan Cao, Leike Zhang, Xinglou Yang, Jia Liu,Mingyue Xu, Zhengli Shi, Zhihong Hu, Wu Zhong and Gengfu Xiao
State Key Laboratory of Virology, Wuhan Institute of Virology and Center for Biosafety Mega-Science, Chinese Academy of Sciences, 430071 Wuhan, China and National Engineering Research Center for the Emergency Drug, Beijing Institute of Pharmacology and Toxicology, 100850 Beijing, China

LETTER TO THE EDITOR: Remdesivir and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro

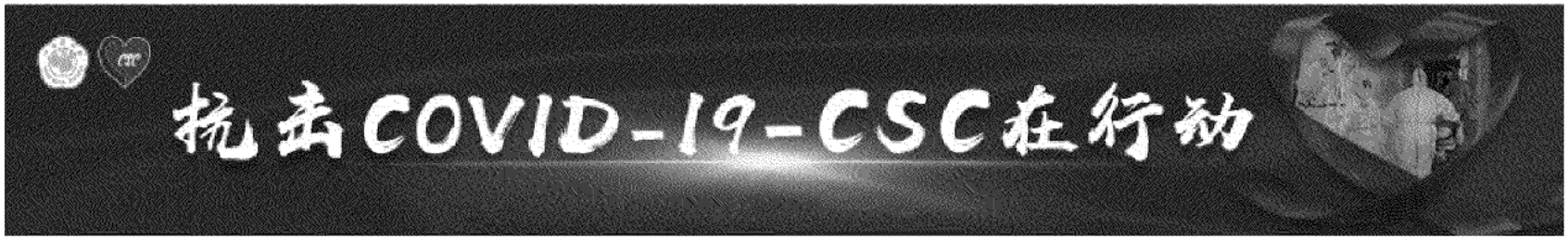
Cell Research (2020) 0:1–3; https://doi.org/10.1038/s41422-020-0282-0, published online Feb 4,2020

2) Jianjun Gao, Zhenxue Tian, Xu Yang
Department of Pharmacology, School of Pharmacy, Qingdao University and Department of Pharmacy, Qingdao Municipal Hospital, Qingdao, China.

Breakthrough: Chloroquine phosphate has shown apparent efficacy in treatment of COVID-19 associated pneumonia in clinical studies

Letter; BioScience Trends; Advance Publication Feb 19. 2020; DOI: 10.5582/bst.2020.01047

3) Guidelines for the Prevention, Diagnosis, and Treatment of Pneumonia Caused by COVID-19 issued by the National Health Commission of the People's Republic of China".



Chinese Clinical Guidance for COVID-19 Pneumonia Diagnosis and Treatment (7th edition)

Chinese Clinical Guidance for COVID-19 Pneumonia Diagnosis and Treatment (7th edition) (published by China National Health Commission on March 4, 2020)

中国国家卫生健康委《新型冠状病毒肺炎诊疗方案（第七版）》，发布时间：2020年3月4日

Since December 2019, a novel coronavirus pneumonia epidemic has appeared in Wuhan City, Hubei Province. With the spread of the epidemic, other cities in China and many countries abroad have also found such cases. As an acute respiratory infectious disease, the disease has been included in the Class B infectious diseases stipulated in the Law of the People's Republic of China on the Prevention and Control of Infectious Diseases, and is managed as a Class A infectious

disease. Through the adoption of a series of preventive control and medical treatment measures, the upward trend of the epidemic situation in China has been contained to a certain extent. The epidemic situation in most provinces has eased, but the number of outbreaks abroad is on the rise. With the deepen understanding of the clinical manifestations, pathological features of this disease and the accumulation of experience in diagnosis and treatment, in order to further strengthen the early diagnosis and early treatment of the disease, improve the cure rate, reduce the mortality rate, and avoid in-hospital infection, and alert for the disease transmission caused by overseas input cases, we revised the previous clinical guidance to form this 7th version.

1. Etiology

The novel coronavirus (termed as COVID-19 by World Health Organization) belongs to the coronavirus β genus, which is encapsulated in round or oval shape, and 60-140mm in diameter. The genetic characteristics of COVID-19 are significantly different from SARS-CoV and MERS-CoV. It shares more than 85% homology with SARS-like coronavirus isolated from bat (bat-SL-CoVZC45). The COVID-19 can be detected in human respiratory epithelial cells for about 96 hours *in vitro*, but it takes about 6 days to isolate and culture in Vero E6 and Huh-7 cell lines.

Our current understandings on the biochemical features of COVID-19are mostly derived from previous studies on SARS-CoV and MERS-CoV. COVID-19 is fragile to ultraviolet and heat (56 °C for 30 minutes). It can also be inactivated by liposoluble solvents, such as ether, 75% ethanol (w/v), chlorine-containing disinfectant and chloroform. However, chlorhexidine has been proved generally ineffective.

2. Epidemiology

a) Source of infection

Infected patients (symptomatic or asymptomatic) are the main source of infection.

b) Route of transmission

COVID-19 is transmitted through respiratory droplets and close contact. Aerosol transmission is plausible when patients are exposed to high concentration virus-containing aerosols for a long period of time and in a relatively closed environment. In addition, because COVID-19 has been isolated from stool and urine specimens, special attention should be paid to human waste disposal to avoid direct contact and/or environment contamination.

c) Susceptible population

Human beings are generally susceptible to COVID-19.

3. Pathology

The following summary is based on limited numbers of autopsy and biopsy findings.

a) Lungs

Lung consolidation was observed in various degrees.

Fibrinous exudation and hyaline membrane formation were filled in alveolar cavity. Exudative cells mainly consist of mononuclear cells and macrophages. Polynuclear giant cells were prominent. Type II alveolar epithelial cells were markedly proliferated, and some were detached into alveolar cavity. Inclusion bodies were found in type II alveolar epithelial cells and macrophages. Hyperemia and edema were apparent in alveolar septal areas. Mononuclear cell and lymphocyte infiltration, intravascular hyaline thrombosis, focal hemorrhage and necrosis of lung tissue could be seen, and hemorrhagic infarction occurred. Pathological features of organizing pneumonia and pulmonary interstitial fibrosis could be observed in pulmonary parenchyma.

Intrapulmonary bronchial epithelial cells were detached, and bronchial cavity was filled with mucus plugs. In some area, pulmonary alveoli were hyperinflated, alveolar septa fractured, and cystic cavities formed.

Coronavirus particles were found in the cytoplasm of bronchial epithelium and type II alveolar epithelial cells under electron microscope. Immunohistochemical staining showed that some alveolar epithelial cells and macrophages were positive for COVID-19 antigens. COVID-19 nuclear acids were detected through RT-PCR.

b) Spleen, hilar lymph nodes, and bone marrow

Spleen was markedly shrunk, in which lymphocytes were significantly reduced in numbers, with apparent focal hemorrhage and necrosis. Macrophage proliferation and phagocytosis were also observed. In lymph nodes, lymphocytes were also depleted and necrotized. In addition, immunohistochemical staining showed that the number of CD4+ T and $CD8^+$ T cells in both spleen and lymph nodes were significantly decreased. All hematopoietic cell linages were reduced in bone marrow.

c) Cardiovascular system

It was found that some cardiomyocytes were degenerated and necrotized, and a small number of monocytes, lymphocytes and/or neutrophils are infiltrated in the myocardium. In some areas, vascular endothelial cells were detached where inflammation and thrombosis occurred.

d) Liver and gallbladder

Liver was characterized by increased volume, dark red color, hepatocyte degeneration, focal necrosis with neutrophil infiltration, hepatic sinus congestion, infiltration of lymphocytes and monocytes in the portal area, and microthrombus formation. Gallbladder

was also significantly increased in size.

e) Kidney

Protein exudate was found in Bowman's capsules. Renal tubular epithelium was denatured and exfoliated, and hyaline cast was formed. Interstitial hyperemia, micro thrombus and focal fibrosis could be seen.

f) Other organs

The brain tissue was congested and edematous, and some neurons were degenerated. Focal necrosis was observed in the adrenal gland. The epithelium of esophagus, stomach and intestines were denatured, necrotic and exfoliated with different degrees.

4. Clinical features

a) Clinical manifestation

Based on the current epidemiological survey, the incubation period of COVID-19 is 1-14 days. Most patients show clinical symptoms in 3-7 days.

Fever, dry cough, and fatigue are the main manifestations. Other symptoms include nasal obstruction, runny nose, sore throat, myalgia and diarrhea. In severe cases, patients presented dyspnea and/or hypoxemia within one week after onset. Some of them rapidly deteriorated to acute respiratory distress syndrome (ARDS), septic shock, refractory metabolic acidosis, coagulation dysfunction, and multiple organ failure. Notably, some severe patients only presented mild- to moderate-grade fever in their entire course of disease, and some even did not show fever at all.

Some children and newborns presented atypical symptoms, such as vomiting, diarrhea and other gastrointestinal discomfort, or only exhibited drowsiness and shortness of breath.

In mild cases, patients only presented low-grade fever and slight fatigue, without evident pneumonia.

From our current observation, most patients have a good prognosis, and only a few patients are critically ill. The prognosis for the elderly and those with chronic comorbidities is relatively worse. The clinical course of COVID-19 pneumonia in pregnant women is similar to that of the same age group. The severity of symptoms in children is relatively mild.

b) Laboratory examination

i. Routine examination

In the early stage of the disease, the total count of peripheral leukocytes could be normal or decreased, and the lymphocyte decreased. In some patients, liver transaminases, lactate dehydrogenase (LDH), creatine kinase and myoglobin were elevated. In some critically severe patients, troponins were also increased. In most

patients, C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) were increased, while procalcitonin generally remains in normal range. Notably, D-dimer was significantly increased in severe patients, and peripheral lymphocytes were progressively decreased. Inflammatory biomarkers are often elevated in severe and critically severe patients.

ii. Etiological and serological examination

(1) Etiological examination: COVID-19 nucleic acids can be detected in nasopharyngeal swabs, sputum and other lower respiratory tract secretions, blood and feces by using RT-PCR and next generation sequencing technology (NGS). It is more accurate to detect the lower respiratory tract specimen (sputum or airway extract). Once collected, specimen examination should be performed as soon as possible.

(2) Serological examination: the COVID-19-specific IgM antibody starts to show positive after 3-5 days from onset. In comparison, the titer of COVID-19-specific IgG antibody is 4 times higher in recovery period than that in acute phase.

iii. Chest imaging

At the early stage of the disease, multiple small patchy shadows and interstitial changes appear, which are more obvious in the periphery of the lung. Then it developed into multiple ground-glass shadows and infiltrates shadows. In severe cases, pulmonary consolidation may occur. Pleural effusion is rare.

5. Diagnostic criteria

a) Suspected cases

Comprehensive analysis of the following epidemiological history and clinical manifestations:

i. Epidemiological history

(1) Travel or residence history of Wuhan and surrounding areas, or other communities with documented COVID-19 positive cases within 14 days before the onset of illness.

(2) History of contact with COVID-19-infected persons (positive for nucleic acid detection) within 14 days before the onset of illness.

(3) History of contact with the patients presenting fever or respiratory symptoms, who travel to or reside in Wuhan and surrounding areas, or in other communities with documented COVID-19 positive cases within 14 days

before the onset of illness.

(4) Clustering onset (2 or more cases of fever and/or respiratory symptoms within 2 weeks in small areas such as home, office, school class, *etc.*)

ii. Clinical manifestation

(1) Presenting with fever and/or respiratory symptoms.

(2) With imaging features of above mentioned COVID-19 pneumonia.

(3) In the early stage of the disease, the total number of leukocytes was normal or decreased, and the lymphocyte count was normal or decreased.

A case that meets any one of the epidemiological history criteria and any two of the clinical manifestations can be identified as a suspected case. If there is no clear epidemiological history, 3 of the clinical manifestations is required.

b) Confirmed cases

Suspected cases with one of the following etiology or serological evidence can be identified as confirmed cases:

(1) Real-time RT-PCR detection is positive for COVID-19 nucleic acid.

(2) The viral gene identified by gene sequencing is highly homologous with known COVID-19;

(3) The COVID-19-specific IgM and IgG antibodies are tested positive. The titer of COVID-19-specific IgG antibody is 4 times higher in recovery period than that in acute phase.

6. Clinical classification

a) Mild type

The clinical symptoms are mild, and there was no sign of pneumonia on chest imaging.

b) Moderate type

These patients had fever and respiratory symptoms. Radiologic assessments found signs of pneumonia.

c) Severe type

Adults meet any of the following criteria:

(1) Shortness of breath, RR≥30 times/min;

(2) Oxygen saturation≤93% at rest;

(3) Alveolar oxygen partial pressure/fraction of inspiration O_2 (PaO_2/FiO_2) ≤300 mmHg (1mmHg=0.133 kPa).

At high altitudes (above 1000 meters), PaO_2/FiO_2should be corrected according to the following formula: PaO_2/FiO_2×[Atmospheric Pressure (mmHg)/760].

Patients whose pulmonary imaging showed significant progression of lesion> 50% within 24-48 hours should be treated as severe type.

Children meet any of the following criteria:

(1) Shortness of breath (<2 months of age, RR≥60 beats/min; 2 to 12 months of age, RR≥50 beats/min; 1 to 5 years old, RR≥40 beats/min;> 5 years old, RR≥30 beats/min), excluding the effects of fever and crying;

(2) In the resting state, the oxygen saturation is ≤92%;

(3) Assisted breathing (groaning, wing flaps, tri-retraction sign), cyanosis, intermittent apnea;

(4) Lethargy and convulsions;

(5) Refuse to feed, and have signs of dehydration.

d) Critically severe type

Patients meet any of the following conditions:

(1) Respiratory failure requiring mechanical ventilation;

(2) Shock;

(3) Patients combined with other organ failure needed ICU monitoring and treatment.

7. Warning signals for severe and critically severe types

a) Adults

(1) Progressive decline in the number of peripheral lymphocytes;

(2) Progressive increase in the levels of peripheral inflammatory biomarkers, such as IL-6 and CRP;

(1) Progressive increase in lactic acid concentration;

(2) Pulmonary lesions progress rapidly in a short time.

b) Children

(1) Increased respiration rate;

(2) Poor mental responsiveness and drowsiness;

(3) Progressive increase in lactic acid concentration;

(4) Imaging showed bilateral or multilobes infiltration and pleural effusion; or pulmonary lesions progress rapidly in a short time;

(5) Infants under 3 months of age, or children having coexisting conditions (congenital heart disease, bronchopulmonary dysplasia, respiratory deformity, abnormal hemoglobin, severe malnutrition, *etc.*), or children with immunodeficiency or under immunosuppressive state (long-term use of immunosuppressants).

8. Differential diagnosis

8. Differential diagnosis

a) The mild manifestations of COVID-19 infections need to be distinguished from upper respiratory tract infections caused by other viruses.

b) The COVID-19 pneumonia needs to be distinguished from other known viral pneumonia or mycoplasma pneumoniae infections, such as influenza virus, adenovirus and respiratory syncytial virus. For suspected cases, technique such as rapid antigen detection and multiplex PCR nucleic acid detection should be taken to detect common respiratory pathogens.

c) It should also be distinguished from non-infectious diseases such as vasculitis, dermatomyositis, and organizing pneumonia.

9. Identifying cases and filing reports

When a COVID-19 suspected case is found by any medical practitioners, it is critical to immediately isolate the suspected person in a solitary cell for further monitoring and treatment. If COVID-19 infection is still suspected after comprehensive evaluation by medical experts and/or physicians, a case report should be submitted through internet to Centers for Disease Control (CDC) within 2 hours after the initial suspicion. In addition, specimens should be collected for COVID-19 nucleic acid test. Meanwhile, the suspected person should be immediately transferred to a predesignated hospital with secured transportation modalities. If the suspected person has a close contact history with patient(s) already diagnosed with COVID-19 pneumonia, COVID-19 nucleic acid test should be performed, even if his or her common respiratory pathogen detection test has shown positive result(s).

If COVID-19 nucleic acid tests are negative for two consecutive times (with at least 24 hours interval between each test), and if COVID-19-specific IgM and IgG antibodies remain negative after 7 days from onset, the suspected diagnosis of COVID-19 can be ruled out.

10. Treatment

a) Determine the treatment place according to patients' condition.

(1) Suspected and confirmed cases should be isolated and treated in designated hospitals with effective isolation and protection conditions. Suspected cases should be isolated in a single ward, while confirmed cases can be admitted to multiple bedded ward.

(2) Critically severe cases should be admitted to ICU as soon as possible.

b) General treatment.

(1) Rest in bed with supportive treatment to ensure sufficient energy supply. The water and electrolyte balance should be noticed to maintain internal environment stability

and electrolyte balance should be noticed to maintain internal environment stability. Vital signs and oxygen saturation should be closely monitored.

(2) Monitor the blood routine, urine routine, CRP, biochemical indicators (liver enzyme, myocardial enzyme, renal function, *etc.*), coagulation function, arterial blood gas analysis, chest imaging according to the condition. If possible, cytokine test should be performed.

(3) Effective oxygen therapy measures should be given in time, including nasal cannula, mask oxygen and high-flow nasal cannula oxygen therapy. Hydrogen-oxygen inhalation (H_2/O_2: 66.6%/33.3%) treatment can be considered for use.

(4) Antiviral therapy: α-interferon (5 million U or equivalent for adult, add 2ml of sterile water, 2 times daily inhalation), lopinavir/ritonavir (200 mg/50 mg/capsule, 2 capsules each time for adults, twice a day, the course of treatment should not exceed 10 days). Ribavirin (combination with interferon or lopinavir/ritonavir is recommended, 500 mg each time for adults, 2 to 3 times intravenous infusions per day, the course of treatment should not exceed 10 days), chloroquine phosphate (for adults whose weigh over 50 kg, 500 mg each time, twice daily for 7 days; for those whose weigh less than 50 kg, 500 mg each time, twice daily for day 1 and day 2, once daily for day 3- day 7), Abidol (200 mg each time, three times a day for adults, the course of treatment should not exceed 10 days) can be tried. Attention should be paid to the adverse reactions of the above drugs, contraindications (such as chloroquine should not be used in patients with heart disease), and interaction with other drugs. It is not recommended to use 3 or more antiviral drugs at the same time. The use of related drugs should be stopped when intolerable side effects occur. The treatment of pregnant women should consider the number of weeks of gestation and choose drugs that have less impact on the fetus.

(5) Antibacterial drug treatment: inappropriate use of antibacterial drugs should be avoided, especially the broad-spectrum antibacterial drugs.

c) Treatment of severe and critically severe cases.

(1) Principles of treatment:

In addition to symptom treatments, it is important to actively prevent complications, treat underlying diseases, prevent secondary infections, and provide organ function support.

(2) Respiratory support:

a) Oxygen therapy: Severe patients should receive nasal cannula or mask to inhale oxygen, and evaluate in time whether respiratory distress and/or

hypoxemia is relieved.

b) High-flow nasal cannula oxygen therapy or non-invasive mechanical ventilation: When patients with respiratory distress and / or hypoxemia cannot be relieved after receiving standard oxygen therapy, high-flow nasal cannula oxygen therapy or non-invasive ventilation can be considered. If the condition does not improve or worsens within a short time (1-2 hours), tracheal intubation and invasive mechanical ventilation should be performed in time.

c) Invasive mechanical ventilation: Using lung protective ventilation strategy, that is, small tidal volume (6-8 mL/kg ideal body weight) and low level of airway plateau pressure (≤30 cm H_2O) for mechanical ventilation to reduce ventilator-related lung injury. When the airway plateau pressure is ≤35 cm H_2O, high PEEP can be appropriately used. Keep the airway warm and humid, avoid prolonged sedation, and awaken patients early and perform pulmonary rehabilitation treatment. For those patients with problem of man-machine synchronization, sedation and muscle relaxants should be used in time. According to the airway secretions, closed sputum suction should be considered, and bronchoscopy should be performed if necessary.

d) Salvage treatment: For patients with severe ARDS, it is recommended to perform lung expansion. Prone ventilation should be performed for more than 12 hours per day. When prone position mechanical ventilation is not effective, if conditions permit, extracorporeal membrane pulmonary oxygenation (ECMO) should be considered as soon as possible. Related indications: ① When FiO_2> 90%, the oxygenation index is less than 80mmHg, which lasts more than 3-4 hours; ② Patients with simple respiratory failure with airway plateau pressure ≥35 cm H_2O, the VV-ECMO mode is preferred; if circulatory support is needed, then VA-ECMO mode will be selected. When the underlying disease is under control and cardiopulmonary function shows signs of recovery, weaning trials should be considered to begin.

(3) Circulation support:

Based on adequate fluid resuscitation, improvement of microcirculation and use of vasoactive drugs may be considered. Changes in patients' blood pressure, heart rate, and urine output, as well as lactic acid and alkali residuals in arterial blood gas analysis should be closely monitored. Noninvasive or invasive hemodynamic monitoring, such as Doppler echocardiography, echocardiography, invasive blood pressure or continuous cardiac output (PiCCO) monitoring, is

necessary. In the process of treatment, attention should be paid to the liquid balance to avoid excess and deficiency.

When the patient's heart rate suddenly increases over 20% of the baseline value or the blood pressure has dropped by more than 20% of the baseline value, accompanying symptoms such as poor skin perfusion and decreased urine output, it should be alert whether patients have septic shock, gastrointestinal bleeding, or severe heart failure.

(4) Renal failure and renal replacement therapy:

When renal insufficiency occurs in critically severe patients, the causes of renal function insufficiency, such as hypoperfusion and drugs, should be analyzed. The treatment of patients with renal failure should pay attention to fluid balance, acid-base balance and electrolyte balance. For nutrition support treatment, attention should be paid to nitrogen balance, and supplement of calorie and minerals. Renal replacement therapy (CRRT) can be considered in severe patients. The indications include: ① hyperkalemia; ② acidosis; ③ pulmonary edema or excessive water load; ④ fluid management when multiple organ dysfunction occurs.

(5) Recovered patients' plasma therapy:

It is suitable for severe and critically severe patients with rapid disease progression.

(6) Blood purification treatment:

The blood purification system includes plasma exchange, adsorption, perfusion, blood/plasma filtration, etc., which can remove inflammatory factors and stop the "cytokine storm", thereby reducing the damage to the body caused by the inflammatory response. It can be used for treatment of early and mid-term cytokine storms in severe and critically severe patients

(7) Immunotherapy:

For patients with extensive lung lesion and severe patients with elevated IL-6 levels, tocilizumab treatment can be tried. The first dose is 4-8mg/kg, the recommended dose is 400mg with dilution of 0.9% physiological saline to 100ml, and the infusion time should be more than 1 hour. If the first medication is not effective, it can be applied once more after 12 hours (the dose is the same as before), cumulative number of administrations should not be more than 2 times, and the maximum single dose should not exceed 800 mg. Pay attention to allergic reactions. It is not recommended for people with active infections such as tuberculosis.

(8) Other treatment measures

For patients with progressive deterioration of oxygenation indicators, rapid imaging progress, and excessive activation of inflammatory response, the use of glucocorticoids in the short term (3 to 5 days) should be considered. The dosage of methylprednisolone should not be over 1-2mg/kg/day. It should be noted that large doses of glucocorticoids will delay the removal of coronavirus due to immunosuppressive effects. Intestinal microecological regulators can be used to maintain intestinal microecological balance and prevent secondary bacterial infections.

For severe and critically severe children patients, intravenous gamma globulin should be considered.

Pregnant women with severe or critically severe COVID-19 pneumonia should consider pregnancy termination, and cesarean delivery is preferred.

Psychological counseling should be strengthened in patients with anxiety and fear.

d) Traditional Chinese medicine treatment

According to the local climate characteristics, patients' illness states and physical conditions, traditional Chinese medicine treatments can be used under the guidance of doctors. Huoxiang Zhengqi Capsules, *ect.* are recommended for patients with asthenia and gastrointestinal discomfort. Jinhua Qinggan granules, Lianhua Qingwen capsules and Shufeng Jiedu Capsules, *ect.* are recommended for patients with asthenia and fever.

11. Discharge criteria and precautions after discharge

a) Discharge criteria.

(1) The body temperature returns to normal for more than 3 days;

(2) Significant improvement in respiratory symptoms;

(3) Pulmonary imaging shows a marked improvement in acute exudative lesions;

(4) Negative nucleic acid test for sputum, nasopharyngeal swabs and other respiratory specimens for two consecutive times (at least 24 hours interval between each test).

Those who meet all the above conditions can be discharged.

b) Precautions after discharge.

(1) The hospital should make good contact with the basic medical and health institutions where the patients live, share the medical records, and timely send the discharged patients' information to the residential committee and the basic medical and health institutions.

(2) After the patient is discharged from the hospital, it is recommended to continue the isolation management and health monitoring for 14 days, wear a mask, and live in a well-ventilated single room, reduce close contact with family members, wash hands frequently, and avoid going out.

(3) It is recommended to follow up and return to the hospital in the 2nd and 4th week after discharge.

Translated by Chinese Society of Cardiology

Translators: Zhang Erli, Li Yang, Guo Qianyun, Misbahul Ferdous, Meng Zhen, Zhao Qinghao, Guo Shuai, Li Ziang, Luo Xiandu, Wu Yongjian, Han Yaling

March 15, 2020，Sunday

翻译单位：中华医学会心血管病学分会

参译人员：张而立、李洋、郭倩云、Misbahul Ferdous、孟真、赵庆豪、郭帅、李子昂、罗贤都、吴永健、韩雅玲

2020 年 3 月 15 日星期日

Letter

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Breakthrough: Chloroquine phosphate has shown apparent efficacy in treatment of COVID-19 associated pneumonia in clinical studies

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SUMMARY The coronavirus disease 2019 (COVID-19) virus is spreading rapidly, and scientists are endeavoring to discover drugs for its efficacious treatment in China. Chloroquine phosphate, an old drug for treatment of malaria, is shown to have apparent efficacy and acceptable safety against COVID-19 associated pneumonia in multicenter clinical trials conducted in China. The drug is recommended to be included in the next version of the Guidelines for the Prevention, Diagnosis, and Treatment of Pneumonia Caused by COVID-19 issued by the National Health Commission of the People's Republic of China for treatment of COVID-19 infection in larger populations in the future.

Keywords COVID-19, SARS-CoV-2, 2019-nCoV, pneumonia, chloroquine

The coronavirus disease 2019 (COVID-19) virus, emerged in December 2019, has spread rapidly, with cases now confirmed in multiple countries. As of February 16, 2020, the virus has caused 70,548 infections and 1,770 deaths in mainland China and 413 infections in Japan (*1*). A great deal of effort has been made to find effective drugs against the virus in China (*2*). On February 17, 2020, the State Council of China held a news briefing indicating that chloroquine phosphate, an old drug for treatment of malaria, had demonstrated marked efficacy and acceptable safety in treating COVID-19 associated pneumonia in multicenter clinical trials conducted in China (*3*).

In the early *in vitro* studies, chloroquine was found to block COVID-19 infection at low-micromolar concentration, with a half-maximal effective concentration (EC_{50}) of 1.13 μM and a half-cytotoxic concentration (CC_{50}) greater than 100 μM (*4*). A number of subsequent clinical trials (ChiCTR2000029939, ChiCTR2000029935, ChiCTR2000029899, ChiCTR2000029898, ChiCTR2000029868, ChiCTR2000029837, ChiCTR2000029826, ChiCTR2000029803, ChiCTR2000029762, ChiCTR2000029761, ChiCTR2000029760, ChiCTR2000029740, ChiCTR2000029609, ChiCTR2000029559, and ChiCTR2000029542) have been quickly conducted in China to test the efficacy and safety of chloroquine or hydroxychloroquine in the treatment of COVID-19 associated pneumonia in more than 10 hospitals in Wuhan, Jingzhou, Guangzhou, Beijing, Shanghai, Chongqing, and Ningbo (*5*). Thus far, results from more than 100 patients have demonstrated that chloroquine phosphate is superior to the control treatment in inhibiting the exacerbation of pneumonia, improving lung imaging findings, promoting a virus-negative conversion, and shortening the disease course according to the news briefing. Severe adverse reactions to chloroquine phosphate were not noted in the aforementioned patients. Given these findings, a conference was held on February 15, 2020; participants including experts from government and regulatory authorities and organizers of clinical trials reached an agreement that chloroquine phosphate has potent activity against COVID-19. The drug is recommended for inclusion in the next version of the Guidelines for the Prevention, Diagnosis, and Treatment of Pneumonia Caused by COVID-19 issued by the National Health Commission of the People's Republic of China.

Chloroquine is used to prevent and treat malaria and is efficacious as an anti-inflammatory agent for the treatment of rheumatoid arthritis and lupus erythematosus. Studies revealed that it also has potential broad-spectrum antiviral activities by increasing endosomal pH required for virus/cell fusion, as well as interfering with the glycosylation of cellular receptors of SARS-CoV (*6,7*). The anti-viral and anti-inflammatory activities of chloroquine may account for its potent efficacy in treating patients with COVID-19 pneumonia.

Chloroquine is a cheap and safe drug that has been used for more than 70 years. In light of the urgent clinical demand, chloroquine phosphate is recommended to treat COVID-19 associated pneumonia in larger populations in the future.

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LETTER TO THE EDITOR OPEN

Remdesivir and chloroquine effectively inhibit the recently emerged novel coronavirus (2019-nCoV) in vitro

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Dear Editor,

In December 2019, a novel pneumonia caused by a previously unknown pathogen emerged in Wuhan, a city of 11 million people in central China. The initial cases were linked to exposures in a seafood market in Wuhan.[1] As of January 27, 2020, the Chinese authorities reported 2835 confirmed cases in mainland China, including 81 deaths. Additionally, 19 confirmed cases were identified in Hong Kong, Macao and Taiwan, and 39 imported cases were identified in Thailand, Japan, South Korea, United States, Vietnam, Singapore, Nepal, France, Australia and Canada. The pathogen was soon identified as a novel coronavirus (2019-nCoV), which is closely related to sever acute respiratory syndrome CoV (SARS-CoV).[2] Currently, there is no specific treatment against the new virus. Therefore, identifying effective antiviral agents to combat the disease is urgently needed.

An efficient approach to drug discovery is to test whether the existing antiviral drugs are effective in treating related viral infections. The 2019-nCoV belongs to *Betacoronavirus* which also contains SARS-CoV and Middle East respiratory syndrome CoV (MERS-CoV). Several drugs, such as ribavirin, interferon, lopinavir-ritonavir, corticosteroids, have been used in patients with SARS or MERS, although the efficacy of some drugs remains controversial.[3] In this study, we evaluated the antiviral efficiency of five FAD-approved drugs including ribavirin, penciclovir, nitazoxanide, nafamostat, chloroquine and two well-known broad-spectrum antiviral drugs remdesivir (GS-5734) and favipiravir (T-705) against a clinical isolate of 2019-nCoV in vitro.

Standard assays were carried out to measure the effects of these compounds on the cytotoxicity, virus yield and infection rates of 2019-nCoVs. Firstly, the cytotoxicity of the candidate compounds in Vero E6 cells (ATCC-1586) was determined by the CCK8 assay. Then, Vero E6 cells were infected with nCoV-2019BetaCoV/Wuhan/WIV04/2019[2] at a multiplicity of infection (MOI) of 0.05 in the presence of varying concentrations of the test drugs. DMSO was used in the controls. Efficacies were evaluated by quantification of viral copy numbers in the cell supernatant via quantitative real-time RT-PCR (qRT-PCR) and confirmed with visualization of virus nucleoprotein (NP) expression through immunofluorescence microscopy at 48 h post infection (p.i.) (cytopathic effect was not obvious at this time point of infection). Among the seven tested drugs, high concentrations of three nucleoside analogs including ribavirin (half-maximal effective concentration (EC_{50}) = 109.50 μM, half-cytotoxic concentration (CC_{50}) > 400 μM, selectivity index (SI) > 3.65), penciclovir (EC_{50} = 95.96 μM, CC_{50} > 400 μM, SI > 4.17) and favipiravir (EC_{50} = 61.88 μM, CC_{50} > 400 μM, SI > 6.46) were required to reduce the viral infection (Fig. 1a and Supplementary information, Fig. S1). However, favipiravir has been shown to be 100% effective in protecting mice against Ebola virus challenge, although its EC_{50} value in Vero E6 cells was as high as 67 μM,[4] suggesting further in vivo studies are recommended to evaluate this antiviral nucleoside. Nafamostat, a potent inhibitor of MERS-CoV, which prevents membrane fusion, was inhibitive against the 2019-nCoV infection (EC_{50} = 22.50 μM, CC_{50} > 100 μM, SI > 4.44). Nitazoxanide, a commercial antiprotozoal agent with an antiviral potential against a broad range of viruses including human and animal coronaviruses, inhibited the 2019-nCoV at a low-micromolar concentration (EC_{50} = 2.12 μM; CC_{50} > 35.53 μM; SI > 16.76). Further in vivo evaluation of this drug against 2019-nCoV infection is recommended. Notably, two compounds remdesivir (EC_{50} = 0.77 μM; CC_{50} > 100 μM; SI > 129.87) and chloroquine (EC_{50} = 1.13 μM; CC_{50} > 100 μM, SI > 88.50) potently blocked virus infection at low-micromolar concentration and showed high SI (Fig. 1a, b).

Remdesivir has been recently recognized as a promising antiviral drug against a wide array of RNA viruses (including SARS/MERS-CoV[5]) infection in cultured cells, mice and nonhuman primate (NHP) models. It is currently under clinical development for the treatment of Ebola virus infection.[6] Remdesivir is an adenosine analogue, which incorporates into nascent viral RNA chains and results in pre-mature termination.[7] Our time-of-addition assay showed remdesivir functioned at a stage post virus entry (Fig. 1c, d), which is in agreement with its putative antiviral mechanism as a nucleotide analogue. Warren et al. showed that in NHP model, intravenous administration of 10 mg/kg dose of remdesivir resulted in concomitant persistent levels of its active form in the blood (10 μM) and conferred 100% protection against Ebola virus infection.[7] Our data showed that EC_{90} value of remdesivir against 2019-nCoV in Vero E6 cells was 1.76 μM, suggesting its working concentration is likely to be achieved in NHP. Our preliminary data (Supplementary information, Fig. S2) showed that remdesivir also inhibited virus infection efficiently in a human cell line (human liver cancer Huh-7 cells), which is sensitive to 2019-nCoV.[2]

Chloroquine, a widely-used anti-malarial and autoimmune disease drug, has recently been reported as a potential broad-spectrum antiviral drug.[8,9] Chloroquine is known to block virus infection by increasing endosomal pH required for virus/cell fusion, as well as interfering with the glycosylation of cellular receptors of SARS-CoV.[10] Our time-of-addition assay demonstrated that chloroquine functioned at both entry, and at post-entry stages of the 2019-nCoV infection in Vero E6 cells (Fig. 1c, d). Besides its antiviral activity, chloroquine has an immune-modulating activity, which may synergistically enhance its antiviral effect in vivo. Chloroquine is widely distributed in the whole body, including lung, after oral administration. The EC_{90} value of chloroquine against the 2019-nCoV in Vero

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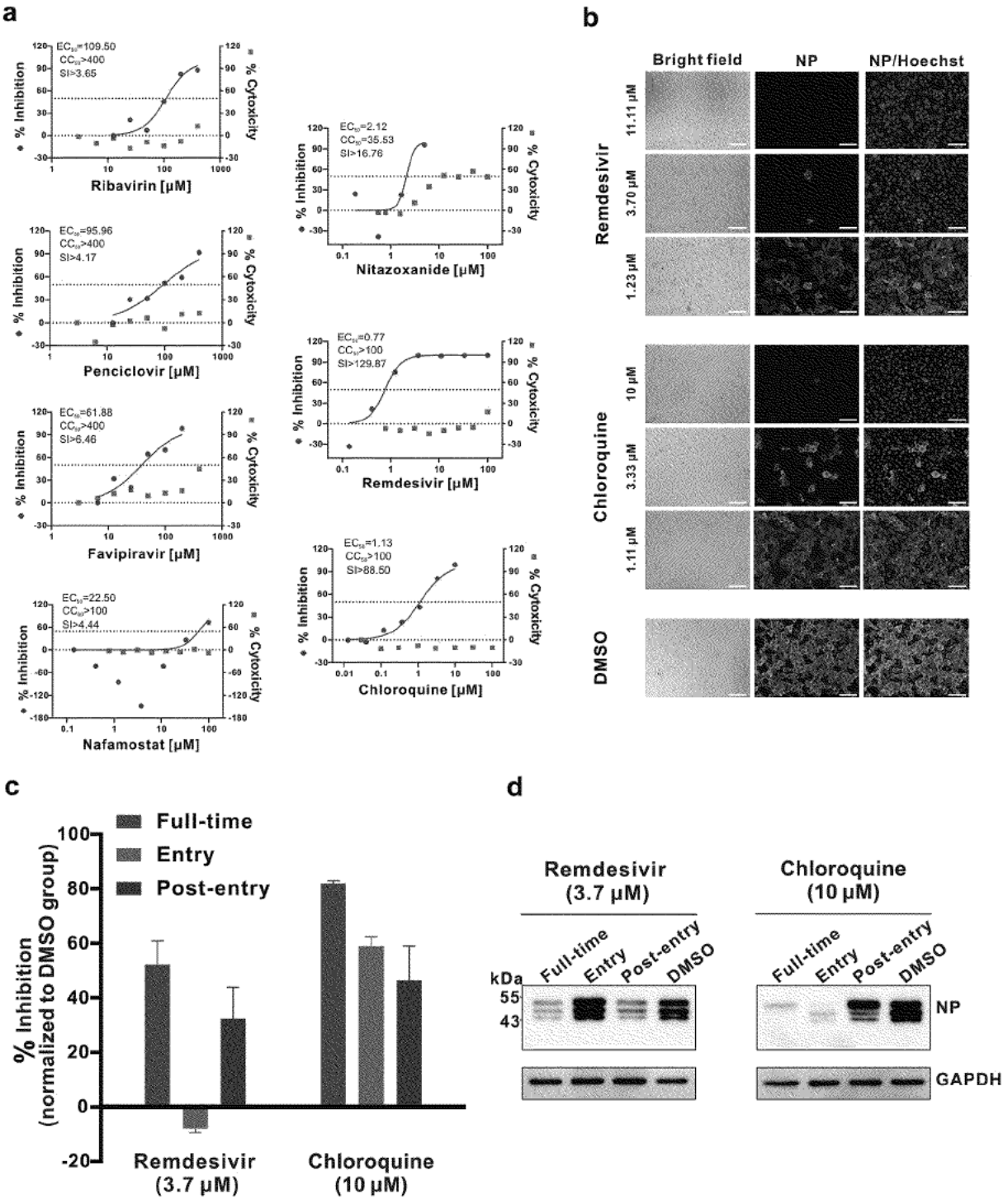

Fig. 1 The antiviral activities of the test drugs against 2019-nCoV in vitro. a Vero E6 cells were infected with 2019-nCoV at an MOI of 0.05 in the treatment of different doses of the indicated antivirals for 48 h. The viral yield in the cell supernatant was then quantified by qRT-PCR. Cytotoxicity of these drugs to Vero E6 cells was measured by CCK-8 assays. The left and right *Y*-axis of the graphs represent mean % inhibition of virus yield and cytotoxicity of the drugs, respectively. The experiments were done in triplicates. **b** Immunofluorescence microscopy of virus infection upon treatment of remdesivir and chloroquine. Virus infection and drug treatment were performed as mentioned above. At 48 h p.i., the infected cells were fixed, and then probed with rabbit sera against the NP of a bat SARS-related CoV[2] as the primary antibody and Alexa 488-labeled goat anti-rabbit IgG (1:500; Abcam) as the secondary antibody, respectively. The nuclei were stained with Hoechst dye. Bars, 100 μm. **c** and **d** Time-of-addition experiment of remdesivir and chloroquine. For "Full-time" treatment, Vero E6 cells were pre-treated with the drugs for 1 h, and virus was then added to allow attachment for 2 h. Afterwards, the virus–drug mixture was removed, and the cells were cultured with drug-containing medium until the end of the experiment. For "Entry" treatment, the drugs were added to the cells for 1 h before viral attachment, and at 2 h p.i., the virus–drug mixture was replaced with fresh culture medium and maintained till the end of the experiment. For "Post-entry" experiment, drugs were added at 2 h p.i., and maintained until the end of the experiment. For all the experimental groups, cells were infected with 2019-nCoV at an MOI of 0.05, and virus yield in the infected cell supernatants was quantified by qRT-PCR **c** and NP expression in infected cells was analyzed by Western blot **d** at 14 h p.i.

E6 cells was 6.90 μM, which can be clinically achievable as demonstrated in the plasma of rheumatoid arthritis patients who received 500 mg administration.[11] Chloroquine is a cheap and a safe drug that has been used for more than 70 years and, therefore, it is potentially clinically applicable against the 2019-nCoV.

Our findings reveal that remdesivir and chloroquine are highly effective in the control of 2019-nCoV infection in vitro. Since these compounds have been used in human patients with a safety track record and shown to be effective against various ailments, we suggest that they should be assessed in human patients suffering from the novel coronavirus disease.

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AUTHOR CONTRIBUTIONS

G.X., W.Z., Z.H., M.W., R.C., and L.Z. conceived and designed the experiments. X.Y., J.L., M.X., M.W., R.C., and L.Z. participated in multiple experiments; G.X., W.Z., Z.H., Z.S., M.W., R.C., and L.Z. analyzed the data. M.W., L.Z., R.C., and Z.H. wrote the manuscript. G.X., W.Z., and Z.H. provided the final approval of the manuscript.

ADDITIONAL INFORMATION

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Competing interests: The authors declare no competing interests.

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From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/17/2020 4:21:20 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
Subject: FW: Resochin (chloroquine phosphate) and COVID19
Attachments: Resochin_Info Package.pdf; Chinese Clinical Guidance for COVID-19 Pneumonia Diagnosis and Treatment (7t.pdf; Gao et al Chloroquine.pdf; Cell Research Jan 2020 Chloroquine.pdf

Fyi jw

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 4:19 PM
To: Farley, John <John.Farley@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Stein, Peter <Peter.Stein@fda.hhs.gov>
Subject: FW: Resochin (chloroquine phosphate) and COVID19

From: Todd Paporello <todd.paporello@bayer.com>
Sent: Tuesday, March 17, 2020 4:02 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: Resochin (chloroquine phosphate) and COVID19

Dear Patrizia

Following on your request for additional information, attached, please find an information package that is intended to provide a general overview of summary level information on safety, known efficacy in the use of Chloroquine (Resochin®) as a potential "Therapeutic / Investigational Agent" in Symptomatic Patients infected with SARS-CoV-2 / COVID-19 Disease of coronavirus, and Chinese guidelines on dosing for the treatment on COVID-19. Please note that the safety information comes from the indicated uses, and not from the use to treat COVID-19. In addition, attached, please find relevant published literature. We are continuing to compile additional information and will send soon. Please note this information is also being sent via Bayer's Government Affairs organization to Joe Hamel (HHS, ASPR).

Todd

Todd Paporello, Pharm.D., MBA
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Sent: Tuesday, March 17, 2020 1:33 PM
To: Todd Paporello <todd.paporello@bayer.com>
Subject: RE: Resochin (chloroquine phosphate) and COVID19

Todd
Thank you for speaking earlier. We are going to speak with BARDA directly and see what we can do to expedite this on our end.
Patrizia

From: Cavazzoni, Patrizia
Sent: Tuesday, March 17, 2020 12:31 PM
To: todd.paporello@bayer.com
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Resochin (chloroquine phosphate) and COVID19

Mr. Paporello

I just tried to reach you on your mobile.
You can call me at (b) (6) to discuss this further.

Patrizia Cavazzoni

From: Todd Paporello <todd.paporello@bayer.com>
Sent: Monday, March 16, 2020 4:35 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Resochin (chloroquine phosphate) and COVID19

Dear Dr. Woodcock

Bayer is actively working to address and contain the COVID-19 disease. In order to inform the U.S. government of our activities, Sebastian Guth, our President of Pharmaceuticals Americas, sent the attached letter to HHS and CDC. In particular, Bayer has donated, or is in the process of donating, Resochin (chloroquine phosphate) to several countries, including Germany, Italy, China, and Israel, as there has been some indication of the efficacy of chloroquine for COVID-19. Chloroquine was discovered in 1934 by Bayer scientists in Germany, and while the Bayer product is not approved in the U.S. chloroquine has been marketed by Bayer in many other countries. The Orange Book indicates there are generic versions of chloroquine approved in the U.S. In the event the U.S. government would like to make available chloroquine to patients with COVID-19, and generic companies are not able to provide adequate supply, Bayer is willing to donate product to the U.S. government through an appropriate regulatory pathway. Please don't hesitate to reach out, if there is anything Bayer can do to assist.

Regards,
Todd

Todd Paporello, Pharm.D., MBA
Vice President & Head

Regulatory Affairs Americas

Research & Development Site Head

//////////////////

Bayer U.S. LLC
Pharmaceuticals Division
100 Bayer Boulevard
Whippany NJ 07981-0915
United States
Tel: +1 862 404-4036
(b) (6)
E-mail: todd.paporello@bayer.com
Web: http://www.bayer.us

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From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 3/9/2020 9:46:34 AM
To: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Subject: RE: Request

Any progress? jw

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Friday, March 6, 2020 5:40 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Request

Hi Janet,

(b) (5)
[redacted]

Thank you. Rick.

On Mar 6, 2020, at 5:03 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

(b) (5) [redacted]

From: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]
Sent: 3/19/2020 11:07:21 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [Rick.Bright@hhs.gov]; Fauci, Anthony S (NIH) (b) (6); Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Guram, Jeet [Jeet.Guram@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Roberts, Rosemary [Rosemary.Roberts@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [Mark.Raza@fda.hhs.gov]; Edmonds, Amanda [Amanda.Edmonds@fda.hhs.gov]; Beers, Donald [Donald.Beers@fda.hhs.gov]; Zembower, Jenna [Jenna.Zembower@fda.hhs.gov]; Uyeki, Timothy M (CDC) [tmu0@cdc.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Wolinetz, Carrie D (NIH) (b) (6); Shuy, Bryan (OS) [Bryan.Shuy@hhs.gov]; Disbrow, Gary (OS) [Gary.Disbrow@hhs.gov]; Auchincloss, Hugh (NIH) (b) (6); Marston, Hilary D (NIH) (b) (6); Lankford, David W (NIH) (b) (6); Mair, Michael [Michael.Mair@fda.hhs.gov]

Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
Location: New Tcon: (b) (6) ,,, (b) (6)

Start: 3/19/2020 11:00:00 AM
End: 3/19/2020 11:45:00 AM
Show Time As: Busy

Required Attendees: Bright, Rick (OS); Fauci, Anthony S (NIH); Woodcock, Janet; Cavazzoni, Patrizia; Guram, Jeet; Farley, John; Roberts, Rosemary; Amin, Stacy; Davis, May M. EOP/WHO; Raza, Mark; Edmonds, Amanda; Beers, Donald; Zembower, Jenna; Uyeki, Timothy M (CDC); Lenihan, Keagan; Wolinetz, Carrie D (NIH); Shuy, Bryan (OS); Disbrow, Gary (OS); Auchincloss, Hugh (NIH); Marston, Hilary D (NIH); Lankford, David W (NIH); Mair, Michael

POC for Scheduling: Jenna Zembower (Office of the Commissioner, FDA)

Agenda

(b) (5)

Participants on this call:

FDA

- Anand Shah, Office of the Commissioner, Deputy Commissioner for Medical & Scientific Affairs
- Keagan Lenihan, Office of the Commissioner, Chief of Staff
- Jeet Guram, Office of the Commissioner, Senior Advisor
- Michael Mair, Acting Assistant Commissioner for Counterterrorism Policy, Office of the Chief Scientist
- Janet Woodcock, CDER, Director
- Patrizia Cavazzoni, CDER, Deputy Director for Operations
- John Farley, CDER Office of Infectious Diseases, Director
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- Stacy Amin, Office of the Chief Counsel, Chief Counsel

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- May Davis, Associate White House Counsel

From: Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]
Sent: 3/18/2020 11:19:53 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [Rick.Bright@hhs.gov]; Fauci, Anthony S (NIH) (b) (6); Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Guram, Jeet [Jeet.Guram@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Roberts, Rosemary [Rosemary.Roberts@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [Mark.Raza@fda.hhs.gov]; Edmonds, Amanda [Amanda.Edmonds@fda.hhs.gov]; Beers, Donald [Donald.Beers@fda.hhs.gov]; Zembower, Jenna [Jenna.Zembower@fda.hhs.gov]; Uyeki, Timothy M (CDC) [tmu0@cdc.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Wolinetz, Carrie D (NIH) (b) (6); Shuy, Bryan (OS) [Bryan.Shuy@hhs.gov]; Disbrow, Gary (OS) [Gary.Disbrow@hhs.gov]; Auchincloss, Hugh (NIH) (b) (6); Marston, Hilary D (NIH) (b) (6)
CC: Lankford, David W (NIH) (b) (6)

Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
Location: (b) (6); (b) (6)

Start: 3/18/2020 12:00:00 PM
End: 3/18/2020 12:45:00 PM
Show Time As: Busy

Required Attendees: Shah, Anand; Bright, Rick (OS); Fauci, Anthony S (NIH); Woodcock, Janet; Cavazzoni, Patrizia; Guram, Jeet; Farley, John; Roberts, Rosemary; Amin, Stacy; Davis, May M. EOP/WHO; Raza, Mark; Edmonds, Amanda; Beers, Donald; Zembower, Jenna; Uyeki, Timothy M (CDC); Lenihan, Keagan; Wolinetz, Carrie D (NIH); Shuy, Bryan (OS); Disbrow, Gary (OS); Auchincloss, Hugh (NIH); Marston, Hilary D (NIH)

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- Hilary Marston, Office of the Chief of Staff, Medical Officer/Policy Advisor

CDC

- Timothy Uyeki, National Center for Immunization and Respiratory Diseases

White House

- May Davis, Associate White House Counsel

(b) (5) [redacted]

Would you both, or a designee, be available for a call at 12:00pm today (Wednesday, March 18th) (b) (5) [redacted] An invitation will be forthcoming, please let me know if you have any questions.

Thank you

Best,
Anand

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From: Janet.Woodcock@fda.hhs.gov [Janet.Woodcock@fda.hhs.gov]
Sent: 3/24/2020 7:26:59 AM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
Subject: Re: URGENT Questions on planned study

Rick (b) (5) Happy to talk. Jw

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 23, 2020 at 10:54:40 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Johnson, Robert (OS) <Robert.Johnson@hhs.gov>, Walker, Robert (OS) <Robert.Walker@hhs.gov>, Faison, Tremel (OS) <Tremel.Faison@hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Marston, Hilary D (NIH) (b) (6), Lane, Henry C (NIH) (b) (6), Patel, Anita (CDC) <bop1@cdc.gov>, Uyeki, Timothy M (CDC) <tmu0@cdc.gov>, Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6), Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>, Beigel, John H (NIH) (b) (6), Higgs, Elizabeth S (NIH) (b) (6), Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Flamberg, Gemma <Gemma.Flamberg@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: Re: URGENT Questions on planned study

From: Janet.Woodcock@fda.hhs.gov [Janet.Woodcock@fda.hhs.gov]
Sent: 3/6/2020 9:39:11 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
Subject: Re: Request

Thanks very much. Jw

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 6, 2020 at 5:40:57 PM EST
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Request

Hi Janet,
W
(b) (5)
[redacted]

Thank you. Rick.

On Mar 6, 2020, at 5:03 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

(b) (5) [redacted]

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/18/2020 10:19:24 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [Rick.Bright@hhs.gov]; Fauci, Anthony S (NIH) (b) (6); Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Guram, Jeet [Jeet.Guram@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Roberts, Rosemary [Rosemary.Roberts@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [Mark.Raza@fda.hhs.gov]; Edmonds, Amanda [Amanda.Edmonds@fda.hhs.gov]; Beers, Donald [Donald.Beers@fda.hhs.gov]; Zembower, Jenna [Jenna.Zembower@fda.hhs.gov]; Uyeki, Timothy M (CDC) [tmu0@cdc.gov]
Subject: Int Call - FDA / BARDA / NIH / CDC (chloroquine)
Location: (b) (6); (b) (6)
Start: 3/18/2020 12:00:00 PM
End: 3/18/2020 12:45:00 PM
Show Time As: Tentative

Required Attendees: Bright, Rick (OS); Fauci, Anthony S (NIH); Woodcock, Janet; Cavazzoni, Patrizia; Guram, Jeet; Farley, John; Roberts, Rosemary; Amin, Stacy; Davis, May M. EOP/WHO; Raza, Mark; Edmonds, Amanda; Beers, Donald; Zembower, Jenna; Uyeki, Timothy M (CDC)

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From: Zembower, Jenna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=83F9EB4B88564C3797B4238DA3842EF8-JENNA.ZEMBO]
Sent: 3/18/2020 3:26:56 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [Rick.Bright@hhs.gov]; Fauci, Anthony S (NIH) (b) (6); Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Guram, Jeet [Jeet.Guram@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Roberts, Rosemary [Rosemary.Roberts@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [Mark.Raza@fda.hhs.gov]; Edmonds, Amanda [Amanda.Edmonds@fda.hhs.gov]; Beers, Donald [Donald.Beers@fda.hhs.gov]; Zembower, Jenna [Jenna.Zembower@fda.hhs.gov]; Uyeki, Timothy M (CDC) [tmu0@cdc.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Wolinetz, Carrie D (NIH) (b) (6); Shuy, Bryan (OS) [Bryan.Shuy@hhs.gov]; Disbrow, Gary (OS) [Gary.Disbrow@hhs.gov]; Auchincloss, Hugh (NIH) (b) (6); Marston, Hilary D (NIH) (b) (6); Lankford, David W (NIH) (b) (6)
Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
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Required Attendees: Bright, Rick (OS); Fauci, Anthony S (NIH); Woodcock, Janet; Cavazzoni, Patrizia; Guram, Jeet; Farley, John; Roberts, Rosemary; Amin, Stacy; Davis, May M. EOP/WHO; Raza, Mark; Edmonds, Amanda; Beers, Donald; Zembower, Jenna; Uyeki, Timothy M (CDC); Lenihan, Keagan; Wolinetz, Carrie D (NIH); Shuy, Bryan (OS); Disbrow, Gary (OS); Auchincloss, Hugh (NIH); Marston, Hilary D (NIH); Lankford, David W (NIH)

Agenda to follow.

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FDA

- Anand Shah, Office of the Commissioner, Deputy Commissioner for Medical & Scientific Affairs
- Keagan Lenihan, Office of the Commissioner, Chief of Staff
- Jeet Guram, Office of the Commissioner, Senior Advisor
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Sent: 3/18/2020 6:28:05 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [Rick.Bright@hhs.gov]; Fauci, Anthony S (NIH) (b) (6); Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Guram, Jeet [Jeet.Guram@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Roberts, Rosemary [Rosemary.Roberts@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [Mark.Raza@fda.hhs.gov]; Edmonds, Amanda [Amanda.Edmonds@fda.hhs.gov]; Beers, Donald [Donald.Beers@fda.hhs.gov]; Zembower, Jenna [Jenna.Zembower@fda.hhs.gov]; Uyeki, Timothy M (CDC) [tmu0@cdc.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Wolinetz, Carrie D (NIH) (b) (6); Shuy, Bryan (OS) [Bryan.Shuy@hhs.gov]; Disbrow, Gary (OS) [Gary.Disbrow@hhs.gov]; Auchincloss, Hugh (NIH) (b) (6); Marston, Hilary D (NIH) (b) (6); Lankford, David W (NIH) (b) (6); Mair, Michael [Michael.Mair@fda.hhs.gov]
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Location: (b) (6) ,,, (b) (6)

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POC for Scheduling: Jenna Zembower (Office of the Commissioner, FDA)

Agenda

(b) (5)

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From: Zembower, Jenna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=83F9EB4B88564C3797B4238DA3842EF8-JENNA.ZEMBO]
Sent: 3/18/2020 10:54:20 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [Rick.Bright@hhs.gov]; Fauci, Anthony S (NIH) (b) (6); Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [Patrizia.Cavazzoni@fda.hhs.gov]; Guram, Jeet [Jeet.Guram@fda.hhs.gov]; Farley, John [John.Farley@fda.hhs.gov]; Roberts, Rosemary [Rosemary.Roberts@fda.hhs.gov]; Amin, Stacy [Stacy.Amin@fda.hhs.gov]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [Mark.Raza@fda.hhs.gov]; Edmonds, Amanda [Amanda.Edmonds@fda.hhs.gov]; Beers, Donald [Donald.Beers@fda.hhs.gov]; Zembower, Jenna [Jenna.Zembower@fda.hhs.gov]; Uyeki, Timothy M (CDC) [tmu0@cdc.gov]; Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]; Wolinetz, Carrie D (NIH) (b) (6); Shuy, Bryan (OS) [Bryan.Shuy@hhs.gov]; Disbrow, Gary (OS) [Gary.Disbrow@hhs.gov]; Auchincloss, Hugh (NIH) (b) (6); Marston, Hilary D (NIH) (b) (6)
Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
Location: (b) (6); (b) (6)
Start: 3/18/2020 12:00:00 PM
End: 3/18/2020 12:45:00 PM
Show Time As: Busy

Required Attendees: Bright, Rick (OS); Fauci, Anthony S (NIH); Woodcock, Janet; Cavazzoni, Patrizia; Guram, Jeet; Farley, John; Roberts, Rosemary; Amin, Stacy; Davis, May M. EOP/WHO; Raza, Mark; Edmonds, Amanda; Beers, Donald; Zembower, Jenna; Uyeki, Timothy M (CDC); Lenihan, Keagan; Wolinetz, Carrie D (NIH); Shuy, Bryan (OS); Disbrow, Gary (OS); Auchincloss, Hugh (NIH); Marston, Hilary D (NIH)

(b) (5)

Would you both, or a designee, be available for a call at 12:00pm today (Wednesday, March 18th) (b) (5) An invitation will be forthcoming, please let me know if you have any questions.

Thank you

Best,
Anand

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

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+1-877-465-7975 US Toll Free
Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

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From: Josie Briggs [jpbriggs@pcori.org]
Sent: 4/8/2020 8:32:32 AM
To: Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Lauren Cohen [lauren.w.cohen@duke.edu]; Kim Marschhauser [kmarschhauser@pcori.org]; Sarah Daugherty [sdaugherty@pcori.org]
Subject: PCORI about to launch HERO

Greetings Cliff, Hilary, Rick, Janet -

(b) (5)

Josie

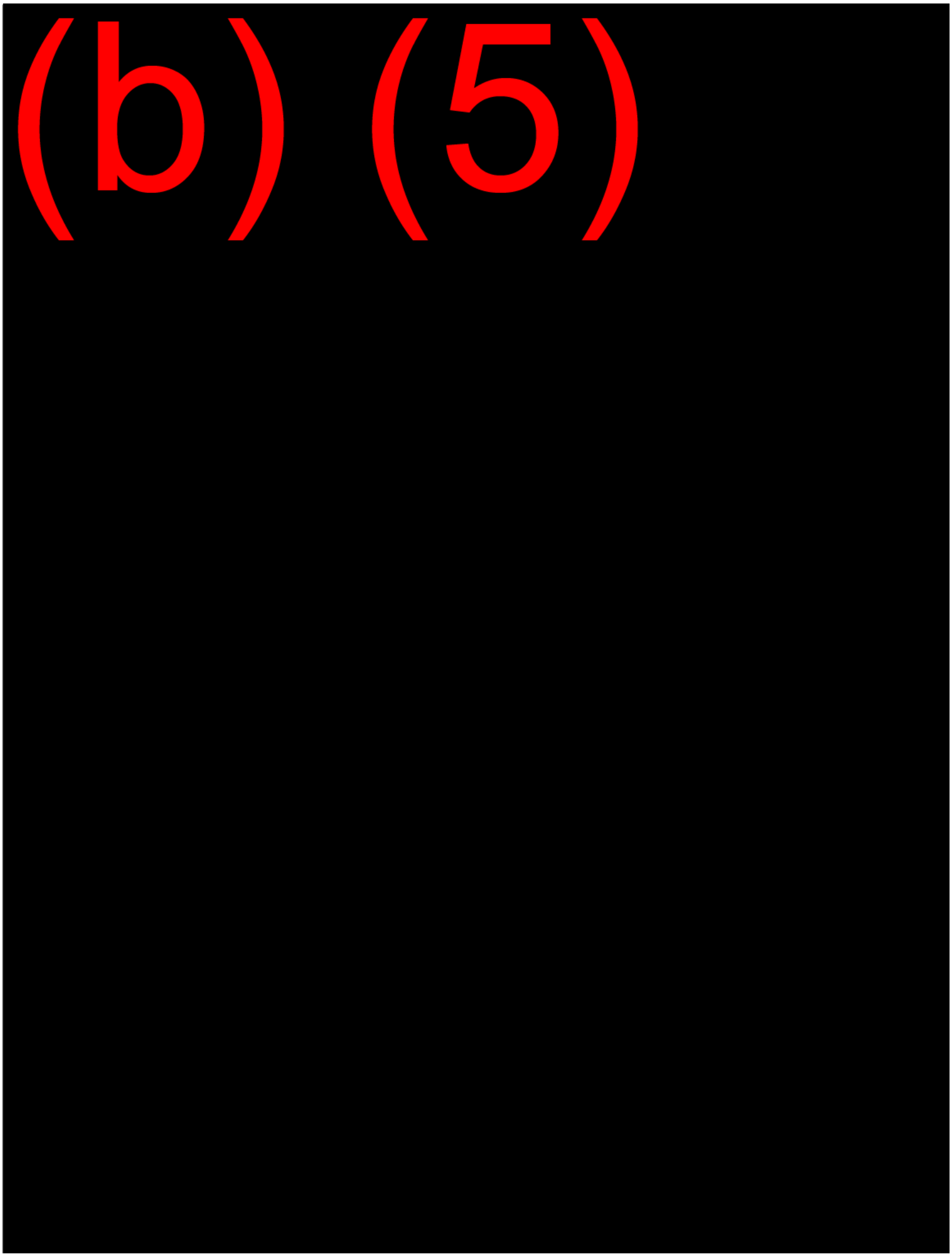
Josephine P. BriggsMD
Interim Executive Director
Patient Centered Outcomes Research Institute

From: Lambert, Linda (OS/ASPR/BARDA) [Linda.Lambert@hhs.gov]
Sent: 3/26/2020 1:37:49 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Walker, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d03cc33ba5c4f15bd581b757dc9daa4-HHS-Robert.]; Faison, Tremel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4945bc9afa3c4d34a274cb286e2f2a09-HHS-Tremel.]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Uyeki, Timothy M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f106bd981def4bfeb945e86b266662b2-HHS-tmu0-cd]; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6) ; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]; Beigel, John H (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db2bc96f962b4661b0494e9fa6ca6bcf-HHS-jbeigel]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Harper, Victor G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d572fe7d36f44ffe86101e5cbef9c957-HHS-Victor.]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Hamel, Joseph (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b90f78a9c02426eb8d62bd1ad9117b8-HHS-Joseph.]; Falcon, Jessica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3824ed33f07143e791acff770662ee48-HHS-Jessica]
CC: Faison, Tremel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4945bc9afa3c4d34a274cb286e2f2a09-HHS-Tremel.]; Walker, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d03cc33ba5c4f15bd581b757dc9daa4-HHS-Robert.]
Subject: Follow up: URGENT request for your agency's participants for the EUA access plan for CQ and HCQ - by 4pm today.

Importance: High

FOUO, Confidential, Pre-Decisional

Dear All,


(b) (5)

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Thank you very much in advance,

Linda

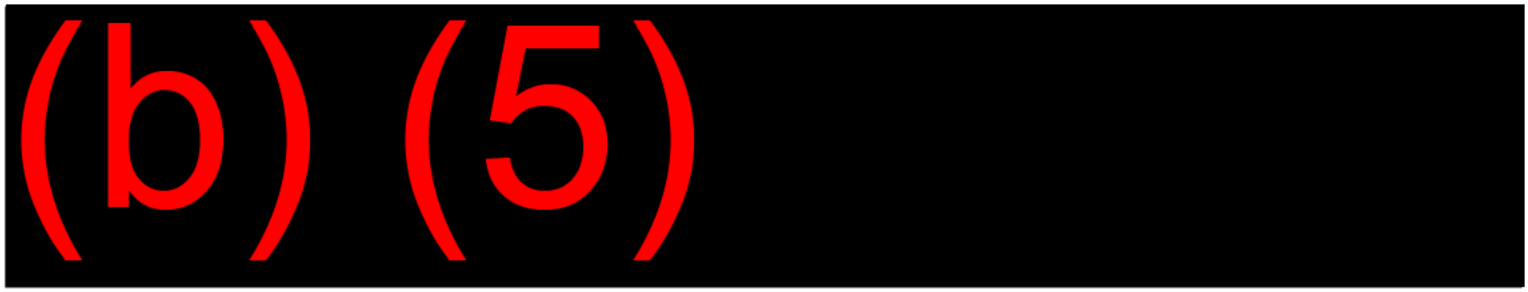
Linda C. Lambert, PhD
Director, Medical Countermeasures Program Support Services
Biomedical Advanced Research and Development Authority (BARDA)
Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201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

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

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

FOUO, Confidential, Pre-Decisional


(b) (5)



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

Rick

From: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Date: Monday, March 23, 2020 at 9:09 PM
To: "Amin, Stacy (FDA/OC)" <Stacy.Amin@fda.hhs.gov>
Cc: Janet Woodcock <Janet.Woodcock@fda.hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>, Robert Walker <Robert.Walker@hhs.gov>, Tremel Faison <Tremel.Faison@hhs.gov>, "Farley, John (FDA/CDER)" <John.Farley@fda.hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Hilary Marston (b) (6) Cliff Lane (b) (6), Anita Patel <bop1@cdc.gov>, Timothy Uyeki <tmu0@cdc.gov>, "Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA)" (b) (6), Debra Birnkrant <Debra.Birnkrant@fda.hhs.gov>, John Beigel (b) (6), Elizabeth Higgs (b) (6), "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>
Subject: URGENT Questions on planned study

Hi Stacy,

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

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

Rick
Rick A. Bright, PhD

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

From: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Sent: 3/26/2020 2:52:43 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Corrigan-Curay, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cff7c455d5d24bc69c1239a23041a596-Jacqu.Corri]
Subject: Re: EUA

Thank you Janet. Very nice to meet you Jacqueline. Thank you both for all you're doing. Rick

On Mar 26, 2020, at 2:47 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

Rick, connecting you with Jacqueline Whois our lead on the EUA. Jw

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From: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Sent: 3/25/2020 2:51:28 PM
To: Howard, Jeff D. Jr. EOP/OVP (b) (6); Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Fwd: Response needed -- FW: [EXTERNAL] Fwd: Immunlight
Attachments: Coronavirus Treatment Technology.pdf

(b) (5)

Jeff

From: Howard, Jeff D. Jr. EOP/OVP (b) (6)
Date: March 25, 2020 at 1:29:46 PM EDT
To: Bright, Rick (OS) <Rick.Bright@hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

Gentlemen,

The following company came to me from Chris Liddell's office who was contacted by Susan Rockefeller. (b) (5)

Jeff Howard, MD, MBA, MPH
Office of the Vice President

From: Frederic Bourke <fabourke@immunolight.com>
Sent: Wednesday, March 25, 2020 8:35 AM
To: Howard, Jeff D. Jr. EOP/OVP (b) (6)
Subject: [EXTERNAL] Fwd:

Jeff this should give you a quick overview of what we are proposing. Thanks so much for your time

Sent from my iPhone

Begin forwarded message:

From: harold <hwalder@immunolight.com>
Date: March 24, 2020 at 9:12:05 AM MDT
To: Rick Bourke <fabourke@immunolight.com>

Harold

Harold Walder

President
Immunolight, LLC
hwalder@immunolight.com
Immunolight.com

From: Howard, Jeff D. Jr. EOP/OVP (b) (6)
Sent: 3/25/2020 5:36:41 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Re: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

Great. Thank you.

(b) (5)

Sent from my iPhone

On Mar 25, 2020, at 5:01 PM, Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov> wrote:

I can have someone from the MCM Task Force call them today to make contact and get more info. (b) (5)

From: Janet Woodcock <Janet.Woodcock@fda.hhs.gov>
Date: Wednesday, March 25, 2020 at 3:34 PM
To: Jeff Shuren <Jeff.Shuren@fda.hhs.gov>, "Howard, Jeff D. Jr. EOP/OVP" (b) (6), "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Subject: RE: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

We will take a look at this. Seems like a long shot. jw

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 2:51 PM
To: Howard, Jeff D. Jr. EOP/OVP (b) (6); Bright, Rick (OS) <Rick.Bright@hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: Fwd: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

(b) (5)

Jeff

From: Howard, Jeff D. Jr. EOP/OVP (b) (6)
Date: March 25, 2020 at 1:29:46 PM EDT
To: Bright, Rick (OS) <Rick.Bright@hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Subject: Response needed -- FW: [EXTERNAL] Fwd: Immunlight

Gentlemen,

The following company came to me from Chris Liddell's office who was contacted by Susan Rockefeller. (b) (5) [redacted]

Jeff Howard, MD, MBA, MPH
Office of the Vice President

From: Frederic Bourke <fabourke@immunolight.com>
Sent: Wednesday, March 25, 2020 8:35 AM
To: Howard, Jeff D. Jr. EOP/OVP (b) (6) [redacted]
Subject: [EXTERNAL] Fwd:

Jeff this should give you a quick overview of what we are proposing. Thanks so much for your time

Sent from my iPhone

Begin forwarded message:

From: harold <hwalder@immunolight.com>
Date: March 24, 2020 at 9:12:05 AM MDT
To: Rick Bourke <fabourke@immunolight.com>

Harold

Harold Walder
President
Immunolight, LLC
hwalder@immunolight.com
Immunolight.com

From: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
Sent: 3/23/2020 4:25:59 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Flanagan, Keith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15dcaab5c1ea4007adbc43e9acd413a6-Keith.Flana]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: By 6pm - Clinical trials underway for chloroquine
Attachments: Re: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

(b) (5) [redacted]

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, March 23, 2020 4:22 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: By 6pm - Clinical trials underway for chloroquine

(b) (5) [redacted]

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Monday, March 23, 2020 4:19 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Flanagan, Keith <Keith.Flanagan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: By 6pm - Clinical trials underway for chloroquine

(b) (5) [redacted]

Let me know if you have any questions – and just to clarify, [redacted] (b) (5) [redacted] Thanks so much.

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
(b) (6) [redacted] | jeet.guram@fda.hhs.gov

From: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Sent: 3/25/2020 6:51:09 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: URGENT Questions on planned study

(b) (5)

On Mar 25, 2020, at 6:22 PM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

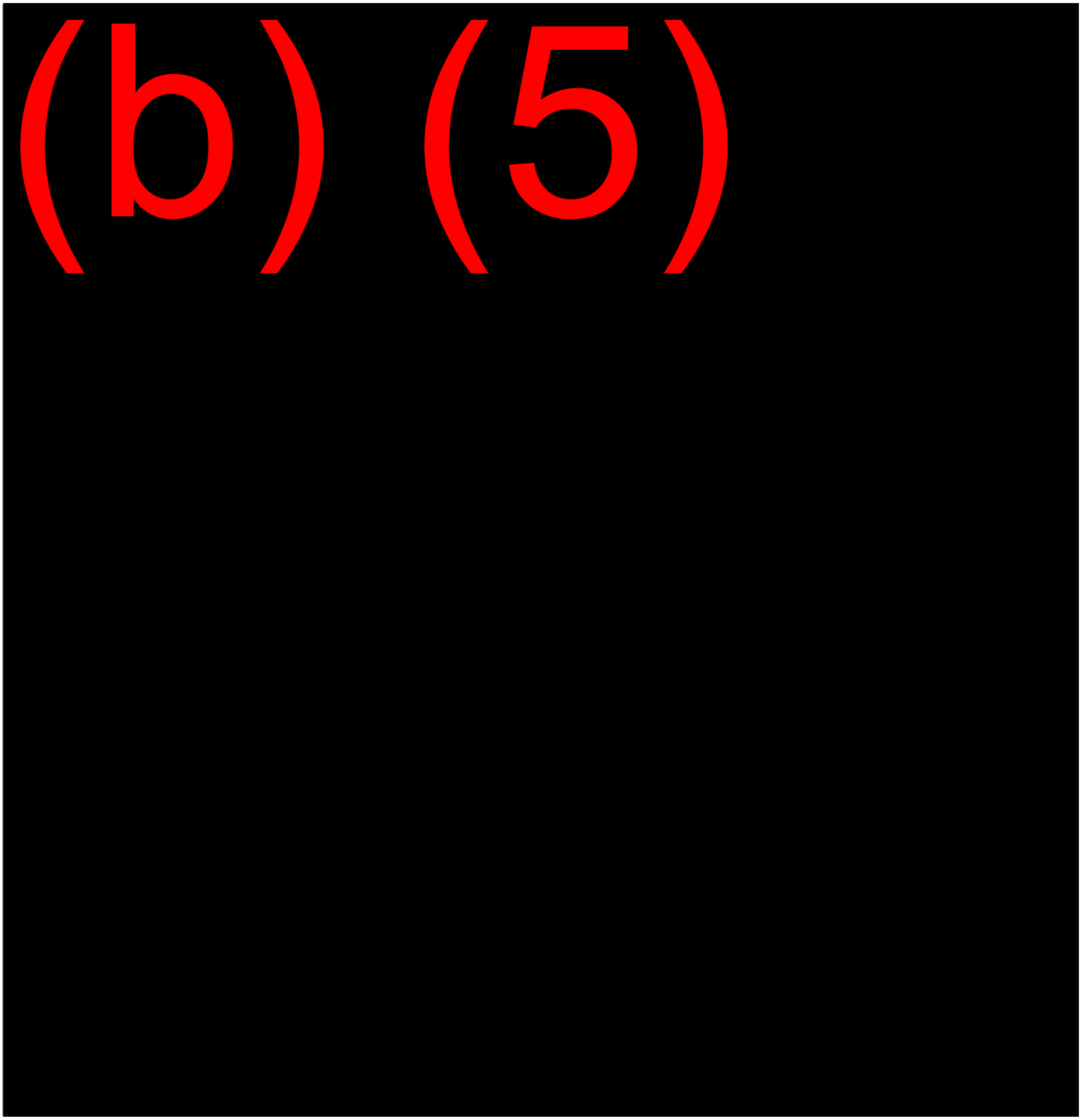
(b) (5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 25, 2020 at 5:57:52 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Walker, Robert (OS) <Robert.Walker@hhs.gov>, Faison, Tremel (OS) <Tremel.Faison@hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Marston, Hilary D (NIH) (b) (6), Lane, Henry C (NIH) (b) (6), Patel, Anita (CDC) <bop1@cdc.gov>, Uyeki, Timothy M (CDC) <tmu0@cdc.gov>, Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6), Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>, Beigel, John H (NIH) (b) (6), Higgs, Elizabeth S (NIH) (b) (6), Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Harper, Victor G (OS) <Victor.Harper@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Johnson, Robert (OS) <Robert.Johnson@hhs.gov>
Subject: Re: URGENT Questions on planned study
Importance: High

FOUO, Confidential, Pre-Decisional

Dear All,

(b) (5)



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

Rick

From: "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>
Date: Monday, March 23, 2020 at 9:09 PM

To: "Amin, Stacy (FDA/OC)" <Stacy.Amin@fda.hhs.gov>
Cc: Janet Woodcock <Janet.Woodcock@fda.hhs.gov>, Robert Johnson <Robert.Johnson@hhs.gov>, Robert Walker <Robert.Walker@hhs.gov>, Tremel Faison <Tremel.Faison@hhs.gov>, "Farley, John (FDA/CDER)" <John.Farley@fda.hhs.gov>, Linda Lambert <Linda.Lambert@hhs.gov>, Christine Oshansky <Christine.Oshansky@hhs.gov>, Gary Disbrow <Gary.Disbrow@hhs.gov>, Hilary Marston (b) (6), Cliff Lane (b) (6), Anita Patel <bop1@cdc.gov>, Timothy Uyeki <tmu0@cdc.gov>, "Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA)" (b) (6), Debra Birnkrant <Debra.Birnkrant@fda.hhs.gov>, John Beigel (b) (6), Elizabeth Higgs (b) (6), "Sherman, Susan (HHS/OGC)" <Susan.Sherman@HHS.GOV>
Subject: URGENT Questions on planned study

Hi Stacy,

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

(b) (5)

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

Rick
Rick A. Bright, PhD
Director, BARDA
Deputy Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services

From: Hamel, Joseph (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b90f78a9c02426eb8d62bd1ad9117b8-HHS-Joseph.]
Sent: 3/23/2020 3:10:58 PM
To: Maffia, Anthony [anthony.maffia@sandoz.com]
CC: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Houchens, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffd780651964b4b999a0a9865886b23-HHS-Christo]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]
Subject: RE: Quick request for support

Anthony,

Thank you for reaching out. There's a NIH PCORI trial about to launch. Adding the BARDA and FDA team to get this over the finish line.

Best,
Joe

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

From: Maffia, Anthony <anthony.maffia@sandoz.com>
Sent: Monday, March 23, 2020 2:08 PM
To: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Subject: Quick request for support

Joe,

Given the COVID-19 pandemic worldwide and the need to access potential treatments, Novartis is urgently developing a clinical protocol to assess the utility of hydroxychloroquine with and without azithromycin in COVID-19 positive patients who have been hospitalized. To facilitate the execution of the study and to maximize the robustness of the results, we propose to collaborate with the Aids Clinical Trials Group (ACTG) to execute the protocol within their trial network. We believe this partnership will accelerate addressing this urgent unmet medical need and address critical gaps in our scientific knowledge.

We request a rapid approval to move quickly to engage with ACTG and execute the study with all due haste. Any push you or members of your team could give as we move ahead would be great.

We are in contact with FDA of course and we will also be reaching out as we move ahead.

Best
A

Anthony Maffia, III
Vice President, Regulatory Affairs, North America

T 609-627-6944
M (b) (6)
F 609-395-2792
anthony.maffia@sandoz.com

"If you believe you can, or believe you can't, you are right."-Henry Ford

Sandoz Inc.
Regulatory Affairs
100 College Road West
Princeton, NJ 08540
USA

From: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Sent: 3/23/2020 10:32:41 PM
To: Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Walker, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4d03cc33ba5c4f15bd581b757dc9daa4-HHS-Robert.]; Faison, Tremel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4945bc9afa3c4d34a274cb286e2f2a09-HHS-Tremel.]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffbd5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Uyeki, Timothy M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f106bd981def4bfeb945e86b266662b2-HHS-tmu0-cd]; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6) ; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]; Beigel, John H (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db2bc96f962b4661b0494e9fa6ca6bcf-HHS-jbeigel]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Flamberg, Gemma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbcd7049351f49009ec2ebc1efbd5513-Gemma.Flamb]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
Subject: RE: URGENT Questions on planned study
Attachments: RE: Quick request for support

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

Happy to talk at your earliest convenience. Could you suggest a time? (b) (5)

I have heard there are WH discussions tomorrow morning to consider (b) (5) [redacted]

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 9:09 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Walker, Robert (OS) <Robert.Walker@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Lambert, Linda (OS) <Linda.Lambert@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Marston, Hilary D (NIH) (b) (6) [redacted]; Lane, Henry C (NIH) (b) (6) [redacted]; Patel, Anita (CDC) <bop1@cdc.gov>; Uyeki, Timothy M (CDC) <tmu0@cdc.gov>; Hepburn, Matthew J CIV USARMY DOD JPEO CBRND (USA) (b) (6) [redacted]; Birnkrant, Debra B <Debra.Birnkrant@fda.hhs.gov>; Beigel, John H (NIH) (b) (6) [redacted]; Higgs, Elizabeth S (NIH) (b) (6) [redacted]; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>
Subject: URGENT Questions on planned study

Hi Stacy,

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

(b) (5) [redacted]

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

Rick
Rick A. Bright, PhD
Director, BARDA
Deputy Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
US Department of Health and Human Services

From: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Sent: 3/19/2020 2:11:25 PM
To: Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Hamel, Joseph (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b90f78a9c02426eb8d62bd1ad9117b8-HHS-Joseph.]
CC: Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Zadecky, Leo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8adc6be4e8ec4f05a6061549feb10ce8-Leo.Zadecky]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]
Subject: Re: Chloroquine

+ Joe

Sent from my iPhone

> On Mar 19, 2020, at 2:09 PM, Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov> wrote:
>
> Mr. Harrison,
>

(b) (4)

> Rosemary Roberts
> 2019 n-CoV FDA IMG Operations/Drug Lead
> FDA/CDER/OCD
>
>
>
> -----Original Message-----
> From: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
> Sent: Wednesday, March 18, 2020 7:28 PM
> To: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>
> Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>

> Subject: FW: Chloroquine
>
> Mr. Harrison,
>
> In response to your request:
>
> Manufacturers with product currently available (in alphabetical order):
> • Chloroquine phosphate tablets, 150 mg and 300 mg
> o Natco Pharma (distributed by Rising Pharmaceuticals)
> Glenda Bryant (US Agent) glenda.bryant@syneoshealth.com (b) (6)
> • Hydroxychloroquine sulfate tablets, 200 mg
> o Alkaloida Chemical Co (distributed by Sun Pharmaceutical)
> Praveen Devakadaksham (US Agent)- Praveen.devakadaksham@sunpharma.com (b) (6)
> o Amneal Pharmaceuticals (distributed by Amneal Pharmaceuticals)
> Janie Gwinn – Janie.gwinn@amneal.com or Candis Edwards – cedwards@amneal.com (b) (6)
> o Concordia Pharmaceuticals (distributed by Concordia (Plaquenil®) and Prasco Laboratories)
> Wayne Vallee (US Agent) – wayne.vallee@cardinalhealth.com (b) (6)
> o Sandoz (distributed by Sandoz)
> Lara Hansen – lara.hansen@sandoz.com (b) (6)
> o Teva Pharmaceuticals (distributed by Actavis Pharma)
> Joe DeVito – Joseph.DeVito@tevapharm.com (b) (6)
> o (b) (4) (distributed by Dr. Reddy's Laboratories)
> (b) (4) (b) (6)
> o Zydus Pharmaceuticals (distributed by Northstar Rx, Zydus Pharmaceuticals)
> Srinivas Gurram – Gsrinivas@zydususa.com (b) (6)
>
> Please let us know if any questions.
>
> Rosemary Roberts
> 2019 n-CoV FDA IMG Operations/Drug Lead
> FDA/CDER/OCD
>
> -----Original Message-----
> From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
> Sent: Wednesday, March 18, 2020 5:48 PM
> To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
> Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>
> Subject: RE: Chloroquine
>
(b) (5)
> Patrizia
>
>
> -----Original Message-----
> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Sent: Wednesday, March 18, 2020 5:44 PM
> To: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
> Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
> Subject: RE: Chloroquine
>
(b) (5)
>
> -----Original Message-----
> From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
> Sent: Wednesday, March 18, 2020 5:37 PM
> To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
> Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
> Subject: Re: Chloroquine
>
> +FDA
>
> Brian Harrison
> Chief of Staff
> U.S. Department of Health and Human Services
> 202.690.7000
> brian.harrison@hhs.gov
>
>

>> On Mar 18, 2020, at 5:35 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:
>>
>> Patrizia- connecting you with HHS leadership to (b) (5) [redacted]
>>
>> Thanks,
>> Keagan
>>
>> Sent from my iPhone
>

From: Cavazzoni, Patrizia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C42ABD33834044ECBAA03D075CC0A5D2-PATRIZIA.CA]
Sent: 3/19/2020 11:50:15 AM
To: Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Zadecky, Leo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8adc6be4e8ec4f05a6061549feb10ce8-Leo.Zadecky]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Hamel, Joseph (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b90f78a9c02426eb8d62bd1ad9117b8-HHS-Joseph.]; Adams, Peter (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93840333b622413cbcda581d938c65f8-HHS-Peter.A]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: RE: Chloroquine

(b) (5)

-----Original Message-----
From: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Sent: Thursday, March 19, 2020 11:09 AM
To: Bright, Rick (OS) <Rick.Bright@hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Hamel, Joseph (OS) <Joseph.Hamel@hhs.gov>; Adams, Peter (OS) <Peter.Adams@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Chloroquine

(b) (4)

(b) (4)

-----Original Message-----
From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Thursday, March 19, 2020 10:49 AM
To: Roberts, Rosemary (FDA/CDER) <Rosemary.Roberts@fda.hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia (FDA/CDER) <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo (FDA/CDER) <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E (FDA/CDER) <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C (FDA/CDER) <Douglas.Throckmorton@fda.hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: Re: Chloroquine

ALCON,

I have contacted TEVA regarding their inventory of Hydroxy Chloroquine.
They have some U.S. supply, more being made now and can quarantine for USG.
They are also very interested in donating the supply to USG for allocation.

(b) (5)

They would like to DONATE to USG ASAP as well. Can someone reach out to them regarding DONATION process, considerations?

Contact for details is Christine Baeder. She is the supply chain expert and very helpful.

Christine Baeder
SVP, Chief Operating Officer US Gx
Tel: 1-215-591-8913 Cell: (b) (6)
Christine.Baeder@tevapharm.com (b) (4)

(b) (4)

On 3/18/20, 7:28 PM, "Roberts, Rosemary" <Rosemary.Roberts@fda.hhs.gov> wrote:

Mr. Harrison,

In response to your request:

Manufacturers with product currently available (in alphabetical order):
•Chloroquine phosphate tablets, 150 mg and 300 mg
oNatco Pharma (distributed by Rising Pharmaceuticals)
Glenda Bryant (US Agent) glenda.bryant@syneoshealth.com (b) (6)
•Hydroxychloroquine sulfate tablets, 200 mg
oAlkaloida Chemical Co (distributed by Sun Pharmaceutical)
Praveen Devakadaksham (US Agent)- Praveen.devakadaksham@sunpharma.com (b) (6)
oAmneal Pharmaceuticals (distributed by Amneal Pharmaceuticals)
Janie Gwinn – Janie.gwinn@amneal.com or Candis Edwards – cedwards@amneal.com (b) (6)
oConcordia Pharmaceuticals (distributed by Concordia (Plaquenil®) and Prasco Laboratories)
Wayne Vallee (US Agent) – wayne.vallee@cardinalhealth.com (b) (6)
oSandoz (distributed by Sandoz)
Lara Hansen – lara.hansen@sandoz.com (b) (6)

oTeva Pharmaceuticals (distributed by Actavis Pharma)
Joe DeVito – Joseph.DeVito@tevapharm.com (b) (6)
(b) (4) (distributed by Dr. Reddy's Laboratories)
(b) (4) (b) (6)
oZydus Pharmaceuticals (distributed by Northstar Rx, Zydus Pharmaceuticals)
Srinivas Gurram – Gsrinivas@zydususa.com (b) (6)

Please let us know if any questions.

Rosemary Roberts
2019 n-CoV FDA IMG Operations/Drug Lead
FDA/CDER/OCD

-----Original Message-----
From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:48 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>
Subject: RE: Chloroquine

(b) (5)

-----Original Message-----
From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:44 PM
To: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Subject: RE: Chloroquine

(b) (5)

-----Original Message-----
From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Sent: Wednesday, March 18, 2020 5:37 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Subject: Re: Chloroquine

+FDA

Brian Harrison
Chief of Staff
U.S. Department of Health and Human Services
202.690.7000
brian.harrison@hhs.gov

> On Mar 18, 2020, at 5:35 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:
>
> Patrizia- connecting you with HHS leadership (b) (5)
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
Sent: 3/19/2020 1:03:26 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Ashley, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40241a76230349cbb195ab1721092196-Donald.Ashl]
Subject: RE: Hydroxy Chloroquine
Attachments: RE: Chloroquine

Stacy

(b) (5)

Patrizia

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Thursday, March 19, 2020 12:45 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: Hydroxy Chloroquine

(b) (5)

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Date: March 19, 2020 at 12:32:13 PM EDT
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Cc: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Hydroxy Chloroquine

FOUO. Confidential.

(b) (5), (b) (4)

From: "Amin, Stacy" <Stacy.Amin@fda.hhs.gov>
Date: Thursday, March 19, 2020 at 12:24 PM
To: "Charrow, Robert (HHS/OGC)" <Robert.Charrow@hhs.gov>
Cc: "Charrow, Robert (HHS/OGC)" <Robert.Charrow@hhs.gov>, "Harrison, Brian (HHS/IOS)" <Brian.Harrison@hhs.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, Bryan Shuy

<Bryan.Shuy@hhs.gov>, "Lenihan, Keagan (FDA/OC)" <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Hydroxy Chloroquine

(b) (5)

From: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Date: March 19, 2020 at 12:20:40 PM EDT
To: christine.baeder@tevapharma.com <christine.baeder@tevapharma.com>
Cc: Charrow, Robert (OS) <Robert.Charrow@hhs.gov>, Harrison, Brian (OS) <Brian.Harrison@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Hydroxy Chloroquine

Christine,

Just got off phone with FedEx; they can move material on their planes direct from (b) (4) to U.S. once you obtain export license. I've copied FDA on this in the event that you need documentation from them. Keep us posted on the export license. Thanks so much, Bob

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

(b) (5)

(b) (5)

(b) (5)

(b) (5)

From: Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) [tmu0@cdc.gov]
Sent: 3/19/2020 12:19:38 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Davis, May M. EOP/WHO (b) (6); Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Zembower, Jenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83f9eb4b88564c3797b4238da3842ef8-Jenna.Zembo]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcfcc02744b3a6-HHS-carrie.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Auchincloss, Hugh (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab02b9d7c8514b538a08bab4a6659fba-HHS-auchinc]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Lankford, David W (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47d9ca5f75534cd8a2f3d22c3beb2e0b-HHS-Lankfor]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]
CC: Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Pillai, Satish K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e43838cb79744d390db5bd55b132650-HHS-vig8-cd]
Subject: RE: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
Attachments: Information for Clinicians on COVID-19 Therapies 03192020_v2.docx

(b) (5)
It is planned for posting on the CDC webpages.
Thanks,

Tim

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Thursday, March 19, 2020 11:10 AM
To: Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Fauci, Anthony (NIH/NIAID) [E] (b) (6); Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Guram, Jeet (FDA/OC) <Jeet.Guram@fda.hhs.gov>; Farley, John (FDA/CDER) <John.Farley@fda.hhs.gov>; Roberts, Rosemary (FDA/CDER) <Rosemary.Roberts@fda.hhs.gov>; Amin, Stacy (FDA/OC) <Stacy.Amin@fda.hhs.gov>; Davis, May M. EOP/WHO (b) (6); Raza, Mark (FDA/OC) <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda (FDA/OC) <Amanda.Edmonds@fda.hhs.gov>; Beers, Donald (FDA/OC) <Donald.Beers@fda.hhs.gov>; Zembower, Jenna (FDA/OC) <Jenna.Zembower@fda.hhs.gov>; Uyeki, Timothy M. (CDC/DDID/NCIRD/ID) <tmu0@cdc.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Wolinetz, Carrie (NIH/OD) [E] (b) (6); Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Auchincloss, Hugh (NIH/NIAID) [E] (b) (6); Marston, Hilary (NIH/NIAID) [E] (b) (6); Lankford, David (NIH/OD) [E] (b) (6); Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>
Subject: RE: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)

Let's all try this alternate number, I will dal in as leader

Dial In Number Local/Toll Number (b) (6) Freephone/Toll Free Number (b) (6) Passcodes Leader: (b) (6) Participant: (b) (6)

-----Original Appointment-----
From: Zembower, Jenna **On Behalf Of** Shah, Anand
Sent: Wednesday, March 18, 2020 3:27 PM
To: Shah, Anand; Bright, Rick (OS); Fauci, Anthony S (NIH); Woodcock, Janet; Cavazzoni, Patrizia; Guram, Jeet; Farley, John; Roberts, Rosemary; Amin, Stacy; Davis, May M. EOP/WHO; Raza, Mark; Edmonds, Amanda; Beers, Donald; Zembower, Jenna; Uyeki, Timothy M (CDC); Lenihan, Keagan; Wolinetz, Carrie D (NIH); Shuy, Bryan (OS); Disbrow, Gary (OS); Auchincloss, Hugh (NIH); Marston, Hilary D (NIH); Lankford, David W (NIH); Mair, Michael
Subject: Int Call - FDA / ASPR / BARDA / NIH / CDC (chloroquine / COVID-19)
When: Thursday, March 19, 2020 11:00 AM-11:45 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6) ,, (b) (6)

POC for Scheduling: Jenna Zembower (Office of the Commissioner, FDA)

Agenda

(b) (5)

Participants on this call:

FDA

- Anand Shah, Office of the Commissioner, Deputy Commissioner for Medical & Scientific Affairs
- Keagan Lenihan, Office of the Commissioner, Chief of Staff
- Jeet Guram, Office of the Commissioner, Senior Advisor
- Michael Mair, Acting Assistant Commissioner for Counterterrorism Policy, Office of the Chief Scientist

- Janet Woodcock, CDER, Director
- Patrizia Cavazzoni, CDER, Deputy Director for Operations
- John Farley, CDER Office of Infectious Diseases, Director
- Rosemary Roberts, CDER Counter-Terrorism and Emergency Coordination Staff, Director
- Stacy Amin, Office of the Chief Counsel, Chief Counsel
- Mark Raza, Office of the Chief Counsel, Deputy Chief Counsel
- Amanda Edmonds, Office of the Chief Counsel, Deputy Chief Counsel for Program Review for Biologics and Drugs

ASPR/BARDA
- Rick Bright, Deputy Assistant Secretary for Preparedness and Response (ASPR) & Director of the Biomedical Advances Research and Development Authority (BARDA)
- Brian Shuy, ASPR Deputy Assistant Secretary and Chief of Staff
- Gary Disbrow, Acting Deputy Director of BARDA

NIH
- Anthony Fauci, NIAID, Director
- Hugh Auchincloss, NIAID, Principal Deputy Director
- Carrie Wolinetz, Acting Chief of Staff
- Hilary Marston, Office of the Chief of Staff, Medical Officer/Policy Advisor

CDC
- Timothy Uyeki, National Center for Immunization and Respiratory Diseases

White House
- May Davis, Associate White House Counsel

-- Do not delete or change any of the following text. --

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Need help? Go to http://help.webex.com

From: Harrison, Brian (HHS/IOS) [Brian.Harrison@hhs.gov]
Sent: 3/19/2020 10:06:36 AM
To: Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Zadecky, Leo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8adc6be4e8ec4f05a6061549feb10ce8-Leo.Zadecky]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Hayes, Jonathan (OS/ASPR/IO) [Jonathan.Hayes@hhs.gov]
Subject: Re: Chloroquine

(b) (5) [redacted]

Brian Harrison
Chief of Staff
U.S. Department of Health and Human Services
202.690.7000
brian.harrison@hhs.gov

> On Mar 19, 2020, at 9:37 AM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov> wrote:
>
> Confirmed. Thanks!
>
> -----Original Message-----
> From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
> Sent: Wednesday, March 18, 2020 10:00 PM
> To: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>
> Cc: Roberts, Rosemary (FDA/CDER) <Rosemary.Roberts@fda.hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia (FDA/CDER) <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo (FDA/CDER) <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E (FDA/CDER) <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C (FDA/CDER) <Douglas.Throckmorton@fda.hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>
> Subject: Re: Chloroquine
>
> Yes.
>
> +Catherine, who was speaking with them.
>
>
> Brian Harrison
> Chief of Staff
> U.S. Department of Health and Human Services
> 202.690.7000

> brian.harrison@hhs.gov
>
>
>> On Mar 18, 2020, at 9:54 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:
>>
>> Thanks Rosemary. Brian- (b) (5)
>>
>> Sent from my iPhone
>>
>>>> On Mar 18, 2020, at 7:28 PM, Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov> wrote:
>>>
>>> Mr. Harrison,
>>>
>>> In response to your request:
>>>
>>> Manufacturers with product currently available (in alphabetical order):
>>> • Chloroquine phosphate tablets, 150 mg and 300 mg
>>> o Natco Pharma (distributed by Rising Pharmaceuticals)
>>> Glenda Bryant (US Agent) glenda.bryant@syneoshealth.com (b) (6)
>>> • Hydroxychloroquine sulfate tablets, 200 mg
>>> o Alkaloida Chemical Co (distributed by Sun Pharmaceutical)
>>> Praveen Devakadaksham (US Agent)- Praveen.devakadaksham@sunpharma.com (b) (6)
>>> o Amneal Pharmaceuticals (distributed by Amneal Pharmaceuticals)
>>> Janie Gwinn – Janie.gwinn@amneal.com or Candis Edwards – cedwards@amneal.com (b) (6)
>>> o Concordia Pharmaceuticals (distributed by Concordia (Plaquenil®) and Prasco Laboratories)
>>> Wayne Vallee (US Agent) – wayne.vallee@cardinalhealth.com (b) (6)
>>> o Sandoz (distributed by Sandoz)
>>> Lara Hansen – lara.hansen@sandoz.com (b) (6)
>>> o Teva Pharmaceuticals (distributed by Actavis Pharma)
>>> Joe DeVito – Joseph.DeVito@tevapharm.com 215-293-7245
>>> o (b) (4) (distributed by Dr. Reddy's Laboratories)
>>> (b) (4) (b) (6)
>>> o Zydus Pharmaceuticals (distributed by Northstar Rx, Zydus Pharmaceuticals)
>>> Srinivas Gurram – Gsrinivas@zydususa.com (b) (6)
>>>
>>> Please let us know if any questions.
>>>
>>> Rosemary Roberts
>>> 2019 n-CoV FDA IMG Operations/Drug Lead FDA/CDER/OCD
>>>
>>> -----Original Message-----
>>> From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
>>> Sent: Wednesday, March 18, 2020 5:48 PM
>>> To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Harrison, Brian
>>> (OS) <Brian.Harrison@hhs.gov>
>>> Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS)
>>> <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>;
>>> Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Throckmorton,
>>> Douglas C <Douglas.Throckmorton@fda.hhs.gov>
>>> Subject: RE: Chloroquine
>>>
(b) (5)
>>> Patrizia
>>>
>>>
>>> -----Original Message-----
>>> From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
>>> Sent: Wednesday, March 18, 2020 5:44 PM
>>> To: Harrison, Brian (OS) <Brian.Harrison@hhs.gov>
>>> Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec,
>>> Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS)
>>> <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
>>> Subject: RE: Chloroquine
>>>
(b) (5)
>>>
>>> -----Original Message-----
>>> From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
>>> Sent: Wednesday, March 18, 2020 5:37 PM
>>> To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
>>> Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec,
>>> Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS)
>>> <Bryan.Shuy@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>;
>>> Charrow, Robert (OS) <Robert.Charrow@hhs.gov>

>>> Subject: Re: Chloroquine
>>>
>>> +FDA
>>>
>>> Brian Harrison
>>> Chief of Staff
>>> U.S. Department of Health and Human Services
>>> 202.690.7000
>>> brian.harrison@hhs.gov
>>>
>>>
>>>>> On Mar 18, 2020, at 5:35 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:
>>>>
>>>> Patrizia- connecting you with HHS leadership (b) (5) [redacted]
>>>>
>>>> Thanks,
>>>> Keagan
>>>>
>>>> Sent from my iPhone
>>>

From: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
Sent: 3/19/2020 11:50:15 AM
To: Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Zadecky, Leo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8adc6be4e8ec4f05a6061549feb10ce8-Leo.Zadecky]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Hamel, Joseph (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b90f78a9c02426eb8d62bd1ad9117b8-HHS-Joseph.]; Adams, Peter (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93840333b622413cbcda581d938c65f8-HHS-Peter.A]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: RE: Chloroquine

(b) (5)

Patrizia

-----Original Message-----
From: Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Sent: Thursday, March 19, 2020 11:09 AM
To: Bright, Rick (OS) <Rick.Bright@hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Hamel, Joseph (OS) <Joseph.Hamel@hhs.gov>; Adams, Peter (OS) <Peter.Adams@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: Chloroquine

(b) (4)

(b) (4)

-----Original Message-----
From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Thursday, March 19, 2020 10:49 AM
To: Roberts, Rosemary (FDA/CDER) <Rosemary.Roberts@fda.hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Cc: Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia (FDA/CDER) <Patrizia.Cavazzoni@fda.hhs.gov>; Zadecky, Leo (FDA/CDER) <Leo.Zadecky@fda.hhs.gov>; Jensen, Valerie E (FDA/CDER) <Valerie.Jensen@fda.hhs.gov>; Throckmorton, Douglas C (FDA/CDER) <Douglas.Throckmorton@fda.hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>; Adams, Peter (OS/ASPR/BARDA) <Peter.Adams@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Johnson, Robert (OS/ASPR/BARDA) <Robert.Johnson@hhs.gov>; Oshansky, Christine (OS/ASPR/BARDA) <Christine.Oshansky@hhs.gov>
Subject: Re: Chloroquine

ALCON,

(b) (5)

Christine Baeder
SVP, Chief Operating Officer US Gx
Tel: 1-215-591-8913 Cell: (b) (6)
Christine.Baeder@tevapharm.com (b) (4)

(b) (4)

On 3/18/20, 7:28 PM, "Roberts, Rosemary" <Rosemary.Roberts@fda.hhs.gov> wrote:

Mr. Harrison,

In response to your request:

Manufacturers with product currently available (in alphabetical order):
•Chloroquine phosphate tablets, 150 mg and 300 mg
oNatco Pharma (distributed by Rising Pharmaceuticals)
Glenda Bryant (US Agent) glenda.bryant@syneoshealth.com (b) (6)
•Hydroxychloroquine sulfate tablets, 200 mg
oAlkaloida Chemical Co (distributed by Sun Pharmaceutical)
Praveen Devakadaksham (US Agent)– Praveen.devakadaksham@sunpharma.com (b) (6)
oAmneal Pharmaceuticals (distributed by Amneal Pharmaceuticals)
Janie Gwinn – Janie.gwinn@amneal.com or Candis Edwards – cedwards@amneal.com (b) (6)
oConcordia Pharmaceuticals (distributed by Concordia (Plaquenil®) and Prasco Laboratories)
Wayne Vallee (US Agent) – wayne.vallee@cardinalhealth.com (b) (6)
oSandoz (distributed by Sandoz)
Lara Hansen – lara.hansen@sandoz.com (b) (6)
oTeva Pharmaceuticals (distributed by Actavis Pharma)

Joe DeVito – Joseph.DeVito@tevapharm.com (b) (6)
(b) (4) (distributed by Dr. Reddy's Laboratories)
(b) (4) (b) (6)
oZydus Pharmaceuticals (distributed by Northstar Rx, Zydus Pharmaceuticals)
Srinivas Gurram – Gsrinivas@zydususa.com (b) (6)

Please let us know if any questions.

Rosemary Roberts
2019 n-CoV FDA IMG Operations/Drug Lead
FDA/CDER/OCD

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From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 5:48 PM
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Cc: Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>
Subject: RE: Chloroquine

(b) (5)

Patrizia

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Subject: RE: Chloroquine

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From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>
Sent: Wednesday, March 18, 2020 5:37 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Charrow, Robert (OS) <Robert.Charrow@hhs.gov>
Subject: Re: Chloroquine

+FDA

Brian Harrison
Chief of Staff
U.S. Department of Health and Human Services
[redacted]
brian.harrison@hhs.gov

> On Mar 18, 2020, at 5:35 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:
>
(b) (5)
>
> Thanks,
> Keagan
>
> Sent from my iPhone

From: Jonas, Seth H. EOP/NSC (b) (6)
Sent: 3/9/2020 9:28:24 PM
To: McCommas, Brendan N. EOP/WHO (b) (6); Abbott, Christopher J. EOP/WHO (b) (6); Storch, Thomas H. EOP/NSC (b) (6); DeBacker, Devin A. EOP/WHO (b) (6); Kan, Derek T. EOP/OMB (b) (6); Williams, James H. EOP/WHO (b) (6); Watson, Ian D. EOP/OSTP (b) (6); Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; John.Mashburn@va.gov; (b) (6); Nazak Nikakhtar [Nazak.Nikakhtar@trade.gov]; Stanich.Ted@epa.gov; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Gerrish, Jeffrey D. EOP/USTR (b) (6); scott.glabe@hq.dhs.gov; joel.doolin@fema.dhs.gov
CC: Butterfield, Nicholas W. EOP/WHO (b) (6); Cavanaugh, Brian J. EOP/NSC (b) (6)
Subject: Snap restricted PCC on supply chain for 03/10/2020

Message sent on behalf of Brian J. Cavanaugh, Special Assistant to the President and Senior Director for Resilience Policy

###

Dear Colleagues,

Tomorrow, we would appreciate your attendance at a snap restricted PCC as a follow up to today's PCC on immediate supply chain challenges brought to light by COVID-19. Please be prepared to discuss your comments on the document.

The meeting will be held tomorrow, 03/10/2020, from 1230-1400, in the West Wing JKF room (WHSR).

Those who were WAVES'd in today have been re-WAVES'd. Please let me know if different staff will be supporting you and we can address accordingly.

From: Bright, Rick (OS/ASPR/BARDA) [Rick.Bright@hhs.gov]
Sent: 3/5/2020 7:28:08 PM
To: 'Martin VanTrieste' [martin@civicarx.org]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Where was it made? Changes for the pharmaceutical industry: Origin of the active pharmaceutical ingredient is not dispositive in sales to U.S. government

Whoa. Thanks for the heads up Martin. (b) (5) I have shared it with relevant colleagues. Thank you. Rick

---

From: Martin VanTrieste <martin@civicarx.org>
Sent: Thursday, March 05, 2020 5:16 PM
To: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Woodcock, Janet (FDA/CDER) <Janet.Woodcock@fda.hhs.gov>
Subject: Re: Where was it made? Changes for the pharmaceutical industry: Origin of the active pharmaceutical ingredient is not dispositive in sales to U.S. government

just in case you have not seen this ruling in the courts

I received the following Client Alert below summarizing a recent Federal Circuit decision, *Acetris Health LLC v. United States*, that I thought would be of interest to you and your team.

This case recently upended prior precedent on the "country-of-origin" determinations under the Trade Agreements Act (TAA) for pharmaceutical products sold to the Federal Government. Previous rulings had held that the country-of-origin was the location of the Active Pharmaceutical Ingredient (API), even if ultimately combined with other ingredients in the United States. The *Acetris* decision turns that on its head by holding that it the "final product that is procured – here, the pill itself – rather than the ingredients of the pill" that determines a product's country of origin. This potentially opens the door to selling pharmaceutical products to the U.S. Government that include an API from a non-TAA country, so long as the drug is ultimately manufactured or substantially transformed in the United States or a TAA-approved country. A more fulsome description of the case below, and we'll be watching to see whether the case is appealed for *en banc* review or goes up to the Supreme Court.

This will clearly hinder the drive to produce APIs in the U.S

Martin VanTrieste | President and CEO

Serving Patients is Our Privilege

2912 Executive Parkway, Ste. 325

Lehi, UT 84043

mobile | (b) (6)

email | martin@civicarx.org

web | https://protect2.fireeye.com/url?k=f46f7e8e-a83a775e-f46f4fb1-0cc47a6a52de-e6889d52ac8f43a1&u=http://www.civicarx.org/

Where was it made? Changes for the pharmaceutical industry: Origin of the active pharmaceutical ingredient is not dispositive in sales to U.S. government

At a Glance…

In a striking recent decision, the U.S. Court of Appeals for the Federal Circuit ruled in *Acetris Health, LLC v. United States*, ___ F.3d ___, 2020 WL 610487 (Fed. Cir. Feb. 10, 2020), that active pharmaceutical ingredients (APIs) are no longer the deciding factor for country of origin determinations under the Trade Agreements Act (TAA). The Court also held that the procuring agency, not the U.S. Customs and Border Protection (CBP), must independently determine whether a good (or drug or device) is eligible for procurement as a "U.S.-made end product" as required under Federal Acquisition Regulations (FAR), the implementing regulations of the TAA.

Authors: Michael J. Lowell (International Trade and National Security), **Manasi Venkatesh** (International Trade and National Security), **Lawrence Sher** (Life Sciences Health Industry Group), **Alison Peters** (Life Sciences Health Industry Group), **Elizabeth Leavy** (Government Contracts), **William Kirkwood** (Government Contracts)

Case background and regulatory framework:

At issue in *Acetris* was the Department of Veteran Affairs' (VA) interpretation of restrictions on the procurement of foreign origin pharmaceutical products under the TAA and the FAR. The FAR requires that, with some exceptions, government agencies must buy goods that are "U.S.-made or designated country end products." FAR 25.403(c). A "U.S.-made end product" may be either: (i) "manufactured in the United States" or a TAA designated country; or (ii) "substantially transformed in the United States" or a TAA designated country. FAR 25.003. Pursuant to 19 CFR 177.21 et seq., CBP issues country of origin advisory rulings and final determinations. In making these determinations, CBP has long held that the country from which a pharmaceutical product's API is sourced generally dictates its country of origin. *Acetris*, 2020 WL 610487 at *6.

In *Acetris*, the plaintiff was a pharmaceutical distributor that specialized in providing pharmaceuticals to the federal government. After seeking an advisory opinion, CBP determined that *Acetris*'s pharmaceutical products originated in India because their APIs were made in India, a non-TAA designated country, and the manufacturing process in the United States did not constitute a "substantial transformation" of the APIs. *See* 83 Fed. Reg. 5132-33 (Feb. 5, 2018). Relying on CBP's determination, the VA determined it could no longer purchase certain pharmaceutical products from *Acetris* because the products were non-TAA compliant. The U.S. Court of Federal Claims (COFC) granted *Acetris* declaratory and injunctive relief, holding that the VA misinterpreted the TAA and the FAR. The VA appealed.

Shifting standard for TAA and FAR compliance:

In recent years, a product's country of origin has been the source of much litigation. *Acetris* represents a dramatic shift from a nearly 70-year-old practice of determining a pharmaceutical product's country of origin under the TAA

based on the source of the product's API. The Federal Circuit's decision shifts the interpretation of the TAA country of origin requirements to the origin of the end product, rather than the origin of the product's individual components. Specifically, the Court explained that it is the "final product that is procured – here, the pill itself – rather than the ingredients of the pill" that determines a product's country of origin, and that because the product at issue was not wholly manufactured or substantially transformed in India, it was not a "product of India" for the purposes of the TAA. *Acetris* 2020 WL 610487 at *24. Further, the Court, in affirming the COFC's ruling, expressly rejected the government's position that CBP country of origin determinations are binding on federal agencies. The Court also clarified that a product may be "manufactured" **or** "substantially transformed" in the United States to qualify as a U.S.-made end product under the FAR, but it **does not** need to meet both requirements.

The *Acetris* decision's impact:

The *Acetris* decision provides clarity on the application of the FAR and TAA in government procurement and adds flexibility for contractors with pharmaceutical products with APIs from non-TAA designated countries. The fact that the country of origin of a company's end product no longer will be determined by a single component or ingredient will make it easier for contractors and pharmaceutical companies with manufacturing facilities in the United States to sell their products to federal agencies, especially those who perform compounding work in the United States. The decision upends the common practice of contracting officers relying on CBP for determinations of country of origin and injects considerable uncertainty into the industry's reliance on CBP country of origin determinations to support conclusions for procurement purposes. The decision also creates uncertainty regarding what standards contracting officers will apply in determining whether an end product was "manufactured" in the United States. Unless the FAR is amended, the *Acetris* decision likely will add unpredictability to the country of origin determination process in government procurement, and may result in potential inconsistency between CBP's country of origin determinations for importers of pharmaceutical products or medical devices and country of origin determinations for government procurement purposes.

The government has not yet disclosed whether it will seek Federal Circuit *en banc* or Supreme Court review of the *Acetris* decision. In the interim, contractors and pharmaceutical companies should closely monitor how courts apply the *Acetris* decision, and whether there is any legislative or regulatory action taken as a result of the Federal Circuit's decision.

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors – listed below – or the Reed Smith lawyer with whom you regularly work.

Michael J. Lowell
Partner, Washington, D.C.
+1 202 414 9253
mlowell@reedsmith.com

Manasi Venkatesh
Associate, Washington, D.C.
+1 202 414 9478
mvenkatesh@reedsmith.com

Lawrence S. Sher
Partner, Washington D.C.
+1 202 414 9209
lsher@reedsmith.com

Alison Peters
Associate, Washington D.C.
+1 202 414 9178
apeters@reedsmith.com

Elizabeth Leavy
Counsel, Washington D.C.
+1 202 414 9242
eleavy@reedsmith.com

William Kirkwood
Associate, Washington D.C.
+1 202 414 9422
wkirkwood@reedsmith.com

This will clearly hinder the drive to make APIs in the U.S