



Case No. 2020-00717-FOIA-OS
American Oversight v. HHS, Civil No. 20-1169

June 7, 2023

Austin Evers
Executive Director
American Oversight
Sent via email: foia@americanoversight.org

Dear Mr. Evers:

This letter is the twenty-fifth interim response to your March 18, 2020, Freedom of Information Act (FOIA) request.

American Oversight requests that HHS produce the following records as soon as practicable, and at least within twenty business days:

All email communications (including email messages, complete email chains, email attachments, calendar invitations) sent by the government officials specified below containing any of the following key terms:

1. Coronavirus
2. Corona
3. Virus
4. Disease
5. Pandemic
6. Epidemic
7. Outbreak
8. containment
9. "public health emergency"
10. "COVID-19"
11. "COVID 19"
12. COVID19
13. SARS
14. "2019-nCoV"
15. POTUS
16. Test
17. Tests
18. Testing
19. EUA
20. Emergency
21. Wuhan
22. Hoax
23. Hubei
24. Princess
25. Cruise
26. Kirkland
27. Seattle
28. "New Rochelle"
29. "BioGen Conference"
30. CPAC
31. AIPAC
32. RNA

33. "Extraction kits"
34. Roche
35. Vaccine
36. Antiviral
37. Antiretroviral
38. Quarantine
39. Distancing
40. Isolation
41. N95
42. Mask
43. Respirator

Government Officials

1. Alex Azar, Secretary
2. Brian Harrison, Chief of Staff
3. Eric Hargan, Deputy Secretary
4. Jerome Adams, Surgeon General
5. Robert Kadlec, Assistant Secretary for Preparedness and Response
6. John Brooks, Senior Advisor to the Secretary for Drug Pricing Reform

On February 10, 2021, you narrowed your request per the following:

Eliminate attachments, documents regarding "Red Dawn" and obvious marketing and news bulletins

- a. Limit the date range of the following key terms as stand-alone search terms from January 15, 2020 through February 29, 2020. ~~[[Limit responsive records to those that also include: (Test OR Tests OR Vaccine OR EUA OR "Emergency Use" OR Shortage OR Shortages OR Supplies OR "the WHO" OR States OR Governor OR Governors OR PPE OR Ventilators OR Respirators OR Swabs OR DPA OR "Defense Production Act" OR Trump OR Pence OR Jared OR Kushner OR "White House" OR "the WH")]]~~

- i. Coronavirus
- ii. Corona
- iii. "COVID-19"
- iv. "COVID 19"
- v. COVID19
- vi. "2019-nCoV"

~~vii. SARS~~

~~viii. Epidemic~~

~~ix. Pandemic~~

~~x. Outbreak~~

~~xi. "Public Health Emergency"~~

-

- b. After March 1, 2020, for the key terms listed in Column A below (the same search terms as identified above), limit responsive records to those that also include one or more of the terms from Column B:

Column A	Column B
• Coronavirus • Corona • “COVID-19” • “COVID 19” • COVID19 • “2019-nCoV” • SARS • Epidemic • Pandemic • Outbreak • “Public Health Emergency”	• Test • Tests • Vaccine • Antiviral • Antiretroviral • EUA • “Emergency Use” • Shortage • Shortages • Supplies • “Emergency Use” • EUA • “the WHO” • “W.H.O.” • “World Health Organization” • States • Governor • Governors • PPE • Ventilators • Respirators • Swabs • DPA • “Defense Production Act”

- c. For the key terms that are in Column A below, limit responsive records to those that also include one or more of the terms from Column B, for the full time period of the search.

Column A	Column B
• Test • Tests • “Extraction Kits”	• CV19 • “CV-19” • C19 • “C-19” • Roche • RNA • Shortage • Shortages • Supplies • “Emergency Use” • “EUA” • “the WHO” • “W.H.O.” • “World Health Organization” • States • Governor • Governors • Kit • Kits • DPA • “Defense Production Act”

- d. ~~[~500 records] For the key terms that are in Column A below, limit responsive records to those that also include one or more of the terms from Column B, for the full time period of the search.~~

Column A	Column B
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• Vaccine • Antiviral • Antiretroviral	• CV19 • “CV-19” • C19 • “C-19” • “EUA” • “Emergency Use” • “DPA” • “Defense Production Act” • “the WHO” • “W.H.O.” • “World Health Organization”
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c. ~~[<50 records] For the key term “Emergency” limit responsive records to those that also include “DPA” or “Defense Production Act,” for the full time period of the search.~~

f. For the following key terms, please limit the time period as indicated:

i. Princess - February 1, 2020, through March 1, 2020 ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

~~ii. [~~150 records~~] Kirkland February 24, 2020, through March 24, 2020~~

~~iii. [~~750 records~~] Seattle February 24, 2020, through March 24, 2020~~

~~iv. [~~200 records~~] “New Rochelle” March 1, 2020, through March 31, 2020~~

~~v. [~~<50 records~~] “BioGen Conference” March 1, 2020, through March 31, 2020~~

~~vi. [~~50 records~~] CPAC February 21, 2020, through March 21, 2020~~

~~vii. [~~<50 records~~] AIPAC February 21, 2020, through March 21, 2020~~

g. For the following key terms, please run the search without any modifiers and using the full date range (i.e., no changes from original search)

i. Wuhan ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

ii. Hoax ~~[[no changes]]~~

iii. Hubei ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

iv. POTUS ~~[[no changes]]~~

v. Cruise ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

vi. Quarantine ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

vii. Distancing ~~[[Limit responsive records to those that also include: Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

~~viii. Isolation~~

ix. N95 ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

x. Mask ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

xi. Respirator ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

xii. Testing ~~[[Limit responsive records to those that also include: (CV19 OR “CV-19” OR C19 OR “C-19” OR Shortage OR Shortages OR Supplies OR “Emergency Use” OR “EUA” OR “the WHO” OR States OR Governor OR Governors OR DPA OR “Defense Production Act” OR Trump OR Pence OR Jared OR Kushner OR “White House” OR “the WH”]]~~

~~xiii. Containment~~

h. Cut the following key terms completely: [[no changes]]

- i. Disease
- ii. Virus

The Department processed **401 pages** of potentially responsive records captured in the agency's search for FOIA request 2020-00717-FOIA-OS. After a careful review of these pages, I have determined to release **136 pages** to you in their entirety and I am further releasing in part **116 pages**, with portions redacted, pursuant to Exemptions (b)(4), (b)(5), and (b)(6) of the FOIA (5 U.S.C. §552 (b)(4), (b)(5), and (b)(6)). Furthermore, I have determined that **149 pages** should be sent for consultation to others and returned to this Department for final disposition.

FOIA exemption (b)(4) permits the withholding of trade secrets and commercial or financial information that is privileged or confidential.

FOIA exemption (b)(5) protects inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the agency. This exemption protects documents that would be covered by any privilege an agency could assert in a civil proceeding. These privileges include, among others, the deliberative process privilege, the attorney-client privilege, the attorney work-product privilege and the presidential communications privilege. I have considered the foreseeable harm standard when reviewing these records and applying the (b)(5) exemption.

FOIA exemption (b)(6) permits a federal agency to withhold information and records about individuals in "personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." The definition of "similar files" has historically been broadly interpreted to include a wide variety of files, and the United States Supreme Court has held that Congress intended the term "similar files" to be interpreted broadly, rather than narrowly. I have analyzed these records and find they meet the threshold requirement of this exemption. Additionally, I have reviewed and weighed the public interest in disclosure of this information against the privacy interest in nondisclosure and found that the privacy interest outweighs the public's interest in disclosure.

I have found that it is reasonably foreseeable that disclosure would harm an interest protected by one or more of the exemptions to the FOIA's general rule of disclosure and/or that disclosure is prohibited by law.

We will continue to review the remaining records as efficiently and expeditiously as possible, consistent with our available resources. Should you have questions or concerns regarding the Department's response and/or the processing of your request, any such issues should be communicated to your legal counsel and Department of Justice Attorney representing the Department in this matter.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigation
FOI/Privacy Act Division

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.SPDLT)/CN=RECIPIENTS/CN=C145629CC8AC4858BF1F0CE5DD0461DC-AMA2!>
To:	Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	Re: Premier
Date:	2020/03/22 14:42:33
Priority:	Normal
Type:	Note

Let's get our policy folks digging in.

On Mar 22, 2020, at 2:41 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Sir,

Yes, I defer to Dr. Kadlec on specifics, but he has sent it to his team to consider. We have also looped in Jim Parker and Danielle Steele for HRSA/FDA.

Catherine

From: AMA2 (OS/IOS) <AMA2@HHS.GOV>
Sent: Sunday, March 22, 2020 2:34 PM
To: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: Re: Premier

Thank you. Have we assigned people to work on considering these items?

On Mar 22, 2020, at 1:16 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Hi Sir,

Please see below an email from Susan DeVore.

Catherine

From: DeVore, Susan <Susan_DeVore@PremierInc.com>
Sent: Sunday, March 22, 2020 12:03 PM
To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>
Cc: Childs, Blair <Blair_Childs@PremierInc.com>; Saha, Soumi <Soumi_Saha@premierinc.com>; Alkire, Mike <Mike_Alkire@PremierInc.com>
Subject: FW: Azar communication

Hi Jonathan,

So appreciate your help in getting this in front of Secretary Azar. Three critical challenges for our health systems right now. The folks copied above can help provide any additional information that you need. They're happy to get on a phone call with the Secretary and team. Just let me know. Thanks so much. Take care. Susan

Secretary Azar,

We are receiving urgent requests from healthcare providers across the nation on important regulatory impediments that impede their ability to manage the current COVID-19 national emergency. Here are the critical issues we have received that we request HHS address as soon as possible:

1. Reduce Drug Shortages by Waiving HRSA's Restrictive Interpretation of the GPO Prohibition:

Hospitals and clinics participating in the 340B drug pricing program (340B program) facing unprecedented problems accessing drugs needed to treat their patients. Most of the 340B hospitals operating in areas hardest hit by covid-19 are subject to a unique 340B statutory prohibition against purchasing covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. HRSA's interpretation of the 340B program's GPO restriction is exacerbating the drug shortage problem for these hospitals which, in turn, is hindering their ability to meet the challenges presented by covid-19. These hospitals are all public or non-profit high-Medicaid hospitals, including children's hospitals.

There are two steps the Secretary's office can take right now to alleviate shortages of drugs that are critically needed during the covid-19 pandemic. Covid-19 has already been declared a public health emergency, which provides the HHS Secretary the authority under section 319 of the Public Health Service Act to "take such action as may be appropriate to respond to the public health emergency."^[1] The Secretary can rely on his section 319 authority to relax HRSA's problematic sub-regulatory interpretations of the GPO restriction.

Waive HRSA's burdensome procedures for using GPO drugs when the drugs are unavailable at non-GPO prices – When a hospital subject to the GPO restriction can only acquire a covered outpatient drug through its GPO account due to drug shortage problems, HRSA allows purchasing of GPO drugs if the hospital follows a four-step process. The hospital must:

1. • Work with the manufacturer to try to obtain the drug at 340B pricing;
2. • Try to purchase the drug at wholesale acquisition cost (WAC);
3. • Notify HRSA that the drug is not available at 340B or WAC prices by filling out a template form providing numerous details about the limited availability of the drug; and

4. • Maintain auditable records of all of the above, including records showing that the hospital attempted to purchase the drug through the 340B and WAC accounts every time a purchase is made on the GPO account.

These procedures are onerous in the best of circumstances and simply impossible to perform for overworked hospital staff struggling to keep up with the demands of the covid-19 pandemic, particularly given the increasing number of drugs that are unavailable at 340B or WAC pricing. The Secretary should invoke his authority to waive or relax these procedures during the covid-19 public health emergency.

Allow Premier's privately-labeled drugs to be purchased at 340B ceiling prices by any 340B hospital – Like other GPOs, Premier has contracted with generic drug manufacturers to produce a defined quantity of commonly-used drugs for the exclusive use of its members. These drugs are privately-labeled under Premier's name and are pre-purchased in sufficient quantities to help its members survive periods of drug shortages.

To address the growing drug shortage problems associated with the coronavirus pandemic, Premier has informed its generic drug suppliers that it will waive the exclusivity restriction in its agreements so that the suppliers can sell the privately-labeled drugs to non-Premier members. Each of the suppliers has an executed pharmaceutical pricing agreement (PPA) with HRSA and is required under its PPA to offer 340B pricing on its full product line. Now that Premier has lifted the exclusivity arrangement with its suppliers, the suppliers are required under their PPAs to sell Premier's privately-labeled drugs to any interested 340B purchaser, whether it is a Premier member or not. However, because HRSA has issued guidance declaring privately-labeled drugs to be GPO drugs, both suppliers and wholesalers are concerned that selling the drugs at 340B ceiling prices will subject them and their hospital purchasers to undue risk of violating the GPO restriction.

Since the drugs will be sold to any 340B covered entity, not just Premier members, at ceiling prices established by statute rather than group negotiation, the GPO restriction cannot possibly be implicated. But the 340B supply chain needs the government's written assurance that the sale of Premier's privately-labeled drugs at 340B ceiling prices to any interested covered entity, including disproportionate share (DSH) and children's hospitals, is compliant with 340B program requirements, including the GPO restriction.

There is increasing demand for Premier's drugs due to coronavirus-related supply shortages and Premier is prepared to help meet that demand. But it needs the Secretary to take the two steps described above first.

2. PPE Decontamination/Sterilization: As hospitals struggle with dwindling PPE supplies, the concept of decontaminating or sterilizing PPE for reuse has been raised. ***There are three options on which we are asking if FDA or CDC would recommend the use of these decontamination or sterilization techniques.*** They are:

- • Nebraska Medicine announced (see attached) that it is leveraging ***UV light to decontaminate*** and reuse PPE. Many hospitals have UV light technology to address MRSA decontamination.

- Several hospitals are also considering leveraging new technology using **ultraviolet germicidal irradiation (UVGI)** to decontaminate PPE. Attached is a study the company provided regarding their decontamination studies for N95 masks.
- Many hospitals also have their own **ethylene oxide sterilization** capabilities and would like to use those capabilities on PPE supplies.

3. One-Mile Radius Rule for Sterile Compounding: With limited staff and PPE constraints, many hospitals would like to consolidate pharmacy services to a single hub. A rate-limiting step to doing so is FDA's guidance compounding guidance that dictates the one-mile radius rule. **We request that FDA temporarily waive the one-mile radius rule for hospital and health system compounding?**

Blair G. Childs

Senior Vice President
444 North Capitol Street, NW
Suite 625
Washington, D.C. 20001-1511
202-879-8009 (O)
(b)(6) (C); 202-879-8009 (F)

Susan Ueberroth, Executive Coordinator: 202 879 8010, Susan_Ueberroth@Premierinc.com

Premier, 2006 Malcolm Baldrige National Quality Award Recipient
13034 Ballantyne Corporate Place, Charlotte, NC 28277

<https://protect2.fireeye.com/url?k=2fa3a975-73f7805e-2fa3984a-0cc47a6d17cc-6d32d9195a239e0b&u=http://www.premierinc.com/baldrige>

<UVGI Effects on the N95 Respirator.pdf>
<3-20 PPE.DOCX>

[1] Determination that a Public Health Emergency Exists, <https://protect2.fireeye.com/url?k=39d59453-6581bd78-39d5a56c-0cc47a6d17cc-3230c44aacac93fa&u=https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

Sender:	AMA2 (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C145629CC8AC4858BF1F0CE5DD0461DC-AMA2!>
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Sent Date:	2020/03/22 14:42:31
Delivered Date:	2020/03/22 14:42:33
Message Flags:	Unread

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.SPDLT)/CN=RECIPIENTS/CN=C145629CC8AC4858BF1F0CE5DD0461DC-AMA2!>
To:	Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>
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Senior Vice President
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(b)(6) (C); 202-879-8009 (F)

Susan Ueberroth, Executive Coordinator: 202 879 8010, Susan_Ueberroth@Premierinc.com

Premier, 2006 Malcolm Baldrige National Quality Award Recipient
13034 Ballantyne Corporate Place, Charlotte, NC 28277

<https://protect2.fireeye.com/url?k=2fa3a975-73f7805e-2fa3984a-0cc47a6d17cc-6d32d9195a239e0b&u=http://www.premierinc.com/baldrige>

<UVGI Effects on the N95 Respirator.pdf>
<3-20 PPE.DOCX>

[1] Determination that a Public Health Emergency Exists, <https://protect2.fireeye.com/url?k=39d59453-6581bd78-39d5a56c-0cc47a6d17cc-3230c44aacac93fa&u=https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

Sender:	AMA2 (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C145629CC8AC4858BF1F0CE5DD0461DC-AMA2!>
Recipient:	Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>

Sent Date:	2020/03/22 14:42:31
Delivered Date:	2020/03/22 14:42:32

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.SPDLT)/CN=RECIPIENTS/CN=C145629CC8AC4858BF1F0CE5DD0461DC-AMA2!>
To:	Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	Re: Premier
Date:	2020/03/22 14:42:32
Priority:	Normal
Type:	Note

Let's get our policy folks digging in.

On Mar 22, 2020, at 2:41 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Sir,

Yes, I defer to Dr. Kadlec on specifics, but he has sent it to his team to consider. We have also looped in Jim Parker and Danielle Steele for HRSA/FDA.

Catherine

From: (b)(6) OS/IOS) <(b)(6)@HHS.GOV>
Sent: Sunday, March 22, 2020 2:34 PM
To: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>
Cc: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: Re: Premier

Thank you. Have we assigned people to work on considering these items?

On Mar 22, 2020, at 1:16 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Hi Sir,

Please see below an email from Susan DeVore.

Catherine

From: DeVore, Susan <Susan_DeVore@PremierInc.com>
Sent: Sunday, March 22, 2020 12:03 PM
To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>
Cc: Childs, Blair <Blair_Childs@PremierInc.com>; Saha, Soumi <Soumi_Saha@premierinc.com>; Alkire, Mike <Mike_Alkire@PremierInc.com>
Subject: FW: Azar communication

Hi Jonathan,

So appreciate your help in getting this in front of Secretary Azar. Three critical challenges for our health systems right now. The folks copied above can help provide any additional information that you need. They're happy to get on a phone call with the Secretary and team. Just let me know. Thanks so much. Take care. Susan

Secretary Azar,

We are receiving urgent requests from healthcare providers across the nation on important regulatory impediments that impede their ability to manage the current COVID-19 national emergency. Here are the critical issues we have received that we request HHS address as soon as possible:

1. Reduce Drug Shortages by Waiving HRSA's Restrictive Interpretation of the GPO Prohibition:

Hospitals and clinics participating in the 340B drug pricing program (340B program) facing unprecedented problems accessing drugs needed to treat their patients. Most of the 340B hospitals operating in areas hardest hit by covid-19 are subject to a unique 340B statutory prohibition against purchasing covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. HRSA's interpretation of the 340B program's GPO restriction is exacerbating the drug shortage problem for these hospitals which, in turn, is hindering their ability to meet the challenges presented by covid-19. These hospitals are all public or non-profit high-Medicaid hospitals, including children's hospitals.

There are two steps the Secretary's office can take right now to alleviate shortages of drugs that are critically needed during the covid-19 pandemic. Covid-19 has already been declared a public health emergency, which provides the HHS Secretary the authority under section 319 of the Public Health Service Act to "take such action as may be appropriate to respond to the public health emergency."^[1] The Secretary can rely on his section 319 authority to relax HRSA's problematic sub-regulatory interpretations of the GPO restriction.

Waive HRSA's burdensome procedures for using GPO drugs when the drugs are unavailable at non-GPO prices – When a hospital subject to the GPO restriction can only acquire a covered outpatient drug through its GPO account due to drug shortage problems, HRSA allows purchasing of GPO drugs if the hospital follows a four-step process. The hospital must:

1. • Work with the manufacturer to try to obtain the drug at 340B pricing;
2. • Try to purchase the drug at wholesale acquisition cost (WAC);
3. • Notify HRSA that the drug is not available at 340B or WAC prices by filling out a template form providing numerous details about the limited availability of the drug; and

4. • Maintain auditable records of all of the above, including records showing that the hospital attempted to purchase the drug through the 340B and WAC accounts every time a purchase is made on the GPO account.

These procedures are onerous in the best of circumstances and simply impossible to perform for overworked hospital staff struggling to keep up with the demands of the covid-19 pandemic, particularly given the increasing number of drugs that are unavailable at 340B or WAC pricing. The Secretary should invoke his authority to waive or relax these procedures during the covid-19 public health emergency.

Allow Premier's privately-labeled drugs to be purchased at 340B ceiling prices by any 340B hospital – Like other GPOs, Premier has contracted with generic drug manufacturers to produce a defined quantity of commonly-used drugs for the exclusive use of its members. These drugs are privately-labeled under Premier's name and are pre-purchased in sufficient quantities to help its members survive periods of drug shortages.

To address the growing drug shortage problems associated with the coronavirus pandemic, Premier has informed its generic drug suppliers that it will waive the exclusivity restriction in its agreements so that the suppliers can sell the privately-labeled drugs to non-Premier members. Each of the suppliers has an executed pharmaceutical pricing agreement (PPA) with HRSA and is required under its PPA to offer 340B pricing on its full product line. Now that Premier has lifted the exclusivity arrangement with its suppliers, the suppliers are required under their PPAs to sell Premier's privately-labeled drugs to any interested 340B purchaser, whether it is a Premier member or not. However, because HRSA has issued guidance declaring privately-labeled drugs to be GPO drugs, both suppliers and wholesalers are concerned that selling the drugs at 340B ceiling prices will subject them and their hospital purchasers to undue risk of violating the GPO restriction.

Since the drugs will be sold to any 340B covered entity, not just Premier members, at ceiling prices established by statute rather than group negotiation, the GPO restriction cannot possibly be implicated. But the 340B supply chain needs the government's written assurance that the sale of Premier's privately-labeled drugs at 340B ceiling prices to any interested covered entity, including disproportionate share (DSH) and children's hospitals, is compliant with 340B program requirements, including the GPO restriction.

There is increasing demand for Premier's drugs due to coronavirus-related supply shortages and Premier is prepared to help meet that demand. But it needs the Secretary to take the two steps described above first.

2. PPE Decontamination/Sterilization: As hospitals struggle with dwindling PPE supplies, the concept of decontaminating or sterilizing PPE for reuse has been raised. ***There are three options on which we are asking if FDA or CDC would recommend the use of these decontamination or sterilization techniques.*** They are:

- • Nebraska Medicine announced (see attached) that it is leveraging ***UV light to decontaminate*** and reuse PPE. Many hospitals have UV light technology to address MRSA decontamination.

- Several hospitals are also considering leveraging new technology using **ultraviolet germicidal irradiation (UVGI)** to decontaminate PPE. Attached is a study the company provided regarding their decontamination studies for N95 masks.
- Many hospitals also have their own **ethylene oxide sterilization** capabilities and would like to use those capabilities on PPE supplies.

3. One-Mile Radius Rule for Sterile Compounding: With limited staff and PPE constraints, many hospitals would like to consolidate pharmacy services to a single hub. A rate-limiting step to doing so is FDA's guidance compounding guidance that dictates the one-mile radius rule. **We request that FDA temporarily waive the one-mile radius rule for hospital and health system compounding?**

Blair G. Childs

Senior Vice President
444 North Capitol Street, NW
Suite 625
Washington, D.C. 20001-1511
202-879-8009 (O)
(b)(6) (C); 202-879-8009 (F)

Susan Ueberroth, Executive Coordinator: 202 879 8010, Susan_Ueberroth@Premierinc.com

Premier, 2006 Malcolm Baldrige National Quality Award Recipient
13034 Ballantyne Corporate Place, Charlotte, NC 28277

<https://protect2.fireeye.com/url?k=2fa3a975-73f7805e-2fa3984a-0cc47a6d17cc-6d32d9195a239e0b&u=http://www.premierinc.com/baldrige>

<UVGI Effects on the N95 Respirator.pdf>
<3-20 PPE.DOCX>

[1] Determination that a Public Health Emergency Exists, <https://protect2.fireeye.com/url?k=39d59453-6581bd78-39d5a56c-0cc47a6d17cc-3230c44aacac93fa&u=https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

Sender:	AMA2 (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C145629CC8AC4858BF1F0CE5DD0461DC-AMA2!>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>

Sent Date:	2020/03/22 14:42:31
Delivered Date:	2020/03/22 14:42:32

From:	Laura Severs (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 15:04:32
Priority:	Normal
Type:	Note

Laura Severs
20 Reading Road
Bloomington, IL 61701

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Laura Severs

Sender:	Laura Severs (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 15:03:55
Delivered Date:	2020/03/22 15:04:32
Message Flags:	Unread

From:	Harrison, Brian (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D145EFC9C35C4865ACA6E9D47786B204-HARRISON, B>
To:	Eyles, Matt <MEyles@ahip.org>; Parker, Jim (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f7ac2e66aa043a6b7cb2eaf967ffa3-Parker, Jam>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Subject:	RE: AHIP-BCBA on Health Insurers as Essential Businesses
Date:	2020/03/22 15:15:00
Priority:	Normal
Type:	Note

Thank you, Matt.

Brian

From: Eyles, Matt <MEyles@ahip.org>
Sent: Saturday, March 21, 2020 6:43 PM
To: Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Subject: AHIP-BCBA on Health Insurers as Essential Businesses

Paul, Brian, Jim – Hope you are all healthy and managing through the 24/7 issues. Wanted to share a joint AHIP-BCBSA letter that we just sent to Governor Hogan in his capacity as NGA Chair asking for his assistance in ensuring that states define health insurers as essential businesses with a copy to Secretary Azar.

I know you appreciate the importance including health insurance providers and the workers and vendors that manage health plans to be defined as essential businesses or we won't be able to provide the services we need to consumers about their health insurance coverage and to ensure that hospitals, doctors and other health care professionals will have uninterrupted flow of funds as they take care of patients and purchase supplies.

But we thought it was important to make sure this was on Secretary Azar's radar and yours as we work to do everything possible to address COVID-19. Don't hesitate to let us know if you have any questions or if we can be helpful in any way.

Be well,
Matt

Matthew Eyles | President & Chief Executive Officer
[America's Health Insurance Plans](#)

601 Pennsylvania Ave, NW | South Building, Suite 500 | Washington, DC 20004
202.778.3269 (o) | (b)(6) (c)

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Sender:	Harrison, Brian (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D145EFC9C35C4865ACA6E9D47786B204-HARRISON, B>
Recipient:	Eyles, Matt <MEyles@ahip.org>; Parker, Jim (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f7ac2e66aa043a6b7cb2eaaf967ffa3-Parker, Jam>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/03/22 15:15:59
Delivered Date:	2020/03/22 15:15:00

From:	Trueman, Laura (HHS/IEA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99DCBA4C6EA342C08D58F63E37D997E7-TRUEMAN, LA>
To:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>
CC:	Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Parker, Jim (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f7ac2e66aa043a6b7cb2eaf967ffa3-Parker, Jam>
Subject:	RE: AHIP-BCBA on Health Insurers as Essential Businesses
Date:	2020/03/22 15:17:47
Priority:	Normal
Type:	Note

I already gave Matt what he needs.

There was guidance put out by DHS that identifies insurance workers as essential, to the extent that they are unable to work remotely.

He was happy.

From: Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>

Sent: Sunday, March 22, 2020 3:16 PM

To: AMA2 (OS/IOS) <AMA2@HHS.GOV>

Cc: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>; Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>

Subject: FW: AHIP-BCBA on Health Insurers as Essential Businesses

From: Eyles, Matt <MEyles@ahip.org>

Sent: Saturday, March 21, 2020 6:43 PM

To: Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>

Subject: AHIP-BCBA on Health Insurers as Essential Businesses

Paul, Brian, Jim – Hope you are all healthy and managing through the 24/7 issues. Wanted to share a joint AHIP-BCBSA letter that we just sent to Governor Hogan in his capacity as NGA Chair asking for his assistance in ensuring that states define health insurers as essential businesses with a copy to Secretary Azar.

I know you appreciate the importance including health insurance providers and the workers and vendors that manage health plans to be defined as essential businesses or we won't be able to provide the services we need to consumers about their health insurance coverage and to ensure that hospitals, doctors and other health care professionals will have uninterrupted flow of funds as they take care of patients and purchase supplies.

But we thought it was important to make sure this was on Secretary Azar's radar and yours as we work to do everything possible to address COVID-19. Don't hesitate to let us know if you have any questions or if we can be helpful in any way.

Be well,
Matt

Matthew Eyles | President & Chief Executive Officer
America's Health Insurance Plans

601 Pennsylvania Ave, NW | South Building, Suite 500 | Washington, DC 20004
202.778.3269 (o) | (b)(6) (c)

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Sender:	Trueman, Laura (HHS/IEA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99DCBA4C6EA342C08D58F63E37D997E7-TRUEMAN, LA>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Parker, Jim (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f7ac2e66aa043a6b7cb2eaaf967ffa3-Parker, Jam>
Sent Date:	2020/03/22 15:17:47

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.OUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8CDFB7232DE4428794F2901218BC1360-HAYES, JONA>
To:	Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>
CC:	Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Parker, Jim (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f7ac2e66aa043a6b7cb2eaaf967ffa3-Parker, Jam>
Subject:	Re: Azar communication
Date:	2020/03/22 15:27:49
Priority:	Normal
Type:	Note

I've shared #2 response with Susan. Will advise ASAP.

JH

Sent from my iPhone

On Mar 22, 2020, at 3:12 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov> wrote:

Great!

ASPR can you confirm that the link Danielle sent does address question 2.

Jim- any update from HRSA?

Sent from my iPhone

On Mar 22, 2020, at 3:10 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov> wrote:

FDA is currently reviewing 2 and 3. CDC has already taken action on 2, which is the link I sent

Danielle Steele

Senior Adviser, IOS, HHS

Sent from my iPhone

On Mar 22, 2020, at 3:09 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov> wrote:

Thanks Danielle,

Can the appropriate policy people look at the three asks and come back with recommendations soon on whether her asks can be moved forward?

Please let me know if I need to convene any conversations for coordination.
Catherine

Sent from my iPhone

On Mar 22, 2020, at 2:57 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>wrote:

Here is CDC's guidance on reuse of PPE
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html>

Danielle Steele
Senior Adviser, IOS, HHS
Sent from my iPhone

On Mar 22, 2020, at 2:48 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>wrote:

I've reached out to FDA and CDC

Danielle Steele
Senior Adviser, IOS, HHS
Sent from my iPhone

On Mar 22, 2020, at 2:42 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Thanks Judy,

Can I get confirmation that these items are actively being considered and worked on by the appropriate people?

Catherine

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Sent: Sunday, March 22, 2020 2:19 PM
To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>
Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>
Subject: Re: Azar communication

Looping in Jim Parker and Danielle Steele who are senior advisors to these operating divisions

Sent from my iPhone

On Mar 22, 2020, at 12:56 PM, Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>wrote:

All:

I spoke with Susan DeVore a bit ago and told her if there was anything HHS specifically could help to please not hesitate to reach out to me if she so desires. She was deeply appreciative and said there were some things she was preparing to email AMA about. I said I would get in front of the right folks ASAP. Please loop who you see fit.

Summary:

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Deliberative, Pre-Decisional, FOUO, SBU, Close Hold

From: DeVore, Susan <Susan_DeVore@PremierInc.com>

Sent: Sunday, March 22, 2020 12:03 PM

To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>

Cc: Childs, Blair <Blair_Childs@PremierInc.com>; Saha, Soumi <Soumi_Saha@premierinc.com>; Alkire, Mike <Mike_Alkire@PremierInc.com>

Subject: FW: Azar communication

Hi Jonathan,

So appreciate your help in getting this in front of Secretary Azar. Three critical challenges for our health systems right now. The folks copied above can help provide any additional information that you need. They're happy to get on a phone call with the Secretary and team. Just let me know. Thanks so much. Take care. Susan

Secretary Azar,

We are receiving urgent requests from healthcare providers across the nation on important regulatory impediments that impede their ability to manage the current COVID-19 national emergency. Here are the critical issues we have received that we request HHS address as soon as possible:

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Blair G. Childs

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<UVGI Effects on the N95 Respirator.pdf>
<3-20 PPE.DOCX>

[1] Determination that a Public Health Emergency Exists, <https://protect2.fireeye.com/url?k=39d59453-6581bd78-39d5a56c-0cc47a6d17cc-3230c44aacac93fa&u=https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

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To:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Wright, Janet (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f672e2527b4f44891fb4f4be08cdfdf-Wright, Jan>; Kotwicki, Lauren (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d62ddbd3fc4b358ab573ccc13fbbb7-Kotwicki, L>
Subject:	USA Today op-ed is live
Date:	2020/03/22 15:28:19
Priority:	Normal
Type:	Note

I will start flagging and will push out to begin promotion.

Surgeon General: Delay elective medical, dental procedures to help us fight coronavirus

The lives of many, especially our most vulnerable, are at stake. We can win this war if we all commit to taking the right actions for our country.

By Jerome M. Adams
Opinion contributor

If you are having a heart attack or have been in a car accident, there is a chance you will need to have a medical or surgical procedure right away. Many procedures are urgent and must be done even in the midst of a global pandemic. Elective procedures are those that are often scheduled days to weeks in advance and often could be postponed without causing great harm. For example, most total joint replacements are elective, but transplants and cancer surgery are not.

As a member of the president's Coronavirus Task Force — and a practicing physician — I am calling on all hospital systems to heed federal recommendations and cancel or delay non-essential elective procedures in a way that minimizes potential harm to patients. These include dental procedures as well. As both Vice President Mike Pence and Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, have said,

this move is imperative for our national COVID-19 response for several reasons.

Why these delays are needed

► First, non-essential planned procedures consume personal protective equipment (PPE) such as masks, gloves and gowns. At a time when health providers in the hardest-hit areas are concerned about having enough PPE to take care of COVID-19 patients, it is imprudent to pull PPE from regional and national pools to do procedures that could be postponed.

► Second, a person rarely comes in alone for a medical procedure. Each additional person, whether a loved one or caregiver, may have an undiagnosed case of COVID-19 that could be transmitted to the medical staff and facility. The president and his task force's guidelines around social distancing mean avoiding unnecessary interactions, and that includes those we could eliminate by postponing elective procedures.

► Third, as we are in the midst of a whole-of-government effort to fight COVID-19, we need all our current health care workforce and more to meet the demands of this challenge. Every non-urgent case takes precious staff time and energy, straining a workforce that is already going above and beyond in this fight.

► Finally, elective cases occasionally require prolonged hospital stays, ventilators and other resources that may soon be necessary to respond to community spread of COVID-19. While the Trump administration and the Department of Health and Human Services are facilitating innovative approaches to repurpose buildings, beds and equipment, we also can increase existing capacity through judicious postponement of elective procedures. Many health providers and facilities have already started acting to preserve these vital resources, like the American College of Plastic Surgeons who are coordinating the donation of unused PPE to be part of our response. The American Hospital Association and American College of Surgeons have urged their members to delay cases when possible to help with the COVID-19 effort. I applaud those who have already stepped forward to help ensure we have adequate materials during this time, and I urge all health providers and facilities to heed this advice.

This is a temporary response

Deferring elective procedures does not mean they cannot or will not be done in the future once we see our COVID-19 response needs decrease. We are at a critical point in our global and national response to an unprecedented pandemic, and it will take sacrifice and an all-of-America effort.

Ultimately, the decision about proceeding or postponing a procedure belongs to clinicians and patients, and I would encourage both to consult new guidance from the Centers for Medicare & Medicaid Services.

I recognize that many hospitals, especially those in small and rural settings, depend on the revenue generated by elective procedures to support salaries, benefits and operations. Our federal and state leaders must — and will — find ways to support them during and following this crisis. But the best way to ensure our long-term success is to act decisively now to conserve resources for the COVID-19 response.

Stopping the spread of COVID-19 will be hard, but we should not make it harder by using vital health care resources for services that could wait. As the president said, “We are at war with an invisible enemy.” The lives of many — especially our most vulnerable — are at stake. We can win this war if we all commit to taking the right and timely actions for our country. My plea to all health care systems, hospitals, clinics and patients: Until we can flatten the COVID-19 curve in the United States — please consider delaying your elective procedures.

Vice Adm. Jerome M. Adams, M.D., is the 20th surgeon general of the United States. He is a board-certified anesthesiologist with a master's degree in public health and a member of the President's Coronavirus Task Force.

Follow him on Twitter: @Surgeon General

<https://www.usatoday.com/story/opinion/2020/03/22/surgeon-general-fight-coronavirus-delay-elective-procedures-column/2894422001/>

Jenn Sherman

Director of Public Affairs

Office of the Surgeon General

Department of Health and Human Services (HHS)

Sender:	Sherman, Jennifer (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F30FE7FAE664419FA654B20EDCCB1E78-SHERMAN, JE>
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Delivered Date:	2020/03/22 15:28:19

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F7AC2E66AA043A6B7CB2EAAF967FFA3-PARKER, JAM>
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Subject:	RE: Azar communication
Date:	2020/03/22 15:42:24
Priority:	Normal
Type:	Note

Working it.

From: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>
Sent: Sunday, March 22, 2020 3:12 PM
To: Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>
Cc: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>
Subject: Re: Azar communication

Great!

ASPR can you confirm that the link Danielle sent does address question 2.

Jim- any update from HRSA?

Sent from my iPhone

On Mar 22, 2020, at 3:10 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>wrote:

FDA is currently reviewing 2 and 3. CDC has already taken action on 2, which is the link I sent

Danielle Steele
Senior Adviser, IOS, HHS

Sent from my iPhone

On Mar 22, 2020, at 3:09 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Thanks Danielle,

Can the appropriate policy people look at the three asks and come back with recommendations soon on whether her asks can be moved forward?

Please let me know if I need to convene any conversations for coordination.

Catherine

Sent from my iPhone

On Mar 22, 2020, at 2:57 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>wrote:

Here is CDC's guidance on reuse of PPE
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html>

Danielle Steele
Senior Adviser, IOS, HHS

Sent from my iPhone

On Mar 22, 2020, at 2:48 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>wrote:

I've reached out to FDA and CDC

Danielle Steele
Senior Adviser, IOS, HHS

Sent from my iPhone

On Mar 22, 2020, at 2:42 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Thanks Judy,

Can I get confirmation that these items are actively being considered and worked on by the appropriate people?

Catherine

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>
Sent: Sunday, March 22, 2020 2:19 PM
To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>

Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>

Subject: Re: Azar communication

Looping in Jim Parker and Danielle Steele who are senior advisors to these operating divisions

Sent from my iPhone

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All:

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To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>

Cc: Childs, Blair <Blair_Childs@PremierInc.com>; Saha, Soumi <Soumi_Saha@premierinc.com>; Alkire, Mike <Mike_Alkire@PremierInc.com>

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<https://protect2.fireeye.com/url?k=2fa3a975-73f7805e-2fa3984a-0cc47a6d17cc-6d32d9195a239e0b&u=http://www.premierinc.com/baldrige>

<UVGI Effects on the N95 Respirator.pdf>
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[1] Determination that a Public Health Emergency Exists, <https://protect2.fireeye.com/url?k=39d59453-6581bd78-39d5a56c-0cc47a6d17cc-3230c44aacac93fa&u=https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

Sender:	Parker, Jim (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F7AC2E66AA043A6B7CB2EAAF967FFA3-PARKER, JAM>
Recipient:	Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>
Sent Date:	2020/03/22 15:42:23
Delivered Date:	2020/03/22 15:42:24

From:	Anand Parekh, MD <aparekh@bipartisanpolicy.org>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	ways to help?
Date:	2020/03/22 15:45:15
Priority:	Normal
Type:	Note

Bob,

Thanks for your leadership on COVID-19 and hope you're staying safe. I wanted to ask about 2 items –

1. • You're probably already tracking some of the private sector led ILI syndromic surveillance efforts, but one in particular, Kinsa, has put together this health weather map, <https://healthweather.us/>. They have a good track record with flu and so I'm wondering whether someone is working in what they have into HHS' syndromic surveillance efforts to help predict spread and surge requirements?
2. • BPC would like to be helpful with ESF-14 (or related effort), catalyzing private industry to team up with current manufacturers or produce newly critical medical material/PPE in short order. How could we help & who should we connect with at HHS/USG to do so?

Please call on me/us if we can be helpful in other ways.

Many thanks,
Anand

Anand Parekh, MD
Chief Medical Advisor
Bipartisan Policy Center

Sender:	Anand Parekh, MD <aparekh@bipartisanpolicy.org>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Sent Date:	2020/03/22 15:44:05
Delivered Date:	2020/03/22 15:45:15

From:	Asbel Montes <asbel.montes@acadian.com>
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.DIBOHF23SPDLT)/cn=Recipients/cn=fa197652dadf4048ad6764b3f9d4a528-Brady, Will>; Hargan, Eric (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a3a3891ba3c4624821f80867da25a4b-Hargan, Eri>
Subject:	Fwd: Non-Emergency Transport Billing Assistance
Date:	2020/03/22 15:45:55
Priority:	Normal
Type:	Note

See below. I am just giving you guys a heads up so you are not surprised. I know y'all are slammed but I cannot believe our first responders and EMS are not being addressed. It's a crisis in some of our communities.

Asbel Montes | Sr. VP of Strategic Initiatives & Innovation

Acadian Companies

130 E Kaliste Saloom | Lafayette, LA | 70508

O: 337.291.3310 | F: 337.291.4230

<https://protect2.fireeye.com/url?k=31ed659f-6db94cb4-31ed54a0-0cc47a6d17cc-7d27da1aa464348b&u=http://www.acadian.com/>



----- Forwarded message -----

From: **Brandt, Kimberly (CMS/OA)** <Kimberly.Brandt1@cms.hhs.gov>

Date: Sun, Mar 22, 2020 at 2:16 PM

Subject: RE: Non-Emergency Transport Billing Assistance

To: Asbel Montes <asbel.montes@acadian.com>

I am working with Demetrios on our CMS waiver policy team so have flagged this issue for the group. We have unprecedented numbers of waiver requests right now and are trying to get answers out to people as quickly as possible.

From: Asbel Montes <asbel.montes@acadian.com>
Sent: Sunday, March 22, 2020 3:05 PM
To: Brandt, Kimberly (CMS/OA) <Kimberly.Brandt1@cms.hhs.gov>
Subject: Re: Non-Emergency Transport Billing Assistance

Hang in there. We are all in this together. Any assistance or direction you feel I should go? I am just trying to bring awareness to issues from the first responder community.

Asbel Montes | Sr. VP of Strategic Initiatives & Innovation

Acadian Companies

130 E Kaliste Saloom | Lafayette, LA | 70508

O: 337.291.3310 | F: 337.291.4230

<https://protect2.fireeye.com/url?k=9d0d0a4c-c1592367-9d0d3b73-0cc47a6d17cc-929abb13b98c4390&u=https://protect2.fireeye.com/url?k=f5fd16d9-a9a81fca-f5fd27e6-0cc47adb5650-76586f35ceb8bd7b&u=http://www.acadian.com/>



<http://www.acadian.com/piclib/1848.jpg>

On Sun, Mar 22, 2020 at 2:01 PM Brandt, Kimberly (CMS/OA) <Kimberly.Brandt1@cms.hhs.gov> wrote:

As are we so I feel your pain

From: Asbel Montes <asbel.montes@acadian.com>
Sent: Sunday, March 22, 2020 2:52 PM
To: Brandt, Kimberly (CMS/OA) <Kimberly.Brandt1@cms.hhs.gov>
Subject: Re: Non-Emergency Transport Billing Assistance

Thank you, thank you!!!! It's getting pretty dire and I am not sure what to do right now....Getting pressure from many officials.....

Asbel Montes | Sr. VP of Strategic Initiatives & Innovation

Acadian Companies

130 E Kaliste Saloom | Lafayette, LA | 70508

O: 337.291.3310 | F: 337.291.4230

<https://protect2.fireeye.com/url?k=cb74aa88-972083a3-cb749bb7-0cc47a6d17cc-b4ecde7102f6fa77&u=https://protect2.fireeye.com/url?k=862b4a89-da7e439a-862b7bb6-0cc47adb5650-d9e898bb9bd9ac1c&u=https://protect2.fireeye.com/url?k=e391edc7-bfc5f4bb-e391dcf8-0cc47adc5fa2-654b06921c6294b2&u=http://www.acadian.com/>



<http://www.acadian.com/piclib/1848.jpg>

On Sun, Mar 22, 2020 at 1:51 PM Brandt, Kimberly (CMS/OA) <Kimberly.Brandt1@cms.hhs.gov> wrote:

We are triaging these as fast as we can. Hoping to get answers on these issues out in the next couple of days.

Sent from my iPhone

On Mar 22, 2020, at 2:49 PM, Asbel Montes <asbel.montes@acadian.com> wrote:

See below....

Can you speak? I am clueless why CMS feels that they don't have authority under the 1135 waiver to do the following:

1. Waive medical necessity requirements that isolation requirements due to CDC guidance for an infectious disease is a primary condition for ambulance transport versus a secondary condition.
2. Allow us to transport to alternative destination sites not currently covered under Medicare regulation for COVID-19 patients. This was allowed during Hurricane Katrina and Rita when we were allowed to transport SNF patients to evacuation sites.
3. Allow us to treat in place to keep low acuity patients out of the ED. A waiver has already been allowed for the ET3 participants which may go live sometime in May but we are asking to make it live now to assist with the patient load. We are having major issues in New Orleans, as well as my colleagues in Chicago, New York City, Los Angeles and San Francisco to name a few.

We are already just treating in place because the hospitals are overloaded and cannot accommodate low acuity patients. We are then trying to work the telemedicine and telehealth mediums and believe we may be able to facilitate this on guidance that CMS just issued.

Help! My next avenue is to get this in front of the media to bring attention to the crisis we are in. I am reaching out to you as a last resort. If you can speak today or at the very latest tomorrow it would be much appreciated. I will accommodate your schedule.

Asbel Montes | Sr. VP of Strategic Initiatives & Innovation

Acadian Companies

130 E Kaliste Saloom | Lafayette, LA | 70508

O: 337.291.3310 | F: 337.291.4230

<https://protect2.fireeye.com/url?k=13cc5f75-4f98765e-13cc6e4a-0cc47a6d17cc-46da3775b8de2419&u=https://protect2.fireeye.com/url?k=3290b062-6ec5b971-3290815d-0cc47adb5650-8ca8eece098b7228&u=https://protect2.fireeye.com/url?k=0d5bcd00-510fd47c-0d5bfc3f-0cc47adc5fa2-7ce10085ce95d383&u=https://protect2.fireeye.com/url?k=d9805640-85d55f53-d980677f-0cc47adb5650-d32327a99a2f8cf1&u=http://www.acadian.com/>



<http://www.acadian.com/piclib/1848.jpg>

----- Forwarded message -----

From: **William T. Salmeron** <Wtsalmeron@nola.gov>

Date: Sun, Mar 22, 2020 at 1:40 PM

Subject: Re: Non-Emergency Transport Billing Assistance

To: Asbel Montes <asbel.montes@acadian.com>

Cc: Alan Ashley <alan.ashley@acadian.com>, Porter Taylor <rtaylor2@acadian.com>, Emily Nichols <Emily.Nichols@nola.gov>

Is this a CMS 1135 Waiver?

Bill Salmeron

Chief | New Orleans EMS

(504)658-1552

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From: Asbel Montes <asbel.montes@acadian.com>

Sent: Sunday, March 22, 2020 13:36

To: William T. Salmeron <Wtsalmeron@nola.gov>

Cc: Alan Ashley <alan.ashley@acadian.com>; Porter Taylor <rtaylor2@acadian.com>; Emily Nichols

<Emily.Nichols@nola.gov>

Subject: Re: Non-Emergency Transport Billing Assistance

Bill,

This can be a FEMA request while we continue to try and get an HHS Waiver.

Due to the PPE requirement and isolation requirement by the CDC, the city is requesting that all COVID-19 positive and PUI cases be transported by ambulance due to NEMT providers not having the medical personnel or the ability to implement the CDC minimum requirements. This is all that is needed. We will then bill through the city for the FEMA response.

Does this make sense?

Asbel Montes | Sr. VP of Strategic Initiatives & Innovation

Acadian Companies

130 E Kaliste Saloom | Lafayette, LA | 70508

O: 337.291.3310 | F: 337.291.4230

<https://protect2.fireeye.com/url?k=e39b045f-bfcf2d74-e39b3560-0cc47a6d17cc-1e66f2a15cc0cd5e&u=https://protect2.fireeye.com/url?k=2807cc1e-7452c50d-2807fd21-0cc47adb5650-36edf3e4129f5732&u=https://protect2.fireeye.com/url?k=53668427-0f329d5b-5366b518-0cc47adc5fa2-e1289793cd3e0878&u=https://protect2.fireeye.com/url?k=eea8df4c-b2fdd65f-eea8ee73-0cc47adb5650-34b9e76659a9f878&u=http://www.acadian.com/>



<http://www.acadian.com/piclib/1848.jpg>

On Sun, Mar 22, 2020 at 1:17 PM William T. Salmeron <Wtsalmeron@nola.gov> wrote:

I wanted to get with our city legislative affairs to help with making connections for the non-emergency transport of COVID-19 patients.

Asbel, can you give me exactly what we need to ask for help with?

Thanks.

Bill Salmeron

Chief | New Orleans EMS

(504)658-1552

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Sender:	Asbel Montes <asbel.montes@acadian.com>
Recipient:	Brady, Will (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa197652dadf4048ad6764b3f9d4a528-Brady, Will>; Hargan, Eric (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a3a3891ba3c4624821f80867da25a4b-Hargan, Eri>
Sent Date:	2020/03/22 15:45:09
Delivered Date:	2020/03/22 15:45:55

From:	Lynn Williams <Lynn.williams@johnmuirhealth.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 15:48:13
Priority:	Normal
Type:	Note

Lynn Williams
1106 via Ensenada ct
Concord, CA 94521

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Lynn Williams

Sender:	Lynn Williams <Lynn.williams@johnmuirhealth.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 15:45:36
Delivered Date:	2020/03/22 15:48:13
Message Flags:	Unread

From:	Robert Levitt (b)(6)
To:	Robert Levitt (b)(6)
Subject:	Dr. Levitt's COVID-19 Update for NOON 22 March 2020/CUOMO'S REQUEST OF FEDS MAKES DATA-SENSE
Date:	2020/03/22 16:12:13
Priority:	Normal
Type:	Note

Dear All,

Below are short takes on the online and journal and media articles I have read or listened to today:

Regarding the high Italian death rate from COVID-19, a frequent Milan visitor reminded me that **Italians all smoke, live in multiple generation homes, hug a lot, have a poor diet, and are overweight when senior citizens.** These factors, esp. smoking, influence death rates in all pulmonary infections.

Gov. Cuomo's press briefing this morning stated the following important facts:

- **President Trump should nationalize medical supply acquisition because States are fighting amongst themselves for these supplies and being 'gouged by industry.** A mask which normally costs 85 cents is going for \$7.00. Cuomo asked the President to put the **Defense Production Act into force today.**

- **FEMA** has been asked to build four 250 bed federal hospitals at Javits Convention Center. When FEMA builds, staff and supplies are included. **Army Corps of Engineers** has been asked to build four field hospitals regionally; staff and supplies not included by ACE.

- Asked CDC to begin using serologic (coronavirus antibody) tests to determine who has been previously infected by SARS-Cov-2.** (These recovered patients can give convalescent serum with the antibodies to help COVID-19 patients).

- Cancelled all elective surgeries except critical surgeries starting Wednesday. This opens 25-35% of hospital beds.** NY hospitals must submit to Cuomo plan to increase bed capacity by 50%. He wants 100% capacity increase to be the goal.

Note that in NY, 50% of COVID-19 cases are <50 y.o.; **50% are >50 y.o.- these are the patients who die.**

- Crowds still filling up NYC Parks. He ask the Mayor to end this gathering now.

- More positive cases identified in last 24 hours; total is now 15,168 infected according to tests. **13% of positive cases are requiring hospitalization. No data released on how many NY hospitalized COVID-19 cases required the ICU.**

- Johns Hopkins** data shows 311,000 infected worldwide and 13,000 deaths or 4% mortality. **Seventy percent of the deaths >70 y.o, with underlying illness, Eighty percent of the deaths <70 y.o, had underlying illness or immunosuppressed.**

- NY has 374 deaths from COVID-19 or 2.5 % (374/15,168). That's too high for U.S. death rate.

American Hospital Association cited CDC report last week that stated 5-12% of hospitalized COVID-19 patients require the ICU (ventilator):

"About 80% of deaths and 45% of hospitalizations for COVID-19 in the U.S. are among adults aged 65 or older, with the risk of serious illness and death increasing with age, according to a report released today by the Centers for Disease Control and Prevention. The findings are similar to data from China, the agency said. While severe COVID-19 illness leading to hospitalization can occur at any age, children appear to have milder illness, with almost no hospitalizations for those under age 19, CDC said. According to the report, an estimated 21% to 31% of U.S. COVID-19 patients between Feb. 12 and March 16 were hospitalized, with 5% to 12% admitted to an intensive care unit. An estimated 1.8% to 3.4% of U.S. COVID-19 patients died over the period."

NYT today stepped up the pace of their COVID-19 reporting and has a Special Section this Sunday on COVID-19 with articles I found informative:

Article on how hospitals go about deciding who gets a ventilator when ventilators are scarce:

<https://www.nytimes.com/2020/03/21/us/coronavirus-medical-rationing.html>

Options include: lottery, age of patient, years of useful living left to patient, patient's wish, failure to wean on ventilator, time on ventilator. **NEJM** published last week a Perspective by Dr. Rosenbaum on **what Italy has done in a flail situation**. See pdf attached above for details. **(Colleen Starkloff, the wife of Dr. Max Starkloff's grandson now deceased, makes the case in the Saint Louis Post Dispatch today, that disability should NOT mean no**

ventilator: https://www.stltoday.com/opinion/columnists/colleen-kelly-starkloff-lives-worth-saving-in-pandemic-triage-decisions/article_699664f5-1966-5b71-854a-15f805e8b8af.html)

Article by Dowd that states Dr. Fauci says that President Trump is smart and 'gets it'. See:

<https://www.nytimes.com/2020/03/21/opinion/sunday/fauci-coronavirus-trump.html>

That's good enough for me. The Press blame game only sets us back and puts more pressure on the Task Force. The President was not trained in virology, evidence-based medicine, genetics, or science. He went to Wharton Business and had unusual mentors as he built his businesses. He is learning late in life, as we all are now.

Article by Dr. Ofre at Bellevue Hospital in NY that says she's scared because SARS-CoV-2 lives in the air for an hour and is viable on surfaces for 72 hours. She asks everyone to not have:

"Narrow vision, data ignorance, image-conscious decision-making, and truncated memory are the very elements of contagion"

I would add the blame game to that list of

promoters. See: <https://www.nytimes.com/2020/03/20/opinion/sunday/coronavirus-hospitals-doctors.html>

Presidential Task Force briefing is later today. Will report on the briefing and add one or two articles to read for 'homework'. The more information people have, the better off America is-always.

Be well,
RGL, M.D.

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Sent from Outlook

Sender:	Robert Levitt (b)(6)
Recipient:	Robert Levitt (b)(6)
Sent Date:	2020/03/22 16:11:47
Delivered Date:	2020/03/22 16:12:13
Message Flags:	Unread

From:	Robert Levitt (b)(6)
To:	Robert Levitt (b)(6)
Subject:	Dr. Levitt's COVID-19 Update for NOON 22 March 2020/CUOMO'S REQUEST OF FEDS MAKES DATA-SENSE
Date:	2020/03/22 16:12:10
Priority:	Normal
Type:	Note

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Article on how hospitals go about deciding who gets a ventilator when ventilators are scarce:

<https://www.nytimes.com/2020/03/21/us/coronavirus-medical-rationing.html>

Options include: lottery, age of patient, years of useful living left to patient, patient's wish, failure to wean on ventilator, time on ventilator. **NEJM** published last week a Perspective by Dr. Rosenbaum on **what Italy has done in a flail situation**. See pdf attached above for details. **(Colleen Starkloff, the wife of Dr. Max Starkloff's grandson now deceased, makes the case in the Saint Louis Post Dispatch today, that disability should NOT mean no**

ventilator: https://www.stltoday.com/opinion/columnists/colleen-kelly-starkloff-lives-worth-saving-in-pandemic-triage-decisions/article_699664f5-1966-5b71-854a-15f805e8b8af.html)

Article by Dowd that states Dr. Fauci says that President Trump is smart and 'gets it'. See:

<https://www.nytimes.com/2020/03/21/opinion/sunday/fauci-coronavirus-trump.html>

That's good enough for me. The Press blame game only sets us back and puts more pressure on the Task Force. The President was not trained in virology, evidence-based medicine, genetics, or science. He went to Wharton Business and had unusual mentors as he built his businesses. He is learning late in life, as we all are now.

Article by Dr. Ofre at Bellevue Hospital in NY that says she's scared because SARS-CoV-2 lives in the air for an hour and is viable on surfaces for 72 hours. She asks everyone to not have:

"Narrow vision, data ignorance, image-conscious decision-making, and truncated memory are the very elements of contagion"

I would add the blame game to that list of

promoters. See: <https://www.nytimes.com/2020/03/20/opinion/sunday/coronavirus-hospitals-doctors.html>

Presidential Task Force briefing is later today. Will report on the briefing and add one or two articles to read for 'homework'. The more information people have, the better off America is-always.

Be well,
RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at levitttrq@hotmail.com and include in the subject line: Unsubscribe.

Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner.

Sent from Outlook

Sender:	Robert Levitt (b)(6)
Recipient:	Robert Levitt (b)(6)
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Delivered Date:	2020/03/22 16:12:10
Message Flags:	Unread

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Subject:	Re: Dr. Kadlec's APPROVAL REQUIRED: Notifying WHO of Updated Temporary Health Measures
Date:	2020/03/22 16:29:25
Priority:	Normal
Type:	Note

Approved. Kadlec sends.

Sent from my iPhone

On Mar 22, 2020, at 2:02 PM, OS ASPR IHR Program <hhs.ihrp@hhs.gov>wrote:

Good Afternoon Dr. Kadlec –

The U.S. IHR National Focal Point Program is writing to you as the message authorizing official for all official IHR communications to the World Health Organization (WHO) for approval to send the below message to WHO informing them of the closing the our borders with Canada and Mexico to non-essential traffic of 30 days as required by IHR Article 43. As this was a joint action with Mexico and Canada, the IHR Program shared this proposed message with the IHR NFPs of both countries and they indicated have no concerns with the U.S. notifying using this language. Both countries are preparing similar notifications to WHO. Please advise if approve this for transmission. Thank you.

On Behalf of the ASPR IHR Program,

Adam Tewell

PROPOSED MESSAGE TO WHO:

SUBJECT: NOTIFICATION - United States – Temporary Health Measures - Update - March 22, 2020

Dear WHO Colleagues:

Pursuant to the International Health Regulations, Article 43, the U.S. IHR National Focal Point is notifying the World Health Organization of updated temporary health measures the United States is implementing, in coordination with the governments of Canada and Mexico, in response to the COVID-19 pandemic, specifically, restricting all non-essential travel across our borders with both countries for a period of 30 days.

These measures became effective at 12:01 a.m. (EDT) on March 21, 2020.

Joint Statement with Mexico:

<https://www.dhs.gov/news/2020/03/20/joint-statement-us-mexico-joint-initiative-combat-covid-19-pandemic>

Joint Statement with Canada:

<https://www.dhs.gov/news/2020/03/20/joint-statement-us-canada-joint-initiative-temporary-restriction-travelers-crossing>

Very respectfully,

U.S. IHR National Focal Point

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
Secretary's Operations Center (SOC)
200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) 619 – 7800
Email: hhs.soc@hhs.gov

Sender:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
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Subject:	Fwd: REUTERS: EXCLUSIVE-U.S. axed CDC expert job in China months before virus outbreak
Date:	2020/03/22 16:33:35
Priority:	Normal
Type:	Note

Sent from my iPhone

Begin forwarded message:

From: "McKeogh, Katherine (OS/ASPA)" <Katherine.McKeogh@hhs.gov>
Date: March 22, 2020 at 4:19:13 PM EDT
To: ASPA-Deputies <ASPA-Deputies@hhs.gov>
Subject: REUTERS: EXCLUSIVE-U.S. axed CDC expert job in China months before virus outbreak

EXCLUSIVE-U.S. axed CDC expert job in China months before virus outbreak
Reuters // Marisa Taylor

Several months before the coronavirus pandemic began, the Trump administration eliminated a key American public health position in Beijing intended to help detect disease outbreaks in China, Reuters has learned.

The American disease expert, a medical epidemiologist embedded in China's disease control agency, left her post in July, according to four sources with knowledge of the issue. The first cases of the new coronavirus may have emerged as early as November, and as cases exploded, the Trump administration in February chastised China for censoring information about the outbreak and keeping U.S. experts from entering the country to help.

"It was heartbreaking to watch," said Bao-Ping Zhu, a Chinese American who served in that role, which was funded by the U.S. Centers for Disease Control and Prevention, between 2007 and 2011. "If someone had been there, public health officials and governments across the world could have moved much faster."

Zhu and the other sources said the American expert, Dr. Linda Quick, was a trainer of Chinese field epidemiologists who were deployed to the epicenter of outbreaks to help track, investigate and contain diseases. As an American CDC employee, they said, Quick was in an ideal position to be the eyes and ears on the ground for the United States and other countries on the coronavirus outbreak, and might have alerted them to the growing threat weeks earlier.

No other foreign disease experts were embedded to lead the program after Quick left in July, according to the sources. Zhu said an embedded expert can often get word of outbreaks early, after forming close relationships with Chinese counterparts.

Zhu and the other sources said Quick could have provided real-time information to U.S. and other officials around the world during the first weeks of the outbreak, when they said the Chinese government tamped down on the release of information and provided erroneous assessments.

Quick left amid a bitter U.S. trade dispute with China when she learned her federally funded post, officially known as resident adviser to the U.S. Field Epidemiology Training Program in China, would be discontinued as of September, the sources said. The U.S. CDC said it first learned of a "cluster of 27 cases of pneumonia" of unexplained origin in Wuhan, China, on Dec. 31.

Since then, the outbreak of the disease known as COVID-19 has spread rapidly worldwide, killing more than 13,600 people, infecting more than 317,000. The epidemic has overwhelmed healthcare systems some countries, including Italy, and threatens to do so in the United States and elsewhere.

In a statement to Reuters, the U.S. CDC said the elimination of the adviser position did not hinder Washington's ability to get information and "had absolutely nothing to do with CDC not learning of cases in China earlier."

The agency said its decision not to have a resident adviser "started well before last summer and was due to China's excellent technical capability and maturity of the program."

The CDC said it has assigned two of its Chinese employees as "mentors" to help with the training program. The agency did not respond to questions about the mentors' specific role or expertise.

"CDC has had a 30-year partnership with China CDC and close collaboration," the statement said. "We had the right staff to engage China and ability to provide technical assistance were it requested."

The CDC would not make Quick, who still works for the agency, available for comment.

Asked for comment on Chinese transparency and responsiveness to the outbreak, China's Ministry of Foreign Affairs referred Reuters to remarks by spokesman Geng Shuang on Friday. Geng said the country "has adopted the strictest, most comprehensive, and most thorough prevention and control measures in an open, transparent, and responsible manner, and informed the (World Health Organization) and relevant countries and regions of the latest situation in a timely manner."

One disease expert told Reuters he was skeptical that the U.S. resident adviser would have been able to get earlier or better information to the Trump administration, given the Chinese government's suppression of information.

"In the end, based on circumstances in China, it probably wouldn't have had made a big difference," Scott McNabb, who was a CDC epidemiologist for 20 years and is now a research professor at Emory University. "The problem was how the Chinese handled it. What should have changed was the Chinese should have acknowledged it earlier and didn't."

ALERT FROM CHINA'S CDC

Alex Azar, secretary of Health and Human Services (HHS) said Friday that his agency learned of the coronavirus in early January, based on Redfield's conversations with "Chinese colleagues."

Redfield learned that "this looks to be a novel coronavirus" from Dr. Gao Fu, the head of the China CDC, according to an HHS administration official, who spoke on condition of anonymity. "Dr. Redfield always talked to Dr. Gao," the official said.

HHS and CDC did not make Azar or Redfield available for comment.

Zhu and other sources said U.S. leaders should not have been relying on the China CDC director for alerts and updates. In general, they said, officials in China downplayed the severity of the outbreak in the early weeks and did not acknowledge evidence of person-to-person transmission until Jan. 20.

After the epidemic exploded and China had imposed strict quarantines, Trump administration officials complained that the Chinese had censored information about the outbreak and that the United States had been unable to get American disease experts into the country to help contain the spread.

Azar told CNN on Feb. 14 that he and CDC director Redfield officially offered to send a CDC team into China on Jan. 6 but still had not received permission for them to enter the country. HHS oversees the CDC.

"Dr. Redfield and I made the offer on January 6th - 36 days ago, 60,000 cases and 1,300 deaths ago," Azar said. "We made the offer to send the CDC experts in to assist their Chinese colleagues to get to the bottom of key scientific questions like, how transmissible is this disease? What is the severity? What is the incubation period and can there be asymptomatic transmission?"

Days later, the World Health Organization secured permission to send a team that included two U.S. experts. The team visited between Feb. 16th and 24th. By then, China had reported more than 75,000 cases.

On Feb. 25, the first day the CDC told the American public to prepare for an outbreak at home, U.S. Secretary of State Mike Pompeo accused China of mishandling the epidemic through its "censorship" of medical professionals and media.

Relations between the two countries have deteriorated since then, as Trump has labeled the coronavirus the "Chinese virus" - a description the Chinese have condemned as stigmatizing. Last week, the Chinese government announced that Americans from three U.S. news organizations, The New York Times, Washington Post and Wall Street Journal, would be expelled from China.

ONCE 'FRIENDS,' NOW RIVALS

The decision to eliminate Quick's job came as the CDC has scaled back the number of U.S. staffers in China over the last two years, the sources told Reuters.

"We had already withdrawn many technical public health experts," the same expert said.

The CDC, however, disputed that staffing was a problem or that its information had been limited by the

move. "It was not the staffing shortage that limited our ability" it said.

The U.S. CDC team in Beijing now includes three American citizens in permanent roles, an additional American who is temporary and around 10 Chinese nationals, the agency said. Of the Americans, one is an influenza expert with expertise in respiratory disease. Coronavirus is not influenza, though it is a respiratory disease.

The CDC team, aside from Quick, was housed at U.S. Embassy facilities. No American CDC staffer besides Quick was embedded with China's disease control agency, the sources said.

China in recent weeks has reported a dramatic slowdown in new cases, the result of drastic containment measures including the lockdown of Hubei province, home to 60 million people. Nevertheless, the infectious disease experts who spoke with Reuters said, the United States could use people like Quick with contacts on the ground, especially if fears of a second wave of infections materializes.

Thomas R. Frieden, a former director of the CDC, said that if the U.S. resident adviser had still been in China, "it is possible that we would know more today about how this coronavirus is spreading and what works best to stop it."

Dr. George Conway, a medical epidemiologist who knows Quick and had served as resident advisor between 2012 and 2015, said funding for the position had been tenuous for years because of a perennial debate among U.S. health officials over whether China should be paying for funding its own training program.

Yet since the training program was launched in 2001, the sources familiar with it say, it has not only strengthened the ranks of Chinese epidemiologists in the field, but also fostered collegial relationships between public health officials in the two countries.

"We go there as credentialed diplomats and return home as close colleagues and often as friends," Conway said.

In 2007, Dr. Robert Fontaine, a CDC epidemiologist and one of the longest serving U.S. officials in the adviser's position, received China's highest honor for outstanding contributions to public health due to his contribution as a foreigner in helping to detect and investigate clusters of pneumonia of unknown cause.

But since last year, Frieden and others said, growing tensions between the Trump administration and China's leadership have apparently damaged the collaboration.

"The message from the administration was, 'Don't work with China, they're our rival,'" Frieden said.

The White House did not immediately respond to a request for comment.

Katie McKeogh

Press Secretary

Office of the Assistant Secretary for Public Affairs (ASPA)

U.S. Department of Health and Human Services

Katherine.McKeogh@hhs.gov

Sender:	Stecker, Judy (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0280B227911B40B6B30A81B8574EDE6B-STECKER, JU>
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From:	Mita Sampat <(b)(6)>
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Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 16:42:08
Priority:	Normal
Type:	Note

Mita Sampat

(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Mita Sampat

Sender:	Mita Sampat <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
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Message Flags:	Unread

From:	Rebecca Johnson <rljohnson@abpath.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 17:16:38
Priority:	Normal
Type:	Note

Rebecca Johnson

(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,
Rebecca Johnson

Sender:	Rebecca Johnson <rljohnson@abpath.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
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From:	Pallavi Kanwar Galera <galerap@mskcc.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 17:27:48
Priority:	Normal
Type:	Note

Pallavi Kanwar Galera
Memorial Sloan Kettering Cancer Center, 1275 York Ave, New York, 10065
New York, NY 10065

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,
Pallavi Kanwar Galera

Sender:	Pallavi Kanwar Galera <galerap@mskcc.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
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Subject:	Re: Azar communication
Date:	2020/03/22 17:30:18
Priority:	Normal
Type:	Note

I believe so. I'm waiting to hear back from FDA, but I've also followed up with CDC to get their official position. Will keep you all posted as answers come in.

Danielle Steele
Senior Adviser, IOS, HHS

Sent from my iPhone

On Mar 22, 2020, at 5:27 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>wrote:

Would FDA?

Sent from my iPhone

On Mar 22, 2020, at 5:24 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>wrote:

I don't believe CDC has that authority, but I will check back in with them.

Danielle Steele
Senior Adviser, IOS, HHS
Sent from my iPhone

On Mar 22, 2020, at 4:50 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Thanks Jonathan!

Danielle- can you circle back with CDC on the specific issues below?

From: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>
Sent: Sunday, March 22, 2020 4:23 PM
To: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>
Cc: Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>
Subject: Re: Azar communication

(b)(5)

On number 2, we don't think the CDC guidance speaks to decontamination or sterilization methods at this time. We are asking them to vet the methods we speak to and update the CDC guidance to include appropriate decontamination and sterilization methods to extend the use of PPE. Thanks so much. So appreciate the help! Take care. Susan

-JH

Deliberative & Pre-Decisional

Sent from my iPhone

On Mar 22, 2020, at 3:12 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Great!

ASPR can you confirm that the link Danielle sent does address question 2.

Jim- any update from HRSA?

Sent from my iPhone

On Mar 22, 2020, at 3:10 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>wrote:

FDA is currently reviewing 2 and 3. CDC has already taken action on 2, which is the link I sent

Danielle Steele
Senior Adviser, IOS, HHS

Sent from my iPhone

On Mar 22, 2020, at 3:09 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Thanks Danielle,

Can the appropriate policy people look at the three asks and come back with recommendations soon on whether her asks can be moved forward?

Please let me know if I need to convene any conversations for coordination.

Catherine

Sent from my iPhone

On Mar 22, 2020, at 2:57 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>wrote:

Here is CDC's guidance on reuse of PPE
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html>

Danielle Steele
Senior Adviser, IOS, HHS

Sent from my iPhone

On Mar 22, 2020, at 2:48 PM, Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>wrote:

I've reached out to FDA and CDC

Danielle Steele
Senior Adviser, IOS, HHS

Sent from my iPhone

On Mar 22, 2020, at 2:42 PM, Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>wrote:

Thanks Judy,

Can I get confirmation that these items are actively being considered and worked on by the appropriate people?

Catherine

From: Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>

Sent: Sunday, March 22, 2020 2:19 PM

To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>

Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>

Subject: Re: Azar communication

Looping in Jim Parker and Danielle Steele who are senior advisors to these operating divisions

Sent from my iPhone

On Mar 22, 2020, at 12:56 PM, Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>wrote:

All:

I spoke with Susan DeVore a bit ago and told her if there was anything HHS specifically could help to please not hesitate to reach out to me if she so desires. She was deeply appreciative and said there were some things she was preparing to email AMA about. I said I would get in front of the right folks ASAP. Please loop who you see fit.

Summary:

1. They request that HRSA provide flexibility in the administration of certain requirements for the 340B program during the national emergency for the COVID-19 pandemic.
2. Guidance on re-use and decontamination of PPE from FDA and/or CDC.
3. We request that FDA temporarily waive the one-mile radius rule for hospital and health system compounding

Deliberative, Pre-Decisional, FOUO, SBU, Close Hold

From: DeVore, Susan <Susan_DeVore@PremierInc.com>

Sent: Sunday, March 22, 2020 12:03 PM

To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>

Cc: Childs, Blair <Blair_Childs@PremierInc.com>; Saha, Soumi <Soumi_Saha@premierinc.com>; Alkire, Mike <Mike_Alkire@PremierInc.com>

Subject: FW: Azar communication

Hi Jonathan,

So appreciate your help in getting this in front of Secretary Azar. Three critical challenges for our health systems right now. The folks copied above can help provide any additional information that you need. They're happy to get on a phone call with the Secretary and team. Just let me know. Thanks so much. Take care. Susan

Secretary Azar,

We are receiving urgent requests from healthcare providers across the nation on important regulatory impediments that impede their ability to manage the current COVID-19 national emergency. Here are the critical issues we have received that we request HHS address as soon as possible:

1. Reduce Drug Shortages by Waiving HRSA's Restrictive Interpretation of the GPO Prohibition:

Hospitals and clinics participating in the 340B drug pricing program (340B program) facing unprecedented problems accessing drugs needed to treat their patients. Most of the 340B hospitals operating in areas hardest hit by covid-19 are subject to a unique 340B statutory prohibition against purchasing covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. HRSA's interpretation of the 340B program's GPO restriction is exacerbating the drug shortage problem for these hospitals which, in turn, is hindering their ability to meet the challenges presented by covid-19. These hospitals are all public or non-profit high-Medicaid hospitals, including children's hospitals.

There are two steps the Secretary's office can take right now to alleviate shortages of drugs that are critically needed during the covid-19 pandemic. Covid-19 has already been declared a public health emergency, which provides the HHS Secretary the authority under section 319 of the Public Health Service Act to "take such action as may be appropriate to respond to the public health emergency."^[1] The Secretary can rely on his section 319 authority to relax HRSA's problematic sub-regulatory interpretations of the GPO restriction.

Waive HRSA's burdensome procedures for using GPO drugs when the drugs are unavailable at non-GPO prices – When a hospital subject to the GPO restriction can only acquire a covered outpatient drug through its GPO account due to drug shortage problems, HRSA allows purchasing of GPO drugs if the hospital follows a four-step process. The hospital must:

1. • Work with the manufacturer to try to obtain the drug at 340B pricing;
2. • Try to purchase the drug at wholesale acquisition cost (WAC);
3. • Notify HRSA that the drug is not available at 340B or WAC prices by filling out a template form providing numerous details about the limited availability of the drug; and
4. • Maintain auditable records of all of the above, including records showing that the hospital attempted to purchase the drug through the 340B and WAC accounts every time a purchase is made on the GPO account.

These procedures are onerous in the best of circumstances and simply impossible to perform for overworked hospital staff struggling to keep up with the demands of the covid-19 pandemic, particularly given the increasing number of drugs that are unavailable at 340B or WAC pricing. The Secretary should invoke his authority to waive or relax these procedures during the covid-19 public health emergency.

Allow Premier's privately-labeled drugs to be purchased at 340B ceiling prices by any 340B hospital – Like other GPOs, Premier has contracted with generic drug manufacturers to produce a defined quantity of commonly-used drugs for the exclusive use of its members. These drugs are privately-labeled under

Premier's name and are pre-purchased in sufficient quantities to help its members survive periods of drug shortages.

To address the growing drug shortage problems associated with the coronavirus pandemic, Premier has informed its generic drug suppliers that it will waive the exclusivity restriction in its agreements so that the suppliers can sell the privately-labeled drugs to non-Premier members. Each of the suppliers has an executed pharmaceutical pricing agreement (PPA) with HRSA and is required under its PPA to offer 340B pricing on its full product line. Now that Premier has lifted the exclusivity arrangement with its suppliers, the suppliers are required under their PPAs to sell Premier's privately-labeled drugs to any interested 340B purchaser, whether it is a Premier member or not. However, because HRSA has issued guidance declaring privately-labeled drugs to be GPO drugs, both suppliers and wholesalers are concerned that selling the drugs at 340B ceiling prices will subject them and their hospital purchasers to undue risk of violating the GPO restriction.

Since the drugs will be sold to any 340B covered entity, not just Premier members, at ceiling prices established by statute rather than group negotiation, the GPO restriction cannot possibly be implicated. But the 340B supply chain needs the government's written assurance that the sale of Premier's privately-labeled drugs at 340B ceiling prices to any interested covered entity, including disproportionate share (DSH) and children's hospitals, is compliant with 340B program requirements, including the GPO restriction.

There is increasing demand for Premier's drugs due to coronavirus-related supply shortages and Premier is prepared to help meet that demand. But it needs the Secretary to take the two steps described above first.

2. PPE Decontamination/Sterilization: As hospitals struggle with dwindling PPE supplies, the concept of decontaminating or sterilizing PPE for reuse has been raised. ***There are three options on which we are asking if FDA or CDC would recommend the use of these decontamination or sterilization techniques.*** They are:

- Nebraska Medicine announced (see attached) that it is leveraging ***UV light to decontaminate*** and reuse PPE. Many hospitals have UV light technology to address MRSA decontamination.
- Several hospitals are also considering leveraging new technology using ***ultraviolet germicidal irradiation (UVGI)*** to decontaminate PPE. Attached is a study the company provided regarding their decontamination studies for N95 masks.
- Many hospitals also have their own ***ethylene oxide sterilization*** capabilities and would like to use those capabilities on PPE supplies.

3. One-Mile Radius Rule for Sterile Compounding: With limited staff and PPE constraints, many hospitals would like to consolidate pharmacy services to a single hub. A rate-limiting step to doing so is FDA's guidance compounding guidance that dictates the one-mile radius rule. ***We request that FDA temporarily waive the one-mile radius rule for hospital and health system compounding?***

Blair G. Childs

Senior Vice President

444 North Capitol Street, NW

Suite 625

Washington, D.C. 20001-1511

202-879-8009 (O)

(b)(6) (C); 202-879-8009 (F)

Susan Ueberroth, Executive Coordinator: 202 879 8010, Susan_Ueberroth@Premierinc.com**Premier**, 2006 Malcolm Baldrige National Quality Award Recipient

13034 Ballantyne Corporate Place, Charlotte, NC 28277

<https://protect2.fireeye.com/url?k=2fa3a975-73f7805e-2fa3984a-0cc47a6d17cc-6d32d9195a239e0b&u=http://www.premierinc.com/baldrige>

<UVGI Effects on the N95 Respirator.pdf>
<3-20 PPE.DOCX>

[1] Determination that a Public Health Emergency Exists, <https://protect2.fireeye.com/url?k=39d59453-6581bd78-39d5a56c-0cc47a6d17cc-3230c44aacac93fa&u=https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

Sender:	Steele, Danielle (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=38849C1F1EA74F2EB9EFF75B531A9544-STEELE, DAN>
Recipient:	Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Parker, Jim (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f7ac2e66aa043a6b7cb2eaf967ffa3-Parker, Jam>
Sent Date:	2020/03/22 17:30:16
Delivered Date:	2020/03/22 17:30:18

From:	Clark Tibbs PhageVax-VHO <PhageVax@roadrunner.com>
	<Press.Office@exec.ny.gov>; <clep@health.ny.gov>; <dohweb@health.ny.gov>; <press@health.ny.gov>; <WC_CRC@westchestergov.com>; 'Valerie Alliger-Bograd' <vab@frontierpharm.com>; 'Howard Alliger' <alge@frontierpharm.com>; <info@abo.ny.gov>; <Brenton.Temple@governor.ohio.gov>; <john.barnard@nationwidechildrens.org>; <Bruce.Vanderhoff@OhioHealth.com>; <Joseph.Gastaldo@OhioHealth.com>; (b)(6) Hamel, Joseph (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose>; Adams, Steven A. (ASPR/SNS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f98462fe8d124743a437c7a80b3f60dd-Adams, Stev>; Falcon, Jessica (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2f34b1b5a874e108d1dedfa20a01eb7-Falcon, Jes>; Wolf, Laura (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c>; To: Blatner, Gretta (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr>; <Brenton.Temple@governor.ohio.gov>; <Amy.Freedman@trade.gov>; <Darren.Srebnick@trade.gov>; <info@abo.ny.gov>; Bright, Rick (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Balsamo, Ralph (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5154e90d1f17484293769cd43eb7447e-Balsamo, Ra>; Armstrong, Kimberly (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong,>; Johnson, Anthony (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7565fc8485c446cf9b65beb58b6d74ce-Johnson, An>; Blatner, Gretta (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr>; Tegeris, John (OS/ASPR/BARDA) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd48e9eb139645df8b45ea8439820e7f-Tegeris, Jo>; Hewitt, Judith (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713b72de7f464bf69290d6c10c1d0dc9-judith.hewi>; Erbeling, Emily (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ac682896fa440d08a36924a220edd00-emily.erbel>
Subject:	To Decision-Makers :: HAND SANITIZER :: WEBSITE: https://frontierpharm.com PRICE for ^CHLORINE DIOXIDE (CIO2) DISINFECTANT for EXPORT^ (1 DOC)
Date:	2020/03/22 17:32:17
Priority:	Normal
Type:	Note

Sunday, March 22, 2020 *Did you hear about Sen. Rand Paul and the German leader, Merkel?*

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As you may have seen on TV, there is an alcohol distiller in PA that is mixing their alcohol with Glycerin and some Hydrogen Peroxide and providing their product to the marketplace. A better alternative would be for you to examine the data at **WEBSITE:**

<https://protect2.fireeye.com/url?k=7cd9618e-208d78f2-7cd950b1-0cc47adc5fa2-a23ae064008101e1&u=https://frontierpharm.com/>

See the white papers and studies at:

<https://protect2.fireeye.com/url?k=437490f8-1f208984-4374a1c7-0cc47adc5fa2-2c2123741d0b2baa&u=https://frontierpharm.com/pages/the-science-of-dioxicare>

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<https://protect2.fireeye.com/url?k=a6dc550f-fa884c73-a6dc6430-0cc47adc5fa2-0ee3495884a95c54&u=https://frontierpharm.com/pages/white-papers>

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<https://protect2.fireeye.com/url?k=7f753e00-2321277c-7f750f3f-0cc47adc5fa2-146ba24cc8b55c6c&u=http://www.frontierpharmvet.com/>

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From: Clark Tibbs PhageVax-VHO [mailto:PhageVax@roadrunner.com]

Sent: Friday, March 13, 2020 4:40 PM

To: 'Press.Office@exec.ny.gov'; 'clep@health.ny.gov'; 'dohweb@health.ny.gov'; 'press@health.ny.gov'; 'WC_CRC@westchestergov.com'; 'Valerie.Alliger-Bograd'; 'Howard.Alliger'; 'info@abo.ny.gov'; 'Brenton.Temple@governor.ohio.gov'; 'john.barnard@nationwidechildrens.org'; 'Bruce.Vanderhoff@OhioHealth.com'; 'Joseph.Gastaldo@OhioHealth.com'; (b)(6)

Cc: 'Mark.Klein@exim.gov'; 'nicole.woods@exim.gov'; 'shontelle.bragg@exim.gov'; 'lataunya.darden@exim.gov'; 'michael.jackson@exim.gov'; 'tammy.maxwell@exim.gov'; 'toya.woods@exim.gov'; 'Amy.Freedman@trade.gov'; 'Darren.Srebnick'; 'Joseph.Hamel@hhs.gov'; 'saa1@cdc.gov'; 'Jessica.Falcon@hhs.gov'; 'Laura.wolf@hhs.gov'; 'Amy.Freedman@trade.gov'; 'Darren.Srebnick@trade.gov'

Subject: TO NYS & OHIO DECISION-MAKERS ... Please go to WEBSITE: <https://protect2.fireeye.com/url?k=3d7f64fc-612b7d80-3d7f55c3-0cc47adc5fa2-278a2238d32dd5b5&u=https://frontierpharm.com/> PRICE for ^CHLORINE DIOXIDE (ClO2) DISINFECTANT for EXPORT^ (1 DOC)

TO: NYS Governor's Press Office Press.Office@exec.ny.gov

Albany: (518) 474-8418

New York City: (212) 681-4640

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The best contact now is the **NYS-based Manufacturer** of the ^CHLORINE DIOXIDE (ClO2) DISINFECTANT for EXPORT^

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Corporate Office (USA)
Frontier Pharmaceutical, Inc.
10 Ponderosa Drive

Melville, New York 11747 USA

Toll Free: (800) 767-3486 -and- Phone: (631) 367-3400 Leave a message 24x7x365 Credit Cards are accepted.

Fax: (631) 692-7642

-

EMAIL for Customer Service: customerservice@frontierpharm.com

-

WEBSITE: <https://protect2.fireeye.com/url?k=fd48abed-a11cb291-fd489ad2-0cc47adc5fa2-fc0193f3f9734062&u=https://frontierpharm.com/>

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Chlorine Dioxide (ClO₂), which is a gas, was utilized only on a large scale, such as for the treatment of municipal water supplies, and paper pulp bleaching. Credit Cards are accepted.

Now, ClO₂ is available as a world-class **disinfectant** and for **personal care and hygiene**.

See the white papers and studies at:

<https://protect2.fireeye.com/url?k=d9534bbd-850752c1-d9537a82-0cc47adc5fa2-991e793e1572c54f&u=https://frontierpharm.com/pages/the-science-of-dioxicare>

<https://protect2.fireeye.com/url?k=6235f9b7-3e61e0cb-6235c888-0cc47adc5fa2-4cc968aa8a93f9c5&u=https://frontierpharm.com/pages/white-papers>

<https://protect2.fireeye.com/url?k=203f6878-7c6b7104-203f5947-0cc47adc5fa2-a22b95828fc831ae&u=http://www.frontierpharmvet.com/>

The new Coronavirus **COVID-19** ... can remain viable of surfaces for up to **8 to 9 days**.

Some victims may not show symptoms for up to **24 days+**

Some **COVID-19** Patients Test Positive DAYS AFTER Recovery [**5 to 13** days later]

Hello Wadsworth Center Personnel. My name is Clark Tibbs.

We are sure you have heard about this:

New Rochelle, N.Y., prepares for **2-week lockdown** in 'containment zone' - MARCH 11, 2020 9:42am ET

https://www.upi.com/Top_News/US/2020/03/11/New-Rochelle-NY-prepares-for-2-week-lockdown-in-containment-zone/1281583929046

The Chinese have been using some type of disinfectant (to kill the COVID-19) with great success.

New Rochelle, NY [and other future **hot-spots / red-zones / clusters**] will need the same ... or better!

Therefore, please consider a reply with your Shipping Address so the NYS-based Manufacturer of Chlorine Dioxide (ClO₂) ... can send 1 Gallon of their **1-Part ClO₂ Concentrate** [you dilute with tap-water] for your testing and Certification?

By the way, said NYS-based Manufacturer of Chlorine Dioxide (ClO₂) ... has exhausted their budget for any further testing.

Please see this attached document?

To:

Mark Klein - cell 312-375-1883 - Mark.Klein@exim.gov

Nicole Woods - 202-565-3296, nicole.woods@exim.gov

Shontelle Bragg - 202-565-3710, shontelle.bragg@exim.gov

Lataunya Darden - 202-565-3900, lataunya.darden@exim.gov

Michael Jackson - 202-565-3479, michael.jackson@exim.gov

Tamara Maxwell - 202-565-3375, tammy.maxwell@exim.gov

Toya Woods - 202- 565- 3355, toya.woods@exim.gov

Ref: [https://protect2.fireeye.com/url?k=c41b9d5c-984f8420-c41bac63-0cc47adc5fa2-](https://protect2.fireeye.com/url?k=c41b9d5c-984f8420-c41bac63-0cc47adc5fa2-22a28f1538dd734a&u=https://www.exim.gov/about/special-initiatives/women-minority-owned)

[22a28f1538dd734a&u=https://www.exim.gov/about/special-initiatives/women-minority-owned](https://www.exim.gov/about/special-initiatives/women-minority-owned)

-

Email list: Mark.Klein@exim.gov ; nicole.woods@exim.gov ; shontelle.bragg@exim.gov ;

lataunya.darden@exim.gov ; michael.jackson@exim.gov ; tammy.maxwell@exim.gov ; toya.woods@exim.gov

-

By the way, PhageVax and Partner [Frontier Pharm.] ... desire **Operating Funding** to ramp-up for **huge demand** for the ^CHLORINE DIOXIDE (ClO2) **DISINFECTANT** for EXPORT^

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To:

Amy Freedman

Senior International Trade Specialist

Education Technology Subsector Team Lead

U.S. Commercial Service-Cleveland, Ohio

U.S. Department of Commerce I International Trade Administration

Howard M. Metzenbaum Courthouse

201 Superior Ave East, Cleveland, OH 44114 USA

[https://protect2.fireeye.com/url?k=4a12c8dd-1646d1a1-4a12f9e2-0cc47adc5fa2-](https://protect2.fireeye.com/url?k=4a12c8dd-1646d1a1-4a12f9e2-0cc47adc5fa2-8d880a306ee31f0d&u=http://www.export.gov/)

[8d880a306ee31f0d&u=http://www.export.gov/](http://www.export.gov/)

O (216) 522-4737 M (b)(6)

Amy.Freedman@trade.gov ; Darren.Sreblick@trade.gov

=====

202-969-3852 Joseph Hamel, Strategic Innovation & Emerging Tech.

Mgr. Joseph.Hamel@hhs.gov

404-639-0692 Steven Adams, Deputy Director, Strategic National Stockpile (SNS)

saa1@cdc.gov

202-401-4055 Jessica Falcon, Director, Office of Security, Intell. & Info. Mgmt.

Jessica.Falcon@hhs.gov

202-260-0666 Laura Wolf, Director, Div. of Critical Infrastructure Protection

Laura.wolf@hhs.gov

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Email list: Joseph.Hamel@hhs.gov ; saa1@cdc.gov ; Jessica.Falcon@hhs.gov ;

Laura.wolf@hhs.gov ;

Gretta.Blatner@hhs.gov at BARDA. Phone: (202) 260-8535

=====

TO:

Clinical Laboratory Evaluation Program

clep@health.ny.gov ; dohweb@health.ny.gov ; press@health.ny.gov ;
WC_CRC@westchestergov.com

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P: (518) 485-5378 F: (518) 485-5414

-

US Postal Service

Wadsworth Center

NYS Department of Health

Empire State Plaza, Albany, NY 12237-0012

-

UPS, FedEx, Courier

Biggs Laboratory

Wadsworth Center

NYS Department of Health - Dock J - P1 Level

Empire State Plaza, Albany, NY 12237

Ref: <https://protect2.fireeye.com/url?k=0d89515c-51dd4820-0d896063-0cc47adc5fa2-ed4d073af0dba3fe&u=https://www.wadsworth.org/regulatory/clep/approved-labs>

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-AND-

NYS Authorities Budget Office info@abo.ny.gov

Phone: (518) 474-1932 (Albany and Capital District)

800-560-1770 (For use outside the 518 area code only)

Ref: <https://www.abo.ny.gov/site/contact.html>

=====

Clark Tibbs, CEO

PhageVax, Inc. <https://protect2.fireeye.com/url?k=9ee8ac77-c2bcb50b-9ee89d48-0cc47adc5fa2-671a93ef3e23bfc&u=http://www.phagevax.com/>

CAGE CODE: 4M4V6 www.sam.gov

Phone: 740.366.9013 Fax: 740.366.5230 Cell: (b)(6)

E-mail: Clark@PhageVax.com -or- PhageVax@roadrunner.com -or- CTA@ee.net

General Offices &HQ: 855 Sharon Valley Road, Suite 101 Newark, Ohio 43055-2860 USA

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Sender:	Clark Tibbs PhageVax-VHO < PhageVax@roadrunner.com >
Recipient:	< Press.Office@exec.ny.gov >; < clep@health.ny.gov >; < dohweb@health.ny.gov >;

	<press@health.ny.gov>; <WC_CRC@westchestergov.com>; 'Valerie Alliger-Bograd' <vab@frontierpharm.com>; 'Howard Alliger' <alge@frontierpharm.com>; <info@abo.ny.gov>; <Brenton.Temple@governor.ohio.gov>; <john.barnard@nationwidechildrens.org>; <Bruce.Vanderhoff@OhioHealth.com>; <Joseph.Gastaldo@OhioHealth.com>; (b)(6) Hamel, Joseph (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose>; Adams, Steven A. (ASPR/SNS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f98462fe8d124743a437c7a80b3f60dd-Adams, Stev>; Falcon, Jessica (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2f34b1b5a874e108d1dedfa20a01eb7-Falcon, Jes>; Wolf, Laura (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c>; Blatner, Gretta (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr>; <Brenton.Temple@governor.ohio.gov>; <Amy.Freedman@trade.gov>; <Darren.Sreblick@trade.gov>; <info@abo.ny.gov>; Bright, Rick (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Balsamo, Ralph (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5154e90d1f17484293769cd43eb7447e-Balsamo, Ra>; Armstrong, Kimberly (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b778c7e17734740b14fbae4d3ed652c-Armstrong,>; Johnson, Anthony (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7565fc8485c446cf9b65beb58b6d74ce-Johnson, An>; Blatner, Gretta (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=623cb123c2324236b1db6fb9153e0bbf-Blatner, Gr>; Tegeris, John (OS/ASPR/BARDA) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd48e9eb139645df8b45ea8439820e7f-Tegeris, Jo>; Hewitt, Judith (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713b72de7f464bf69290d6c10c1d0dc9-judith.hewi>; Erbeling, Emily (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ac682896fa440d08a36924a220edd00-emily.erbel>
Sent Date:	2020/03/22 17:31:27
Delivered Date:	2020/03/22 17:32:17
Message Flags:	Unread NotifyRead

From:	Kim Powell (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 18:39:57
Priority:	Normal
Type:	Note

Kim Powell

(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Kim Powell

Sender:	Kim Powell (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 18:35:46
Delivered Date:	2020/03/22 18:39:57
Message Flags:	Unread

From:	Denise Francois <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 19:00:31
Priority:	Normal
Type:	Note

Denise Francois

(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,

Denise Francois

Sender:	Denise Francois <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 18:55:46
Delivered Date:	2020/03/22 19:00:31
Message Flags:	Unread

From:	Bryan Dangott <Bryan.Dangott@interpace.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 19:24:08
Priority:	Normal
Type:	Note

Bryan Dangott

(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Bryan Dangott

Sender:	Bryan Dangott <Bryan.Dangott@interpace.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 19:15:47
Delivered Date:	2020/03/22 19:24:08
Message Flags:	Unread

From:	Oakley, Caitlin B. (OS/ASPA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E5EE4C35534C4AF9BDAC46789C034790-OAKLEY, CAI>
To:	ASPA-Deputies </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=884d75c735db47cca76a4c0fc74a06b8-ASPA-Deputi>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	FW: Pence promises coronavirus testing backlog will be addressed this week
Date:	2020/03/22 19:24:47
Priority:	Normal
Type:	Note

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Sent: Sunday, March 22, 2020 7:24 PM
To: Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>
Subject: Pence promises coronavirus testing backlog will be addressed this week

Pence promises coronavirus testing backlog will be addressed this week

By Mohana Ravindranath

03/22/2020 07:21 PM EDT

The White House is expecting commercial labs to catch up on a testing backlog by mid-week, Vice President Mike Pence said at a White House coronavirus task force briefing today.

Pence said 254,000 Americans had been tested and had received results; a little more than 30,000 tested positive. He added that the number didn't include local hospitals and labs.

President Donald Trump at the briefing pointed to a new test that can deliver results within 45 minutes; FDA granted emergency authorization for the rapid point-of-care test on Saturday.

Faster testing "would be a game changer," Trump said at the briefing.

The U.S. public response to the outbreak has been hampered by shortages of critical materials. Widespread testing is necessary to tracking the spread of the disease, public health experts say.

Pence also said the administration would give all commercial labs guidance to prioritize in-patient testing, so that patients who have been checked into hospitals for the coronavirus or coronavirus-like symptoms could be tested more quickly.

Amid the testing shortages, public labs have called for targeted testing for those most at-risk, such as health care workers, first responders and the elderly.

To view online:

<https://protect2.fireeye.com/url?k=ec72ebfb-b026f287-ec72dac4-0cc47adc5fa2-1930cca5bd24165f&u=https://subscriber.politicopro.com/health-care/whiteboard/2020/03/pence->

[promises-coronavirus-testing-backlog-will-be-addressed-this-week-3978336](#)

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Sender:	Oakley, Caitlin B. (OS/ASPA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E5EE4C35534C4AF9BDAC46789C034790-OAKLEY, CAI>
Recipient:	ASPA-Deputies </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=884d75c735db47cca76a4c0fc74a06b8-ASPA-Deputi>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/03/22 19:24:46
Delivered Date:	2020/03/22 19:24:47

From:	Tom Polen <tom_polen@bd.com>
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.p (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose>
CC:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	Re: Follow-up - POC Diagnostics, Drug Delivery Devices for Vaccination, Medmined Software for COVID-19/Emerging Pathogen Surveillance & ETO Sterilization
Date:	2020/03/22 19:27:29
Priority:	Normal
Type:	Note

Great. 8am or anytime 2-5pm

Tom Polen

CEO and President

tom_polen@bd.com

From: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>

Sent: Sunday, March 22, 2020 7:25:24 PM

To: Tom Polen <tom_polen@bd.com>

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

Subject: Re: Follow-up - POC Diagnostics, Drug Delivery Devices for Vaccination, Medmined Software for COVID-19/Emerging Pathogen Surveillance & ETO Sterilization

Tom,

Thank you for the rundown. Let's talk tomorrow. Let me know a good time and I'll give you a shout.

Best,

Joe

Strategic Innovation and Emerging Technology Manager

Assistant Secretary for Preparedness and Response

Office: 202-969-3852

Cell: (b)(6)

On Mar 22, 2020, at 7:19 PM, Tom Polen <tom_polen@bd.com> wrote:

Hi Bob and Joe,

I wanted to circle back to express my thanks for your collaboration on issues related to the COVID-19 response. I understand that our teams have made progress in a couple of particular areas and wanted to reinforce our commitment to partner, specifically on:

(b)(4)

(b)(4)

Thank you again for your partnership, and I look forward to our teams continuing to make progress in these areas.

Tom

Tom Polen

Chief Executive Officer and President

BD

1 Becton Drive , Franklin Lakes, NJ 07417

tel: 201-847-3176 mobile: (b)(6)

email: tom_polen@bd.com website: www.bd.com

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Corporate Headquarters Mailing Address: BD (Becton, Dickinson and Company) 1 Becton Drive Franklin Lakes, NJ 07417 U.S.A.

<2020_0310 BD Response to BARDA Inquiry_Updated.pptx>

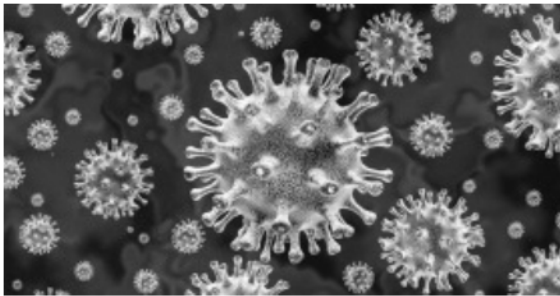
Sender:	Tom Polen < tom_polen@bd.com >
Recipient:	Hamel, Joseph (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96d2c1602dfa45e5a5e21452a098b96d-Hamel, Jose>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Sent Date:	2020/03/22 19:27:05
Delivered Date:	2020/03/22 19:27:29
Message Flags:	Unread

From:	Peter Smith <(b)(6)>
To:	Sari Priscilla SETIOGI <setiogis@who.int>
CC:	<cnect-ehealth@ec.europa.eu>
Subject:	KATHLEEN SPREADING KINDNESS/ COVID 19 REPORT
Date:	2020/03/22 20:44:37
Priority:	Normal
Type:	Note

WHO

Old because their more vulnerable, young because they just want to do stupid things, wont listen because they just want to hang out and Party!

New CDC report on US COVID-19 cases affirms seriousness for the young



A new report from the CDC offers the first analysis of COVID-19 cases in the United States. While patient ages and fatalities resemble data from other countries, the numbers are a reminder the disease can be dang

A new CDC report notes almost 40 percent of all COVID-19 hospitalizations in the US were in people younger than 54 years

cc: Patty Hajjdu
cc: EU
cc: Mr. Conte
cc: Queens Commonwealth Trust
cc: Royal Foundation
cc: Mandela
cc: Ibrahim
cc: Royal Thai Family
cc: Asia
cc: Eric Hargan
cc: Dr. Dobson

cc: Bonnie Henry
cc: CFP
cc: Dr. Lee
cc: SFU
cc: Bangkok Hospital
cc: Angkor Hospital
cc: Kathleen

Lots of love sweet heart, hope all well so see you soon!

This Flu Shot was good idea wasn't it who would have known all this was going to happen!
xxxxoooo

Peter
Cudles

Mr. Peter Smith Chief Executive Officer
CAVE MAN ENVIRONMENTAL CONSULTING

Bringing rational decision making back to Government
E Mail: (b)(6)

(b)(6)

Sender:	Peter Smith <(b)(6)>
Recipient:	Sari Priscilla SETIOGI <setiogis@who.int>; <cnect-ehealth@ec.europa.eu>
Sent Date:	2020/03/22 20:44:00
Delivered Date:	2020/03/22 20:44:37

From:	Schwartz, Erica (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=603E84A0E3744A5D8DCBD759F5DCAD91-SCHWARTZ, E>
To:	Arthur Kellermann (b)(6)
CC:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
Subject:	RE: Emory and CDC COVID Self-checker websites
Date:	2020/03/22 20:54:57
Priority:	Normal
Type:	Note

Art,

Thank you for bringing this to our attention. I will share the Emory site with the task force team.

RADM Erica Schwartz, MD, JD, MPH

Deputy Surgeon General
Office of the Surgeon General
United States Public Health Service
U.S. Department of Health and Human Services
200 Independence Ave SW, Suite 701-H
Washington, DC 20201
Office Phone: 202-401-4660
Email: erica.schwartz@hhs.gov

From: Arthur Kellermann (b)(6)
Sent: Sunday, March 22, 2020 8:51 PM
To: Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Schwartz, Erica (HHS/OASH) <Erica.Schwartz@hhs.gov>
Subject: Emory and CDC COVID Self-checker websites

Dear Jerome and Erica,

Art Kellermann here - I expect that you know that the CDC has launched a COVID self-assessment website, but you may not know that my former department at Emory and a tech startup have also launched a free self-assessment site,
<https://protect2.fireeye.com/url?k=f21004a7-ae450db4-f2103598-0cc47adb5650-c5b9dd075db8d5d3&u=http://www.c2019check.com/>

Both sites were featured in a NY Times story last Friday:
<https://www.nytimes.com/reuters/2020/03/20/us/20reuters-health-coronavirus-screening.html>

Both sites have a lot in common which is not surprising, since they both trace their lineage back to a website I helped develop that was hosted on flu.gov and Microsoft.com during the 2009H1N1 pandemic (see attached article).

Both sites risk-stratify users based on age, symptom severity and co-morbid conditions, and both give user-specific CDC guidance in return. In my opinion, Emory's new website is more user-friendly (particularly by older individuals), was vetted by military health experts and former CDC luminaries like Jeff Koplan and Jim Hughes, and has functionality and features that the CDC website lacks.

In an attempt to accelerate this work, I reached out to the CDC 12 days ago, advised them of Emory's effort, and had the Emory team share their algorithms and logic with the CDC. At the time, I hoped that the CDC would once again partner with Emory as it had during the 2009 H1N1 flu pandemic, and failing that, at least give Emory its most current COVID guidance. Unfortunately, Emory got nothing in return.

Even so, I reached out to the CDC again today to plead that going forward, they and the Emory team share algorithms and analytics to assure that both websites are constantly updated to work as well as possible and provide equivalent guidance. Anything you can do to encourage them to communicate will be greatly appreciated.

I realize that you both must support a fellow PHS agency, but I hope you will recommend the Emory site as well, since it is free, user-friendly, clinically oriented, generate data that could be valuable to local and state health departments, and communicates CDC guidance.

Respectfully,

Art

Arthur L. Kellermann, MD, MPH, FACEP
Professor and Dean
F Edward Hebert School of Medicine – "America's Medical School"
Uniformed Services University of the Health Sciences
Bethesda, MD
301-295-3016

Sender:	Schwartz, Erica (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=603E84A0E3744A5D8DCBD759F5DCAD91-SCHWARTZ, E>
Recipient:	Arthur Kellermann (b)(6); Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
Sent Date:	2020/03/22 20:54:56
Delivered Date:	2020/03/22 20:54:57
Message Flags:	Unread

From:	Sherman, Jennifer (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F30FE7FAE664419FA654B20EDCCB1E78-SHERMAN, JE>
To:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
CC:	Kotwicki, Lauren (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d62ddb3fc4b358ab573ccc13fbbb7-Kotwicki, L>
Subject:	Principal-Comms Prep notes
Date:	2020/03/22 21:03:00
Priority:	Normal
Type:	Note

Dr. Adams,

Below are my notes from tonight's messaging call. I also put together a sketch for your opening and closing (if there's a chance for one!) for your interviews tomorrow. Let me know if you have any questions or need anything additional.

(b)(5)

(b)(5)

Jenn Sherman

Director of Public Affairs

Office of the Surgeon General

Department of Health and Human Services (HHS)

Sender:	Sherman, Jennifer (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F30FE7FAE664419FA654B20EDCCB1E78-SHERMAN, JE>
Recipient:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Kotwicki, Lauren (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54d62ddb3fc4b358ab573ccc13fbbb7-Kotwicki, L>
Sent Date:	2020/03/22 21:02:58
Delivered Date:	2020/03/22 21:03:00

From:	Wright, Janet (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=41F672E2527B4F44891FB4FBE08CDFDF-WRIGHT, JAN>
To:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
CC:	Sherman, Jennifer (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30fe7fae664419fa654b20edccb1e78-Sherman, Je>
Subject:	If there is a chance to acknowledge healthcare professionals, here are some actions
Date:	2020/03/22 21:18:34
Priority:	Normal
Type:	Note

Could hear you start the sentence (b)(5) with

(b)(5)

(b)(5)

Janet S. Wright, MD, FACC

Director of Science and Policy (Acting), Office of the Surgeon General

U.S. Department of Health and Human Services, 200 Independence Ave SW, Suite 701H, Washington, DC 20201

Office Phone: 202-690-5157

Email: janet.wright@hhs.gov

Sender:	Wright, Janet (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=41F672E2527B4F44891FB4FBE08CDFDF-WRIGHT, JAN>
Recipient:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Sherman, Jennifer (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30fe7fae664419fa654b20edccb1e78-Sherman, Je>
Sent Date:	2020/03/22 21:18:32
Delivered Date:	2020/03/22 21:18:34

From:	Allison Eberly (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 21:35:22
Priority:	Normal
Type:	Note

Allison Eberly
(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Allison Eberly

Sender:	Allison Eberly (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 21:35:00
Delivered Date:	2020/03/22 21:35:22
Message Flags:	Unread

From:	Pam Schweitzer <(b)(6)>
To:	Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
Subject:	CDC information communicated to healthcare professionals
Date:	2020/03/22 21:37:36
Priority:	Normal
Type:	Note

ADM Giroir and VADM Adams,

Thank you for your selfless service! Our country is grateful to you for the lengthy hours you are putting to help our country.

Is there any way the CDC web site for **healthcare professionals** can be updated to emphasize communication of the "if you are sick information/steps when sick" to patients, which is well done and clear (<https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>) versus the healthcare professional section which does not really address that patients that are symptomatic but not tested. - <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html> (last reviewed 3/14/2020).

In our community (Arizona) people with "COVID-19 symptoms" are not being tested because of the CDC stringent criteria, which is fine (due to shortage of PPE), EXCEPT, they (physicians) are also saying:

"There are not many cases in Arizona, so it is unlikely you have the COVID-19 virus."

COVID-19 is not a consideration and there is no suggestion of quarantining (or referring to CDC guidelines for people are sick), so these folks are still out and about with their families (including elders) - most are being told they have allergies or bronchitis (symptoms of fever, cough, shortness of breath, no travel history).

It is really difficult for people to be serious about social distancing when the COVID-19 count is so low. The website only says to quarantine if someone in the family has tested positive, but it's been challenging for the first person to be tested (testing is only being done on those admitted to the hospital).

On the state web site:

"If someone in your family has tested positive for COVID-19, keep the entire household at home and contact your medical provider. "

An ER doc we know said our local "small" hospital turned away hundreds of patients yesterday because they were not sick enough to be admitted. I am sure some of these had COVID-19. This would be a perfect opportunity to share the CDC "if you are sick" information, but I don't think providers are all up-to-speed with all the information that is out there.

1. • It would be ideal if there could be communication/posting for healthcare professionals on the CDC website - <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html>) that would emphasize the "if you are sick" section to patients; this information should be given to anyone with respiratory symptoms, regardless of testing.
2. • Note - not everyone has a primary care provider.

On a new topic - the pharmacy organizations, community pharmacies, and pharmacists in general are doing an amazing job, very engaged and really stepping up. So pleased pharmacies are considered "essential" businesses.

Thank you for your leadership and service!

Pam

--

RADM (ret) Pamela Schweitzer, Pharm.D.

Former Assistant Surgeon General

10th Chief Pharmacist Officer, USPHS Commissioned Corps

e-mail: (b)(6)

(m) (b)(6)

Sender:	Pam Schweitzer (b)(6)
Recipient:	Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>
Sent Date:	2020/03/22 21:37:15
Delivered Date:	2020/03/22 21:37:36
Message Flags:	Unread

From:	Orsega, Susan (OS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D8171C34A0CD4581A49F33CB8F60F684-ORSEGA, SUS>
To:	Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Trent-Adams, Sylvia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=650dc3276414421693345147bfafd132-Trent-Adams>; Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcdb759f5dcad91-Schwartz, E>
CC:	Valentine, Steven (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd508090f8984b1caf04069bc6000dc2-Valentine,>; Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Subject:	COVID-19 CCHQ Mission Update 22 MAR 2020
Date:	2020/03/22 21:42:18
Priority:	Normal
Type:	Note

Sirs and Ma'ams

As of 22Mar2020 at 2000, **1199** Commissioned Corps have deployed.

Commissioned Corps Headquarters has deployed a total of 784 officers; 281 officers are currently deployed

77 officers are currently deployed for the Community-Based Testing Sites Initiative

****415 Agency Deployments:** ACF (8), CDC (315), CMS (3), FDA (24), IHS (3), Interior (27), NIH (22), USDA (3), VA (10)

Rear Admiral Susan M. Orsega, FNP-BC, FAAN, FAANP

Director, Commissioned Corps Headquarters

Office of the Surgeon General

United States Public Health Service

U.S. Department of Health and Human Services

1101 Wooten Parkway

Rockville, Maryland 20852

Office Phone: 240-453-6080

Cell phone: (b)(6)

Email: susan.orsega@hhs.gov

Sender:	Orsega, Susan (OS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D8171C34A0CD4581A49F33CB8F60F684-ORSEGA, SUS>
Recipient:	Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Trent-Adams, Sylvia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=650dc3276414421693345147bfafd132-Trent-Adams>; Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcdb759f5dcad91-Schwartz, E>;

	Valentine, Steven (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd508090f8984b1caf04069bc6000dc2-Valentine,>; Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Sent Date:	2020/03/22 21:42:15
Delivered Date:	2020/03/22 21:42:18

From:	elizabeth Hebert <bhebert@chartermi.net>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 21:55:49
Priority:	Normal
Type:	Note

elizabeth Hebert

(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
elizabeth Hebert

Sender:	elizabeth Hebert <bhebert@chartermi.net>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 21:55:01
Delivered Date:	2020/03/22 21:55:49
Message Flags:	Unread

From:	Warren Conrow <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 22:07:14
Priority:	Normal
Type:	Note

Warren Conrow

(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,

Warren Conrow

Sender:	Warren Conrow <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 22:05:01
Delivered Date:	2020/03/22 22:07:14
Message Flags:	Unread

From:	Barry Silbermann (b)(6)
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826965b24a314ffca7eddc6e8229aa7-anthony.fau>; Hahn, Stephen (FDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0666f41e4514dd3b294a23789487280-stephen.hah>
CC:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Harry Holmes Ph D (b)(6); Jason Crace, CPA <jason@craceandbeam.com>; Paul M Griffin, PhD (b)(6); Joseph Lombardo PhD (b)(6)
Subject:	Fwd: PROJECT: COVID-19 HC Systems - Proposed Immediate Attack Solutions
Date:	2020/03/22 22:11:25
Priority:	Normal
Type:	Note

Dr. Fauci and Dr. Hahn

This is to fast track include you both into distribution of The Institute's PROJECT: COVID-19 Healthcare Systems Proposals to the Secretary DHHS.

That is a feature of having dedicated professionals advising on to whom to send this information as did my good friend and supporter Harry Holmes, PhD, Government Affairs Advisor. Harry and I first worked together when he was in the President's Office University of Texas,/MD Anderson and I was principle advisor to the Chairman of the Board and the President of the John Wayne Cancer Institute.

- As I work tough this national problem, the University of Texas with possible Level 4 COVID-19 testing capability is shut down not taking meetings. Purdue University with the Reganstreif Center for Healthcare Engineering and my analytics capability is shut down.
- **Our goal should be to get both institutions open ASAP and working this problem with us!**

What is the benefit to adding expertise in Operations Research to the President and Vice President's need to have optimum solutions to:

- finding vaccine, maintaining the mental health of nearly an entire national population; and
- getting that population and the national economy breathing since there are no ventilators for the economy; and
- the supply of money may be as finite as the supply of ventilators and masks is the problem solving we would like to introduce.

The Institute's PROJECT COVID-19 offers two of three immediate solutions:

- Urging to immediately engage in testing of the Puradigm pathogen air filtration units. and
- The Institute will work with DHHS and NIH and CDC to find how to ramp up to a wartime production level.
- Just a historical comparison for which we cannot afford to repeat by comparison:
 - the modern electrical air conditioning unit was invented in 1902,
 - combined and patented moisture with ventilation to "condition" and change the air in the factories by Willis Carrier in 1906,
 - first placed in a private home in 1914 and
 - a portable, in-window air conditioner invented in 1945.
- By contrast, after December 7, 1941, by February 1942, American civilian automobile factories only made weapons and military vehicles.
- Perhaps we can attack COVID-19 as fast or faster starting now, by taking the Caronavirus pathogen out of the air than is possible if we just work to find and produce a vaccine and in sufficient quantities?

I respectfully urge that we should find out the answer to that question **and how we can concurrently, just as efficiently attack the fear and panic in this country from Caronavirus by testing programs for mass delivery form the Institute's PROJECT COVID-19 Mental Health Wellness Program of clinical hypnotherapy (offered by such as the Mayo Clinic and EFT technique (clinically tested).**

We are available to just first take a phone call from you to further enlighten and explain. Thank you for considering this urgent offer to help you make a difference.

Best,

Barry

Barry D. Silbermann, BSIE, JD

(b)(6)

Tel: (310) 702-6699

Begin forwarded message:

From: Barry Silbermann <(b)(6)>

Subject: PROJECT: COVID-19 HC Systems - Proposed Immediate Attack Solutions

Date: March 22, 2020 at 3:14:38 PM PDT

To: "Secretary@hhs.gov" <Secretary@HHS.gov>, Brian.Harrison@hhs.gov

Cc: sginvitations@hhs.gov, execsec1@od.nih.gov, olx1@cdc.gov

VIA Email Brian.Harrison@hhs.gov

The Honorable Alex M. Azar II, Secretary

Department Health and Human Services

Attn: **Brian Harrison**, Chief of Staff

RE: The Institute's PROJECT: COVID-19 HC Systems

Our Joint Challenge

To Salvage: A Safe Work Place & America's Confidence

Please see attached and forward copies to each of the DHHS ccs.

It is urged that the Secretary of DHHS, the Surgeon General, The Director of CDC conduct or cause IMMEDIATE REVIEW AND UNDERSTANDING of the Institute's Project COVID-19. Review of the Projects listed is also urged of the NIH and ONC and other operating DHHS Divisions as the Secretary may determine.

I am requesting that you (Mr Harrison) or your Deputy Chief of Staff and I speak by phone for you to learn more in the next few days (call me at (310-702-6699, I'll take your call). From that call, you and I should plan a conference call of key, next step, people for each of us.

Thank you for your immediate attention to and review of this urgent proposal in addressing resolutions to COVID-19.

Sincerely,

Barry D. Silbermann, BSIE, JD

(b)(6)

Tel: (310) 702-6699

Sender:	Barry Silbermann (b)(6)
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Harry Holmes Ph D (b)(6); Jason Crace, CPA <jason@craceandbeam.com>; Paul M Griffin, PhD (b)(6); Joseph Lombardo PhD (b)(6); Fauci, Anthony (NIH/NIAID) [E] </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=826965b24a314ffca7eddc6e8229aa7-anthony.fau>; Hahn, Stephen (FDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0666f41e4514dd3b294a23789487280-stephen.hah>
Sent Date:	2020/03/22 22:10:02
Delivered Date:	2020/03/22 22:11:25

From:	Robert Levitt (b)(6)
To:	Robert Levitt (b)(6)
Subject:	Dr. Levitt's COVID-19 Update for EVENING 22 March 2020/ ANOTHER SCARY NEIL FERGUSON PAPER/Thank you 3M and Honeywell
Date:	2020/03/22 22:16:17
Priority:	Normal
Type:	Note

Dear All,

Below is my summary on the President's Task Force on Coronavirus Press Briefing late this afternoon. An article for review by Neil Ferguson is attached above. It is another scary paper from the Imperial College in London. Please read the Summary of this 'modeling paper'.

Task Force/President announced important actions this afternoon:

- FEMA/Army Corps of Engineers (ACE) will build federal and field hospitals in NY, CA, WA. National Guard will build the hospitals for FEMA at 100% federal expense. Total beds to CA are 2000; NY and WA get 1000 beds.
- Hospital ships "Mercy" and "Comfort" to Port of Los Angeles and NYC Harbor; each has 1000 beds. **CA expected to have 5x the number of COVID-19 cases that WA has accumulated.**
- Corporations are stepping up to the plate: 3M has increased mask production; Honeywell is reconfiguring plant in RI to make N95 masks; IBM partnering with Google, Amazon, academic centers, and NIH/NASA to make 'supercomputers' available to researchers.
- VP Pence said backlog of tests for inpatients will be made up by Wednesday.
- CDC will have this week a test that has a turnaround time of 45 minutes and is a saliva test that can be self-administered.
- VA has set up restricted visitor hours at long term care facilities, distance learning for vets, and works with veterans' service organizations.
- CDC will announce new orders for First Responders tomorrow to get more police, fire, paramedics back to work.

When asked about enforcing the **Defense Protection Act**, the President and Peter Navarro both said **DPA would be applied 'surgically'- only when they couldn't get the voluntary cooperation of industry to focus on supplying needed products for the fight against the virus.**

MSNBC flashed a message on their news shows today which read GM, Ford, and Tesla would retrofit and build ventilators. I hope this is true, because ventilators are the 'missiles of WWII' that Gov. Cuomo speaks about for this war.

All the news from the Task Force is encouraging, **but still 'behind the curve'**. Why 'behind the curve'? Tests for the virus need to be limited to inpatients so we can't identify the asymptomatic carriers in the public or in hospitals; no announcement of new ventilators being manufactured by retrofitted plants as of tomorrow; local health care providers are asking those with symptoms to stay at home for 14 days unless seriously ill rather than go to testing centers.

We are on the steep part of the exponential curve of COVID-19. The next week or two weeks will show if U.S. actions have flattened the curve or we missed our chance.

Note that **Neil Ferguson** who modeled 2.2 million U.S. deaths if no mitigation or suppression done has **printed another article that states that mitigation which is isolation of PUI, isolation of family members and social distancing of elderly/comorbidity persons only reduces deaths in U.S. by 50%. Suppression which is basically mitigation for 18 months (until vaccine produced for the population) plus social distancing for entire population is better but not possible in democratic society. SEE PDF ATTACHED ABOVE. Ferguson still models hundred of thousand of U.S. deaths if we only mitigate SARS-CoV-2.**

RGL, M.D.

If you wish to unsubscribe to this email service, please contact Dr. Robert Levitt at (b)(6) and include in the subject line: Unsubscribe.

Disclaimer: This email expresses the views, thoughts, and opinions of the author and no other organization, group or individual. The information in this email is intended solely for personal non-commercial use. The author may have made unintentional errors. This email may contain copyrighted material; its inclusion in this email constitutes a "fair use" of copyrighted material as provided in Section 107 of the US Copyright Law. If you wish to use the copyrighted material beyond "fair use", you must obtain permission from the copyright owner.

Sent from Outlook

Sender:	Robert Levitt <(b)(6)>
Recipient:	Robert Levitt <(b)(6)>
Sent Date:	2020/03/22 22:15:35
Delivered Date:	2020/03/22 22:16:17
Message Flags:	Unread

From:	Ford-Barnes, Arwenithia (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D533ABC24CBE44B79F6FDDC6B08737A6-FORD-BARNES>
To:	Bartrum, John (OS/ASPR) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb2cc9052221421c8d5b7fd480f25bbe-Bartrum, Jo>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Callahan, Victoria (OS/ASPR/IO) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95162cb185624a6ebe5fadf08484c141-Callanhan,>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Moreno, Rafael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dcc2da7031645b39c430a140fd4c446-Moreno, Raf>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Hassell, David (Chris) (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aedbfb0ff96e4119ac7a3b3abaf71a3d-Hassell, Da>; Sauer, Michael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc2ae02156624623b24d3a400f592229-Sauer, Mich>
Subject:	RE: Bartrum Contact Information -- while on Mil Duty
Date:	2020/03/22 22:17:09
Priority:	Normal
Type:	Note

Oh yes....I forgot....we will surely miss you Sir -

Arwenithia Ford-Barnes

Executive Assistant to the ASPR | *Dr. Robert Kadlec*

Office: (202) 205-8905 Mobile: (b)(6)

Email: Arwenithia.FordBarnes@hhs.gov

(Please make sure your telephone is at the bottom of your salutation)

While others rest...we 'ASPR' are fighting the mission...

From: Bartrum, John (OS/ASPR) (CTR) <John.Bartrum@hhs.gov>

Sent: Sunday, March 22, 2020 10:13 PM

To: Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Ford-Barnes, Arwenithia (OS/ASPR/IO) <Arwenithia.FordBarnes@hhs.gov>; Callahan, Victoria (OS/ASPR/IO) (CTR) <Victoria.Callahan@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Moreno, Rafael (OS/ASPR) <Rafael.Moreno@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Sauer, Michael (OS/ASPR) <Michael.Sauer@hhs.gov>

Subject: Bartrum Contact Information -- while on Mil Duty

Due to COVID 19, I begin my extended military tour tomorrow morning with the Air Force Office of the Surgeon General. If you need to contact me my contact information is as follows;

Home: (b)(6)

Personal Cell: (b)(6)

Air Force Surgeon General (SG) Office
Pentagon: 703-692-6800
Defense Health HQ: 703-681-6994

Please note the SG Pentagon office is a secure location, as such I lock up my personal cell phone during duty times.

I know you will continue to excel in the COVID 19 response. I look forward to working with the team as the process moves forward.

Best,
John

John J. Bartrum
Senior Advisor to the Assistant Secretary for Preparedness and Response, Brightstar Innovations Group, LLC.
Contractor
Office of the Assistant Secretary for Preparedness and Response - (ASPR)
United States Department of Health and Human Services - (HHS)
Washington, DC 20024
HHS Phone: 202.770.5491
Email: John.Bartrum@hhs.gov

Sender:	Ford-Barnes, Arwenitha (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D533ABC24CBE44B79F6FDDC6B08737A6-FORD-BARNES>
Recipient:	Bartrum, John (OS/ASPR) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb2cc9052221421c8d5b7fd480f25bbe-Bartrum, Jo>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Callahan, Victoria (OS/ASPR/IO) (CTR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95162cb185624a6be5fadf08484c141-Callanhan,>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Moreno, Rafael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dcc2da7031645b39c430a140fd4c446-Moreno, Raf>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Hassell, David (Chris) (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aedbf0ff96e4119ac7a3b3abaf71a3d-Hassell, Da>; Sauer, Michael (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc2ae02156624623b24d3a400f592229-Sauer, Mich>
Sent Date:	2020/03/22 22:17:08
Delivered Date:	2020/03/22 22:17:09

From:	Melissa Murray <murraym@mskcc.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 22:49:52
Priority:	Normal
Type:	Note

Melissa Murray

(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,
Melissa Murray

Sender:	Melissa Murray <murraym@mskcc.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 22:45:03
Delivered Date:	2020/03/22 22:49:52
Message Flags:	Unread

From:	Chad Scherr (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
CC:	Hargan, Eric (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a3a3891ba3c4624821f80867da25a4b-Hargan, Eri>
Subject:	U.S. Department of Health & Human Services
Date:	2020/03/22 22:46:00
Priority:	Normal
Type:	Note

Sunday, March 22, 2020

Alex M. Azar II
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201
Phone: (202) 690-7000
Fax: (202) 690-7203
Email: alex.azar@hhs.gov

Re: <https://www.coronavirus.gov>

Dear Alex M. Azar II,

My name is Chad Scherr. I am a citizen of the United States.

I have some questions that are reasonable and within the scope of your work.

HHS related communications have ended up in households, work places, and communities.

However, my family and I are unable to make objective, judicious, and informed decisions.

- (1) What constitutes a novel Coronavirus and COVID-19 case?
- (2) What constitutes a novel Coronavirus and COVID-19 presumptive case?
- (3) What constitutes a novel Coronavirus and COVID-19 confirmed case?
- (4) What are the origins and causes of novel Coronavirus and COVID-19?
- (5) What branches of medicine are applicable to novel Coronavirus and COVID-19?
- (6) What differential diagnoses are associated with novel Coronavirus and COVID-19?
- (7) What possible diagnoses are associated with novel Coronavirus and COVID-19 like symptoms?
- (8) What probable diagnoses are associated with novel Coronavirus and COVID-19 like symptoms?

- (9) What rule out diagnoses are associated with novel Coronavirus and COVID-19 like symptoms?
- (10) What conditions can resemble, and can be confused with novel Coronavirus and COVID-19?
- (11) What clinical course and prognosis tables are applicable to novel Coronavirus and COVID-19?
- (12) Aside from the novel Coronavirus and COVID-19, what other conditions can be acquired?
- (13) If people were screened for all conditions, what would be the outcome?

I was unable to locate the information at <https://www.coronavirus.gov> Let me know by reply email.

Thank you,

Chad Scherr
City of Jefferson
County of Cole
State of Missouri
Country of United States
Continent of North America
Hemisphere of Western

Cc: Eric D. Hargan, Deputy Secretary, U.S. Department of Health & Human Services,
Email: eric.hargan@hhs.gov

Sent with [ProtonMail](#) Secure Email.

Sender:	Chad Scherr <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>; Hargan, Eric (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a3a3891ba3c4624821f80867da25a4b-Hargan, Eri>
Sent Date:	2020/03/22 22:45:42
Delivered Date:	2020/03/22 22:46:00

From:	Buer Song (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/22 23:51:48
Priority:	Normal
Type:	Note

Buer Song
(b)(6)

March 22, 2020

Dear Alex Azar,

Dear Administrator Verma:

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Sincerely,
Buer Song

Sender:	Buer Song (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/22 23:45:06
Delivered Date:	2020/03/22 23:51:48
Message Flags:	Unread

From:	Mohamed Adas (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 01:29:51
Priority:	Normal
Type:	Note

Mohamed Adas
(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

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Sincerely,
Mohamed Adas

Sender:	Mohamed Adas (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 01:25:10
Delivered Date:	2020/03/23 01:29:51
Message Flags:	Unread

From:	Darlene Sanders <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 03:04:54
Priority:	Normal
Type:	Note

Darlene Sanders

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,

Darlene Sanders

Sender:	Darlene Sanders <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 02:55:14
Delivered Date:	2020/03/23 03:04:54
Message Flags:	Unread

From:	Marcia Edelweiss <edelweim@mskcc.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 04:39:25
Priority:	Normal
Type:	Note

Marcia Edelweiss

(b)(6)

March 23, 2020

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Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,

Marcia Edelweiss

Sender:	Marcia Edelweiss <edelweim@mskcc.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 04:35:33
Delivered Date:	2020/03/23 04:39:25
Message Flags:	Unread

From:	Mike Allen <mike@axios.com>
To:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	Axios AM: Mike's Top 10 — New: Early signs of a coming Trump pivot — 1 smile to go
Date:	2020/03/23 06:39:10
Priority:	Normal
Type:	Note



☐ **Wishing you and yours** safety and serenity as we begin another trying week.

• • ☕ **Keep your team,** family and friends on the same page. If you value our daily con

1 big thing: Who's hurting most



Sender:	Mike Allen <mike@axios.com>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/03/23 06:39:01
Delivered Date:	2020/03/23 06:39:10

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS Executive Summary 23Mar20
Date:	2020/03/23 06:45:51
Priority:	Normal
Type:	Note

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HHS Executive Summary: Monday, 23Mar20

1. HHS

Today's Noteworthy Topics:

COVID-19 (Novel Coronavirus)

As of 22Mar20, 1700ET, the CDC confirmed and presumptive positive U.S. cases of COVID-19 have reached 26,514 across 50 states and D.C., Guam, PR and USVI; Deaths: 342. Combined CDC and WHO reported global cases: 266,073; global deaths: 11,184; Countries with cases: 177. Testing: 250,262 cumulative tests completed (including 67,263 tests in State/Local Public Health Labs) as of March 22. FEMA Regional Administrators continue coordinating closely with Governors, tribal leaders, state emergency managers, and state public health officials to develop shared situational awareness of the outbreak and support they deployment of resources to effectively respond, including PPE, ventilators, and surge bed capacity solution. This includes using the Logistics Supply Chain Management System to procure and track commodities to supplement state and tribal purchases. FEMA assisting HHS with the movement of personal protective equipment, such as gloves, aprons, legging covers, and masks to multiple states.

Daily Operational Schedule:

0830 – FEMA Daily Operations Briefing
 1100 – Grand Princess Call
 1200 – DoD Senior Leader Coronavirus Sync
 1230 – Joint HHS/FEMA Interagency VTC
 1400 – COVID-19 Resource Coordination Call

Public Health Emergency of National Significance:

Puerto Rico (Earthquake): 08Jan20
 Opioid Crisis, Nationwide: 24Jan20
 Novel Coronavirus (COVID-19): 31Jan20

HHS Response Status Summary:

HHS SOC: Level I (Full Activation)
 CDC EOC: Level III (Polio/Ebola)
 CDC EOC: COVID-19 (Agency-Wide Response)
 FDA EOC: Level II (Vape Product Response, COVID-19)

Emergency Support Function (ESF) Activation:

ESF – 8: Activated

ESF – 6: Not Activated

Recovery Support Function (RSF) Activation:

H&SS RSF: Activated Region II (2017 Irma/Maria, Puerto Rico projected end date of 30Jun20). Activated Region IX (2018 California Wildfires projected end date of 31Mar20).

HHS Deployments: (Total = 1,387)

ASPR: 1,111 – (9) Earthquake Puerto Rico, (1,088) COVID-19, (5) Irma/Maria Recovery, (3) Irma, (2) FY Funded Training Q1, (2) FY Non-Funded Training Q1, (1) California Wildfires, (1) California Wildfires Recovery

CDC: 276 – (247) COVID-19, (5) Polio, (24) Ebola

FMS Status:

- • * 32 (250 Bed) FMS sets are deployable
- • * 9 (50 Bed) FMS sets are deployable

New Mission Assignments (MA): NSTR**Active Situations (7):**

- • * Influenza Season
- • * Irma/Maria, Puerto Rico, & USVI (Recovery)
- • * Ebola in Eastern Democratic Republic of the Congo
- • * California Wildfires (Recovery)
- • * Novel Coronavirus (COVID-19)
- • * Bravo Response
- • * Earthquake, Puerto Rico

U.S. International Health Regulation National Focal Point Status: NSTR**2. FEMA:****Interagency Response Status Summary:**

NWC: Monitoring

NRCC: Level I

National IMATs: Red – Fully Mission Capable; Blue – Fully Mission Capable; Gold – Not Mission Capable

Regional IMATs: Region II, NY; Region III, RRCC; Region IV-2, TN; Region IX-1, PMC; Region IX-2, RRCC; Region X, RRCC

Significant National Weather:

A low pressure system will move into California today with rain, thunderstorms, gusty winds and mountain snow. Isolated strong thunderstorms and locally heavy rain for the south-central coast and mountain snow for the Sierra and southern California mountains. Meanwhile, heavy rain and thunderstorms may produce localized flooding from the Lower Mississippi Valley into the Tennessee Valley today.

3. OPDIV/STAFFDIV Overnight Reports:

CDC: NSTR

FDA: NSTR

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave., S.W.
Washington, D.C. 20201
Office: (202) 619 – 7800
Fax: 1-800-514-4256
Email: hhs.soc@hhs.gov



cid:image001.png@01D5F637.9AFA0B50

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Sender:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/03/23 06:45:29
Delivered Date:	2020/03/23 06:45:51

From:	OS Secretarys Operations Center </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=32B1F28D808B43B6903C00083291303E-SECRETARYS>
To:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Subject:	HHS Executive Summary 23Mar20
Date:	2020/03/23 06:45:54
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A low pressure system will move into California today with rain, thunderstorms, gusty winds and mountain snow. Isolated strong thunderstorms and locally heavy rain for the south-central coast and mountain snow for the Sierra and southern California mountains. Meanwhile, heavy rain and thunderstorms may produce localized flooding from the Lower Mississippi Valley into the Tennessee Valley today.

3. OPDIV/STAFFDIV Overnight Reports:

CDC: NSTR

FDA: NSTR

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave., S.W.
Washington, D.C. 20201
Office: (202) 619 – 7800
Fax: 1-800-514-4256
Email: hhs.soc@hhs.gov



cid:image001.png@01D5F637.9AFA0B50

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Recipient:	OS Secretarys Operations Center </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32b1f28d808b43b6903c00083291303e-Secretarys>
Sent Date:	2020/03/23 06:45:29
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To:	Wright, Janet (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f672e2527b4f44891fb4fbe08cdfd-Wright, Jan>
CC:	Sherman, Jennifer (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30fe7fae664419fa654b20edccb1e78-Sherman, Je>
Subject:	Re: If there is a chance to acknowledge healthcare professionals, here are some actions
Date:	2020/03/23 06:46:55
Priority:	Normal
Type:	Note

Great stuff Janet!

VADM Jerome Adams
20th US Surgeon General

On Mar 22, 2020, at 9:18 PM, Wright, Janet (HHS/OASH) <Janet.Wright@hhs.gov>wrote:

Could hear you start the sentence (b)(5) with

(b)(5)

Janet S. Wright, MD, FACC

Director of Science and Policy (Acting), Office of the Surgeon General

U.S. Department of Health and Human Services, 200 Independence Ave SW, Suite 701H, Washington, DC 20201

Office Phone: 202-690-5157

Email: janet.wright@hhs.gov

Sender:	Adams, Jerome (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=184FE51F7350400B8A99DABD65AC0DB5-ADAMS, JERO>
Recipient:	Sherman, Jennifer (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30fe7fae664419fa654b20edccb1e78-Sherman, Je>; Wright, Janet (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f672e2527b4f44891fb4fbe08cdfdf-Wright, Jan>
Sent Date:	2020/03/23 06:46:54
Delivered Date:	2020/03/23 06:46:55

From:	Americans for Limited Government <media@limitgov.org>
To:	Hargan, Eric (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a3a3891ba3c4624821f80867da25a4b-Hargan, Eri>
Subject:	Senate Democrats must quit playing politics and get serious
Date:	2020/03/23 07:01:51
Priority:	Normal
Type:	Note



6

For Immediate Release

Contact: Robert Romano

March 23, 2020

Phone: 703-383-0880 ext. 1

Senate Democrats must quit playing politics and get serious to protect 30 million small businesses

March 23, 2020, Fairfax, Va.—Americans for Limited Government President Rick Manning today issued the following statement in response to the failed vote in the Senate to provide relief to the U.S. economy including 30 million small businesses in the unprecedented economic shutdown response to the Chinese coronavirus outbreak:

"It is abhorrent that Senate Democrats are attempting to hold our nation's economy and 30 million small businesses hostage in their neverending quest to turn crisis into political opportunity.

"The magnitude of the health emergency and the proposed Senate response emphasize how serious Senate Republicans are taking this crisis. No Republican was elected to spend trillions of dollars to revive an economy deliberately shut down to save a million American lives, and yet they have stood up and done what they believe is necessary to

ensure Americans can get by while they wait in their homes for the virus to pass. We continue to believe that all spending should be targeted to the specific needs created by the emergency, and any attempt to make permanent spending increases should be rejected.

"What's more, any attempts to fundamentally change our nation's health care system including the creation of any one size fits all medical billing system that lays the groundwork for socialized medicine should be rejected. These rate setting proposals fundamentally change the ability for the very heroes in the health provider community to be paid a fair price for their labor and it would be a punch in their guts to enact legislation now that punishes them while they are working tirelessly to save American lives.

"While Americans for Limited Government is uncomfortable with the amount of spending authorized, and the changes to the unemployment laws that dramatically expand the program having the likely unintended impact of encouraging businesses to lay off employees, rather than fight through the crisis, it remains important Congress come together. Democrats must stop their putting politics ahead of the lives and livelihoods of the American people.

"America is the greatest country in the history of mankind. We will survive this national challenge, and by passing legislation providing a safety net to allow the small business foundation of our economy to hit the ground running once we're past this crisis, we will come back rapidly and stronger than ever."

To view online: <https://protect2.fireeye.com/url?k=27bbac34-7bef851f-27bb9d0b-0cc47a6d17cc-43777a45abdb6343&u=https://getliberty.org/2020/03/senate-democrats-must-quit-playing-politics-and-get-serious-to-protect-30-million-small-businesses/>

Attachments:

"Trump virus response calls for covering payroll for every small business in America with \$300 billion," By Robert Romano, March 20, 2020 at <https://protect2.fireeye.com/url?k=35d9dec4-698df7ef-35d9effb-0cc47a6d17cc-5101c99f4510d502&u=http://dailytorch.com/2020/03/trump-virus-response-calls-for-covering-payroll-for-every-small-business-in-america-with-300-billion/>

Interview Availability: Please contact Americans for Limited Government at 703-383-0880 ext. 1 or at media@limitgov.org.

###

Americans for Limited Government is dedicated to fighting for the survival of America by restoring constitutionally limited government, allowing individuals to pursue life, liberty and happiness. For more information on ALG please visit our website at <https://protect2.fireeye.com/url?k=dbb57c15-87e1553e-dbb54d2a-0cc47a6d17cc-dcd4ac3d5adc49ba&u=http://www.getliberty.org/> and <https://protect2.fireeye.com/url?k=6be02bfb-37b402d0-6be01ac4-0cc47a6d17cc-a4cfa09b6790a39b&u=http://www.dailytorch.com/>.

Americans for Limited Government
10332 Main Street # 326
Fairfax Virginia 22030
United States

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Sent Date:	2020/03/23 07:00:54
Delivered Date:	2020/03/23 07:01:51

From:	Americans for Limited Government <media@limitgov.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Senate Democrats must quit playing politics and get serious
Date:	2020/03/23 07:02:17
Priority:	Normal
Type:	Note



6

For Immediate Release

Contact: Robert Romano

March 23, 2020

Phone: 703-383-0880 ext. 1

Senate Democrats must quit playing politics and get serious to protect 30 million small businesses

March 23, 2020, Fairfax, Va.—Americans for Limited Government President Rick Manning today issued the following statement in response to the failed vote in the Senate to provide relief to the U.S. economy including 30 million small businesses in the unprecedented economic shutdown response to the Chinese coronavirus outbreak:

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"While Americans for Limited Government is uncomfortable with the amount of spending authorized, and the changes to the unemployment laws that dramatically expand the program having the likely unintended impact of encouraging businesses to lay off employees, rather than fight through the crisis, it remains important Congress come together. Democrats must stop their putting politics ahead of the lives and livelihoods of the American people.

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Interview Availability: Please contact Americans for Limited Government at 703-383-0880 ext. 1 or at media@limitgov.org.

###

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Americans for Limited Government
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United States

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Sent Date:	2020/03/23 07:00:54
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From:	Shoultz, David <david.shoultz@philips.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
CC:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Beck, Gary (OS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a049f8137013412bbf472fc1833391be-Beck, Miche>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Houten, Frans van <Frans.A.van.Houten@philips.com>; Tignor, Beth (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=464729cc8a584516adbbbc50d76a94a8-Tignor, Bet>
Subject:	Map Demonstrating Global Interdependence of World Ventilator Supply
Date:	2020/03/23 07:24:01
Importance:	High
Priority:	Urgent
Type:	Note

Good Morning Mr. Secretary –

At the request of Philips CEO, Frans van Houten, and as a follow up to yesterday's call, he asked me to thank you for taking the time on a Sunday to discuss the critical issue of ventilator supply in the context of the Defense Production Act (DAP).

With your mention yesterday of the upcoming Cabinet meeting to discuss the DPA, Frans asked me to provide you with the attached map of the world showing the location of every global ventilator manufacturer.

To summarize the map: while Philips is the largest producer of ventilators in the US, actually most ventilators are produced outside the US. The attached slide shows how the ventilator producers are spread in different locations across the world. Moreover, there are 1000s of suppliers of essential components and materials located all over the world that are needed to produce these ventilators. The same also holds true for all other medical devices and their suppliers that are needed to combat COVID-19, such as patient monitors (for use in ICUs), CT scanners, ultrasound and XRay machines.

It is essential that governments commit to keeping global supply chains open. The role of the US is therefore critical in helping other countries understand that it is important to keep manufacturing, transport, import & export, and movement of essential employees open.

At the same time, it is critical that the US maintains open borders itself and commits to a fair allocation of medicines and medical supplies/devices with the rest of the world. Invoking the DPA on ventilators or other essential supplies is likely to provoke a reaction from allies and others. It is imperative that we prevent a chain reaction that grinds supply chains to a halt across the world.

As Frans said on his call with you yesterday, Philips is fully committed and in the process of ramping up our production capacity multifold. He appreciates all the help we can get from the US government to do so, and as you discussed only if we all work together can we combat this pandemic.

Please let me know if you need anything else or if there is anything else I can provide you. Thank you for your support and sensitivity to this issue.

Regards –

Dave

David Shoultz
Head of Government Affairs (U.S.)
Philips
1050 K Street, N.W.
Washington, D.C. 20001



http://2.bp.blogspot.com/-5ACVHUTK_9E/UoPpo0u13pl/AAAAAAAAAcq8/Nz4s4L9eSNQ/s1600/Philips+shield+2013.png

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Subject:	Fwd: CLEARANCE_0307 (URGENT): HHS Announces Grants to Provide Meals for Older Adults
Date:	2020/03/23 07:27:04
Priority:	Normal
Type:	Note

Fysa

Aspa is working with ovp and our hope is for announcement from you at today's presser potentially. That is still tbd.

Sent from my iPhone

Begin forwarded message:

From: "OS HHSPress (HHS/ASPA)" <HHSPress@hhs.gov>
Date: March 23, 2020 at 2:15:05 AM EDT
To: OS - ASPA - Clearance <OS.ASPA-Clearance@hhs.gov>, OS - ASPA - Human Services Clearance <OS.ASPA-HumanservicesClearance@hhs.gov>
Cc: "OS HHSPress (HHS/ASPA)" <HHSPress@hhs.gov>, "Mack, Kelly (ACL)" <Kelly.Mack@acl.hhs.gov>
Subject: CLEARANCE_0307 (URGENT): HHS Announces Grants to Provide Meals for Older Adults

Agency/Office: ACL

Subject (or headline): HHS Announces Grants to Provide Meals for Older Adults

Material: Draft release and social media posts (one document)

COMMENT DEADLINE: 12PM, Monday, March 23

Planned release date: Monday, March 23, time TBD

Driving event: The senior nutrition programs authorized under the Older Americans Act received \$250M in the second COVID-19 supplemental. Grants to states and territories will be awarded Monday and tribes will receive grants next week for subsequent distribution to Area Agencies on Aging and other local meal providers.

Carla L. Daniels
Public Affairs Specialist
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Office: 202-690-4595
Cell: (b)(6)

Sender:	Stecker, Judy (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0280B227911B40B6B30A81B8574EDE6B-STECKER, JU>
Recipient:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/03/23 07:27:03
Delivered Date:	2020/03/23 07:27:04

From:	Richard Torres <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 07:37:40
Priority:	Normal
Type:	Note

Richard Torres

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

Clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by outdated components of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Richard Torres MD

Sender:	Richard Torres <richard.torres@yale.edu>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 07:34:31
Delivered Date:	2020/03/23 07:37:40
Message Flags:	Unread

From:	Brianna James <brianna.james@nortonhealthcare.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 07:49:07
Priority:	Normal
Type:	Note

Brianna James

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Brianna James

Sender:	Brianna James <brianna.james@nortonhealthcare.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 07:44:31
Delivered Date:	2020/03/23 07:49:07
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From:	Shoultz, David <david.shoultz@philips.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
CC:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Houten, Frans van <Frans.A.van.Houten@philips.com>; Beck, Gary (OS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a049f8137013412bbf472fc1833391be-Beck, Miche>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Tignor, Beth (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=464729cc8a584516adbbbc50d76a94a8-Tignor, Bet>
Subject:	Philips Public Statement on Ramping up Critical COVID-19 Products (including ventillators)
Date:	2020/03/23 07:49:14
Priority:	Normal
Type:	Note

Mr. Secretary –

My apologies, but in my previous email I forgot to include as I had intended, at Frans' request, a copy of Philips' press release issued yesterday outlining our plans to ramp up production of ventilators and other of our products critical to treating patients with the COVID-19 virus.

Again, we very much appreciate your support and look forward to partnering with you to provide maximum support during this crisis.

Thank you –

Dave

David Shoultz
Head of Government Affairs (U.S.)
Philips
1050 K Street, N.W.
Washington, D.C. 20001



http://2.bp.blogspot.com/-5ACVHUTK_9E/UoPpo0u13pl/AAAAAAAAAcq8/Nz4s4L9eSNQ/s1600/Philips+shield+2013.png

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Sender:	Shoultz, David <david.shoultz@philips.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Houten, Frans van <Frans.A.van.Houten@philips.com>; Beck, Gary (OS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a049f8137013412bbf472fc1833391be-Beck, Miche>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Tignor, Beth (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=464729cc8a584516addbbc50d76a94a8-Tignor, Bet>
Sent Date:	2020/03/23 07:48:16
Delivered Date:	2020/03/23 07:49:14

From:	Kadlec, Robert (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A182EDA693D040D3832BAE6EFCF7A255-KADLEC, ROB>
To:	Polowczyk, John P (MIL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9601fb487104533a91fbf61381d884e-john.p.polo>; <jeffery.s.baum2.civ@mail.mil>; Redd, John (OS/ASPR/SPPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ba3fed4ee8646ec849a5a87136a24f6-Redd, John>; Wolf, Laura (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c>
Subject:	FW: Map Demonstrating Global Interdependence of World Ventilator Supply
Date:	2020/03/23 07:49:00
Importance:	High
Priority:	Urgent
Type:	Note

FYSA from the call yesterday with the CEO of Phillips and the HHS S1

From: Shoultz, David <david.shoultz@philips.com>
Sent: Monday, March 23, 2020 7:22 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Houten, Frans van <Frans.A.van.Houten@philips.com>; Tignor, Beth (HHS/IOS) <Beth.Tignor@hhs.gov>
Subject: Map Demonstrating Global Interdependence of World Ventilator Supply
Importance: High

Good Morning Mr. Secretary –

At the request of Philips CEO, Frans van Houten, and as a follow up to yesterday's call, he asked me to thank you for taking the time on a Sunday to discuss the critical issue of ventilator supply in the context of the Defense Production Act (DAP).

With your mention yesterday of the upcoming Cabinet meeting to discuss the DPA, Frans asked me to provide you with the attached map of the world showing the location of every global ventilator manufacturer.

To summarize the map: while Philips is the largest producer of ventilators in the US, actually most ventilators are produced outside the US. The attached slide shows how the ventilator producers are spread in different locations across the world. Moreover, there are 1000s of suppliers of essential components and materials located all over the world that are needed to produce these ventilators. The same also holds true for all other medical devices and their suppliers that are needed to combat COVID-19, such as patient monitors (for use in ICUs), CT scanners, ultrasound and XRay machines.

It is essential that governments commit to keeping global supply chains open. The role of the US is therefore critical in helping other countries understand that it is important to keep manufacturing, transport, import & export, and movement of essential employees open.

At the same time, it is critical that the US maintains open borders itself and commits to a fair allocation of medicines and medical supplies/devices with the rest of the world. Invoking the DPA on ventilators or other essential supplies is likely to provoke a reaction from allies and others. It is imperative that we prevent a chain reaction that grinds supply chains to a halt across the world.

As Frans said on his call with you yesterday, Philips is fully committed and in the process of ramping up our production capacity multifold. He appreciates all the help we can get from the US government to do so, and as you discussed only if we all work together can we combat this pandemic.

Please let me know if you need anything else or if there is anything else I can provide you. Thank you for your support and sensitivity to this issue.

Regards –

Dave

David Shoultz
Head of Government Affairs (U.S.)
Philips
1050 K Street, N.W.
Washington, D.C. 20001



http://2.bp.blogspot.com/-5ACVHUTK_9E/UoPpo0u13pl/AAAAAAAAAcq8/Nz4s4L9eSNQ/s1600/Philips+shield+2013.png

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Recipient:	Polowczyk, John P (MIL) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9601fb487104533a91fbf61381d884e-john.p.polo>; <jeffery.s.baum2.civ@mail.mil>; Redd, John (OS/ASPR/SPPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ba3fed4ee8646ec849a5a87136a24f6-Redd, John>; Wolf, Laura (OS/ASPR/SIIM) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb232d38c>
Sent Date:	2020/03/23 07:48:47
Delivered Date:	2020/03/23 07:49:00

From:	Carol King (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 07:58:57
Priority:	Normal
Type:	Note

Carol King

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Carol King

Sender:	Carol King (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 07:54:32
Delivered Date:	2020/03/23 07:58:57
Message Flags:	Unread

From:	Violet Swazer <vswazer@dmc.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 08:12:12
Priority:	Normal
Type:	Note

Violet Swazer

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,
Violet Swazer

Sender:	Violet Swazer <vswazer@dmc.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 08:04:32
Delivered Date:	2020/03/23 08:12:12
Message Flags:	Unread

From:	Elizabeth Ellers <eberkeridge@mpcp.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 08:12:16
Priority:	Normal
Type:	Note

Elizabeth Ellers

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,
Elizabeth Ellers

Sender:	Elizabeth Ellers <eberkeridge@mpcp.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
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Delivered Date:	2020/03/23 08:12:16
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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FDEB5CA04B6B4ED19FEC2209B5F571E7-SHUY, BRYAN>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	Fwd: Update from discussion with anesthesiologists—
Date:	2020/03/23 08:09:46
Priority:	Normal
Type:	Note

Fysa

Sent from my iPhone

Begin forwarded message:

From: Bryan.Shuy@hhs.gov
Date: March 22, 2020 at 6:52:44 PM EDT
To: John.Redd@hhs.gov
Cc: John.Herrmann@hhs.gov
Subject: Update from discussion with anesthesiologists—

From them by text to me—
Three items -

1) ASA and APSF will be coming out with a statement recommending that anesthesia professionals wear N95 masks or have equivalent protection (CAPR/PAPR) for ALL intubations. We are beginning to see more community spread and instances where one day a person is not a PUI and the next day they are ill with COVID 19. We can't afford to lose our workforce at this critical time and those performing intubations are at the highest risk for aerosolized particles and the close proximity required for intubation. We understand that many hospitals are running low on N95s.

2) On ventilators, here is our plan for the week:

A. By Tuesday evening we will have more specific, practical guidance to anesthesiologists on how to convert anesthesia gas machines to ventilate COVID19 patients that would include the common ventilatory modes needed and how to accomplish that. We will have short videos that demo this with the most common anesthesia gas machines as well as an FAQ section.

B. By the end of the week we will have a educational approach for critical care patient management

Common dos and don'ts

Infectious Disease 101- the right antibiotics to consider with co-infections

Nutrition 101

The role of ECMO (very limited)

(b)(5)

(b)(5)

3) Alexis Carmer, MD, a senior staff fellow at FDA at Alexis.carmer@fda.hhs.gov is our key contact on ventilators issues. She can tell you how much O2 is needed.

Sent from my iPhone

Sender:	Shuy, Bryan (OS/ASPR/IO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FDEB5CA04B6B4ED19FEC2209B5F571E7-SHUY, BRYAN>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Sent Date:	2020/03/23 08:09:45
Delivered Date:	2020/03/23 08:09:46

From:	Gleason, Brigitte (CDC/DDID/NCEZID/DFWED) <yer7@cdc.gov>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	Automatic reply: AAMC-HHS concept note for medical students
Date:	2020/03/23 08:19:59
Priority:	Normal
Type:	Note

I am currently deployed in support of the COVID-19 response. The NORS points of contact, in my absence, are:
Hannah Kisselburgh (kmq9@cdc.gov) on 3/20/20 and Preethi Sundararaman (vzy6@cdc.gov) from 3/23/20 through 4/3/20.

For urgent issues, the best number to reach me is (b)(6)

Brigitte L. Gleason, MD, MPH
LCDR, United States Public Health Service

Team Lead, National Outbreak Reporting System (NORS)
Enteric Diseases Epidemiology Branch
Division of Foodborne, Waterborne, and Environmental Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Office phone/Skype: 404-718-5335 | Work cell: (b)(6)
yer7@cdc.gov

Sender:	Gleason, Brigitte (CDC/DDID/NCEZID/DFWED) <yer7@cdc.gov>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Sent Date:	2020/03/23 08:19:33
Delivered Date:	2020/03/23 08:19:59

From:	Sheila Larson <sheila.larson@wisehealthsystem.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 08:28:11
Priority:	Normal
Type:	Note

Sheila Larson

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,
Sheila Larson

Sender:	Sheila Larson <sheila.larson@wisehealthsystem.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 08:24:34
Delivered Date:	2020/03/23 08:28:11
Message Flags:	Unread

From: CARL TUTTLE (b)(6)

(b)(6)
(b)(6)

To: <a.mitchell@nature.com>;
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=bda3a527cbc247e7b2b52b192f68b92d-Tick-Borne>

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<jgs@jacquessimon.com>;
<liawl@mmc.org>;
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<lda@lymediseaseassociation.org>;
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<c.perronne@aphp.fr>;
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Redfield, Robert R. (CDC/OD) </o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9ab74a26317547b8a754285d9eaa847c-robert.redf>;
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<allen.l.richards.civ@mail.mil>;
<chris.smith@mail.house.gov>;
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<collin.peterson@mail.house.gov>;
Jones, Estella (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group
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(b)(6)
<wendyadams1@gmail.com>;
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CC: (b)(6)
(b)(6)
Beard, Charles (Ben) (CDC/DDID/NCEZID/DVBD) </o=ExchangeLabs/ou=Exchange Administrative
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<rsabatino@lymesocietyinc.org>;
<schutzer@gmail.com>;
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<andrew.dillon@nice.org.uk>;
<nice@nice.org.uk>;
<phil.fontanarosa@jamanetwork.org>;
<howard.bauchner@jamanetwork.org>;
<leah.colton@us.af.mil>;
(b)(6)
<vanessa.r.melanson.ctr@mail.mil>;
<jlubom2@gmail.com>;
Weahkee, Michael (IHS/HQ) </o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e3cef0a48d0842dfb636569257ca0e92-michael.wea>;
<bryant.webber@us.af.mil>;
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=650dc3276414421693345147bfafd132-Trent-Adams>;
<Las@silverleafconsulting.net>;
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<beto.perezdeleon@ars.usda.gov>;
<chien-chung.c.chao.civ@mail.mil>;
Jilani, Shahla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group

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 States, Leith (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a073452f5de48bf8241641fd493f85e-States, Lei>;
 <Angel.Davey@mail.mil>;
 <david.scharfenberg@globe.com>;
 <jennifer.peter@globe.com>;
 <brian.mcgrory@globe.com>;
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 <emberry@medscape.net>;
 <prmead@cdc.gov>;
 <ddutko@rustyhardin.com>;
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 (b)(6)
 <shlee01@snet.net>;
 <letters@nytimes.com>;
 <editorial@nytimes.com>;
 <editbd@nytimes.com>;
 <bilanow@nytimes.com>;
 HHS Secretary (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group
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 <Shannon.Chandley@leg.state.nh.us>;
 <martha.fullerclark@leg.state.nh.us>;
 <James.Gray@leg.state.nh.us>;
 <Jeb.Bradley@leg.state.nh.us>;
 <Howard.Moffett@leg.state.nh.us>;
 <james.potter@nhms.org>;
 <michael.padmore@nhms.org>;
 <kathie@kathiefife.com>;
 <arankin@herald.ca>;
 Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group
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 <Tom.Sherman@leg.state.nh.us>

Subject: Re: The proximal origin of SARS-CoV-2

Date: 2020/03/23 08:34:01

Priority: Normal

Type: Note

I made the following announcement to the petition update:

The proximal origin of SARS-CoV-2

<https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf/u/26057692>

Note: It should be known that Karl Sirotkin, PhD is a co-author of the article:
Debunking “The proximal origin of SARS-CoV-2” claiming COVID-19 definitely wasn’t from a lab.

KARL SIROTKIN, LLC (Co-author)
99 Silver Maple Road
Groveland, FL 34736

Best,

Carl Tuttle

On March 22, 2020 at 10:20 AM CARL TUTTLE (b)(6)

Nature

Published: 17 March 2020

The proximal origin of SARS-CoV-2

<https://www.nature.com/articles/s41591-020-0820-9>

“Our analyses clearly show that SARS-CoV-2 is not a laboratory construct or a purposefully manipulated virus”

March 22, 2020

Columbia University

Center for Infection and Immunity

722 West 168th Street, Room 1703a

New York NY USA 10032

Attn: W. Ian Lipkin, Director, Center for Infection and Immunity

Dear Dr. Lipkin,

I read your *Nature* article with great interest but then read “From Harvard to the Big House” response [i] debunking your publication with great concern.

If our public health officials can pull off a thirty-year deception on the American public that Lyme is a simple nuisance disease through its network of paid academics (now defendants in a racketeering lawsuit) [ii] how much trust should we lend to your work Dr. Lipkin?

Lyme patient testimony all across America is describing a disease that is destroying lives, ending careers while leaving its victim in financial ruin. [iii]

No disrespect Dr. Lipkin, but as a victim of this government fraud, I question **EVERYTHING.** [iv]

Respectfully submitted,

Carl Tuttle

Lyme Endemic Hudson, NH

Cc: The Tick-Borne Disease Working group

Alison Mitchell Editorial & Publishing Director, Nature Journals

References:

[i] China owns Nature magazine's ass – Debunking “The proximal origin of SARS-CoV-2” claiming COVID-19 definitely wasn't from a lab

Posted on March 19, 2020 by harvard2thebighouse

<https://protect2.fireeye.com/url?k=c68f55d8-9adb7cf3-c68f64e7-0cc47a6d17cc-ebf9537c9121646c&u=https://harvardtothebighouse.com/2020/03/19/china-owns-nature-magazines-ass-debunking-the-proximal-origin-of-sars-cov-2-claiming-covid-19-wasnt-from-a-lab/>

[ii] Court Document:

<https://protect2.fireeye.com/url?k=9e882df8-c2dc04d3-9e881cc7-0cc47a6d17cc-4cbc02277143b83e&u=https://www.dropbox.com/s/18uyrli878ug51m/LymeDisease%20RICO%20Lawsuit.pdf?dl=0>

[iii] Under Our Skin - Extended Trailer

https://www.youtube.com/watch?v=sxWgS0XLVqw&feature=channel_page

[iv] Lyme Disease and Biowarfare

by KARL GROSSMAN

<https://www.counterpunch.org/2019/08/14/lyme-disease-and-biowarfare/>

On March 15, 2020 at 12:51 PM CARL TUTTLE (b)(6)

Mar 15, 2020

State House
107 North Main Street
Concord NH 03301
Attn: Senator Tom Sherman

Dear Senator Sherman and the Senate Health and Human Services Committee,

The CDC estimates this year's flu season involved 36 million flu illnesses, 370,000 hospitalizations and 22,000 deaths. As of March 13, 2020, there have been 1629 cases of COVID-19 and 41 deaths.

With Lyme disease however no one is counting casualties; patients whose lives are ruined as a result of a missing bulls-eye rash, false negative Lyme test, inadequate treatment and medical community practicing willful ignorance all misguided by the existing dogma propagated through the IDSA, CDC and American Lyme Disease Foundation.

-No one is actively looking for congenital Lyme disease. (Reported back in 1985)
1

-No one is routinely looking for Borrelia in tissue after surgery.
(Documented in many PubMed studies)²

-No one is investigating sexual transmission of Lyme disease.
(Suspected in 2003 by Doctors William T. Harvey and Paola Salvato)³

-No one is screening the blood supply for Borrelia. (Borrilia is capable of surviving blood banking conditions reported in 1990)⁴

-No one is looking for the Borrelia spirochete in Alzheimer's brains at autopsy. (Alzheimer Borreliosis has been identified by pathologist Dr. Allen MacDonald)⁵

-No one is developing direct detection methods for Lyme disease.
(Translation: No rash, no positive test, no treatment.)

So how prevalent is Lyme when the 30-year focus has been to keep case numbers artificially low through strict case definition requirements and deliberate avoidance of the horribly disabled.

Acknowledging Lyme as a horribly disabling disease will incriminate our public health officials so they're all pleading the fifth. ⁶

And with COVID-19 the exact same errors/mistakes/conflicts of interest/ proprietary patenting-attempts/ interference with competing testing methods/direct detection/inappropriately narrow case definitions etc. etc. etc. as in Lyme - but this is MUCH MUCH broader and affecting ALL of society and with devastating economic consequences. ⁷

The mishandling of disease in this country is a direct consequence of the Bayh-Dole patent and trademark law dealing with inventions arising from federal government-funded research as government employees can benefit financially through these patents. Is the right decision being made or is the promise of financial gain the driving force?

Case in point: Employees of the U.S. Centers for Disease Control hold patents on metabolomics relating to Lyme disease ⁸ **Inventor:** Theresa M. RUSSELL and Barbara J.B. JOHNSON

A congressional investigation into the mishandling of Lyme disease is long overdue as we have witnessed the same failures with the handling of the coronavirus pandemic.

I implore you, your fellow senators and congressmen to initiate a congressional investigation into the mishandling of Lyme disease because you and your family members (and the rest of the residents of New Hampshire) are a single tick bite away from experiencing this travesty. **Lyme disease is not going away anytime soon and increasing.**

Calling for a Congressional investigation of the CDC, IDSA and ALDF (88,796 signatures)

<https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf>

Respectfully submitted,

Carl Tuttle

Lyme Endemic Hudson, NH

P.S. The mishandling of Lyme disease here in the US has had a ripple effect globally as the European Union monitored Lyme disease via each country through voluntary reporting. In 2018 they defined 57 diseases for 'mandatory' surveillance by each country. The list starts at Anthrax, Botulism and moves through to Zika virus and congenital Zika virus. **NO LYME DISEASE.** Neuroborreliosis is on the list however reported cases must meet strict conditions including positive intrathecal testing of cerebrospinal fluid.

The power of **IDS/CDC/ALDF** transcends the US borders as the cover-up is now established under European law. Just like here in the U.S., the EUCALB does not want the true level of LB known.⁹

Knowing the true level would expose their incompetence and criminal activities over the last few decades and threaten their endless money stream.

REFERENCES

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<https://protect2.fireeye.com/url?k=fa6adde1-a63ef4ca-fa6aecde-0cc47a6d17cc-8f79d76d485fb126&u=https://www.dropbox.com/s/z10em0szgpm8bll/Congenital%20Transmission%20of%20Lyme%202015.doc?dl=0>

² **Persistent Borrelia Infection in Patients with Ongoing Symptoms of Lyme Disease.**
<https://www.ncbi.nlm.nih.gov/pubmed/29662016>

³ **Lyme disease': ancient engine of an unrecognized borreliosis pandemic?**
<https://www.ncbi.nlm.nih.gov/pubmed/12710914>

⁴ **Survival of *Borrelia burgdorferi* in human blood stored under blood banking conditions**

<https://www.ncbi.nlm.nih.gov/pubmed/2349627>

⁵ **Alzheimer Borreliosis**

<https://protect2.fireeye.com/url?k=b011c8d0-ec45e1fb-b011f9ef-0cc47a6d17cc-daeb8887df1d41c2&u=https://alzheimerborreliosis.net/>

⁶ **Under Our Skin - Extended Trailer**

<https://www.youtube.com/watch?v=sxWgS0XLVqw>

⁷ **Lessons From Lyme Disease: Six Reasons The CDC's COVID-19 Failure Was Predictable**

<https://www.forbes.com/sites/marybethpfeiffer/2020/03/13/lessons-from-lyme-disease-six-reasons-the-cdcs-covid-19-failure-was-predictable>

⁸ **CDC Employee Patent:**

<https://protect2.fireeye.com/url?k=2ccc5647-70987f6c-2ccc6778-0cc47a6d17cc-55e1e56699169fd6&u=https://www.google.com/patents/EP2805168A1?cl=en>

⁹ **COMMISSION IMPLEMENTING DECISION (EU) 2018/945** of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A32018D0945&from=EN%29>

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 <Tom.Sherman@leg.state.nh.us>

Subject: Re: The proximal origin of SARS-CoV-2

Date: 2020/03/23 08:33:42

Priority: Normal

Type: Note

I made the following announcement to the petition update:

The proximal origin of SARS-CoV-2

<https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf/u/26057692>

Note: It should be known that Karl Sirotkin, PhD is a co-author of the article:
Debunking “The proximal origin of SARS-CoV-2” claiming COVID-19 definitely wasn’t from a lab.

KARL SIROTKIN, LLC (Co-author)
99 Silver Maple Road
Groveland, FL 34736

Best,

Carl Tuttle

On March 22, 2020 at 10:20 AM CARL TUTTLE (b)(6)

Nature

Published: 17 March 2020

The proximal origin of SARS-CoV-2

<https://www.nature.com/articles/s41591-020-0820-9>

“Our analyses clearly show that SARS-CoV-2 is not a laboratory construct or a purposefully manipulated virus”

March 22, 2020

Columbia University

Center for Infection and Immunity

722 West 168th Street, Room 1703a

New York NY USA 10032

Attn: W. Ian Lipkin, Director, Center for Infection and Immunity

Dear Dr. Lipkin,

I read your *Nature* article with great interest but then read “From Harvard to the Big House” response [i] debunking your publication with great concern.

If our public health officials can pull off a thirty-year deception on the American public that Lyme is a simple nuisance disease through its network of paid academics (now defendants in a racketeering lawsuit) [ii] how much trust should we lend to your work Dr. Lipkin?

Lyme patient testimony all across America is describing a disease that is destroying lives, ending careers while leaving its victim in financial ruin. [iii]

No disrespect Dr. Lipkin, but as a victim of this government fraud, I question **EVERYTHING.** [iv]

Respectfully submitted,

Carl Tuttle

Lyme Endemic Hudson, NH

Cc: The Tick-Borne Disease Working group

Alison Mitchell Editorial & Publishing Director, Nature Journals

References:

[i] China owns Nature magazine's ass – Debunking “The proximal origin of SARS-CoV-2” claiming COVID-19 definitely wasn't from a lab

Posted on March 19, 2020 by harvard2thebighouse

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[ii] Court Document:

<https://protect2.fireeye.com/url?k=7dd7344a-21823d59-7dd70575-0cc47adb5650-a8d6960f208ba525&u=https://www.dropbox.com/s/18uyrli878ug51m/LymeDisease%20RICO%20Lawsuit.pdf?dl=0>

[iii] Under Our Skin - Extended Trailer

https://www.youtube.com/watch?v=sxWgS0XLVqw&feature=channel_page

[iv] Lyme Disease and Biowarfare

by KARL GROSSMAN

<https://www.counterpunch.org/2019/08/14/lyme-disease-and-biowarfare/>

On March 15, 2020 at 12:51 PM CARL TUTTLE (b)(6)

Mar 15, 2020

State House
107 North Main Street
Concord NH 03301
Attn: Senator Tom Sherman

Dear Senator Sherman and the Senate Health and Human Services Committee,

The CDC estimates this year's flu season involved 36 million flu illnesses, 370,000 hospitalizations and 22,000 deaths. As of March 13, 2020, there have been 1629 cases of COVID-19 and 41 deaths.

With Lyme disease however no one is counting casualties; patients whose lives are ruined as a result of a missing bulls-eye rash, false negative Lyme test, inadequate treatment and medical community practicing willful ignorance all misguided by the existing dogma propagated through the IDSA, CDC and American Lyme Disease Foundation.

-No one is actively looking for congenital Lyme disease. (Reported back in 1985)
1

-No one is routinely looking for Borrelia in tissue after surgery.
(Documented in many PubMed studies) ²

-No one is investigating sexual transmission of Lyme disease.
(Suspected in 2003 by Doctors William T. Harvey and Paola Salvato) ³

-No one is screening the blood supply for Borrelia. (Borrilia is capable of surviving blood banking conditions reported in 1990) ⁴

-No one is looking for the Borrelia spirochete in Alzheimer's brains at autopsy. (Alzheimer Borreliosis has been identified by pathologist Dr. Allen MacDonald) ⁵

-No one is developing direct detection methods for Lyme disease.
(Translation: No rash, no positive test, no treatment.)

So how prevalent is Lyme when the 30-year focus has been to keep case numbers artificially low through strict case definition requirements and deliberate avoidance of the horribly disabled.

Acknowledging Lyme as a horribly disabling disease will incriminate our public health officials so they're all pleading the fifth. ⁶

And with COVID-19 the exact same errors/mistakes/conflicts of interest/ proprietary patenting-attempts/ interference with competing testing methods/direct detection/inappropriately narrow case definitions etc. etc. etc. as in Lyme - but this is MUCH MUCH broader and affecting ALL of society and with devastating economic consequences. ⁷

The mishandling of disease in this country is a direct consequence of the Bayh-Dole patent and trademark law dealing with inventions arising from federal government-funded research as government employees can benefit financially through these patents. Is the right decision being made or is the promise of financial gain the driving force?

Case in point: Employees of the U.S. Centers for Disease Control hold patents on metabolomics relating to Lyme disease ⁸ **Inventor:** Theresa M. RUSSELL and Barbara J.B. JOHNSON

A congressional investigation into the mishandling of Lyme disease is long overdue as we have witnessed the same failures with the handling of the coronavirus pandemic.

I implore you, your fellow senators and congressmen to initiate a congressional investigation into the mishandling of Lyme disease because you and your family members (and the rest of the residents of New Hampshire) are a single tick bite away from experiencing this travesty. **Lyme disease is not going away anytime soon and increasing.**

Calling for a Congressional investigation of the CDC, IDSA and ALDF (88,796 signatures)

<https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf>

Respectfully submitted,

Carl Tuttle

Lyme Endemic Hudson, NH

P.S. The mishandling of Lyme disease here in the US has had a ripple effect globally as the European Union monitored Lyme disease via each country through voluntary reporting. In 2018 they defined 57 diseases for ‘mandatory’ surveillance by each country. The list starts at Anthrax, Botulism and moves through to Zika virus and congenital Zika virus. **NO LYME DISEASE.** Neuroborreliosis is on the list however reported cases must meet strict conditions including positive intrathecal testing of cerebrospinal fluid.

The power of **IDSA/CDC/ALDF** transcends the US borders as the cover-up is now established under European law. Just like here in the U.S., the EUCALB does not want the true level of LB known.⁹

Knowing the true level would expose their incompetence and criminal activities over the last few decades and threaten their endless money stream.

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² **Persistent Borrelia Infection in Patients with Ongoing Symptoms of Lyme Disease.**
<https://www.ncbi.nlm.nih.gov/pubmed/29662016>

³ **Lyme disease': ancient engine of an unrecognized borreliosis pandemic?**
<https://www.ncbi.nlm.nih.gov/pubmed/12710914>

⁴ **Survival of *Borrelia burgdorferi* in human blood stored under blood banking conditions**

<https://www.ncbi.nlm.nih.gov/pubmed/2349627>

⁵ **Alzheimer Borreliosis**

<https://protect2.fireeye.com/url?k=905fd5b3-cc0adca0-905fe48c-0cc47adb5650-ef1e61646642b4e5&u=https://alzheimerborreliosis.net/>

⁶ **Under Our Skin - Extended Trailer**

<https://www.youtube.com/watch?v=sxWgS0XLVqw>

⁷ **Lessons From Lyme Disease: Six Reasons The CDC's COVID-19 Failure Was Predictable**

<https://www.forbes.com/sites/marybethpfeiffer/2020/03/13/lessons-from-lyme-disease-six-reasons-the-cdcs-covid-19-failure-was-predictable>

⁸ **CDC Employee Patent:**

<https://protect2.fireeye.com/url?k=16bb92dc-4aee9bcf-16bba3e3-0cc47adb5650-882ac13d145eda93&u=https://www.google.com/patents/EP2805168A1?cl=en>

⁹ **COMMISSION IMPLEMENTING DECISION (EU) 2018/945** of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A32018D0945&from=EN%29>

Sender: CARL TUTTLE (b)(6)

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 <Tom.Sherman@leg.state.nh.us>

Subject: Re: The proximal origin of SARS-CoV-2

Date: 2020/03/23 08:33:59

Priority: Normal

Type: Note

I made the following announcement to the petition update:

The proximal origin of SARS-CoV-2

<https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf/u/26057692>

Note: It should be known that Karl Sirotkin, PhD is a co-author of the article:
Debunking “The proximal origin of SARS-CoV-2” claiming COVID-19 definitely wasn’t from a lab.

KARL SIROTKIN, LLC (Co-author)
99 Silver Maple Road
Groveland, FL 34736

Best,

Carl Tuttle

On March 22, 2020 at 10:20 AM CARL TUTTLE (b)(6)

Nature

Published: 17 March 2020

The proximal origin of SARS-CoV-2

<https://www.nature.com/articles/s41591-020-0820-9>

“Our analyses clearly show that SARS-CoV-2 is not a laboratory construct or a purposefully manipulated virus”

March 22, 2020

Columbia University

Center for Infection and Immunity

722 West 168th Street, Room 1703a

New York NY USA 10032

Attn: W. Ian Lipkin, Director, Center for Infection and Immunity

Dear Dr. Lipkin,

I read your *Nature* article with great interest but then read “From Harvard to the Big House” response [i] debunking your publication with great concern.

If our public health officials can pull off a thirty-year deception on the American public that Lyme is a simple nuisance disease through its network of paid academics (now defendants in a racketeering lawsuit) [ii] how much trust should we lend to your work Dr. Lipkin?

Lyme patient testimony all across America is describing a disease that is destroying lives, ending careers while leaving its victim in financial ruin. [iii]

No disrespect Dr. Lipkin, but as a victim of this government fraud, I question **EVERYTHING.** [iv]

Respectfully submitted,

Carl Tuttle

Lyme Endemic Hudson, NH

Cc: The Tick-Borne Disease Working group

Alison Mitchell Editorial & Publishing Director, Nature Journals

References:

[i] China owns Nature magazine's ass – Debunking “The proximal origin of SARS-CoV-2” claiming COVID-19 definitely wasn't from a lab

Posted on March 19, 2020 by harvard2thebighouse

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[ii] Court Document:

<https://protect2.fireeye.com/url?k=79bcb2dc-25e9bb0c-79bc83e3-0cc47a6a52de-63ef3296cadd68f5&u=https://www.dropbox.com/s/18uyrli878ug51m/LymeDisease%20RICO%20Lawsuit.pdf?dl=0>

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Attn: Senator Tom Sherman

Dear Senator Sherman and the Senate Health and Human Services Committee,

The CDC estimates this year's flu season involved 36 million flu illnesses, 370,000 hospitalizations and 22,000 deaths. As of March 13, 2020, there have been 1629 cases of COVID-19 and 41 deaths.

With Lyme disease however no one is counting casualties; patients whose lives are ruined as a result of a missing bulls-eye rash, false negative Lyme test, inadequate treatment and medical community practicing willful ignorance all misguided by the existing dogma propagated through the IDSA, CDC and American Lyme Disease Foundation.

-No one is actively looking for congenital Lyme disease. (Reported back in 1985)
1

-No one is routinely looking for Borrelia in tissue after surgery.
(Documented in many PubMed studies)²

-No one is investigating sexual transmission of Lyme disease.
(Suspected in 2003 by Doctors William T. Harvey and Paola Salvato)³

-No one is screening the blood supply for Borrelia. (Borrilia is capable of surviving blood banking conditions reported in 1990)⁴

-No one is looking for the Borrelia spirochete in Alzheimer's brains at autopsy. (Alzheimer Borreliosis has been identified by pathologist Dr. Allen MacDonald)⁵

-No one is developing direct detection methods for Lyme disease.
(Translation: No rash, no positive test, no treatment.)

So how prevalent is Lyme when the 30-year focus has been to keep case numbers artificially low through strict case definition requirements and deliberate avoidance of the horribly disabled.

Acknowledging Lyme as a horribly disabling disease will incriminate our public health officials so they're all pleading the fifth. ⁶

And with COVID-19 the exact same errors/mistakes/conflicts of interest/ proprietary patenting-attempts/ interference with competing testing methods/direct detection/inappropriately narrow case definitions etc. etc. etc. as in Lyme - but this is MUCH MUCH broader and affecting ALL of society and with devastating economic consequences. ⁷

The mishandling of disease in this country is a direct consequence of the Bayh-Dole patent and trademark law dealing with inventions arising from federal government-funded research as government employees can benefit financially through these patents. Is the right decision being made or is the promise of financial gain the driving force?

Case in point: Employees of the U.S. Centers for Disease Control hold patents on metabolomics relating to Lyme disease ⁸ **Inventor:** Theresa M. RUSSELL and Barbara J.B. JOHNSON

A congressional investigation into the mishandling of Lyme disease is long overdue as we have witnessed the same failures with the handling of the coronavirus pandemic.

I implore you, your fellow senators and congressmen to initiate a congressional investigation into the mishandling of Lyme disease because you and your family members (and the rest of the residents of New Hampshire) are a single tick bite away from experiencing this travesty. **Lyme disease is not going away anytime soon and increasing.**

Calling for a Congressional investigation of the CDC, IDSA and ALDF (88,796 signatures)

<https://www.change.org/p/the-us-senate-calling-for-a-congressional-investigation-of-the-cdc-idsa-and-aldf>

Respectfully submitted,

Carl Tuttle

Lyme Endemic Hudson, NH

P.S. The mishandling of Lyme disease here in the US has had a ripple effect globally as the European Union monitored Lyme disease via each country through voluntary reporting. In 2018 they defined 57 diseases for ‘mandatory’ surveillance by each country. The list starts at Anthrax, Botulism and moves through to Zika virus and congenital Zika virus. **NO LYME DISEASE.** Neuroborreliosis is on the list however reported cases must meet strict conditions including positive intrathecal testing of cerebrospinal fluid.

The power of **IDSA/CDC/ALDF** transcends the US borders as the cover-up is now established under European law. Just like here in the U.S., the EUCALB does not want the true level of LB known.⁹

Knowing the true level would expose their incompetence and criminal activities over the last few decades and threaten their endless money stream.

REFERENCES

¹ **Congenital Transmission of Lyme**

<https://protect2.fireeye.com/url?k=92d63a44-ce833394-92d60b7b-0cc47a6a52de-d97306dc0eb03c1c&u=https://www.dropbox.com/s/z10em0szgpm8bll/Congenital%20Transmission%20of%20Lyme%202015.doc?dl=0>

² **Persistent Borrelia Infection in Patients with Ongoing Symptoms of Lyme Disease.**
<https://www.ncbi.nlm.nih.gov/pubmed/29662016>

³ **Lyme disease': ancient engine of an unrecognized borreliosis pandemic?**
<https://www.ncbi.nlm.nih.gov/pubmed/12710914>

⁴ **Survival of *Borrelia burgdorferi* in human blood stored under blood banking conditions**

<https://www.ncbi.nlm.nih.gov/pubmed/2349627>

⁵ **Alzheimer Borreliosis**

<https://protect2.fireeye.com/url?k=7bf3c25a-27a6cb8a-7bf3f365-0cc47a6a52de-8f5ea1fa394d1023&u=https://alzheimerborreliosis.net/>

⁶ **Under Our Skin - Extended Trailer**

<https://www.youtube.com/watch?v=sxWgS0XLVqw>

⁷ **Lessons From Lyme Disease: Six Reasons The CDC's COVID-19 Failure Was Predictable**

<https://www.forbes.com/sites/marybethpfeiffer/2020/03/13/lessons-from-lyme-disease-six-reasons-the-cdcs-covid-19-failure-was-predictable>

⁸ **CDC Employee Patent:**

<https://protect2.fireeye.com/url?k=1fa83c31-43fd35e1-1fa80d0e-0cc47a6a52de-c32ad5914a4cb6c7&u=https://www.google.com/patents/EP2805168A1?cl=en>

⁹ **COMMISSION IMPLEMENTING DECISION (EU) 2018/945** of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX%3A32018D0945&from=EN%29>

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Message Flags:	Unread

From:	Weiqliang Zhao (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 08:45:31
Priority:	Normal
Type:	Note

Weiqliang Zhao

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Weiqliang Zhao

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Message Flags:	Unread

From:	Kimberly Rose <kimberly.rose@vcuhealth.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 08:46:27
Priority:	Normal
Type:	Note

Kimberly Rose

(b)(6)

March 23, 2020

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From:	Jennifer Faur (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 08:46:39
Priority:	Normal
Type:	Note

Jennifer Faur

(b)(6)

March 23, 2020

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Sincerely,
Jennifer Faur

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To:	Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
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Subject:	FW: Map Demonstrating Global Interdependence of World Ventilator Supply
Date:	2020/03/23 08:40:47
Importance:	High
Priority:	Urgent
Type:	Note

Beth Tignor
 Director of Scheduling
 The Department of Health and Human Services
 202-868-9795

From: Shoultz, David <david.shoultz@philips.com>
Sent: Monday, March 23, 2020 7:22 AM
To: Azar, Alex (OS/IOS) <Alex.Azar@HHS.GOV>
Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Houten, Frans van <Frans.A.van.Houten@philips.com>; Tignor, Beth (HHS/IOS) <Beth.Tignor@hhs.gov>
Subject: Map Demonstrating Global Interdependence of World Ventilator Supply
Importance: High

Good Morning Mr. Secretary –

At the request of Philips CEO, Frans van Houten, and as a follow up to yesterday's call, he asked me to thank you for taking the time on a Sunday to discuss the critical issue of ventilator supply in the context of the Defense Production Act (DAP).

With your mention yesterday of the upcoming Cabinet meeting to discuss the DPA, Frans asked me to provide you with the attached map of the world showing the location of every global ventilator manufacturer.

To summarize the map: while Philips is the largest producer of ventilators in the US, actually most ventilators are produced outside the US. The attached slide shows how the ventilator producers are

spread in different locations across the world. Moreover, there are 1000s of suppliers of essential components and materials located all over the world that are needed to produce these ventilators. The same also holds true for all other medical devices and their suppliers that are needed to combat COVID-19, such as patient monitors (for use in ICUs), CT scanners, ultrasound and XRay machines.

It is essential that governments commit to keeping global supply chains open. The role of the US is therefore critical in helping other countries understand that it is important to keep manufacturing, transport, import & export, and movement of essential employees open.

At the same time, it is critical that the US maintains open borders itself and commits to a fair allocation of medicines and medical supplies/devices with the rest of the world. Invoking the DPA on ventilators or other essential supplies is likely to provoke a reaction from allies and others. It is imperative that we prevent a chain reaction that grinds supply chains to a halt across the world.

As Frans said on his call with you yesterday, Philips is fully committed and in the process of ramping up our production capacity multifold. He appreciates all the help we can get from the US government to do so, and as you discussed only if we all work together can we combat this pandemic.

Please let me know if you need anything else or if there is anything else I can provide you. Thank you for your support and sensitivity to this issue.

Regards –

Dave

David Shoultz
Head of Government Affairs (U.S.)
Philips
1050 K Street, N.W.
Washington, D.C. 20001



http://2.bp.blogspot.com/-5ACVHUTK_9E/UoPpo0u13pl/AAAAAAAAAcq8/Nz4s4L9eSNQ/s1600/Philips+shield+2013.png

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Sent Date:	2020/03/23 08:40:31
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From:	Tignor, Beth (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=464729CC8A584516ADDBBC50D76A94A8-TIGNOR, BET>
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CC:	Apple, Matthew (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2d31099399446eab9bff69d52880932-Apple, Matt>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Subject:	FW: Philips Public Statement on Ramping up Critical COVID-19 Products (including ventialtors)
Date:	2020/03/23 08:40:39
Priority:	Normal
Type:	Note

Beth Tignor
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Cc: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Houten, Frans van <Frans.A.van.Houten@philips.com>; Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Tignor, Beth (HHS/IOS) <Beth.Tignor@hhs.gov>
Subject: Philips Public Statement on Ramping up Critical COVID-19 Products (including ventialtors)

Mr. Secretary –

My apologies, but in my previous email I forgot to include as I had intended, at Frans' request, a copy of Philips' press release issued yesterday outlining our plans to ramp up production of ventilators and other of our products critical to treating patients with the COVID-19 virus.

Again, we very much appreciate your support and look forward to partnering with you to provide maximum support during this crisis.

Thank you –

Dave

David Shoultz
Head of Government Affairs (U.S.)
Philips
1050 K Street, N.W.
Washington, D.C. 20001



http://2.bp.blogspot.com/-5ACVHUTK_9E/UoPpo0u13pI/AAAAAAAAAcq8/Nz4s4L9eSNQ/s1600/Philips+shield+2013.png

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Sender:	Tignor, Beth (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=464729CC8A584516ADDBBC50D76A94A8-TIGNOR, BET>
Recipient:	Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Apple, Matthew (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2d31099399446eab9bff69d52880932-Apple, Matt>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>
Sent Date:	2020/03/23 08:40:38
Delivered Date:	2020/03/23 08:40:39

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0892A057F83497E9390288C813B61D9-STANNARD, P>
To:	Puesan, Cesar (HHS/OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1704b662180d4631b7b64cb17de301cd-Puesan Juar>
CC:	OS OGC-IO ControlDesk (HHS/OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c9f99a0b2364cb5bd1b739db7851e43-controldesk>; Barry, Daniel J (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3e449ce0>; Keveney, Sean (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e13823250af4ccf93b3de562380e78e-Keveney, Se>; Chang, William (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cf70c842da144ab9bee61f353d932a0-Chang, Will>; Strom, John (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=087650d67a204508963541a6eba69ea5-Strom, John>; Hecht, Jonah (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de0acd2f82294cd7befc09c5444f616c-Hecht, Jona>; ASPR Exec Sec (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e561b3f0bfd4331bc7c93e4419316ae-ASPRExecSec>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; OASHIO Control Desk (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8407017e8889478bbd764b389bdcd6ac-OASHIOContr>; Campbell, Taylor (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cca29818d7440d8a21b2c349f2e4f6a-Campbell, T>; Giror, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Callahan, Kenneth (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e1240d1d62d49b3ba2e4e51c0920908-Callahan, K>; White, Caroline (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=755298af43a64d6c92b600e5d8b7d76a-White, Caro>; Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>; Agnew, Ann (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5174d56b97948d0820e90e8d8136ee5-Agnew, Ann>; Brennan, Patrick (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51c3d9a49fd4882951eca2417c19dcf-Brennan, Pa>; Foster, Timothy (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2265a29a6468468397bae80a642620fc-Foster, Tim>
Subject:	Re: Quick Review: COVID-19 Anti-hoarding EO
Date:	2020/03/23 08:42:41
Priority:	Normal
Type:	Note

No comments.

Paula

Sent from my iPhone

On Mar 23, 2020, at 12:23 AM, Puesan, Cesar (HHS/OS/IOS) <Cesar.Puesan@hhs.gov> wrote:

All,

Please see attached for an updated EO draft. Please send any critical edits by **10am tomorrow Monday 3/23.**

From: Puesan, Cesar (HHS/OS/IOS)

Sent: Saturday, March 21, 2020 4:23 PM

To: OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; OASHIO Control Desk (OS/OASH) <OASHIOControlDesk@hhs.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>

Cc: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>

Subject: RE: Quick Review: COVID-19 Anti-hoarding EO

All,

Please see an updated draft attached, and send any critical edits or feedback by **10 AM tomorrow, March 22.**

From: Puesan, Cesar (HHS/OS/IOS)

Sent: Saturday, March 21, 2020 9:46 AM

To: OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; OASHIO Control Desk (OS/OASH) <OASHIOControlDesk@hhs.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Horska, Katerina (HHS/IOS) <Katerina.Horska@hhs.gov>

Cc: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>

Subject: Re: Quick Review: COVID-19 Anti-hoarding EO

Following up on this— please let met know if you have any comments or edits.

Thanks

Sent from my iPhone

On Mar 20, 2020, at 7:29 PM, Puesan, Cesar (HHS/OS/IOS) <Cesar.Puesan@hhs.gov>wrote:

All,

Attached for your quick review is a draft EO drafted by WHCO that (b)(5)

(b)(5) Affirmative clearance is requested from HHS.

Please send all comments and clearances by **9 AM tomorrow, Saturday, March 21.**

Thank you,

(b)(5)

Sender:	Stannard, Paula (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0892A057F83497E9390288C813B61D9-STANNARD, P>
Recipient:	Puesan, Cesar (HHS/OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1704b662180d4631b7b64cb17de301cd-Puesan Juar>; OS OGC-IO ControlDesk (HHS/OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c9f99a0b2364cb5bd1b739db7851e43-controldesk>; Barry, Daniel J (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3e449ce0>; Keveney, Sean (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e13823250af4ccf93b3de562380e78e-Keveney, Se>; Chang, William (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cf70c842da144ab9bee61f353d932a0-Chang, Will>; Strom, John (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=087650d67a204508963541a6eba69ea5-Strom, John>; Hecht, Jonah (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de0acd2f82294cd7befc09c5444f616c-Hecht, Jona>; ASPR Exec Sec (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e561b3f0bfd4331bc7c93e4419316ae-ASPRExecSec>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; OASHIO Control Desk (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8407017e8889478bbd764b389bdc6ac-OASHIOContr>; Campbell, Taylor (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cca29818d7440d8a21b2c349f2e4f6a-Campbell, T>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Callahan, Kenneth (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e1240d1d62d49b3ba2e4e51c0920908-Callahan, K>; White, Caroline (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=755298af43a64d6c92b600e5d8b7d76a-White, Caro>; Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>; Agnew, Ann (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5174d56b97948d0820e90e8d8136ee5-Agnew, Ann>; Brennan, Patrick (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51c3d9a49fd4882951eca2417c19dcf-Brennan, Pa>; Foster, Timothy (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2265a29a6468468397bae80a642620fc-Foster, Tim>
Sent Date:	2020/03/23 08:42:39
Delivered Date:	2020/03/23 08:42:41
Message Flags:	Unread

From:	Diana Macfarlane (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 08:47:43
Priority:	Normal
Type:	Note

Diana Macfarlane

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,

Diana Macfarlane

Sender:	Diana Macfarlane (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 08:44:36
Delivered Date:	2020/03/23 08:47:43
Message Flags:	Unread

From:	Ellen Durand <lnpaul@atlanticbb.net>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 08:59:24
Priority:	Normal
Type:	Note

Ellen Durand

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Ellen Durand

Sender:	Ellen Durand <lnpaul@atlanticbb.net>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 08:54:37
Delivered Date:	2020/03/23 08:59:24
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To:	Bright, Rick (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Hahn, Stephen <SH1@fda.hhs.gov>
CC:	Disbrow, Gary (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga>; Adams, Steven A. (ASPR/SNS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f98462fe8d124743a437c7a80b3f60dd-Adams, Stev>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bced884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Subject:	RE: as discussed
Date:	2020/03/23 08:56:14
Priority:	Normal
Type:	Note

Thanks Bob & Rick. I'll have an assay guy unwind this for us today. Looks like more than one product. At least one runs on the 7500Fast Dx, which we already have multiple Offerors for kits for that platform and more than one is already EUA'd will look to see what additional things are on this list.

Stay tuned.

Rodney L. Wallace

Director, Detection, Diagnostics, & Devices Infrastructure Division (DDD)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response (ASPR)
US Department of Health and Human Services (HHS)

Mailing Address:

330 Independence Avenue, SW, Room G644
Washington, DC 20201
Office: +1-202-205-3983
Mobile: (b)(6)

Email: rodney.wallace@hhs.gov

Website: <https://MedicalCountermeasures.gov>

Open Solicitation: <https://www.fbo.gov/spg/HHS/OOS/OASPEP/BAA-18-100-SOL-00003/listing.html>

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

From: Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>
Sent: Monday, March 23, 2020 8:47 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Wallace, Rodney (OS/ASPR/BARDA) <Rodney.Wallace@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>; Shuren, Jeff (FDA/CDRH) <Jeff.Shuren@fda.hhs.gov>
Subject: Re: as discussed

Rodney, please investigate.

(b)(5)

Rodney and FDA, please advise.

Thanks Rick

From: Robert Kadlec <Robert.Kadlec@hhs.gov>
Date: Monday, March 23, 2020 at 7:52 AM
To: Brett Giroir <Brett.Giroir@hhs.gov>, Rodney Wallace <Rodney.Wallace@hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>
Cc: Gary Disbrow <Gary.Disbrow@hhs.gov>, "Bright, Rick (OS/ASPR/BARDA)" <Rick.Bright@hhs.gov>, "Adams, Steven A. (ASPR/SNS)" <saa1@cdc.gov>
Subject: FW: as discussed

You fellows have familiarity with any of these tests pasting in additional email form this chap

On the test kit from BG - should receive FDA approval on Wednesday or Thursday. With your nod, I am pretty sure we can commandeer the full 4 and 8 week requirement before they ship elsewhere.

From: Sam Fairchild <(b)(6)>
Sent: Monday, March 23, 2020 7:34 AM
To: Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>
Subject: Re: as discussed

Focusing the search now. Also, is this on your radar? Danish manufacturer, manufacturing site in Wuhan.

Real-time fluorescent RT-PCR kit for detecting 2019-nCoV

【Generic product name】

Real-time fluorescent RT-PCR kit for detecting 2019-nCoV

【Package size】 50 tests/kit

【Catalogue Number】 MFG030010

【Intended use】

The kit is a qualitative in vitro nucleic acid amplification assay to detect the new coronavirus identified in China in 2019 using Reverse transcription PCR in specimen of throat swab and Bronchoalveolar Lavage Fluid (BALF) from suspects.

In end of 2019, some pneumonia cases were reported in Wuhan, China and the pathogen was confirmed as a new strain. World Health organization has named the newly identified coronavirus as 2019-nCoV. Although more intensive researches must be conducted later to well understand the virus, in response to the emergency in disease control, simple and rapid kit is necessary to identify the virus timely and implement efficient interventions to contain the spread. The kit will qualitatively detect the nucleic acid of 2019-nCoV in specimen from suspects enabling to assess the infection situation of 2019-nCoV in suspects in clinical and public health practice.

【Principle of the procedures】

The kit is based on in vitro RT-PCR combining fluorescent probing. Primers and a sequence-specific fluorescence probes were designed tailored to high conservative region in 2019-nCoV genome. The probes are oligonucleotide attached fluorophores at the 5' end with FAM as reporter and 3' end with quencher. In a meantime, specific primers and probes were developed as internal reference with fluorophores VIC/HEX attached at 5' end as reporter. During the PCR procedures, the DNA polymerase cleaves the probe at the 5' end and separates the reporter dye from the quencher dye when the probes hybridize to the target DNA. This cleavage results in the fluorescent signal generated by the cleaved reporter dye, which is monitored real-time by the PCR detection system. Monitoring the fluorescence intensities during Real Time allows the qualitative detection of 2019-nCoV in specimens.

【Key contents】

Item(50 tests/kit)

Specification

Quantity

Description

2019-nCoV Reaction Mix

1mL /vial

1 vial

Composed of reagent for amplification and probes and primers of target gene and internal reference

2019-nCoV Enzyme Mix

80µL /vial

1 vial

Taq polymerase, Reverse transcriptase and UDG

2019-nCoV Positive control

750µL/vial

1 vial

Mix solution of pseudo-virus with target virus genes and internal reference

2019-nCoV Blank control

750µL/vial

1 vial

DNase/RNase free water

Materials required but not provided

- Reagents: TIANamp Virus RNA extraction Kit (DP315-R) manufactured by TIANGEN, or QIAamp Viral RNA

Mini Kit (52904) by QIAGEN.

- 1.5 mL RNase/DNase-free microcentrifuge tube, RNase/DNase-free tips for pipettes, 0.2mL 8-tube strips for real-time PCR, Bench centrifuge, Vortex mixer.
- Notes: Components contained within a kit are intended to be used together. Do not mix components from different kit lots.

【Storage and shelf-life】

- The RT-PCR Kit should be stored at temperature lower than -18°C in dark. It is stable with shelf-life at 2-8 °C for 5 days and at -18°C for 6 months(tentative). Unpacked kit should avoid repeated thaw-freeze cycle (within 4 times)
- The PCR Kit can be transported at -18°C in dark stable for 5 days. The manufacture date and shelf life would be provided in the labelling.

【Applicable instruments】

Applied Biosystems™ Real time PCR system 7500; SLAN-96P PCR system

【Specimen】 Sample collection

- Collect fresh specimen of throat swabs and BALF from suspects. The operation of specimen should avoid possible contamination in collection, storage and transportation. The specimen should be presumed contagious and be operated according to related regulations.
- Throat swabs: Carefully take out the swab from package and quickly rotate it around two sides of fauces, throat and tonsil a few times applying pressure to collect as much secretions as possible. Avoid touching tongue. Break the swab stick and put the head into sampling solution in specimen tubes. Screw the tube cap tightly to ensure no leakage.
- BALF: Collect 3ml of unprocessed BALF in sterile, dry and clean DNase/RNase free Cryotubes. Screw the tube cap tightly to ensure no leakage and seal the tube with film.

Storage

- The specimen should be kept in proper condition, at -18°C for not longer than 1 weeks and at -70°C for not longer than 6 months.

- Frozen specimen should be thawed thoroughly while avoiding repeated thaw-freeze cycle.

Transportation

- The specimen should be shipped in low temperature condition using dry ice or ice bag.

【Laboratory procedures】 (Please read the procedures carefully before your operation)

Sample processing

- The fresh specimen should be collected to ensure the qualified RNA in terms of quality and quantity for the

assay. RNA should be extracted using Nucleic Acid extracting Kit in line with the manufacturer's instruction. Equivalent volume of positive control and blank control should be processed simultaneously. The assay was validated by the recommended RNA extraction kits by TIANGEN (DP315-R) and QIAGEN (52904).

- The extracted RNA should be tested immediately or stored at -70°C for test later.

Reagent preparation

- Take out all the kit contents and thaw them thoroughly at ambient temperature. Vortex and centrifuge briefly.

The Enzyme Mix should be kept in ice continuously.

- Estimate the number of reactions (N) in the test, which includes the number of Blank control (1 tube), Positive control (1 tube), and specimens prepared. Prepare 8-tube strips for PCR based on the estimated N of reaction and develop the PCR mix as ingredients in following table. Pipette 20μL PCR Mix per tube into the 8-tube strips. Capped them fastened and transfer them to sample processing Area. The remaining Nucleic acid reaction Mix and Enzyme Mix should be stored at -18°C immediately.

Add sample

- Add 10μL the extracted RNA of specimens, Blank control and Positive controls respectively into the 8-tube strips prefilled with PCR Mix. Capped them fastened and centrifuge them at 2000rpm for 10 seconds. Place the tubes into thermal cycler and record the exact location of controls and every specimen.

Real time PCR

- Set the fluorescent channels: Please refer to the manufacturer's instructions of thermocycler for detailed information on channel setting.

FAM channel (Reporter: FAM, Quencher: None) for RNA of 2019-nCoV;

VIC/HEX channel (Reporter: VIC/HEX, Quencher: None) for internal reference; Reference Dye: None (only for ABI PCR system);

Sample Volume: 30.

- Configure PCR protocol

2019-nCoV Reaction Mix (μL)

2019-nCoV Enzyme Mix (μL)

PCR-Mix (μL)

18.5×N

1.5×N

Step

Cycle
Temperature
Duration
Fluorescence measured(Y/N?)

1
1 cycle
50°C
20minutes
N
2
1 cycle
95°C
10minutes
N
3
40cycles
95°C
15 seconds
N
60°C
30 seconds
Y

Data analysis

- Baseline and threshold for ABI7500 PCR system

Baseline starting point at 3 and ending at 15

The threshold of each fluorescent channel should be set separately. In setting the threshold for a channel, the blank control should be selected firstly and click off the Automatic standard curve by changing the option from “☒√Auto” to “☐Auto”. Set the threshold manually just above the maximum level of blank control curve (random noise curve) at FAM channel.

- Data from SLAN-96P PCR system

The starting and ending points of baseline should be set as 6 and 12 respectively.

The threshold of each fluorescent channel should be set separately. In setting the threshold for a channel, change the configuration of baseline optimization in basic parameter from automatic to manual. Then, manually set the threshold just above the maximum level of blank control curve (random noise curve) at FAM/ VIC(HEX).

Quality control

- Blank control: Ct values at FAM and VIC/HEX channels are 0 or no data available.
- Positive control: Standard curves at channel FAM and VIC/HEX channels are in S-shape with Ct values not higher than 32.
- Testing specimen: Standard curves at VIC/HEX channel is in S-shape with Ct not higher than 32.
- Above requirements should be met in a single test. Otherwise, the test is invalid. Please operate the retest strictly in line with the package insert.

【Threshold and reference range】

- Cut-off value of the kit was determined based on the Receiver Operator characteristic curve from testing clinical samples. Ct value for 2019-nCoV positive by the kit is not high than 38.

【Testing result interpretation】

- The specimen is positive of 2019-nCoV if standard curve at FAM channel is in S-shape with Ct value not higher than 38.
- The specimen is negative of 2019-nCoV if standard curve at FAM channel is not in S-shape with Ct at FAM as 0 or no data available while Ct at VIC/HEX not higher than 32.
- The specimen should be retested if standard curve at FAM is in S-shape with Ct higher than 38. The specimen can be reported on basis of retesting results as positive of 2019-nCoV for Ct higher than 38 and as negative of 2019-nCoV for standard curve not in S-shape and Ct of internal reference not higher than 32 at VIC/HEX.
- In case that standard curve at FAM is not in S-shape with Ct value as 0 or no data available, the specimen should be retested if Ct at VIC is higher than 32 or no data available.

【Limitation of the assay】

- The Results of the test is just for information in clinical practices to assess infection condition of patients combining

with clinical presentations and other laboratory markers.

- The incorrect result can be caused by incorrect operations in sample collection, transportation or processing, very low concentration of target virus in the specimens, mutations within the viral genome covered by the kit's primers and/or probe, and unproved external interference factors, such as PCR inhibitor.

【Performance characteristics】

- The package is intact and liquid contents are clear, transparent and no sediments. All contents are in correct quantity as the package insert listed.
- Positive control is positive at both FAM and VIC/HEX channel in testing while blank control is negative at both channels.
- Limitation of Detection (LOD) of the kit is 100 copies/mL for detecting 2019-nCoV.
- The kit was validated by national positive and negative standards.
- A potential cross-reactivity of the RT-PCR Kit was tested and none of the tested pathogens and human gene have been reactive. The tested pathogens include 54 pathogens, such as human coronavirus includes OC43,229E, HKU1 and NL63(HCoV-OC43, HCoV-229E, HCoV-HKU1, HCoV-NL63) and other pathogens.
- The reproducibility of the assay was validated by manufacturer's precision standards (CV1 and CV 2), LOD standard and negative standard. All samples were tested repeatedly for 20 times, respectively. Coefficient of variance (CV) for Ct values were analyzed to evaluate the variability of inter- and intra-batches, within day and day-to-day operation. The CVs are all less than 5% respective (n=20).
- The repeatability of assay was validated by manufacturer's repeatability standards, LOD standard and negative standard repeatedly for 20 times. Coefficient of variance (CV) for Ct values were analyzed to evaluate the inter- batch variability. They are all less than 5%.

- Interference trial shows that performance of the kit is stable with endogenous and exogenous interfering substances such as some anti-microorganism drugs, nasal sprays and nasal drops in specimen. Specimen with elevated level of mucoprotein at a concentration of 60 mg / mL and other substances do not influence the kit performance at virus concentration higher than Limit of Detection.

【Warning and precautions】

- **FOR IN VITRO TEST ONLY.** Please read the package insert carefully before your operation. The appropriate operations from specimen collection, storage and transportation, and laboratory test should be strictly manipulated in line with relevant regulations of biosafety and molecular laboratory management. Please contact BGI sales for the most up-to-date information in the event of damage to the protective packaging
- The false positive or negative testing result can be led by poor quality of specimen, incorrect operations in sample collection, transportation or laboratory processing, or limitation of the technology. Operator should understand well the principles of the procedures and its limitation in performance in advance and avoid any potential mistakes intentionally.
- Separate laboratory areas are recommended to performing predefined procedures of the assay.

a) 1st Area:Preparation Area—Prepare testing reagent;

b) 2nd Area:Sample processing—Process the specimen and controls;

c) 3rd:Amplification Area—PCR conducted.

- All materials used in one area should always be remained in the area and should not be moved or used in other areas. After the assay procedures, the workbench and lab supplies should be cleaned and disinfected timely.

- All contents in the package are prepared dedicatedly for the intended testing purpose and validated. Replacing any of them will affect the testing performance of the kit. Components contained within a kit are intended to be used together. Do not mix components from different kit lots.

- Thaw all kit components thoroughly and centrifuge them briefly before starting an assay. Avoid repeated thaw- freeze cycle.

- 8-tube strips for real time PCR capped fasten and transferred to specimen processing area immediately after addition of Nucleic Acid reaction Mix.

- To prevent the contamination from exogenous RNA, sample addition should follow the sequence of negative control, specimen RNA and positive control. Filtered tips should be prepared and used separately in preparing reagent and sample addition.

- Ensure to pipette the samples exactly into the reaction mix in PCR tubes and avoid sticking the samples to the inside tube wall. The tubes should be capped fasten immediately after the addition.

- After the protocol of amplification is done, remove PCR tubes from the thermal cycler and discard them in a sealable plastic bag for autoclave and decontamination.

- Ensure no foam or bubbles present in the tubes when aliquoting nucleic acid Mix. All PCR tubes capped fasten before loading them into the thermal cycler to avoid any possible leakage and contamination.

- The workbench and lab supplies should be cleaned and disinfected regularly using 75% ethanol or UV light.

- All pipette tips and centrifuge tubes in the assay should be DNase/RNase-free. The used centrifuge tubes and pipette tips should be discarded in waste bin with Clorox (84) disinfectant and disposed with other laboratory wastes after decontamination.
- Operator should receive professional training before operating.

【References】

[1] LU Rou-jian, ZHANG Ling-lin, TAN Wen-jie, ZHOU Wei-min, WANG Zhong, PENG Kun, RUAN Li. Development and Comparison of Real-Time and Conventional RT-PCR Assay for Detection of Human Coronavirus NL63 and HKU1[J]. CHINESE JOURNAL OF VIROLOGY, 2008(4).
 [2] NIU P, LU R, LAN J, LIU G, WANG W, TAN W. Development of Novel Multiplex Real-time RT-PCR Assays for Detection of MERS-CoV Infection[J]. CHINESE JOURNAL OF VIROLOGY, 2016(3).

[3] CHEN Yu-jing. Development of two-panel reactions of real-time PCR for detection of 18 types/subtypes of respiratory viruses[D]. 2015

【Contact details】 Manufacturer: BGI Europe A/S

Manufacturer Address: Ole Maaløes Vej 3, DK-2200 Copenhagen N, Denmark

Manufacturing Site: BGI Biotechnology (Wuhan) Co.,Ltd

Site Address: Building B2, Zone B/C/D, Wuhan National Bioindustry Base, NO.666 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan

Please contact:

BGI Europe A/S

Service hotline:

Copenhagen, Denmark: 0045-80300800/ 0045-70260806

Website:<https://protect2.fireeye.com/url?k=19662191-453238ed-196610ae-0cc47adc5fa2-7c907fa3556bef91&u=http://www.bgi.com/>

【Language edition】

For the requirements of Instruction for Use in other languages, please contact BGI Europe A/S.

【Release date of the user manual】

This manual was released on 2020-02-26

【Key to symbols used】

IN VITRO DIAGNOSTIC MEDICAL DEVICE

MANUFACTURER

USE BY DATE

BATCH CODE

DATE OF MANUFACTURE

CATALOGUE NUMBER

CAUTION

UPPER LIMIT OF TEMPERATURE

CE MARK

CONSULT INSTRUCTIONS FOR USE

KEEP AWAY FROM SUNLIGHT

KEEP DRY

DO NOT RE-USE

POSITIVE CONTROL

CONTAINS SUFFICIENT FOR N TESTS

Sent from my iPhone

On Mar 23, 2020, at 6:59 AM, Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>wrote:

Sam thanks this is great news. You can drop the ventilators for the moment as we are working domestic producers gloves glasses face shield and Tyvek like suits are the high priority need.

Sent from my iPhone

On Mar 22, 2020, at 11:56 PM, Sam Fairchild <(b)(6)> wrote:

Bob - David has set up SinoPharma and JY Pharma as the two procurement throats for the supplies and equipment. This serves three purposes -- first, they will certify that supplies moving through the procurements meet FDA standards (weeding out non-compliant materials) and serve as quality control thereof. Second, they are capable of providing the necessary working capital to procure and stage materials in concert with HHS procurement terms. Third, they will not be hindered by customs bureaucrats and others who may delay movements. I should see detailed quotes on certain items in the next 24 - 48 hours.

I do need some more detailed specs on several items -- glove standards, respirator specs and ventilator specs -- can you get someone to send me the next layer down on these.

It looks quite hopeful on being able to fulfill your 4 week and 8 week lists.

Let me know on those specs. Also, can someone send me a sample HHS purchase order to lays out payment terms so I can preposition that for acceptance in China?

All the best, my friend. Keep up the impossibly good job that you all are doing! A grateful nation and all that!! Sam

On Thu, Mar 19, 2020 at 6:50 PM Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>wrote:

Sender:	Wallace, Rodney (OS/ASPR/BARDA) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B4654F8F0C0F4623B9E47465E9E1037A-WALLACE, RO>
Recipient:	Bright, Rick (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53034752f35a4317aa74f46348442d39-Bright, Ric>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Hahn, Stephen <SH1@fda.hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0fd5845defda4dc0bb45f8fac629cf09-Disbrow, Ga>;

	Adams, Steven A. (ASPR/SNS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f98462fe8d124743a437c7a80b3f60dd-Adams, Stev>; Shuren, Jeff (FDA/CDRH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcede884c4434f4da6f4fe4b4c3885cd-jeffrey.shu>
Sent Date:	2020/03/23 08:56:13
Delivered Date:	2020/03/23 08:56:14

From:	White House: Office of the Vice President <info@mail.whitehouse.gov>
To:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Subject:	VP DAILY GUIDANCE AND PRESS SCHEDULE FOR MONDAY, MARCH 23, 2020
Date:	2020/03/23 08:59:45
Priority:	Normal
Type:	Note

-->



The White House

Office of the Vice President

FOR IMMEDIATE RELEASE

March 23, 2020

DAILY GUIDANCE AND PRESS SCHEDULE FOR MONDAY, MARCH 23, 2020

Pool Coverage:

TV: ABC News

EDT

12:30 PM THE VICE PRESIDENT joins THE PRESIDENT for lunch

Private Dining Room

Closed Press

**2:00 PM THE VICE PRESIDENT leads a video teleconference with
Governors on Partnership to Prepare, Mitigate, and Respond to COVID-19**

Federal Emergency Management Agency Headquarters

Pool Spray

**4:00 PM THE VICE PRESIDENT leads a White House Coronavirus Task
Force meeting**

Situation Room

Closed Press

Briefing Schedule

5:30 PM Members of the Coronavirus Task Force hold a press briefing

James S. Brady Briefing Room

On Camera

###

[Unsubscribe](#)

The White House · 1600 Pennsylvania Ave NW · Washington, DC 20500-0003 · USA · 202-456-1111

Sender:	White House: Office of the Vice President <info@mail.whitehouse.gov>
Recipient:	Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>
Sent Date:	2020/03/23 08:59:35
Delivered Date:	2020/03/23 08:59:45

From:	Gabriela Quiroga <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 09:10:46
Priority:	Normal
Type:	Note

Gabriela Quiroga

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

The federal Clinical Laboratory Improvement Advisory Committee recently recommended allowing qualified professionals to review and interpret digital images remotely when data is exchanged via a secure connection but CMS has not yet authorized this policy. Many U.S. laboratories have well-validated digital systems to allow for quality remote diagnosis using secure virtual personal networks (VPNs). Given dire shortages of pathologists and laboratory personnel at many laboratories and the need to follow the President's call for social distancing, CLIA is unnecessarily putting our work force at risk and imposing barriers to optimal patient care.

Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Gabriela Quiroga

Sender:	Gabriela Quiroga <(b)(6)>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:04:38
Delivered Date:	2020/03/23 09:10:46
Message Flags:	Unread

From:	Mona Moosavi (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 09:11:43
Priority:	Normal
Type:	Note

Mona Moosavi

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

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Sincerely,

Mona Moosavi

Sender:	Mona Moosavi (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:04:38
Delivered Date:	2020/03/23 09:11:43
Message Flags:	Unread

From:	Claudius Mueller (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 09:12:45
Priority:	Normal
Type:	Note

Claudius Mueller

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,
Claudius Mueller

Sender:	Claudius Mueller (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:04:38
Delivered Date:	2020/03/23 09:12:45
Message Flags:	Unread

From:	Erika Porcelli <E.Porcelli@rcainc.com>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Subject:	FDA Compliance Support for Non Medical Device Manufacturers - COVID-19
Date:	2020/03/23 09:04:58
Priority:	Normal
Type:	Note

Dear Mr. Kadlec,

I understand that you are helping to lead the effort with getting additional manufacturers online to support the growing medical needs during this time of crisis. Regulatory Compliance Associates Inc. is headquartered in Pleasant Prairie, WI. Our firm specializes in helping Medical Device, Pharmaceutical and Biotech manufacturers in regulatory, quality system and manufacturing optimization. This could be particularly helpful as non-medical device manufacturers initiate making medical devices and medical supplies during the Covid-19 outbreak.

Medical devices and their manufacturing are governed by a specific set of FDA regulations, ISO standards, and Quality System requirements. Our firm can help new manufacturers in setting up systems to comply with these regulations and standards, and thereby streamline the process of getting these critical items manufactured and distributed. We also have extensive expertise in medical device design and manufacturing optimization.

An in depth description of our expertise and capabilities can be found on our website at <https://protect2.fireeye.com/url?k=3100e469-6d55edb9-3100d556-0cc47a6a52de-993b7ae65851aa91&u=http://www.rcainc.com/> . I can be reached at 203.308.8290.

I would love the opportunity to connect to those charged with increasing critical medical device and medical supply availability during the Covid-19 outbreak. We would be happy and proud to participate and help.

Best regards,

Erika Porcelli
Chief Executive Officer



RCA Logo HORIZONTAL RBG

Regulatory Affairs * Quality Services * Compliance Assurance *
Remediation Strategy & Support * Strategic Consulting

262.288.6318 direct * (b)(6) cell * e.porcelli@rcainc.com

<https://protect2.fireeye.com/url?k=eada1d32-b68f14e2-eada2c0d-0cc47a6a52de-020fd2d51f705b51&u=http://www.rcainc.com/>
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Sender:	Erika Porcelli <E.Porcelli@rcainc.com>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>
Sent Date:	2020/03/23 09:04:42
Delivered Date:	2020/03/23 09:04:58

From:	Erika Porcelli <E.Porcelli@rcainc.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	FDA Compliance Support for Non Medical Device Manufacturers - COVID-19
Date:	2020/03/23 09:05:19
Priority:	Normal
Type:	Note

Dear Mr. Azar,

I understand that you are helping to lead the effort with getting additional manufacturers online to support the growing medical needs during this time of crisis. Regulatory Compliance Associates Inc. is headquartered in Pleasant Prairie, WI. Our firm specializes in helping Medical Device, Pharmaceutical and Biotech manufacturers in regulatory, quality system and manufacturing optimization. This could be particularly helpful as non-medical device manufacturers initiate making medical devices and medical supplies during the Covid-19 outbreak.

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Best regards,

Erika Porcelli
Chief Executive Officer



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Regulatory Affairs * Quality Services * Compliance Assurance *
Remediation Strategy & Support * Strategic Consulting

262.288.6318 direct * (b)(6) cell * e.porcelli@rcainc.com

<https://protect2.fireeye.com/url?k=51025f3f-0d567614-51026e00-0cc47a6d17cc-5e319f6ecb68c6da&u=http://www.rcainc.com/>
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Sender:	Erika Porcelli <E.Porcelli@rcainc.com>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:05:04
Delivered Date:	2020/03/23 09:05:19

From:	Kara Roncin <Kara.Roncin@UHHospitals.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 09:24:48
Priority:	Normal
Type:	Note

Kara Roncin

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Kara Roncin, MD

Sender:	Kara Roncin <Kara.Roncin@UHHospitals.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:14:39
Delivered Date:	2020/03/23 09:24:48
Message Flags:	Unread

From:	Mark Kellogg (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 09:29:48
Priority:	Normal
Type:	Note

Mark Kellogg

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,
Mark Kellogg

Sender:	Mark Kellogg (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:24:39
Delivered Date:	2020/03/23 09:29:48
Message Flags:	Unread

From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.YDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0280B227911B40B6B30A81B8574EDE6B-STECKER, JU>
To:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>
Subject:	Fwd: FDA Compliance Support for Non Medical Device Manufacturers - COVID-19
Date:	2020/03/23 09:26:44
Priority:	Normal
Type:	Note

Passing along for appropriate action.

Sent from my iPhone

Begin forwarded message:

From: Erika Porcelli <E.Porcelli@rcainc.com>
Date: March 23, 2020 at 9:08:04 AM EDT
To: "Stecker, Judy (OS/IOS)" <Judy.Stecker@hhs.gov>
Subject: FDA Compliance Support for Non Medical Device Manufacturers - COVID-19

Dear Ms. Stecker,

I understand that you are helping to lead the effort with getting additional manufacturers online to support the growing medical needs during this time of crisis. Regulatory Compliance Associates Inc. is headquartered in Pleasant Prairie, WI. Our firm specializes in helping Medical Device, Pharmaceutical and Biotech manufacturers in regulatory, quality system and manufacturing optimization. This could be particularly helpful as non-medical device manufacturers initiate making medical devices and medical supplies during the Covid-19 outbreak.

Medical devices and their manufacturing are governed by a specific set of FDA regulations, ISO standards, and Quality System requirements. Our firm can help new manufacturers in setting up systems to comply with these regulations and standards, and thereby streamline the process of getting these critical items manufactured and distributed. We also have extensive expertise in medical device design and manufacturing optimization.

An in depth description of our expertise and capabilities can be found on our website at <https://protect2.fireeye.com/url?k=fcbf21d8-a0ea28cb-fcbf10e7-0cc47adb5650-e6a8436c18bfe6d5&u=http://www.rcainc.com/>. I can be reached at 203.308.8290.

I would love the opportunity to connect to those charged with increasing critical medical device and medical supply availability during the Covid-19 outbreak. We would be happy and proud to participate and help.

Best regards,

Erika Porcelli
Chief Executive Officer



RCA Logo Horizontal RBG

Regulatory Affairs * Quality Services * Compliance Assurance *
Remediation Strategy & Support * Strategic Consulting

262.288.6318 direct * (b)(6) cell * e.porcelli@rcainc.com

<https://protect2.fireeye.com/url?k=f368a056-af3da945-f3689169-0cc47adb5650-4af47ff0275ed659&u=http://www.rcainc.com/>
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RCA's Podcast, [RCA Radio](#)

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Sender:	Stecker, Judy (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0280B227911B40B6B30A81B8574EDE6B-STECKER, JU>
Recipient:	Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Lenihan, Keagan (FDA/OC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cd1b7aba9034ddb936017780583af7d-keagan.leni>; Steele, Danielle (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38849c1f1ea74f2eb9eff75b531a9544-Steele, Dan>
Sent Date:	2020/03/23 09:26:43
Delivered Date:	2020/03/23 09:26:44

From:	Secretary Scheduler (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6801B3307D554C04B245714132602E16-SECRETARY S>
To:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>; Apple, Matthew (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2d31099399446eab9bfff69d52880932-Apple, Matt>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Puesan, Cesar (HHS/OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1704b662180d4631b7b64cb17de301cd-Puesan Juar>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Tignor, Beth (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=464729cc8a584516addbbc50d76a94a8-Tignor, Bet>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Giroir, Bre>; Bante, Katie (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dc7b1305e642648084faafdc789697-Bante, Kati>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Parker, Jim (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f7ac2e66aa043a6b7cb2eaa9f67ffa3-Parker, Jam>; Trueman, Laura (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcba4c6ea342c08d58f63e37d997e7-Trueman, La>; Beck, Gary (OS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a049f8137013412bbf472fc1833391be-Beck, Miche>
Subject:	AMA call with Joe Almedia, Baxter
Date:	2020/03/23 09:35:52
Start Date:	2020/03/24 15:30:00
End Date:	2020/03/24 15:45:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	615-F // CALL (b)(6)
Attendees:	AMA2 (OS/IOS); Apple, Matthew (HHS/IOS); Harrison, Brian (HHS/IOS); Paul Mango ; Puesan, Cesar (HHS/OS/IOS); Stecker, Judy (OS/IOS); Tignor, Beth (HHS/IOS); Brett Giroir (HHS/OASH) (Brett.Giroir@hhs.gov); Bante, Katie (OS/OASH); Kadlec, Robert (OS/ASPR/IO) (Robert.Kadlec@hhs.gov); Ford-Barnes, Arwenithia (OS/ASPR/IO); Hayes, Jonathan (OS/ASPR/IO); Shuy, Bryan (OS/ASPR/IO) (Bryan.Shuy@hhs.gov); Jim Parker (HHS/IOS) (Jim.Parker@hhs.gov); Trueman, Laura (HHS/IEA); Beck, Gary (OS/IEA) (Gary.Beck@hhs.gov)

(b)(6)

Leader: (b)(6)

Topic: Meeting with Baxter International

Objective: Work with a private sector partner to find how they can help in the Administration's efforts to combat the COVID-19 emergency

AMA's Role: Dialogue with Baxter representatives

Project Lead (IOS Senior Staff): Paul Mango and Laura Trueman

Working Project Lead (Name, Cell and email): Gary Beck. (b)(6). Gary.beck@hhs.gov

Is Conference Call Line needed? Yes

Who will initiate the conference call? IEA

Who will provide Briefing materials? IEA

HHS Staff Attendees:

- Brett Giroir
- Robert Kadlec
- Jonathan Hayes
- Bryan Shuy
- Jim Parker
- Laura Trueman
- Gary Beck

External Attendees:

- Joe Almeida
- Baxter staff

Schedule Request Justification:

Baxter primary business focus during the COVID-19 emergency is to continue to meet the needs of their home dialysis patients across the global, who are a vulnerable population. The company's delivery drivers have started to take extra precautions to protect their customers.

Baxter has also began to increase the amount of PPE available for their employees and partners. The Administration might be able to partner with Baxter and their global partners to ensure PPE is getting to areas where it is most needed.

Sender:	Secretary Scheduler (OS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6801B3307D554C04B245714132602E16-SECRETARY S>
Recipient:	AMA2 (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c145629cc8ac4858bf1f0ce5dd0461dc-AMA2!>; Apple, Matthew (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2d31099399446eab9bff69d52880932-Apple, Matt>; Harrison, Brian (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d145efc9c35c4865aca6e9d47786b204-Harrison, B>; Mango, Paul (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d8863b643654b1aad9a38c952af613e-Mango, Paul>; Puesan, Cesar (HHS/OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1704b662180d4631b7b64cb17de301cd-Puesan Juar>; Stecker, Judy (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0280b227911b40b6b30a81b8574ede6b-Stecker, Ju>; Tignor, Beth (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=464729cc8a584516addbbc50d76a94a8-Tignor, Bet>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Bante, Katie (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89dc7b1305e642648084faafdc789697-Bante, Kati>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Ford-Barnes, Arwenithia (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d533abc24cbe44b79f6fddc6b08737a6-Ford-Barnes>; Hayes, Jonathan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cdfb7232de4428794f2901218bc1360-Hayes, Jona>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; Parker, Jim (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f7ac2e66aa043a6b7cb2eaaf967ffa3-Parker, Jam>; Trueman, Laura (HHS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99dcba4c6ea342c08d58f63e37d997e7-Trueman, La>; Beck, Gary (OS/IEA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a049f8137013412bbf472fc1833391be-Beck, Miche>
Sent Date:	2020/03/23 09:35:50
Delivered Date:	2020/03/23 09:35:52

From:	Joanne Savage <joanne.savage@illinois.gov>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 09:52:36
Priority:	Normal
Type:	Note

Joanne Savage

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,

Joanne Savage

Sender:	Joanne Savage <joanne.savage@illinois.gov>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:46:02
Delivered Date:	2020/03/23 09:52:36
Message Flags:	Unread

From:	John Tinsley <john.tinsley@healthnetworklabs.com>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 09:52:47
Priority:	Normal
Type:	Note

John Tinsley

(b)(6)

March 23, 2020

Dear Alex Azar,

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John Tinsley

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Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:46:03
Delivered Date:	2020/03/23 09:52:47
Message Flags:	Unread

From:	Melinda Schumacher (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 10:05:56
Priority:	Normal
Type:	Note

Melinda Schumacher

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Sincerely,

Melinda Schumacher

Sender:	Melinda Schumacher (b)(6)
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:56:03
Delivered Date:	2020/03/23 10:05:56
Message Flags:	Unread

From:	Roger Smith <roger.smith@spectrumhealth.org>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 10:05:50
Priority:	Normal
Type:	Note

Roger Smith

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Given that HHS just provided other physician specialties with the flexibility to provide telemedicine services, pathologists and laboratory professionals should also be allowed the same flexibility. I request expedited consideration of this request to ensure laboratories can promptly respond to our patients' needs now.

Sincerely,
Roger Smith

Sender:	Roger Smith <roger.smith@spectrumhealth.org>
Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 09:56:04
Delivered Date:	2020/03/23 10:05:50
Message Flags:	Unread

From:	Wright, Janet (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=41F672E2527B4F44891FB4FBE08CDFD-WRIGHT, JAN>
To:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Sherman, Jennifer (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30fe7fae664419fa654b20edccb1e78-Sherman, Je>
CC:	Anderson-Villaluz, Dennis (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61dfc265c6ce45f686ad00f9dfd27901-Anderson-Vi>
Subject:	Re: Hello from Wake Forest
Date:	2020/03/23 09:59:08
Priority:	Normal
Type:	Note

+ Jenn

*Janet S. Wright MD, FACC
Director of Science and Policy
Office of the Surgeon General
Dept Health and Human Svcs
200 Independence Ave SW
Washington, DC
202-690-5157*

On: 23 March 2020 09:58,
"Wright, Janet (HHS/OASH)" <Janet.Wright@HHS.GOV>wrote:

Forwarding a good piece from one of your tribe.

Original Message----- From: Scott Segal, M.D. Sent: Saturday, March 21, 2020 5:51 PM To: Halliburton, Ida (HHS/OASH/OSG) Cc: Anderson-Villaluz, Dennis (HHS/OASH) ; Palladino, Erica (HHS/OS/IOS) (CTR) Subject: Hello from Wake Forest Dear Ida (copies to Lt. Anderson-Villaluz and Ms. Palladino), You may recall corresponding about Dr. Adams' visit in February. We thoroughly enjoyed his visit! A colleague is trying to promulgate the idea of a low cost, "good enough" ventilator for the COVID-19 response. He has a piece in the Boston Globe this weekend about his idea, and he's trying to work with engineers and others to get it going. I was wondering if you could show the following text from the upcoming article to Dr. Adams? Thanks, Scott Segal B. Scott Segal, MD, MHCM Thomas H. Irving Professor and Chair Co-executive director, Perioperative Shared Service Line [cid:image001.gif@01D31C13.99A04450] Department of Anesthesiology Medical Center Boulevard \ Winston-Salem, NC 27157 p 336-716-4497 f 336-716-8190
Boston Globe article: A doctor's coronavirus challenge: reimagine the ventilator Hacking together cheaper, simpler breathing machines could save the day in hospitals overwhelmed by COVID-19. By Ben Moor, Updated March 20, 2020, 2 hours ago In 1941, Britain, alone and isolated, faced the grim prospect of a starving submission to German U-boat wolf packs. The

only hope for survival was a huge quantity of food from the United States, which required the Americans to create countless tons of shipping capacity. But building ships is a long, complicated process and time was rapidly running out. The American solution was simplicity itself: Liberty Ships. The complete redesign of a standard cargo ship — literally from the bottom up — gave rise to a fleet of workhorse freighters that would eventually deliver food, munitions, and victory in Europe. To build the ships quickly, the number of individual parts was hacked back drastically. Rather than having their hulls laboriously riveted together, Liberty Ships were made out of prefabricated parts that could be welded into place, a process that required less skill and shaved weeks off production. And because the design was simple and processes standardized, ships could be built at any one of 18 shipyards. By the end of the war, 2,700 of these "Ugly Ducklings" had been produced. By the end of 1943, American shipyards were averaging a launch every six hours. We need a similar effort now that hospitals around the country are facing a terrifying shortage of ventilators — the machines that push air into the lungs of patients beset by respiratory diseases like COVID-19. Just as the Allies redesigned ships so they'd be cheaper and easier to produce, we need to reimagine the ventilator. Rather than racing to produce more of the same kind of expensive, state-of-the-art ventilators hospitals typically use, what we need now is speed and simplicity. Reports from intensive-care doctors in Italy and China tell the same story: even before there's a vaccine or antiviral medications, critically ill COVID-19 patients often will pull through if there are enough mechanical ventilation machines that can buy time for them to recover. A new ventilator is a beautifully sleek, complicated piece of electronics running nuanced algorithms to deliver a near perfect "machine breath" to the patient. That perfection comes at a price — \$20,000 to more than \$40,000 — and requires specialized production facilities. Money aside, production time far exceeds what we have right now. Once patients are on ventilators, we let them rest while the machines ensure they have the oxygen necessary for the lungs to heal. Modifications to these machines' settings are planned by the medical staff as the patients' conditions change or as test results become available. At the moment, this might involve summoning a specialist because nobody else dares touch the bewildering display. But at its heart, an ICU ventilator is a profoundly simple device. Here's how it works: the patient is sedated enough to tolerate having a breathing tube secured in the trachea. The breathing tube connects to the ventilator by a hose. As the patient initiates a breath, the machine detects a slight drop in pressure, and a piston-driven cylinder pushes a measured volume of oxygen into the patient's lungs. If the patient doesn't or can't start a breath, the machine will automatically do so after a few seconds. At some point, the machine either successfully delivers the required volume or reaches a maximum safe pressure and automatically cycles so that air can come back out of the patient's lungs and through a separate hose. Pause. Repeat. Minute after minute, hour after hour. If necessary, for days. This is not a machine that needs to cost tens of thousands of dollars. The current models have touch screens, graphical displays, and highly nuanced modes such as "neutrally adjusted ventilatory assist" and automated ventilator-weaning protocols. Those features are nice to have in a tiny minority of cases, but they are unnecessary complexities in a mass casualty situation. So while Elon Musk very well may try to convert Tesla or SpaceX assembly lines to the production of ventilators, they shouldn't need to be produced in factories at Tesla, or Apple, or General Motors. They should be produced everywhere. At the other end of the technology spectrum, hobbyists and survivalists are posting designs for their own ventilators. These tend toward one-off homemade contraptions. Deployable medical equipment will still need approval from the Food and Drug Administration and should not be so reliant on duct tape. In a city with the finest medical minds

and universities, we should be able to design, test, and certify a scaled-down but effective ventilator that can be built in many sites around the country and the world within weeks. That's my challenge to the medical, engineering, and academic community: come up with a ventilator that delivers what we need in the ICU but is simple enough to be assembled in an unsophisticated factory using established techniques from prefabricated units. It should have as few parts as possible. All parts should be commonly available. It should be repairable by a hospital technician. Electronics should be simple, sensors replaceable, and controls adequate but not excessive. An experienced nurse or respiratory therapist should be able to master it within a couple of hours. It should be robust, easy to clean, and ugly. We have all seen the graph — two mythical bell curves and a dotted line denoting the capacity of the health system. We are all self-isolating, desperately trying to flatten the curve. Who knows if that will work? But we also can raise that dotted line by increasing our capacity to support critically ill patients. We have probably missed our opportunity to get significant respirator capacity online for the first peak, but there will doubtless be other surges later this year and into next. To increase our capacity, we must produce and run thousands of simple ventilators and train up healthcare providers within weeks. I don't need a Tesla. Just give me an Ugly Duckling. Dr. Ben Moor is an anesthesiologist at Beth Israel Deaconess Hospital in Plymouth.

Sender:	Wright, Janet (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=41F672E2527B4F44891FB4FBE08CDFDF-WRIGHT, JAN>
Recipient:	Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Sherman, Jennifer (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f30fe7fae664419fa654b20edccb1e78-Sherman, Je>; Anderson-Villaluz, Dennis (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61dfc265c6ce45f686ad00f9dfd27901-Anderson-Vi>
Sent Date:	2020/03/23 09:59:07
Delivered Date:	2020/03/23 09:59:08

From:	William McGuire (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 10:17:02
Priority:	Normal
Type:	Note

William McGuire

(b)(6)

March 23, 2020

Dear Alex Azar,

Dear Administrator Verma:

President Donald Trump's recent emergency declaration gives the U.S. Secretary of Health and Human Services vast authority to waive certain laws and regulations to provide the U.S. healthcare system "maximum flexibility to respond to the virus". Unfortunately, clinical laboratories across the U.S. are being hampered in their efforts to respond to COVID-19 by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). To help address this, I urge that the Secretary provide laboratories with more flexibility by temporarily relaxing the CLIA requirement regarding remote digital pathology interpretations.

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Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 10:16:06
Delivered Date:	2020/03/23 10:17:02
Message Flags:	Unread

From:	Anjali Satoskar (b)(6)
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 10:17:54
Priority:	Normal
Type:	Note

Anjali Satoskar

(b)(6)

March 23, 2020

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Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 10:16:06
Delivered Date:	2020/03/23 10:17:54
Message Flags:	Unread

From:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
To:	Orsega, Susan (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8171c34a0cd4581a49f33cb8f60f684-Orsega, Sus>; Trent-Adams, Sylvia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=650dc3276414421693345147bfafd132-Trent-Adams>; Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcdb759f5dcad91-Schwartz, E>
CC:	Valentine, Steven (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd508090f8984b1caf04069bc6000dc2-Valentine,>; Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Subject:	RE: COVID-19 CCHQ Mission Update 22 MAR 2020
Date:	2020/03/23 10:23:55
Priority:	Normal
Type:	Note

Thank you

Brett P. Giroir, MD

ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Sent: Sunday, March 22, 2020 9:42 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Trent-Adams, Sylvia (HHS/OASH) <Sylvia.Trent-Adams@hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Schwartz, Erica (HHS/OASH) <Erica.Schwartz@hhs.gov>
Cc: Valentine, Steven (HHS/OASH) <Steven.Valentine@hhs.gov>; Haddad, Carla (HHS/OASH) <Carla.Haddad@hhs.gov>
Subject: COVID-19 CCHQ Mission Update 22 MAR 2020

Sirs and Ma'ams

As of 22Mar2020 at 2000, **1199** Commissioned Corps have deployed.
Commissioned Corps Headquarters has deployed a total of 784 officers; 281 officers are currently deployed
77 officers are currently deployed for the Community-Based Testing Sites Initiative
****415 Agency Deployments:** ACF (8), CDC (315), CMS (3), FDA (24), IHS (3), Interior (27), NIH (22), USDA (3), VA (10)

Rear Admiral Susan M. Orsega, FNP-BC, FAAN, FAANP

Director, Commissioned Corps Headquarters
Office of the Surgeon General
United States Public Health Service
U.S. Department of Health and Human Services
1101 Wooten Parkway
Rockville, Maryland 20852
Office Phone: 240-453-6080
Cell phone: (b)(6)
Email: susan.orsega@hhs.gov

Sender:	Giroir, Brett (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A56FCE4755704C4CA031D621B46FD6F7-GIRORI, BRE>
Recipient:	Orsega, Susan (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8171c34a0cd4581a49f33cb8f60f684-Orsega, Sus>; Trent-Adams, Sylvia (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=650dc3276414421693345147bfafd132-Trent-Adams>; Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcdb759f5dcad91-Schwartz, E>; Valentine, Steven (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd508090f8984b1caf04069bc6000dc2-Valentine,>; Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Sent Date:	2020/03/23 10:23:53
Delivered Date:	2020/03/23 10:23:55
Message Flags:	Unread

From:	Kenichi Tamama <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 10:30:38
Priority:	Normal
Type:	Note

Kenichi Tamama

(b)(6)

March 23, 2020

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Sincerely,

Kenichi Tamama, MD, PhD

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Recipient:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Sent Date:	2020/03/23 10:26:07
Delivered Date:	2020/03/23 10:30:38
Message Flags:	Unread

From:	Xiaoyan Cui <(b)(6)>
To:	Azar, Alex (OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd4875f6a7414810934ed443c7f34740-Azar, Alex>
Subject:	Clinical Labs Need Remote Pathology Authorization
Date:	2020/03/23 10:32:08
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Type:	Note

Xiaoyan Cui

(b)(6)

March 23, 2020

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd. (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0892A057F83497E9390288C813B61D9-STANNARD, P>
To:	Barry, Daniel J (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3e449ce0>; Puesan, Cesar (HHS/OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1704b662180d4631b7b64cb17de301cd-Puesan Juar>; OS OGC-IO ControlDesk (HHS/OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c9f99a0b2364cb5bd1b739db7851e43-controldesk>; Keveney, Sean (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e13823250af4ccf93b3de562380e78e-Keveney, Se>; Chang, William (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cf70c842da144ab9bee61f353d932a0-Chang, Will>; Strom, John (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=087650d67a204508963541a6eba69ea5-Strom, John>; Hecht, Jonah (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de0acd2f82294cd7befc09c5444f616c-Hecht, Jona>; ASPR Exec Sec (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e561b3f0bfd4331bc7c93e4419316ae-ASPRExecSec>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; OASHIO Control Desk (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8407017e8889478bbd764b389bdc6ac-OASHIOContr>; Campbell, Taylor (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cca29818d7440d8a21b2c349f2e4f6a-Campbell, T>; Girori, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Callahan, Kenneth (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e1240d1d62d49b3ba2e4e51c0920908-Callahan, K>; White, Caroline (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=755298af43a64d6c92b600e5d8b7d76a-White, Caro>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>
CC:	Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>; Agnew, Ann (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5174d56b97948d0820e90e8d8136ee5-Agnew, Ann>; Brennan, Patrick (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51c3d9a49fd4882951eca2417c19dcf-Brennan, Pa>; Foster, Timothy (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2265a29a6468468397bae80a642620fc-Foster, Tim>
Subject:	RE: Quick Review: COVID-19 Anti-hoarding EO
Date:	2020/03/23 10:31:30
Priority:	Normal
Type:	Note

Nor do I.

Paula

From: Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>

Sent: Monday, March 23, 2020 10:31 AM

To: Puesan, Cesar (HHS/OS/IOS) <Cesar.Puesan@hhs.gov>; OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Hecht, Jonah

(HHS/OGC) <Jonah.Hecht@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; OASHIO Control Desk (OS/OASH) <OASHIOControlDesk@hhs.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Callahan, Kenneth (HHS/IOS) <Kenneth.Callahan@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Cc: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>
Subject: RE: Quick Review: COVID-19 Anti-hoarding EO

I have no additional comments. Thanks, Dan

From: Puesan, Cesar (HHS/OS/IOS) <Cesar.Puesan@hhs.gov>
Sent: Monday, March 23, 2020 9:33 AM
To: OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OCGIO@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; OASHIO Control Desk (OS/OASH) <OASHIOControlDesk@hhs.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Callahan, Kenneth (HHS/IOS) <Kenneth.Callahan@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Charrow, Robert (HHS/OGC) <Robert.Charrow@hhs.gov>
Cc: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>
Subject: RE: Quick Review: COVID-19 Anti-hoarding EO

All,

Attached is the final draft that is expected to move forward today. Any critical final edits or concerns will be sent to Staff Secretary **by 10:20 am this morning.**

From: Puesan, Cesar (HHS/OS/IOS)
Sent: Monday, March 23, 2020 12:23 AM
To: OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OCGIO@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; OASHIO Control Desk (OS/OASH) <OASHIOControlDesk@hhs.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Stannard, Paula

(HHS/IOS) <Paula.Stannard@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Kenneth Callahan (HHS/IOS) (Kenneth.Callahan@hhs.gov) <Kenneth.Callahan@hhs.gov>; Caroline White (HHS/OGC) (Caroline.White@hhs.gov) <Caroline.White@hhs.gov>

Cc: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>

Subject: RE: Quick Review: COVID-19 Anti-hoarding EO

Importance: High

All,

Please see attached for an updated EO draft. Please send any critical edits by **10am tomorrow Monday 3/23.**

From: Puesan, Cesar (HHS/OS/IOS)

Sent: Saturday, March 21, 2020 4:23 PM

To: OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; OASHIO Control Desk (OS/OASH) <OASHIOControlDesk@hhs.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>

Cc: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>

Subject: RE: Quick Review: COVID-19 Anti-hoarding EO

All,

Please see an updated draft attached, and send any critical edits or feedback by **10 AM tomorrow, March 22.**

From: Puesan, Cesar (HHS/OS/IOS)

Sent: Saturday, March 21, 2020 9:46 AM

To: OS OGC-IO ControlDesk (HHS/OS/OGC) <ControlDesk.OGCIO@hhs.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Keveney, Sean (HHS/OGC) <Sean.Keveney@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; OASHIO Control Desk (OS/OASH) <OASHIOControlDesk@hhs.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Horska, Katerina (HHS/IOS) <Katerina.Horska@hhs.gov>

Cc: Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Foster, Timothy

(OS/ASPA) <Timothy.Foster@hhs.gov>

Subject: Re: Quick Review: COVID-19 Anti-hoarding EO

Following up on this— please let me know if you have any comments or edits.

Thanks

Sent from my iPhone

On Mar 20, 2020, at 7:29 PM, Puesan, Cesar (HHS/OS/IOS) <Cesar.Puesan@hhs.gov> wrote:

All,

Attached for your quick review is a draft EO drafted by WHCO that (b)(5)

(b)(5) Affirmative clearance is requested from HHS.

Please send all comments and clearances by **9 AM tomorrow, Saturday, March 21.**

Thank you,

(b)(5)

Sender:	Stannard, Paula (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0892A057F83497E9390288C813B61D9-STANNARD, P>
Recipient:	Barry, Daniel J (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3e449ce0>; Puesan, Cesar (HHS/OS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1704b662180d4631b7b64cb17de301cd-Puesan Juar>; OS OGC-IO ControlDesk (HHS/OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c9f99a0b2364cb5bd1b739db7851e43-controldesk>; Keveney, Sean (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e13823250af4ccf93b3de562380e78e-Keveney, Se>; Chang, William (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cf70c842da144ab9bee61f353d932a0-Chang, Will>; Strom, John (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=087650d67a204508963541a6eba69ea5-Strom, John>; Hecht, Jonah (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=de0acd2f82294cd7befc09c5444f616c-Hecht, Jona>; ASPR Exec Sec (OS/ASPR) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e561b3f0bfd4331bc7c93e4419316ae-ASPRExecSec>; Kadlec, Robert (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a182eda693d040d3832bae6efcf7a255-Kadlec, Rob>; Shuy, Bryan (OS/ASPR/IO) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdeb5ca04b6b4ed19fec2209b5f571e7-Shuy, Bryan>; OASHIO Control Desk (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8407017e8889478bbd764b389bdc6ac-OASHIOContr>; Campbell, Taylor (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cca29818d7440d8a21b2c349f2e4f6a-Campbell, T>; Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Callahan, Kenneth (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e1240d1d62d49b3ba2e4e51c0920908-Callahan, K>; White, Caroline (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=755298af43a64d6c92b600e5d8b7d76a-White, Caro>; Charrow, Robert (HHS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=00531138af454ce3ac0b5885bead345f-Charrow, Ro>; Bird, Catherine (OS/OGC) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb9d9180497c49c4a06a0dd1f6043dc7-Bird, Cathe>; Agnew, Ann (HHS/IOS) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5174d56b97948d0820e90e8d8136ee5-Agnew, Ann>; Brennan, Patrick (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b51c3d9a49fd4882951eca2417c19dcf-Brennan, Pa>; Foster, Timothy (OS/ASPA) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2265a29a6468468397bae80a642620fc-Foster, Tim>
Sent Date:	2020/03/23 10:31:29
Delivered Date:	2020/03/23 10:31:30
Message Flags:	Unread

From:	Trent-Adams, Sylvia (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=650DC3276414421693345147BFAFD132-TRENT-ADAMS>
To:	Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Orsega, Susan (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8171c34a0cd4581a49f33cb8f60f684-Orsega, Sus>; Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65acd65-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcdb759f5dcad91-Schwartz, E>
CC:	Valentine, Steven (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd508090f8984b1caf04069bc6000dc2-Valentine,>; Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Subject:	RE: COVID-19 CCHQ Mission Update 22 MAR 2020
Date:	2020/03/23 10:31:45
Priority:	Normal
Type:	Note

Sir,
We will get on this right away.

Thank you,
STA

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Monday, March 23, 2020 10:26 AM
To: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>; Trent-Adams, Sylvia (HHS/OASH) <Sylvia.Trent-Adams@hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Schwartz, Erica (HHS/OASH) <Erica.Schwartz@hhs.gov>
Cc: Valentine, Steven (HHS/OASH) <Steven.Valentine@hhs.gov>; Haddad, Carla (HHS/OASH) <Carla.Haddad@hhs.gov>
Subject: RE: COVID-19 CCHQ Mission Update 22 MAR 2020

Can someone do a quick chart or just raw numbers of % of officers in agency deployed. So IHS has 139/1800 for a rate?
Just to show which agencies are taking the load.

And I assume you have me and you and DSG deployed as well

Brett P. Giroir, MD
 ADM, US Public Health Service
 Assistant Secretary for Health (ASH)
 200 Independence Avenue, SW
 Washington, DC 20201
 Office Phone: 202-690-7694

From: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Sent: Sunday, March 22, 2020 9:42 PM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Trent-Adams, Sylvia (HHS/OASH) <Sylvia.Trent-Adams@hhs.gov>; Adams, Jerome (HHS/OASH) <Jerome.Adams@hhs.gov>; Schwartz, Erica (HHS/OASH) <Erica.Schwartz@hhs.gov>
Cc: Valentine, Steven (HHS/OASH) <Steven.Valentine@hhs.gov>; Haddad, Carla (HHS/OASH) <Carla.Haddad@hhs.gov>
Subject: COVID-19 CCHQ Mission Update 22 MAR 2020

Sirs and Ma'ams

As of 22Mar2020 at 2000, **1199** Commissioned Corps have deployed.
Commissioned Corps Headquarters has deployed a total of 784 officers; 281 officers are currently deployed
77 officers are currently deployed for the Community-Based Testing Sites Initiative
****415 Agency Deployments:** ACF (8), CDC (315), CMS (3), FDA (24), IHS (3), Interior (27), NIH (22), USDA (3), VA (10)

Rear Admiral Susan M. Orsega, FNP-BC, FAAN, FAANP

Director, Commissioned Corps Headquarters
Office of the Surgeon General
United States Public Health Service
U.S. Department of Health and Human Services
1101 Wooten Parkway
Rockville, Maryland 20852
Office Phone: 240-453-6080
Cell phone: (b)(6)
Email: susan.orsega@hhs.gov

Sender:	Trent-Adams, Sylvia (HHS/OASH) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=650DC3276414421693345147BFAFD132-TRENT-ADAMS>
Recipient:	Giroir, Brett (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56fce4755704c4ca031d621b46fd6f7-Girori, Bre>; Orsega, Susan (OS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8171c34a0cd4581a49f33cb8f60f684-Orsega, Sus>; Adams, Jerome (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=184fe51f7350400b8a99dabd65ac0db5-Adams, Jero>; Schwartz, Erica (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=603e84a0e3744a5d8dcdb759f5dcad91-Schwartz, E>; Valentine, Steven (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd508090f8984b1caf04069bc6000dc2-Valentine,>; Haddad, Carla (HHS/OASH) </o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0345ed373884c068792954d8f18aa54-Haddad, Car>
Sent Date:	2020/03/23 10:31:44
Delivered Date:	2020/03/23 10:31:45
Message Flags:	Unread