From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 5/7/2021 5:58:29 PM
To: Kosub, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e3eccf57f4e4fcfaecaa7885f39bee5-kosubd]; Bulls, Michelle G. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b366f1a4382d44c1bde626e7730c3dd4-bullsmg]; Ta, Kristin (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72dc8e6c4cae4efcaa9e72eabbff2ee3-takr]
CC: Columbus, Megan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8878f99917841749c5ae3fad8d90c73-columbum]; Rabin, Elise (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3426cfac5b54e8dae0d1aca72262bf3-rabine]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Grassley letter re COVID
Attachments: 2021-03-08 CEG to ODNI HHS (COVID Origins)[2][1][1].pdf; NIH Response to EcoHealth Response to Suspension_10_23_20[1].pdf; NIH letter to UCI re Wuhan Institute of Virology 5-20-2020 msl[2][1][1][1].pdf; Daszak 7 8 20[3][1].pdf

Thanks David – I'll take the lead on this.

Mike

From: "Kosub, David (NIH/OD) [E]" (b) (6)
Date: Friday, May 7, 2021 at 11:32 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6), "Bulls, Michelle G. (NIH/OD) [E]" (b) (6), "Ta, Kristin (NIH/OD) [E]" (b) (6)
Cc: "Columbus, Megan (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6)
Subject: FW: Grassley letter re COVID

Good day Mike, Michelle, and Kristin,

HHS requested NIH draft a response to Q#9 from Senator Grassley's letter (first attachment) regarding the origins of COVID-19: "In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology."

Mike previously shared the additional EcoHealth correspondence with OLPA to address this question. Please advise who should take lead on drafting the proposed answer.

Thank you
David

From: LaMontagne, Karen (NIH/OD) [E] (b) (6)
Sent: Friday, May 7, 2021 9:30 AM
To: Kosub, David (NIH/OD) [E] (b) (6)
Cc: Rabin, Elise (NIH/OD) [E] (b) (6); Lohmann, Larry (NIH/OD) [E] (b) (6)
Subject: FW: Grassley letter re COVID

Good Morning, David,

HHS came back to us on the attached letter from Sen. Grassley to ODNI. They are asking us to draft a narrative response to question #9. Dr. Lauer had previously indicated that we might base that response on the letters that we sent to EcoHealth.

I've looped in Larry who can help answer any questions on the background on this letter.

Thank you,
Karen

From: "Lohmann, Larry (NIH/OD) [E]" (b) (6)
Date: Tuesday, May 4, 2021 at 4:58 PM
To: Karen LaMontagne (b) (6)
Subject: Re: Grassley letter re COVID

Good afternoon,

This is back again. HHS asked if we could draft a narrative response to question number 9, "In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology." My guess is (b) (5) Can you see if OER would be willing to draft it, guessing NIAID might have to look at it as well?

Very respectfully,
Larry

From: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Date: Tuesday, March 23, 2021 at 6:21 PM
To: "LaMontagne, Karen (NIH/OD) [E]" (b) (6)
Cc: "Kosub, David (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Re: Grassley letter re COVID

Thanks Karen – agree ODNI for #8. For #9 we have the letters we sent to EcoHealth Alliance. We also sent a letter to UC Irvine suspending a subaward.

Mike

From: "LaMontagne, Karen (NIH/OD) [E]" (b) (6)
Date: Tuesday, March 23, 2021 at 3:36 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: "Kosub, David (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6)
Subject: FW: Grassley letter re COVID

Hi, Dr. Lauer,

Flagging the attached letter to ODNI from Senator Grassley. You will recall that Sen. Grassley is the former Chairman of the Senate Finance Committee. He now serves as the Ranking Minority Member of the Senate Judiciary Committee.

HHS/ASL reached out to OLPA to gauge whether NIH can answer #8 & #9. (Although I would think ODNI should answer #8?) Would you please let us know what you think?

Thanks very much,
Karen

Karen LaMontagne
Office of Legislative Policy & Analysis
National Institutes of Health
(b) (6)

From: "Schmalz, Jennifer (HHS/ASL)" (b) (6)
Date: Tuesday, March 23, 2021 at 2:55 PM
To: "Lohmann, Larry (NIH/OD) [E]" (b) (6)
Subject: FW: Grassley letter re COVID

Here's the SFC letter.

Can you advise on whether NIH could respond to #8 and #9?

United States Senate

WASHINGTON, DC 20510

March 8, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Avril Haines
Director of National Intelligence

Mr. Norris Cochran
Acting Director
Department of Health and Human Services

Dear Director Haines and Acting Director Cochran:

On February 4, 2020, my oversight and investigations staff received a classified briefing from the Department of Health and Human Services (HHS), Office of National Security regarding the SARS-CoV-2 (hereinafter "coronavirus") threat and the status of the U.S. government's efforts to combat the spread of the deadly virus.[1] From the beginning, my goal has been to ensure a robust federal response to the threat and to better understand the origins of the virus. For example, there is still considerable debate about whether the coronavirus is a naturally occurring virus, a naturally occurring virus that escaped from a lab, or a laboratory manipulated virus that escaped from a lab.

In December 2020, a team of World Health Organization (WHO) researchers and scientists traveled to Wuhan, China to investigate the origins of coronavirus. However, according to recent reports, China refused to grant WHO researchers access to anonymized raw data from the earliest days of the outbreak which would help pinpoint the origins of the virus.[2] Instead, China produced self-generated summaries and analyses of the data which could have been manipulated by the communist Chinese government, effectively preventing a real review.[3]

In early February last year, I warned about China's reluctance to share data regarding the coronavirus outbreak.[4] I also noted that China's failure to cooperate made it more important for the Intelligence Community and HHS to work together to ensure information is efficiently

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[1] Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.
[2] Jeremy Page et al., *China Refuse to Give WHO Raw Data on Early COVID-19 Cases*, WALL ST. J. (Feb. 12, 2021), https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580.
[3] *Id.*
[4] Press Release, Grassley Urges More Information Sharing Between Health, Intelligence Agencies (Mar. 24, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-urges-more-information-sharing-between-health-intelligence-agencies; Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.

shared between them. The Trump administration ensured that federal health agencies had a seat at the table within the Intelligence Community and access to information relating to the pandemic. That cooperation and access must continue and be built upon to better combat the virus and determine its origins.

More than 500,000 Americans have died as a result of the coronavirus pandemic and trillions of taxpayer dollars have been spent to shore up our economy and take care of our citizens. Congress and the American public have a right to know and understand what work the government has done to determine the origins of the coronavirus. Accordingly, in light of your agency's role with respect to the pandemic, no later than March 22, 2021, please provide the following:

1. All information disseminated to the National Intelligence Council relating to the coronavirus pandemic.

2. All records relating to detailed genomic sequencing analyses for SARS-CoV-2 and related coronaviruses, including all records relating to research about the receptor binding domain of pangolin origin coronavirus and furin-cleavage site insertion.

3. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and any previous published and/or unpublished work by the Wuhan Institute of Virology on coronavirus chimeras.

4. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and genomic sequencing analyses on miners that were hospitalized in Yunnan Province in and around 2012.

5. All records relating to all analyses with respect to the capabilities of the Wuhan Institute of Virology to manipulate bat coronaviruses using reverse genetic technologies.

6. All records relating to illnesses at the Wuhan Institute of Virology among its personnel and scientific staff during the Fall of 2019. In your answer, please describe the type of work these employees were engaged in.

7. All records relating to work conducted at the Wuhan Institute of Virology by Chinese government agencies prior to and during Fall of 2019.

8. Please describe the steps you have taken to continue to incorporate the Department of Health and Human Services into missions involving threats to the nation's health care, including access to Intelligence Community information, and the steps you have taken to improve upon the information access provided by the Trump administration.

9. In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.

Please send all unclassified material directly to the Committee. In keeping with the requirements of Executive Order 13526, if any of the responsive documents do contain classified information, please segregate all unclassified material within the classified documents, provide all unclassified information directly to the Committee, and provide a classified addendum to the Office of Senate Security. Although the Committee complies with all laws and regulations governing the handling of classified information, it is not bound, absent its prior agreement, by any handling restrictions.

Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

23 October 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

I am following up on Mr. Krinsky's August 13, 2020, letter on behalf of EcoHealth Alliance, Inc. ("EcoHealth") responding to NIH's suspension of grant R01AI110964, which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project"). Per my letter of July 8, 2020, NIH reinstated the grant but suspended all award activities because we have concerns that the Wuhan Institute of Virology (WIV), which previously served as a subrecipient of the Project, had not satisfied safety requirements that applied to its subawards with EcoHealth, and that EcoHealth had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. EcoHealth objected to the suspension on the grounds that WIV has no *current* connection to the Project or EcoHealth's research, and EcoHealth had not issued any subawards in connection with the Grant *at the time of the suspension*.

The fact that EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension does not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964. While EcoHealth did not issue a subaward to WIV for year 6 of the grant, WIV served as a subrecipient for years 1 through 5. NIH awarded EcoHealth grant R01AI110964 in 2014, with a project period of June 1, 2014, through June 30, 2024, as renewed. In EcoHealth's grant application, EcoHealth listed Drs. Zheng Li Shi and Xing Yi Ge of WIV as co-investigators and senior/key personnel. It stated that "Drs. Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences, and shipping samples into and out of China." EcoHealth listed WIV as a Project/Performance Site Location. In describing WIV's facilities, EcoHealth described WIV as China's premier institute for virological research" and touted WIV's "fully equipped biosafety level 3 laboratory" and "a newly opened BLS-4 laboratory." In support of the application, Dr. Zheng Li Shi's personal statement indicated that "My lab will be responsible for diagnosis, genomics and isolation of coronavirus from wild and domestic animals in Southern China and for analyzing their receptor binding domains." The application stated that "Wuhan Institute of Virology and the Wuhan University Center for Animal Experiment BSL-3

lab have an Internal Biosafety Committee and are accredited BSL-2 and BSL 3 laboratories. All experimental work using infectious material will be conducted under appropriate biosafety standards. Disposal of hazardous materials will be conducted according to the institutional biosafety regulations."

EcoHealth requested funding specifically for activities to be carried out by WIV. NIH awarded EcoHealth a total of $749,976 for WIV's work in the following annual amounts for years 1 through 5:

	-Yr 1	-Yr 2	-Yr 3	-Yr 4	-Yr 5
Total Direct Costs	$123,699	$128,718	$147,335	$147,335	$147,335
F&A Costs @ 8%	$9,896	$10,297	$11,787	$11,787	$11,787
TOTAL COSTS	$133,595	$139,015	$159,122	$159,122	$159,122

As stated in the Notices of Award for each budget period of the grant, the awards were subject to terms and conditions, which include the NIH Grants Policy Statement (GPS) and applicable HHS grant regulations. As I indicated in my letter of July 8, 2020, as a term and condition of award EcoHealth was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). See also, 45 C.F.R. § 75.342(a) ("The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities."). Moreover, EcoHealth was required to "Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award[.]" 45 C.F.R. § 75.303(a). The Notice of Award stated that as a term and condition of award, "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]." Moreover, the NIH GPS provides that NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients, so these terms applied to WIV. 45 C.F.R. § 75.101.

As I stated, NIH has concerns of non-compliance with terms and conditions of award—namely, that WIV had not satisfied safety requirements under the award and that EcoHealth Alliance had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. Accordingly, NIH suspended all activities related to R01AI110964, pursuant to 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare.

In my letter of July 8, 2020, I provided EcoHealth with the opportunity to object and to provide information and documentation challenging the suspension. Specifically, I sought information and materials that speak to WIV's lab safety and EcoHealth's oversight of its subrecipient, and an inspection of WIV's laboratory records and facilities. I indicated that as a specific condition of award, during the period of suspension, EcoHealth Alliance may not allow research under this

project to be conducted and that no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients.

EcoHealth objected to the requests on the grounds that "NIAID is not authorized under 45 CFR§§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates."

These provisions are irrelevant to NIH's requests. NIH is required to permit the opportunity for recipients to object and provide information and documentation challenging a suspension, 45 C.F.R. § 75.374, so we specifically gave EcoHealth the opportunity to provide information that speaks to NIH's concerns. Moreover, as a granting agency, NIH is required to "manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare [and] the environment[.]" 45 C.F.R. § 75.300(a). In addition to seeking information that speaks to compliance with terms and conditions of award, NIH is entitled to "make site visits as warranted by program needs." 45 C.F.R. § 75.342. As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit specified in my letter of July 8, 2020.

In addition to objecting to NIH's authority to seek the materials, information, and a site visit, EcoHealth has responded that it lacks knowledge or information regarding the requests; that it is not in possession, custody, or control of the specified items; and that it has no authority to grant NIAID and the U.S. National Academy of Sciences access to WIV's facility to conduct an inspection. EcoHealth's responses have not satisfied NIH's concerns that EcoHealth had failed to adequately monitor the compliance of its subrecipient, and that the subrecipient, WIV, had failed to comply with safety requirements.

Notwithstanding this, NIH is providing an additional opportunity for EcoHealth to provide information and documentation challenging these concerns of non-compliance. Accordingly, in addition to reiterating our prior requests (1) through (6) per our letter of July 8, 2020, NIH requests the following information and materials, which must be complete and accurate:

1. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.
2. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
3. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

During the ongoing period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess whether EcoHealth Alliance and WIV complied with the terms and conditions of award, including compliance with other terms and conditions of award that may be implicated. We remind you that during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the continued suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 C.F.R. Part 75, including, but not limited to, terminating the grant award or disallowing costs. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.10.23 13:34:25 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May 20, 2020

Mr. Mark Bourbonnais
Director
Research Support Services
School of Medicine
University of California, Irvine
(b) (6)

Dear Mr. Bourbonnais:

I am writing to inform you that the National Institutes of Health (NIH) has been made aware of reports that Wuhan Institute of Virology (WIV) has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, health and welfare threats to the public, both in China and other countries, including the United States. The University of California, Irvine (UCI) has an NIH grant award that supports Wuhan Institute of Virology as a subrecipient consortium.

It is the NIH mission to protect public health and welfare from a serious deficiency such as unsafe laboratory practices. Therefore, effective the date of this letter, May 20, 2020, NIH is suspending all activities related to RF1 MH120020-01, *Genetically engineered anterograde monosynaptic viral tracers for multi-species neural circuit analysis*, Dr. Xiangmin Xu (Contact PI), for which the Wuhan Institute of Virology is a subaward participant, awarded by the National Institute of Mental Health (NIMH).

This action is taken in accordance with the NIH Grants Policy Statement (GPS), a term and condition all NIH grant awards, Section 8.5.2, Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support, which implements our governing regulations 45 CFR Part 75.371, Remedies for Noncompliance. This section states that NIH may take immediate action to terminate a grant when necessary to protect the public health and welfare. However, in this case NIH has chosen to suspend the sub-contractual activities directly supporting WIV, while the safety measures outlined in the NIH GPS Section 4.1.12 Health and Safety Regulations and Guidelines, are reviewed. This action is not appealable in accordance with the NIH GPS Section 8.7, Grant Appeals Procedures.

During the period of suspension, UCI may not allow research under this project to be conducted by WIV. Further, no funds may be provided to or expended by WIV; all such charges are unallowable. Other grant funding for this project will remain available for the conduct of research that is not subject to this suspension action. It is UCI's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by WIV. UCI must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms must be immediately reported to NIH. NIH has taken additional steps to restrict funding in the HHS Payment Management System in the amount of $660,054, the total costs awarded for the research that is being conducted at WIV. UCI will receive a revised Notice of Award from NIMH indicating the suspension of these research activates and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from imposing additional special award conditions, corrective actions, or enforcement actions pursuant to 45 CFR including, but not limited to, terminating the grant award.

Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

Lauer, Michael (NIH/OD) [E]

Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2020.05.20 06:09:28 -04'00'

Michael S. Lauer, M.D.
Deputy Director Extramural Research
1 Center Drive, Room 144
Bethesda, MD 20892
(b) (6)
(b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 5/10/2021 9:14:40 AM
To: Kosub, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e3eccf57f4e4fcfaecaa7885f39bee5-kosubd]; Bulls, Michelle G. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b366f1a4382d44c1bde626e7730c3dd4-bullsmg]; Ta, Kristin (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72dc8e6c4cae4efcaa9e72eabbff2ee3-takr]
CC: Columbus, Megan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8878f99917841749c5ae3fad8d90c73-columbum]; Rabin, Elise (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3426cfac5b54e8dae0d1aca72262bf3-rabine]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Grassley letter re COVID
Attachments: FW: Grassley letter re COVID; Response to Senator Grassley re WIV.docx

Hi David, Michelle, and Kristin – Here's my draft response to Q9.

Thanks, Mike

From: "Kosub, David (NIH/OD) [E]" (b) (6)
Date: Friday, May 7, 2021 at 11:32 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6), "Bulls, Michelle G. (NIH/OD) [E]" (b) (6), "Ta, Kristin (NIH/OD) [E]" (b) (6)
Cc: "Columbus, Megan (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6)
Subject: FW: Grassley letter re COVID

Good day Mike, Michelle, and Kristin,

HHS requested NIH draft a response to Q#9 from Senator Grassley's letter (first attachment) regarding the origins of COVID-19: "In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology."

Mike previously shared the additional EcoHealth correspondence with OLPA to address this question. Please advise who should take lead on drafting the proposed answer.

Thank you
David

From: LaMontagne, Karen (NIH/OD) [E] (b) (6)
Sent: Friday, May 7, 2021 9:30 AM
To: Kosub, David (NIH/OD) [E] (b) (6)
Cc: Rabin, Elise (NIH/OD) [E] (b) (6); Lohmann, Larry (NIH/OD) [E] (b) (6)
Subject: FW: Grassley letter re COVID

Good Morning, David,

HHS came back to us on the attached letter from Sen. Grassley to ODNI. They are asking us to draft a narrative response to question #9. Dr. Lauer had previously indicated that we might base that response on the letters that we sent to EcoHealth.

I've looped in Larry who can help answer any questions on the background on this letter.

Thank you,
Karen

From: "Lohmann, Larry (NIH/OD) [E]" (b) (6)
Date: Tuesday, May 4, 2021 at 4:58 PM
To: Karen LaMontagne (b) (6)
Subject: Re: Grassley letter re COVID

Good afternoon,

This is back again. HHS asked if we could draft a narrative response to question number 9, "In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology." My guess is (b) (5) Can you see if OER would be willing to draft it, guessing NIAID might have to look at it as well?

Very respectfully,
Larry

From: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Date: Tuesday, March 23, 2021 at 6:21 PM
To: "LaMontagne, Karen (NIH/OD) [E]" (b) (6)
Cc: "Kosub, David (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Re: Grassley letter re COVID

Thanks Karen – agree ODNI for #8. For #9 we have the letters we sent to EcoHealth Alliance. We also sent a letter to UC Irvine suspending a subaward.

Mike

From: "LaMontagne, Karen (NIH/OD) [E]" (b) (6)
Date: Tuesday, March 23, 2021 at 3:36 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: "Kosub, David (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6)
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Hi, Dr. Lauer,

Flagging the attached letter to ODNI from Senator Grassley. You will recall that Sen. Grassley is the former Chairman of the Senate Finance Committee. He now serves as the Ranking Minority Member of the Senate Judiciary Committee.

HHS/ASL reached out to OLPA to gauge whether NIH can answer #8 & #9. (Although I would think ODNI should answer #8?) Would you please let us know what you think?

Thanks very much,
Karen

Karen LaMontagne
Office of Legislative Policy & Analysis
National Institutes of Health
(b) (6)

National Institutes of Health
Turning Discovery Into Health

From: "Schmalz, Jennifer (HHS/ASL)" (b) (6)
Date: Tuesday, March 23, 2021 at 2:55 PM
To: "Lohmann, Larry (NIH/OD) [E]" (b) (6)
Subject: FW: Grassley letter re COVID

Here's the SFC letter.

Can you advise on whether NIH could respond to #8 and #9?

From: Kosub, David (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3E3ECCF57F4E4FCFAECAA7885F39BEE5-KOSUBD]
Sent: 5/7/2021 3:32:46 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Bulls, Michelle G. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b366f1a4382d44c1bde626e7730c3dd4-bullsmg]; Ta, Kristin (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72dc8e6c4cae4efcaa9e72eabbff2ee3-takr]
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Subject: FW: Grassley letter re COVID
Attachments: 2021-03-08 CEG to ODNI HHS (COVID Origins)[2][1].pdf; NIH Response to EcoHealth Response to Suspension_10_23_20.pdf; NIH letter to UCI re Wuhan Institute of Virology 5-20-2020 msl[2][1][1].pdf; Daszak 7 8 20[3].pdf

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Cc: Rabin, Elise (NIH/OD) [E] (b) (6); Lohmann, Larry (NIH/OD) [E] (b) (6)
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Karen LaMontagne
Office of Legislative Policy & Analysis
National Institutes of Health
(b) (6)

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Can you advise on whether NIH could respond to #8 and #9?

United States Senate

WASHINGTON, DC 20510

March 8, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Avril Haines
Director of National Intelligence

Mr. Norris Cochran
Acting Director
Department of Health and Human Services

Dear Director Haines and Acting Director Cochran:

On February 4, 2020, my oversight and investigations staff received a classified briefing from the Department of Health and Human Services (HHS), Office of National Security regarding the SARS-CoV-2 (hereinafter "coronavirus") threat and the status of the U.S. government's efforts to combat the spread of the deadly virus.[1] From the beginning, my goal has been to ensure a robust federal response to the threat and to better understand the origins of the virus. For example, there is still considerable debate about whether the coronavirus is a naturally occurring virus, a naturally occurring virus that escaped from a lab, or a laboratory manipulated virus that escaped from a lab.

In December 2020, a team of World Health Organization (WHO) researchers and scientists traveled to Wuhan, China to investigate the origins of coronavirus. However, according to recent reports, China refused to grant WHO researchers access to anonymized raw data from the earliest days of the outbreak which would help pinpoint the origins of the virus.[2] Instead, China produced self-generated summaries and analyses of the data which could have been manipulated by the communist Chinese government, effectively preventing a real review.[3]

In early February last year, I warned about China's reluctance to share data regarding the coronavirus outbreak.[4] I also noted that China's failure to cooperate made it more important for the Intelligence Community and HHS to work together to ensure information is efficiently

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[1] Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.
[2] Jeremy Page et al., *China Refuse to Give WHO Raw Data on Early COVID-19 Cases*, WALL ST. J. (Feb. 12, 2021), https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580.
[3] *Id.*
[4] Press Release, Grassley Urges More Information Sharing Between Health, Intelligence Agencies (Mar. 24, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-urges-more-information-sharing-between-health-intelligence-agencies; Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.

shared between them. The Trump administration ensured that federal health agencies had a seat at the table within the Intelligence Community and access to information relating to the pandemic. That cooperation and access must continue and be built upon to better combat the virus and determine its origins.

More than 500,000 Americans have died as a result of the coronavirus pandemic and trillions of taxpayer dollars have been spent to shore up our economy and take care of our citizens. Congress and the American public have a right to know and understand what work the government has done to determine the origins of the coronavirus. Accordingly, in light of your agency's role with respect to the pandemic, no later than March 22, 2021, please provide the following:

1. All information disseminated to the National Intelligence Council relating to the coronavirus pandemic.

2. All records relating to detailed genomic sequencing analyses for SARS-CoV-2 and related coronaviruses, including all records relating to research about the receptor binding domain of pangolin origin coronavirus and furin-cleavage site insertion.

3. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and any previous published and/or unpublished work by the Wuhan Institute of Virology on coronavirus chimeras.

4. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and genomic sequencing analyses on miners that were hospitalized in Yunnan Province in and around 2012.

5. All records relating to all analyses with respect to the capabilities of the Wuhan Institute of Virology to manipulate bat coronaviruses using reverse genetic technologies.

6. All records relating to illnesses at the Wuhan Institute of Virology among its personnel and scientific staff during the Fall of 2019. In your answer, please describe the type of work these employees were engaged in.

7. All records relating to work conducted at the Wuhan Institute of Virology by Chinese government agencies prior to and during Fall of 2019.

8. Please describe the steps you have taken to continue to incorporate the Department of Health and Human Services into missions involving threats to the nation's health care, including access to Intelligence Community information, and the steps you have taken to improve upon the information access provided by the Trump administration.

9. In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.

Please send all unclassified material directly to the Committee. In keeping with the requirements of Executive Order 13526, if any of the responsive documents do contain classified information, please segregate all unclassified material within the classified documents, provide all unclassified information directly to the Committee, and provide a classified addendum to the Office of Senate Security. Although the Committee complies with all laws and regulations governing the handling of classified information, it is not bound, absent its prior agreement, by any handling restrictions.

Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

23 October 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

I am following up on Mr. Krinsky's August 13, 2020, letter on behalf of EcoHealth Alliance, Inc. ("EcoHealth") responding to NIH's suspension of grant R01AI110964, which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project"). Per my letter of July 8, 2020, NIH reinstated the grant but suspended all award activities because we have concerns that the Wuhan Institute of Virology (WIV), which previously served as a subrecipient of the Project, had not satisfied safety requirements that applied to its subawards with EcoHealth, and that EcoHealth had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. EcoHealth objected to the suspension on the grounds that WIV has no *current* connection to the Project or EcoHealth's research, and EcoHealth had not issued any subawards in connection with the Grant *at the time of the suspension*.

The fact that EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension does not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964. While EcoHealth did not issue a subaward to WIV for year 6 of the grant, WIV served as a subrecipient for years 1 through 5. NIH awarded EcoHealth grant R01AI110964 in 2014, with a project period of June 1, 2014, through June 30, 2024, as renewed. In EcoHealth's grant application, EcoHealth listed Drs. Zheng Li Shi and Xing Yi Ge of WIV as co-investigators and senior/key personnel. It stated that "Drs. Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences, and shipping samples into and out of China." EcoHealth listed WIV as a Project/Performance Site Location. In describing WIV's facilities, EcoHealth described WIV as China's premier institute for virological research" and touted WIV's "fully equipped biosafety level 3 laboratory" and "a newly opened BLS-4 laboratory." In support of the application, Dr. Zheng Li Shi's personal statement indicated that "My lab will be responsible for diagnosis, genomics and isolation of coronavirus from wild and domestic animals in Southern China and for analyzing their receptor binding domains." The application stated that "Wuhan Institute of Virology and the Wuhan University Center for Animal Experiment BSL-3

lab have an Internal Biosafety Committee and are accredited BSL-2 and BSL 3 laboratories. All experimental work using infectious material will be conducted under appropriate biosafety standards. Disposal of hazardous materials will be conducted according to the institutional biosafety regulations."

EcoHealth requested funding specifically for activities to be carried out by WIV. NIH awarded EcoHealth a total of $749,976 for WIV's work in the following annual amounts for years 1 through 5:

	-Yr 1	-Yr 2	-Yr 3	-Yr 4	-Yr 5
Total Direct Costs	$123,699	$128,718	$147,335	$147,335	$147,335
F&A Costs @ 8%	$9,896	$10,297	$11,787	$11,787	$11,787
TOTAL COSTS	$133,595	$139,015	$159,122	$159,122	$159,122

As stated in the Notices of Award for each budget period of the grant, the awards were subject to terms and conditions, which include the NIH Grants Policy Statement (GPS) and applicable HHS grant regulations. As I indicated in my letter of July 8, 2020, as a term and condition of award EcoHealth was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). See also, 45 C.F.R. § 75.342(a) ("The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities."). Moreover, EcoHealth was required to "Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award[.]" 45 C.F.R. § 75.303(a). The Notice of Award stated that as a term and condition of award, "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]." Moreover, the NIH GPS provides that NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients, so these terms applied to WIV. 45 C.F.R. § 75.101.

As I stated, NIH has concerns of non-compliance with terms and conditions of award—namely, that WIV had not satisfied safety requirements under the award and that EcoHealth Alliance had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. Accordingly, NIH suspended all activities related to R01AI110964, pursuant to 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare.

In my letter of July 8, 2020, I provided EcoHealth with the opportunity to object and to provide information and documentation challenging the suspension. Specifically, I sought information and materials that speak to WIV's lab safety and EcoHealth's oversight of its subrecipient, and an inspection of WIV's laboratory records and facilities. I indicated that as a specific condition of award, during the period of suspension, EcoHealth Alliance may not allow research under this

project to be conducted and that no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients.

EcoHealth objected to the requests on the grounds that "NIAID is not authorized under 45 CFR§§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates."

These provisions are irrelevant to NIH's requests. NIH is required to permit the opportunity for recipients to object and provide information and documentation challenging a suspension, 45 C.F.R. § 75.374, so we specifically gave EcoHealth the opportunity to provide information that speaks to NIH's concerns. Moreover, as a granting agency, NIH is required to "manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare [and] the environment[.]" 45 C.F.R. § 75.300(a). In addition to seeking information that speaks to compliance with terms and conditions of award, NIH is entitled to "make site visits as warranted by program needs." 45 C.F.R. § 75.342. As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit specified in my letter of July 8, 2020.

In addition to objecting to NIH's authority to seek the materials, information, and a site visit, EcoHealth has responded that it lacks knowledge or information regarding the requests; that it is not in possession, custody, or control of the specified items; and that it has no authority to grant NIAID and the U.S. National Academy of Sciences access to WIV's facility to conduct an inspection. EcoHealth's responses have not satisfied NIH's concerns that EcoHealth had failed to adequately monitor the compliance of its subrecipient, and that the subrecipient, WIV, had failed to comply with safety requirements.

Notwithstanding this, NIH is providing an additional opportunity for EcoHealth to provide information and documentation challenging these concerns of non-compliance. Accordingly, in addition to reiterating our prior requests (1) through (6) per our letter of July 8, 2020, NIH requests the following information and materials, which must be complete and accurate:

1. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.
2. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
3. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

During the ongoing period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess whether EcoHealth Alliance and WIV complied with the terms and conditions of award, including compliance with other terms and conditions of award that may be implicated. We remind you that during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the continued suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 C.F.R. Part 75, including, but not limited to, terminating the grant award or disallowing costs. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.10.23 13:34:25 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May 20, 2020

Mr. Mark Bourbonnais
Director
Research Support Services
School of Medicine
University of California, Irvine
(b) (6)

Dear Mr. Bourbonnais:

I am writing to inform you that the National Institutes of Health (NIH) has been made aware of reports that Wuhan Institute of Virology (WIV) has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, health and welfare threats to the public, both in China and other countries, including the United States. The University of California, Irvine (UCI) has an NIH grant award that supports Wuhan Institute of Virology as a subrecipient consortium.

It is the NIH mission to protect public health and welfare from a serious deficiency such as unsafe laboratory practices. Therefore, effective the date of this letter, May 20, 2020, NIH is suspending all activities related to RF1 MH120020-01, *Genetically engineered anterograde monosynaptic viral tracers for multi-species neural circuit analysis*, Dr. Xiangmin Xu (Contact PI), for which the Wuhan Institute of Virology is a subaward participant, awarded by the National Institute of Mental Health (NIMH).

This action is taken in accordance with the NIH Grants Policy Statement (GPS), a term and condition all NIH grant awards, Section 8.5.2, Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support, which implements our governing regulations 45 CFR Part 75.371, Remedies for Noncompliance. This section states that NIH may take immediate action to terminate a grant when necessary to protect the public health and welfare. However, in this case NIH has chosen to suspend the sub-contractual activities directly supporting WIV, while the safety measures outlined in the NIH GPS Section 4.1.12 Health and Safety Regulations and Guidelines, are reviewed. This action is not appealable in accordance with the NIH GPS Section 8.7, Grant Appeals Procedures.

During the period of suspension, UCI may not allow research under this project to be conducted by WIV. Further, no funds may be provided to or expended by WIV; all such charges are unallowable. Other grant funding for this project will remain available for the conduct of research that is not subject to this suspension action. It is UCI's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by WIV. UCI must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms must be immediately reported to NIH. NIH has taken additional steps to restrict funding in the HHS Payment Management System in the amount of $660,054, the total costs awarded for the research that is being conducted at WIV. UCI will receive a revised Notice of Award from NIMH indicating the suspension of these research activates and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from imposing additional special award conditions, corrective actions, or enforcement actions pursuant to 45 CFR including, but not limited to, terminating the grant award.

Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

Lauer, Michael (NIH/OD) [E]

Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2020.05.20 06:09:28 -04'00'

Michael S. Lauer, M.D.
Deputy Director Extramural Research
1 Center Drive, Room 144
Bethesda, MD 20892
(b) (6)
(b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

Response to Senator Grassley re WIV
Draft May 10, 2021
Mike Lauer (OER)

Q: In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.

(b) (5)

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 5/11/2021 9:44:09 PM
To: Bulls, Michelle G. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b366f1a4382d44c1bde626e7730c3dd4-bullsmg]; Kosub, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e3eccf57f4e4fcfaecaa7885f39bee5-kosubd]; Ta, Kristin (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72dc8e6c4cae4efcaa9e72eabbff2ee3-takr]
CC: Columbus, Megan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8878f99917841749c5ae3fad8d90c73-columbum]; Rabin, Elise (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3426cfac5b54e8dae0d1aca72262bf3-rabine]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Grassley letter re COVID
Attachments: Response to Senator Grassley re WIV v2.docx; FW: Grassley letter re COVID

Thanks Michelle. Here's a revised draft.

Mike

From: "Bulls, Michelle G. (NIH/OD) [E]" (b) (6)
Date: Tuesday, May 11, 2021 at 5:36 PM
To: "Kosub, David (NIH/OD) [E]" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6), "Ta, Kristin (NIH/OD) [E]" (b) (6)
Cc: "Columbus, Megan (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6), "Bulls, Michelle G. (NIH/OD) [E]" (b) (6)
Subject: RE: Grassley letter re COVID

Hi,

(b) (5)

Thanks,
Michelle

From: Kosub, David (NIH/OD) [E] (b) (6)
Sent: Friday, May 7, 2021 11:33 AM
To: Lauer, Michael (NIH/OD) [E] (b) (6); Bulls, Michelle G. (NIH/OD) [E] (b) (6); Ta, Kristin (NIH/OD) [E] (b) (6)
Cc: Columbus, Megan (NIH/OD) [E] (b) (6); Rabin, Elise (NIH/OD) [E] (b) (6)
Subject: FW: Grassley letter re COVID

Good day Mike, Michelle, and Kristin,

HHS requested NIH draft a response to Q#9 from Senator Grassley's letter (first attachment) regarding the origins of COVID-19: "In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology."

Mike previously shared the additional EcoHealth correspondence with OLPA to address this question. Please advise who should take lead on drafting the proposed answer.

Thank you
David

From: LaMontagne, Karen (NIH/OD) [E] (b) (6)
Sent: Friday, May 7, 2021 9:30 AM
To: Kosub, David (NIH/OD) [E] (b) (6)
Cc: Rabin, Elise (NIH/OD) [E] (b) (6); Lohmann, Larry (NIH/OD) [E] (b) (6)
Subject: FW: Grassley letter re COVID

Good Morning, David,

HHS came back to us on the attached letter from Sen. Grassley to ODNI. They are asking us to draft a narrative response to question #9. Dr. Lauer had previously indicated that we might base that response on the letters that we sent to EcoHealth.

I've looped in Larry who can help answer any questions on the background on this letter.

Thank you,
Karen

From: "Lohmann, Larry (NIH/OD) [E]" (b) (6)
Date: Tuesday, May 4, 2021 at 4:58 PM
To: Karen LaMontagne (b) (6)
Subject: Re: Grassley letter re COVID

Good afternoon,

This is back again. HHS asked if we could draft a narrative response to question number 9, "In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology." My guess is (b) (5) Can you see if OER would be willing to draft it, guessing NIAID might have to look at it as well?

Very respectfully,
Larry

From: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Date: Tuesday, March 23, 2021 at 6:21 PM
To: "LaMontagne, Karen (NIH/OD) [E]" (b) (6)
Cc: "Kosub, David (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Re: Grassley letter re COVID

Thanks Karen – agree ODNI for #8. For #9 we have the letters we sent to EcoHealth Alliance. We also sent a letter to UC Irvine suspending a subaward.

Mike

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Date: Tuesday, March 23, 2021 at 3:36 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: "Kosub, David (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6)
Subject: FW: Grassley letter re COVID

Hi, Dr. Lauer,

Flagging the attached letter to ODNI from Senator Grassley. You will recall that Sen. Grassley is the former Chairman of the Senate Finance Committee. He now serves as the Ranking Minority Member of the Senate Judiciary Committee.

HHS/ASL reached out to OLPA to gauge whether NIH can answer #8 & #9. (Although I would think ODNI should answer #8?) Would you please let us know what you think?

Thanks very much,
Karen

Karen LaMontagne
Office of Legislative Policy & Analysis
National Institutes of Health
(b) (6)

National Institutes of Health
Turning Discovery Into Health

From: "Schmalz, Jennifer (HHS/ASL)" (b) (6)
Date: Tuesday, March 23, 2021 at 2:55 PM
To: "Lohmann, Larry (NIH/OD) [E]" (b) (6)
Subject: FW: Grassley letter re COVID

Here's the SFC letter.

Can you advise on whether NIH could respond to #8 and #9?

Response to Senator Grassley re WIV
Draft May 110, 2021
Mike Lauer (OER)

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Sent: 5/7/2021 3:32:46 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Bulls, Michelle G. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b366f1a4382d44c1bde626e7730c3dd4-bullsmg]; Ta, Kristin (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72dc8e6c4cae4efcaa9e72eabbff2ee3-takr]
CC: Columbus, Megan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8878f99917841749c5ae3fad8d90c73-columbum]; Rabin, Elise (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3426cfac5b54e8dae0d1aca72262bf3-rabine]
Subject: FW: Grassley letter re COVID
Attachments: 2021-03-08 CEG to ODNI HHS (COVID Origins)[2][1].pdf; NIH Response to EcoHealth Response to Suspension_10_23_20.pdf; NIH letter to UCI re Wuhan Institute of Virology 5-20-2020 msl[2][1][1].pdf; Daszak 7 8 20[3].pdf

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Cc: "Kosub, David (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Re: Grassley letter re COVID

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Mike

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Date: Tuesday, March 23, 2021 at 3:36 PM
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Cc: "Kosub, David (NIH/OD) [E]" (b) (6), "Rabin, Elise (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6)
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Thanks very much,
Karen

Karen LaMontagne
Office of Legislative Policy & Analysis
National Institutes of Health
(b) (6)

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To: "Lohmann, Larry (NIH/OD) [E]" (b) (6)
Subject: FW: Grassley letter re COVID

Here's the SFC letter.

Can you advise on whether NIH could respond to #8 and #9?

United States Senate

WASHINGTON, DC 20510

March 8, 2021

VIA ELECTRONIC TRANSMISSION

The Honorable Avril Haines
Director of National Intelligence

Mr. Norris Cochran
Acting Director
Department of Health and Human Services

Dear Director Haines and Acting Director Cochran:

On February 4, 2020, my oversight and investigations staff received a classified briefing from the Department of Health and Human Services (HHS), Office of National Security regarding the SARS-CoV-2 (hereinafter "coronavirus") threat and the status of the U.S. government's efforts to combat the spread of the deadly virus.[1] From the beginning, my goal has been to ensure a robust federal response to the threat and to better understand the origins of the virus. For example, there is still considerable debate about whether the coronavirus is a naturally occurring virus, a naturally occurring virus that escaped from a lab, or a laboratory manipulated virus that escaped from a lab.

In December 2020, a team of World Health Organization (WHO) researchers and scientists traveled to Wuhan, China to investigate the origins of coronavirus. However, according to recent reports, China refused to grant WHO researchers access to anonymized raw data from the earliest days of the outbreak which would help pinpoint the origins of the virus.[2] Instead, China produced self-generated summaries and analyses of the data which could have been manipulated by the communist Chinese government, effectively preventing a real review.[3]

In early February last year, I warned about China's reluctance to share data regarding the coronavirus outbreak.[4] I also noted that China's failure to cooperate made it more important for the Intelligence Community and HHS to work together to ensure information is efficiently

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[1] Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.
[2] Jeremy Page et al., *China Refuse to Give WHO Raw Data on Early COVID-19 Cases*, WALL ST. J. (Feb. 12, 2021), https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580.
[3] *Id.*
[4] Press Release, Grassley Urges More Information Sharing Between Health, Intelligence Agencies (Mar. 24, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-urges-more-information-sharing-between-health-intelligence-agencies; Press Release, Grassley Receives Classified Briefing on Coronavirus (Feb. 4, 2020), https://www.grassley.senate.gov/news/news-releases/grassley-receives-classified-briefing-coronavirus.

shared between them. The Trump administration ensured that federal health agencies had a seat at the table within the Intelligence Community and access to information relating to the pandemic. That cooperation and access must continue and be built upon to better combat the virus and determine its origins.

More than 500,000 Americans have died as a result of the coronavirus pandemic and trillions of taxpayer dollars have been spent to shore up our economy and take care of our citizens. Congress and the American public have a right to know and understand what work the government has done to determine the origins of the coronavirus. Accordingly, in light of your agency's role with respect to the pandemic, no later than March 22, 2021, please provide the following:

1. All information disseminated to the National Intelligence Council relating to the coronavirus pandemic.

2. All records relating to detailed genomic sequencing analyses for SARS-CoV-2 and related coronaviruses, including all records relating to research about the receptor binding domain of pangolin origin coronavirus and furin-cleavage site insertion.

3. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and any previous published and/or unpublished work by the Wuhan Institute of Virology on coronavirus chimeras.

4. All records relating to detailed genomic sequencing analyses on the similarities between SARS-CoV-2 and genomic sequencing analyses on miners that were hospitalized in Yunnan Province in and around 2012.

5. All records relating to all analyses with respect to the capabilities of the Wuhan Institute of Virology to manipulate bat coronaviruses using reverse genetic technologies.

6. All records relating to illnesses at the Wuhan Institute of Virology among its personnel and scientific staff during the Fall of 2019. In your answer, please describe the type of work these employees were engaged in.

7. All records relating to work conducted at the Wuhan Institute of Virology by Chinese government agencies prior to and during Fall of 2019.

8. Please describe the steps you have taken to continue to incorporate the Department of Health and Human Services into missions involving threats to the nation's health care, including access to Intelligence Community information, and the steps you have taken to improve upon the information access provided by the Trump administration.

9. In light of the National Institutes of Health funding operations at the Wuhan Institute of Virology, please describe the steps you took to oversee the research done at the Wuhan Institute of Virology.

Please send all unclassified material directly to the Committee. In keeping with the requirements of Executive Order 13526, if any of the responsive documents do contain classified information, please segregate all unclassified material within the classified documents, provide all unclassified information directly to the Committee, and provide a classified addendum to the Office of Senate Security. Although the Committee complies with all laws and regulations governing the handling of classified information, it is not bound, absent its prior agreement, by any handling restrictions.

Thank you for your attention to this important matter.

Sincerely,

Charles E. Grassley
Ranking Member
Committee on the Judiciary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

23 October 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

I am following up on Mr. Krinsky's August 13, 2020, letter on behalf of EcoHealth Alliance, Inc. ("EcoHealth") responding to NIH's suspension of grant R01AI110964, which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project"). Per my letter of July 8, 2020, NIH reinstated the grant but suspended all award activities because we have concerns that the Wuhan Institute of Virology (WIV), which previously served as a subrecipient of the Project, had not satisfied safety requirements that applied to its subawards with EcoHealth, and that EcoHealth had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. EcoHealth objected to the suspension on the grounds that WIV has no *current* connection to the Project or EcoHealth's research, and EcoHealth had not issued any subawards in connection with the Grant *at the time of the suspension*.

The fact that EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension does not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964. While EcoHealth did not issue a subaward to WIV for year 6 of the grant, WIV served as a subrecipient for years 1 through 5. NIH awarded EcoHealth grant R01AI110964 in 2014, with a project period of June 1, 2014, through June 30, 2024, as renewed. In EcoHealth's grant application, EcoHealth listed Drs. Zheng Li Shi and Xing Yi Ge of WIV as co-investigators and senior/key personnel. It stated that "Drs. Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences, and shipping samples into and out of China." EcoHealth listed WIV as a Project/Performance Site Location. In describing WIV's facilities, EcoHealth described WIV as China's premier institute for virological research" and touted WIV's "fully equipped biosafety level 3 laboratory" and "a newly opened BLS-4 laboratory." In support of the application, Dr. Zheng Li Shi's personal statement indicated that "My lab will be responsible for diagnosis, genomics and isolation of coronavirus from wild and domestic animals in Southern China and for analyzing their receptor binding domains." The application stated that "Wuhan Institute of Virology and the Wuhan University Center for Animal Experiment BSL-3

lab have an Internal Biosafety Committee and are accredited BSL-2 and BSL 3 laboratories. All experimental work using infectious material will be conducted under appropriate biosafety standards. Disposal of hazardous materials will be conducted according to the institutional biosafety regulations."

EcoHealth requested funding specifically for activities to be carried out by WIV. NIH awarded EcoHealth a total of $749,976 for WIV's work in the following annual amounts for years 1 through 5:

	-Yr 1	-Yr 2	-Yr 3	-Yr 4	-Yr 5
Total Direct Costs	$123,699	$128,718	$147,335	$147,335	$147,335
F&A Costs @ 8%	$9,896	$10,297	$11,787	$11,787	$11,787
TOTAL COSTS	$133,595	$139,015	$159,122	$159,122	$159,122

As stated in the Notices of Award for each budget period of the grant, the awards were subject to terms and conditions, which include the NIH Grants Policy Statement (GPS) and applicable HHS grant regulations. As I indicated in my letter of July 8, 2020, as a term and condition of award EcoHealth was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). See also, 45 C.F.R. § 75.342(a) ("The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities."). Moreover, EcoHealth was required to "Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award[.]" 45 C.F.R. § 75.303(a). The Notice of Award stated that as a term and condition of award, "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]." Moreover, the NIH GPS provides that NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients, so these terms applied to WIV. 45 C.F.R. § 75.101.

As I stated, NIH has concerns of non-compliance with terms and conditions of award—namely, that WIV had not satisfied safety requirements under the award and that EcoHealth Alliance had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. Accordingly, NIH suspended all activities related to R01AI110964, pursuant to 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare.

In my letter of July 8, 2020, I provided EcoHealth with the opportunity to object and to provide information and documentation challenging the suspension. Specifically, I sought information and materials that speak to WIV's lab safety and EcoHealth's oversight of its subrecipient, and an inspection of WIV's laboratory records and facilities. I indicated that as a specific condition of award, during the period of suspension, EcoHealth Alliance may not allow research under this

project to be conducted and that no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients.

EcoHealth objected to the requests on the grounds that "NIAID is not authorized under 45 CFR§§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates."

These provisions are irrelevant to NIH's requests. NIH is required to permit the opportunity for recipients to object and provide information and documentation challenging a suspension, 45 C.F.R. § 75.374, so we specifically gave EcoHealth the opportunity to provide information that speaks to NIH's concerns. Moreover, as a granting agency, NIH is required to "manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare [and] the environment[.]" 45 C.F.R. § 75.300(a). In addition to seeking information that speaks to compliance with terms and conditions of award, NIH is entitled to "make site visits as warranted by program needs." 45 C.F.R. § 75.342. As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit specified in my letter of July 8, 2020.

In addition to objecting to NIH's authority to seek the materials, information, and a site visit, EcoHealth has responded that it lacks knowledge or information regarding the requests; that it is not in possession, custody, or control of the specified items; and that it has no authority to grant NIAID and the U.S. National Academy of Sciences access to WIV's facility to conduct an inspection. EcoHealth's responses have not satisfied NIH's concerns that EcoHealth had failed to adequately monitor the compliance of its subrecipient, and that the subrecipient, WIV, had failed to comply with safety requirements.

Notwithstanding this, NIH is providing an additional opportunity for EcoHealth to provide information and documentation challenging these concerns of non-compliance. Accordingly, in addition to reiterating our prior requests (1) through (6) per our letter of July 8, 2020, NIH requests the following information and materials, which must be complete and accurate:

1. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.
2. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
3. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

During the ongoing period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess whether EcoHealth Alliance and WIV complied with the terms and conditions of award, including compliance with other terms and conditions of award that may be implicated. We remind you that during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the continued suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 C.F.R. Part 75, including, but not limited to, terminating the grant award or disallowing costs. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.10.23 13:34:25 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May 20, 2020

Mr. Mark Bourbonnais
Director
Research Support Services
School of Medicine
University of California, Irvine
(b) (6)

Dear Mr. Bourbonnais:

I am writing to inform you that the National Institutes of Health (NIH) has been made aware of reports that Wuhan Institute of Virology (WIV) has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, health and welfare threats to the public, both in China and other countries, including the United States. The University of California, Irvine (UCI) has an NIH grant award that supports Wuhan Institute of Virology as a subrecipient consortium.

It is the NIH mission to protect public health and welfare from a serious deficiency such as unsafe laboratory practices. Therefore, effective the date of this letter, May 20, 2020, NIH is suspending all activities related to RF1 MH120020-01, *Genetically engineered anterograde monosynaptic viral tracers for multi-species neural circuit analysis*, Dr. Xiangmin Xu (Contact PI), for which the Wuhan Institute of Virology is a subaward participant, awarded by the National Institute of Mental Health (NIMH).

This action is taken in accordance with the NIH Grants Policy Statement (GPS), a term and condition all NIH grant awards, Section 8.5.2, Remedies for Noncompliance or Enforcement Actions: Suspension, Termination, and Withholding of Support, which implements our governing regulations 45 CFR Part 75.371, Remedies for Noncompliance. This section states that NIH may take immediate action to terminate a grant when necessary to protect the public health and welfare. However, in this case NIH has chosen to suspend the sub-contractual activities directly supporting WIV, while the safety measures outlined in the NIH GPS Section 4.1.12 Health and Safety Regulations and Guidelines, are reviewed. This action is not appealable in accordance with the NIH GPS Section 8.7, Grant Appeals Procedures.

During the period of suspension, UCI may not allow research under this project to be conducted by WIV. Further, no funds may be provided to or expended by WIV; all such charges are unallowable. Other grant funding for this project will remain available for the conduct of research that is not subject to this suspension action. It is UCI's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by WIV. UCI must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms must be immediately reported to NIH. NIH has taken additional steps to restrict funding in the HHS Payment Management System in the amount of $660,054, the total costs awarded for the research that is being conducted at WIV. UCI will receive a revised Notice of Award from NIMH indicating the suspension of these research activates and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from imposing additional special award conditions, corrective actions, or enforcement actions pursuant to 45 CFR including, but not limited to, terminating the grant award.

Please let me know if you have any questions concerning the information in this letter. My complete contact information follows my signature below.

Sincerely,

Lauer, Michael (NIH/OD) [E]

Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2020.05.20 06:09:28 -04'00'

Michael S. Lauer, M.D.
Deputy Director Extramural Research
1 Center Drive, Room 144
Bethesda, MD 20892
(b) (6)
(b) (6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 5/12/2021 10:53:13 AM
To: Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: USE THIS ONE. Re: For our 5 PM today. See page 11
Attachments: PLOS WIV 2017 Daszak ppat.1006698[1].pdf; Journal of Virology-2016-Zeng-6573.full.pdf

Hi Lyric – here's another paper. See what you / your colleagues think.

Many thanks, Mike

From: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Date: Tuesday, May 11, 2021 at 5:52 PM
To: "Jorgenson, Lyric (NIH/OD) [E]" (b) (6)
Cc: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: USE THIS ONE. Re: For our 5 PM today. See page 11

Hi Lyric – I highlighted what I think is the relevant text. Page 11.

Thanks, Mike

From: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Date: Tuesday, May 11, 2021 at 10:25 AM
To: "Jorgenson, Lyric (NIH/OD) [E]" (b) (6)
Cc: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: For our 5 PM today

Hi Lyric – could we talk about this paper?

Many thanks, Mike

PLOS | PATHOGENS

RESEARCH ARTICLE

Discovery of a rich gene pool of bat SARS-related coronaviruses provides new insights into the origin of SARS coronavirus

Ben Hu[1☯], Lei-Ping Zeng[1☯], Xing-Lou Yang[1☯], Xing-Yi Ge[1], Wei Zhang[1], Bei Li[1], Jia-Zheng Xie[1], Xu-Rui Shen[1], Yun-Zhi Zhang[2,3], Ning Wang[1], Dong-Sheng Luo[1], Xiao-Shuang Zheng[1], Mei-Niang Wang[1], Peter Daszak[4], Lin-Fa Wang[5], Jie Cui[1]*, Zheng-Li Shi[1]*

1 CAS Key Laboratory of Special Pathogens and Biosafety, Center for Emerging Infectious Diseases of Wuhan Institute of Virology, Chinese Academy of Sciences, Wuhan, China, **2** Yunnan Institute of Endemic Diseases Control and Prevention, Dali, China, **3** Dali University, Dali, China, **4** EcoHealth Alliance, New York, New York, United States of America, **5** Programme in Emerging Infectious Diseases, Duke-NUS Medical School, Singapore

☯ These authors contributed equally to this work.
* jiecui@wh.iov.cn (JC); zlshi@wh.iov.cn (Z-LS)

Citation: Hu B, Zeng L-P, Yang X-L, Ge X-Y, Zhang W, Li B, et al. (2017) Discovery of a rich gene pool of bat SARS-related coronaviruses provides new insights into the origin of SARS coronavirus. PLoS Pathog 13(11): e1006698. https://doi.org/10.1371/journal.ppat.1006698

Editor: Christian Drosten, Charite Universitatsmedizin Berlin, GERMANY

Received: February 10, 2017

Accepted: October 17, 2017

Published: November 30, 2017

Data Availability Statement: All relevant data are within the paper and its Supporting Information files. The complete genome sequences of the 11 bat SARS-related coronaviruses newly identified in this study have been deposited in the GenBank database and assigned accession numbers KY417142 to KY417152, respectively.

Funding: This work was jointly funded by National Natural Science Foundation of China (81290341, 31621061) to ZLS, China Mega-Project for Infectious Disease (2014ZX10004001-003) to ZLS,

Abstract

A large number of SARS-related coronaviruses (SARSr-CoV) have been detected in horseshoe bats since 2005 in different areas of China. However, these bat SARSr-CoVs show sequence differences from SARS coronavirus (SARS-CoV) in different genes (S, ORF8, ORF3, *etc*) and are considered unlikely to represent the direct progenitor of SARS-CoV. Herein, we report the findings of our 5-year surveillance of SARSr-CoVs in a cave inhabited by multiple species of horseshoe bats in Yunnan Province, China. The full-length genomes of 11 newly discovered SARSr-CoV strains, together with our previous findings, reveals that the SARSr-CoVs circulating in this single location are highly diverse in the S gene, ORF3 and ORF8. Importantly, strains with high genetic similarity to SARS-CoV in the hypervariable N-terminal domain (NTD) and receptor-binding domain (RBD) of the S1 gene, the ORF3 and ORF8 region, respectively, were all discovered in this cave. In addition, we report the first discovery of bat SARSr-CoVs highly similar to human SARS-CoV in ORF3b and in the split ORF8a and 8b. Moreover, SARSr-CoV strains from this cave were more closely related to SARS-CoV in the non-structural protein genes ORF1a and 1b compared with those detected elsewhere. Recombination analysis shows evidence of frequent recombination events within the S gene and around the ORF8 between these SARSr-CoVs. We hypothesize that the direct progenitor of SARS-CoV may have originated after sequential recombination events between the precursors of these SARSr-CoVs. Cell entry studies demonstrated that three newly identified SARSr-CoVs with different S protein sequences are all able to use human ACE2 as the receptor, further exhibiting the close relationship between strains in this cave and SARS-CoV. This work provides new insights into the origin and evolution of SARS-CoV and highlights the necessity of preparedness for future emergence of SARS-like diseases.

Scientific and technological basis special project (2013FY113500) to YZZ and ZLS from the Ministry of Science and Technology of China, the Strategic Priority Research Program of the Chinese Academy of Sciences (XDPB0301) to ZLS, the National Institutes of Health (NIAID R01AI110964), the USAID Emerging Pandemic Threats (EPT) PREDICT program to PD and ZLS, CAS Pioneer Hundred Talents Program to JC, NRF-CRP grant (NRF-CRP10-2012-05) to LFW and WIV "One-Three-Five" Strategic Program (WIV-135-TP1) to JC and ZLS. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: The authors have declared that no competing interests exist.

Author summary

Increasing evidence has been gathered to support the bat origin of SARS coronavirus (SARS-CoV) in the past decade. However, none of the currently known bat SARSr-CoVs is thought to be the direct ancestor of SARS-CoV. Herein, we report the identification of a diverse group of bat SARSr-CoVs in a single cave in Yunnan, China. Importantly, all of the building blocks of SARS-CoV genome, including the highly variable S gene, ORF8 and ORF3, could be found in the genomes of different SARSr-CoV strains from this single location. Based on the analysis of full-length genome sequences of the newly identified bat SARSr-CoVs, we speculate that the direct ancestor of SARS-CoV may have arisen from sequential recombination events between the precursors of these bat SARSr-CoVs prior to spillover to an intermediate host. In addition, we found bat SARSr-CoV strains with different S proteins that can all use the receptor of SARS-CoV in humans (ACE2) for cell entry, suggesting diverse SARSr-CoVs capable of direct transmission to humans are circulating in bats in this cave. Our current study therefore offers a clearer picture on the evolutionary origin of SARS-CoV and highlights the risk of future emergence of SARS-like diseases.

Introduction

Severe Acute Respiratory Syndrome (SARS) is a severe emerging viral disease with high fatality characterized by fever, headache and severe respiratory symptoms including cough, dyspnea and pneumonia [1]. Due to its high transmissibility among humans, after its first emergence in southern China in late 2002, it rapidly led to a global pandemic in 2003 and was marked as one of the most significant public health threats in the 21st century [2,3]. The causative agent, SARS coronavirus (SARS-CoV), has been previously assigned to group 2b CoV and is now a member of the lineage B of genus *Betacoronavirus* in the family *Coronaviridae* [4]. It shares similar genome organization with other coronaviruses, but exhibits a unique genomic structure which includes a number of specific accessory genes, including ORF3a, 3b, ORF6, ORF7a, 7b, ORF8a, 8b and 9b [5,6].

Masked palm civets (*Paguma larvata*) were initially hypothesized to be the animal origin of SARS-CoV [7,8]. However, since a large number of genetically diverse SARS-related coronaviruses (SARSr-CoV) have been detected in multiple species of horseshoe bats (genus *Rhinolophus*) from different areas of China and Europe in the aftermath of SARS, it is prevailingly considered that SARS-CoV originated in horseshoe bats with civets acting as the intermediate amplifying and transmitting host [9–16]. Recently we have reported four novel SARSr-CoVs from Chinese horseshoe bats that shared much higher genomic sequence similarity to the epidemic strains, particularly in their S gene, of which two strains (termed WIV1 and WIV16) have been successfully cultured *in vitro* [17,18]. These newly identified SARSr-CoVs have been demonstrated to use the same cellular receptor (angiotensin converting enzyme-2 [ACE-2]) as SARS-CoV does and replicate efficiently in primary human airway cells [17–19].

Despite the cumulative evidence for the emergence of SARS-CoV from bats, all bat SARSr-CoVs described so far are clearly distinct from SARS-CoV in the S gene and/or one or more accessory genes such as ORF3 and ORF8, suggesting they are likely not the direct ancestor of SARS-CoV. Thus a critical gap remains in our understanding of how and where SARS-CoV originated from bat reservoirs. Previously, we reported a number of bat SARSr-CoVs with diverse S protein sequences from a single cave in Yunnan Province, including the four strains

mentioned above most closely related to SARS-CoV [17,18]. Here we report the latest results of our 5-year longitudinal surveillance of bat SARSr-CoVs in this single location and systematic evolutionary analysis using full-length genome sequences of 15 SARSr-CoV strains (11 novel ones and 4 from previous studies). Efficiency of human ACE2 usage and the functions of accessory genes ORF8 and 8a were also evaluated for some of the newly identified strains.

Results

Continued circulation of diverse SARSr-CoVs in bats from a single location

We have carried out a five-year longitudinal surveillance (April 2011 to October 2015) on SARSr-CoVs in bats from a single habitat in proximity to Kunming city, Yunnan province, China, which was mainly inhabited by horseshoe bats. A total of 602 alimentary specimens (anal swabs or feces) were collected and tested for the presence of CoVs by a Pan-CoV RT-PCR targeting the 440-nt RdRp fragment that is conserved among all known α- and β-CoVs [20]. In total, 84 samples tested positive for CoVs. Sequencing of the PCR amplicons revealed the presence of SARSr-CoVs in the majority (64/84) of the CoV-positive samples (Table 1). Host species identification by amplification of either *Cytb* or *ND1* gene suggested that most (57/64) of the SARSr-CoV positive samples were from *Rhinolophus sinicus*, while the remaining 7 samples were from *Rhinolophus ferrumequinum*, *Rhinolophus affinis* and from *Aselliscus stoliczkanus* which belongs to the family *Hipposideridae*.

Based on the preliminary analysis of the partial RdRp sequences, all of the 64 bat SARSr-CoV sequences showed high similarity among themselves and with other reported bat SARSr-CoVs and SARS-CoVs from humans and civets. To understand the genetic diversity of these bat SARSr-CoVs, the most variable region of the SARSr-CoV S gene, corresponding to the receptor-binding domain (RBD) of SARS-CoV, were amplified and sequenced. Due to low viral load in some samples, RBD sequences were successfully amplified only from 49 samples. These RBD sequences displayed high genetic diversity and could be divided into two large clades, both of which included multiple genotypes. Clade 1 strains shared an identical size and higher amino acid (aa) sequence identity with SARS-CoV RBD, while clade 2 had a shorter size than SARS-CoV S due to two deletions (5 and 12–13 aa, respectively) (S1 Fig). Co-infections by two strains of different clades were detected in two samples, Rs3262 and Rs4087 (S1 Fig).

Table 1. Summary of SARSr-CoV detection in bats from a single habitat in Kunming, Yunnan.

Sampling time	Sample type	Sample Numbers			SARSr-CoV + bat species (No.)
		Total	CoV +	SARSr-CoV +	
April, 2011	anal swab	14	1	1	*R. sinicus* (1)
October, 2011	anal swab	8	3	3	*R. sinicus* (3)
May, 2012	anal swab & feces	54	9	4	*R. sinicus* (4)
September, 2012	feces	39	20	19	*R. sinicus* (16)
					R. ferrumequinum (3)
April, 2013	feces	52	21	16	*R. sinicus* (16)
July, 2013	anal swab & feces	115	9	8	*R. sinicus* (8)
May, 2014	feces	131	8	4	*A. stoliczkamus* (3)
					R. affinis (1)
October, 2014	anal swab	19	4	4	*R. sinicus* (4)
May, 2015	feces	145	3	0	
October, 2015	anal swab	25	6	5	*R. sinicus* (5)
Total		***602***	***84***	***64***	***R (61) A (3)***

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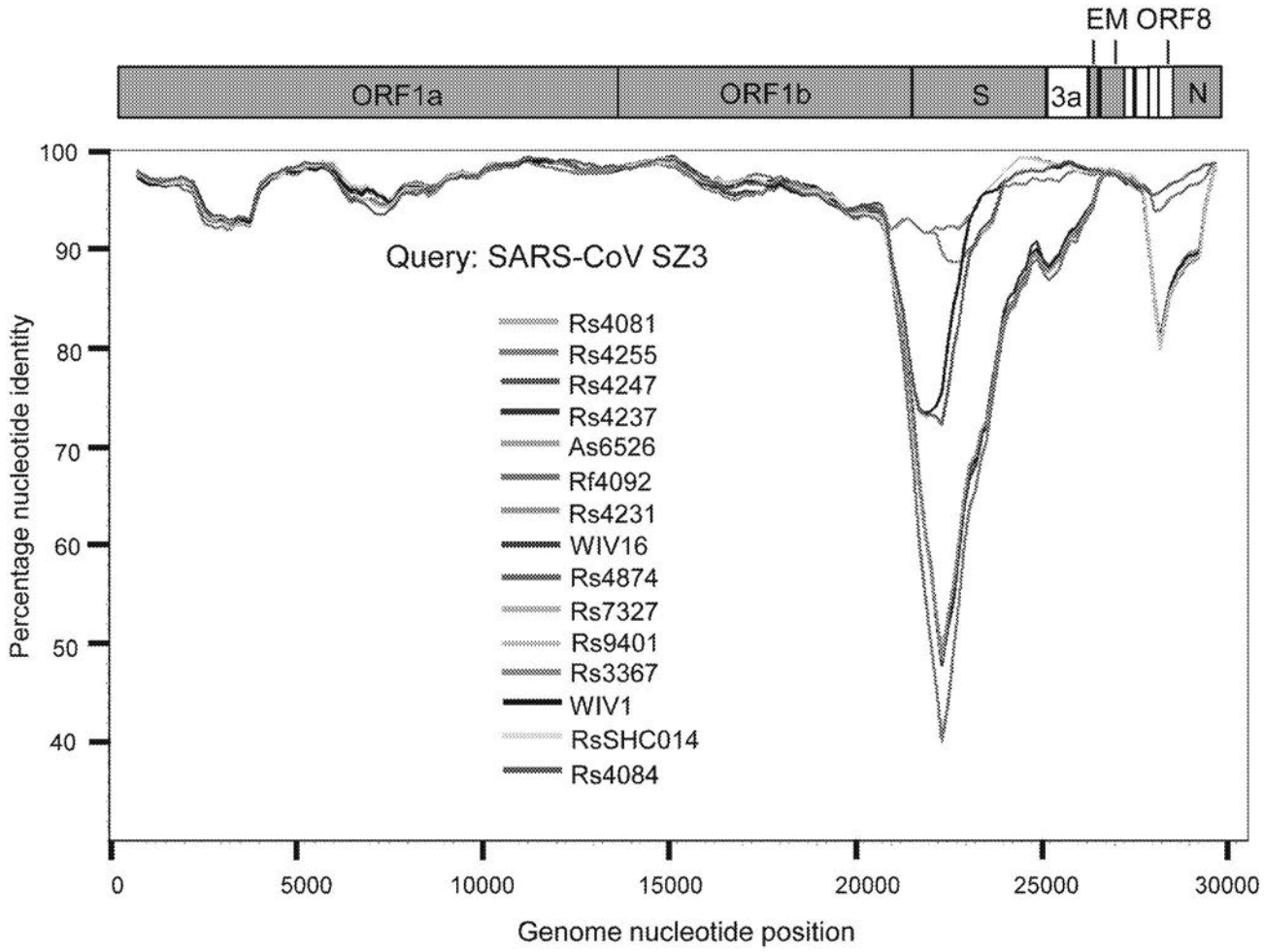

Fig 1. Similarity plot based on the full-length genome sequence of civet SARS CoV SZ3. Full-length genome sequences of all SARSr-CoV detected in bats from the cave investigated in this study were used as reference sequences. The analysis was performed with the Kimura model, a window size of 1500 base pairs and a step size of 150 base pairs.

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Genomic characterization of the novel SARSr-CoVs

Based on the diversity of RBD sequences, 11 novel SARSr-CoV strains named by abbreviation of bat species and sample ID (Rs4081, Rs4084, Rs4231, Rs4237, Rs4247, Rs4255, Rs4874, Rs7327, Rs9401, Rf4092 and As6526) were selected for full-length genomic sequencing based on sample abundance, genotype of RBD as well as sampling time. For each RBD genotype and each time of sampling, at least one representative strain was selected. The genome size of these novel SARSr-CoVs ranged from 29694 to 30291 nucleotides (nt). This gave a total of 15 full-length genomes of bat SARSr-CoVs from this single location (13 from *R.sinicus*, and one each from *R. ferrumequinum* and *A. stoliczkanus*), including our previously reported strains, Rs3367, RsSHC014, WIV1 and WIV16 [17,18]. The genomes of all 15 SARSr-CoVs circulating in this single cave shared 92.0% to 99.9% nt sequence identity. The overall nt sequence identity between these SARSr-CoVs and human and civet SARS-CoVs is 93.2% to 96%, significantly higher than that observed for bat SARSr-CoVs reported from other locations in China (88–93%) [9,10,12,14,21,22]. The genome sequence similarity among the 15 SARSr-CoVs and SARS-CoV SZ3 strain was examined by Simplot analysis (Fig 1). The 15 SARSr-CoVs are

highly conserved and share a uniformly high sequence similarity to SARS-CoV in the non-structural gene ORF1a (96.6% to 97.1% nt sequence identity, 98.0% to 98.3% aa sequence identity) and ORF1b (96.1% to 96.6% nt sequence identity, 99.0% to 99.4% aa sequence identity). In contrast, a considerable genetic diversity is shown in the S gene (corresponding to SZ3 genome position 21477 to 25244) and ORF8 (corresponding to SZ3 genome position 27764 to 28132) (Fig 1).

The 11 novel SARSr-CoVs identified from this single location generally shared similar genome organization with SARS-CoV and other bat SARSr-CoVs. In our previous study, we identified an additional ORF termed ORFx present between ORF6 and ORF7 in strain WIV1 and WIV16 [18,23]. In this study, ORFx was also found in the genomes of Rs7327 and Rs4874. Compared with that of WIV1 and WIV16, the length of ORFx in Rs7327 and Rs4874 was extended to 510 nt due to a deletion of 2 nt in a poly-T sequence that resulted in a shift of reading frame (Fig 2 and S2 Fig).

Co-circulation of different bat SARSr-CoVs with S, ORF8 and ORF3 sequences similar to those in SARS-CoV at a single location

The primary difference between SARS-CoV and most bat SARSr-CoVs is located in S gene. The S protein is functionally divided into two subunits, denoted S1 and S2, which is responsible for receptor binding and cellular membrane fusion, respectively. S1 consists of two domains, the N-terminal domain (NTD) and C-terminal domain (CTD) which is also known as the RBD in SARS-CoV [24]. SARS-CoV and bat SARSr-CoVs share high sequence identity in the S2 region in contrast to the S1 region. Among the 15 SARSr-CoVs identified from bats in the surveyed cave, six strains with deletions in their RBD regions (Rs4081, Rs4237, Rs4247, Rs4255, Rf4092 and As6526) showed 78.2% to 80.2% aa sequence identity to SARS-CoV in the S protein, while the other nine strains without deletions were much more closely related to SARS-CoV, with 90.0% (Rs4084) to 97.2% (Rs4874) aa sequence identity. These nine SARSr-CoVs can be further divided into four genotypes according to their S1 sequences (Fig 2): RsSHC014/Rs4084 showed more genetic differences from SARS-CoV in both NTD and RBD regions; The RBD sequences of SARSr-CoV Rs7327, Rs9401 and previously reported WIV1/Rs3367 closely resembled that of SARS-CoV. However, they were distinct from SARS-CoV but similar to RsSHC014 in NTD. In contrast, we found a novel SARSr-CoV, termed Rs4231, which shared highly similar NTD, but not RBD sequence with SARS-CoV (Figs 2 and 3). Its S protein showed 94.6% to 95% aa sequence identity to those of human and civet SARS-CoVs (S1 Table). Strains with both NTD and RBD highly homologous to those of SARS-CoV were also present in this cave. In addition to WIV16 which we described previously [18], Rs4874 was also found to have the S protein closest to SARS-CoV S (> 97% aa sequence identity) of all the bat SARSr-CoVs reported to date (Figs 2 and 3). In addition to the SARSr-CoVs subjected to full-length genome sequencing, we also obtained the RBD and NTD sequences from other samples collected in this cave. The sequences with high identity to SARS-CoV RBD were amplified from 10 more *R. sinicus* samples. SARSr-CoVs with this genotype of RBD were detected in different seasons throughout the five years. Strains containing the NTD similar to SARS-CoV were only found in 2013 (S2 Table).

ORF8 is another highly variable gene among different SARS-CoV and SARSr-CoV strains [25,26]. We aligned the ORF8 nt sequences of the representative SARSr-CoVs discovered in this surveillance with those of other SARSr-CoVs and SARS-CoVs (Fig 4). Though WIV16, WIV1, Rs4231 and RsSHC014 were genetically closer to SARS-CoV in S gene, they contained a single 366-nt ORF8 without the 29-nt deletion present in most human SARS-CoVs and showed only 47.1% to 51.0% nt sequence identity to human and civet SARS-CoVs. However,

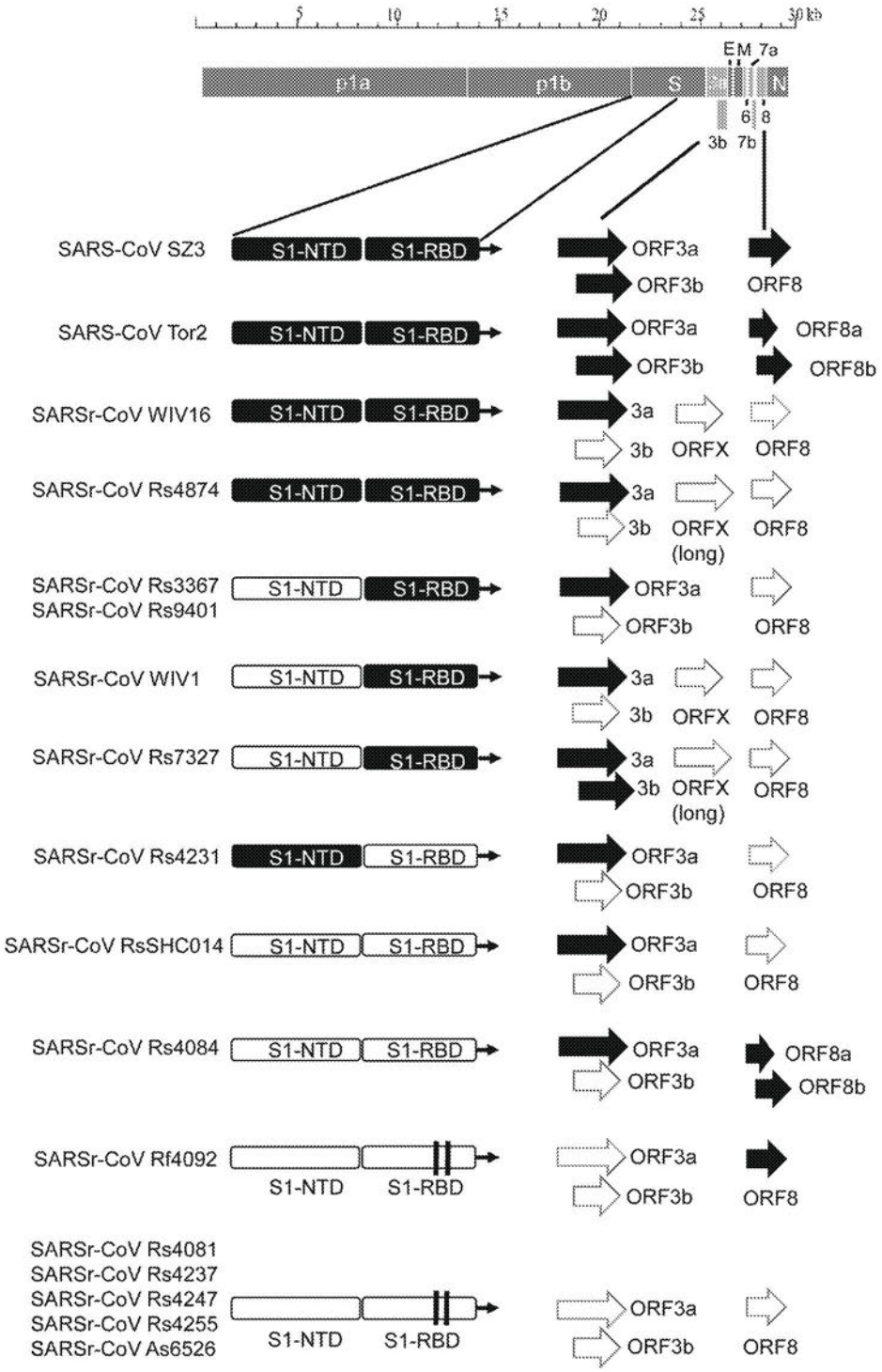

Fig 2. Schematic diagram illustrating the genomic regions or ORFs with most variation between different SARS-CoV and SARSr-CoV isolates. Coding regions of the N-terminal domain (NTD) and receptor-binding domain (RBD) of the spike protein, ORF3a/b and ORF8 (8a/b) in bat SARSr-CoV genomes highly similar to those in SARS CoV genome are indicated with black boxes or arrows while the hollow boxes or arrows represent corresponding regions with less sequence similarity to those of SARS-CoV. The deletions in the RBD of some SARSr-CoVs are indicated by two vertical lines.

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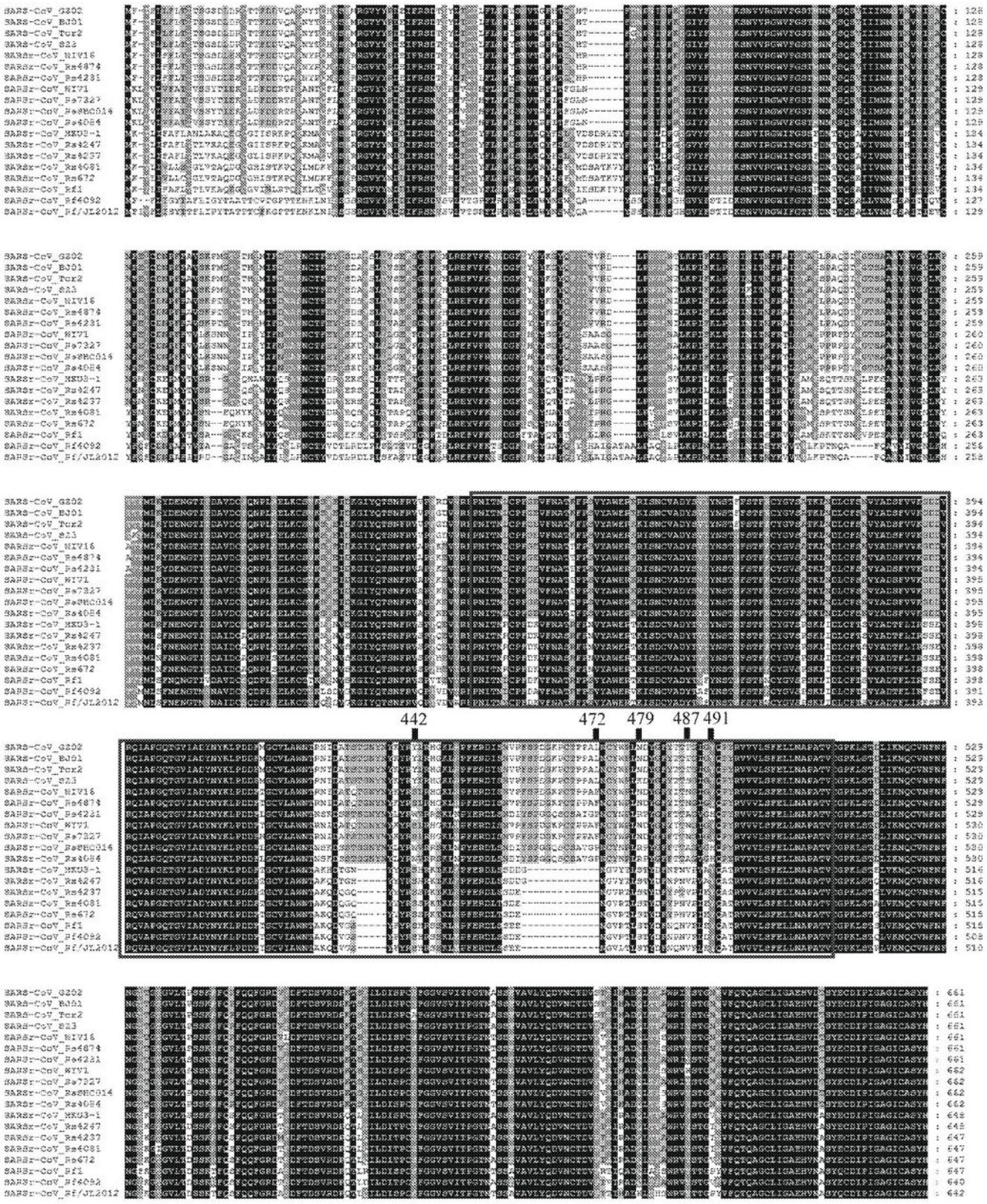

Fig 3. Amino acid sequence comparison of the S1 subunit (corresponding to aa 1–660 of the spike protein of SARS-CoV). The receptor-binding domain (aa 318–510) of SARS-CoV and the homologous region of bat SARSr-CoVs are indicated by the red box. The key aa

residues involved in the interaction with human ACE2 are numbered on top of the aligned sequences. SARS-CoV GZ02, BJ01 and Tor2 were isolated from patients in the early, middle and late phase, respectively, of the SARS outbreak in 2003. SARS-CoV SZ3 was identified from civets in 2003. SARSr-CoV Rs 672 and YN2013 were identified from *R. sinicus* collected in Guizhou and Yunnan Province, respectively. SARSr-CoV Rf1 and JL2012 were identified from *R. ferrumequinum* collected in Hubei and Jilin Province, respectively. WIV1, WIV16, RsSHC014, Rs4081, Rs4084, Rs4231, Rs4237, Rs4247, Rs7327 and Rs4874 were identified from *R.sinicus*, and Rf4092 from *R. ferrumequinum* in the cave surveyed in this study.

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the ORF8 of strain Rf4092 from *R. ferrumequinum* exhibited high similarity to that of civet SARS-CoV. It possessed a single long ORF8 of the same length (369 nt) as that of civet SARS--CoV strain SZ3, with only 10 nt mutations and 3 aa mutations detected (Fig 4). Similar ORF8 sequences were also amplified from other 7 samples collected in the cave during 2011 to 2013, from both *R. ferrumequinum* and *R. sinicus* (S2 Table). The ORF8 of Rs4084 was highly similar to Rf4092's but was split into two overlapping ORFs, ORF8a and ORF8b, due to a short 5-nt deletion (Figs 2 and 4). The position of start codons and stop codons of the two ORFs were consistent with those in most human SARS-CoV strains. Excluding the 8-aa insertion, Rs4084 and SARS-CoV strain BJ01 displayed identical aa sequence of ORF8a, and only three different

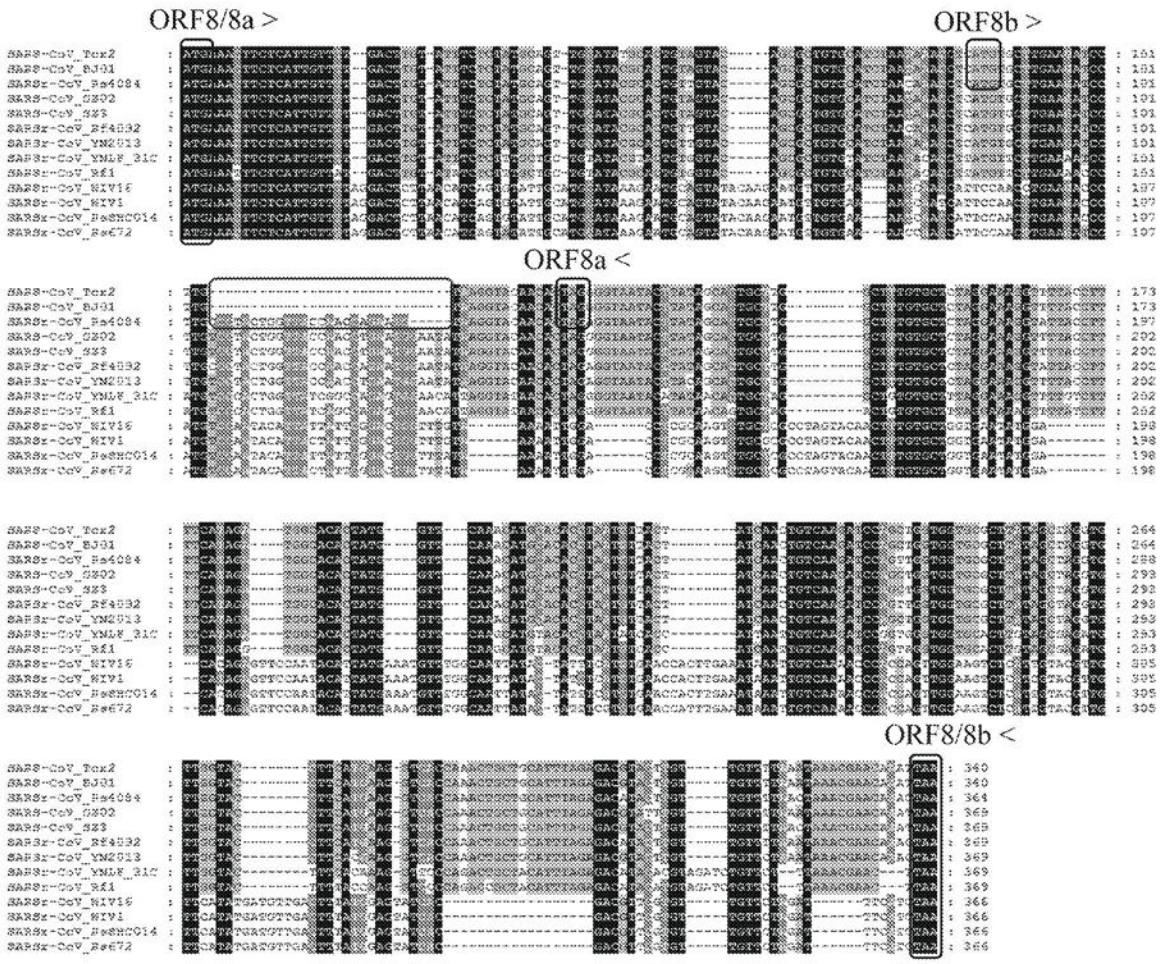

Fig 4. Alignment of nucleotide sequences of ORF8 or ORF8a/8b. The start codons and stop codons of ORF8, 8a and 8b are marked with black boxes and the forward and reverse arrows, respectively. The deletion responsible for the split ORF8a and 8b in human SARS-CoV BJ01, Tor2 and bat SARSr-CoV Rs4084 is marked with red boxes. See the legend for Fig 3 for the origin of various sequences used in this alignment.

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aa residues were observed between their ORF8b (Fig 4). To our knowledge, Rs4084 was the first bat SARSr-CoV reported that resembled the late human SARS-CoVs in both ORF8 gene organization and sequence.

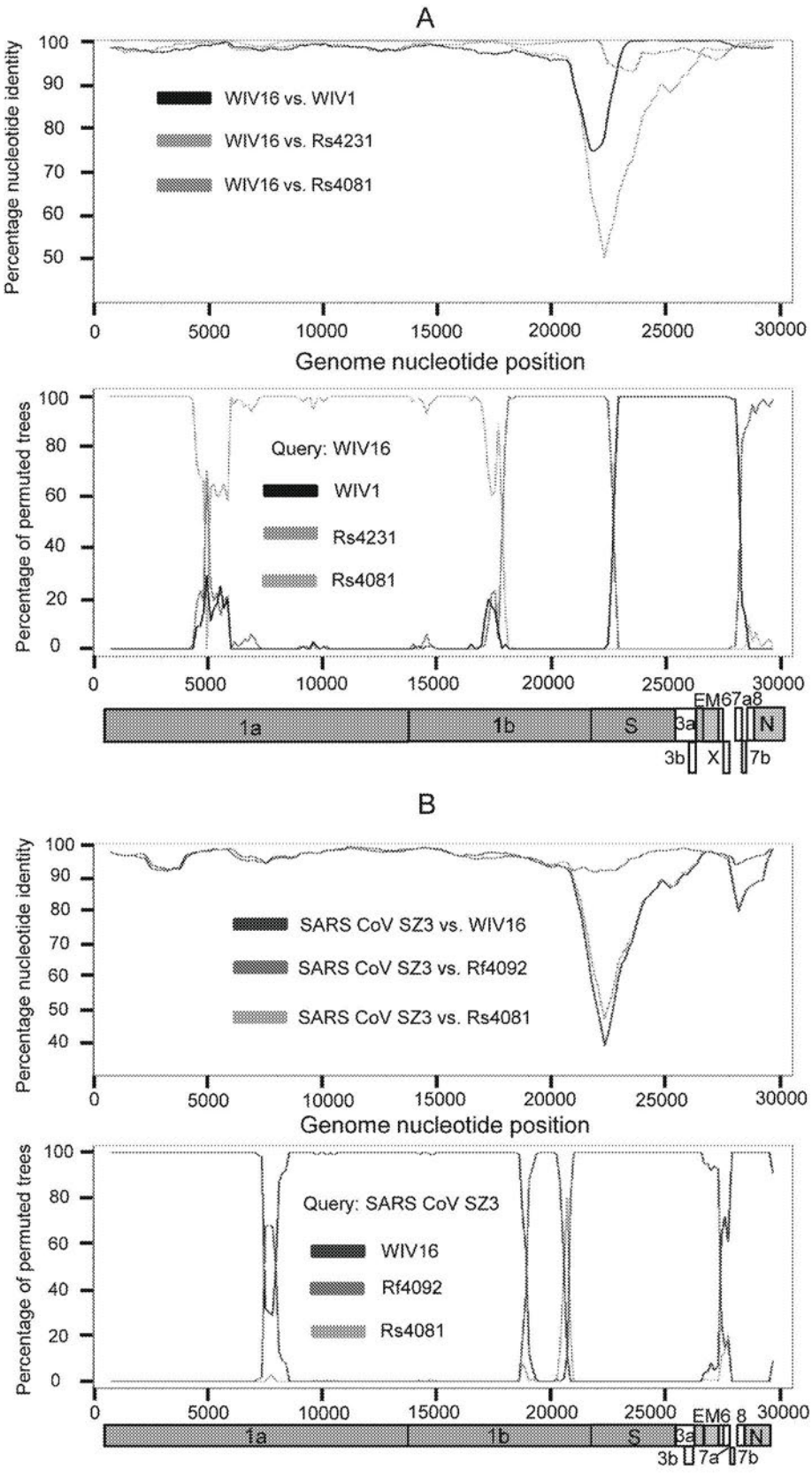
Another key difference between SARS-CoV and bat SARSr-CoV genomes is the ORF3 coding region [10,17,21]. We analyzed the ORF3a sequences amplified from 42 samples and found that most of the SARSr-CoVs closely related to SARS-CoV in the S gene shared higher ORF3a sequence similarity (96.4% to 98.9% aa identity) with SARS-CoV (S3 Fig and S2 Table). The ORF3b of SARS CoV, sharing a large part of its coding sequence with the ORF3a, encodes a 154-aa protein [27], but it is truncated to different extents at the C-terminal in previously described bat SARSr-CoVs including WIV1 and WIV16 (S4 Fig). In the current study, we identified a non-truncated ORF3b for the first time (Rs7327), which maintained the nuclear localization signal at its C-terminal. Moreover, it shared 98.1% aa sequence identity with SARS-CoV strain Tor2 with only three aa substitutions (S4 Fig). Thus, Rs7327 is the bat SARSr-CoV most similar to SARS-CoV in the ORF3 region known to date.

Recombination analysis

The full-length genome sequences of all 15 SARSr-CoVs from the surveyed cave were screened for evidence of potential recombination events. Both similarity plot and bootscan analyses revealed frequent recombination events among these SARSr-CoV strains. It was suggested that WIV16, the closest progenitor of human SARS-CoV known to date [18], was likely to be a recombinant strain from three SARSr-CoVs harbored by bats in the same cave, namely WIV1, Rs4231 and Rs4081, with strong P value ($<10^{-30}$). Breakpoints were identified at genome positions nt 18391, 22615 and 28160 (Fig 5A). In the genomic region between nt 22615 and 28160, which contained the region encoding the RBD and the S2 subunit of the S protein, WIV16 was highly similar to WIV1, sharing 99% sequence identity. In contrast, in the region between nt 18391 and 22615, which covered a part of ORF1b and the region encoding the NTD of the S gene, WIV16 showed substantially closer relationship to Rs4231. Meanwhile, the ORF1ab sequences upstream from nt 18391 of WIV16 displayed the highest genetic similarity (99.8% nt sequence identity) to that of Rs4081.

Evidence of recombination event was also detected in the genome of the novel SARSr-CoV Rs4084, which had a unique genome organization with split ORF8a and 8b. The previously reported strain RsSHC014 and the newly identified strain Rf4092 were suggested to be the major and minor parent of Rs4084, respectively (P value $< 10^{-80}$). The breakpoint was located at nt 26796 (S5 Fig). In the region downstream of the breakpoint including ORF8, Rs4084 showed closet genetic relationship with Rf4092, sharing 98.9% nt sequence identity, while it shared the highest nt sequence identity (99.4%) with RsSHC014 in the majority of its genome upstream from the breakpoint.

When civet SARS-CoV SZ3 was used as the query sequence in similarity plot and bootscan analysis, evidence for recombination events was also detected (Fig 5B). In the region between the two breakpoints at the genome positions nt 21161 and nt 27766, including the S gene, closer genetic relationship between SZ3 and WIV16 was observed. However, from position nt 27766 towards the 3' end of its genome, a notably close genetic relationship was observed between SZ3 and Rf4092 instead. Throughout the non-structural gene, moreover, SZ3 shared a similarly high sequence identity with WIV16 and Rf4092. It indicates that civet SARS-CoV was likely to be the descendent from a recombinant of the precursors of WIV16 and Rf4092, or that the SARSr-CoVs found in this cave, like WIV16 or Rf4092, may have been the descendants of the SARS-CoV lineage.


A
Percentage nucleotide identity
WIV16 vs. WIV1
WIV16 vs. Rs4231
WIV16 vs. Rs4081
Genome nucleotide position
Percentage of permuted trees
Query: WIV16
WIV1
Rs4231
Rs4081
1a
1b
S
3a
EM
6
7a
8
N
3b
X
7b
B
Percentage nucleotide identity
SARS CoV SZ3 vs. WIV16
SARS CoV SZ3 vs. Rf4092
SARS CoV SZ3 vs. Rs4081
Genome nucleotide position
Percentage of permuted trees
Query: SARS CoV SZ3
WIV16
Rf4092
Rs4081
1a
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EM
6
8
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3b
7a
7b

Fig 5. Detection of potential recombination events by similarity plot and boot scan analysis. (A) Full-length genome sequence of SARSr-CoV WIV16 was used as query sequence and WIV1, Rs4231 and Rs4081 as reference sequences. (B) Full-length genome sequence of SARS-CoV SZ3 was used as query sequence and SARSr-CoV WIV16, Rf4092 and Rs4081 as reference sequences. All analyses were performed with a Kimura model, a window size of 1500 base pairs, and a step size of 150 base pairs. The gene map of query genome sequences are used to position breakpoints.

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Phylogenetic analysis

Phylogenetic trees were constructed using the nt sequences of nonstructural protein gene ORF1a and ORF1b. Unlike the high genetic diversity in the S gene, nearly all SARSr-CoVs from the bat cave we surveyed were closely clustered, and showed closer phylogenetic relationship to SARS-CoV than the majority of currently known bat SARSr-CoVs discovered from other locations, except YNLF_31C and 34C which were recently reported in greater horseshoe bats from another location in Yunnan [22] (Fig 6). The phylogeny of SARSr-CoVs in ORF1a and ORF1b appeared to be associated with their geographical distribution rather than with host species. Regardless of different host bat species, SARS-CoV and SARSr-CoVs detected in bats from southwestern China (Yunnan, Guizhou and Guangxi province) formed one clade, in which SARSr-CoV strains showing closer relationship to SARS-CoV were all from Yunnan. SARSr-CoVs detected in southeastern, central and northern provinces, such as Hong Kong, Hubei and Shaanxi, formed the other clade which was phylogenetically distant to human and civet SARS-CoVs (Fig 6 and S6 Fig).

Rescue of bat SARSr-CoVs and virus infectivity experiments

In the current study, we successfully cultured an additional novel SARSr-CoV Rs4874 from a single fecal sample using an optimized protocol and Vero E6 cells [17]. Its S protein shared 99.9% aa sequence identity with that of previously isolated WIV16 and it was identical to WIV16 in RBD. Using the reverse genetics technique we previously developed for WIV1 [23], we constructed a group of infectious bacterial artificial chromosome (BAC) clones with the backbone of WIV1 and variants of S genes from 8 different bat SARSr-CoVs. Only the infectious clones for Rs4231 and Rs7327 led to cytopathic effects in Vero E6 cells after transfection (S7 Fig). The other six strains with deletions in the RBD region, Rf4075, Rs4081, Rs4085, Rs4235, As6526 and Rp3 (S1 Fig) failed to be rescued, as no cytopathic effects was observed and viral replication cannot be detected by immunofluorescence assay in Vero E6 cells (S7 Fig). In contrast, when Vero E6 cells were respectively infected with the two successfully rescued chimeric SARSr-CoVs, WIV1-Rs4231S and WIV1-Rs7327S, and the newly isolated Rs4874, efficient virus replication was detected in all infections (Fig 7). To assess whether the three novel SARSr-CoVs can use human ACE2 as a cellular entry receptor, we conducted virus infectivity studies using HeLa cells with or without the expression of human ACE2. All viruses replicated efficiently in the human ACE2-expressing cells. The results were further confirmed by quantification of viral RNA using real-time RT-PCR (Fig 8).

Activation of activating transcription factor 6 (ATF6) by the ORF8 proteins of different bat SARSr-CoVs

The induction of the ATF6-dependent transcription by the ORF8s of SARS-CoV and bat SARSr-CoVs were investigated using a luciferase reporter, 5×ATF6-GL3. In HeLa cells transiently transfected with the expression plasmids of the ORF8s of bat SARSr-CoV Rf1, Rf4092 and WIV1, the relative luciferase activities of the 5×ATF6-GL3 reporter was enhanced by 5.56 to 9.26 folds compared with cells transfected with the pCAGGS empty vector, while it was

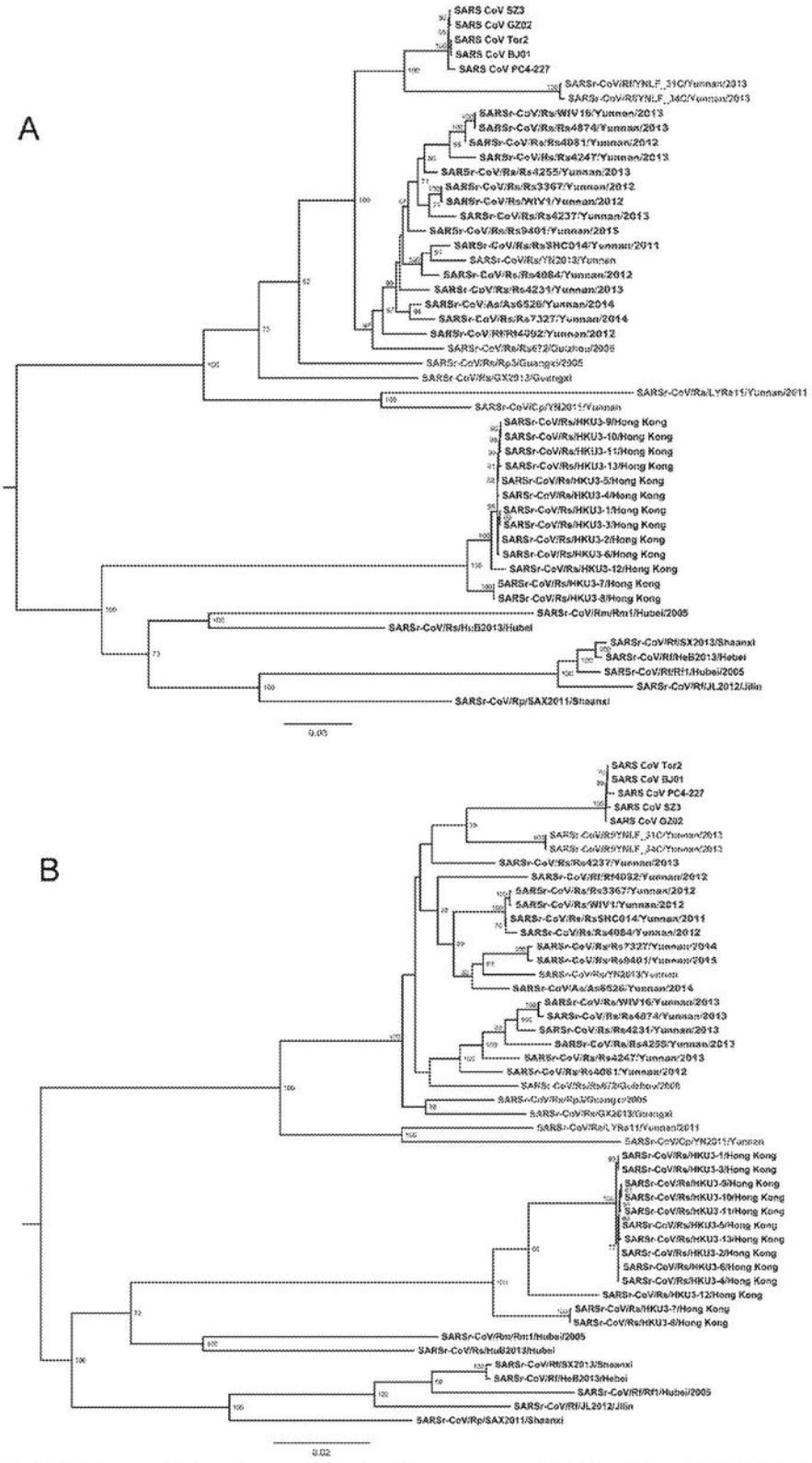

Fig 6. Phylogenetic trees based on nucleotide sequences of ORF1a (A) and ORF1b (B). The trees were constructed by the maximum likelihood method using the LG model with bootstrap values determined by 1000 replicates. Only bootstraps > 50% are shown. The scale bars represent 0.03 (A) and 0.02 (B) substitutions per

nucleotide position. Rs, *Rhinolophus sinicus*; Rf, *Rhinolophus ferremequinum*; Rm, *Rhinolophus macrotis*; Ra, *Rhinolophus affinis*; Rp, *Rhinolophus pusillus*; As, *Aselliscus stoliczkanus*; Cp, *Chaerephon plicata*. SARSr-CoVs detected in bats from the single cave surveyed in this study are in bold. Sequences detected in southwestern China are indicated in red.

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increased by 4.42 fold by the SARS-CoV GZ02 ORF8. As a control, the treatment with tunicamyxin (TM) stimulated the transcription by about 11 folds (Fig 9A). The results suggests that various ORF8 proteins of bat SARSr-CoVs can activate ATF6, and those of some strains have a stronger effect than the SARS-CoV ORF8.

Induction of apoptosis by the ORF8a of the newly identified bat SARSr-CoV

We conducted transient transfection to examine whether the ORF8a of SARSr-CoV Rs4084 triggered apoptosis. As shown in Fig 9B, 11.76% and 9.40% of the 293T cells transfected with the SARSr-CoV Rs4084-ORF8a and SARS-CoV Tor2-ORF8a expression plasmid underwent apoptosis, respectively. In contrast, transfection with the empty vector resulted in apoptosis in only 2.79% of the cells. The results indicate that Rs4084 ORF8a has an apoptosis induction activity similar to that of SARS-CoV [28].

Discussion

Genetically diverse SARSr-CoVs have been detected in various horseshoe bat species across a wide geographic range in China in the past decade [9–12,14,29]. However, most bat SARSr-CoVs show considerable genetic distance to SARS-CoV, particularly in the highly variable S1, ORF8 and ORF3 regions [10,25]. Recently, several novel SARSr-CoVs have been described to be more closely related to SARS-CoV, either in the S gene or in ORF8. The S proteins of RsSHC014, Rs3367, WIV1 and WIV16, which were reported in our previous studies, shared 90% to 97% aa sequence identities to those of human/civet SARS-CoVs [17,18]. Another strain from *Rhinolophus affinis* in Yunnan termed LYRa11 showed 90% aa sequence identity to SARS-CoV in the S gene [13]. In addition, two studies have described 4 novel SARSr-CoVs (YNLF_31C/34C and GX2013/YN2013) which possessed a full-length ORF8 with substantially higher similarity to that of SARS-CoV [22,30]. These findings provide strong genetic evidence for the bat origin of SARS-CoV with regard to the S gene or ORF8. However, all of these SARSr-CoVs were distinct from SARS-CoV in at least one other gene, suggesting that none of them was the immediate progenitor of SARS-CoV. Moreover, these SARSr-CoVs were discovered in bat populations from physically distinct locations. The site of origin of the true progenitor of SARS-CoV and the evolutionary origin of SARS-CoV have until now remained elusive. In the current study, we have identified a bat habitat potentially important for SARSr-CoV evolution where a series of recombination events have likely occurred among different SARSr-CoV strains, which provides new insights into the origin of SARS-CoV.

SARS first emerged in Guangdong province in late 2002 [7]. However, SARSr-CoVs discovered in bats from neighboring areas of Guangdong to date have shown phylogenetic disparity from SARS-CoV especially in the S gene [9,10,14], suggesting SARS-CoV may have originated from another region. Our analysis of the phylogeny of SARS-CoVs and all known bat SARSr-CoVs using the nt sequence of their non-structural ORF1a and ORF1b genes, which constitute the majority of the genome, shows that SARSr-CoV evolution is strongly correlated with their geographical origin, but not host species. It is noteworthy that SARSr-CoVs detected in Yunnan are more closely related to SARS-CoV than strains from other regions in China. This finding implies that Yunnan, or southwestern China, is more likely to be the geographical source

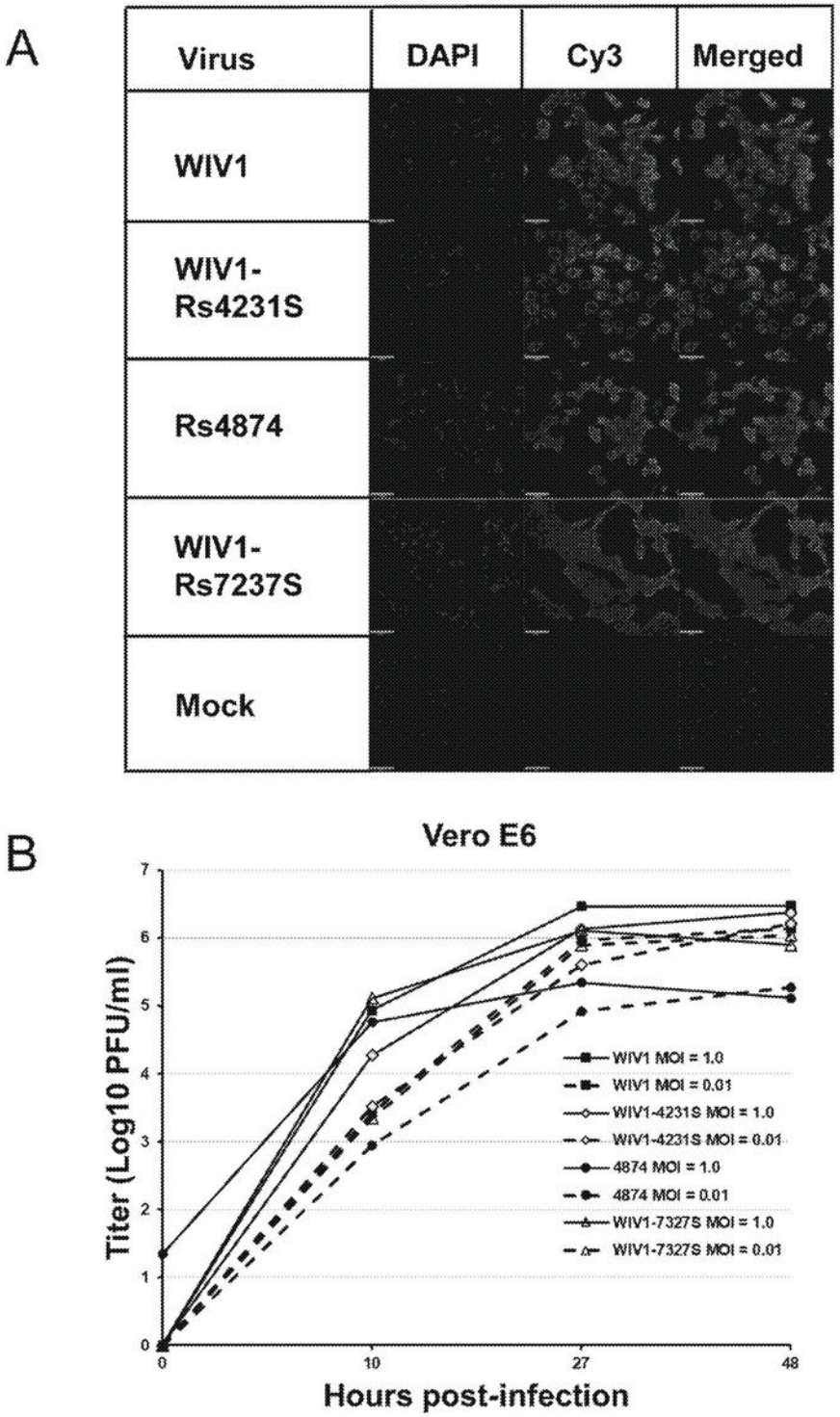

Fig 7. Infection of Vero E6 cells by bat SARSr-CoV WIV1, Rs4874, WIV1-Rs4231S and WIV1-Rs7327S. (A) The successful infection was confirmed by immunofluorescent antibody staining using rabbit antibody against the SARSr-CoV Rp3 nucleocapsid protein. The columns (from left to right) show staining of nuclei (blue), virus replication (red), and both nuclei and virus replication (merged double-stain images). (B) The growth curves in Vero E6 cells with a MOI of 1.0 and 0.01.

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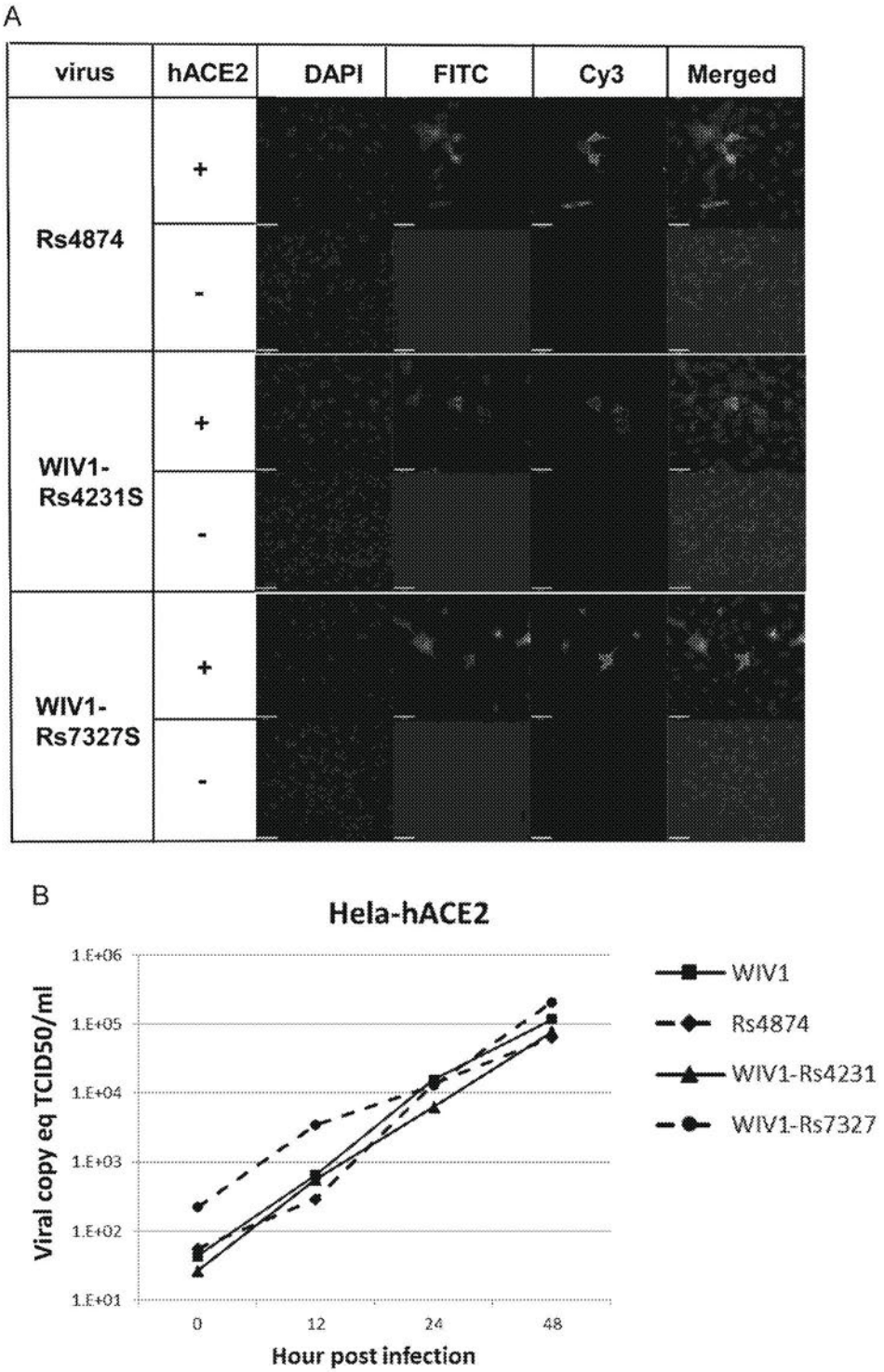

Fig 8. Analysis of receptor usage by immunofluorescence assay (A) and real-time PCR (B). Virus infectivity of Rs4874, WIV1-Rs4231S and WIV1-Rs7327S was determined in HeLa cells with and without the expression of human ACE2. ACE2 expression was detected with goat anti-human ACE2 antibody followed by fluorescein isothiocyanate (FITC)-conjugated donkey anti-goat IgG. Virus replication was detected with rabbit antibody against the SARSr-CoV Rp3 nucleocapsid protein followed by cyanine 3 (Cy3)-conjugated mouse anti-rabbit IgG. Nuclei were stained with DAPI (49,6-diamidino-2-phenylindole).The columns (from left to right) show staining of nuclei (blue), ACE2 expression (green), virus replication (red) and the merged triple-stained images, respectively.

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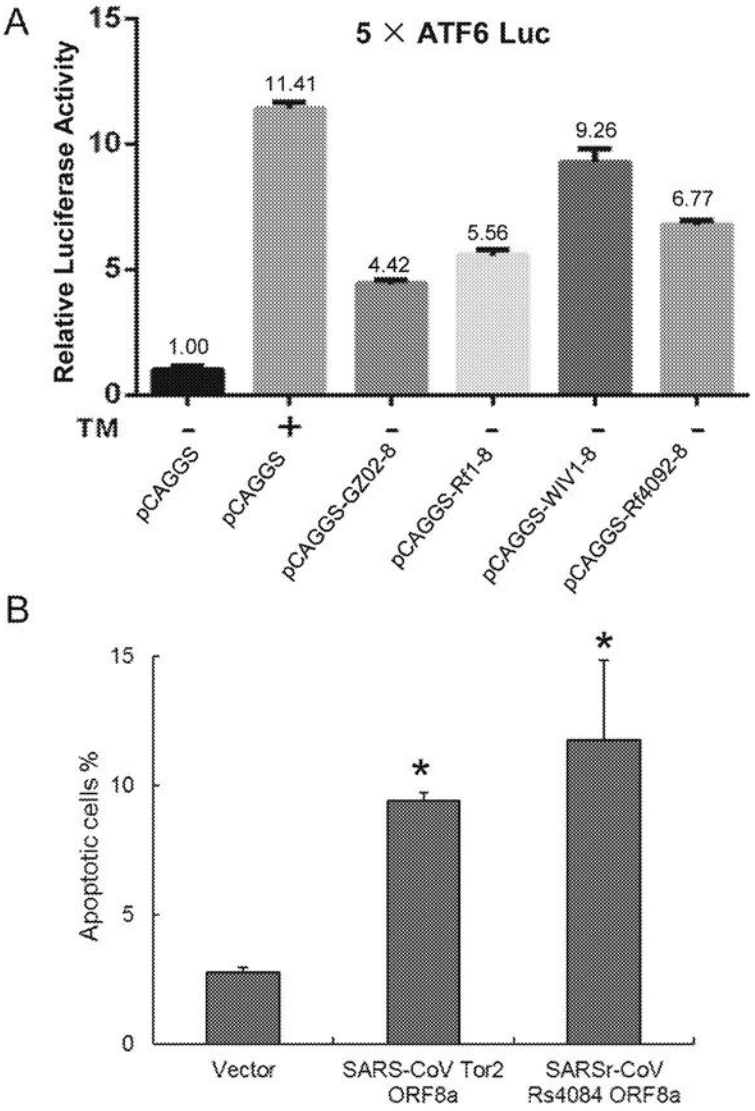

Fig 9. Functional characterization of diverse ORF8 and ORF8a proteins of bat SARSr-CoVs. (A) The ORF8 proteins of SARS-CoV and bat SARSr-CoVs induces the ATF6-dependent transcriptional activity. HeLa cells were transiently transfected with the pcAGGS expression plasmids of the ORF8 of SARS-CoV GZ02, bat SARSr-CoV Rf1, WIV1 and Rf4092 and the reporter plasmid 5×ATF6-GL3 for 40h. Control cells were co-transfected with the reporter plasmid and the empty pCAGGS vector for 24h, and treated with or without TM (2μg/ml) for an additional 16h. The cell lysates were harvested for dual luciferase assay and data are shown as the average values from triplicate wells. (B) The ORF8a proteins of SARS-CoV and bat SARSr-CoV triggered apoptosis. 293T cells were transfected with the expression plasmids of the ORF8a of SARS-CoV Tor2 and bat SARSr-CoV Rs4084 and a pcAGGS vector control for 24h. Apoptosis was analyzed by flow cytometry after annexin V staining and the percentage of apoptotic cells were calculated. Data are shown as the average values from triplicate cells. Error bars indicate SDs. * $P<0.05$.

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of SARS-CoV than other regions in China, but data from more extensive surveillance are yet needed to support this inference.

In our longitudinal surveillance of SARSr-CoVs in a single cave in Yunnan where we discovered Rs3367, RsSHC014, WIV1 and WIV16, the CoV prevalence in fecal samples varied among different sampling time. Generally, a higher prevalence was observed in autumn (September and October) than in spring and early summer (April and May). This may be due to

the establishment of a susceptible subpopulation of newborn bats which had not developed their own immunity after the parturition period [31]. Another factor may be the changes in the composition of bat species in the cave at different sampling dates. For example, in September 2012 when the CoV prevalence reached 51.3%, the majority of samples were from *R. sinicus*, but in May 2015 when only 3 out of the 145 samples tested positive, *Aselliscus stoliczkanus* was the predominant bat species in the cave. We failed to amplify the RBD sequences from 15 of the 64 SARSr-CoV positive samples. Most of these samples had comparatively low viral concentration ($< 10^7$ copies/g) (S8 Fig), as revealed by our previous quantitative studies [32]. The unsuccessful amplification of RBD in some samples with high viral concentration was probably because of the more divergent sequences in this region of these SARSr-CoV genomes.

In this cave, we have now obtained full-length genome sequences of additional 11 novel SARSr-CoVs from bats. Our findings suggest the co-circulation of different bat SARSr-CoVs highly similar to SARS-CoV in the most variable S1 (NTD and RBD), ORF8 and ORF3 regions, respectively, in this single location. In the ORF1a, ORF1b, E, M and N genes, the SARSr-CoVs circulating in this cave also shared > 98% aa sequence identities with human/civet SARS-CoVs. Thus, all of the building blocks of the SARS-CoV genome were present in SARSr-CoVs from this single location in Yunnan during our sampling period. Furthermore, strains closely related to different representative bat SARSr-CoVs from other provinces (e.g. Rs672, HKU3 and Rf1) in the RBD region were also detected there. Therefore, this cave could be regarded as a rich gene pool of bat SARSr-CoVs, wherein concurrent circulation of a high diversity of SARSr-CoV strains has led to an unusually diverse assemblage of SARSr-CoVs.

During our 5-year surveillance in this single cave, we first reported Rs3367 and WIV1 in 2013, with RBD sequence closely resembling that of SARS-CoV [17]. More recently, we discovered WIV16 which had an RBD almost identical to WIV1's but shared much higher similarity with SARS-CoV than WIV1 in the NTD region of S1, making it the closest SARSr-CoV to the epidemic strains identified to date [18]. In this study, we found a novel strain Rs4231 from the same location sharing almost identical NTD sequence with WIV16 but distinct from it in the RBD, with evidence of a recombination event. Our recombination analysis indicated that a recombination event may have taken place at the junction between the coding region of NTD and RBD in the Rs4231 and WIV1 genomes and resulted in WIV16. Recombination at this genomic position also happened among other SARSr-CoVs relatively distant to SARS-CoV found in this location (e.g. Rs4081 and Rs4247, S5 Fig). The frequent recombination at this hotspot in the S gene increased the genetic diversity of SARSr-CoVs harbored in these bat populations and might have been responsible for the generation of the S gene of the direct progenitor strain of SARS-CoV.

The genomes of SARS-CoVs from patients during the early epidemic phase and civet SARS-CoVs all contained a single full-length ORF8 [3,7]. We have found that a number of bat SARSr-CoVs from this cave possessed a complete ORF8 highly similar to that of early human/civet SARS-CoV (>97% nt sequence identity), represented by strain Rf4092 (S3C Fig). This provided further evidence for the source of human SARS-CoV ORF8 in bats [22,30]. In contrast, the ORF8 was split into overlapping ORF8a and ORF8b in most human SARS-CoV strains from later-phase patients due to the acquisition of a 29-nt deletion [8,26]. In this study, we have discovered for the first time a bat SARSr-CoV with ORF8a and ORF8b highly similar to the later-phase human SARS-CoVs, though the split of ORF8 in the bat SARSr-CoV and that in human SARS-CoV were two independent events. Our recombination analysis suggests that this strain, Rs4084, likely acquired its ORF8 from Rf4092 through recombination, followed by the development of the 5-nt deletion which led to the splitting. It suggests that ORF8 region in bat SARSr-CoV genomes is prone to deletions as in human SARS-CoV [3,25]. Finally, the recombination analysis suggests that an ancestral strain of SARS-CoV SZ3 would have been generated if the recombination around ORF8 had occurred between the lineages that led to WIV16 and Rf4092.

Taken together, the evidence of recombination events among SARSr-CoVs harbored by bats in this single location suggests that the direct progenitor of SARS-CoV may have originated as a result of a series of recombination within the S gene and around ORF8. This could have been followed by the spillover from bats to civets and people either in the region, or during movement of infected animals through the wildlife trade. However, given the paucity of data on animal trade prior to the SARS outbreak, the likely high geographical sampling bias in bat surveillance for SARSr-CoVs in southern China, and the possibility that other caves harbor similar bat species assemblages and a rich diversity of SARSr-CoVs, a definite conclusion about the geographical origin of SARS-CoV cannot be drawn at this point.

R. sinicus are regarded as the primary natural host of SARS-CoV, as all SARSr-CoVs highly homologous to SARS-CoV in the S gene were predominantly found in this species. However, it is noted that two SARSr-CoVs previously reported from *R. ferrumequinum* showed the closest phylogenetic position to SARS-CoV in the ORF1a/1b trees. These strains were discovered in another location in Yunnan 80 km from the cave surveyed in the current study [22]. This information also supports the speculation that SARS-CoV may have originated from this region. Nonetheless, since the correlation between the host species and the phylogeny of SARSr-CoV ORF1ab seems limited, more SARSr-CoV sequences need to be obtained from different *Rhinolophus* bat species in both locations in Yunnan, and from other locations in southern China. In particular, it will be important to assess whether *R. ferrumequinum* played a more important role in the evolution of SARS-CoV ORF1ab.

The cave we studied is located approximately 60 km from the city of Kunming. Beside a number of rhinolophid and hipposiderid species from which SARSr-CoVs have been detected, other bats like myotis were also present there. The temperature in the cave is around 22–25˚C and the humidity around 85%-90%. The physical nature of the cave is not unique, but it does appear to host a particularly dense population of bats in the reproductive season. Similar caves co-inhabited by bat populations of different species are not rare in other areas in Yunnan. We propose that efforts to study the ecology, host species diversity, and viral strain populations of these caves may provide critical information on what drives SARSr-CoV evolution.

Our previous studies demonstrated the capacity of both WIV1 and WIV16 to use ACE2 orthologs for cell entry and to efficiently replicate in human cells [17,18]. In this study, we confirmed the use of human ACE2 as receptor of two novel SARSr-CoVs by using chimeric viruses with the WIV1 backbone replaced with the S gene of the newly identified SARSr-CoVs. Rs7327's S protein varied from that of WIV1 and WIV16 at three aa residues in the receptor-binding motif, including one contact residue (aa 484) with human ACE2. This difference did not seem to affect its entry and replication efficiency in human ACE2-expressing cells. A previous study using the SARS-CoV infectious clone showed that the RsSHC014 S protein could efficiently utilize human ACE2 [33], despite being distinct from SARS-CoV and WIV1 in the RBD (S1 Fig). We examined the infectivity of Rs4231, which shared similar RBD sequence with RsSHC014 but had a distinct NTD sequence, and found the chimeric virus WIV1-Rs4231S also readily replicated in HeLa cells expressing human ACE2 molecule. The novel live SARSr-CoV we isolated in the current study (Rs4874) has an S gene almost identical to that of WIV16. As expected, it is also capable of utilizing human ACE2. These results indicate that diverse variants of SARSr-CoV S protein without deletions in their RBD are able to use human ACE2. In contrast, our previous study revealed that the S protein of a *R. sinicus* SARSr-CoV with deletions (Rp3) failed to use human, civet and bat ACE2 for cell entry [34]. In this study, in addition to Rs4231 and Rs7327, we also constructed infectious clones with the S gene of Rs4081, Rf4075, Rs4085, Rs4235 and As6526, which all contained the deletions in their RBD. These 7 strains, plus Rs4874 and the previously studied WIV1 and RsSHC014, could represent all types of S variants of SARSr-CoVs in this location (S3A Fig). However, none of the strains

with deletions in the RBD could be rescued from Vero E6 cells. Therefore, the two distinct clades of SARSr-CoV S gene may represent the usage of different receptors in their bat hosts.

The full-length ORF8 protein of SARS-CoV is a luminal endoplasmic reticulum (ER) membrane-associated protein that induces the activation of ATF6, an ER stress-regulated transcription factor that activates the transcription of ER chaperones involved in protein folding [35]. We amplified the ORF8 genes of Rf1, Rf4092 and WIV1, which represent three different genotypes of bat SARSr-CoV ORF8 (S3C Fig), and constructed the expression plasmids. All of the three ORF8 proteins transiently expressed in HeLa cells can stimulate the ATF6-dependent transcription. Among them, the WIV1 ORF8, which is highly divergent from the SARS-CoV ORF8, exhibited the strongest activation. The results indicate that the variants of bat SARSr-CoV ORF8 proteins may play a role in modulating ER stress by activating the ATF6 pathway. In addition, the ORF8a protein of SARS-CoV from the later phase has been demonstrated to induce apoptosis [28]. In this study, we have found that the ORF8a protein of the newly identified SARSr-CoV Rs4084, which contained an 8-aa insertion compared with the SARS-CoV ORF8a, significantly triggered apoptosis in 293T cells as well.

Compared with the 154-aa ORF3b of SARS-CoV, the ORF3b proteins of all previously identified bat SARSr-CoVs were smaller in size due to the early translation termination. However, for the first time, we discovered an ORF3b without the C-terminal truncation in a bat SARSr-CoV, Rs7327, which differed from the ORF 3b of SARS-CoV GZ02 strain at only one aa residue. The SARS-CoV ORF3b antagonizes interferon function by modulating the activity of IFN regulatory factor 3 (IRF3) [27]. As previous studies suggested, the nuclear localization signal-containing C-terminal may not be required for the IFN antagonist activity of ORF3b [36]. Our previous studies also demonstrated that the ORF3b protein of a bat SARSr-CoV, termed Rm1, which was C-terminally truncated to 56 aa and shared 62% aa sequence identity with SARS-CoV, still displayed the IFN antagonist activity [37]. It is very interesting to investigate in further studies whether Rs7327's ORF3b and other versions of truncated ORF3b such as WIV1 and WIV16 also show IFN antagonism profiles.

As a whole, our findings from a 5-year longitudinal study conclusively demonstrate that all building blocks of the pandemic SARS-CoV genome are present in bat SARSr-CoVs from a single location in Yunnan. The data show that frequent recombination events have happened among those SARSr-CoVs in the same cave. While we cannot rule out the possibility that similar gene pools of SARSr-CoVs exist elsewhere, we have provided sufficient evidence to conclude that SARS-CoV most likely originated from horseshoe bats via recombination events among existing SARSr-CoVs. In addition, we have also revealed that various SARSr-CoVs capable of using human ACE2 are still circulating among bats in this region. Thus, the risk of spillover into people and emergence of a disease similar to SARS is possible. This is particularly important given that the nearest village to the bat cave we surveyed is only 1.1 km away, which indicates a potential risk of exposure to bats for the local residents. Thus, we propose that monitoring of SARSr-CoV evolution at this and other sites should continue, as well as examination of human behavioral risk for infection and serological surveys of people, to determine if spillover is already occurring at these sites and to design intervention strategies to avoid future disease emergence.

Materials and methods

Ethics statement

All sampling procedures were performed by veterinarians with approval from Animal Ethics Committee of the Wuhan Institute of Virology (WIVH05210201). The study was conducted in accordance with the Guide for the Care and Use of Wild Mammals in Research of the People's Republic of China.

Sampling

Bat samplings were conducted ten times from April 2011 to October 2015 at different seasons in their natural habitat at a single location (cave) in Kunming, Yunnan Province, China. All members of field teams wore appropriate personal protective equipment, including N95 masks, tear-resistant gloves, disposable outerwear, and safety glasses. Bats were trapped and fecal swab samples were collected as described previously [9]. Clean plastic sheets measuring 2.0 by 2.0 m were placed under known bat roosting sites at about 18:00 h each evening for collection of fecal samples. Fresh fecal pellets were collected from sheets early in the next morning. Each sample (approximately 1 gram of fecal pellet) was collected in 1ml of viral transport medium composed of Hank's balanced salt solution at pH7.4 containing BSA (1%), amphotericin (15 μg/ml), penicillin G (100 units/ml), and streptomycin (50 μg/ml), and were stored at -80˚C until processing. Bats trapped for this study were released back into their habitat.

RNA extraction, PCR screening and sequencing

Fecal swab or pellet samples were vortexed for 1 min, and 140 μl of supernatant was collected from each sample after centrifuge at 3000 rpm under 4˚C for 1min. Viral RNA was extracted with Viral RNA Mini Kit (Qiagen) following the manufacturer's instructions. RNA was eluted in 60 μl of buffer AVE (RNase-free water with 0.04% sodium azide, Qiagen), aliquoted, and stored at -80˚C. One-step hemi-nested RT-PCR (Invitrogen) was employed to detect the presence of coronavirus sequences as described previously using a set of primers that target a 440-nt fragment in the RNA-dependent RNA polymerase gene (*RdRp*) of all known alpha- and betacoronaviruses [20]. For the first round PCR, the 25 μl reaction mix contained 12.5 μl PCR 2 × reaction mix buffer, 10 pmol of each primer, 2.5 mM $MgSO_4$, 20 U RNase inhibitor, 1 μl SuperScript III/Platinum Taq Enzyme Mix and 5 μl RNA template. The amplification was performed as follows: 50˚C for 30 min, 94˚C for 2 min, followed by 40 cycles consisting of 94˚C for 15 sec, 52˚C for 30 sec, 68˚C for 40 sec, and a final extension of 68˚C for 5 min. For the second round PCR, the 25 μl reaction mix contained 2.5 μl PCR reaction buffer, 5 pmol of each primer, 50 mM $MgCl_2$, 0.5mM dNTP, 0.1 μl Platinum Taq Enzyme (Invitrogen) and 1 μl product of the first round PCR. The amplification was performed as follows: 94˚C for 3 min followed by 35 cycles consisting of 94˚C for 30 sec, 52˚C for 30 sec, 72˚C for 40 sec, and a final extension of 72˚C for 7 min. The RBD region was amplified using the one-step nested RT-PCR method previously described [17].

PCR products were gel purified and sequenced with an ABI Prism 3730 DNA analyzer (Applied Biosystems, USA). PCR products with low concentration or generating heterogeneity in the sequencing chromatograms were cloned into pGEM-T Easy Vector (Promega) for sequencing. The positive samples in this study were termed using the abbreviated name of bat species plus the sample ID number (e.g. Rs4081). To confirm the bat species of individual sample, PCR amplification of cytochrome b (*Cytob*) or NADH dehydrogenase subunit 1 (*ND1*) gene was performed using DNA extracted from the feces or swabs [38,39].

Sequencing of full-length genomes

Full genomic sequences of 11 SARSr-CoVs were determined by One-step PCR (Invitrogen) amplification of overlapping genomic fragments with degenerate primers designed by multiple alignment of available SARS-CoV and bat SARSr- CoV sequences deposited in GenBank, and additional specific primers designed from the results of previous rounds of sequencing in this study. Primer sequences are available upon request. Sequences of the 5' and 3' genomic ends were obtained by 5' and 3' RACE (Roche), respectively. PCR products with expected size were gel-purified and subjected directly to sequencing. Each fragment was sequenced at least twice.

The sequencing chromatogram of each product was thoroughly examined and sequence heterogeneity was not observed. For some fragments with low concentration of amplicons, the PCR products were cloned into pGEM-T Easy Vector (Promega) for sequencing. At least five independent clones were sequenced to obtain a consensus sequence. Co-presence of sequences of distinct SARSr-CoVs was not found in any of the amplicons. The sequences of overlapping genomic fragments were assembled to obtain the full-length genome sequences, with each overlapping sequence longer than 100 bp.

Evolution analysis

Full-length genome sequences of the 15 SARSr-CoVs detected from bats in the cave surveyed in this study were aligned with those of selected SARS-CoVs using MUSCLE [40]. The aligned sequences were scanned for recombination events by Recombination Detection Program (RDP) [41]. The potential recombination events suggested by strong *P* values ($<10^{-20}$) were further confirmed using similarity plot and bootscan analyses implemented in Simplot 3.5.1 [42]. Phylogenetic trees based on nucleotide sequences were constructed using the Maximum Likelihood algorithm under the LG model with bootstrap values determined by 1000 replicates in the PhyML (version 3.0) software package [43].

Virus isolation

The Vero E6 cell line was kindly provided by Australian Animal Health Laboratory, CSIRO (Geelong, Australia). Vero E6 monolayer was maintained in DMEM medium supplemented with 10% fetal calf serum (FCS). Fecal samples (in 200 μl buffer) were gradient centrifuged at 3,000–12,000 g, and the supernatant was diluted 1:10 in DMEM before being added to Vero E6 cells. After incubation at 37˚C for 1 h, the inoculum was removed and replaced with fresh DMEM medium with 2% FCS. The cells were incubated at 37˚C and checked daily for cytopathic effect. All tissue culture media were supplemented with triple antibiotics penicillin/streptomycin/amphotericin (Gibco) (penicillin 200 IU/ml, streptomycin 0.2 mg/ml, amphotericin 0.5 μg/ml). Three blind passages were carried out for each sample. After each passage, both the culture supernatant and cell pellet were examined for presence of SARSr-CoV by RT-PCR using specific primers targeting the RdRp or S gene. The viruses which caused obvious cytopathic effect and could be detected in three blind passages by RT-PCR were further confirmed by electron microscopy.

Construction of recombinant viruses

Recombinant viruses with the S gene of the novel bat SARSr-CoVs and the backbone of the infectious clone of SARSr-CoV WIV1 were constructed using the reverse genetic system described previously [23] (S9 Fig). The fragments E and F were re-amplified with primer pairs (FE, 5'-AGGGCCCACCTGGCACTGGTAAGAGTCATTTTGC-3', R-EsBsaI, 5'-ACTGGTCTCTTCGTTTAGTTATTAACTAAAATATCACTAGACACC-3') and (F-FsBsaI, 5'-TGAGGTCTCCGAACTTATGGATTTGTTTATGAG-3', RF, 5'-AGGTAGGCCTCTAGGGCAGCTAAC-3'), respectively. The products were named as fragment Es and Fs, which leave the spike gene coding region as an independent fragment. BsaI sites (5'-GGTCTCN|NNNN-3') were introduced into the 3' terminal of the Es fragment and the 5' terminal of the Fs fragment, respectively. The spike sequence of Rs4231 was amplified with the primer pair (F-Rs4231-BsmBI, 5'-AGTCGTCTCAACGAACATGTTTATTTTCTTATTCTTTCTCACTCTCAC-3' and R-Rs4231-BsmBI, 5'-TCACGTCTCAGTTCGTTTATGTGTAATGTAATTTGACACCCTTG-3'). The S gene sequence of Rs7327 was amplified with primer pair (F-Rs7327-BsaI, 5'-AGTGGTCTCAACGAACATGAAATTGTTAGTTTTAGTTTTTGCTAC-3' and R-

Rs7327-BsaI, 5'- TCAGGTCTCAGTTCGTTTATGTGTAATGTAATTTAACACCCTTG-3'). The fragment Es and Fs were both digested with BglI (NEB) and BsaI (NEB). The Rs4231 S gene was digested with BsmBI. The Rs7327 S gene was digested with BsaI. The other fragments and bacterial artificial chromosome (BAC) were prepared as described previously. Then the two prepared spike DNA fragments were separately inserted into BAC with Es, Fs and other fragments. The correct infectious BAC clones were screened. The chimeric viruses were rescued as described previously [23].

Determination of virus infectivity by immunofluorescence assay

The HeLa cell line was kindly provided by Australian Animal Health Laboratory, CSIRO (Geelong, Australia). HeLa cells expressing human ACE2 were constructed as described previously [17]. HeLa cells expressing human ACE2 and Vero E6 cells were cultured on coverslips in 24-well plates (Corning) incubated with the newly isolated or recombinant bat SARSr-CoVs at a multiplicity of infection (MOI) = 1.0 for 1h. The inoculum was removed and the cells were washed twice with PBS and supplemented with medium. Vero E6 cells without virus inoculation and HeLa cells without ACE2 were used as negative control. Twenty-four hours after infection, cells were rinsed with PBS and fixed with 4% formaldehyde in PBS (pH7.4) at 4˚C for 20 min. ACE2 expression was detected by using goat anti-human ACE2 immunoglobulin followed by FITC-labelled donkey anti-goat immunoglobulin (PTGLab). Virus replication was detected by using rabbit antibody against the nucleocapsid protein of bat SARSr-CoV Rp3 followed by Cy3-conjugated mouse anti-rabbit IgG. Nuclei were stained with DAPI. Staining patterns were observed under an FV1200 confocal microscope (Olympus).

Determination of virus replication in Vero E6 cells by plaque assay

Vero E6 cells were infected with WIV1, Rs4874, WIV1-Rs4231S, and WIV1-Rs7327S at an MOI of 1.0 and 0.01. After incubation for an hour, the cells were washed with DHanks for three times and supplied with DMEM containing 2% FCS. Samples were collected at 0, 10, 27, and 48 h post infection. The viral titers were determined by plaque assay.

Determination of virus replication in HeLa cells expressing human ACE2 by quantitative RT-PCR

HeLa cells expressing human ACE2 were inoculated with WIV1, Rs4874, WIV1-Rs4231S, and WIV1-Rs7327S at an MOI of 1.0, and were incubated for 1h at 37˚C. After the inoculum was removed, the cells were supplemented with medium containing 1% FBS. Supernatants were collected at 0, 12, 24 and 48h. Virus titers were determined using quantitative RT-PCR targeting the partial N gene with a standard curve which expresses the correlation between Ct value and virus titer (shown as TCID50/ml). The standard curve was made using RNA dilutions from the purified Rs4874 virus stock (with a titer of 2.15×10^6 TCID50/ml). For qPCR, RNA was extracted from 140 μl of each supernatant with Viral RNA Mini Kit (Qiagen) following manufacturer's instructions and eluted in 60 μl AVE buffer. The PCR was performed with the TaqMan AgPath-ID One-Step RT–PCR Kit (Applied Biosystems) in a 25 μl reaction mix containing 4 μl RNA, 1 × RT–PCR enzyme mix, 1 × RT–PCR buffer, 40 pmol forward primer (5'-GTGGTGGTGACGGCA AAATG-3'), 40 pmol reverse primer (5'-AAGTGAAGCTTCTGG GCCAG-3') and 12 pmol probe (5'-FAM-AAAGAGCTCAGCCCCAGATG-BHQ1-3'). The amplification was performed as follows: 50˚C for 10 min, 95˚C for 10 min followed by 50 cycles consisting of 95˚C for 15 sec and 60˚C for 20 sec.

Plasmids

The ORF8 genes of bat SARSr-CoV WIV1 and Rf4092 and the ORF8a gene of bat SARSr-CoV Rs4084 were amplified by PCR from the viral RNA extracted from the isolated virus or fecal samples. The ORF8 gene of SARS-CoV GZ02 and bat SARSr-CoV Rf1, and the ORF8a gene of SARS-CoV Tor2 were synthesized by Tsingke Biological Technology Co., Ltd (Wuhan, China). All genes were cloned into the pCAGGS vector constructed with a C-terminal HA tag. Expression of the proteins was confirmed by Western blotting using a mAb against the HA tag. Five tandem copies of the ATF6 consensus binding sites were synthesized and inserted into the pGL3-Basic vector to construct the luciferase reporter plasmid 5×ATF6-GL3, in which the luciferase gene is under the control of the c-*fos* minimal promoter and the ATF6 consensus binding sites.

Luciferase reporter assay

HeLa cells in 24-well plates were transfected using Lipofectamine 3000 reagent (Life Technologies) following the manufacturer's instruction. Cells per well were co-transfected with 600ng of the 5×ATF6-GL3 reporter plasmid, with 300ng of each expression plasmid of SARS-CoV and SARSr-CoV ORF8 or empty vector and 20ng of pRL-TK (Promega) which served as an internal control. The cells were incubated for 24h, and were treated with or without 2μg/ml tunicamycin for 16h. Cells were harvested and lysed. Luciferase activity was determined using a dual-luciferase assay system (Promega). The experiment was performed in triplicate wells.

Quantification of apoptotic cells

293T cells in 12-well plates were transfected using Lipofectamine 3000 reagent (Life Technologies) following the manufacturer's instruction. Cells per well were transfected with 3μg of the expression plasmid of SARS-CoV Tor2 or SARSr-CoV Rs4084 ORF8a, or the empty vector. 24h post transfection, apoptotic cells were quantified by using the Annexin V-fluorescein isothiocyanate (FITC)/PI Apoptosis Detection Kit (Yeasen Biotech, Shanghai) in accordance with the manufacturer's instruction. Apoptosis was analyzed by flow cytometry. The experiment was performed in triplicate wells.

Accession numbers

The complete genome sequences of bat SARS-related coronavirus strains As6526, Rs4081, Rs4084, Rf4092, Rs4231, Rs4237, Rs4247, Rs4255, Rs4874, Rs7327 and Rs9401 have been deposited in the GenBank database with the accession numbers from KY417142 to KY417152, respectively.

Supporting information

S1 Fig. Alignment of amino acid sequences of the receptor-binding motif (corresponding to aa 424–495 of SARS-CoV S protein). Two clades of the SARSr-CoVs identified from bats in the studied cave are indicated with vertical lines on the left.
(PPTX)

S2 Fig. Alignment of nucleotide sequences of a genomic region covering ORF6 to ORF7a. ORFX is located between ORF6 and ORF7a in the genomes of WIV1, WIV16, Rs7327 and Rs4874. The start codon and stop codon of ORFX are marked with red boxes. The deletion responsible for the long ORFX in Rs7327 and Rs4874 is marked with the blue box.
(PPTX)

S3 Fig. Phylogenetic analyses based on nucleotide sequences of the S gene (A), ORF3a (B) and ORF8 (C). The trees were constructed by the maximum likelihood method using the LG model with bootstrap values determined by 1000 replicates. Only bootstraps > 50% are shown. Rs, *Rhinolophus sinicus*; Rf, *Rhinolophus ferremequinum*; Rm, *Rhinolophus macrotis*; Ra, *Rhinolophus affinis*; Rp, *Rhinolophus pusillus*; As, *Aselliscus stoliczkanus*; Cp, *Chaerephon plicata*. SARSr-CoVs detected in bats from the single cave surveyed in this study are in bold.
(PPTX)

S4 Fig. Alignment of amino acid sequences of ORF3b protein.
(PPTX)

S5 Fig. Detection of potential recombination events by similarity plot and boot scan analysis. (A) Full-length genome sequence of SARSr-CoV Rs4084 was used as query sequence and RsSHC014, Rf4092 and Rs4081 as reference sequences. (B) Full-length genome sequence of SARSr-CoV Rs4237 was used as query sequence and SARSr-CoV Rs4247, Rs4081 and Rs3367 as reference sequences. All analyses were performed with a Kimura model, a window size of 1500 base pairs, and a step size of 150 base pairs.
(PPTX)

S6 Fig. Chinese provinces where bat SARSr-CoVs have been detected.
(PPTX)

S7 Fig. The successful or failed rescue of the chimeric SARSr-CoVs. (A) Cytopathic effects in Vero E6 cells transfected with the infectious BAC clones constructed with the backbone of WIV1 and various S genes of different bat SARSr-CoV strains. Microphotographs were taken 24 hours post transfection. (B) The culture media supernatant collected from the cells transfected with the infectious BAC clones was used to infect Vero E6 cells. Immunofluorescent assay (IFA) was performed to detect infection and viral replication. Cells were fixed 24 hours post infection, and stained using rabbit antibody against the SARSr-CoV Rp3 nucleocapsid protein and a Cy3-conjugated anti-rabbit IgG.
(PPTX)

S8 Fig. Quantification of SARSr-CoV in individual bat fecal samples. The number of genome copies of SARSr-CoV per gram of bat feces was determined by quantitative real-time PCR targeting the RdRp gene. Samples from which the SARSr-CoV RBD sequences were successfully amplified are indicated in red.
(PPTX)

S9 Fig. Spike substitution strategy. The original fragments E and F were shortened to leave spike gene as an independent fragment. The new fragments were designated as Es and Fs. BsaI or BsmBI sites were introduced into the junctions of Es/Spike and Spike/Fs. Then any spike could be substituted into the genome of SARSr-CoV WIV1 through this strategy.
(TIF)

S1 Table. Comparison of the novel bat SARSr-CoVs identified in this study with human/civet SARS-CoVs and previously described bat SARSr-CoVs.
(DOCX)

S2 Table. Distribution of SARSr-CoVs highly similar to SARS-CoV in the variable S, ORF3 and ORF8 genes in the single cave.
(DOCX)

S1 Dataset. Full-length genome sequences of bat SARSr-CoVs newly identified in this study.
(FAS)

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Bat Severe Acute Respiratory Syndrome-Like Coronavirus WIV1 Encodes an Extra Accessory Protein, ORFX, Involved in Modulation of the Host Immune Response

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ABSTRACT

Bats harbor severe acute respiratory syndrome (SARS)-like coronaviruses (SL-CoVs) from which the causative agent of the 2002-2003 SARS pandemic is thought to have originated. However, despite the fact that a large number of genetically diverse SL-CoV sequences have been detected in bats, only two strains (named WIV1 and WIV16) have been successfully cultured *in vitro*. These two strains differ from SARS-CoV only in containing an extra open reading frame (ORF) (named ORFX), between ORF6 and ORF7, which has no homology to any known protein sequences. In this study, we constructed a full-length cDNA clone of SL-CoV WIV1 (rWIV1), an ORFX deletion mutant (rWIV1-ΔX), and a green fluorescent protein (GFP)-expressing mutant (rWIV1-GFP-ΔX). Northern blotting and fluorescence microscopy indicate that ORFX was expressed during WIV1 infection. A virus infection assay showed that rWIV1-ΔX replicated as efficiently as rWIV1 in Vero E6, Calu-3, and HeLa-hACE2 cells. Further study showed that ORFX could inhibit interferon production and activate NF-κB. Our results demonstrate for the first time that the unique ORFX in the WIV1 strain is a functional gene involving modulation of the host immune response but is not essential for *in vitro* viral replication.

IMPORTANCE

Bats harbor genetically diverse SARS-like coronaviruses (SL-CoVs), and some of them have the potential for interspecies transmission. A unique open reading frame (ORFX) was identified in the genomes of two recently isolated bat SL-CoV strains (WIV1 and -16). It will therefore be critical to clarify whether and how this protein contributes to virulence during viral infection. Here we revealed that the unique ORFX is a functional gene that is involved in the modulation of the host immune response but is not essential for *in vitro* viral replication. Our results provide important information for further exploration of the ORFX function in the future. Moreover, the reverse genetics system we constructed will be helpful for study of the pathogenesis of this group of viruses and to develop therapeutics for future control of emerging SARS-like infections.

Severe acute respiratory syndrome coronavirus (SARS-CoV) is a zoonotic pathogen that caused the 2002-2003 SARS pandemic, which originated in China (1). Since then, genetically diverse SARS-like coronaviruses (SL-CoVs) have been reported in bats in China, Europe, and Africa (2–11), indicating a wide geographic distribution of this group of viruses. However, most bat SL-CoVs have been identified only by sequences and are not fully characterized due to the lack of cultured viruses. Thus, their potential for transmission to and likely pathogenesis in domestic animals and humans remain untested. WIV1 and WIV16 are two recently identified SL-CoV strains with high genomic similarity to human SARS-CoV. These two strains have been successfully cultured *in vitro* and have been shown to use the same molecule (angiotensin-converting enzyme [ACE2]) for cellular entry as SARS-CoV (2, 10). Recently, another bat SL-CoV strain, SHC014, has been demonstrated to use human ACE2 by the construction of an infectious cDNA clone (12). Furthermore, animal infection experiments indicated that SL-CoV WIV1 and SHC014 could replicate efficiently and caused low pathogenesis in ACE2 transgenic mice (12, 13). The fact that the native bat SL-CoVs could use human ACE2 without any mutations indicates a high risk of interspecies transmission for these and similar coronaviruses that may exist in natural reservoirs.

Coronaviruses have the largest genomes among RNA viruses. Their genomes consist of a positive, single-stranded RNA of around 30,000 nucleotides (nt), with two-thirds at the 5′ end encoding genome replication proteins (ORF1ab) and one-third at the 3′ end encoding structural proteins, including a spike glycoprotein (S), a small envelope protein (E), a membrane protein (M), and a nucleocapsid protein (N). Coronaviruses carry a set of open reading frames (ORFs) expressed from full-length mRNAs and subgenomic-length mRNAs (sgRNAs), which have a common 3′ end originating at distinct transcription regulatory sequences (TRS) and joined with a common leader sequence encoded at the 5′ end of genomic RNA (14). Currently, coronaviruses are divided into the genera *Alphacoronavirus*, *Betacoronavirus*, and *Gammacoronavirus* and the proposed genus *Deltacoronavirus* (15). SARS-CoV and SL-CoVs are grouped into the same coronavirus species, SARS-related coronavirus (SARSr-CoV),

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within the genus *Betacoronavirus*. Besides the family-conserved genes, SARSr-CoV possesses several accessory genes, including ORF3, ORF6, ORF7, ORF8, and ORF9, which are specific for this group of coronaviruses but not essential for *in vitro* viral replication (16–18). Accessory genes in coronavirus genomes play important roles in regulating the host immune response (19). The SARS-CoV ORF3a, ORF3b, and ORF6 have been reported to inhibit the host interferon (IFN) response during virus infection and contribute to pathogenesis (20, 21). ORF3a and ORF7a activate NF-κB and upregulate interleukin-8 (IL-8) and CCL5 production (22, 23). Bat SL-CoVs display great genetic diversity and share overall nucleotide sequence identities of 88 to 97% with human SARS-CoV (2–11). Bat SL-CoVs WIV1 and WIV16 are the closest relatives to human SARS-CoV discovered so far. These two viruses are identical in genomic structures except that WIV1 and -16 have an extra ORF (named ORFX) between ORF6 and ORF7 with no homology to any known protein sequences (2, 10).

In this study, we explored the function of ORFX in modulating the host immune response through the use of eukaryotic overexpression assays and recombinant viruses generated through reverse genetics techniques.

MATERIALS AND METHODS

Virus and cells. The SL-CoV WIV1 strain (GenBank accession number KF367457) and other viruses were propagated as described previously (2). Sendai virus (SeV) strain Cantell (kindly provided by Hanzhong Wang) was propagated in 10-day-old embryonated chicken eggs at 37°C for 48 h (24). All experiments using live virus was conducted under biosafety level 2 (BSL2) conditions. HeLa cells stably expressing human ACE2 (HeLa-hACE2) were described previously (25). 293T, Vero E6, HeLa, and HeLa-hACE2 cells were grown and propagated in Dulbecco's modified Eagle's medium (GIBCO, Invitrogen) supplemented with 10% fetal bovine serum (Life Technologies). Calu-3 cells were grown and propagated in Dulbecco's modified Eagle's medium–nutrient mixture F-12 medium supplemented with 15% fetal bovine serum. Cells were grown at 37°C in a humidified atmosphere with 5% CO_2.

Plasmids. The coding region of ORFX was amplified by reverse transcription-PCR (RT-PCR) from viral RNA using the Superscript one-step RT-PCR kit (Invitrogen). The amplified gene was cloned into plasmid pCAGGS with a C-terminal hemagglutinin (HA) tag (pCAGGS-ORFX) for eukaryotic expression. Reporter plasmids used included pIFNκ-Luc (expressing firefly luciferase under the control of the IFN-β promoter), pNF-κB-Luc (expressing firefly luciferase under the control of the NF-κB promoter), and pRL-TK (expressing *Renilla* luciferase under the control of the herpes simplex virus thymidine kinase promoter), as well as an expression plasmid for influenza virus NS1, as described previously (24). Plasmids expressing subcellular organelle markers, including SecG1β-green fluorescent protein (GFP) (endoplasmic reticulum [ER] marker), B4Gal-Ti-red fluorescent protein (RFP) (Golgi apparatus marker), and Mito-yellow fluorescent protein (YFP) (mitochondrion marker), were kindly provided by Yanyi Wang of the Wuhan Institute of Virology.

Viral infection assays. Vero E6, Calu-3, and HeLa-hACE2 cells were infected with viruses at a multiplicity of infection (MOI) of 1.0, 0.1, or 0.001 in 25-cm^2 flasks with a 1-h adsorption period, followed by two washes with D-Hanks solution and culturing by adding 3 ml of medium. The viral supernatants were harvested, at 0, 2, 6, 12, 18, 24, 36, 48, and 72 h postinoculation, with 300 μl removed and 300 μl medium added back at each time point. The virus concentration was titrated by plaque assay in Vero E6 cells.

Vero E6 cells were infected by rWIV1-GFP-ΔX or mock infected. After 24 h, fluorescence micrographs was taken to check the expression of green fluorescent protein.

Cloning of WIV1 cDNAs. The virus genome was divided into 8 continuous fragments (A to G) and amplified using specific primers (primer sequences are available upon request). Viral RNA was extracted from the supernatant of WIV1-infected cultures and reverse transcribed with Moloney murine leukemia virus (M-MLV) reverse transcriptase (Promega) and random hexamer deoxynucleotide primers. The cDNA was denatured for 5 min at 95°C and amplified by PCR with KOD DNA polymerase (Toyobo) for 20 cycles of 95°C for 30 s, 60°C for 30 s with a 0.5°C decrease per cycle, and 68°C for 5 min, 15 cycles of 95°C for 30 s, 50°C for 30 s, and 68°C for 5 min, and a final extension at 68°C for 10 min. The amplicons were cloned into pGEM-T Easy (Promega). Besides three natural BglI sites, several BglI sites were introduced by synonymous mutations in the PCR process to make all contiguous cDNA fragments capable of unidirectional ligation. SacII and AscI sites were introduced into the 5′ terminus of fragment A and the 3′ terminus of fragment G, respectively. A poly(A) sequence (25 nt) was added to the 3′ terminus of fragment G. At least three colonies of each cDNA clone were sequenced, and the one identical to or with some synonymous mutations to the reported sequence was selected for assembly.

To ablate a natural BglI site at position 1575, primers FA, F-c1575a, R-c1575a, and RA were used for overlap extension PCR (OE-PCR) to introduce the synonymous mutation C1575A (primer sequences are available upon request). Based on previous *in vitro* transcription tests, the synonymous mutation T27527C was also introduced to interrupt a potential T7 termination site via OE-PCR.

Strategy for modifying pBeloBAC11. The cytomegalovirus (CMV) promoter was amplified from pcDNA3.1(+) (Thermo Fisher Scientific) with forward primer 5′-TGAGGATCCCGTTGACATTGATTATTGACTAG-3′ and reverse primer 5′-CCTGACTGCAGGTCGACTGCCGCGGAGCTCTGCTTATATAGACC-3′. Hepatitis delta virus (HDV) ribozyme was synthesized as described previously (26), and amplified with forward primer 5′-CAGTCGACCTGCAGTCAGGCGCGCCGGGTCGGCATGGCATCTCC-3′ and reverse primer 5′-CTAGAAGGCACAGCTCCCTTAGCCATCCGAGTGG-3′. The bovine growth hormone (BGH) transcription terminal signal was amplified from pcDNA3.1(+) with forward primer 5′-GGATGGCTAAGGGAGCTGTGCCTTCTAGTTGCCAGC-3′ and reverse primer 5′-TGAAAGCTTCCATAGAGCCCACCGCATCC-3′. The three PCR products then were ligated using OE-PCR, with BamHI and HindIII sites flanking the amplicon and SacII and AscI sites between the CMV promoter and HDV ribozyme. The amplicon was then inserted into pBeloBAC11 (New England BioLabs) between BamHI and HindIII sites. The construct was designated pBAC-CMV.

Construction of infectious bacterial artificial chromosome (BAC) clones of WIV1. Subclone A and subclone G were first digested with SacII and AscI (New England BioLabs), respectively, followed by treatment with calf intestinal alkaline phosphatase (CIAP) (TaKaRa), chloroform extraction, and isopropanol precipitation, and then restricted with BglI (TaKaRa). Subclones B to F were digested with BglI. pBAC-CMV was digested with SacII and AscI. All digestion products were then separated using 1% agarose gels, excised, and purified by using a gel extraction kit (Omega). Digested fragments A to G and pBAC-CMV were ligated overnight at 4°C, transformed into DH10B competent cells, and plated on Chl^+ LB culture. Ten clones were screened by restriction fragment length polymorphism (RFLP) analysis with NcoI, StuI, or HindIII. The correct clone was named pBAC-CMV-rWIV1 (Fig. 1).

Construction of WIV1 mutants. To delete ORFX, the fragment F was PCR amplified with primers FF (5′-ACCTGTGCCCTTTTGGCGAGGTTTTTAATGCTACTAC-3′) and RFox (5′-GCCTCTAGGGCTCAAGGATAATCTATCTCCATAGG-3′). Fragment G was PCR amplified with FGox (5′-GCCCTAGAGGCAACGAACATGAAAATTATTCTCTTCC-3′) and RG (5′-ACTGGCGCGCCTTTTTTTTTTTTTTTTTTTTTTTGTCATTCTCCTGAGAAGC-3′). This new fragment was named Gox. These two products were then cloned into pGEM-T Easy. The two fragments were inserted into the BAC along with the other fragments as described above. The rescued mutant was named as rWIV1-ΔX. To place

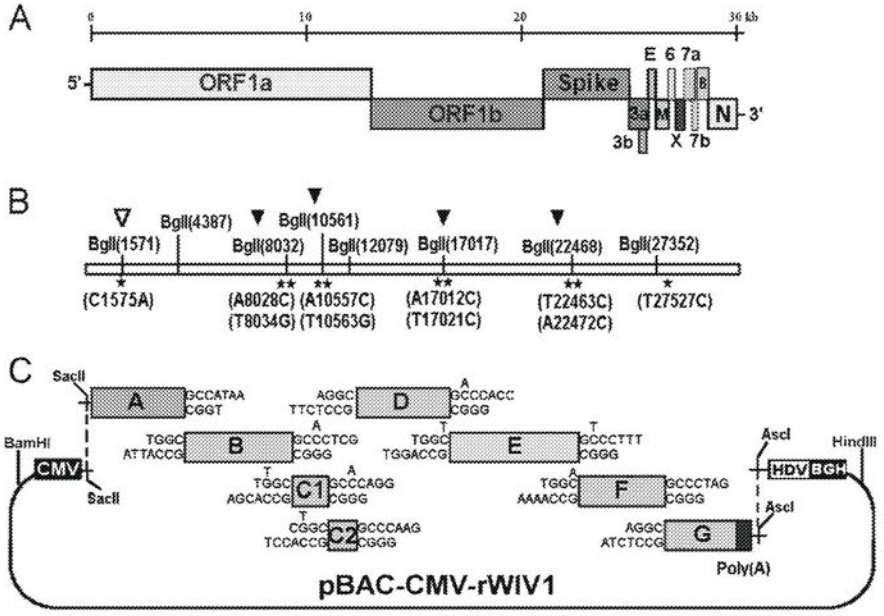

FIG 1 Strategy for construction of an infectious WIV1 BAC clone. (A) Genomic structure of WIV1. (B) The mutations are indicated under the stars. C1575A was used to ablate a natural BglI site at nucleotide 1571 (▽), and T27527C was used to disrupt a potential T7 stop site. The others were for introducing BglI sites (▼). (C) The WIV1 genome was split into eight contiguous cDNAs (A to G): A, nt 1 to 4387; B, nt 4388 to 8032; C1, nt 8033 to 10561; C2, nt 10562 to 12079; D, nt 12080 to 17017; E, nt 17018 to 22468; F, nt 22469 to 27352; G, nt 27353 to 30309. Unique BglI sites were introduced into the fragments by synonymous mutations to make these fragments capable of unidirectional ligation along with native BglI sites in the genome. The original nucleotides are shown above the flanking sequences of corresponding fragments. A poly(A) sequence was added to the 3′ terminus of fragment G. A CMV promoter, HDV ribozyme, and BGH transcriptional terminal signal were inserted into pBeloBAC11 between BamHI and HindIII sites. SacII and AscI sites were introduced between the CMV promoter and ribozyme. Fragments A to G were inserted into the pBAC-CMV plasmid in a single step.

GFP into the open reading frame of ORFX, the F fragment was amplified with primers FF and RFoeGFP (5′-GCTCACCATAGTGGTTCGTTTAT CAAGGATAATCTATCTCC-3′). The GFP gene was amplified with primers 5′-CCTTGATAAACGAACCACTATGGTGAGCAAGGGCGAG GAGC-3′ and 5′-TGCCTCTAGGGCTTACTTGTACAGCTCGTCCAT GCC-3′. The two PCR products were ligated by OE-PCR, and the product was inserted into pGEM-T Easy. The rescued mutant was named rWIV1-GFP-ΔX.

Transfection of infectious WIV1 BAC clones. Vero E6 cells were seeded in a 6-well plate a day in advance, and then one well was transfected with 6 μg infectious BAC plasmids constructed as described above with Lipofectamine LTX and Plus reagent (Life Technologies). Virus progeny was plaque purified once. One clone was passaged once in Vero E6 cells for 72 h and used to generate a stock for future use.

RFLP. RNAs extracted from wild-type and recombinant viruses were reverse transcribed with random hexamer primers. RT-PCR was used to generate five amplicons containing the five mutations designed in the strategy. These amplicons included a 1,124-bp amplicon (nucleotide positions 1312 to 2435) spanning a naturally occurring BglI site at nucleotide 1571 that had been ablated in recombinant viruses, a 1,438-bp amplicon spanning the B/C1 junction (nucleotide positions 7560 to 8997), a 1,437-bp amplicon spanning the C1/C2 junction (nucleotide positions 10196 to 11632), a 1,437-bp amplicon spanning the D/E junction (nucleotide positions 16793 to 18229), and a 1,438-bp amplicon spanning the E/F junction (nucleotide positions 21908 to 23345) (these amplicons correspond to fragments F1 to F5 in Fig. 1). The first amplicon of wild-type WIV1 (wtWIV1) that contains nucleotide 1571 can be cleaved by BglI, but the other four amplicons cannot. In contrast, the five amplicons of recombinant viruses are different from those of wild-type virus in the capability of being cut by BglI.

Northern blot analysis. The N gene was amplified with primers WIV1-NF (5′-ATGTCTGATAATGGACCCCA-3′) and WIV1-3R (5′-G TCATTCTCCTGAGAAGCTA-3′) and used as a template for probe preparation according to the description in the DIG-High Prime DNA labeling and detection starter kit II (Roche). Vero E6 cells were infected with wild-type and recombinant viruses at an MOI of 1.0. At 24 h postinfection, intracellular RNA was isolated using TRIzol reagent (Ambion). RNA (20 μg) was precipitated, treated with 17 μl sample buffer (50% formamide, 2.2 M formaldehyde [37%], 1× morpholinepropanesulfonic acid [MOPS]) at 65°C for 10 min, supplemented with 3 μl 10× dye solution (50% glycerol, 0.25% bromophenol blue, 0.25% xylene cyanole FF), and then separated in a denaturing 0.8% agarose–2.2 M formaldehyde gel at 28 V for ~17 h. The RNA was hydrolyzed with 0.05 M NaOH for 40 min, transferred to a Hybond-N+ membrane (GE Healthcare) for ~18 h, and then cross-linked to the membrane using UV light. The membrane was prehybridized, probed with a digoxigenin (DIG)-labeled probe for the N gene, and washed, and detection was performed according to the instructions for the DIG-High Prime DNA labeling and detection starter kit II (Roche).

RT-PCR of leader-containing transcripts. Intracellular RNA was isolated from wtWIV1. A forward primer (Leader-F) located in the leader sequence, along with various reverse primers located in several ORFs, was used for amplifying leader-containing sequences (primer sequences are available upon request). Leader-containing amplicons were sequenced with the corresponding reverse primers.

ORFX subcellular location. HeLa cells were transfected with an ORFX-expressing plasmid and cotransfected with organelle markers expressing plasmid SecG1β-GFP, B4Gal-Ti-RFP, or Mito-YFP. After 24 h, the cells were fixed and stained with a mouse anti-HA IgG (Promoter). A Cy3-conjugated goat anti-mouse IgG (Promoter) was used for secondary detection in cells expressing ER or mitochondrial markers. A fluorescein isothiocyanate (FITC)-conjugated goat anti-mouse IgG (Promoter) was used for secondary detection in cells expressing the Golgi marker. Nuclei were stained with 4′,6-diamidino-2-phenylindole (DAPI). Staining patterns were examined with an Olympus Fluoview upright confocal microscope (Olympus).

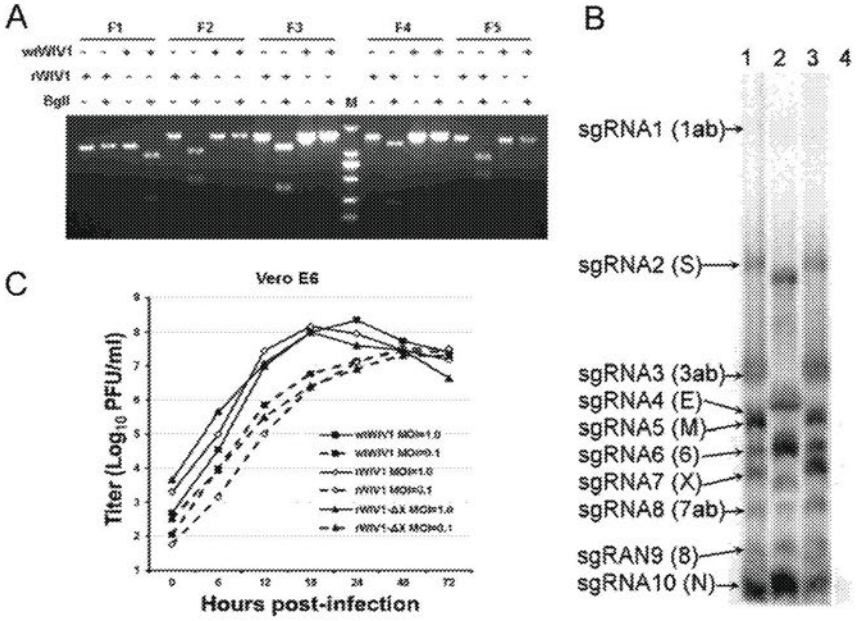

FIG 2 Recovery and characterization of recombinant viruses. (A) Restriction fragment length polymorphism. Amplicons flanking five mutated sites of wild-type and recombinant viruses were digested by BglI. The first amplicon (F1) of wild-type virus can be digested by BglI, and its other four amplicons (F2 to F5) cannot be. In contrast, for amplicons of rWIV1, the first amplicon (F1) cannot be digested by BglI and its other four amplicons (F2 to F5) can be. Lane M, DL2000 DNA ladder (TaKaRa). (B) Detection of viral genomic transcription and replication by Northern blotting. Vero E6 cells were infected with wild-type or recombinant viruses, and intracellular RNA was extracted for Northern blot analysis. Lane 1, wtWIV1; lane 2, rWIV1-ΔX; lane 3, rWIV1; lane 4, uninfected control. (C) Growth kinetics of wild-type and recombinant viruses. Vero E6 cells were infected with wtWIV1 (■), rWIV1 (◇), or rWIV1-ΔX (▲) at an MOI of 1.0 or 0.1 PFU/cell. Cell supernatants were taken at the indicated time points postinfection, and virus titers were determined by plaque assay in Vero E6 cells.

Luciferase assays and quantitative PCR. For the ORFX-mediated IFN promoter assay, 293T cells were seeded in 12-well plates and cotransfected with empty vector plasmid pCAGGS, plasmid pCAGGS-NS1, or increasing amounts (100, 200, 400, 600, and 800 ng) of pCAGGS-ORFX with the indicated reporter plasmids. At 24 h posttransfection, cells were infected with Sendai virus (SeV) (100 hemagglutinin units [HAU]/ml) for 12 h to induce IFN production or were treated with tumor necrosis factor alpha (TNF-α) for 1 h to activate NF-κB. Cell lysates were prepared, and luciferase activity was measured using dual-luciferase assay kits (Promega) according to the manufacturer's instructions.

293T cells were transfected with empty vector, NS1-expressing plasmid, or increasing amounts (100, 300, and 600 ng) of ORFX-expressing plasmid. After 24 h, the cells were infected with SeV (100 HAU/ml). At 12 h postinfection, the cells were lysed. The mRNA was extracted and reverse transcribed with PrimeScript RT master mix (TaKaRa). The expression level of IFN-β mRNA was determined by quantitative PCR using SYBR Premix *Ex Taq* II (TaKaRa). The GAPDH (glyceraldehyde-3-phosphate dehydrogenase) mRNA was quantified as an inner control. 293T cells were transfected as described above. After 24 h, the cells were treated with TNF-α for 6 h, and the cell RNA was extracted and used for quantification of the expression of IL-8 mRNA. All experiments were performed in triplicate and repeated at least three times. All primer sequences used in the quantitative PCRs are available upon request.

IRF3 translocation assay. 293T cells were transfected with empty vector, NS1, or ORFX-expressing plasmid. After 24 h, IFN regulatory factor 3 (IRF3) nuclear translocation was induced by infecting the cells with SeV for 8 h. The cells were fixed and stained with a rabbit anti-IRF3 polyclonal IgG (Proteintech) and a mouse anti-HA IgG (Promoter). An Alexa Fluor 488-conjugated donkey anti-rabbit IgG (Yeasen) and an Alexa Fluor 555-conjugated donkey anti-mouse IgG (Beyotime) were used to detect IRF3 and ORFX, respectively. The cells transfected with empty vector were stained with a rabbit anti-IRF3 polyclonal IgG and a goat anti-SeV IgG (kindly provided by Lin-Fa Wang, Duke-NUS Graduate Medical School, Singapore) as an indication of infection efficiency. An Alexa Fluor 488-conjugated donkey anti-rabbit IgG and a Cy3-conjugated donkey anti-goat IgG (Promoter) were used to detect IRF3 and SeV, respectively. Nuclei were stained with DAPI.

Quantification of mRNA expression of cytokines in infected Calu-3 cells. Calu-3 cells grown in 24-well plates were mock infected or infected with rWIV1 or rWIV1-ΔX at an MOI of 5 or with SeV (100 HAU/ml). The cells were lysed at 4, 12, 24, and 30 h postinfection. The mRNA expression levels of IFN-β, IL-6, IL-8, and TNF-α were quantified by quantitative PCRs. The expression of GAPDH mRNA was measured as an internal control. All primer sequences used in the quantitative PCRs are available upon request. The experiment was performed twice.

IFN-β sensitivity assay. Vero E6 cells were seeded a day in advance. The cells were pretreated with 10, 100, or 1,000 U/ml IFN-β (PBL, Piscataway, NJ) for 24 h, infected with wtWIV1, rWIV1, and rWIV1-ΔX at an MOI of 0.1 PFU/cell, and posttreated with the same amount of IFN-β as used previously. At 24 h postinfection, the viral replication was analyzed by plaque assay. The experiment was performed in triplicate.

Statistics. The statistical significance of the obtained data was analyzed using a Student *t* test in GraphPad Prism (GraphPad Software, San Diego, CA). A P value of <0.05 was considered statistically significant. Data are presented as the means ± standard errors of the means (SEM).

RESULTS

Strategy for construction of an infectious WIV1 BAC. Originally, the genome was split into seven contiguous cDNAs (A to G) (Fig. 1A and C). Due to plasmid instability, fragment C was separated into two segments (C1 and C2). Besides three naturally occurring BglI sites (GCCNNNN ↓ NGGC), four BglI sites were successfully introduced by synonymous mutations in the genome (Fig. 1B). Different asymmetric 3-nt overhangs at the junctions of each two contiguous fragments were created by these BglI sites. The eight fragments were then linked in one direction. A SacII site was added to the 5′ terminus of fragment A. A poly(A) sequence

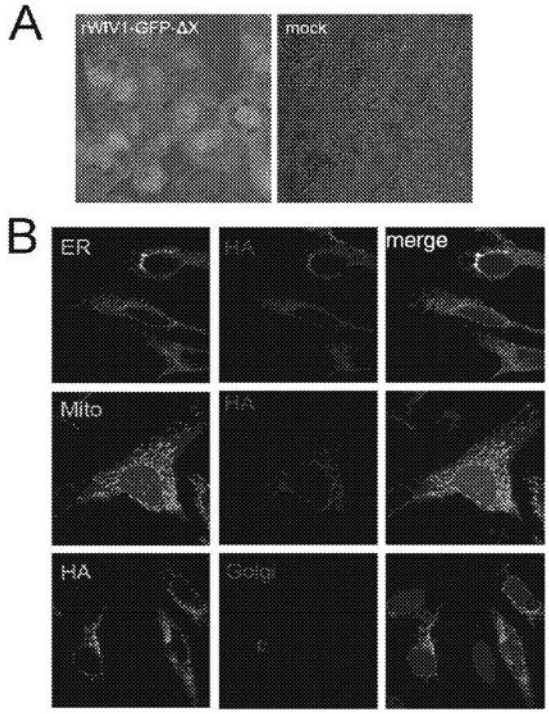

FIG 3 Expression and subcellular location of ORFX protein. (A) The open reading frame of ORFX was replaced by the GFP sequence, and the recombinant virus was rescued. Vero E6 cells were infected with the recombinant virus or mock infected. Green fluorescence was visualized at 24 h postinfection. (B) ORFX protein with an HA tag at the C terminus was expressed in HeLa cells, along with SecG1β-GFP (ER marker), Mito-YFP (mitochondria marker), or B4Gal-Ti-RFP (Golgi marker). The cells were fixed after 24 h and stained with a mouse anti-HA IgG. A Cy3-conjugated goat anti-mouse IgG was used for secondary detection in cells expressing an ER or mitochondrial marker. An FITC-conjugated goat anti-mouse IgG was used for secondary detection in cells expressing a Golgi marker. ORFX protein showed a cytoplasmic distribution and colocalized with the ER maker SecG1β.

(25 nt) and an AscI site were added to the 3′ terminus of fragment G. A naturally occurring BglI site at nucleotide 1571 was removed by the synonymous mutation C1575A (Fig. 1B). Other unexpected synonymous mutations also occurred, including T1422C, T12984C, T14213C, T17130C, C17934T, and T26068G.

The plasmid pBAC-CMV was constructed by inserting the cytomegalovirus (CMV) promoter, hepatitis delta virus (HDV) ribozyme, and bovine growth hormone (BGH) transcription terminal signal sequences into pBeloBAC11, along with the introduction of the SacII and AscI sites between the CMV promoter and HDV ribozyme (Fig. 1C). The eight genomic fragments were inserted into pBAC-CMV in one step. Recombinant viruses could be rescued by direct transfection with the BAC constructs.

Rescue of recombinant viruses. To rescue recombinant WIV1 (rWIV1), fragments A and G were digested with SacII and AscI, respectively. Following calf intestinal alkaline phosphatase (CIAP) dephosphorylation, the two fragments, along with fragments B to F, were digested using BglI and inserted into pBAC-CMV between SacII and AscI sites in one step. The constructed clone (pBAC-CMV-rWIV1) was transfected into Vero E6 cells. A cytopathic effect was observed at 72 h posttransfection. The one ablated natural BglI site and four introduced BglI sites in the rescued viral genome were confirmed by restriction fragment length polymorphism (RFLP) analysis with BglI digestion (Fig. 2A). Using this method, we also rescued an ORFX deletion mutant virus (rWIV1-ΔX) (Fig. 2B, lane 2) and a mutant with a GFP sequence placed in the coding region of ORFX (rWIV1-GFP-ΔX) (Fig. 3A).

ORFX is a functional gene not essential for virus replication. The one-step growth curves for the two rescued recombinant viruses (rWIV1-ΔX and rWIV1) and wild-type WIV1 (wtWIV1) determined by plaque assay showed that rWIV1-ΔX and rWIV1 both replicated to titers close to those of wild-type virus (Fig. 2C). The expected set of appropriately sized 10 sgRNAs, including sgRNA7 (ORFX), were observed in Northern blot analysis in cells infected with wtWIV1 and rWIV1 (Fig. 2B, lanes 1 and 3). As expected, sgRNA7 was not observed in rWIV1-ΔX infected cells (Fig. 2B, lane 2). Analysis of leader-containing sequences indicated that all 10 sgRNAs in wtWIV1 share an identical core sequence, ACGAAC (Table 1), which further confirmed that ORFX is expressed as sgRNA7. The fact that GFP was expressed in rWIV1-GFP-ΔX-infected cells further confirmed that the open reading frame of ORFX could be expressed (Fig. 3A). Subcellular location analyses showed that the ORFX protein colocalized with the ER marker but not with the Golgi and mitochondrial markers (Fig. 3B).

ORFX protein inhibits production of IFN-β. To determine whether ORFX inhibits the induction of IFN, 293T cells were transfected with plasmids pIFNβ-Luc and pRL-TK and a plasmid expressing ORFX, influenza virus strain PR8 NS1 (positive control), or empty vector (negative control). As expected, SeV activated IFN production in cells transfected with empty vector. The positive control, influenza virus NS1 protein dramatically inhibited the expression from the IFN promoter. ORFX protein exhibited an inhibition effect, but the effect decreased when more

TABLE 1 Leader-containing sequences of sgRNAs

sgRNA	ORF(s)	Leader-containing sequence[a]	Consensus sequence positions
1	1a/b	GTAGATCTGTTCTCTAA**ACGAAC**TTTAAAATCTGT	67–72
2	S	GTAGATCTGTTCTCTAA**ACGAAC**ATGAAATTGTTA	21486–21491
3	3a/b	GTAGATCTGTTCTCTAA**ACGAAC**TTATGGATTTGT	25263–25268
4	E	GTAGATCTGTTCTCTAA**ACGAAC**TTATGTACTCAT	26112–26117
5	M	GTAGATCTGTTCTCTAA**ACGAAC**TAACTATTATTA	26351–26356
6	6	GTAGATCTGTTCTCTAA**ACGAAC**GCTTTCTTATTA	26916–26921
7	X	GTAGATCTGTTCTCTAA**ACGAAC**CACTATGTTACT	27272–27277
8	7a/b	GTAGATCTGTTCTCTAA**ACGAAC**ATGAAAATTATT	27794–27799
9	8	GTAGATCTGTTCTCTAA**ACGAAC**ATGAAACTTCTC	28300–28305
10	N	GTAGATCTGTTCTCTAA**ACGAAC**AAACTAAAATGT	28672–28677

[a] The consensus sequence is in bold. Underlining indicates the initiation codon.

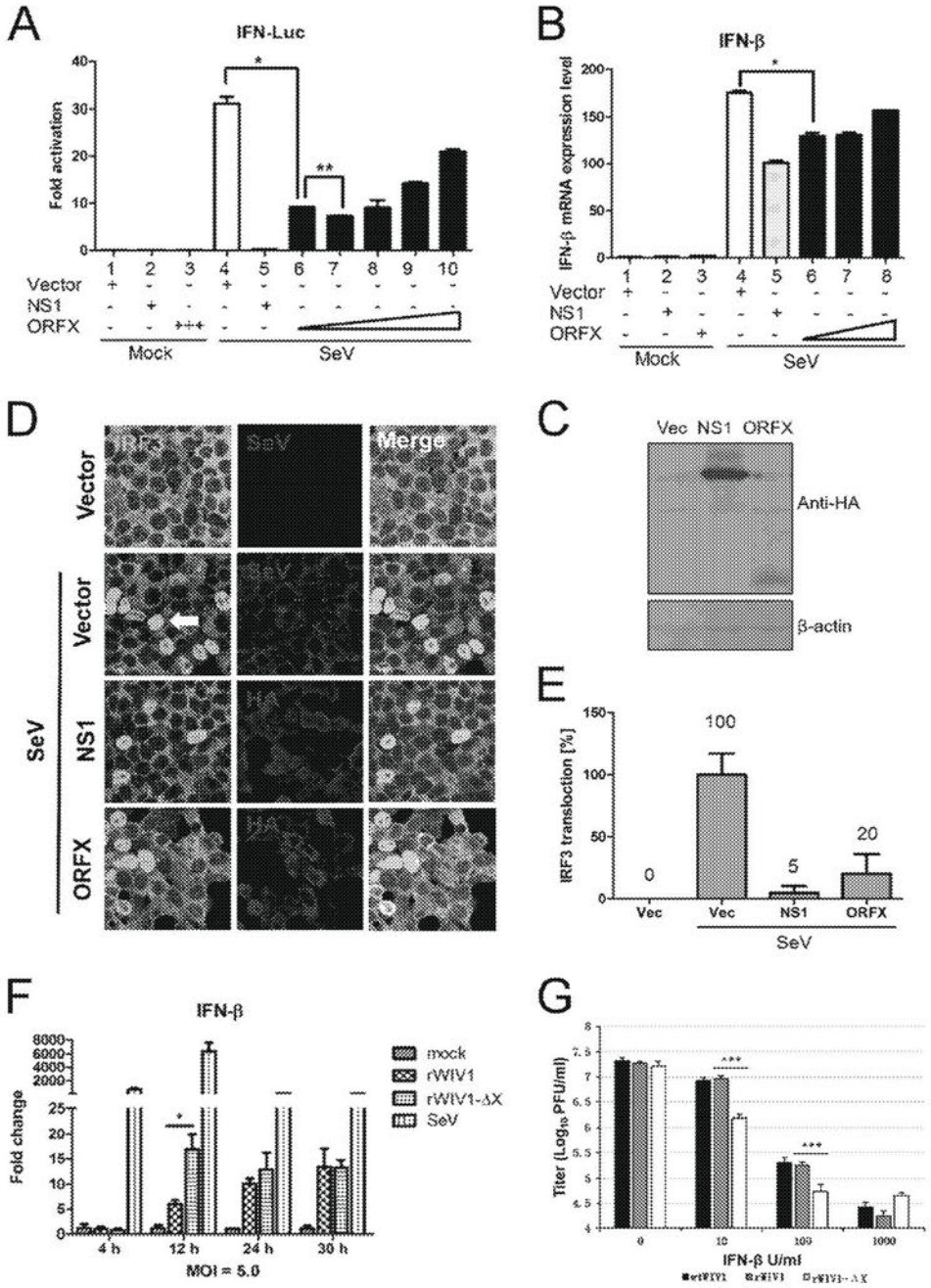

FIG 4 ORFX protein inhibits the production of type I interferon. (A and B) 293T cells seeded in 12-well plates were transfected with 100 ng pIFN-β-Luc, 5 ng pRL-TK, empty vector, an influenza A NS1-expressing plasmid, or increasing doses (100, 200, 400, 600, and 800 ng) of an ORFX-expressing plasmid. Empty vector was added appropriately to ensure that cells in each well were transfected with the same amount of plasmids. The cells were infected with Sendai virus (100 hemagglutinating units/ml) at 24 h posttransfection. Samples were collected at 12 h postinfection, followed by dual-luciferase assay. The results were expressed as the firefly luciferase value normalized to that of *Renilla* luciferase. The relative expression of IFN-β mRNA was determined by quantitative RT-PCR and normalized to the expression level of GAPDH mRNA. (C) The expression of the NS1 and ORFX proteins was analyzed by Western blotting with an antibody against HA tag. The experiments were replicated three times. (D and E) For the IRF3 translocation assay, 293T cells were transfected with empty vector-, NS1-, or ORFX-expressing plasmid. After 24 h, the cells were infected with Sendai virus to induce IRF3 nuclear translocation. The cells were fixed at 8 h postinfection and stained with anti-HA IgG. A goat anti-Sendai virus polyclonal IgG was used to stain the cells transfected with empty vector. A rabbit anti-IRF3 polyclonal IgG was used to label IRF3. The white arrow indicates IRF3 nuclear translocation. The relative IRF3 translocation ratios were calculated for each group by counting the number of IRF3 nuclear translocation cells (randomly selected from at least 4 fields) and dividing by the total number of infected or transfected cells. The IRF3 nuclear translocation efficiency of each group was expressed as the percentage of their relative IRF3 translocation ratios to that of the control (cells transfected with empty vector). (F) Calu-3 cells were mock infected or infected with rWIV1 or rWIV1-ΔX (MOI of 5) or SeV (100 HAU/ml). At 4, 12, 24, and 30 h postinfection, the cell RNA was extracted and used for quantitative RT-PCR of the expression level of IFN-β mRNA. The experiment was performed in triplicate and replicated twice. (G) Vero E6 cells were pretreated with indicated amount of IFN-β, infected with wtWIV1, rWIV1, or rWIV1-ΔX at an MOI of 0.1 PFU/cell, and posttreated with IFN-β. Viral replication was analyzed at 24 h postinfection by plaque assay. The experiment was performed in triplicate and replicated twice. The differences between selected groups were significant, with P values of less than 0.05, as follows: 0.0049 (*; bars 4 and 6 in panel A), 0.0008 (**; bars 6 and 7 in panel A), 0.0072 (*; bars 4 and 6 in panel B), 0.018 (*; bars for rWIV1 and rWIV1-ΔX in panel F), and <0.0001 (*** in panel G).

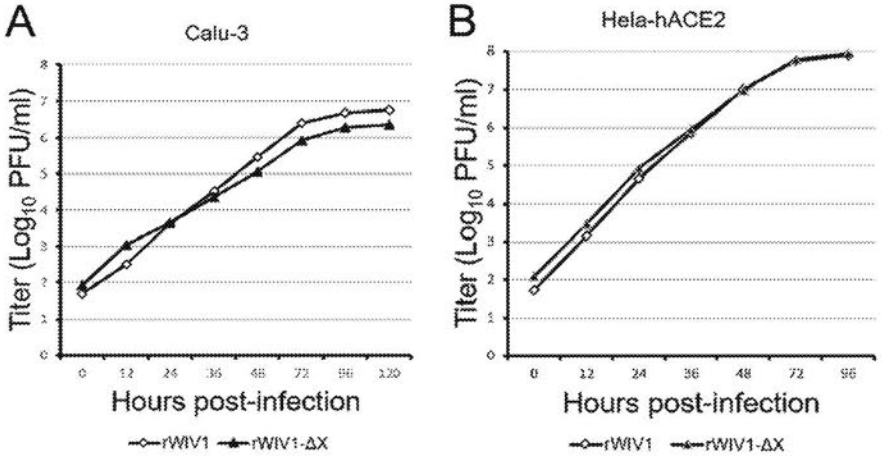

FIG 5 Comparison of viral replication efficiencies of rWIV1-ΔX and rWIV1 in IFN-competent cells. Calu-3 (A) and HeLa-hACE2 (B) cells were infected with rWIV1 or rWIV1-ΔX at an MOI of 0.001. Samples were collected at 0, 12, 24, 36, 48, 72, 96, and 120 h postinfection. The viral titers were measured by plaque assay.

ORFX protein was expressed (Fig. 4A). Similar results were observed for IFN-β mRNA quantification (Fig. 4B and C).

An IRF3 nuclear translocation assay was performed to see whether ORFX protein inhibits IFN production through inhibiting this process. 293T cells were transfected with an empty vector-, NS1-, or ORFX-expressing plasmid. After 24 h, IRF3 nuclear translocation was induced by infection with SeV for 8 h. The relative IRF3 translocation ratios were calculated for each group by counting the number of the IRF3 nuclear translocation cells (randomly selected from at least 4 fields) divided by the number of total infected or transfected cells. The IRF3 nuclear translocation efficiency of each group was expressed as the percentage of their relative IRF3 translocation ratios to that of the control (cells transfected with empty vector). As expected, NS1 strongly inhibited translocation of IRF3, while ORFX protein also showed inhibition of IRF3 translocation but less efficiently (Fig. 4D and E).

To further investigate the IFN inhibition activity of ORFX, the deletion mutant and wild-type recombinant virus were used to infect Calu-3 cells at an MOI of 5. Mock-infected cells were used as negative control. Calu-3 cells infected with SeV were used as positive control. Samples were collected at 4, 12, 24, and 30 h postinfection. The relative expression of IFN-β mRNA was determined by quantitative PCR and normalized to the expression of GAPDH mRNA. Compared to SeV, WIV1 recombinants induced low levels of IFN-β mRNA in Calu-3 cells (Fig. 4F). The ORFX deletion mutant induced a significantly higher level of IFN-β mRNA than wild-type recombinant virus in infected cells at 12 h postinfection, but there were no significant differences at 24 and 30 h postinfection (Fig. 4F). These results indicate that ORFX protein may play a role in antagonizing IFN only at early times during WIV1 infection.

An ORFX deletion mutant shows increased sensitivity to IFN-β. To further investigate the effect of ORFX on the viral sensitivity of IFN, we tested the replication efficiencies of wtWIV1, rWIV1, and rWIV1-ΔX in Vero E6 cells which were pretreated and posttreated with IFN-β. The replication of rWIV1-ΔX was inhibited and reduced by ~0.5 log compared to that of wtWIV1 and rWIV1 at concentrations of 10 and 100 U/ml IFN-β (Fig. 4G), whereas at a higher IFN-β concentration (1,000 U/ml), the rWIV1-ΔX titers did not show an obvious decrease compared to those of wild-type virus. We expected that the ORFX deletion mutant would replicate less efficiently than the wild-type virus in IFN-competent cells. However, we did not find a significant difference when we grew the two viruses in Calu-3 and HeLa-hACE2 cells, even at a very low MOI of 0.001 (Fig. 5).

ORFX protein activates NF-κB. NF-κB plays an important role in regulating the immune response to viral infection and is also a key factor frequently targeted by viruses for taking over the host cell (27). Several proteins (Nsp1, N, and 3a) encoded by SARS-CoV have activities in both IFN antagonism and NF-κB activation (28). In this study, we also tested whether ORFX protein could activate NF-κB. 293T cells were transfected with pNF-κB-Luc, pRL-TK, empty vector, NS1, or increasing amounts (200, 400, and 600 ng) of ORFX expressing plasmid. After 24 h, the cells were mock treated or treated with TNF-α for 6 h, and luciferase activity was determined. ORFX protein obviously activated NF-κB, no matter whether the cells were treated with TNF-α or not (Fig. 6A), whereas IL-8 was upregulated only when the cells were treated with TNF-α (Fig. 6B). However, no significant difference was observed for IL-6 and IL-8 transcription levels between the rWIV1-ΔX- and rWIV1-infected Calu-3 cells (Fig. 6C and D). A significant difference was observed only for the induction of TNF-α mRNA at the late time of virus infection, when the ORFX deletion mutant induced less TNF-α mRNA (Fig. 6E).

DISCUSSION

In this study, we have developed a fast and cost-effective method for reverse genetics of coronaviruses by combining two approaches developed by others (29, 30). Our method allows the genomes of coronaviruses to be split into multiple fragments and inserted into a BAC plasmid with a single step. Recombinant viruses can then be efficiently rescued by direct transfection of the BAC constructs. As the genomes can be divided into multiple short fragments, mutations can be introduced into individual fragments easily (31). Using this method, we successfully rescued three recombinant viruses derived from SL-CoV WIV1 (rWIV1, rWIV1-ΔX, and rWIV1-GFP-ΔX). The recombinant rWIV1 and rWIV1-ΔX replicated to titers close to those of wtWIV1 in Vero

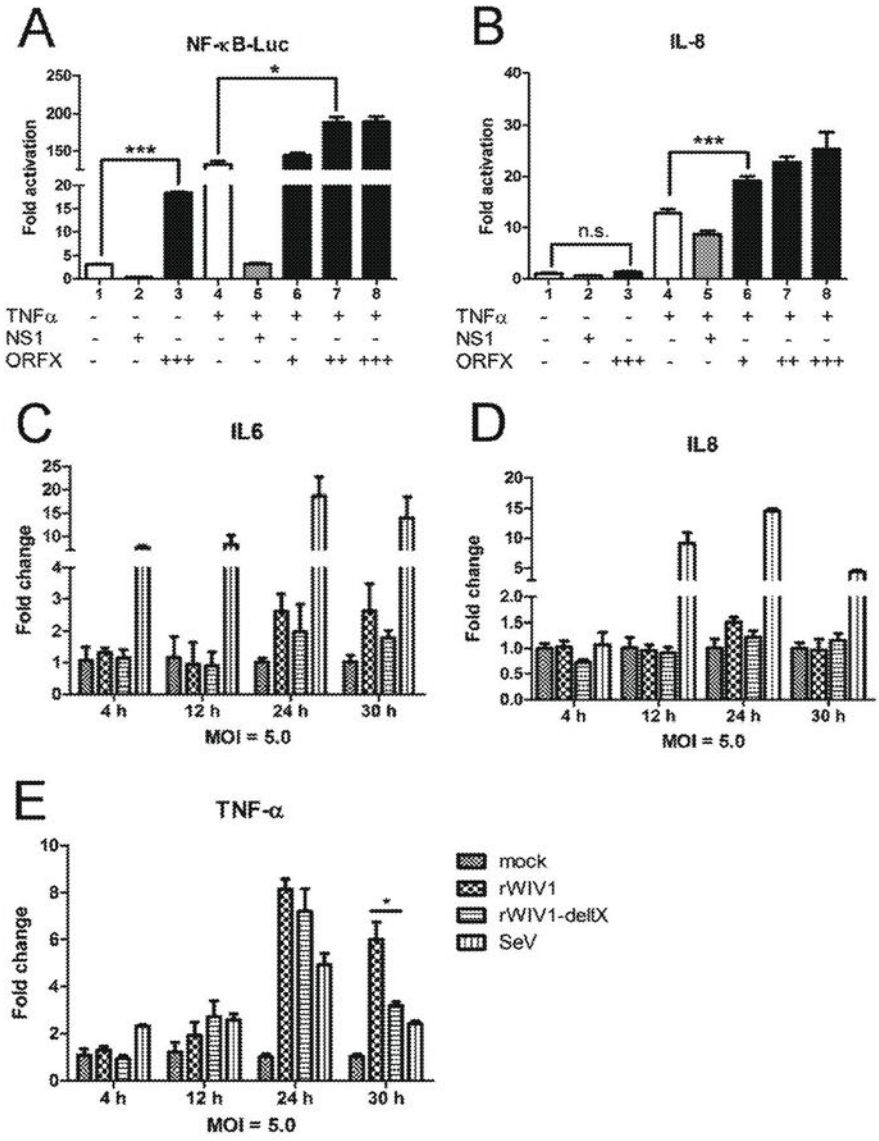

FIG 6 ORFX protein activates NF-κB. 293T cells were transfected with 100 ng pNF-κB-Luc, 10 ng pRL-TK, empty vector, an NS1-expressing plasmid, or increasing amounts (200, 400, and 600 ng) of an ORFX-expressing plasmid. After 24 h, the cells were treated with TNF-α. (A) Dual-luciferase activity was determined after 6 h. The results were expressed as the firefly luciferase activity normalized to that of *Renilla* luciferase. (B) The relative expression of IL-8 mRNA was quantified through quantitative RT-PCR and normalized to that of GAPDH mRNA. Differences between selected groups were significant, with *P* value less than 0.05, as follows: <0.0001 (***; bars 1 and 3 in panel A), 0.0339 (*; bars 4 and 7 in panel A), and 0.0002 (***; bars 4 and 6 in panel B). n.s., not significant. The experiments were performed three times. (C to E) The RNA extracted from Calu-3 cells for Fig. 4 was used for quantification of the expression of IL-6 (C), IL-8 (D), and TNF-α (E) mRNAs.

E6 cells (Fig. 2C), suggesting that the deletion of ORFX did not affect WIV1 replication *in vitro*. Northern blotting and fluorescence microscopy further confirmed that ORFX is transcribed as sgRNA7 and translated in virus-infected cells. These results demonstrated that the unique ORFX in SL-CoV WIV1 is a functional gene but is not essential for virus replication. We propose that the ORFX sgRNA is the template for the translation of a novel 11-kDa accessory protein of WIV1, bringing the total number of group-specific accessory proteins to ten.

In previous studies, it has been proved that SARS-CoV group-specific accessory genes ORF3b and ORF6 inhibit host IFN production and/or signaling during virus infection and contribute to viral pathogenesis (20). It is interesting to know whether the ORFX has a similar function in antagonizing IFN. In this study, ORFX protein showed an inhibitory effect on IFN production, but the effect decreased when more ORFX protein was expressed (Fig. 4A and B). Moreover, the ORFX deletion mutant had a significantly lower inhibitory effect on IFN production than wild-type recombinant virus in infected Calu-3 cells, but only at an early time after infection (Fig. 4F). Furthermore, the IFN sensitivity assay indicated that the ORFX deletion mutant was more sensitive to IFN-β (Fig. 4G), suggesting that ORFX protein may participate in subverting the antiviral state stimulated by IFN-β. All these results suggested that ORFX participates in the modulation of the IFN response. Previous studies showed that SARS-CoV ORF3a and ORF7a activate NF-κB and upregulate IL-8 and CCL5 pro-

duction (22, 23). In our study, we also found through a dual-luciferase assay that overexpressed ORFX can activate NF-κB (Fig. 6A). Furthermore, the level of TNF-α mRNA induced by wild-type recombinant virus was significantly higher than that induced by the ORFX deletion mutant, but only at the late stage of infection (Fig. 6E). These results indicated that ORFX also participates in activation of NF-κB. We noted that the IFN inhibition activity of ORFX was not dose dependent and decreased when there was more ORFX expression. One possible hypothesis is that ORFX inhibits IFN only at the early stage of infection. At the late stage, it activates NF-κB, which in turn stimulate IFN expression, and this leads to the attenuation of its IFN antagonist activity.

Coronavirus was previously shown to induce the unfolded-protein response (UPR) and ER stress in infected cell culture (32). Normally, ER is an active organelle for protein folding and modification. Loss of protein folding homeostasis would cause ER stress and induce the UPR, leading to the activation of three ER stress transducers. These transducers work in concert to attenuate translation and improve ER folding capacity to restore ER homeostasis (33). In this process, NF-κB is activated, and apoptosis will be induced if ER stress is prolonged (32, 33). In this study, we observed that the overexpression of ORFX protein led to cell death and the decrease of *Renilla* values (data not shown). This may imply that ORFX has a cytotoxic effect and an influence on overall protein translation. We also found that ORFX colocalizes with an ER marker. We hypothesize that ORFX may induce the UPR and cause ER stress which would activate NF-κB and induce apoptosis, promoting viral release at the late stage of infection.

It should be noted that the IFN and NF-κB detection systems used in this study were derived from and used in human cells. Since the innate immune system of bats is special and probably deficient in some aspects compared to the human system (34), it will be interesting to conduct the same studies in bat cells to determine whether ORFX protein has the same profiles as those observed in the human cell system. The development of different cell lines from the *Rhinolophus* bat, which is the reservoir host of SL-CoV, will facilitate this research in the future.

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From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 6/22/2021 12:00:15 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: FW: Question from the WSJ
Attachments: NIHLetter8July.pdf

Hi Renate, Amanda, and Emma – this in from WSJ. Happy to discuss.

Thanks, Mike

From: "Gordon, Michael" <michael.gordon@wsj.com>
Date: Tuesday, June 22, 2021 at 7:55 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Fwd: Question from the WSJ

Dr. Lauer,

I am a reporter for The Wall Street Journal and have a question for you. I would be happy to discuss this by phone or in person, including on a background not-for-attribution basis. I am looking for some guidance on a July 8, 2020 letter you wrote, which has been in the public domain for nearly a year. I am neither a proponent of the lab theory nor a supporter of the zoonotic hypothesis regarding the origins of Covid-19 in China. I am just trying to understand and present the facts as best I can.

In your July 8 letter you described some restrictions at the Wuhan Institute of Virology in 2019. Specifically, you wrote that there was "diminished cell-phone traffic in October 2019" at or near that facility. You also wrote that "there was evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019."

My WSJ colleague, Betsy McKay, wrote in August about this letter, which was addressed to the EcoHealth Alliance. (https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400). It has also been distributed on Capitol Hill.

My questions are as follows. Do you or NIH still stand by the statement that there was diminished cell traffic in and around the WIV in October 2019? What was the source of that information and is it a source in which NIH has confidence? The letter suggests that it is a fact that there was diminished cell phone traffic. To your understanding, is it a fact or merely a possibility? Have you and NIH changed that position based on more recent information? Did EcoHealth Alliance ever provide any information regarding your questions? What about the roadblocks? Is there any similar information on that? I have attached a copy of the letter to this email.

Again, we can talk on a background, not-for-attribution basis if you wish. I am trying to better understand a complicated situation and fully understand that new information may have arisen over the past year and that some prior impressions may have been discomfirmed. I also want to be sure that I am interpreting your letter correctly, and it has been interpreted as stating for a fact that there was disminished cell phone traffic. So I would like to be sure that this is what you intended. I am trying to be very careful about all this. Thanks for your attention, and I would be happy to answer any questions on this request.

Michael Gordon
National Security Correspondent
The Wall Street Journal
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
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CC: Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; OER Press Group [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0373283dff404a969ea109f86919dc9b-OER Press G]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Question from the WSJ
Attachments: NIHLetter8July.pdf

Thanks Renate – looks great!

Mike

From: "Myles, Renate (NIH/OD) [E]" (b) (6)
Date: Tuesday, June 22, 2021 at 1:04 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: "Fine, Amanda (NIH/OD) [E]" (b) (6) "Wojtowicz, Emma (NIH/OD) [E]" (b) (6), OER Press Group <OERPressGroup@mail.nih.gov>
Subject: FW: Question from the WSJ

Hi Mike:

Thanks for jumping on a call with us. Here's a proposed response based on our discussion.

(b) (5)

Thanks,
Renate

From: "Gordon, Michael" <michael.gordon@wsj.com>
Date: Tuesday, June 22, 2021 at 7:55 AM
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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8 July 2020

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Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 6/22/2021 2:45:11 PM
To: Bulls, Michelle G. (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b366f1a4382d44c1bde626e7730c3dd4-bullsmg]; Ta, Kristin (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=72dc8e6c4cae4efcaa9e72eabbff2ee3-takr]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
Subject: FYI … grant support
Attachments: EcoHealth RePORTER 6 22 21.pdf

Hi Michelle and Kristin – see attached.

Happy to discuss

Many thanks, Mike

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Results are sorted by Relevance

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- Principal Investigators

T	Act	Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
Understanding Risk of Zoonotic Virus Emergence in EID Hotspots of Southeast Asia											
5	U01	AI151797-02			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2021	NIAID	NIAID	$1,505,568	View
Study of Nipah virus dynamics and genetics in its bat reservoir and of human exposure to NiV across Bangladesh to understand patterns of human outbreaks											
1	U01	AI153420-01			EPSTEIN, JONATHAN H	ECOHEALTH ALLIANCE, INC.	2020	NIAID	NIAID	$530,858	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-Ghana											
3	U01	TW010103-05S1			FOBIL, JULIUS N. ROBINS, THOMAS G	UNIVERSITY OF GHANA	2020	FIC	FIC	$199,975	View
Understanding Risk of Zoonotic Virus Emergence in EID Hotspots of Southeast Asia											
1	U01	AI151797-01			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2020	NIAID	NIAID	$1,546,744	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-USA											
5	U2R	TW010110-05			ROBINS, THOMAS G FOBIL, JULIUS N.	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2019	FIC	FIC NIEHS	$176,915 $89,698	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-Ghana											
5	U01	TW010103-05			FOBIL, JULIUS N. ROBINS, THOMAS G	UNIVERSITY OF GHANA	2019	FIC	FIC NIEHS	$54,990 $58,396	View
Understanding the Risk of Bat Coronavirus Emergence											
2	R01	AI110964-06			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2019	NIAID	NIAID	$661,980	View
Translational Core											
5	U19	AI109761-05	8490		KARESH, WILLIAM BAMBERGER	COLUMBIA UNIVERSITY HEALTH SCIENCES	2018	NIAID		*$805,675*	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-USA											
5	U2R	TW010110-04			ROBINS, THOMAS G FOBIL, JULIUS N.	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2018	FIC	FIC NIEHS	$106,262 $93,058	View
Understanding the Risk of Bat Coronavirus Emergence											
5	R01	AI110964-05			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2018	NIAID	NIAID	$581,646	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-Ghana											
5	U01	TW010103-04			FOBIL, JULIUS N. ROBINS, THOMAS G	UNIVERSITY OF GHANA	2018	FIC	FIC NIEHS	$99,756 $80,924	View
Translational Core											
5	U19	AI109761-04	8490		KARESH, WILLIAM BAMBERGER	COLUMBIA UNIVERSITY HEALTH SCIENCES	2017	NIAID		*$812,305*	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-USA											
5	U2R	TW010110-03			ROBINS, THOMAS G FOBIL, JULIUS N.	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2017	FIC	FIC NIEHS	$179,799 $109,245	View
Understanding the Risk of Bat Coronavirus Emergence											
5	R01	AI110964-04			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2017	NIAID	NIAID	$597,112	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-Ghana											
5	U01	TW010103-03			FOBIL, JULIUS N. ROBINS, THOMAS G	UNIVERSITY OF GHANA	2017	FIC	FIC NIEHS	$32,188 $58,766	View
Translational Core											
5	U19	AI109761-03	8490		KARESH, WILLIAM BAMBERGER	COLUMBIA UNIVERSITY HEALTH SCIENCES	2016	NIAID		*$866,074*	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-USA											
5	U2R	TW010110-02			ROBINS, THOMAS G FOBIL, JULIUS N.	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2016	FIC	FIC NIEHS	$190,371 $96,519	View
Understanding the Risk of Bat Coronavirus Emergence											
5	R01	AI110964-03			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2016	NIAID	NIAID	$611,090	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-Ghana											
5	U01	TW010103-02			FOBIL, JULIUS N. ROBINS, THOMAS G	UNIVERSITY OF GHANA	2016	FIC	FIC NIEHS	$41,952 $51,159	View
Translational Core											
5	U19	AI109761-02	8490		KARESH, WILLIAM BAMBERGER	COLUMBIA UNIVERSITY HEALTH SCIENCES	2015	NIAID		*$899,197*	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-USA											
1	U2R	TW010110-01			ROBINS, THOMAS G FOBIL, JULIUS N.	UNIVERSITY OF MICHIGAN AT ANN ARBOR	2015	FIC	FIC NIEHS	$195,542 $99,141	View
Understanding the Risk of Bat Coronavirus Emergence											
5	R01	AI110964-02			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2015	NIAID	NIAID	$630,445	View
1/2-The West Africa-Michigan CHARTER II for GEOHealth-Ghana											
1	U01	TW010103-01			FOBIL, JULIUS N. ROBINS, THOMAS G	UNIVERSITY OF GHANA	2015	FIC	FIC NIEHS	$37,133 $48,185	View
Translational Core											
1	U19	AI109761-01	8490		KARESH, WILLIAM BAMBERGER	COLUMBIA UNIVERSITY HEALTH SCIENCES	2014	NIAID		*$826,333*	View
Modeling Anthropogenic Effects in the Spread of Infectious Diseases											
5	R01	GM100471-04			PERRINGS, CHARLES	ARIZONA STATE UNIVERSITY-TEMPE CAMPUS	2014	NIGMS	NIGMS	$384,633	View
Understanding the Risk of Bat Coronavirus Emergence											
1	R01	AI110964-01			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2014	NIAID	NIAID	$666,442	View
Modeling Anthropogenic Effects in the Spread of Infectious Diseases											
5	R01	GM100471-03			PERRINGS, CHARLES	ARIZONA STATE UNIVERSITY-TEMPE CAMPUS	2013	NIGMS	NIGMS	$375,772	View
Comparative Spillover Dynamics of Avian Influenza in Endemic Countries											
1	R56	TW009502-01			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2012	FIC	FIC	$300,000	View
Modeling Anthropogenic Effects in the Spread of Infectious Diseases											
5	R01	GM100471-02			PERRINGS, CHARLES	ARIZONA STATE UNIVERSITY-TEMPE CAMPUS	2012	NIGMS	NIGMS	$398,953	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
3	R01	TW005869-08S2			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2012	FIC	FIC	$6,982	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
5	R01	TW005869-09			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2012	FIC	FIC	$494,455	View
Risk of Viral Emergence from Bats											
5	R01	AI079231-05			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2012	NIAID	NIAID	$518,980	View
Modeling Anthropogenic Effects in the Spread of Infectious Diseases											
1	R01	GM100471-01			PERRINGS, CHARLES	ARIZONA STATE UNIVERSITY-TEMPE CAMPUS	2011	NIGMS	NIGMS	$381,544	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
5	R01	TW005869-08			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2011	FIC	FIC	$494,455	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
3	R01	TW005869-08S1			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2011	FIC	FIC	$266,919	View
Risk of Viral Emergence from Bats											
5	R01	AI079231-04			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2011	NIAID	NIAID	$510,005	View
Risk for Future Outbreaks of Henipaviruses in South Asia											
5	K08	AI067549-04			EPSTEIN, JONATHAN H	ECOHEALTH ALLIANCE, INC.	2010	NIAID	NIAID	$130,950	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
3	R01	TW005869-07S1			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2010	FIC	FIC	$63,018	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
5	R01	TW005869-07			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2010	FIC	FIC	$499,998	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
3	R01	TW005869-07S2			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2010	FIC	FIC	$199,992	View
Risk of Viral Emergence from Bats											
5	R01	AI079231-03			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2010	NIAID	NIAID	$480,423	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
5	R01	TW005869-06			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2009	FIC	FIC	$499,975	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
3	R01	TW005869-06S4			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2009	FIC	FIC	$46,399	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
3	R01	TW005869-06S1			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2009	FIC	FIC	$204,688	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
3	R01	TW005869-06S3			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2009	FIC	FIC	$199,698	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
3	R01	TW005869-06S2			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2009	FIC	FIC	$51,225	View
Risk for Future Outbreaks of Henipaviruses in South Asia											
5	K08	AI067549-03			EPSTEIN, JONATHAN H	ECOHEALTH ALLIANCE, INC.	2009	NIAID	NIAID	$130,950	View
Risk for Future Outbreaks of Henipaviruses in South Asia											
3	K08	AI067549-03S1			EPSTEIN, JONATHAN H	ECOHEALTH ALLIANCE, INC.	2009	NIAID	NIAID	$49,994	View
Risk of Viral Emergence from Bats											
5	R01	AI079231-02			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2009	NIAID	NIAID	$535,156	View
The Ecology, Emergence and Pandemic Potential of Nipah virus in Bangladesh											
2	R01	TW005869-05			DASZAK, PETER	ECOHEALTH ALLIANCE, INC.	2008	FIC	FIC	$568,956	View

From: Bundesen, Liza (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CDED900576A49AEA461D26E93BDDAC3-LBUNDESE]
Sent: 6/29/2021 9:27:38 PM
To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]; Simanich, Sasha (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62114870dc66475a8c0ce0047413ed92-simanichs2]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Stein, Meredith (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3324d143a8c4975b4f1d405d1a54d14-steinme]; Brown, Tiffany (NIH/OD/OMA) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14def436a4f74669a6c9fdc45f3b0f0f-brownty1]
Subject: RE: OIG EcoHealth

I agree—thank you!

From: Jacobs, Anna (NIH/OD) [E] (b) (6)
Sent: Tuesday, June 29, 2021 5:22 PM
To: Simanich, Sasha (NIH/OD) [E] (b) (6); Bundesen, Liza (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6); Brown, Tiffany (NIH/OD/OMA) [E] (b) (6)
Subject: Re: OIG EcoHealth

I think that is a fantastic idea. Thank you, Sasha!

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm.2B-50
Bethesda, MD 20892
(b) (6) (main)
301-402-1034 (fax)
(b) (6)

From: Simanich, Sasha (NIH/OD) [E] (b) (6)
Sent: Tuesday, June 29, 2021 5:08:53 PM
To: Jacobs, Anna (NIH/OD) [E] (b) (6); Bundesen, Liza (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6); Brown, Tiffany (NIH/OD/OMA) [E] (b) (6)
Subject: RE: OIG EcoHealth

Hi Anna and Liza,

We would recommend the following:

- For OGC's review, internal deadline by **July 13**
- For OIG's final delivery, first batch, external deadline by **July 16**

We would also recommend implementing a cutoff date for data uploads into Box prior to OGC's review. Additionally, we recommend creating separate folders in Box for each data call.

For example:

- OIG audit of EcoHealth Alliance (Parent Folder)
    - Create new sub-folder, e.g., "Entrance Conference Data Request"
        - Create new sub-folder, e.g., "First Batch"
        - Create new sub-folder, e.g., "Second Batch" and start uploading new data after first batch cutoff date

We can continue leveraging this folder method for all new requests as they come in. After we establish a cutoff date for each data call, we would have OGC review and approve prior to us sharing the folder with OIG. That's one way to limit controls while we're in the process of collecting and reviewing data without inadvertently allowing OIG access. Let us know if you're comfortable with this approach or if you have alternative options. We're flexible and here to support you.

Many thanks,
Sasha

From: Jacobs, Anna (NIH/OD) [E] (b) (6)
Sent: Tuesday, June 29, 2021 3:59 PM
To: Bundesen, Liza (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6); Simanich, Sasha (NIH/OD) [E] (b) (6); Brown, Tiffany (NIH/OD/OMA) [E] (b) (6)
Subject: RE: OIG EcoHealth

Thanks, Liza!

On the two items flagged as needing documents from NIAID and your question to me — my colleague, Lena Yueh, is going to speak with the NIH FOIA Office tomorrow at 2pm, and she will ask them whether the documents pulled for the FOIA productions would contain these documents requested by OIG:

(b) (5)

(She will also ask them whether they have anything responsive to question 6a of the GAO questions: (b) (5)

(b) (5)

If that is the case, I will let you know (hopefully tomorrow).

On the review of documents in Box, because there are 3 or 4 attorneys who will be reviewing the documents, I'm not sure if creating a "Reviewed by OGC" folder will help. I may get a better sense as we go through the documents, but for now, don't worry about that.

Sasha, can you remind me of the deadline for OGC's review of the first batch?

Thanks,

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm.2B-50
Bethesda, MD 20892
(b) (6) *(phone)*
301-402-1034 (fax)
(b) (6)

From: Bundesen, Liza (NIH/OD) [E] (b) (6)
Sent: Tuesday, June 29, 2021 2:43 PM
To: Lauer, Michael (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6); Simanich, Sasha (NIH/OD) [E] (b) (6); Brown, Tiffany (NIH/OD/OMA) [E] (b) (6); Jacobs, Anna (NIH/OD) [E] (b) (6)
Subject: OIG EcoHealth

Hi Everyone,

Thank you for the helpful call today. Attached are draft responses to OIG's questions. I've flagged things that we need in comment bubbles.

In addition to the FOIA and OLPA requests, we will need NIAID to address the following questions (Anna, I think you were going to take a look at what may have already been collected?):

(b) (5)

I've given all of you access to Box, as well as Tamra Clark, David Lankford, and Lena Yueh.

I've been tinkering with Box Help, and I'm not seeing a feature that will help us flag that a document has been reviewed by OGC. Perhaps we could just create a folder that says "Reviewed by OGC" and move other folders in there when complete? I welcome other ideas.

Liza

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 6/22/2021 7:51:56 PM
To: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Draft documents
Attachments: EcoHealth Alliance grant R01AI110964 timeline 6 13 21.docx; Lauer NIH Oversight of Grantee-Subgrantee Entrance Conference Agenda...6.21.21.docx; April 19 2020 EcoHealth Alliance re AI grant 4 19 20.pdf; April 24 2020 Daszak letter 4 24 20.pdf; July 8 2020 Daszak 7 8 20.pdf; October 23 2020 NIH Response to EcoHealth Response to Suspension_10_23_20.pdf; April 11 2021 Daszak Response to NIH April 2021 re. reactivation and suspension of 2R01AI110964.pdf; April 13 2021 To Daszak 4 13 21.pdf; May 16, 2021 EcoHealth analysis - table and outstanding NIH asks jsrev- MGB final.docx

Hi Liza – here's a draft plus the timeline. I'm also attaching some of the most critical documents. I also added you to a Box Folder with the EcoHealth documents we received on April 25, 2021.

Thanks, Mike

EcoHealth Alliance grant R01AI110964 timeline
Mike Lauer (OER)
June 13, 2021

- June 5, 2013: Type 1 proposal submitted
- December 18, 2013: Reviewed, PS 20, percentile 8
- May 27, 2014: Type 1 awarded
    - Proposals and RPPRs in separate folder
    - NOAs in separate folder
- July 7, 2016: Letter from NIAID with determination that this is not "Gain-of-Function" research
- January 19, 2018: State Department Cables re WIV
- November 5, 2018: Type 2 submitted
- February 14, 2019: Type 2 reviewed, PS 20, percentile 3
- July 24, 2019: Type 2 awarded
- April 14, 2020: Larry Tabak ("LT") loops in Mike Lauer ("ML") on email string regarding Animal Rights and Congressional complaints
- April 19, 2020: ML sends letter to EcoHealth suspending WIV subaward
- April 20, 2020: Joshua Rogin Op-Ed in Washington Post about State Department cables
- April 22, 2020: ML send LT detailed information about EcoHealth and WIV
- April 24, 2020: ML sends letter to EcoHealth terminating entire grant (appealable under 42 CFR 50, subpart D)
- May 6, 2020: ML sends detailed information about EcoHealth and WIV to OIG OI / ONS
- May 21, 2020: Protest letter from 77 Nobel laureates
- May 22, 2020: Letter from Krinsky (attorney) to ML appealing termination
- July 8, 2020: Letter from ML to EcoHealth – grant reinstated but suspended (not appealable under 42 CFR 50, subpart D); request information and answers to questions; note failure to submit required reports to Federal Subaward Reporting System
- August 13, 2020: Letter from Krinsky (attorney) to ML objecting to suspension
- October 23, 2020: Letter from ML to EcoHealth rebutting Krinsky and requesting additional documents
- February 16, 2021: News story about WIV receiving OLAW assurance
- March 4, 2021: Daszak send email to ML requesting phone call; ML speaks with NIAID DEA; ML re-sends two prior letters (July 8, 2020 and October 23, 2020) to Daszak on March 10, 2021
- March 18, 2021: CMR letter (one of many Congressional queries)
- April 11, 2021: Daszak response to ML; no documents
- April 13, 2021: ML again asks Daszak for documents
- April 23, 2021: Daszak submits some documents to ML, being reviewed by OPERA and OGC
- May 16, 2021: OPERA analyses complete, multiple deficiencies
- May 26, 2021: DDER, OPERA, and OGC meeting: suggest OIG audit of EcoHealth
- June 11, 2021: OIG notifies NIH of planned audit of NIH and EcoHealth

Audit of National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees
CIN: A-05-21-00025

(b) (5)

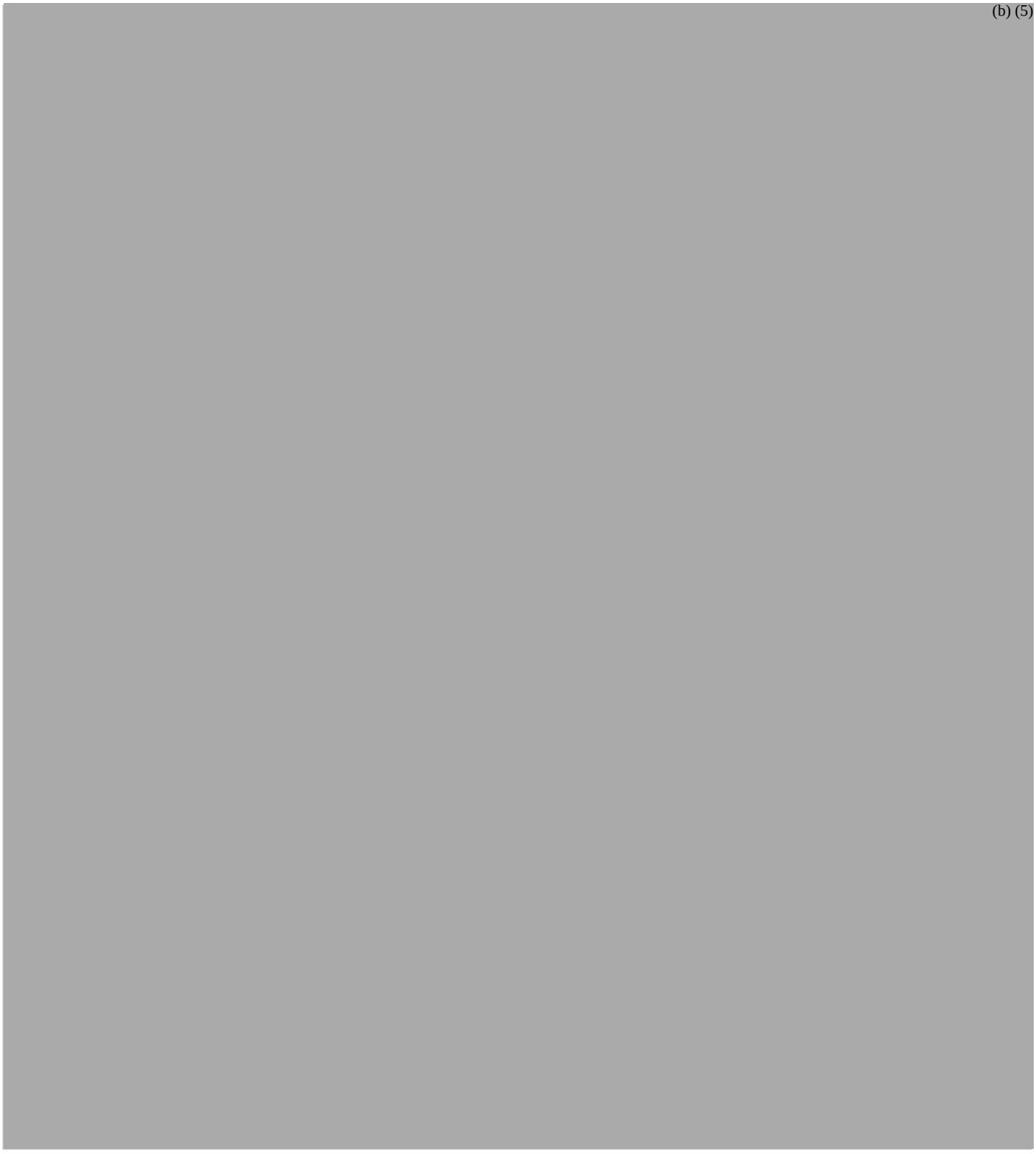
- Select and review various types of costs claimed by EcoHealth Alliance, including those for payments made to subrecipients.

Questions & Discussion Topics

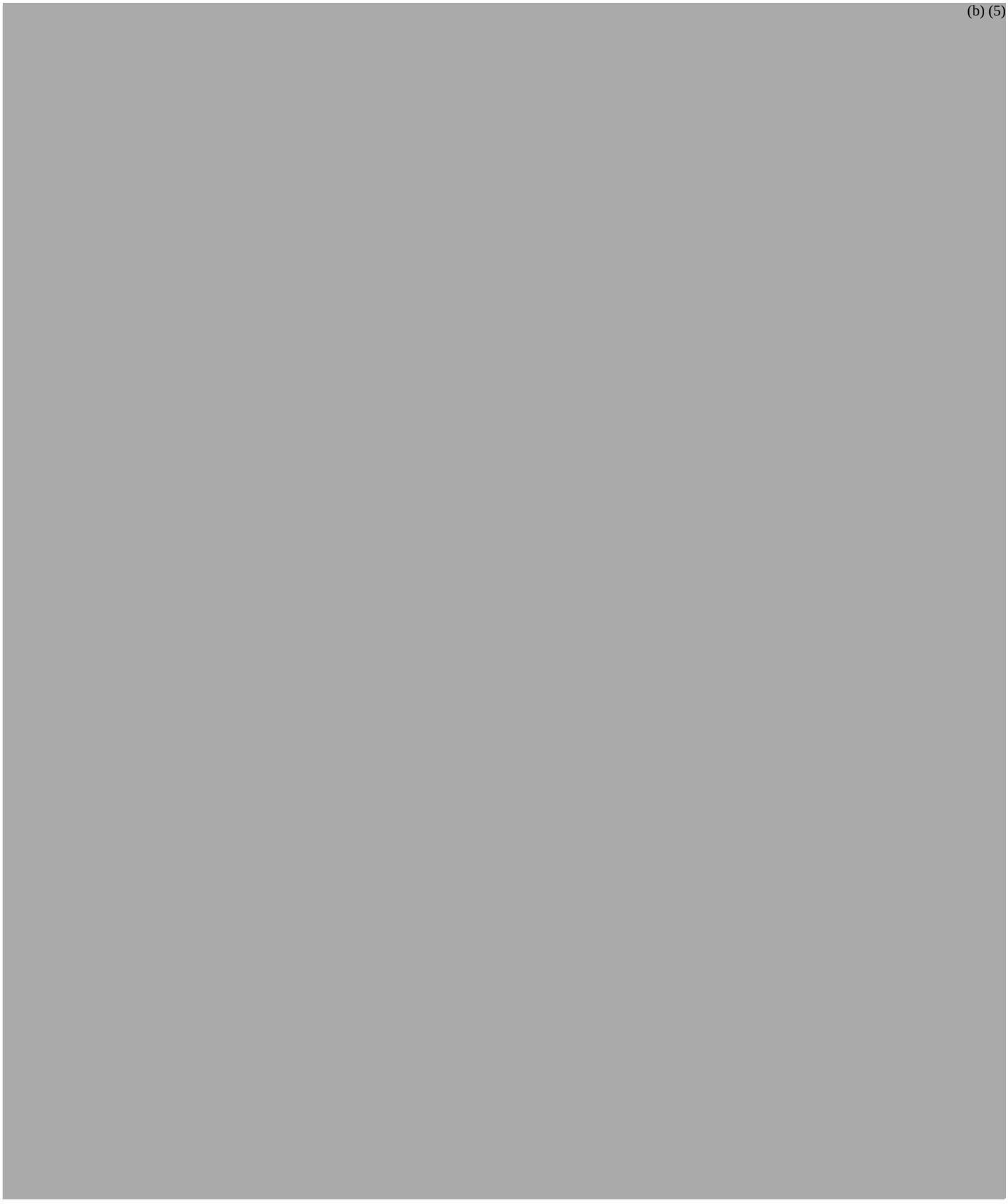
(b) (5)

[redacted]

(b) (5)



(b) (5)



(b) (5)

Date: April 19, 2020

From: Michael S Lauer, MD
NIH Deputy Director for Extramural Research

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E] Date: 2020.04.19 10:47:40 -04'00'

To: Kevin Olival, PhD
Vice-President for Research
EcoHealth Alliance
(b) (6)

Naomi Schrag, JD
Vice-President for Research Compliance, Training, and Policy
Columbia University
(b) (6)

Subject: Project Number 2R01AI110964-06

Dear Dr. Olival and Ms. Schrag:

EcoHealth Alliance, Inc. is the recipient, as grantee, of an NIH grant entitled "Understanding the Risk of Bat Coronavirus Emergence." It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ("WIV"). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs.

While we review these allegations during the period of suspension, you are instructed to cease providing any funds from the above noted grant to the WIV. This temporary action is authorized by 45 C.F.R. § 75.371(d) ("Initiate suspension or debarment proceedings as authorized under 2 C.F.R. part 180"). The incorporated OMB provision provides that the funding agency may, through suspension, immediately and temporarily exclude from Federal programs persons who are not presently responsible where "immediate action is necessary to protect the public interest." 2 C.F.R. § 180.700(c). It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

24 April 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: Termination of NIH Grant R01 AI 110964

Dear Drs. Chmura and Daszak:

I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS) has elected to terminate the project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant R01 AI110964, for convenience. This grant project was issued under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284). This grant was funded as a discretionary grant as outlined in the NIH Grants Policy Statement, which states that the decision not to award a grant, or to award a grant at a particular funding level, is at the discretion of the agency, in accordance with NIH's dual review system.

At this time, NIH does not believe that the current project outcomes align with the program goals and agency priorities. NIAID has determined there are no animal and human ethical considerations, as this project is not a clinical trial, but rather an observational study.

As a result of this termination, a total of $369,819.56 will be remitted to NIAID and additional drawdowns will not be supported. The remaining funds have been restricted in the HHS Payment Management System, effective immediately.

Please let me know if you have any questions concerning the information in this letter.

Sincerely,

Lauer, Michael (NIH/OD) [E] Digitally signed by Lauer, Michael (NIH/OD) [E]
Date: 2020.04.24 16:41:16 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

23 October 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

I am following up on Mr. Krinsky's August 13, 2020, letter on behalf of EcoHealth Alliance, Inc. ("EcoHealth") responding to NIH's suspension of grant R01AI110964, which funds the project *Understanding the Risk of Bat Coronavirus Emergence* (the "Project"). Per my letter of July 8, 2020, NIH reinstated the grant but suspended all award activities because we have concerns that the Wuhan Institute of Virology (WIV), which previously served as a subrecipient of the Project, had not satisfied safety requirements that applied to its subawards with EcoHealth, and that EcoHealth had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. EcoHealth objected to the suspension on the grounds that WIV has no *current* connection to the Project or EcoHealth's research, and EcoHealth had not issued any subawards in connection with the Grant *at the time of the suspension*.

The fact that EcoHealth does not currently have a subrecipient relationship with WIV and had not issued subawards to WIV at the time of suspension does not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964. While EcoHealth did not issue a subaward to WIV for year 6 of the grant, WIV served as a subrecipient for years 1 through 5. NIH awarded EcoHealth grant R01AI110964 in 2014, with a project period of June 1, 2014, through June 30, 2024, as renewed. In EcoHealth's grant application, EcoHealth listed Drs. Zheng Li Shi and Xing Yi Ge of WIV as co-investigators and senior/key personnel. It stated that "Drs. Shi, Zhang, and Daszak have collaborated together since 2002 and have been involved in running joint conferences, and shipping samples into and out of China." EcoHealth listed WIV as a Project/Performance Site Location. In describing WIV's facilities, EcoHealth described WIV as China's premier institute for virological research" and touted WIV's "fully equipped biosafety level 3 laboratory" and "a newly opened BLS-4 laboratory." In support of the application, Dr. Zheng Li Shi's personal statement indicated that "My lab will be responsible for diagnosis, genomics and isolation of coronavirus from wild and domestic animals in Southern China and for analyzing their receptor binding domains." The application stated that "Wuhan Institute of Virology and the Wuhan University Center for Animal Experiment BSL-3

lab have an Internal Biosafety Committee and are accredited BSL-2 and BSL 3 laboratories. All experimental work using infectious material will be conducted under appropriate biosafety standards. Disposal of hazardous materials will be conducted according to the institutional biosafety regulations."

EcoHealth requested funding specifically for activities to be carried out by WIV. NIH awarded EcoHealth a total of $749,976 for WIV's work in the following annual amounts for years 1 through 5:

	-Yr 1	-Yr 2	-Yr 3	-Yr 4	-Yr 5
Total Direct Costs	$123,699	$128,718	$147,335	$147,335	$147,335
F&A Costs @ 8%	$9,896	$10,297	$11,787	$11,787	$11,787
TOTAL COSTS	$133,595	$139,015	$159,122	$159,122	$159,122

As stated in the Notices of Award for each budget period of the grant, the awards were subject to terms and conditions, which include the NIH Grants Policy Statement (GPS) and applicable HHS grant regulations. As I indicated in my letter of July 8, 2020, as a term and condition of award EcoHealth was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). See also, 45 C.F.R. § 75.342(a) ("The non-Federal entity is responsible for oversight of the operations of the Federal award supported activities."). Moreover, EcoHealth was required to "Establish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award[.]" 45 C.F.R. § 75.303(a). The Notice of Award stated that as a term and condition of award, "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]." Moreover, the NIH GPS provides that NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients, so these terms applied to WIV. 45 C.F.R. § 75.101.

As I stated, NIH has concerns of non-compliance with terms and conditions of award—namely, that WIV had not satisfied safety requirements under the award and that EcoHealth Alliance had not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance. Accordingly, NIH suspended all activities related to R01AI110964, pursuant to 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare.

In my letter of July 8, 2020, I provided EcoHealth with the opportunity to object and to provide information and documentation challenging the suspension. Specifically, I sought information and materials that speak to WIV's lab safety and EcoHealth's oversight of its subrecipient, and an inspection of WIV's laboratory records and facilities. I indicated that as a specific condition of award, during the period of suspension, EcoHealth Alliance may not allow research under this

project to be conducted and that no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients.

EcoHealth objected to the requests on the grounds that "NIAID is not authorized under 45 CFR§§ 75.371, 75.205, and 75.207, entitled *Specific Award Conditions*, to impose, *inter alia*, conditions that consist of demands for information regarding entities that are neither subrecipients of grant funds nor project affiliates."

These provisions are irrelevant to NIH's requests. NIH is required to permit the opportunity for recipients to object and provide information and documentation challenging a suspension, 45 C.F.R. § 75.374, so we specifically gave EcoHealth the opportunity to provide information that speaks to NIH's concerns. Moreover, as a granting agency, NIH is required to "manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare [and] the environment[.]" 45 C.F.R. § 75.300(a). In addition to seeking information that speaks to compliance with terms and conditions of award, NIH is entitled to "make site visits as warranted by program needs." 45 C.F.R. § 75.342. As a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit specified in my letter of July 8, 2020.

In addition to objecting to NIH's authority to seek the materials, information, and a site visit, EcoHealth has responded that it lacks knowledge or information regarding the requests; that it is not in possession, custody, or control of the specified items; and that it has no authority to grant NIAID and the U.S. National Academy of Sciences access to WIV's facility to conduct an inspection. EcoHealth's responses have not satisfied NIH's concerns that EcoHealth had failed to adequately monitor the compliance of its subrecipient, and that the subrecipient, WIV, had failed to comply with safety requirements.

Notwithstanding this, NIH is providing an additional opportunity for EcoHealth to provide information and documentation challenging these concerns of non-compliance. Accordingly, in addition to reiterating our prior requests (1) through (6) per our letter of July 8, 2020, NIH requests the following information and materials, which must be complete and accurate:

1. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.
2. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.
3. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

During the ongoing period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further assess whether EcoHealth Alliance and WIV complied with the terms and conditions of award, including compliance with other terms and conditions of award that may be implicated. We remind you that during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the continued suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 C.F.R. Part 75, including, but not limited to, terminating the grant award or disallowing costs. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.10.23 13:34:25 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy (NIAID)
Ms. Emily Linde (NIAID)

EcoHealth Alliance

Dr. Michael Lauer
Deputy Director for Extramural Research,
NIH, Bethesda, MD.

Response to the Reinstatement and immediate suspension of 2R01AI110964 "Understanding the Risk of Bat Coronavirus Emergence"

April 11th 2021

Dear Dr. Lauer,

I am responding your letters of 7/8/2020 and 10/3/2020 regarding the reinstatement and immediate suspension of NIH grant 2R01AI110964 "*Understanding the Risk of Bat Coronavirus Emergence*", that was terminated "for convenience" on 4/24/2020. In particular, this letter addresses the conditions you state would need to be fulfilled in order for us to have access to the funds to continue this work.

As you know, we had not set up any subcontracts to the Wuhan Institute of Virology under this renewal R01. Immediately following NIH's letter on 4/19/2020 that the WIV was being 'investigated', we suspended all plans for contractual work with WIV. This termination of a funded relationship with the institute makes it extraordinarily difficult and more likely impossible to provide the information requested about an autonomous foreign organization – as would also be the case for a domestic one - that our organization neither works with currently, nor has control over.

Additionally, our collaborative work with the Wuhan Institute of Virology prior to your grant termination letter of 4/24/2020 and that planned in the suspended grant, is wholly unrelated to many of the conditions listed below. These conditions also pertain to certain events and situations that in no way involve EcoHealth Alliance or are not under our control. Thus, most of the conditions below are either unrelated to EcoHealth Alliance's planned research in our highly rated, approved and funded grant application, and/or to the biosafety of our continued research funded by the suspended grant when it is reinstated in full.

Furthermore, in our recent correspondence with NIH regarding the latest in a series of FoIA requests, we were informed (1/26/2021 – see email correspondence at the end of this letter) by an NIH staff member Garcia-Malene Gorka that "any indication from my program that there is an ongoing investigation into WIV can now be disregarded, as we recently confirmed there are no pending investigations into that organization." Because this was the explanation in your initial letter of 4/19/2020 for the decisions from your office regarding restrictions on, termination of, then reinstatement and suspension of our grant, we believe that these decisions should now be reassessed.

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018
212.380.4460
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Despite our concerns about the relevance, fairness, or ability to fulfil the conditions as set forth in detail below, I have made extensive efforts to satisfy NIH's broad concerns, and have provided details of how these are relevant to each condition below. This includes serving as an expert on the WHO-China joint Mission on the Animal Origins of COVID-19, which involved 1 month on the ground in China (including 2 weeks locked in quarantine), at great personal burden and risk to me, to our organization, and to my family. I undertook this mission at a time when I have had increasing levels of personal attack and harassment, including a white-powder letter to my home address a few weeks after the details of our grant termination went public, and death threats that begun at the same time and continue to this day. It is clear in the wording of these attacks that many are a direct result of dangerous conspiracy theories inadvertently amplified by NIH's grant termination, and repeated in the conditions listed below. This type of harassment has accelerated to the point that personal security guards are now stationed at my home address, where I have also had to install invasive equipment and set up procedures to protect my family against expected violent attacks. Additionally, I now meet regularly with FBI agents and others at my home to monitor these threats. As I am sure you appreciate, this has a significant toll on my work, my personal life and my family.

Below, I detail our response to each of the conditions placed on our suspended grant, in an effort to provide as much information as possible and to explain the limitations on what we can do to respond. I look forward to your reply and hope that these will allow NIH to lift the suspension on funding so that we can continue our work to help protect our nation, indeed the global population, against future coronavirus pandemics. Should you wish, I feel certain we may discuss these points without legal counsel in a scientist-to-scientist conversation, as you have suggested verbally to others at NIH, and they have conveyed to me.

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
We believe this condition is effectively impossible for us to fulfil, for the following reasons. Firstly, there is no scientific nor administrative rationale for us to attempt to obtain a SARS-CoV-2 aliquot given that it is not part of our funded collaboration with WIV. Secondly, EcoHealth Alliance scientists do not have any capacity to work on such an aliquot (EHA does not conduct virological laboratory work on SARS-CoV-2) in the USA. This further reduces the validity of a scientific basis for this request to WIV. Thirdly, EcoHealth Alliance scientists were not part of the work that WIV conducted to determine the viral sequence of SARS-CoV-2, and this was not part of our (then active) R01 funded collaboration. This is publicly stated by the lack of EHA authors listed on the paper and the lack of acknowledgement of our grant as a funding source for this work. This publicly discounts any claim of sample ownership or control. Fourthly, the collaborative research laid out in our now-suspended grant does not include the shipping of human viral isolates out of China. Finally, during the last 16 months, there has been a series of vitriolic attacks from the US Government accusing China of bioengineering and releasing SARS-CoV-2 or of otherwise allowing COVID to become pandemic. Given these attacks, and WIV's status as a government entity, it seems to us incredulous that any request, particularly without scientific rationale, from a US non-profit to a Chinese Government laboratory for an active sample of a pathogenic human virus would likely be successful. We note that 1) to our knowledge China has not supplied such an aliquot to any formal request from a government; and 2) that if circumstances were reversed and a Chinese non-

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governmental institution requested a similar pathogenic viral aliquot from a US government BSL-4 laboratory, this would also be unlikely to be fulfilled.

While we understand that it may be of scientific interest to some US-based researchers to analyze this viral sequence, this scientific interest could easily be satisfied without the need for an aliquot. The full genome of this viral sequence was uploaded to a freely accessible database on January 10 2020, and has been used widely by scientists in the USA (included those funded by NIH) and around the world in their work. Furthermore, isolates of the virus from patients in Thailand and Australia during early 2020 are essentially the same, and have been shared extensively.

2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.

International experts on the WHO COVID-19 origins mission, including myself, asked direct questions on this issue to staff at WIV, including the Director of the institute, the P4 Lab Director, Dr. Shi and others. The response from all was consistent, as stated in the WHO mission report published 3/30/2020: "This person according the WIV staff was an alumnus who graduated in 2015 and was now working in a different province and did not accept to talk with media. The person had been contacted and tested and ascertained to be healthy."

Given that the WHO team was not given access to this individual, and that China's personal privacy laws are preclude our ability to insist on a meeting, it is difficult to see how a request from a US non-profit would have been approved. It seems at the least to be significantly outside the remit of a US-based non-profit organization to inquire further about the whereabouts of a citizen of a foreign country who has never to our knowledge been involved in our work, and over whom we have no control, influence, nor legal responsibility.

Finally, while many conspiracy theorists have suggested that the lack of a web presence of this person suggests some nefarious activity, there are dozens of unremarkable and routine reasons why a person may be removed from a web listing of employees or students. Not least of these is when a staff member leaves an institution, or a student graduates.

3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.

We believe that WIV senior staff comments reported in the WHO COVID origins mission report directly address this request in that they publicly state that no significant safety issues were found in their laboratory prior to, or following, the emergence of COVID. Any questions regarding the safety of the WIV also need to be put into the context of the widely published history of this lab as being built to international safety engineering standards, adhering to international safety practice standards indicated in the BMBL, and with lead WIV staff trained in safety in the United States by a known authority running the BSL-4 lab at the University of Texas Medical Branch in Galveston (as reported in the U.S. Dept of State cables). Furthermore, no verifiable evidence of safety issues have been reported prior to, or following the U.S. Dept of State cables.

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Regarding the U.S. Dept. of State cables, these do not in fact provide evidence of safety concerns at the laboratory. Neither do they convincingly imply safety issues. In fact, they may be simply interpreted as a request for funding from a diplomatic mission set up to further joint US-China research. It is important to note that initially only very limited phrases from these cables were selectively leaked by a Washington Post reporter in an opinion piece that did not verify nor quote direct sources. This opinion piece is demonstrably incomplete in its reporting, however it has been widely cited as providing evidence of safety issues at WIV (https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/). I have some detailed knowledge of the background to these cables because the diplomatic visit to WIV that they report was a direct result of our NIH-funded work. As part of EcoHealth Alliance's work in China over the past 15 years, including that funded by NIAID, I visited the US Embassy in Beijing regularly and was involved in discussions with US Embassy staff to set up a field visit to the WIV in order to generate goodwill between the US and China at a time when President Trump was planning a state visit. I did this out of a sense of duty to our government, and to the NIH so that our project could help foster goodwill between our countries, as well as provide an indication of the importance of NIH's work. Following the US Embassy staff mission, I was told by people privy to the cable's contents that the articles were positive and supportive of the work we were doing under NIAID funding, and that the trip was a success.

Now that the full text of these cables (embedded at the end of this letter) has been released with minor redactions (https://news.slashdot.org/story/20/07/20/0611205/full-text-of-us-state-department-cables-finally-released-showing-safety-in-chinese-lab), it seems that this more positive interpretation is justified. As you can see in the excerpts below, the request for more laboratory technician support could be reasonably interpreted as simply a request for the funding for more laboratory technician support, rather than a statement that the lab was unsafe, particularly given that the visit was set up as part of an effort to further develop US-China collaborative research opportunities. Furthermore, the cables are extremely positive about the importance of the collaborative work we were conducting with WIV under NIAID funding:

"**REDACTED** noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from GTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China."

"The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study **REDACTED** (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS

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Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronaviruses isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like corona viruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention."

4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.

The WIV staff categorically stated to the WHO mission that their lab is audited annually and no unusual events have been identified. The reports of diminished cell-phone traffic and roadblocks have not been verified or published by reliable sources. Furthermore, should hard evidence of diminished cell-phone traffic and roadblocks exist, it is not necessarily indicative of any issues related to concerns about the laboratory studies underway or safety or security incidents within the laboratory. These issues could be explained by any one of a series of issues that occur regularly in the US without nefarious connotations. For example, they could be due to roadwork or other infrastructure repair or maintenance, technical problems with cell-phone transmission, or rerouting of traffic as regularly occurs in Washington DC and other cities due to transport of visiting dignitaries or other events. Finally, there is no credible reason to think that any request a US non-profit might make to the Chinese government for an explanation of traffic or cell-phone issues would result in any response.

5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.

Since your letter of 7/8/2020, it has been widely reported that WIV scientists have published an addendum to their original paper in *Nature* that described SARS-CoV-2 and compared it phylogenetically to RaTG13. In this follow-up publication, they explain the rationale for conducting work in this mine, and any potential connection to the miner's illnesses and deaths. Importantly, they state that serological results in their lab at the time of the incident did not show that these miners were positive for SARSr-CoVs as some media articles have suggested. They then re-tested the miner samples in 2020 using a range of assays, and found no evidence of SARS-related CoV, nor of SARS-CoV-2 specific antibodies or nucleic acid. During the meeting of the WHO mission team with WIV staff, they were asked a series of questions about the miner's illnesses. The responses were that, while symptoms identified were similar to COVID in that they had pneumonia (a common occupational hazard for miners), their symptoms were also similar to other bacterial or fungal pneumonias. This, and the lack of evidence for SARSr-CoV infection, led them to conclude that SARS or COVID infection was not the cause of these miner's illnesses.

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6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV fieldwork (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.

The WHO mission was negotiated at the very highest levels as the legitimate way to proceed in an investigation of COVID-19 origins, particularly with such critical geopolitical ramifications from this pandemic. Given the intensity of political attacks and conspiracy theories around this lab, it is unreasonable to expect that the Chinese government or WIV would respond to a request from a US non-profit for an outside inspection team. The 11 international expert members of the WHO team included authorities on epidemiology, animal-origin viral infections and One Health. Members of this team have extensive experience conducting lab audits (e.g. Dr. Peter Ben Embarek), running laboratories dealing with human clinical samples (e.g. Drs. Dominic Dwyer, Thea Fischer), and commissioning, managing and accrediting laboratories in foreign countries (myself, Dr. Fabian Leendertz). The WHO-China Joint Study report details the field site visits to multiple labs in Wuhan, including the WIV and summarizes our findings. This includes information on the management of the WIV, safety at the labs, audits and training and testing of staff. I acted in good faith to try to conform to the WHO terms of reference while ensuring that as much information on the laboratory was provided in the report. This information specifically addresses one of your questions above, with categorical statements from WIV senior staff that they did not have SARS-CoV-2 in their possession prior to December 2019.

After returning to the USA, and in the weeks prior to the publication of the report, I worked hard to make sure this critical information was shared as rapidly as possible with the US Government and agencies, including by:

- Briefing Drs. Anthony Fauci and Clifford Lane of NIAID on the findings of the mission;
- Presenting a full talk about the work to the NIAID COVID PI group that meets weekly
- Briefing FBI and other US Government intelligence agency staff
- Briefing members of the US NASEM Forum on Microbial Threats
- Briefing staff on the White House National Security Council
- Briefing staff on the House Committee for Science, Space, and Technology

7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

This has been done and all subawards fully reported as soon as we could once you notified us of this requirement in your letter of 7/8/2020.

8. Provide copies of all EcoHealth Alliance – WIV subrecipient agreements as well as any other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety.

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As we related in response to your letter of 4/19/2020 that asked us to suspend work with WIV, we had not yet set up a subcontract with WIV for the period of this award, therefore no such subrecipient agreements exist. Our plan was to monitor WIV's compliance as we had in the 5 years prior, by means of semi-annual meetings with the lead investigator and assessments of compliance against all conditions of the award. Additionally, following the NIH's termination, then reinstatement and suspension of our funding, we have contracted with a leading lab biosafety contractor based in Southeast Asia (Dr. Paul Selleck) who has extensive experience commissioning, accrediting and auditing BSL-2, -3, and -4 labs, and has worked for over a decade at the BSL-4 Australian Animal Health Lab. We will be using their services where appropriate for foreign lab subcontractees to assess lab biosafety procedures and conduct audits, including following the full reinstatement of 2R01AI110964. Finally, we have appointed a Senior Field Veterinarian who will oversee all EcoHealth Alliance fieldwork in the region and ensure continued compliance with biosafety when conducting animal capture, sampling and sample handling. We have done this at EcoHealth Alliance's own expense, despite our unblemished record on biosafety, to pre-empt calls for further sanctions against our work given the continued attacks against EcoHealth Alliance in the press after the termination of our NIH grant.

9. Describe EcoHealth's efforts to evaluate WIV's risk of noncompliance with Federal statutes, regulations, and the terms and conditions of the subaward.

Over a 15-year period of collaboration with WIV, we have found no evidence to suggest that there was any element of noncompliance with any of the conditions of the grants or contracts covering our collaboration. Our interactions with all staff at the institute have been professional, respectful, open, and with a focus on the science at a very high level. This has contributed to a relationship built on trust and one that is entirely comparable to our scientific collaborations with laboratories in the US, Europe, Australia, Thailand and over 20 other countries. We continue to believe that this laboratory is highly competent and is an extremely low risk for undisclosed accidental release of virus, and there is no verifiable indication as to why we should not continue to believe so. We would of course consider a change in this assessment if significant and verifiable evidence of lab biosafety issues or breach of other Federal statutes are brought forth, but to date we are aware of none.

10. Provide copies of all WIV biosafety reports from June 1, 2014 through May 31, 2019.

Given the intense geopolitical pressure around the accusations that WIV intentionally or accidentally released SARS-CoV-2 (something which the WHO mission deemed 'extremely unlikely'), obtaining such information is not a plausible option at present.

11. Additional information, re. Lack of ongoing investigation into Wuhan Institute of Virology by NIH:

From: Garcia-Malene, Gorka (NIH/OD) [E] (b) (6)
Sent: Tuesday, January 26, 2021 12:20:51 PM
To: [REDACTED]
Cc: [REDACTED] Bartok, Lauren (NIH/NIAID) [E]; NIH FOIA
Subject: [EXT] FW: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

Good afternoon, **[REDACTED]** –

I'd like to insert myself into the unfolding FOIA conversation in hopes of providing some helpful context. Our records show that this competing renewal has in fact been funded. In addition, any indication from my program that there is an ongoing investigation into WIV can now be disregarded, as we recently confirmed there are no pending investigations into that organization. If we can agree on the above, all that would remain is to receive your proposed redactions to the records sought under the FOIA request.

Please let me know if there are any questions. I look forward to facilitating the Pre-Disclosure Notification process as efficiently as possible.

Best regards.

Gorka Garcia-Malene | FOIA Officer for the National Institutes of Health

From: [REDACTED]
Sent: Monday, January 25, 2021 5:21 PM
To: Bartok, Lauren (NIH/NIAID) [E] (b) (6)
Cc: [REDACTED]
Subject: FOIA Case No. 55702 re: EcoHealth Alliance & Grant No. R01AI110964-6

Dear Ms. Bartok:

As you may recall, this firm represents EcoHealth Alliance, Inc. ("EcoHealth Alliance"), with respect to certain FOIA requests, including the instant request, FOIA Case No. 55702. The instant request seeks the same documents sought last year in FOIA Case No. 53996, regarding the research project *Understanding the Risk of Bat Coronavirus Emergence*, funded under grant 2R01AI110964. A copy of our prior letter regarding FOIA 53996 is available via the link provided below using the password **[REDACTED]**. On the grounds set forth in the letter, FOIA 53996 was denied in its entirety.

Likewise, FOIA 55702 should be denied and the grant documents should be withheld. First, grant 2R01AI110964-06 remains an unfunded competing renewal grant that is the subject of a pending first-level appeal and, thus, the materials are not subject to disclosure under NIH Grants Policy Statement §2.3.11.2.2. Moreover, in the context of the appeal, NIH has made multiple requests for further information regarding The Wuhan Institute of Virology ("WIV"), which requests indicate that a law enforcement investigation concerning WIV remains ongoing. Second, as demonstrated by the recent attack on the US Capital fueled by disinformation and conspiracy theories, the need to protect the privacy of EcoHealth Alliance's employees and affiliates is more important than ever. Last, while EcoHealth Alliance did not initially identify that the grant proposal contained confidential-commercial and propriety information, this is not dispositive. Moreover, since the

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filing of the renewal application, there has been a global COVID-19 pandemic, which has sparked international and highly competitive research in the area of bat coronaviruses.

At the very least, the responsive documents will require significant redactions. While the grant documents were previously reviewed and redacted in connection with FOIA 53996, we require a further opportunity to review the documents to confirm, *inter alia*, that all personnel information has been removed given the heightened risk of harm in this unprecedented political environment. Accordingly, EcoHealth Alliance respectfully requests a forty-five (45) day extension of time to respond to FOIA 55702, to allow sufficient time for EcoHealth Alliance to conduct a further review of the responsive documents and provide an updated letter response that incorporates recent developments and specific justifications for additional redactions.

Please confirm that NIH will deny FOIA 55702 in its entirety or that NIH is agreeable to EcoHealth Alliance's request for an extension of time to provide a particularized response to FOIA 55702. Please also confirm NIH's receipt of this email.

Thank you.

Best,
[REDACTED]

FOIA Case No. 53996 - EcoHealth Alliance's Letter Response to FOIA Request, dated June 5, 2020 (With Exhibits)
[REDACTED]

[REDACTED]

Tarter Krinsky & Drogin LLP
1350 Broadway | New York | NY | 10018
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COVID-19 RESOURCE CENTER

12. Publicly released details of U.S. Department of State Cables regarding visit to Wuhan Institute of Virology, as cited in condition #3 above. These are available from a number of sources, including the Washington Post and (https://news.slashdot.org/story/20/07/20/0611205/full-text-of-us-state-department-cables-finally-released-showing-safety-in-chinese-lab).

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MRN:	18 BEIJING 138
Date/DTG:	Jan 19, 2018 / 190739Z JAN 18
From:	AMEMBASSY BEIJING
Action:	WASHDC, SECSTATE *ROUTINE*
E.O.:	13526
TAGS:	SHLH, ETRD, ECON, PGOV, CN
Captions:	SENSITIVE
Reference:	17 WUHAN 48
Subject:	China Opens First Bio Safety Level 4 Laboratory

1. (SBU) **Summary and Comment:** The Chinese Academy of Sciences (CAS) has recently established what is reportedly China's first Biosafety Level 4 (BSL-4) laboratory in Wuhan. This state-of-the-art facility is designed for prevention and control research on diseases that require the highest level of biosafety and biosecurity containment. Ultimately, scientists hope the lab will contribute to the development of new antiviral drugs and vaccines, but its current productivity is limited by a shortage of the highly trained technicians and investigators required to safely operate a BSL-4 laboratory and a lack of clarity in related Chinese government policies and guidelines. (b)(5)

(b)(5)

(b)(5) **End Summary and Comment.**

China Investing in Infectious Disease Control

2. (U) Between November 2002 and July 2003, China faced an outbreak of Severe Acute Respiratory Syndrome (SARS), which, according to the World Health Organization, resulting in 8,098 cases and leading to 774 deaths reported in 37 countries. A majority of cases occurred in China, where the fatality rate was 9.6%. This incident convinced China to prioritize international cooperation for infectious disease control. An aspect of this prioritization was China's work with the Jean Merieux BSL-4 Laboratory in Lyon, France, to build China's first high containment laboratory at Wuhan's Institute of Virology (WIV), an institute under the auspices of the Chinese Academy of Sciences (CAS). Construction took 11 years and $44 million USD, and construction on the facility was completed on January 31, 2015. Following

two years of effort, which is not unusual for such facilities, the WIV lab was accredited in February 2017 by the China National Accreditation Service for Conformity Assessment. It occupies four floors and consists of over 32,000 square feet. WIV leadership now considers the lab operational and ready for research on class-four pathogens (P4), among which are the most virulent viruses that pose a high risk of aerosolized person-to-person transmission.

Unclear Guidelines on Virus Access and a Lack of Trained Talent Impede Research

3. (SBU) In addition to accreditation, the lab must also receive permission from the National Health and Family Planning Commission (NHFPC) to initiate research on specific highly contagious pathogens. According to some WIV scientists, it is unclear how NHFPC determines what viruses can or cannot be studied in the new laboratory. To date, WIV has obtained permission for research on three viruses: Ebola virus, Nipah virus, and Xinjiang hemorrhagic fever virus (a strain of Crimean Congo hemorrhagic fever found in China's Xinjiang Province). Despite this permission, however, the Chinese government has not allowed the WIV to import Ebola viruses for study in the BSL-4 lab. Therefore, WIV scientists are frustrated and have pointed out that they won't be able to conduct research project with Ebola viruses at the new BSL-4 lab despite of the permission.

(b)(6)

(b)(6) Thus, while the BSL-4 lab is ostensibly fully accredited, its utilization is limited by lack of access to specific organisms and by opaque government review and approval processes. As long as this situation continues, Beijing's commitment to prioritizing infectious disease control - on the regional and international level, especially in relation to highly pathogenic viruses, remains in doubt.

(b)(6) noted that the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory. University of Texas Medical Branch in Galveston (UTMB), which has one of several well-established BSL-4 labs in the United States (supported by the National Institute of Allergy and Infectious Diseases (NIAID of NIH)), has scientific collaborations with WIV, which may help alleviate this talent gap over time. Reportedly, researchers from GTMB are helping train technicians who work in the WIV BSL-4 lab. Despite this, (b)(6) they would welcome more help from U.S. and international organizations as they establish "gold standard" operating procedures and training courses for the first time in China. As China is building more BSL-4 labs, including one in Harbin Veterinary Research Institute subordinated to the Chinese Academy of Agricultural Sciences (CAAS) for veterinary research use (b)(6) the training for technicians and investigators working on dangerous pathogens will certainly be in demand.

Despite Limitations, WIV Researchers Produce SARS Discoveries

6. (SBU) The ability of WIV scientists to undertake productive research despite limitations on the use of the new BSL-4 facility is demonstrated by a recent publication on the origins of SARS. Over a five-year study, (b)(6) (and their research team) widely sampled bats in Yunnan province with funding support from NIAID/NIH, USAID, and several Chinese funding agencies. The study results were published in PLoS Pathogens online on Nov. 30, 2017 (1), and it demonstrated that a SARS-like coronaviruses isolated from horseshoe bats in a single cave contain all the building blocks of the pandemic SARS-coronavirus genome that caused the human outbreak. These results strongly suggest that the highly pathogenic SARS-coronavirus originated in this bat population. Most importantly, the researchers also showed that various SARS-like coronaviruses can interact with ACE2, the human receptor identified for SARS-coronavirus. This finding strongly suggests that SARS-like coronaviruses from bats can be transmitted to humans to cause SARS-like disease. From a public health perspective, this makes the continued surveillance of SARS-like coronaviruses in bats and study of the animal-human interface critical to future emerging coronavirus outbreak prediction and prevention. (b)(5) (b)(5) WIV scientists are allowed to study the SARS-like coronaviruses isolated from bats while they are precluded from studying human-disease causing SARS coronavirus in their new BSL-4 lab until permission for such work is granted by the NHFCP.

1. Hu B, Zeng L-P, Yang X-L, Ge X-Y, Zhang W, Li B, et al. (2017) Discovery of a rich gene pool of bat SARS-related coronaviruses provides new insights into the origin of SARS coronavirus. PLoS Pathog 13(11): e1006698. https://doi.org/10.1371/journal.ppat.1006698

Signature:	BRANSTAD
Drafted By:	(b)(6)
Cleared By:	
Approved By:	
Released By:	
Info:	CHINA POSTS COLLECTIVE *ROUTINE*
Dissemination Rule:	Archive Copy

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SBU

We await your response at the earliest opportunity.

Yours sincerely,

Dr. Peter Daszak
President

(t) (b) (6); (e) (b) (6)
cc. Dr. Aleksei A. Chmura (Chief-of-Staff)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

13 April 2021

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964 and your letter of April 11, 2021

Dear Drs. Chmura and Daszak:

Thank you for your letter of April 11, 2021. We are reviewing your responses in detail.

In the meantime, though, and in interest of expediting our review, we would note that our previous letters were concerned with NIH Grant R01AI110964 (which started on started on June 1, 2014 as documented in RePORTER) and not solely with 2R01AI110964-06. Therefore, as we asked on October 23, 2020, please send us copies of *all* EcoHealth Alliance – WIV subrecipient agreements as well as any and all other documents and information describing how EcoHealth Alliance monitored WIV's compliance with the terms and conditions of award, including with respect to biosafety. While we understand that you may not have activated a subaward for year 6, we would expect there to be substantial documentation of your oversight of WIV subaward activities during years 1 through 5.

Also, as we asked, please send us copies of *all* biosafety reports; we would expect that as part of your oversight you would have copies of all such reports through at least year 5.

As a reminder, as a term and condition of award, NIH "must have the right of access to any documents, papers, or other records of the non-Federal entity which are pertinent to the Federal award, in order to make audits, examinations, excerpts, and transcripts" (45 C.F.R. § 75.364); and must have "timely and reasonable access to the non-Federal entity's personnel for the purpose of interview and discussion related to such documents" (id.). These requirements flow down to subawards to subrecipients. 45 C.F.R. § 75.101. "Non-Federal entities must comply with requirements in [45 C.F.R. Part 75] regardless of whether the non-Federal entity is a recipient or subrecipient of a Federal award." 45 C.F.R. 75.101. As the grantee, EcoHealth was required to have in place, "A requirement that the subrecipient permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity to meet the requirements of this part." 45 C.F.R. § 75.352(a)(5). For each of these reasons, NIH is justified in seeking the materials, information, and a site visit as requested.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2021.04.13 13:12:57 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)


(b) (5)

(b) (5)

(b) (5)

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 7/7/2021 8:56:12 AM
To: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]; Simanich, Sasha (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62114870dc66475a8c0ce0047413ed92-simanichs2]; Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]; Stein, Meredith (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3324d143a8c4975b4f1d405d1a54d14-steinme]; Brown, Tiffany (NIH/OD/OMA) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14def436a4f74669a6c9fdc45f3b0f0f-brownty1]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: OIG EcoHealth
Attachments: REVISED NIH Oversight of Grantee-Subgrantee Entrance Conference Agenda...06.29.2021[2].docx

Many thanks, Liza, and yes agree, ready for OGC review. (b) (5)

Mike

From: "Bundesen, Liza (NIH/OD) [E]" (b) (6)
Date: Tuesday, July 6, 2021 at 2:38 PM
To: "Simanich, Sasha (NIH/OD) [E]" (b) (6), "Jacobs, Anna (NIH/OD) [E]" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6), "Stein, Meredith (NIH/OD) [E]" (b) (6), "Brown, Tiffany (NIH/OD/OMA) [E]" (b) (6)
Subject: RE: OIG EcoHealth

Hi All,

I have revised the filing architecture in Box per Sasha's suggestion. I think the "First Batch" is ready for OGC review.

Thanks,
Liza

From: Simanich, Sasha (NIH/OD) [E] (b) (6)
Sent: Tuesday, June 29, 2021 5:09 PM
To: Jacobs, Anna (NIH/OD) [E] (b) (6); Bundesen, Liza (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6); Brown, Tiffany (NIH/OD/OMA) [E] (b) (6)
Subject: RE: OIG EcoHealth

Hi Anna and Liza,

We would recommend the following:

- For OGC's review, internal deadline by **July 13**
- For OIG's final delivery, first batch, external deadline by **July 16**

We would also recommend implementing a cutoff date for data uploads into Box prior to OGC's review. Additionally, we recommend creating separate folders in Box for each data call.

For example:

- OIG audit of EcoHealth Alliance (Parent Folder)
  - Create new sub-folder, e.g., "Entrance Conference Data Request"
    - Create new sub-folder, e.g., "First Batch"
    - Create new sub-folder, e.g., "Second Batch" and start uploading new data after first batch cutoff date

We can continue leveraging this folder method for all new requests as they come in. After we establish a cutoff date for each data call, we would have OGC review and approve prior to us sharing the folder with OIG. That's one way to limit controls while we're in the process of collecting and reviewing data without inadvertently allowing OIG access. Let us know if you're comfortable with this approach or if you have alternative options. We're flexible and here to support you.

Many thanks,
Sasha

From: Jacobs, Anna (NIH/OD) [E] (b) (6)
Sent: Tuesday, June 29, 2021 3:59 PM
To: Bundesen, Liza (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6); Simanich, Sasha (NIH/OD) [E] (b) (6); Brown, Tiffany (NIH/OD/OMA) [E] (b) (6)
Subject: RE: OIG EcoHealth

Thanks, Liza!

On the two items flagged as needing documents from NIAID and your question to me — my colleague, Lena Yueh, is going to speak with the NIH FOIA Office tomorrow at 2pm, and she will ask them whether the documents pulled for the FOIA productions would contain these documents requested by OIG:

(b) (5)

(She will also ask them whether they have anything responsive to question 6a of the GAO questions: (b) (5)

(b) (5)

. If that is the case, I will let you know (hopefully tomorrow).

On the review of documents in Box, because there are 3 or 4 attorneys who will be reviewing the documents, I'm not sure if creating a "Reviewed by OGC" folder will help. I may get a better sense as we go through the documents, but for now, don't worry about that.

Sasha, can you remind me of the deadline for OGC's review of the first batch?

Thanks,

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm.2B-50
Bethesda, MD 20892
(b) (6) *(phone)*
301-402-1034 (fax)
(b) (6)

From: Bundesen, Liza (NIH/OD) [E] (b) (6)
Sent: Tuesday, June 29, 2021 2:43 PM
To: Lauer, Michael (NIH/OD) [E] (b) (6); Stein, Meredith (NIH/OD) [E] (b) (6); Simanich, Sasha (NIH/OD) [E] (b) (6); Brown, Tiffany (NIH/OD/OMA) [E] (b) (6); Jacobs, Anna (NIH/OD) [E] (b) (6)
Subject: OIG EcoHealth

Hi Everyone,

Thank you for the helpful call today. Attached are draft responses to OIG's questions. I've flagged things that we need in comment bubbles.

In addition to the FOIA and OLPA requests, we will need NIAID to address the following questions (Anna, I think you were going to take a look at what may have already been collected?):

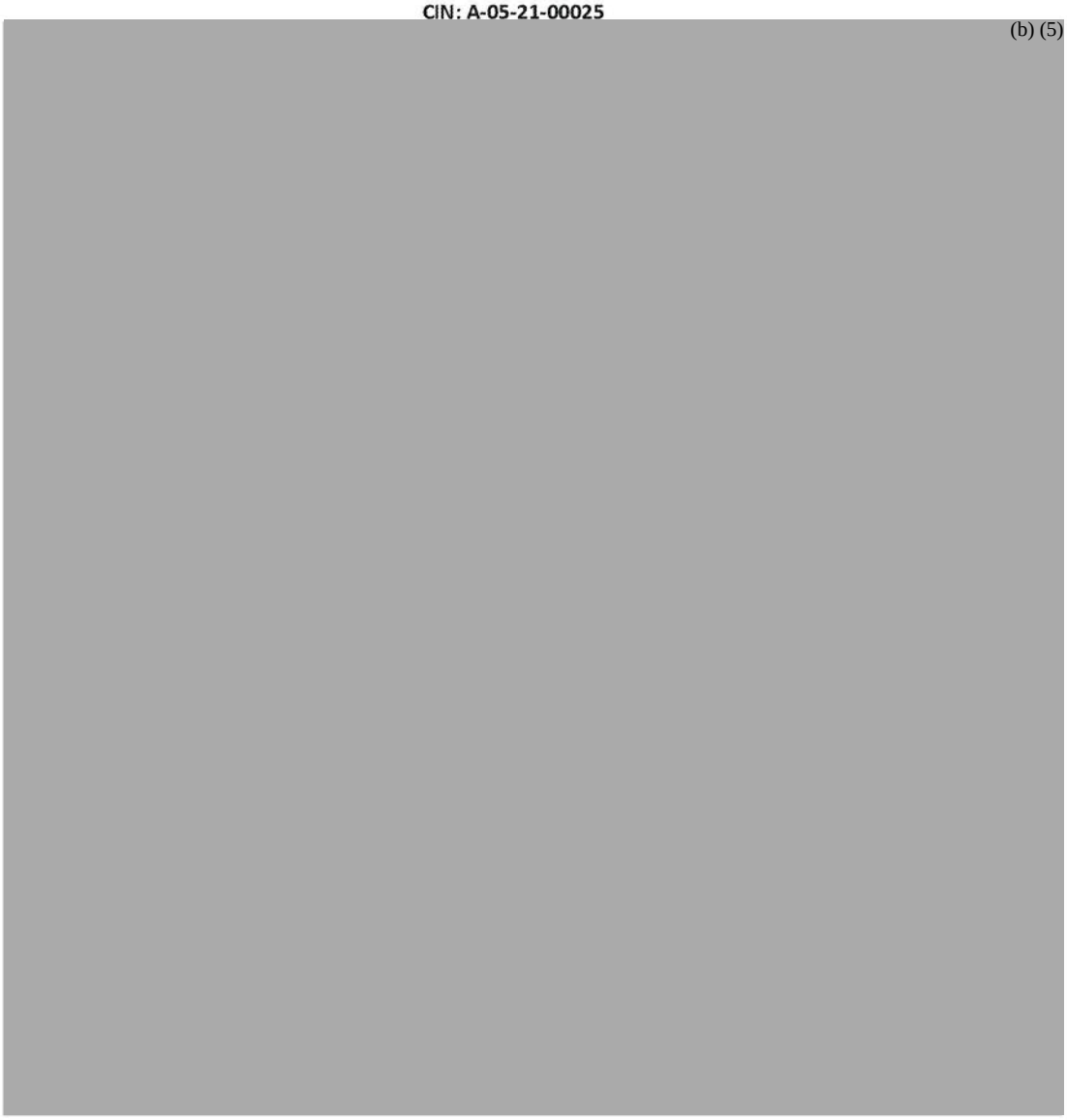
(b) (5)

I've given all of you access to Box, as well as Tamra Clark, David Lankford, and Lena Yueh.

I've been tinkering with Box Help, and I'm not seeing a feature that will help us flag that a document has been reviewed by OGC. Perhaps we could just create a folder that says "Reviewed by OGC" and move other folders in there when complete? I welcome other ideas.

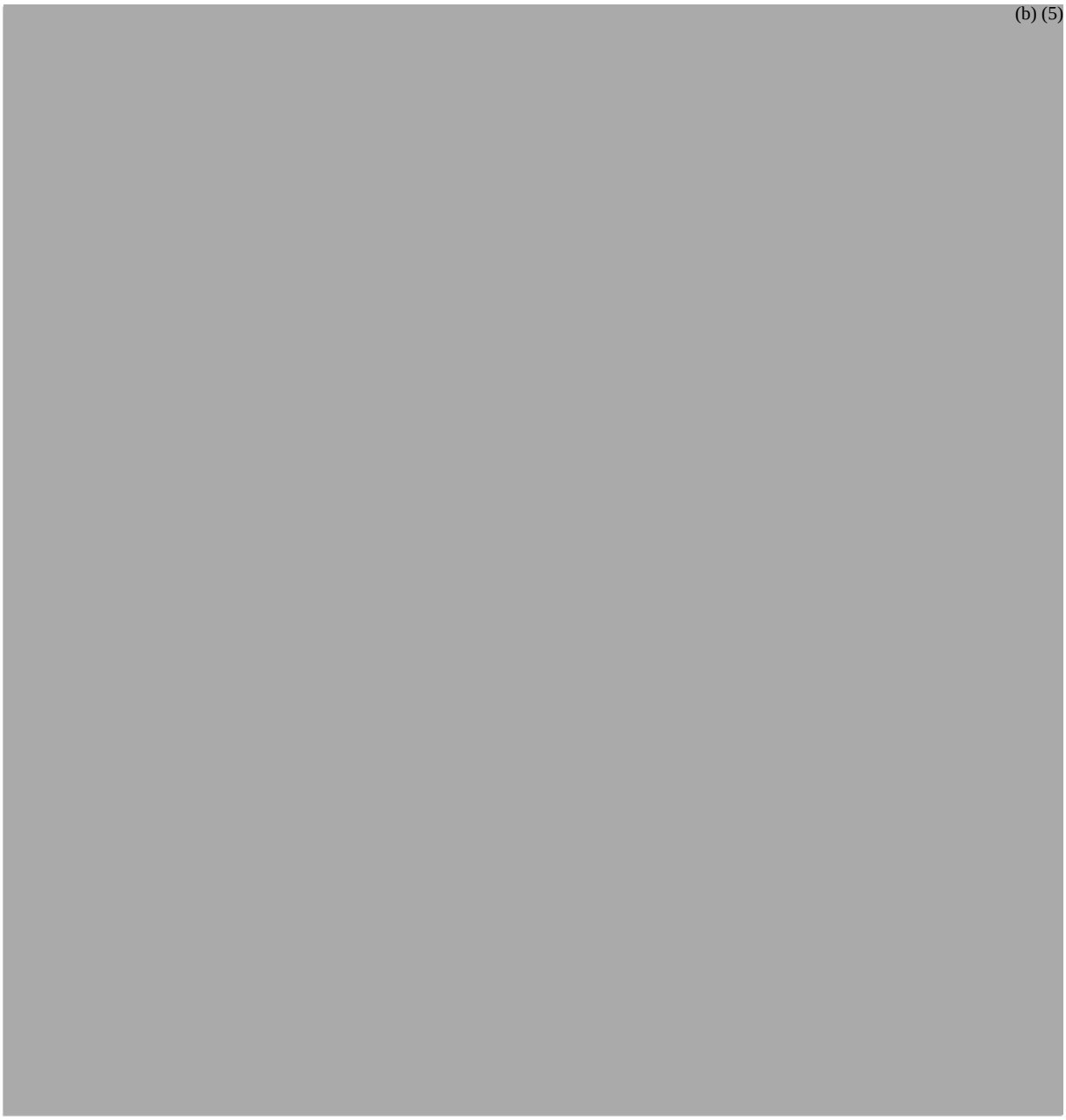
Liza

(b) (5)

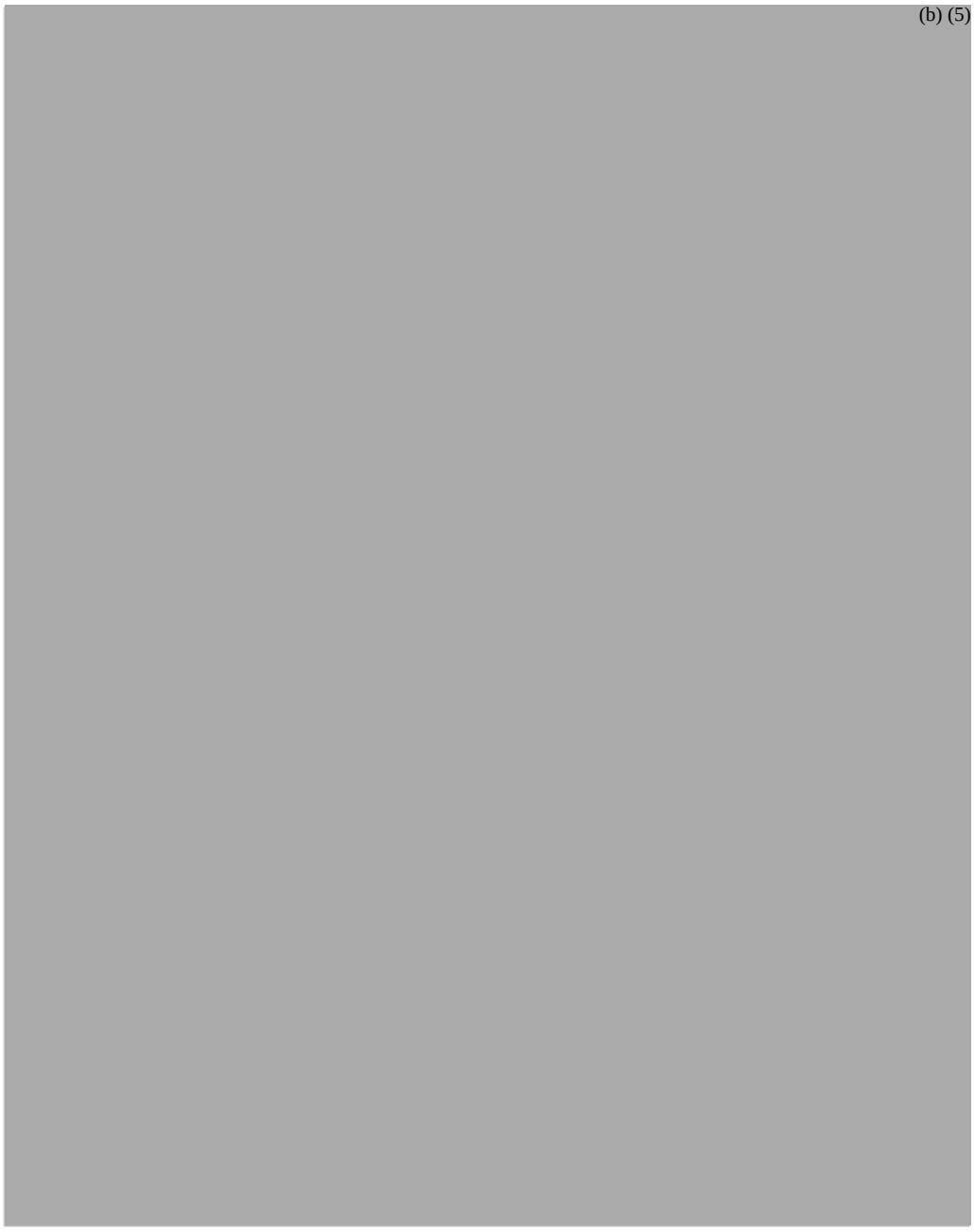


(b) (5)

(b) (5)



(b) (5)



(b) (5)

(b) (5)

(b) (5)

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 6/30/2021 3:39:17 PM
To: Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: follow-up
Attachments: Draft - AI110964 June 2021 mgb msl.docx

Thanks so much Anna – you had me very well prepped!

And thanks for looking at the letter. Given the conversation this morning, I'm thinking we should leave the sentence in (you'll see my comment).

(b) (5)

Mike

From: "Jacobs, Anna (NIH/OD) [E]" (b) (6)
Date: Wednesday, June 30, 2021 at 11:28 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: follow-up

Mike, you did a great job today. FYI that I will proceed with reviewing the letter, and I'll send you edits as soon as I can. Many thanks,

Anna L. Jacobs, J.D., M.S.
Senior Attorney
HHS Office of the General Counsel
Public Health Division, NIH Branch
31 Center Drive, Bldg. 31, Rm.2B-50
Bethesda, MD 20892
(b) (6) *(phone)*
301-402-1034 (fax)
(b) (6)

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 6/22/2021 8:47:46 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lankford, David (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f29a9bef672409d967e3aa5fb36e96a-lankford]; Jacobs, Anna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e76eeb11df9a4024b53864ffac4c4c56-jacobsal]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Jorgenson, Lyric (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbde7d361374981a4d336b6eeb17521-jorgensonla]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]
Subject: PLEASE REVIEW: Question from the WSJ
Attachments: NIHLetter8July.pdf

Hi all:

Mike received the below inquiry from the WSJ and we propose responding with the below. Please let us know if you have any concerns.

(b) (5)

Thanks,
Renate

From: "Gordon, Michael" <michael.gordon@wsj.com>
Date: Tuesday, June 22, 2021 at 7:55 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Fwd: Question from the WSJ

Dr. Lauer,

I am a reporter for The Wall Street Journal and have a question for you. I would be happy to discuss this by phone or in person, including on a background not-for-attribution basis. I am looking for some guidance on a July 8, 2020 letter you wrote, which has been in the public domain for nearly a year. I am neither a proponent of the lab theory nor a supporter of the zoonotic hypothesis regarding the origins of Covid-19 in China. I am just trying to understand and present the facts as best I can.

In your July 8 letter you described some restrictions at the Wuhan Institute of Virology in 2019. Specifically, you wrote that there was "diminished cell-phone traffic in October 2019" at or near that facility. You also wrote that "there was evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019."

My WSJ colleague, Betsy McKay, wrote in August about this letter, which was addressed to the EcoHealth Alliance. (https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400). It has also been distributed on Capitol Hill.

My questions are as follows.

Do you or NIH still stand by the statement that there was diminished cell traffic in and around the WIV in October 2019? What was the source of that information and is it a source in which NIH has confidence? The letter suggests that it is a fact that there was diminished cell phone traffic. To your understanding, is it a fact or merely a possibility? Have you and NIH changed that position based on more recent information? Did EcoHealth Alliance ever provide any information regarding your questions? What about the roadblocks? Is there any similar information on that? I have attached a copy of the letter to this email.

Again, we can talk on a background, not-for-attribution basis if you wish. I am trying to better understand a complicated situation and fully understand that new information may have arisen over the past year and that some prior impressions may have been discomfirmed. I also want to be sure that I am interpreting your letter correctly, and it has been interpreted as stating for a fact that there was disminished cell phone traffic. So I would like to be sure that this is what you intended. I am trying to be very careful about all this. Thanks for your attention, and I would be happy to answer any questions on this request.

Michael Gordon
National Security Correspondent
The Wall Street Journal
(b) (6) (cell, WhatsApp, Signal)
michael.gordon@wsj.com (work email)
MGWSJ@protonmail.com (encrypted email)
Book site: michaelrgordon.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

.

Sincerely,

Michael S. Lauer -S Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 6/29/2021 10:33:15 AM
To: Bundesen, Liza (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cded900576a49aea461d26e93bddac3-lbundese]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: REVISED entrance agenda: OIG Entrance Conference: "National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)
Attachments: FW: REVISED entrance agenda: OIG Entrance Conference: "National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025); REVISED NIH Oversight of Grantee-Subgrantee Entrance Conference Agenda...6.25.21 msl lqb msl.docx

Many thanks Liza – I've added materials and comments to your most recent version.

Mike

From: "Bundesen, Liza (NIH/OD) [E]" (b) (6)
Date: Monday, June 28, 2021 at 11:10 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: FW: REVISED entrance agenda: OIG Entrance Conference: "National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)

Hi Mike—in track changes, I added the file names and to-do's. See the last attachment with my initials. I still need to contact Tiffany about coordinating documents with NIAID, FOIA, and OLPA, but I'll hold off until we have our chat at 12:15.

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Sunday, June 27, 2021 11:57 AM
To: Bundesen, Liza (NIH/OD) [E] (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] (b) (6); Bulls, Michelle G. (NIH/OD) [E] (b) (6)
Subject: FW: REVISED entrance agenda: OIG Entrance Conference: "National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)

Hi Liza – the second attachment has my updated, revised answers, including to the new question on the other EcoHealth grants.

Thanks, Mike

From: "Brown, Tiffany (NIH/OD/OMA) [E]" (b) (6)
Date: Friday, June 25, 2021 at 12:12 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6), "Bundesen, Liza (NIH/OD) [E]" (b) (6), "Bulls, Michelle G. (NIH/OD) [E]" (b) (6), "Ta, Kristin (NIH/OD) [E]" (b) (6), "Haskins, Melinda (NIH/NIAID) [E]" (b) (6), "Harper, Jill (NIH/NIAID) [E]" (b) (6), "Embry, Alan

(NIH/NIAID) [E]" [redacted], "Fenton, Matthew (NIH/NIAID) [E]" [redacted], "Linde, Emily (NIH/NIAID) [E]" [redacted], "LaMontagne, Karen (NIH/OD) [E]" [redacted], "Lohmann, Larry (NIH/OD) [E]" [redacted], "Spady, Tyrone (NIH/OD) [E]" [redacted] "Chakraborty, Trisha (NIH/OD) [E]" [redacted], "Tucker, Jessica (NIH/OD) [E]" [redacted], "Jacobs, Anna (NIH/OD) [E]" [redacted], "Lankford, David (NIH/OD) [E]" [redacted], "Clark, Tamara (OS/OGC)" [redacted], "Yueh, Lena (CDC/OCOO/OGC)' [redacted], "Simanich, Sasha (NIH/OD) [E]" < [redacted], "Stein, Meredith (NIH/OD) [E]" [redacted], "Valentine, Megan (OS/ASFR)" [redacted]
Cc: "Jorgenson, Lyric (NIH/OD) [E]" [redacted], "Petruccelli, Anthony J. (HHS/ASFR)" [redacted]
Subject: REVISED entrance agenda: OIG Entrance Conference: "National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)

Good afternoon,

Attached is the revised agenda for next week's entrance conference. The changes reflects the 3rd grant that was added by the OIG (dollar amount and fiscal year) and they added Just in Time Documentation to the document request.

Have a great weekend.

Thanks!

Tiffany Brown
NIH/OD/OMA/RMAL
[redacted] (Direct)
(301) 402-0169 (Fax)

-----Original Appointment----
From: Brown, Tiffany (NIH/OD/OMA) [E] [redacted]
Sent: Thursday, June 24, 2021 10:47 AM
To: Brown, Tiffany (NIH/OD/OMA) [E]; Lauer, Michael (NIH/OD) [E]; Bundesen, Liza (NIH/OD) [E]; Bulls, Michelle G. (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Haskins, Melinda (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Fenton, Matthew (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]; LaMontagne, Karen (NIH/OD) [E]; Lohmann, Larry (NIH/OD) [E]; Spady, Tyrone (NIH/OD) [E]; Chakraborty, Trisha (NIH/OD) [E]; Tucker, Jessica (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Clark, Tamara (OS/OGC); Yueh, Lena (CDC/OCOO/OGC); Simanich, Sasha (NIH/OD) [E]; Stein, Meredith (NIH/OD) [E]; Valentine, Megan (OS/ASFR); Lewis, Carla J (OIG/OAS); Stitz, Jeffrey D (OIG/OAS); Sin, Kyu (OIG/OAS); Fulcher, Sheri L (OIG/OAS); Barton, Mike M (OIG/OAS); Burbey, Allen (OIG/OAS); Capuano, Joseph G (OIG/OAS); Ullrich, Jack W (OIG/OAS); Sobota, Jennifer M (OIG/OAS); Corcoran, Nancy A (OIG/OAS); Frontz, Amy J (OIG/OAS); Taschenberger, Peter A (OIG/OCIG)
Cc: Showe, Melanie (NIH/OD) [E]; McCaskill, Ronika (NIH/OD) [C]; Jorgenson, Lyric (NIH/OD) [E]; Petruccelli, Anthony J. (HHS/ASFR); Taylor, Geeta (OIG/OCIG)
Subject: OIG Entrance Conference: "National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)

When: Wednesday, June 30, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where:

The OIG will send a modified agenda on June 28th.

NIH Participants:

Michael Lauer, Deputy Director for Extramural Research, Office of Extramural Research (OER)

Liza Bundesen, Special Assistant to Deputy Director for Extramural Research, OER

Michelle Bulls, Director, Office of Policy for Extramural Research Administration (OPERA), OER

Kristen Ta, Senior Advisor, OER/OPERA

Melinda Haskins, Legislative Affairs and Correspondence Management Branch (LACMB), Chief, National Institute of Allergy and Infectious Diseases (NIAID)

Jill Harper, NIAID Deputy Director for Science Management, NIAID

Alan Embry, Chief, Respiratory Diseases Branch (RDB), NIAID

Matthew Fenton, Director of the Division of Extramural Activities (DEA), NIAID

Emily Linde, Director, Grants Management Program, NIAID/DEA

Karen LaMontagne, Legislative Analyst, Office of Legislative Policy & Analysis (OLPA)

Larry Lohman, Legislative Analyst, OLPA

Tyrone Spady, Director, Science Policy Coordination, Collaboration, and Reporting (SPCCR), Office of Science Policy (OSP)

Trisha Chakraborty, Health Science Policy Analyst, OSP/SPCCR

Jessica Tucker, Director, Biosafety, Biosecurity, and Emerging Biotechnology Policy (BBEBP), OSP

Anna Jacobs, Senior Attorney, Office of General Counsel (OGC)

Tamara Clark, Senior Attorney, OGC

Lena Yueh, Senior Attorney, OGC

David Lankford, NIH Legal Advisor, OGC

Meredith Stein, Acting Director, Office of Management Assessment (OMA)

Sasha Simanich, Acting Director, Division of Risk Management and Audit Liaison (RMAL), OMA

Tiffany Brown, Management Analyst, POC for this engagement, OMA/RMAL

HHS Participant:
Megan Valentine, Management and Program Analyst, Assistant Secretary for Financial Resources (ASFR), Health and Human Services (HHS)

Anthony Petruccelli, Policy Analyst, ASFR

OIG Participants:

Carla Lewis, Assistant Inspector General, Office of Audits Services (OAS), Office of Inspector General (OIG)

Sheri Fulcher, Regional Inspector General

Jeffrey Stitz, Assistant Director

Mike Barton, Assistant Regional Inspector General

Allen Burbey, Senior Auditor (Audit Lead)

Joe Capuano, Senior Auditor

Jack Ullrich, Senior Auditor

Kyu Sin, Senior Auditor

Jennifer Sobota – Senior Auditor

Nancy Corcoran, Auditor

Amy Frontz, Deputy Inspector General for Audit Services

Peter Taschenberger, Deputy Branch Chief

Geeta Taylor, Senior Counsel

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From: Bundesen, Liza (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3CDED900576A49AEA461D26E93BDDAC3-LBUNDESE]
Sent: 6/28/2021 3:10:53 PM
To: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: FW: REVISED entrance agenda: OIG Entrance Conference: "National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)
Attachments: REVISED NIH Oversight of Grantee-Subgrantee Entrance Conference Agenda...6.25.21 msl.docx; OPERA assessment of EcoHealth Grants 6 25 21.docx; Draft - AI110964 June 2021 mgb.docx; Ecohealth WIV Subaward - Summary_.docx; REVISED NIH Oversight of Grantee-Subgrantee Entrance Conference Agenda...6.25.21 msl lqb.docx

Hi Mike—in track changes, I added the file names and to-do's. See the last attachment with my initials. I still need to contact Tiffany about coordinating documents with NIAID, FOIA, and OLPA, but I'll hold off until we have our chat at 12:15.

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Sunday, June 27, 2021 11:57 AM
To: Bundesen, Liza (NIH/OD) [E] (b) (6)
Cc: Lauer, Michael (NIH/OD) [E] (b) (6); Bulls, Michelle G. (NIH/OD) [E] (b) (6)
Subject: FW: REVISED entrance agenda: OIG Entrance Conference: "National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)

Hi Liza – the second attachment has my updated, revised answers, including to the new question on the other EcoHealth grants.

Thanks, Mike

From: "Brown, Tiffany (NIH/OD/OMA) [E]" (b) (6)
Date: Friday, June 25, 2021 at 12:12 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6), "Bundesen, Liza (NIH/OD) [E]" (b) (6), "Bulls, Michelle G. (NIH/OD) [E]" (b) (6), "Ta, Kristin (NIH/OD) [E]" (b) (6), "Haskins, Melinda (NIH/NIAID) [E]" (b) (6), "Harper, Jill (NIH/NIAID) [E]" (b) (6), "Embry, Alan (NIH/NIAID) [E]" (b) (6), "Fenton, Matthew (NIH/NIAID) [E]" (b) (6), "Linde, Emily (NIH/NIAID) [E]" (b) (6), "LaMontagne, Karen (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6), "Spady, Tyrone (NIH/OD) [E]" (b) (6), "Chakraborty, Trisha (NIH/OD) [E]" (b) (6), "Tucker, Jessica (NIH/OD) [E]" (b) (6), "Jacobs, Anna (NIH/OD) [E]" (b) (6), "Lankford, David (NIH/OD) [E]" (b) (6), "Clark, Tamara (OS/OGC)" (b) (6), "Yueh, Lena (CDC/OCOO/OGC)" (b) (6), "Simanich, Sasha (NIH/OD) [E]" (b) (6), "Stein, Meredith (NIH/OD) [E]" (b) (6), "Valentine, Megan (OS/ASFR)" (b) (6)
Cc: "Jorgenson, Lyric (NIH/OD) [E]" (b) (6), "Petruccelli, Anthony J. (HHS/ASFR)" (b) (6)
Subject: REVISED entrance agenda: OIG Entrance Conference: "National Institutes of Health and

Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)

Good afternoon,

Attached is the revised agenda for next week's entrance conference. The changes reflects the 3rd grant that was added by the OIG (dollar amount and fiscal year) and they added Just in Time Documentation to the document request.

Have a great weekend.

Thanks!

Tiffany Brown
NIH/OD/OMA/RMAL
(b) (6) (Direct)
(301) 402-0169 (Fax)

-----Original Appointment-----
From: Brown, Tiffany (NIH/OD/OMA) [E] (b) (6)
Sent: Thursday, June 24, 2021 10:47 AM
To: Brown, Tiffany (NIH/OD/OMA) [E]; Lauer, Michael (NIH/OD) [E]; Bundesen, Liza (NIH/OD) [E]; Bulls, Michelle G. (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Haskins, Melinda (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Fenton, Matthew (NIH/NIAID) [E]; Linde, Emily (NIH/NIAID) [E]; LaMontagne, Karen (NIH/OD) [E]; Lohmann, Larry (NIH/OD) [E]; Spady, Tyrone (NIH/OD) [E]; Chakraborty, Trisha (NIH/OD) [E]; Tucker, Jessica (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Clark, Tamara (OS/OGC); Yueh, Lena (CDC/OCOO/OGC); Simanich, Sasha (NIH/OD) [E]; Stein, Meredith (NIH/OD) [E]; Valentine, Megan (OS/ASFR); Lewis, Carla J (OIG/OAS); Stitz, Jeffrey D (OIG/OAS); Sin, Kyu (OIG/OAS); Fulcher, Sheri L (OIG/OAS); Barton, Mike M (OIG/OAS); Burbey, Allen (OIG/OAS); Capuano, Joseph G (OIG/OAS); Ullrich, Jack W (OIG/OAS); Sobota, Jennifer M (OIG/OAS); Corcoran, Nancy A (OIG/OAS); Frontz, Amy J (OIG/OAS); Taschenberger, Peter A (OIG/OCIG)
Cc: Showe, Melanie (NIH/OD) [E]; McCaskill, Ronika (NIH/OD) [C]; Jorgenson, Lyric (NIH/OD) [E]; Petruccelli, Anthony J. (HHS/ASFR); Taylor, Geeta (OIG/OCIG)
Subject: OIG Entrance Conference: "National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)
When: Wednesday, June 30, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where:

The OIG will send a modified agenda on June 28th.

NIH Participants:

Michael Lauer, Deputy Director for Extramural Research, Office of Extramural Research (OER)

Liza Bundesen, Special Assistant to Deputy Director for Extramural Research, OER

Michelle Bulls, Director, Office of Policy for Extramural Research Administration (OPERA), OER

Kristen Ta, Senior Advisor, OER/OPERA

Melinda Haskins, Legislative Affairs and Correspondence Management Branch (LACMB), Chief, National Institute of Allergy and Infectious Diseases (NIAID)

Jill Harper, NIAID Deputy Director for Science Management, NIAID

Alan Embry, Chief, Respiratory Diseases Branch (RDB), NIAID

Matthew Fenton, Director of the Division of Extramural Activities (DEA), NIAID

Emily Linde, Director, Grants Management Program, NIAID/DEA

Karen LaMontagne, Legislative Analyst, Office of Legislative Policy & Analysis (OLPA)

Larry Lohman, Legislative Analyst, OLPA

Tyrone Spady, Director, Science Policy Coordination, Collaboration, and Reporting (SPCCR), Office of Science Policy (OSP)

Trisha Chakraborty, Health Science Policy Analyst, OSP/SPCCR

Jessica Tucker, Director, Biosafety, Biosecurity, and Emerging Biotechnology Policy (BBEBP), OSP

Anna Jacobs, Senior Attorney, Office of General Counsel (OGC)

Tamara Clark, Senior Attorney, OGC

Lena Yueh, Senior Attorney, OGC

David Lankford, NIH Legal Advisor, OGC

Meredith Stein, Acting Director, Office of Management Assessment (OMA)

Sasha Simanich, Acting Director, Division of Risk Management and Audit Liaison (RMAL), OMA

Tiffany Brown, Management Analyst, POC for this engagement, OMA/RMAL

HHS Participant:

Megan Valentine, Management and Program Analyst, Assistant Secretary for Financial Resources (ASFR), Health and Human Services (HHS)

Anthony Petruccelli, Policy Analyst, ASFR

OIG Participants:

Carla Lewis, Assistant Inspector General, Office of Audits Services (OAS), Office of Inspector General (OIG)

Sheri Fulcher, Regional Inspector General

Jeffrey Stitz, Assistant Director

Mike Barton, Assistant Regional Inspector General

Allen Burbey, Senior Auditor (Audit Lead)

Joe Capuano, Senior Auditor

Jack Ullrich, Senior Auditor

Kyu Sin, Senior Auditor

Jennifer Sobota – Senior Auditor

Nancy Corcoran, Auditor

Amy Frontz, Deputy Inspector General for Audit Services

Peter Taschenberger, Deputy Branch Chief

Geeta Taylor, Senior Counsel

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Audit of National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees
CIN: A-05-21-00025

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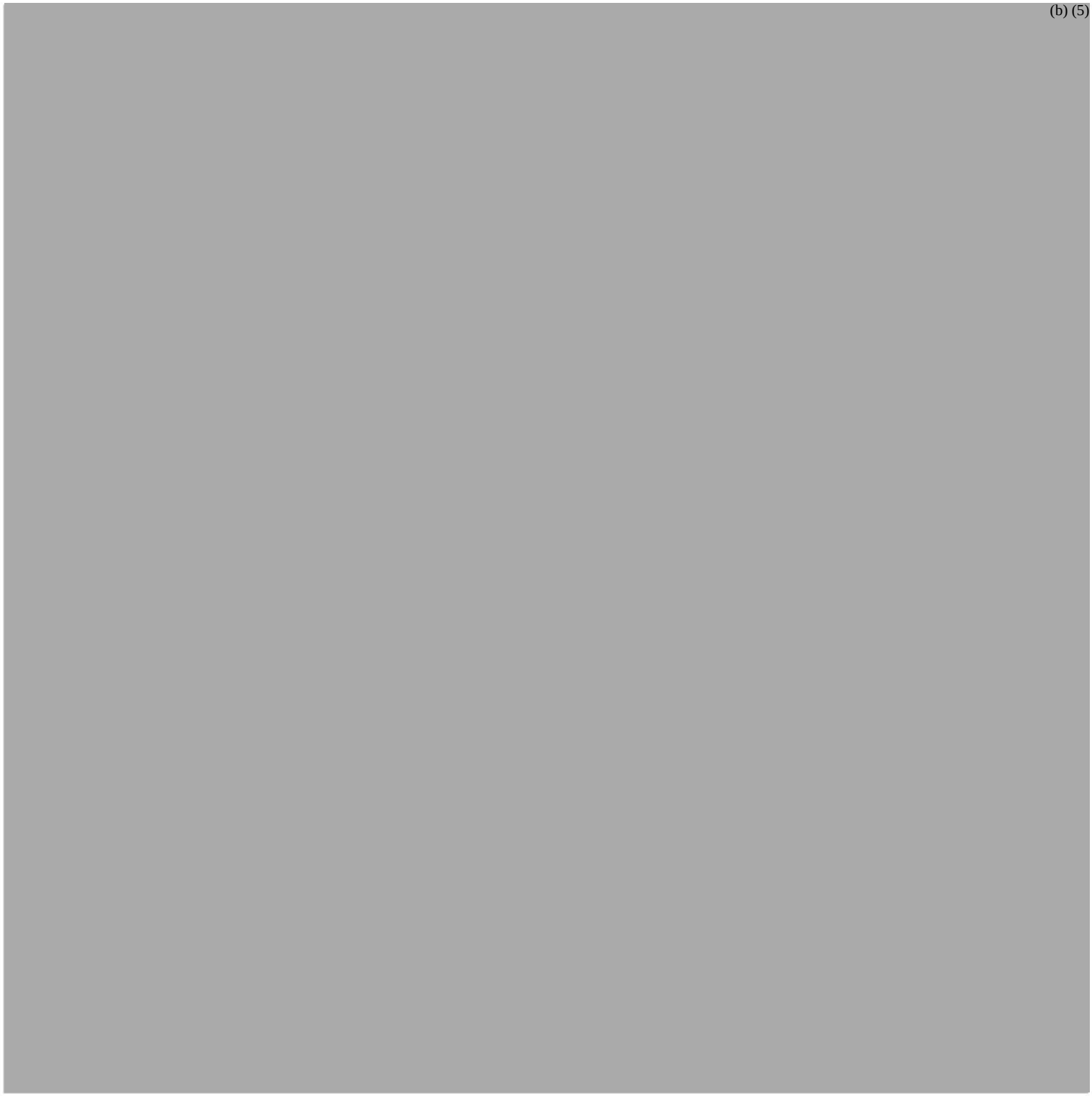

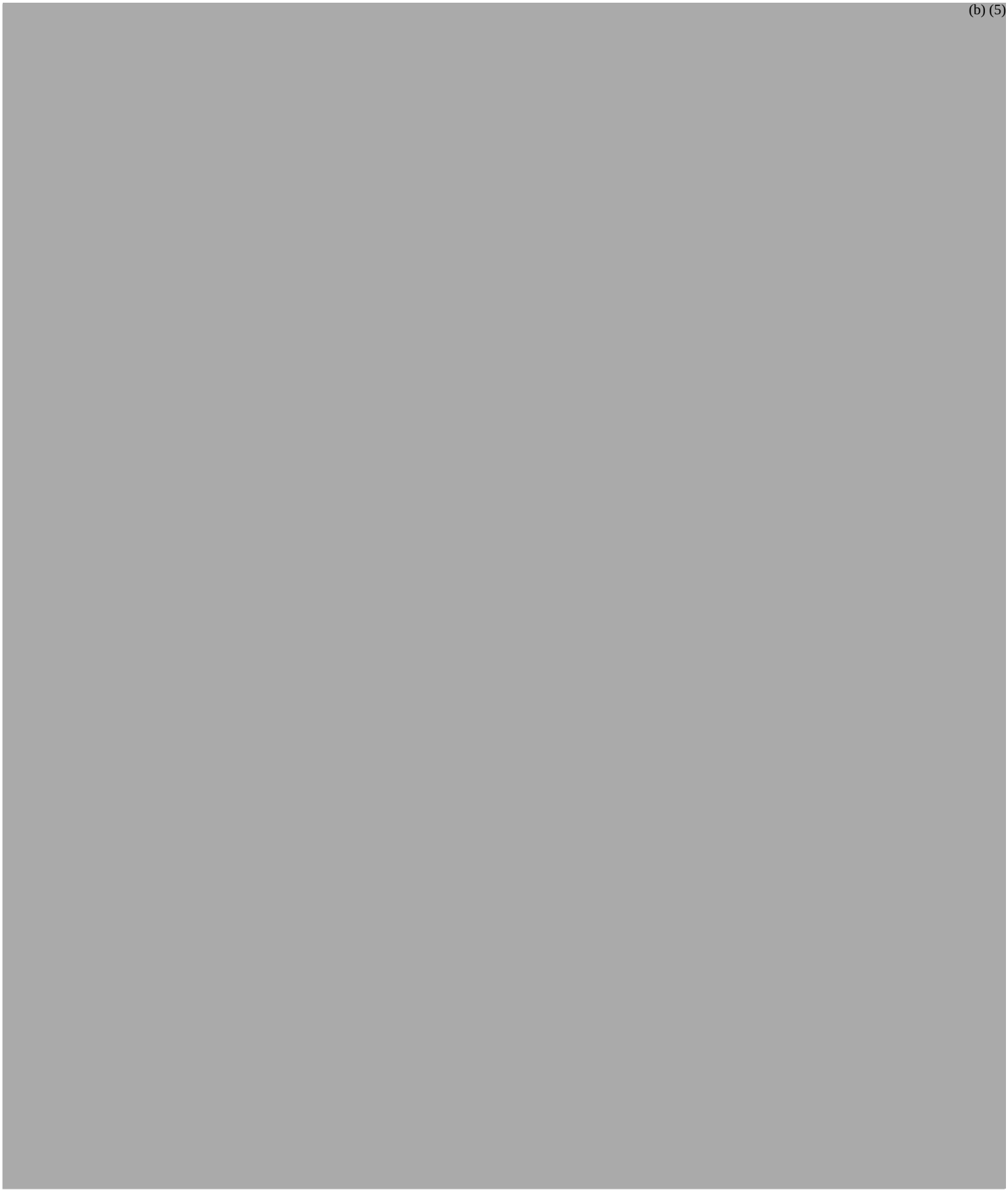

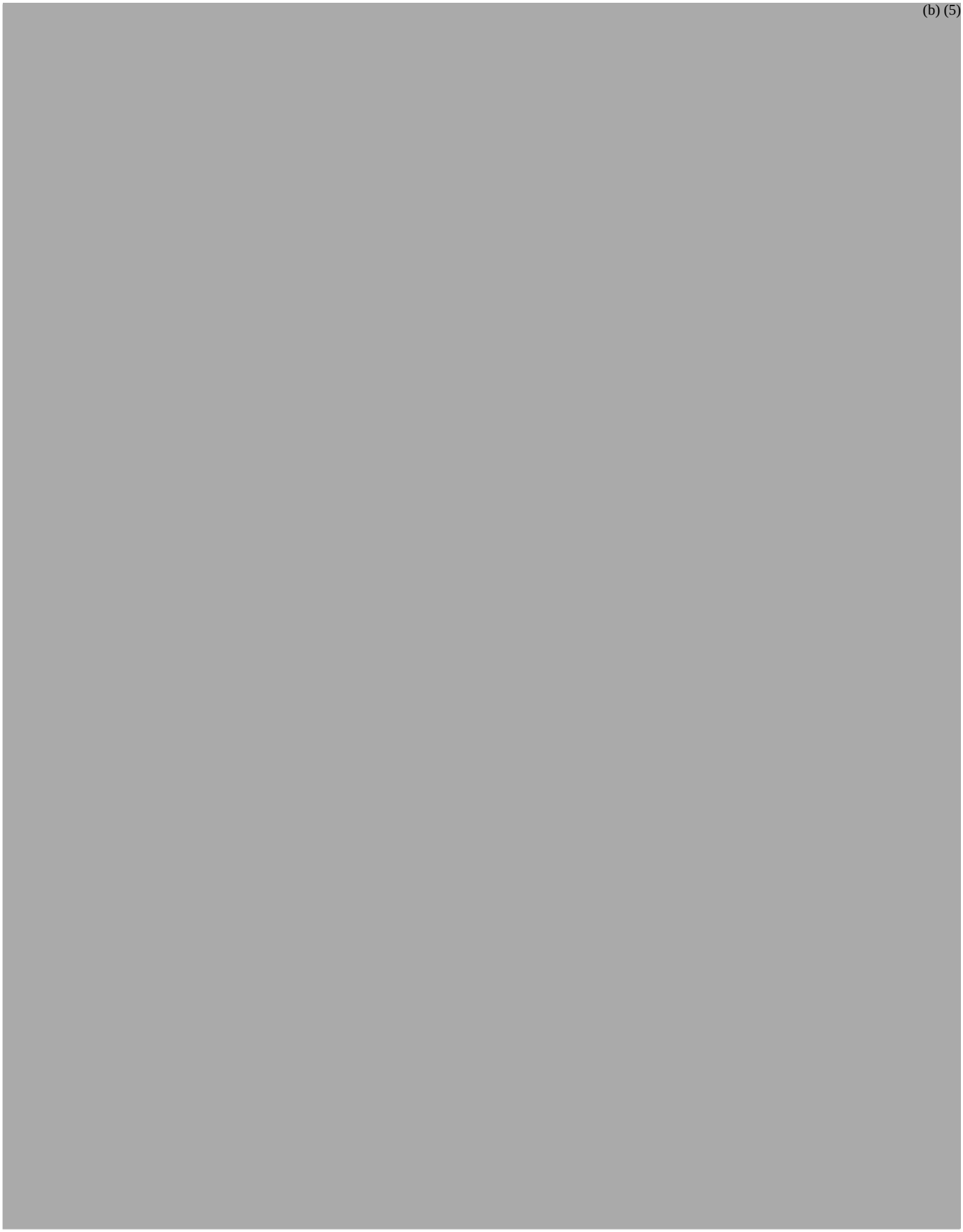
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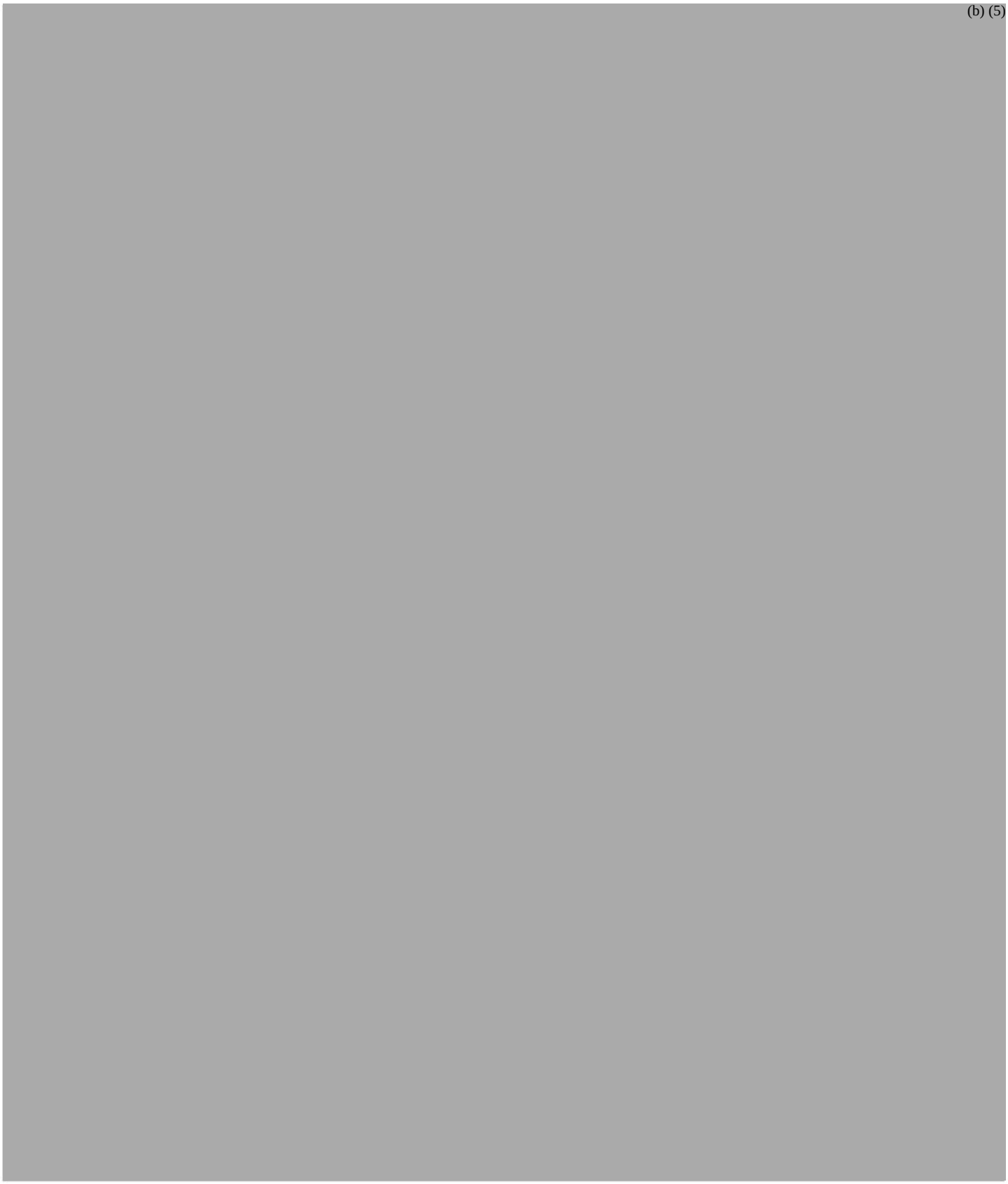

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OPERA assessment of EcoHealth Grants 6 25 21

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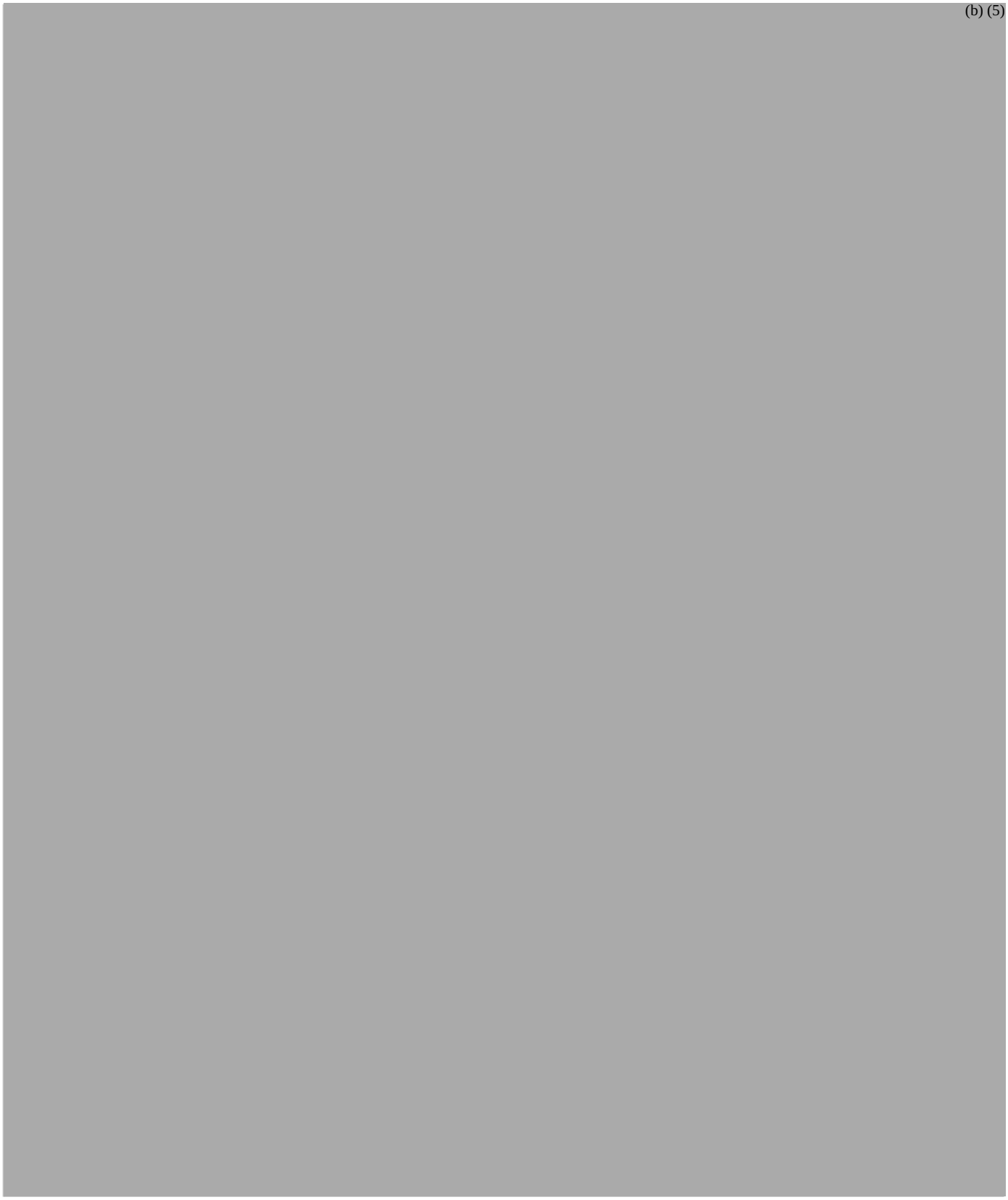

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

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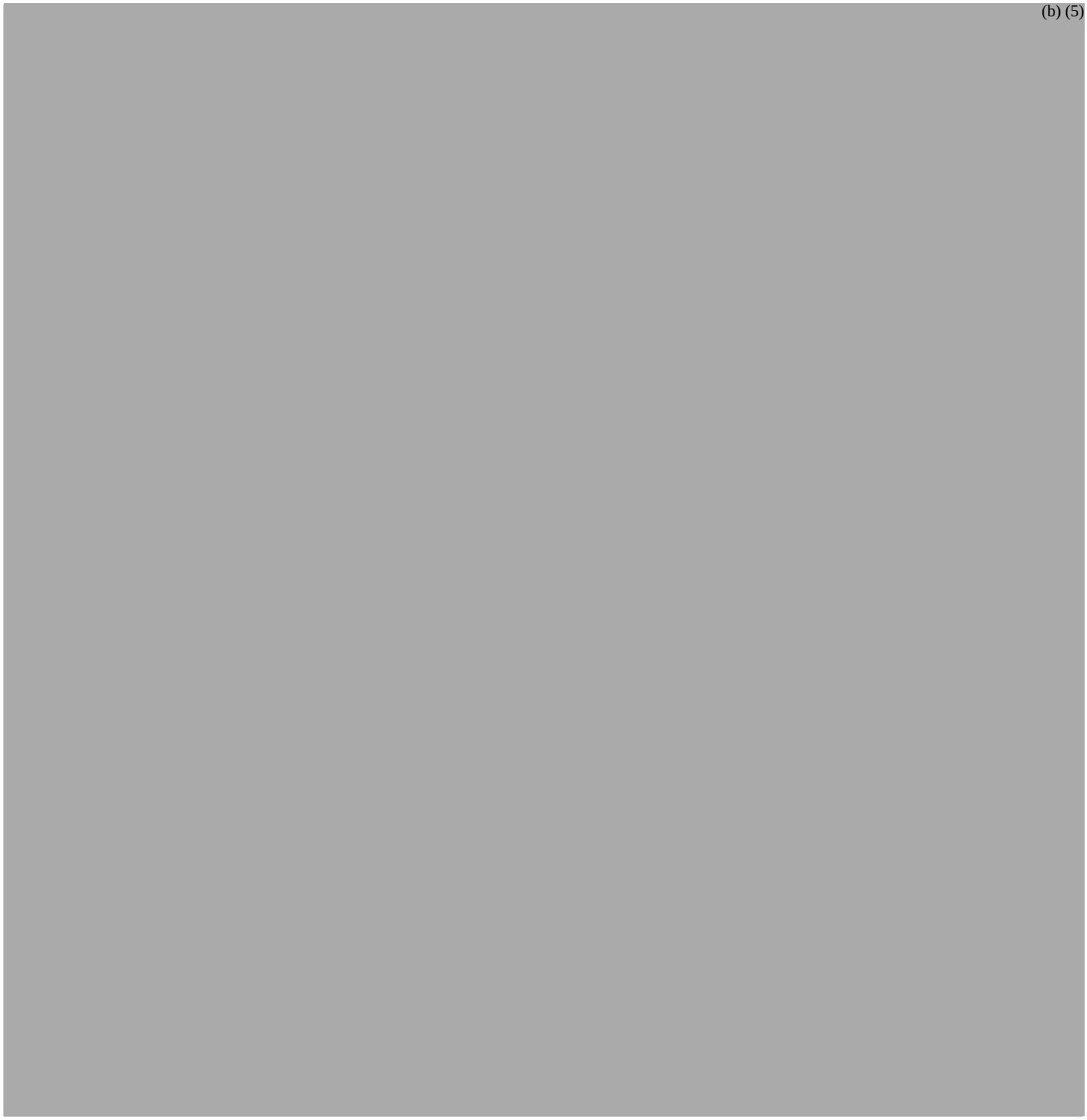

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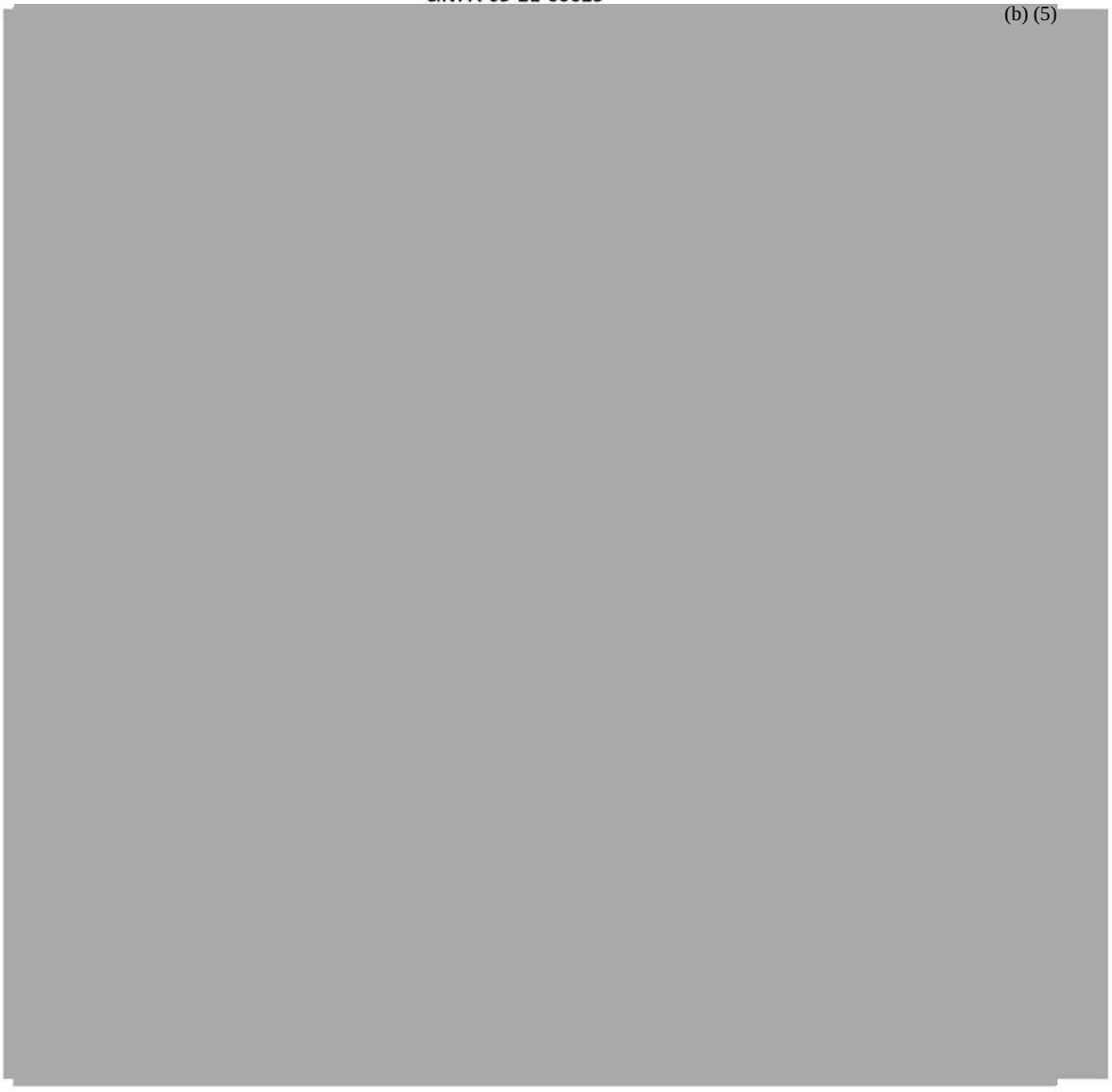

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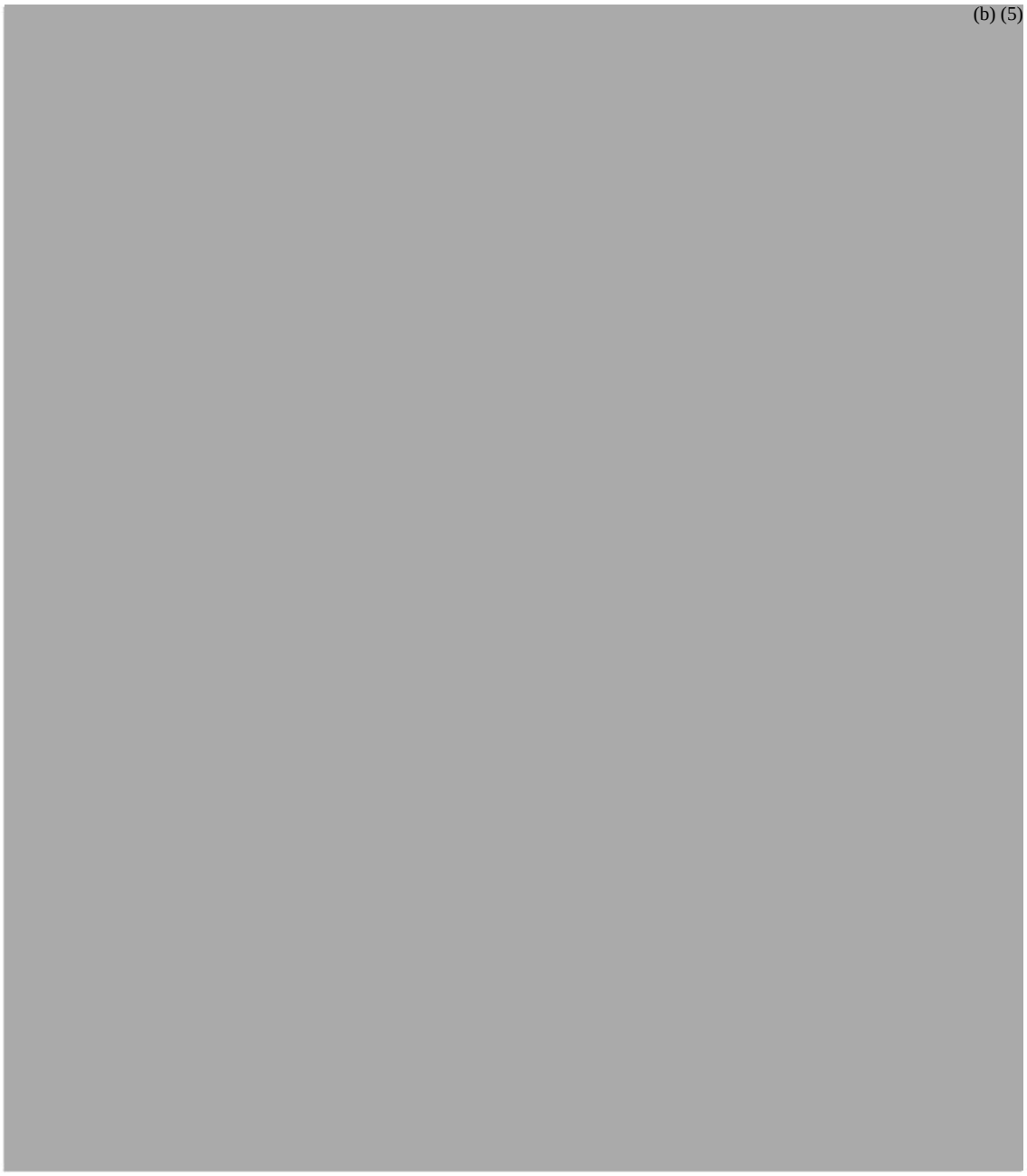

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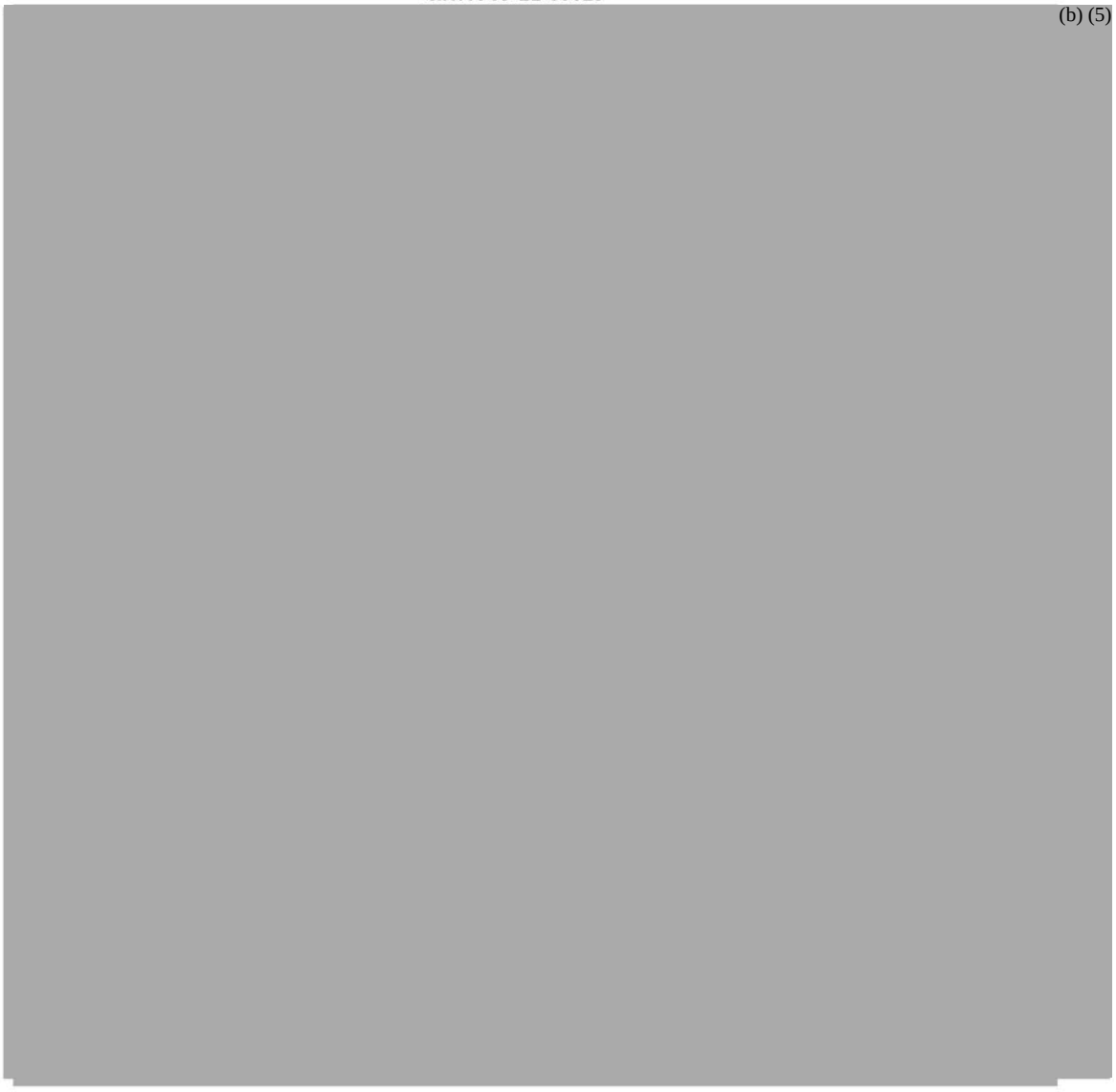

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From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 6/27/2021 4:55:28 PM
To: Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Showe, Melanie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbbbc74184e64f7e8a12d9faf8deb58f-showem]
CC: Casselle, Julia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13031ef577de4ca791adddf09f2f6125-casselleje]; Lohmann, Larry (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f4206cbb2c4d82adbc1eda15e035c4-lohmannll]; Everett, Chris (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10f3011a5ef4472594cc0aef86875864-everettcl]; Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: 6.28 Briefing Packet
Attachments: E&C WIV Response Briefing 6.28.pdf

This is enormously helpful helpful, Adrienne, thanks so much.

Mike

From: "Hallett, Adrienne (NIH/OD) [E]" (b) (6)
Date: Friday, June 25, 2021 at 9:29 AM
To: "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6), "Simon, Dina (NIH/OD) [C]" (b) (6), "Burrus-Shaw, Cyndi (NIH/OD) [E]" (b) (6), "Showe, Melanie (NIH/OD) [E]" (b) (6)
Cc: "Casselle, Julia (NIH/OD) [E]" (b) (6), "Lohmann, Larry (NIH/OD) [E]" (b) (6), "Everett, Chris (NIH/OD) [E]" (b) (6)
Subject: 6.28 Briefing Packet

One fact to note: Diane Cutler is on detail to the Committee from the HHS OIG office. She is planning to attend the briefing.

House Committee on Energy and Commerce Briefing Materials

Logistics:

DATE:	Monday, June 28, 2021
TIME:	3:30 – 4:30 pm
COORDINATES:	BY Video Format TBD
PURPOSE:	NIH Bipartisan Briefing with E&C Committee re EcoHealth
ATTENDEES:	Lawrence Tabak Michael Lauer House E&C Committee Staff Alan Slobodin (Minority) Bijuan "BJ" Koohmaraie (Minority) Diane Cutler (Minority) Kevin McAloon (Majority, tentative) Chris Knauer (Majority, tentative) Larry Lohmann (NIH OLPA) Kelsey Mellette (HHS/ASL) Jenn Schmalz (HHS/ASL) Anne Tatem (HHS/ASL, tentative) Kimberly Espinosa (HHS/ASL, tentative)

Background:

- On March 18, 2021, E&C's Ranking Member Cathy McMorris Rodgers (R-WA), along with two subcommittee Ranking Members (Reps. Guthrie and Griffiths), sent Dr. Collins a letter to investigate the origins of COVID-19.
    - The letter is 11 pages long with 49 questions and sub-questions.
    - NIH sent a narrative response to this letter on May 21, 2021 and offered a briefing.
- On June 10, 2021, E&C's Ranking Member, along with 25 Republican Members, sent Dr. Collins a follow-up letter with 10 additional questions regarding the origins of COVID-19.
- Note: Diane Cutler is on detail to the Committee from the HHS OIG office.

Recommendations:

- The compliance actions the letter asks about are being formally contested so we are advised by OGC:

(b) (5)

(b) (5)

Run of Show:

- HHS ASL staff will open the call and make introductions.
- They will then reiterate the parameters for the call.
    - The briefing is in response to the first letter.
    - The response to the letter from June 10, 2021 is in process.
    - The Call has a hard stop at 1 hour.
- HHS will then hand it over to Dr. Tabak and Dr. Lauer.
- Dr Tabak will open and proceed through the grant timeline (attached).
- Dr. Tabak and Dr. Lauer proceed through the questions from the letter with committee staff.
- Open for Q&A.

Background/Briefing Materials:

- Timeline
- March 18, 2021 letter from E&C
- May 21, 2021 response
- June 10, 2021 letter from E&C
- Staff profiles

Timeline:

At the April 17, 2020 White House coronavirus task force briefing, President Trump announced that the administration would "end that grant very quickly" referring to the 2R01AI110964-06 NIH grant (or "the grant") of which your letter requests information.

On April 19, 2020, NIH sent a letter to the EcoHealth Alliance, the institutional awardee of the grant, ordering the suspension of funds to the Wuhan Institute of Virology ("WIV"), one of the grants sub-recipients.

On April 24, 2020 NIH sent a second letter to EcoHealth Alliance, terminating the grant.

On May 20, 2020, NIH sent a letter to the University of California, Irvine, suspending all activities related to RF1 MH120020-01, Genetically engineered anterograde monosynaptic viral tracers for multi-species neural circuit analysis, Dr. Xiangmin Xu (Contact PI), for which the Wuhan Institute of Virology is a subaward participant, awarded by the National Institute of Mental Health (NIMH).

In June 2020, NIAID awarded grants to new centers for research in emerging infectious diseases; one of the 11 grants was awarded to EcoHealth Alliance.

On July 8, 2020, NIH sent a letter to EcoHealth Alliance (attached), indicating the grant was going to be reinstated. However, funding and activities were suspended pending complete, accurate, and satisfactory return of answers, material, and information regarding a number of specific concerns about biosafety practices at its sub-recipient WIV. Furthermore, EcoHealth Alliance was instructed to correct its repeated noncompliance due to its failure to report all sub-awards in the Federal Subaward Report System. EcoHealth Alliance had been directed in NIH Notices of Award to generate these reports as required by the Transparency Act sub-award and executive compensation reporting requirement of 2 C.F.R. Part 170.

The July 8 letter to EcoHealth Alliance indicated that the suspension of the grant was taken in accordance with 45 C.F.R. § 75.371, which permits suspension of award activities in cases of non-compliance, and the NIH Grants Policy Statement, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable under 42 C.F.R. §50.404 and the NIH GPS Section 8.7.

On August 14, 2020, EcoHealth Alliance responded by letter declining to address any of the seven specific concerns NIH requested in the July 8 letter. The grant has been reinstated with all funding and activities suspended pending EcoHealth Alliance's answers to the government's safety and compliance concerns. As this matter is still pending, no further documentation can be provided at this time.

On October 23, 2020, NIH sent a letter to EcoHealth Alliance in response to their response to suspension. The letter noted that EcoHealth not currently having a subrecipient relationship with WIV and not issuing subawards to WIV at the time of suspension did not absolve EcoHealth of any past non-compliance with the terms and conditions of award for grant R01AI110964.

In April of 2021, EcoHealth Alliance submitted documents in response to the October letter.

On June 11, 2021, the HHS OIG initiated an audit into the EcoHealth Alliance grant and all actions related to it.

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

March 18, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

We write to request information, assistance, and needed-leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.

The COVID-19 pandemic has been the worst public health crisis in the U.S. in about a hundred years. Over a year has passed since the deadly virus reached our shores and yet, the origin of the virus has yet to be determined. An independent, expert investigation of the origin of COVID-19 is of paramount importance to public health and biosecurity. As noted by Stanford Medical School Professor David Relman:

> A more complete understanding of the origins of COVID-19 clearly serves the interests of every person in every country on this planet. It will limit further recriminations and diminish the likelihood of conflict; it will lead to more effective responses to this pandemic, as well as efforts to anticipate and prevent the next one. It will also advance our discussions about risky science. And it will do something else: Delineating COVID-19's origin story will help elucidate the nature of our very precarious coexistence within the biosphere.[1]

Recently, the World Health Organization (WHO) attempted to investigate the origin of COVID-19. The WHO said that this investigative mission would be guided by the science, be

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[1] David A. Relman, *Opinion: To stop the next pandemic, we need to unravel the origins of COVID-19*, PNAS (Nov. 2020), *available at* https://www.pnas.org/content/117/47/29246.

"open-minded," and "not exclude[e] any hypothesis."[2] Unfortunately, China did not provide complete access or independence for the critical WHO mission. On February 13, 2021, National Security Advisor Jake Sullivan issued the following statement:

> We have deep concerns about the way in which the early findings of the COVID-19 investigation were communicated and questions about the process used to reach them. It is imperative that this report be independent, with expert findings free from intervention or alteration by the Chinese government. To better understand this pandemic and prepare for the next one, China must make available its data from the earliest days of the outbreak.[3]

Because of rising tensions between the U.S. and China, the WHO scrapped plans for an interim report.[4] An international group of science experts, including specialists in virology, microbiology, and zoology, asked for a new review.[5]

The NIH, as a premier scientific institution, must lead in order to foster a transparent, independent, and science-based investigation into the origin of the COVID-19 pandemic. Such an effort must meet the WHO's stated goals of an open-minded investigation that does not exclude any plausible hypothesis.[6] In addition, the NIH is well-positioned to gather and provide information through oversight of its grants and other federal awards. Thus, the NIH is in a unique position to investigate the possibility that the pandemic stemmed from a laboratory accident or leak, especially regarding the Wuhan Institute of Virology (WIV).

NIH raised concerns over a possible link between WIV and the COVID-19 outbreak during its review of federal awards to EcoHealth Alliance, a global environmental health nonprofit organization dedicated to protecting wildlife and public health from the emergence of disease. Of the $13.7 million in federal awards that NIH authorized for EcoHealth Alliance, 17

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[2] Smriti Mallapaty, *Where did COVID come from? WHO investigation begins but faces challenges*, NATURE (Nov. 11, 2020), *available at* https://www.nature.com/articles/d41586-020-03165-9.

[3] The White House, Statement of National Security Advisor Jake Sullivan (Feb. 13, 2021), *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/13/statement-by-national-security-advisor-jake-sullivan/.

[4] Betsy McKay, Drew Hinshaw and Jeremy Page, *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, THE WALL STREET JOURNAL (Mar. 4, 2021), *available at* https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067?mod=latest_headlines

[5] Jaime Metzl, et al, *Call for a Full and Unrestricted International Forensic Investigation into the Origins of COVID-19* (March 4, 2021), *available at* https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%20(1).pdf. The co-organizer of the letter and a WHO advisor on human genome editing, Jaime Metzl, PhD, said there is an eighty-five percent chance the pandemic started with an accidental leak from the WIV or Wuhan CDC laboratory, *available at* https://jamiemetzl.com/origins-of-sars-cov-2/. ("I have no definitive way of proving this thesis but the evidence is, in my view, extremely convincing. If forced to place odds on the confidence of my hypothesis, I would say there's an 85% chance the pandemic started with an accidental leak from the Wuhan Institute of Virology or Wuhan CDC and a 15% chance it began in some other way (in fairness, here is an article making the case for a zoonotic jump "in the wild"). If China keeps preventing a full and unrestricted international forensic investigation into the origins of the pandemic, I believe it is fair to deny Beijing the benefit of the doubt.")

[6] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

projects sponsored by the National Institute of Allergy and Infectious Disease (NIAID) have provided over $7.9 million in federal awards for research of viral emergence from bats in Southeast Asia.[7] EcoHealth Alliance passed some of its funding to the WIV, and in 2020, NIH made efforts to obtain information from EcoHealth Alliance about WIV related to concerns about the origins of COVID-19. In April 2020, NIH wrote to EcoHealth Alliance and Columbia University about an NIH-funded project entitled, "Understanding the Risk of Bat Coronavirus Emergency:"

> It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ('WIV'). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs. It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.[8]

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV.[9] Among other revelations, it reported the following:

- The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illnesses. This raises questions about the credibility of WIV senior researcher Shi Zhengli's public claim that there was "zero infection" among the WIV's staff and students of SARS-CoV-2 or SARS-related viruses.[10]

- Starting in at least 2016, WIV researchers conducted experiments involving RaTG13, the bat coronavirus identified by the WIV in January 2020 as the closest sample to SARS-CoV-2 (96.2 percent similar).[11] There was no indication that this research was suspended at any time prior to the COVID-19 outbreak.

- The WIV has a published record of conducting "gain-of-function" research to engineer chimeric viruses.[12] But the WIV has not been transparent or consistent about its record of

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[7] NIH RePORTER, *Research Portfolio Online Reporting Tools* (queried Mar. 4, 2021), *available at* https://reporter.nih.gov/search/qlYUeI9DIk2JfWUdCcWxcA/projects/charts.
[8] Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, NEW YORK POST (Apr. 28, 2020), *available at* https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/.
[9] U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, Office of the Spokesperson (Jan. 15, 2021), *available at* https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology//index.html.
[10] *Id.*
[11] *Id.*
[12] *Id.*

studying viruses similar to the COVID-19 virus, including "RaTG13," which was sampled from a cave in Yunnan Province in 2013 after several miners died of SARS-like illness.[13]

- WHO investigators must have access to the records of the WIV's work on bat and other coronaviruses before the COVID-19 outbreak. As part of a thorough inquiry, they must have a full accounting of why the WIV altered and then removed online records of its work with RaTG13 and other viruses.[14]

- Despite the WIV presenting itself as a civilian institution, the U.S. has determined that the WIV has collaborated on projects with China's military.[15] The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.[16]

- The U.S. and other donors who funded or collaborated on civilian research at the WIV have a right and obligation to determine whether any of our research funding was diverted to secret Chinese military projects at the WIV.[17]

Notably, the State Department's former lead investigator who oversaw the Task Force into the COVID-19 virus origin stated recently that he not only believes the virus escaped from the WIV, but that it may have been the result of research that the Chinese military, or People's Liberation Army, was doing on a bioweapon.[18]

Accordingly, it is imperative to determine not only where SARS-CoV-2 originated, but also how and if NIH's funding and research to projects at the WIV could have contributed to SARS CoV-2. To assist our requests and inquiry, please provide the following by April 19, 2021:

1. An assessment from a classified U.S. Defense Intelligence Agency (DIA) report included the possibility that the origins of SARS CoV-2 could have emerged accidentally from a laboratory in Wuhan, China due to unsafe laboratory practices.[19] The DIA report cited U.S. government and Chinese researchers who found "about 33 percent of the original 41 identified cases did not have direct exposure" to the market.[20] That, along with what is known of the WIV's work in past few years, raised reasonable suspicion that the

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[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

[18] Jennifer Griffin, Former top State Dept. investigator says COVID-19 outbreak may have resulted from bioweapons research accident, Fox News (March 13, 2021), *available at* https://www.foxnews.com/world/top-state-official-coronavirus-bioweapon-accident

[19] Fred Guterl, Naveed Jamali and Tom O'Connor, *The Controversial Experiments ad Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, NEWSWEEK (Apr. 27, 2020), *available at* https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503.
[20] *Id.*

pandemic may have been caused by a lab error, not a wet market.[21] Further, a WHO inspector on the recent mission noted that "we know not all of those first 174 early COVID-19 cases visited the market, including the man diagnosed in December 2019 with the earliest onset date."[22] What information does the NIH have on the earliest COVID-19 cases?

2. According to an editorial on February 23, 2021, in *The Wall Street Journal* by former Secretary of State Mike Pompeo and Miles Yu, "[China's] army of scientists claim to have discovered almost 2,000 new viruses in a little over a decade."[23] How many of these discovered viruses does the NIH have information on and were any of these viruses discovered at the WIV?

3. According to *The Wall Street Journal* editorial mentioned in the previous question, some have alleged that the WIV's virus-carrying animals were sold as pets and may even show up at local wet markets.[24] Is the NIH aware of these allegations? If so, please provide any information the NIH has related to these allegations.

4. Please provide all information that NIH has about laboratory accidents and/or biosafety practices at the WIV since January 1, 2015.

5. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about communications and events at the WIV from August 2019 to the present.

6. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about their communications with China-based NIH, Chinese National Science Foundation, CDC, and China CDC about events at the WIV from August 2019 to the present.

State Department Cables

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[21] *Id.*

[22] Dominic Dwyer, I was the Australian doctor on the WHO's COVID-19 mission to China. Here's what we found about the origins of the coronavirus, THE CONVERSATION (Feb. 21, 2021), *available at*https://www.theguardian.com/commentisfree/2021/feb/22/i-was-on-the-whos-covid-mission-to-china-heres-what-we-found. *See also* Jeremy Page and Drew Hinshaw, *China Refuses to Give WHO Raw Data on Early Covid-19 Cases*, THE WALL STREET JOURNAL (Feb. 12, 2021), *available at* https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580#:~:text=BEIJING%E2%80%94Chinese%20authorities%20refused%20to,over%20the%20lack%20of%20detail. ("Chinese authorities refused to provide World Health Organization investigators with raw, personalized data on early Covid-19 cases that could help them determine how and when the coronavirus first began to spread in China, according to WHO investigators who described heated exchanges over the lack of detail. The Chinese authorities turned down requests to provide such data on 174 cases of Covid-19 that they have identified from the early phase of the outbreak in the Chinese city of Wuhan in December 2019. Investigators are part of a WHO team that this week completed a monthlong mission in China aimed at determining the origins of the pandemic.")

[23] *Id.*

[24] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab,* THE WALL STREET JOURNAL (Feb. 23, 2021), available at https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

7. What information does NIH have about the WIV's responses to the 2018 U.S. Department of State cables (attached to this letter) regarding safety concerns?

8. The April 2018 cable from the U.S. Department of State stated that the WIV planned to invite University of Texas Medical Branch Galveston (UTMBG) researchers to do research in Wuhan's labs. Please provide any information NIH received that indicates whether the WIV invited UTMBG researchers, and whether UTMBG researchers conducted any research in Wuhan's labs.

    a. If there was such research, please provide information and any documents related to this research.

9. Why was it pertinent to the NIH investigation that the "nonprofit [EcoHealth Alliance] must provide the "WIV's responses to the 2018 Department of State cables regarding safety concerns"?[25]

    a. Did EcoHealth Alliance provide this information? If so, how did NIH use the information to further its investigation?

EcoHealth Alliance, Columbia University Health Sciences

10. Was the 2019 NIH federal award to EcoHealth Alliance reviewed and approved by the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) committee?[26]

    a. If so, please provide the documentation with the committee's decision.

    b. Please also provide the names of the individuals who were members of the committee at the time.

11. Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.

12. In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with "program goals and agency priorities."[27] Please specify the work that was done by the EcoHealth Alliance that did

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[25] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[26] National Institutes of Health, *Notice Announcing the Removal of the Funding Pause for Gain-of-Function Research Project* (Dec. 19, 2017), *available at* https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html.
[27] *Id.*

not align with the agency's program goals and priorities, and when that work was conducted.

a. Was an evaluation of EcoHealth Alliance's work and whether it aligned with the agency's program goals and priorities conducted by the NIH before the award was issued? If yes, please provide any related documentation. If not, why not?

13. In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it "received reports that the Wuhan Institute of Virology…has been conducting research at its facilities in China that pose serious bio-safety concerns."[28] What are the sources for those reports to NIH and what were the specific allegations reported?

14. Why did the NIH request that EcoHealth Alliance provide a sample of the pandemic coronavirus that the WIV used to determine its genetic sequence for SARS CoV-2?[29]

a. Why is this information important to NIH's investigation?

b. Has NIH obtained the sample and if so, what evaluations have been done, and for what purpose?

c. If NIH has not yet obtained the sample, what are the planned studies and evaluations NIH will conduct with the sample when it is obtained?

15. What is the nature of NIH's concerns about purported restrictions at the WIV including "diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019[,]" about the WIV lab or virus origin?[30]

a. What is the basis of information to NIH about the purported restrictions at the WIV?

b. What are the other purported restrictions at the WIV in October 2019?

16. After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions.[31]

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[28] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

[29] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.

[30] *Id.*

[31] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

a. Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement.

b. What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?

c. One condition for the federal award reinstatement was for EcoHealth Alliance to arrange for an outside inspection of the WIV and its records, "with specific attention to addressing the question of whether WIV staff had SARS-CoV-2their possession prior to December 2019."[32] Why is it pertinent to the NIH's investigation if staff at WIV had SARS-CoV-2 in their possession prior to December 2019? What is the potential significance if the staff did have the virus in their possession prior to December 2019?

d. What information does NIH have that was used for the basis of requesting that the EcoHealth Alliance "must 'explain the apparent disappearance' of a scientist who worked in the Wuhan lab," and on social media was rumored to be "patient zero" of the pandemic?[33]

    i. What is the potential significance about the whereabouts of this scientist and the photo being removed from the website?

17. Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University.

    a. In an April 2020 email, Dr. Lauer advised Naomi Schrag of Columbia University that it would be helpful for NIH "to know about all China-based participants in this work since the Type 1 grant started in 2014 - who they were and how much money they received."[34] Why did NIH request that Columbia University provide information about all of the China-based participants?

        i. What is the pertinence of the timeframe starting in 2014 for the requested information?

        ii. Did Columbia University provide the NIH with the requested information about all of the China-based participants from all grantees since 2014? If so, please provide the information1. If not, why not?

Federal Funding Records

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[32] *Id.*
[33] *Id.*
[34] Meredith Wadman and Jon Cohen, *NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say*, SCIENCEMAG (Apr. 30, 2020), *available at* https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say.

18. Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support.[35]

19. What is the total amount of NIH federal funding per year from 2017 through 2021 that has directly or indirectly supported the WIV scientists or research through grant recipients, including to EcoHealth Alliance; Wildlife Trust, Inc.; Columbia University Health Sciences; Trustees of Columbia University; University of North Carolina Chapel Hill; Vanderbilt University; University of Virginia; and Oregon Health and Science University?[36]

20. According to a report in *The Washington Post* on April 14, 2020, the WIV issued a news release in English about the final visit from U.S. Embassy scientist diplomats in Beijing, which occurred on March 27, 2018.[37] Does the NIH have a copy of this news release? If so, please provide a copy.

21. For NIH award recipients that have provided support to the WIV since January 1, 2012, please provide annual reports, trip reports related to the WIV, documentation of any survey or field trips by the WIV, and interim data summaries from the WIV.

22. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 where foreign sites for all Type 1 and Type 2 awards have been documented as involving the WIV.

23. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 for NIH domestic grantee awards with a foreign component involving the WIV.

24. Please provide the name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility.

25. Please provide the name(s) of the NIH Scientific Review Officers responsible for reviewing and approving any NIH financial awards to EcoHealth Alliance and any other funding recipients that supported the WIV.

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[35] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

[36] National Institutes of Health, Research Portfolio online Reporting Tools, NIH RePorter *available at* https://report.nih.gov/ (last accessed March 6, 2020).

[37] Josh Rogin, *Opinion: State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses*, THE WASHINGTON POST (Apr. 14, 2020), *available at* https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/.

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.[38] Please provide any information the NIH has on the number of bat samples and animals at the WIV.

    a. Did any NIH scientists who are fluent in Mandarin review the Chinese scientific literature on the WIV research related to coronaviruses that is dated before February 1, 2020?

27. Does the NIH have the unpublished sequences of bat coronaviruses that were maintained in the WIV database before December 30, 2019, or before the database was removed from the internet?[39] Does NIH have the full sequences of the eight viruses sampled in the Yunnan province on an EcoHealth Alliance bat-virus sampling trip in 2015?

    a. Please provide NIH's analysis if the sequences have been analyzed.

    b. If NIH does not have the sequences, can NIH get this information from the EcoHealth Alliance or from other NIH-funded sources?

28. Please provide the original version of "Origin and cross-species transmission of bat coronaviruses in China" that was submitted to *Nature* by EcoHealth Alliance on October 6, 2019, published August 25, 2020, and funded in part by NIAID (award number R01AI110964).[40] If NIH does not have the October 6, 2019 report, can NIH obtain it from EcoHealth Alliance for this response? If so, please provide the report.

29. Have NIH, EcoHealth Alliance, or other NIH award recipient(s) been denied permission or access to results of any WIV research, which indirectly received financial support from NIH awards? If so, please provide the date(s), individuals involved, and circumstances of each denial.

We request that the NIH provide the requested documents and information in a coordinated response from all stakeholders and the appropriate divisions within NIH, including but not limited to subject matter experts from NIH's Division of Security and Emergency Response, the Office of Management Assessment, the Center for Scientific Review, the National Institute of Allergy and Infectious Diseases, and the Office of Extramural Research. After the requested information has been provided, we ask that the NIH provide a briefing to the Minority Committee staff to discuss the information that the NIH has related to the origins of SARS-CoV-2, including any potential links to the WIV. Finally, we request that you appoint an NIH working group representing an appropriate diversity of scientific disciplines to collect data and

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[38] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Feb. 23, 2021), *available at* https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

[39] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

[40] Latinne, A., Hu, B., Olival, K.J. et al,. *Origin and cross-species transmission of bat coronaviruses in China*, Nature (Aug. 25, 2020), *available at* https://www.nature.com/articles/s41467-020-17687-3#Ack1.

information related to COVID-19 origins (including the WIV), and that the NIH working group coordinate and consult with foreign scientific agencies involved in similar work.

Your assistance with this request is greatly appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Health

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Attachment

Cc: The Honorable Frank Pallone, Chairman
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Anna Eshoo, Chair, Subcommittee on Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May 21, 2021

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
Washington, DC 20515

Dear Representative McMorris Rodgers:

Thank you for your letter regarding the National Institutes of Health's (NIH) support for biomedical research related to SARS-CoV-2, "gain of function" (GOF) research, and the NIH grant to the EcoHealth Alliance. As Principal Deputy Director of NIH, I am pleased to respond to your inquiry.

Neither NIH nor the National Institute of Allergy and Infectious Diseases has ever approved any grant that would have supported GOF research on coronaviruses that would have increased their transmissibility or lethality for humans.

Some scientists use the term GOF research broadly to refer to *any* modification of a biological agent that confers new or enhanced activity to that agent. In some cases, this research is performed to give new properties to agents to allow them to grow and be studied in the lab; for example, the agent may be modified so that it can be studied in research animals. However, not all research that some label as GOF research entails the same level of risk. The subset of GOF research that is anticipated to enhance the *transmissibility* and/or *virulence* of potential pandemic pathogens, which could make them more dangerous to humans, has been the subject of substantial scrutiny and deliberation.

In 2017, the U.S. Department of Health and Human Services (HHS) issued its Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework). The HHS P3CO Framework is intended to guide HHS funding decisions on proposed research that is reasonably anticipated to create, transfer, or use Potential Pandemic Pathogens (PPPs) resulting from the enhancement of a pathogen's transmissibility or virulence in humans (enhanced PPP) and seeks to preserve the benefits of life sciences research involving enhanced PPPs while minimizing potential biosafety and biosecurity risks.

As your letter notes and has been publicly stated, NIH awarded a grant to EcoHealth Alliance Inc., a research organization based in New York City, in June 2014. The application was subjected to rigorous peer review and did not propose research to enhance any coronavirus to be more transmissible or virulent.

The research proposed in the grant application sought to understand how bat coronaviruses evolve naturally in the environment to become transmissible to the human population. This

included studying viral diversity in bat reservoirs, surveying people who work in live animal markets or other jobs with high exposure to wildlife for evidence of bat-coronavirus infection, and analyzing data to predict which newly discovered viruses pose the greatest threat to human health. To support its work, EcoHealth made sub-awards to the Wuhan Institute of Virology and other institutions based in East Asia where coronaviruses tend to emerge and are prevalent. NIH is not currently funding the Wuhan Institute of Virology.

I would be happy to further discuss this grant, and this issue, at your convenience. NIH is committed to upholding the highest standards within the conduct of science and the oversight of federal funding.

In conclusion, NIH strongly supports the need for further investigation by the World Health Organization (WHO) into the origins of the SARS-CoV-2 coronavirus. Working with a cross-regional coalition of 13 countries, we urge the WHO to begin the second phase of their study without delay.

Thank you again for the opportunity to address these questions. An identical response has been sent to the co-signers of your letter.

Sincerely,

(b) (6)

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director

cc: The Honorable Frank Pallone
Chairman, House Committee on Energy and Commerce

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

June 10, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins:

As the committee of jurisdiction over public health, the Energy and Commerce Committee has authorizing responsibilities over the U.S. National Institutes of Health (NIH). We strongly support a comprehensive investigation into the origins of the COVID-19 pandemic, including the possibility of an accidental laboratory leak.

The Chinese Communist government has not yet allowed Chinese scientists to cooperate with an investigation into COVID-19 origins, and has admitted to destroying samples and records pertinent to such an investigation.[1] Thus, it is imperative we assemble all data and information in U.S. possession about bat coronavirus research experiments and lab safety protocols from all sources outside of China, particularly from EcoHealth Alliance (EHA). EHA is an NIH grantee who has been involved in bat coronavirus research in China and has issued grant subawards to the Wuhan Institute of Virology (WIV). It is also essential to collect information about the WIV, the laboratory that was conducting bat coronavirus experiments located in Wuhan, China, the epicenter of the COVID-19 outbreak. As a federal cognizant grant-making agency that funded bat coronavirus research at the WIV through EHA awards, NIH is in a unique position to publicly share detailed research reports in its possession. Importantly, NIH has full access to EHA records and EHA has refused to cooperate with our inquiry. Therefore, it is critical for NIH to cooperate with our objective fact-finding investigation as we continue to collect data about U.S. funded bat coronavirus research.

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[1] Josh Chin, *China Told Labs to Destroy Coronavirus Samples to Reduce Safety Risks*, The Wall Street Journal (May 16, 2020) *available at* https://www.wsj.com/articles/china-told-labs-to-destroy-coronavirus-samples-to-reduce-biosafety-risks-11589684291/.

Since the Republican committee leaders March 18, 2021 letter to NIH, our investigation has found a number of additional issues that raise very serious concerns about the adequacy of NIH's oversight of grantees. The following newly found issues appear troubling and given the significance of these concerns, we expect the NIH to respond fully and substantively. Minority committee staff is continuing to work with your staff to schedule an NIH briefing. The NIH should be prepared to address these issues at the briefing, in addition to all of the questions from the March 18, 2021 letter that presently remain unanswered.

1. NIH's Award of $2 million to EHA Despite Grant Suspension

On May 25, 2021, a spokesperson for EHA told Fox Business that its NIH funding is frozen and NIH did not give them guidance on when funds will be unfrozen.[2] EHA's representation about their NIH funding was not forthcoming. NIH terminated grant R01AI110964 to EHA entitled, "Understanding the Risk of Bat Coronavirus Emergence" in April 2020.[3] NIH eventually converted the grant termination to a suspension on July 8, 2020, pending EHA's responses to seven requests from NIH related to WIV's actions. NIH could unfreeze the funding if EHA cooperates with NIH's requests, but apparently EHA has not yet done so. Despite EHA's obstruction of NIH requests, NIH gave new financial awards to EHA in June 2020 and August 2020, totaling $2,127,602.[4] By NIH authorizing new funding to EHA, an NIH-suspended grantee, the NIH undercut its July 8, 2020 suspension and has incentivized its grantees to defy NIH oversight with impunity.

2. NIH's Inadequate Oversight of EHA's Other Support

You testified during a May 25, 2021 Congressional hearing that NIH was, "...of course not aware of other sources of funds or other activities they might have undertaken outside of what our approved grant allowed," when asked about NIH grant recipient EHA, and the WIV, an EHA subaward recipient.[5] Pursuant to the NIH Grants Policy, EHA was required to report all "other support," in-kind contributions such as laboratory space, equipment and supplies, and facilities and other resources for all individuals designated as the Principal Investigator (PI) personnel.[6] Per the NIH grants policy, the grant Principal Investigator Dr. Peter Daszak and EHA were required to report its other research funding sources and activities to NIH.[7] Without

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[2] Fox News, *Biden State Department quietly ended team's work probing COVID origin*, State Department (May 25, 2021) *available at* https://www.foxnews.com/politics/biden-state-department-shut-down-team-covid-origin-investigation.

[3] National Institutes of Health, *Understanding the Risk of Bat Coronavirus Emergence*, REPORTER (last accessed June 2, 2021) *available at* https://reporter.nih.gov/search/p1odLH_U1kyZgyOhClrN2w/project-details/9320765#similar-Projects/.

[4] USASpending.gov, *Cooperative agreement numbers U01AI151797 and U01AI153420*, EcoHealth Alliance available at

[5] House Committee on Appropriations, *FY 2022 Budget Request for the National Institutes of Health*, Hearings (May 25, 2021) *available at* https://appropriations.house.gov/events/hearings/fy-2022-budget-request-for-the-national-institutes-of-health.

[6] National Institutes of Health, Other Support, Grants & Funding (last accessed June 1, 2021) available at https://grants.nih.gov/grants/forms/othersupport.htm.

[7] *Id.*

further details or documentation, your testimony bolsters the notion that NIH oversight is largely ignorant of other awards to the grantee.

3. NIH's Inadequate Oversight of EHA's Delinquent Financial Reports

As the prime recipient of NIH grant R01AI110964, EHA gave a total $598,500 in five subaward transactions to the WIV from 2015 to 2019 for the WIV to, "conduct high-quality testing, sequencing, and analyses of field samples; maintenance of cold-chains from field to lab; ensuring quality control of sample storage and testing; collaborating on scientific publications and programmatic reporting."[8] EHA also gave a total of $201,217.10 in two subaward transactions to the Wuhan University School of Public Health (WUSPH) to "conduct targeted site-analyses, human behavioral surveillance including qualitative and quantitative surveys; analyses of data; collaborating on scientific publications and programmatic reporting," from 2016 through 2017.[9]

EHA is required to report its subawards to GSA's FFATA Subaward Reporting System (FSRS) by the end of the month following the month when the subaward was made.[10] For example, when EHA issued a $133,000 subaward to the WIV on May 29, 2015, EHA was required to report that subaward to FSRS by June 30, 2015.[11] USASpending is the U.S. government's open federal spending data source and when the grant number R01AI110964 data is downloaded, details reveal that EHA did not report subawards for that grant until 2020, even though EHA made subawards starting in 2015.[12] EHA reported all seven subaward transactions for R01AI110964 on July 13, 2020, five days following NIH's July 8, 2020 letter to EHA instructing EHA to ensure EHA reported all subaward data to FSRS.[13] Before the year 2020, only one other EHA subaward grant is reported in USASpending.gov, in which three subaward transactions for NIH grant number R56TW009502 are recorded in 2014.[14] EHA's apparent non-compliance of required financial reporting raises concerns about the adequacy of NIH oversight of NIH grants.

4. NIH's Possible Funding of EHA for Duplicative Research in China

EHA received federal funding as both a prime and sub-recipient not only from NIH, but also from the U.S. Agency for International Development (USAID) for its bat coronavirus research. The project descriptions and research articles are so similar that a distinction between the NIH bat coronavirus research objectives and achievements for the awards to EHA are almost interchangeable with EHA's USAID-funded bat coronavirus research objectives and

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[8] *Id.*
[9] *Id.*
[10] USAspending.gov, *Data Sources,* About (last accessed June 1, 2021), *available at* https://www.usaspending.gov/about.
[11] *Id.*
[12] USASpending.gov, *Advanced Search: Recipient – EcoHealth Alliance* (June 1, 2021) *available at* USASpending.gov/.
[13] *Id.*
[14] *Id.* See NIH grant number R56TW009502.

achievements.[15] The NIH grant progress reports will reveal details about the bat coronavirus research that can be compared to the reports from USAID-funded research. In its research funded by the USAID, EHA partnered with the WIV and with East China Normal University.[16] We are very concerned that the NIH and USAID may have funded duplicate projects and that EHA partnered with additional unreported entities in China for NIH-funded research.

5. NIH's Inadequate Reconciliation of EHA's Grant Subawards

As far back as 2005, Peter Daszak of EHA has authored over 20 bat coronavirus and other zoonic pathogen research articles with Dr. Zhengli Shi of the WIV, plus other researchers, about experiments funded by NIH.[17] Their collaborative research has resulted in a 2005 publication entitled "Bats Are Natural Reservoirs of SARS-Like Coronaviruses," funded by NIH.[18] In 2013, they published "Isolation and characterization of a bat SARS-like coronavirus that uses the ACE2 receptor," funded by NIH and USAID. [19] Their numerous publications acknowledge NIH as a research sponsor yet the only EHA support to the WIV in USASpending.gov was reported by EHA on July 13, 2020 (see concern number three above).[20] Vanity Fair reported that Dr. Shi "herself listed U.S. government grant support of more than $1.2 million on her curriculum vitae: $665,000 from the NIH between 2014 and 2019; and $559,500 over the same period from USAID."[21] EHA's late and potentially incomplete reporting of the WIV as its sub-award recipient raises questions about EHA's compliance with required financial reporting and also raises concerns about NIH's oversight of grant awards to EHA.

6. NIH's Inadequate Oversight of EHA's Place of Performance Reporting

The Federal Funding Accountability and Transparency Act of 2006 (FFATA) requires that federal award reporting must include the primary location of where the work will be performed, (including the city, state, congressional district, and country).[22] For EHA's NIH awards, China is not listed as the place of performance in USASpending.gov and instead, EHA's

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[15] USASpending.gov, *Advanced Search: Recipient – EcoHealth Alliance* (June 1, 2021) *available at* USASpending.gov/.
[16] USAID PREDICT-1 CONSORTIUM, *Reducing Pandemic Risk, Promoting Global Health*, Final Report (Dec. 2014) *available at* https://ohi.sf.ucdavis.edu/sites/g/files/dgvnsk5251/files/files/page/predict-final-report-lo.pdf.
[17] NIH Reporter, *Anthropogenic change & emerging zoonic paramyxoviruses*, Project Number 5R01TW005869-04 (Budget Start Date June 1, 2005) *available at* https://reporter.nih.gov/search/WMYBIQPE20aG4fAZLFj0lw/project-details/6923645#details, NIH National Library of Medicine, *Advanced Search for 'Shi, Daszak,'* National Center for Biotechnology Information (June 2, 2021) *available at* https://pubmed.ncbi.nlm.nih.gov/?term=Daszak%2C+Shi&sort=date&sort_order=asc&size=200.
[18] NIH National Library of Medicine, *Bats Are Natural Reservoirs of SARS-Like Coronaviruses*, PubMed (Sept.5, 2005) *available at* https://pubmed.ncbi.nlm.nih.gov/16195424/.
[19] Ge, XY., *et al., Isolation and characterization of a bat SARS-like coronavirus that uses the ACE2 receptor*, Nature 503, 535–538 (May 16, 2013) *available at* https://doi.org/10.1038/nature12711.
[20] *Id.*
[21] Katherine Eban, The Lab-Leak Theory – Inside the Fight to Uncover COVID-19 Origins, Vanity Fair (June 3, 2021) *available at* https://www.vanityfair.com/news/2021/06/the-lab-leak-theory-inside-the-fight-to-uncover-covid-19s-origins.
[22] PL 109-282, Sept. 26, 2006 *available at* https://www.govinfo.gov/content/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf.

primary place of performance is identified as New York.[23] The NIH grant documents, and the financial and progress reports we have requested will contain travel budgets and research details that will confirm the location(s) where EHA actually performed its research. Published research articles about NIH-funded experiments describe EHA's bat coronavirus research and surveillance activities often partnered with the WIV in China. We are very concerned about the discrepancy in EHA's primary place of performance as being New York in USASpending.gov when research articles, publications, and media interviews suggest EHA's primary place of performance is not domestic.[24]

7. NIH's Lack of Visibility into EHA's Grant Subawards

USASpending.gov limits visible data to prime and subaward recipients, and does not disclose funds that are further disbursed subaward recipients.[25] EHA is a subaward recipient of NIH grant funds from the Arizona State University and the Trustees of Columbia University in New York City.[26] As a subaward recipient, EHA does not publicly report when it further distributes subaward funds to other organizations such as the WIV or other recipients in China.[27] NIH questions to EHA in the July 8, 2020 grant suspension letter suggest that NIH lacks information and visibility on sub-grant awards that are either issued or received by EHA.[28]

8. NIH's Inadequate Oversight of EHA's Grant Fund Accounting

In our April 18, 2021 letter to EHA, we raised the issue that EHA reported a $319,570 cash award grant and a $126,792 cash award grant disbursed by wire to China for the purpose of "[u]understanding the risk of bat coronavirus emergence" on its IRS Form 990, calendar year 2016.[29] EHA reported giving $321,700 for coronavirus and emerging diseases to China on its IRS Form 990, calendar year 2015.[30] EHA IRS Form 990's for other years do not include that purpose or identify the WIV as an organization to which funds were paid. With EHA organized as a 501 (c)(3) non-profit organization, its IRS Form 990's are public documents able to be reviewed by NIH. As a non-federal entity that expends more $750,000 or more in federal funds in one year, EHA is required to submit a Single Audit report, previously known as the OMB Circular A-133 audit. The purpose of a Single Audit report is to provide assurance to the Federal Government that a non-federal entity has adequate internal controls in place, and is generally in

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[23] *Id.*
[24] Nidhi Subbaraman, *'Heinous!': Coronavirus researcher shut down for Wuhan-lab link slams new funding restrictions*, Nature (Aug. 21, 2020), *available at* https://www.nature.com/articles/d41586-020-02473-4.
[25] USASpending.gov, *Advanced Search: Recipient - EcoHealth Alliance* (June 1, 2021) *available at* USASpending.gov/.
[26] *Id.*
[27] *Id.*
[28] Internal Revenue Service, EHA 990 final, Schedule F, Parts I and II (May 3, 2017) *available at* https://apps.irs.gov/pub/epostcard/cor/311726494_201606_990_2017090514700974.pdf.
[29] U.S. Energy and Commerce Republicans, *Letter to EcoHealth Alliance*, The COVID-19 Origins Investigation (Apr. 16, 2021) *available at* https://republicans-energycommerce.house.gov/the-covid-19-origins-investigation/.
[30] Internal Revenue Service, *EHA 990 final 2015, Schedule F, Parts I and II* (May 3, 2017) *available at* https://apps.irs.gov/pub/epostcard/cor/311726494_201606_990_2017090514700974.pdf.

compliance with program requirements.[31] In EHA's Single Audit reports for years 2016 to 2020, no payments are evident for EHA funds paid to the WIV.[32]

9. NIH's Inadequate Oversight of Its Funded Researchers in China

The WIV named NIH and EHA on its website as WIV international partner as of and prior to the date of our March 18, 2021 letter to NIH.[33] By March 22, 2021, the WIV had removed NIH as a partner from its website.[34] The NIH has characterized its relationship Chinese scientists as respectable scientific partners.[35] However, within three days following our letter to NIH which inquired about NIH grants to the WIV, the WIV quickly concealed its long-standing relationship with NIH by deleting evidence of its NIH partnership from its website. This action does not seem consistent with NIH's claim that the WIV and its scientists were a respectable scientific partner. It has been reported that some Chinese scientists working with EHA are current or former members of the People's Liberation Army of China.[36] It has also been reported that the Chinese military were conducting research at the WIV.[37] We are concerned that NIH-funded coronavirus research in China may not have undergone proper biodefense risk analysis.

10. NIH's Lack of Cooperation with Congressional Oversight Inquiry

NIH is supposed to be a transparent institution and the grant documents we requested should be a matter of public record.[38] Contrary to your public statement implying that we asked for "pretty sensitive materials, not quite classified, but getting close to that," the grant documents we requested are releasable to the public per NIH's own policy and should have already been provided to us.[39]

As you are aware, the NIH grant documents and progress reports we requested will include details pertinent to our COVID-19 origins investigation, including information about: all research participants and collaborating organizations; location(s) of work performed; instruments, equipment and monies provided to grant sub-recipients; financial accounting

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[31] U.S. Department of Health and Human Services, *Single Audit* (Apr. 25, 2016) *available at* (https://www.hhs.gov/about/agencies/asfr/data-act-program-management-office/single-audit/index.html.

[32] Federal Audit Clearinghouse, *EcoHealth Alliance, Inc and Wildlife Preservation Trust Int. Single Audit Reports 2017-2021* (June7, 2021) *available at* https://facdissem.census.gov/SearchResults.aspx.

[33] Internet Archive Wayback Machine, *Wuhan Institute of Virology, CAS*, Partnerships (Mar. 18, 2021) *available at* https://web.archive.org/web/20210318052528/http://english.whiov.cas.cn/International_Cooperation2016/Partnerships/.

[34] Internet Archive Wayback Machine, *Wuhan Institute of Virology, CAS*, Partnerships (Mar. 22, 2021) *available at* https://web.archive.org/web/20210322053537/http://english.whiov.cas.cn/International_Cooperation2016/Partnerships/

[35] House Committee on Appropriations, *FY 2022 Budget Request for the National Institutes of Health*, Hearings (May 25, 2021) *available at* https://appropriations.house.gov/events/hearings/fy-2022-budget-request-for-the-national-institutes-of-health.

[36] Alexis, Shi Zhengli: Weaponizing Coronaviruses, with Pentagon Funding, at a Chinese Military Lab, https://enviroshop.com/shi-zhengli-weaponizing-coronaviruses-with-pentagon-funding-at-a-chinese-military-lab/

[37] *Id.*

[38] National Institutes of Health, *NIH Grants Policy Statement*, Policy and Compliance (June 1, 2021) *available at* https://grants.nih.gov/policy/nihgps/index.htm.

[39] *Id.*

reports; research techniques and accomplishments; research products such as: technologies, patent applications, data or databases, physical collections, and models; significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents; and budgetary information and project outcomes.[40]

As the federal grant awarding agency, NIH must have the right of access to any of EHA's documents or other records which are pertinent to NIH federal awards.[41] The NIH grants policy states that the Freedom of Information Act (FOIA) and U.S. Department of Health and Human Services regulations require NIH to release certain grant documents and records requested by members of the public, regardless of the intended use of the information.[42] Per NIH policy, NIH will generally release funded applications and progress reports pursuant to a FOIA request.[43] NIH considers most grant-related information in the application or post-award phases as being public information (emphasis added).[44]

In support of this inquiry and the public interest in the origins of the COVID-19 pandemic, please provide written responses to the following by June 24, 2021:

1. We again renew our request for NIH's immediate compliance with our oversight inquiry for production of the grant documents and progress reports forthwith that we first requested on March 18, 2021.

2. What is NIH's policy for awarding funds to organizations when the organization has NIH grant funds in suspended status and are not cooperating NIH requests? If the NIH permits new award funding under these circumstances, please provide the policy, and explain how such funding does not undercut NIH's ability to oversee grantees and does not incentivize grantees to defy NIH's requests for information.

3. Please explain all oversight steps NIH has taken to ensure EHA's full compliance with federal financial subaward reporting requirements for all NIH grants. Please explain if EHA reported to NIH any subaward recipients other than the WIV or the WUSPH for NIH grant R01AI110964. Please provide all financial records of all NIH funds given to Dr. Zhengli Shi of the WIV.

4. For all NIH awards in which EHA was a subrecipient, please provide a financial accounting of EHA's subawards to the WIV or other organizations in China.

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[40] Hugh Hewitt, *Dr. Francis Collis On The U.S. Funding of the Wuhan Lab and Congressional Oversight,* The Hugh Hewitt Show (June 2, 2021) *available at* https://hughhewitt.com/dr-francis-collins-on-the-u-s-funding-of-the-wuhan-lab-and-congressional-oversight/, National Institutes of Health, *Research Performance Progress Report,* Grants & Funding (May 4, 2021) *available at* https://grants.nih.gov/grants/rppr/index.htm.
[41] *Id.*
[42] National Institutes of Health, *NIH Grants Policy Statement*, Policy and Compliance (June 1, 2021) *available at* https://grants.nih.gov/policy/nihgps/index.htm.
[43] *Id.*
[44] *Id.*

5. How does NIH ensure it does not award unapproved duplicate grants for same or similar research already funded by other agencies, to EHA or other NIH grant recipients? For all NIH awards to EHA, please provide accounting information for EHA subawards to recipients in China.

6. Please explain how NIH has reviewed EHA annual Single Audit reports to ensure how EHA has met program and reporting requirements.

7. How does NIH audit the financial reports submitted to the IRS by its 501(c)(3) non-profit organization grant award recipients to ensure NIH awards are accurately reported? How does NIH ensure its grantees do not act as a pass-through or money laundering provider to send U.S. research funding to China?

8. Please explain NIH's policy for ensuring its awardees accurately report the actual place of research performance. For all NIH-funded research, please provide all China site locations where EHA's work was performed.

9. Please explain if EHA reported its other funding or in-kind support, including awards from federal agency, to NIH. Please explain if EHA reported any support from organizations in China.

10. Did NIH perform a biodefense risk analysis for coronavirus research conducted at the WIV as research with potential for dual use of research concern, pandemic pathogen or bioweapon development, as outlined in the HHS *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*?[45] Please describe NIH's coordination procedures with the U.S. Intelligence Community that are completed before NIH funds research projects in foreign countries with existing biodefense programs.

Please make arrangements to schedule the briefing for Committee staff by June 24, 2021. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff. Thank you for your attention to this request.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Fred Upton
Republican Leader
Subcommittee on Energy

[45] U.S. Department of Health and Human Services, *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*, Science Safety Security (Dec. 2017) *available at* https://www.phe.gov/s3/dualuse/Pages/p3co.aspx.

Bob Latta
Republican Leader
Subcommittee on Communications and Technology

Brett Guthrie
Republican Leader
Subcommittee on Health

David McKinley
Republican Leader
Subcommittee on Environment and Climate Change

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Gus Bilirakis
Republican Leader
Subcommittee on Consumer Protection and Commerce

Michael C. Burgess, M.D.
Member of Congress

Steve Scalise
Member of Congress

Adam Kinzinger
Member of Congress

Bill Johnson
Member of Congress

Billy Long
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Markwayne Mullin
Member of Congress

Richard Hudson
Member of Congress

Tim Walberg
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

Jeff Duncan
Member of Congress

Gary Palmer
Member of Congress

Neal P. Dunn, M.D.
Member of Congress

John Curtis
Member of Congress

Debbie Lesko
Member of Congress

Greg Pence
Member of Congress

Dan Crenshaw
Member of Congress

John Joyce, M.D.
Member of Congress

Kelly Armstrong
Member of Congress

Alan Slobodin
Job Title
Chief Investigative Counsel, Republican/Staff Director, Republican

Education

- **George Washington University Law School**
  - JD
  - 1984
- **Temple University-of The Commonwealth System of Higher Education**
  - BBA, business management, magna cum laude
  - 1979

Career History

- **Chief Investigative Counsel, Republican/Staff Director, Republican** House Subcommittee on Oversight and Investigations

January 2021 - Present

- **Chief Investigative Counsel** House Subcommittee on Oversight and Investigations

January 2019 - January 2021

- **Chief Investigative Counsel** House Subcommittee on Oversight and Investigations

December 2017 - January 2019

- **Chief Investigative Counsel** House Subcommittee on Oversight and Investigations

October 2017 - December 2017

- **Chief Investigative Counsel** House Subcommittee on Oversight and Investigations

2014 - October 2017

- **Deputy Chief Counsel** House Subcommittee on Oversight and Investigations

May 2004 - 2013

- **Senior Counsel, Oversight** House Subcommittee on Oversight and Investigations

1995 - April 2004

- **President and General Counsel, Legal Studies Division** Washington Legal Foundation

1989 - 1995

- **Counsel, Republican** House Subcommittee on Constitution, Civil Rights, and Civil Liberties

1986 - 1989

- **Assistant General Counsel** Washington Legal Foundation

1985 - 1986

- **Attorney** Ross, Dixon and Bell LLP

1984 - 1985

B.J. Koohmaraie
Job Title
Chief Counsel, Republican

Education

- **University of Nebraska College of Law**
  - JD
  - 2014
- **Nebraska Wesleyan University**
  - BS, political science
  - 2011

Career History

- **Chief Counsel, Republican**House Committee on Energy and Commerce

January 2021 - Present

- **Chief Counsel, Republican**House Subcommittee on Oversight and Investigations

February 2021 - Present

- **Coalitions Director/Deputy Chief Counsel**House Committee on Energy and Commerce

June 2020 - January 2021

- **Deputy Chief Counsel**House Subcommittee on Consumer Protection and Commerce

August 2019 - June 2020

- **Counsel**House Subcommittee on Consumer Protection and Commerce

January 2019 - August 2019

- **Counsel**House Subcommittee on Consumer Protection and Commerce

March 2017 - January 2019

- **Assistant Attorney General**Nebraska Office of the Attorney General

September 2014 - February 2017

- **Senior Certified Law Clerk**Nebraska Office of the Attorney General

March 2013 - September 2014

- **Research Assistant**University of Nebraska College of Law

August 2012 - May 2013

- **Regulatory Policy Intern**American Action Forum

May 2012 - August 2012

- **Staff Assistant**Rep. Adrian Smith (R-NE-3)

May 2010 - July 2011

- **Intern** Rep. Adrian Smith (R-NE-3)

April 2010 - May 2010

Diane Cutler
Job Title
U.S. Department of Health and Human Services Office of Inspector General Detailee

Career History

- **U.S. Department of Health and Human Services Office of Inspector General Detailee** House Committee on Energy and Commerce

January 2021 - Present

- **U.S. Department of Health and Human Services Office of Inspector General Detailee** House Committee on Energy and Commerce

August 2019 - January 2021

Chris Knauer
Job Title
Oversight Staff Director, Democratic

Education

- **McCourt School of Public Policy**
  - MPP
  - 1990
- **University of California Berkeley**
  - BA
  - 1987

Career History

- **Oversight Staff Director, Democratic** House Subcommittee on Oversight and Investigations

March 2015 - Present

- **Senior Investigator** House Committee on Oversight and Reform

January 2012 - February 2015

- **Investigator** House Committee on Oversight and Reform

January 2011 - January 2012

- **Senior Investigator** House Committee on Oversight and Reform

September 2009 - January 2011

- **Education Coordinator** House Committee on Oversight and Reform

August 2009 - August 2009

- **Senior Investigative Counsel** House Committee on Oversight and Reform

March 2009 - August 2009

- **Senior Investigator/Professional Staff Member** House Committee on Energy and Commerce

March 2007 - February 2009

- **Senior Investigator** House Committee on Energy and Commerce

January 2007 - February 2007

- **Investigator** House Committee on Energy and Commerce

1993 - January 2007

- **Evaluator** U.S. Government Accountability Office

1991 - 1993

Kevin McAloon
Job Title
Oversight Investigator, Democratic

Education

- **Villanova University**
  - MA, political science
  - 2009
- **Villanova University**
  - BA, political science
  - 2008

Career History

- **Oversight Investigator** House Subcommittee on Oversight and Investigations

January 2019 - Present

- **Professional Staff Member** House Committee on Energy and Commerce

March 2017 - January 2019

- **Senior Communications Analyst** U.S. Government Accountability Office

June 2015 - March 2017

- **Program Analyst Team Leader** U.S. Department of Health and Human Services Office of the Inspector General

February 2008 - May 2015

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TO: THE DIRECTOR AND SENIOR STAFF

DATE: FRIDAY, JULY 2, 2021 7:30 AM EDT

TODAY'S EDITION

Health & Medical News

Global Health News

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National Front Page News

Last Laughs

National News

Holiday Message. In observance of the U.S. federal Independence Day holiday, we will not publish on Monday, July 5, 2021. Service will resume on Tuesday, July 6, 2021. We wish our readers a safe and happy holiday.

NIH News

CDC: Covid Cases Up 10 Percent As 'Hypertransmissible' Delta Variant Spreads.

NBC News (7/1, Edwards, 4.91M) reports "the number of Covid-19 cases in the United States rose 10 percent this week as the highly contagious delta variant gained further ground, the Centers for Disease Control and Prevention said Thursday." The US' "lagging vaccination rate coupled with the 'hypertransmissible delta variant,' first detected in India, could account for the increase, CDC Director Dr. Rochelle Walensky said during a White House briefing." The vaccines are effective "against all the variants in the U.S., including the delta variant, Dr. Anthony Fauci, director of the National [Institute] of Allergy and Infectious Diseases, said during the briefing."

Additional Sources. Politico (7/1, Banco, Cancryn, Goldberg, 6.73M) reports "Walensky issued her gravest warning yet Thursday about the highly contagious Delta variant, which has driven a sharp increase in new Covid-19 cases across the country." Almost 25% "of new infections have been linked to Delta, she said, up from 6 percent in early June." Walensky said, "Looking state by state and county by [county] it is clear communities where people remain unvaccinated are communities that are vulnerable."

Fox News (7/1, Wulfsohn, 23.99M) reports "members of the media are sounding the alarm on the Delta variant of the coronavirus that has been surging in recent weeks." For example, "MSNBC anchor Chuck Todd informed viewers of 'breaking coronavirus news' as the country is 'moving in the wrong direction' in combatting the pandemic."

The New York Daily News (7/1, Goldiner, 2.51M) reports "Walensky said areas with low vaccination rates are quickly turning into hot spots even as the overall national picture remains very hopeful."

ABC News (7/2, Schumaker, 2.44M) reports on "how to approach masking this summer, as the delta variant continues to spread." According to ABC, "the best evidence we have" suggests "it's safe for fully vaccinated people to forgo masks indoors this summer."

Among other news outlets reporting on the story are ABC World News Tonight (7/1, story 3, 2:25, Davis, 5.71M), the CBS Evening News (7/1, story 4, 2:15, O'Donnell, 3.63M), and NBC Nightly News (7/1, story 3, 2:00, Holt, 4.7M).

Analyses: Delta Variant Exploiting Undervaccinated Populations To Reinfect Countries. The AP (7/1, Neergaard) examines the rapidly growing reach of the Delta coronavirus variant, which "is exploiting low global vaccination rates and a rush to ease pandemic restrictions, adding new urgency to the drive to get more shots in arms and slow its supercharged spread." While existing vaccines "appear to offer strong protection against the highly contagious delta variant," the virus "poses the most danger in countries where vaccinations are sparse." CDC Director Rochelle Walensky said on Thursday, "Any suffering or death from COVID-19 is tragic. With vaccines available across the country, the suffering and loss we are now seeing is nearly entirely avoidable."

In a similar analysis, the Washington Post (7/1, Alemany, 10.52M) says the Delta variant "is rapidly spreading through unvaccinated areas" of the US as the Biden Administration falls short of its July 4 vaccination goal of having vaccinated at least 70% of US adults. NIAID Director Anthony Fauci on Tuesday said "there is a danger – a real danger – that if there is a persistence of a recalcitrance to getting vaccinated, that you could see localized surges." Meanwhile, former FDA Commissioner Scott Gottlieb "said Sunday that a fall surge could occur even if 75 percent of the eligible population is vaccinated."

White House Launches 'Surge Response' Teams To Delta Variant Hot Spots.

The Washington Post (7/1, Diamond, 10.52M) reports on Thursday, the Biden Administration "announced the formation of 'surge response' teams intended to combat the fast-moving delta variant of the coronavirus by deploying additional expertise and supplies to hot spots." White House coronavirus coordinator Jeff Zients said, "These are dedicated teams working with communities at higher risk for, or already experiencing, outbreaks due to the spread of the delta variant and their low vaccination rate." The Delta variant is already the dominant strain in several states. CDC Director Dr. Rochelle Walensky stated, "In some regions of the country, nearly one in two sequences is the delta variant." Meanwhile, NIAID Director Dr. Anthony Fauci called the variant the "greatest threat" to eradicating COVID-19 in the US.

Additional Sources. CNBC (7/1, Lovelace, 7.34M) reports that these "teams, comprised of officials from the Centers for Disease Control and Prevention and other federal agencies, will work with communities at higher risk of experiencing outbreaks and will focus on increasing the rate of Covid-19 vaccinations, White House Covid czar Jeff Zients said."

CNN (7/1, Collins, Sullivan, 89.21M) reports, "The White House has deployed similar response teams in the past, but this is the first time they are focused on the Delta variant, a White House official said."

Reuters (7/1, O'Donnell, Shalal) reports, "The speedy U.S. vaccination campaign has dramatically reduced COVID-19 cases among residents." However, the number of new cases linked to the Delta variant is increasing.

Among other news outlets covering the story are The Hill (7/1, Weixel, 5.69M), the New York Post (7/1, Moore, 7.45M), Bloomberg (7/1, 3.57M), and Axios (7/1, Fernandez, 1.26M).

CDC Mask Recommendations For Vaccinated Individuals 'Remains Unchanged,' Fauci Says.

Fox News (7/1, Hein, 23.99M) reports CDC "guidance that states fully vaccinated people no longer need to wear masks in indoor or outdoor settings 'remains unchanged,' Dr. Anthony Fauci said Thursday." Questioned "about changing guidance issued by the WHO and even Los Angeles officials," Fauci "said the agency made its 'broad recommendation' based on the efficacy of COVID-19 vaccines." Fauci stated, "As I was alluding to in my comments, you have a broad recommendation for the country as a whole, which is CDC recommendation that if you are vaccinated, you have a high degree of protection, so you need not wear a mask whether indoor or outdoor." The article mentions CDC Director Dr. Rochelle Walensky.

Additional Source. US News & World Report (7/1, Smith-Schoenwalder, 1.91M) also covers the story.

J&J Covid-19 Vaccine Shows Promising Preliminary Signs Of Protecting Against Delta Variant.

The Wall Street Journal (7/1, Cooper, Subscription Publication, 8.41M) reports that the Johnson & Johnson COVID-19 vaccine showed promise in a lab study against the Delta variant, the company said. The shot prompted a strong immune response in eight blood samples, J&J said Thursday.

Additional Sources. The Washington Post (7/1, Ang, 10.52M) reports "blood samples obtained from eight inoculated people who participated in a laboratory study showed that Johnson & Johnson's single-dose shot generated a strong immune response against the delta variant, the New Brunswick, N.J.-based company said." However, "the results have not been peer reviewed."

The New York Times (7/1, Mandavilli, 20.6M) reports the vaccine is effective against the "variant, even eight months after inoculation, the company reported." The J&J "vaccine showed a small drop in potency against the variant, compared with its effectiveness against the original virus, the company said." However, "the vaccine was more effective against the Delta variant than the Beta variant, first identified in South Africa – the pattern also seen with mRNA vaccines."

Bloomberg (7/1, Griffin, 3.57M) reports Johan Van Hoof, J&J's global head of infectious diseases and vaccines, said, "We're extremely happy, actually, and confident there's no need for the booster at the moment and we're protected against different strains." The vaccine "neutralized the delta variant within 29 days of a first dose, and protection matured and improved over time, the company said."

CNN (7/1, Fox, 89.21M) reports "the company said one dose of the vaccine elicits both a lasting antibody response and generates immune cells called T-cells that last eight months." NIAID Director Anthony Fauci said, "With regard to the idea of boosting, there's a lot of talk about that – but right now I think we still need to remember that in fact, the J&J vaccine is a highly effective vaccine that has been recommended very clearly and has received an emergency use authorization." J&J and NIH are "testing to see whether giving people two doses of its vaccine will provide better protection."

The Hill (7/1, Williams, 5.69M) reports "Johnson & Johnson said Thursday in its statement that the data for the company's vaccine came from two studies." CDC Director Rochelle Walensky is mentioned.

Also reporting on the story are Reuters (7/1, Bhalla) and the Boston Globe (7/1, Saltzman, 1.04M).

Covid-19 Global Updates Coronavirus Cases Rise In Europe For First Time In 10 Weeks As Delta Variant Spreads.

The Washington Post (7/1, Cunningham, 10.52M) reports, "The number of new coronavirus cases increased across Europe for the first time in 10 weeks, the World Health Organization said Thursday, ending a stretch that had raised hopes the pandemic would recede as vaccinations were on the rise." New cases rose "10 percent during the past week in the 53 countries that make up the WHO European region, the agency's regional director for Europe, Hans Kluge, said in a briefing."

Additional Sources. Forbes (7/1, Hart, 10.33M) reports, "Dr. Hans Kluge, the WHO's European director, told reporters the three conditions needed for a deadly new wave – low vaccination levels, increased social mixing and new coronavirus variants – were now in place." Even with "valiant efforts, Kluge said not nearly enough people across the region have yet been vaccinated against the disease to safeguard against new outbreaks, with 63% still waiting for

their first shot." The piece mentions NIAID Director Dr. Anthony Fauci.

The Hill (7/1, Choi, 5.69M) also covers the story.

Columbia Professor Who Thanked Fauci For Wuhan Lab Messaging Maintains Close Ties To China. Fox News (7/1, Schoffstall, 23.99M) reports Walter Ian Lipkin, "a Columbia University professor who expressed his gratitude to Dr. Anthony Fauci for downplaying the possibility that COVID-19 leaked from the Wuhan Institute of Virology, maintains close ties to China, including Chinese Communist Party members." The professor, who is considered "a 'virus hunter,' thanked Fauci last year for publicly dismissing notions that the virus could have originated and leaked from the Wuhan lab."

The Delta And Delta Plus Variants: Everything You Need To Know. NBC News (7/2, Chow, 4.91M) reports the more contagious Delta variant of coronavirus is spreading in the US "and around the world, causing a surge of cases in some countries and prompting several nations to introduce new lockdowns." The variant "now accounts for 25 percent of new Covid-19 cases in the U.S., and is on track to become the dominant version of the virus circulating in the country, according to the Centers for Disease Control and Prevention." In a news briefing, NIAID Director Dr. Anthony Fauci last week "called the delta variant the 'greatest threat' to eliminating Covid-19 in the U.S."

Biden's First Big Social Event To Mark 'Summer Of Joy' As Pandemic Risk Remains In Some Places. USA Today (7/2, Groppe, 12.7M) reports, "President Joe Biden is hosting his first large social gathering on the White House lawn Sunday, an event meant in part to signal that life is getting back to normal after more than a year of social distancing." The article adds, "The Independence Day celebration on the South Lawn...comes at a time when other countries are masking up and locking down as a more contagious variant of COVID-19 spreads." In the US, "coronavirus rates are rising in some areas with low vaccination rates." CDC Director Dr. Rochelle Walensky said Thursday, "We expect to see increased transmission in these communities, unless we can vaccinate more people now." Still, White House coronavirus coordinator Jeff Zients and NIAID Director Dr. Anthony Fauci "said it's appropriate for the nation to recognize, through Sunday's White House event, the progress made."

'Now We Are Trying To Figure Out How To Live With It': Inside Biden's Push To Crush Covid. The Washington Post (7/1, 10.52M) reports on the Biden Administration's efforts to combat the COVID-19 pandemic. White House coronavirus coordinator Jeff "Zients and his Covid-19 Response Team had considered how to rebuild trust in government, set up mass vaccination sites, reopen schools and deal with racial inequities exacerbated by a global pandemic." The Biden team "has put all its effort into making the barriers to vaccination low enough that it can nudge people over them." Meanwhile, "Anthony Fauci, Biden's chief medical adviser, said that for the country to be where it is today despite the obstacles is itself 'an enormous accomplishment.'" Fauci told the Post, "I would think if we get to 68 percent on an average, that should not be interpreted as failing anything."

Local Officials Sound The Alarm Over Another Possible Wave Of Covid-19 Infections. CNN (7/2, Elamroussi, 89.21M) reports, "Local officials are sounding the alarm over an increase in Covid-19 infections just as the nation prepares to celebrate a Fourth of July holiday that many hoped would mark the start of the resumption of normal life." CDC Director Dr. Rochelle Walensky notes that the US has seen a 10% overall increase in the seven-day average of COVID-19 cases. Meanwhile, NIAID Director "Dr. Anthony Fauci offered a glimmer of good news ahead of the holiday: Americans can celebrate with the proper precautions, he said." Fauci said, "That is, if you were vaccinated, you have a high degree of protection. If you are not, you should wear a mask, and you should think very seriously about getting vaccinated."

J.D. Vance Joins Already Chaotic Ohio Senate Primary. Politico (7/1, Arkin, 6.73M) reports venture capitalist and best-selling author J.D. Vance (R) "officially launched his campaign Thursday, joining the crowded race to replace retiring GOP Sen. Rob Portman." During a rally in his home town of Middletown, Ohio, Vance "echoed themes from his book," "Hillbilly Elegy," talking about "his family and community. But he also hit on a handful of major issues for conservatives that have already played a central role in Senate primaries, including railing against critical race theory, attacking the Biden administration's border policies and criticizing Dr. Anthony Fauci." Vance "enters the race with some name ID for a first-time candidate," but "he will also have to grapple with his past criticisms of [former President Donald] Trump from 2016."

1,000 Counties In The U.S. Have Covid Vaccination Coverage Of Less Than 30%, CDC Says. CNBC (7/1, Mendez, 7.34M) reports some "1,000 counties in the United States have vaccination coverage of less than 30%, the director of the Centers for Disease Control and Prevention said Thursday." These areas "are mostly located in the Southeast and Midwest and are most

vulnerable to Covid infection, according to CDC Director Dr. Rochelle Walensky." The CDC "is already seeing increasing rates of disease in these counties due to further spread of the more transmissible delta variant, Walensky said." The article mentions NIAID Director Dr. Anthony Fauci.

Reports Of Some Getting Pfizer, Moderna 'Boosters' After J&J Vaccine Prompts Calls For More Guidance. US News & World Report (7/1, Cirruzzo, Smith-Schoenwalder, 1.91M) says that as concerns mount over the Delta variant, many who received Johnson & Johnson's single-dose coronavirus vaccine are "looking for ways to boost protection." Several "respected infectious disease experts have taken the Pfizer or Moderna booster shot plunge, too." According to the article, "In a recent podcast episode, Andy Slavitt, former senior White House adviser on the COVID-19 response, said he asked [NIAID Director Anthony] Fauci, [CDC Director Rochelle] Walensky and seven clinicians treating patients for their advice on mixing vaccine doses for people who received the J&J shot and are worried about the delta variant." Slavitt "said those people have two options: do nothing and wait for the next available data or receive an mRNA shot, like a Pfizer or Moderna" shot.

Delta Variant Causes New Lockdowns And Coronavirus Restrictions Across The Globe. The Los Angeles Times (7/1, Tebor, 3.37M) reports the Delta coronavirus "variant's quick spread globally is causing countries to again take precautions such as reinstating lockdowns, travel restrictions, curfews and mask mandates, medical and government officials said." The Delta "variant has been identified in at least 96 countries, according to the World Health Organization." A recent study "found that getting both doses of the Pfizer-BioNTech vaccine was 88% effective at preventing COVID-19 caused by the Delta variant, while two doses of the [AstraZeneca] vaccine were 60% effective, Dr. Anthony Fauci said at a briefing by the White House COVID-19 Response Team."

Growing Alarm Over Highly Contagious Delta Variant In L.A. County As Cases Keep Rising. The Los Angeles Times (7/1, Money, Lin, 3.37M) reports "Los Angeles County's top public health official expressed growing alarm about increasing circulation of the highly contagious Delta variant of the coronavirus, particularly as the region grapples with an uptick in new infections." Although the situation "is nowhere near as dire as over the fall and winter, Public Health Director Barbara Ferrer said the increases seen recently are nevertheless concerning – and are at the heart of this week's recommendation that even residents vaccinated for COVID-19 should resume wearing face coverings in public indoor settings as a precaution." CDC Director Rochelle Walensky stated, "With vaccines available across the country, the suffering and loss we are now seeing is nearly entirely avoidable." NIAID Director Anthony Fauci is mentioned.

St. Louis Area Health Officials Urge All Residents To Wear Masks Indoors As Delta Variant Takes Hold. The St. Louis Post-Dispatch (7/1, Munz, 694K) reports, "Health officials for St. Louis, St. Louis County and Jefferson County are recommending that all residents, regardless of vaccine status, wear a mask during indoor gatherings as the more infectious and dangerous delta variant takes hold across Missouri."

Additional Source. The Hill (7/1, Coleman, 5.69M) reports that on Thursday, NIAID Director Anthony Fauci said, "People at the local level depending on the on-ground situation will make recommendations or not according to the local situation." He added, "But the broad recommendation that the CDC makes based on the high degree of effectiveness of the vaccine remains unchanged."

180 Million Americans Have Had At Least 1 COVID Vaccine Dose. CIDRAP (7/1, Soucheray) reports White House COVID-19 coordinator Jeff Zients on Thursday "said 180 million Americans now have had at least one dose of a COVID-19 vaccine, and White House Chief Medical Advisor Anthony Fauci, MD, reassured the country that the three vaccines with emergency use authorization in the United States are likely effective against the Delta (B11617.2) variant." Zients said the 67% of US adults with at least one shot falls 3% short of President Biden's goal of 70%.

Dr. Anthony Fauci Named 2021 Humanist Of The Year. Religion News Service (7/1, Post, 9K) reports, "The American Humanist Association announced Thursday (July 1) that Dr. Anthony S. Fauci is its 2021 Humanist of the Year." Fauci "is chief medical adviser to President Joe Biden and has been director of the National Institute of Allergy and Infectious Diseases at the U.S. National Institutes of Health since 1984." Fauci "played a pivotal role in advocating for evidence-based solutions in the global fight against COVID-19."

Could Editing The Genomes Of Bats Prevent Future Pandemics? STAT (7/1, Check Hayden, 262K) reports, "Amid the devastating Covid-19 pandemic, two researchers are proposing a drastic way to stop future pandemics." US NIAID immunologist Daniel Douek and Israel's Interdisciplinary Center Herzliya geneticist Yaniv Erlich propose "creating a gene drive to render wild horseshoe bats immune to the types of coronavirus infections

that are thought to have triggered the SARS, MERS, and Covid-19 pandemics." The researchers "realize they face enormous technical, societal, and political obstacles, but want to spark a fresh conversation about additional ways to control diseases that are emerging with growing frequency."

Diet Rich In Omega 3 Fatty Acids Cuts Migraines In Adults. HealthDay (7/1, 11K) reports, "Interventions that increase dietary intake of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), with or without a decrease in linoleic acid, alter bioactive mediators that are implicated in migraine and reduce headaches, but they do not improve headache-related quality of life, according to a study published online June 30 in The BMJ." Christopher E. Ramsden, "M.D., from the National Institute on Aging in Baltimore, and colleagues conducted a three-arm trial involving 182 participants with migraines on five to 20 days per month."

Phase 2 Study Explores Use Of Fosciclopirox In Newly Diagnosed, Recurrent Bladder Cancer. Targeted Oncology (7/1, Tucker) reports, "Fosciclopirox (CPX-POM) will be investigated for the treatment of newly-diagnosed and recurrent bladder cancer in a phase 2 study, according to an announcement from the developer, CicloMed, LLC." The National Cancer Institute (NCI) funded study (NCT04525131) "is a window of opportunity analysis designed to determine the safety, dose tolerance, pharmacokinetics, and pharmacodynamics of CPX-POM in patients with newly diagnosed or recurrent bladder tumors with a target enrollment of 12 patients who will be given CPX-POM intravenously over 20 minutes once daily." The primary end point of the study "include[s] the number of patients with adverse events (AEs) or serious AEs, and dose-limiting toxicities."

Too Much Southern Food Can Cause A Sudden Heart Attack, But Mediterranean Diet Reduced Risk. CNN (7/1, LaMotte, 89.21M) reports that a new study "found eating a steady diet of traditional Southern food can make you 46% more likely to die from a sudden cardiac death – that's when the heart suddenly stops – than people who don't often eat those foods." The study, "published Wednesday in the Journal of the American Heart Association, also examined the impact of eating a Mediterranean-style diet on the risk of sudden cardiac death." In what researchers "are calling the first observational study to evaluate the role of dietary patterns in sudden cardiac death, the team analyzed data from a national study called Regards (Reasons for Geographic and Racial Differences in Stroke)." Sponsored by the National Institutes of Health, Regards "was designed to discover why 'Southerners and Black Americans have higher rates of stroke and related diseases that affect brain health.'"

Eating Disorder Behaviors Linked To Changes In Brain Reward Processing. Healio (7/1, Gramigna, 40K) reports, "Eating disorder behaviors appeared to change brain reward processing," researchers concluded in a functional brain imaging study that sought "to evaluate brain response during unexpected receipt or omission of a salient sweet stimulus in 317 women, of whom 197 had eating disorders and 120 served as healthy controls, and to determine whether this brain response was linked to the ventral striatal-hypothalamic circuitry, which has correlated with food intake control." The study revealed that "BMI modulated prediction error and food intake control circuitry in the brain, and alteration of this circuitry may reinforce eating disorder behaviors when paired with behavioral traits linked to overeating or undereating, researchers noted." Janani Prabhakar, "of the translational research division at the National Institute of Mental Health, part of the U.S. National Institutes of Health (NIH), said: 'This work is significant because it links biological and behavioral factors that interact to adversely impact eating behaviors.'" The findings were published online June 30 in JAMA Psychiatry.

Additional Source. HealthDay (7/1, Preidt, 11K) also covers the study.

Using SDOH Data to Boost Population Health Management in Alzheimer's. Health IT Analytics (7/1, McNemar) reports "the Institute for Translational Research at The University of North Texas Health Science Center at Fort Worth is providing scientists with early demographic and social determinants of health (SDOH) data to help them understand the biology of Alzheimer's disease." The increase "in data quality will assist providers in improving population health management for diverse communities and eliminate health disparities." The data come "from the Health and Aging Brain among Latino Elders (HABLE) study launched in 2017," which "was funded by the National Institutes of Health and headed by Sid O'Bryant, PhD, executive director of the Institute."

Trials To Test Vaccine Mixing With Booster Doses. WebMD (6/30, Ellis, 4.27M) reports that clinical trials "are being conducted across the United States to see if giving fully vaccinated adults a different kind of booster dose is effective." One of the participating sites "is the University of Pittsburgh School of Medicine, which is now recruiting volunteers." Judy Martin, "MS, a professor of pediatrics at the Pitt Medical School and a member of Pitt's Center for Vaccine Research, said in a news release: 'As more and more COVID-19 variants are identified, we need to figure out how

we, as a community, can stay protected.'" Initial results "are expected in late summer of 2021, though the study will run 1 year." The sites "are operating under a program run by the National Institute of Allergy and Infectious Diseases."

Pentagon Gave Millions To EcoHealth Alliance For Weapons Research Program. The New York Post (7/1, Chamberlain, 7.45M) reports "the Defense Department doled out millions of dollars to the same nonprofit that funneled federal grant money to the Wuhan Institute of Virology for bat coronavirus research – with most of the Pentagon money going toward murky research on countering biological weapons." EcoHealth Alliance has "come under scrutiny for redirecting funds from the National Institutes of Health (NIH) to the Chinese lab, from where many believe COVID-19 leaked." US spending data show "EcoHealth has a long and profitable relationship with the Pentagon, receiving $41.91 million in awards since fiscal year 2008." Meanwhile, emails show "EcoHealth was allocated approximately $7.5 million over 11 years from" NIAID "to carry out its study 'Understanding the Risk of Bat Coronavirus Emergence.'"

Tech Contractors Urge NIH To Answer Their Questions About $50B CIO-SP4 Contract. FedScoop (7/1, Nyczepir) reports, "The Professional Services Council has urged the National Institutes of Health to explain its treatment of tech industry questions about the request for proposals (RFP) issued for a long-awaited, $50 billion health IT contract." In a letter of complaint "sent Monday, PSC queried the agency's decision to modify and consolidate industry questions before responding to them in RFP amendments." The advocacy group "described NIH's response as inequitable and confusing."

Reports: US Sprinter Sha'Carri Richardson Will Miss Olympic Event After Positive Marijuana Test. Forbes (7/2, 10.33M) reports, "U.S. champion sprinter Sha'Carri Richardson will miss a key event at the upcoming Tokyo Olympics after she tested positive for marijuana, according to multiple reports." Richardson "was an early favorite to capture the U.S.'s first gold medal in the event since 1996." According to the article, "If the suspension is upheld, Richardson will miss the 100m sprint at the Tokyo Olympics, which begin July 23." The National Institute on Drug Abuse is mentioned.

Director Lander, The Time Is Now. In an editorial for Science (7/2, 484K) reports, University of Michigan professor Omolola Eniola-Adefeso and University of California-San Francisco professor Hana El-Samad write, "The Biden administration's decision to elevate the Director of the White House Office of Science and Technology Policy (OSTP) to a cabinet-level position is a win for science. Eric Lander, confirmed in May by the Senate, is now advising the president on the scientific, engineering, and technological policies of the US government." They write, "If the fruits of science and technology are to be truly shared, they should be produced by all Americans. This cannot happen if the scientific enterprise tolerates insidious systemic racism and sexism." They write, "For example, National Institutes of Health (NIH) intramural senior investigators from underrepresented groups (Black, Hispanic, Alaska Native/American Indian) constitute only 5.1% (and women only 24%), and Black scientists remain 55% less likely than white scientists to receive NIH's extramural funding."

IU School Of Medicine Receives $30M NIA Grant. Inside INdiana Business (7/1, Roberts) reports, "The National Institute on Aging has renewed its funding for the National Centralized Repository for Alzheimer's Disease and Related Dementias at the Indiana University School of Medicine." IU "says the funding, which is expected to total $30 million, will support the NCRAD for another five years." The NCRAD "supports research about causes, early detection, and therapeutic development for Alzheimer's and other dementias."

Additional Source. National Geographic (7/1, Vernimmen, 30.3M) also reports.

OTHER COVID-19 NEWS

Jobless Claims Fell To Pandemic Low Of 364K Last Week. The AP (7/1, Wiseman) reports the Labor Department said Thursday that US jobless claims fell to 364,000 last week, which is the lowest level since the onset of the coronavirus pandemic last year.

Over 99% Of People Who Died From COVID-19 During Last Six Months Were Not Vaccinated, CDC Director Says. Forbes (7/1, McEvoy, 10.33M) reports "CDC Director Dr. Rochelle Walensky said at a Thursday White House briefing that preliminary data reviewed by her agency suggests 99.5% of the people who died from Covid-19 over the past six months were unvaccinated, a stunning statistic in support of her assertion that nearly every virus-linked death is now preventable." The CDC director "said the early data 'from a collection of states' indicates nearly every coronavirus victim since January – a month after the U.S. first began administering shots – was not vaccinated against the virus."

US Fails To Meet Goal Of Sending 80M COVID-19 Vaccine Doses To Other Countries By June

30. Newsweek (7/1, Marnin, 2.67M) reports the United States "missed President Joe Biden's goal of sending 80 million COVID-19 vaccines to other countries by the end of June by more than half." Fewer "than 24 million doses have been distributed to 10 countries by the U.S., according to the Associated Press. The Biden administration previously promised 50 countries and entities will receive the doses," which "are ready to be sent but the White House said regulatory issues involving other nations are preventing the deliveries."

The Washington Times (7/1, Howell, 626K) also covers the story.

Arkansas Reports Largest One-Day Increase In COVID-19 Cases In Four Months For Second Consecutive Day. The AP (7/1) reports that "for the second day in a row, Arkansas reported Thursday its biggest one-day spike in four months of the coronavirus that causes COVID-19, an increase officials have blamed on the delta variant of the virus." Arkansas "reported 700 new virus cases, bringing its total since the pandemic began to 350,085." The one-day jump "in cases was the state's highest since it reported 726 on Feb. 25."

The Hill (7/1, Castronuovo, 5.69M) reports "the state also reported 12 new coronavirus-related hospitalizations Thursday, bringing the total to 337, though Arkansas recorded no new fatalities due to the virus."

Nevada's Washoe County Reports First COVID-19 Death Tied To Delta Variant. The AP (7/1, Sonner) reports, "Northern Nevada's Washoe County has confirmed its first death related to the COVID-19 Delta variant, which was the most common variant among samples collected at the state public health lab last month and is accounting for one in four new cases reported nationally, the health district said Thursday." The woman, who was in her 40s and died from the variant, "had not received the COVID-19 vaccination, had no underlying conditions and had been hospitalized in the Reno-Sparks area, the county health district said Thursday."

Ohio Reports Large Increase In COVID-19 Cases Compared To 21-Day Average. The Dayton (OH) Daily News (7/1, Balduf, Spicker, 228K) reports "the number of new coronavirus cases reported Thursday in Ohio was more than double the state's 21-day case average." Ohio's health department "reported 579 new COVID-19 cases and 48 new hospitalizations, compared to 200 new cases reported Wednesday." The state's "21-day average is now 278, up from 267 reported Wednesday."

Delta Coronavirus Variant Gaining Strength In Iowa, Test Results Show. The Des Moines (IA) Register (7/1, Leys, Coltrain, 469K) reports the Delta coronavirus variant "appears to be gaining strength across Iowa, according to test results from the Iowa State Hygienic Laboratory." During both "of the past two weeks, the delta variant accounted for more than half of positive coronavirus tests from Iowa that included variants of the virus, the Iowa Department of Public Health said." The Register adds that "Surgeon General Vivek Murthy told MSNBC this week there's reason to hope the Johnson & Johnson vaccine would prevent people from becoming seriously ill from the delta variant."

Biden Administration Taking Correct Approach To Combat Delta Coronavirus Variant, Gottlieb Says. CNBC (7/1, DeCiccio, 7.34M) reports "the Biden administration is taking the right approach in fighting the highly contagious Covid-19 delta variant by deploying response teams to vulnerable communities, [former FDA Commissioner] Dr. Scott Gottlieb said Thursday." Gottlieb said on CNBC, "I think that the administration is doing the right thing, in terms of shifting their strategy." He "explained that the targeted response can help teams focus on vaccinating those communities vulnerable to Covid and the delta variant." CDC Director Rochelle Walensky is mentioned.

Biden Administration To Share Tens Of Millions More COVID-19 Vaccine Doses This Summer Worldwide, Zients Says. CNN (7/1, Sullivan, 89.21M) reports "the Biden administration will share tens of millions of US Covid-19 vaccines this summer to countries around the globe, in addition to the 80 million it has already allocated, White House Covid-19 response director Jeff Zients said Thursday." Zients said to reporters, "Just as our work to vaccinate Americans does not stop on July Fourth, our work to help vaccinate the world does not stop at these 80 million doses. ... We will continue to share tens of millions more US doses over the summer months as we help lead the fight to end the pandemic across the globe."

Murthy Discusses Dangers Associated With Delta Coronavirus Variant. In a video on the Fox News (7/1, 23.99M) website, Surgeon General Vivek Murthy "discusses the dangers of the new" Delta coronavirus variant. Murthy said the variant is "far more transmissible" than the other coronavirus variants.

Over 40% Of Nursing Home Workers In US Have Not Received COVID-19 Vaccine, CDC Data Show. The Philadelphia Inquirer (7/1, Burling)

reports "half a year after vaccines became available at many nursing homes, more than 40% of employees nationally still have not gotten the shots, according to data posted Thursday by the" CDC. The numbers in Pennsylvania "were in line with the national average, while New Jersey has done better." In February, a pair of "national organizations that represent providers of senior housing and services, including nursing homes, announced that they wanted 75% of the country's 1.5 million nursing home workers vaccinated against COVID-19 by the end of June." Vaccination rates among employees "have been flat over the last month."

Editorial: Missouri Governor Must Demonstrate Through Actions, Words That He Cares About If Residents Die From COVID-19. In an editorial, the St. Louis Post-Dispatch (7/1, 694K) says that according to the CDC, "Missouri now leads the nation with the highest rate of new coronavirus infections," and "until Wednesday, all Missourians heard from the governor's mansion were crickets." After a "long silence about the mounting infection rate," Gov. Mike "Parson finally acknowledged to reporters that people need to take precautions." However, "he stopped far short of the kind of insistent and persistent advocacy for vaccinations and mask-wearing among the unvaccinated to convey the kind of message Missourians need to hear." The Post-Dispatch asserts, "It is time for Parson to come up with a better plan and demonstrate through words and actions that he truly cares about whether Missourians live or die."

Return To Socialization As COVID-19 Restrictions Are Lifted Means Rise In Respiratory Illnesses, Physicians Say. The Boston Herald (7/1, Cohan, 327K) reports "a return to society and socialization now that most coronavirus restrictions have been lifted also means an uptick in summer colds and other respiratory illnesses, local doctors have observed." Jeannie Kenkare, chief medical officer and co-founder of PhysicianOne Urgent Care, said, "Those usually typical bugs that we have been so lucky not to have in the past year are coming back in full force." The Herald says "it is unusual to see lots of respiratory illness in the spring and summer, but it's happening."

Trade Associations, Medical Societies Silent On COVID-19 Vaccine Mandates. Modern Healthcare (7/1, Christ, Subscription Publication, 215K) reports "professional medical societies" and national trade associations have remained silent in regard to COVID-19 vaccine mandates. In the US, "hospitals and health systems have had to take that plunge on their own, without guidance from medical societies or major associations like the American Hospital Association or the American Medical Association on whether to mandate the vaccine." That is "in stark contrast to their stances on the flu vaccine, which associations like the AHA support being mandatory."

Delta Variant Not Driving A Surge In Hospitalization Rates In England, Data Show. The New York Times (7/1, Anthes, 20.6M) reports, "The Delta variant, which is now responsible for most coronavirus infections in England, is not driving a surge in the rate of hospitalizations there, according to data released by Public Health England on Thursday." Despite the fact that "the number of coronavirus infections has risen sharply in recent weeks, hospitalization rates remain low."

The Hill (7/1, Coleman, 5.69M) reports, "The rate is drastically lower than during the winter surge, which saw a peak rate in January at 37.2 hospitalizations per 100,000 new cases." Data indicate "that nations with higher vaccination rates may not experience spikes in hospitalizations, as England has reached one of the highest in the world."

Delta Coronavirus Variant Outbreak In Africa Underway Amid COVID-19 Vaccine Shortage. The Washington Post (7/1, Wroughton, Bearak, Athumani, Paquette, 10.52M) reports, "The variant-driven coronavirus outbreak that public health officials across Africa had warned about for months is underway – and it's happening without the urgently needed ramping up of the continent's access to vaccines." Big "moves to quicken commercial vaccine rollout across the continent have come too late to prevent calamities, officials said."

The New York Times (7/1, Dahir, 20.6M) reports, "The African Union's special envoy on Covid-19 urged Europe to relax restrictions on vaccine makers' exports so that African countries could buy more doses and try to stem a fast-surging third wave of the pandemic driven mainly by the more contagious Delta variant." The special "envoy, Strive Masiyiwa, criticized wealthy nations for giving short shrift to Africa's needs while monopolizing manufacturers' vaccine output for their own citizens."

The Hill (7/1, Lonas, 5.69M) reports, "Masiyiwa said Africa has purchased 400 million vaccine doses but has not received them yet." In addition, he directed comments at "the COVAX program, which is meant to give poorer countries vaccine doses, saying less than 50 million of the 700 million doses the program has promised this year have arrived in Africa."

The AP (7/1, Anna) also covers the story.

Russia Launches COVID-19 Booster Shots Amid Surge In New Infections, Deaths. The AP (7/1, Isachenkov) reports, "Russian health authorities on Thursday launched booster coronavirus vaccinations for

people immunized more than six months ago, as the country faces a surge in new infections and deaths." Moscow health officials "on Thursday started offering booster shots with the domestically produced, two-shot Sputnik V vaccine and its one-shot Sputnik Light version."

Business Leaders, Union Urge British Government To Defer Winding Down Of Salary Support Program. The AP (7/1, Pylas) reports, "Business leaders and unions joined forces Thursday to urge the British government to maintain a salary subsidy program that is being wound down over the coming months – or else see unemployment rise sharply." The article says, "The Job Retention Scheme was introduced at the start of the pandemic last March to ensure unemployment didn't rise substantially when lockdown restrictions were imposed." Under the scheme, "the government paid 80% of the salaries of those workers unable to work because of lockdown measures."

Australians Not Embracing COVID-19 Vaccinations Could Delay Return To Normalcy. The AP (7/1, McGuirk) reports, "Australia has weathered the pandemic far better than many nations – recording just a single coronavirus death since last October – but its success means many Australians are not in a rush to get vaccinated and that could delay the country's return to normalcy." Apprehension is "growing about the economic cost to Australia of being left behind by countries that suffered far higher death tolls, but urgently embraced vaccines and are increasingly opening up."

UK PM Says Unspecified "Extra Precautions" To Contain COVID-19 Will Be Needed In Coming Weeks. The AP (7/1) reports, "British Prime Minister Boris Johnson said unspecified 'extra precautions' to contain the spread of the pandemic will be needed in coming weeks, even as he voiced confidence Thursday that the remaining restrictions on social contact in England can be lifted as planned on July 19." Cases "in the U.K. have risen sharply in recent weeks, with government figures showing another 27,989 new cases across the U.K. on Thursday. That's the highest level since the end of January."

Reuters (7/1, Schomberg) also covers the story.

Rio De Janeiro Police Evict Several Hundred Homeless Families From Tent City As Poverty Increases Amid Pandemic. The AP (7/1, Jeantet) reports, "Police started evicting several hundred homeless families from a recently established tent city near Rio de Janeiro on Thursday, an event that underscored Brazil's resurgent poverty during the pandemic." Broadcast media "showed residents blocking the entrance to the campsite with bonfires as police launched tear gas canisters and fired water cannons at the tents."

Turkey Eases Most Pandemic Restrictions As New Infections Plateau. The AP (7/1, Guzel, Bilginsoy) reports, "Turkey has eased nearly all pandemic restrictions on businesses and events starting Thursday, and lifted nighttime and Sunday curfews as new infections remain steadily below recent record high levels." The country "has been gradually easing restrictions since mid-May after the end of a so-called 'full lockdown' from which millions of workers and tourists were exempt."

Digital COVID-19 Vaccine Certificate Distribution Begins In Europe. The Wall Street Journal (7/1, Michaels, Katz, Subscription Publication, 8.41M) reports the EU has begun distributing digital vaccine certificates for those who have received a coronavirus vaccination, a recent negative COVID-19 test, or proof of antibodies. The document allows holders to travel easily within the bloc.

The AP (7/1, Casert) reports that the certificate "came officially into effect Thursday even though many member states had started introducing it over the past month, seeking to boost their summer season by making movement as seamless as possible." EU Commission spokesman Christian Wigand "said that 'already...more than two hundred million certificates have been generated.'"

Crowds At EU Championship Soccer Games Driving COVID-19 Cases, The WHO Says. The New York Times (7/1, Peltier, 20.6M) reports, "Crowds gathering in stadiums, pubs and bars to watch the European Championship soccer games have driven a rise in coronavirus cases across Europe, the World Health Organization said on Thursday, raising concerns about another virus wave even though vaccination campaigns have made progress." The article says, "In Scotland, more than 2,000 people tested positive after watching a Euro 2020 game either at a stadium, a fan zone or at a pub, according to National Health Scotland."

Reuters (7/1, Skydsgaard, Gronholt-Pedersen) reports, "Germany's interior minister called European soccer's governing body UEFA 'utterly irresponsible' for allowing big crowds at the tournament." In addition, the WHO said the mingling "of crowds in Euro 2020 host cities, travel and easing of social restrictions had driven up the number of new cases rose by 10%."

The Hill (7/1, Weixel, 5.69M) reports, "Scotland was only allocated 2,600 tickets because of virus concerns, but

officials said they suspect tens of thousands of fans traveled to London regardless."

The Washington Times (7/1, Howell, 626K) also covers the story.

Greece To Vaccinate Teenagers Once It Receives Approval From Medical Experts. Reuters (7/1, Koutantou, Georgiopoulos) reports, "Greece will start vaccinating teenagers once it gets the go-ahead from medical experts and will require vaccination certificates or negative tests from everyone heading to its islands from Monday, authorities said." A slight increase in cases "last week and concerns over the more contagious Delta variant prompted the government to impose stricter rules to cover the islands."

Six People Fully Vaccinated Against COVID-19 Die In Seychelles, Most Vaccinated Nation. Bloomberg (7/1, Gappy, Sguazzin, 3.57M) reports, "The coronavirus has killed six fully vaccinated people in the Seychelles, which is suffering heightened Covid-19 infections despite inoculating a greater proportion of its people than any other nation." Of the six, "five had taken Covishield, a version of the AstraZeneca Plc vaccine made in India, and one had been given Sinopharm, Jude Gedeon, the island nation's public health commissioner said at a press conference on Thursday."

Top Executive Of Air France-KLM Wants US To Ease Travel Restrictions On European Visitors. The New York Times (7/1, Chokshi, 20.6M) reports, "The top executive of Air France-KLM, one of the world's largest airline companies, was thrilled when Europe eased restrictions on American visitors last month," but "he wants the United States to return the favor." The article adds, "The U.S. Chamber of Commerce last week called for the easing of travel restrictions put in place under the Trump administration, saying that the return of European business travelers and tourists would 'help drive economic growth and job creation for Americans across the country.'"

Puerto Rico To Ease Face Mask Requirement For Those Fully Vaccinated Against COVID-19. The AP (7/1) reports, "Fully vaccinated people in Puerto Rico will no longer be required to wear face masks starting next week with few exceptions, Gov. Pedro Pierluisi announced on Thursday." Pierluisi "also said that capacity restrictions at all businesses will be lifted as the number of COVID-19 cases, deaths and hospitalizations across the U.S. territory keeps dropping."

Portugal To Reintroduce Curfews In Municipalities Where COVID-19 Cases Have Risen. The New York Times (7/1, Minder, 20.6M) reports, "Portugal's government on Thursday announced that it would reintroduce nighttime curfews in municipalities where the coronavirus case rate has risen fastest – including some of its tourism hubs – as it struggles to cope with the spread of the Delta variant." In the last two weeks, "the average number of daily cases in Portugal has nearly doubled to over 1,600, according to a New York Times database, though they remain far below their January peak of over 12,000 per day."

Analysis: COVID-19 Vaccine Inequality Hurting Many Parts Of Asia. CNN (7/1, Yeung, 89.21M) says at the end of 2020, "Thailand and Vietnam had reported fewer than 200 deaths between them, and Cambodia and Laos didn't report any at all." However, by spring of 2021 "many parts of Asia battled stubborn Covid-19 outbreaks that have infiltrated factories and other businesses critical to the global supply chain, threatening to disrupt the already strained flow of international trade." The transmission "of COVID-19 in countries that had been praised for their early success in containing the virus has exposed the gaps in their vaccination rollouts, affecting vulnerable migrant workers who work long hours in close quarters to support families back home."

Singapore Focuses On New Way Of Living With COVID-19. The Wall Street Journal (7/1, Mandhana, Subscription Publication, 8.41M) reports that Singapore has made progress with its restrictions to keep coronavirus infections as low as possible. With almost 40% of its citizens fully vaccinated, the focus has shifted to a new phase of handling COVID-19 as a less threatening disease, as something endemic.

Australia Agrees To Halve Number Of International Arrivals Amid Delta Variant Outbreaks. The Washington Post (7/2, Pannett, 10.52M) reports, "Facing outbreaks of the contagious delta variant and a floundering vaccination campaign, Australia moved Friday to further seal itself off from the world as its earlier success in tackling the coronavirus continued to unravel." Authorities "agreed to halve the number of people permitted to enter the nation under an already strict border policy that almost exclusively bars entry to everyone except returning citizens, residents and their immediate families, who are required to complete two weeks in hotel quarantine at their own expense." Starting "July 14, the number of international arrivals will be cut to about 3,000 a week, further dimming repatriation hopes for some 34,000 Australians who are stranded overseas."

The AP (7/2, McGuirk) reports, "The government will charter more airliners to repatriate Australians, but the reduced limit on commercial passenger arrivals could continue until next year."

Reuters (7/1) also covers the story.

WHO Says Countries Should Accept Travelers Vaccinated With Any COVID-19 Shots It Authorized For Emergency Use. The AP (7/1) reports that on Thursday, the World Health Organization "said...that any COVID-19 vaccines it has authorized for emergency use should be recognized by countries as they open up their borders to inoculated travelers." According to the article, "The move could challenge Western countries to broaden their acceptance of two apparently less effective Chinese vaccines, which the U.N. health agency has licensed but most European and North American countries have not. In addition to vaccines by Pfizer-BioNTech, Moderna Inc., AstraZeneca and Johnson & Johnson, the WHO has also given the green light to the two Chinese jabs, made by Sinovac and Sinopharm."

Newsweek (7/1, Klapper, 2.67M) also reports.

CureVac To "Plow Forward" With EU Regulatory Approval Of COVID-19 Vaccine Despite Lackluster Trial Results. CNBC (7/1, Ellyatt, 7.34M) reports CureVac executives confirmed Thursday the company "plans to continue work on its Covid-19 vaccine despite disappointing clinical trial results." In a CNBC interview, CFO Pierre Kemula said, "We have a contract with the European Commission to supply 225 million doses of the drug so I think, with that in mind, we need to plow forward. ... There's plenty of jabs to be given, there's plenty of people under the age of 60 that haven't had access to the vaccine to date."

Reuters (7/1, Burger) reports the company "said it was in discussions with its prospective customer, the European Union, about where in the world to best deploy its experimental COVID-19 vaccine if it wins approval." CEO Franz-Werner Haas said, "We have a supply obligation towards the EU and we are in discussions with the EU where the vaccine should best be used after approval. ... This is about a broad approach to vaccinate the world population." Reuters notes, "Many low and middle-income countries, which have fallen far behind developed [nations] in the global vaccination campaign, have a younger overall population than Europe."

J&J To Initiate COVID-19 Vaccine Study For Adolescents In Fall. The Hill (7/1, Coleman, 5.69M) reports, "Johnson & Johnson plans to initiate its first study of its COVID-19 vaccine involving adolescents ages 12-17 in the fall, an executive said Wednesday during a Johns Hopkins University of Washington event." The study will assess how the "vaccine works among children and adolescents, Macaya Douoguih, the head of clinical development and medical affairs for Janssen Vaccines and Prevention B.V., said." A further three "studies will analyze the vaccine's effectiveness among 2- to 11-year-olds, those younger than 2 years old and immunocompromised and high-risk children ages 1-17."

India's Cadila Healthcare Seeks EUA For DNA-Based COVID-19 Vaccine After Clinical Trial Success. Bloomberg (7/1, Shrivastava, Lyu, 3.57M) reports India's Cadila Healthcare Ltd. sought emergency use authorization "from the local drug regulator for its DNA-based vaccine against Covid-19 after the shot proved effective in clinical trials." According to the article, "The Phase 3 trials on more than 28,000 volunteers across 50 centers showed an efficacy rate of 67%, Cadila said," which is "below the rates of the shots from Moderna Inc. and Pfizer-BioNTech."

Public Health England Says AstraZeneca COVID-19 Vaccine Was 94% Protective Against Death In Those Over 65. Reuters (7/1, Smout) reports, "Two doses of the Oxford/AstraZeneca COVID-19 vaccine gives an estimated 94% protection against death from the disease in people over 65, Public Health England said on Thursday in a weekly surveillance report of real-world data." The agency "said the majority of the data was derived from a period when the Alpha variant, first detected in England, was still dominant and did not provide a specific estimate of protection from death that the vaccine offered against the now more widespread Delta variant, first detected in India."

EMA Says EU-Approved COVID-19 Vaccines Offer Protection Against Delta Variant. Reuters (7/1, Aripaka, Burger) reports the European Medicines Agency "said on Thursday the COVID-19 vaccines approved in the European Union offered protection against all coronavirus variants, including Delta, but called for active monitoring by vaccine manufacturers to stay alert." EMA Head of Vaccine Strategy said during a briefing, "There have been a number of variants over the last months and we expect more. ... It's very important that there is continuous monitoring and a close surveillance of the performance of all the approved vaccines against emerging variants."

COVAX Chief Says Group Is On Track To Deliver 1.8B COVID-19 Vaccine Doses By Early 2022. Bloomberg (7/1, Kazan, 3.57M) reports, "At the Bloomberg New Economy Catalyst, the Eurasia Group's Alex Kazan caught up with Covax Managing Director Aurélia Nguyen, who says the group is on track to deliver 1.8 billion"

COVID-19 vaccine "doses by early 2022 despite falling short of its targets in the initial months of the rollout." The article features "edited excerpts from their conversation."

COVID-19 Experts Lay Out Benefits, Risks Of Vaccinating Children During Symposium. The Baltimore Sun (7/1, Cohn, 629K) reports, "A collection of experts laid out the benefits – and a few risks – of vaccinating kids" against COVID-19 "during a symposium hosted by the Johns Hopkins University and the University of Washington." CDC Director Dr. Rochelle Walensky said, "We should look at COVID-19 as a vaccine-preventable disease in children. ... In terms of preventable disease and death, COVID should rank high."

Novavax Working With Global Authorities To Help Verify COVID-19 Vaccination Status For Trial Participants. FierceBiotech (7/1, Armstrong, 4K) reports, "As debate about COVID-19 vaccine passports continues and countries start to open up to travel again, participants in clinical trials for shots that are yet to be authorized are finding themselves lost in the shuffle." For example, Novavax "spoke up Wednesday to say that clinical trial participants should not be disadvantaged in situations where they need to provide proof of vaccination." The biotech "said U.S. trial participants were eligible for a modified vaccination card once efficacy data was available for the company's phase 3 Prevent-19 trial." Novavax stated, "We are actively supporting authorities working to provide proof of vaccination for all who volunteered in our pivotal Phase 3 clinical trials."

Guest Essay: mRNA COVID-19 Vaccines From Moderna, Pfizer Should Receive Full Approval As Soon As Possible From FDA. In a guest essay for the New York Times (7/1, 20.6M), contributor Eric J. Topol writes that "mRNA coronavirus vaccines are not yet fully licensed despite massive evidence of their benefits," but "a new drug for Alzheimer's disease, aducanumab, gets approved by the Food and Drug Administration through an accelerated process without sufficient data." Topol writes that few biologics "have had their safety and efficacy scrutinized" to the same degree, with "more than 180 million doses of the Pfizer vaccine and 133 million of Moderna's...administered in the United States, with millions more doses distributed worldwide." However, Topol adds that "the vaccines' approvals remain conditional, and the urgency of full approvals cannot be overstated."

America's Largest Teachers' Union Holding Vote On Requiring COVID-19 Vaccinations, Masks, Testing For Students Before Fall. Fox News (7/1, Conklin, 23.99M) reports, "The National Education Association, America's largest teachers' union, is holding a vote on requiring mandatory COVID-19 vaccinations, masks and testing for students before classes return in the fall." The CDC "said in January that there is 'little evidence' schools 'have contributed meaningfully to increased community transmission.'"

Flight Attendants Say It Is "Crucial" CDC Transportation Mask Mandate Remains In Place. Senior contributor Ted Reed writes in Forbes (7/1, 10.33M) that numerous "senators are pushing to end the transportation mask mandate in the immediate future, rather than await its Sept. 13 expiration." However, Association of Flight Attendants President Sara Nelson sent a letter "Wednesday to the leaders of the Transportation Security Administration and the Centers for Disease Control and Prevention," arguing that it is crucial that the agency's mask order remains in place at this time.

CDC Urges Women To Get Cancer Screenings After Study Suggests Screenings Fell 80% During COVID-19 Pandemic. The New York Post (7/1, Sparks, 7.45M) reports the CDC "is urging women, especially those of low-income and minority backgrounds, to get screened for cancer as a new study has revealed that breast and cervical cancer screenings plunged by more than 80% among these underprivileged groups." Lead study author and CDC health scientist Amy DeGroff stated that the results "reinforce the need to safely maintain routine health care services during the pandemic, especially when the health care environment meets COVID-19 safety guidelines."

DC Attorney General Subpoenas Facebook For Records Related To Platform's Handling Of COVID-19 Misinformation. Politico (7/1, Lima, 6.73M) reports, "D.C. Attorney General Karl Racine has subpoenaed Facebook for records related to the platform's handling of coronavirus misinformation as part of a previously undisclosed investigation into whether the tech giant is violating consumer protection laws." Racine has called "on Facebook to release by the end of next week an internal study it conducted looking into vaccine hesitancy among its users, as first revealed by news reports in March." The subpoena "also calls on Facebook to provide records identifying all groups, pages and accounts that have violated its policies against Covid-19 misinformation and documents detailing how many resources the tech giant has devoted to the cause."

Military, VA Struggling With COVID-19 Vaccination Rates As Biden Declines To

Require Vaccination. The New York Times (7/1, Steinhauer, 20.6M) reports that United States Secretary of Veterans Affairs Denis McDonough "said this week that he was considering a move to compel workers at V.A. hospitals to get vaccinated, fearing that centers with low vaccination rates were risking the health of veterans seeking care." According to the article, "The military is also struggling to fully vaccinate more troops across all service branches. While the Army and Navy are outpacing the civilian population in vaccine uptake, the Air Force and the Marine Corps have faced greater challenges. About 68 percent of active-duty members have had at least one dose, officials said." President Biden has so far declined to require members of the military to get the COVID-19 vaccine "even as the highly contagious Delta variant has become an increasing threat to unvaccinated Americans."

FDA Authorizes Birmingham Firm's COVID-19 Test. Alabama Live (7/1, Thornton, 497K) reports the FDA "has issued an emergency use authorization for a Birmingham company's COVID-19 test." According to the article, "BioGX's Xfree COVID-19 test is described as a simple-to-use, complete freeze-dried test in a single tube."

The Birmingham (AL) Business Journal (7/1, Patchen, Subscription Publication, 849K) also reports.

Michigan Launches $5M Sweepstakes To Boost COVID-19 Vaccinations. The AP (7/1, Eggert) reports that on Tuesday, Michigan Gov. Gretchen Whitmer (D) announced "about $5 million in cash and college scholarships will be given away in lottery-style drawings aimed at raising Michigan's COVID-19 vaccination rate." The MI Shot to Win Sweepstakes "features a $2 million jackpot, a $1 million prize and 30 daily drawings of $50,000 for residents age[d] 18 and older who have received at least one shot." Additionally, "vaccinated residents age[d] 12 to 17 are eligible for one of nine four-year prepaid tuition contracts valued at $55,000."

The Detroit News (7/1, Mauger, 1.16M) reports, "The effort...a collaboration of Meijer, Michigan Association of United Ways, Blue Cross Blue Shield of Michigan and other groups, is meant to encourage more Michiganians to get vaccinated and achieve the governor's goal of having 70% of the adult population protected."

The Detroit Free Press (7/1, Shamus, 2.16M) also covers the story.

Indiana Governor Extends Public Health Emergency. The AP (7/1, Davies) reports that on Wednesday, Indiana Gov. Eric Holcomb (R) extended the state's public health emergency until at the least the end of the month.

New Mexico Lifts COVID-19 Pandemic Restrictions On Gatherings, Businesses. The AP (7/1) reports, "New Mexico lifted all pandemic-related restrictions on public gatherings and business operations on Thursday." Businesses may now "operate at 100% capacity, and all limitations on mass gatherings are gone." However, "businesses and local governments may still adopt and require additional precautions at their discretion."

Pennsylvania Governor Vetoes Bill Banning Vaccine Passports. The AP (7/1, Scolforo) reports Pennsylvania Gov. Tom Wolf (D) vetoed "a Republican-crafted bill to ban so-called COVID-19 'vaccine passports' in some cases and to restrict the health secretary's actions during health emergencies." The governor's "office has said he will not move to establish vaccine passports by the government but believes private entities, venues and businesses should be able to set their own rules about vaccine status."

COVID-19 Pandemic Raises Awareness Of Inequities Queens Residents Face. The New York Times (7/1, Correal, Blue, 20.6M) chronicles the daily lives of New Yorkers who live in Queens. Many explained the struggles they are still facing. Local city councilman Francisco Moya (D) "said the pandemic had exposed longstanding issues with housing, health care and employment that left residents here particularly vulnerable to the virus and shutdown." He added, "We can't pat ourselves on the shoulder and say, 'Good, we are making a comeback.'"

Op-Ed: LA Mask Guidance "Undermines" COVID-19 Vaccination Efforts. In an op-ed for the Washington Post (7/1, 10.52M), Johns Hopkins School of Medicine professor Marty Makary writes, "The latest guidance from Los Angeles County officials that fully vaccinated residents should once again wear masks to stop the spread of the delta variant is not just excessive; it also undermines vaccination efforts and perpetuates fearmongering." He adds, "Sending an anti-science message on masking, as Los Angeles has done, threatens the effectiveness of other recommendations at a time when health officials need to win back public support." Makary concludes, "Moving backwards on the return to normal for immune Americans could hinder public health efforts in the short-term and have long-term repercussions for trust in the medical profession."

No Changes To Colorado's Mask Guidance Amid Delta Variant Spread. The Denver Post (7/1, Seaman, 660K) reports, "As the delta variant spreads rapidly across the globe, the World Health Organization and a handful of other public health agencies have begun

encouraging fully vaccinated people to once again wear masks indoors to protect against COVID-19." However, "public health officials at the federal and state levels have not revised their guidance that Coloradans immunized against the coronavirus do not need to wear face coverings in most situations." CDC Director Rochelle Walensky "said Wednesday that local governments should be the ones making decisions about any changes to mask policies."

Colorado Students Do Not Have To Wear Masks In School Under New Rules. The Denver Post (7/1, Wingerter, 660K) reports that on Thursday, the Colorado Department of Public Health and Environment announced "students won't need to wear masks when they head back to school."

Missouri Seeks Aid From Federal "Surge Response" Teams As COVID-19 Cases Rise. The Kansas City (MO) Star (7/1, Shorman, Wilner, 519K) reports, "As Missouri experiences a rise in COVID-19 cases and hospitalizations, state officials have requested aid from newly-formed federal 'surge response teams' to assist communities struggling with low vaccination rates as the virulent Delta variant spreads." A White House official confirmed the CDC is "closely working with the Missouri Department of Health and Senior Services to identify their specific needs...preparing to mobilize a team to the state that will focus on vaccine confidence efforts, epidemiology, surveillance and sequencing support related to the Delta variant."

The St. Louis Post-Dispatch (7/1, Suntrup, 694K) also covers the story.

More Than 70% Of Adult Population Vaccinated Against COVID-19 In Some States. US News & World Report (7/1, Hubbard, 1.91M) reports, "With President Joe Biden's July 4 deadline fast approaching, his 70% partial vaccination goal for adults 18 and older remains just out of reach." However, there are a few states that "have already met or exceeded the goal: Vermont, Massachusetts and Hawaii lead the nation with more than 80% of their adult populations having received at least one dose of a coronavirus vaccine." Also, "at least 15 other states and the District of Columbia had met the benchmark as of June 30."

Minnesota Just Misses July 1 COVID-19 Vaccination Goal. The Minneapolis Star Tribune (7/1, Olson, 855K) reports, "Roughly 67% of Minnesotans 16 and older had received COVID-19 vaccine as of Thursday...but fell short of the state goal of 70% by July 1." However, the state "surpassed President Joe Biden's challenge of providing vaccine to 70% of adults 18 and older by July 4," according to the CDC.

Tennessee To End COVID-19 Federal Unemployment Benefits Saturday. The Tennessean (7/1, Stephenson, 645K) reports, "Federal unemployment benefits will end Saturday for thousands of jobless Tennesseans, opting Tennessee's unemployed out of $300 in additional weekly payments and programs that give benefits to workers not typically covered by state unemployment insurance." The state "will switch to providing unemployment benefits only through Tennessee's Unemployment Compensation program on Sunday."

Minneapolis City Council Extends COVID-19 Emergency. The AP (7/1) reports, "Minneapolis City Council members on Thursday voted to extend the city's COVID-19 emergency." City Council President Lisa Bender "said members want to provide a 'phased approach' rather than abruptly ending some programs that businesses and others in the community are currently relying on."

NYC Hospitals Have Stockpiles Of PPE. The Wall Street Journal (7/1, West, Subscription Publication, 8.41M) reports New York City hospitals have stockpiles of personal protective equipment. Some hospitals even need warehouses to store supplies. However, executives say the extra equipment will eventually be used.

AFT President Randi Weingarten Criticized For Statement On Union's School Reopening Position. Fox News (7/1, Fordham, 23.99M) reports American Federation of Teachers President Randi Weingarten is facing criticism after writing in response to an anonymous user on Twitter that the AFT "tried to open schools safely since April 2020." Critics allege Weingarten and the AFT were prominent advocates for keeping schools closed for in-person learning during the pandemic, citing examples including a tweet from Weingarten on April 28, 2020 which read, "Re-opening this soon will bring an even more powerful second wave of #COVID19. We have to be sure we are re-opening safely and not rushing things." AFT spokesperson Andrew Crook said in an email, "[T]he AFT released its reopening plan in April, 2020. It was one of the first groups to do so," referring to the group's first "road map" for reopening schools that it released in April 2020.

Study Estimates One In Five Pets With COVID-Positive Owners Were Infected. Reuters (7/1) reports a study presented at the European Congress of Microbiology and Infectious Diseases found that nearly one in five pets whose owners had COVID-19 "had antibodies for

COVID-19, suggesting they had been infected." However, "Later testing showed those animals recovered quickly and did not pass it on to other pets in the same household," according to study author Dr. Els Broens of Utrecht University. He added, "Luckily, the animals do not get very ill from it."

Frontline Healthcare Workers Feeling "Battered And Burned Out." The New York Times (7/1, Jacobs, 20.6M) reports, "America's health care workers are in crisis, even in places that have had sharp declines in coronavirus infections and deaths." They are "battered and burned out," and "feel unappreciated by a nation that lionized them as Covid heroes but often scoffed at mask mandates and refused to follow social distancing guidelines." In addition, physicians and nurses are "overworked, thanks to chronic staffing shortages made worse by a pandemic that drove thousands from the field." This "emotional fallout of the last 16 months takes many forms, including a spate of early retirements and suicides among health care providers."

Experts Worry About Lifelong Impact Of Pandemic On Children's Education, Health. Kaiser Health News (7/1, Szabo) reports experts are worried that "many of the youngest Americans have fallen behind socially, academically and emotionally in ways that could harm their physical and mental health for years or even decades" as a result of the pandemic and its associated social isolation and financial instability. Dr. Jack Shonkoff, a pediatrician with the Center for the Developing Child at Harvard University, said, "This could affect a whole generation for the rest of their lives. ... All kids will be affected. Some will get through this and be fine. They will learn from it and grow. But lots of kids are going to be in big trouble." A report from McKinsey & Co. found that the average US child "lost the equivalent of five to nine months of learning during the pandemic"; for Black and Hispanic students, the effects are more severe, with students losing the equivalent of six to 12 months of learning. Meanwhile, mental health-related emergency room visits for children aged 12 to 17 "increased 31% from 2019 to 2020, according to the Centers for Disease Control and Prevention."

Reps. Foster, Miller-Meeks Call On More Americans To Get COVID-19 Vaccines. USA Today (7/1, 12.7M) features an opinion piece from Reps. Bill Foster (D-IL) and Mariannette Miller-Meeks (R-IA), two members of the Select Subcommittee on the Coronavirus Crisis, concerning the need for more Americans to receive a COVID-19 vaccine. Foster and Miller-Meeks write, "Thanks to the scientists engaged in Operation Warp Speed and many others, lifesaving vaccines are widely available and the end of our struggle is, at last, coming into view. ... At this critical moment, to finally overcome the virus and avoid continued outbreaks, more Americans need to get vaccinated." Foster and Miller-Meeks promote the three FDA-approved vaccines, writing, "The three vaccines are based on decades of rigorous research and large clinical trials, and have few side effects. The long-term side effects of COVID-19 infection are far worse than any from the vaccines. ... Additionally, getting the vaccine dramatically lowers your chances of spreading this deadly virus to your loved ones."

Britain Reports Over 50K Cases Of Delta Coronavirus Variant Over One-Week Period. Reuters (7/2) says "Britain has reported 50,824 new cases of the highly transmissible Delta coronavirus variant of concern in the latest week, Public Health England (PHE) said on Friday." The agency "said the new total cases of Delta had risen to 161,981, a 46% increase from last week."

South Korea Sees Biggest Daily COVID-19 Rise In Six Months. The AP (7/1) reports, "South Korea has reported 826 new cases of the coronavirus, its biggest daily jump in about six months, as fears grow about another huge wave of the virus in the greater capital area." According to the article, "The Korea Disease Control and Prevention Agency said Friday that 633 of the cases came from the Seoul metropolitan area, home to half of the country's 51 million people, where officials pushed back an easing of social distancing measures as infections soared over the past week."

HEALTH & MEDICAL NEWS

Opioid Trial Defendants Say Pharmaceutical Distributors Cannot Be Held Liable For Addiction Crisis. In coverage of the New York opioid trial, Reuters (7/1, Pierson) reports attorneys for pharmaceutical distributors are arguing that "changing healthcare industry standards led to a surge in opioid prescriptions" which means that their clients can't be held "liable for a nationwide addiction crisis." In opening statements, "lawyers for Teva Pharmaceutical Industries Ltd, AbbVie Inc unit Allergan and Endo International PLC said the drugmakers adequately warned of opioid drugs' risks and did not engage in misleading marketing." Furthermore, "lawyers for drug wholesalers McKesson Corp, Cardinal Health Inc and AmerisourceBergen Corp said their companies had systems in place to flag suspicious orders."

Biogen Must Complete Study Confirming Efficacy Of Aducanumab Against Alzheimer's

Under FDA Approval Terms. The AP (7/1, Perrone) reports, "Biogen has until 2030 to complete a study confirming whether its new drug Aduhelm [aducanumab] truly slows" Alzheimer's disease, which is "under the terms of the Food and Drug Administration's conditional approval of the drug, a decision that has been praised by patients as overdue and condemned by the agency's own outside experts." However, "both camps agree: 2030 is far too long to wait for answers on the $56,000-a-year drug."

FluGen Awarded $11.4M Grant From Defense Department To Study Experimental Flu Vaccine. The Wisconsin State Journal (7/1, Wahlberg, 355K) reports, "Madison-based FluGen has been awarded a $11.4 million grant from the Department of Defense to study the ability of its experimental flu vaccine to protect against drifted flu virus strains in older adults, the company said Thursday." FluGen CEO Paul Radspinner stated, "We believe M2SR has the potential to be a more effective vaccine option in older adults, as it induces a broad antibody response, including mucosal, humoral, and cellular immunity, even in the presence of pre-existing immunity to the flu."

Colorado Chooses Attorneys To Probe Allegations That Officials Told Workers To Stop Measuring Toxic Pollution At Industrial Sites. The Denver Post (7/1, Finley, 660K) reports "Colorado has chosen outside attorneys to investigate whistleblower allegations that state health department managers ordered employees to stop measuring harmful surges of toxic pollution at industrial sites." Troutman Pepper Hamilton Sanders attorneys "will serve as independent special assistants to conduct the investigation into 'alleged improper non-enforcement of air quality standards,' Colorado Attorney General Phil Weiser said Thursday."

Minnesota Reports 8% Drop In Abortions From 2019 To 2020. The Minneapolis Star Tribune (7/1, Olson, 855K) reports "Minnesota on Thursday reported a historic 8% decline in abortions from 2019 to 2020, but reporting problems amid the COVID-19 pandemic might have led to an undercount that masked a smaller decline or an increase." The yearly "report released each July 1 by the Minnesota Department of Health showed 9,108 elective abortions in 2020, down from 9,945 in 2019, but it also showed a decline from 2,114 to 137 in abortions provided by Whole Woman's Health." Whole Woman's Health's chief executive "said it provided 1,266 abortions last year and that a location move to Bloomington from Minneapolis likely disrupted the state's reporting."

Lack Of Clear Vision Around Engaging Patients, Providers Presents Largest "Blind Spot" In Digital Transformation, Insurers Say. Modern Healthcare (7/1, Tepper, Subscription Publication, 215K) reports "health insurers are digitizing their operations by taking notes from, say, people who shop at Warby Parker." However, "while member claims can provide a window into a patient's health, personalizing coverage and healthcare is not as simple as picking up a pair of spectacles." A "Deloitte survey of 35 technology leaders at health plans with 50,000 members or more highlighted this challenge, with 49% of respondents saying a lack of clear vision around how to best engage patients and providers presents the biggest blind spot in their digital transformation."

New Jersey Smoking Ban Inside Atlantic City Casinos To End On Sunday. The New York Times (7/1, Tully, 20.6M) reports, "New Jersey's yearlong ban on smoking inside casinos in Atlantic City will end on Sunday as the state continues to relax its coronavirus-related mandates." However, "even as Gov. Philip D. Murphy acknowledged an end to the safety rule he implemented when casinos reopened a year ago, he strongly suggested that he supported efforts to make Atlantic City's nine remaining casinos smoke free permanently."

R.J. Reynolds, Philip Morris Win Dismissal Of $37M Jury Award After Court Found "Inflammatory" References To Literary Characters. Bloomberg Law (7/1, Hayes, Subscription Publication, 4K) reports, "R.J. Reynolds Tobacco Co. and Philip Morris USA Inc. won dismissal of a $37 million jury award to the estate of a deceased smoker, after a Florida appeals court found plaintiffs' counsel's references to infamous literary characters" in novels by George Orwell and Oscar Wilde "improperly inflamed the jury against the companies." The appeals "court reversed the jury verdict and award and remanded for a new trial."

Debate Remains Over Vaping Flavors, Advertising Targeting Children. WBRE-TV Wilkes-Barre, PA (7/1, Rogers) reports that the CDC "estimates 1 in 13 children in America will die from a smoking related illness if tobacco use continues at its current rate." A lot of "debate remains over vaping and how new flavors and advertising are targeting the next generation."

Antitrust Actions Could Limit Major Healthcare Initiatives From Amazon, Google. STAT (7/1, Cohrs, 262K) reports behind a paywall, "Washington is abuzz with an ambitious new antitrust effort to rein in the power of

tech industry power players like Apple, Amazon, Google, and Facebook – and the effort could limit their ascent in the health care industry." Should "major antitrust reform passes, it could inject legal uncertainty into future plans, analysts and attorneys said."

Respiratory Syncytial Virus Spreading Throughout US. The Wall Street Journal (7/1, Abbott, Subscription Publication, 8.41M) reports respiratory syncytial virus (RSV) cases are unseasonably high. They usually occur in the fall and winter, but as people are taking less precautions as COVID-19 restrictions are lifted, the virus is spreading at an unusually high rate.

Researchers Question Genetic Risk Scores Companies Use For Parents To Select Embryos Based On Genetic Abnormalities. STAT (7/1, Lopez, 262K) reports, "As more people turn to in vitro fertilization for help with conceiving, a host of companies is capitalizing on the opportunity by offering screening services that allow hopeful parents to select embryos least likely to result in a baby with genetic abnormalities or life-threatening diseases." However, researchers are "questioning the strength and ethical implications of such risk screening services." The authors' "report underscores the concern among geneticists, legal scholars, and ethicists that applying genetic research to develop risk scores and select embryos might be imperfect and less robust than patients and companies think." They "also outline strategies for companies and clinicians to use when communicating with parents seeking to use these tools."

Rural Colorado Town Crowdsources Prescription Delivery System. Kaiser Health News (7/1, Hawryluk) reports Walden, Colorado "has suffered the fate of many small towns across the United States, as the economics of the pharmacy business have made it difficult for community drugstores to survive." The closest pharmacy is an hourlong drive, so the community "has crowdsourced a delivery system, taking advantage of anyone's trip to those bigger cities to pick up medications for the rest of the town." The senior center also "runs a regular shuttle to the bigger locales." However, "these solutions can't replace a bricks-and-mortar pharmacy, as pharmacists do much more than count pills."

Commentary Reflects On Meaning Behind "Miracles" In ICUs. In an opinion piece for the New York Times (7/2, 20.6M), Daniela Lamas, a pulmonary and critical-care physician at Brigham and Women's Hospital in Boston, says physicians "all have cases that shake us and that we find ourselves revisiting, particularly amid this pandemic," and oftentimes "these are cases of the patients that we were unable to save, but there are also patients whose very survival proves us wrong." Lamas writes, "The longer I practice critical care, the more I wonder: What does it mean for a miracle to happen in the intensive care unit?" Lamas writes that physicians "do not want to deprive our patients of the chance to surprise us." However, she writes, "we must also ask ourselves how many deaths we are willing to prolong for the possibility of one great save."

Sen. Wyden Outlines Changes To Pharmaceutical Market He Believes Need To Be Addressed. Forbes (7/1, Cohen, 10.33M) reports Sen. Ron Wyden (D-OR) in June released a manifesto outlining "a number of changes to the pharmaceutical market that the lawmaker believes must be addressed." The proposal "would confer Medicare the ability to negotiate prescription drug prices and reduce out-of-pocket costs for Medicare beneficiaries." According to the article, "The principles for drug pricing reform that Wyden proposes blend elements from two bills drafted in Congress: S.2543 (Prescription Drug Pricing Reduction Act), which Wyden co-sponsored with Senator [Chuck] Grassley (R-Iowa), and the House Democrat-led H.R.3 (Lower Drug Costs Now Act)."

Minnesota AG Says States Have Right To Regulate PBMs. The Minneapolis Star Tribune (7/1, Carlson, 855K) reports "Minnesota Attorney General Keith Ellison said in a court filing Thursday that states have a fundamental right to regulate prescription-drug middlemen firms called 'pharmacy benefit managers' (PBMs), which control a growing share of the $370 billion-plus retail U.S. prescription drug market." A filing from Ellison's office said, "PBMs have exploited decades of lax or non-existent regulation to become a massive part of the prescription-medication industry. ... State regulation is necessary to curb PBM practices that harm pharmacies, consumers and states." The filing is part of "a case involving a regulatory dispute in North Dakota before the 8th U.S. Circuit Court of Appeals."

GLOBAL HEALTH NEWS

Biden Administration Designates 17 Nations As Lacking On Human Trafficking Efforts, Says Pandemic Worsened Human Slavery. The AP (7/1, Lee) reports "the Biden administration on Thursday designated 17 countries as not doing enough to combat human trafficking and warned them of potential U.S. sanctions." The Biden Administration "also called out several U.S. allies and friends, including Israel, New Zealand,

Norway, Portugal and Turkey, for backsliding in their efforts." The designations were part of "the State Department's annual 'Trafficking in Persons' report, which cited the coronavirus pandemic as a cause for a surge in human slavery between 2020 and 2021."

Reuters (7/1, Psaledakis, Landay) says the State Department report "said discriminatory policies perpetuated human trafficking, drawing a link with systemic racism in the United States and abroad for the first time." According to Reuters, "Secretary of State Antony Blinken said in the Trafficking in Persons report that inequities undercut Washington's battle against human trafficking."

CNN (7/1, Hansler, 89.21M) reports "the Covid-19 pandemic increased the number of people at risk for human trafficking as traffickers took advantage of the social and economic crisis created by the global outbreak, the State Department said."

Forbes (7/1, Dangor, 10.33M) reports the "pandemic gave human traffickers more chances to prey on people, according to" the report. It "found that losing income, isolating to avoid the virus and doing more work or schooling online put people at greater risk of being recruited into forced and coerced labor." As countries "turned their attention to the pandemic, traffickers have 'seized the opportunity to grow their operations,'...Blinken said."

Malaysia's Main Human Trafficking Crime Is Forced Labor, US State Department Says. Reuters (7/2, Chu, Setboonsarng) reports "Malaysia's predominant human trafficking crime is forced labour, the U.S State Department said on Friday, after downgrading the Southeast Asian country to the worst tier in its annual report on human trafficking." Malaysia dropped "to 'Tier 3' in this year's closely watched Trafficking in Persons (TIP) report as it continued to conflate human trafficking and migrant smuggling crimes, and did not adequately address or criminally pursue credible allegations on labour trafficking, the report said."

House Appropriators' Foreign Aid Spending Bill Repeals Helms Amendment. Roll Call (7/1, Oswald, 130K) reports, "After several hours of debate and votes on 10 amendments, House Appropriators on Thursday advanced to the floor annual foreign aid spending legislation that would make history with its repeal of a decades-old anti-abortion provision and significant increases in family planning funding." The Helms amendment "bans U.S. foreign aid from being used to pay for abortions." The article adds, "Republicans made three attempts at the committee's markup of the bill to reinsert the abortion-related provisions," but "those efforts all failed." However, "Republicans predicted that bicameral negotiations would result in either a more palatable version of the measure or risk sinking the entire funding bill."

Smoking Rose In The Past Year Among Young People In UK, Reversing 40-Year Decline. The Telegraph (UK) (7/1, Fawehinmi, 249K) reports smoking in the UK "has been on the decline for years, and in 2019 Health Secretary Matt Hancock set out a plan to 'finish the job' of smoking by eradicating it altogether by 2030, in a green paper on health prevention." Yet, "according to a recent study conducted by Future Health, founded by Richard Sloggett, a former policy adviser to Hancock, the surge in young people smoking in the past year has reversed the 40-year decline in the habit."

HHS IN THE NEWS

Biden Administration Unveils First Set Of Rules Banning Surprise Medical Billing. The Washington Post (7/1, Goldstein, 10.52M) reports on Thursday, the Biden Administration unveiled new rules "to shield Americans from large, unexpected medical bills after patients wind up in emergency rooms or receive other care they did not realize lay outside their insurance networks." The regulations, which will take effect "in January, are the first in a series of coordinated steps that four federal agencies are required to take to set in motion a law Congress adopted last year to protect health-care consumers against a practice known as surprise billing." HHS Secretary Xavier Becerra said, "Congress actually got something good done."

The New York Times (7/1, Kliff, Sanger-Katz, 20.6M) reports that these rules were the "first steps...toward finalizing the details of a ban on surprise medical bills that Congress passed and President Trump signed into law last winter. Some experts see the policy as the most important consumer protection in health care to come out of Washington in more than a decade." This issue "had been widely seen, by academics and legislators, as one of the most exasperating common practices in medicine." Becerra said, "The A.C.A. took us a long way; expanded Medicaid took us a long way – but there was still this black hole. ... Getting rid of surprise billing is like removing the boogeyman from your nighttime sleep."

The AP (7/1, Alonso-Zaldivar) reports that the rules "jointly issued by four federal agencies spell out protections for insured patients against surprise billing in medical emergencies, and unexpected charges from out-of-network doctors at an in-network facility." In addition, "out-of-network clinicians and service providers would...be barred from billing patients for the difference between their charges and what insurance paid." Becerra said, "It's about getting good health care at a good price for all Americans – it's a bipartisan effort. ... You will no longer be stuck in the middle of a payments dispute because you were blindsided by a charge you weren't expecting."

The Wall Street Journal (7/1, Armour, Subscription Publication, 8.41M) reports Becerra added, "No patient should forgo care for fear of surprise billing. ... Health insurance should offer patients peace of mind that they won't be saddled with unexpected costs."

The Hill (7/1, Sullivan, 5.69M) reports that according to Becerra, "the protections 'probably only second to the Affordable Care Act will make a major difference in the lives, the health care, of millions of Americans.'"

Dr. John J.H. "Joe" Schwarz, a lecturer in public policy at the University of Michigan, writes in the Detroit Free Press (7/1, 2.16M) that in 2020, amid "the COVID-19 pandemic, Congress took the essential step of passing the bipartisan No Surprises Act, which ended the practice of surprise medical billing." Schwarz says "it's now up to the Biden administration and Department of Health and Human Services (HHS) Secretary Xavier Becerra to implement the law. It is critical that HHS undertake the full rulemaking process and hear from all concerned stakeholders – patients and healthcare providers above all – to ensure that the best policies, especially a robust independent dispute resolution mechanism, are implemented."

Among other news outlets covering the story are CNN (7/1, Luhby, 89.21M), Fox Business (7/1, Lea, 3.06M), Congressional Quarterly (7/1, McIntire, Subscription Publication), Modern Healthcare (7/1, Brady, Subscription Publication, 215K), HealthLeaders Media (7/1, Commins, 118K), and Healthcare Dive (7/1, Pifer).

Oklahoma's Medicaid Expansion Takes Effect.

The Washington Post (7/1, Winfield Cunningham, 10.52M) reports additional federal funding "hasn't yet furthered Democrats' efforts to finally get Medicaid expansion in every single state." However, "one state – Oklahoma – will become the first to start pocketing the extra dollars provided by Congress." Oklahoma "voters had already decided to expand the health insurance program before the incentive money was ever on the table." As of July 1, "Oklahomans earning up to 138 percent of the federal poverty level (about $36,000 for a family of four) can sign up for SoonerCare, the state's Medicaid program." The article says this issue is a priority for the Biden Administration. That is why HHS Secretary Xavier Becerra and CMS Administrator Chiquita Brooks-LaSure visited the state to mark the occasion.

The AP (7/1, Alonso-Zaldivar) reports Oklahoma is expanding Medicaid "at a time when Democrats in Washington and across the states are pressing to complete the work of the Obama-era Affordable Care Act, recently upheld by the Supreme Court for the third time in a decade." To date, "38 states and Washington, D.C., have expanded Medicaid, and expansion in a dozen mostly Southern states may be the biggest piece of unfinished business."

The Hill (7/1, Sullivan, 5.69M) reports Becerra said, "Today is a victory for the nearly 200,000 Oklahomans who have been waiting for health care. ... I want to congratulate Oklahoma on joining the ranks of states that are bringing quality health coverage to our neighbors and families. I encourage the remaining 13 states to look at the opportunities included in the American Rescue Plan and join us, so that every person eligible can get covered."

Among other news outlets covering the story are the Oklahoman (7/1, Forman, 205K), Tulsa (OK) World (7/1, 241K), the Public Radio Tulsa (OK) (7/1, Trotter), KOKI-TV Tulsa, OK (7/1, 12K), KJRH-TV Tulsa, OK (7/1, 8K), KOKH-TV Oklahoma City (7/1, 10K), KTUL-TV Tulsa, OK (7/1, 34K), and Healthcare Dive (7/1, Pifer).

Following Britney Spears' Case, Two Democratic Senators Call For More Oversight Of US Conservatorship Systems.

The New York Times (7/1, Cameron, 20.6M) reports Sens. Elizabeth Warren (D-MA) and Bob Casey (D-PA) "are calling on federal agencies to increase oversight of the country's conservatorship systems, following testimony from the pop star Britney Spears that she had been abused under her conservatorship." The article adds, "The senators, in a letter to Xavier Becerra, the health secretary, and Merrick B. Garland, the attorney general, asked for more data within the next two weeks on conservatorships in the United States, and how their agencies interact with the state programs." This "move could signal the beginning of a legislative effort to overhaul the system."

The Hill (7/1, Choi, 5.69M) reports the senators "acknowledged that many conservators 'often serve selflessly and in the best interest of the person under guardianship,' but argued that there is a lack of sufficient data and oversight around guardianship proceedings that leads to 'opportunities for neglect, exploitation, and abuse.'"

Among other news outlets covering the story are the Boston Globe (7/1, Kaufman, 1.04M), the New York Post (7/1, Degregory, 7.45M) and TIME (7/1, Abrams, 18.1M).

Massachusetts Nurses To Visit Tenet Healthcare's Headquarters To Call Out Company's "Disdain For Nurses" During Pandemic.

The Dallas Morning News (7/1, Lieberman, 772K) reports "striking nurses from Massachusetts will travel to Tenet Healthcare's Dallas headquarters on Wednesday to deliver a petition calling out the hospital company's 'complete disdain for its nurses' during the COVID-19 pandemic." The nurses "plan to make a direct appeal to Tenet CEO Ronald Rittenmeyer to address what they call a patient safety crisis at the company's St. Vincent Hospital in Worcester caused by a lack of sufficient PPE and understaffing." Reps. Katie Porter

(D-CA) and Rosa Delauro (D-CT) sent a letter to HHS Secretary Xavier Becerra "and Federal Trade Commission chairwoman Rebecca Slaughter requested a federal investigation to determine whether Tenet and other major hospital operators misused stimulus grants and other pandemic-related relief funds."

Democratic Lawmakers Demand Tenet Disclose Spending Of COVID-19 Relief Funds. Modern Healthcare (7/1, Bannow, Subscription Publication, 215K) reports "four Massachusetts Democratic lawmakers are demanding that Tenet Healthcare disclose how it spent COVID-19 relief funds, accusing the health system of enriching its executives and shareholders instead of supporting its providers and communities." Sen. Elizabeth Warren (D-MA), Sen. Edward Markey (D-MA), Rep. Jim McGovern (D-MA) and Rep. Lori Trahan (D-MA) blasted "the company for accepting federal money while shortchanging its workers, including nurses at St. Vincent Hospital in Worcester, Massachusetts, who currently are on strike."

Tennessee Officials Suspend License Of Shelter For Immigrant Minors In Chattanooga.

The AP (7/1) reports "Tennessee officials on Thursday suspended the license of a Chattanooga shelter for immigrant children after one of the employees was arrested following abuse allegations." Department of Children's Services Commissioner Jennifer Nichols has "told lawmakers that in early June during an unannounced inspection of a Chattanooga shelter, a young boy reported he had witnessed 'an act that, in our policy, would substantiate and require an investigation' while at the facility." In a press "release, Nichols on Thursday cited the abuse allegation and other issues that had plagued the shelter over the past month as reasons for the suspension." The Chattanooga "shelter has a federal contract with the Office of Refugee Resettlement to temporarily house unaccompanied" immigrant minors.

The Chattanooga (TN) Times Free Press (7/1, Sher, Massey, 168K) reports "the Tennessee Department of Children's Services said the license was suspended due to a series of issues related to the facility, including an allegation of child abuse and a teenage boy running away from the shelter in mid-June." All minors "were moved from the facility on June 22."

CMS Releases First Value-Based Payment Model Which Seeks To Tackle Health Equity.

Modern Healthcare (7/1, Brady, Subscription Publication, 215K) reports that on Thursday, CMS released "its first value-based payment model directly addressing health equity, a top Biden administration priority." This "pay model is part of the agency's 2022 end-stage renal disease prospective payment system proposed rule." The agency intends "to modify the ESRD Treatment Choices Model's benchmarking and scoring methodology to encourage dialysis providers to reduce disparities in home dialysis and kidney transplant rates among ESRD patients from disadvantaged communities." CMS Administrator Chiquita Brooks-LaSure stated, "Health equity is at the center of our work here at CMS. ... When CMS encourages dialysis providers to offer more options for Medicare patients to receive dialysis treatments, it can be life-changing and lead to better health outcomes, greater autonomy and better quality of life for patients with kidney disease."

Fierce Healthcare (7/1, King, 150K) also covers the story.

Rep. Bera: Infrastructure Plan Should Address Broadband Access For Telemedicine.

Axios (7/1, Frazier, 1.26M) reports "any infrastructure plan passed by Congress should address broadband access for telemedicine, Rep. Ami Bera (D-Calif) said at" an Axios event on Thursday. Bera said, "Telehealth, telemedicine was great for a lot of folks, but a lot of communities don't actually have broadband and access to those tools. ... I do think Congress has a role in working with the Biden administration as we put together this infrastructure plan. 'Can we address that broadband access?'" CMS Administrator Chiquita Brooks-LaSure "agreed Congress should move," saying, "There are some pieces of telehealth that CMS will have some authority, but Congress is going to need to act on some of the critical pieces to make telehealth permanent." Axios adds that "many communities, like Native American tribes, lack access to high-speed internet."

HHS Assistant Secretary Discusses Need To Advance Health Equity.

Federal News Network (7/1, 220) reports that during an interview with Community Health Center, Inc., US Department of Health and Human Services Assistant Secretary for Health Dr. Rachel Levine discussed "the dramatic toll exacted on the nation's children by the pandemic, the need to advance health equity for the LGBTQ and all vulnerable populations, and the promise of telehealth to eliminate barriers to care." Levine is "the first transgender presidential appointee approved by the Senate."

NC State Baseball Team Eliminated From College World Series Because Of COVID-19 Cases; Health Official Urge Young People To Get Vaccinated.

The Fayetteville (NC) Observer (7/1, DeVane, 157K) reports North Carolina State University's baseball team "was a win away from qualifying for the national championship series," but "was sent home from the College World Series when [eight] of its players tested positive for COVID-19." This situation "shows that young

people who have not gotten a COVID-19 vaccine should be especially concerned about a new variant of the virus, a top federal health official said." US Department of Health and Human Services Assistant Secretary for Health Dr. Rachel Levine noted "health officials have found it challenging to convince 18- to 26-year-olds to get the vaccines," so the officials have turned to "social media platforms and influencers on sites such as Instagram and TikTok to reach out to that group."

US Regulators Take Aim At "Information Walls" Between Providers, Social Services To Reduce Health Disparities. Bloomberg Law (7/1, Brown, Subscription Publication, 4K) reports "federal regulators are taking aim at the information walls between health-care providers and the social services sector as part of their effort to reduce health disparities, Micky Tripathi, the nation's top Health IT official, said Thursday." Connecting healthcare "providers with social services organizations through health information technology will allow patients to receive more holistic care and enable better interventions to address social problems that can lead to poor health outcomes, said Tripathi, head of the Office of National Coordinator for Health Information Technology," which is housed in HHS.

FDA Responds To Growing Cybersecurity Threats By Creating New Leadership Position At CDRH. Healthcare Dive (7/1, Slabodkin) reports in response to "growing cybersecurity threats from increasingly sophisticated hackers," the FDA created "a new leadership position in early 2021 at its Center for Devices and Radiological Health for overseeing medical device security." The agency selected University of Michigan Associate Professor Kevin Fu "to serve a one-year term as acting director of medical device cybersecurity at CDRH." The appointment "was applauded by pundits as a sign the agency is making security a priority."

FDA Still Grappling With Curbing Carcinogens Years After Recalls Began. Bloomberg Law (7/1, Edney, Subscription Publication, 4K) reports the FDA is "still grappling with curbing contaminants that keep turning up in tainted drugs" even "after millions of blood-pressure pills were recalled for containing potentially cancer-causing chemicals." An agency task force has "been meeting regularly since 2018 to find out how the chemicals, called nitrosamines, get into drugs, how widespread the issue is – and how to eliminate them from medicines."

NPR Lists Takeaways From Newly Public Hospital Pricing Data. NPR (7/2, Appleby, 3.69M) reports price variations between hospitals "are supposed to be available in stark black and white under a Trump administration price transparency rule that took effect at the start of this year." The rule "requires hospitals to post a range of actual prices – everything from the rates they offer cash-paying customers to costs negotiated with insurers." However, "some hospitals bury the data deep on their websites or have not included all the categories of prices required, according to industry analysts." Meanwhile, "a sizable minority of hospitals have not disclosed the information at all." In May, CMS "sent letters to some of the hospitals that have not complied, giving them 90 days to do so or potentially face penalties." NPR provides "five takeaways from the newly public data and tips for how you might be able to use it to your benefit."

National Front Page News

Headlines From Today's Front Pages.

Wall Street Journal:

Supreme Court Upholds Arizona Election Rules
US Wins International Backing For Global Minimum Tax
A Historic Nashville Music Venue – Now Open – Is Fighting To Survive. 'Everything Has Changed.'
Robinhood Wants You To Buy Robinhood Stock On Robinhood
Car Sales Continue Hot Streak, But Market Shows Signs of Cooling

New York Times:

Inspector Who Said Florida Tower Appeared In 'Good Shape' Is Now Under Scrutiny
Trump Was Not Indicted. But The Charges Still Threaten Him.
Trump Organization Is Charged With Running 15-Year Employee Tax Scheme
Supreme Court Upholds Arizona Voting Restrictions
US Proposal For 15% Global Minimum Tax Wins Support From 130 Countries
Marking Party's Centennial, Xi Warns That China Will Not Be Bullied

Washington Post:

Prosecutors Allege Fraud At Trump Firm
Justices Uphold Ariz. Vote Limits
US Unready For Wildfire Escalation
Indictments Become Trump's Latest Rallying Cry
130 Nations Back Plan For A Global Minimum Tax, In Boost For Biden
Washington Football Team Is Fined $10 Million By NFL

FINANCIAL TIMES:

World's Leading Economies Agree Global Minimum Corporate Tax Rate
Trump Organization And Top Executive Charged With Fraud
Midfield Duo Lead Cast As Mancini Plots An Italian Job Against Belgium
Nissan Unveils First UK battery Factory In £1bn Sunderland Plan
ECB To Lift Cap On Eurozone Banks' Dividends And Share Buybacks
Instagram Boss Says It Is 'No Longer A Photo-sharing App'
Chinese Communist Party Centenary Culminates With Warning To Foreign Rivals

STORY LINEUP FROM LAST NIGHT'S NETWORK NEWS:

ABC: Trump Organization-charges; Surfside Condo Collapse; COVID Update; Extreme Weather; Supreme Court-Voting Rights; Los Angeles-Explosion; Fourth of July Travel.
CBS: Surfside Condo Collapse-Biden; Trump Organization-Charges; Extreme Weather; COVID Update; Supreme Court-Voting Rights; January 6th Investigation; Los Angeles-Explosion.
NBC: Trump Organization-Charges; Bill Cosby Released; COVID Update; Surfside Condo Collapse; Washington Football Team-Fine; Supreme Court-Voting Rights; January 6th Investigation; Los Angeles-Explosion; Pinterest Bans Weight Loss Ads.

NETWORK TV AT A GLANCE:

Trump Organization-Charges – 9 minutes
Surfside Condo Collapse – 8 minutes, 20 seconds
COVID Update – 6 minutes, 40 seconds
Supreme Court-Voting Rights – 6 minutes
Extreme Weather – 2 minutes, 55 seconds
January 6th Investigation – 2 minute, 25 seconds
Los Angeles-Explosion – 1 minute, 55 seconds

LAST LAUGHS

Late Night Political Humor.

Stephen Colbert: "Today, the former President's company was indicted by New York prosecutors. The bell tolled. And I want to join you in that feeling, but I have been hurt too many times. First, I fell in love with the Mueller report, then I bounced back with the impeachment, then I gave it one more chance with the other impeachment. I just hurt, you know."

Stephen Colbert: "I do have a glimmer of hope for a sliver of consequences for the January 6th insurrection, because House Speaker Nancy Pelosi is launching an investigation, appointing a group of House members called a select committee. Which really sounds like the store brand, but still good. I love select committee lemon pies."

Stephen Colbert: "Today, Pelosi named seven prominent Democrats to the committee, but the big news was the Republican she named: Congresswoman Liz Cheney has patriotically agreed to serve on the committee. So the committee has seven Democrats to grill the seditionists, and if that doesn't work, they've got one Cheney to shoot 'em in the face."

James Corden: "According to a recent survey, over half of Europeans said they would be more than happy with the idea of handing the business of government over to artificial intelligence. Here in America, when it comes to Congress, we'd settle for any kind of intelligence."

James Corden: "Europeans are open to the idea of an artificial intelligence government. I'm not sure I'm ready to hear a news report like the Prime Minister had an accident in the tub this morning. He's currently soaking in a bowl of rice."

NATIONAL NEWS

Biden Meets With Families Of The Missing And First Responders In Florida. The AP (7/1, Jaffe, Lemire) reports that on Thursday, President Biden "drew on his own experiences with grief and loss to comfort families affected by the Florida condo collapse, telling them to 'never give up hope' even as the search for survivors paused early Thursday, a week after the building came down." The AP adds that "addressing some of the families touched by the tragedy, Biden spoke in deeply personal terms as he offered his prayers and support in the private meeting. 'I just wish there was something I could do to ease the pain,' he said in a video posted on Instagram by" by a woman "who was close to a couple and their daughter who are still missing." Still, Reuters (7/1, Johnson, Holland) reports Biden "acknowledged that hopes of finding any survivors dimmed with each passing day, but said it was possible someone might still be pulled out alive. 'Hope springs eternal,' he said."

The Wall Street Journal (7/1, Subscription Publication, 8.41M) reports that the President, "drawing on his own experiences of grief, said: 'The people you may have lost, they're gonna be with you your whole life—a part of your soul, a part of who you are.'" The New York Times (7/1, Shear, 20.6M) reports that for the President, "who has faced his own personal tragedy — including the deaths of his wife and daughter, and later his grown son — it is a role that is all too familiar. His successful campaign for the presidency was built in part on his ability to display an empathy for those suffering that often eluded" former President Trump.

In its coverage, the South Florida Sun Sentinel (7/1, Man, 525K) says the "president — a man who personally knows the devastation of tragic loss — acted as the nation's consoler-in-chief." The Miami Herald (7/1, Hanks, Padró Ocasio, Vassolo, Ovalle, Harris, 647K) reports that Biden's trip "included visits with first responders and grieving families as well as a brief stop at one of the memorial walls. He and first lady Jill Biden laid a bouquet of white flowers next to several saint candles. They held hands while they looked at the photos of some of the faces of victims and missing persons." The Miami Herald (7/1, 647K) also posed a video presentation of the President's visit.

CNBC (7/1, Wilkie, 7.34M) reports on its website that Biden said after meeting families of those missing in the rubble, "What amazed me is their resilience, and their absolute commitment and willingness to do whatever it takes to find an answer. I walked away impressed by their strength." Biden added, "The families are very realistic. They know that as each day goes by, the chances are diminished. ... At a minimum, at a minimum, they want to recover the bodies." WKMG-TV Orlando, FL (7/1, 37K) reported Biden said "the country stands with Surfside." Biden: "They had basic heart-wrenching questions. Will I be able to recover the body of my son or daughter, my husband, my cousin, my mom and dad? How can I have closure without being able to bury them, if I don't get the body, what do I do? Jill and I wanted them to know that we are with them, and the country is with them. Our message today is that we're here for you as one nation." However, the Wall Street Journal (7/1, Caldwell, Bauerlein, Hernandez, Subscription Publication, 8.41M) reports that while there were early concerns that the missing may not be found alive, now the fear is that the destruction was so great that they may not be found at all.

The President's visit with highlighted on all three nightly news programs. In its lead segment, The CBS Evening News (7/1, lead story, 3:55, O'Donnell, 3.63M) reported, "President Biden, who visited with families affected by the disaster today, says they are going through hell and that he told the families that federal engineers are working to ensure that it is safe for the full search to resume. Mr. Biden spent much of the day meeting with first responders, officials, and family members, telling them that he understands personal experience the difficulty of not knowing what happened to their loved ones. The President says he is ordering a federal probe into what caused the building to fold in on itself early Thursday. "

ABC World News Tonight (7/1, story 2, 2:35, Davis, 5.71M) reported, "Today, President Biden visiting, thanking first responders and rescue crews. And after spending several hours with families in private, he and the first lady paying their respects at the makeshift memorial that's grown larger every day." ABC (Oquendo) added that the President spent "time privately for hours with grieving families." For NBC Nightly News (7/1, story 4, 1:50, Holt, 4.7M), Morgan Chesky reported that the President "spent this morning meeting with first responders and families left waiting for word on their loved ones." NBC added, "In briefings, President Biden pledging federal funds to cover all state and county costs."

WINK-TV Fort Myers, FL (7/1, 2.22M) reported Biden "spoke in Surfside to the families of the deadly condo collapse all afternoon, saying that he's mourning with them. The President and the First Lady stopped by what the community is calling the Wall of Hope and the Missing, filled with pictures of those loved ones who were in the condo building at the time of the collapse." WINK added, "The President and the First Lady met behind closed doors with the families of building residents." WSVN-TV Miami-Dade, FL (7/1, 32K) reported Biden "wanted to spend the day with a chance to sit down with the families who have been suffering now for a week. ... The President wanted to make it a point during this trip to have some one-on-one time with them. And that is really what took up a majority of his day."

President, First Lady Meet With First Responders, Offers Federal Aid. The Washington Post (7/1, 10.52M) reports that the President and First Lady Jill Biden also "met with and thanked a group of first responders. The President also told officials on the ground that he intends to have the federal government pay for all of the costs incurred by the state and county in the response." Biden is quoted as saying. "There's going to be a lot of pain and suffering and even need for psychological help in the days and months that follow, so we're not going anywhere. Tell me what you need."

Bloomberg (7/1, Fabian, Cook, 3.57M) reports that Biden "praised first responders searching for survivors in the rubble of the collapsed building. ... 'I just wanted to come down and say thanks,' Biden told a group of about 50 uniformed personnel. 'What you're doing now is hard as hell.'" The Los Angeles Times (7/1, Jarvie, 3.37M) reports that the President told the first responders, "Until we need you, no one fully appreciates what you do. But I promise you, we know. We know. What you're doing here is incredible, having to deal with the uncertainty and worrying about the families." The Miami Herald (7/1, Vassolo, 647K) reports that Surfside Police Officer Craig Lovelette and his colleagues met with both Biden and DeSantis.

WWSB-TV Sarasota, FL (7/1, 4K) reported Biden "is offering comfort to the grieving" and "is also offering federal support for the efforts to search for the missing and rebuild of the high-rise condo."

Overall, Fabiola Santiago writes for the Miami Herald (7/1, 647K)that the President's visit "wasn't a stirring call to unity, but he defined the path taken, calling the way local, state, and federal officials and resources have come together, 'remarkable.' 'Everybody is in the same team, pulling together,' he said in remarks, praising South Florida

Republican and Democratic elected officials alike, and adding 'there's much more to be done.'"

Also reporting on Biden's visit are The Hill (7/1, Gangitano, 5.69M), among others.

Biden, DeSantis Share "Moment Of Bipartisan Bonhomie." Politico (7/1, Forgey, 6.73M) reports that on Thursday, Florida Gov. Ron DeSantis (R) "praised...Biden's federal response to the collapse of a condo building...providing a moment of bipartisan bonhomie between the leader of the Democratic Party and a rising star within Donald Trump's GOP. Speaking at a command briefing near the site of the deadly disaster, DeSantis – seated beside Biden – said the president had 'recognized the severity of this tragedy from day one, and you've been very supportive.'" DeSantis praised the cooperation of those at all levels, saying to Biden, "You guys have not only been supportive at the federal level, but we've had no bureaucracy." Reuters (7/1, Hunnicutt, Holland) reports that "sitting next to one of his fiercest critics," Biden "managed to find a silver lining in the grave tragedy that brought them together. 'You know what's good about this?' Biden asked Florida Governor Ron DeSantis, not waiting for an answer. 'We're letting the nation know we can cooperate.'" Similarly, the Washington Post (6/30, Sullivan, Gearan, 10.52M) that the President "summoned two defining features of his political identity: empathy and bipartisanship."

The New York Times (7/1, Shear, 20.6M) says Biden also "hailed the cooperation between state, local and federal agencies in the wake of the tragedy. 'I mean just the simple act of everybody doing whatever needs to be done really makes a difference,' he said."

In another item, Reuters (7/1, Oliphant, Layne, Borter) reports that DeSantis, a "Republican firebrand who relishes partisan warfare," has "tried to abstain from politics in the wake of a fatal building collapse near Miami, spending much of his week meeting with rescue workers and grieving families at the disaster scene." However, "politics will be unavoidable on Saturday, when former President Donald Trump will stage a campaign-style rally 250 miles across the state, as part of his return to public life."

Rescue Efforts Temporarily Halted Due To Instability. USA Today (7/1, Ortiz, 12.7M) reports that rescue efforts "were halted early Thursday because of concerns about the instability of a condo section still standing a week after the building collapsed outside Miami, dimming hopes of finding any survivors." Miami-Dade Mayor Daniella Levine Cava said, "We've been forced to halt operations ... in early hours of the morning due to structural concerns about the standing structure. We're doing everything we can to ensure the safety of our first responders." The AP (7/1, Spencer) reports that rescue efforts "resumed Thursday evening after a 15-hour pause for safety concerns, and officials said they had started planning for the likely demolition of the remaining structure."

Meanwhile, CNN (7/1, Waldrop, Holcombe, Almasy, 89.21M) reports that officials "are considering demolishing the rest of the Champlain Towers South as operations continue in sections that crumbled to the ground a week ago," Levine Cava said Thursday evening. The Mayor "said officials need to make the decision about a 'likely' demolition 'extremely carefully and methodically,' taking into consideration the impact it could have on the existing pile of rubble."

Building Collapses In Washington, DC. Reuters (7/1) reports that "search and rescue crews were attempting on Thursday to free a construction worker trapped inside a partially-built five-story building that collapsed during a rain storm in Washington. Four other construction workers were removed from the debris shortly after the building in the U.S. capital came down at about 3:30 pm (1930 GMT), said John Donnelly, assistant chief of D.C. Fire and EMS."

Administration Decries SCOTUS Ruling Upholding Arizona Voting Rules.

The AP (7/1, Sherman) reports that on Thursday, the Supreme Court "upheld voting restrictions in Arizona in a decision that could make it harder to challenge other states' voting limits put in place by Republican lawmakers following last year's elections." The "6-3 ruling by the conservative-majority court fueled new calls from Democrats to pass federal legislation, blocked by Senate Republicans, that would counter the new state laws and make Supreme Court changes that include expanding the nine-justice bench."

Reuters (7/1, Chung) reports that the case "involves a 2016 Arizona law that made it a crime to provide another person's completed early ballot to election officials, with the exception of family members or caregivers." Reuters says "community activists sometimes engage in ballot collection to facilitate voting and increase voter turnout." According to Reuters, "Ballot collection is legal in most states, with varying limitations." On its website, CNBC (7/1, Higgins, 7.34M) reports that the Democratic National Committee "challenged the two measures under Section 2 of the Voting Rights Act, which requires elections to be equally open to people of all races," and "the 9th U.S. Circuit Court of Appeals sided with the DNC."

The Wall Street Journal (7/1, Kendall, Bravin, Subscription Publication, 8.41M) reports that the case was a head-to-head fight between the two major parties, with the DNC and allied groups suing the state and Arizona's AG, Mark Brnovich (R) and the state GOP, defending the rules.

Bloomberg (7/1, Stohr, 3.57M) says the decision "builds on a 2013 Supreme Court ruling that wiped out part of the Voting Rights Act. In the new decision, the court's conservative majority restricted the use of a different

provision, known as Section 2, to challenge policies that make it harder for minorities to register and vote." Writing "for the majority, Justice Samuel Alito said 'mere inconvenience' wasn't reason to invalidate voting rules, and he said a small disparity in the impact on different racial groups might not be enough either." Alito wrote, "The mere fact there is some disparity in impact does not necessarily mean that a system is not equally open or that it does not give everyone an equal opportunity to vote." The New York Times (7/1, Liptak, 20.6M) reports that Alito "added that states had a legitimate interest in rooting out fraud," writing, "Fraud can affect the outcome of a close election, and fraudulent votes dilute the right of citizens to cast ballots that carry appropriate weight. Fraud can also undermine public confidence in the fairness of elections and the perceived legitimacy of the announced outcome."

NBC Nightly News (7/1, story 6, 1:35, Holt, 4.7M) reported, "Justice Samuel Alito's majority opinion said all voting laws impose some burden, and they don't cross the line even if they create small disparities in voting as long as the state has some justification for them."

Reuters (7/1, Chung) reports that in a "scathing dissent," Justice Kagan "called the ruling 'tragic,'" noting that it "comes as states are erecting new barriers to voting, even banning the handout of water to voters standing in line." She wrote, "So the court decides this Voting Rights Act case at a perilous moment for the nation's commitment to equal citizenship. It decides this case in an era of voting-rights retrenchment – when too many states and localities are restricting access to voting in ways that will predictably deprive members of minority groups of equal access to the ballot box." The Hill (7/1, Bolton, 5.69M) says that Kagan's "fiery dissenting opinion in a voting rights case, which was joined by the two other liberal members of the court, Justices Stephen Breyer and Sonia Sotomayor, accused her conservative colleagues of undermining Section 2 of the landmark Voting Rights Act and tragically weakening what she called 'a statute that stands as a monument to America's greatness.'"

Ruling Likely To Make It Easier To Tighten Voting Laws, Harder To Challenge Them. The Washington Post (7/1, Barnes, 10.52M) reports that "both supporters and detractors of the decision said that it would probably strengthen the hand of state legislatures that say tighter voting laws are necessary to combat election fraud and that it would make it more difficult for challengers to eliminate laws they contend fall most heavily on minority voters." The Post notes that President Biden released a statement reading: "I am deeply disappointed in today's decision by the United States Supreme Court that undercuts the Voting Rights Act, and upholds what Justice Kagan called 'a significant race-based disparity in voting opportunities. ... In a span of just eight years, the Court has now done severe damage to two of the most important provisions of the Voting Rights Act of 1965 – a law that took years of struggle and strife to secure." CBS Evening News (7/1, story 5, 2:15, Holt, 3.63M) reported that the court "ended its term today with a major decision on voting rights." CBS (Crawford) adds that Biden "said he was deeply disappointed in the decision and called on congress to pass new legislation. At the same time, his Justice Department is suing one state, Georgia, saying its new voting law intentionally discriminates against black voters. The decision today may make that lawsuit more difficult, and...the message from the justices is clear."

Fox News (7/1, Olson, 23.99M) reports that for her part, House Speaker Pelosi "said the court's decision in the Arizona case is part of an 'unprecedented assault on voting rights' from the court."

Axios (7/1, Baker, 1.26M) says the ruling shows that "as long as state legislatures don't cross the line into overt racial discrimination, they will get wide latitude from the courts to change the rules that govern their elections." In a second piece, Politico (7/1, Gerstein, Montellaro, 6.73M) says that while the ruling "may appear modest in scope and subdued in rhetoric," it will "have a sweeping impact — undercutting efforts to challenge a slew of new laws Republican-led states have passed imposing new restrictions on the ballot, lawyers and civil rights activists said." The loss "also resurfaced second-guessing of the Democratic National Committee's decision to file" the suit against the two laws. David Cole of the ACLU said, "Certainly in retrospect, one would say this case was not the best case to bring," while "conceding that evidence of discrimination was 'fairly weak' for the two practices challenged."

According to the New York Times (7/1, Corasaniti, Epstein, 20.6M), "there are other legal avenues to challenge restrictive voting laws besides the Voting Rights Act, including under the First, 14th and 15th Amendments to the Constitution. But the act has been paramount in helping to rein in laws that could disproportionately affect communities of color, and the decision could threaten some of the legal strategies that voting rights groups and election lawyers have been drafting to challenge some of the new laws."

For ABC World News Tonight (7/1, story 5, 2:10, Davis, 5.71M), Terry Moran says that the Biden Administration is "learning it's going to be harder for the Justice Department or anyone else to challenge these new laws, to prove that they have a discriminatory impact on minorities. They'll need more evidence, meticulous evidence or evidence they were passed with a discriminatory intent. And that's hard. But President Biden in that statement vowed to continue the fight, saying, democracy is on the line." Along those lines, Politico (7/1, Gerstein, Montellaro, 6.73M) says that "in a suit the Justice Department filed last week against Georgia over its newly-enacted voting rules, Biden administration lawyers seemed to be trying to steer clear of the uncertainty about the so-called

'results' test added into the statute after a 1980 Supreme Court decision ruled out such challenges." Politico adds, "Instead, the DOJ based its new suit entirely on the claim that the state's changes were motivated by a desire to limit African Americans' voting strength."

In an analysis for the Washington Post (7/1, 10.52M), Aaron Blake writes that the ruling "didn't go as far in limiting the Voting Rights Act as some on the left feared — or as far as the court went in 2013 in effectively scrapping an entire section of the law, Section 5, that required states with histories of discrimination to pre-clear election laws with the DOJ — there is no question the ruling will make future legal challenges like the Biden Justice Department's much more difficult."

Editorial Pages Split Along Partisan Lines On Decision. In an editorial, the Washington Post (7/1, 10.52M) says that "at times," Chief Justice Roberts "has labored to maintain the Supreme Court's legitimacy against the gale-force pressures of partisan acrimony and social division. When it comes to voting rights, he has pushed in the opposite direction, presiding over the court's systematic dismantling of the Voting Rights Act, overriding Congress's clear intentions and gravely injuring U.S. democracy."

In its editorial on the ruling, the New York Times (7/1, 20.6M) also condemns the ruling, and says that the "current conservative majority on the Supreme Court...shows no interest in thwarting this attack on democracy [new voting laws] and protecting Americans' fundamental constitutional right to vote. The ball is in Congress's court, and time is fast running out."

In sharp contrast, the Wall Street Journal (7/1, Subscription Publication, 8.41M) approves of the decision, saying it should have been a 9-0 decision. The Journal says that the court is establishing parameters for lower courts in order to prevent political abuse.

WPost Poll Finds Partisan Split On Voting Laws. The Washington Post (7/1, 10.52M) reports that "by a roughly 2-to-1 margin, Americans prioritize making lawful voting easier rather than making voter fraud more difficult, according to a Washington Post-ABC News poll released Thursday. The poll finds 62 percent of adults saying it is more important to pass new laws 'making it easier for people to vote lawfully,' while 30 percent say it's more important to pass new laws 'making it harder for people to vote fraudulently.'" According to the Post, "A 59 percent majority of Republicans say it's more important to pass new laws making it harder to vote fraudulently, while 62 percent of independents and 89 percent of Democrats say new laws should make it easier for people to vote lawfully."

More Commentary. In an op-ed for the New York Times (7/1, 20.6M), Richard L. Hasen, a professor at UC-Irvine, writes that with both this ruling and a second involving California's charity donor reporting requirements, the majority on the court "has shown itself hostile to American democracy."

Ezra Klein writes in the New York Times (7/1, 20.6M), "It is a fearful thing to watch one of America's two political parties develop the view that democracy itself is its problem, and an agenda with which to try to neuter the threat." But, he says it "has been a cheering development to watch more and more Democrats realize that they actually need to fight for democracy. And with a simple change to the filibuster, they could pass legislation that would do more to better America's electoral institutions than anything since the Voting Rights Act in 1965. In that way, Republicans perceive the threat correctly: A country that is far closer to being truly democratic, where the unpopularity of their ideas would expose them to punishing electoral consequences. A country worthy of the stories we tell about it."

SCOTUS Overturns California Law Requiring Charities To Disclose Significant Donors.

The AP (6/28, Gresko) reports that on Thursday, the Supreme Court "ordered California to stop collecting the names and addresses of top donors to charities." The AP says the justices "voted 6-3 along ideological lines to side with two nonprofit groups, including one with links to billionaire Charles Koch," which "argued that California's policy of collecting the information violates the First Amendment."

Reuters (7/1, Hurley) reports that California "has said the donor information is required as part of the state attorney general's duty to prevent charitable fraud." However, Chief Justice Roberts wrote, "We are left to conclude that the Attorney General's disclosure requirement imposes a widespread burden on donors' associational rights." Roberts added that the state's interest in "amassing sensitive information for its own convenience is weak."

Axios (7/1, Baker, 1.26M) reports that "although conservative organizations brought the suit, the ACLU and the NAACP Legal Defense and Education Fund took their side. The most relevant precedent in this case was set in the 1950s when Alabama tried to publicly disclose a list of NAACP members as a way to intimidate civil rights activists."

Bloomberg (7/1, Stohr, 3.57M) reports that California "was one of four states – along with New York, New Jersey and Hawaii – that required charities to provide a copy of their Schedule B, a form organizations routinely file with their federal tax returns. That form generally provides the names and addresses of people who contributed more than $5,000." Bloomberg reports that "liberal Justices" Sonia Sotomayor, Stephen Breyer and Elena Kagan "dissented, saying the challengers hadn't shown the donors wanted privacy or were burdened by disclosure." The New York Times (7/1, Liptak, 20.6M) reports "the decision concerned charitable donations but its logic was sweeping, Justice Sonia Sotomayor wrote in

dissent, suggesting that it could erode disclosure laws concerning political campaigns, too."

Politico (7/1, Gerstein, Montellaro, 6.73M) says the ruling "dealt a blow...to efforts to rein in so-called dark money political groups." The "ruling could have a political impact, complicating donor-disclosure requirements for groups that often pour large sums into elections but stop just short of the 'express advocacy' for or against candidates that triggers stricter rules on revealing the sources of donations."

The Washington Post (7/1, Barnes, 10.52M) reports that the Biden Administration "took a middle-of-the-road approach to the question. It said the requirement should not be found unconstitutional in all applications but that the groups should have another opportunity to prove that the rights of their donors had been violated."

Roll Call (7/1, Ruger, 130K) reports that the case "drew briefs from members of Congress from sides of the aisle." Senate Minority Leader McConnell, "who has played a leading role in legal challenges to campaign finance laws, filed a brief in the cases arguing that donor disclosure requirements threaten great practical harm to those with unpopular views." Sen. Sheldon Whitehouse (D-RI), "who led a brief from his colleagues on the case, said Thursday that the ruling extends protections to fossil fuel billionaires and massive corporations who want to keep their political spending private."

In an editorial, the Wall Street Journal (7/1, Subscription Publication, 8.41M) hails the ruling, arguing its necessity in a time when individuals can be "publicly cancelled" for having the wrong views or giving to the wrong groups.

As SCOTUS Finishes Term, Breyer Silent On Retirement Plans. Reuters (7/1, Hurley, Chung) reports that as the Supreme Court delivered the final two rulings of its 2020 term on Thursday, 82-year-old Justice Stephen Breyer "remained mum about his future" despite earlier calls from liberal activists that he retire to make way for a Biden appointee. Reuters explains that it has been traditional for justices to announce their retirements after the court issues the final rulings for a term, but so far Breyer "has given no public indication that he plans to retire."

Trump Organization, CFO Indicted In Tax Fraud Scheme. The AP (7/1, Sisak) reports the Trump Organization, former President Donald Trump's company, and its longtime Chief Financial Officer Allen Weisselberg, "were charged Thursday in what prosecutors called a 'sweeping and audacious' tax fraud scheme in which the executive collected more than $1.7 million in off-the-books compensation, including apartment rent, car payments and school tuition." According to the indictment, from 2005 through this year, the Trump Organization and Weisselberg "cheated tax authorities by conspiring to pay senior executives off the books by way of lucrative fringe benefits and other means." Trump "was not charged with any wrongdoing, but prosecutors noted he signed some of the checks at the center of the case. And one top prosecutor said the 15-year scheme was 'orchestrated by the most senior executives' at the Trump Organization." Hallie Jackson said in the lead story for NBC Nightly News (7/1, lead story, 3:00, Holt, 4.7M) Trump "could still end up indicted, a development that might make months or years if it even happens at all."

The Washington Post (7/1, 10.52M) reports fifteen charges "were filed against Weisselberg, according to a copy of the indictment obtained by The Washington Post. They included counts of conspiracy, criminal tax fraud and falsifying business records." CNBC (7/1, Mangan, 7.34M) reports on its website that Weisselberg "surrendered Thursday morning to the Manhattan district attorney's office." In the lead story for ABC World News Tonight (7/1, lead story, 3:30, Davis, 5.71M), Jonathan Karl said, "One potentially key witness is Weisselberg's former daughter-in-law, who is cooperating with investigators." Former Trump attorney Michael Cohen "says the soon to be 74-year-old Weisselberg could turn on Trump, too." Trump "told ABC News Weisselberg is, quote, a tremendous person. They are pressuring him, setting him up. They want him to lie against Trump." But Axios (6/30, Basu, 1.26M) says, "There is no sign Weisselberg is planning to cooperate."

CBS Evening News (7/1, story 2, 2:30, O'Donnell, 3.63M) reported, "The Trump Organization called it a political play with a bigger target in mind." Politico (7/1, Forgey, 6.73M) says Trump Organization lawyers "accused prosecutors of improper motives." Alan Futerfas said, "If the name of the company was something else, I don't think these charges would have been brought." Trump's personal lawyer Ron Fischetti said in a statement, "After years of investigation and the collection of millions of documents and devoting the resources of dozens of prosecutors and outside consultants, this is all they have?" he said. "In my 50 years of practice, I have never seen this office bring a case like this and, quite frankly, I am astonished. The District Attorney is supposed to be apolitical, but everyone knows that the only reason they are proceeding with this case is because it is 'Trump'. As far as we are concerned, this case is over." The Wall Street Journal (7/1, Ramey, Paul, Ballhaus, Subscription Publication, 8.41M) reports Trump said Thursday that the case is "political Witch Hunt by the Radical Left Democrats." Bloomberg (7/1, Farrell, Hurtado, 3.57M) provides similar coverage.

The New York Times (7/1, Protess, Rashbaum, Bromwich, 20.6M) says the charges "ushered in a new phase of the district attorney's sweeping inquiry into the business practices of Mr. Trump and his company. And while the indictment was narrowly focused on the tax scheme, the

charges could lay the groundwork for the next steps in the wider investigation, which will focus on Mr. Trump." Reuters (7/1) says the indictments "could undermine the company's relationships with banks and business partners, and complicate Trump's political future as the Republican contemplates running again for president in 2024."

A Politico (7/1, Kruse, 6.73M) analysis says the indictments are "most elementally a direct and personal hit. ... The Trump Organization, always, right from the get-go, was nothing if not an extension and reflection of Trump himself." Similarly, a New York Times (7/1, Bromwich, Rashbaum, Protess, Haberman, 20.6M) analysis says although there is "no indication that Mr. Trump himself will face criminal charges anytime soon," the case "has already struck at the heart of Mr. Trump's public image – the business of the businessman – in a way no other investigation has done." The Times says there could be "significant" fallout. An "indictment against a company — let alone a conviction — can jeopardize relationships with banks and business partners. The former president is facing down hundreds of millions of dollars in loans that need to be repaid, and the legal threat to his business could deal a blow to his finances." In addition, the charges "could play into Mr. Trump's decisions about his political future."

A second New York Times (7/1, Russonello, 20.6M) analysis says "the Manhattan D.A.'s investigation is only one of a smattering of legal obstacles that Mr. Trump may need to overcome, as he considers a possible return." The Times goes on to provide "a look at the many investigations and lawsuits that he's currently fighting – touching on his business dealings, accusations of misconduct toward women, and his role in drumming up the Capitol riot."

Dana Milbank writes in the Washington Post (7/1, 10.52M) that Trump on Thursday "joined those extremists who cast" Ashli Babbitt, who was shot by Capitol Police during the Capitol riot "as the victim and the Capitol Police as the villains of that day. Now we know the disgraced former president still stands, remorselessly and unapologetically, with those who attempted the violent overthrow of Congress and of a democratic election. No grand jury could return an indictment worse than the one Trump returned against himself Thursday." Trump's "attempt at distraction," Milbank writes, "is more of an indictment than the indictment."

Judge Expresses Skepticism Over House Democrats' Trump Subpoena.

Bloomberg (7/1, 3.57M) reports US Judge Ahmit Mehta in Washington "expressed skepticism over the latest efforts by Democrats in the House of Representatives to obtain former President Donald Trump's financial records from his accounting firm." During a hearing Thursday, Mehta "quizzed a lawyer for the Democrats on whether the materials the House is seeking from Mazars USA are truly essential to its legislative goals." Democrats "have argued that they would use the records to devise laws that protect against financial conflicts of interest." But in "an exchange with Douglas Letter, the general counsel of the U.S. House," Mehta "pushed back." Mehta said, "There are others who have fairly complex financial holdings and are wealthy. ... Why couldn't you learn what you feel like you need to learn by using someone else's financials?" Letter "responded that the House was considering legislation that could specifically address conflicts of interest involving the president."

The Washington Post (7/1, 10.52M) reports Trump's lawyers told Mehta that the former President "has offered to give House Democrats a peek at financial statements related to his complex business empire from before his 2016 presidential bid and eight years of contracts with his accounting firm, but refused to divulge more sensitive source data or internal communications." The offer was "made in late June in unsuccessful court-ordered mediation." But, Letter said Trump lawyers' "never offered to produce a single document." Rather, "they proposed that a handful of committee aides and lawmakers view a small sample of records in private; take notes instead of copy or photograph them; and keep the information confidential to the committee, Letter said."

White House To Welcome LA Dodgers Friday.

The Hill (7/1, Samuels, 5.69M) reports that on Friday, the Los Angeles Dodgers "will visit the White House on Friday, becoming the first championship team to meet with President Biden since he took office." The Hill explains that the Dodger's won last year's World Series and their meeting with Biden will mark the resumption of traditional White House visits by championship teams that have been suspended since the outbreak of the pandemic last year.

FTC Votes To Expand Agency's Discretion In Move Targeting Big Tech.

The Wall Street Journal (7/1, McKinnon, Subscription Publication, 8.41M) reports that in a 3-2 party-line vote on Thursday, the Federal Trade Commission approved a policy change to expand the agency's discretion to challenge a broader category of unfair competition practices. The Journal explains the move may expose big technology competition to more antitrust enforcement actions.

USDOT Aims To "Become A Driver Of Justice."

Bloomberg (7/1, Bliss, Lowenkron, 3.57M) reports Transportation Secretary Buttigieg "has spoken often about the injustices created by federal highways built over the last 70 years, raising interest in the idea of tearing some of them down." However, Bloomberg says, "turning the Department of Transportation into a driver of justice is a tall order for a

federal agency that hasn't made sweeping policy change since the 1950s and '60s."

Trump Launches New Social Media Platform GETTR. Politico (7/1, McGraw, Nguyen, Lima, 6.73M) reports that on Thursday, former President Trump "quietly launched a new social media platform" called GETTR. "The site...advertised its mission statement as 'fighting cancel culture, promoting common sense, defending free speech, challenging social media monopolies, and creating a true marketplace of ideas.'" Politico adds that "debut immediately ran into confusion about whether it was the former president's long-promised bid to offer his legions of followers their own social media haven or merely the next attempt to build a MAGA-alternative to the main platforms."

Newsom Recall Election Set For Sept. 14. The AP (7/1, Blood, Ronayne) reports California Lt. Gov. Eleni Kounalakis (D) on Thursday scheduled the recall election "that could drive Democratic Gov. Gavin Newsom from office," for Sept. 14. The AP says the election "will be a marquee contest with national implications, watched closely as a barometer of the public mood heading toward the 2022 elections, when a closely divided Congress again will be in play." the announcement "will set off a furious, 10-week burst of campaigning through the California summer, a time when voters typically are ignoring politics to enjoy vacationing, backyard barbecuing and travel."

The Los Angeles Times (7/1, 3.37M) says Newsom and his backers "have dismissed the recall effort as a longshot ploy by the Republican Party to force its unpopular conservative agenda on Californians who support the governor's policies, including his response to the COVID-19 pandemic, protecting the environment and advocating for gun control measures. ... Still, one the greatest potential threats to Newsom's political survival would be a challenge from the left." So far, "no prominent California Democrats have publicly entertained entering the race, and most have pledged to stay out of it."

Youngkin's Work With Private Equity Group Faces Scrutiny In Virginia Governor's Race. The AP (7/1, Peoples, Rankin) reports real estate deals by the private equity firm the Carlyle Group "could become a political liability for Carlyle's former co-CEO, Glenn Youngkin, who is now running as the Republican candidate for governor in Virginia and highlighting his experience 'building businesses and creating jobs.'" Youngkin "helped Carlyle make money for investors by targeting nursing homes, auto parts manufacturers, energy companies and even a business that produces 'less-lethal' weapons used by governments that have cracked down on democracy advocates. More than 1,000 jobs were moved offshore in recent years as companies were restructured," and hundreds were laid off "after Carlyle instituted a series of cost-cutting measures at a nationwide nursing home chain; complaints of deteriorating service and neglect followed." While there are "no allegations of illegality or wrongdoing," the AP says "Youngkin's political aspirations have drawn new scrutiny to his dealings at the Washington-based investment firm."

Vance Enters Ohio GOP Senate Primary. Politico (7/1, Arkin, 6.73M) reports venture capitalist and best-selling author J.D. Vance (R) "officially launched his campaign Thursday, joining the crowded race to replace retiring GOP Sen. Rob Portman." During a rally in his home town of Middletown, Ohio, Vance "echoed themes from his book," "Hillbilly Elegy," talking about "his family and community. But he also hit on a handful of major issues for conservatives that have already played a central role in Senate primaries, including railing against critical race theory, attacking the Biden administration's border policies and criticizing Dr. Anthony Fauci." Vance "enters the race with some name ID for a first-time candidate," but "he will also have to grapple with his past criticisms of [former President Donald] Trump from 2016."

Heat Wave Deaths Believed To Number In Hundreds Despite Assistance, Planning. The AP (7/1, Selsky) reports that "hundreds of people are believed to have died" during "a record-breaking heat wave" that struck the Pacific Northwest and western Canada from Friday to Tuesday. The AP says the deaths occurred despite efforts by officials to establish cooling centers and distribute water to the homeless.

The Washington Post (7/1, 10.52M) says that since Friday, Oregon --- one of the states under the heat dome – has seen 63 deaths, "with police noting that a preliminary investigation suggested that the deaths 'may be associated with the Pacific Northwest heat wave.'" And, in the Canadian British Columbia, there have been "at least 486 'sudden and unexpected deaths'" in the same period – "hundreds more" than normal. CBS Evening News (7/1, story 3, 1:50, O'Donnell, 3.63M) added that wildfires have also broken out with one burning 90% of the town of Lytten, Canada, forcing residents to evacuate.

ABC World News Tonight (7/1, story 4, 1:05, Davis, 5.71M) reported the deadly heat wave has come amid a bout of "extreme weather." ABC explained that in addition to extreme heat in the Northwest, there are flash flood watches in effect for the front range of Colorado, storm watches in Maryland, New Jersey and Virginia, as well as a tropical storm heading for Haiti.

NFL Fines WFT For Toxic Work Culture. The Washington Post (7/1, 10.52M) reports that on Thursday, the

National Football League announced a $10 million fine against the Washington Football Team "for fostering a workplace culture where sexual harassment, bullying and intimidation was commonplace throughout most of Daniel Snyder's ownership." However, the league did not suspend Snyder – though it "said that his wife Tanya, named the team's co-CEO earlier this week will assume responsibilities for all day-to-day team operations." The Post adds that the league has "declined to release a detailed investigative report or address any allegations levied by former employees against Snyder."

LAPD Fireworks Disposal Causes Explosion, Injures Seventeen. ABC World News Tonight (7/1, story 6, 1:20, Davis, 5.71M) reported that "what was supposed to be a controlled detonation of illegal fireworks by the LAPD turned to disaster" when a bomb containment truck exploded, "causing widespread damage" and "injuring 17 people, including police officers." NBC Nightly News (7/1, story 8, 0:15, Holt, 4.7M) explained that "the armored truck was filled with illegal fireworks seized earlier in the day" and "blew up as a bomb squad was trying to safely detonate the stash." CBS Evening News (7/1, story 7, 0:20, O'Donnell, 3.63M) reported that an investigation into the explosion is under way.

Bacon Lists Pros And Cons Of "Bidenism." In his Washington Post (7/1, 10.52M) column, Perry Bacon Jr. offers his "view of the good and bad of Bidenism." Among the good, Bacon lists "economic populism," a "real commitment to issues of race and identity," "respect for the Democratic left," "useful outreach to Republicans," and "detail-oriented governing." Bacon says the "key item" of "deference to bipartisanship and tradition" is "still to be determined." Bacon adds that "there is some bad" including: "a lack of urgency on the threat to democracy," and "status quo foreign policy." Bacon writes, "Bidenism looks like a bet that effective policies on economic and identity issues, managing the government well and projecting a positive attitude toward the other side will address this democracy crisis. I hope Biden is right. I fear he is wrong."

Ethicist Supports Catholic Bishops Stance On Biden, Communion. In an op-ed for the Wall Street Journal (7/1, Anderson, Subscription Publication, 8.41M), Ryan T. Anderson, president of the Ethics and Public Policy Center, writes in support of the US Conference of Catholic Bishops withholding communion from President Biden over his support for abortion rights. Anderson argues withholding communion is a means of teaching the faithful and hopefully bringing them to repent.

Boot Decries "Radicalization" Of GOP. Max Boot writes in the Washington Post (7/1, 10.52M) that a vote this week by 120 House Republicans "against removing the busts of Confederate leaders and other white supremacists from the Capitol," and another by 190 House Republicans "against setting up a special committee to probe the Jan. 6 riot" were not surprising but "should still shock anyone who remembers the days – not so long ago – when the GOP was nominating the likes of John McCain and Mitt Romney. The radicalization that has occurred in the past few years is dizzying and dismaying." The Republican Party, Boot writes, "is in full deflect-and-appease mode – appeasing both racists and authoritarians. Appeasement may be too kind a description, actually, because it suggests a tactical maneuver. All too many Republicans give every appearance that they are promoting despicable views out of conviction, not expediency."

Gerson: Nation Needs Effort At Civic Healing. Michael Gerson writes in the Washington Post (7/1, 10.52M) that "significant actors in our political life have lost something important. They no longer care about the integrity of our constitutional process or accept the existence of a shared public reality. They care only about achieving their preferred political outcomes." Gerson says this "is the main threat to American democracy. It must be confronted. But one sure way to make things worse is to respond in kind." Gerson argues, "Our civic crisis of vicious polarization can yield only to efforts at civic healing." The Partnership for American Democracy "has been created to catalyze a national effort at civic healing. It has been designed as an infrastructure for organizations to share information, encourage innovation, pool resources and coordinate messaging." Gerson argues, "We need the social return of love – love of country and love for our impossible, invaluable neighbors. This may be sentiment, but it is also sanity."

Thiessen Eulogizes Rumsfeld. In his Washington Post (7/1, 10.52M) column, Marc Thiessen eulogizes former Defense Secretary Donald Rumsfeld as "a great leader," a "great boss and a dear friend who transformed my life in countless ways."

WSJournal: Congress Must Stop Economic Warfare Between States. The Wall Street Journal (7/1, Subscription Publication, 8.41M) laments the Supreme Court's refusal to hear a case challenging California's ban on state-funded travel to several red states over discriminatory LGBT laws. As red states retaliate with bans of their own, the trend toward this kind of economic warfare is troubling. The Journal says since the courts won't intervene, Congress must.

From: Hallett, Adrienne (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F1705E2E7C254B84A77F058DBF75B31B-HALLETTAA]
Sent: 6/23/2021 10:55:14 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]
Subject: Re: Meeting with authorizers
Attachments: CMR 3.18.pdf; CMR - NIH Response to 3.18.pdf; CMR 6.10.pdf

Larry,

I'm happy to schedule a short get-together if it would be helpful?

Two things you should know:

1) Alan has responded to the Department's request that he invite the majority staff with a requirement that the minority be given the full hour he requested. We said fine, but that means we need to find new times later.
2) At this point, the Department realized that this was in person and started freaking out. They claim it is an Administration requirement that we not do briefings in person. So, we are now briefing Alan via zoom. Which means we have time to accommodate the 1.5 hour request. (how this helps us, I don't understand)

We are prepping a packet to be delivered to you tomorrow which will have all of the pieces so you aren't looking for them. That said, I've attached the letters here in case you want to get a jump on it.

Adrienne

From: Lawrence Tabak (b) (6)
Date: Wednesday, June 23, 2021 at 6:06 PM
To: Adrienne Hallett (b) (6)
Cc: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Meeting with authorizers

Adrienne,

Did you want to meet with us prior to this meeting (Mon afternoon)?
Could you resend original letter with questions so I know I have the correct version (too many things flying around).

Thanks,
Larry

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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Majority (202) 225-2927
Minority (202) 225-3641

March 18, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins,

We write to request information, assistance, and needed-leadership from the National Institutes of Health (NIH) to advance an independent, scientific investigation into the origins of the COVID-19 pandemic.

The COVID-19 pandemic has been the worst public health crisis in the U.S. in about a hundred years. Over a year has passed since the deadly virus reached our shores and yet, the origin of the virus has yet to be determined. An independent, expert investigation of the origin of COVID-19 is of paramount importance to public health and biosecurity. As noted by Stanford Medical School Professor David Relman:

> A more complete understanding of the origins of COVID-19 clearly serves the interests of every person in every country on this planet. It will limit further recriminations and diminish the likelihood of conflict; it will lead to more effective responses to this pandemic, as well as efforts to anticipate and prevent the next one. It will also advance our discussions about risky science. And it will do something else: Delineating COVID-19's origin story will help elucidate the nature of our very precarious coexistence within the biosphere.[1]

Recently, the World Health Organization (WHO) attempted to investigate the origin of COVID-19. The WHO said that this investigative mission would be guided by the science, be

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[1] David A. Relman, *Opinion: To stop the next pandemic, we need to unravel the origins of COVID-19*, PNAS (Nov. 2020), *available at* https://www.pnas.org/content/117/47/29246.

"open-minded," and "not exclude[e] any hypothesis."[2] Unfortunately, China did not provide complete access or independence for the critical WHO mission. On February 13, 2021, National Security Advisor Jake Sullivan issued the following statement:

> We have deep concerns about the way in which the early findings of the COVID-19 investigation were communicated and questions about the process used to reach them. It is imperative that this report be independent, with expert findings free from intervention or alteration by the Chinese government. To better understand this pandemic and prepare for the next one, China must make available its data from the earliest days of the outbreak.[3]

Because of rising tensions between the U.S. and China, the WHO scrapped plans for an interim report.[4] An international group of science experts, including specialists in virology, microbiology, and zoology, asked for a new review.[5]

The NIH, as a premier scientific institution, must lead in order to foster a transparent, independent, and science-based investigation into the origin of the COVID-19 pandemic. Such an effort must meet the WHO's stated goals of an open-minded investigation that does not exclude any plausible hypothesis.[6] In addition, the NIH is well-positioned to gather and provide information through oversight of its grants and other federal awards. Thus, the NIH is in a unique position to investigate the possibility that the pandemic stemmed from a laboratory accident or leak, especially regarding the Wuhan Institute of Virology (WIV).

NIH raised concerns over a possible link between WIV and the COVID-19 outbreak during its review of federal awards to EcoHealth Alliance, a global environmental health nonprofit organization dedicated to protecting wildlife and public health from the emergence of disease. Of the $13.7 million in federal awards that NIH authorized for EcoHealth Alliance, 17

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[2] Smriti Mallapaty, *Where did COVID come from? WHO investigation begins but faces challenges*, NATURE (Nov. 11, 2020), *available at* https://www.nature.com/articles/d41586-020-03165-9.

[3] The White House, Statement of National Security Advisor Jake Sullivan (Feb. 13, 2021), *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/13/statement-by-national-security-advisor-jake-sullivan/.

[4] Betsy McKay, Drew Hinshaw and Jeremy Page, *WHO Investigators to Scrap Plans for Interim Report on Probe of Covid-19 Origins*, THE WALL STREET JOURNAL (Mar. 4, 2021), *available at* https://www.wsj.com/articles/who-investigators-to-scrap-interim-report-on-probe-of-covid-19-origins-11614865067?mod=latest_headlines

[5] Jaime Metzl, et al, *Call for a Full and Unrestricted International Forensic Investigation into the Origins of COVID-19* (March 4, 2021), *available at* https://s.wsj.net/public/resources/documents/COVID%20OPEN%20LETTER%20FINAL%20030421%20(1).pdf. The co-organizer of the letter and a WHO advisor on human genome editing, Jaime Metzl, PhD, said there is an eighty-five percent chance the pandemic started with an accidental leak from the WIV or Wuhan CDC laboratory, *available at* https://jamiemetzl.com/origins-of-sars-cov-2/. ("I have no definitive way of proving this thesis but the evidence is, in my view, extremely convincing. If forced to place odds on the confidence of my hypothesis, I would say there's an 85% chance the pandemic started with an accidental leak from the Wuhan Institute of Virology or Wuhan CDC and a 15% chance it began in some other way (in fairness, here is an article making the case for a zoonotic jump "in the wild"). If China keeps preventing a full and unrestricted international forensic investigation into the origins of the pandemic, I believe it is fair to deny Beijing the benefit of the doubt.")

[6] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

projects sponsored by the National Institute of Allergy and Infectious Disease (NIAID) have provided over $7.9 million in federal awards for research of viral emergence from bats in Southeast Asia.[7] EcoHealth Alliance passed some of its funding to the WIV, and in 2020, NIH made efforts to obtain information from EcoHealth Alliance about WIV related to concerns about the origins of COVID-19. In April 2020, NIH wrote to EcoHealth Alliance and Columbia University about an NIH-funded project entitled, "Understanding the Risk of Bat Coronavirus Emergency:"

> It is our understanding that one of the sub-recipients of the grant funds is the Wuhan Institute of Virology ('WIV'). It is our understanding that WIV studies the interaction between corona viruses and bats. The scientific community believes that the coronavirus causing COVID-19 jumped from bats to humans likely in Wuhan where the COVID-19 pandemic began. There are now allegations that the current crisis was precipitated by the release from WIV of the coronavirus responsible for COVID-19. Given these concerns, we are pursuing suspension of WIV from participation in Federal programs. It is in the public interest that NIH ensure that a sub-recipient has taken all appropriate precautions to prevent the release of pathogens that it is studying. This suspension of the sub-recipient does not affect the remainder of your grant assuming that no grant funds are provided to WIV following receipt of this email during the period of suspension.[8]

In January 2021, the U.S. Department of State issued a fact sheet about the activity at the WIV.[9] Among other revelations, it reported the following:

- The U.S. government has reason to believe that several researchers inside the WIV became sick in autumn 2019, before the first identified case of the outbreak, with symptoms consistent with both COVID-19 and common seasonal illnesses. This raises questions about the credibility of WIV senior researcher Shi Zhengli's public claim that there was "zero infection" among the WIV's staff and students of SARS-CoV-2 or SARS-related viruses.[10]

- Starting in at least 2016, WIV researchers conducted experiments involving RaTG13, the bat coronavirus identified by the WIV in January 2020 as the closest sample to SARS-CoV-2 (96.2 percent similar).[11] There was no indication that this research was suspended at any time prior to the COVID-19 outbreak.

- The WIV has a published record of conducting "gain-of-function" research to engineer chimeric viruses.[12] But the WIV has not been transparent or consistent about its record of

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[7] NIH RePORTER, *Research Portfolio Online Reporting Tools* (queried Mar. 4, 2021), *available at* https://reporter.nih.gov/search/qlYUeI9DIk2JfWUdCcWxcA/projects/charts.
[8] Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, NEW YORK POST (Apr. 28, 2020), *available at* https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/.
[9] U.S. Department of State, *Fact Sheet: Activity at the Wuhan Institute of Virology*, Office of the Spokesperson (Jan. 15, 2021), *available at* https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology//index.html.
[10] *Id.*
[11] *Id.*
[12] *Id.*

studying viruses similar to the COVID-19 virus, including "RaTG13," which was sampled from a cave in Yunnan Province in 2013 after several miners died of SARS-like illness.[13]

- WHO investigators must have access to the records of the WIV's work on bat and other coronaviruses before the COVID-19 outbreak. As part of a thorough inquiry, they must have a full accounting of why the WIV altered and then removed online records of its work with RaTG13 and other viruses.[14]

- Despite the WIV presenting itself as a civilian institution, the U.S. has determined that the WIV has collaborated on projects with China's military.[15] The WIV has engaged in classified research, including laboratory animal experiments, on behalf of the Chinese military since at least 2017.[16]

- The U.S. and other donors who funded or collaborated on civilian research at the WIV have a right and obligation to determine whether any of our research funding was diverted to secret Chinese military projects at the WIV.[17]

Notably, the State Department's former lead investigator who oversaw the Task Force into the COVID-19 virus origin stated recently that he not only believes the virus escaped from the WIV, but that it may have been the result of research that the Chinese military, or People's Liberation Army, was doing on a bioweapon.[18]

Accordingly, it is imperative to determine not only where SARS-CoV-2 originated, but also how and if NIH's funding and research to projects at the WIV could have contributed to SARS CoV-2. To assist our requests and inquiry, please provide the following by April 19, 2021:

1. An assessment from a classified U.S. Defense Intelligence Agency (DIA) report included the possibility that the origins of SARS CoV-2 could have emerged accidentally from a laboratory in Wuhan, China due to unsafe laboratory practices.[19] The DIA report cited U.S. government and Chinese researchers who found "about 33 percent of the original 41 identified cases did not have direct exposure" to the market.[20] That, along with what is known of the WIV's work in past few years, raised reasonable suspicion that the

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[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*

[18] Jennifer Griffin, Former top State Dept. investigator says COVID-19 outbreak may have resulted from bioweapons research accident, Fox News (March 13, 2021), *available at* https://www.foxnews.com/world/top-state-official-coronavirus-bioweapon-accident

[19] Fred Guterl, Naveed Jamali and Tom O'Connor, *The Controversial Experiments ad Wuhan Lab Suspected of Starting the Coronavirus Pandemic*, NEWSWEEK (Apr. 27, 2020), *available at* https://www.newsweek.com/controversial-wuhan-lab-experiments-that-may-have-started-coronavirus-pandemic-1500503.
[20] *Id.*

pandemic may have been caused by a lab error, not a wet market.[21] Further, a WHO inspector on the recent mission noted that "we know not all of those first 174 early COVID-19 cases visited the market, including the man diagnosed in December 2019 with the earliest onset date."[22] What information does the NIH have on the earliest COVID-19 cases?

2. According to an editorial on February 23, 2021, in *The Wall Street Journal* by former Secretary of State Mike Pompeo and Miles Yu, "[China's] army of scientists claim to have discovered almost 2,000 new viruses in a little over a decade."[23] How many of these discovered viruses does the NIH have information on and were any of these viruses discovered at the WIV?

3. According to *The Wall Street Journal* editorial mentioned in the previous question, some have alleged that the WIV's virus-carrying animals were sold as pets and may even show up at local wet markets.[24] Is the NIH aware of these allegations? If so, please provide any information the NIH has related to these allegations.

4. Please provide all information that NIH has about laboratory accidents and/or biosafety practices at the WIV since January 1, 2015.

5. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about communications and events at the WIV from August 2019 to the present.

6. Please provide all information that NIH has from NIH staff, grantees, sub-grantees, contractors, or subcontractors about their communications with China-based NIH, Chinese National Science Foundation, CDC, and China CDC about events at the WIV from August 2019 to the present.

State Department Cables

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[21] *Id.*

[22] Dominic Dwyer, I was the Australian doctor on the WHO's COVID-19 mission to China. Here's what we found about the origins of the coronavirus, THE CONVERSATION (Feb. 21, 2021), *available at*https://www.theguardian.com/commentisfree/2021/feb/22/i-was-on-the-whos-covid-mission-to-china-heres-what-we-found. *See also* Jeremy Page and Drew Hinshaw, *China Refuses to Give WHO Raw Data on Early Covid-19 Cases*, THE WALL STREET JOURNAL (Feb. 12, 2021), *available at* https://www.wsj.com/articles/china-refuses-to-give-who-raw-data-on-early-covid-19-cases-11613150580#:~:text=BEIJING%E2%80%94Chinese%20authorities%20refused%20to,over%20the%20lack%20of%20detail. ("Chinese authorities refused to provide World Health Organization investigators with raw, personalized data on early Covid-19 cases that could help them determine how and when the coronavirus first began to spread in China, according to WHO investigators who described heated exchanges over the lack of detail. The Chinese authorities turned down requests to provide such data on 174 cases of Covid-19 that they have identified from the early phase of the outbreak in the Chinese city of Wuhan in December 2019. Investigators are part of a WHO team that this week completed a monthlong mission in China aimed at determining the origins of the pandemic.")

[23] *Id.*

[24] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab,* THE WALL STREET JOURNAL (Feb. 23, 2021), available at https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

7. What information does NIH have about the WIV's responses to the 2018 U.S. Department of State cables (attached to this letter) regarding safety concerns?

8. The April 2018 cable from the U.S. Department of State stated that the WIV planned to invite University of Texas Medical Branch Galveston (UTMBG) researchers to do research in Wuhan's labs. Please provide any information NIH received that indicates whether the WIV invited UTMBG researchers, and whether UTMBG researchers conducted any research in Wuhan's labs.

    a. If there was such research, please provide information and any documents related to this research.

9. Why was it pertinent to the NIH investigation that the "nonprofit [EcoHealth Alliance] must provide the "WIV's responses to the 2018 Department of State cables regarding safety concerns"?[25]

    a. Did EcoHealth Alliance provide this information? If so, how did NIH use the information to further its investigation?

EcoHealth Alliance, Columbia University Health Sciences

10. Was the 2019 NIH federal award to EcoHealth Alliance reviewed and approved by the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) committee?[26]

    a. If so, please provide the documentation with the committee's decision.

    b. Please also provide the names of the individuals who were members of the committee at the time.

11. Please provide all correspondence and communications between NIH and EcoHealth Alliance, since January 1, 2020, related to federal funding involving the WIV. The documentation should include, but not be limited to, correspondence between NIH and EcoHealth Alliance dated sometime in April 2020, on July 8, 2020, and sometime in August 2020.

12. In April 2020, NIH suspended a 2019 federal award to EcoHealth Alliance, in part, because NIH did not believe the work aligned with "program goals and agency priorities."[27] Please specify the work that was done by the EcoHealth Alliance that did

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[25] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.
[26] National Institutes of Health, *Notice Announcing the Removal of the Funding Pause for Gain-of-Function Research Project* (Dec. 19, 2017), *available at* https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html.
[27] *Id.*

not align with the agency's program goals and priorities, and when that work was conducted.

a. Was an evaluation of EcoHealth Alliance's work and whether it aligned with the agency's program goals and priorities conducted by the NIH before the award was issued? If yes, please provide any related documentation. If not, why not?

13. In April 2020 correspondence with EcoHealth Alliance, NIH wrote that it "received reports that the Wuhan Institute of Virology…has been conducting research at its facilities in China that pose serious bio-safety concerns."[28] What are the sources for those reports to NIH and what were the specific allegations reported?

14. Why did the NIH request that EcoHealth Alliance provide a sample of the pandemic coronavirus that the WIV used to determine its genetic sequence for SARS CoV-2?[29]

a. Why is this information important to NIH's investigation?

b. Has NIH obtained the sample and if so, what evaluations have been done, and for what purpose?

c. If NIH has not yet obtained the sample, what are the planned studies and evaluations NIH will conduct with the sample when it is obtained?

15. What is the nature of NIH's concerns about purported restrictions at the WIV including "diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019[,]" about the WIV lab or virus origin?[30]

a. What is the basis of information to NIH about the purported restrictions at the WIV?

b. What are the other purported restrictions at the WIV in October 2019?

16. After terminating EcoHealth Alliance's 2019 project entitled "Understanding the Risk of Bat Coronavirus Emergence," the NIH later offered to reinstate the EcoHealth Alliance funding in July 2020 if EcoHealth Alliance agreed to meet certain conditions.[31]

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[28] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

[29] Meredith Wadman, *NIH imposes 'outrageous' conditions on resuming coronavirus grant targeted by Trump*, SCIENCEMAG (Aug. 19, 2020), *available at* https://www.sciencemag.org/news/2020/08/nih-imposes-outrageous-conditions-resuming-coronavirus-grant-targeted-trump.

[30] *Id.*

[31] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

a. Please provide all of the information presented to NIH from EcoHealth Alliance in response to NIH's conditions for reinstatement.

b. What actions did NIH take based upon the information received? How has the information been used in NIH's investigation?

c. One condition for the federal award reinstatement was for EcoHealth Alliance to arrange for an outside inspection of the WIV and its records, "with specific attention to addressing the question of whether WIV staff had SARS-CoV-2their possession prior to December 2019."[32] Why is it pertinent to the NIH's investigation if staff at WIV had SARS-CoV-2 in their possession prior to December 2019? What is the potential significance if the staff did have the virus in their possession prior to December 2019?

d. What information does NIH have that was used for the basis of requesting that the EcoHealth Alliance "must 'explain the apparent disappearance' of a scientist who worked in the Wuhan lab," and on social media was rumored to be "patient zero" of the pandemic?[33]

    i. What is the potential significance about the whereabouts of this scientist and the photo being removed from the website?

17. Please provide all correspondence and communications between NIH and Columbia University related to federal funding involving the WIV, including email correspondence in April 2020 between Dr. Michael Lauer, Deputy Director of extramural research, and Naomi Schrag of Columbia University.

    a. In an April 2020 email, Dr. Lauer advised Naomi Schrag of Columbia University that it would be helpful for NIH "to know about all China-based participants in this work since the Type 1 grant started in 2014 - who they were and how much money they received."[34] Why did NIH request that Columbia University provide information about all of the China-based participants?

        i. What is the pertinence of the timeframe starting in 2014 for the requested information?

        ii. Did Columbia University provide the NIH with the requested information about all of the China-based participants from all grantees since 2014? If so, please provide the information1. If not, why not?

Federal Funding Records

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[32] *Id.*
[33] *Id.*
[34] Meredith Wadman and Jon Cohen, *NIH's axing of bat coronavirus grant a 'horrible precedent' and might break rules, critics say*, SCIENCEMAG (Apr. 30, 2020), *available at* https://www.sciencemag.org/news/2020/04/nih-s-axing-bat-coronavirus-grant-horrible-precedent-and-might-break-rules-critics-say.

18. Please provide ledgers or any accounting for dispersion of all NIH federal funding awards that EcoHealth Alliance has sent to the WIV, including through contracts, grants, donations, cooperative agreements, staffing, or any other support or means. In addition, please provide the results and outcomes from the funding and support.[35]

19. What is the total amount of NIH federal funding per year from 2017 through 2021 that has directly or indirectly supported the WIV scientists or research through grant recipients, including to EcoHealth Alliance; Wildlife Trust, Inc.; Columbia University Health Sciences; Trustees of Columbia University; University of North Carolina Chapel Hill; Vanderbilt University; University of Virginia; and Oregon Health and Science University?[36]

20. According to a report in *The Washington Post* on April 14, 2020, the WIV issued a news release in English about the final visit from U.S. Embassy scientist diplomats in Beijing, which occurred on March 27, 2018.[37] Does the NIH have a copy of this news release? If so, please provide a copy.

21. For NIH award recipients that have provided support to the WIV since January 1, 2012, please provide annual reports, trip reports related to the WIV, documentation of any survey or field trips by the WIV, and interim data summaries from the WIV.

22. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 where foreign sites for all Type 1 and Type 2 awards have been documented as involving the WIV.

23. Please provide copies of all grantee annual reports, progress reports, projects, studies, and observations since 2014 for NIH domestic grantee awards with a foreign component involving the WIV.

24. Please provide the name(s) of the NIH program manager(s) or officer(s) responsible for overseeing the grants to EcoHealth Alliance and time period(s) of responsibility.

25. Please provide the name(s) of the NIH Scientific Review Officers responsible for reviewing and approving any NIH financial awards to EcoHealth Alliance and any other funding recipients that supported the WIV.

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[35] Betsy McKay, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Aug. 19. 2020), *available at* https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400.

[36] National Institutes of Health, Research Portfolio online Reporting Tools, NIH RePorter *available at* https://report.nih.gov/ (last accessed March 6, 2020).

[37] Josh Rogin, *Opinion: State Department cables warned of safety issues at Wuhan lab studying bat coronaviruses*, THE WASHINGTON POST (Apr. 14, 2020), *available at* https://www.washingtonpost.com/opinions/2020/04/14/state-department-cables-warned-safety-issues-wuhan-lab-studying-bat-coronaviruses/.

26. According to an editorial in *The Wall Street Journal*, the WIV housed tens of thousands of bat samples and laboratory animals in 2019.[38] Please provide any information the NIH has on the number of bat samples and animals at the WIV.

    a. Did any NIH scientists who are fluent in Mandarin review the Chinese scientific literature on the WIV research related to coronaviruses that is dated before February 1, 2020?

27. Does the NIH have the unpublished sequences of bat coronaviruses that were maintained in the WIV database before December 30, 2019, or before the database was removed from the internet?[39] Does NIH have the full sequences of the eight viruses sampled in the Yunnan province on an EcoHealth Alliance bat-virus sampling trip in 2015?

    a. Please provide NIH's analysis if the sequences have been analyzed.

    b. If NIH does not have the sequences, can NIH get this information from the EcoHealth Alliance or from other NIH-funded sources?

28. Please provide the original version of "Origin and cross-species transmission of bat coronaviruses in China" that was submitted to *Nature* by EcoHealth Alliance on October 6, 2019, published August 25, 2020, and funded in part by NIAID (award number R01AI110964).[40] If NIH does not have the October 6, 2019 report, can NIH obtain it from EcoHealth Alliance for this response? If so, please provide the report.

29. Have NIH, EcoHealth Alliance, or other NIH award recipient(s) been denied permission or access to results of any WIV research, which indirectly received financial support from NIH awards? If so, please provide the date(s), individuals involved, and circumstances of each denial.

We request that the NIH provide the requested documents and information in a coordinated response from all stakeholders and the appropriate divisions within NIH, including but not limited to subject matter experts from NIH's Division of Security and Emergency Response, the Office of Management Assessment, the Center for Scientific Review, the National Institute of Allergy and Infectious Diseases, and the Office of Extramural Research. After the requested information has been provided, we ask that the NIH provide a briefing to the Minority Committee staff to discuss the information that the NIH has related to the origins of SARS-CoV-2, including any potential links to the WIV. Finally, we request that you appoint an NIH working group representing an appropriate diversity of scientific disciplines to collect data and

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[38] Mike Pompeo and Miles Yu, *NIH Presses U.S. Nonprofit for Information on Wuhan Virology Lab*, THE WALL STREET JOURNAL (Feb. 23, 2021), *available at* https://www.wsj.com/articles/chinas-reckless-labs-put-the-world-at-risk-11614102828.

[39] Washington Post Editorial Board, *We're still missing the origin story of this pandemic. China is sitting on the answers*, THE WASHINGTON POST (Feb. 5, 2021), *available at* https://www.washingtonpost.com/opinions/2021/02/05/coronavirus-origins-mystery-china/?arc404=true.

[40] Latinne, A., Hu, B., Olival, K.J. et al,. *Origin and cross-species transmission of bat coronaviruses in China*, Nature (Aug. 25, 2020), *available at* https://www.nature.com/articles/s41467-020-17687-3#Ack1.

information related to COVID-19 origins (including the WIV), and that the NIH working group coordinate and consult with foreign scientific agencies involved in similar work.

Your assistance with this request is greatly appreciated. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Brett Guthrie
Republican Leader
Subcommittee on Health

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Attachment

Cc: The Honorable Frank Pallone, Chairman
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Anna Eshoo, Chair, Subcommittee on Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May 21, 2021

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
Washington, DC 20515

Dear Representative McMorris Rodgers:

Thank you for your letter regarding the National Institutes of Health's (NIH) support for biomedical research related to SARS-CoV-2, "gain of function" (GOF) research, and the NIH grant to the EcoHealth Alliance. As Principal Deputy Director of NIH, I am pleased to respond to your inquiry.

Neither NIH nor the National Institute of Allergy and Infectious Diseases has ever approved any grant that would have supported GOF research on coronaviruses that would have increased their transmissibility or lethality for humans.

Some scientists use the term GOF research broadly to refer to *any* modification of a biological agent that confers new or enhanced activity to that agent. In some cases, this research is performed to give new properties to agents to allow them to grow and be studied in the lab; for example, the agent may be modified so that it can be studied in research animals. However, not all research that some label as GOF research entails the same level of risk. The subset of GOF research that is anticipated to enhance the *transmissibility* and/or *virulence* of potential pandemic pathogens, which could make them more dangerous to humans, has been the subject of substantial scrutiny and deliberation.

In 2017, the U.S. Department of Health and Human Services (HHS) issued its Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework). The HHS P3CO Framework is intended to guide HHS funding decisions on proposed research that is reasonably anticipated to create, transfer, or use Potential Pandemic Pathogens (PPPs) resulting from the enhancement of a pathogen's transmissibility or virulence in humans (enhanced PPP) and seeks to preserve the benefits of life sciences research involving enhanced PPPs while minimizing potential biosafety and biosecurity risks.

As your letter notes and has been publicly stated, NIH awarded a grant to EcoHealth Alliance Inc., a research organization based in New York City, in June 2014. The application was subjected to rigorous peer review and did not propose research to enhance any coronavirus to be more transmissible or virulent.

The research proposed in the grant application sought to understand how bat coronaviruses evolve naturally in the environment to become transmissible to the human population. This

included studying viral diversity in bat reservoirs, surveying people who work in live animal markets or other jobs with high exposure to wildlife for evidence of bat-coronavirus infection, and analyzing data to predict which newly discovered viruses pose the greatest threat to human health. To support its work, EcoHealth made sub-awards to the Wuhan Institute of Virology and other institutions based in East Asia where coronaviruses tend to emerge and are prevalent. NIH is not currently funding the Wuhan Institute of Virology.

I would be happy to further discuss this grant, and this issue, at your convenience. NIH is committed to upholding the highest standards within the conduct of science and the oversight of federal funding.

In conclusion, NIH strongly supports the need for further investigation by the World Health Organization (WHO) into the origins of the SARS-CoV-2 coronavirus. Working with a cross-regional coalition of 13 countries, we urge the WHO to begin the second phase of their study without delay.

Thank you again for the opportunity to address these questions. An identical response has been sent to the co-signers of your letter.

Sincerely,

(b) (6)

Lawrence A. Tabak, D.D.S., Ph.D.
Principal Deputy Director

cc: The Honorable Frank Pallone
Chairman, House Committee on Energy and Commerce

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

CATHY McMORRIS RODGERS, WASHINGTON
RANKING MEMBER

ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

June 10, 2021

The Honorable Francis Collins, M.D., Ph.D.
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Collins:

As the committee of jurisdiction over public health, the Energy and Commerce Committee has authorizing responsibilities over the U.S. National Institutes of Health (NIH). We strongly support a comprehensive investigation into the origins of the COVID-19 pandemic, including the possibility of an accidental laboratory leak.

The Chinese Communist government has not yet allowed Chinese scientists to cooperate with an investigation into COVID-19 origins, and has admitted to destroying samples and records pertinent to such an investigation.[1] Thus, it is imperative we assemble all data and information in U.S. possession about bat coronavirus research experiments and lab safety protocols from all sources outside of China, particularly from EcoHealth Alliance (EHA). EHA is an NIH grantee who has been involved in bat coronavirus research in China and has issued grant subawards to the Wuhan Institute of Virology (WIV). It is also essential to collect information about the WIV, the laboratory that was conducting bat coronavirus experiments located in Wuhan, China, the epicenter of the COVID-19 outbreak. As a federal cognizant grant-making agency that funded bat coronavirus research at the WIV through EHA awards, NIH is in a unique position to publicly share detailed research reports in its possession. Importantly, NIH has full access to EHA records and EHA has refused to cooperate with our inquiry. Therefore, it is critical for NIH to cooperate with our objective fact-finding investigation as we continue to collect data about U.S. funded bat coronavirus research.

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[1] Josh Chin, *China Told Labs to Destroy Coronavirus Samples to Reduce Safety Risks*, The Wall Street Journal (May 16, 2020) *available at* https://www.wsj.com/articles/china-told-labs-to-destroy-coronavirus-samples-to-reduce-biosafety-risks-11589684291/.

Since the Republican committee leaders March 18, 2021 letter to NIH, our investigation has found a number of additional issues that raise very serious concerns about the adequacy of NIH's oversight of grantees. The following newly found issues appear troubling and given the significance of these concerns, we expect the NIH to respond fully and substantively. Minority committee staff is continuing to work with your staff to schedule an NIH briefing. The NIH should be prepared to address these issues at the briefing, in addition to all of the questions from the March 18, 2021 letter that presently remain unanswered.

1. NIH's Award of $2 million to EHA Despite Grant Suspension

On May 25, 2021, a spokesperson for EHA told Fox Business that its NIH funding is frozen and NIH did not give them guidance on when funds will be unfrozen.[2] EHA's representation about their NIH funding was not forthcoming. NIH terminated grant R01AI110964 to EHA entitled, "Understanding the Risk of Bat Coronavirus Emergence" in April 2020.[3] NIH eventually converted the grant termination to a suspension on July 8, 2020, pending EHA's responses to seven requests from NIH related to WIV's actions. NIH could unfreeze the funding if EHA cooperates with NIH's requests, but apparently EHA has not yet done so. Despite EHA's obstruction of NIH requests, NIH gave new financial awards to EHA in June 2020 and August 2020, totaling $2,127,602.[4] By NIH authorizing new funding to EHA, an NIH-suspended grantee, the NIH undercut its July 8, 2020 suspension and has incentivized its grantees to defy NIH oversight with impunity.

2. NIH's Inadequate Oversight of EHA's Other Support

You testified during a May 25, 2021 Congressional hearing that NIH was, "...of course not aware of other sources of funds or other activities they might have undertaken outside of what our approved grant allowed," when asked about NIH grant recipient EHA, and the WIV, an EHA subaward recipient.[5] Pursuant to the NIH Grants Policy, EHA was required to report all "other support," in-kind contributions such as laboratory space, equipment and supplies, and facilities and other resources for all individuals designated as the Principal Investigator (PI) personnel.[6] Per the NIH grants policy, the grant Principal Investigator Dr. Peter Daszak and EHA were required to report its other research funding sources and activities to NIH.[7] Without

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[2] Fox News, *Biden State Department quietly ended team's work probing COVID origin*, State Department (May 25, 2021) *available at* https://www.foxnews.com/politics/biden-state-department-shut-down-team-covid-origin-investigation.

[3] National Institutes of Health, *Understanding the Risk of Bat Coronavirus Emergence*, REPORTER (last accessed June 2, 2021) *available at* https://reporter.nih.gov/search/p1odLH_U1kyZgyOhClrN2w/project-details/9320765#similar-Projects/.

[4] USASpending.gov, *Cooperative agreement numbers U01AI151797 and U01AI153420*, EcoHealth Alliance available at

[5] House Committee on Appropriations, *FY 2022 Budget Request for the National Institutes of Health*, Hearings (May 25, 2021) *available at* https://appropriations.house.gov/events/hearings/fy-2022-budget-request-for-the-national-institutes-of-health.

[6] National Institutes of Health, Other Support, Grants & Funding (last accessed June 1, 2021) available at https://grants.nih.gov/grants/forms/othersupport.htm.

[7] *Id.*

further details or documentation, your testimony bolsters the notion that NIH oversight is largely ignorant of other awards to the grantee.

3. NIH's Inadequate Oversight of EHA's Delinquent Financial Reports

As the prime recipient of NIH grant R01AI110964, EHA gave a total $598,500 in five subaward transactions to the WIV from 2015 to 2019 for the WIV to, "conduct high-quality testing, sequencing, and analyses of field samples; maintenance of cold-chains from field to lab; ensuring quality control of sample storage and testing; collaborating on scientific publications and programmatic reporting."[8] EHA also gave a total of $201,217.10 in two subaward transactions to the Wuhan University School of Public Health (WUSPH) to "conduct targeted site-analyses, human behavioral surveillance including qualitative and quantitative surveys; analyses of data; collaborating on scientific publications and programmatic reporting," from 2016 through 2017.[9]

EHA is required to report its subawards to GSA's FFATA Subaward Reporting System (FSRS) by the end of the month following the month when the subaward was made.[10] For example, when EHA issued a $133,000 subaward to the WIV on May 29, 2015, EHA was required to report that subaward to FSRS by June 30, 2015.[11] USASpending is the U.S. government's open federal spending data source and when the grant number R01AI110964 data is downloaded, details reveal that EHA did not report subawards for that grant until 2020, even though EHA made subawards starting in 2015.[12] EHA reported all seven subaward transactions for R01AI110964 on July 13, 2020, five days following NIH's July 8, 2020 letter to EHA instructing EHA to ensure EHA reported all subaward data to FSRS.[13] Before the year 2020, only one other EHA subaward grant is reported in USASpending.gov, in which three subaward transactions for NIH grant number R56TW009502 are recorded in 2014.[14] EHA's apparent non-compliance of required financial reporting raises concerns about the adequacy of NIH oversight of NIH grants.

4. NIH's Possible Funding of EHA for Duplicative Research in China

EHA received federal funding as both a prime and sub-recipient not only from NIH, but also from the U.S. Agency for International Development (USAID) for its bat coronavirus research. The project descriptions and research articles are so similar that a distinction between the NIH bat coronavirus research objectives and achievements for the awards to EHA are almost interchangeable with EHA's USAID-funded bat coronavirus research objectives and

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[8] *Id.*
[9] *Id.*
[10] USAspending.gov, *Data Sources,* About (last accessed June 1, 2021), *available at* https://www.usaspending.gov/about.
[11] *Id.*
[12] USASpending.gov, *Advanced Search: Recipient – EcoHealth Alliance* (June 1, 2021) *available at* USASpending.gov/.
[13] *Id.*
[14] *Id.* See NIH grant number R56TW009502.

achievements.[15] The NIH grant progress reports will reveal details about the bat coronavirus research that can be compared to the reports from USAID-funded research. In its research funded by the USAID, EHA partnered with the WIV and with East China Normal University.[16] We are very concerned that the NIH and USAID may have funded duplicate projects and that EHA partnered with additional unreported entities in China for NIH-funded research.

5. NIH's Inadequate Reconciliation of EHA's Grant Subawards

As far back as 2005, Peter Daszak of EHA has authored over 20 bat coronavirus and other zoonic pathogen research articles with Dr. Zhengli Shi of the WIV, plus other researchers, about experiments funded by NIH.[17] Their collaborative research has resulted in a 2005 publication entitled "Bats Are Natural Reservoirs of SARS-Like Coronaviruses," funded by NIH.[18] In 2013, they published "Isolation and characterization of a bat SARS-like coronavirus that uses the ACE2 receptor," funded by NIH and USAID. [19] Their numerous publications acknowledge NIH as a research sponsor yet the only EHA support to the WIV in USASpending.gov was reported by EHA on July 13, 2020 (see concern number three above).[20] Vanity Fair reported that Dr. Shi "herself listed U.S. government grant support of more than $1.2 million on her curriculum vitae: $665,000 from the NIH between 2014 and 2019; and $559,500 over the same period from USAID."[21] EHA's late and potentially incomplete reporting of the WIV as its sub-award recipient raises questions about EHA's compliance with required financial reporting and also raises concerns about NIH's oversight of grant awards to EHA.

6. NIH's Inadequate Oversight of EHA's Place of Performance Reporting

The Federal Funding Accountability and Transparency Act of 2006 (FFATA) requires that federal award reporting must include the primary location of where the work will be performed, (including the city, state, congressional district, and country).[22] For EHA's NIH awards, China is not listed as the place of performance in USASpending.gov and instead, EHA's

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[15] USASpending.gov, *Advanced Search: Recipient – EcoHealth Alliance* (June 1, 2021) *available at* USASpending.gov/.
[16] USAID PREDICT-1 CONSORTIUM, *Reducing Pandemic Risk, Promoting Global Health*, Final Report (Dec. 2014) *available at* https://ohi.sf.ucdavis.edu/sites/g/files/dgvnsk5251/files/files/page/predict-final-report-lo.pdf.
[17] NIH Reporter, *Anthropogenic change & emerging zoonic paramyxoviruses*, Project Number 5R01TW005869-04 (Budget Start Date June 1, 2005) *available at* https://reporter.nih.gov/search/WMYBIQPE20aG4fAZLFj0lw/project-details/6923645#details, NIH National Library of Medicine, *Advanced Search for 'Shi, Daszak,'* National Center for Biotechnology Information (June 2, 2021) *available at* https://pubmed.ncbi.nlm.nih.gov/?term=Daszak%2C+Shi&sort=date&sort_order=asc&size=200.
[18] NIH National Library of Medicine, *Bats Are Natural Reservoirs of SARS-Like Coronaviruses*, PubMed (Sept.5, 2005) *available at* https://pubmed.ncbi.nlm.nih.gov/16195424/.
[19] Ge, XY., *et al., Isolation and characterization of a bat SARS-like coronavirus that uses the ACE2 receptor*, Nature 503, 535–538 (May 16, 2013) *available at* https://doi.org/10.1038/nature12711.
[20] *Id.*
[21] Katherine Eban, The Lab-Leak Theory – Inside the Fight to Uncover COVID-19 Origins, Vanity Fair (June 3, 2021) *available at* https://www.vanityfair.com/news/2021/06/the-lab-leak-theory-inside-the-fight-to-uncover-covid-19s-origins.
[22] PL 109-282, Sept. 26, 2006 *available at* https://www.govinfo.gov/content/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf.

primary place of performance is identified as New York.[23] The NIH grant documents, and the financial and progress reports we have requested will contain travel budgets and research details that will confirm the location(s) where EHA actually performed its research. Published research articles about NIH-funded experiments describe EHA's bat coronavirus research and surveillance activities often partnered with the WIV in China. We are very concerned about the discrepancy in EHA's primary place of performance as being New York in USASpending.gov when research articles, publications, and media interviews suggest EHA's primary place of performance is not domestic.[24]

7. NIH's Lack of Visibility into EHA's Grant Subawards

USASpending.gov limits visible data to prime and subaward recipients, and does not disclose funds that are further disbursed subaward recipients.[25] EHA is a subaward recipient of NIH grant funds from the Arizona State University and the Trustees of Columbia University in New York City.[26] As a subaward recipient, EHA does not publicly report when it further distributes subaward funds to other organizations such as the WIV or other recipients in China.[27] NIH questions to EHA in the July 8, 2020 grant suspension letter suggest that NIH lacks information and visibility on sub-grant awards that are either issued or received by EHA.[28]

8. NIH's Inadequate Oversight of EHA's Grant Fund Accounting

In our April 18, 2021 letter to EHA, we raised the issue that EHA reported a $319,570 cash award grant and a $126,792 cash award grant disbursed by wire to China for the purpose of "[u]understanding the risk of bat coronavirus emergence" on its IRS Form 990, calendar year 2016.[29] EHA reported giving $321,700 for coronavirus and emerging diseases to China on its IRS Form 990, calendar year 2015.[30] EHA IRS Form 990's for other years do not include that purpose or identify the WIV as an organization to which funds were paid. With EHA organized as a 501 (c)(3) non-profit organization, its IRS Form 990's are public documents able to be reviewed by NIH. As a non-federal entity that expends more $750,000 or more in federal funds in one year, EHA is required to submit a Single Audit report, previously known as the OMB Circular A-133 audit. The purpose of a Single Audit report is to provide assurance to the Federal Government that a non-federal entity has adequate internal controls in place, and is generally in

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[23] *Id.*
[24] Nidhi Subbaraman, *'Heinous!': Coronavirus researcher shut down for Wuhan-lab link slams new funding restrictions*, Nature (Aug. 21, 2020), *available at* https://www.nature.com/articles/d41586-020-02473-4.
[25] USASpending.gov, *Advanced Search: Recipient - EcoHealth Alliance* (June 1, 2021) *available at* USASpending.gov/.
[26] *Id.*
[27] *Id.*
[28] Internal Revenue Service, EHA 990 final, Schedule F, Parts I and II (May 3, 2017) *available at* https://apps.irs.gov/pub/epostcard/cor/311726494_201606_990_2017090514700974.pdf.
[29] U.S. Energy and Commerce Republicans, *Letter to EcoHealth Alliance*, The COVID-19 Origins Investigation (Apr. 16, 2021) *available at* https://republicans-energycommerce.house.gov/the-covid-19-origins-investigation/.
[30] Internal Revenue Service, *EHA 990 final 2015, Schedule F, Parts I and II* (May 3, 2017) *available at* https://apps.irs.gov/pub/epostcard/cor/311726494_201606_990_2017090514700974.pdf.

compliance with program requirements.[31] In EHA's Single Audit reports for years 2016 to 2020, no payments are evident for EHA funds paid to the WIV.[32]

9. NIH's Inadequate Oversight of Its Funded Researchers in China

The WIV named NIH and EHA on its website as WIV international partner as of and prior to the date of our March 18, 2021 letter to NIH.[33] By March 22, 2021, the WIV had removed NIH as a partner from its website.[34] The NIH has characterized its relationship Chinese scientists as respectable scientific partners.[35] However, within three days following our letter to NIH which inquired about NIH grants to the WIV, the WIV quickly concealed its long-standing relationship with NIH by deleting evidence of its NIH partnership from its website. This action does not seem consistent with NIH's claim that the WIV and its scientists were a respectable scientific partner. It has been reported that some Chinese scientists working with EHA are current or former members of the People's Liberation Army of China.[36] It has also been reported that the Chinese military were conducting research at the WIV.[37] We are concerned that NIH-funded coronavirus research in China may not have undergone proper biodefense risk analysis.

10. NIH's Lack of Cooperation with Congressional Oversight Inquiry

NIH is supposed to be a transparent institution and the grant documents we requested should be a matter of public record.[38] Contrary to your public statement implying that we asked for "pretty sensitive materials, not quite classified, but getting close to that," the grant documents we requested are releasable to the public per NIH's own policy and should have already been provided to us.[39]

As you are aware, the NIH grant documents and progress reports we requested will include details pertinent to our COVID-19 origins investigation, including information about: all research participants and collaborating organizations; location(s) of work performed; instruments, equipment and monies provided to grant sub-recipients; financial accounting

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[31] U.S. Department of Health and Human Services, *Single Audit* (Apr. 25, 2016) *available at* (https://www.hhs.gov/about/agencies/asfr/data-act-program-management-office/single-audit/index.html.

[32] Federal Audit Clearinghouse, *EcoHealth Alliance, Inc and Wildlife Preservation Trust Int. Single Audit Reports 2017-2021* (June7, 2021) *available at* https://facdissem.census.gov/SearchResults.aspx.

[33] Internet Archive Wayback Machine, *Wuhan Institute of Virology, CAS*, Partnerships (Mar. 18, 2021) *available at* https://web.archive.org/web/20210318052528/http://english.whiov.cas.cn/International_Cooperation2016/Partnerships/.

[34] Internet Archive Wayback Machine, *Wuhan Institute of Virology, CAS*, Partnerships (Mar. 22, 2021) *available at* https://web.archive.org/web/20210322053537/http://english.whiov.cas.cn/International_Cooperation2016/Partnerships/

[35] House Committee on Appropriations, *FY 2022 Budget Request for the National Institutes of Health*, Hearings (May 25, 2021) *available at* https://appropriations.house.gov/events/hearings/fy-2022-budget-request-for-the-national-institutes-of-health.

[36] Alexis, Shi Zhengli: Weaponizing Coronaviruses, with Pentagon Funding, at a Chinese Military Lab, https://enviroshop.com/shi-zhengli-weaponizing-coronaviruses-with-pentagon-funding-at-a-chinese-military-lab/

[37] *Id.*

[38] National Institutes of Health, *NIH Grants Policy Statement*, Policy and Compliance (June 1, 2021) *available at* https://grants.nih.gov/policy/nihgps/index.htm.

[39] *Id.*

reports; research techniques and accomplishments; research products such as: technologies, patent applications, data or databases, physical collections, and models; significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents; and budgetary information and project outcomes.[40]

As the federal grant awarding agency, NIH must have the right of access to any of EHA's documents or other records which are pertinent to NIH federal awards.[41] The NIH grants policy states that the Freedom of Information Act (FOIA) and U.S. Department of Health and Human Services regulations require NIH to release certain grant documents and records requested by members of the public, regardless of the intended use of the information.[42] Per NIH policy, NIH will generally release funded applications and progress reports pursuant to a FOIA request.[43] NIH considers most grant-related information in the application or post-award phases as being public information (emphasis added).[44]

In support of this inquiry and the public interest in the origins of the COVID-19 pandemic, please provide written responses to the following by June 24, 2021:

1. We again renew our request for NIH's immediate compliance with our oversight inquiry for production of the grant documents and progress reports forthwith that we first requested on March 18, 2021.

2. What is NIH's policy for awarding funds to organizations when the organization has NIH grant funds in suspended status and are not cooperating NIH requests? If the NIH permits new award funding under these circumstances, please provide the policy, and explain how such funding does not undercut NIH's ability to oversee grantees and does not incentivize grantees to defy NIH's requests for information.

3. Please explain all oversight steps NIH has taken to ensure EHA's full compliance with federal financial subaward reporting requirements for all NIH grants. Please explain if EHA reported to NIH any subaward recipients other than the WIV or the WUSPH for NIH grant R01AI110964. Please provide all financial records of all NIH funds given to Dr. Zhengli Shi of the WIV.

4. For all NIH awards in which EHA was a subrecipient, please provide a financial accounting of EHA's subawards to the WIV or other organizations in China.

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[40] Hugh Hewitt, *Dr. Francis Collis On The U.S. Funding of the Wuhan Lab and Congressional Oversight,* The Hugh Hewitt Show (June 2, 2021) *available at* https://hughhewitt.com/dr-francis-collins-on-the-u-s-funding-of-the-wuhan-lab-and-congressional-oversight/, National Institutes of Health, *Research Performance Progress Report,* Grants & Funding (May 4, 2021) *available at* https://grants.nih.gov/grants/rppr/index.htm.
[41] *Id.*
[42] National Institutes of Health, *NIH Grants Policy Statement*, Policy and Compliance (June 1, 2021) *available at* https://grants.nih.gov/policy/nihgps/index.htm.
[43] *Id.*
[44] *Id.*

5. How does NIH ensure it does not award unapproved duplicate grants for same or similar research already funded by other agencies, to EHA or other NIH grant recipients? For all NIH awards to EHA, please provide accounting information for EHA subawards to recipients in China.

6. Please explain how NIH has reviewed EHA annual Single Audit reports to ensure how EHA has met program and reporting requirements.

7. How does NIH audit the financial reports submitted to the IRS by its 501(c)(3) non-profit organization grant award recipients to ensure NIH awards are accurately reported? How does NIH ensure its grantees do not act as a pass-through or money laundering provider to send U.S. research funding to China?

8. Please explain NIH's policy for ensuring its awardees accurately report the actual place of research performance. For all NIH-funded research, please provide all China site locations where EHA's work was performed.

9. Please explain if EHA reported its other funding or in-kind support, including awards from federal agency, to NIH. Please explain if EHA reported any support from organizations in China.

10. Did NIH perform a biodefense risk analysis for coronavirus research conducted at the WIV as research with potential for dual use of research concern, pandemic pathogen or bioweapon development, as outlined in the HHS *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*?[45] Please describe NIH's coordination procedures with the U.S. Intelligence Community that are completed before NIH funds research projects in foreign countries with existing biodefense programs.

Please make arrangements to schedule the briefing for Committee staff by June 24, 2021. If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff. Thank you for your attention to this request.

Sincerely,

Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce

Fred Upton
Republican Leader
Subcommittee on Energy

[45] U.S. Department of Health and Human Services, *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*, Science Safety Security (Dec. 2017) *available at* https://www.phe.gov/s3/dualuse/Pages/p3co.aspx.

Bob Latta
Republican Leader
Subcommittee on Communications and Technology

Brett Guthrie
Republican Leader
Subcommittee on Health

David McKinley
Republican Leader
Subcommittee on Environment and Climate Change

H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Gus Bilirakis
Republican Leader
Subcommittee on Consumer Protection and Commerce

Michael C. Burgess, M.D.
Member of Congress

Steve Scalise
Member of Congress

Adam Kinzinger
Member of Congress

Bill Johnson
Member of Congress

Billy Long
Member of Congress

Larry Bucshon, M.D.
Member of Congress

Markwayne Mullin
Member of Congress

Richard Hudson
Member of Congress

Tim Walberg
Member of Congress

Earl L. "Buddy" Carter
Member of Congress

Jeff Duncan
Member of Congress

Gary Palmer
Member of Congress

Neal P. Dunn, M.D.
Member of Congress

John Curtis
Member of Congress

Debbie Lesko
Member of Congress

Greg Pence
Member of Congress

Dan Crenshaw
Member of Congress

John Joyce, M.D.
Member of Congress

Kelly Armstrong
Member of Congress

From:	Lauer, Michael (NIH/OD) [E]
To:	Myles, Renate (NIH/OD) [E]
Cc:	Fine, Amanda (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]; OER Press Group; Lauer, Michael (NIH/OD) [E]
Subject:	Re: Question from the WSJ
Date:	Tuesday, June 22, 2021 1:48:30 PM
Attachments:	NIHLetter8July.pdf

Thanks Renate – looks great!

Mike

From: "Myles, Renate (NIH/OD) [E]" (b) (6)
Date: Tuesday, June 22, 2021 at 1:04 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: "Fine, Amanda (NIH/OD) [E]" (b) (6), "Wojtowicz, Emma (NIH/OD) [E]" (b) (6), OER Press Group <OERPressGroup@mail.nih.gov>
Subject: FW: Question from the WSJ

Hi Mike:

Thanks for jumping on a call with us. Here's a proposed response based on our discussion.

(b) (5)

Thanks,
Renate

From: "Gordon, Michael" (b) (6)
Date: Tuesday, June 22, 2021 at 7:55 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Fwd: Question from the WSJ

Dr. Lauer,

I am a reporter for The Wall Street Journal and have a question for you. I would be happy to discuss this by phone or in person, including on a background not-for-

attribution basis. I am looking for some guidance on a July 8, 2020 letter you wrote, which has been in the public domain for nearly a year. I am neither a proponent of the lab theory nor a supporter of the zoonotic hypothesis regarding the origins of Covid-19 in China. I am just trying to understand and present the facts as best I can.

In your July 8 letter you described some restrictions at the Wuhan Institute of Virology in 2019. Specifically, you wrote that there was "diminished cell-phone traffic in October 2019" at or near that facility. You also wrote that "there was evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019."

My WSJ colleague, Betsy McKay, wrote in August about this letter, which was addressed to the EcoHealth Alliance. (https://www.wsj.com/articles/nih-presses-u-s-nonprofit-for-information-on-wuhan-virology-lab-11597829400). It has also been distributed on Capitol Hill.

My questions are as follows.

Do you or NIH still stand by the statement that there was diminished cell traffic in and around the WIV in October 2019? What was the source of that information and is it a source in which NIH has confidence? The letter suggests that it is a fact that there was diminished cell phone traffic. To your understanding, is it a fact or merely a possibility? Have you and NIH changed that position based on more recent information? Did EcoHealth Alliance ever provide any information regarding your questions? What about the roadblocks? Is there any similar information on that? I have attached a copy of the letter to this email.

Again, we can talk on a background, not-for-attribution basis if you wish. I am trying to better understand a complicated situation and fully understand that new information may have arisen over the past year and that some prior impressions may have been discomfirmed. I also want to be sure that I am interpreting your letter correctly, and it has been interpreted as stating for a fact that there was disminished cell phone traffic. So I would like to be sure that this is what you intended. I am trying to be very careful about all this. Thanks for your attention, and I would be happy to answer any questions on this request.

Michael Gordon
National Security Correspondent
The Wall Street Journal
(b) (6) (cell, WhatsApp, Signal)
michael.gordon@wsj.com (work email)
MGWSJ@protonmail.com (encrypted email)
Book site: michaelrgordon.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

Dear Drs. Chmura and Daszak:

In follow-up to my previous letter of April 24, 2020, I am writing to notify you that the National Institute of Allergy and Infectious Diseases (NIAID), an Institute within the National Institutes of Health (NIH), under the Department of Health and Human Services (HHS), has withdrawn its termination of grant R01AI110964, which supports the project *Understanding the Risk of Bat Coronavirus Emergence*. Accordingly, the grant is reinstated.

However, as you are aware, the NIH has received reports that the Wuhan Institute of Virology (WIV), a subrecipient of EcoHealth Alliance under R01AI110964, has been conducting research at its facilities in China that pose serious bio-safety concerns and, as a result, create health and welfare threats to the public in China and other countries, including the United States. Grant award R01AI110964 is subject to biosafety requirements set forth in the NIH Grants Policy Statement (e.g., NIH GPS, Section 4.1.24 "Public Health Security") and the Notice of Award (e.g., requiring that "Research funded under this grant must adhere to the [CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)]."). Moreover, NIH grant recipients are expected to provide safe working conditions for their employees and foster work environments conducive to high-quality research. NIH GPS, Section 4. The terms and conditions of the grant award flow down to subawards to subrecipients. 45 C.F.R. § 75.101.

As the grantee, EcoHealth Alliance was required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ." 45 C.F.R. § 75.352(d). We have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.

Moreover, as we have informed you through prior Notices of Award, this award is subject to the Transparency Act subaward and executive compensation reporting requirement of 2 C.F.R. Part

170. To date you have not reported any subawards in the Federal Subaward Reporting System.

Therefore, effective the date of this letter, July 8, 2020, NIH is suspending all activities related to R01AI110964, until such time as these concerns have been addressed to NIH's satisfaction. This suspension is taken in accordance with 45 C.F.R. § 75.371, Remedies for Noncompliance, which permits suspension of award activities in cases of non-compliance, and the NIH GPS, Section 8.5.2, which permits NIH to take immediate action to suspend a grant when necessary to protect the public health and welfare. This action is not appealable in accordance with 42 C.F.R. § 50.404 and the NIH GPS Section 8.7, Grant Appeals Procedures. However, EcoHealth Alliance has the opportunity to provide information and documentation demonstrating that WIV and EcoHealth Alliance have satisfied the above-mentioned requirements.

Specifically, to address the NIH's concerns, EcoHealth must provide the NIH with the following information and materials, which must be complete and accurate:

1. Provide an aliquot of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.
2. Explain the apparent disappearance of Huang Yanling, a scientist / technician who worked in the WIV lab but whose lab web presence has been deleted.
3. Provide the NIH with WIV's responses to the 2018 U.S. Department of State cables regarding safety concerns.
4. Disclose and explain out-of-ordinary restrictions on laboratory facilities, as suggested, for example, by diminished cell-phone traffic in October 2019, and the evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019.
5. Explain why WIV failed to note that the RaTG13 virus, the bat-derived coronavirus in its collection with the greatest similarity to SARS-CoV-2, was actually isolated from an abandoned mine where three men died in 2012 with an illness remarkably similar to COVID-19, and explain why this was not followed up.
6. Additionally, EcoHealth Alliance must arrange for WIV to submit to an outside inspection team charged to review the lab facilities and lab records, with specific attention to addressing the question of whether WIV staff had SARS-CoV-2 in their possession prior to December 2019. The inspection team should be granted full access to review the processes and safety of procedures of all of the WIV field work (including but not limited to collection of animals and biospecimens in caves, abandoned man-made underground cavities, or outdoor sites). The inspection team could be organized by NIAID, or, if preferred, by the U.S. National Academy of Sciences.
7. Lastly, EcoHealth Alliance must ensure that all of its subawards are fully reported in the Federal Subaward Reporting System

During this period of suspension, NIH will continue to review the activities under this award, taking into consideration information provided by EcoHealth Alliance, to further asses compliance by EcoHealth Alliance and WIV, including compliance with other terms and conditions of award that may be implicated. Additionally, during the period of suspension, EcoHealth Alliance may not allow research under this project to be conducted. Further, no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance or any subrecipients; all such charges are unallowable. It is EcoHealth Alliance's responsibility as the

recipient of this grant award to ensure that the terms of this suspension are communicated to and understood by all subrecipients. EcoHealth Alliance must provide adequate oversight to ensure compliance with the terms of the suspension. Any noncompliance of the terms of this suspension must be immediately reported to NIH. Once the original award is reinstated, NIH will take additional steps to restrict all funding in the HHS Payment Management System in the amount of $369,819. EcoHealth Alliance will receive a revised Notice of Award from NIAID indicating the suspension of these research activities and funding restrictions as a specific condition of award.

Please note that this action does not preclude NIH from taking additional corrective or enforcement actions pursuant to 45 CFR Part 75, including, but not limited to, terminating the grant award. NIH may also take other remedies that may be legally available if NIH discovers other violations of terms and conditions of award on the part of EcoHealth Alliance or WIV.

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Sincerely,

Michael S. Lauer -S

Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Lauer, Michael (NIH/OD) [E]
To: Myles, Renate (NIH/OD) [E]; Fine, Amanda (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]
Cc: Lauer, Michael (NIH/OD) [E]
Subject: FW: Question from the WSJ
Date: Tuesday, June 22, 2021 8:00:17 AM
Attachments: NIHLetter8July.pdf

Hi Renate, Amanda, and Emma – this in from WSJ. Happy to discuss.

Thanks, Mike

From: "Gordon, Michael" <michael.gordon@wsj.com>
Date: Tuesday, June 22, 2021 at 7:55 AM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Subject: Fwd: Question from the WSJ

Dr. Lauer,

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In your July 8 letter you described some restrictions at the Wuhan Institute of Virology in 2019. Specifically, you wrote that there was "diminished cell-phone traffic in October 2019" at or near that facility. You also wrote that "there was evidence that there may have been roadblocks surrounding the facility from October 14-19, 2019."

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Michael Gordon
National Security Correspondent
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MGWSJ@protonmail.com (encrypted email)
Book site: michaelrgordon.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

8 July 2020

Drs. Aleksei Chmura and Peter Daszak
EcoHealth Alliance, Inc.
460 W 34th St
Suite 1701
New York, NY 10001

Re: NIH Grant R01AI110964

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Sincerely,

Michael S. Lauer -S

Digitally signed by Michael S. Lauer -S
Date: 2020.07.08 21:43:41 -04'00'

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Simanich, Sasha (NIH/OD) [E][/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62114870DC66475A8C0CE0047413ED92-SIMANICHS2]

Attendees: Lauer, Michael (NIH/OD) [E]; Bundesen, Liza (NIH/OD) [E]; Bulls, Michelle G. (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Haskins, Melinda (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Fenton, Matthew (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; LaMontagne, Karen (NIH/OD) [E]; Lohmann, Larry (NIH/OD) [E]; Spady, Tyrone (NIH/OD) [E]; Chakraborty, Trisha (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Stein, Meredith (NIH/OD) [E]

Location: Webex Meeting

Importance: Normal

Subject: Internal Pre-brief Meeting for Upcoming OIG Entrance Conference: “National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees" (A-05-21-00025)

Start Time: Thur 6/24/2021 7:00:00 AM (UTC-05:00)

End Time: Thur 6/24/2021 8:00:00 AM (UTC-05:00)

Required Attendees: Lauer, Michael (NIH/OD) [E]; Bundesen, Liza (NIH/OD) [E]; Bulls, Michelle G. (NIH/OD) [E]; Ta, Kristin (NIH/OD) [E]; Haskins, Melinda (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Fenton, Matthew (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; LaMontagne, Karen (NIH/OD) [E]; Lohmann, Larry (NIH/OD) [E]; Spady, Tyrone (NIH/OD) [E]; Chakraborty, Trisha (NIH/OD) [E]; Jacobs, Anna (NIH/OD) [E]; Stein, Meredith (NIH/OD) [E]

NIH Overssight of Grantee-Subgrantee Entrance Conference Agenda...6.21.21.docx

This meeting is to discuss the upcoming entrance conference with the OIG (TBD). You have received an itinerary/document request, but the OIG informed us that this document will be modified, based on their discussion with Dr. Lauer on 6/22.

We plan on scheduling the entrance conference for next week.

Participants:

Michael Lauer, Deputy Director for Extramural Research, Office of Extramural Research (OER)
Liza Bundesen, Special Assistant to Deputy Director for Extramural Research, OER
Michelle Bulls, Director, Office of Policy for Extramural Research Administration (OPERA), OER
Kristen Ta, Senior Advisor, OER/OPERA
Melinda Haskins, Legislative Affairs and Correspondence Management Branch (LACMB), Chief, National Institute of Allergy and Infectious Diseases (NIAID)
Jill Harper, NIAID Deputy Director for Science Management, NIAID
Matthew Fenton, Director of the Division of Extramural Activities (DEA), NIAID
Alan Embry Chief, Respiratory Diseases Branch (RDB), NIAID
Karen LaMontagne, Legislative Analyst, Office of Legislative Policy & Analysis (OLPA)
Larry Lohman, Legislative Analyst, OLPA
Tyrone Spady, Director, Science Policy Coordination, Collaboration, and Reporting (SPCCR), Office of Science Policy (OSP)
Trisha Chakraborty, Health Science Policy Analyst, OSP/SPCCR
Anna Jacobs, Senior Attorney, Office of General Counsel (OGC)
Meredith Stein, Acting Director, Office of Management Assessment (OMA)
Sasha Simanich, Acting Director, Division of Risk Management and Audit Liaison (RMAL)

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Audit of National Institutes of Health and Grantee Compliance With Federal Requirements To Ensure Proper Monitoring and Use of Grant Funds by Selected Grantees and Subgrantees
CIN: A-05-21-00025

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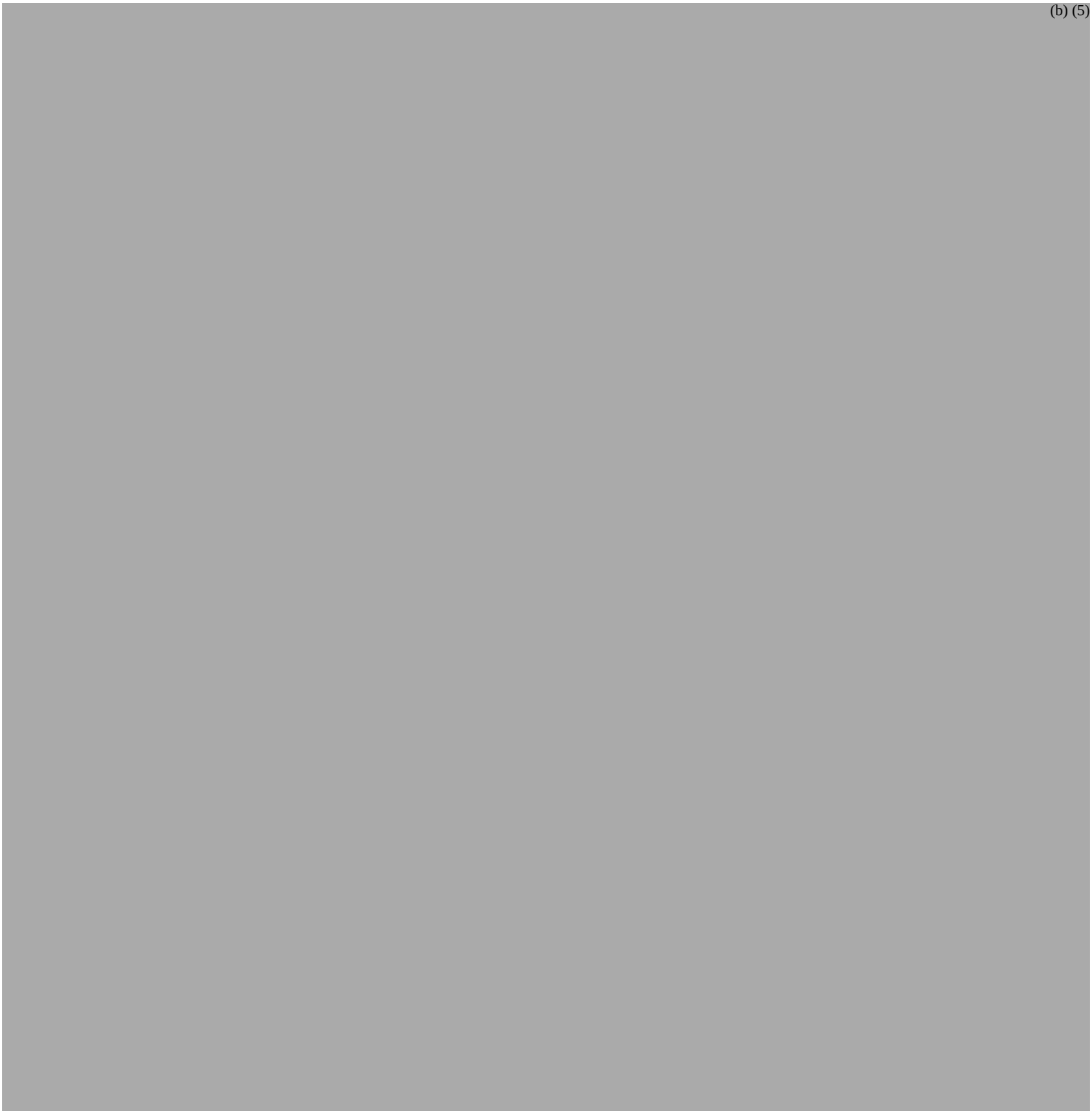

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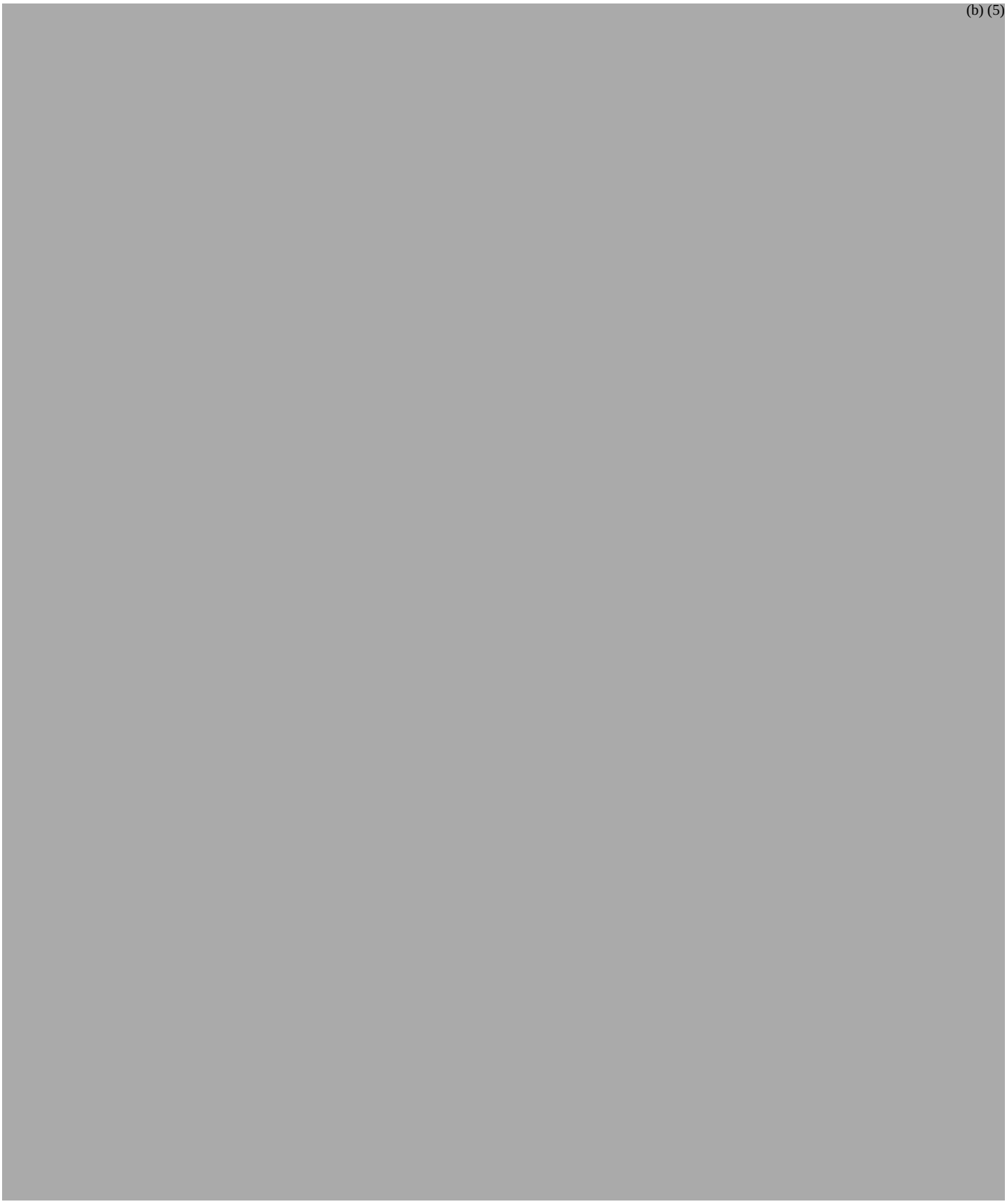

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From:	Lauer, Michael (NIH/OD) [E]
To:	Rabin, Elise (NIH/OD) [E]
Cc:	Kosub, David (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
Subject:	Re: For Your Review - HHS Passback - June 23 E&C Hearing QFRs
Date:	Monday, November 16, 2020 12:57:28 PM
Attachments:	QFR - COVID-19 Oversight 20200623 - Fauci_Final1.ogc.docx

Thanks Elise – I agree with the OGC edits.

Mike

From: "Rabin, Elise (NIH/OD) [E]" (b) (6)
Date: Monday, November 16, 2020 at 12:55 PM
To: "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: "Kosub, David (NIH/OD) [E]" (b) (6)
Subject: For Your Review - HHS Passback - June 23 E&C Hearing QFRs

Hi Mike –

OLPA has asked OER to review and let them know by Wednesday, Nov. 18 if OER accepts or rejects the suggested edits from OGC to NIH responses for Rep. Pallone questions 1a and 1b. The questions are related to the EcoHealth Alliance grant. NIAID provided the initial draft responses that OGC is proposing to strike and revise.

Thankfully these are very brief and appear on pages 1 and 2 of the attached.

- Elise

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Elise Rabin
Division of Communications and Outreach
NIH Office of Extramural Research
(b) (6) *Phone*
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(b) (6)

NIH . . . Turning Discovery Into Health

Committee on Energy and Commerce

Hearing on
"Oversight of the Trump Administration's Response to the COVID-19 Pandemic"

June 23, 2020

Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health

The Honorable Frank Pallone, Jr. (D-NJ)

1. It is perplexing that the Trump Administration decided to cancel a research grant that was specificallyfocused on coronavirus emergence while we are in the midst of a coronavirus pandemic.

   Over 70 Nobel-prize winning American scientists raised alarm about this move, saying it "sets a dangerous precedent by interfering in the conduct of science" and "deprives the nation and the world of highly regarded science that could help control one of the greatest health crises in modern history and those that may arise in the future." More than 30 different scientific societies expressed concern with this decision as well.

   The reported reason for this grant's cancellation was because the Administration "does not believe the current project outcome aligns with the program goals and agency priorities."

   a. What does the science around the coronavirus show regarding the virus's origins? Does the science show that the coronavirus was initially created in a lab or does it show that it was transmitted from an animal to a human?

NIH Response:

(b) (5)

   b. How would research such as the EcoHealth Alliance grant titled, "Understanding the Risk of Bat Coronavirus Emergence" (funded under grant R01 AI110964 and terminated on April 24, 2020), be relevant to the coronavirus pandemic we are experiencing today?

NIH Response:

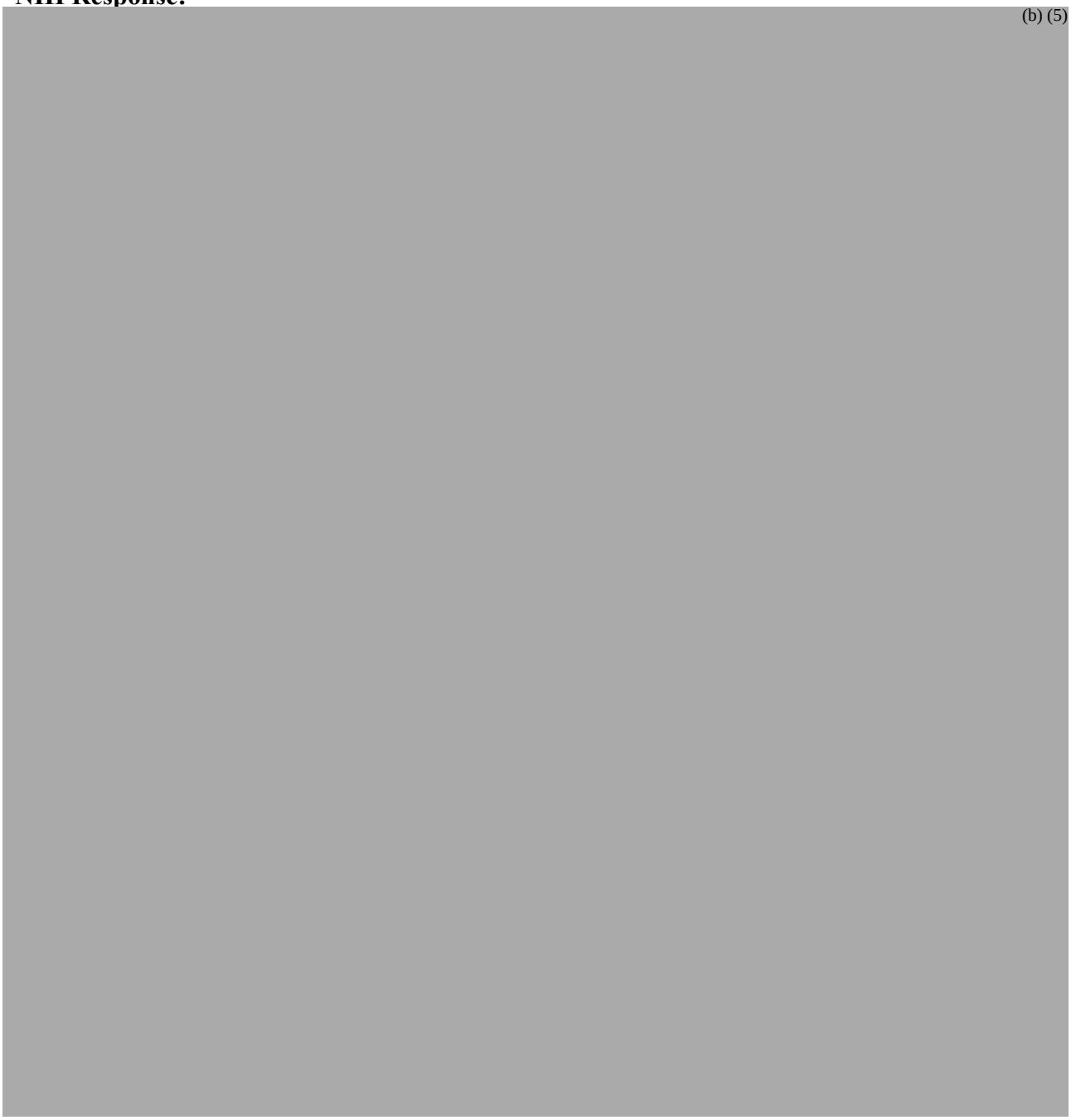
(b) (5)

2. The ongoing inequities in health and health care access among communities of color are concerning, and one critical way to help address these gaps is to ensure diverse participation in the development of medical treatments.

    a. What actions is Operation Warp Speed or the ACTIV partnership taking to address inequities in our research and development of vaccines or treatments for COVID-19?

NIH Response:

(b) (5)



Question 2 from The Honorable Frank Pallone, Jr. (D-NJ) continued

Participation aside, we must also make sure approved treatments are effective for all communities. In the case of coronavirus treatment candidates, for example, while results

from the Remdesivir clinical trial were positive, the recovery rate ratio reported for Black, Hispanic/Latino, and Asian participants was less than that of White participants. No such reporting line for American Indians or Alaska Natives existed.

Additionally, while news has emerged about another possible breakthrough treatment from the University of Oxford, there is some evidence that some minority populations may respond differently to this type of drug compared to White patients

b. What have the studies shown regarding why Remdesivir may be less effective for Black, Hispanic/Latino, and Asian patient populations? How will the Department of Health and Human Services (HHS) ensure that clinical trials for medical treatments for COVID-19 move forward that benefits or risks for certain populations are adequately communicated?

NIH Response:

(b) (5)

[redacted]

[1] https://www.nejm.org/doi/full/10.1056/NEJMoa2007764

(b) (5)

[redacted]

The Honorable Anna G. Eshoo (D-CA)

1. When does the National Institutes of Health (NIH) anticipate beginning human clinical trials on candidates you are supporting?

NIH Response:

(b) (5)

[redacted]

(b) (5)

2. How many people will need to enroll in these clinical trials to get adequate data?

NIH Response:

(b) (5)

3. How quickly will you be able to assess a vaccine candidate's safety and effectiveness, the standards for the Food and Drug Administration (FDA) approval, after the trials begin?

NIH Response:

(b) (5)

(b) (5)

4. Would early clinical trial data showing that a patient develops high levels of antibodies without severe side effects be enough to demonstrate safety and effectiveness of a vaccine?

NIH Response:

(b) (5)

5. What additional data is necessary to prove that a vaccine is safe and effective?

NIH Response:

(b) (5)

The Honorable Diana DeGette (D-CO)

1. We have seen the importance of medical research that relies on fetal tissue for developing vaccines including polio, rubella, measles, chickenpox, adenovirus, rabies, as well as treatments for debilitating diseases such as rheumatoid arthritis, cystic fibrosis, and hemophilia. Hundreds of millions of lives have been saved worldwide because of these advancements. What ways can research using fetal tissue be used to help scientists find a treatment, cure, or vaccine for COVID-19?

NIH Response:

(b) (5)

[redacted]

The Honorable Jerry McNerney (D-CA)

1. Do you think that the President's words, actions, or lack of actions, much of which either have ignored or acted against expert medical or epidemiological advice, has enabled the virus to spread beyond what it should have, causing unnecessary illness and death?

NIH Response:

(b) (5)

[redacted]

(b) (5)

[redacted]

The Honorable Gus M. Bilirakis (R-FL)

1. What have you learned about the management of chronic care conditions (like diabetes, hypertension, asthma, etc.) with regard to complications and poor outcomes associated with COVID-19?

    a. Are there differences between patients who manage their condition well versus those who don't?

NIH Response:

(b) (5)

[redacted]

    b. Can certain treatments make these patients even more susceptible to adverse COVID-19 outcomes – how is this data captured and communicated to patients and their providers expeditiously?

NIH Response:

(b) (5)

[redacted]

(b) (5)

2. As policy makers consult the data to direct response efforts, where do you suggest the goal posts be erected – in other words, where should the bulk of our attention and resources be directed as states reopen?

    a. Is it about total confirmed cases, hospitalizations, or deaths?

NIH Response:

(b) (5)

    b. Does a response addressing mortality have different considerations than one that prioritizes transmissibility?

NIH Response:

(b) (5)

[2] https://www.covid19treatmentguidelines.nih.gov/
[3] https://www.whitehouse.gov/openingamerica/

(b) (5)

[redacted]

(b) (5)

3. As we learn more about how COVID has unfolded in our country, we are seeing that it has had a disproportionate impact on certain populations, especially those in nursing homes, frontline healthcare workers, and Native Americans. The underlying challenges that caused these populations to be hard hit in the first place will still be around when we get to the resurgence of COVID in the fall. For example, nursing home patients will continue to have major underlying health conditions; healthcare workers will continue to have the highest exposure risks, even as the demands placed on them increase; and Native Americans will continue to have challenges receiving primary and secondary care services.

    a. Recognizing the challenges for each of these populations, can you describe what special considerations should be made for testing and treatment needs of these populations above and beyond what a response plan might be for the general population?

NIH Response:

(b) (5)

[4] https://www.covid19treatmentguidelines.nih.gov/

(b) (5)

[redacted]

b. Can you describe the role of the Federal government to ensure that it is able to provide sufficient testing and treatment needs of these populations?

NIH Response:

(b) (5)

[redacted]

4. Are there any underreported successes in the Administration's COVID-19 response that you would like to discuss?

NIH Response:

(b) (5)

[redacted]

(b) (5)

[redacted]

The Honorable Earl L. "Buddy" Carter (R-GA)

1. My understanding is that there are a number of drugs currently in shortage or at-risk of being in shortage. In some cases, the ingredients that go into making these drugs are manufactured exclusively overseas which presents national security concerns. I also read that some of the products in the national stockpile needed to be discarded because they had passed their expiration date.

    a. What do you think about using the existing commercial distribution network here in the U.S. to manage and replenish a supply of pharmaceutical products identified by the government as being at high risk of market disruption?

NIH Response:

(b) (5)

[redacted]

b. Wouldn't a government-private sector arrangement to ensure we have a stockpile of needed medicines available enable us to address the ongoing shortage concerns and more urgently, ensure we are prepared for future unforeseen health care outbreaks?

NIH Response:

(b) (5)

NIH Response:

(b) (5)

2. All of the vaccines being developed appear to be focused on the spike protein which can and does mutate. Should we be looking at the non-mutating part of the virus?

a. In particular, what about consideration of other targets for immune-therapy?

NIH Response:

(b) (5)

(b) (5)

3. I understand that the National Institute of Allergy and Infectious Diseases (NIAID) has worked in the past with an immunotherapy company that tested ligand epitope antigen presentation system (LEAPS) technology as a new immune-based treatment for influenza virus infection in a mouse model. The study demonstrated a reduction in virus replication in the lungs, enhance survival, and modulate the protective immune responses that eliminate the virus while preventing excessive cytokines that could injure the host. In other words, it reduced mortality and morbidity. And that further work in collaboration with the University of Georgia Vaccine Center is prepared to move forward with further research in this direction.

    a. Do you think this approach (based on previous studies at NIAID) holds some promise as an adjunct to antiviral treatment of COVID-19?

NIH Response:

(b) (5)