Message

From: Navarro, Peter K. EOP/WHO [redacted]
Sent: 3/26/2020 7:07:20 PM
To: Polowczyk, John P RADM USN JS J4 (USA) [redacted]; Eric Edwards [redacted]
CC: Abbott, Christopher J. EOP/WHO [redacted]; Amerau, Colin C LT USN JS J4 (USA) [redacted]; Kadlec,Robert (OS/ASPR/IO) [redacted]
Subject: RE: COVID-19 Essential Medicine Briefing Update

So glad to have your support. I want to flip the switch there asap with POTUS smiling on.

From: Polowczyk, John P RADM USN JS J4 (USA) <[redacted]>
Sent: Thursday, March 26, 2020 7:06 PM
To: Navarro, Peter K. EOP/WHO <[redacted]>; Eric Edwards <[redacted]>
Cc: Abbott, Christopher J. EOP/WHO <[redacted]>; Amerau, Colin C LT USN JS J4 (USA) [redacted]; Kadlec, Robert (OS/ASPR/IO) [redacted]
Subject: Re: COVID-19 Essential Medicine Briefing Update

Sir

I talked to him today. Wow. Very important effort. I'm on it. Yes we need that contract.
Vr
John

From: "Navarro, Peter K. EOP/WHO" <[redacted]>
Date: Thursday, March 26, 2020 at 6:55:52 PM
To: "Eric Edwards" <[redacted]>, "Polowczyk, John P RADM USN JS J4 (USA)" <[redacted]>
Cc: "Abbott, Christopher J. EOP/WHO" <[redacted]>, "Amerau, Colin C LT USN JS J4 (USA)" <[redacted]>, "Kadlec, Robert (OS/ASPR/IO)" <[redacted]>
Subject: RE: COVID-19 Essential Medicine Briefing Update

Team,

Phlow needs to get greenlit as soon as humanly possible. It is a critical part of our Advanced Manufacturing strategy at WH. Please move this puppy in Trump time.

From: Eric Edwards <[redacted]>
Sent: Thursday, March 26, 2020 6:53 PM
To: John Polowczyk [redacted]
Cc: Navarro, Peter K. EOP/WHO <[redacted]>; Abbott, Christopher J. EOP/WHO <[redacted]>; Amerau, Colin C LT USN JS J4 (USA) <[redacted]>
Subject: [EXTERNAL] COVID-19 Essential Medicine Briefing Update

Rear Adm. Polowczyk

It was nice speaking with you. While we work through the HHS BARDA proposal diligence (proposal for a large BARDA contract is under review and we are answering numerous questions daily to move this forward as

fast as possible), we are working hard, in parallel, on the objective of securing the nation's most essential medicines for COVID-19. See attached for progress in just a few days as well as concerns.

Thank you,

Eric

Eric Edwards, MD, PhD
Co-Founder, President and CEO
Phlow Corp.
[redacted]
737 North 5th Street
Richmond, VA 23219
>>http://www.phlow-usa.com<<

Message

From: Abbott, Christopher J. EOP/WHO [redacted]
Sent: 5/22/2020 5:37:58 PM
To: Eric Edwards [redacted]; Frank Gupton
CC: Continenza, James V [redacted] Taber, Terry [Terry] R [redacted]
Subject: Kodak Continuous Conversion

Eric and Frank,

Thanks for the call earlier. I'm connecting you here with Jim Continenza, CEO of Kodak, and Terry Taber, Kodak's CTO and SVP for Advanced Materials. As I mentioned, we are working to get Kodak converted to making API at their existing site using continuous manufacturing practices. I know you have some technical expertise on how to convert batch facilities to continuous. Could you please work with Jim and the team to see what that conversion would take at their existing site? We are looking to have a well-fleshed out proposal back from Kodak by Wednesday, so if you could have a call with Jim and the team before then, it would be much appreciated.

Jim/ Terry, Eric is the CEO of Phlow, and Frank Gupton is the other co-founder of Phlow, as well as the genius behind their manufacturing techniques.

For all of you, I think there is also a potential for a useful partnership of having Kodak supply starting material and chemical intermediates to Phlow to use in Phlow's API manufacturing processes. Happy to help facilitate that further if there is any more we can do on that front.

Best,
Chris

Christopher Abbott
Deputy Director
Office of Trade & Manufacturing Policy
The White House
[redacted]

Message

From: Abbott, Christopher J. EOP/WHO [redacted]
Sent: 5/25/2020 9:31:35 AM
To: Eric Edwards [redacted]
Subject: Re: [EXTERNAL] Re: Kodak Continuous Conversion

Perfect

On May 25, 2020, at 8:57 AM, Eric Edwards <[redacted]> wrote:

Chris-

FYI... I am speaking with Jim tomorrow and am working to help them with the right info for a package today.

Eric

Sent from my iPhone

On May 22, 2020, at 5:38 PM, Abbott, Christopher J. EOP/WHO <[redacted]> wrote:

Eric and Frank,

Thanks for the call earlier. I'm connecting you here with Jim Continenza, CEO of Kodak, and Terry Taber, Kodak's CTO and SVP for Advanced Materials. As I mentioned, we are working to get Kodak converted to making API at their existing site using continuous manufacturing practices. I know you have some technical expertise on how to convert batch facilities to continuous. Could you please work with Jim and the team to see what that conversion would take at their existing site? We are looking to have a well-fleshed out proposal back from Kodak by Wednesday, so if you could have a call with Jim and the team before then, it would be much appreciated.

Jim/ Terry, Eric is the CEO of Phlow, and Frank Gupton is the other co-founder of Phlow, as well as the genius behind their manufacturing techniques.

For all of you, I think there is also a potential for a useful partnership of having Kodak supply starting material and chemical intermediates to Phlow to use in Phlow's API manufacturing processes. Happy to help facilitate that further if there is any more we can do on that front.

Best,
Chris

Christopher Abbott
Deputy Director
Office of Trade & Manufacturing Policy
The White House
[redacted]

June 8, 2020

Dear Dr. Edwards,

The attached draft of a non-binding LOI is intended to capture the nature of our discussions on Phlow & Kodak working together to ensure a 100% American-based manufacturing solution for KSMs and APIs for essential medicines within the United States. Kodak is committed to this goal as we know you and Phlow are as well.

It also reflects the conversations with the WH and with DFC on achieving this US-based manufacturing solution. Recently, these discussions have highlighted the necessity for Phlow and Kodak to formalize their intent with a supply agreement that enables this manufacturing solution and provides part of the basis for a DFC loan to fund Kodak's proposal. We have been asked to work with Phlow to achieve the necessary agreement(s) and this initial draft is to start that discussion and process in earnest. It is our understanding that Kodak needs to show some commitments to secure funding, and we are attempting to reflect that in this letter.

We appreciate working with Phlow and look forward to your feedback on the draft LOI.

Sincerely,

Terry R. Taber

Terry R. Taber
Kodak CTO
SVP, Advanced Materials & Chemicals
Eastman Kodak Company

LETTER OF INTENT

June 8, 2020

Phlow Corp.
737 North 5th Street, Suite 605
Richmond VA 23219
Attention: Eric Edwards, MD, PhD

Dear Dr. Edwards:

This letter confirms the preliminary, non-binding summary of mutual intentions with respect to the potential transaction described herein between Eastman Kodak Company ("Kodak") and Phlow Corp. ("Phlow"). This document, in and of itself, does not represent an enforceable legal contract.

1. **Terms**. The principal terms of the proposed transaction would be substantially as follows:

(a) **Description**.

The proposed transaction consists of a long-term supply contract (the "Supply Contract") pursuant to which Kodak will supply Phlow certain key starting materials (KSMs) and active pharmaceutical ingredients (APIs), as mutually agreed upon, from a combination of Kodak's existing facilities and newly-built facilities, to be developed using proceeds of DFC financing supported by the committed revenue stream under the Supply Contract.

The Supply Contract is intended to create full supply chain alignment through Phlow, as well as with their partner, Civica ("Civica").

Kodak—Phlow—Civica Supply Chain - Unregulated KSMs
Kodak will immediately supply certain unregulated KSMs to Phlow, as mutually agreed upon, using its existing facilities, and Phlow will use such KSMs in the manufacture of certain APIs. Phlow will provide these APIs to Civica, which will manufacture the finished drug products.

Kodak—Phlow—Civica Supply Chain - Regulated KSMs
Upon the successful completion and FDA approval of the facilities upgrade enabling Kodak to manufacture regulated KSMs, Kodak will also supply certain regulated KSMs to Phlow and Phlow will use such KSMs in the manufacture of certain APIs. Phlow will provide these APIs to Civica, which will manufacture the finished drug products.

Kodak—Civica Supply Chain (limited)– Regulated APIss

Upon the successful completion and FDA approval of the facilities upgrade enabling Kodak to manufacture APIs, Kodak may supply an API to Civica directly ONLY IF Phlow confirms it is unable to, in a reasonable time frame, manufacture that particular API in quantities sufficient to meet the demand from Civica. Phlow has right of first refusal to supply certain APIs to Civica. Phlow will provide a list of these APIs to Kodak.

Upon Kodak's construction of the federal SAPIR facility, Kodak can, (if Kodak has available capacity), store regulated KSMs and certain APIs for Phlow as a part of the United States Government SAPIR initiative. Kodak will determine the fees for such storage and monitoring of APIs and KSMs. Phlow agrees to utilize Kodak's SAPIR facility in preference to a different third party or adding more capacity itself.

.

Typical commercial terms and including warranties (including those related to the quality of the manufactured KSMs), remedies, indemnification, intellectual property, and limitations of liability will be agreed upon in the definitive agreements. Quality assurance obligations and responsibilities with respect to the KSMs will be defined in the definitive agreement.

Payment terms will be net 15-30 from date of invoice

Items will be made to order at lead time, and Phlow will accept the entire volume ordered, except in the case of material quality issues or delays in violation of agreed upon terms and/or thresholds.

Kodak and Phlow agree to a list of KSMs needed to manufacture Phlow APIs. Phlow will source a KSM exclusively from Kodak ONLY WHEN Kodak provides best available pricing for that KSM as compared to multiple other U.S.-based custom chemical/KSM providers involving similar quality and quantity of product and (a) assuming Kodak is able to timely manufacture requested KSMs according to FDA and cGMP standards and (b) Kodak declines to match such pricing..

(b) **Confidential Information**. Any Confidential Information obtained by Kodak related to the Supply Contract will be maintained by Kodak using at least the same levels of protection described in the Confidentiality Agreement executed by the parties and dated May 29, 2020 (the "Confidentiality Agreement"). The parties will cooperate to complete due diligence expeditiously.

(c) **Definitive Agreement**. All of the terms and conditions of the proposed transaction would be stated in the definitive supply agreement, to be negotiated, agreed and executed by Phlow and Kodak. Neither party intends to be bound by any oral or written statements or correspondence concerning the definitive agreement arising during the course of negotiations, notwithstanding that the same may be expressed in terms signifying a partial, preliminary or interim agreement between the parties.

(d) **Expediency**. All parties would use all reasonable efforts to complete and sign the definitive agreement on or before 60 days from the date hereof and to close the transaction as promptly as practicable thereafter.

2. **Expenses**. Phlow and Kodak will pay our respective expenses incident to this letter of intent, the definitive agreement and the transactions contemplated hereby and thereby.

3. **Public Announcements**. Neither Phlow nor Kodak will make any announcement of the proposed transaction contemplated by this letter of intent prior to the execution of the definitive supply agreement without the prior written approval of the other, which approval will not be unreasonably withheld or delayed. The foregoing shall not restrict in any respect your or our ability to communicate information concerning this letter of intent and the transactions contemplated hereby to your and our, and your and our respective affiliates', officers, directors, employees and professional advisers, and, to the extent relevant, to third parties whose consent is required in connection with the transaction contemplated by this letter of intent.

4. **Miscellaneous**. This letter shall be governed by the substantive laws of the State of Delaware without regard to conflict of law principles. This letter constitutes the entire understanding and agreement between the parties hereto and their affiliates with respect to its subject matter and supersedes all prior or contemporaneous agreements, representations, warranties and understandings of such parties (whether oral or written). No promise, inducement, representation or agreement, other than as expressly set forth herein, has been made to or by the parties hereto. This letter may be amended only by written agreement, signed by the parties to be bound by the amendment. Evidence shall be inadmissible to show agreement by and between such parties to any term or condition contrary to or in addition to the terms and conditions contained in this letter. This letter shall be construed according to its fair meaning and not strictly for or against either party.

5. **No Binding Obligation.** This letter of intent does not constitute or create, and shall not be deemed to constitute or create, any legally binding or enforceable obligation on the part of either party to this letter of intent. No such obligation shall be created, except by the execution and delivery of the definitive agreement containing such terms and conditions of the proposed transaction as shall be agreed upon by the parties, and then only in accordance with the terms and conditions of

such definitive agreement. The Confidentiality Agreement is hereby ratified and confirmed as a separate agreement between the parties thereto.

If the foregoing terms and conditions are acceptable to you, please so indicate by initialing each page and signing the enclosed copy of this letter and returning it to the attention of the undersigned.

Sincerely,

Eastman Kodak Company

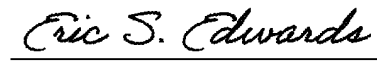
By: 

Title: Executive Chairman

Date June 15, 2020

ACCEPTED AND AGREED

Phlow Corp.

By: 

Title: Eric S. Edwards

Date June 15, 2020

Message

From: Eric Edwards [redacted]
Sent: 2/28/2020 10:04:26 AM
To: Ziegler, Garrett M. EOP/WHO [redacted]
CC: Abbott, Christopher J. EOP/WHO [redacted]
Subject: Re: FYI

Here are the slides we are sharing today- first with coronawatch team ... then more detailed info with Barda and FDA experts. Specifically – we are presenting a short term solution with immediate impact to secure the manufacturing capacity and capability for the most essential generic drugs, APIs and starting materials.... followed by a focus on the longer term, chronic issue, of bringing back our domestic generic medicine production with advanced continuous manufacturing technology that we can take a leadership position in over China with a focus on cost transparency.

https://spaces.hightail.com/receive/3hBU0LotXV

Eric
Sent from my iPhone

On Feb 28, 2020, at 9:23 AM, Ziegler, Garrett M. EOP/WHO [redacted] wrote:

Eric,

Thank you for sending. I'll make sure Peter sees this before your meeting with him. Wish I could be there; I'm going to DoD to talk about this very issue.

Regards,

Garrett

From: Eric Edwards [redacted]
Sent: Friday, February 28, 2020 5:59 AM
To: Ziegler, Garrett M. EOP/WHO [redacted]
Cc: Abbott, Christopher J. EOP/WHO [redacted]
Subject: [EXTERNAL] FYI

Garrett and Chris

Making sure you saw this as it emphasizes our focus...it emphasizes why API mfg must be brought back to US for domestic production of essential medicines, beginning with medicines at risk of shortage. We will be discussing a short term solution to respond to the coronavirus crisis today with FDA/HHS/and BARDA officials as well as the longer-term solution to deal with the chronic issue. We look forward to briefing Mr. Navarro

>http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update<

Eric

Sent from my iPhone

Message

From: Frank Gupton [redacted]
Sent: 3/31/2020 6:53:34 PM
To: Steve Hatfill [redacted]
CC: Eric Edwards [redacted]; Miller, Joanna R. EOP/WHO [redacted]
Subject: Following Up

Steve-

It was great hearing from you. We are excited and stand ready to work with HHS-BARDA on bringing advanced manufacturing, including this continuous Hydroxychloroquine process, to fruition. We are working closely with BARDA to get our proposal entitled **"Phlow Corp. Response to U.S. Based Advanced Manufacturing for COVID-19 Essential Medicines and Future Threats for BAA-18-100-SOL-00003 Amendment 14 Area of Interest #17: Advanced Manufacturing Technologies"** over the finish line and are making daily progress. They have been collaborative and are working as fast as possible We appreciate you reaching out to Rick to encourage our program and support its quick realization.

Thank you

Frank

B. Frank Gupton, PhD
Floyd D. Gottwald Chair of Pharmaceutical Engineering
Department Chair, Chemical and Life Science Engineering
Virginia Commonwealth University
601 Main Street
[redacted]
Richmond, VA 23284-9068
Phone: [redacted] Fax: [redacted]
E-mail: [redacted]

Message

From: Eric Edwards [redacted]
Sent: 2/10/2020 9:07:25 PM
To: Ziegler, Garrett M. EOP/WHO [redacted]
Subject: Re: BARDA

Thx

Eric

Eric Edwards, MD, PhD
Co-Founder, President and CEO
Phlow Corporation
[redacted]
2093 PHILADELPHIA PIKE #7075
Claymont, DE 19703
http://www.phlow-usa.com

On Feb 10, 2020, at 3:00 PM, Ziegler, Garrett M. EOP/WHO [redacted] wrote:

Move forward with it. I think it'd help. Mention that you spoke with us. And afterwards, please give me a readout and any POCs that you think it'd be helpful for me to reach out to.

Thanks,

Garrett

From: Eric Edwards [redacted]
Sent: Monday, February 10, 2020 2:01 PM
To: Ziegler, Garrett M. EOP/WHO [redacted]
Subject: [EXTERNAL] BARDA

Garrett-

We were previously on requesting a meeting with BARDA through their Techwatch program. Would you advise that we hold off on this or go ahead and move forward with this parallel USG work stream?

Thanks

Eric

Eric Edwards, MD, PhD
Co-Founder, President and CEO
Phlow Corporation
[redacted]
2093 PHILADELPHIA PIKE #7075
Claymont, DE 19703
>http://www.phlow-usa.com<

Message

From: Ziegler, Garrett M. EOP/WHO [redacted]
Sent: 2/26/2020 10:56:49 AM
To: Eric Edwards [redacted]
Subject: RE: [EXTERNAL] FYI

Just tried to call you. Call back whenever you're free.

-----Original Message-----
From: Eric Edwards [redacted]
Sent: Wednesday, February 26, 2020 9:55 AM
To: Ziegler, Garrett M. EOP/WHO [redacted]
Subject: Re: [EXTERNAL] FYI

1pm HHS...have not been provided the exact location but believe it is where they conduct TechWatch meetings at BARDA. Do you know how much in the supplemental was appropriated to BARDA for advanced pharmaceutical manufacturing to secure our domestic API industrial base?

Is your office coordinating with Rick Bright and BARDA on needs?

We just want to make sure we are aligned on messaging and goals going into Friday' s mtg

Thanks

Eric

Sent from my iPhone, apologies for any errors in spelling or grammar

> On Feb 26, 2020, at 9:52 AM, Ziegler, Garrett M. EOP/WHO [redacted] wrote:
>
> Eric, good news. What time and where?
>
> -----Original Message-----
> From: Eric Edwards [redacted]
> Sent: Tuesday, February 25, 2020 5:51 PM
> To: Ziegler, Garrett M. EOP/WHO [redacted]
> Subject: [EXTERNAL] FYI
>
> We have been invited to meet with BARDA on Friday
>
> Eric
>
> Sent from my iPhone, apologies for any errors in spelling or grammar

Message

From: Navarro, Peter K. EOP/WHO [redacted]
Sent: 3/20/2020 6:10:48 PM
To: Eric Edwards [redacted]; Bright, Rick (OS/ASPR/BARDA) [redacted]; Kadlec, Robert (OS/ASPR/IO) [redacted]
CC: Abbott, Christopher J. EOP/WHO [redacted]; McCormack, Brian V. EOP/OMB [redacted]
Subject: RE: [EXTERNAL] Phlow Corp Proposal

Rick, Bob,

My head is going to explode if this contract does not get immediately approved. This is a travesty.

I need PHLOW noticed by Monday morning. This is being screwed up.

Let's move this now. We need to flip the switch and they can't move until you do. FULL funding as we discussed.

Navarro

From: Eric Edwards [redacted]
Sent: Friday, March 20, 2020 5:50 PM
To: Navarro, Peter K. EOP/WHO [redacted]
Cc: Abbott, Christopher J. EOP/WHO [redacted]
Subject: [EXTERNAL] Phlow Corp Proposal

Mr. Navarro

I am writing to confirm that the proposal entitled "U.S. – Based Advanced Manufacturing for COVID-19 Essential Medicines and Future Threats" for consideration under BARDA's BAA-18-100-SOL-00003, Area of Interest #17: Advanced Manufacturing Technologies was successfully submitted on Wednesday at 1130pm. With BARDA confirming receipt shortly thereafter. See attached Transmittal letter. This was a monumental achievement involving the work of so many in record time.

Although we have yet to hear from HHS- BARDA, we stand ready once we receive notice on an award decision to immediately procure and begin the manufacturing of key Essential Medicines and their Ingredients needed to help with the COVID-19 Response. We appreciate the opportunity to have HHS-BARDA review this proposal as we work to help in the near term while, in parallel, re-securing this critical manufacturing industrial base on US Soil.

Warm regards,

Eric

Message

From: Ziegler, Garrett M. EOP/WHO [redacted]
Sent: 2/3/2020 12:32:13 PM
To: Eric Edwards [redacted]
CC: Rosemary Gibson [redacted]
Subject: RE: Agenda for Saturday

Dr Edwards,

Could you re-send the agenda in a PDF format? It didn't go through.

Very excited for Saturday.

From: Eric Edwards [redacted]
Sent: Monday, February 3, 2020 12:05 PM
To: Ziegler, Garrett M. EOP/WHO [redacted]
Cc: Rosemary Gibson [redacted] Dr. Eric S. Edwards, MD, PhD [redacted]
Subject: [EXTERNAL] Agenda for Saturday

Garrett-

We wanted to make sure we are planning appropriately for Saturday's meeting. Our thinking is that your team would want an overview of the organization and partnering entities, a tour of the R&D facility as well as proposed site for standing up a highly secure, domestic API manufacturing facility, discussion of phasing and costs, as well as discussion on the proposed model here for moving forward with the US Government. The overall proposed goal here is to assess how we would propose securing the industrial base of our Nation's most essential and critical medicines as well as active pharmaceutical ingredients.

Do you agree or have other thoughts here?

We want to make this as productive as possible. In addition to Rosemary and myself, we will have leadership from Ampac, Medicines for All, VCU Chemical Engineering, and Civica Rx. I will explain how we are proposing to build out this advanced capability and integrated supply chain with a single US-based API manufacturing entity that has been incorporated to strategically take the lead.

Thanks

Eric

Eric Edwards, MD, PhD
Co-Founder, President and CEO
Phlow Corporation
[redacted]
2093 PHILADELPHIA PIKE #7075
Claymont, DE 19703
>http://www.phlow-usa.com<

Message

From: Abbott, Christopher J. EOP/WHO [redacted]
Sent: 3/2/2020 9:51:11 AM
To: Eric Edwards [redacted]
Subject: Fwd: Memo
Attachments: 01 Memo to Potus 2.0.docx; ATT00001.htm

Sent from my iPhone

Christopher Abbott
Associate Director
Office of Trade and Manufacturing Policy
The White House
[redacted]

Begin forwarded message:

From: "Ziegler, Garrett M. EOP/WHO" [redacted]
Date: March 2, 2020 at 9:44:21 AM EST
To: "Abbott, Christopher J. EOP/WHO" [redacted]
Subject: Memo

This is what Peter sent although, as you can see, there is a lot of proprietary stuff in here. I defer to you on what you cut out so you can send a revised version to Eric.

Garrett

Garrett Ziegler
[redacted]

3.1.20

MEMORANDUM TO THE PRESIDENT
THROUGH NSA O'BRIEN
FROM PETER NAVARRO
RE: MOVE IN 'TRUMP TIME' TO STAY AHEAD OF VIRUS CURVE

Since the first news from China of a viral epidemic, I forecast a *significant* global pandemic. Since that time, my focus has been on:

1. Ensuring sufficient *personal protective gear* such as N95 masks;
2. Rapidly developing a diverse set of *treatment options*
3. Cutting *vaccine development* time in half;
4. Procuring adequate *diagnostics* such as test kits and point of care devices
5. Bringing home our globalized Essential Medicine supply chains

Over the last month, I have presented the Task Force with action memos to combat the virus swiftly in "Trump Time," but movement has been slow.

There is NO downside risk to taking swift actions as an insurance policy against what may be a very serious public health emergency. If the COVID-19 crisis quickly recedes, the only thing we will have been guilty of is prudence.

This memo recommends the following **actions**. In some cases, there is already SOME movement BUT the movement is NOT fast enough.

- Industrial Mobilization of Supply Chains
- Mobilize Point-of-Care Diagnostics
- Expedite Oral Antiviral Effort
- Fast-Track Athersys and Celularity as Fourth and Fifth Treatment Options
- Bootstrap Regeneron's COVID-19 Capabilities
- **"Manhattan Project" for Advanced Manufacturing to Bring Production Onshore**

To ensure these (and additional) recommendations are implemented swiftly, I further recommend setting up a SMALL rapid response team (e.g., VPOTUS, RSA, Birkes, Kushner, Pottinger, Navarro) empowered to swiftly move such recommendations.

Approximately 30 essential generic medicines are needed to treat COVID-19 patients who become ill, are hospitalized, or are admitted to intensive care (See Appendix 1). Eleven of these include Active Pharmaceuticals Ingredients (API) that are only available from foreign suppliers, many in countries seeking to contain their own COVID-19 emergencies. Additionally, nearly all of the chemical precursors used to make the API, including precursors to manufacturing fluoroquinolone antibiotics such as ciprofloxacin, foreign-sourced, especially from China.

Accordingly, our supply chains remain extremely vulnerable; and it is urgent to immediately re-secure and mobilize our Public Health Industrial Base.

Recommendations

- Direct FDA and CDC to immediately identify the projected numbers of drug requirements by dosage form and strength based on moderate and severe COVID-19 epidemiological models for each of the necessary COVID-19 medications listed in Appendix 1.
- Direct FDA to require any current manufacturer of generic medicines to list which country makes the API and which country completes final formulation and manufacturing of the finished drug product.
- Direct VA, HHS, CDC, and Commerce to identify current hospital system, wholesaler, manufacturer, pharmaceutical, and agricultural inventory levels and surge production capacity of essential generic medicines listed in Appendix 1.
- Direct COVID-19 Supply Chain Working Group to immediately begin identifying all available Chemical Precursors and API sources for Appendix 1. Bolster and secure manufacturing capacity for essential generic medicines required for COVID-19 related illnesses.
- Direct HHS to determine a strategy among relevant buyers (including DOD, VA, and state governments) to immediately procure the generic medicines and starting materials that are unable to be manufactured in the US. This should include all Beta Lactams antibiotics used to treat COVID-19 related illnesses, any critical fluorinated starting material compounds such as those used to make Midazolam and Ciprofloxacin, and relevant opioids, including codeine.

Mobilize Hand-Held, Point-of-Care Diagnostics

People and their health care providers need to know who is infected. Currently, all diagnostics for COVID-19 are housed in public health laboratories; and it simply takes too long for patients to get results. We need a more rapid, hand-held point of care diagnostic test that can be used by less skilled medical personnel in more accessible facilities (doctor office, pharmacy, urgent care center).

Point-of-care, hand-held devices should be able to identify when a person is actively infected with nCoV and when they have safely cleared the virus and are no longer infectious. These front line diagnostics will dramatically reduce the time between diagnosis, care, and treatment. In addition, they will aid in earlier release of patients from hospital care to free limited resources.

HHS, through Biomedical Advanced Research and Development Authority (BARDA), has recently identified three technologies to expedite for development: (1) MesaBiotech; (2) Visby Medical/Click Diagnostics; and 3) Hound Labs Breathalyzer. We need to mobilize these resources immediately. They can be out in the field within 3-4 months (and possibly faster) if the following recommendations are adopted:

Recommendations

- Provide additional funding of $250 M if not already in the proposed Supplemental funding bill for HHS to accelerate the development
- Direct HHS to expedite the contracting process to immediately award contracts for development of POC diagnostics when supplemental funding available
- Direct HHS FDA to prioritize and streamline the regulatory pathway and reviews of POC diagnostics for COVID-19
- Direct HHS to prioritize the distribution of limited clinical specimens, reagents, etc. to USG contracted developers to expedite the development and delivery of medical countermeasures for COVID-19
- Prioritize development of tests that are produced in the US and rely on US-based raw materials – current technologies are located primarily offshore and pose a risk regarding accessibility

Expedite Oral Antiviral Effort

The only possible drug we have now to treat COVID-19 is REMDESIVIR. Because it must be administered intravenously, our hospitals, urgent care clinics, and other units of our healthcare system will be quickly overwhelmed if large numbers need to be treated.

This observation militates for the development of a small molecule antiviral drug delivered orally. This can be used to treat people in early stages of infection, reduce severe illness and thereby reduce the need for large numbers to enter the hospital system.

Prophylactic therapeutics, such as monoclonal antibodies can provide protection to high risk groups, including healthcare workers and emergency response workforce in absence of a vaccine. This work needs to be expedited!

The following recommendations closely track those I made for development of a vaccine. We need to do this for an oral antiviral. This process will also help strengthen the domestic supply chain.

Recommendations

- Direct HHS to further expedite the high-throughput screening of drugs from industry partners to identify drugs for activity against the nCoV.
- Direct HHS to further prioritize companies and labs under USG contract to receive virus and materials immediately to establish the screening assays to start screening immediately. (There may be a drug already available)
- Work closely with HHS and FDA to identify critical pathways to implement US-based advanced manufacturing development for human use.

In addition, WH/OMB should support HHS request for $1.9 billion for therapeutics and oral antivirals.

Fast Track Athersys and Celularity for Fourth and Fifth Treatment Options

We are moving forward with three possible treatment options: (1) Gilead's REMDESIVIR, (2) oral antivirals, and (3) Regeneron's monoclonal antibodies. A fourth treatment from Celularity appears to be worthy of the same kind of fast-tracking and support we are offering the above three options.

Celularity's CYNK-100 is an off-the-shelf, allogeneic that uses anti-tumor "attack cell" therapy under 3 open INDs. It has an excellent safety profile in 25 cancer patients and appears to have putative clinical benefits.

Athersys has developed off-the-shelf regenerative medicine technology to address multiple areas of critical care medicine. They currently have an FDA Fast Track designation for their stem cell medicine to treat Acute Respiratory Distress Syndrome (ARDS). The Athersys technology is relevant to COVID-19 and other emergent pathogens that include severe pulmonary inflammation and ARDS following infection.

Recommendations

- Direct HHS to prioritize review of Athersys and Celularity in the ongoing NIH-lead RCT for treatment of COVID-19.
- Direct FDA to expedite review of Celularity's IND 19650 Phase I/II Study and allow Celularity to modify dose level, frequency and interval. This will reduce the approval time from 30-60 days to as little as 3-4 days.
- Direct HHS to assist Celularity in gaining access to current COVID-19 sites within the US and overseas so it can engage with clinical investigators and conduct its trial.
- Provide up to $2.5 million in financial support to Celularity to offset the expense of the clinical trial and additional funds to allow for a prompt scale-up in production.
- Direct HHS to provide funding to Athersys to support expediting the Phase 3 study for ARDS.
- Direct HHS to support the scale up of the domestic production capacity for the Athersys MultiStem technology.

Bootstrap Regeneron's COVID-19 Capabilities

Regeneron's monoclonal antibody therapies are safe and effective for a number of therapeutic targets, including seven approved medicines for dermatitis, asthma, skin cancer and macular degeneration; and Regeneron's rapid antibody discovery platform was demonstrated against infectious diseases in the recent Ebola outbreak.

In the absence of a vaccine, which is many months away, Regeneron's antibodies should be expedited for development and evaluation for use as a prophylactic treatment. This approach would provide protection against COVID-19 infection for healthcare workers and prioritized emergency and critical infrastructure personnel.

Regeneron has already initiated intensive efforts to leverage its proprietary technologies and expertise to develop multiple monoclonal antibodies that, individually or in combination, may be used for short term prophylaxis and/or treatment against the emerging coronavirus.

Regeneron's VelocImmune® mice have already been immunized with the viral targets and have begun to produce antibodies against this virus. Within a few weeks, the VelociMab® technologies will be employed to allow for an unprecedented rapid transition to full scale manufacturing of these antibodies, so that the emerging threat can be met in a useful timeframe.

Regeneron plans to combine the two best antibodies it obtains – from either source – to create an "antibody cocktail" to increase efficacy, potency, neutralization, and to minimize chance of viral escape.

Recommendations

- Direct FDA to immediately expedite review of the Regeneron Ebola BLA submission. This will provide confidence on the end-to-end platform of technologies to deliver a monoclonal treatment for emerging infectious disease threats.
- Direct HHS BARDA to further expedite all contractual agreements and timelines for production, scale-up, and clinical evaluation of the Regeneron antibodies for both prophylactic and treatment options
- Direct HHS FDA and NIH to collaborate closely with Regeneron for Fast Track evaluation of their COVID-19 antibodies.
- NIH should be directed to expedite review process to include Regeneron monoclonal antibodies in their adaptive clinical trial as soon as antibodies are ready.

"Manhattan Project" for Advanced Manufacturing to Bring Production Onshore

US-based manufacturing capabilities for our most essential medicines and their Active Pharmaceutical Ingredients (API) have been critically depleted over the last several decades due to the globalization of the industry. Currently, over 85% of APIs and precursor chemical ingredients for generic medicines come from foreign supplies, primarily China.

It is a matter of economic and national security to rebuild our domestic API and pharmaceutical manufacturing industrial base. The fastest and most efficient way to do so is with continuous Advanced Manufacturing technology. This cutting edge technology is more efficient, higher quality, safer, and less costly than the methods used in China and other foreign countries and thus will allow the U.S. to become globally competitive.

Phlow is a public benefit corporation working in partnership with CivicaRx, AMPAC, and Virginia Commonwealth University to secure a manufacturing site in Petersburg, Virginia. This partnership would allow for large-scale, low-cost, reliable end-to-end production using continuous pharmaceutical manufacturing technology that can meet domestic needs for the COVID-19 outbreak while addressing longer term supply chain vulnerabilities.

HHS' BARDA is working closely with Phlow and should be strongly encouraged to immediately launch this initiative. The partnership can be up and running within 30 days and produce its first shipments of essential generic medicines within weeks.

Recommendation

- Direct HHS BARDA to immediately provide $300 million in funding to establish a public-private partnership with Phlow to accelerate domestic advanced and continuous manufacturing capabilities, as well as the infrastructure necessary to re-secure the manufacturing of APIs for essential generic medicines in the US. **This is our BEST shot for near term implementation.**

Appendix 1

Essential Drugs Needed to Treat COVID-19	
Crystalloid I.V.	
Dextrose 5% Water	Ringers
Normal Saline	
Bronchodilator	
Isoproterenol	
Salbutanol Liquid	
Sedation & Induction	
Atropine	Propofol
Fentanyl Injection	Rucoronium Injection
Ketamine Injection	Suxamethonium
Midazolam	
Anti-hypertensive	
Diltiazem Injection	Labetolol Injection
Esmolol Injection	
Pressor Agents	
Norepinephrine Injection	*Phenylephrine*
Antibiotics	
Azithromycin	Vancomycin
Ciprofloxacin	*Piperacillin*
Ceftriaxone	
Pseudonomas Coverage	
Meropenem	Zosyn
General Medications	
Acetaminophen	*Guaifenesin Capsules*
Codeine	Lidocaine Injection
Renal Support	
Bicarbonate Injection	Furosemide Injection

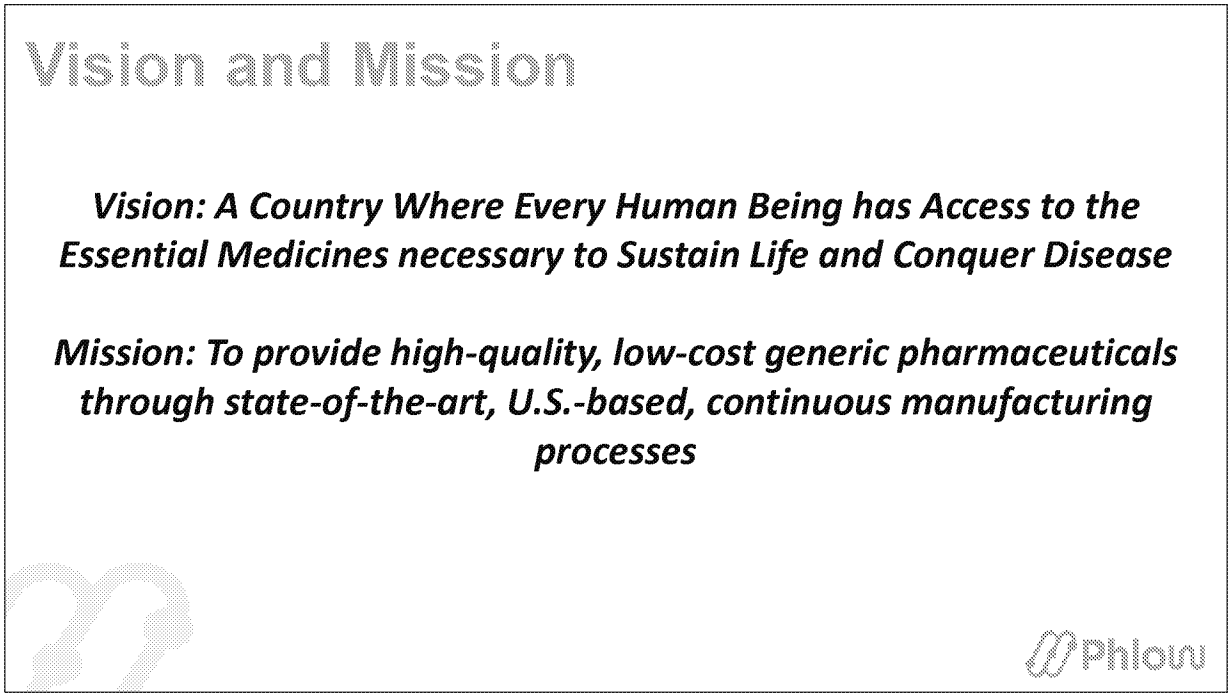
Items in Red are completely dependent on Foreign Sources
Items *italicized* are already on the FDA Drug Shortage List

Message

From: Eric Edwards [redacted]
Sent: 2/28/2020 3:43:30 PM
To: Peter Navarro [redacted]
Subject: One more time
Attachments: BARDA FDA SME Pres.pptx; smime.p7s

Advanced Manufacturing of Active Pharmaceutical Ingredients (API) And Generic Medicines Essential for the Nation's Health Security

Phlow



To provide high-quality, low-cost generic pharmaceuticals through state-of-the-art, U.S.-based, continuous manufacturing processes

Strategic API Reserve "SAPIR"?

- We will begin stockpiling essential Precursor Ingredients and API immediately
- Current Strategic National Stockpile includes Finished Dosage Forms Only…with much shorter expiry
- Would provide an insurance policy against potential future interruptions in the U.S. Active Pharmaceutical Ingredient Supply chain, whether originating from international supply problems, hurricanes, infectious disease epidemics, accidents or terrorist activities.
- A release of API from the SAPIR could mitigate potential economic damage of an actual disruption in the domestic pharmaceutical ingredient supply chain as well as mitigate the likely accompanying price increases of medicines the US relies upon

Phlow

How Would This Work?

Phlow Corporation would:

- Contract with Medicines for All as the CRO to handle R&D/Process Development for Continuous Manufacturing of certain strategic APIs
- Complete the infrastructure build, leveraging existing engineering plans for a dedicated continuous manufacturing facility, on the Virginia site
- Partner with AMPAC for additional capacity for raw material and API production
- Sub-contract with Civica to build a Finished dosage form facility on the Petersburg Site
- Operationalize the SAPIR on the 300 acre Virginia site
- Leverage the VCU Center for Pharmaceutical Engineering and Sciences for workforce training and development

Phlow

Timing and Estimated Costs

- To Do this Well and Serve the Needs of the USG – the estimate is $300M

- $100M for Securing API and finished dosage form manufacturing capacity in the US with dedicated teams, SAPIR development and distribution operation (12-18 months, but Civica will ramp up manufacturing **immediately** for certain medications)

- $50M to provide feasibility, process development, construction planning, and a Kilo Lab build with cGMP operations and FDA registration with goal of delivering first US Government identified product using advanced, continuous manufacturing process (18-24 months)

- $150M for a Full-scale Commercial cGMP API Advanced Continuous Manufacturing Capability and adjacent Finished Goods facility (36 - 48 months)

- Understanding government customer needs in the short term, including begin able to assess volume requirements and technical feasibility is critical to planning
- Coordination with FDA (e.g. Pre-approval inspections) is critical for expediting timing
- Long-term supply agreements with full price transparency is critical for sustainability

Phlow

Phasing:

AMPAC: CMO in Virginia can get to work...we will qualify suppliers in Western
They will install continuous where it makes sense....hybrid continuous/

Unprintable Digital Signature

Message

From: Andrew Stiles [redacted]
Sent: 4/4/2020 9:33:01 AM
To: Eric Edwards [redacted]
CC: Alan Taggart
Subject: EMAIL to Send BARDA

Eric - I would suggest sending this email out today. You have a better pulse on the dynamics behind the scenes so edit accordingly. This will not only help put further pressure on contracting office to get this award finalized and makes Phlow look proactive, but will also document the underlying assumptions of our indirect rate calculations in the event BARDA does not eventually come through with the entire $200M infrastructure investment (this is absolutely critical to mitigate Phlow's financial risk). It also allows Rick to appear in control, and makes Mark Kim look good.....all important as well.

Navarro's "if your contracting people mess this up, you're fired" email to Rick and Kadlec several weeks ago was a big deal. CC'ing Navarro cranks up the pressure.

Give me a call anytime if you want to discuss.

To: Rick Bright & Mike
CC: Mark Kim, James Harris, Navarro, Alan

Subject: Phlow Contract - Expected Order Volume?

Hi Rick & Mike,

Mark Kim is our BARDA Auditor. He is doing a fantastic job and we are close to getting things wrapped up on that end. However, he cannot finalize our indirect rates for contract award without a reasonable estimate of business activity expected under this IDIQ contract for the next 2 years.

Phlow's G&A rate is equal to the company's operating expenses divided by the total direct cost activity of this potential program:

Example 1:	*Example 2:*	*Example 3:*
$\text{G\&A\%} = \frac{\text{Phlow Operating \& Administrative Expenses}}{\text{Total Direct Costs}}$	$20\% = \frac{\$20,000,000}{\$100,000,000}$	$40\% = \frac{\$20,000,000}{\$50,000,000}$

As you can see in the above examples, Phlow's G&A rate will be strongly correlated with the volume of business activity resulting from Task Orders executed under this program.

The current IDIQ contract proposed by BARDA only includes a guaranteed minimum order of $50k.

Phlow's initial OTA proposal included a base period with the following critical infrastructure builds over the next 2 years to establish U.S.-based advanced continuous manufacturing capabilities for COVID-19 essential medicines:

Critical Build	Description	Direct Cost
Fill Finish Facility	Will allow production of drug product in a GMP Fill Finish facility in Virginia	[redacted]
Kilo Lab	Will allow BARDA to optimize and scale up Advanced Manufacturing processes	[redacted]
S5 Facility & Production	Will allow rapid production of bulk API for COVID-19 essential medications.	[redacted]
SAPIR Facility	Will store more than a years worth of 100 APIs for essential medicines for emergencies	[redacted]
Hybrid Manufacturing Facility	Will allow the Advanced Manufacturing for emergency response APIs.	[redacted]
Total		***$196,194,062***

Will you please confirm if it is BARDA's intention to move forward with all critical infrastructure builds listed above? And if not all, then which ones?

The answer to this will allow us to accurately calculate Phlow's provisional indirect rates for inclusion in the contract.

Thanks a lot for your continued efforts to get this program in place. We are excited to be working collaboratively together at BARDA's direction to save lives and strengthen our national security.

Andrew Stiles
Managing Director
Industry Specialty Services -
Biodefense & Government Contracts
[redacted]

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