

Subject: talkers for the Reckitt conversation

Date: 2022/07/21 15:46:27

Priority: Normal

Type: Note

(b)(5)

(b)(5)



Sent Date: 2022/07/21 15:18:57

Delivered Date: 2022/07/21 15:46:27

Message Flags: Unread Unsent

Yiannas, Frank (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=30587673b40d4fc8be62a6af700889e4-frank.yiann
(b)(6)
To: Buckner, Rebecca J (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6e04ae770cbb41ee967dda356e864d29-rebecca.buc
(b)(6)
Colonius, Tristan (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=43769a3f24954a2f96df0578ebc4ca12-tristan.col
(b)(6)
Fristedt, Andi (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group
CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9f53d20d2ec49188eb5c2959ceedd8a-andi.friste
(b)(6)
Wolff, Kate (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f31d33a2e743b4a1b6e9797827008d-Wolff, Kate
<Kate.Wolff@hhs.gov>

Subject: FW: Follow-Up Meeting This Evening

Date: 2022/09/11 15:35:18

Priority: Normal

Type: Note

FDA friends, any idea what this is about?

From: Erickson, Audrae <Audrae.Erickson@reckitt.com>

Sent: Sunday, September 11, 2022 1:22 PM

To: Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Yiannas, Frank (FDA/OC)

(b)(6) Buckner, Rebecca J (FDA/CFSAN) (b)(6)

Cc: Newkirk, Ryan (FDA/CFSAN) (b)(6) Sprow, Kyle (OS/ASPR/SPPR)

<Kyle.Spro@hhs.gov>

Subject: Follow-Up Meeting This Evening

Dear Stephen, Frank, Rebecca &HHS/FDA team,

We would like to respectfully request a follow up meeting this evening, if possible, concerning the topic we discussed late Friday afternoon. Attendees will be:

Robert Cleveland, SVP Nutrition, N. America &Europe
Alex Grillet, SVP Supply, Nutrition
Art Pike, Global Manufacturing Footprint Director
Audrae Erickson, VP Global External &Public Affairs

Please let us know if you would be available to meet this evening at 6:00pm or 8:30pm, both Eastern times. Thank you for sending a Zoom invite for your preferred time for the call.

Kind regards,

Audrae



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NOTICE

P Please Consider the Environment before printing this Email

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Yiannas, Frank (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=30587673b40d4fc8be62a6af700889e4-frank.yiann
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Recipient: Colonius, Tristan (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group
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Wolff, Kate (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f31d33a2e743b4a1b6e9797827008d-Wolff, Kate
<Kate.Wolff@hhs.gov>

Sent Date: 2022/09/11 15:35:25

Delivered Date: 2022/09/11 15:35:18

Message Flags: Unread Unsent

From: Cha, Stephen (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23E67977D77947D69BAF2ACE846821A8-CHA, STEPHE>
To: Orozco, Esmeralda (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b0828fef0414c538c6def9f15bbb6c1-Orozco, Esm <Esmeralda.Orozco@hhs.gov>
Palafox, Cynthia (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc909aa52772499d9b0aa2d3b88ea6eb-Palafox, Cy <Cynthia.Palafox@hhs.gov>;
CC: Czerwinski, William (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07599aa9156047509ca85594140caa82-Czerwinski, <William.Czerwinski@hhs.gov>
Subject: RE: MEETING WITH THE RECKETT CEO LAXMAN NARASIMHAN
Date: 2022/07/21 22:12:00
Priority: Normal
Type: Note

Yes, I think that makes sense.

From: Orozco, Esmeralda (HHS/IOS) <Esmeralda.Orozco@hhs.gov>
Sent: Thursday, July 21, 2022 9:35 PM
To: Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>
Cc: Palafox, Cynthia (HHS/IOS) <Cynthia.Palafox@hhs.gov>; Czerwinski, William (OS/IOS) <William.Czerwinski@hhs.gov>
Subject: Re: MEETING WITH THE RECKETT CEO LAXMAN NARASIMHAN

Great, we have let USDA know. Ok with keeping the Reckitt team with +2? See below.

Mr. Laxman Narasimhan, Chief Executive Officer, Mr. Pat Sly, Global President Nutrition, and Mr. Robert Cleveland, SVP Nutrition, N. America and Europe

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From: Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>
Sent: Thursday, July 21, 2022 8:46:09 PM
To: Orozco, Esmeralda (HHS/IOS) <Esmeralda.Orozco@hhs.gov>; Mccluskie, Sean (HHS/IOS) <Sean.Mccluskie@hhs.gov>; Ramirez, Angela (HHS/IOS) <Angela.Ramirez@hhs.gov>;
(b)(6) (b)(6) Tierney, Julia (FDA/OC) (b)(6)
Colonius, Tristan (FDA/CFSAN) <Tristan.Colonius@fda.hhs.gov>; Palafox, Cynthia (HHS/IOS) <Cynthia.Palafox@hhs.gov>
Cc: Sheehy, Janice (FDA/ORA) (b)(6)
Subject: RE: MEETING WITH THE RECKETT CEO LAXMAN NARASIMHAN

Hi all—so we've been requested to keep this tighter—so maybe principals plus 1 on this one?

IOS: S1 plus me

FDA: RC plus Julie (I assume, let us know)?

Apologies to rest!!!

-----Original Appointment-----

From: OS Scheduling (HHS/OS) <scheduling@hhs.gov>

Sent: Thursday, July 21, 2022 6:17 PM

To: OS Scheduling (HHS/OS); OS Scheduling (HHS/OS); Mccluskie, Sean (HHS/IOS); Ramirez, Angela (HHS/IOS); Cha, Stephen (HHS/IOS); (b)(6); Tierney, Julia (FDA/OC); Colonius, Tristan (FDA/CFSAN)

Cc: Sheehy, Janice (FDA/ORA)

Subject: MEETING WITH THE RECKETT CEO LAXMAN NARASIMHAN

When: Friday, July 22, 2022 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US &Canada).

Where:

Esmeralda Orozco is inviting you to a scheduled ZoomGov meeting.

Topic: RECKITT/HH5/USDA/FDA

Time: Jul 22, 2022 08:30 AM Eastern Time (US and Canada)

Join ZoomGov Meeting

(b)(6)

Meeting ID: (b)(6)

Passcode: (b)(6)

One tap mobile

(b)(6)

US (San Jose)

US (New York)

Dial by your location

(b)(6)

US (San Jose)

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US

US (San Jose)

Meeting ID: (b)(6)

Find your local number: (b)(6)

Join by SIP

(b)(6)

Join by (b)(6)

(b)(6)

US West)

US East)

Meeting ID: (b)(6)

Passcode: (b)(6)

Sender: Cha, Stephen (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23E67977D77947D69BAF2ACE846821A8-CHA, STEPHE>

Orozco, Esmeralda (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1b0828fef0414c538c6def9f15bbb6c1-Orozco, Esm
<Esmeralda.Orozco@hhs.gov>;

Palafox, Cynthia (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group

Recipient: (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc909aa52772499d9b0aa2d3b88ea6eb-Palafox, Cy
<Cynthia.Palafox@hhs.gov>;

Czerwinski, William (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=07599aa9156047509ca85594140caa82-Czerwinski,
<William.Czerwinski@hhs.gov>

Sent Date: 2022/07/21 22:12:21

Delivered Date: 2022/07/21 22:12:00

From: Cha, Stephen (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23E67977D77947D69BAF2ACE846821A8-CHA, STEPHE>
Fristedt, Andi (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9f53d20d2ec49188eb5c2959ceedd8a-andi.friste (b)(6)
To: Tierney, Julia (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=367e11c5deec4593ac4dc9b66d0a2e15-julia.tiern (b)(6)
Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group
CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>
Subject: FW: Meeting Request: Exela Pharma Research CEO Phanesh Koneru
Date: 2023/06/06 11:14:00
Priority: Normal
Type: Note

Sounds like they are talking to FDA—but not clear what recent communications have been—can we send them back to you?

From: Ramirez, Angela (HHS/IOS) <Angela.Ramirez@hhs.gov>
Sent: Tuesday, June 6, 2023 9:51 AM
To: Figueroa, Marvin (HHS/IEA) <Marvin.Figueroa@hhs.gov>; Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Kaplun, Brian (HHS/IOS) <Brian.Kaplun@hhs.gov>
Cc: Adesina, Adeola (OS/IEA) <Adeola.Adesina@hhs.gov>; Despres, Sarah (HHS/IOS) <Sarah.Despres@hhs.gov>; Rangel, Isabel (HHS/IOS) <Isabel.Rangel@hhs.gov>
Subject: RE: Meeting Request: Exela Pharma Research CEO Phanesh Koneru

Apologies if I missed a response—but circling back on this. Any steer on where to send them?

From: Ramirez, Angela (HHS/IOS)
Sent: Thursday, June 1, 2023 5:15 PM
To: Figueroa, Marvin (HHS/IEA) <Marvin.Figueroa@hhs.gov>; Cha, Stephen (HHS/IOS) <Stephen.Cha@hhs.gov>; Kaplun, Brian (HHS/IOS) <Brian.Kaplun@hhs.gov>
Cc: Adesina, Adeola (OS/IEA) <Adeola.Adesina@hhs.gov>; Despres, Sarah (HHS/IOS) <Sarah.Despres@hhs.gov>; Rangel, Isabel (HHS/IOS) <Isabel.Rangel@hhs.gov>
Subject: FW: Meeting Request: Exela Pharma Research CEO Phanesh Koneru

Thoughts on the best person to connect them with?

From: Darren Peters <dpeters@peterdamongroup.com>
Sent: Thursday, June 1, 2023 11:47 AM
To: Ramirez, Angela (HHS/IOS) <Angela.Ramirez@hhs.gov>
Subject: Meeting Request: Exela Pharma Research CEO Phanesh Koneru

Angela,

Good afternoon. I hope all is well with you.

I am working with Exela Pharma Sciences, an award winning injectable research, development, and manufacturing company located in Lenoir, North Carolina. I would like to request a meeting with you and the founder, president and CEO of Exela Pharma Services, Phanesh Koneru, to discuss a serious health public concern affecting preterm babies and adults with compromised liver and kidney functions.

Some background:

The FDA in 200 published a final rule establishing a safe level of aluminum exposure of no more than 4-5 micrograms/kg/day and asked drug manufacturers to reduce aluminum levels in parenteral nutrition (PN) products. Exela and a few other manufacturers were successful in reducing their levels based on the FDA rule.

Exela and some others have learned that the FDA has been approving products with higher aluminum levels for these same drug products in the past few years. After Exela contacted FDA about their approval of an ANDA product with much higher aluminum levels than what has been determined by FDA to be unsafe, the FDA issued on April 27, 2023 a temporary stay against the ANDA launch which is expected to last about 4-12 weeks. Exela and other groups are concerned that FDA may lift the stay.

Some public awareness is increasing on this issue. We have been made aware that a coalition letter has been written that includes these organizations: ASPIRA Association, Center for Black Equity, Health Equity Collaborative, MANA Action Fund, National Hispanic Medical Association, Partnership for Innovation and Empowerment, SER National, Southern Christian Leadership-Global Policy Initiative (SCL-GPI)

I have also attached a link to an Op-Ed by a prominent ex-FDA official published in "The Hill" a few months ago: <https://thehill.com/opinion/healthcare/3943031-fda-needs-to-protect-vulnerable-newborns-from-aluminum-toxicity/> and have attached a timeline related to the FDA policy and Exela related to this issue.

Let me know if you and/or an appropriate colleague would be willing to meet with Dr. Koneru in the next few weeks. We will be flexible and accommodate a day and time convenient for you and any other appropriate colleague.

Thank you for considering this request.

Darren

Darren Peters
Founder and Managing Partner
PETER DAMON GROUP
700 12th Street, NW, Suite 700
Washington, DC 20005
P: 202-904-2406

C (b)(6)



Image removed by sender.

www.peterdamongroup.com

Sender: Cha, Stephen (HHS/IOS) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=23E67977D77947D69BAF2ACE846821A8-CHA, STEPHE>

Fristedt, Andi (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9f53d20d2ec49188eb5c2959ceedd8a-andi.friste
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Recipient: Tierney, Julia (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=367e11c5deec4593ac4dc9b66d0a2e15-julia.tiern
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Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa
<Sarah.Despres@hhs.gov>

Sent Date: 2023/06/06 11:14:55

Delivered Date: 2023/06/06 11:14:00

From: Tobias, Lindsay (b)(6)

Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>;

To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephen <Stephen.Cha@hhs.gov>;

Miller - Tolbert, Kimberly (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae7fdbbb6735470bab1203afb08f5b7d-Miller - To <Kimberly.Miller-tolbert@hhs.gov>

Califf, Robert (b)(6)

Woodcock, Janet (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f925e9a0f9147b186d40072d474d13d-janet.woodc (b)(6)

Tierney, Julia (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=367e11c5deec4593ac4dc9b66d0a2e15-julia.tiern (b)(6)

Fristedt, Andi (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9f53d20d2ec49188eb5c2959ceedd8a-andi.friste (b)(6)

Raza, Mark (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c960812d65a14b868f25f86bf01edef6-mark.raza.f (b)(6)

Roth, Lauren (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8155cc4dbe59472097297783db05a764-lauren.roth (b)(6)

Erica.Jefferson /o=ExchangeLabs/ou=Exchange Administrative Group

CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfae5830a (b)(6)

Rebello, Heidi (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97fe04738e9d4ad6bf21ae2f687dd211-heidi.rebel (b)(6)

Felberbaum, Michael (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bf791710e5f44e88474611dbd070f11-michael.fel (b)(6)

Cacomo, Stephanie (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b415b3f6cff4b18980c5f723fad2ce0-stephanie.c (b)(6)

Colonus, Tristan (FDA/CFSAN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43769a3f24954a2f96df0578ebc4ca12-tristan.col (b)(6)

Olivarria, Frank (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ff7e12b327d4c2a820f1915b0d4b7af-frank.oliva (b)(6)

Helms Williams, Emily (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a5f275fcc04808a7bb8d8c591e4d0d-emily.helms (b)(6)

Subject: Night Note for Thursday, 4/21- Internal, Confidential, Deliberative

Date: 2022/04/20 15:05:59

Priority: Normal

Type: Note

PRESS PAPERS:

There is nothing to report at this time.

OTHER FLAGS:

INTERNAL, CONFIDENTIAL, MARKET SENSITIVE, NOT FOR PUBLIC DISTRIBUTION

(b)(5)

Lindsay R. Tobias

Special Assistant to the Chief of Staff

Office of the Commissioner
Office of the Chief of Staff
U.S. Food and Drug Administration
Tel: 301-796-6743

Cell: (b)(6)
Lindsay.Tobias@fda.hhs.gov



Sender: Tobias, Lindsay (b)(6)

Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>;
Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe <Stephen.Cha@hhs.gov>;
Miller - Tolbert, Kimberly (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae7fdbbb6735470bab1203afb08f5b7d-Miller - To <Kimberly.Miller-tolbert@hhs.gov>;
Califf, Robert (b)(6)
Woodcock, Janet (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5f925e9a0f9147b186d40072d474d13d-janet.woodc (b)(6)
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Recipient: Roth, Lauren (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8155cc4dbe59472097297783db05a764-lauren.roth (b)(6)
Erica.Jefferson /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfae5830a (b)(6)
Rebello, Heidi (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97fe04738e9d4ad6bf21ae2f687dd211-heidi.rebel (b)(6)
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Caccomo, Stephanie (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b415b3f6cff4b18980c5f723fad2ce0-stephanie.c (b)(6)
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Olivarria, Frank (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ff7e12b327d4c2a820f1915b0d4b7af-frank.oliva (b)(6)
Helms Williams, Emily (FDA/OC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a5f275fcc04808a7bb8d8c591e4d0d-emily.helms (b)(6)

Sent Date: 2022/04/20 15:05:43

Delivered Date: 2022/04/20 15:05:59

Message Flags: Unread

From: Jones, Kamara (HHS/ASPA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=05CEF78E341B467099676C353121C1ED-JONES, KAMA <Kamara.Jones@hhs.gov>

Lovenheim, Sarah (HHS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47f3afc033df47b1aaa46c8e43961db5-Goldfarb, S <Sarah.Lovenheim@hhs.gov>;

To: ASPA Deputies /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1eec59ca42f640d69de277e5fc41badf-ASPADeputie <ASPADeputies@hhs.gov>

Sibori, Gabriela (HHS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73a324bc75dd4a2eab4d0f3145fc2dc4-Sibori, Gab <Gabriela.Sibori@hhs.gov>

Subject: HHS Major Press and Policy Announcements (9/18 - 10/1)

Date: 2022/09/18 22:33:28

Priority: Normal

Type: Note

See below. Have a good night. – Kamara

HHS MAJOR PRESS AND POLICY ANNOUNCEMENTS

September 18 – October 1, 2022

WEEK OF SEPTEMBER 18

TBD

- **TBD Time:** HHS Participates in a Monkeypox Vaccine Event with the WH Monkeypox Coordinator and Deputy Coordinator (Event)

Sunday, September 18

Secretary/HHS

- **2:30 PM – 3:00 PM ET:** Secretary Becerra Delivers the Opening Address at the UNGA 77 (Opening Remarks)
- **6:20 PM ET – 7:30 PM ET:** Secretary Becerra Delivers Closing Address at the UNGA 77 (Closing Remarks)

Monday, September 19

Secretary/HHS

- **9:00 AM – 10:30 AM ET:** Secretary Becerra Visits an Open Access Clinic in NY for a Booster and Pediatrics Vaccine Event (Event)
- **2:30 PM – 3:30 PM ET:** Secretary Becerra Participates in a Fireside Chat with Secretary Hillary Clinton (Event)

Tuesday, September 20

Secretary/HHS

- **7:30 PM – 8:00 PM ET:** Secretary Becerra Delivers Keynote Remarks and Participates in Q&A at the Healthcare Leadership Council Annual Membership Meeting (Remarks)

Health Care

- **TBD Time:** HRSA Awards Funding to 11 HRSA-Funded Health Centers Across Seven States (Press Release)

Wednesday, September 21

Health Care

- **TBD Time:** HHS Invests in New Programs to Expand and Strengthen the Community Health Worker and Public Health Workforces (Press Release)

Thursday, September 22

Secretary/HHS

- **9:00 AM – 10:00 AM ET:** HOLD: Monkeypox Press Call with Latino Press (Press Call)

Health Care

- **TBD Time:** CMS Approves a Postpartum Coverage Extension State Plan Amendment for a State (Press Release)

Human Services

- **TBD Time:** HHS releases WH Recovery Event Grant Bundle (Press Release)

Friday, September 23

Secretary/HHS

- **TBD Time:** Secretary Becerra Travels to Madison, Wisconsin, for Two Site Visits with Rep. Mark Pocan (Events)

Health Care

- **TBD Time:** HRSA Announces Funding across Three Rural Community Opioid Response Programs (Press Release)

Public Health

- **TBD Time:** CDC and Kaiser Health Authors Publish a Study in *Academic Pediatrics* (Study)
- **TBD Time:** Twitter Spaces with Dr. Daskalakis and Dr. Mena from the CDC to Talk About Monkeypox (Twitter)

Human Services

- **TBD Time:** HHS Releases White House Recovery Event Grant Bundle (Press Release)

WEEK OF SEPTEMBER 25

Monday, September 26

Secretary/HHS

- **9:00 AM – 1:30 PM ET:** Secretary Becerra Participates in PAHO's Sanitary Conference (Bilateral Meetings)
- **3:30 PM – 4:30 PM ET:** TBD – White House Competition Council Meeting (Meeting)

Tuesday, September 27, 2022

Secretary/HHS

- **9:00 AM – 11:00 AM ET:** Secretary Becerra Participates in the U.S.-World Health Organization Dialogue (Event)
- **11:30 AM – 12:00 PM ET:** Secretary Becerra Holds the Swearing-In Ceremony for the Co-Chairs of the President's Council on Sports, Fitness and Nutrition (Ceremony)

Wednesday, September 28

Secretary/HHS

- **9:00 AM – 10:00 AM ET:** Secretary Becerra Participates in WHIAANHPI Commission Meeting (Meeting)
- **1:30 PM – 3:00 PM ET:** Secretary Becerra Attends the White House Conference on Hunger, Nutrition, and Health (Event)
- **4:45 PM – 5:45 PM ET:** Secretary Becerra Provides Closing Remarks at the White House Conference on Hunger, Nutrition, and Health (Closing Remarks)

Health Care

- **TBD Time:** CMS Approves 1115 Demonstration Waivers for Two States (Press Release, Internal Q&As)

Friday, September 30

Secretary/HHS

- **5:30 PM PT – 7:00 PM PT:** Secretary Becerra Receives the Luchando Por Justicia Award from the California Rural Legal Assistance Foundation (Award)

WEEK OF SEPTEMBER 18

TBD

- HHS participates in a Monkeypox vaccine event with the WH Monkeypox Coordinator and Deputy Coordinator.

Sunday, September 18

Secretary/HHS

- **2:30 PM – 3:00 PM ET:** As part of the 77th Session of the United Nations General Assembly (UNGA 77) Secretary Becerra delivers the opening address at Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) Replenishment Conference Campaign Event and Reception Opening Session (New York, NY)
- **6:20 PM ET – 7:30 PM ET:** Secretary Becerra delivers the closing address at Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) Replenishment Conference Campaign Event and Reception Opening Session (New York, NY)

Monday, September 19

Secretary/HHS

- **9:00 AM – 10:30 AM ET:** Secretary Becerra visits Pediatrics 2000, an open access clinic for a booster and pediatrics vaccine event. (Washington Heights, NY).
- **2:30 PM – 3:30 PM ET:** Secretary Becerra participates in a fireside chat with Secretary Hillary Clinton at the Clinton Global Initiative: A Pivotal Window for Reproductive and Maternal Health: How We Can Lead the Vanguard for Availability, Agency, and Access

Tuesday, September 20

Secretary/HHS

- **7:30 PM – 8:00 PM ET:** Secretary Becerra delivers keynote remarks and participates in Q&A at the Healthcare Leadership Council Annual Membership Meeting (Willard InterContinental DC). His remarks will focus on innovation.

Health Care

- HRSA awards over \$5 million to 11 HRSA-funded health centers across seven states (CA, FL, KS, OK, TN, TX, and VA) to increase equitable access to life-saving cancer screenings and referral for care and treatment. These landmark awards will provide health centers with resources to engage and support underserved patients in overcoming all-too-common

obstacles to accessing cancer screening, prevention, and early detection services. **Aligns with Cancer Moonshot Initiative and Unity Agenda** (Press release with Secretary quote)

Wednesday, September 21

Secretary/HHS

- **9:00 AM – 10:30 AM ET:** ASPA Media Hold
- **11:00 AM – 11:30 AM ET:** Secretary Becerra participates virtually in the United States Mission to the United Nations Universal Health Coverage Meeting

Health Care

- HHS Invests \$266 Million in New Programs to Expand and Strengthen the Community Health Worker and Public Health Workforces (ARP funding.) HRSA is awarding \$225.5 million to 83 grantees as part of the Community Health Worker Training Program, which is a new, multiyear program that will support training and apprenticeship to support new community health workers. Also \$40.7 million to 29 grantees through the Public Health Scholarship Program, which will incentivize individuals to pursue training and careers in public health, including as epidemiologists and other positions critical to community public health needs.

Thursday, September 22

Secretary/HHS

- **9:00 AM – 10:00 AM ET:** HOLD: Monkeypox Press Call with Latino Press (Informal, Zoom)

Health Care

- CMS approves a postpartum coverage extension state plan amendment (SPA) for state in the south. The state will receive SPA approval to extend postpartum coverage for individuals enrolled in Medicaid and the Children's Health Insurance Program--an opportunity made possible by the American Rescue Plan (ARP). This will be the 24th state approval. *(Press Release with Secretary's Quote, Social Media, and Internal Q&As)*

Human Services

- HHS releases WH Recovery Event grant bundle - Grants to Expand Substance Abuse Treatment Capacity in Adult and Family Treatment Drug Courts, \$7.1M - State Opioid Response Grants, \$1.440B - Tribal Opioid Response Grants, \$55M – Rural Community Opioid Response Programs, \$104 million.

Friday, September 23

Secretary/HHS

- Secretary Becerra travels to Madison, Wisconsin, for two site visits with Representative Mark Pocan
 - 1) Youth Mental Health (University of Wisconsin, Madison)
 - 2) Cancer Moonshot (Exact Sciences)

Health Care

- HRSA announces awards of more than \$104 million across three Rural Community Opioid Response Programs (RCORP), part of HRSA's RCORP initiative to address the barriers to treatment for substance use disorder, including opioid use disorder, in rural communities. The initiative works toward the HHS goal of ending the opioid epidemic. Aligns with ONDCP conference. (Press Release with Secretary Quote)

Public Health

- CDC and Kaiser Health authors publish a study in *Academic Pediatrics*: Association Between Aluminum Exposure from Vaccines Before Age 24 Months and Persistent Asthma at Age 24-59 Months. Summary: In a large observational study, a positive association was found between vaccine related aluminum exposure and persistent asthma. While recognizing the small effect sizes identified and the potential for residual confounding, additional investigation of this hypothesis appears warranted.
- Twitter Spaces with Dr. Daskalakis and Dr. Mena from the CDC to talk about monkeypox

Human Services

- HHS releases WH Recovery Event grant bundle -Grants to Expand Substance Abuse Treatment Capacity in Adult and Family Treatment Drug Courts, \$7.1M - State Opioid Response Grants, \$1.440B - Tribal Opioid Response Grants, \$55M – Rural Community Opioid Response Programs, \$104 million.

WEEK OF SEPTEMBER 25

Monday, September 26

Secretary/HHS

- **9:00 AM – 1:30 PM ET:** Secretary Becerra participates in the Pan-American Health Organization's Sanitary Conference in DC. This includes the Inaugural Ceremony, various bilateral meetings and the Health Workforce Side Meeting
- **3:30 PM – 4:30 PM ET:** TBD – WH Competition Council Meeting (The White House)

Health Care

- AHRQ is announcing a challenge competition to explore the resources and infrastructure needed to integrate real-world evidence from healthcare systems into systematic review findings. (Press Release – but not with Secretary quote) [Scheduled date based on anticipated Federal Register notice date]

Tuesday, September 27, 2022

White House

- **5:00 AM:** The White House releases its nutrition strategy the day before the conference.

Secretary/HHS

- **9:00 AM – 11:00 AM ET:** Secretary Becerra participates in the U.S.-World Health Organization Dialogue (HHHB)
- **11:30 AM – 12:00 PM ET:** Secretary Becerra holds the swearing-In ceremony for the co-chairs of the President's Council on Sports, Fitness and Nutrition (PCSFN). The co-chairs are Jose Andres, humanitarian and chef, and Elena Delle Donne, WNBA player

COVID-19

- MMWR: Effectiveness of a second COVID-19 booster dose for prevention of infection, hospitalization, or death among nursing home residents— March–June, 2022.

Wednesday, September 28

Secretary/HHS

- **9:00 AM – 10:00 AM ET:** Secretary Becerra participates in WHIAANHPI Commission Meeting (The White House)
- **1:30 PM – 3:00 PM ET:** Secretary Becerra attends the WH Conference on Hunger, Nutrition, and Health during the President's Remarks
- **4:45 PM – 5:45 PM ET:** Secretary Becerra provides closing remarks at the WH Conference on Hunger, Nutrition, and Health

Public Health

- White House hosts Conference on Hunger, Nutrition and Health, Ronald Reagan Building.
- CDC will update its Adult Obesity Prevalence Maps page on the CDC/DNPAO website. This will include 2021 obesity prevalence data by states and territories, as well as by age and education level. Race/ethnicity data are combined from 2019-2021. The data estimate BMI based on self-reported height and weight information gathered from the 2021 Behavioral Risk Factor Surveillance System.

Health Care

- CMS approved Section 1115 waivers for two states. These approvals coincide with the White House Conference on Hunger, Nutrition, and Health. *(Press Release with Secretary's quote, internal Q&As)*
- CMS' Center for Program Integrity (CPI) is working in collaboration with the Center for Clinical Standards and Quality (CCSQ) to release new data on data.cms.gov for enrolled Skilled Nursing Facilities (SNF) and their ownership/managerial control information. *(Press release and internal Q&As)*

Thursday, September 29

Secretary/HHS

- **12:00 PM – 12:15 PM ET:** Secretary Becerra participates in the Young Invincibles Event
- **TBD:** Potential Congressional Black Caucus Conference Evening Event

Public Health

- CDC MMWR: Effectiveness of a second COVID-19 booster dose for prevention of infection, hospitalization, or death among nursing home residents— March–June, 2022
- CDC/NCHS report: Infant Mortality in the United States, 2020

Friday, September 30

Secretary/HHS

- **5:30 PM PT – 7:00 PM PT:** Secretary Becerra receives the Luchando Por Justicia Award from the California Rural Legal Assistance Foundation in Sacramento, CA

###

Kamara Jones
Principal Deputy Assistant Secretary for Public Affairs
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Jones, Kamara (HHS/ASPA) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=05CEF78E341B467099676C353121C1ED-JONES, KAMA
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<Sarah.Lovenheim@hhs.gov>;
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To: Johnson, Robert (OS/ASPR/CAG) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0851e89240324306b78740a4a60745e2-Johnson, Ro <Robert.Johnson@hhs.gov>;

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O'Connell, Dawn (OS/ASPR/IO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18214a88325a46739f963c2056d46cd1-O'Connell, <Dawn.Oconnell@hhs.gov>;

Michael Boyd <michael.boyd1@gilead.com>;

Levine, Rachel (HHS/OASH) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e691235ff2f3496e9b53eeb5f538b2f6-Levine, Rac <Rachel.Levine@hhs.gov>;

Miknyoczki, Sheila (OS/ASPR/BARDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7ce8e6eb0b84ebd81cfee9d6cb1fab-Miknyoczki, <Sheila.Miknyoczki@hhs.gov>

Murphy, Lauren (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77f071471c024433a729012d780762b9-Murphy, Lau <Lauren.Murphy@hhs.gov>;

Lucas, Pamela (OS/ASPR/IO) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=32c227dd4946456caa0526d1cd8693fe-Lucas, Pame <Pamela.Lucas@hhs.gov>;

Michelle Springer <michelle.springer1@gilead.com>;

Lee, Kinbo (HHS/OASH) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25da49a3105c470a9cd2be9b83c57458-Lee, Kinbo <Kinbo.Lee@hhs.gov>;

Chaloupek, Jeffrey (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5e16d64acc24cc0bf4afbc71e248fa0-Chaloupek, <Jeffrey.Chaloupek@hhs.gov>;

CC: Howe, Ryan P. (CMS/CM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63933c853d3c46469aa699a7b23f01c6-H4JL <Ryan.Howe@cms.hhs.gov>;

Ventura, Robert J. (CMS/CM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2fc9fabff4e44009383478fbaa62582-PC32 <Robert.Ventura@cms.hhs.gov>;

Sams, Ian (HHS/ASPA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=486e1c5f2f544391bf4b50abc329b44-Sams, Ian <Ian.Sams@hhs.gov>;

Brian Nilstoft <Brian.Nilstoft@gilead.com>;

Kristie Banks <Kristie.Banks@gilead.com>;

Tomas Cihlar <Tomas.Cihlar@gilead.com>;

Daniel O'Day <daniel.oday@gilead.com>;

Rekha Ramesh <Rekha.Ramesh@gilead.com>;

Seshamani, Meena (CMS/OA) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=de12693faf9347edad1be4de20223303-SD1P
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Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group
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<Stephen.Cha@hhs.gov>;
Barclay, Lisa (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=872be990f41a4c7aaef491129db0ab89-Barclay, Li
<Lisa.Barclay@hhs.gov>

Subject: RE: UPDATED: Discussion - USG || Gilead

Date: 2021/12/27 13:56:39

Priority: Normal

Type: Note

Attendees for the call at 2pm are as follows:

Gilead Sciences

- Daniel O'Day, Chief Executive Officer
- Merdad Parsey, Chief Medical Officer
- Kristie Banks, VP COVID-19 Business Unit
- Michael Boyd, SVP Government Affairs & Policy
- Tomas Cihlar, SVP Virology Research
- Chuck Clapton, VP Government Affairs
- Kathleen Love-Weitz, VP Program Strategy Lead, Veklury
- Brian Nilstoft, Exec. Director Pharmaceutical Manufacturing
- Anu Osinusi, VP Virology Clinical Development
- Rekha Ramesh, VP Policy

USG

- David Kessler
- Jason Roos, incoming Chief Operating Officer for H-CORE (formerly known as CAG and OWS)
- Robert Johnson, outgoing Chief Operating Officer for the Countermeasure Acceleration Group and Deputy Director of BARDA
- Cliff Lane, Deputy Director for Clinical Research and Special Projects, NIAID
- Carl Dieffenbach, Director of the Division of AIDS, NIAID and senior advisor for COVID small molecule therapeutics
- Jay Epstein, Senior advisor for COVID monoclonal antibody therapeutics
- Meredith Chuk, outgoing COVID response lead for clinical outreach, reimbursement and communications
- Derek Eisnor, incoming COVID response lead for clinical outreach, reimbursement and communications
- Sheila Miknyoczki, project officer, BARDA – moving forward, Sheila will be your main point of contact
- Kim Armstrong, Chief of the Immunology and Emerging Infectious Diseases Therapeutics Branch, BARDA

-----Original Appointment-----

From: Kessler, David (HHS/IOS) <David.Kessler@hhs.gov>

Sent: Sunday, December 26, 2021 10:57 PM

To: Kessler, David (HHS/IOS); Armstrong, Kimberly (OS/ASPR/BARDA); Chuk, Meredith (FDA/OC); Epstein, Jay (OS/ASPR/IO); Eisnor, Derek (OS/ASPR/BARDA); Roos, Jason (OS/ASPR/H-CORE); Johnson, Robert (OS/ASPR/CAG); Lane, Cliff (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID) [E]; O'Connell, Dawn (OS/ASPR/IO); Michael Boyd; Levine, Rachel (HHS/OASH); Miknyoczki, Sheila (OS/ASPR/BARDA)

Cc: Murphy, Lauren (OS/ASPR/BARDA) (CTR); Lucas, Pamela (OS/ASPR/IO) (CTR); Michelle Springer; Lee, Kinbo (HHS/OASH); Chaloupek, Jeffrey (OS/ASPR/BARDA) (CTR); Howe, Ryan P. (CMS/CM); Ventura, Robert J. (CMS/CM); Sams, Ian (HHS/ASPA); Brian Nilstoft; Kristie Banks; Tomas Cihlar; Daniel O'Day; Rekha Ramesh; Seshamani, Meena (CMS/OA); Cha, Stephen (HHS/IOS); Lisa Barclay (Lisa.Barclay@hhs.gov)

Subject: UPDATED: Discussion - USG || Gilead

When: Monday, December 27, 2021 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where:

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Murphy, Lauren (OS/ASPR/BARDA) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77f071471c024433a729012d780762b9-Murphy, Lau <Lauren.Murphy@hhs.gov>;

Lucas, Pamela (OS/ASPR/IO) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group

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<Pamela.Lucas@hhs.gov>;
Michelle Springer <michelle.springer1@gilead.com>;
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<Ian.Sams@hhs.gov>;
Brian Nilstoft <Brian.Nilstoft@gilead.com>;
Kristie Banks <Kristie.Banks@gilead.com>;
Tomas Cihlar <Tomas.Cihlar@gilead.com>;
Daniel O'Day <daniel.oday@gilead.com>;
Rekha Ramesh <Rekha.Ramesh@gilead.com>;
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<Meena.Seshamani@cms.hhs.gov>;
Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group
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<Stephen.Cha@hhs.gov>;
Barclay, Lisa (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=872be990f41a4c7aaef491129db0ab89-Barclay, Li
<Lisa.Barclay@hhs.gov>

Sent Date: 2021/12/27 13:56:38

Delivered Date: 2021/12/27 13:56:39

From: Cristinzio, Dayle (b)(6)

Dickson, Josh J. EOP/WHO <Joshua.J.Dickson@who.eop.gov>;
catherine.r.oakar (eop.gov) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0ba955faff6544fa82bf23878d1a5a8e-catherine.r
<catherine.r.oakar@who.eop.gov>;

To: Adesina, Adeola (OS/IEA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb22e6ba7ef143e4b81f21f1ad7c1959-Adesina, Ad
<Adeola.Adesina@hhs.gov>;
Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe
<Stephen.Cha@hhs.gov>

Subject: FW: [EXTERNAL] FMI statement on FDA flexibilities

Date: 2022/07/07 13:55:03

Priority: Normal

Type: Note

FYI – great statement below

FMI's statement is now live - <https://www.fmi.org/newsroom/latest-news/view/2022/07/07/fmi-welcomes-additional-fda-flexibilities-on-infant-formula>

Hilary Thesmar, PhD, RD, CFS

Chief Science Officer and SVP Food Safety

FMI

Direct 202-220-0658

Cell (b)(6)

www.fmi.org



A close up of a sign Description automatically generated

Sender: Cristinzio, Dayle (b)(6)

Dickson, Josh J. EOP/WHO <Joshua.J.Dickson@who.eop.gov>;
catherine.r.oakar (eop.gov) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0ba955faff6544fa82bf23878d1a5a8e-catherine.r
<catherine.r.oakar@who.eop.gov>;

Recipient: Adesina, Adeola (OS/IEA) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fb22e6ba7ef143e4b81f21f1ad7c1959-Adesina, Ad
<Adeola.Adesina@hhs.gov>;
Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe

<Stephen.Cha@hhs.gov>

Sent Date: 2022/07/07 13:54:40

Delivered Date: 2022/07/07 13:55:03

From: Pratt, Abby <apratt@AdvaMed.org>

Friedman, Jennifer (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8a66be214774b15a58e5aa9b867e51c-Friedman, J <Jennifer.Friedman@hhs.gov>;

Smith-Goodwin, Serena (HHS/IOS) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f651ce5471b465e9c4cdeba7ce0e814-Goodwin, Se <Serena.Smith-Goodwin@hhs.gov>;

To: Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>;

Burgess, Angela (HHS/IOS) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e97930a9728e4db7af6776e2c61680f5-Burgess, An <Angela.Burgess@hhs.gov>;

Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe <Stephen.Cha@hhs.gov>

CC: Price, Richard <RPrice@AdvaMed.org>

Subject: RE: [EXTERNAL] Meeting Request: RE: Supply Chain Issues w/ Richard Price, ADVAMed

Date: 2022/03/03 14:00:24

Priority: Normal

Type: Note

Dear all,

In advance of our call, I wanted to share a few key documents related to the chips shortages and the impact on medtech. No need to read in advance but I wanted to be sure you have them on hand:

- • AdvaMed paper for WH/NSC (attached)
- • AdvaMed submission to DOC in response to their RFI (attached)
- • AdvaMed/Deloitte Study on chips and medtech
- • Joint AdvaMed/SIA press release

Many thanks,
Abby

Abby Pratt

(she/her/hers)

SVP, Global Strategy & Analysis

Staff Lead, Supply Chain

P :: 202.549.4565

E :: apratt@AdvaMed.org

701 Pennsylvania Ave. NW, Suite 800

Washington, DC 20004-2654

advamed.org

-----Original Appointment-----

From: Friedman, Jennifer (OS/IOS) <Jennifer.Friedman@hhs.gov>

Sent: Wednesday, March 2, 2022 12:47 PM

To: Friedman, Jennifer (OS/IOS); Price, Richard; Pratt, Abby; Despres, Sarah (HHS/IOS); Cha, Stephen (HHS/IOS)

Cc: Smith-Goodwin, Serena (HHS/IOS) (CTR); Burgess, Angela (HHS/IOS) (CTR)

Subject: [EXTERNAL] Meeting Request: RE: Supply Chain Issues w/ Richard Price, ADVAMed

When: Thursday, March 3, 2022 2:30 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: (b)(6)

Jennifer Friedman is inviting you to a scheduled ZoomGov meeting.

Join ZoomGov Meeting

(b)(6)

Meeting ID: (b)(6)

Passcode: (b)(6)

One tap mobile

(b)(6)

US (San Jose)

US (New York)

Dial by your location

(b)(6)

US (San Jose)

US (New York)

US (San Jose)

US

Meeting ID: (b)(6)

Find your local numbers: (b)(6)

Join by SIP

(b)(6)

Join by: (b)(6)

(b)(6)

(US West)

(US East)

Meeting ID: (b)(6)

Passcode: (b)(6)

Sender: Pratt, Abby <apratt@AdvaMed.org>

Friedman, Jennifer (OS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8a66be214774b15a58e5aa9b867e51c-Friedman, J <Jennifer.Friedman@hhs.gov>;

Recipient: Smith-Goodwin, Serena (HHS/IOS) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f651ce5471b465e9c4cdeba7ce0e814-Goodwin, Se <Serena.Smith-Goodwin@hhs.gov>;

Despres, Sarah (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15d1d64eacdf46b8a378310ae7caf6bd-Despres, Sa <Sarah.Despres@hhs.gov>;

Burgess, Angela (HHS/IOS) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e97930a9728e4db7af6776e2c61680f5-Burgess, An
<Angela.Burgess@hhs.gov>;
Cha, Stephen (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=23e67977d77947d69baf2ace846821a8-Cha, Stephe
<Stephen.Cha@hhs.gov>;
Price, Richard <RPrice@AdvaMed.org>

Sent Date: 2022/03/03 13:59:05

Delivered Date: 2022/03/03 14:00:24

From: Blair Childs <blairchilds@premierinc.com>

To: Brady, Will (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa197652dadf4048ad6764b3f9d4a528-Brady, Will <William.Brady@hhs.gov>

Subject: Augmenting Domestic Manufacturing is Key to Pandemic Preparedness

Date: 2022/04/11 18:21:13

Priority: Normal

Type: Note

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Image

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Augmenting Domestic Manufacturing is Key to Pandemic Preparedness

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The pandemic, recent global events and ongoing global supply chain disruptions have brought into sharp focus the U.S.'s dependence on foreign manufacturing in accessing critical medical products during public health emergencies. This vulnerability threatens our national security.

Premier, alongside over 100 health system partners, is taking these vulnerabilities head on by creating new domestic sources of medical supplies to build resiliency into America's supply chain. While these private-sector innovations have bolstered the nation's supply, persistent challenges remain that require accelerated solutions from the federal government to incentivize domestic manufacturing.

Premier and U.S. hospitals are committing to purchase domestic products, creating sustainability for domestic manufacturers of high-quality PPE, drugs and other supplies;

- • More than 100 health systems in the Premier healthcare alliance have invested in and committed to purchasing domestically manufactured products, creating market predictability for essential domestic manufacturers. These efforts include:
 - • Acquiring a minority stake in and making purchasing commitments to Prestige Ameritech, the nation's largest domestic producer of face masks located in Texas, to produce 8 million N95s

- and more than 45 million other PPE products annually.
- • Collaborating with Honeywell to support the expansion of the U.S. production of nitrile exam gloves in Honeywell's Fort Worth, TX-based facility. Starting in Q3 of 2022, the collaboration will produce at least 750 million U.S.-made exam gloves in the first year alone.
- • Creating a joint venture partnership with DeRoyal Industries Inc. that is expected to produce more than 40 million domestically manufactured gowns annually in Knoxville, TN. The gowns are now coming off the line and deliveries have begun.
- • Acquiring a minority stake and committing to product purchasing in Exela Pharma Sciences to secure vital supply of 19 pharmaceutical products, including several generic injectables that frequently appear on the FDA's drug shortage list. Exela manufactures in Lenoir, NC.
- • Leveraging data and member health system feedback to identify products most at-risk, Premier is also prioritizing business collaborations that leverage existing production capacity.

Congress can strengthen these private sector initiatives by providing greater incentives for domestic manufacturing, purchasing American-made products to create sustainability, and creating pricing parity between domestically and globally sourced products by:

- • Providing tax incentives for investments to support the domestic manufacturing of critical medical supplies and drugs, including their raw materials, as is done in the *American Made Medicine Act* (H.R. 7410).
- • Requiring government purchasers to contract for critical medical supplies and pharmaceuticals from a mixture of onshore, near-shore and off-shore, as is done in the *COMPETES Act* (H.R. 4521) and *PREVENT Pandemics Act* (S. 3799).
- • Providing a tax credit with appropriate guardrails on the income generated from the sale of domestically manufactured goods—such as H.R. 7410 would do—to reward those who have already invested in manufacturing and to make them price competitive with globally sourced products.

Contact Soumi Saha at soumi_saha@premierinc.com for more information on Premier's supply chain recommendations.

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Premier Inc. 13034 Ballantyne Corporate Pl, Charlotte, NC 28277

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Sender: Blair Childs <blairchilds@premierinc.com>

Recipient: Brady, Will (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa197652dadf4048ad6764b3f9d4a528-Brady, Will <William.Brady@hhs.gov>

Sent Date: 2022/04/11 18:20:27

Delivered Date: 2022/04/11 18:21:13

Message Flags: Unread

From: Blair Childs <blairchilds@premierinc.com>

To: Brady, Will (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa197652dadf4048ad6764b3f9d4a528-Brady, Will <William.Brady@hhs.gov>

Subject: Getting Life-Saving Medications into the Hands of Providers and Patients

Date: 2022/02/09 13:21:10

Priority: Normal

Type: Note

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Image

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Getting Life-Saving Medications into the Hands of Providers and Patients

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Drug shortages continue to plague the healthcare system, threatening patients' access to critical life-saving therapies and driving up drug costs. Even without a public health emergency, these susceptibilities are untenable. But while pharmaceutical supply chain disruptions remain prevalent, innovative strategies are enabling us to make progress in eliminating drug shortages.

A new [Premier report](#) provides insights and recommendations for how stakeholders across the supply chain — including U.S. regulators, manufacturers, distributors, purchasing groups and providers, can manage and mitigate future drug shortages.

Hospitals and health systems working through the Premier alliance have taken a comprehensive approach to solving the drug shortage crisis. This includes systematically addressing the root causes of shortages and providing the right economic models that incent manufacturers to compete, invest in redundancies, enter or re-enter markets and explore new therapeutic categories

for innovation.

Premier's strategy to eliminate drug shortages is focused on driving maximum market competition, expanding capacity and improving the economic health of the market

- • An essential step in addressing drug shortages is ensuring a market for manufacturers willing to produce shortage products. Through committed purchasing and aggregated demand, Premier and its members are providing the surety needed for manufacturers to produce drugs in short supply.
- • Premier has brought 29 manufacturers to market with new generic injectable products.
- • Since 2020, Premier programs have successfully resolved 14 drug shortages, resulting in their official delisting from the FDA shortage list.
- • We have been able to ensure uninterrupted supply of many shortage drugs despite demand spikes of more than 150 percent during the pandemic.
- • This approach has also focused on bringing more domestic manufacturers to market, including VGYAAN and Exela Pharma Sciences. Combined these investments are working to bring new sources of competition for 20 different shortage drugs and counting.
- • Premier also continues to leverage robust data and analytics to help identify and predict drug shortages and alert the FDA, ASHP, our health system members and others.

Continued action by the federal government is needed to bolster these private sector efforts

- • For more than a decade, Premier has communicated to the FDA and Congressional committees on the root causes of drug shortages and urged action to prevent or mitigate shortages.
- • The FDA has repeatedly identified the primary causes of drug shortages as a lack of market competition and manufacturer issues.
- • Premier recently urged Congress to grant FDA additional authority to proactively address drug shortages, as well as market-based incentives for the manufacturing of critical drugs, including on-shore manufacturing, that were included in the Coronavirus Aid, Relief, and Economic Security (CARES) Act.
- • Premier continues to advocate for sustainable policy solutions, including:
 - • Requiring manufacturers, including API manufacturers, to report the volume of product that is manufactured in each FDA registered facility;
 - • Expanding the FDA drug shortage list to include regional shortages as well as shortages based on strength and dosage form;
 - • Temporarily extending expiration dates for drug shortage products if determined to be scientifically sound;

- • Creating a supply chain data infrastructure to enable tracking of product availability from manufacturing to hospital inventory so that policymakers can understand shortage risks;
- • Actively consulting with stakeholders on a thorough and complete essential drugs list for both the acute and non-acute spaces; and
- • Incenting domestic and diverse manufacturing.

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Premier Inc. 13034 Ballantyne Corporate Pl. Charlotte, NC 28277

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Sender: Blair Childs <blairchilds@premierinc.com>

Recipient: Brady, Will (HHS/IOS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa197652dadf4048ad6764b3f9d4a528-Brady, Will <William.Brady@hhs.gov>

Sent Date: 2022/02/09 13:20:21

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Message Flags: Unread