From:	Wood, Gretchen (NIH/OD) [E]
To:	Tabak, Lawrence (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]
Cc:	Kolberg, Rebecca (NIH/OD) [E]; Mazzucco, Anna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; George, Jill (NIH/OD) [E]; Pelis, Kim (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]
Subject:	Re: TPs for Tomorrow"s ACD Meeting
Date:	Tuesday, May 26, 2020 8:14:47 AM
Attachments:	Annotated May 26 2020 RADx Project teleconference ACD agenda.docx May RADx teleconference member poll results.xlsx

Good morning,

Final annotated agenda and the polling results for quorum.

Thank you,

Gretchen

From: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Date: Tuesday, May 26, 2020 at 6:13 AM
To: "Schwetz, Tara (NIH/OD) [E]" <(b) (6) Francis Collins <(b) (6)
Cc: "Kolberg, Rebecca (NIH/OD) [E]" <(b) (6) Anna Mazzucco <(b) (6) John Burklow <(b) (6) "Myles, Renate (NIH/OD) [E]" <(b) (6) Jill George <(b) (6) Kimberly Pelis <(b) (6) Jordan Gladman <(b) (6) Gretchen Wood <(b) (6) Cyndi Burrus-Shaw <(b) (6) "McManus, Ayanna (NIH/OD) [E]" <(b) (6) Dina Simon <(b) (6)
Subject: Re: TPs for Tomorrow's ACD Meeting

Sorry -sent the wrong version – please use this one attached.

From: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Date: Tuesday, May 26, 2020 at 6:09 AM
To: "Schwetz, Tara (NIH/OD) [E]" <(b) (6) Francis Collins <(b) (6)
Cc: "Kolberg, Rebecca (NIH/OD) [E]" <(b) (6) "Mazzucco, Anna (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Myles, Renate (NIH/OD) [E]" <(b) (6) "George, Jill (NIH/OD) [E]" <(b) (6) "Pelis, Kim (NIH/OD) [E]" <(b) (6) "Gladman, Jordan (NIH/OD) [E]" <(b) (6) "Wood, Gretchen (NIH/OD) [E]" <(b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]" <(b) (6) "McManus, Ayanna (NIH/OD) [E]" <(b) (6) "Simon, Dina (NIH/OD) [C]" <(b) (6)
Subject: Re: TPs for Tomorrow's ACD Meeting

Please see edits – Gretchen please insert COI statement that I must read.
Thanks
Larry

From: "Schwetz, Tara (NIH/OD) [E]" <(b) (6)
Date: Tuesday, May 26, 2020 at 12:05 AM
To: Francis Collins <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Cc: "Kolberg, Rebecca (NIH/OD) [E]" <(b) (6) "Mazzucco, Anna (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Myles, Renate (NIH/OD) [E]" <(b) (6) "George, Jill (NIH/OD) [E]" <(b) (6) "Pelis, Kim (NIH/OD) [E]" <(b) (6) "Gladman, Jordan (NIH/OD) [E]" <(b) (6) "Wood, Gretchen (NIH/OD) [E]" <(b) (6) "Burrus-Shaw, Cyndi (NIH/OD) [E]" <(b) (6) "McManus, Ayanna (NIH/OD) [E]" <(b) (6) "Simon, Dina (NIH/OD) [C]" <(b) (6)
Subject: TPs for Tomorrow's ACD Meeting

Francis and Larry,

Please find attached TPs for tomorrow's ACD call. Do let us know if you need anything else.

Best,

Tara A. Schwetz, PhD
Acting Director, NINR
Associate Deputy Director, NIH
A: Building 1, Room 138
P: (b) (6) | **M:** (b) (6)

Teleconference of the Advisory Committee to the Director

National Institutes of Health

May 26, 2020

1:00 PM-2:00 PM ET

(b) (6) Passcode: (b) (6)

Annotated Agenda

1:00 PM Opening Remarks

Francis S. Collins, MD, PhD, Director, NIH

.....

FC Opening Remarks:

- Thank you all for making time in your schedules to accommodate this meeting request.

Roll Call of Members—Review of Confidentiality & Conflicts of Interest

Lawrence A. Tabak, DDS, PhD, Principal Deputy Director, NIH

Turn to Larry to do roll call and read conflict of interest statement

Thank you, Francis.

[Roll Call and acknowledgement of ACD members]. SIMPLE MAJORITY =9 MEMBERS FOR QUORUM

SHELLEY BERGER

ROBERTA DIAZ BRINTON

WENDY CHAPMAN

ANNE CHURCHLAND

FRANCIS CUSS

REBEKAH DREZEK

MARK DYBUL

DAVID GLAZER

JAMES HILDRETH

KRISTINA JOHNSON

DINA KATABI

JUDITH KIMBLE

BRENDAN LEE

SPERO MANSON

JAY SHENDURE

ROY WILSON

BARBARA WOLD

I have a few key administrative remarks:

- This meeting is open to the public and a notice of the meeting was published in the Federal Register on May 22.
- Council members are required to absent themselves from the teleconference during the review of any application if their presence would constitute or appear to constitute a conflict of interest. During the teleconference today, there may be brief delays to ensure that members are participating when appropriate.
- According to Federal Law, Council members may not engage in any lobbying activities while attending Council meetings or sponsored events.
- Prior to the meeting, you were emailed a conflict of interest form. Immediately following today's meeting, please sign and email it to Gretchen Wood.
- Some of the members of this group may be in conflict with some of the projects. To avoid concerns with conflict of interest, we will discuss and vote for *en bloc* concurrence. However, if someone wishes to discuss a specific project, we will ask you to indicate that so that we can allow conflicted individuals to be sequestered while we have that discussion.

Larry to acknowledge receipt of letter expressing concern about grant that was terminated

- I have already discussed this with several of you; I can confirm that a grant issued to EcoHealth Alliance was terminated. As you know NIH does not publicly discuss or comment on the specific deliberations or plans regarding individual grants, but the general issue will be discussed with ACD at a later time [TO BE DISCUSSED at EXCOM today}

Turn back to FC for his comments

- NIH is meeting the unprecedented challenge of COVID-19 through several coordinated efforts, which I will take a few moments to briefly describe.
- Asked to join the White House Coronavirus Task Force earlier this month, which Tony has already been diligently serving on.

- In April, announced the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to develop a coordinated research strategy for prioritizing and speeding development of the most promising vaccines and treatments.
    - Coordinated by FNIH, ACTIV brings together agencies in HHS, including BARDA, CDC, FDA; other government agencies DOD, VA, the EM; and representatives from academia, philanthropic organizations, and more than 15 biopharmaceutical companies.
- Recently, NIAID's Vaccine Research Center released encouraging results in their Phase I vaccine trial with Moderna Therapeutics, with a phase III trial expected to start in July. NIAID supported investigators have also seen progress with treatments, as the antiviral remdesivir was shown to speed recovery from advanced COVID-19. The next iteration of the study has begun to test remdesivir plus the anti-inflammatory drug baricitinib.
- NHLBI is redirecting the entire efforts of its PETAL network to COVID-19, including studying hydroxychloroquine and launching both retrospective and prospective observational studies on hospitalized patients with COVID-19.
- NCATS is supporting the National COVID Cohort Collaborative (N3C). The N3C is a new effort that aims to build a centralized national data resource that the research community can use to study COVID-19 and identify potential treatments as the pandemic continues to evolve.
- The NIEHS Worker Training Program (WTP) has been tracking information about COVID-19 as it pertains to protecting workers involved in emergency response and cleanup activities performed in the United States.
- NCI is spearheading an effort to develop, improve and implement serology testing to address the need for reliable, widely available COVID-19 serological testing.
    - Includes a collaboration with FDA and development of a national network for development and deployment of serological assays.
- Another effort central to NIH's role in the federal response to the COVID-19 pandemic is the Rapid Acceleration of Diagnostics (RADx) initiative, which we will hear about in more detail shortly. This effort will be coordinated through the Office of the Director and NIBIB, leveraging the expertise of our institutes and centers.
- This initiative is aimed at speeding innovation, development and commercialization, and implementation of COVID-19 testing.
- One component of this is the RADx-Tech program, which is being run through NIBIB and is not being presented here today, also falls under this umbrella and is focused on rapid production of innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities.
    - RADx-Tech has been established as a fast-track innovation funnel that will leverage the structure and resources of the National Institutes of Health (NIH) Point-of-Care Technology Research Network (POCTRN).

    - RADx Tech will support the development of new tests with improved technical performance and convenience, such as tests that can be used at home and at the point-of-care, as well as innovations that make current lab tests faster, more efficient, and more widely accessible.
- This initiative will also have several other components:
    - **RADx-UP (Underserved Populations)** to enhance testing in underserved populations
    - **RADx-RAD (Non-traditional Approaches)** to accelerate testing through non-traditional approaches
    - **RADx-ATP (Accelerating Technology Platforms)** to rapidly scale-up testing
- Additionally, as we recognize the incredible importance of standardizing and sharing data, we are also developing a data management plan to build an infrastructure for COVID-19 data. {Larry will discuss this further?}
- We will hear a bit more about these programs today, and we welcome your wisdom as we move forward both as rapidly and thoughtfully as we can.

LAT Opening Remarks:

- Thank you, Francis, for summarizing some of the many efforts the IC and OD have been devoting tremendous effort to developing to address the COVID-19 pandemic.
- The Rapid Acceleration of Diagnostics (RADx) initiatives represent a major effort by the NIH to help improve the testing capacity of the nation.
- Dr. Tara Schwetz, the NIH Associate Deputy Director, and an executive committee of NIH IC directors, including Rick Woychik, Eliseo Perez-Stable, and Richard Hodes, among others, have taken the lead to develop the RADx concepts that will be presented today.

1:10 PM	Presentation
	Rapid Acceleration of Diagnostics (RADx) OD Projects
	Tara A. Schwetz, PhD, Associate Deputy Director, NIH
1:30 PM	En Bloc Review of Projects and Vote
	Lawrence A. Tabak, DDS, PhD, Principal Deputy Director, NIH
1:55 PM	Closing Remarks
	Francis S. Collins, MD, PhD, Director, NIH
2:00 PM	Adjourn

Name	May 26 1:00 PM-2:00 PM	May 27 3:00 PM-4:00 PM	Quorum=9
Berger, Shelley	1:30 PM	X	
Brinton, Roberta Diaz	X	X	
Chapman, Wendy			
Churchland, Anne			
Cuss, Francis	X	X	
Drezek, Rebekah	X	X	
Dybul, Mark	X	No	
Glazer, David	X	X	
Hildreth, James			
Johnson, Kristina	X	X	
Katabi, Dina	X	X	
Kimble, Judith			
Lee, Brendan, MD, PhD	X	No	
Manson, Spero	X	No	
Shendure, Jay, MD, PhD	X	X	
Wilson, M. Roy, MD, MS	X	X	
Wold, Barbara			

From:	Lauer, Michael (NIH/OD) [E]
To:	Tabak, Lawrence (NIH/OD) [E]
Cc:	Lauer, Michael (NIH/OD) [E]
Subject:	FW: Letter to Francis Collins about EcoHealth Alliance grant
Date:	Thursday, May 21, 2020 2:56:11 PM
Attachments:	nobellettergrant[1].pdf

Hi Larry – I'll put this on the agenda for our 1:1 tomorrow. Maybe also Microstaff?
Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Date: Thursday, May 21, 2020 at 2:19 PM
To: "Myles, Renate (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: "Burklow, John (NIH/OD) [E]" <(b) (6) "Fine, Amanda (NIH/OD) [E]" <(b) (6) "Wojtowicz, Emma (NIH/OD) [E]" <(b) (6)
Subject: Re: Letter to Francis Collins about EcoHealth Alliance grant
This has been sent to Francis, and to me, as well. (b) (5)
We can certainly discuss to inform that effort.
Larry

From: "Myles, Renate (NIH/OD) [E]" <(b) (6)
Date: Thursday, May 21, 2020 at 2:14 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Cc: "Burklow, John (NIH/OD) [E]" <(b) (6) "Fine, Amanda (NIH/OD) [E]" <(b) (6) "Wojtowicz, Emma (NIH/OD) [E]" <(b) (6)
Subject: FW: Letter to Francis Collins about EcoHealth Alliance grant
Hi Larry and Mike:
Perhaps we should discuss best way to handle by phone?
Thanks,
Renate
From: James Gorman <jmg@nytimes.com>
Sent: Thursday, May 21, 2020 2:10 PM
To: Myles, Renate (NIH/OD) [E] <(b) (6)
Subject: Letter to Francis Collins about EcoHealth Alliance grant
Hi Renate,
I hope you are well. A group of Nobel laureates sent a letter to Dr. Collins via Larry Tabak and to Alex Azar asking for an investigation of the cancellation of a grant to EcoHealth Alliance about bat virus research in China.
Would it be possible to get a comment from Dr. Collins? Please let me know, if you can, whether he or anyone at NIH would comment either in email or by phone.
Thanks. The letter is attached.
Jim Gorman
--
James Gorman

jmg@nytimes.com
@jimgorman

77 US Nobel Laureates in Science

May 21, 2020

Secretary Azar and Director Collins:

The 77 signatories of this letter, American Nobel Laureates in Physiology or Medicine, Chemistry, and Physics, are gravely concerned about the recent cancellation of a grant from the National Institutes of Health (NIH) to Dr. Peter Daszak at the EcoHealth Alliance in New York. We believe that this action sets a dangerous precedent by interfering in the conduct of science and jeopardizes public trust in the process of awarding federal funds for research.

For many years, Dr. Daszak and his colleagues have been conducting highly regarded, NIH-supported research on coronaviruses and other infectious agents, focusing on the transmission of these viruses from animal hosts to human beings. Their work depends on productive collaborations with scientists in other countries, including scientists in Wuhan, China, where the current pandemic caused by a novel coronavirus arose. Now is precisely the time when we need to support this kind of research if we aim to control the pandemic and prevent subsequent ones.

As has now been widely reported, the grant to the EcoHealth Alliance was abruptly terminated by NIH on April 24, 2020, just a few days after President Trump responded to a question from a reporter who erroneously claimed that the grant awarded millions of dollars to investigators in Wuhan. Despite the misrepresentation of Dr. Daszak's grant, despite the high relevance of the studies to the current pandemic, and despite the very high priority score that his application for renewal had received during peer review, the NIH informed Dr. Daszak and his colleagues that the grant was being terminated because "NIH does not believe that the current project outcomes align with the program goals and agency priorities." Such explanations are preposterous under the circumstances.

We are scientists who have devoted our careers to research, both in medical and related scientific disciplines that bear on the overall health and well-being of society, as well as fundamental scientific research, much of it supported by NIH and other federal agencies. We take pride in our nation's widely admired system for allocating funds based on expert review and public health needs. The abrupt revoking of the award to Dr. Daszak contravenes these basic tenets 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.

We ask that you act urgently to conduct and release a thorough review of the actions that led to the decision to terminate the grant, and that, following this review, you take appropriate steps to rectify the injustices that may have been committed in revoking it.

Peter Agre	Chemistry	2003	James P. Allison	Medicine	2018
Sidney Altman	Chemistry	1989	Frances H. Arnold	Chemistry	2018
David Baltimore	Medicine	1975	Barry Clark Barish	Physics	2017
Paul Berg	Chemistry	1980	J. Michael Bishop	Medicine	1989
Elizabeth H. Blackburn	Medicine	2009	Michael S. Brown	Medicine	1985
William C. Campbell	Medicine	2015	Mario R. Capecchi	Medicine	2007
Thomas R. Cech	Chemistry	1989	Martin Chalfie	Chemistry	2008
Steven Chu	Physics	1997	Elias James Corey	Chemistry	1990
Robert F. Curl Jr.	Chemistry	1996	Johann Deisenhofer	Chemistry	1988
Andrew Z. Fire	Medicine	2006	Edmond H. Fischer	Medicine	1992
Joachim Frank	Chemistry	2017	Jerome I. Friedman	Physics	1990
Walter Gilbert	Chemistry	1980	Sheldon Glashow	Physics	1979
Joseph L. Goldstein	Medicine	1985	Carol W. Greider	Medicine	2009
David J. Gross	Physics	2004	Roger Guillemin	Medicine	1977
Leland H. Hartwell	Medicine	2001	Dudley R. Herschbach	Chemistry	1986
Roald Hoffmann	Chemistry	1981	H. Robert Horvitz	Medicine	2002
Louis J. Ignarro	Medicine	1998	William G. Kaelin Jr.	Medicine	2019
Eric R. Kandel	Medicine	2000	Wolfgang Ketterle	Physics	2001
Brian K. Kobilka	Chemistry	2012	Roger D. Kornberg	Chemistry	2006
Robert J. Lefkowitz	Chemistry	2012	Anthony J. Leggett	Physics	2003
Michael Levitt	Chemistry	2013	Roderick MacKinnon	Chemistry	2003
John C. Mather	Physics	2006	Craig C. Mello	Medicine	2006
William E. Moerner	Chemistry	2014	Mario J. Molina	Chemistry	1995
Ferid Murad	Medicine	1998	Douglas D. Osheroff	Physics	1996

James Peebles	Physics	2019	Saul Perlmutter	Physics	2011
William D. Phillips	Physics	1997	H. David Politzer	Physics	2004
Sir Richard J. Roberts	Medicine	1993	Michael Rosbash	Medicine	2017
James E. Rothman	Medicine	2013	Randy W. Schekman	Medicine	2013
Richard R. Schrock	Chemistry	2005	Gregg L. Semenza	Medicine	2019
Phillip A. Sharp	Medicine	1993	Hamilton O. Smith	Medicine	1978
George P. Smith	Chemistry	2018	Horst L. Stormer	Physics	1998
Thomas C. Sudhof	Medicine	2013	Jack W. Szostak	Medicine	2009
Joseph H. Taylor Jr.	Physics	1993	Kip Stephen Thorne	Physics	2017
Susumu Tonegawa	Medicine	1987	Daniel C. Tsui	Physics	1998
Harold E. Varmus	Medicine	1989	Steve Weinberg	Physics	1979
Rainer Weiss	Physics	2017	Carl E. Wieman	Physics	2001
Eric F. Wieschaus	Medicine	1995	Torsten N. Wiesel	Medicine	1981
Frank Wilczek	Physics	2004	Robert Woodrow Wilson	Physics	1978
Michael W. Young	Medicine	2017			

From: Tabak, Lawrence (NIH/OD) [E]
To: Wood, Gretchen (NIH/OD) [E]
Subject: Re: Letter to Alex Azar and Francis Collins
Date: Friday, May 22, 2020 8:40:00 AM

(b) (5) I will reach out to him.

From: "Wood, Gretchen (NIH/OD) [E]" <(b) (6)
Date: Friday, May 22, 2020 at 8:37 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Subject: FW: Letter to Alex Azar and Francis Collins

Good morning, Larry,
This is not our usual request to bring something to the attention of the ACD. Sir Rich wants me to send their actual names and email addresses. Please let me know how best to proceed.
Thank you,
Gretchen

From: Rich Roberts <(b) (6)
Date: Thursday, May 21, 2020 at 11:23 PM
To: Gretchen Wood <(b) (6)
Subject: Letter to Alex Azar and Francis Collins

Dear Ms. Wood:
I would very much like to send the attached letter to the members of Francis' Advisory Board, together with a personal letter asking them to help get to the bottom of this matter. Could you send me their names and email addresses for each please?
The letter draws attention to a very serious discontinuation of an NIH grant to Dr. Peter Daszak at the EcoHealth Alliance in New York. This story was well covered by 60 Minutes on May 10th
https://www.cbsnews.com/news/nih-cancelled-coronavirus-research-grant-60-minutes-2020-05-10/
Sincerely

Rich Roberts (b) (6)
Sir Richard J. Roberts Ph.D. F.R.S.
1993 Nobel Laureate in Physiology or Medicine
Chief Scientific Officer
New England Biolabs
240 County Road
Ipswich, MA 01938-2723 USA
Tel: (978) 380-7405
Fax: (978) 412 9910
email: (b) (6)
Executive Assistant: Karen Otto
Tel: (b) (5)
Fax: (978) 412 9910
email: (b) (6)

Congress of the United States
Washington, DC 20515

May 27, 2020

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

Dear Dr. Collins,

While we applaud the tireless work the National Institutes of Health are doing to combat the global COVID-19 pandemic, we are alarmed at action you have taken to halt potentially life-saving research to understand the origin and transmission of coronaviruses.

On April 24, the NIH abruptly cut funding for disease ecology research at EcoHealth Alliance, going so far as to prohibit researchers from accessing the remaining $369,819 granted for Fiscal Year 2020. Disease ecology allows scientists to research coronaviruses and other diseases in wildlife to identify emerging threats to human life. The necessity for this work is clear, now more than ever.

EcoHealth Alliance has been receiving federal funding since 2014 to study the risk of bat coronavirus emergence—the specific global health emergency we now face. That research is closely aligned with the National Institute of Allergy and Infectious Diseases' own stated priorities for improving our understanding of SARS-CoV-2 and COVID-19 by tracking natural history and viral transmission of disease.

With the timeliness of the research into coronavirus emergence and ongoing efforts at NIH to gain greater knowledge in our fight against this pandemic, why did the NIH choose to eliminate this funding without warning?

The explanation from your agency, that "at this time, NIH does not believe that the current project outcomes align with the program goals and agency priorities" is simply not sufficient to explain the unprecedented steps of withdrawing a grant repeatedly approved by both the Obama and Trump Administrations without proper investigation or reasonable explanation.

It seems from news reports and statements made by President Trump that this funding has been eliminated based on misunderstanding at best and conspiracy theory at worst. If that is not the case, we would appreciate a full accounting of how this funding came to be cut, why the NIH

believes this research is not worth funding during COVID-19, and what projects will be funded instead to replace the gaps left by its elimination.

This funding was taken away from American research, paid for by American taxpayers, and aimed at saving American lives.

We applaud the work you have been during on behalf of the American people, but now is not the time to play politics with science. We look forward to your response.

Sincerely,

Joseph D. Morelle
Member of Congress

Seth Moulton
Member of Congress

Sheila Jackson Lee
Member of Congress

Diana DeGette
Member of Congress

Steve Cohen
Member of Congress

Nydia M. Velázquez
Member of Congress

Jan Schakowsky
Member of Congress

Congress of the United States
Washington, DC 20515

May 27, 2020

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

Dear Dr. Collins,

While we applaud the tireless work the National Institutes of Health are doing to combat the global COVID-19 pandemic, we are alarmed at action you have taken to halt potentially life-saving research to understand the origin and transmission of coronaviruses.

On April 24, the NIH abruptly cut funding for disease ecology research at EcoHealth Alliance, going so far as to prohibit researchers from accessing the remaining $369,819 granted for Fiscal Year 2020. Disease ecology allows scientists to research coronaviruses and other diseases in wildlife to identify emerging threats to human life. The necessity for this work is clear, now more than ever.

EcoHealth Alliance has been receiving federal funding since 2014 to study the risk of bat coronavirus emergence—the specific global health emergency we now face. That research is closely aligned with the National Institute of Allergy and Infectious Diseases' own stated priorities for improving our understanding of SARS-CoV-2 and COVID-19 by tracking natural history and viral transmission of disease.

With the timeliness of the research into coronavirus emergence and ongoing efforts at NIH to gain greater knowledge in our fight against this pandemic, why did the NIH choose to eliminate this funding without warning?

The explanation from your agency, that "at this time, NIH does not believe that the current project outcomes align with the program goals and agency priorities" is simply not sufficient to explain the unprecedented steps of withdrawing a grant repeatedly approved by both the Obama and Trump Administrations without proper investigation or reasonable explanation.

It seems from news reports and statements made by President Trump that this funding has been eliminated based on misunderstanding at best and conspiracy theory at worst. If that is not the case, we would appreciate a full accounting of how this funding came to be cut, why the NIH

believes this research is not worth funding during COVID-19, and what projects will be funded instead to replace the gaps left by its elimination.

This funding was taken away from American research, paid for by American taxpayers, and aimed at saving American lives.

We applaud the work you have been during on behalf of the American people, but now is not the time to play politics with science. We look forward to your response.

Sincerely,

Joseph D. Morelle
Member of Congress

Seth Moulton
Member of Congress

Sheila Jackson Lee
Member of Congress

Diana DeGette
Member of Congress

Steve Cohen
Member of Congress

Nydia M. Velázquez
Member of Congress

Jan Schakowsky
Member of Congress

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

(b) (5)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

July XX, 2020

The Honorable Joseph D. Morelle
U.S. House of Representatives
Washington, DC 20515

Dear Representative Morelle:

(b) (5)

U.S. Department of Health and Human Services
National Institutes of Health
Advisory Committee to the Director

120th Meeting of the Advisory Committee to the Director
June 11–12, 2020

Table of Contents

Participants

Advisory Committee to the Director (ACD)

Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health (NIH); Chair, ACD
Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; Executive Director, ACD
Shelley Berger, Ph.D., Director, Epigenetics Institute, University of Pennsylvania, Philadelphia
Roberta Diaz Brinton, Ph.D., Director, Center for Innovation in Brain Science, University of Arizona, Tucson
Wendy Chapman, Ph.D., Associate Dean, Digital Health & Informatics Director, Centre for Digital Transformation of Health, University of Melbourne, Australia
Anne Churchland, Ph.D., Associate Professor of Neuroscience, University of California, San Francisco
Francis Cuss, M.B. B.Chir., Retired Executive Vice President, Chief Scientific Officer, Head of Research and Development, Bristol-Myers Squibb, Princeton, NJ
Rebekah Drezek, Ph.D., Associate Chair of Bioengineering, Rice University, Houston, TX
Mark Dybul, M.D., Professor of Medicine, Co-Faculty Director, Center for Global Health Practice and Impact, Georgetown University, Washington, DC
David Glazer, Engineering Director, Verily Life Sciences, San Francisco, CA
Kristina Johnson, Ph.D., Chancellor, State University of New York, Albany (Day 2 only)
Dina Katabi, Ph.D., Director, Center for Wireless Networks and Mobile Computing, Massachusetts Institute of Technology, Cambridge
Judith Kimble, Ph.D., Professor of Biochemistry, University of Wisconsin–Madison
Brendan Lee, M.D., Ph.D., Chairman, Molecular and Human Genetics, Baylor College of Medicine, Houston, TX
Spero Manson, Ph.D., Colorado Trust Chair in American Indian Health, University of Colorado, Aurora
Jay Shendure, M.D., Ph.D., Professor of Genome Sciences, University of Washington School of Medicine, Seattle
M. Roy Wilson, M.D., M.S., President, Wayne State University, Detroit, MI
Barbara Wold, Ph.D., Professor of Molecular Biology, California Institute of Technology, Pasadena

NIH

Michael M. Gottesman, M.D., Deputy Director for Intramural Research
Michael S. Lauer, M.D., Deputy Director for Extramural Research and Director, Office of Extramural Research
Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy and Acting Chief of Staff

Executive Summary

The 120th meeting of the Advisory Committee to the Director (ACD) of the National Institutes of Health (NIH) took place virtually on June 11–12, 2020, via videoconference. The meeting was open to the public and webcast live. NIH Director Francis S. Collins, M.D., Ph.D., announced new members of the NIH leadership team and described some notable awards and events at NIH over the past 6 months. Associate Budget Director Neil Shapiro, J.D., M.B.A., and Legislative Analyst Adrienne A. Hallett, M.T.A., provided updates.

Anthony Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases, gave an overview of current COVID-19 science and described his Institute's strategic plan for COVID-19 research. NIH leadership outlined plans for the Accelerating COVID-19 Therapeutic Interventions and Vaccines program, a public–private partnership to standardize and share research methods. Key personnel guiding the Rapid Acceleration of Diagnostics (RADx) program summarized its four arms: RADx Tech (supporting early innovation), RADx Advanced Technology Program (advancing existing efforts), RADx Radical (promoting long-term, nontraditional approaches), and RADx for Underserved Populations.

Diana Bianchi, M.D., Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, described rapid efforts to initiate research on multisystem inflammatory syndrome in children at risk for or exposed to COVID-19. She also summarized investigations of drugs to treat children with COVID-19 and a large retrospective analysis of pregnant women to assess COVID-19's impact on pregnancy. Other NIH leaders presented NIH's activities to address COVID-19 on its campuses and through intramural research and the lasting impact of the pandemic shutdown on extramural research.

The ACD approved the list of external awards to NIH employees that had been vetted by Lawrence A. Tabak, D.D.S., Ph.D., NIH's Principal Deputy Director, and selected ACD members. Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy at NIH and Cochair of the HeLa Genome Data Access Working Group (WG), presented a new request for access to HeLa genome sequencing data, for which the ACD unanimously recommended approval.

Barbara Wold, Ph.D., Cochair of the ACD WG on Enhancing Rigor, Transparency, and Translatability in Animal Research, related the highlights of the WG's discussions and the key themes it plans to put forth in a report and recommendations by December. Dr. Wolinetz described initial implementation of the ACD's 2019 recommendations to end sexual harassment, bullying, and retaliation in the scientific research environment. Michael Lauer, M.D., Deputy Director for Extramural Research at NIH, updated the ACD on NIH's work to root out foreign threats to research, in response to recommendations made by the ACD WG on Foreign Influences on Research Integrity in 2018.

M. Roy Wilson, M.D., M.S., Cochair of the ACD WG on Diversity, expressed the importance of continuing to address inequities and work toward diversity in the scientific workplace despite the pandemic. WG Cochair Hannah Valantine, M.D., laid out the plans of the WG and described progress on programs implemented by the Office of Scientific Workforce Diversity.

Meeting Summary
Thursday, June 11, 2020

Open Session: Welcome and National Institutes of Health (NIH) Director's Report

Francis S. Collins, M.D., Ph.D., Director, NIH

The 120th meeting of the NIH Advisory Committee to the Director (ACD) took place virtually on June 11 and 12, 2020, via videoconference. Dr. Collins called the meeting to order at 1:00 p.m. The meeting was open to the public and webcast live. Dr. Collins thanked his staff for figuring out how to bring the ACD together virtually and for juggling NIH's many important priorities despite the challenges posed by the COVID-19 pandemic.

Dr. Collins announced that Rick Woychik, Ph.D., was named Director of the National Institute of Environmental Health Sciences. Joshua Denny, M.D., M.S., began his tenure as Chief Executive Officer (CEO) for the *All of Us* Research Program. John Ngai, Ph.D., was named Director of the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative.

In December, NIH held its annual meeting with the Bill & Melinda Gates Foundation to discuss next steps for their partnership. In the past 6 years, the partnership has created working groups (WGs) on 10 topics to advance biomedical research. High-profile visitors to the NIH campus included First Lady Melania Trump and Maryland First Lady Yumi Hogan, who visited the Children's Inn on separate occasions in February.

COVID-19 has been a full-time concern of NIH since being recognized as a pandemic in early March. Some intramural laboratories have retooled to address the virus, and others have been working on the front lines to develop vaccines and therapeutics. Anthony Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases (NIAID), has served on the White House Task Force on COVID-19 since its inception, and Dr. Collins joined the Task Force recently. President Trump visited the NIH campus in early March and heard from scientists leading the Dale and Betty Bumpers Vaccine Research Center's efforts. Also in early March, Dr. Collins testified at a congressional budget hearing. He pointed out that NIH continues to have strong bipartisan support from Congress, reflected in budget increases in each of the past 5 years.

NIAID supported clinical trials showing that the antiviral drug remdesivir shortens the hospital stay for COVID-19 patients by 31% and may reduce mortality. To develop new approaches to COVID-19 testing, Congress tasked NIH and the Biomedical Advanced Research and Development Authority (BARDA) with leading the Rapid Acceleration of Diagnostics (RADx) program. In May, the White House announced Operation Warp Speed, an effort to coordinate work across the U.S. government on COVID-19 vaccines, therapeutics, and diagnostics, with attention to scaling up and manufacturing products quickly. In June, White House Task Force members Deborah Birx, M.D., and Jared Kushner toured NIH and discussed diagnostics further with Dr. Collins and colleagues.

Dr. Collins acknowledged the challenges that NIH staff is facing during the pandemic, with most NIH offices and laboratories closed. He particularly sympathized with trainees who have lost out on opportunities to pursue their work, and he said NIH will do what it can to support them. Much work has continued successfully through virtual mechanisms. The NIH Clinical Center has remained open, with restrictions, to serve patients. NIH testing facilities identified more than 200 people with COVID-19; they were quarantined immediately, and most did not require hospitalization. NIH has a staged plan for returning staff to work that includes closely monitoring for infection and maintaining protective practices.

NIH has already held three virtual town hall meetings, involving as many as 20,000 participants, to field questions about COVID-19 and to come together to grieve the more than 100,000 deaths to date. Dr. Collins praised Dr. Fauci for his excellent and extensive work communicating candidly about the pandemic with the public.

Dr. Collins announced that Diana Bianchi, M.D., Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), was awarded an honorary doctorate from the University of Amsterdam in January and Nora Volkow, M.D., Director of the National Institute on Drug Abuse, received the American Medical Association's Dr. Nathan Davis Award for Outstanding Government Science. A number of awards within the Department of Health and Human Services (HHS) recognized NIH employees. Five NIH representatives were named as finalists for the Samuel J. Heyman Service to America Medals.

Budget Update

Neil Shapiro, J.D., M.B.A., Associate Director for Budget, NIH

Mr. Shapiro explained that NIH received nearly all of its funding at the beginning of fiscal year (FY) 2019, which was unusual. For FY 2020, NIH operated under partial funding through a continuing resolution. NIH's type 1 diabetes research is funded through a separate mechanism, which was partially funded through late May 2020. In March, Congress completed the FY 2020 funding for NIH and finalized a partial funding resolution for type 1 diabetes research for FY 2021 through November.

The total budget for FY 2020 ($41.7 million) represents a 6.4% increase over the budget for FY 2019. With that and the increases provided for the past 4 years, NIH has restored its purchasing power to within 5% of what it was in 2003. The budget includes targeted increases for Alzheimer's disease and dementia research and National Cancer Institute awards. The *All of Us* Research Program and the BRAIN Initiative now have $500 million each in annual funding. The budget includes $100 million for NIH buildings and facilities to address a backlog of maintenance projects. The Investigation of Co-Occurring Conditions Across the Lifespan to Understand Down Syndrome (INCLUDE) Project and research related to the Childhood Cancer Survival, Treatment, Access, and Research Act also received substantial funding.

The President's FY 2020 budget proposal to fold the Agency for Healthcare Quality and Research into NIH was not enacted. Congress directed HHS to spend $225 million of its

nonrecurring expenses fund on NIH building and facilities projects, which will allow the construction of a new surgery, radiology, and laboratory medicine wing for the Clinical Center.

Mr. Shapiro summarized the funding allotted to NIH so far through Congress and HHS emergency funding for COVID-19 research, totaling more than $3.5 billion. The President's proposed budget for FY 2021 originally recommended a cut to NIH, but after the pandemic started, the proposal was revised to recommend the same level of funding for FY 2021 as FY 2020. The FY 2021 proposal again recommends moving the Agency for Healthcare Quality and Research into NIH. The proposed 2021 budget would add another $100 million for buildings and facilities and give NIH authority to move money from the accounts of Institutes and Centers (ICs) to supplement funding for maintenance backlogs or large facilities projects. The proposal targets high-priority areas, including artificial intelligence for addressing chronic disease, neonatal research, and methamphetamine research. Funding levels for research on opioids and pain relief, pediatric cancer, and influenza would be maintained.

Legislative Update

Adrienne A. Hallett, M.T.A., Associate Director for Legislative Policy and Analysis and Director of the Office of Legislative Policy and Analysis, NIH

Ms. Hallett reviewed the timeline of congressional budget activity since February. Both houses of Congress have returned to session, but with different procedures for voting. Congress moved quickly to pass legislation providing money for the COVID-19 response, including $3.6 billion for NIH research. The House passed the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act. The Senate agrees on the need for additional funds but wants to limit the total dollars and suspend negotiations until after the July 4 holiday, Ms. Hallett said.

Appropriations bills must move forward or the government will run out of money, but the processes and timing for marking up the bills and voting are uncertain. Ms. Hallett suspected that both houses would move forward in early July, around the same time as the HEROES Act, likely resulting in some confusion around spending.

Ms. Hallett noted that FY 2021 is the last year that Congress must abide by statutory spending caps for non-defense-related spending. An amendment passed in 2019 provides about $12 billion to address non-defense-related spending in FY 2021. The Department of Veterans Affairs Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act expires in 2020 and requires $11 billion to continue. Ms. Hallett believes the MISSION Act will be exempt from the budget caps. She also noted discussion about the national debt increasing, driven by the pandemic and its effect on the economy.

The impact of the debt and the pandemic on the November 2020 elections is unknown. The pandemic may limit in-person campaigning, and it is not clear whether Congress will stay in session longer if members do not need to return to their districts to campaign in

person. The results of the elections will determine whether Congress tries to complete legislation before the end of the year or leave it for the next Congress.

Statement on Racism and Inclusivity

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins acknowledged the turmoil of recent weeks as protests erupted around the world in response to the killings of George Floyd, Breonna Taylor, Ahmaud Arbery, and others. He recognized the pervasiveness of racism, which many try not to see, that has persisted since slavery was introduced in America. He called for deep introspection about racial injustice across the board, including within the biomedical community. Dr. Collins called on himself and others to create a more inclusive culture, to work harder to nurture the diversity of the workforce, and to redouble efforts to minimize disparities as current events shine a light on what was already known.

As the leading biomedical research organization in the world, NIH must look unflinchingly at its culture, embrace the challenge, and enlist those who can bring their experience to bear, including those who have studied racial disparities and violence and also lived it. Dr. Collins said the biomedical community is capable, resilient, remarkably visionary, and diverse in many ways. Diversity fuels creativity and drives innovation. He urged the community to embrace the moment and not let it pass. The ACD, NIH staff, and others should consider what they can do to end the scourge of racism and related health disparities, a goal that is part of NIH's mission. Dr. Collins said he has felt anger, grief, and distress over the events in the news. He believes that NIH must address racism in new and productive ways with the many tools and resources it has.

Statement from the ACD Members

Brendan Lee, M.D., Ph.D., Chairman, Molecular and Human Genetics, Baylor College of Medicine, Houston, TX; ACD Member

Speaking on behalf of the ACD members, Dr. Lee said that the ACD joins with numerous scientific organizations and leaders in the biomedical community in expressing concern about the motivation for terminating NIH funding to Peter Daszak, who headed EcoHealth Alliance. The move circumvented the normal peer review process and contradicts long-held NIH traditions and policies. The ACD recommends that the termination be reviewed and that, if flaws in the process are revealed, NIH reverse the decision and implement mechanisms to avoid repeating them. Dr. Lee said 15 of the ACD's members endorsed the recommendation, and two abstained.

COVID-19 Science

Anthony S. Fauci, M.D., Director, NIAID, NIH

Dr. Fauci described the emergence of COVID-19, the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), so named because of its similarity to severe acute respiratory syndrome (SARS), identified in 2002. At the time of his talk, about 7 million people around the world ad been diagnosed with COVID-19 and 400,000 had died. In the United States, 2 million people had been diagnosed so far, and 116,000

had died. New York City was particularly hard hit; cases there are decreasing now but are offset by rises in infections in Louisiana, Arizona, North Carolina, and other states. Deaths from COVID-19 are decreasing. As the country moves to reopen, it is not known whether infections and deaths will increase.

Some symptoms of COVID-19 look like typical influenza, while others do not. The disease manifests in many ways, which Dr. Fauci called puzzling. People infected may be asymptomatic or experience anything from a mild influenza-like illness to severe disease to death. Scientists now estimate that about 25% to 45% of people infected are asymptomatic or presymptomatic, a finding that is critical to learning about the spread of infection and the effectiveness of contact tracing. Among the populations at high risk for severe illness are those who are obese or have other chronic diseases, including cardiovascular disease, chronic kidney disease and diabetes.

Clear racial and ethnic disparities in disease have been reported in various cohorts. Dr. Fauci said that African Americans and other racial and ethnic minorities are disproportionately impacted by certain social determinants of health, including employment that places them at greater risk. They also have a higher prevalence than whites of underlying conditions associated with COVID-19 infection.

Dr. Fauci summarized NIAID's strategic plan for COVID-19 research:

- **Improve fundamental knowledge** of the disease by supporting basic research intramurally and extramurally, including studying the virus's molecular structure and mechanism of action; making viral isolates and reagents widely available to the research community; conducting research to identify animal models of disease; and supporting epidemiological research.
- **Develop diagnostics and assays** by validating novel and existing tests and facilitating the RADx initiative.
- **Characterize and test therapeutics**, including remdesivir and other antivirals, convalescent plasma and hyperimmune immunoglobulins, repurposed drugs, host modifiers and immune-based therapies, and monoclonal antibodies (mAbs). Building on early findings that remdesivir has a modest effect, research is assessing the combination of remdesivir with baricitinib. NIAID also has created treatment guidelines for COVID-19 that will be updated as new findings emerge.
- **Develop safe and effective vaccines** by partnering with BARDA to advance promising candidates, including some developed at NIH's Vaccine Research Center (e.g., Moderna's mRNA-based vaccine), and supporting Operation Warp Speed.

NIH's strategic approach to vaccine development was published in *Science* in May. In April, NIH launched Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), a public–private partnership to standardize and share research methods, an effort to maximize clinical trial capacity. As a member of the White House COVID-19 Task Force, Dr. Fauci has presented information and research from NIH's work to the President and Vice President.

ACTIV Partnership

Dr. Collins explained how ACTIV was created through rapid national and international cooperation, and he described its organizational structure. He said the planning stage was a useful framework for working through what needs to be accomplished, such as how to prioritize treatments for clinical trials, map clinical trial capacity across sectors, and coordinate vaccine development efforts, as well as the need for in vitro assays and animal models.

Overview

John R. Mascola, M.D., Director, Dale and Betty Bumpers Vaccine Research Center, NIAID, NIH

Dr. Mascola said ACTIV brings biotech and pharmaceutical companies together with federal research entities in an extraordinary environment to tackle a disease about which little is known. Operation Warp Speed is a subset of ACTIV. Because of the amount of vaccine needed and the number of people who must be vaccinated to stop the spread of COVID-19, there is strong interest in developing multiple vaccines and platforms. ACTIV is supporting research on vaccines involving traditional proteins, nucleic acids (e.g., mRNA, DNA), and live replicating vectors, all of which are in various stages of development.

NIAID is coordinating plans for Phase III clinical studies for some vaccine candidates, with extensive input from industry, regulators, and other government entities. Dr. Mascola expects several Phase III trials to begin in the next few months. NIH will set up a central data safety monitoring board to oversee the trials. All Phase III studies will collect similar data on endpoints to support product comparison across studies. Dr. Mascola projected that results of vaccine efficacy trials could be available by the end of 2020 if assumptions about the incidence of COVID-19 play out and subject enrollment is successful.

Types of Therapeutics in Development

H. Clifford Lane, M.D., Deputy Director for Clinical Research and Special Projects, NIAID, NIH

Dr. Lane described three passive immunotherapy approaches under study that use antibodies against SARS-CoV-2. These include single-donor convalescent plasma, hyperimmune IVIg and monoclonal antibodies.

A number of evaluations of single-donor convalescent plasma are being conducted with approval from the Food and Drug Administration (FDA). The majority of these infusions were initially provided under single-patient emergency investigational new drug approvals. This has recently evolved to an expanded access protocol run out of the Mayo Clinic. Close to 100 additional studies are also underway, among them a limited number of randomized, controlled trials. Of these, 8 trials are comparing high-titer versus low-titer plasma, which Dr. Lane thought was the approach most likely to provide results. A

large program at the Mayo Clinic has already reported data on the first 5,000 patients. From the Mayo Clinic experience of their first 5,000 patients on the expanded access program, 36 experienced a serious adverse event within 4 hours of transfusion, including 15 deaths categorized as possibly or probably related to the plasma treatment.

At this point a variety of mostly small and observational studies have suggested that convalescent plasma has some benefit. Thus far, robust data are lacking. In general, convalescent plasma has not been shown to be very effective for disease when evaluated in randomized, controlle trials. An exception to this is the treatment of Argentine Hemorhagic Fever where treatment within 8 days of symptoms led to a statistically significant decrease in mortality.

Hyperimmune intravenous immunoglobulin derived from genetically engineered cattle or human convalescent plasma is another approach being explored with studies anticipated to be launched in late summer. Hyperimmune Ig from humans has the potential to be a standardized product that could be widely distributed.

At least 21 mAb products are in development, most targeting the coronavirus spike protein. Phase I clinical trials are being planned for later this summer for both treatment and prevention of COVID-19.

Rapidly Advancing Understanding, Prevention, and Treatment of COVID-19–Associated Coagulopathy (CAC)

Gary H. Gibbons, M.D., Director, National Heart, Lung, and Blood Institute (NHLBI), NIH

Dr. Gibbons explained that CAC manifests in many ways and appears to increase the risk of severe disease and death. There is no clear standard of care or evidence-based guidance for treating patients with CAC. Under the ACTIV partnership, NHLBI and NIAID are looking at treatment options across various stages of COVID-19, from asymptomatic to convalescent patients. Dr. Gibbons said the key might lie in identifying what triggers the clotting phenomenon. He hoped findings would guide therapy, which is critically needed in the absence of a vaccine.

The impact of CAC underscores the importance of having a nimble, adaptive clinical trial platform. Investigators are learning about the disease as it unfolds, and ACTIV provides mechanisms for testing new treatments, such as antithrombotics, as they become available. The partnership also takes advantage of existing clinical trial platforms across NIH. Various projects are working together in real time, providing an exciting opportunity for advancement, Dr. Gibbons noted.

A master protocol for the first open-label protocol comparing blood clotting regimens in patients with COVID-19 is in the final stages of approval. The adaptive platform will allow investigators to consider other anticoagulant and antiplatelet agents. Studies should also reveal risk profiles that can help with risk stratification, which will further contribute

to treatment guidelines. Dr. Gibbons said the research is one step under toward short-term treatment options while a vaccine is developed.

Discussion
Dr. Mascola said BARDA is primarily responsible for creating mechanisms to scale up and manufacture a COVID-19 vaccine rapidly. Dr. Collins added that Operation Warp Speed will manufacture promising candidates, even if the findings are not finalized. He added that different vaccines will require different manufacturing capacity, which further complicates the process.

Dr. Collins said ACTIV's Preclinical WG seeks to determine the utility and availability of tools to assist with preclinical research. For example, the National Center for Advancing Translational Sciences is gathering relevant assays, identifying approved drugs that may be useful, and assessing animal models. Dr. Lee noted the need to validate findings to inform future work.

Dr. Gibson observed that data from a New York City hospital found that COVID-19 patients who were on anticoagulants were less likely to be admitted for intensive care and had better survival rates than others, which hints that coagulopathies might increase morbidity and mortality. An RCT is needed to test the hypothesis. Understanding the cell types affected and how they respond over time may inform research on host-directed therapies.

RADx Initiative

Dr. Collins explained that the RADx initiative has four arms addressing different diagnostic needs, plus funding dedicated to data management and support across the program.

RADx Tech

Bruce J. Tromberg, Ph.D., Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB), NIH

The RADx initiative aims to increase testing capacity broadly, for various settings and populations, necessitating multiple strategies. Congress allotted $500 million to RADx Tech to foster innovation in the development of COVID-19 diagnostics and optimization of their use. Dr. Tromberg said the availability of testing and platforms for analysis should not be the limiting factor in broad testing goals. At present, most tests require laboratory analysis; over time, point-of-care testing will become more widely available and easier to use, possibly as soon as early 2021.

NIBIB's Point-of-Care Technologies Research Network is anchored by the Center for Integration of Medicine and Innovative Technology (CIMIT). RADx Tech relies on CIMIT to evaluate applications for likelihood of success (going beyond an assessment of readiness) and then links applicants to a team of experts from various fields for further discussion about whether to proceed. Most proposals have come from small businesses, but other types of applicants are well represented. The sampling approaches proposed and

the types of support requested indicate a robust and varied response to the RADx Tech call for innovation.

RADx Tech is made up of three cores that oversee test validation, clinical trials, and large-scale operations. Notably, the test validation core, which involves FDA and academic partners, will provide independent validation that normally would be done by the test maker. Dr. Tromberg said the RADx Tech approach, facilitated by Operation Warp Speed, is critical to derisking the research and matching the technology to the appropriate user community. He also noted that the various RADx components complement each other to move diagnostics from concept to deployment.

RADx Advanced Technology Platforms (RADx-ATP)

Rick A. Bright, Ph.D., Senior Advisor to the Director, NIH

RADx-ATP seeks to optimize throughput of point-of-care diagnostics by identifying and advancing existing technology or promising products in late stages of development. Candidates could be identified through RADx Tech applications, BARDA-supported projects in progress, or outreach to industry, for example. Dr. Bright hoped to identify three to five candidates suitable for immediate scale-up to expand test availability and testing capacity by the end of fall 2020.

In addition, RADx-ATP will assess whether large, platform-based technologies already in laboratories can be boosted to increase throughput. Some research has already demonstrated such capacity. The effort will also explore the creation of a diagnostic innovation hub to identify developments on the horizon that could benefit from optimization and accelerate research into innovative technologies, such as next-generation sequencing. RADx-ATP received $230 million from Congress and is working closely with the other arms of RADx.

RADx Radical (RADx-rad)

Tara A. Schwetz, Ph.D., Associate Deputy Director, NIH; Acting Director, National Institute of Nursing Research, NIH

RADx-rad allots $200 million to focus on nontraditional approaches to testing. Unlike the other arms of RADx, it provides a longer timeline for development, with emphasis on platforms that could be applicable to detect other viruses, including as-yet-unknown threats. Suggestions were solicited from all NIH ICs, and a subset of IC directors weighed in to identify the best ideas to pursue. Dr. Schwetz said a cohesive research plan is being developed. A portion of funding will be set aside to give NIH flexibility to adapt the program to meet future needs.

RADx-rad will support efforts to apply existing diagnostic technologies in new ways and to develop unconventional technologies, such as biomarkers that can predict severity of disease or mechanisms to reveal the presence of SARS-CoV-2 virus in wastewater samples. Research could yield complex screening panels that identify COVID-19 along with other infectious diseases. RADx-rad will establish a data coordinating center that links to the broader NIH COVID-19 data management and coordination effort. Funding

opportunity announcements (FOAs) will be released this summer, and awards will be made beginning in late 2020.

RADx for Underserved Populations (RADx-UP)

Eliseo J. Pérez-Stable, M.D., Director, National Institute on Minority Health and Health Disparities, NIH

Dr. Pérez-Stable appreciated that NIH is acknowledging the health disparities spotlighted by the pandemic and other current events. In addition to facing longstanding structural disparities, racial and ethnic minorities have higher rates of comorbid conditions that place them at higher risk for COVID-19. Moreover, racial and ethnic minorities tend to work in public-facing jobs that have been considered essential during the pandemic, increasing the likelihood of exposure to the virus. Many underserved persons live in crowded housing and communities. Dr. Pérez-Stable said it is imperative to implement prevention and health care strategies aligned with the needs of racial and ethnic minority communities to address effects of the pandemic and underlying inequities.

Cases of COVID-19 are distributed unequally across the United States, and the distribution changes daily. RADx-UP seeks to better understand the factors contributing to disparities and implement interventions to reduce them. It will expand the capacity to test broadly for viral nucleic acids in the populations most affected, including testing people who are asymptomatic. RADx-UP will put mitigation strategies in place based on isolation and contact tracing to limit community transmission. It will anticipate opportunities to evaluate and distribute vaccines and therapeutics through networks. It also offers an opportunity to deploy validated point-of-care tests, including self-test methods and use of saliva samples for testing. FOAs for RADx-UP will be released shortly, and initial awards will be made by the end of September.

With $500 million from Congress, RADx-UP will begin with a project to leverage existing community partnerships to implement culturally relevant testing strategies in underserved and vulnerable populations. In its first phase, a central data coordination and collection center will be established, followed by a network of research centers with experience in community engagement and a track record of working with vulnerable and minority populations. A second phase of funding will renew and expand awards on the basis of the evolution of the pandemic.

Multisystem Inflammatory Syndrome in Children (MIS-C)

Diana Bianchi, M.D., Director, NICHD, NIH

Dr. Bianchi described emerging awareness of a spike in Kawasaki disease–like symptoms in children who were infected with or exposed to COVID-19. Most children initially had mild illness that progressed to full-blown MIS-C. Federal partners collaborated to establish a research platform to study children who are at risk for or have MIS-C to better understand the disease. The platform will test the leading hypothesis that there is a genetic predisposition to a vigorous immune response, which is thought to be distinct from the initial illness. The platform will also follow a cohort over the long term to assess

ongoing complications, such as the impact of cardiac involvement. The project emphasizes the importance of sharing data, especially given the small number of cases, and includes funding for a data coordination center.

A pediatric trials network will assess the pharmacokinetics and safety of drugs not typically used in children and determine the appropriate dosing for children with COVID-19. Another effort will use existing infrastructures supported by NIH to gather information on up to 10,000 children with COVID-19 to use as a control group for comparison with those who develop MIS-C.

Dr. Bianchi said NICHD is also using its existing networks to study COVID-19 in pregnancy. NICHD will gather information from a racially and ethnically diverse sample of 21,000 pregnant women at 12 study sites to assess the effects of COVID-19 on prenatal care, maternal health complications, cesarean delivery rates, and maternal mortality, comparing 2020 and 2019 data over the same period (March through December). The study will also encompass an evaluation of the natural history of COVID-19 in pregnancy to assess the potential for vertical transmission and fetal complications. Dr. Bianchi noted that NICHD is working to ensure that pregnant women, children, and people with developmental disabilities are included in ACTIV and RADx studies so that they will benefit from the research.

Discussion

Dr. Bianchi said the immediate concerns of the pediatric studies are sharing data and biospecimens to facilitate research that can improve understanding of MIS-C. The studies also incorporate adaptive design so that investigators can compare new approaches to treatment as they emerge.

Francis Cuss, M.B. B.Chir., said the enormous number of COVID-19 studies underway will generate an avalanche of data, which he hoped would be used to drive new guidelines for care. He also hoped NIH would ensure that patients have a voice in the process so that guidelines are clear. Specifically, pregnant women and new mothers should provide feedback on guidelines for treating COVID-19 in pregnancy. Dr. Bianchi responded that NICHD's advisory councils invite input from study participants and others to ensure they get needed insights. She noted that the results from studies conducted by NICHD's Maternal–Fetal Medicine Units Network, which is facilitating the study of COVID-19 in pregnancy, frequently show up in professional guidelines for care, and the Network is in a position to address immediate concerns.

Wendy Chapman, Ph.D., emphasized the need to translate the data into guidance for health care providers and information that consumers can use to make decisions about their behavior. She called for better clinical decision support tools, integrated into electronic health record systems; tools for virtual health tracking; and more communication with health care providers. Lawrence A. Tabak, D.D.S., Ph.D., noted that many ICs have expressed a renewed interest in telehealth, and there is a new urgency around integrating electronic health records.

Dr. Collins agreed that there are lots of efforts around data and technology integration. He also said that NIH is crafting guidelines for health care providers that it anticipates revising frequently; patients' perspectives will inform those guidelines. Dr. Collins said that for most conditions, NIH has input from patient advocacy organizations. He apologized for not pursuing patients' input more aggressively for COVID-19.

Closing Remarks and Adjournment

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins gave an overview of the agenda for the next day. He thanked the speakers and recessed the meeting for the day at 4:26 p.m.

Friday, June 12, 2020

Open Session: Opening Remarks

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins called the meeting to order at 1:00 p.m. and reviewed the agenda for the day.

NIH Administrative Response to COVID-19

Addressing Safety on Campus

Alfred C. Johnson, Ph.D., Deputy Director for Management, NIH

Dr. Johnson described challenges facing NIH, such as bringing staff who were on travel or working overseas back to the United States when the pandemic broke out and shifting most staff to telework. His office also coordinated volunteers to work with other government agencies in response to the pandemic.

To date, more than 2,700 tests for COVID-19 have been conducted on campus, followed by contact tracing as needed. As plans develop for a phased approach for staff to return to work, NIH is addressing safety on campus with additional cleaning and decontamination, as well as more testing at all of its campuses. NIH created a tracker to identify where COVID-19 cases occurred that is used to guide evaluation and cleaning protocols. NIH has added physical barriers where appropriate and bought personal protective equipment in bulk to meet staff needs.

Travel is now limited to mission critical efforts and must be approved by Dr. Johnson. NIH has eliminated paper processing for paying invoices. As of June 12, about 5,000 of the Bethesda campus's 25,000 staff are on site each day, and more will return to their offices in the coming weeks. The phased plan includes criteria that must be met and maintained for a few weeks before proceeding to the next step.

Intramural Research

Michael M. Gottesman, M.D., Deputy Director for Intramural Research, NIH

The Office of Intramural Research responded to the pandemic by quickly establishing a COVID-19 scientific interest group with subject matter experts from various fields to identify scientific activities to address the pandemic. The Office also created a dashboard with links to 357 COVID-19–related intramural projects underway (representing 250 principal investigators [PIs]). Its website directs users to reagents and repositories for research, as well as a weekly clinical series. With NIAID funding, NIH is supporting novel intramural research on approaches to COVID-19. A central review committee evaluates the research proposals to ensure they are highly applicable and conducted safely.

NIH has maintained 60 beds at the Clinical Center to provide continuous care. It is increasing capacity now, aiming for 90 to 100 beds. Clinical Center staff, patients, and visitors are tested frequently for COVID-19. NIH recently bought equipment that will increase throughput, which may allow NIH to test substantially more people. The Clinical

Center is conducting the clinical trial comparing remdesivir with and without baricitinib in infected patients. In addition, NIH is maintaining animal research colonies to ensure the well-being of the animals, support mission critical and COVID-19 research, and ensure colonies are available for research when laboratories are fully reopened.

Extramural Research

Michael Lauer, M.D., Deputy Director for Extramural Research, NIH

The pandemic forced a lot of research to suspend or shut down activities, causing substantial and possibly lasting disruption to the field of biomedical research. NIH estimated that COVID-19 might cost the field $10 billion in lost productivity. Dr. Lauer said NIH has received more applications for funding than last year and will be issuing more awards than last year, so staff have been working remotely to process applications, coordinate virtual peer review, and prepare new FOAs.

In response to the pandemic, NIH has made accommodations to allow for flexibility in the following research areas:

- Application deadlines
- Donation of research supplies
- Salaries and stipends
- Human subjects research and clinical trials
- Animal research and oversight
- Reporting requirements and expenditures
- Loss of time

The Office of Extramural Research's website provides advice for applicants and grant recipients and strongly encourages people to contact staff with questions. Dr. Lauer said the situation has caused unprecedented stress, and concerns persist about the pandemic's long-term impact on the biomedical research workforce, especially for people in the early stages of their careers, underrepresented groups, and women (particularly those affected by the lack of child care options).

Discussion

Dr. Lauer noted that early-stage investigators (ESIs) can apply online for an extension of their status that takes into account time lost during the pandemic shutdown. The committee that reviews the applications has been very flexible in its determinations. Applicants can propose what accommodations they think they need. Roberta Diaz Brinton, Ph.D., stated that the pandemic reveals the challenges of sustaining a system that is structured to support ESIs until they get their own grants. Dr. Lauer said that the topic has been discussed as part of the Next Generation Researchers Initiative and that NIH has committed to funding ESIs. Under current conditions, NIH is doing all it can with the flexibility it has.

Dr. Lee pointed out that the problems caused by the pandemic and the lockdown are likely to continue. He suggested the research community look at the long-term impact, including assessing the opportunity costs for at least the next 2 years.

Dr. Lauer noted that surveys are being considered to shed light on the impact of the pandemic on researchers (especially women) who have young children so that steps can be taken to mitigate the impact on their careers. Hannah Valantine, M.D., said her office anticipates that women and underrepresented groups will be disproportionately affected by the career disruptions, so data on the topic are being collected.

Kristina Johnson, Ph.D., asked for guidance on the use of pool testing of samples in higher education settings. Dr. Gottesman said NIH is considering pooling samples, as analysis indicates that such testing can be sufficiently sensitive. Dr. Tabak and Dr. Johnson agreed to exchange relevant data on pool testing.

Review of Outside Awards for ACD Approval

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH

Dr. Tabak explained that NIH employees may not receive additional, outside payment for their work, so selected ACD members work with the NIH Ethics Program staff to screen all outside awards. Dr. Tabak asked the ACD to consider the list of awards to NIH employees who are deemed eligible by the NIH Ethics Program.

Vote: ACD members approved the awards unanimously.

HeLa Genome Data Access WG

Spero Manson, Ph.D., Colorado Trust Chair in American Indian Health, University of Colorado, Aurora; WG Cochair
Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH; WG Cochair

Dr. Wolinetz explained that the HeLa Genome Data Use Agreement (DUA) is an agreement between the NIH and the family of Henrietta Lacks that provides a way for whole genome sequence data generated from HeLa cells to be used to advance research, while respecting the family's privacy and interests. The HeLa Genome Data Access Working Group (WG) evaluates requests to access HeLa cell genome data for consistency with the terms of the DUA and reports its findings to the ACD. Per the DUA, investigators (requestors) requesting access to HeLa whole genome sequence agree to not make contact with the Lacks family, only use the data for biomedical research, disclose commercial plans, include an acknowledgment in publications and presentations, and deposit future whole genome sequence data into the database of Genotypes and Phenotypes (dbGaP).

Of the 89 requests evaluated and the findings reported to the ACD by the WG, 82 have been approved by the NIH Director to date. At this ACD meeting, the WG presented its findings of one new request; the WG reported that the pending request was consistent with the DUA.

Vote: The ACD voted unanimously in favor, informed by the findings of the WG, of recommending that Dr. Collins approve the pending request.

ACD WG on Enhancing Reproducibility and Rigor in Animal Research (Interim Report)

Barbara Wold, Ph.D., Professor of Molecular Biology, California Institute of Technology; WG Cochair
Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; WG Cochair

To better reflect its charge, the WG was renamed to the ACD WG on Enhancing Rigor, Transparency, and Translatability in Animal Research. Dr. Wold reiterated the extensive charge to the WG and described its membership, major discussion topics, and subgroups.

Animal research is often the foundation for clinical trials. If translation is the goal, closer attention must be paid to the standards for design and analysis of the studies, the utility of preregistration, and the role of studies that reproduce or replicate the findings. The Vocabulary Subgroup pointed out that a binary approach to reproducibility is not helpful, nor is it useful to conclude that findings from one setting are equally applicable in all settings. Scientific rigor and transparency are the building blocks for consistent results across studies. The Vocabulary Subgroup outlined one approach, adapted from Goodman, Steven N., Daniele Fanelli, and John PA Ioannidis. "What does research reproducibility mean?." *Science translational medicine* 8.341 (2016): 341ps12-341ps12, that identifies three categories of reproducibility, all of which are important:

- *Methods reproducibility* requires full transparency about the details of the work so that it can be replicated by others.
- *Results reproducibility* refers to the capacity of other researchers to obtain the same results using procedures as close as possible to the original; expectations should be clear from the outset, and statistical analysis should be well defined up front to avoid data manipulation.
- *Inferential reproducibility* draws similar conclusions from different experiments that center around the same question; it requires complete data availability.

Statistical significance is not enough to demonstrate reproducibility, Dr. Wold emphasized.

The WG heard input from invited experts on selection of models, improving and finding alternatives to animal models, and use of preregistration to improve study design. Selection of an animal model should take into account how well the model addresses the research question. Dr. Wold noted that the WG's recommendations would not list the best animal models for specific human disease research, because the research question matters. Furthermore, if the work is intended to be translational, the data collected must be appropriate to the goal. Improving model selection will require cultural change at all levels so that researchers focus on what works for a given question, rather than selecting models based on tradition or convenience.

NIH can play a role by creating incentives to develop new models as needed. The National Institute of General Medical Sciences (NIGMS) tackled this concept by

focusing on the failure of animal models to advance research on sepsis. It convened a WG that made recommendations to develop better models and support alternative approaches, and those recommendations led to changes in the field.

Nonanimal models, such as organoids and tissue-on-a-chip approaches, merit more attention and funding. These models can catalyze intense interdisciplinary work and incorporate systems design principles.

Preregistration—or publishing the hypothesis, methods, and design of proposed research—can inform the field about work underway. If done well, it forces investigators to design studies better. Preregistration of exploratory research is allowed and encouraged as long as researchers clarify their intentions. Preregistration requires additional administrative work, and there is no consensus on what type of research plans should be published or at what stage in the research process preregistration should occur. Other questions to consider are whether preregistration should be mandatory, what role it plays in peer review, what minimum elements should be required, and how intellectual property can be protected. The WG intends to continue to explore the role of preregistration as it finalizes its recomendations.

The Financial Implications Subgroup, led by Dr. Lauer, is assessing the impact of potential WG recommendations on NIH resources. The Subgroup is focusing mostly on immediate preclinical work and seeks to estimate the costs of increasing sample sizes, training and hiring more specialized statisticians, requiring more replication, encouraging preregistration, and standardizing meta-analyses. Using a random set of approved grant applications, the Subgroup seeks to compare the administrative data, research proposals, and subsequent publications to determine whether the awardees described a rigorous methodological approach and whether published results reflected that methodology. The Subgroup will also gather input from other entities that have analyzed the financial implications of raising the bar for rigor and reproducibility.

NIH will publish a request for information inviting input on enhancing rigor, transparency, and translatability in animal models, specifically requesting comments on optimizing the relevance to human biology and disease and improving the research culture.

The WG plans to refine the following themes in its report:

- Selecting or developing the most appropriate animal or other model for human disease to address the question of interest
- Strengthening experimental design and analysis, with appropriate expectations for reproducibility
- Recognizing the impact of animal care and husbandry on experimental outcomes
- Enhancing transparency, recognizing that digital publishing allows for publication of more detailed background and supplemental materials
- Training and continuing education, including vocabulary, around animal research
- Measuring and evaluating the effects of any interventions
- Tackling the cultural incentives that maintain the status quo

Dr. Wold concluded that the WG will present its final report and recommendations to the ACD at the December 2020 meeting.

Discussion

Dr. Brinton suggested the WG mention in its report that including clinicians on the research team (whether the research is basic, clinical, or translational) is a key element to successful translational research. She added that selecting a contract research organization that engages in the work like a true partner is also important to success. Dr. Brinton noted that the Alzheimer's Drug Discovery Foundation developed a list of recommended contract research organizations on the basis of input from the Alzheimer's research community.

Dr. Brinton observed that, in epigenetics research, clinical trials of pharmaceuticals often do not carry out good research to determine whether the trial compound reaches the target, an issue that speaks to an important aspect of the interface between basic and clinical research. Dr. Wold said the issue reflects the need to ensure that the data collected are appropriate to the research question. It is one of many areas that would be improved by increased transparency, and NIH can incentivize steps in that direction, said Dr. Wold.

Dr. Lee hoped the WG would offer guidelines on selecting models and determining endpoints that answer the research question. Case studies may be helpful in that regard.

Dr. Collins asked whether the WG has considered distinguishing the different types of research (e.g., exploratory and hypothesis-generating experiments) from the perspective of interpreting the results. Dr. Wold said the WG is wrestling with the issue. Ultimately, the research community at all levels—including researchers who review grant applications and submissions for journal publication—must become better educated and more sophisticated in understanding the types of research and outcomes.

Dr. Wold clarified that scientific rigor is as important as translatability. Dr. Brinton pointed out that translatability and validity are part of the long journey from planning to results, and rigor and reproducibility are incorporated and expanded along the way.

ACD WG on Changing the Culture of Science to End Sexual Harassment

Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH; Sexual Harassment WG Cochair

Dr. Wolinetz reiterated the themes and conclusions of the WG's report and recommendations, which were accepted by the ACD in December 2019 and immediately approved by Dr. Collins. Dr. Wolinetz said NIH not only has a moral obligation to end the culture of sexual harassment in biomedical research but also recognizes that safe and harassment-free research environments are essential for conducting high-quality science.

In 2019, NIH evaluated 115 reports of sexual harassment. So far in 2020, it has evaluated 27 cases. Reports have come from 71 institutions, and 14 PIs have been removed as a

result. Many incidents are still being investigated. Dr. Wolinetz summarized some progress toward NIH's goals, emphasizing that much more work lies ahead. Internally, NIH's ICs have tailored plans to address the culture and instated best practices to address sexual harassment, including a consistent approach to disciplinary actions. These efforts were informed by the results of NIH's climate survey.

The 2019 report recommended creating a parallel process that treats professional misconduct (including sexual harassment) as seriously as research misconduct and establishing mechanisms to address it. NIH is publishing guidance for extramural institutions that speaks to these recommendations and seeks to close some loopholes. NIH has updated policies to indicate that researchers who have committed professional misconduct, including sexual harassment, may not participate in NIH peer review or advisory groups. Steps are also being taken to support research on policies that model and promote a positive workplace climate, including a stakeholder workshop, the outcome of which could ultimately be used by funding agencies to support effective approaches.

Toward the goal of restorative justice, NIH has established new incentives and funding opportunities for people whose careers have been affected because they were targeted for harassment or bullying. Several new mechanisms are in development to fund some trainees directly as a way to promote a safe research environment. Release of the Katz Award to enable ESIs to pursue work that differs from their training focus was delayed because of COVID-19 but will take place in the fall. Other NIH entities are evaluating the use of career development (K) and fellowship (F) awards to provide direct funding. NIH has taken a number of steps to clarify that standards of professional conduct for NIH-funded researchers apply to other settings, particularly conferences.

The NIH Center for Scientific Review is finalizing a report on a study to assess gender bias in peer review. NIH is offering administrative supplements to extend projects that promote diversity in research settings.

Dr. Wolinetz said NIH is seeing a worrisome trend: When an incident is reported, investigated, and found to be credible, some extramural institutions acknowledge the findings and remove the individual from training and supervisory responsibilities but request that NIH make no changes to the grant and retain the PI. This approach supports the perception that institutions protect their highly funded researchers even if they compromise the safety of the research environment, and NIH believes it is not in keeping with good stewardship of public funds.

Dr. Wolinetz noted that a lot of work is underway across HHS and in partnership with the National Academies of Science, Engineering, and Medicine. The pandemic has slowed progress. There have been conversations about how the pandemic will affect workforce diversity and the research environment.

Discussion

Dr. Cuss, who cochaired the WG, said he was disappointed but not surprised that extramural institutions are adapting to the new reality. The WG anticipated resistance and believes that the recommendations may need to include stronger consequences. In

addition, said Dr. Cuss, it has become clear that COVID-19 affects women in science differently, as the number of scientific publications by women has already gone down. He hoped NIH would consider the long-term impact on women's careers. Dr. Johnson, also a cochair, said that her institution has responded to the pandemic by extending the clock for tenure and applying that across the board, with an opt-out provision for people who did not wish to extend so that it would not be perceived as a stigma.

Dr. Wolinetz pointed out that once NIH reframed sexual harassment and other misconduct as a threat to workplace safety, it was able to use its existing authority to move forward on many fronts. Some of the recommended actions remain difficult to achieve, but NIH is not giving up on them, she said. Dr. Wolinetz clarified that in all of its efforts, NIH defines professional misconduct as including not just sexual harassment but other forms of bullying and retaliation as well. She hoped to have more details to report on revisions to F and K awards in the future. Dr. Collins concluded that it is not easy to change culture, but NIH is taking the recommendations seriously and believes that diversity correlates with scientific productivity.

Update: ACD WG on Foreign Influences on Research Integrity

Michael Lauer, M.D., Deputy Director for Extramural Research, NIH

Dr. Lauer recapped the concerns that led to formation of the WG and its recommendations, approved by the ACD in December 2018 and implemented by NIH. He highlighted some notable civil, criminal, and compliance cases. For example, six prominent scientists at the Moffitt Cancer Center, including the CEO, who had substantial undisclosed ties to China's Thousand Talents Program were removed for various instances of receiving unreported personal payments, benefits, and research support.

NIH is aware of nearly 400 scientists of concern, identified through tips, self-disclosure, or discrepancies between grant applications and public reporting; most are linked to China. NIH has reached out to 189 institutions. Significant violations were found in more than 80% of cases. Of the 189 institutions involved, 41% have been removed from NIH-funded activities.

Dr. Lauer noted that violations have occurred across the country, in all areas of biomedicine. Most of the work involves animal research. Among institutions that NIH contacted about concerns, about half have instituted new measures to protect research integrity. A recent article on the Thousand Talents Program points out that moving one's research is not in itself illegal but does transfer intellectual property created with U.S. tax dollars to another country. The author recommended more transparency and more dialogue between China and America.

Dr. Lauer concluded that the WG's recommendations were implemented and have yielded results, including a lot of self-disclosure and more cooperation with other agencies and stakeholders. He stressed that NIH believes that foreign researchers contribute to biomedical science and that the climate must not be unwelcoming to them.

Discussion

Dr. Lauer pointed out that the Thousand Talents Program is substantial and has been involved in most of the cases of concern. NIH is looking into threats from Russia and elsewhere, but they occur on a much smaller scale.

Dr. Lauer said the number of scientists of concern has risen since the WG's recommendations were made, in part because institutions are discovering and revealing problems. He said it will take many more months to understand the full extent of the issue. The Thousand Talents Program has gone dark; there is evidence that China has instructed participants not to name the program in email or other communications, and it is not clear whether China is still recruiting scientists for the program.

Update: ACD WG on Diversity

M. Roy Wilson, M.D., M.S., President, Wayne State University; WG Cochair
Hannah Valantine, M.D., Chief Officer for Scientific Workforce Diversity, NIH; WG Cochair

Dr. Wilson said that the lack of diversity in biomedical and scientific research workforce has been recognized for some time, but recent events, specifically the pandemic and the murder of George Floyd, have brought racial injustice into sharp focus and increased the urgency of the WG's work. The WG held two virtual meetings in recent months to discuss how to sustain diversity efforts amid the pandemic rather than back off.

COVID-19 has been devastating to the African American community, Dr. Wilson observed, and so has police brutality, which represents another public health crisis. The root causes of both involve systemic racism, poverty, and unequal education and opportunity—all of which have also stymied diversity in the biomedical workforce. Dr. Wilson said the impact of COVID-19 is high but still represents only half the number of African American men who are likely to die at the hands of police officers. The WG believes it must not shirk its responsibility to address underlying inequities. Speaking for all the WG members, Dr. Wilson said the WG feels a sense of urgency and also cautious optimism. NIH has been a strong leader, and some extraordinary steps have been taken. The WG will continue, Dr. Wilson concluded.

Dr. Valantine said the WG has had meaningful discussions raising various important points. The field of science needs to do some soul searching and correct inequities. One key step is to openly acknowledge the problems faced by Black people in science. (Dr. Valantine recognized that other underrepresented groups also have unique experiences and problems in the field, but now is the moment to act on issues specific to Black people.) Black peer support is vital during this time of turmoil and hopelessness exacerbated by COVID-19. Admission and selection committees must revise their criteria to cast a broader net. As with sexual harassment, acts of racial bias should be reported and perpetrators held accountable. Recognizing implicit bias is important, but explicit racism remains. Allies should be empowered to be actively anti-racist, or they risk falling back into complicity.

The WG identified three priorities for 2020:

1. Develop a plan to communicate NIH's progress on enhancing diversity to the larger community, for ACD's consideration.
2. Help update NIH's 5-year Scientific Workforce Diversity Strategic Plan (2021–2025), encompassing actionable steps for implementing 2019 recommendations, for ACD's consideration.
3. Coordinate a subset of ACD WG members to prepare a white paper on individuals with disabilities in the scientific workforce, in their individual capacities.

For the communication plan, the WG identified target audiences that would benefit from education and more awareness of NIH programs, tools, resources, and activities around diversity, but progress stalled when the pandemic hit. The WG decided to monitor the impact of COVID-19 on diversity and inclusion efforts. The WG is also moving forward with updating the strategic plan and creating a subgroup to address issues faced by people with disabilities.

Among NIH activities to implement ACD recommendations on diversity is the Faculty Institutional Recruitment for Sustainable Transformation program. One intramural pilot program has demonstrated success in changing the demographics of tenure-track investigators. The first FOA for the Faculty Institutional Recruitment for Sustainable Transformation program will go out this summer, with awards announced in summer 2021. Also, an online training module on implicit bias will be available soon through NIH's learning portal.

NIH's COVID-19 Action Plan targets the ways in which the pandemic contributes to a less diverse workplace culture and places added burden on women and African Americans. As a first step, NIH will leverage existing flexibility and accommodations in extramural programs to mitigate these effects. It will collect data about the workforce and seek other trans-NIH approaches. A survey is planned for July, and Dr. Valantine hoped it would provide information that could inform evidence-based interventions by the fall.

Discussion

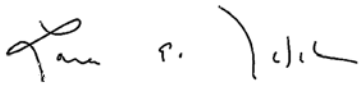
Dr. Valantine clarified that NIH's cohort model for diversity measures productivity and time at the individual level to attain an independent grant or tenure, then compares those findings with a control group. Another key measure is the extent of diversity among the faculty cohort and whether that affects the diversity of the department. Another indicator of success is a shift in institutional culture, which Dr. Valantine hoped to measure with a standardized tool. She stressed the importance of evaluating the models rather than dictating actions to the community. Dr. Wilson added that previous NIH diversity programs may have lacked sufficient rigor in measurement, so there is a strong emphasis now on measurement. Dr. Valantine also pointed out that evaluation will be conducted by the Coordination and Evaluation Center, not the individual institutions involved in the model, and the model was designed to capture comparisons.

Dr. Valantine sits on a federal interagency scientific workforce group that includes representatives from the Department of Education and is seeking to improve diversity and engagement starting in preschool. NIH has a number of programs that target K–12 education, but much more needs to be done. Dr. Collins noted that K–12 education is seen as the job of the National Science Foundation, so NIH's role is limited. Dr. Brinton said her institution takes advantage of the mentoring requirements in training grants to reach out to underserved elementary and high school science students. Dr. Valantine agreed to raise the idea for further consideration. NIGMS recently expanded mentoring requirements to take into account the diversity of mentors and their ability to connect across different cultural backgrounds, and the new approach has been very effective.

Closing Remarks and Adjournment

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins thanked the ACD members for their valuable insight and NIH staff for their hard work in organizing and preparing for this meeting. The next ACD meeting is scheduled for December 10–11, 2020, and will likely take place virtually. Dr. Collins adjourned the meeting at 4:00 p.m.



Lawrence A. Tabak, D.D.S., Ph.D.
Executive Director, Advisory Committee to the Director
Principal Deputy Director, NIH

Francis S. Collins, M.D., Ph.D.
Chair, Advisory Committee to the Director
Director, NIH

Abbreviations and Acronyms

ACD	Advisory Committee to the Director
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
BARDA	Biomedical Advanced Research and Development Authority
BRAIN	Brain Research Through Advancing Innovative Neurotechnologies
CAC	COVID-19-associated coagulopathy
CEO	chief executive officer
DUA	data use agreement
ESI	early-stage investigator
FDA	Food and Drug Administration
FIRST	Faculty Institutional Recruitment for Sustainable Transformation
FOA	funding opportunity announcement
FY	fiscal year
HEROES (Act)	Health and Economic Recovery Omnibus Emergency Solutions
HHS	Department of Health and Human Services
ICs	Institutes and Centers
mAb	monoclonal antibody
MIS-C	multisystem inflammatory syndrome in children
MISSION (Act)	Maintaining Internal Systems and Strengthening Integrated Outside Networks
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
PI	principal investigator
RADx	Rapid Acceleration of Diagnostics
RADx-ATP	Rapid Acceleration of Diagnostics Advanced Technology Program
RADx-rad	Rapid Acceleration of Diagnostics Radical
RADx-UP	Rapid Acceleration of Diagnostics for Underserved Populations
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
WG	working group

From: Myles, Renate (NIH/OD) [E]
To: Wojtowicz, Emma (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]
Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Fine, Amanda (NIH/OD) [E]; NIH NMB (NIH/OD)
Subject: RE: Interview Request for Dr. Collins: NPR All Things Considered/COVID-19
Date: Wednesday, June 3, 2020 3:54:11 PM

Hi Francis:

Also adding what you said during your last interview during this question:

[A] question about one of the most prominent faces of U.S. anti-virus efforts, Dr. Anthony Fauci ... Have you come under any pressure to fire him?

Absolutely not. He is a wonderful public servant, an amazingly smart infectious disease expert. He and I have a nightly phone call every evening to catch up on what's happened with his life down at the White House and mine trying to manage the NIH. He's the best ally I could ever have.

From: Wojtowicz, Emma (NIH/OD) [E] < (b) (6)
Sent: Wednesday, June 3, 2020 3:48 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6)
Cc: Wood, Gretchen (NIH/OD) [E] < (b) (6) McManus, Ayanna (NIH/OD) [E] < (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) Myles, Renate (NIH/OD) [E] < (b) (6) Fine, Amanda (NIH/OD) [E] < (b) (6) NIH NMB (NIH/OD) < (b) (6)
Subject: RE: Interview Request for Dr. Collins: NPR All Things Considered/COVID-19

Hi Dr. Collins-

We checked with HHS to see if we could identify any of the vaccine candidates that are being supported by OWS and they provided the following TP:

HHS announced 14 potential vaccine candidates but has only formally announced that the AstraZeneca AZD1222 vaccine will be part of Operation Warp Speed. Information about selection of final candidates is market sensitive; HHS will announce the final candidates in coordination with the selected organizations at a later date.

For background, (b) (5)

We wanted to flag for your awareness that the NPR producer indicated that they wanted to ask you about the EcoHealth Alliance/Wuhan Institute of Virology grant and related bat research, but then followed up to say they would not have time to ask about it. (b) (5)

Also, you will now be interviewed by host Sarah McCammon and Andrea Hsu will be your technical point of contact. I included her contact information below the information from NIAID. Please let us know if you need additional materials.

Thank you-
Emma

July 2020:

- Moderna mRNA "mRNA-1273"
    - BARDA has noted funding: https://www.hhs.gov/about/news/2020/03/30/hhs-accelerates-clinical-trials-prepares-manufacturing-covid-19-vaccines.html
    - Moderna announced funding: https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-award-us-government-agency-barda-483-million
    - Dr. Fauci has discussed the large-scale testing of this candidate publicly—for an example you can listen to his conversation with JAMA yesterday—he mentions very early in interview. https://www.youtube.com/watch?v=3MH-3ICY-N4
- AstraZeneca ChAdOx1 "AZD1222"
    - BARDA release on the AstraZeneca candidate specifically notes Phase 3 clinical studies will begin this summer with approximately 30,000 volunteers in the United States: https://www.hhs.gov/about/news/2020/05/21/trump-administration-accelerates-astrazeneca-covid-19-vaccine-to-be-available-beginning-in-october.html
    - Dr. Fauci has also discussed the large-scale testing of this candidate publicly—for an example you can listen to his conversation with JAMA yesterday—he mentions very early in interview: https://www.youtube.com/watch?v=3MH-3ICY-N4

September 2020:

- Janssen Ad26 "Ad26 SARS-CoV-2"
    - BARDA noted funding for Phase 1: https://www.hhs.gov/about/news/2020/03/30/hhs-accelerates-clinical-trials-prepares-manufacturing-covid-19-vaccines.html.

December 2020:

- Sanofi baculovirus prefusion protein
    - BARDA noted back in February that they are engaging with Sanofi on this vaccine: https://www.hhs.gov/about/news/2020/02/18/hhs-engages-sanofis-recombinant-technology-for-2019-novel-coronavirus-vaccine.html. Also announced by Sanofi: https://www.sanofi.com/en/media-room/press-releases/2020/2020-02-18-16-00-00
    - Sanofi announced on April 14 their collaboration with GSK and clinical testing plans, all supported by BARDA: https://www.sanofi.com/en/media-room/press-releases/2020/2020-04-14-13-00-00. (GSK will provide the adjuvant)
    - Note that Sanofi is also producing an mRNA candidate with BARDA support, but this is not on the clinical testing timeline yet: https://www.sanofi.com/en/media-room/press-releases/2020/2020-03-27-07-00-00

Technical Point of Contact:

Andrea Hsu
Senior Producer, All Things Considered
ahsu@npr.org
(b) (6)

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Wednesday, June 3, 2020 6:17 AM
To: Wojtowicz, Emma (NIH/OD) [E] <(b) (6)
Cc: Wood, Gretchen (NIH/OD) [E] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6) Burklow, John (NIH/OD) [E] <(b) (6) Myles, Renate (NIH/OD) [E] <(b) (6) Fine, Amanda (NIH/OD) [E] <(b) (6) NIH NMB (NIH/OD) <(b) (6)
Subject: RE: Interview Request for Dr. Collins: NPR All Things Considered/COVID-19

I will need an up-to-date summary on which of the vaccine trials has been publicly discussed.

FC

From: Wojtowicz, Emma (NIH/OD) [E] <(b) (6)
Sent: Tuesday, June 2, 2020 5:11 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Wood, Gretchen (NIH/OD) [E] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6) Burklow, John (NIH/OD) [E] <(b) (6) Myles, Renate (NIH/OD) [E] <(b) (6) Fine, Amanda (NIH/OD) [E] <(b) (6) NIH NMB (NIH/OD) <(b) (6)
Subject: RE: Interview Request for Dr. Collins: NPR All Things Considered/COVID-19

Thanks, Dr. Collins. And to close the loop, this has been cleared by the WH.

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Tuesday, June 2, 2020 3:08 PM
To: Wojtowicz, Emma (NIH/OD) [E] <(b) (6)
Cc: Wood, Gretchen (NIH/OD) [E] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6) Burklow, John (NIH/OD) [E] <(b) (6) Myles, Renate (NIH/OD) [E] <(b) (6) Fine, Amanda (NIH/OD) [E] <(b) (6) NIH NMB (NIH/OD) <(b) (6)
Subject: Re: Interview Request for Dr. Collins: NPR All Things Considered/COVID-19

Back up phone would be Diane's cell (b) (6)

Sent from my iPhone

On Jun 2, 2020, at 10:55 AM, Wojtowicz, Emma (NIH/OD) [E]
<(b) (6) wrote:

Hi Gretchen-

The NPR producer asked if we can shift the time for the interview tomorrow from 4:30pm to 4:15pm. She asked for Dr. Collins to call the studio using the Report-IT app at 4:15pm and then the live interview would start at 4:20pm. Please let us know if this works.

NPR also asked for a back up phone number for FC that is not the phone that he is using for the interview. Please see the instructions for the Report-IT app below; since Dr. Collins already downloaded the app he should start at step 4. The NPR studio contact also is below after the instructions if Dr. Collins has any technical issues.

We are still waiting for this interview to be cleared by the WH and will follow up if we need to reschedule. In the meantime, please let us know if the time change works.

Thank you!
Emma

Report-IT Live Instructions:

1. Download "Report-IT Enterprise" app from the Apple Store.
2. Make sure you are on a strong wifi signal if possible.
3. When you launch the app, allow for it to access your microphone and any other allowances it requires for the interview
4. Log in with these credentials:
   User Name: (b) (6) (all lowercase)
   Password: (b) (6) (all lowercase)
5. Make sure the app is set to "Report Live" at the top of the screen (there's a menu at the top right to switch settings if you don't see "Report Live")
6. Drag the input slider (how loud we'll hear you) down to around 25% and the return slider (how loud you'll hear us) to around 35%
7. A few minutes before the interview, press the green "connect" button
8. Press the lock icon in the lower left corner
9. Hold the phone to your ear for the interview, just like a normal phone call (not out in front of your mouth)

Technical Point of Contact:

Jonaki Mehta
Producer | All Things Considered
(b) (6)
jmehta@npr.org

From: Wood, Gretchen (NIH/OD) [E] <(b) (6)
Sent: Wednesday, May 27, 2020 4:04 PM
To: Wojtowicz, Emma (NIH/OD) [E] <(b) (6) Collins, Francis (NIH/OD) [E] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6)
Cc: Burklow, John (NIH/OD) [E] <(b) (6) Myles, Renate (NIH/OD) [E] <(b) (6) Fine, Amanda (NIH/OD) [E] <(b) (6) NIH NMB (NIH/OD) <(b) (6)
Subject: Re: Interview Request for Dr. Collins: NPR All Things Considered/COVID-19

Hi Emma,

Yes, we are confirmed for 4:30 PM on June 3. Thank you.

Gretchen

From: "Wojtowicz, Emma (NIH/OD) [E]" <(b) (6)
Date: Wednesday, May 27, 2020 at 3:59 PM
To: Francis Collins <(b) (6) Gretchen Wood <(b) (6) "McManus, Ayanna (NIH/OD) [E]" <(b) (6)
Cc: John Burklow <(b) (6) "Myles, Renate (NIH/OD) [E]" <(b) (6) Amanda Fine <(b) (6) "NIH NMB (NIH/OD)" <(b) (6)
Subject: RE: Interview Request for Dr. Collins: NPR All Things Considered/COVID-19

Hi Gretchen-

Does Wednesday, June 3 at 4:30pm work for FC? NPR wants to use the Report-IT app. Also, Ailsa Chang is the available host at that time and will conduct the interview, not Mary Louise Kelly.

Thanks-
Emma

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Friday, May 22, 2020 4:38 PM
To: Wojtowicz, Emma (NIH/OD) [E] <(b) (6) Wood, Gretchen (NIH/OD) [E] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6)
Cc: Burklow, John (NIH/OD) [E] <(b) (6) Myles, Renate (NIH/OD) [E] <(b) (6) Fine, Amanda (NIH/OD) [E] <(b) (6) NIH NMB (NIH/OD) <(b) (6)
Subject: RE: Interview Request for Dr. Collins: NPR All Things Considered/COVID-19

Sure

From: Wojtowicz, Emma (NIH/OD) [E] <(b) (6)
Sent: Friday, May 22, 2020 3:51 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Wood, Gretchen (NIH/OD) [E] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6)
Cc: Burklow, John (NIH/OD) [E] <(b) (6) Myles, Renate (NIH/OD) [E] <(b) (6) Fine, Amanda (NIH/OD) [E] <(b) (6) NIH NMB (NIH/OD) <(b) (6)
Subject: Interview Request for Dr. Collins: NPR All Things Considered/COVID-19

Interview Request for Dr. Collins
May 22, 2020

Request: Topic – COVID-19

Deadline: Friday, May 29; 15-minute interview either pre-recorded between 12:00-3:00 p.m. ET or live between 4:00-6:00 p.m. ET

Additional information:
NPR Producer Carol Klinger asked to schedule an interview with Dr. Collins for All Things Considered with Mary Louise Kelly. This would be a catchup interview on COVID-19 research and vaccines since Dr. Collins was a guest on the program on April 17.

Recommendation:
We recommend Dr. Collins accept.

Submitted by:
Emma Wojtowicz, (b) (6)
NIH News Media Branch

Contact information:
Carol Klinger
NPR All Things Considered
caklinger@npr.org
(b) (6)

Other important notes:

Accept: ____
Decline: ____
Need more information: ____

FUNDING

Did the NIH fund or indirectly fund the Wuhan lab and, if so, how much money went to the Wuhan lab and what was the rationale for the program?

EcoHealth Alliance Inc. is the grantee organization, which made sub-awards to Wuhan Institute of Virology (Wuhan), East China Normal University (Shanghai), the Institute of Pathogen Biology (Beijing), and Duke-NUS Medical School (Singapore). The grant funding totaled $3.4 million over 6 years and was distributed across all sites. The grant was terminated on April 24, 2020. Publicly available information about the grant to EcoHealth Alliance Inc. is available on NIH RePORTER at this link. Information about the distribution to sub-awardees is not publicly available. We recommend you contact EcoHealth Alliance Inc. to get this information.

How much money from the $3.7 million awarded to EcoHealth Alliance went to the infectious disease lab in Wuhan?

Publicly available information about the grant to EcoHealth Alliance Inc. is available on NIH RePORTER at this link. Information about the distribution to sub-awardees is not publicly available. We recommend you contact EcoHealth Alliance Inc. to get this information since they made the subawards.

Would it be accurate to say that the initial grant was appropriated under the Obama administration and a renewal application was approved in 2019 by the NIH under the Trump administration?

The grant budget began in 2014 and ended in 2019. More information about the grant can be found on NIH RePORTER link. In the "History" tab, funding for each year of the grant is provided. In the "Details" tab in the "Other Information" section, start dates and end dates for the grant are provided. For your background, generally, grants are made for a period of time, for example 5 years, and funding is allocated every year based on a variety of performance reports the grantee is required to submit to NIH, which are due at specific times during the life cycle of a grant award.

Has NIH been directed to cut all funding to this lab?

NIH can confirm that the grant to EcoHealth Alliance, Inc. has been terminated. NIH does not discuss internal deliberations on grant terminations.

Is the project done, and has any money due to Wuhan been withdrawn/put on hold, etc?

NIH can confirm that the grant to EcoHealth Alliance, Inc. has been terminated. Upon termination the funds were restricted in the HHS Payment Management System, and the funds are no longer available to EcoHealth Alliance. The remaining balance of $369,819.56 will be returned to NIH.

GRANT OVERVIEW

What was the motivation and purpose of the grant?

Most emerging human viruses come from wildlife, and these represent a significant threat to public health and biosecurity in the United States and globally, as demonstrated by the SARS epidemic of 2002-03, and the current COVID-19 pandemic. The grant you are referencing is a multi-site, multi-country project supporting research that aims to understand what factors allow coronaviruses, including close relatives to SARS, to evolve and jump into the human population and cause disease (called a spillover event). Specifically, the project includes studying viral diversity in animal (bats) reservoirs, surveying people that live in high-risk communities for evidence of bat-coronavirus infection, and conducting laboratory experiments to analyze and predict which newly discovered viruses pose the greatest threat to human health.

Details on the grant are available on this NIH RePORTER link.

Was this grant unique? What other countries or labs received funding?

More information about the grant can be found at the NIH RePORTER link. If you select the "Similar Projects" tab, you will see other projects funded by NIH that may be similar.

SUBAWARDS

How do you define a "sub-awardee" and who chooses/approves them?

This NIH webpage has information on subawards: https://www.niaid.nih.gov/grants-contracts/refresher-subawar

What role did the NIH play in deciding how the money is allocated?

This NIH webpage has information on subawards: https://www.niaid.nih.gov/grants-contracts/refresher-subawar

In general, NIH recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities.

Did the WIV subaward have to be cleared by the State Department to be included in the grant to EcoHealth?

NIH policy requires U.S. Department of State (DOS) approval for all grants, cooperative agreements, and contracts that are issued to foreign institutions, subawards, as well as all

foreign components. For this grant, State Department clearance for all sites in China (including WIV) was submitted to and approved by DOS in May 2019.

I also understand that EcoHealth submitted annual reports on the status of their research that were reviewed by a panel of experts. Can NIH share those reports?

NIH requires grantees to submit a variety of reports which are due at specific times during the life cycle of a grant award. All reports must be accurate, complete, and submitted on time. More information about post-award monitoring and reporting is available on this page: https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm Such reports are not publicly available. You would need to submit a FOIA request for the reports.

EcoHealth Alliance said the Wuhan Institute of Virology was included as a collaborator on the grant - and NIH and State Dept have a process to approve such collaborators, so does that mean the NIH signed off?

This NIH webpage has information on subawards: https://www.niaid.nih.gov/grants-contracts/refresher-subawar

In general, NIH recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities.

Do you happen to know whether any of the sites are continuing work on the project despite the termination of the grant?

You would need to ask EcoHealth Alliance directly about their research.

Would there be any way to tell from the NIH RePorter site whether EcoHealth Alliance or any of the sites have requested funding for a new grant related to this project or would that be something I would have to ask them specifically?

Information on grant applications is not publicly available as they contain proprietary information. NIH makes information available on grants it awards on NIH Report and NIH Reporter.

DECISION TO TERMINATE

What was the reason the grant was terminated?

NIH does not discuss internal deliberations on grant terminations.

Was this done at the direction of officials within the White House, or any other branches of the Administration (ie. outside of NIH)? If so, which?

Did the White House communicate with NIH/NIAID about cutting funding? Who made the decision to do so?

Critics list a number of reasons they say the decision was unwarranted -- what is NIH's response to each of these:

- **very little of the grant was being directed to the Wuhan Institute of Virology**
- **many researchers say the preponderance of evidence suggests the Wuhan Institute of Virology was not responsible for unleashing the coronavirus causing the current pandemic accidentally or otherwise.**
- **the research project is fundamental to scientific efforts to address the current pandemic as well to foresee and prepare for future ones -- and EcoHealth was the only U.S. research group working in China. So termination of the project will cause the U.S. to lose crucial access to data and significantly set back research and future preparedness.**

NIH does not discuss internal deliberations on grant terminations.

The Office of the Director of National Intelligence issued a statement on their investigation into the origins of the outbreak. Any questions related to the origins of the outbreak should be directed to ODNI.

Was the NIH decision politically motivated because of allegations that EcoHealth had subcontracted to the Wuhan Institute of Virology?

NIH does not discuss internal deliberations on grant terminations.

The Office of the Director of National Intelligence issued a statement on their investigation into the origins of the outbreak. Any questions related to the origins of the outbreak should be directed to ODNI.

If the concern was that the PI was working with the Wuhan Institute of Virology, and NIH was informed that in fact no 2019 or 2020 grant money had flowed to WIV, nor would it, why did the entire grant need to be cancelled?

NIH does not discuss internal deliberations on grant terminations.

The New York Post has reported that funding was cut because NIH is investigating the Wuhan lab where the pandemic may have begun, and Eco Health Alliance was using taxpayer dollars to support that lab. Is that accurate?

NIH does not discuss internal deliberations on grant terminations.

The Office of the Director of National Intelligence issued a statement on their investigation into the origins of the outbreak. Any questions related to the origins of the outbreak should be directed to ODNI.

EcoHealth Alliance says the experiments under that grant and the previous grant couldn't have violated the NIH moratorium on gain of function studies because NIH approved them. Is that accurate? Did they violate the moratorium?

The study we funded is described in the RePORTER entry shared with you: https://projectreporter.nih.gov/project_info_description.cfm?aid=9819304&icde=49588715&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=. The research supported under grant characterized the function of newly discovered bat spike proteins and naturally occurring pathogens and did not involve the enhancement of the pathogenicity or transmissibility of the viruses studied. Therefore, after review NIAID determined the awards were not subject to either the Gain-of-Function Research Funding Pause or its successor, the DHHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens.

REINSTATEMENT/WHAT COMES NEXT

Are there plans to reinstate the funding in some fashion?

No, the grant was terminated.

Letters to EcoHealth Alliance

Why did Mike Lauer write that the grant was being terminated "for convenience" if in fact it was being terminated "for cause" as you indicate below?

NIH does not discuss internal deliberations on grant terminations. Under no circumstance did Mike Lauer or NIH indicate the grant was being terminated "for convenience".

Could he also state how the grant which last year was deemed of high priority for public health (it scored in the 3rd percentile) had become instead a danger to public health such that its cancellation was necessary "to protect the public health and welfare from the effects of a serious deficiency." ? How exactly was the grant's execution threatening the US public health and welfare?

NIH does not discuss internal deliberations on grant terminations.

Why did you [Mike Lauer] ask for a list of all Chinese participants in the project days before the decision to cut funding?

NIH does not discuss internal deliberations on grant terminations.

I have seen communications suggesting that the decision was rooted in concerns that EcoHealth funding was going to the Wuhan Institute of Virology. Is this true? Also, is it common to revoke funding effective immediately and demand funds be remitted? How often has that happened and what scenarios has it happened in during the past?

NIH does not discuss internal deliberations on grant terminations.

From: Parker, Ashley (NIH/OD) [E]
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Fleurence, Rachael (NIH/OD) [C]
Subject: RE: Materials for Meeting with Secretary Azar June 15
Date: Wednesday, June 10, 2020 10:18:37 PM
Attachments: DRAFT Agenda for Meeting with Secretary Azar June 15 2020.docx

---

Hi Francis and Larry,

The meeting with the Secretary is rescheduled for Monday, June 15th with revised materials due by COB tomorrow. Would you prefer to include additional items, (b) (5)

AGENDA ITEMS:

(b) (5)

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Friday, June 5, 2020 10:59 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: RE: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Yes ok

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Friday, June 5, 2020 7:50 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)

Subject: RE: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Please see updated attachment 1 – OK to send?

Thanks,
Ashley

From: Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Sent: Friday, June 5, 2020 7:12 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: Re: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Good morning,

Attached are:

-final meeting agenda and materials for the June 2nd meeting

-list of participants to which I added the 3 late additions from June 2nd that we requested: Robert Kadlec, Carlo de Notaristefani and
Tammy Beckham. (Please note the 3 tabs to the Excel spreadsheet for industry, NIH/HHS, BMGF staff).

Rachael

Rachael L. Fleurence, PhD
Special Assistant to the NIH Director for COVID-19 Diagnostics

---

From: "Parker, Ashley (NIH/OD) [E]" <(b) (6)
Date: Thursday, June 4, 2020 at 11:43 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6) "Fleurence, Rachael (NIH/OD) [C]" <(b) (6)
Cc: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: Re: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

(b) (5)

Thanks,
Ashley

On Jun 4, 2020, at 10:38 PM, Collins, Francis (NIH/OD) [E] <(b) (6) wrote:

OK, except Attachment 1 doesn't look quite right – (b) (5)

FC

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 4, 2020 9:27 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Subject: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

With thanks to Rachael, + attachments 1 and 2.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, June 4, 2020 5:57 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 9

Hi Francis,

Please see the attached package – I need the first two attachments, please – cc'ing Rachael. (b) (5)

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, June 4, 2020 6:32 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)

Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: Re: Materials for Meeting with Secretary Azar June 9

Got it, thanks!

On Jun 4, 2020, at 6:14 AM, Collins, Francis (NIH/OD) [E] <(b) (6) wrote:

> See suggested changes on the attachment. (b) (5) Another briefing being set up with Ned Sharpless.
>
> FC
>
> ---
>
> **From:** Parker, Ashley (NIH/OD) [E] <(b) (6)
> **Sent:** Wednesday, June 3, 2020 10:13 PM
> **To:** Collins, Francis (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
> **Cc:** Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
> **Subject:** Materials for Meeting with Secretary Azar June 9
>
> Hi Francis and Larry,
>
> Please see attached draft agenda for the meeting with the Secretary scheduled for June 9th. The draft agenda is due tomorrow with final MATs due on Friday – we standby for edits.
>
> **DRAFT AGENDA ITEMS:**
>
> (b) (5)

(b) (5)

Thanks,
Ashley

<Draft Agenda for Meeting with Secretary Azar June 9 2020 fsc.docx>

Dr. Francis Collins, NIH Director
Meeting with HHS Secretary Alex Azar II
Monday, June 15, 2020
1:00 – 1:45 PM

AGENDA ITEMS:

(b) (5)

From: Collins, Francis (NIH/OD) [E]
To: Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Fleurence, Rachael (NIH/OD) [C]
Subject: RE: Materials for Meeting with Secretary Azar June 15
Date: Thursday, June 11, 2020 10:54:00 AM

Looks good to me.
FC

From: Parker, Ashley (NIH/OD) [E] < (b) (6)
Sent: Thursday, June 11, 2020 10:03 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Fleurence, Rachael (NIH/OD) [C] < (b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

Please see attached updated package for the AMA2 meeting 6/15. We will send to IOS once you've had a chance to approve.

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] < (b) (6)
Sent: Thursday, June 11, 2020 5:45 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Fleurence, Rachael (NIH/OD) [C] < (b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

There are two other sensitive items (b) (5), but I don't think we'll put them on the agenda.

Please add another attachment – the agenda for the VRC visit by Kushner and Birx.

FC

From: Parker, Ashley (NIH/OD) [E] < (b) (6)
Sent: Wednesday, June 10, 2020 10:18 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Fleurence, Rachael (NIH/OD) [C] < (b) (6)

Subject: RE: Materials for Meeting with Secretary Azar June 15

Hi Francis and Larry,

The meeting with the Secretary is rescheduled for Monday, June 15th with revised materials due by COB tomorrow. Would you prefer to include additional items, (b) (5)

AGENDA ITEMS:

(b) (5)

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Friday, June 5, 2020 10:59 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: RE: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Yes ok

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Friday, June 5, 2020 7:50 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: RE: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Please see updated attachment 1 – OK to send?

Thanks,
Ashley

From: Fleurence, Rachael (NIH/OD) [C] < (b) (6)
Sent: Friday, June 5, 2020 7:12 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6)
Subject: Re: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Good morning,

Attached are:

-final meeting agenda and materials for the June 2nd meeting

-list of participants to which I added the 3 late additions from June 2nd that we requested: Robert Kadlec, Carlo de Notaristefani and
Tammy Beckham. (Please note the 3 tabs to the Excel spreadsheet for industry, NIH/HHS, BMGF staff).

Rachael

Rachael L. Fleurence, PhD
Special Assistant to the NIH Director for COVID-19 Diagnostics

---

From: "Parker, Ashley (NIH/OD) [E]" < (b) (6)
Date: Thursday, June 4, 2020 at 11:43 PM
To: "Collins, Francis (NIH/OD) [E]" < (b) (6) "Fleurence, Rachael (NIH/OD) [C]" < (b) (6)
Cc: "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Wolinetz, Carrie (NIH/OD) [E]" < (b) (6)
Subject: Re: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

(b) (5)

Thanks,
Ashley

On Jun 4, 2020, at 10:38 PM, Collins, Francis (NIH/OD) [E] < (b) (6) wrote:

> OK, except Attachment 1 doesn't look quite right – (b) (5)

(b) (5)

FC

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 4, 2020 9:27 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Subject: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

With thanks to Rachael, + attachments 1 and 2.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, June 4, 2020 5:57 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 9

Hi Francis,

Please see the attached package – I need the first two attachments, please – cc'ing Rachael. (b) (5)

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, June 4, 2020 6:32 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: Re: Materials for Meeting with Secretary Azar June 9

Got it, thanks!

On Jun 4, 2020, at 6:14 AM, Collins, Francis (NIH/OD) [E] <(b) (6)> wrote:

> See suggested changes on the attachment. (b) (5) Another briefing being set up with Ned Sharpless.
>
> FC
>
> ---
>
> **From:** Parker, Ashley (NIH/OD) [E] <(b) (6)>
> **Sent:** Wednesday, June 3, 2020 10:13 PM
> **To:** Collins, Francis (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>
> **Cc:** Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
> **Subject:** Materials for Meeting with Secretary Azar June 9
>
> Hi Francis and Larry,
>
> Please see attached draft agenda for the meeting with the Secretary scheduled for June 9th. The draft agenda is due tomorrow with final MATs due on Friday – we standby for edits.
>
> **DRAFT AGENDA ITEMS:**
>
> (b) (5)

(b) (5)

Thanks,
Ashley

<Draft Agenda for Meeting with Secretary Azar June 9 2020 fsc.docx>

From: Parker, Ashley (NIH/OD) [E]
To: Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Cc: Wolinetz, Carrie (NIH/OD) [E]; Fleurence, Rachael (NIH/OD) [C]; McManus, Ayanna (NIH/OD) [E]
Subject: RE: Materials for Meeting with Secretary Azar
Date: Thursday, June 18, 2020 8:28:29 AM

Sounds good to me – thanks.

Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 18, 2020 8:25 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar

(b) (5)

FC

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 18, 2020 7:55 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar

Hi Francis and Larry,

The Secretary's meeting with a hold for Friday, 6/19 is pending reschedule for a different day/time – the standing meeting is on the calendar for next Tues. 6/23. We should plan to send final materials by COB tomorrow if the meeting is confirmed for next Tues. – cc'ing Ayanna for updates.

Attached is a revised agenda for consideration with new items in red, please let me know if we should remove any items that may no longer need discussing.

AGENDA ITEMS:

(b) (5)

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 11, 2020 10:54 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

Looks good to me.
FC

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 11, 2020 10:03 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

Please see attached updated package for the AMA2 meeting 6/15. We will send to IOS once you've had a chance to approve.

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] < (b) (6)
Sent: Thursday, June 11, 2020 5:45 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Fleurence, Rachael (NIH/OD) [C] < (b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

There are two other sensitive items (b) (5) but I don't think we'll put them on the agenda.

Please add another attachment – the agenda for the VRC visit by Kushner and Birx.

FC

From: Parker, Ashley (NIH/OD) [E] < (b) (6)
Sent: Wednesday, June 10, 2020 10:18 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Fleurence, Rachael (NIH/OD) [C] < (b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

Hi Francis and Larry,

The meeting with the Secretary is rescheduled for Monday, June 15th with revised materials due by COB tomorrow. Would you prefer to include additional items, i.e. WH visit, other items?

AGENDA ITEMS:

(b) (5)

(b) (5)

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Friday, June 5, 2020 10:59 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: RE: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Yes ok

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Friday, June 5, 2020 7:50 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: RE: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Please see updated attachment 1 – OK to send?

Thanks,
Ashley

From: Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Sent: Friday, June 5, 2020 7:12 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: Re: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Good morning,

Attached are:

-final meeting agenda and materials for the June 2nd meeting

-list of participants to which I added the 3 late additions from June 2nd that we requested: Robert Kadlec, Carlo de Notaristefani and

Tammy Beckham. (Please note the 3 tabs to the Excel spreadsheet for industry, NIH/HHS, BMGF staff).

Rachael

Rachael L. Fleurence, PhD
Special Assistant to the NIH Director for COVID-19 Diagnostics

---

From: "Parker, Ashley (NIH/OD) [E]" <(b) (6)
Date: Thursday, June 4, 2020 at 11:43 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6) "Fleurence, Rachael (NIH/OD) [C]" <(b) (6)
Cc: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: Re: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

(b) (5)

Thanks,
Ashley

On Jun 4, 2020, at 10:38 PM, Collins, Francis (NIH/OD) [E] <(b) (6) wrote:

> OK, except Attachment 1 doesn't look quite right – (b) (5)
>
> FC
>
> ---
>
> **From:** Parker, Ashley (NIH/OD) [E] <(b) (6)
> **Sent:** Thursday, June 4, 2020 9:27 PM
> **To:** Collins, Francis (NIH/OD) [E] <(b) (6)
> **Cc:** Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
> **Subject:** PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9
>
> With thanks to Rachael, + attachments 1 and 2.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, June 4, 2020 5:57 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Fleurence, Rachael (NIH/OD) [C] < (b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 9

Hi Francis,

Please see the attached package – I need the first two attachments, please – cc'ing Rachael. (b) (5)

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, June 4, 2020 6:32 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6)
Subject: Re: Materials for Meeting with Secretary Azar June 9

Got it, thanks!

On Jun 4, 2020, at 6:14 AM, Collins, Francis (NIH/OD) [E] < (b) (6) wrote:

> See suggested changes on the attachment. (b) (5) Another briefing being set up with Ned Sharpless.
>
> FC
>
> ---
>
> **From:** Parker, Ashley (NIH/OD) [E] < (b) (6)
> **Sent:** Wednesday, June 3, 2020 10:13 PM
> **To:** Collins, Francis (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6)
> **Cc:** Wolinetz, Carrie (NIH/OD) [E] < (b) (6)
> **Subject:** Materials for Meeting with Secretary Azar June 9

Hi Francis and Larry,

Please see attached draft agenda for the meeting with the Secretary scheduled for June 9th. The draft agenda is due tomorrow with final MATs due on Friday – we standby for edits.

DRAFT AGENDA ITEMS:

(b) (5)

[redacted]

Thanks,
Ashley

<Draft Agenda for Meeting with Secretary Azar June 9 2020 fsc.docx>

From:	Fleurence, Rachael (NIH/OD) [C]
To:	Collins, Francis (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Cc:	Wolinetz, Carrie (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]
Subject:	Re: Materials for Meeting with Secretary Azar June 25
Date:	Tuesday, June 23, 2020 8:48:04 AM
Attachments:	Attachment 3 – Current RADx-tech dashboard June 23.pptx

I'm hoping this is the one. It has the latest numbers for June 22.
Rachael

Rachael L. Fleurence, PhD
Special Assistant to the NIH Director for COVID-19 Diagnostics

---

From: "Collins, Francis (NIH/OD) [E]" <(b) (6)
Date: Tuesday, June 23, 2020 at 6:39 AM
To: "Fleurence, Rachael (NIH/OD) [C]" <(b) (6) "Parker, Ashley (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Cc: "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6) "McManus, Ayanna (NIH/OD) [E]" <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 25

Nope, (b) (5)

From: Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Sent: Tuesday, June 23, 2020 6:21 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Parker, Ashley (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6)
Subject: Re: Materials for Meeting with Secretary Azar June 25

Francis, I think this is the one you mean, attached.
Rachael

Rachael L. Fleurence, PhD
Special Assistant to the NIH Director for COVID-19 Diagnostics

---

From: "Collins, Francis (NIH/OD) [E]" <(b) (6)
Date: Tuesday, June 23, 2020 at 6:18 AM
To: "Parker, Ashley (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Cc: "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6) "Fleurence, Rachael (NIH/OD)

[C]" < (b) (6) "McManus, Ayanna (NIH/OD) [E]"
< (b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 25

Looks good, (b) (5)
Maybe Rachael can help with that?

FC

From: Parker, Ashley (NIH/OD) [E] < (b) (6)
Sent: Monday, June 22, 2020 9:22 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E]
< (b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Fleurence, Rachael (NIH/OD) [C]
< (b) (6) McManus, Ayanna (NIH/OD) [E] < (b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 25

Hi Francis and Larry,

The meeting with the Secretary is now scheduled for Thursday, June 25th – if this day/time holds materials will be due by COB tomorrow. Please see attached materials for consideration.

AGENDA ITEMS:

(b) (5)

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 18, 2020 8:25 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar

(b) (5)

FC

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 18, 2020 7:55 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6) McManus, Ayanna (NIH/OD) [E] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar

Hi Francis and Larry,

The Secretary's meeting with a hold for Friday, 6/19 is pending reschedule for a different day/time – the standing meeting is on the calendar for next Tues. 6/23. We should plan to send final materials by COB tomorrow if the meeting is confirmed for next Tues. – cc'ing Ayanna for updates.

Attached is a revised agenda for consideration with new items in red, please let me know if we should remove any items that may no longer need discussing.

AGENDA ITEMS:

(b) (5)

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 11, 2020 10:54 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

Looks good to me.
FC

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 11, 2020 10:03 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

Please see attached updated package for the AMA2 meeting 6/15. We will send to IOS once you've had a chance to approve.

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Thursday, June 11, 2020 5:45 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C]

< (b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

There are two other sensitive items (b) (5) but I don't think we'll put them on the agenda.

Please add another attachment – the agenda for the VRC visit by Kushner and Birx.

FC

From: Parker, Ashley (NIH/OD) [E] < (b) (6)
Sent: Wednesday, June 10, 2020 10:18 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E]
< (b) (6)
Cc: Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Fleurence, Rachael (NIH/OD) [C]
< (b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 15

Hi Francis and Larry,

The meeting with the Secretary is rescheduled for Monday, June 15th with revised materials due by COB tomorrow. Would you prefer to include additional items, i.e. WH visit, other items?

AGENDA ITEMS:

(b) (5)

Thank you,

Ashley

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Friday, June 5, 2020 10:59 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: RE: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Yes ok

From: Parker, Ashley (NIH/OD) [E] <(b) (6)
Sent: Friday, June 5, 2020 7:50 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: RE: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Please see updated attachment 1 – OK to send?

Thanks,
Ashley

From: Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Sent: Friday, June 5, 2020 7:12 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6) Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: Re: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

Good morning,

Attached are:

-final meeting agenda and materials for the June 2nd meeting

-list of participants to which I added the 3 late additions from June 2nd that we requested: Robert Kadlec, Carlo de Notaristefani and
Tammy Beckham. (Please note the 3 tabs to the Excel spreadsheet for industry, NIH/HHS, BMGF staff).

Rachael

Rachael L. Fleurence, PhD
Special Assistant to the NIH Director for COVID-19 Diagnostics

---

From: "Parker, Ashley (NIH/OD) [E]" <(b) (6)
Date: Thursday, June 4, 2020 at 11:43 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6) "Fleurence, Rachael (NIH/OD) [C]" <(b) (6)
Cc: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: Re: PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9

(b) (5)

Thanks,
Ashley

On Jun 4, 2020, at 10:38 PM, Collins, Francis (NIH/OD) [E] <(b) (6) wrote:

> OK, except Attachment 1 doesn't look quite right – (b) (5)
>
> FC
>
> ---
>
> **From:** Parker, Ashley (NIH/OD) [E] <(b) (6)
> **Sent:** Thursday, June 4, 2020 9:27 PM
> **To:** Collins, Francis (NIH/OD) [E] <(b) (6)
> **Cc:** Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
> **Subject:** PLEASE READ THIS ONE: Materials for Meeting with Secretary Azar June 9
>
> With thanks to Rachael, + attachments 1 and 2.
>
> Thanks,
> Ashley
>
> ---
>
> **From:** Parker, Ashley (NIH/OD) [E]

Sent: Thursday, June 4, 2020 5:57 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Fleurence, Rachael (NIH/OD) [C] <(b) (6)
Subject: RE: Materials for Meeting with Secretary Azar June 9

Hi Francis,

Please see the attached package – I need the first two attachments, please – cc'ing Rachael. (b) (5)

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, June 4, 2020 6:32 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
Subject: Re: Materials for Meeting with Secretary Azar June 9

Got it, thanks!

On Jun 4, 2020, at 6:14 AM, Collins, Francis (NIH/OD) [E] <(b) (6) wrote:

> See suggested changes on the attachment. (b) (5) Another briefing being set up with Ned Sharpless.
>
> FC
>
> ---
>
> **From:** Parker, Ashley (NIH/OD) [E] <(b) (6)
> **Sent:** Wednesday, June 3, 2020 10:13 PM
> **To:** Collins, Francis (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
> **Cc:** Wolinetz, Carrie (NIH/OD) [E] <(b) (6)
> **Subject:** Materials for Meeting with Secretary Azar June 9
>
> Hi Francis and Larry,
>
> Please see attached draft agenda for the meeting with the Secretary

scheduled for June 9th. The draft agenda is due tomorrow with final MATs due on Friday – we standby for edits.

DRAFT AGENDA ITEMS:

(b) (5)

Thanks,
Ashley

<Draft Agenda for Meeting with Secretary Azar June 9 2020 fsc.docx>

(b) (5)

*As of 8:00 am 6/22/20

From:	Wolinetz, Carrie (NIH/OD) [E]
To:	Tabak, Lawrence (NIH/OD) [E]; Burklow, John (NIH/OD) [E]
Cc:	Collins, Francis (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]
Subject:	Re: draft of ACD story
Date:	Wednesday, June 24, 2020 9:28:41 PM

(b) (5)

From: "Tabak, Lawrence (NIH/OD) [E]"
Date: Wed, Jun 24, 2020, 9:15 PM
To: "Burklow, John (NIH/OD) [E]"
CC: "Collins, Francis (NIH/OD) [E]" , "Wolinetz, Carrie (NIH/OD) [E]" , "Schwetz, Tara (NIH/OD) [E]" , "Wood, Gretchen (NIH/OD) [E]"
Subject: Re: draft of ACD story

(b) (5)

Thanks John,
Larry

From: "Burklow, John (NIH/OD) [E]" <(b) (6)
Date: Wednesday, June 24, 2020 at 9:05 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Cc: Francis Collins <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6) "Schwetz, Tara (NIH/OD) [E]" <(b) (6) "Wood, Gretchen (NIH/OD) [E]" <(b) (6)
Subject: Re: draft of ACD story

Thanks, Larry. I'll make sure the WG report is included. (b) (5) Thanks again.

John

Sent from my iPhone

> On Jun 24, 2020, at 8:57 PM, Tabak, Lawrence (NIH/OD) [E] <(b) (6) wrote:
>
> John,
> The ACD WG report on Enhancing Rigor, Transparency, and Translatability of Animals in Research, masterfully delivered by Barbara Wold was omitted. It should be added please.

[redacted] (b) (5)

Thanks
Larry

From: "Burklow, John (NIH/OD) [E]" <[redacted] (b) (6)
Date: Wednesday, June 24, 2020 at 4:55 PM
To: Francis Collins <[redacted] (b) (6) "Tabak, Lawrence (NIH/OD) [E]" <[redacted] (b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <[redacted] (b) (6) "Schwetz, Tara (NIH/OD) [E]" <[redacted] (b) (6)
Cc: "Wood, Gretchen (NIH/OD) [E]" <[redacted] (b) (6)
Subject: FW: draft of ACD story

Hello, Everyone—

Here is the NIH Record's write-up of the ACD meeting for your review.

Thanks,

John

From: McManus, Rich (NIH/OD) [E] <[redacted] (b) (6)
Sent: Wednesday, June 24, 2020 4:52 PM
To: Burklow, John (NIH/OD) [E] <[redacted] (b) (6)
Subject: draft of ACD story
Importance: High

Hi John,

We would love to have review by Friday, but Tuesday would be the latest. We'd like to run this in our July 10 issue.

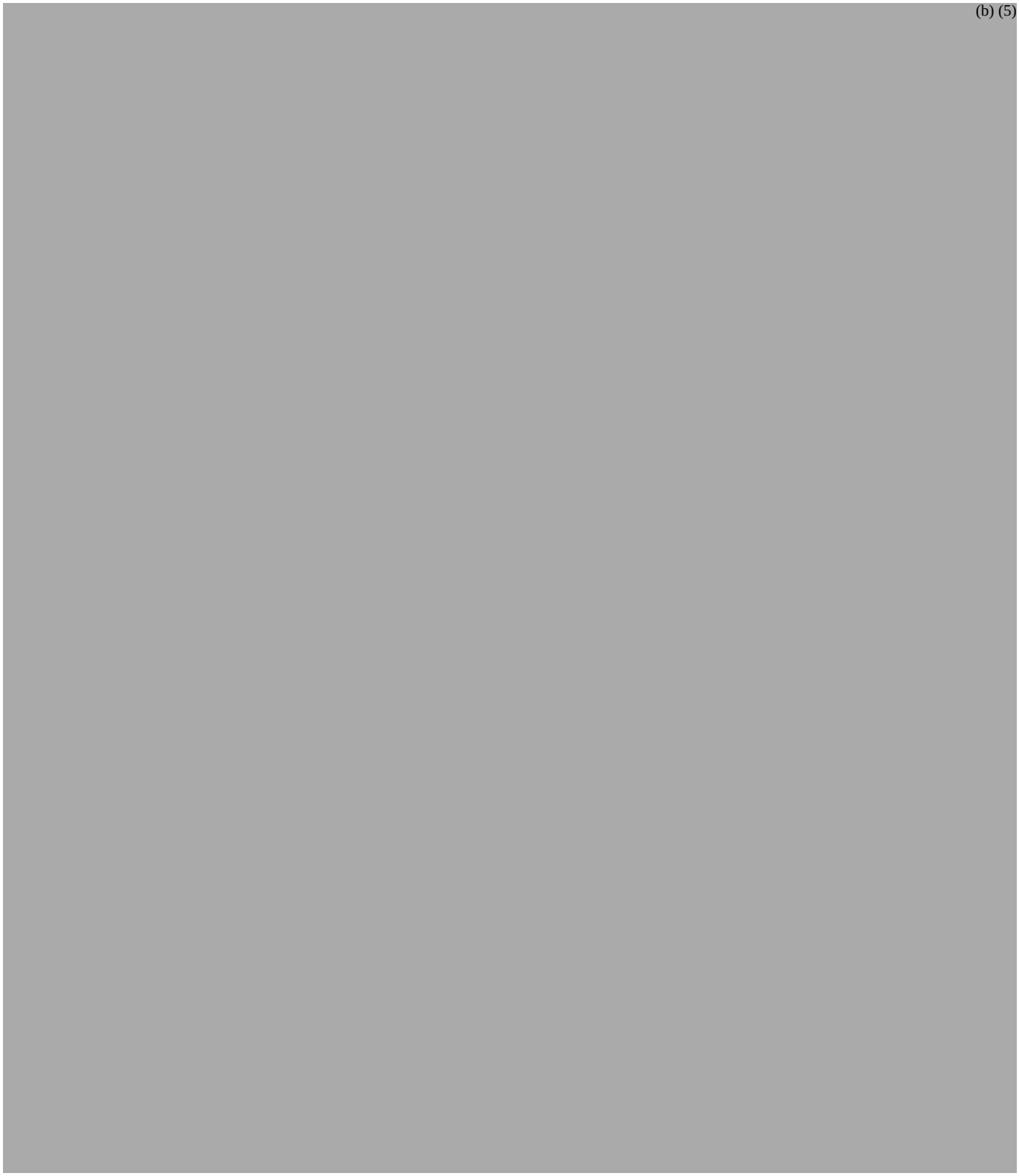
Thanks for your help.

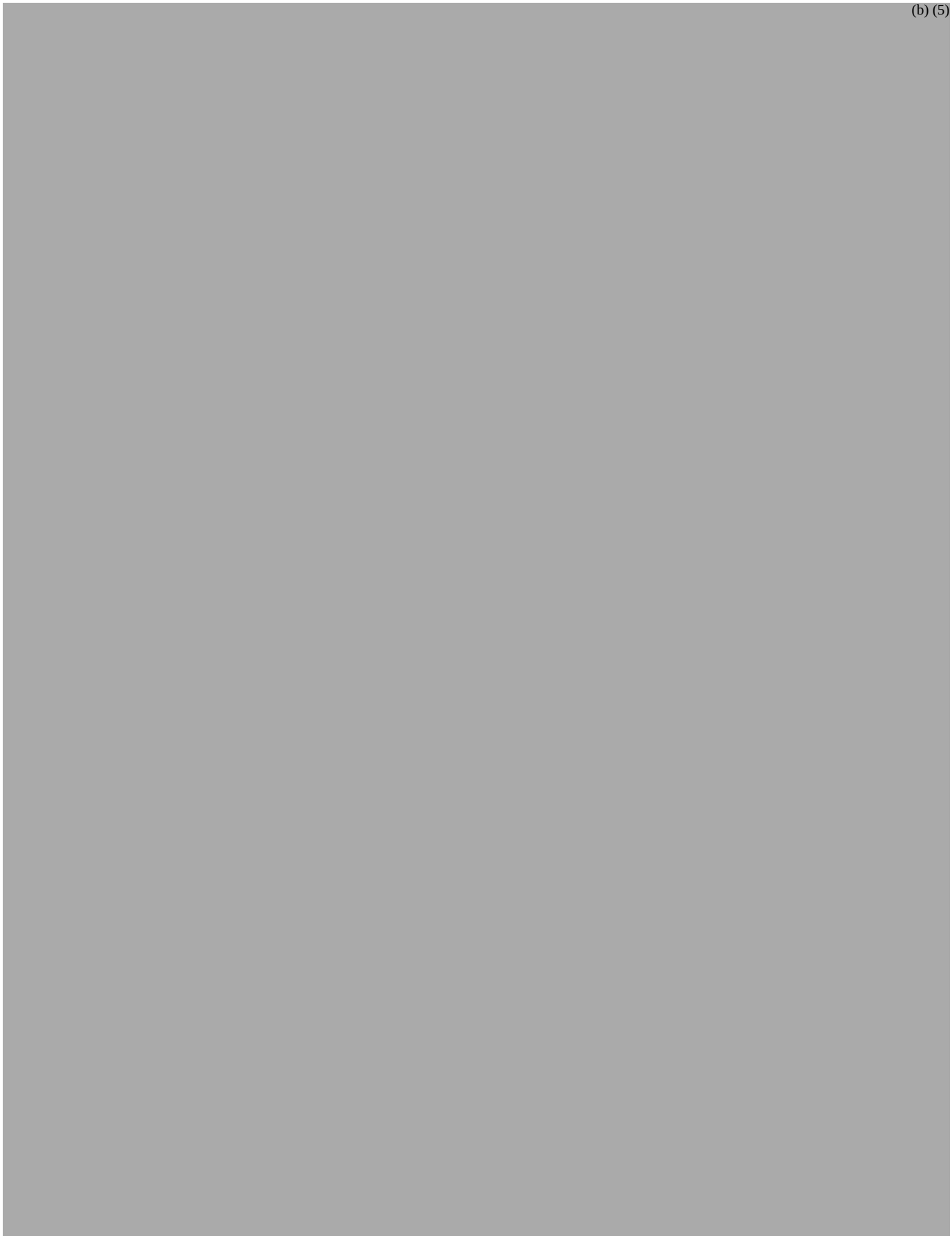
Rich

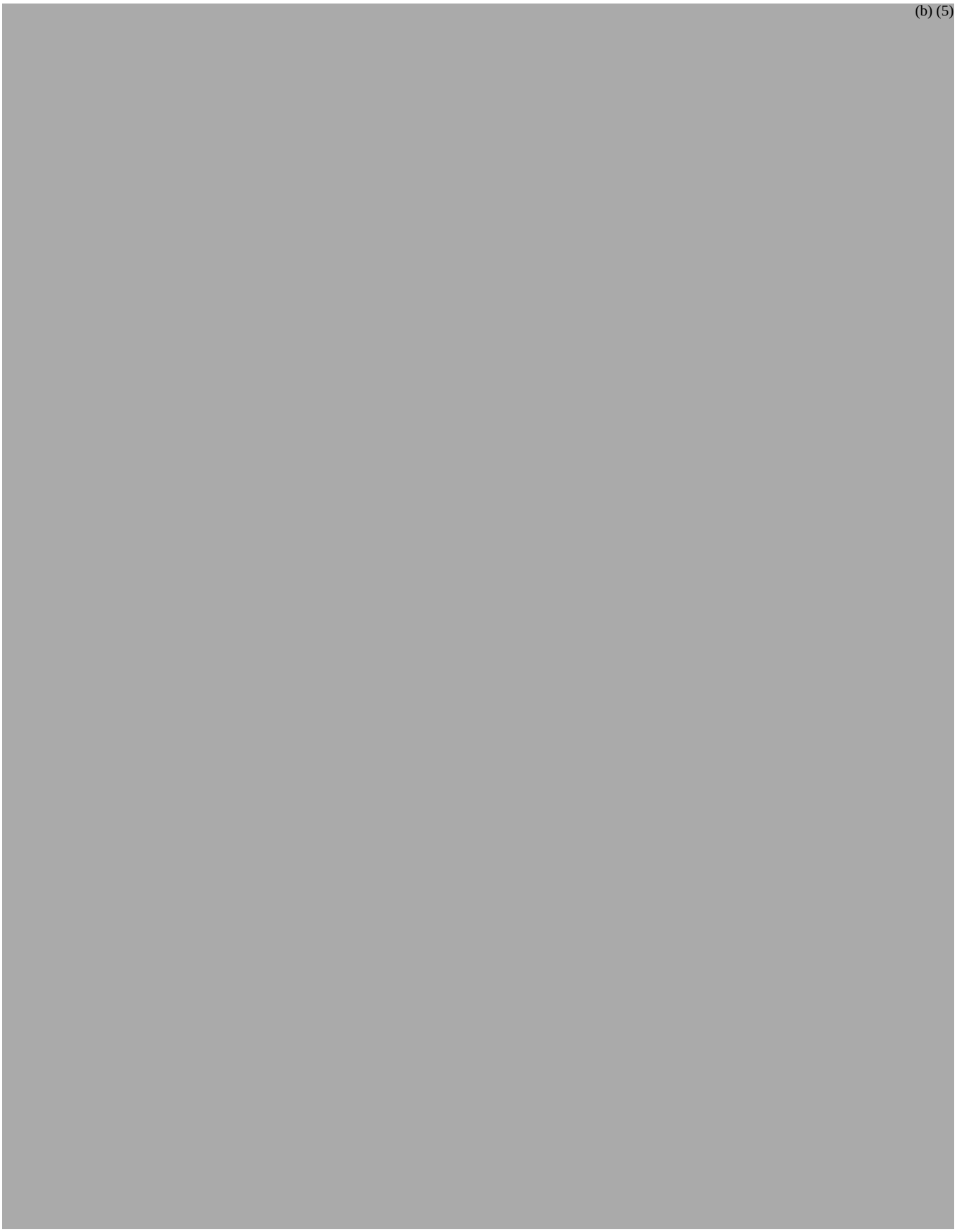
First Virtual Version

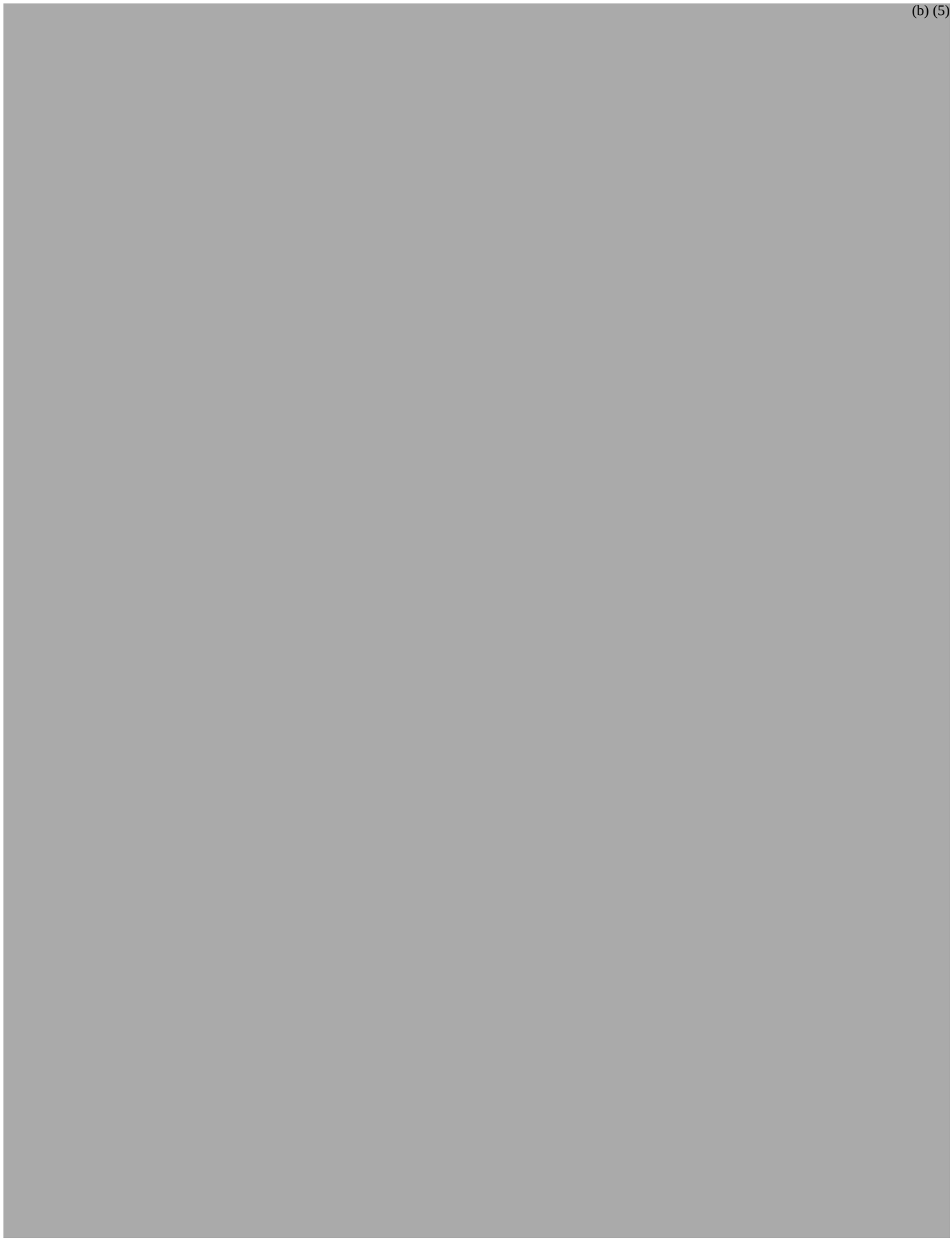
ACD Recounts Progress in Era of Calamity

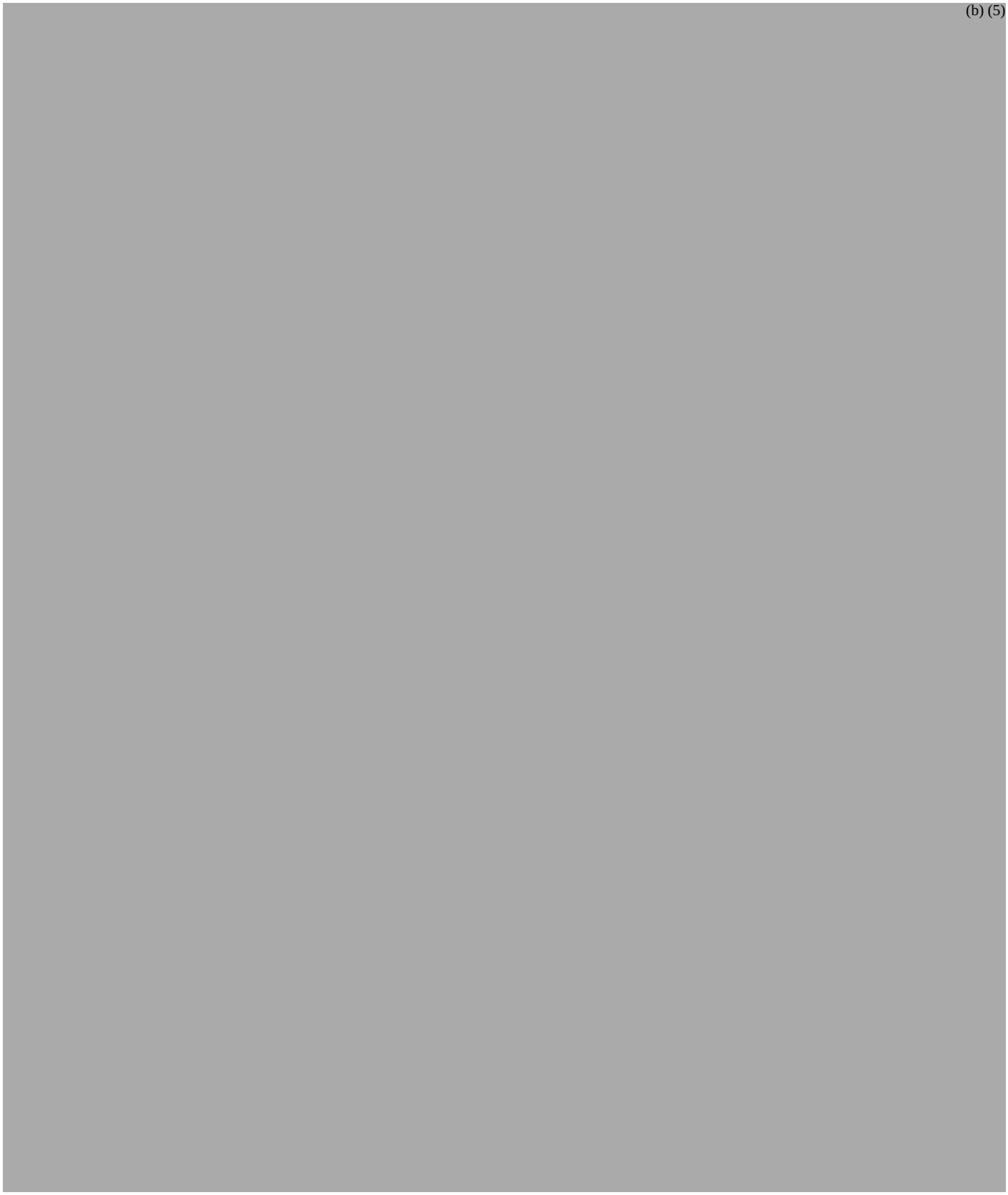
By Rich McManus






(b) (5)


(b) (5)


(b) (5)


(b) (5)

From:	Wojtowicz, Emma (NIH/OD) [E]
To:	Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Shapiro, Neil (NIH/OD) [E]
Cc:	Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Fine, Amanda (NIH/OD) [E]
Subject:	Prep materials for Senate Appropriations Hearing
Date:	Wednesday, July 1, 2020 12:41:27 PM
Attachments:	News Clips_Senate Appropriations Hearing.docx News Releases_Senate Appropriations Hearing.docx Media_QA_EcoHealth_Grant_5.6.2020 Final.docx SARS-CoV-2 Biosafety Fact Sheet for OCPL_06122020.docx Foreign_Influence_Background_6.18.20.docx

---

Hi Dr. Collins-

In preparation for tomorrow's Senate Appropriations hearing, please see attached for the following documents:

- News clips on topics of particular interest. Please see the Bulletin Intelligence daily news clips for the most recent coverage of COVID-19: https://nih.bulletinintelligence.com//
- Recent relevant news releases and media availabilities
- Media QA on EcoHealth Grant cancellation
- Background on OSP on SARS-CoV-2 Biosafety
- Background on Foreign Influence that we provide to reporters who query the topic

Thank you-
Emma

Emma Wojtowicz
Public Affairs Specialist
National Institutes of Health
Tel: (b) (6)
Email: (b) (6)
Web: http://www.nih.gov

NIH . . . Turning Discovery Into Health

News Clips for Senate Appropriations Hearing

Fauci Says U.S. Could Reach 100,000 Virus Cases a Day as Warnings Grow Darker

The government's top infectious disease expert told a Senate panel that bars needed to be closed, and the Fed chairman cautioned that "a full recovery is unlikely" until safety is restored.

New York Times
July 1, 2020
By Sheryl Gay Stolberg and Noah Weiland

WASHINGTON — The government's top infectious disease expert said on Tuesday that the rate of new coronavirus infections could more than double to 100,000 a day if current outbreaks were not contained, warning that the virus's march across the South and the West "puts the entire country at risk."

Dr. Anthony S. Fauci, the director of the National Institute of Allergy and Infectious Diseases, offered the grim prediction while testifying on Capitol Hill, telling senators that no region of the country is safe from the virus's resurgence. The number of new cases in the United States has shot up by 80 percent in the past two weeks, according to a New York Times database, with new hot spots flaring far from the Sun Belt epicenters.

"I can't make an accurate prediction, but it is going to be very disturbing, I will guarantee you that," Dr. Fauci said, "because when you have an outbreak in one part of the country, even though in other parts of the country they are doing well, they are vulnerable."

New flash points have weighed down talk of a resumption of normal life and a quick economic rebound. The chairman of the Federal Reserve, Jerome H. Powell, issued his own gloomy assessment, cautioning lawmakers on Tuesday of an "extraordinarily uncertain" moment facing the American economy.

"A full recovery is unlikely until people are confident that it is safe to re-engage in a broad range of activities," Mr. Powell told a House committee, adding that a second wave "could force people to withdraw" and "undermine public confidence, which is what we need to get back to lots of kinds of economic activity that involve crowds."

The twin hearings on Capitol Hill mirrored concerns roiling states where hospitalizations are rising, intensive care units are filling up and business establishments are again shutting their doors. Dr. Fauci particularly implored states to shut down indoor drinking establishments, declaring, "Congregation at a bar, inside, is bad news."

And Dr. Robert Redfield, the director of the Centers for Disease Control and Prevention, admonished American Airlines for beginning to sell flights to their capacity, which would make onboard social distancing impossible.

"When they announced that the other day, obviously there was substantial disappointment," Dr. Redfield said, adding, "We don't think it's the right message."

Around the nation, and the world, it became painfully clear that, despite President Trump's recent suggestion that the virus would "fade away," the pandemic is getting worse.

More than 48,000 coronavirus cases were announced across the United States on Tuesday, the most of any day of the pandemic. Officials in eight states — Alaska, Arizona, California, Georgia, Idaho, Oklahoma, South Carolina and Texas — also announced single-day highs.

Case counts have climbed sharply in many of the states that were the first to reopen, including Florida and Texas, which recently forced bars to close again. In Texas, the bar closures spurred protests at the State Capitol and the governor's mansion on Tuesday.

In Arizona, officials identified more than 4,600 new coronavirus infections on Tuesday, by far the state's most in a single day. California's case count has soared, surpassing 220,000 known infections.

Vice President Mike Pence, the administration's point person on the virus, insisted that the situation was not dire, telling reporters in suburban Washington, "We're in a much better place than four months ago, even two months ago." Mr. Pence has said the new infections are primarily hitting younger people who get less sick.

The governors of New York, New Jersey and Connecticut — three former hot spots in the Northeast — were less sanguine, telling travelers coming into the region to quarantine for 14 days. New York added eight states — California, Georgia, Idaho, Iowa, Louisiana, Mississippi, Nevada and Tennessee — to a quarantine list that already included Alabama, Arkansas, Arizona, Florida, North Carolina, South Carolina, Texas and Utah. New Jersey and Connecticut are advising travelers from the 16 states to quarantine.

But in Florida, where more than 6,000 new cases were reported on Tuesday, Gov. Ron DeSantis, a Republican, remained defiant. On Friday, the state abruptly banned drinking in bars, though they can still sell food and alcohol for takeout. On Tuesday, Mr. DeSantis said at a news conference in Juno Beach that was enough: "We're not going back, closing things."

With the virus not under control in the United States, the European Union announced on Tuesday that it would open its borders to visitors from 15 countries — but not from America.

Even states that had reported improvements were starting to see the number of new cases rise, causing governors to rethink their plans to get residents back to work.

"We are now having 40-plus-thousand new cases a day. I would not be surprised if we go up to 100,000 a day if this does not turn around," Dr. Fauci testified, adding, "I think it is important to tell you and the American public that I'm very concerned because it could get very bad."

As to bars, he said, in his customary clipped fashion: "Outdoor better than indoor. Bars really not good. Really not good. Congregation in a bar inside is bad news. We've really got to stop that right now when you have areas that are surging like we see right now."

Dr. Fauci and Dr. Redfield were among four top government doctors involved in the coronavirus response to testify on Tuesday; Adm. Brett P. Giroir, the assistant secretary for public health, and Dr. Stephen Hahn, the commissioner of food and drugs, also appeared. All four officials also appeared before House lawmakers last week, when Dr. Redfield warned of a potentially crippling second wave of the virus that would coincide with flu season — a warning he reiterated on Tuesday.

But beyond the spike in cases, they told lawmakers they had another pressing concern: Large swaths of the American population may refuse a coronavirus vaccine once one becomes available, which could seriously hamper efforts to control the pandemic and prevent the nation from turning the corner toward a full reopening.

Dr. Redfield told senators that his agency has spent about three months developing a plan to rebuild "vaccine confidence." Senator Patty Murray of Washington, the top Democrat on the Health Committee, sounded alarmed, telling Dr. Redfield to speed up the work.

"We need to see that plan," she said. "We need to know what it is. The public needs to know what it is."

Dr. Redfield said that the C.D.C.'s plan was being developed with Operation Warp Speed, the Trump administration's crash vaccine program that aims to have 300 million doses of a vaccine by early next year. Officials at the Defense Department and the Department of Health and Human Services involved in that project have spent significant time discussing a public-relations campaign that will in part try to win over Americans suspicious of a coronavirus vaccine, according to a senior administration official.

There are more than 140 vaccines being developed against the coronavirus. Seven in 10 Americans have said they would get vaccinated against the novel coronavirus if immunizations were free and available to everyone, according to recent polling — a number that health officials fear may not be enough to achieve "herd immunity," a term that signifies that a vast majority of a population has protection against infection.

At least 70 percent will need to be immune to the virus to reach that point, according to researchers at Johns Hopkins University.

Officials are particularly concerned that African-Americans and others who have been hit hard by the pandemic may be hesitant about vaccinations because of longstanding suspicions of government programs like the Tuskegee experiment, in which poor Black men suffering from syphilis were left untreated and monitored.

"It is a reality: a lack of trust of authority, a lack of trust in government and a concern about vaccines in general," Dr. Fauci said. He added that there needed to be "boots on the ground," especially near minority communities that "have not always been treated fairly by the government."

The official topic of Tuesday's hearing was how to get children safely back to school, but there seemed to be no agreement on that, and no universal plan to do so. The American Academy of Pediatrics has come out strongly in favor of bringing children back to the classroom in the fall, saying in a statement that "schools are fundamental to child and adolescent development and well-being."

Dr. Fauci agreed, but said each school district must make decisions based on the course of the pandemic in its area.

Masks — and Mr. Trump's refusal to wear one — were a central issue at the hearing. The Republican chairman of the Health Committee, Senator Lamar Alexander of Tennessee, prefaced his opening statement with an appeal to the president to set a better example by occasionally covering his face.

Mr. Alexander lamented that masks had "become part of the political debate," with people's decision about whether to wear one dependent on their views of Mr. Trump.

"The president has plenty of admirers," Mr. Alexander said. "They would follow his lead; it would help end this political debate. The stakes are too high for this political debate about pro-Trump, anti-Trump to continue."

In his testimony before the House Energy and Commerce Committee last week, Dr. Fauci warned that the next two weeks would be critical to controlling the virus's spread, and said it was not yet under control in the United States. On Tuesday he sounded even more downbeat, provoking a backlash from one Republican, Senator Rand Paul of Kentucky, who delivered a five-minute sermon denouncing "central planners" and health experts who opine on matters like sports.

"Dr. Fauci, every day, virtually every day, we seem to hear from you things we can't do," Mr. Paul, an ophthalmologist, said, adding: "All I hear is, we can't do this. We can't do that. We can't play baseball."

Dr. Fauci agreed that he was "completely unqualified to tell you whether you can play a sport or not," but added that he was only trying, "to the best of my ability," to disseminate facts and evidence about the outbreak.

The senator sounded exasperated. "We just need more optimism," he said.

But Dr. Fauci stood firm. "We cannot forget," he told senators at the end of the session, "that what was thought to be unimaginable turned out to be the reality that we're facing right now."

Fauci worries U.S. covid-19 cases could climb to 100,000 daily

Washington Post
June 30, 2020
By Amy Goldstein

Anthony S. Fauci, the government's top infectious-disease specialist, warned Tuesday that the United States could soon have 100,000 new coronavirus cases a day "if this does not turn around" — a surge that would be more than twice as many as the record so far and three times as many as the original peak this spring.

Fauci said that recent images of Americans gathering in bars or other crowds foreshadow a greater spike in infections that "is going to be very disturbing … We're going to continue to be in a lot of trouble, and there's going to be a lot of hurt if that does not go away."

Fauci gave his bleak assessment in response to questions during his latest appearance on Capitol Hill to brief lawmakers on the state of the pandemic as new infections are rampant across much of the South and West, with hospitalizations escalating in a dozen states.

He and other top health officials acknowledge that the nation's public health system was ill prepared for a major infectious-disease outbreak, as the Republican chairman of the Senate Health, Education, Labor and Pensions Committee called on President Trump to start heeding federal guidance to wear a mask in public.

"Unfortunately, this simple lifesaving practice has become part of the political debate that says this: If you're for Trump, you don't wear a mask. If you're against Trump, you do," said the chairman, Sen. Lamar Alexander (Tenn.). "That's why I've suggested that the president occasionally wear a mask, even though in most case it's not necessary for him to do so. The president has plenty of admirers. They would follow his lead."

The rare rebuke from a senator of the president's own political party attests to a disturbing reality for GOP politicians that the pandemic has veered lately from primarily Democratic-leaning states to red parts of the United States.

The hearing took place as Republican governors of newly hard hit states, including Texas and Florida, have been rescinding reopening plans in the face of surging cases of the virus that has killed at least 124,000 people in the U.S. since February.

Last weekend, the U.S. had a record daily number of confirmed new cases — 44,792. That is 30 percent higher than 34,203 on April 25, the peak day in the original surge of covid cases this spring.

At Tuesday's hearing, Fauci, director of the National Institutes of Health's National Institute for Allergy and Infectious Diseases, initially declined to directly answer a question by Sen. Elizabeth Warren (D-Mass.) about how many deaths and infections Americans should expect before the pandemic ends.

"It's going to be very disturbing," Fauci replied. "I will guarantee you that, because when you have an outbreak in one part of the country, even though in other parts of the country they're doing well, they are vulnerable … It puts the entire country at risk."
Then Fauci added, "I would not be surprised if we go up to 100,000 a day if this does not turn around, and so I am very concerned."

He also told senators that federal and state guidance this spring for people to stay at home to avoid exposure to the virus led about half the United States to shut down — far less compliance than in many European countries, he said, where 95 percent of activities in those nations shut down. As a result, he said, the slowdown of the virus's spread among Americans has been less pronounced.

On another aspect of the nation's response to the pandemic, Robert Redfield, director of the Centers for Disease Control and Prevention, acknowledged the ability to trace the contacts of people infected by the coronavirus has been hampered by outdated public health data systems.

In response to questions from Sen. Lisa Murkowski (R-Alaska), Redfield said, that records of people possibly exposed to the virus "really are in need of aggressive modernization … There are a number of counties still doing this pen and pencil."

Contact tracing — finding the people with whom an infected person has been in proximity — is regarded by public health specialists as a crucial tool in trying to contain an infectious virus, along with testing and isolating the people who have been exposed.

And Sen. Amy Baldwin (D-Wis.) asked Redfield whether the Trump administration would consider moving from recommendations to businesses about how to reopen safely to compulsory standards by the Labor Department's Occupational Safety and Health Administration.

Baldwin noted that some companies are following federal guidance, but others are not. She singled out American Airlines for returning to its practice of trying to fill every seat on planes, rather than leaving a distance between passengers.

Redfield replied that Labor Secretary Eugene Scalia is a member of the White House's coronavirus task force, but said, "that specific topic we have not had directly."

Also at the hearing, Brett Giroir, an assistant secretary at the Department of Health and Human Services who coordinates coronavirus testing, said that as far as he knows, he remains the U.S. representative to the World Health Organization. Trump said a month ago that the United States "will today be terminating our relationship" with the WHO.

Giroir told senators he was confirmed as a WHO representative in early May. "I have not been recalled," he said. "I have not been given direction to recall myself."

Former NIH Director Calls Trump Administration's Pandemic Response 'Amateur Hour'

NPR
June 29, 2020
By Joe Palca

Dr. Elias Zerhouni knows the dangers of infectious disease outbreaks. He was director of the National Institutes of Health in 2005 when bird flu appeared poised to become more infectious to humans. Fortunately, that pandemic never materialized, but he says it served as a warning of what was to come.

Zerhouni has been a member of the faculty of the Johns Hopkins University School of Medicine and head of global research and development for the pharmaceutical company Sanofi.

NPR asked him about the difficulties of responding to pandemics in general, and in particular the government's response to the COVID-19 outbreak.

Some of the wording has been edited for clarity.

On the Trump administration's pandemic response

It was basically amateur hour. There is no central concept of operations for preparedness, for pandemics, period. This administration doesn't want to or has no concept of what it takes to protect the American people and the world because it is codependent. You can't close your borders and say, "OK, we're going

to be safe." You're not going to be able to do that in this world. So it's a lack of vision, basically just a lack of understanding, of what it takes to protect the American people.

It's what I call the boom and bust of preparedness. The old saying that we use for NIH is if you think research is expensive, try disease. And in this case, Claire Pomeroy from the Lasker Foundation came up with a different sentence: "If you think preparedness is expensive, try a pandemic." That's where we're living. It's a result of lack of preparation and short-term thinking.

Preparedness going forward

Pandemic control is going to depend on surveillance of the animal-to-human transfers that we're witnessing around the world. Animal health and human health have to be combined into a surveillance network worldwide, just like you do for weather. We have weather satellites. We have weather stations around the world that exchange data on a harmonized system. That's how you predict hurricanes. It's hard to manage a hurricane if you don't know it was coming. The question is, can we do that for global health?

By the time you get the disease and you say, "Oh my God, we must do [treatments] and vaccines at warp speed," that's too late already.

On being asked to lead the White House pandemic response program known as Operation Warp Speed

I discussed it. It was really obvious to me that what they wanted was a vaccine. That's it. Deliver a vaccine by the end of the year. There are political overtones to that, and I said I don't think I'm the right person for that because I don't believe you can do vaccines independent of therapeutics.

Other health threats going forward

I was in academia. I was in government. I was in industry. And the one thing that I've been shocked by is the fact that the commercial powers in pharma always, say, "You know what? Work on cancer or on immunology. Don't work on an infectious disease. We never make money there." And then what you get is a complete destruction of the apparatus that is needed to do [research and development] and science in infectious diseases. Yet the world is more and more exposed to [infectious disease]. It doesn't make any sense.

The same thing is for antibiotic resistance. That's a pandemic, a slow moving pandemic. It's not like the acute one that we're living with. But I tell you, it's happening in front of our eyes. It's almost like HIV when it started in 1980. People say it's nothing — it's a disease in San Francisco and they definitely underestimated the impact it would have. I feel like we have the same sort of pattern right now.

I'm advocating at every level I can to say let's not waste this crisis [the coronavirus pandemic] and let's create a world that would be better protected going forward.

It's going to need to be an international response of some kind. You really need something like a global Centers for Disease Control and Prevention, not a World Health Organization, which is policy and framing.

I'm trying to basically be an apostle for change. So I do whatever I can. I'm not a big influential guy, but I try.

Senate bill to curb foreign threats raises alarms

Science
June 26, 2020

By Jeffrey Mervis

A bipartisan group of U.S. senators last week proposed sweeping—and controversial—changes in how the federal government manages academic research in the face of foreign threats.

The authors of the legislation, more than 1 year in the making, claim it will stop China and other countries from stealing the fruits of federally funded research without weakening a system that has made the United States a global leader in innovation. But research advocates worry the bill, if enacted, would restrict the exchange of talent and ideas.

Drafted by Senators Rob Portman (R–OH) and Tom Carper (D–DE) and with eight Republican and five Democratic co-sponsors, the Safeguarding American Innovation Act is the latest and most substantive attempt in Congress to reconcile scientific security and openness. One contentious provision would give the State Department grounds to reject a visa application from anyone with ties to a foreign government seen as hostile to the United States. Critics worry such power could be used to keep out the tens of thousands of Chinese graduate students and postdocs who seek to study in the United States each year.

Other provisions would expose scientists who fail to disclose ties to foreign governments to criminal penalties including jail time, require international partners to embrace U.S. scientific norms, lower the size of foreign gifts that universities must report, and give the White House budget office new powers to oversee research security.

“For nearly 2 decades, the federal government has been asleep at the wheel while foreign governments have exploited the lack of transparency in our education system and bought access and influence,” says Portman, who leads the Permanent Subcommittee on Investigations, which has issued several reports sharply critical of current federal efforts. “This bill will help us stop foreign governments from stealing our research and innovation.”

The sponsors don't hide their intended target. “America's research enterprise is the best in the world and the Chinese Communist Party knows it,” says Senator Josh Hawley (R–MO). “That's why they've spent the last 20 years stealing American taxpayer-funded intellectual property.”

Carper, the top Democrat on the investigative panel and a co-sponsor, uses more judicious language. The legislation, he says, is a “common sense [approach] to protect American intellectual property and better leverage our international research partnerships.”

A Portman press release claims “widespread support” from academia. But all of the supportive statements come from institutions in his home state of Ohio, and many also hint at the need to tweak some of its provisions. “We endorse [its] goals to modernize the safety and security of our nation and we look forward to continuing to collaborate with Sen. Portman as the legislation moves forward,” says Barbara Snyder, who is stepping down this fall as president of Case Western Reserve University in Cleveland to lead the Association of American Universities (AAU), a coalition of 65 major research institutions.

In private, research advocates express grave reservations. “It violates the culture of openness that is fundamental to academic research,” one says. “I don't think the higher education community is going to like any of this,” says another, who, like many advocates, requested anonymity because they were not authorized to speak for their organization.

Although the bill's language is subtle, it contains “key provisions … [that] are overly broad and will only serve to harm American science without improving national security,” says AAU's Tobin Smith. One such provision, Smith and others say, would give the State Department the authority to reject a visa application from anyone based on their “cooperation with … military organizations adversarial to the United States, foreign institutions involved in the theft of United States research, [or] a government that seeks to undermine the integrity and security of the United States research community.”

But staffers on the subcommittee that Portman leads say the language would apply to fewer researchers than the critics fear. “The focus of the bill is on bad actors,” one staffer noted. “The vast majority of foreign researchers [asking to come to the United States] are benign, and we need their talents.”

The bill would also empower the State Department to reject or restrict the activities of a visa applicant if officials decide that giving the applicant access to “goods, technologies, or sensitive information” would harm the United States. Extensive rules already limit the sharing and export of research products deemed sensitive. But lobbyists say the new provision could require universities to impose additional restrictions on visa holders, such as blocking them from attending open lectures or visiting laboratories doing unclassified research.

Again, the staffers accuse the research community of overreacting. “We're not locking down campuses,” one staffer says. But universities and other federally funded institutions “don't need to give everyone access to everything.”

There is no companion bill in the House of Representatives, and the House's Democratic leadership is more skeptical that the problem of foreign influence warrants wholesale legislative changes. Little time remains for the Senate to act on the legislation before the November elections. But research advocates expect the debate in Congress to continue regardless of the outcome of the vote.

NIH’s new sexual-harassment rules are still too weak, say critics

The agency has outlined actions it may take to deal with bullies and harassers, but it still relies on universities to report bad behaviour.

Nature
June 25, 2020
By Nidhi Subbaraman

The US National Institutes of Health (NIH) this month published new guidelines for tracking sexual-harassment complaints involving scientists funded by the agency. On 24 June, it described the actions it will take when alerted to reports of unsafe behaviour, including restricting scientists from peer-review panels, holding back pending grants and refusing university requests to transfer funding to other institutions in cases where a harasser changes jobs.

Advocates who have campaigned for changes at the US$41-billion biomedical-research agency say the adjustments are necessary, but are still weaker than rules issued by other funding agencies, such as the National Science Foundation (NSF).

Measures introduced on 11 June say that universities must inform the NIH when major changes are made to a grant owing to an investigation about scientists creating an unsafe work environment. “We have specifically defined that as including harassment, bullying, sexual harassment and other inappropriate behaviour,” says Carrie Wolinetz, NIH associate director for science policy.

The NIH began collecting information about sexual-harassment investigations at the institutions it funds in 2019. But ahead of the June announcement, disclosures had been voluntary. According to NIH officials, the new measures put harassment on the same level as research misconduct, fraud, issues of foreign influence and violations of peer-review integrity.

Critics say that the policy still relies too heavily on universities, who might be disinclined to report bad behaviour to the agency that funds them, and that a raft of steps must follow to change the status quo.

It “assumes good faith on the part of the institutions”, says BethAnn McLaughlin, a neuroscientist and founder of the nonprofit group MeTooSTEM. “What an absurd and insulting notion.”

Others are awaiting the agency's next play. "This guidance is a good start, but there is much more that needs to be done," says Angela Rasmussen, a virologist at Columbia University in New York City, who was part of a working group convened by the NIH to examine its policies and suggest ways the agency could improve.

Changes and challenges

Agencies and institutions in the United States have begun making changes after acknowledging the scope and harm of sexual harassment in science. A 2018 report by the US National Academies of Sciences, Engineering, and Medicine in Washington DC found that incidents of harassment are rampant, that such behavior pushes talented researchers out of science, and that university and federal policies for keeping it in check are lacking.

In a June presentation to a panel of advisers to the NIH director, Wolinetz said that the NIH has received information about 115 cases of sexual harassment in 2019, and 27 cases in 2020 as of 8 June, from 71 institutions altogether. This year, it has removed 24 people from peer-review committees so far. In 2019, it removed 64.

According to the information provided to the NIH only 14 principal investigators have been removed from grants so far, in part because investigations at their institutions are ongoing. But even in cases where there have been findings of harassment, some institutions have pushed back against removing the harassers, arguing to keep the funding in place after the offender has been disciplined. "We are starting to see people, upsettingly, try to game the system a little bit," Wolinetz says.

Alysha Dicke, a member of the NIH's working group, is concerned this pattern will continue if the NIH is not more transparent about affected universities and grants, and about what constitutes reportable behavior. "I think it's important for NIH to point out how institutions are not responding as intended/desired, as it will likely be even more difficult to change some of the undesirable institutional behavior if it's never called out," she wrote in an e-mail to Nature.

The new guidance won't provide a comprehensive view of harassment at funded institutions. The NIH requests that universities report, "concerns" about scientists that have led to changes in grants — including pending investigations. But lawyer Kristina Larsen is sceptical that many institutions will report anything other than the findings of completed investigations — which only rarely occur. Larsen was an administrator at the University of California, San Diego, before she began representing people who filed sexual-harassment complaints. "I don't think it's realistic," she says.

Other funding agencies in the United States have stronger rules. The NSF, for example, in 2018 began requiring universities to report findings that an NSF-funded scientist committed sexual harassment within ten business days. NASA adopted similar rules in March. But the NIH rules require reporting only when the status of a grant changes. Wolinetz says that's because the NIH does not have the authority to ask institutions to report investigations or their results outside of the grant-update cycle.

"The NSF has direct oversight of civil-rights violations at NSF-funded organizations, and NIH does not," Wolinetz says. "It does present some legal limitations in what we're able to do."

National Institutes of Health director: 'The virus is very much out there'

Dr. Francis Collins, a member of the White House coronavirus task force, discusses vaccines, vulnerable communities and the importance of mask-wearing in a wide-ranging Q&A with the Editorial Board

USA TODAY

June 24, 2020

As COVID-19 cases continued to spike in the South and West, USA TODAY's Editorial Board spoke Tuesday with Dr. Francis Collins, director of the National Institutes of Health and a member of the White House coronavirus task force. Collins, 70, led the international Human Genome Project and is noted for

his landmark discoveries of disease genes. Questions and answers have been edited for length, clarity and flow.

Q: One of the big mysteries about COVID-19 is why some people get the disease and some don't, and why some people have far worse outcomes than others. Do you think the answer is in our genes?

A. You're asking me to say it's not? Probably one of the factors is the genetic endowment we all bring to whatever encounters we have (with the virus), but it's probably not the only one.

Q. What are the other factors?

A. It's obvious that age plays a role. Why is that? The obvious potential explanation is that the immune system is less responsive as you get older. We also know that chronic illnesses play a role in who's going to have a severe case. Certainly hypertension and diabetes and obesity are in there as well. Anything that hits your system hard, and SARS-CoV-2 (the virus that causes COVID-19) is capable of that, will bring out other weaknesses in the system and cause them to become less stabilized.

Q. And genetics?

A. We have now this indication that the ABO blood group may be a factor — that people who are A group are more susceptible. People who are O, like me, are less. At least that's a suggestion that needs to be confirmed with other large studies. Chromosome 3 does seem to have some genes in it that could be pretty relevant for immune response ability. That's probably in there.

Q. How important is the amount of virus you are exposed to?

A. Something that's really hard to assess is: Just how big a dose of the virus did you happen to get when you got exposed? Did somebody cough all over you and give you zillions of viral particles, or did you get a little whiff going past you at the supermarket? And how would that affect how your system responded? We don't know. It does seem like that's likely to be a factor. There is some also potential possibility of your prior immune exposures playing a role.

Q. How many people might have some sort of natural immunity to COVID based on genetics or some other factor?

A. I don't have a good sense of that, and I would doubt that there are very many people who are completely immune. Is there anybody out there who you could give an intentional large dose of this virus and have nothing? That would be surprising. It's a virus we haven't seen before. This is new to our entire world's population.

Q. How long until we get the answers to some of these questions?

A. Give us another year or two, and we might begin to sort that out. The fact that this disease was pretty much not even on the radar six months ago means that we have all these questions that are coming up. We have designs of studies to answer them, but we don't have the answers yet.

Q. President Trump has resumed his political rallies. Do you have concerns about mass indoor events?

A. We know this virus spreads by person-to-person contact, and we know that close contact is particularly likely to be risky, especially if people are not wearing masks as source control.

Q. What advice would you give to people who are going?

A. I would certainly advise people who are at risk, because of age or chronic illness, to avoid those kinds of risky situations or potentially face a really serious consequence.

Q. And what's your advice about wearing face masks?

A. When I wear a mask, it is not because I'm protecting myself from others, although maybe I'm doing a little bit of that. I'm mostly protecting everybody else from me in case I am today one of those asymptomatic viral carriers and I don't know it.

Q. There seems to be a cultural divide over masks. What are your thoughts on that?

A. Well, the data would say that mask wearing has been protective. We figured out that there are asymptomatic people who are capable of spreading the illness, which we didn't really know until about March or so. We have undoubtedly protected people from infection and saved lives. I don't particularly like wearing a mask when it's hot outside like it is today, but it's the sensible thing for a responsible American to do. It is heartbreaking to see that this has become somehow a political statement, because that never should have happened. This is really about public health, and it shouldn't matter exactly what your politics are.

Q. Have you or the White House task force advised the president on these large indoor rallies?

A. Since I joined the task force, which has only been for the last three weeks, we have been meeting regularly in the White House with the vice president as the chair of the group. We have not had a meeting directly with the president.

Q. The president made remarks the other day about slowing down COVID testing. Are you aware of any steps that were taken by the administration to try to curtail or slow down testing?

A. Absolutely not. Brett Giroir, who has sort of become the czar of the testing process, reports every morning about the total number of tests that have been done across the country. I think it's now 23 million and it goes up every day, and we are all totally motivated to see it go up even faster.

Q. How important is testing to reopening schools?

A. To bring schools back in September, we will want to take something in the neighborhood of half a million tests a day and greatly increase that, if we can, to get early warnings of trouble. Ideally, these ought to be tests which can be done right on the site with an answer within an hour, as opposed to sending the sample off to a central laboratory where it might be a day or two before you get the results. If somebody is carrying the virus, that means you just lost a day or two where they could have been quarantined and you could have had the chance to avoid more spread.

Q. Is the nation suffering from coronavirus fatigue?

A. Everybody is kind of tired of the whole thing. But the virus doesn't really care that we're tired of this. The virus is very much out there, and most of us, probably 95% of us, are still just as vulnerable to this virus as we were back in January. Any notion that we can just decide that this is over doesn't fit with the science at all.

Q: Could you see us reaching a point where everyone gets some sort of personal risk score, and that might help determine who gets vaccinated first?

A. That could be a factor. I think if we had vaccines right now, we would already be planning how we would want to distribute them, and certain high-risk people ought to be first in line. If we were really sure about some of the other factors like genetics or pre-existing immunity, we might want to factor that in.

Q. Dr. Robert Gallo, the famed HIV researcher, thinks the oral polio vaccine might help boost the body's defenses against the coronavirus while we wait for a COVID-specific vaccine. Others think different existing vaccines could help. Are those theories worthy of trials?

A. I've talked to Bob Gallo about this. There is some circumstantial evidence to suggest that nonspecific agents that activate your immune system might provide some benefit, and certainly oral polio vaccine is the one that he's championing. People have also looked at what's happened in Africa for lots of people who get the (tuberculosis) vaccine and wondered, is there actually some benefit there as well? It is all interesting but not compelling.

Q. You sound skeptical.

A. I think history would say you need a specific vaccine that targets that specific agent. These other ideas may be of interest, but they are not going to be a substitute for what we're working incredibly hard on right now, which is to come up with that specific vaccine.

Q. How is the NIH initiative known as ACTIV working with the president's Operation Warp Speed for vaccine development?

A. I think it's actually working pretty well. This is one of those moments where we need to get all of the sectors to work together. ACTIV (Accelerating COVID-19 Therapeutic Interventions and Vaccines) is a public-private partnership. Warp Speed is purely government, but the two of them need to talk to each other and many of the people involved, like me, are in a position to make sure that happens.

Q. Does the term "Warp Speed" suggest some corners are being cut?

A. I want to push back on that to say that what we're doing is, in fact, dramatic in terms of the pace of research and the opportunity to talk about having a vaccine that might actually reach approval by the end of calendar 2020. But it's not by cutting corners on safety or efficacy. It's basically by doing other things to limit some of the delay times that normally happen between Phase I, II and III trials, and also to do the at-risk manufacturing. So if you have a vaccine that looks like it's working, you don't then wait another six months to build up the factory and make the doses that people will want. But safety and efficacy absolutely will not be compromised.

Q. Of the many vaccines under development, is there a particular one you are most optimistic about at this point?

A. Well, I love them all. It is a really good thing that we don't just have one that we're banking on. This is one of those urgent moments where you want to have as many shots on goal as you can, because the world is waiting for this kind of protection. And it's great that the vaccines being tested have different kinds of science, different kinds of technologies, different kinds of platforms. There are RNA vaccines and there are viral vector vaccines and there are protein-based vaccines, and that's exactly what I would have hoped to see. Let's hope that maybe several of them turn out to be successful, but I'm certainly hoping at least one is.

Q. What about treatments?

A. There's the monoclonal antibodies (immune system molecules identified from recovered patients that can then be manufactured with predictability and consistency). I'm pretty excited about this because it worked for Ebola. Same idea. At least six companies have monoclonals that are getting pretty close to being ready for clinical trials. If I had to sort of put my hopes on one therapeutic that might be a real game changer as soon as this fall, it would probably be the monoclonals.

Q. How will you find out if they will work?

A. A lot of energy is going into that right now. Again, this will involve networks across the country. We'll have to figure out how to enroll patients where they are, which is where people are getting sick. That means we probably will not be running this tomorrow in Montana but we might be running it in South Carolina. We'll sort of see where the epidemic is going.

Q. Clinical trial participation is typically lower among racial minorities. What can be done at this time, with such a pressing public health need, to encourage diversity in clinical trials?

A. We all, I think, would agree that it will be critical with any of these trials to particularly reach out to those communities that have been hardest hit. And looking at the statistics here, it is heartbreaking to see the way in which this disease has particularly affected those of lower socioeconomic status, how it's affected African American communities and Hispanic communities. We want to be sure, therefore, that the trials reach out in a particularly vigorous way in those communities. And yet, without being exactly sure where geographically the trials are going to need to be placed because this is such a moving target, it's a little hard to plan for that.

Q. A lot of African Americans are distrustful of clinical trials because of past unethical government experiments. What are you doing to address cultural sensitivity and build trust?

A. If we wish to actually win the trust and deserve the trust from communities that are suspicious about this, we have to be completely open about what we know and what we don't know, and we need to engage with their leadership, with people from various walks of life who do have credibility in that group. That's probably not me. I'm an old white guy at NIH. We are certainly engaged through community action groups to try to achieve that kind of connectivity through churches and universities that serve minority communities. And through other spokespeople who have credibility in this space, many of whom I think are quite willing to do what they can. Credibility is not going to come from another bunch of government officials pounding the table and saying, “This is good for you.” It's going to have to come from the grassroots.

Q. Do you think that it's safe for people to be going on vacation right now and for the rest of the year?

A. Well, everything is going to be a benefit-risk calculation. As long as this virus is circulating in our country and as long as we have not yet developed a vaccine that can protect people, then making a decision about what you're doing today is going to play out in terms of that benefit and risk. Certainly being out in public, getting on a plane, traveling somewhere should be considered in that light.

Q. What are the considerations for activities like flying?

A. I know a lot of efforts are being made to try to minimize the risks of those sorts of things, and I know people are really hoping to have a chance to get out and do something besides sitting at home, like I am right now for the 13th week in a row. But at the same time, that does come with certain consequences, and particularly for people who have greater vulnerability because of age or chronic disease, I would think that ought to be taken with great seriousness.

Q. Are you taking a summer vacation?

A. I will tell you, as a grandfather and a guy who hoped to have a beach week (in South Carolina) with my grandkids and my daughters coming up in about a month, we're not doing it. It just didn't seem like it was going to be a wise circumstance, given that the family is all over the country and some of them live in hot spots. There would be no way to know if we all assembled in some big, rambling beach house that somebody wasn't bringing a virus to the party. It just didn't seem like it was worth it, but that's a very personal reaction.

Q. How can people decide?

A. Everybody has to size up their own risks figuring out what is the current spread of the virus in their communities. Local information's going to be pretty important, and there's a lot of places to get that from. The CDC (Centers for Disease Control and Prevention) will show you that county by county, and that would certainly influence me if I was trying to make such a decision today.

Q. As we go into the summer and fall, what coronavirus trends can we expect?

A. I don't know what's going to happen because a lot of it will depend on all of us. Human behavior is the least predictable thing around. If you look at the numbers, there's no question that the number of cases turned back up again a few weeks ago, and that seems to be headed very much in the wrong direction. Yet the number of deaths continues to drop day by day. Still, every one of those is a terrible tragedy that should not have happened.

Q. So why are cases rising and deaths declining?

A. I think we're all trying to puzzle our way through that. The new cases do tend to be younger people than the ones that were so prominent back when we were having the worst of the first wave. Younger people are going to have a better outcome and easier course of it. Certainly the medical care has gotten better for people who get very sick. Our ability to see them through with things like Remdesivir, with steroids, just with good care that people in ICUs have figured out how to deliver. Your chance of surviving with a bad case of COVID-19 is better if you roll into the ICU today than it would have been in early April.

Q. That's encouraging.

A. We shouldn't be too complacent. I'm holding my breath here that we don't see the curve of deaths start back up again. I hope and pray that does not happen. We have clearly some important weeks ahead of us. We don't have a victory yet. We're a long way from it.

Q. Are we ready for a potential second wave?

A. We shouldn't be talking about a second wave. We've got to get through the first wave, which we are still seeing the tail end of, and maybe even then it's a bit of a herky-jerky wave that's not coming down the way that it should be, certainly in terms of the number of cases. You've got to get to calm water before you can say the first wave is over and the second wave has begun.

NIH director: COVID-19's 'heartbreaking' harm to Black and Hispanic Americans demands testing

USA TODAY
June 23, 2020
By Ken Alltucker and Karen Weintraub

COVID-19's disproportionate harm on communities of color is "heartbreaking" and demands more inclusive efforts as the federal government underwrites attempts to develop a vaccine and improve testing, the head of the National Institutes of Health said.

Dr. Francis Collins, director of the NIH, the federal agency funding vaccine development efforts, said it's critically important to build trust in Black and Hispanic communities as vaccine and drug developers seek volunteers to test potential vaccines and drugs.

"We recognize that credibility is not going to come from another bunch of government officials pounding the table and saying this is good for you," Collins said Tuesday in an interview with USA TODAY's Editorial Board. "It is going to have to come from the grassroots."

Collins said recruiting volunteers for clinical trials must be "particularly vigorous" and involve outreach groups to encourage participation as Black Americans join medical studies at lower rates than whites, in part due to historic distrust stemming from experiments such as the decades-long Tuskegee syphilis study, which tracked the progression of the disease last century in Black men who were not given treatment.

Collins said he's already heard questions about the federal agency's aggressive timeline for the vaccine, but said it's important the public knows the federal agency won't cut corners on safety and effectiveness.

He said the agency, which includes the National Institute on Minority Health and Health Disparities, has worked to recruit more racial and ethnic groups to medical studies and address health disparities. For example, the agency's All of Us precision medicine study includes about 300,000 volunteers, over half of whom are racial minorities. He hopes similar outreach efforts will boost diverse enrollment in vaccine studies for COVID-19, a disease that "has taken way too many lives."

Collins also said the NIH will spend $500 million to accelerate testing through a new initiative that aims to make millions of tests available each week, particularly in hard-hit communities. He said vulnerable communities “suffered severe consequences” because the lack of access to testing.

"It’s heartbreaking to see the way in which this disease has particularly affected those of lower socioeconomic status – how it’s affected African-American communities and Hispanic communities," Collins said.

Collins predicted that the nation would have "a vaccine that might actually reach approval by the end of 2020." He said vaccine development is proceeding at an unprecedented pace by limiting delay time between different stages of research, and by making candidate vaccines before they have been fully vetted, so that the supply will be there if one or more prove successful.

Asked whether he had a favorite among the vaccine candidates, Collins said: "I love them all."

He's thrilled, he added, that there are multiple vaccine candidates. Eleven candidate vaccines have begun to be tested or will soon be tried in people.

"It’s a really good thing that we don’t just have one that we’re banking on," he said. "We know there is a history here of vaccines not always working. We want to have as many shots on goal as we can, because the world is waiting for this kind of protection."

He then went on to explain the government's role in helping to develop one of the candidate vaccines, based on new genetic technology, which Collins, a geneticist, said he finds particularly exciting.

"It looks like it's on the right track," he said, but the approach is new, "so, who knows" whether it will prove safe and effective.

In terms of treatments, Collins referenced remdesivir, an antiviral that has shown to be helpful for hospitalized patients, and a steroid, dexamethasone, that a recent study found life-saving for some of the sickest COVID-19 patients.

He said the government is working to winnow a list of more than 400 possible treatments, planning to support the most promising of them with clinical trials to start next month.

Collins said he's been impressed with the safety of convalescent plasma – a blood product from people who have recovered from COVID-19. But research has not yet shown whether convalescent plasma is truly effective for COVID-19 patients and at what stage of disease.

More promising, he said, is what are called monoclonal antibodies – immune system molecules identified from recovered patients that can then be manufactured with predictability and consistently.

"It worked for Ebola, so it’s got a precedent," said Collins, who was head of the NIH when that outbreak occurred. At least six companies are developing monoclonal antibodies that are ready for testing in people.

"If I had to put my hopes on one therapeutic that might be a real game-changer as soon as this fall, it would be monoclonals," Collins said. "But we don’t know until we actually go there and try that."

Asked about the idea that other vaccines – such as ones to treat polio, tuberculosis, or measles, mumps and rubella – might be effective against COVID-19, Collins said that there was "some circumstantial evidence" that activating the immune system with another vaccine might be helpful. But, he described that evidence as "interesting, but not compelling. If we're trying to come up with a way to prevent this disease really effectively, I think history would say we need a specific vaccine to target that specific agent."

In a more political section of the conversation, Collins admitted that it can be tough to balance the scientific advice of how to deal with a pandemic, with economic and political realities.

Asked whether he had advised the President on whether it is safe to hold large public gatherings, including a campaign rally, Collins answered indirectly. He said he joined the White House Coronavirus Task Force, chaired by Vice President Mike Pence, three weeks ago, but that the panel has not met with the President during that time.

Collins said he has decided that it is safe in Washington, D.C. to slowly begin allowing NIH scientists to return to work. He has eight people in his own research lab who are now coming in every other day, wearing a mask all the time, remaining six feet away from each other, and cleaning their space when they leave. He compared this to what will have to happen to keep people safe as businesses and universities begin to reopen.

Testing, he said, will be crucial, "so it would be possible for universities or businesses to know if they're getting into a difficult circumstance." He said the hospital at NIH is testing everyone involved in patient care once a week even if they have no symptoms, so that the institution will quickly find out if the virus is circulating there.

Fauci says White House told NIH to cancel funding for bat virus study
"Why was it canceled? It was canceled because the NIH was told to cancel it," Fauci said.

Politico
June 23, 2020
By David Lim and Brianna Ehley

The White House directed the National Institutes of Health to cancel funding for a project studying how coronaviruses spread from bats to people, the government's top infectious disease expert said Tuesday.

"Why was it canceled? It was canceled because the NIH was told to cancel it," said Anthony Fauci, director of the NIH's National Institute of Allergy and Infectious Diseases, in response to a question during a House Energy & Commerce Hearing. "I don't know the reason, but we were told to cancel it."

Fauci later told POLITICO that the White House ordered NIH to cut the research grant to the nonprofit EcoHealth Alliance.

The backstory: The Trump administration abruptly cut funding for the research in April, with more than $350,000 in grant money remaining in EcoHealth's 2020 grant.

The cancellation came shortly after reports had linked the project to the Wuhan Institute of Virology, a research facility in the city where the coronavirus first emerged — and one that has been the subject of unproven conspiracy theories about the pandemic's origins. EcoHealth Alliance scientists have collaborated with researchers from the Wuhan lab in the past, but were not doing so when the grant was ended.

The NIH typically only cancels a grant when there is scientific misconduct or improper financial behavior, neither of which it has alleged in this case. Instead, a top agency official told the EcoHealth Alliance at the time that "NIH does not believe the current project outcomes align with the program goals and agency priorities."

The administration weighs in: A White House official said that the White House encouraged the decision to cut the funding, but that HHS ultimately made the call. A HHS spokesperson said that "the grantee was not in compliance with NIH's grant policy," and declined further comment.

What's next: Expect lawmakers to more closely scrutinize the decision to cut funding for the research.

NIH director skips South Carolina beach vacation, warns public about coronavirus travel risks

USA TODAY
June 23, 2020
By David Oliver

National Institutes of Health Director Dr. Francis Collins knows you're tired of being cooped up in the house for more than a dozen weeks – but that doesn't mean it's time to break your quarantine and travel just yet.

"I know people are really hoping to have a chance to get out and do something besides sitting at home like I am right now for the 13th week in a row," Collins said during a USA TODAY editorial board meeting Tuesday. "But at the same time, that does come with certain consequences, and particularly for people who have greater vulnerability because of age or chronic disease, I would think that ought to be taken with great seriousness."

He said that if you look at the numbers, there's no question that the number of cases has trended upward over the past few weeks, and more than half of U.S. states are seeing an uptick in daily infections. But Collins said that while the number of deaths is still dropping (a fact that should not be glossed over), the hundreds of people who are dying are still "people who shouldn't have died and who did."

He said Americans shouldn't be too complacent as the case curve heads upward, since there's a delay between the relationship of new cases and when you start to see more deaths.

"I'm kind of holding my breath here that we don't see the curve of deaths start back up again," Collins said. "I hope and pray that does not happen."

Those looking to travel will have to make their own benefit-risk calculation.

"As long as this virus is circulating in our country, and as long as we have not yet developed a vaccine that can protect people, then making a decision about what you're doing today is going to play out in terms of that benefit and risk," Collins said.

That includes everything from just going out in public to getting on a plane, despite efforts to minimize risks. Airlines and hotels have administered intense cleaning regimens and policies to help stop the spread of coronavirus and lure travelers back, and cruises remain suspended in the U.S.

How much coronavirus risk is there in common travel activities? We asked an expert

Collins' own beach trip to South Carolina is now on hold. The number of confirmed new cases in the state is growing: 6,288 for the seven days ending June 22, up from 4,578 the week before.

"As a grandfather and a guy who hoped to have a beach week with my grandkids and my daughters coming up in about a month, we're not doing it," he said. "It just didn't seem like it was going to be a wise circumstance given that the family's all over the country and some of them live in hot spots. And there would be no way to know if we all assemble in some big, rambling beach house that somebody wasn't bringing a virus to the party."

He added that it's ultimately a personal decision: "Everybody has to size up their own risks, figuring out what is the current spread of the virus in their communities."

‘Has it peaked? I don’t know.’ NIH official details foreign influence probe

Science
June 22, 2020
By Jeffrey Mervis

Four years after the National Institutes of Health (NIH) began to investigate grantees who it believed had failed to disclose their ties to foreign governments, officials still don’t know the full extent of the problem.

“We’ve learned of 150 cases in the past 12 months,” says the head of NIH’s extramural research program, Michael Lauer, who oversees an ongoing probe that has swept up 399 scientists since NIH received the first allegation in June 2016. “But has it peaked, and will we have the same number of new cases over the next 12 months? I just don’t know.”

On 12 June, Lauer offered the fullest analysis to date of the pool of scientists NIH has been investigating and the nature of their offenses. But the data left many questions unanswered. Last week, Lauer fleshed out that analysis during an interview with ScienceInsider, offering new details on the scope of NIH’s investigation and how it fits into the larger debate now roiling Congress over how to prevent other countries from acquiring federally funded research in ways that threaten U.S. economic and national security.

Since July 2018, Lauer says, NIH has sent letters to 87 institutions raising questions about the behavior of 189 scientists. That group is a subset of the 399 grantees who have so far come to NIH’s attention, Lauer explained. Of those 399 scientists, he says, NIH determined that 251 warranted further scrutiny. NIH has since exonerated 76 scientists; 72 cases are still pending.

Lost jobs
Within the group of 189, 54 have subsequently lost their jobs. (NIH has declined to make their names public, although media reports have described and identified roughly two dozen scientists who appear to fall into that category.)

Asked why they were fired or dismissed, Lauer says the decisions were made by their institutions, not by NIH. “We do not render an opinion on HR [human resources] matters,” he says.

He notes that 70 of the 189 scientists were found to have violated rules at their institution, most notably a ban on receiving outside support for their research without prior approval from their employer. (In 93% of the 189 cases, the funding came from China, and the vast majority of the scientists under scrutiny are Asian men in their 50s.)

Lauer emphasized that NIH is examining only a narrow slice of the broader issue of inappropriate or illegal activity involving foreign sources of funding. “We focus on grant noncompliance,” he says, referring to a long-standing NIH policy that grantees must disclose material support for their research from any outside source.

The data Lauer presented are in line with that explanation. Of the 189 scientists flagged in its letters to institutions, 133 of them (70%) failed to disclose a grant from a foreign entity, and 102 failed to disclose their participation in a foreign talent recruitment program, such as China’s Thousand Talents Program.

Cases involving the alleged theft of intellectual property or economic espionage, he says, are referred to either the inspector general for NIH’s parent body, the Department of Health and Human Services, or to the Department of Justice (DOJ). DOJ’s China Initiative, launched in November 2018, has led to the arrests of several scientists, including biochemist Charles Lieber of Harvard University.

Although the U.S. government asserts that many of them have helped the Chinese government illegally acquire U.S. technology, they are typically charged with other offenses, such as lying to the Federal Bureau of Investiation (FBI). Lauer's data show a relative handful of the 189 scientists tagged appeared to be active in commercializing their research: Only 17 had hidden their involvement with a foreign company, for example, and seven had failed to tell NIH about a foreign patent.

Few mistakes claimed
Investigating alleged nondisclosure by an NIH grantee is a very labor-intensive process that can take "as long as several months," Lauer says. It encompasses looking for mentions of foreign ties and grants in published papers, press releases, and other public descriptions of their research activities. Although NIH's own sleuthing accounts for the majority of the workload, FBI did the initial legwork in some 30% of the 399 cases, according to Lauer's data. In 11% of the cases, the scientist's own institution contacted NIH with concerns.

Lauer says NIH is rarely wrong once it decides an NIH-funded scientist is likely to have violated its policies on disclosure. The data he presented on 12 June show 71% of the 87 institutions that received letters "acknowledged noncompliance." He says there are additional cases in which an institution took action without admitting liability. He cited, for example, a December 2019 settlement between DOJ and the Van Andel Research Institute, in which the institute agreed to repay NIH $5.5 million in a case involving two scientists that had received funding from the Chinese government.

"They claimed that because the [Chinese] research did not overlap with what we were funding, they had no obligation to report it to us," Lauer says. "But that is false," he asserts.

"Of course, an institution has the right to disagree with us," Lauer says. But he estimates that there are "fewer than 10 cases" in which institutions persuaded NIH that it had erred in claiming a grant recipient had violated the agency's policy on disclosure.

As suicide, addiction death projections soar amid COVID-19, treatment centers struggle to stay alive too

USA TODAY
June 21, 2020
By Jayne O'Donnell

MANCHESTER, Conn. – In early March, Zoraida Diaz was coming to twice-weekly yoga classes here at Community Health Resources' offices. She's in recovery from colon cancer and alcoholism while in treatment for severe anxiety and depression.

Carla Mitchell showed up for intensive PTSD therapy, happy to be free from her stressful home life and the racist taunts she hears walking in her neighborhood.

And Tara Kulikowski, who has schizoaffective and bipolar disorders, lupus and is in recovery from drug addiction, organized craft classes and other activities at CHR's nearby "We Can Clubhouse."

By mid-March, however, the answer was "we can't" for all in-person encounters at Connecticut's largest mental health and addiction treatment facility and thousands like it across the U.S.

Amid projections of soaring suicide, drug and alcohol deaths from the pandemic-spawned social and economic collapse, centers like these and their patients are struggling to keep going. They've been largely left out of the murky formula for federal COVID-19 health care funding, which has focused on the immediate financial impact on hospitals caring for patients with the virus and lost revenue from elective procedures.

Nearly 30 mental health and substance abuse groups representing everyone from addiction psychiatrists to family therapists sent a letter to Health and Human Services Deputy Secretary Eric Hargan on Thursday asking for a separate distribution of money because they've been blocked from getting "desperately needed relief funds."

The lack of government support has come at a deep emotional cost for patients and a steep financial one for centers such as CHR, both groups say. It has also stymied and undermined progress to better integrate mental health care with primary care and into communities and the social services arena to help keep people functioning in society, experts say.

COVID-19 should be the "door opener" for the health care system to focus on the direct link between physical and mental health, said former Rep. Patrick Kennedy, D-RI, a longtime mental health advocate. Depression, he noted, quadruples the risk of a heart attack, and heart disease is one of the chronic health problems that dramatically increase the risk of serious illness or death from the virus.

Diaz ended up at CHR after she collapsed on the street with heat stroke following her release from a psychiatric hospital. Caseworkers connected her to a doctor, who diagnosed the colon cancer. Another CHR client relapsed on alcohol when he couldn't attend or connect to 12-step meetings because of shelter-in-place rules and because he had only a flip phone.

"Our volume of service dropped through the floor," said CHR CEO Heather Gates. "This is not elective."

Loss of funding threatens another public health 'catastrophe'
It took years for Timothy Washington, who has schizophrenia, to leave his apartment to go to the corner store without worrying someone was following and planning to hurt him.

He credits the therapy and various day programs and services he got through the Washington D.C.-based McClendon Center for his progress. Now patients like Washington struggle to cope with the lack of a routine and face-to-face contact, said Aisha Shabazz, who heads the center's day programs.

By early May, she managed to connect just a third of the 90-day program clients with virtual therapy, including using art and music. But that was too late for another McClendon client CEO Dennis Hobb declined to identify by name, who took particularly hard the loss of activities such as daily meals and Friday karaoke in the center's church basement.

The 49-year-old client remained in contact with the "core services" staff who helped her with food, medication management and other basic needs but was "really struggling after we had to close down," said Hobb.

"She really missed (and) needed the social contact," said Hobb. "She was found dead in her apartment about six weeks ago. Hers was a tragic loss for all of us."

Hobb estimates the McClendon Center is losing about $250,000 a month – $95,000 or so from Medicaid due to the cutback in day programs.

At CHR, Gates said the coronavirus outbreak has cost the center about $500,000 in lost Medicaid revenue.Earlier this month, it received a $36,000 deposit from HHS; Gates said she was expecting $213,000. Since the pandemic hit, the center has spent about $100,000 on technology to interact with clients and $25,000 on personal protective equipment, including masks, that it will continue to buy.

CHR and other centers learned recently they may now be ineligible for Medicaid reimbursement payments if they applied for and got even a tiny slice of their lost Medicare money.

Chuck Ingoglia, CEO of the National Council for Behavioral Health, says "HHS keeps changing the rules," and without a fast fix there could be a "secondary and devastating public health catastrophe." He predicts layoffs and program closures at centers.

In a statement late Friday to USA TODAY, the agency said it "has maintained an open line of communication with health care providers to address urgent concerns and we are answering provider questions on a rolling basis."

Dr. Elinore McCance-Katz, assistant secretary of mental health and substance abuse for HHS, said Friday that there already has been a huge impact on treatment providers. Data on the increases in the percentage of emergency room visits in April and May because of suicide attempts highlight the need, she said.

McCance-Katz supports special funding for these behavioral health providers but also says states should revisit guidance requiring masks and 6-foot distancing at centers, which "tanks our mental health and substance abuse treatment system." The World Health Organization's recommendation for mask use and distancing of 1 meter, or a little over 3 feet,would address the issue, she said.

"We are in a very great state of distress," she said. "People need these services."

'Everybody needs help'
Back in Connecticut, as CHR's government insurance payments were drying up because of COVID-19, caseworker Kevin Rodriguez was canvassing Manchester looking for a homeless man he was told was named David and was living in a box truck.

Rodriguez found David Lamay in a truck behind a friend's house, where he had been for six years since losing his home to foreclosure.

Lamay is blind in one eye and struggles with severe anxiety and depression, which makes it hard to focus on his other health problems including chronic obstructive pulmonary disorder, diabetes and related grand mal seizures.

Three weeks after finding him, Rodriguez got Lamay a spot at a Hartford Best Western converted into a homeless shelter and hopes to get him in permanent housing soon. That, and all the forms Rodriguez helped him fill out, means Lamay will have a place to get the Social Security Disability benefits for which he has been eligible for years but never received.

"Everybody needs help," said Lamay, who calls Rodriguez "a blessing."

"He's the most proficient, effective worker I’ve ever seen."

Diaz is among those CHR clients in most contact with caseworkers who, along with psychiatrists, typically go to the client's home. This Assertive Community Treatment Team needs to "see how the client lives," including whether they have enough food, furniture and health services, said nurse and team member Cathy Martel.

"We assert into their life and manage all of their care as a unit," Martel said.

When Diaz, for example, had her power cut off because she lost a check and didn't have money to pay, her treatment team called the utility. CHR loaned her money that she paid back at a rate of $10 a month, when she had it.

May, June and July have always been the hardest for Carla Mitchell. Her beloved father died in May 2015 of the lung disease COPD. She would almost be over the anniversary of his death when Father's Day would arrive, followed by his birthday in July. She'd cry for months.

But that has stopped since her latest session of trauma therapy, known as Eye Movement Desensitization Reprocessing, or EMDR. She describes the treatment, seldom available to Medicaid patients, as like hypnosis that helps her emotionally detach from the traumatic event.

Proof it's working? She has already made plans to go over a friends' for a Father's Day cookout.

Mitchell actually prefers doing her therapy remotely, and CHR's Gates said she's definitely in favor of continuing telemedicine for those who have trouble getting into the clinic. For those and others during the pandemic, "it's been a lifesaver." It's all the others who are drinking, using drugs and experiencing more trauma along with the social isolation Gates worries about.

Without more funding, new and exacerbated cases will go untreated and people will have "the equivalent of PTSD" from the first round of social isolation that will come back if states close again. Then they'll have "chronic trauma" to go with their other chronic health conditions, Gates said.

"We are working with individuals with serious, persistent mental health issues," she said. "You can't just shut off face-to-face contact."

Scientists worry 'Operation Warp Speed' is missing tried and true vaccines

CNN
June 17, 2020
By Elizabeth Cohen, Dana Vigue and John Bonifield

(CNN)In the search to find a vaccine to put an end to the coronavirus pandemic, some scientists worry that President Trump's "Operation Warp Speed" is missing out on tried and true vaccine technologies that have over and over again resulted in proven winners.

The Trump administration is not funding vaccine approaches that have been used for more than 50 years, including for current vaccines against hepatitis, flu, polio, and rabies.

Instead, the United States is investing up to more than $2 billion in newer approaches that are promising, but for the most part, have not resulted in approved vaccines, much less vaccines with long track records.

Saad Omer, a Yale University infectious disease expert, said Operation Warp Speed needs to widen its portfolio to include the older technologies.

"New technologies are good, and they could perform well, but we should really be hedging our bets," said Omer, who has helped develop several vaccines.

Dr. Paul Offit, a University of Pennsylvania professor who developed a vaccine against rotavirus, agrees.

"Just because it's new doesn't mean it's better," he said.

China and US taking drastically different approaches
China has taken a very different approach than the US, with four of its five vaccines in clinical trials using the older approach.

But the director of the US National Institutes of Health says there's a "need for speed," and the older approach takes "considerably longer" to develop.

"We have no time to waste," Dr. Francis Collins told CNN.

Collins said he also has safety concerns about the older approach favored by the Chinese. That approach takes the entire virus to illicit an immune response from the body, but the virus is first inactivated so it won't cause harm.

"If you weren't completely successful in inactivating the virus, you'd have the fear that the vaccine itself could be dangerous," he said. "There's always much more concern about safety."

The newer vaccines use only part of the virus, or even just its genetic material. Collins said these types of vaccines "carry no risk of conveying the actual disease."

Dr. Philip Russell, a retired major general and former commander of the US Army Medical Research and Development Command who helped develop several vaccines, also noted safety concerns with an inactivated virus vaccine.

"I think they're doing the right thing," Russell said of the US approach.
But some other scientists question if the older technology really takes that much longer, or really is more unsafe.

"The Chinese wouldn't be doing this if they didn't have a rational plan for it. They do not mess around," said John Moore, a professor of microbiology and immunology at Weill Cornell Medical College. "The Chinese are not illogical."

An announcement this week bears that out.

According to Brazilian health authorities, a Chinese company, Sinovac Biotech, will start Phase 3 clinical trials with an inactivated virus vaccine in the first week in July. Such trials are the last step before a vaccine seeks approval from regulators.

"The proof is in the pudding," said Dr. Peter Hotez, a vaccine specialist at Baylor College of Medicine who is working on a Covid vaccine that uses a different approach from the Chinese.
But vaccine experts say the older approaches can be done safely, pointing to the vaccines on the market that use inactivated viruses.

They also point out that most of the US government money is being spent on new technology that has been studied experimentally, but has never gotten to market.

"We just don't know if they're really safer," said Offit, the University of Pennsylvania vaccinologist.

Vaccines receiving US funding
So far, the US government has announced it will be funding Phase 3 trials for vaccines made by three teams: Moderna, AstraZeneca and Johnson & Johnson.

Moderna is expected to start its trial next month. AstraZeneca is scheduled to start in August, and its partner, the University of Oxford, has already started in the UK. Johnson & Johnson's Phase 3 trials are expected to start in September.

Those three teams use approaches that have been studied in clinical trials for other viruses but have never resulted in an approved vaccine.

It's unclear if funding for Phase 3 studies for other companies will follow.

In addition, the government has funded -- at significantly lower levels -- pre-Phase 3 research for three other companies that are developing Covid-19 vaccines. Of those, Merck has used the same technology for an approved Ebola vaccine, and Sanofi has used the technology for an approved flu vaccine. Versions of the platform used by the third company, Novavax, have been used on several vaccines.

The bulk of the US funding has come from the Biomedical Advanced Research and Development Authority, or BARDA, a part of the Department of Health and Human Services.

"Given the urgency of making hundreds of millions of doses of at least one safe and effective vaccine available as quickly as possible, the U.S. government is creating a COVID-19 vaccine portfolio that first leverages proven platform technologies," according to a statement to CNN from BARDA Acting Director Gary Disbrow.

"So far, we have selected vaccine candidates for this flexible portfolio based on a combination of attributes of those platforms, such as the safety and efficacy data of vaccines broadly used or licensed on those platforms for other diseases, the scalability, and the domestic manufacturing capacity. We continue to add to the portfolio as other candidates produce compelling data," Disbrow added.

That portfolio is still not wide enough for some experts.

They say if one of the US approaches works, then all will be well.

But if the Chinese are right and the US is wrong, it's unclear when the Chinese would share their vaccine with the rest of the world.

And if the first US vaccine to come on the market is only somewhat effective, or has safety concerns, some fear the American public won't believe public health authorities if they say to try the next vaccine that comes along.

The scientific community will "lose some credibility if that's the way it plays out," said Offit, the University of Pennsylvania vaccine specialist.

That's why he and others want the US to spread its wings a bit and fund a more diverse field of vaccine candidates, including the older type favored by the Chinese.

"As a scientist, I'm super excited about the new technology," said Omer, the Yale vaccine expert. "But if you think about this from a policy perspective, it's good to spread your risk."

[The ultimate covid-19 mystery: Why does it spare some and kill others?]

Washington Post
June 17, 2020
By Joel Achenbach, Karin Brulliard and Ariana Eunjung Cha

The novel coronavirus can be a killer — or no big deal. It can put a person in the intensive care unit on a ventilator, isolated from family, facing a lonely death — or it can come and go without leaving a mark, a ghost pathogen, more rumor than reality.

Six months into a pandemic that has killed more than 400,000 people globally, scientists are still trying to understand the wildly variable nature of covid-19, the disease caused by the virus.

Among their lines of inquiry: Are distinct strains of the coronavirus more dangerous? Does a patient’s blood type affect the severity of the illness? Do other genetic factors play a role? Are some people partially protected from covid-19 because they’ve had recent exposure to other coronaviruses?

Much of the research remains provisional or ambiguous, and for now scientists can’t do much better than say that covid-19 is more likely to be worse for older people — often described as over the age of 60 — and for those with chronic conditions such as hypertension, diabetes, lung disease and heart disease.

That describes tens of millions of people in the United States alone. It also isn’t much of an explanation: The link between chronic disease and the severity of covid-19 is more in the category of correlation than causation. The “why” of the matter remains unclear.

The issue of disease variability “is the most critical question about covid,” said Edward Behrens, chief of the rheumatology division at Children’s Hospital of Philadelphia.

“Why do some people get sick? Why do some people have no problem at all?” he said.

Social and demographic factors, including sex, race, ethnicity, income and access to quality health care, play major roles in how this pandemic affects people and who suffers the most. The ultimate goal of many researchers is to develop a personalized risk score — so that a person who has covid-19, or remains vulnerable to catching the disease, would have some idea of how to navigate the pandemic.

Blood markers

One potential breakthrough was highlighted by National Institutes of Health Director Francis Collins on his blog: Scientists developed an artificial intelligence tool that sorted the blood of covid-19 patients and found 22 proteins that consistently appear among the patients who are severely ill.

At this point, such a blood marker only tells doctors what they can already see with their own eyes — a very sick patient. But if such a blood test and analysis could be rolled out early in the course of the disease, it could help doctors decide which patients are most vulnerable.

Blood-type research is also intriguing. This month, European scientists posted online a study — not yet peer-reviewed — that found strong links between variations on two places in the genome and respiratory failure in covid-19 patients in Italy and Spain.

One, the ABO gene, determines blood type. The researchers found that patients who had Type A blood had a 50 percent higher risk of needing oxygen or a ventilator. Type O blood seemed to have a partial protective effect.

Why that gene matters remains unknown, according to co-author Andre Franke, a professor of molecular medicine at the University of Kiel in Germany. The genetic variant may cause the risk by being associated with inflammation.

Another possibility is that Type A blood is associated with small blood clots that characterize some severe covid-19 cases. And “there may be other things cooking in that region” of the genome, Franke said.

The consumer genetics giants Ancestry.com and 23andMe are getting involved. 23andMe recently released preliminary findings showing that people with Type O blood are 9 to 18 percent less likely to test positive for covid-19 than people with other blood types. The company is still exploring links between blood type and disease severity.

More than 750,000 of the company’s customers have completed a web-based survey about their experiences with covid-19, and 2,000 of them said they’d been hospitalized from the disease. The company is now recruiting 10,000 non-customers who have been hospitalized with covid-19.

“It would be very nice if there was a single gene that we could understand as conferring different levels of risk for covid-19,” said Adam Auton, 23andMe’s principal scientist. “In reality, dozens or hundreds or even thousands of genes are all making very small contributions toward disease risk.”

Jean-Laurent Casanova, head of the St. Giles Laboratory of Human Genetics of Infectious Diseases at Rockefeller University, is co-leading an international team searching the genomes of “outliers” — patients younger than 50 who had no known preexisting conditions, but were hospitalized with life-threatening cases of covid-19. They’re looking for unusual gene variants that these patients have in common.

Casanova and his colleagues have previously found genetic mutations that increase a person’s susceptibility to infectious diseases, such as severe pneumonia caused by influenza.

“There are many, many infectious diseases for which genetic variations have been shown to be causal,” Casanova said. “So when covid occurred, if I may say, it’s business as usual.”

How the virus infects you — and how much

Numerous papers have explored whether different strains of the virus are more transmissible or lethal. One strain has become dominant in much of Europe and the United States. That strain has a genetic mutation affecting what is called the spike protein — the structure that lets the virus bind to receptor cells in humans.

So far, there is no consensus that this or other mutations are significant from a clinical standpoint. Collins, director of NIH, says of the different strains, “I think they’re all acting the same.”

Another possibility frequently discussed by researchers is that the mode of transmission is key to understanding the severity of the disease. Many scientists argue that, contrary to what the World Health Organization and the Centers for Disease Control and Prevention have repeatedly stated, the virus sometimes spreads through tiny aerosol particles, not simply through large respiratory droplets.

That leads some scientists to think the aerosol transmission could enable the virus to penetrate deep into the lungs and trigger a more severe infection.

The body has an “innate immune system” that includes physical obstacles for any invading viruses. But tiny particles can go with the air flow and potentially reach the deepest regions of the lungs, said Raymond Tellier, a microbiologist at McGill University Health Center.

For Tellier, that’s a sign that this virus must be spreading in part through aerosols.

“How else would the virus go down the lower respiratory tract where the cells can be infected?” he asks.

The amount of virus initially transmitted from one person to another could play a role in determining the course of illness: more virus, sicker patients. Albert Ko, an infectious-disease epidemiologist at the Yale School of Public Health, said, “If I spew out a lot of virus at you and you’re one foot away, you’re going to get a higher inoculum than if you’re six feet away.”

Immune system idiosyncrasies

Even with all the focus on the virus, and its potential mutations and dosages, the most critical factor is the person getting infected — the “host.” Not everyone hosts the virus the same way. The human immune system is “a complicated tangle of pathways and partners,” as Collins puts it.

It’s conceivable, Collins said, that some people have immune systems that are better primed for this new invader because of previous exposure to genetically related coronaviruses. That’s still highly conjectural.

The immune system not only can be protective, it can also go haywire and make an illness catastrophically worse. If the immune system is an army that attacks infections, molecules called cytokines are the messengers that tell the troops what to do to beat back the invader. Too few cytokines, and the defense will be too weak, allowing the infection to progress. Too many, and the commands become a cacophony that causes an erratic and overreactive immune response — a cytokine storm.

“The army goes crazy and just sort of does more damage than they would intend to do,” said Behrens, of Children’s Hospital of Philadelphia.

“You start making too many cytokines all at the same time. Now your immune cells are confused. They’re trying to do everything all at once,” he said. “Now it’s no longer the virus that’s killing you, it’s the immune system that’s killing you.”

Some children infected with the coronavirus have a severe, sometimes fatal Kawasaki-like syndrome. It affects multiple organs — “the gut, the heart, the skin, the eyes,” Behrens said — and research by his

team suggests it is a cytokine storm. Behrens hopes the team's study of children with covid-19 will also shed light on why some adults get so sick.

Quickly identifying a storm of cytokines, which can be detected in blood tests, is key, he said. In March, CHOP developed a rapid diagnostic test, which delivers patients' results in a day. But there's much more to learn.

"What is their particular storm? Where in the process are they? Which drug should we pull off the shelf?" Behrens said. "That kind of personalized precision medicine is the holy grail for all this."

Obesity
In the United Kingdom, health officials have released two different measures of risk. One developed by the National Health Service looks at age, gender and very granular medical factors such as whether you have preexisting conditions such as high blood pressure or diabetes.

Those at low risk are asked to social distance as the economy reopens. Those at higher risk are asked to "shield," which means staying inside as much as possible and avoiding contact with others.

Jennifer Lighter, a hospital epidemiologist at NYU Langone, found that obesity was the No. 1 risk factor in her hospital system among those younger than 60. Patients with a body mass index between 30 and 34 — obese under CDC definitions — were two times as likely to be admitted to the ICU than patients with a BMI under 30. Those with a BMI of 35 and over were three times more likely to die than those with a healthy BMI.

"As we are opening up the nation, one idea is to consider opening up by risk groups," Lighter said.

In the broadest sense, the risk of a bad outcome is pretty clear. It's better to be young and healthy if the coronavirus pays a visit.

Among the 238 sailors aboard the aircraft carrier USS Theodore Roosevelt who tested positive for the virus after an outbreak on the ship, only two required hospitalization, according to a new study from the CDC. One out of 5 reported no symptoms at all.

Older people suffer from immunosenescence. Their immune systems become "dysregulated." Casanova describes this as "the inevitable descending slope of life from about the age of 18 or 19."

The median age of people who died in virus-ravaged northern Italy was 81.

"The difference between catching covid and dying is so stark the older you get, it's important to recognize that," said Carl Heneghan, director of the Center for Evidence-Based Medicine at Oxford University. In the U.K., there's been "virtually no excess death" for people under age 45 since the pandemic began, he said.

Another wrinkle: People who have little history of viral infections tend to have more severe reactions when they get infected later in life.

"You have to try and stay healthy, get fit," Heneghan said. "If you've got diabetes, you've got to lose weight and moderate that. If you do all those things, your risk of dying is small, or very small."

[There Isn't a Coronavirus 'Second Wave']
With testing, treatments and vaccine trials ramping up, we are far better off than the media report.

WSJ
June 16, 2020
By Mike Pence

In recent days, the media has taken to sounding the alarm bells over a “second wave” of coronavirus infections. Such panic is overblown. Thanks to the leadership of President Trump and the courage and compassion of the American people, our public health system is far stronger than it was four months ago, and we are winning the fight against the invisible enemy.

While talk of an increase in cases dominates cable news coverage, more than half of states are actually seeing cases decline or remain stable. Every state, territory and major metropolitan area, with the exception of three, have positive test rates under 10%. And in the six states that have reached more than 1,000 new cases a day, increased testing has allowed public health officials to identify most of the outbreaks in particular settings—prisons, nursing homes and meatpacking facilities—and contain them.

Lost in the coverage is the fact that today less than 6% of Americans tested each week are found to have the virus. Cases have stabilized over the past two weeks, with the daily average case rate across the U.S. dropping to 20,000—down from 30,000 in April and 25,000 in May. And in the past five days, deaths are down to fewer than 750 a day, a dramatic decline from 2,500 a day a few weeks ago—and a far cry from the 5,000 a day that some were predicting.

The truth is that we’ve made great progress over the past four months, and it’s a testament to the leadership of President Trump. When the president asked me to chair the White House Coronavirus Task Force at the end of February, he directed us to pursue not only a whole-of-government approach but a whole-of-America approach. The president brought together major commercial labs to expand our testing capacity, manufacturers to produce much-needed medical equipment, and major pharmaceutical companies to begin research on new medicines and vaccines. He rallied the American people to embrace social-distancing guidelines. And the progress we’ve made is remarkable.

We’ve expanded testing across the board. At the end of February, between Centers for Disease Control and Prevention labs and state public health facilities, the U.S. had performed only about 8,000 coronavirus tests. As of this week, we are performing roughly 500,000 tests a day, and more than 23 million tests have been performed in total.

We’ve also vastly expanded our supplies of crucial medical equipment. In March, there were genuine fears that hospitals in our hot spots would run out of personal protective equipment like N95 masks, gloves or, even worse, ventilators for patients battling respiratory failure. The Strategic National Stockpile hadn’t been refilled since the H1N1 influenza outbreak in 2009, and it had only 10,000 ventilators on hand.

Since then, we’ve increased the supply of personal protective equipment by the billions. Our administration launched a partnership with private industry that, as of June 12, had delivered more than 143 million N95 masks, 598 million surgical and procedural masks, 20 million eye and face shields, 265 million gowns and coveralls, and 14 billion gloves. Part of this effort, Project Air Bridge, has conducted more than 200 flights bringing equipment from overseas. In addition, we’ve worked with the private sector to ramp up ventilator production. Today, we have more than 30,000 ventilators in the Strategic National Stockpile, and we’re well on our way to building 100,000 ventilators in 100 days. No American who required a ventilator was ever denied one.

We’ve also made great progress on developing therapeutics and a vaccine. Last month, the pharmaceutical company Gilead Sciences announced it would donate about 940,000 vials of its new drug remdesivir to treat more than 120,000 patients in the U.S. Under Operation Warp Speed, the federal government is already funding research into multiple vaccine candidates, and we are well on our way to having a viable vaccine by the fall.

But our greatest strength is the resilience of the American people. From the outset of this pandemic, the American people have stepped up and made great personal sacrifices to protect the health and safety of our nation. And it’s because of their embrace of social-distancing guidelines that all 50 states have begun to reopen in a safe and responsible manner.

The media has tried to scare the American people every step of the way, and these grim predictions of a second wave are no different. The truth is, whatever the media says, our whole-of-America approach has been a success. We've slowed the spread, we've cared for the most vulnerable, we've saved lives, and we've created a solid foundation for whatever challenges we may face in the future. That's a cause for celebration, not the media's fear mongering.

Mr. Pence is vice president of the United States.

Correction
An earlier version misattributed the total numbers of personal protective equipment delivered through FEMA to just Project Air Bridge.

Volunteers sign up to put their lives on the line for a coronavirus vaccine

Washington Post
June 15, 2020
By Ben Guarino and Carolyn Y. Johnson

Lehua Gray, a 32-year-old product manager in Austin, wants to risk her life for a coronavirus vaccine. A cloud of potentially deadly microbes would be spritzed up her nose — if she's allowed to participate in what's called a human challenge trial.

It's built on a deceptively simple premise: Researchers inject healthy volunteers with an experimental vaccine and then expose them to a pathogen. If the vaccine prevents volunteers from getting sick, the study can accelerate development of a promising formula.

This approach has been used to test malaria and cholera vaccines — and now, in laboratories and conference rooms, preliminary discussions are unfolding about the feasibility of employing it in the quest to find a weapon against the novel coronavirus.

The obstacles are formidable. Infecting healthy people with a potentially lethal virus, with no treatment to save them from severe illness or death, raises some of the most fraught ethical, scientific and philosophical issues in the history of medicine. Exposure to pathogens in challenge trials is usually permitted only for diseases that aren't fatal or that have treatments available. No such assurances exist for the coronavirus, which has killed more than 435,000 people worldwide.

Francis Collins, director of the National Institutes of Health, said in an interview that challenge trials are "on the table for discussion — not on the table to start designing a plan."

Large-scale trials of coronavirus vaccine candidates are slated to begin this summer and fall, but they involve more conventional approaches.

When Gray explains to her family her interest in potentially participating in a challenge trial, "it starts out being a conversation about FDA processes and ends up being a conversation about how I'm about to risk my life," she said.

Despite that risk, Gray and more than 28,000 other volunteers have joined a new online organization, 1Day Sooner, hoping that by placing themselves in the path of the virus, the pandemic will end sooner.

Ethical quandaries
One of the first studies to endorse coronavirus challenge trials was published in March in the Journal of Infectious Diseases. Rutgers University bioethics specialist Nir Eyal and his colleagues proposed using challenge trials to supplement or even supplant a Phase 3 trial, the lengthiest and final step in vaccine creation.

In a typical Phase 3 vaccine trial, which is required for Food and Drug Administration approval, thousands of participants receive an inoculation, either an experimental vaccine or a placebo. To test whether a vaccine prevents infection, researchers wait until subjects have been naturally exposed in their communities. This process can take six months or more. Even as pharmaceutical companies race to make a coronavirus inoculation, the wait may stretch a year or longer for a vaccine to reach the market.

As coronavirus cases decline in the regions hit hardest in the spring, some experts worry a traditional Phase 3 trial may take too long or not gather enough evidence to be conclusive. Because challenge trials guarantee exposure, these studies require as few as 100 subjects and can be completed in two or three months.

A challenge trial may not be able to bypass a Phase 3 trial or efficacy study but can help in other ways. “If you’re looking at 100 vaccines, some of them might turn out be total busts,” said Neal Dickert, a bioethics specialist at Emory University who has studied flu challenge trials. Using that approach with the coronavirus trial could help scientists shelve the busts sooner.

In the months since Eyal and his co-authors published their paper, support for challenge trials has grown among specialists in bioethics. Charles Weijer, a professor at Canada’s Western University, said coronavirus challenge trials presented the hardest question he has faced in 24 years as a bioethics expert.

A paramount tenet of conducting human research, dating to the Nuremberg Code, is informed consent — in which people fully understand the risks and limitations of participating.

“Most ethicists agree there is an upper limit of risk,” said Seema Shah, an ethics professor at Northwestern University’s Feinberg School of Medicine. “It wouldn’t be okay to sacrifice one individual for the benefit of many others.”

When Weijer helped develop guidelines for challenge studies in 2015, a central idea was “that volunteers in human challenge studies in no circumstance will be exposed to diseases that are irreversible, incurable or possibly fatal,” he said. Coronavirus trials violate that concept.

“It makes me very worried that in a covid-19 challenge study, should we go ahead, that odds are some people are going to be seriously injured and some people are going to die,” Weijer said. “The question for me then is: What can we do to mitigate those risks?”

To answer that, the World Health Organization convened a panel of ethics experts and researchers from around the globe, including Weijer and Shah. They wrote a 19-page document explaining criteria for conducting these studies. The report emphasized informed consent, minimizing risk (people 18 to 30 have the lowest fatal infection rate, the authors noted) and the need for “strong scientific justification.”

Careful site selection is also important. Drawing participants from communities where transmission is high may reduce the relative risk to volunteers because they would be more likely to catch the virus anyway — but this should not exploit populations vulnerable to the virus, ethics experts agreed. “This disease has obvious socioeconomic disparities and racial disparities that we have to be aware of in the context of doing things like challenge studies,” Dickert said.

The WHO panel opened the door for challenge trials to proceed. “Well designed challenge studies might thus not only accelerate covid-19 vaccine development,” they wrote, “but also make it more likely that the vaccines ultimately deployed are more effective.”

Shah and another group recently published in the journal Science an ethical framework for coronavirus challenge trials. “Moral disagreements about upper limits to risk” exist, they wrote, but risks can be tempered by isolating subjects in inpatient facilities under careful observation.

Challenge trials have been compared with other selfless acts. There's a flaw in that thinking, Shah said. Firefighters and kidney donors can feel confident their altruism will benefit someone, she said. It's uncertain any clinical study will make a difference.

"The Ebola experience is one cautionary tale where there were these two massive trials that tried to determine whether vaccines worked," Shah said. These traditional vaccine trials "couldn't come to completion. They couldn't get an answer." A third trial worked: A "ring" vaccination, in which clusters of people who were friends or relatives of infected people received vaccines.

Shah said she is reasonably confident challenge trials will happen somewhere. "I don't know if they'll happen in the United States," she said.

Uncertain possibility

In April, dozens of members of the House of Representatives sent a letter to Health and Human Services Secretary Alex Azar and FDA Commissioner Stephen Hahn urging them to consider implementing challenge trials.

The risk of death looms large. "If this went all wrong, and some healthy volunteer died as a result, that would be impossible to forgive ourselves," Collins, the NIH director, said.

Collins and other leaders of the U.S. vaccine effort wrote in Science in May that such experiments would have to be carefully considered by an independent panel of specialists in ethics, clinical trials and vaccines.

"Some vaccine makers have communicated to us that they would be interested if FDA let them do it," Eyal said, though he declined to name them.

Johnson & Johnson chief scientist Paul Stoffels said in an interview that the company was not currently considering challenge trials and was focused on a traditional large-scale trial slated to begin in mid-September.

"We don't think, at the moment, it will help in the speed to results," Stoffels said, noting that important scientific work would have to be done to develop a model for challenge experiments and a medication would have to exist to treat people who became ill.

But if countries are successful at controlling their outbreaks, it will pose an obstacle to vaccine researchers who in traditional trials give half the participants a dummy shot and depend on enough people becoming infected to see whether their vaccines are protective.

"If the disease gets to a very low level, maybe challenge studies will have to be considered," Pascal Soriot, chief executive of AstraZeneca, said at a briefing with other pharmaceutical executives.

Other manufacturers are apprehensive. Leaders from Moderna and Inovio Pharmaceuticals, two biotechnology companies with vaccines in early human trials, have said the risks of challenge studies outweigh the benefits.

A joint effort to develop a vaccine by Sanofi and GlaxoSmithKline will not use human infection trials because "we have sufficient knowledge of the vaccine technology we're using, as it is based on a technology we are using for another vaccine," said Sanofi spokesman Nicolas Kressmann.

Pfizer is not considering challenge trials at this time, except in animal experiments, a spokeswoman said.

Some sponsors of influenza challenge trials, such as the Bill & Melinda Gates Foundation, are worried that if the covid-19 challenge trials proceed and people die, the field will suffer.

Another objection is the scientific interpretation. If young, healthy people who participate don't develop severe disease or have only mild illness, what would it mean? A sizable fraction of people — particularly those at low risk — who are infected do not develop severe disease or even symptoms.

"People we're really worried about — the elderly and with chronic diseases — would not be volunteering," Collins said. "And can you really extrapolate from saying this 22-year-old recruit from the military did fine, that 72-year-olds and people with [chronic obstructive pulmonary disease] would do well and be protected?"

Kathleen Neuzil, director of the Center for Vaccine Development and Global Health at the University of Maryland School of Medicine, is experienced running challenge trials involving potential vaccines for diseases that have treatments. "We've done them for malaria, influenza, shigella. What makes me personally cautious about doing them for SARS-CoV-2 is, at the moment, we don't have a rescue medication," Neuzil said, meaning a way to save an infected person's life.

If challenge trials were to proceed, she said, "this is going to take some very careful thought and very careful planning."

Challenge trials need to be run in facilities with extensive infection control, where participants may have to live for weeks under close supervision — explaining why many bioethics experts conclude challenge trial volunteers should be paid. Only a few organizations, such as NIH, operate these high-level biosecurity facilities.

Researchers will need to cultivate, at scale, the virus in a laboratory; one option is to use a weakened strain less likely to cause severe sickness. And after the virus is grown, scientists must determine the proper amounts to give volunteers.

28,000 volunteers and counting

Two months ago, Josh Morrison, a 34-year-old attorney and activist who represents kidney donors, read Eyal's paper. Inspired, he and friends founded a website called TheCovidChallenge.org. Sign-ups snowballed — by mid-May, as many as 1,500 new people were joining daily — and the organization was renamed 1Day Sooner.

1Day Sooner now employs Morrison and three other people. It has more than 28,000 volunteers and a German-language chapter in Austria. "Our job is advocating for or representing people. We want people to sign up," Morrison said.

The organization is collecting donations, which Morrison said will be used to pay for a $50,000 research survey on volunteers. The organization is also trying to hire a vendor to manufacture the microbe.

Most members of 1Day Sooner are young, but Morrison said some who have joined are in their 80s. Many have backgrounds in public health or science. Yet signing up with the organization is no guarantee members will get to participate in a challenge trial.

Volunteers say the trials could provide a sense of purpose in a time of chaos and helplessness.

"Being able to do something constructive and useful, that meant a lot to me," said Morrison, who in 2011 donated a kidney to a stranger. "The risks are very meaningful and significant, but also roughly on par with childbirth or kidney donation." The risk of death for kidney donors is about 1 in 3,000 people, which mirrors the coronavirus infection fatality ratio among people in China in their 20s.

Eyal, who has been in contact with 1Day Sooner, said he held the volunteers in high esteem. "They certainly can't be dismissed as people who misunderstood what this is about," he said. They "actually comprehend the risk and still want to participate."

There is little precedent for the creation of this organization — akin to a Screen Actors Guild for human subjects — let alone one established for study participants before studies exist.

Human subjects are often viewed as “people to worry about” or guinea pigs, Shah said. “So I have a lot of respect for the idea of bringing together research participants.”

Gray said she draws motivation to participate in a challenge trial from her grandmother, who is vulnerable to respiratory disease because of lung problems. Gray’s girlfriend and parents have been supportive. A close friend is not.

“Whenever she reads something about long-term damage, that’s what she’s worried about,” Gray said. “It’s possible that I wouldn’t die, but I would have permanent lung scarring or something like that.”

Gray said she was among the first 1,000 people to join after reading about the project on Facebook. “If I can save lives with very little risk to myself,” she said, “I almost feel like: How could I not?”

Fifty-four scientists have lost their jobs as a result of NIH probe into foreign ties

Science
June 12, 2020
By Jeffrey Mervis

Some 54 scientists have resigned or been fired as a result of an ongoing investigation by the National Institutes of Health into the failure of NIH grantees to disclose financial ties to foreign governments. For 93% of the 189 scientists whom NIH has investigated to date, China was the source of their undisclosed support.

The new numbers come from Michael Lauer, NIH’s head of extramural research. Lauer had previously provided some information on the scope of NIH’s investigation, which had targeted 189 scientists at 87 institutions. But his presentation today to a senior advisory panel offered by far the most detailed breakout of an effort NIH launched in August 2018 that has roiled the U.S. biomedical community, and resulted in criminal charges against some prominent researchers, including Charles Lieber, chair of Harvard University’s department of chemistry and chemical biology.

“It’s not what we had hoped, and it’s not a fun task,” NIH Director Francis Collins said in characterizing the ongoing investigation. He called the data “sobering.”

In the vast majority of cases, Lauer reported, the person being investigated has been an Asian man in his 50s. Some three-quarters of those under investigation had active NIH grants, and nearly half had at least two grants. The 285 active grants totaled $164 million.

Lauer also presented data on the nature of the violations that NIH has uncovered. Some 70% (133) of the researchers had failed to disclose to NIH the receipt of a foreign grant, and 54% had failed to disclose participation in a foreign talent program. In contrast, Lauer said, only 9% hid ties to a foreign company, and only 4% had an undisclosed foreign patent. Some 5% of cases involved a violation of NIH’s peer-review system.

Lauer said the fact that 82% of those being investigated are Asian “is not surprising” because “that’s who the Chinese target” in their foreign talent recruitment programs. Some 82% are men, and their median age is 56, with the youngest being 48 and the oldest 59. Slightly more than one-half had been an NIH peer reviewer in the past 2 years, and 41% of those under investigation (77 scientists) have been barred by their institutions from submitting a grant proposal to NIH or serving as a principal investigator on an NIH award.

NIH has been in the forefront of federal efforts to identify and block behavior that many U.S. government officials say poses a significant threat to the country's economic well-being and to national security. Several bills pending in Congress seek to limit that threat in various ways, including by limiting the flow of scientific talent from China to the United States, and by restricting access to federally funded research that provides a foundation for cutting-edge technologies and new industries.

Lauer's presentation also provided a glimpse into the scope of that broader investigation. There are 399 scientists "of possible concern" to NIH, he told the advisory council, and the Federal Bureau of Investigation has fingered 30% (121) of them. An additional 44 have been flagged by their own institutions. Of that pool, Lauer said, investigations into 63%, or 256 scientists, came out "positive." Investigations into some 19% came up "negative," he noted, whereas the status of the remaining 18% is "pending."

*Correction, 19 June, 1:15 p.m.: This story has been revised to clarify the pool of scientists who have failed to disclose financial support from foreign sources and the actions that their institutions have taken.

'Having an Effective Vaccine by the End of this Calendar Year Is Achievable.' NIH's Francis Collins on the Big Push

TIME
June 11, 2020
By Belinda Luscombe

Dr. Francis Collins is a geneticist, former head of the Human Genome Project and the current director of the National Institutes of Health, the government agency primarily responsible for health research in the United States. In May, he joined the White House Coronavirus Taskforce. He also won the Templeton Prize, a $1.3 million prize for scientists who explore issues of faith. He talked to TIME about vaccine research, the World Health Organization, and whether evangelicals are more given to conspiracy theories.

Do you have a best guess for when we might have a vaccine for COVID-19?

Having an effective vaccine by the end of this calendar year is achievable. But let no one imagine that that's a done deal. People say this is like going to the Moon, you just decide to do it. No. That was engineering. Those laws are pretty well worked out. We know how gravity and electronics work. We still don't know enough about how the human body and the immune system and viruses and their biology work. So we are doing everything humanly possible to get that vaccine out there. But there are certain unknowns that we can't ignore.

What were the driving factors in choosing the vaccines that the U.S. is focusing on?

The COVID-19 vaccines chosen for testing on a large scale this summer are those that have moved quickly enough to show evidence of producing a good immune response in a small number of volunteers. It was also important to invest in vaccines that used different scientific strategies, because this is a new virus, time is of the essence, and we want to be sure that we have the best possible chance of success for at least one of these vaccines. And finally, it was really important that the approaches being funded would be as safe as possible.

Are you worried when we get a vaccine that people will accept it?

I am worried. Naively, I thought if people actually saw a disease around them that was causing suffering and death of people they knew, that they would have a harder time resisting the idea that this could be our best hope as a nation. But I'm seeing stirrings that may not actually have that turn out to be true. We don't at the moment have sort of an organized counter approach, but maybe we should start thinking about that. Talk about a terrible outcome here: suppose we are fortunate and by January of 2021 have

three hundred million doses of vaccine to give to people in the U.S. and millions more in the rest of the world. And a significant proportion of the people, whose lives could be saved, decide they don't want it, because of conspiracy theories and other false information. And as a result, we end up not achieving the kind of herd immunity that you need to keep this from coming back year after year. What a terrible tragedy for us, supposedly advanced society.

You have in past called yourself an Evangelical, but it seems in our current situation that the people pushing back at the need for such drastic actions to stop the spread of the coronavirus are also often people who would call themselves Evangelicals. Why do you think that is?

You will hear from the extreme views because they make news. But I actually think most believers don't buy into the idea that this is a conspiracy, nor do they buy into the idea that you can ignore the public health recommendations. Those rare ones who do and assemble anyway, who say I don't need no vaccine because I got Jesus, those are probably not representing the majority by far of people who both know that science is the best hope we've got in this crisis and also believe in God.

Why do you think the U.S. has not been able to manage the pandemic as well as other countries?

The U.S. is a big sprawling country, with people who have very strong opinions about who's allowed to tell them what to do. And so even in circumstances where efforts were made early on to try to encourage people to take care about not distributing the virus by their own behavior, it took a while for that to click in. We're not China. We don't have an authoritarian government who can basically say now hear this. We are basically a sort of a bottom up public health system, not a top down. And we're counting on the American public, now that they've had the information, to act accordingly.

Many states are opening up now. Too soon?

It depends. Every state is in a different situation. Every part of every state is in a different situation. Certainly in places where they have not had any cases of COVID-19 and where they're doing adequate testing to be able to say it's really not out there in their community, the idea of beginning to open up makes sense because this is causing great economic stress and suffering for people. On the other hand, if you're in a circumstance like where I am right now in the outskirts of Washington D.C. where this epidemic is still going strong, it would be quite dangerous to decide to simply open up and hope for the best.

You recently won the $1.3 million Templeton Prize, which is given for "celebrating scientific and spiritual curiosity." What does that mean?

John Templeton started this prize because he was interested in how in a modern world spirituality could still be significant in the lives of people and be a contributor to the enrichment of their experience. I assume that the selection this year was based upon the fact that I have been very outspoken about the harmony that I see between science and faith.

In money the Templeton is worth more than the Nobel, but it doesn't quite have the buzz. The Bible says it's wrong to lie, so which would you prefer?

Oh my. Can I have both please?

In April the NIH launched a public private partnership to fund research and development treatments for COVID-19 and included some European agencies. Why did you feel the need to do that?

It was clear that we needed to pull all of the resources, all of the talents, all of the organizations together and work in a coherent way and not go after COVID-19 with a whole bunch of scattershot projects. And the only way to really do that in my experience is you get everybody around the same table. That means bringing together industry, 18 companies now, the National Institutes of Health, the largest supporter of medical research with public funding, the CDC, the FDA, the Europeans, and saying 'OK everybody, let's

not do this in an uncoordinated way, let's figure out what are the most critical things that need to happen and let's do them together.' And that's what we are now doing. I've never seen it happen quite like this, with such a broad endorsement of that kind of collaborative effort. And I've certainly never seen it happen this fast.

It sounds like the World Health Organization (WHO). Do you have concerns about WHO and its ability to bring together people in that way?

WHO has a tough job. They can't generally draw conclusions or move in a direction until they get sign-off from more than 100 countries. And they have to take that very seriously as part of their mandate. They are our partners in many ways and have been for many decades.

Are you a supporter of the moves to distance America from WHO and to withdraw funding?

Illnesses don't care too much about country boundaries. I don't think it's a good idea when it comes to health issues for us to consider that we can really handle those effectively just by looking at our own nation. We could be not just the soldiers to the world, which we have been over history, but also the doctors.

You're Anthony Fauci's boss. What do you say to him?

Tony and I talk some time between 8:00 and 10:00 o'clock every night. It's a wonderful partnership. I have joined him as part of the White House task force [on COVID-19], so he has another ally in the room when those discussions are happening about what's the right thing to do and is it too soon to open up and what do we really know about the effectiveness or this or that treatment. It'll be nice to be there with him.

Why did you feel the need to join him?

I was invited, it made me feel that the White House is interested in getting even additional scientific input. I see that the task force is shifting its emphasis now even more in the direction of the scientific arguments about what we need to do next and particularly about treatments and vaccines and how can we speed that up. I'm right in the middle of that, so it makes more sense now.

What has surprised you most about this pandemic?

I was unprepared for a virus that could infect people without any symptoms and have them be highly infectious. That's new.

Has this made you rethink whether or not the US would benefit from a system of healthcare that has more universal basic health coverage?

There's no question that COVID-19 has shone a bright light on the very serious issue about health disparities in the United States. Look at the State of Georgia where 30% of its citizens are African American, but 80% of the people in the hospital with COVID-19 are African American. We've kind of known that; NIH has been deeply engaged in trying to come up with ways to change that. But most of the public hasn't really paid that much attention to the fact that our healthcare system has so many inequities built into it. You can't look at this now without seeing those. And it does make you wish for a better system.

Are you a supporter of some form of universal public healthcare?

I think healthcare ought to be a right and not a privilege. To the extent that that is not true in the United States, we've got work to do. Our current systems have not achieved that kind of principle. And we've got to keep trying.

What does a day look like for you?

I got up this morning at 3:30, because I had so may things I needed to get ready before the day kicked in. Everything matters. I've never felt the same sense of urgency in 27 years at NIH than I do right now. One feels that even one little mistake could cost a day, might have a real consequence in a few more months in terms of somebody's life. We have to press on with every kind of energy, collaborative potential, and intelligence and creativity that we can, and not make mistakes. But we also have to take risks. So put that all together, that's why I'm getting up at 3:30.

You wrote in your book The Language of God that the principles of faith are complementary with the principles of science. Since it's impossible to prove that God exists, how can this be true?

Faith, as you say, does not involve proof, but there's certainly plenty of rational arguments to support the belief in a creator god. That's where I found myself at age 27 when I was trying to prove my atheism and discovered that atheism is probably the least rational of all the choices, because it takes the position of asserting a universal negative, which scientists in general are discouraged from doing.

NIH strengthens policies to alert agency to sexual harassment by grantees

Science
June 11, 2020
By Jocelyn Kaiser

The National Institutes of Health (NIH) is tightening grant rules that until now have sometimes left the agency in the dark about sexual harassment cases involving researchers it supports. Starting tomorrow with new awards, NIH will require institutions it funds to report to the agency when an investigator is removed from a grant because of harassment findings or allegations.

NIH also wants to know when an investigator is moving their grant to another institution because of sexual harassment findings or concerns, Director Francis Collins and other officials announced in an editorial in Science today. Along with other new policies, the changes will "further foster a culture whereby sexual harassment and other inappropriate behaviors are not tolerated in the research and training environment," the NIH officials write.

Together, the new reporting requirements will "close two important gaps" in the agency's policies, says NIH Associate Director for Science Policy Carrie Wolinetz, and should prevent cases in which institutions

The changes put the NIH closer—but still not on the same level—as the National Science Foundation (NSF). That agency requires institutions to report sexual misconduct findings even if there's no change in an investigator's grant status. NIH has said it doesn't have the legal authority to adopt that policy.

Still, "I'm very pleased. It's definitely a step in the right direction," says Johns Hopkins University biologist Carol Greider, a member of a working group that in December 2019 advised NIH to make today's policy changes.

Scientists can step down from their grant for a range of reasons including medical leave, a job change, or a misconduct investigation. Institutions must report such changes in status, but until now, NIH did not ask why. The agency has said it did not have the legal authority to ask.

But after "many conversations" with legal experts, Wolinetz says, the agency realized it could fold harassment into grant rules that require "safe and healthful working conditions." That's usually been limited to things like chemical safety. But a notice says any request to NIH to change the grant's key personnel should "mention as to whether change(s) … is related to concerns about safety and/or work environments (e.g. due to concerns about harassment, bullying, retaliation, or hostile working conditions)."

If an institution reports allegations or findings of harassment, NIH staff will review the information and decide, for example, whether the grant should end or be transferred, and whether the investigator should remain eligible for NIH funding. If a grantee is moving to a new institution because of harassment findings, the agency plans to inform the new institution about the investigator's record.

The policy doesn't go as far as NSF's, which requires that the agency be notified within 10 days of sexual harassment findings or when the institution takes an administrative action, such as putting an investigator on leave because of harassment allegations. (NIH's new reporting requirements merely say NIH should be informed "promptly.") Although the working group recommended such a direct reporting requirement—and it is part of draft legislation in Congress creating a governmentwide policy—doing so now would require NIH to go through lengthy formal policymaking steps, Wolinetz says. The new policy changes "will hopefully capture the vast majority of cases," she says. "This gets us nearly all the way there."

Greider worries, however, that there may still be loopholes. For example, an investigator found guilty of harassment could transfer their grant to a colleague, then move to a new institution and apply for a new grant. "How would the new institution know" about the earlier misconduct, she asks.

Columbia University virologist Angela Rasmussen, another working group member, agrees with Greider that NIH still has work to do to encourage institutions to create a safe lab culture. The new policy "is a necessary first step in a much longer journey," she says.

And BethAnn McLaughlin, a leader of the #MeTooSTEM movement, thinks NIH should go further by making public how it responds to cases of sexual harassment by grantees. "I don't have a lot of good faith in a process where some closed door NIH people are making decisions," she says.

Both NIH and NSF have tightened their policies in response to a series of prominent sexual harassment cases that the agencies only learned about from media reports even though it was funding the alleged harassers. NIH has already beefed up its processes, for instance by creating a web form for victims to report sexual harassment allegations to the agency. Since the start of 2019, the agency has learned of 142 harassment cases and removed 14 investigators from grants, Wolinetz will report tomorrow to NIH's Advisory Committee to the Director.

[As pandemic pounds U.S. universities, federal support helps their labs stay afloat]

Science
June 5, 2020
By Jeffrey Mervis

This spring, as the coronavirus pandemic shuttered U.S. higher education, many college presidents began to warn of the dire financial impact of a frozen U.S. economy on their institutions.

Their mix of revenue sources largely determined how much they might be hurt. Universities that operate their own hospitals issued the shrillest warnings—with some forecasting losses of a half-billion dollars and more from the temporary suspension of elective surgeries and the added cost of treating COVID-19 patients. Public institutions that receive a significant amount of state funding said they were bracing for double-digit cuts from legislatures facing huge losses in tax revenue. Those with large endowments cited the stock market's steep plunge in March as a major setback, although equities have since staged a strong recovery. In every case, those alarm bells were accompanied by a slew of cost-cutting measures designed to soften the financial blow from the pandemic.

Amidst the sea of red ink, however, one stream of revenue has remained healthy: the money universities receive from others—especially the federal government—to carry out research. That fact looms large in any effort to forecast the impact of COVID-19 on U.S. academic research.

The federal government is by far the largest supporter of what is called sponsored research, providing roughly 53%, or $42 billion, of the $79 billion worth of research done on U.S. campuses in 2018. That's more than twice what institutions themselves put up, with the remainder coming from industry, foundations, and state and local governments.

Moreover, federal support for academic research seems likely to grow during the pandemic. This spring, Congress included an additional $3.6 billion for research related to COVID-19 in a string of economic relief packages, and some of that money will flow to university laboratories. There's a good chance that future packages also will contain additional funding for research.

That prognosis has put university research administrators like Chris Cramer in an enviable position during ongoing budget meetings with other senior academic officers. "These days, I'm the only one who gets to say that, even with large error bars, none of my projected numbers are in the red," says Cramer, who oversees the University of Minnesota's $870 million portfolio of sponsored research.

"Getting the job done"

One reason Cramer can be upbeat is that the U.S. government, unlike most sectors of the economy, has remained open during the pandemic. And its machinery for awarding grants has been minimally affected, even as the number of COVID-19 cases in the United States has risen to 1.8 million and the death toll has topped 107,000.

"We went to 100% virtual peer review [of grant proposals] practically overnight, and it's gone remarkably well," says Michael Lauer, director of the Office of Extramural Research at the National Institutes of Health (NIH). NIH provides about two-thirds of all federal funding for academic research, so the state of its operations is vitally important to the community. And despite the fact that almost all NIH staff have been working from home since mid-March, Lauer says, "We are getting the job done without major problems."

Cramer can testify to that. "I just got our third quarter numbers and they are holding up well," he says about the university's overall research portfolio, which nationally ranks in the top 20 by size and for which NIH is the single largest source. "In fact, we're actually $2 million ahead of last year."

Adding to the good news for academic researchers is the fact that, although some 40 million U.S. workers have filed for unemployment since the start of the pandemic, scientists supported by federal grants have continued to draw their pay, even as their campuses are shuttered. In March, the White House Office of Management and Budget (OMB) gave institutions permission to continue to charge salaries to their federal grants during the closures. (To be sure, the pandemic has still squeezed the personal finances of most faculty members, whose institutions have frozen salaries and, in some cases, suspended contributions to retirement accounts.)

University administrators hope the OMB policy, which now expires on 17 June, will be extended. And they applaud the government's recognition of how research is actually conducted. A federal grant covers much more than the cost of just running experiments or collecting field data, they note. And many grantees can continue to draw pay for performing those many other activities—such as writing and reviewing papers, analyzing data, and supervising students and postdocs—even if they are at home.

COVID-19 hasn't relieved him of any of those duties, says Dominique Durand, a professor of neural engineering at Case Western Reserve University. Like most professors, Durand functions as the de facto owner of a small business, with responsibility for hiring people, meeting payroll, and maintaining inventory. He must also satisfy the customer—in this case, the federal agency that is funding his research.

"To be honest, the impact [of the pandemic] on my research hasn't been that significant," says Durand, whose lab has received core support from NIH for decades. "There are things we haven't been able to do, for sure, but as long as you're still making progress on the grant, NIH says it's OK." (Full disclosure: Durand is married to this reporter's sister.)

Behind the projections
Depending on the source of funding and the nature of the work, academic research can help subsidize other university activities—or require additional institutional funds. Annual financial reports don't reveal those differences. But in baring his school's financial soul in response to COVID-19, the president of Johns Hopkins University shed some light on how things operate at an institution that leads the nation in the amount it spends on sponsored research, some $2.5 billion annually.

In a 21 April letter to the Johns Hopkins community, Ronald Daniels wrote that income is projected to dip by $175 million for the fiscal year ending 30 June, and that next year's shortfall could total $475 million. But the impact on research will be comparatively small, his analysis suggests.

More than half of the projected drop in income over the next 15 months comes from the loss of up to $300 million in revenue at its vast network of hospitals and clinics, Daniels wrote. But that blow will be felt mainly by the physicians who perform those procedures. In contrast, he explained, the university itself expects to be eventually reimbursed for the additional cost of caring for COVID-19 patients.

Individual faculty members will also feel the pinch. The university expects to save $100 million by suspending retirement contributions for 1 year, he writes, and another $20 million by freezing salaries.

A 1-year hiring freeze is expected to save an additional $40 million, he wrote. But the freeze doesn't mean there won't be fresh faces on campus; the unceasing competition among top research institutions to attract talent and funding all but guarantees that there will be exceptions.

"The university must emerge from this crisis stronger, and making strategically important faculty hires is crucial to that end," a university spokesperson says. "We expect our schools will … make the investments necessary to excel even in a constrained budgetary environment."

Those hires, often accompanied by multimillion-dollar startup packages, would normally be paid out of what Daniels said is an operating surplus of 1% to 2% in an annual budget that this year stands at $6.5 billion. COVID-19 has erased that surplus, he said, leaving administrators with the task of finding other sources for such investments in talent.

The role of endowments
One such source could be the institution's endowment. But because of their sometimes immense size and the secrecy that surrounds how the money is managed and spent, endowments are one of the most contentious components of university funding.

As a rule, private institutions sit on much larger endowments than do public universities. Harvard University's towers over the rest of U.S. higher education, at roughly $40 billion, although dozens of institutions have endowments that top $1 billion. Johns Hopkins's falls in the top tier, at more than $6 billion.

Although Daniels called philanthropy "a cornerstone of our overall financial picture," he said the endowment supplies only about 4% of the university's annual operating budget, or about $200 million annually. (By comparison, Harvard's Faculty of Arts and Sciences, which houses many of its natural science departments but not its medical and applied science programs, receives half of its annual $1.5 billion operating budget from the endowment.)

Originally, Johns Hopkins had projected receiving an additional $5 million from endowment income this year, Daniels noted. But the stock market's plunge in March reduced the endowment's value by $350 million as of mid-April, he said, resulting in a projected $5 million drop in this year's payout.

Other institutions have been far less transparent in describing their financial situation, much less how research might be affected. For example, Harvard's executive provost, Katie Lapp, projected last month that overall university revenues next year would be $750 million short of initial estimates. Those losses,

she wrote in a letter to the Harvard community, “will require difficult cost saving measures.” But the university has provided no details.

One uncertainty facing research universities is COVID-19’s impact on what are called indirect costs. That category encompasses the supplies, facilities, and administrative staff needed to carry out research and comply with federal regulations.

Roughly one-third of every federal research grant going to a university is spent on reimbursing the institution for such costs.

At Johns Hopkins, Daniels said the university expects to lose $55 million this spring on indirect cost recovery. Its scientists working on non–COVID-19 related research have stopped buying lab animals and reagents, for example, so the university isn’t billing the government for them. At the same time, the university is still paying for such fixed costs as utility bills.

But those losses will be only temporary, Daniels acknowledged. As Johns Hopkins reopens its laboratories, he wrote, “Our reimbursements will recover.”

Sweating the details

Although most institutions are still figuring out what the fall semester will look like for undergraduates, many have already begun to reopen their labs, albeit under very strict protocols regulating access to and use of lab space. The nature of the academic research has helped, research administrators say. “Scientists are familiar with keeping things clean, following protocols, and operating safely,” says David Conover, senior vice president for research at the University of Oregon, which recently began a phased reopening of its campus.

On 21 May the University of Michigan (UM), which ranks second to Johns Hopkins in the size of its sponsored research portfolio, reopened eight buildings in the first of four phases. Its goal is to have all 50 of its research buildings, housing some 5000 labs, up and running by early July. Every component of the university has been involved in the planning, says Rebecca Cunningham, UM’s vice president for research. But that doesn’t mean every faculty member is on board.

“There’s a bimodal distribution,” she says. “Some are trampling down the doors, and others have serious concerns. They want to do research, and they want to be safe.”

To address such concerns, Cunningham and five other senior administrators at research universities last week offered guidance for institutions on reopening safely. Their suggested checklist includes conducting health checks at entrances, controlling access, reducing density, revising work schedules, and requiring personal protective equipment and deep cleaning, as well as contact tracing and quarantining when someone tests positive for the coronavirus.

At UM, Cunningham and her team believe paying close attention to the details is essential for success. Results from its first wave of lab openings, for example, included collecting data on wait times for entering the buildings (an average of 3 minutes) and the number of scientists who tested positive (zero, from the first cohort of 667).

“It’s a new way of working,” she says, “like with grocery shopping. But people understand that it’s necessary.”

A plea for federal help

Even as some universities reopen labs, administrators and research agency officials say billions more in federal dollars will be needed to keep academic science healthy once the pandemic subsides. One problem, they say, is that the money now being used to sustain the scientific workforce isn’t producing the full output envisioned when the grant was awarded.

Testifying last month before a Senate health panel, NIH Director Francis Collins said he views the lost productivity—an estimated $10 billion—as money that has simply “disappeared” from the agency’s budget. Asked how NIH arrived at that figure, Lauer said that he assumed grantees had worked at just 25% of their expected efficiency for the first 3 months of the pandemic (March to May), and that their productivity will rise to 50% productivity over the next 2 months (June and July) as their labs reopen.

Lobbyists for science and university groups have arrived at a similar number using a different formula. They argue that any savings by grantees during the first 4 months of the pandemic—from canceling supply orders and travel, for example—will be erased by the additional costs of shutting down and restarting research.

To make up for such losses—and much more—a 330-member coalition called the Ad Hoc Group for Medical Research asked Congress on 27 April to add $31 billion in supplemental emergency funding to NIH’s budget for the fiscal year ending on 30 September. Analysts say some of that money could be used to supplement existing grants so that researchers will have the additional time—and resources—they will need to complete their projects. Many of the same organizations are also asking legislators to approve $46 billion in direct payments to universities to recoup lost tuition and other costs created by COVID-19.

University officials hope the prominent role their scientists are playing in fighting the pandemic will help persuade lawmakers to provide aid. “When have research universities ever been more in the news?” Cramer asks. “We’re on the front pages every day.”

Helping themselves

It may be weeks before Congress settles on the next pandemic recovery package. In the meantime, some institutions have already begun to lower their initial projections of staggering losses.

On 24 April, for example, UM President Mark Schlissel warned of a shortfall running anywhere from $400 million to $1 billion; as at Johns Hopkins, much of it was from the disruption to its vast medical system. But 1 month later, Schlissel told the UM community the belt-tightening moves he implemented this spring, including salary and hiring freezes and a suspension of new construction, would likely cover the “lower range of projected shortfalls” under the latest scenario.

The $370 million that the school’s $12 billion endowment contributes to operating expenses “is helping us a lot,” he acknowledged, even if the stock market is still below its February highs. That rosier outlook comes despite what Schlissel warned was likely to be a significant drop in state aid as a result of a $3 billion hole in the state’s budget.

The sheer size of many top U.S. research universities may help insulate them from the worst economic effects of the pandemic, according to a trio of public school leaders who participated in a 27 May town hall on higher education and the pandemic that was hosted by the National Academies of Sciences, Engineering, and Medicine.

“We’ll be absolutely fine because we have banked reserves,” said Purdue University’s Mitch Daniels, who has invited all 45,000 Purdue students to spend their fall semester on campus. Its size also makes Purdue an essential part of the region’s economy, Daniels says, as well as the biggest employer in town.

But there are thousands of institutions that don’t have such reserves—or such economic clout, he warned. “Many smaller schools are facing huge challenges,” he said, “and I’m afraid that we’re going to see a serious shakeout.”

Michael Crow, president of Arizona State University, recently described his 65,000-student institution as a “battleship” that was plowing ahead despite “40-foot waves” and even stormier seas on the horizon. Crow thinks the key to success will lie in partnerships—between institutions that share departments, for example, as well as teaming up with companies that can help universities operate more efficiently.

But even the biggest universities with the largest research budgets can't take their continued success for granted, said Ana-Mari Cauce, president of the University of Washington, another top five performer of academic research. They also need to remember why they exist.

"If we are asking for a larger public investment, we have to put our public mission front and center," Cauce said. "A lot of us are already doing that. And those who don't, won't do well."

NIH chief worried vaccine "skepticism" might cause some to skip coronavirus vaccine

CNN
June 4, 2020
By Elizabeth Cohen

(CNN)The director of the National Institutes of Health said Thursday he's concerned that vaccine "skepticism" could hinder the effort to immunize the country against Covid-19.

"I'm a bit concerned to see there's a fair amount of skepticism in the American public about whether or not they would take such a vaccine," Dr. Francis Collins told CNN in an interview. "We won't get past Covid-19 unless we have a substantial majority of our public ultimately rendered immune."

Some vaccine experts are concerned that President Trump's chosen moniker for the vaccine development campaign -- "Operation Warp Speed" -- isn't helping. They fear that name could leave the impression that speed is more important than safety.

"I want to assure everybody who's heard the [words] 'warp speed' and worried that that means we're cutting corners on safety, that we absolutely will not do this," Collins said. "No vaccine is going to be put forward unless it's been checked out very thoroughly, both in terms of is it safe and does it protect you."

A vaccine could come out on the market early next year, and Collins said he hopes "the American public will embrace this as an opportunity to protect themselves, and the rest of their community, in order to get us all back to some sort of normal state."

But in some US communities, anti-vaccine sentiment runs so high that last year, more than 1,200 people contracted measles, a disease that's preventable with a vaccine.

Explaining why speed doesn't always sacrifice safety
Collins said once a coronavirus vaccine comes on the market, there might have to be some effective communication.

"Maybe we've got some work to do to try to explain exactly once we have the data, why these vaccines are in fact proven to be safe and effective," he said.

The US Biomedical Advanced Research and Development Authority, a part of the Department of Health and Human Services, is currently funding research on five different experimental coronavirus vaccines.

Pharmaceutical companies Moderna and AstraZeneca are currently in clinical trials, testing the vaccines on humans. Johnson & Johnson, Sanofi, and Merck are developing a vaccine, but have not yet started clinical trials, according to the World Health Organization.

"Because we have a number of these, and they all use a different strategy, I am optimistic that at least one maybe two, maybe three will come through looking like what we need," Collins told CNN. "We want to hedge our bets by having a number of different approaches, so that it's very likely that at least one of them and maybe more will work."

He said that large-scale clinical trials of "several" vaccines will start in July. He said each vaccine would be tested in a Phase 3 trial involving 30,000 people, some of them receiving a vaccine and some receiving a placebo -- a shot that does nothing. The volunteers will then go about their lives, and the researchers will tally up who contracted Covid-19 and who did not.

When asked when a coronavirus vaccine would be approved and available to the public, Collins said we could "perhaps have, if all goes well, maybe as many as 100 million doses by early 2021."

That's somewhat less optimistic than what Dr. Anthony Fauci, director of the National Institutes of Allergy and Infectious Diseases said Wednesday.
"By the beginning of 2021, we hope to have a couple hundred million doses," Fauci said during a live question and answer session sponsored by the Journal of the American Medical Association.
A coronavirus vaccine could require two doses, Collins said.

"Obviously that's not our favorite. It would be much better if this could all be done with a single injection," Collins said.

Generally, with any vaccine, one dose is preferred for cost reasons, and also because people might not show up for the second shot.

Collins said the Phase 3 trials will reveal whether one or two injections will be necessary.

"There is certainly a chance that one or more of these vaccines might turn out to require two shots in order to get full immune response. That's one of the reasons to do the experiments and the research trials to find that out," he said. "If what it takes to provide full protection for any of these is two doses, we want to know that."

Whatever the number of shots, Collins gave his personal promise that it wouldn't be rushed through.

"As a scientist, a physician, and the director of the National Institutes of Health, we will make these decisions solely on the basis of the evidence for individual vaccines. This will not be influenced by other factors that might put people at risk," he said.

NIH Director Hopes For At Least 1 Safe And Effective Vaccine By Year's End

NPR
June 4, 2020
By Sarah McCammon

As the number of confirmed coronavirus cases globally approaches 6.5 million, scientists are racing to develop a vaccine. Currently, there are 10 vaccine candidates in development around the world that are in the beginnings of human trials.

Some will be ready for large-scale testing as soon as the beginning of July, says Dr. Francis Collins, director of the National Institutes of Health and a member of the White House coronavirus task force.

These phase 3 trials involve roughly 30,000 volunteers for each candidate vaccine, with half the volunteers receiving a placebo, he says.

"That is a phenomenal thing to be able to say, considering these things usually take several years," and considering how recently the virus was identified, Collins tells All Things Considered.

He hopes that at least one vaccine that's been proved safe and effective against the coronavirus will be ready in 2021.

Here are excerpts from the interview.

Who ultimately decides which vaccines move forward? Is that up to your agency? Or what the president has called his Operation Warp Speed vaccine task force?

These vaccines are put forward by various companies. They are in different phases of being ready. They have to first go through a phase 1 trial to see whether they, in fact, in a small number of volunteers, do produce a decent level of antibodies — which would tend to predict that they're going to work against this coronavirus. And they have to also show in a small number of volunteers that they're safe. And not all of them have even quite yet gotten to that point.

The ones that do — we want to have a whole menu of vaccine opportunities because these don't always work. ... So it is a very good thing that we're going to end up with several different vaccines that are going through this large-scale testing in the course of the coming months. And my hope is they'll all work. ... But if some of them drop out along the way, we just want to be sure that by the end of this calendar year, we have at least one or maybe two or maybe three that have shown that they're both safe and they're effective.

And let me emphasize that word 'safe.' This brand that we're using, Operation Warp Speed, is supposed to convey the speed with which we're trying to move because of this intense public health need. But it is not a means of compromising safety. We will not do that. We're just skipping over some of the steps that tend to go slowly for regulatory reasons and for business reasons and trying to make those go faster. We are not compromising on safety.

Has the president's term [warp speed] made it difficult for you as a public health official to message exactly how this works?

Not really. I kind of like the idea of conveying that we're in a hurry here — I just need to quickly explain after I say that what that means. One of the things we're doing is to make sure that when a vaccine looks like it's got some promise, it's going into one of these large-scale trials — let's assume it might work. And let's go ahead and start manufacturing lots and lots of doses [at that point], with U.S. government support, so that if it does work, you don't then have to wait for many months to have the vaccine ready to distribute. ... This so-called "at-risk manufacturing" — you wouldn't normally do that because some of this is going to go to waste. But when you consider what's happening here and the people's lives at risk, it seems like the right thing to do. That's part of the warp speed idea.

How will you make sure that once the vaccine is ready, it is equitably distributed and that anyone who needs one can get one?

The first doses ... will need to go to the people who are at highest risk. ... particularly health care providers, people in long-term care facilities. ... But the goal would be certainly to start scaling this up as soon as you have a vaccine that's safe and effective, so that by 2021, maybe even in the first or second quarter, we would have 100 million doses or so, so it wouldn't have to be rationed so severely. But at first, there won't be enough for everybody.

[The Mental Health Toll from the Coronavirus Could Rival that of the Disease Itself]

Newsweek
May 29, 2020
By Adam Piore

Tom Insel has watched the nation grapple with plenty of psychologically challenging situations over his long career in the field of mental health. The psychiatrist became director of the National Institute of Mental Health (NIMH) in the months following 9-11, when Americans were traumatized over the twin

tower bombings. He watched residents of Louisiana and Mississippi dig out from the waterlogged rubble of Hurricane Katrina. He's seen mass shootings in Tucson, Fort Hood and Newtown.

But nothing in Insel's experience has tested the nation's psychological resilience like COVID-19, which has millions of Americans living in fear of contracting a deadly new disease, hunkering down in involuntary confinement, contemplating rising unemployment and the prospect of a worldwide economic collapse, cut off and worried about loved ones, besieged by a parade of bad news and tormented by boredom, fear and loneliness.

Mental health experts are now bracing for what Insel calls a "mental health tsunami." They're anticipating a steep rise in the diseases of isolation—suicides, opioid abuse, domestic violence and depression—that will unfold over the next few months and could stretch on for years.

The plague is not only fueling these mental health problems. The same economic collapse that is putting people out of work is also eroding the ability of society to deal with the crisis. In particular peril are the federally-funded mental-health clinics that treat millions of the poorest and sickest. Two months into a crisis that could last years, they are already on the edge of failure.

Casualties from the mental-health problems are expected to rival the pandemic itself. Deaths from drug overdoses and suicide totaled about 110,000 a year before COVID-19 struck. Historically, each five percent increase in the unemployment rate leads to about 3,000 additional suicides and 4,800 overdose deaths, says Insel. That means an unemployment rate of 20 percent would cause an additional 20,000 deaths.

"We've never seen a moment where the demand for mental health care will be as great as it's going to be in the next few months and next couple of years," says Insel. "If you add the spike in suicides and drug overdoses we are likely to see to those we were already expecting, the psychological toll from deaths of despair in the months ahead could very likely surpass the final mortality numbers for COVID."

The disaster model

Mental health fallout usually follows a disaster. In hurricanes, there's generally a 60 to 90 day lag from the "acute" phase of the crisis before the full psychological fallout is felt. Once the imperative to survive the immediate calamity passes and people begin to grapple with what they have just been through and what it means for the future, their resilience faces its true test. The psychological impact begins to show up in a rise in suicides, alcohol and drug-related incidences, and new mental health-related cases. Economic downturns typically take a couple of years before the impact begins to show up in the statistics that suggest the true mental costs on the population.

The 2003 SARS epidemic was followed by a 30 percent increase in suicide deaths among those 65 and older in Hong Kong. Half the population remained anxious in the months that followed. As many as 50 percent of New Orleans residents who were present during Hurricane Katrina experienced a diagnosable mental disorder such as PTSD, major depression or an anxiety disorder.

Likewise, says Stefan Hofmann, a clinical psychologist who directs Boston University's Psychotherapy and Emotion Research Laboratory at the Center for Anxiety and Related Disorders, "once the viral pandemic passes, there will be the pandemic of emotional distress." Hofmann predicts the full extent of the damage won't be clear for months, and it may unfold at a different pace for different people.

For some, the challenges are already beginning. Presently, about one third of Americans say they have experienced "high levels" of psychological distress such as anxiety, sleeplessness or depression at some point during the extended period of social distancing because of the present circumstances, according to a study by Pew Research Center, released in early May. Kaiser Family Foundation put the number Americans for whom worry or stress had caused at least one negative effect on mental health and wellness at 56 percent. Calls to a government disaster distress helpline were up tenfold in April from the previous year; a Los Angeles suicide and help hotline handled 8,000 percent more calls than usual in February and March.

Domestic abuse hotlines are also seeing increased activity: More than 5,000 people have reportedly called the National Domestic Violence Hotline since mid-March, specifically referring to COVID as the catalyst for their problems.

In recent years, psychologists have established strong evidence that loneliness is linked to higher levels of anxiety, depression, alcoholism and drug abuse. It can also be a threat to physical health. Lonely people feel more pain, which has some public health officials worried about a second spike in opium use. Lonely people are also more likely to get physically sick. The impact of social isolation on mortality is greater than obesity, smoking 15 cigarettes a day or high blood pressure, researchers have found.

"The recognition of the impact of social isolation on the rest of our mental health is going to hit everyone really soon," says Kay Tye, a neuroscientist at the Salk Institute for Biological Science who studies the brain circuits involved in loneliness. "The impact on mental health will be pretty intense and pretty immediate."

How lethal the fallout turns out to be may depend on the depth and duration of the current economic downturn. One study based on data from Hurricanes Katrina and Harvey found that every 1 percent rise in unemployment preceded a 2 percent increase in the number of drug overdose deaths. Another found it that a 1 percent uptick in unemployment was associated with a 1.6 percent rise in the number of people who succeed in taking their own lives.

Suicides were already rising when the pandemic hit. The U.S. has seen a 33 percent increase since the year 2000, according to an analysis released last year by the Centers for Disease Control and Prevention, which placed the rate at 14 deaths by suicide for every 100,000 Americans—the highest age-adjusted suicide rate recorded in the U.S. since 1942. Although men were still three times as likely to kill themselves as women, female suicide rates increased by 53 percent between 1999 and 2017, almost twice the rate of increase for men.

Insel attributes the spike to a wide range of factors ranging from a lack of treatment options for the mentally ill to societal factors that are adding to stress and uncertainty. COVID-19, however, "really adds fuel to the fire."

The most ominous warnings are emerging from a report on "projected deaths of despair" from COVID-19 by the Robert Graham Center, a think tank associated with the American Academy of Family Physicians and the nonprofit Well Being Trust. They are predicting tens of thousands of additional deaths from suicide, alcohol and drug overdoses, depending on the extent of the economic dislocations and action taken to help those who are struggling. Their estimates range from an additional 27,644 if there is a quick recovery, with the smallest impact on unemployment. In a worst case scenario, they predict the number of additional Americans who will die from suicide, drug overdoses and alcohol-related deaths will hit 154,037.

Self-medicating

Even if the mental health system had the capacity to treat everyone, research and history show that 50 to 60 percent of those who need treatment fall through the cracks. Most people don't seek care, instead turning to alcohol and drugs. Some withdraw, becoming more isolated. Some become angry and uncontrollably violent or self-destructive. In the months and years ahead, we will be battling an epidemic we may not always be able to see.

Social distancing may be fueling opioid abuse, worries Elinore F. McCance-Katz, assistant secretary for mental health and substance use at the Department of Health and Human Services. When doctors cannot meet face to face with patients, they are more likely to prescribe addictive drugs, she says.

COVID-19 could erase progress of the last few years in dealing with the opioid epidemic. By some accounts, federal efforts to get the crisis under control were beginning to yield results. In 2017, more than 70,000 people died of drug overdoses—68 percent involving prescription or illicit opioids—making it the

leading cause of injury-related deaths in the U.S. Between 2017 and 2018, overall overdose death rates decreased by 4.1 percent—with prescription opioid-involved overdose death rates decreasing by 13.5 percent. (Deaths from synthetic opioids, excluding methadone, increased by 10 percent over the same period.)

However, previous studies have found that for every 1 point increase in unemployment, drug related deaths increase by between 3.3. percent and 3.9 percent. An unemployment rate of 20 percent or higher, which economists predict is likely in May and June, would probably be devastating.

Data on domestic violence and child abuse is spotty, but local officials tell McCance-Katz that cases seem to be rising. She recently issued a document of resources for victims to access help (here) and has been pleading with the media to publicize it. "It's very important to get the message out there that for thousands of Americans staying home isn't safe," she says. "We expect that we are going to see great increases in these numbers. We know from some cities that they're already seeing big increases in calls to domestic violence hotlines. We're quite concerned."

A lack of action

There's no shortage of efforts to attract attention to the problem. Second Lady Karen Pence launched a three-year initiative aimed at changing the culture around mental health and suicide just as COVID-19 struck. Pence, serving as a "lead ambassador" along with a dozen other "influencers"—including Surgeon General Jerome Adams, the celebrity DJ Nash and several former presidents of the American Psychiatric Association—will try and attract attention via social media and get people talking to one another.

Joshua Gordon, director of the National Institute of Mental Health (NIMH), and former Congressman Patrick J. Kennedy, founder of The Kennedy Forum, also announced a new effort in late April to raise money and awareness to address mental health and prevent suicide. "I'm particularly concerned about those who might have trouble accessing mental health care, such as homeless, seriously mentally ill, incarcerated individuals because they might have challenges staying well," Gordon told Newsweek.

So far, there's been little action where it is needed most: providing funding to address the mental health challenges brought on by the pandemic. Of the $3 trillion passed for economic stimulus and relief, only a tiny sliver has been allocated for mental health. "People have been speaking up about the mental health effects of this emergency, but we have yet to see real concrete actions to shore up our mental health system," says Angela Kimball, national director of advocacy and public policy for the National Alliance on Mental Illness. "Any shortfall is likely to hit the poorest the hardest."

The nation's existing mental health infrastructure is not even remotely equipped to handle the rise in mental health problems, says Insel, and he should know—he spent last year surveying California's mental health system. He found the prisons filled with mental health patients and mental health facilities filled with the criminally insane. "We were in a bad place before," he says. "And now we have COVID."

Mental health agencies, which operate on a shoestring budget in the best of times, have seen reimbursements plummet. The federal Medicaid program funds behavioral health clinics to low-income Americans with the most severe conditions, such as schizophrenia, psychosis, depression, OCD and other disorders—usually the last stop before the streets or prison. When COVID-19 hit, federal officials at the U.S. Centers for Medicare & Medicaid Services moved with uncharacteristic speed to revise its regulations and allow reimbursement for telehealth appointments, which some mental health advocates have been urging for years. (Many private insurers followed suit.) But the poorest patients don't have laptops or access to broadband internet; many are homeless.

Instead, patients have inundated crisis services lines. One mother called NAMI pleading for help for her daughter, an Iraqi-war vet, who was psychotic, homeless, off her meds and unable to get help. "She's desperately worried, because her daughter believes we are being invaded by aliens," says Kimball. "She's been in contact via cell phone. But she can't get mental health services to come help her daughter." Kimball has compiled a list of more than 600 such stories to share with lawmakers and the media in the hope of getting more funding.

The problems appear to be widespread and getting worse. The National Council for Behavioral Health, the nation's biggest association of mental health and community substance abuse clinics, found in a survey of members that more than 90 percent had cut back on some programs, and 30 percent were turning people away.

The initial relief bill passed by Congress included about $425 million in additional federal funds to help HHS boost suicide prevention efforts and treat patients with serious mental illnesses and substance abuse disorders through certified community behavioral health centers. To keep operating, mental health advocates claim they need $38 billion—about 90 times that amount. "Urgent assistance is needed to keep the doors open," the National Alliance on Mental Illness wrote in a letter.

In early April, President Trump held a half-hour call with leaders of the mental health and substance abuse community to hear their concerns. Last month, a coalition of lawmakers sent a letter to congressional leaders to increase funding for mental health in the next coronavirus package.

"Many organizations that primarily treat individuals with mental health and/or substance use disorders ... are at risk of closing their doors as a result of the COVID-19 pandemic," the lawmakers wrote. "The immediate and long-term effects of this cannot be overstated." Congressional leaders, having already doled out more than $3 trillion, have been deadlocked over the next spending package.

Experts agree that most of the population will get through the crisis intact. "We are all highly, highly stressed," says Insel. "But most people are resilient. As long as there is an endpoint, as long as they know this isn't forever, they will find a way to make it through." How many tens of thousands of fellow Americans we lose along the way, he notes, will depend on the actions we take in the weeks and months ahead to help them get through it, too.

National Institutes of Health chief says he understands why coronavirus guidelines confused Americans

Yahoo News
May 29, 2020
By Jon Ward

WASHINGTON — The head of the National Institutes of Health said it’s understandable that Americans have been confused by shifting medical guidance around the issue of wearing face masks to protect against COVID-19, but denied that the different messages have been contradictory.

“I do understand that must be confusing to people because the message did change,” said Francis Collins, director of the NIH.

But Collins, in an interview on “The Long Game,” a Yahoo News podcast, said that Surgeon General Jerome Adams “was doing exactly the right thing” when he repeatedly told the American public not to buy masks for more than a month from late February to early April.

Adams, who was echoing the guidance from the World Health Organization and the Centers for Disease Control and Prevention, was “trying to preserve a precious resource for those who needed it most,” Collins said.

And at the time, a limited supply of masks — especially those that filter air before it is breathed — were in short supply. This prompted medical experts and government leaders to urge the public not to buy them to make sure that hospital workers and other first responders had enough.

But Adams, like others, also said at the time that masks had “not been proven to be effective in preventing the spread of coronavirus amongst the general public.”

Collins told Yahoo News that public health experts at the time didn't understand the degree to which asymptomatic people could spread the virus, and the degree to which the virus could be spread through respiratory droplets, which are heavier than air and fall to the ground, but can still be spread person-to-person by coughing or close breathing.

Transmission through respiratory droplets made the novel coronavirus "different than most viruses we've known about," Collins said. And "probably 40 percent of the new infections with COVID-19 are derived from people who have no symptoms at the time they pass the virus on. That wasn't clear until some time had gone by. So it really does reflect a change in what the public health needs are."

"There's nothing here that's not consistent. It's just based upon new information that we've been gathering over the last three months," Collins said. "This is a totally different idea. That is, 'I should now wear a mask so that I'm not infecting somebody else.' It's not to save me. It's to save them from me."

Masks have become a politically charged issue in large part because President Trump has repeatedly refused to wear one. He has also mocked a reporter for wearing a mask and poked fun at Democratic presidential candidate Joe Biden for wearing one. And on Tuesday the president retweeted an article that said masks were promoting "social control" as well as a "culture of silence, slavery, and social death."

But the president is increasingly isolated in this view even among his most loyal allies. Senate Majority Leader Mitch McConnell said this week that people "have an obligation to others" who are at risk to wear masks and that there is "no stigma attached to wearing a mask … to staying 6 feet apart."

Even Sean Hannity, the Fox News host who is one of the president's fiercest and most bombastic cheerleaders, chastised people who gathered over the Memorial Day weekend without social distancing and masks. "If you can't social-distance, please wear the mask for your mom, dad, grandma, grandpa. My humble advice," Hannity said Tuesday night.

Collins, a prominent convert to Christianity, expressed surprise and dismay at the level of resistance to wearing masks, especially among other Christians.

"The church ought to be a place where politics is not the currency. It ought to be the place where truth really is valued. And it particularly ought to be a place where we're worried about the most vulnerable people," Collins said. "And for the church to adopt approaches that put people at risk of getting a terrible disease really doesn't seem right in the current climate. And yet, in some instances you see that.

"Now let's not overstate it. I would say most churches are, in fact, doing everything they can. They're making masks. They're running food banks. They're making sure to wear masks themselves if they're out and about. They're not having large gatherings, even if their state has told them they could start to do so. But there are exceptions, and they get the most attention, as is always the case in our current media climate."

Collins is a significant figure in American science, having overseen the Human Genome Project. He also received the Presidential Medal of Freedom from President George W. Bush.

President Barack Obama appointed Collins to head the NIH in 2009, and Trump reappointed him at the beginning of his presidency. Collins in 2011 was included on a list of Washington's "most powerful, least famous people."

That partly explains why even though Dr. Anthony Fauci, the head of the National Institute of Allergy and Infectious Diseases, reports to Collins, Fauci is by far the more well-known figure.

But Collins is in charge of coordinating the hunt for a vaccine in the U.S. He said there are now 18 pharmaceutical companies joining with several U.S. government agencies under the umbrella of the NIH effort known as "Accelerating COVID-19 Therapeutic Interventions and Vaccines," or ACTIV.

And Collins said that “in an optimistic scenario, by the end of 2020, we might have 100 million doses of a successful and safe vaccine.

“That would be pretty remarkable in such a timetable. But there are lots of things that could go wrong. So one needs to be realistic about this,” he cautioned.

Collins admitted he is concerned about the levels of skepticism regarding a vaccine for COVID-19, which are building on years of anti-vaccine activism by those who continue to make the debunked claim that vaccines are linked with autism.

A recent Yahoo News/YouGov poll found that 44 percent of Republicans surveyed believe that Bill Gates is plotting to use a mass COVID-19 vaccination campaign as a pretext to implant microchips in billions of people and monitor their movements — a widely debunked conspiracy theory with no basis in fact.

Collins called these kinds of conspiracy theories “deeply disturbing.”

“I am worried if we get a vaccine for COVID-19 by the end of the year, current polls would say maybe 20 percent of Americans say that they wouldn’t take it. And why would they not take it? Just because they don’t trust that vaccines are going to be safe, and that all sort of builds upon the stories coming from anti-vaxxers in the past,” he said.

“This is a terrible tragedy. Hundreds of thousands of people are dying across the world. We could stop that. And 20 percent of Americans say, ‘I wouldn’t want that vaccine, because it might not be what I think it should be because maybe they’re lying to me about whether it’s safe.’ How did we get there?”

But Collins also acknowledged that establishment organizations and leaders need to engage more meaningfully with the concerns of anti-vaccine activists.

“There’s virtually no human intervention, including drinking water, that is without risk for certain people in certain doses. So let’s be clear. When I say vaccines are generally safe, that doesn’t mean that there’s not a rare instance where a vaccine does lead to a negative outcome, some sort of side effect or a secondary illness of some sort. What we ask, I think, though, scientifically is how do you balance the benefits and the risks? And I think we ask every consumer to do that same calculation,” he said.

“I’m afraid we have not done a great job in terms of explaining how one makes a thoughtful, rational decision, that you have to really get quantitative about it,” he said.

“If somebody says, ‘Well, there’s a risk there.’ Of course there is. How big is the risk? What does that mean for the individual? And how do you factor that into what’s the benefit? Then you could have a reasonable conversation.”

NIH director: ‘No way of knowing’ if coronavirus escaped from Wuhan lab
"Nature created this virus, and has proven once again to be the most effective bioterrorist."

Politico
May 27, 2020
By Zachary Brennan

National Institutes of Health Director Francis Collins said the coronavirus is “absolutely not" manmade but he could not rule out the idea that it escaped from a lab in Wuhan, China, where the first known cases emerged.

“Whether [the coronavirus] could have been in some way isolated and studied in this laboratory in Wuhan, we have no way of knowing,” he told POLITICO on Wednesday.

What is clear, he said, is that "Nature created this virus, and has proven once again to be the most effective bioterrorist."

President Donald Trump and Secretary of State Mike Pompeo have repeatedly suggested that the virus might have somehow emerged from the Wuhan Institute of Virology — claims that the center's director has called "pure fabrication."

The Office of the Director of National Intelligence confirmed late last month that the government is investigating the pandemic's origin, but said that there is no reason to believe the coronavirus was manmade or genetically modified.

Collins refused to comment on his agency's recent — and controversial — decision to pull funding from researchers studying how coronaviruses spread from bats to people. In late April the NIH told the EcoHealth Alliance, whose collaborators included scientists at the Wuhan virology lab, that its project did not "align with the program goals and agency priorities."

Prominent scientific societies and 77 Nobel laureates have asked the administration to investigate why the nonprofit group's grant was terminated, alleging that the decision was made for political, rather than scientific, reasons. The NIH awards grants using a merit-based system in which researchers evaluate the work of their peers, and ending a grant early is unusual.

Collins, who had not previously commented publicly on the situation, told POLITICO that "the NIH cannot discuss individual grants."

The agency chief, who is leading a public-private partnership called ACTIV to hunt for coronavirus vaccines and drugs, said that if "all goes perfectly," a few million doses of vaccine could be available in October for high-risk groups — with doses available sometime next winter for the rest of the country.

Trump has repeatedly promised a vaccine by the end of the year, much faster than any has ever been developed for any condition.

If China develops a coronavirus vaccine before the U.S. does, Collins said he "seriously hopes" that any tensions between the countries "wouldn't be a dominant factor" in determining whether the U.S. would have access to a Chinese-manufactured shot.

Race Is On to Create Rapid Covid-19 Tests for the Fall

Hundreds of teams are competing a la 'Shark Tank' for NIH funding to develop at-home diagnostic strips and other options

WSJ
May 26, 2020
By Brianna Abbott and Amy Dockser Marcus

Even as coronavirus testing ramps up around the country, businesses and public-health authorities seeking to safely reopen are hitting a speed-bump: Standard testing techniques still require sophisticated lab equipment and can take hours or even days for results.

To stretch beyond the lab, test developers are racing to produce next-stage technologies that could allow for rapid widespread testing as quickly as an at-home pregnancy test.

"The truly ideal test is the test that you can do in your house every morning," said Elizabeth McNally, the director at the Center for Genetic Medicine at Northwestern University.

Yet diagnostics experts estimate wide access to quality rapid tests is still months away. Among the challenges is finding noninvasive ways to collect the patient sample while maintaining the sensitivity of

current standard tests. The nasalpharyngeal swabs used in most current Covid-19 tests are invasive and difficult to successfully conduct in a home setting.

The industry is trying to move quickly, especially before flu season arrives in the fall. That is when public-health experts worry about another surge of Covid-19 cases, and the ability to quickly distinguish between respiratory illnesses would become even more crucial.

“I don’t want to underestimate the magnitude of the challenge,” said Charles Y. Chiu, a professor of infectious diseases at University of California, San Francisco, and a member of the science advisory board at Mammoth Biosciences.

The South San Francisco biotech is working to develop a hand-held rapid test for Covid-19 using the Crispr system. The technology is best known for enabling gene editing and is now being turned toward detecting the genetic signature of the coronavirus.

Sherlock Biosciences in Cambridge, Mass., earlier this month received emergency use authorization from the Food and Drug Administration for a Crispr-based Covid-19 lab test that can provide results in an hour. The test is the first authorized Crispr-based infectious-disease diagnostic, the FDA said, but is still limited to specialized laboratories. The company aims to submit a test that can be used in urgent clinics and doctors’ offices for authorization in the fall, said Sherlock’s chief executive officer, Rahul Dhanda, while the rapid hand-held test is still further off.

Mammoth signed a deal this month with GlaxoSmithKline PLC’s GSK Consumer Healthcare to develop its rapid test. A GSK spokesperson said they aim to have a prototype before the end of 2020, and potentially available in clinics by the first quarter of 2021. Over-the-counter availability to consumers would come after that, the spokesperson said.

U.S. labs have conducted at least 300,000 daily tests since May 11, according to the Covid Tracking Project, a marked improvement from previous weeks. That daily count is still well below the level that public-health experts say is necessary—along with tracing close contacts and quarantining, among other measures—to stem the spread of the virus.

The chief current testing method, the polymerase chain reaction test, is considered the gold standard but has drawbacks. The PCR test relies on a strained supply chain for materials, including protective equipment; samples have to be sent to a lab; and patients sometimes wait days for results.

“It’s hard to imagine getting to the numbers that people are talking about without some sort of technical breakthrough, and that’s what everyone’s searching for,” said Gary Samuels, vice president of corporate communications at laboratory-testing giant Quest Diagnostics.

Rapid tests at a doctor’s office or urgent-care clinic, called “point-of-care” tests, and tests done in homes, offices and other places without lab access all “allow you to decentralize testing,” said Dr. Chiu.

OraSure Technologies Inc., of Bethlehem, Pa., said it has a contract with the Health and Human Services department to develop a rapid Covid-19 antigen test called a lateral flow assay. It uses strips to find viral proteins in oral fluid taken from between the gums and the cheek. The test is based on technology already deployed in the company’s HIV self-test.

The lateral flow assay strips, similar to a home pregnancy test, look for viral antigens in saliva or a nose swab and are one of the major technologies companies are exploring. These tests are different, though technologically similar, to rapid antibody tests, which look for signs of past infection in a small sample of blood. Antibody tests, however, can’t diagnose a current infection.

Last month, the National Institutes of Health announced a competition meant to speed up development of diagnostic technologies, with the goal of millions of rapid tests a week available by the end of summer, and more by flu season. The Rapid Acceleration of Diagnostics, or RADx, initiative, often compared with

the TV show “Shark Tank,” will provide finalists with up to $500 million and technical, business and manufacturing expertise.

Over 1,700 groups have registered, more than 280 have applied, and 40 have advanced to a “deep dive” review stage. Bruce Tromberg, director of the National Institute of Biomedical Imaging and Bioengineering at the NIH, which is leading the initiative, says he is expecting five to 10 finalists to emerge.

“These advances would normally happen over five years, but we need them now,” Dr. Tromberg said. “We need them in more diverse settings, and we need a diversity of technologies to get us there.”

A few point-of-care tests, including Abbott Laboratories ’ ID Now or Cepheid Inc.’s GeneXpert, are on the market though not widely available. Quidel Corp. earlier this month gained FDA authorization for the first point-of-care antigen test.

Creating a viable rapid at-home test depends not only on accuracy but also on consumer utility, said Feng Zhang of the Broad Institute of MIT and Harvard and a co-founder of Sherlock Biosciences, one of the Crispr companies. Saliva is easy to collect, but if the person recently ate, drank or chewed gum, that can affect the results. Nasal swabs have to collect sufficient amounts of virus without being invasive. “It has to be super easy to use,” he said.

There are no fully at-home diagnostic tests currently authorized by the FDA, though several at-home collection devices, to be sent to a lab for analysis, are on the market.

Rapid tests are likely to be less sensitive than laboratory PCR diagnostics and they can process only one or a few samples at a time, while the highly complex laboratory machines can run many more simultaneously.

“If you want easy-to-use and low cost, you’re going to sacrifice some performance. That’s just the way it is,” said Ron Chiarello, founder and chief executive of Alveo Technologies Inc., which is developing a point-of-care device with Janssen Pharmaceuticals Inc.

OmniVis, in San Francisco, is working on an early-stage rapid test that would attach to a phone. “With these rapid tests, are we trading off some sensitivity? And if we go with these slower tests, are we losing a lot of time?” said Katherine Clayton, co-founder and CEO of the diagnostics company. “You start to see the convergence of all those principles.”

A quick test with good-enough sensitivity and a known error rate, paired with the right testing strategy, could pick up most Covid-19 infections, infectious-disease experts say, and be especially useful in a triage situation or absent a nearby lab. Some technologies, such as Crispr, might be able to bridge the gap between speed and sensitivity.

Whether the diagnostics industry can ramp up to produce millions of rapid tests a week by the fall remains an open question. The NIH's Dr. Tromberg and others say it can be done. OraSure said it aims to submit its at-home test for FDA authorization in September, while Alveo Technologies and others anticipate seeking authorization in late 2020 or 2021.

NIH director Francis Collins, at a May 7 Senate committee hearing, called the proposed fall target “a stretch goal that goes well beyond what most experts think will be possible.”

“The scientific and logistical challenges are truly daunting, but I remain optimistic,” he added.

Exclusive: U.S. plans massive coronavirus vaccine testing effort to meet year-end deadline

Reuters

May 22, 2020
By Julie Steenhuysen

CHICAGO (Reuters) - The United States plans a massive testing effort involving more than 100,000 volunteers and a half dozen or so of the most promising vaccine candidates in an effort to deliver a safe and effective one by the end of 2020, scientists leading the program told Reuters.

The project will compress what is typically 10 years of vaccine development and testing into a matter of months, testimony to the urgency to halt a pandemic that has infected more than 5 million people, killed over 335,000 and battered economies worldwide.

To get there, leading vaccine makers have agreed to share data and lend the use of their clinical trial networks to competitors should their own candidate fail, the scientists said.

Candidates that demonstrate safety in small early studies will be tested in huge trials of 20,000 to 30,000 subjects for each vaccine, slated to start in July.

Between 100,000 and 150,000 people may be enrolled in the studies, said Dr. Larry Corey, a vaccine expert at Fred Hutchinson Cancer Center in Seattle, who is helping design the trials. “If you don’t see a safety problem, you just keep going,” Dr. Francis Collins, director of the National Institutes of Health (NIH), told Reuters. The vaccine effort is part of a public-private partnership called Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) announced last month.

The effort fits into the research and development arm of “Operation Warp Speed,” the White House program announced last week to accelerate coronavirus vaccine development. Vaccines, which are intended for use in healthy people, are typically tested in successive steps, starting with trials in animals.

Human testing begins with a small safety trial in healthy volunteers, followed by a larger study to find the right dose and get an early read on efficacy. The final stage consists of large-scale testing in thousands of people. Only then would a vaccine developer commit to manufacturing millions of doses. In the era of coronavirus, many of those steps will overlap, particularly the mid-stage and late-stage trials, Collins and Corey said.

The approach has its risks, as certain safety issues may only appear in large-scale trials. Americans are concerned about the speed of the vaccine effort, a Reuters/Ipsos poll showed. A highly effective vaccine could be tested in as little as six months if there is a big difference in benefit between the vaccine and placebo groups, Corey said. For a modestly effective vaccine, trials could take nine to 12 months.

The U.S. government has committed billions of dollars to help manufacturers produce doses of vaccines that may never prove successful.

THE SHORTLIST
To get the quickest answer, vaccines will be tested in healthcare workers and communities where the virus is still spreading to show whether they reduced new cases of COVID-19. Washington, D.C, which has not reached the peak of its outbreak, is one likely test site. Trials may be conducted abroad, including in Africa, where the virus has just started to spread, Collins said.

The government plans to tap its own trial networks, including the Department of Veterans Affairs’ 100 healthcare facilities, for potential study volunteers, while drugmakers will recruit from their clinical research networks.

A Moderna Inc vaccine, developed in partnership with the NIH, will be the first to the enter large-scale testing in July, and may be joined by a vaccine from Britain’s Oxford University and AstraZeneca Plc, Collins said.

The U.S. government said on Thursday it would spend $1.2 billion to secure 300 million doses of the Oxford vaccine. “What we might try to do is run those two side by side, but with a control arm” that would also include 10,000 healthy individuals who got a dummy vaccine, Collins said. Moderna’s candidate is already proceeding to mid-stage human trials. Vaccines by Johnson & Johnson, Sanofi and Merck & Co are a month or two behind the frontrunners and “may get added over the course of the summer” following early-stage human trials, Collins said.

Merck has not made any specific announcements on its vaccine program and declined to comment.

Collins would not name other candidates on the U.S. shortlist of 14, but said they will need to finish early safety testing by this summer to make it into the bigger trials. Trials will need to assess if the vaccines cause disease enhancement - a potentially dangerous side effect in which the vaccine makes the disease worse in some individuals instead of preventing it. Disease enhancement has been seen in animal studies of vaccines developed to fight a close cousin of the virus that causes COVID-19. “If there is enhancement, that’s a big stop sign for everything,” said Dr. Anthony Fauci, director of the National Institutes of Allergy and Infectious Diseases at NIH.

“If all the cards fall into the right place and all the stars are aligned, you definitely could get a vaccine by December or January,” Fauci said.

Is the Pandemic Sparking Suicide?
Psychiatrists are confronted with an urgent natural experiment, and the outcome is far from predictable.

New York Times
May 21, 2020
By Benedict Carey

The mental health toll of the coronavirus pandemic is only beginning to show itself, and it is too early to predict the scale of the impact.

The coronavirus pandemic is an altogether different kind of cataclysm — an ongoing, wavelike, poorly understood threat that seems to be both everywhere and nowhere, a contagion nearly as psychological as it is physical. Death feels closer, even well away from the front lines of emergency rooms, and social isolation — which in pre-Covid times was often a sign of a mind turning in on itself — is the new normal for tens of millions of people around the world.

The ultimate marker of the virus’s mental toll, some experts say, will show up in the nation’s suicide rate, in this and coming years. The immediate effect is not at all clear, despite President Trump’s recent claim that lockdown conditions were causing deaths. “Just look at what’s happening with drug addiction, look at what’s happening with suicides,” he said in a press briefing in the White House Rose Garden on Monday.

In fact, doctors won’t know for many months if suicide is spiking in 2020; each death must be carefully investigated to determine its cause. The rolling impact of Covid-19 on these rates give scientists a sense of how extended uncertainty and repeating undercurrents of anxiety affect people’s will to live.

“It’s a natural experiment, in a way,” said Matthew Nock, a psychology professor at Harvard. “There’s not only an increase in anxiety, but the more important piece is social isolation.” He added, “We’ve never had anything like this — and we know social isolation is related to suicide.”

The earliest signs of whether the pandemic is driving up suicides will likely emerge among those who have had a history of managing persistent waves of self-destructive distress. Many of these people, who number in the millions worldwide, go through each day compulsively tuned to the world’s casual cruelties — its suspicious glances and rude remarks — and are prone to isolate themselves, at times contemplating a final exit plan.

“That’s how I am,” said Josh, 35, a college instructor in North Carolina who has been consumed in the past with thoughts of suicide. “I see all the bad, the suffering, and I have a tendency to crawl into a hole. Now, with this Covid threat, we’re being told to isolate and stay away from others. It’s like, ‘Oh, I was right all along, and the world was crazy.’”

He added, “I haven’t backslid, I haven’t moved. But longer term — I don’t know.” He asked that his last name be omitted for privacy.

Research done in the wake of natural disasters offers little guidance as to how this group will respond. In a widely cited 1999 paper in The New England Journal of Medicine, researchers from the Centers for Disease Control and Prevention reported that, in communities hit by an earthquake, flood or hurricane, rates of suicide spiked in the years after. But the study authors later retracted that finding, after discovering an error that, when corrected, revealed “no significant increase in suicide rates after natural disasters, either for all types of disasters combined or for individual types of disasters.” Other studies have found increases, or decreases, depending on the group and disaster studied.

The evidence is stronger when it comes to the impact of economic hardship. Suicide rates in the United States have been rising steadily since 2000 — by 35 percent overall, across most age groups — but the rate of increase roughly doubled in the wake of the 2008 downturn. Historically, the job losses, evictions and displacements caused by recessions tend to lead to an increased numbers of suicides.

“I think during the actual crisis, suicide will be lower,” said Dr. Marianne Goodman, a psychiatrist at the Department of Veterans Affairs, in the Bronx. “And once the longer-term economic impact is felt, I suspect, suicide will be rising again.”

But the imminent threat of a potentially deadly virus is very different, psychologically, from the exhausting anxiety of facing a future with few job prospects. The descent of a pandemic alters the thinking and behavior of distressed people in ways that are simply not well understood.

For now, many people who have had to manage self-destructive thoughts have found that their inner dialogue has shifted since the pandemic descended.

“I was in a relatively good place when this started, and I think one of the reasons I’ve stayed that way is that, having had all this experience with depression and anxiety, you learn a lot of skills that are applicable in this pandemic,” said Michelle, 37, a New York teacher with a history of chronic suicidal tendencies, including two attempts.

“It’s interesting, I’m having conversations where everyone is feeling anxious about the same thing,” she said. “It’s been awhile — since grad school, I think — that I have been a part of conversations like that, and it’s strangely nice.”

Dr. Owen Muir, a co-founder of Brooklyn Minds, a program that treats many highly suicidal individuals, said his own clients appear to be doing well so far, despite or perhaps partly because of Covid-related adjustments.

“The fact you could die any minute, that is very different situation from previously, where you thought, ‘The only way I’m going to die is if I kill myself,’” Dr. Muir said. “That theoretical struggle is very real now, in peoples’ minds, and what I’m seeing in many of our patients is that they make sense of it by wanting to help — like, now is the time to stay healthy and cope with this, for everyone’s sake.”

The Coronavirus Outbreak
Today’s Question: I’ve heard about a treatment called dexamethasone. Does it work?
The steroid, dexamethasone, is the first treatment shown to reduce mortality in severely ill patients, according to scientists in Britain. The drug appears to reduce inflammation caused by the immune system, protecting the tissues. In the study, dexamethasone reduced deaths of patients on ventilators by one-third, and deaths of patients on oxygen by one-fifth.

This is not to say that self-destructive urges are somehow fading, only that they now compete with adaptations to a broader, outside threat, therapists and researchers say. In many high-risk people, suicidal thoughts are now more frequent than before, new research suggests.

In a continuing study, a research team led by Dr. Nock is monitoring smartphone data of highly suicidal people for six months after they present in a hospital at risk of suicide. The team has gathered thousands of surveys from people 12 years and older. “From before to after Covid-19, we’re seeing increases in suicidal thinking, among adults, that are predicted by increases in feeling isolated,” Dr. Nock said. But preliminary results suggest that such thoughts are not more frequent among the high-risk adolescent, for reasons the team is trying to work out.

The relationship between suicidal thoughts, which are fairly common in people with mental health diagnoses, and completed acts, which are comparatively rare, remains a subject of intense study. A fear of infection may push over the edge some people who would otherwise manage.

Dr. Makeda Jones, a New York psychiatrist, said that a colleague recently called because her teenage daughter tried to hang herself. “For some people who have not learned the skills to cope, this pandemic makes them feel more vulnerable and out of control,” Dr. Jones said. “And those two things will make some want to seize back control and say, ‘I don’t want to die of this disease, I can do it on my own terms.’”

Only careful study — the first pass, in this morbid, real-time experiment — will determine whether the acute fear of infection outweighs the effects of longer-term economic anxiety. For now, many people who have had to live with a nihilistic inner darkness see everyone in the world outside as suddenly having to do the same — a new experience indeed.

“It’s almost like you’re in the eye of the hurricane, that’s the way it feels,” said Josh, the college instructor in North Carolina. “I have been sitting with therapists all my life, telling them that the world is on fire, does anything I do matter? Now the world really is on fire, sort of, and I’m trying to teach myself to see both the good and the bad, and to see how I can actually be of help.”

'Deaths of despair': Coronavirus pandemic could push suicide, drug deaths as high as 150k, study says

USA TODAY
May 8, 2020
Jayne O'Donnell

The federal mental health czar is calling for more money to expand services to help people suffering amid the social isolation imposed by the coronavirus pandemic, as a new study estimates related deaths from alcohol, drug overdose and suicide could reach 150,000.

"We see very troubling signs across the nation," said Dr. Elinore McCance-Katz, assistant secretary at Department of Health and Human Services and head of the Substance Abuse and Mental Health Administration. "There's more substance abuse, more overdoses, more domestic violence and neglect and abuse of children."

McCance-Katz said the agency wants more money for services to address an anticipated surge in need for mental health and addiction treatment, which was already in short supply. She cited HHS' own substance abuse and mental health research and a February report in the British journal The Lancet on the psychological effects of quarantine.

The Lancet study said the effects can include post-traumatic stress disorder and suicide and are "wide-ranging, substantial, and can be long lasting." That's especially true if there isn't a clear end in sight, like now, said McCance-Katz.

"The impetus is COVID-19, but the need was there before and it's just been increased by what's happened as a result of the virus," she said.

The new study, released Friday by the Well Being Trust and the American Academy of Family Physicians, factored in isolation and uncertainty when it calculated the expected deaths from suicide, alcohol and drugs, based on nine unemployment scenarios.

The likely toll from these "deaths of despair" was the loss of an additional 75,000 lives, the study found. Death estimates ranged from 27,644 if the economy recovers quickly, to 154,037 if recovery is slow.

"We already had a major problem on our hands," said psychologist Benjamin Miller, the Well Being Trust's chief strategy officer. "Now people are disconnected and lonely with a level of uncertainty, fear and dread."

Alcohol sales have spiked since shelter in place orders were imposed. Aside from economy security, having a job provides boundaries for potential problem drinkers that help them self regulate, Miller said.

McCance-Katz also noted reports of more people seeking treatment for alcohol problems in regions where coronavirus has hit the hardest, including the Northeast. Addiction treatment centers report far higher call volumes and outpatient treatment, now typically conducted on video.

"There's a level of powerlessness with the economy, retirement funds, unemployment and trying to get unemployment checks," said Doug Tieman, CEO of Caron Treatment Centers in Pennsylvania. "All of them are anxiety-causing, and people feel lousy and then don’t see a light at the end of the tunnel."

Adults and even teens with substance abuse disorders struggle to reconcile often crushing addictions with their fears of contracting COVID-19. The chance of coronavirus transmission compounds parents' concerns when teens sneak out to buy drugs, especially when grandparents live in the home, said Dr. Joseph Lee, medical director of the Hazelden Betty Ford Foundation's youth continuum.

While April residential admissions at Hazelden were down about 2% over April 2019, intensive outpatient admissions soared 17%, thanks to virtual services launched in March, Lee said.

The stories leading to treatment can be startling.

New Hazelden patients include "multiple kids who drank everything in the house," and others who inhaled household products including the "air dusters" used to clean computer keyboards, Lee said.

Dr. Joseph Lee, is a psychiatrist and the medical director of the Hazelden Betty Ford Foundation youth continuum, where he is hearing from many parents worried about their children's now very apparent addictions.
A teenage girl addicted to heroin told her mother that she would kill herself if her mother didn't buy her heroin. The girl was afraid of contracting the virus, Lee said, so the mother complied.

Lee said the girl is entering treatment despite her fear of flying to get there. As with other out of state patients, Lee said he talked through the risks of both coronavirus and addiction to help the family "problem solve."

"For anyone who didn’t believe addiction was addiction, we are seeing it in all its glory now," said Lee, who works with 14- to 25-year-olds. "You see the power of the compulsive drive and this learned pathological conditioning."

@SandyHooper
Stay at home orders can affect mental health and impact those with substance use disorders. Are you currently managing addiction during COVID-19? Is managing recovery difficult due to social distancing? @USATODAY wants to hear your story in a video diary. https://forms.gle/5pqujEeiZYhNd7Zk7 …
Navigating addiction and mental health during COVID-19
Stay at home orders can affect mental health and impact those with substance use disorders. Are you currently managing addiction during COVID-19? Is managing recovery difficult due to social distan...

Bob Poznanovich, Hazelden's vice president of business development, added: "The needs are growing, and we're fully expecting and prepared for a surge in demand soon,"

To prevent "a disastrous wave of deaths of despair," the new Well Being Trust and AAFP report recommends an increased focus on reducing unemployment, easier access to treatment and more mental health and addiction services integrated into the healthcare system.

"More resources for mental health is a good thing," Miller said.. "Let's just make sure that we are investing in strategies we know work for communities and that integrate mental health into the places people want it."

SAMHSA got $425 million from the Coronavirus Aid, Relief, and Economic Security Act to boost mental health and addiction services. That compares with more than $100 billion for hospitals and is far from what critics say is needed.

"It's embarrassing the lack of attention our Congress places on mental health in a crisis," Miller said.

The SAMHSA funding is being used for services in Certified Community Behavioral Health Clinics, which were defined in 2017 by the Excellence in Mental Health and Addiction Act as a way to boost addiction treatment services and coordinate health care to disadvantaged individuals.

The clinics offer mental health and addiction treatment, along with primary care in the same facilities. Crisis intervention services are available around the clock to keep people experiencing breakdowns out of emergency rooms.

McCance-Katz said they are an example of "where the successes are" in behavioral health and she hopes to expand them further.

"We are given the opportunity to tell the administration what we think is needed," McCance-Katz said. "I do believe they're listening, so I'm hoping that we will get more resources."

FUNDING

Did the NIH fund or indirectly fund the Wuhan lab and, if so, how much money went to the Wuhan lab and what was the rationale for the program?

EcoHealth Alliance Inc. is the grantee organization, which made sub-awards to Wuhan Institute of Virology (Wuhan), East China Normal University (Shanghai), the Institute of Pathogen Biology (Beijing), and Duke-NUS Medical School (Singapore). The grant funding totaled $3.4 million over 6 years and was distributed across all sites. The grant was terminated on April 24, 2020. Publicly available information about the grant to EcoHealth Alliance Inc. is available on NIH RePORTER at this link. Information about the distribution to sub-awardees is not publicly available. We recommend you contact EcoHealth Alliance Inc. to get this information.

How much money from the $3.7 million awarded to EcoHealth Alliance went to the infectious disease lab in Wuhan?

Publicly available information about the grant to EcoHealth Alliance Inc. is available on NIH RePORTER at this link. Information about the distribution to sub-awardees is not publicly available. We recommend you contact EcoHealth Alliance Inc. to get this information since they made the subawards.

Would it be accurate to say that the initial grant was appropriated under the Obama administration and a renewal application was approved in 2019 by the NIH under the Trump administration?

The grant budget began in 2014 and ended in 2019. More information about the grant can be found on NIH RePORTER link. In the "History" tab, funding for each year of the grant is provided. In the "Details" tab in the "Other Information" section, start dates and end dates for the grant are provided. For your background, generally, grants are made for a period of time, for example 5 years, and funding is allocated every year based on a variety of performance reports the grantee is required to submit to NIH, which are due at specific times during the life cycle of a grant award.

Has NIH been directed to cut all funding to this lab?

NIH can confirm that the grant to EcoHealth Alliance, Inc. has been terminated. NIH does not discuss internal deliberations on grant terminations.

Is the project done, and has any money due to Wuhan been withdrawn/put on hold, etc?

NIH can confirm that the grant to EcoHealth Alliance, Inc. has been terminated. Upon termination the funds were restricted in the HHS Payment Management System, and the funds are no longer available to EcoHealth Alliance. The remaining balance of $369,819.56 will be returned to NIH.

GRANT OVERVIEW

What was the motivation and purpose of the grant?

Most emerging human viruses come from wildlife, and these represent a significant threat to public health and biosecurity in the United States and globally, as demonstrated by the SARS epidemic of 2002-03, and the current COVID-19 pandemic. The grant you are referencing is a multi-site, multi-country project supporting research that aims to understand what factors allow coronaviruses, including close relatives to SARS, to evolve and jump into the human population and cause disease (called a spillover event). Specifically, the project includes studying viral diversity in animal (bats) reservoirs, surveying people that live in high-risk communities for evidence of bat-coronavirus infection, and conducting laboratory experiments to analyze and predict which newly discovered viruses pose the greatest threat to human health.

Details on the grant are available on this NIH RePORTER link.

Was this grant unique? What other countries or labs received funding?

More information about the grant can be found at the NIH RePORTER link. If you select the "Similar Projects" tab, you will see other projects funded by NIH that may be similar.

SUBAWARDS

How do you define a "sub-awardee" and who chooses/approves them?

This NIH webpage has information on subawards: https://www.niaid.nih.gov/grants-contracts/refresher-subawar

What role did the NIH play in deciding how the money is allocated?

This NIH webpage has information on subawards: https://www.niaid.nih.gov/grants-contracts/refresher-subawar

In general, NIH recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities.

Did the WIV subaward have to be cleared by the State Department to be included in the grant to EcoHealth?

NIH policy requires U.S. Department of State (DOS) approval for all grants, cooperative agreements, and contracts that are issued to foreign institutions, subawards, as well as all

foreign components. For this grant, State Department clearance for all sites in China (including WIV) was submitted to and approved by DOS in May 2019.

I also understand that EcoHealth submitted annual reports on the status of their research that were reviewed by a panel of experts. Can NIH share those reports?

NIH requires grantees to submit a variety of reports which are due at specific times during the life cycle of a grant award. All reports must be accurate, complete, and submitted on time. More information about post-award monitoring and reporting is available on this page: https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm Such reports are not publicly available. You would need to submit a FOIA request for the reports.

EcoHealth Alliance said the Wuhan Institute of Virology was included as a collaborator on the grant - and NIH and State Dept have a process to approve such collaborators, so does that mean the NIH signed off?

This NIH webpage has information on subawards: https://www.niaid.nih.gov/grants-contracts/refresher-subawar

In general, NIH recipients are allowed a certain degree of latitude to rebudget within and between budget categories to meet unanticipated needs and to make other types of post-award changes. Some changes may be made at the recipient's discretion as long as they are within the limits established by NIH. In other cases, NIH prior written approval may be required before a recipient makes certain budget modifications or undertakes particular activities.

Do you happen to know whether any of the sites are continuing work on the project despite the termination of the grant?

You would need to ask EcoHealth Alliance directly about their research.

Would there be any way to tell from the NIH RePorter site whether EcoHealth Alliance or any of the sites have requested funding for a new grant related to this project or would that be something I would have to ask them specifically?

Information on grant applications is not publicly available as they contain proprietary information. NIH makes information available on grants it awards on NIH Report and NIH Reporter.

DECISION TO TERMINATE

What was the reason the grant was terminated?

NIH does not discuss internal deliberations on grant terminations.

Was this done at the direction of officials within the White House, or any other branches of the Administration (ie. outside of NIH)? If so, which?

Did the White House communicate with NIH/NIAID about cutting funding? Who made the decision to do so?

Critics list a number of reasons they say the decision was unwarranted -- what is NIH's response to each of these:

- **very little of the grant was being directed to the Wuhan Institute of Virology**
- **many researchers say the preponderance of evidence suggests the Wuhan Institute of Virology was not responsible for unleashing the coronavirus causing the current pandemic accidentally or otherwise.**
- **the research project is fundamental to scientific efforts to address the current pandemic as well to foresee and prepare for future ones -- and EcoHealth was the only U.S. research group working in China. So termination of the project will cause the U.S. to lose crucial access to data and significantly set back research and future preparedness.**

NIH does not discuss internal deliberations on grant terminations.

The Office of the Director of National Intelligence issued a statement on their investigation into the origins of the outbreak. Any questions related to the origins of the outbreak should be directed to ODNI.

Was the NIH decision politically motivated because of allegations that EcoHealth had subcontracted to the Wuhan Institute of Virology?

NIH does not discuss internal deliberations on grant terminations.

The Office of the Director of National Intelligence issued a statement on their investigation into the origins of the outbreak. Any questions related to the origins of the outbreak should be directed to ODNI.

If the concern was that the PI was working with the Wuhan Institute of Virology, and NIH was informed that in fact no 2019 or 2020 grant money had flowed to WIV, nor would it, why did the entire grant need to be cancelled?

NIH does not discuss internal deliberations on grant terminations.

The New York Post has reported that funding was cut because NIH is investigating the Wuhan lab where the pandemic may have begun, and Eco Health Alliance was using taxpayer dollars to support that lab. Is that accurate?

NIH does not discuss internal deliberations on grant terminations.

The Office of the Director of National Intelligence issued a statement on their investigation into the origins of the outbreak. Any questions related to the origins of the outbreak should be directed to ODNI.

EcoHealth Alliance says the experiments under that grant and the previous grant couldn't have violated the NIH moratorium on gain of function studies because NIH approved them. Is that accurate? Did they violate the moratorium?

The study we funded is described in the RePORTER entry shared with you: https://projectreporter.nih.gov/project_info_description.cfm?aid=9819304&icde=49588715&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=. The research supported under grant characterized the function of newly discovered bat spike proteins and naturally occurring pathogens and did not involve the enhancement of the pathogenicity or transmissibility of the viruses studied. Therefore, after review NIAID determined the awards were not subject to either the Gain-of-Function Research Funding Pause or its successor, the DHHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens.

REINSTATEMENT/WHAT COMES NEXT

Are there plans to reinstate the funding in some fashion?

No, the grant was terminated.

Letters to EcoHealth Alliance

Why did Mike Lauer write that the grant was being terminated "for convenience" if in fact it was being terminated "for cause" as you indicate below?

NIH does not discuss internal deliberations on grant terminations. Under no circumstance did Mike Lauer or NIH indicate the grant was being terminated "for convenience".

Could he also state how the grant which last year was deemed of high priority for public health (it scored in the 3rd percentile) had become instead a danger to public health such that its cancellation was necessary "to protect the public health and welfare from the effects of a serious deficiency." ? How exactly was the grant's execution threatening the US public health and welfare?

NIH does not discuss internal deliberations on grant terminations.

Why did you [Mike Lauer] ask for a list of all Chinese participants in the project days before the decision to cut funding?

NIH does not discuss internal deliberations on grant terminations.

I have seen communications suggesting that the decision was rooted in concerns that EcoHealth funding was going to the Wuhan Institute of Virology. Is this true? Also, is it common to revoke funding effective immediately and demand funds be remitted? How often has that happened and what scenarios has it happened in during the past?

NIH does not discuss internal deliberations on grant terminations.

From: Tabak, Lawrence (NIH/OD) [E]
To: Collins, Francis (NIH/OD) [E]
Subject: FW: Statement of ACD concern and its followup
Date: Saturday, June 13, 2020 1:33:33 PM

From: JUDITH KIMBLE <(b) (6)
Date: Saturday, June 13, 2020 at 11:28 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Subject: Re: Statement of ACD concern and its followup

Look forward to talking at 4pm EST. An email from Bob Horvitz, pasted in below, just arrived in my inbox, and I wanted you to be aware of it:

Dear All,

Yesterday's CLS meeting (which unfortunately Judith had to miss because of the overlapping ACD meeting) included extensive conversations with three members of Congress: Senators Bill Cassidy (R-LA) and Roy Blunt (R-MO) and Representative Donna Shalala (D-FL). Before the three joined, the CLS voted to endorse the Nobel statement concerning EcoHealth Alliance/Peter Daszak. In each of the three conversations I explicitly raised this issue, and in each case Keith followed with a statement about the broad concern of the biomedical community and the endorsement of the letter by the CLS.

Bill Cassidy: He seemed to possibly have heard about the letter, but not to have really absorbed it or thought about it. At one point he said he had not seen the letter. His statement was "I know what I've been told, but not what I know," by which he seemed to mean he hadn't done his homework. He offered a number of potential issues — safety concerns ("was supposed to be BSL-4 and was only BSL-2") and IP/cyper espionage, China — but stressed that he was "committed to the free exchange of science." In discussing his support of foreign, including Chinese, students, he told us that his sone goes to the University of Chicago and has a girl friend from Shanghai who has been afraid to go home for fear she couldn't return; he indicated a personal frustration with the inappropriate challenges of this situation. This part of the conversation ended with his asking us to send him the letter with an accompanying note addressing his concerns explicitly. He said to send this to his "personal" e-mail at (b) (6) (I don't know if there is a space after William). I think we should do this ASAP. With what language might we best address his two concerns? Help, please.

Roy Blunt: He was aware of the letter but said, "I don't know enough about it." He stressed that there is always a balance and that there are some legitimate concerns, by which he seemed to be implying IPI issues. Keith responded strongly by saying "There was no IP issue or security threat involved." Blunt said a number of times "I will look at that," and it seemed at the end that we should send him a copy of the letter with a cover note probably identical to the one we send to Cassidy.

Donna Shalala: I opened the conversation with her very differently from the way I started with Cassidy and Blunt. In the latter cases I began with, "I would like to ask if you are aware of … ?", whereas with Donna I began with, "I would like your advice and help — we have not had a response from Azar or Collins; what can we do to force them to respond?" Her answer was refreshing and clear — "A member of Congress should ask them to respond at a Congessional hearing they are both at." She added that there will be such a hearing in 1 1/2 weeks. Donna was very aware of the letter and said that she "was horrified" at what happened. She did not quite say that she would ask the question of Azar/Collins. Harold, do you think you could/should ask Donna to be that member of Congress who does so? If not, how should we proceed?

Keith, please feel free to add/correct to my summaries.

Best,

Bob

From: Larry Tabak <(b) (6)

Date: Saturday, June 13, 2020 at 8:22 AM
To: Judith Kimble <(b) (6)
Subject: Re: Statement of ACD concern and its followup
4 is fine

Sent from my iPhone

On Jun 13, 2020, at 8:35 AM, JUDITH KIMBLE <(b) (6) wrote:

Thanks Larry. How about 3pm or 4pm EST? Is 4pm EST too late?
Judith

From: Larry Tabak <(b) (6)
Date: Saturday, June 13, 2020 at 6:14 AM
To: Judith Kimble <(b) (6)
Subject: Re: Statement of ACD concern and its followup
Judith,
Pleased to speak with you either today or tomorrow, anytime in the mid-afternoon on. Let me know what time is convenient for you.
Best wishes,
Larry

From: JUDITH KIMBLE <(b) (6)
Date: Friday, June 12, 2020 at 10:53 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Subject: Re: Statement of ACD concern and its followup
The idea is that you and I talk first, which I assume will not need to be open to the public.
Let me know if there is a good time for you over the week end or Monday, and I'll make it work.
Judith

From: Larry Tabak <(b) (6)
Date: Friday, June 12, 2020 at 8:39 PM
To: Judith Kimble <(b) (6) "Collins, Francis (NIH/OD) [E]" <(b) (6)
Cc: Anne Churchland <(b) (6) "Berger, Shelley" <(b) (6) "Lee, Brendan" <(b) (6) "Barbara Wold, Ph.D." <(b) (6) "Dina Katabi, Ph.D." <(b) (6) Francis Cuss <(b) (6) "James Hildreth, M.D., Ph.D." <(b) (6) "Shendure, Jay" <(b) (6) "Kristina Johnson, Ph.D." <(b) (6) "M. D. Mark Dybul (b) (6) <(b) (6) "M.

Roy Wilson, M.D." <(b) (6) "Rebekah Drezek, Ph.D." <(b) (6) "Roberta Brinton, Ph.D." <(b) (6) "Shelley Berger Ph. D. (<(b) (6) "Spero Martin Manson, Ph.D." <(b) (6) "Wendy Chapman, Ph.D." <(b) (6)

Subject: Re: Statement of ACD concern and its followup

Judith,

Of course I am willing to speak with any ACD member informally. However, as you know a FACA committee cannot meet without posting a notice in the Federal Register and then the meeting must be held in an open session that is accessible to the public. Please let me know who would like to speak with me and we can arrange a phone call.

Best wishes,

Larry

From: JUDITH KIMBLE <(b) (6)

Date: Friday, June 12, 2020 at 7:38 PM

To: Francis Collins <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)

Cc: Anne Churchland <(b) (6) "Berger, Shelley" <(b) (6) JUDITH KIMBLE <(b) (6) Brendan Lee <(b) (6) "Barbara Wold, Ph.D." <(b) (6) "Dina Katabi, Ph.D." <(b) (6) Francis Cuss <(b) (6) "James Hildreth, M.D., Ph.D." <(b) (6) "Shendure, Jay" <(b) (6) "Kristina Johnson, Ph.D." <(b) (6) "M. D. Mark Dybul (<(b) (6) <(b) (6) "<(b) (6) <(b) (6) "Rebekah Drezek, Ph.D." <(b) (6) "Roberta Brinton, Ph.D." <(b) (6) "Shelley Berger Ph. D. (<(b) (6) <(b) (6) "Spero Martin Manson, Ph.D." <(b) (6) "Wendy Chapman, Ph.D." <(b) (6)

Subject: Statement of ACD concern and its followup

Dear Drs Collins and Tabak, Francis and Larry,

I write on behalf of the NIH ACD to thank you for the opportunity to present our statement of concern at the meeting yesterday. This email is a follow up. At the meeting, we reported that it had been endorsed by 15 of 17 members of the ACD with two abstentions; however, it has now been endorsed by 16 of the 17 ACD (one person initially listed as an abstention had not received our communications because of an email glitch). The other abstention has been confirmed. A pdf of the statement is attached.

We understand that this is an extremely thorny issue, though I doubt we fully understand the extent of all its thorns. However, the integrity of the NIH peer review process has been challenged broadly in the biomedical community, and that challenge cannot be ignored. We therefore very much hope you will consider our

recommendations. Indeed, we would appreciate your advice and guidance moving forward and would like to work with you if that would be helpful. Towards that end, we wonder if a phone conversation might be possible with one or both of you. Since the statement is already public (e.g. the ACD meeting and now twitter), a call in the next day or two would be great.

With sincere respect and best wishes in this difficult time,

Judith

Lima, Jason (NIH/OD) [E]

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Tuesday, June 30, 2020 5:54 AM
To: Collins, Francis (NIH/OD) [E]
Subject: Re: fyi

Ok; thanks.

From: Francis Collins <(b) (6)
Date: Tuesday, June 30, 2020 at 5:53 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Subject: RE: fyi

Let's discuss. Noted one typo near bottom of p. 2 – (b) (5)

FC

From: Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Sent: Monday, June 29, 2020 9:41 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)
Subject: fyi

Francis,
Bob has cleared this.
Larry

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

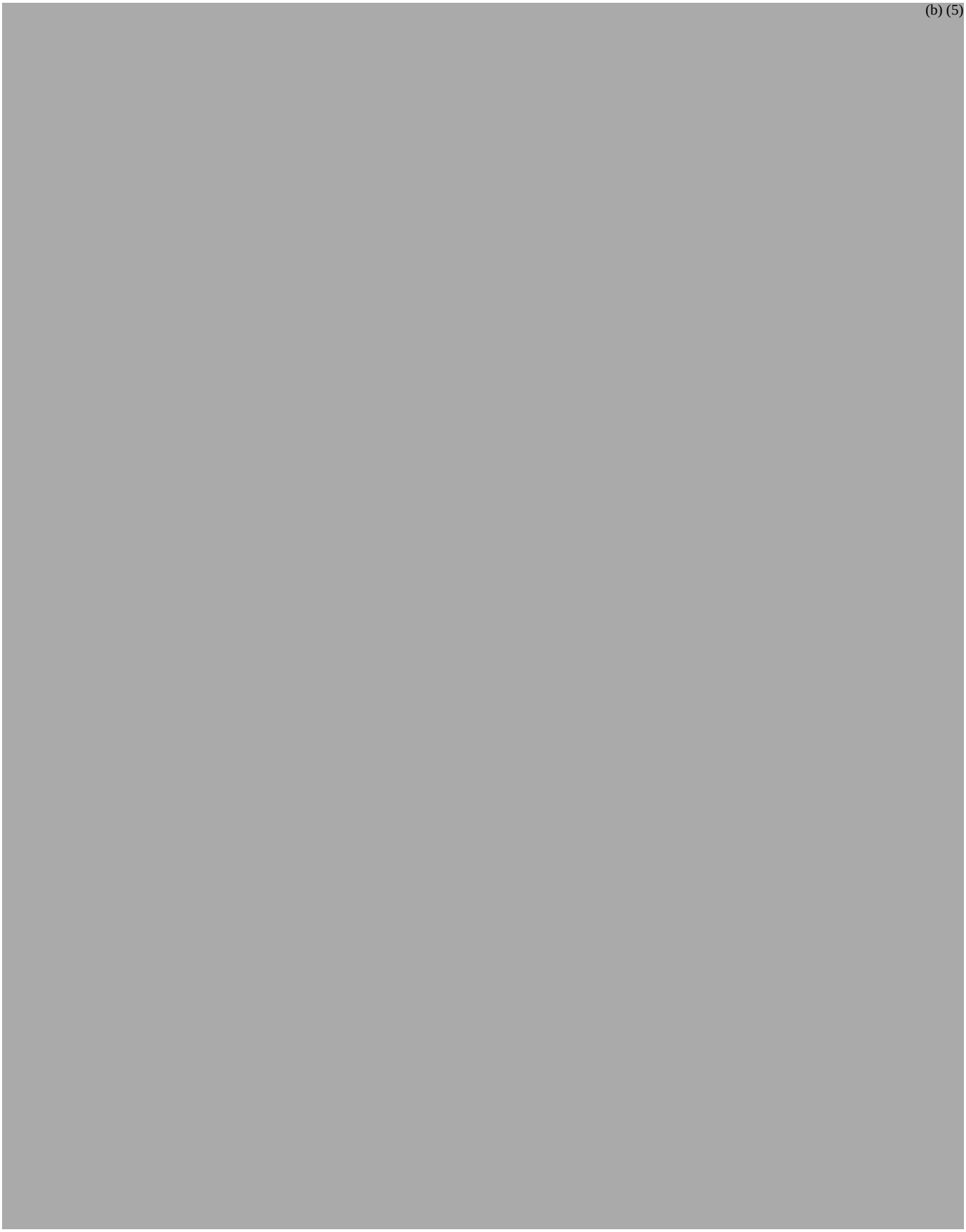
6 July 2020

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:

(b) (5)


(b) (5)


(b) (5)

From: Burklow, John (NIH/OD) [E]
To: Collins, Francis (NIH/OD) [E]
Subject: Fwd: Wuhan lab grant
Date: Tuesday, June 23, 2020 8:45:15 PM
Attachments: image001.png
ATT00001.htm
Termination question E&C 6-23-20.docx
ATT00002.htm

FYI—Adrienne typed it up!

Sent from my iPhone

Begin forwarded message:

> **From:** "Hallett, Adrienne (NIH/OD) [E]" < (b) (6)
> **Date:** June 23, 2020 at 5:49:46 PM EDT
> **To:** "Burklow, John (NIH/OD) [E]" < (b) (6) "Higgins, Lauren (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Wolinetz, Carrie (NIH/OD) [E]" < (b) (6)
> **Subject: Re: Wuhan lab grant**
>
> The transcript won't be out for another few hours so I transcribed it myself. It is attached.

From: John Burklow < (b) (6)
Date: Tuesday, June 23, 2020 at 4:49 PM
To: Adrienne Hallett < (b) (6) Lauren Higgins < (b) (6)
Subject: Fwd: Wuhan lab grant

Pls see below—is there a fast way to get the transcript of the hearing?

Thx,

John

Sent from my iPhone

Begin forwarded message:

> **From:** "Collins, Francis (NIH/OD) [E]" < (b) (6)
> **Date:** June 23, 2020 at 4:25:19 PM EDT

To: "Burklow, John (NIH/OD) [E]" <(b) (6)
Cc: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
"Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: RE: Wuhan lab grant

Can we get the transcript?

From: Burklow, John (NIH/OD) [E] <(b) (6)
Sent: Tuesday, June 23, 2020 4:22 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6) NIH Director's Executive Committee <(b) (6)
Cc: Myles, Renate (NIH/OD) [E] <(b) (6)
Subject: Fwd: Wuhan lab grant

FYI

Sent from my iPhone

Begin forwarded message:

> **From:** "Hall, Bill (HHS/ASPA)" <(b) (6)
> **Date:** June 23, 2020 at 4:18:51 PM EDT
> **To:** "Myles, Renate (NIH/OD) [E]" <(b) (6)
> "Burklow, John (NIH/OD) [E]" <(b) (6)
> "Billet, Courtney (NIH/NIAID) [E]" <(b) (6)
> **Subject: Wuhan lab grant**
>
> Not sure if you've been watching but ASF was just asked why NIH cancelled the EcoHealth Alliance grant (and Wuhan lab). He made quite clear that NIH was simply told to cancel it.

William Hall
Deputy Assistant Secretary for Public Affairs (Public Health)
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health & Human Services
Washington, DC`
Direct: (b) (6)
Mobile: (b) (6)
Email: (b) (6)
www.hhs.gov

Rep. Marc Veasey (D-TX): Dr Fauci, there was a grant that was, it was a coronavirus related grant that was not renewed and I wanted to talk with you to make sure that we just get the facts straight about this because I was really concerned about this. Do you know why this grant was canceled or if anyone at the White House or HHS pressured your colleagues to do so and, specifically, I wanted to talk with you about the National Institutes of Health. There was a decision made by the Trump Administration to cancel research on a grant that was specifically focused on coronavirus emergence while we are in the midst of this coronavirus pandemic and it just didn't make any sense to me why this grant would be canceled.

Dr. Fauci: The question you're asking is why was it cancelled?

Veasey: Yes, that's right. Why was this grant canceled when we're in the middle of this pandemic. It seems like it would have been very helpful for us to have this research considering that we know very little about COVID-19.

Fauci: Okay. It was cancelled because the NIH was told to cancel it.

Veasey: And why were they told to cancel it?

Fauci: I don't know the reason but we were told to cancel it.

Veasey: Okay, thank you very much.

From: Fauci, Anthony (NIH/NIAID) [E]
To: Collins, Francis (NIH/OD) [E]
Subject: RE: EcoHealth grant
Date: Thursday, July 9, 2020 6:24:51 AM

Thanks, Francis. You are correct. I would not be surprised if this letter ultimately goes public. If so, the press will be all over it, especially the part about the 2012 infections in China. Fasten our seat belts.
Tony

From: Collins, Francis (NIH/OD) [E] <(b) (6)
Sent: Thursday, July 9, 2020 6:16 AM
To: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)
Cc: Tabak, Lawrence (NIH/OD) [E] <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: EcoHealth grant

Hi Tony,

I wanted to be sure you were aware that the letter to the EcoHealth PI went out yesterday. This reinstates the grant but immediately suspends it, pending responses to a number of important questions about WIV.

I don't know whether the PI will make this public, but I'd be surprised if the press doesn't get wind of this somehow.

Francis

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

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Burklow, John (NIH/OD) [E]
To: Tabak, Lawrence (NIH/OD) [E]
Cc: Collins, Francis (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Subject: Re: EcoHealth
Date: Thursday, July 9, 2020 7:37:03 AM

In fact, Amanda and Renate discussed yesterday. Thought it was happening today. (b) (5)

Sent from my iPhone

> On Jul 9, 2020, at 7:29 AM, Burklow, John (NIH/OD) [E] <(b) (6) wrote:
>
> (b) (5)
>
> Sent from my iPhone
>
> > On Jul 9, 2020, at 6:50 AM, Tabak, Lawrence (NIH/OD) [E] <(b) (6) wrote:
> >
> > Again – (b) (5)
> > If the grantee organization chooses to make it public, so be it. (b) (5)
> > Laryr
> >
> > ---
> >
> > **From:** Francis Collins <(b) (6)
> > **Date:** Thursday, July 9, 2020 at 5:59 AM
> > **To:** "Burklow, John (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Hallett, Adrienne (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
> > **Subject:** FW: EcoHealth
> >
> > Get ready for the press to find out. (b) (5)
> >
> > FC

P.S. to Mike: Can I have a copy of the final letter?

From: Lauer, Michael (NIH/OD) [E] <(b) (6)
Sent: Wednesday, July 8, 2020 10:40 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6) Hallett, Adrienne (NIH/OD) [E] <(b) (6)
Cc: Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: Re: EcoHealth

Hi Francis – yes, it's out!

Many thanks, Mike

From: "Collins, Francis (NIH/OD) [E]" <(b) (6)
Date: Wednesday, July 8, 2020 at 9:35 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Subject: EcoHealth

Did letter go to PI today?

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

cc: Dr. Erik Stemmy
Ms. Emily Linde

From: Hallett, Adrienne (NIH/OD) [E]
To: Collins, Francis (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]
Subject: Re: EcoHealth Oversight request
Date: Monday, July 20, 2020 9:03:49 PM

I just got it from HHS this evening.

> On Jul 20, 2020, at 8:42 PM, Collins, Francis (NIH/OD) [E] <(b) (6)> wrote:
>
> Let's discuss at ExComm tomorrow. I note the letter is dated June 26 – is the first time we've seen it?
>
> FC
>
> ---
>
> **From:** Hallett, Adrienne (NIH/OD) [E] <(b) (6)>
> **Sent:** Monday, July 20, 2020 7:39 PM
> **To:** Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Lauer, Michael (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)>
> **Subject:** EcoHealth Oversight request
>
> (b) (5) Please see attached Oversight investigation into the issue. Please note the signers:
>
> Frank Pallone, Chair of E&C Cmte
> Diana DeGette, Chair of E&C Subcmte on Investigations
> Eddie Bernice Johnson, Chair of Science Cmte
> Bill Foster, Chair of Science Subcmte on Investigations
>
> <06.26.20 SST EC Letter to HHS.pdf>

Congress of the United States
House of Representatives
Washington, DC 20515

June 26, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar,

We write with strong concerns surrounding the Administration's termination of the National Institutes of Health (NIH) grant to EcoHealth Alliance on April 24, 2020.[1] In the letter communicating the grant's termination, NIH Deputy Director for Extramural Research, Dr. Michael Lauer, wrote that "At this time, NIH does not believe the current project outcomes align with the program goals and agency priorities."[2] However, press reports indicate that the grant was canceled because a small portion of the funding was to be given to the Wuhan Institute of Virology for on-the-ground sample collection and analysis.[3] Given the potential for this study to inform our knowledge of coronavirus disease 2019 (COVID-19) transmission, it is deeply concerning that it may have been canceled for political reasons in the midst of the current pandemic.

It is always important that federal research priorities are driven by science-based decisions. This is especially true in a time that requires unparalleled investment in research that may help bring an end to this public health crisis. It is therefore troubling that this abrupt grant cancellation came just a week after President Trump announced that the Administration was looking into "grants going to that area" and continued that "we will end that grant very quickly."[4] This was in response to a reporter referencing false claims that COVID-19 "likely

[1] Sharah Owermohle, "Trump cuts U.S. research on bat-human virus transmission over China ties," *Politico*, April 27, 2020, accessed here: https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076
[2] Nurith Aizenman, "Why The U.S. Government Stopped Funding A Research Project On Bats And Coronaviruses," *NPR*, May 1, 2020, accessed here: https://www.npr.org/sections/goatsandsoda/2020/04/29/847948272/why-the-u-s-government-stopped-funding-a-research-project-on-bats-and-coronaviru
[3] *Id.*
[4] Clip of President Trump with Coronavirus Task Force Briefing, *CSPAN*, April 17, 2020, accessed here: https://www.c-span.org/video/?c4869590/user-clip-us-2015-grant-wuhan-lab-question

came from a Level 4 lab in Wuhan."[5] The Administration has been pushing this theory[6] despite scientific experts saying this path of transmission would be virtually impossible given what is known about the virus and lab safety protocols.[7] If this theory is the basis for the grant termination, it would be an egregious example of the Administration politicizing scientific decision making in order to further a politically convenient narrative.

EcoHealth Alliance's grant was renewed in 2019 after an initial five-year grant on the same topic. The grant it received was extremely competitive – only 22 percent of proposals were funded in 2019.[8] The July 2019 project proposal was titled, "Understanding the Risk of Bat Coronavirus Emergence."[9] In the midst of the COVID-19 pandemic that has taken over 115,000 American lives, it is inconceivable that this project would no longer "align with the program goals and agency priorities" of NIH. Any termination of a grant that has gone through NIH's rigorous scientific review process must be adequately justified on a scientific basis – particularly a grant which would appear to be so relevant to understanding our current health crisis.

As the Committees of jurisdiction over public health and science, we need to better understand the decision to terminate EcoHealth Alliance's NIH grant. We are especially concerned given Dr. Anthony Fauci's, Director of NIH's National Institute of Allergy and Infectious Diseases, assertion at a Committee on Energy and Commerce hearing on June 23 that "the grant was canceled because NIH was told to cancel it."[10] In order to understand how this decision was reached, we request a briefing to be delivered by July 15, 2020. At this briefing, we ask that you be prepared to address the following questions:

1. When the decision was made to terminate the grant to EcoHealth Alliance;

2. Who at HHS was involved in the decision to terminate the grant;

3. Whether entities outside HHS, including but not limited to the White House, the State Department, the National Security Council, and intelligence agencies, were involved in this decision;

---

[5] *Id.*

[6] Mark Mazzetti, Julian E. Barnes, Edward Wong, and Adam Goldman, "Trump Officials Are Said to Press Spies to Link Virus and Wuhan Labs," *New York Times*, April 30, 2020, accessed here: https://www.nytimes.com/2020/04/30/us/politics/trump-administration-intelligence-coronavirus-china.html

[7] Geoff Brumfel and Emily Kwong, "Virus Researchers Cast Doubt On Theory Of Coronavirus Lab Accident," *NPR*, April 23, 2020, accessed here: https://www.npr.org/sections/goatsandsoda/2020/04/23/841729646/virus-researchers-cast-doubt-on-theory-of-coronavirus-lab-accident

[8] Research Grants: Competing Applications, Awards, and Success Rates, National Institutes of Health, January 2020, accessed here: https://report.nih.gov/nihdatabook/category/6

[9] "Understanding the Risk of Bat Coronavirus Emergence," National Institutes of Health Research Portfolio Online Reporting Tools, July 2019, accessed here: https://projectreporter.nih.gov/project_info_description.cfm?aid=9819304&icde=49752569

[10] House Committee on Energy and Commerce, Testimony of Anthony S. Fauci, M.D., Director, National Institute for Allergy and Infectious Diseases, *Oversight of the Trump Administration's Response to the COVID-19 Pandemic*, 116th Cong. (Jun. 23, 2020).

4. The analysis conducted to determine that the EcoHealth Alliance grant's project outcomes did not align with program goals and NIH priorities;

5. Any analysis conducted to determine EcoHealth Alliance's alleged improper disbursal of NIH funds to the Wuhan Institute of Virology;

6. Any other decision NIH has made to terminate grants since January 1, 2020; and

7. Any further action NIH is considering taking regarding EcoHealth Alliance or any other grant holder regarding alleged relationships with international laboratories.

In addition to the briefing, we request the following materials be provided to the Committees no later than July 10, 2020. Please provide these materials in a searchable electronic format.

1. All documents and communications relating to the cancellation of EcoHealth Alliance's grant, including the notification to and any response from EcoHealth Alliance;

2. All documents and communications regarding any potential direction from outside entities, including the White House or other Agencies or Departments, to terminate grants based on suspicion of collaboration with international laboratories;

3. All documentation of audits or other analyses conducted to determine improper disbursement of federal grant money from grant-holding institutions to other entities; and

4. The criteria that NIH used to assess the EcoHealth Alliance grant and determine that such grant merited cancelation, and documentation thereof.

Any decision to terminate a research grant should be conducted in a deliberative and transparent process that adheres to the highest standards of scientific integrity. Especially in this unprecedented time, it is important that our public health and science agencies remain free from political pressure and be allowed to pursue federally-funded research based on scientific merit.

Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space,
and Technology

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce

Bill Foster
Chairman
Subcommittee on Investigations and Oversight

Diana DeGette
Chair
Subcommittee on Oversight and Investigations

From:	Hallett, Adrienne (NIH/OD) [E]
To:	Collins, Francis (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Cc:	Lohmann, Larry (NIH/OD) [E]; LaMontagne, Karen (NIH/OD) [E]
Subject:	Re: EcoHealth oversight response
Date:	Tuesday, July 21, 2020 1:50:23 PM

I think they'd like to but I don't know. I'm surprised they didn't publicize the letter, in which case we would have heard of it earlier.

From: Francis Collins <(b) (6)
Date: Tuesday, July 21, 2020 at 1:38 PM
To: Adrienne Hallett <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) Lawrence Tabak <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) Karen LaMontagne <(b) (6)
Subject: RE: EcoHealth oversight response

Sounds like a good plan. Will the Committee be likely to make our response public?

FC

From: Hallett, Adrienne (NIH/OD) [E] <(b) (6)
Sent: Tuesday, July 21, 2020 12:59 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Lohmann, Larry (NIH/OD) [E] <(b) (6) LaMontagne, Karen (NIH/OD) [E] <(b) (6)
Subject: EcoHealth oversight response

Good news! I talked HHS out of Mike doing a briefing. .

We are going to draft a response to the letter that doesn't actually answer the questions in the letter but rather presents a narrative of what happened at a high level, ending with the reinstatement and attaching the NIH reinstatement letter. The Committee may come back for other documents but I'm hoping to run out the clock.

Mike, can you help with the draft?

Thanks!
Adrienne

From:	Lauer, Michael (NIH/OD) [E]
To:	Hallett, Adrienne (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Cc:	Lohmann, Larry (NIH/OD) [E]; LaMontagne, Karen (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
Subject:	Re: EcoHealth oversight response
Date:	Wednesday, July 22, 2020 6:29:05 AM

Thanks so much Adrienne! I'll draft something today.

Mike

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Tuesday, July 21, 2020 at 1:50 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) "LaMontagne, Karen (NIH/OD) [E]" <(b) (6)
Subject: Re: EcoHealth oversight response

I think they'd like to but I don't know. I'm surprised they didn't publicize the letter, in which case we would have heard of it earlier.

From: Francis Collins <(b) (6)
Date: Tuesday, July 21, 2020 at 1:38 PM
To: Adrienne Hallett <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) Lawrence Tabak <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) Karen LaMontagne <(b) (6)
Subject: RE: EcoHealth oversight response

Sounds like a good plan. Will the Committee be likely to make our response public?

FC

From: Hallett, Adrienne (NIH/OD) [E] <(b) (6)
Sent: Tuesday, July 21, 2020 12:59 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Lohmann, Larry (NIH/OD) [E] <(b) (6) LaMontagne, Karen (NIH/OD) [E] <(b) (6)
Subject: EcoHealth oversight response

Good news! (b) (5)

(b) (5)

Mike, can you help with the draft?

Thanks!
Adrienne

From:	Lauer, Michael (NIH/OD) [E]
To:	Hallett, Adrienne (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Cc:	Lohmann, Larry (NIH/OD) [E]; LaMontagne, Karen (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Black, Jodi (NIH/OD) [E]
Subject:	Re: EcoHealth oversight response
Date:	Thursday, July 23, 2020 6:29:08 AM
Attachments:	EcoHealth Alliance narrative 7 23 20.docx Daszak 7 8 20.pdf

Hi Adrienne – Taking FC off. Here is a draft narrative along with a copy of the July 8 letter. See what you think.
Thanks again!
Mike

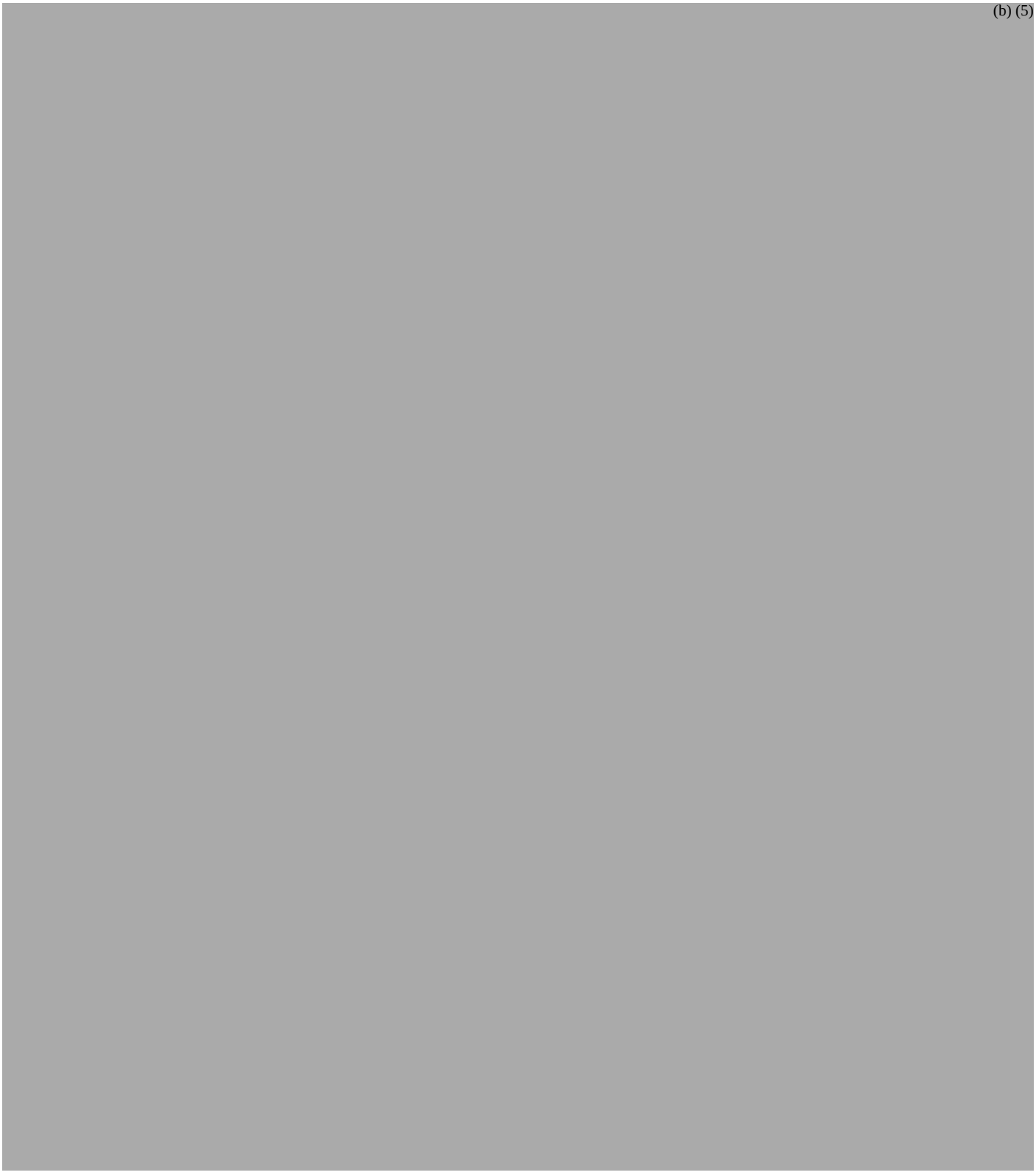
From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Tuesday, July 21, 2020 at 1:50 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) "LaMontagne, Karen (NIH/OD) [E]" <(b) (6)
Subject: Re: EcoHealth oversight response
I think they'd like to but I don't know. I'm surprised they didn't publicize the letter, in which case we would have heard of it earlier.

From: Francis Collins <(b) (6)
Date: Tuesday, July 21, 2020 at 1:38 PM
To: Adrienne Hallett <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) Lawrence Tabak <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) Karen LaMontagne <(b) (6)
Subject: RE: EcoHealth oversight response
Sounds like a good plan. Will the Committee be likely to make our response public?
FC

From: Hallett, Adrienne (NIH/OD) [E] <(b) (6)
Sent: Tuesday, July 21, 2020 12:59 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Cc: Lohmann, Larry (NIH/OD) [E] <(b) (6) LaMontagne, Karen (NIH/OD) [E] <(b) (6)
Subject: EcoHealth oversight response
Good news! I (b) (5)
(b) (5)
Mike, can you help with the draft?
Thanks!

Adrienne

EcoHealth Alliance narrative
Mike Lauer (OER)
July 23, 2020




(b) (5)

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

cc: Dr. Erik Stemmy
Ms. Emily Linde

From:	Hallett, Adrienne (NIH/OD) [E]
To:	Lauer, Michael (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]
Cc:	Lohmann, Larry (NIH/OD) [E]; LaMontagne, Karen (NIH/OD) [E]
Subject:	Re: EcoHealth oversight response
Date:	Monday, July 27, 2020 3:58:31 PM
Attachments:	EcoHealth Alliance narrative 7-27-20.docx 06.26.20 SST EC Letter to HHS.pdf

Attached is the incoming EcoHealth Alliance letter plus Mike's draft of the response, with some edits and additions from me.

A few issues to note:

(b) (5)

Please let me know how you would like to proceed.
Adrienne

From: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Date: Wednesday, July 22, 2020 at 6:29 AM
To: Adrienne Hallett <(b) (6) Francis Collins <(b) (6) Lawrence Tabak <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) Karen LaMontagne <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Subject: Re: EcoHealth oversight response

Thanks so much Adrienne! I'll draft something today.

Mike

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Tuesday, July 21, 2020 at 1:50 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) "LaMontagne, Karen (NIH/OD)

[E]" < (b) (6)
Subject: Re: EcoHealth oversight response

I think they'd like to but I don't know. I'm surprised they didn't publicize the letter, in which case we would have heard of it earlier.

From: Francis Collins < (b) (6)
Date: Tuesday, July 21, 2020 at 1:38 PM
To: Adrienne Hallett < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6) Lawrence Tabak < (b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" < (b) (6) Karen LaMontagne < (b) (6)
Subject: RE: EcoHealth oversight response

Sounds like a good plan. Will the Committee be likely to make our response public?

FC

From: Hallett, Adrienne (NIH/OD) [E] < (b) (6)
Sent: Tuesday, July 21, 2020 12:59 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6)
Cc: Lohmann, Larry (NIH/OD) [E] < (b) (6) LaMontagne, Karen (NIH/OD) [E] < (b) (6)
Subject: EcoHealth oversight response

Good news! (b) (5)

(b) (5)

Mike, can you help with the draft?

Thanks!
Adrienne

EcoHealth Alliance narrative
Mike Lauer (OER)
July 23, 2020

(b) (5)

[redacted]


(b) (5)

Congress of the United States
House of Representatives
Washington, DC 20515

June 26, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar,

We write with strong concerns surrounding the Administration's termination of the National Institutes of Health (NIH) grant to EcoHealth Alliance on April 24, 2020.[1] In the letter communicating the grant's termination, NIH Deputy Director for Extramural Research, Dr. Michael Lauer, wrote that "At this time, NIH does not believe the current project outcomes align with the program goals and agency priorities."[2] However, press reports indicate that the grant was canceled because a small portion of the funding was to be given to the Wuhan Institute of Virology for on-the-ground sample collection and analysis.[3] Given the potential for this study to inform our knowledge of coronavirus disease 2019 (COVID-19) transmission, it is deeply concerning that it may have been canceled for political reasons in the midst of the current pandemic.

It is always important that federal research priorities are driven by science-based decisions. This is especially true in a time that requires unparalleled investment in research that may help bring an end to this public health crisis. It is therefore troubling that this abrupt grant cancellation came just a week after President Trump announced that the Administration was looking into "grants going to that area" and continued that "we will end that grant very quickly."[4] This was in response to a reporter referencing false claims that COVID-19 "likely

[1] Sharah Owermohle, "Trump cuts U.S. research on bat-human virus transmission over China ties," *Politico*, April 27, 2020, accessed here: https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076
[2] Nurith Aizenman, "Why The U.S. Government Stopped Funding A Research Project On Bats And Coronaviruses," *NPR*, May 1, 2020, accessed here: https://www.npr.org/sections/goatsandsoda/2020/04/29/847948272/why-the-u-s-government-stopped-funding-a-research-project-on-bats-and-coronaviru
[3] *Id.*
[4] Clip of President Trump with Coronavirus Task Force Briefing, *CSPAN*, April 17, 2020, accessed here: https://www.c-span.org/video/?c4869590/user-clip-us-2015-grant-wuhan-lab-question

came from a Level 4 lab in Wuhan."[5] The Administration has been pushing this theory[6] despite scientific experts saying this path of transmission would be virtually impossible given what is known about the virus and lab safety protocols.[7] If this theory is the basis for the grant termination, it would be an egregious example of the Administration politicizing scientific decision making in order to further a politically convenient narrative.

EcoHealth Alliance's grant was renewed in 2019 after an initial five-year grant on the same topic. The grant it received was extremely competitive – only 22 percent of proposals were funded in 2019.[8] The July 2019 project proposal was titled, "Understanding the Risk of Bat Coronavirus Emergence."[9] In the midst of the COVID-19 pandemic that has taken over 115,000 American lives, it is inconceivable that this project would no longer "align with the program goals and agency priorities" of NIH. Any termination of a grant that has gone through NIH's rigorous scientific review process must be adequately justified on a scientific basis – particularly a grant which would appear to be so relevant to understanding our current health crisis.

As the Committees of jurisdiction over public health and science, we need to better understand the decision to terminate EcoHealth Alliance's NIH grant. We are especially concerned given Dr. Anthony Fauci's, Director of NIH's National Institute of Allergy and Infectious Diseases, assertion at a Committee on Energy and Commerce hearing on June 23 that "the grant was canceled because NIH was told to cancel it."[10] In order to understand how this decision was reached, we request a briefing to be delivered by July 15, 2020. At this briefing, we ask that you be prepared to address the following questions:

1. When the decision was made to terminate the grant to EcoHealth Alliance;

2. Who at HHS was involved in the decision to terminate the grant;

3. Whether entities outside HHS, including but not limited to the White House, the State Department, the National Security Council, and intelligence agencies, were involved in this decision;

---

[5] *Id.*

[6] Mark Mazzetti, Julian E. Barnes, Edward Wong, and Adam Goldman, "Trump Officials Are Said to Press Spies to Link Virus and Wuhan Labs," *New York Times*, April 30, 2020, accessed here: https://www.nytimes.com/2020/04/30/us/politics/trump-administration-intelligence-coronavirus-china.html

[7] Geoff Brumfel and Emily Kwong, "Virus Researchers Cast Doubt On Theory Of Coronavirus Lab Accident," *NPR*, April 23, 2020, accessed here: https://www.npr.org/sections/goatsandsoda/2020/04/23/841729646/virus-researchers-cast-doubt-on-theory-of-coronavirus-lab-accident

[8] Research Grants: Competing Applications, Awards, and Success Rates, National Institutes of Health, January 2020, accessed here: https://report.nih.gov/nihdatabook/category/6

[9] "Understanding the Risk of Bat Coronavirus Emergence," National Institutes of Health Research Portfolio Online Reporting Tools, July 2019, accessed here: https://projectreporter.nih.gov/project_info_description.cfm?aid=9819304&icde=49752569

[10] House Committee on Energy and Commerce, Testimony of Anthony S. Fauci, M.D., Director, National Institute for Allergy and Infectious Diseases, *Oversight of the Trump Administration's Response to the COVID-19 Pandemic*, 116th Cong. (Jun. 23, 2020).

4. The analysis conducted to determine that the EcoHealth Alliance grant's project outcomes did not align with program goals and NIH priorities;

5. Any analysis conducted to determine EcoHealth Alliance's alleged improper disbursal of NIH funds to the Wuhan Institute of Virology;

6. Any other decision NIH has made to terminate grants since January 1, 2020; and

7. Any further action NIH is considering taking regarding EcoHealth Alliance or any other grant holder regarding alleged relationships with international laboratories.

In addition to the briefing, we request the following materials be provided to the Committees no later than July 10, 2020. Please provide these materials in a searchable electronic format.

1. All documents and communications relating to the cancellation of EcoHealth Alliance's grant, including the notification to and any response from EcoHealth Alliance;

2. All documents and communications regarding any potential direction from outside entities, including the White House or other Agencies or Departments, to terminate grants based on suspicion of collaboration with international laboratories;

3. All documentation of audits or other analyses conducted to determine improper disbursement of federal grant money from grant-holding institutions to other entities; and

4. The criteria that NIH used to assess the EcoHealth Alliance grant and determine that such grant merited cancelation, and documentation thereof.

Any decision to terminate a research grant should be conducted in a deliberative and transparent process that adheres to the highest standards of scientific integrity. Especially in this unprecedented time, it is important that our public health and science agencies remain free from political pressure and be allowed to pursue federally-funded research based on scientific merit.

Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space,
and Technology

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce

Bill Foster
Chairman
Subcommittee on Investigations and Oversight

Diana DeGette
Chair
Subcommittee on Oversight and Investigations

From: Lauer, Michael (NIH/OD) [E]
To: Collins, Francis (NIH/OD) [E]
Cc: Lauer, Michael (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]
Subject: FW: EcoHealth oversight response
Date: Tuesday, July 28, 2020 4:53:51 PM
Attachments: 06.26.20 SST EC Letter to HHS[1].pdf
EcoHealth Alliance narrative 7-27-20 Option 1c msl clean.docx

---

Hi Francis – we have discussed this (b) (5)

I'm attaching the incoming letter and proposed our draft response.

Many thanks, Mike

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Monday, July 27, 2020 at 3:58 PM
To: "Lauer, Michael (NIH/OD) [E]" <(b) (6) "Collins, Francis (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) "LaMontagne, Karen (NIH/OD) [E]" <(b) (6)
Subject: Re: EcoHealth oversight response

Attached is the incoming EcoHealth Alliance letter plus Mike's draft of the response, with some edits and additions from me.

A few issues to note:

(b) (5)

Please let me know how you would like to proceed.
Adrienne

From: "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Date: Wednesday, July 22, 2020 at 6:29 AM
To: Adrienne Hallett <(b) (6) Francis Collins <(b) (6) Lawrence Tabak <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) Karen LaMontagne <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Subject: Re: EcoHealth oversight response

Thanks so much Adrienne! I'll draft something today.

Mike

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Tuesday, July 21, 2020 at 1:50 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) "LaMontagne, Karen (NIH/OD) [E]" <(b) (6)
Subject: Re: EcoHealth oversight response

I think they'd like to but I don't know. I'm surprised they didn't publicize the letter, in which case we would have heard of it earlier.

From: Francis Collins <(b) (6)
Date: Tuesday, July 21, 2020 at 1:38 PM
To: Adrienne Hallett <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) Lawrence Tabak <(b) (6)
Cc: "Lohmann, Larry (NIH/OD) [E]" <(b) (6) Karen LaMontagne <(b) (6)
Subject: RE: EcoHealth oversight response

Sounds like a good plan. Will the Committee be likely to make our response public?

FC

From: Hallett, Adrienne (NIH/OD) [E] <(b) (6)
Sent: Tuesday, July 21, 2020 12:59 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6) Tabak, Lawrence (NIH/OD) [E] <(b) (6)

Cc: Lohmann, Larry (NIH/OD) [E] < (b) (6) LaMontagne, Karen (NIH/OD) [E] < (b) (6)

Subject: EcoHealth oversight response

Good news! (b) (5)

(b) (5)

Mike, can you help with the draft?

Thanks!
Adrienne

Congress of the United States
House of Representatives
Washington, DC 20515

June 26, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar,

We write with strong concerns surrounding the Administration's termination of the National Institutes of Health (NIH) grant to EcoHealth Alliance on April 24, 2020.[1] In the letter communicating the grant's termination, NIH Deputy Director for Extramural Research, Dr. Michael Lauer, wrote that "At this time, NIH does not believe the current project outcomes align with the program goals and agency priorities."[2] However, press reports indicate that the grant was canceled because a small portion of the funding was to be given to the Wuhan Institute of Virology for on-the-ground sample collection and analysis.[3] Given the potential for this study to inform our knowledge of coronavirus disease 2019 (COVID-19) transmission, it is deeply concerning that it may have been canceled for political reasons in the midst of the current pandemic.

It is always important that federal research priorities are driven by science-based decisions. This is especially true in a time that requires unparalleled investment in research that may help bring an end to this public health crisis. It is therefore troubling that this abrupt grant cancellation came just a week after President Trump announced that the Administration was looking into "grants going to that area" and continued that "we will end that grant very quickly."[4] This was in response to a reporter referencing false claims that COVID-19 "likely

[1] Sharah Owermohle, "Trump cuts U.S. research on bat-human virus transmission over China ties," *Politico*, April 27, 2020, accessed here: https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076
[2] Nurith Aizenman, "Why The U.S. Government Stopped Funding A Research Project On Bats And Coronaviruses," *NPR*, May 1, 2020, accessed here: https://www.npr.org/sections/goatsandsoda/2020/04/29/847948272/why-the-u-s-government-stopped-funding-a-research-project-on-bats-and-coronaviru
[3] *Id.*
[4] Clip of President Trump with Coronavirus Task Force Briefing, *CSPAN*, April 17, 2020, accessed here: https://www.c-span.org/video/?c4869590/user-clip-us-2015-grant-wuhan-lab-question

came from a Level 4 lab in Wuhan."[5] The Administration has been pushing this theory[6] despite scientific experts saying this path of transmission would be virtually impossible given what is known about the virus and lab safety protocols.[7] If this theory is the basis for the grant termination, it would be an egregious example of the Administration politicizing scientific decision making in order to further a politically convenient narrative.

EcoHealth Alliance's grant was renewed in 2019 after an initial five-year grant on the same topic. The grant it received was extremely competitive – only 22 percent of proposals were funded in 2019.[8] The July 2019 project proposal was titled, "Understanding the Risk of Bat Coronavirus Emergence."[9] In the midst of the COVID-19 pandemic that has taken over 115,000 American lives, it is inconceivable that this project would no longer "align with the program goals and agency priorities" of NIH. Any termination of a grant that has gone through NIH's rigorous scientific review process must be adequately justified on a scientific basis – particularly a grant which would appear to be so relevant to understanding our current health crisis.

As the Committees of jurisdiction over public health and science, we need to better understand the decision to terminate EcoHealth Alliance's NIH grant. We are especially concerned given Dr. Anthony Fauci's, Director of NIH's National Institute of Allergy and Infectious Diseases, assertion at a Committee on Energy and Commerce hearing on June 23 that "the grant was canceled because NIH was told to cancel it."[10] In order to understand how this decision was reached, we request a briefing to be delivered by July 15, 2020. At this briefing, we ask that you be prepared to address the following questions:

1. When the decision was made to terminate the grant to EcoHealth Alliance;

2. Who at HHS was involved in the decision to terminate the grant;

3. Whether entities outside HHS, including but not limited to the White House, the State Department, the National Security Council, and intelligence agencies, were involved in this decision;

---

[5] *Id.*

[6] Mark Mazzetti, Julian E. Barnes, Edward Wong, and Adam Goldman, "Trump Officials Are Said to Press Spies to Link Virus and Wuhan Labs," *New York Times*, April 30, 2020, accessed here: https://www.nytimes.com/2020/04/30/us/politics/trump-administration-intelligence-coronavirus-china.html

[7] Geoff Brumfel and Emily Kwong, "Virus Researchers Cast Doubt On Theory Of Coronavirus Lab Accident," *NPR*, April 23, 2020, accessed here: https://www.npr.org/sections/goatsandsoda/2020/04/23/841729646/virus-researchers-cast-doubt-on-theory-of-coronavirus-lab-accident

[8] Research Grants: Competing Applications, Awards, and Success Rates, National Institutes of Health, January 2020, accessed here: https://report.nih.gov/nihdatabook/category/6

[9] "Understanding the Risk of Bat Coronavirus Emergence," National Institutes of Health Research Portfolio Online Reporting Tools, July 2019, accessed here: https://projectreporter.nih.gov/project_info_description.cfm?aid=9819304&icde=49752569

[10] House Committee on Energy and Commerce, Testimony of Anthony S. Fauci, M.D., Director, National Institute for Allergy and Infectious Diseases, *Oversight of the Trump Administration's Response to the COVID-19 Pandemic*, 116th Cong. (Jun. 23, 2020).

4. The analysis conducted to determine that the EcoHealth Alliance grant's project outcomes did not align with program goals and NIH priorities;

5. Any analysis conducted to determine EcoHealth Alliance's alleged improper disbursal of NIH funds to the Wuhan Institute of Virology;

6. Any other decision NIH has made to terminate grants since January 1, 2020; and

7. Any further action NIH is considering taking regarding EcoHealth Alliance or any other grant holder regarding alleged relationships with international laboratories.

In addition to the briefing, we request the following materials be provided to the Committees no later than July 10, 2020. Please provide these materials in a searchable electronic format.

1. All documents and communications relating to the cancellation of EcoHealth Alliance's grant, including the notification to and any response from EcoHealth Alliance;

2. All documents and communications regarding any potential direction from outside entities, including the White House or other Agencies or Departments, to terminate grants based on suspicion of collaboration with international laboratories;

3. All documentation of audits or other analyses conducted to determine improper disbursement of federal grant money from grant-holding institutions to other entities; and

4. The criteria that NIH used to assess the EcoHealth Alliance grant and determine that such grant merited cancelation, and documentation thereof.

Any decision to terminate a research grant should be conducted in a deliberative and transparent process that adheres to the highest standards of scientific integrity. Especially in this unprecedented time, it is important that our public health and science agencies remain free from political pressure and be allowed to pursue federally-funded research based on scientific merit.

Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space,
and Technology

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce

Bill Foster
Chairman
Subcommittee on Investigations and Oversight

Diana DeGette
Chair
Subcommittee on Oversight and Investigations

EcoHealth Alliance narrative
Mike Lauer (OER)
July 27, 2020
“Option 1c”

(b) (5)

From:	Lauer, Michael (NIH/OD) [E]
To:	Tabak, Lawrence (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]
Cc:	Lauer, Michael (NIH/OD) [E]
Subject:	Re: Wuhan lab grant
Date:	Wednesday, June 24, 2020 11:35:04 AM
Attachments:	image001.png

Sounds good. I have a hard stop at 5 PM for a PCORI clinical trial panel that I'm chairing. I'm free between 3 and 4:15 if that works for a more "relaxed" discussion.
Thanks, Mike

From: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)
Date: Wednesday, June 24, 2020 at 11:25 AM
To: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Higgins, Lauren (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) "Schwetz, Tara (NIH/OD) [E]" <(b) (6)
Subject: Re: Wuhan lab grant
Correct – just realized need to add Tara as well.
Thanks

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Wednesday, June 24, 2020 at 11:24 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Higgins, Lauren (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Subject: Re: Wuhan lab grant
One note: (b) (5)

From: Lawrence Tabak <(b) (6)
Date: Wednesday, June 24, 2020 at 11:21 AM
To: Carrie Wolinetz <(b) (6) Adrienne Hallett <(b) (6) John Burklow <(b) (6) Lauren Higgins <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Subject: Re: Wuhan lab grant
Schedule seems quite fluid today – lets add to labor hhs prep please.

From: "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Date: Wednesday, June 24, 2020 at 11:14 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Hallett, Adrienne (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Higgins, Lauren (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6)
Subject: RE: Wuhan lab grant

Practical question – try to schedule discussion today? Add it on to Labor-HHS prep? Wait until microstaff tomorrow?

From: Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Sent: Wednesday, June 24, 2020 11:13 AM
To: Hallett, Adrienne (NIH/OD) [E] <(b) (6) Burklow, John (NIH/OD) [E] <(b) (6) Higgins, Lauren (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: Re: Wuhan lab grant
Should discuss. Looping in Mike Lauer.
Thanks

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Wednesday, June 24, 2020 at 11:06 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Higgins, Lauren (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: Re: Wuhan lab grant
via Politico:

The administration weighs in: A White House official said that the White House encouraged the decision to cut the funding, but that HHS ultimately made the call. A HHS spokesperson said that "the grantee was not in compliance with NIH's grant policy," and declined further comment.

From: Lawrence Tabak <(b) (6)
Date: Tuesday, June 23, 2020 at 8:03 PM
To: Adrienne Hallett <(b) (6) John Burklow <(b) (6) Lauren Higgins <(b) (6) Carrie Wolinetz <(b) (6)
Subject: Re: Wuhan lab grant
Thanks Adrienne.

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Tuesday, June 23, 2020 at 5:49 PM
To: "Burklow, John (NIH/OD) [E]" <(b) (6) "Higgins, Lauren (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: Re: Wuhan lab grant
The transcript won't be out for another few hours so I transcribed it myself. It is attached.

From: John Burklow <(b) (6)
Date: Tuesday, June 23, 2020 at 4:49 PM
To: Adrienne Hallett <(b) (6) Lauren Higgins <(b) (6)
Subject: Fwd: Wuhan lab grant
Pls see below—is there a fast way to get the transcript of the hearing?
Thx,
John

Sent from my iPhone

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" <(b) (6)
Date: June 23, 2020 at 4:25:19 PM EDT
To: "Burklow, John (NIH/OD) [E]" <(b) (6)
Cc: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: RE: Wuhan lab grant

Can we get the transcript?

From: Burklow, John (NIH/OD) [E] <(b) (6)
Sent: Tuesday, June 23, 2020 4:22 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6) NIH Director's Executive Committee <(b) (6)
Cc: Myles, Renate (NIH/OD) [E] <(b) (6)
Subject: Fwd: Wuhan lab grant
FYI

Sent from my iPhone

Begin forwarded message:

From: "Hall, Bill (HHS/ASPA)" <(b) (6)
Date: June 23, 2020 at 4:18:51 PM EDT
To: "Myles, Renate (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Billet, Courtney (NIH/NIAID) [E]" <(b) (6)
Subject: Wuhan lab grant

Not sure if you've been watching but ASF was just asked why NIH cancelled the EcoHealth Alliance grant (and Wuhan lab). He made quite clear that NIH was simply told to cancel it.

William Hall
Deputy Assistant Secretary for Public Affairs (Public Health)
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health & Human Services
Washington, DC`
Direct: (b) (6)
Mobile: (b) (6)
Email: (b) (6)
www.hhs.gov

From: Burklow, John (NIH/OD) [E]
To: Tabak, Lawrence (NIH/OD) [E]
Cc: Hallett, Adrienne (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Higgins, Lauren (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Schwetz, Tara (NIH/OD) [E]
Subject: Re: Wuhan lab grant
Date: Wednesday, June 24, 2020 11:43:52 AM
Attachments: image001.png

And Renate, since she and her team are fielding press calls. Thx.

Sent from my iPhone

> On Jun 24, 2020, at 11:25 AM, Tabak, Lawrence (NIH/OD) [E] < (b) (6) wrote:
>
> Correct – just realized need to add Tara as well.
> Thanks
>
> **From:** "Hallett, Adrienne (NIH/OD) [E]" < (b) (6)
> **Date:** Wednesday, June 24, 2020 at 11:24 AM
> **To:** "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Wolinetz, Carrie (NIH/OD) [E]" < (b) (6) "Burklow, John (NIH/OD) [E]" < (b) (6) "Higgins, Lauren (NIH/OD) [E]" < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6)
> **Subject:** Re: Wuhan lab grant
> One note: (b) (5)
>
> **From:** Lawrence Tabak < (b) (6)
> **Date:** Wednesday, June 24, 2020 at 11:21 AM
> **To:** Carrie Wolinetz < (b) (6) Adrienne Hallett < (b) (6) John Burklow < (b) (6) Lauren Higgins < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6)
> **Subject:** Re: Wuhan lab grant
> Schedule seems quite fluid today – lets add to labor hhs prep please.
>
> **From:** "Wolinetz, Carrie (NIH/OD) [E]" < (b) (6)
> **Date:** Wednesday, June 24, 2020 at 11:14 AM
> **To:** "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Hallett, Adrienne (NIH/OD) [E]" < (b) (6) "Burklow, John (NIH/OD) [E]" < (b) (6) "Higgins, Lauren (NIH/OD) [E]" < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6)
> **Subject:** RE: Wuhan lab grant
> Practical question – try to schedule discussion today? Add it on to Labor-HHS prep?

Wait until microstaff tomorrow?

From: Tabak, Lawrence (NIH/OD) [E] <(b) (6)
Sent: Wednesday, June 24, 2020 11:13 AM
To: Hallett, Adrienne (NIH/OD) [E] <(b) (6) Burklow, John (NIH/OD) [E] <(b) (6) Higgins, Lauren (NIH/OD) [E] <(b) (6) Wolinetz, Carrie (NIH/OD) [E] <(b) (6) Lauer, Michael (NIH/OD) [E] <(b) (6)
Subject: Re: Wuhan lab grant
Should discuss. Looping in Mike Lauer.
Thanks

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Wednesday, June 24, 2020 at 11:06 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Higgins, Lauren (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: Re: Wuhan lab grant
via Politico:

The administration weighs in: A White House official said that the White House encouraged the decision to cut the funding, but that HHS ultimately made the call. A HHS spokesperson said that "the grantee was not in compliance with NIH's grant policy," and declined further comment.

From: Lawrence Tabak <(b) (6)
Date: Tuesday, June 23, 2020 at 8:03 PM
To: Adrienne Hallett <(b) (6) John Burklow <(b) (6) Lauren Higgins <(b) (6) Carrie Wolinetz <(b) (6)
Subject: Re: Wuhan lab grant
Thanks Adrienne.

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Tuesday, June 23, 2020 at 5:49 PM
To: "Burklow, John (NIH/OD) [E]" <(b) (6) "Higgins, Lauren (NIH/OD) [E]" <(b) (6) "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: Re: Wuhan lab grant
The transcript won't be out for another few hours so I transcribed it myself. It is attached.

From: John Burklow <(b) (6)
Date: Tuesday, June 23, 2020 at 4:49 PM
To: Adrienne Hallett <(b) (6) Lauren Higgins

< (b) (6)

Subject: Fwd: Wuhan lab grant

Pls see below—is there a fast way to get the transcript of the hearing?

Thx,

John

Sent from my iPhone

Begin forwarded message:

> **From:** "Collins, Francis (NIH/OD) [E]" < (b) (6)
> **Date:** June 23, 2020 at 4:25:19 PM EDT
> **To:** "Burklow, John (NIH/OD) [E]" < (b) (6)
> **Cc:** "Tabak, Lawrence (NIH/OD) [E]" < (b) (6)
> "Wolinetz, Carrie (NIH/OD) [E]" < (b) (6)
> **Subject: RE: Wuhan lab grant**
>
> Can we get the transcript?
>
> **From:** Burklow, John (NIH/OD) [E] < (b) (6)
> **Sent:** Tuesday, June 23, 2020 4:22 PM
> **To:** Collins, Francis (NIH/OD) [E] < (b) (6) NIH Director's Executive Committee < (b) (6)
> **Cc:** Myles, Renate (NIH/OD) [E] < (b) (6)
> **Subject:** Fwd: Wuhan lab grant
> FYI
>
> Sent from my iPhone
>
> Begin forwarded message:
>
> > **From:** "Hall, Bill (HHS/ASPA)" < (b) (6)
> > **Date:** June 23, 2020 at 4:18:51 PM EDT
> > **To:** "Myles, Renate (NIH/OD) [E]" < (b) (6)
> > "Burklow, John (NIH/OD) [E]" < (b) (6)
> > "Billet, Courtney (NIH/NIAID) [E]" < (b) (6)
> > **Subject: Wuhan lab grant**
> >
> > Not sure if you've been watching but ASF was just asked why NIH cancelled the EcoHealth Alliance grant (and Wuhan lab). He made quite clear that NIH was simply told to cancel it.
> >
> > ---
> >
> > **William Hall**
> > Deputy Assistant Secretary for Public Affairs (Public Health)
> > Office of the Assistant Secretary for Public Affairs
> > U.S. Department of Health & Human Services
> > Washington, DC`
> > Direct: (b) (6)
> > Mobile: (b) (6)

Email: (b) (6)
www.hhs.gov

From:	Lauer, Michael (NIH/OD) [E]
To:	Hallett, Adrienne (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]
Cc:	Lauer, Michael (NIH/OD) [E]
Subject:	Re: EcoHealth Oversight request
Date:	Monday, July 20, 2020 7:58:22 PM
Attachments:	Screen Shot 2020-07-20 at 7.56.49 PM.png

Taking FC off. The grant has been officially reinstated; the revised NoA was sent on July 15, 2020. The NoA indicated that the grant was reinstated, but all activities suspended pending satisfactory answers to all of NIH's questions.
The grant is once again identified as active on RePORTER.
Best, Mike

From: "Hallett, Adrienne (NIH/OD) [E]" <(b) (6)
Date: Monday, July 20, 2020 at 7:39 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6) "Collins, Francis (NIH/OD) [E]" <(b) (6) "Lauer, Michael (NIH/OD) [E]" <(b) (6) "Burklow, John (NIH/OD) [E]" <(b) (6) "Wolinetz, Carrie (NIH/OD) [E]" <(b) (6)
Subject: EcoHealth Oversight request
(b) (5) Please see attached Oversight investigation into the issue. Please note the signers:
Frank Pallone, Chair of E&C Cmte
Diana DeGette, Chair of E&C Subcmte on Investigations
Eddie Bernice Johnson, Chair of Science Cmte
Bill Foster, Chair of Science Subcmte on Investigations

Project Information

2R01AI110964-06

Back to Query Form | Back to Search Results | Print Version

Project **1** of **2** NEXT

PI PROFILE LINKS MORE INFO

DESCRIPTION | DETAILS | RESULTS | HISTORY | SUBPROJECTS | SIMILAR PROJECTS | NEARBY PROJECTS BETA | LINKS | NEWS AND MORE

Project Number: 2R01AI110964-06
Title: UNDERSTANDING THE RISK OF BAT CORONAVIRUS EMERGENCE

Contact PI / Project Leader: DASZAK, PETER
Awardee Organization: ECOHEALTH ALLIANCE, INC.

Contact PI / Project Leader Information:

Name: DASZAK, PETER
Email: Click to view Contact PI / Project Leader email address
Title: PRESIDENT

Program Official Information:

Name: STEMMY, ERIK J
Email: Click to view PO email address

Other PI Information: Profile Exists No Profile

Not Applicable

Organization:

Name: ECOHEALTH ALLIANCE, INC.
City: NEW YORK **Country:** UNITED STATES (US)

Department Type/ Organization Type:

Unavailable
Other Domestic Non-Profits

Congressional District:

State Code: NY
District: 10

Other Information:

FOA: PA-18-484
Study Section: Clinical Research and Field Studies of Infectious Diseases Study Section (CRFS)
Fiscal Year: 2019 **Award Notice Date:** 24-JUL-2019

DUNS Number: 077090066
Project Start Date: 1-JUN-2014
Budget Start Date: 24-JUL-2019

CFDA Code: 855
Project End Date: 30-JUN-2025
Budget End Date: 30-JUN-2021

Administering Institutes or Centers:

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Project Funding Information for 2019:

Total Funding: $661,980 **Direct Costs:** $538,926 **Indirect Costs:** $123,054

Year	Funding IC	FY Total Cost by IC
2019	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$661,980

Categorical Spending by IC:

Click here for more information on NIH Categorical Spending

From:	Wood, Gretchen (NIH/OD) [E]
To:	Ellis, Chelsea (NIH/OD) [E]
Cc:	Pollock, Rachel (NIH/OD) [E]; Allen-Gifford, Patrice (NIH/OD) [E]
Subject:	Meeting summaries for LAT e-sig
Date:	Friday, October 9, 2020 10:30:00 AM
Attachments:	NIH ACD June 11-12 2020 final for review.docx NIH CCRHB July 2020 Summary_FINAL for review.docx

---

Good morning, Chelsea,

Can you kindly affix Dr Tabak's electronic signature on both of the meeting summaries and return them to me for LAT to get FC's permission this weekend? Below is the approval from LAT from last week's homework. Thank you.

- June meeting summary for the ACD (attached docx) - For review, approval, request to sign on autopen. Principals and/or their staff reviewed and provided edits. **this is fine; ok to use autopen for me; will then send on to FC for his approval and signature**
- NIH CCRHB July Summary (attached docx) – review, approval, request to auto pen after we receive Dr. Forese signature. All sections were review/edited by CC staff. **this is fine; ok to use autopen for me; will then send on to FC for his approval and signature**

U.S. Department of Health and Human Services
National Institutes of Health
Advisory Committee to the Director

120th Meeting of the Advisory Committee to the Director
June 11–12, 2020

Table of Contents

Participants

Advisory Committee to the Director (ACD)

Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health (NIH); Chair, ACD
Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; Executive Director, ACD
Shelley Berger, Ph.D., Director, Epigenetics Institute, University of Pennsylvania, Philadelphia
Roberta Diaz Brinton, Ph.D., Director, Center for Innovation in Brain Science, University of Arizona, Tucson
Wendy Chapman, Ph.D., Associate Dean, Digital Health & Informatics Director, Centre for Digital Transformation of Health, University of Melbourne, Australia
Anne Churchland, Ph.D., Associate Professor of Neuroscience, University of California, San Francisco
Francis Cuss, M.B. B.Chir., Retired Executive Vice President, Chief Scientific Officer, Head of Research and Development, Bristol-Myers Squibb, Princeton, NJ
Rebekah Drezek, Ph.D., Associate Chair of Bioengineering, Rice University, Houston, TX
Mark Dybul, M.D., Professor of Medicine, Co-Faculty Director, Center for Global Health Practice and Impact, Georgetown University, Washington, DC
David Glazer, Engineering Director, Verily Life Sciences, San Francisco, CA
Kristina Johnson, Ph.D., Chancellor, State University of New York, Albany (Day 2 only)
Dina Katabi, Ph.D., Director, Center for Wireless Networks and Mobile Computing, Massachusetts Institute of Technology, Cambridge
Judith Kimble, Ph.D., Professor of Biochemistry, University of Wisconsin–Madison
Brendan Lee, M.D., Ph.D., Chairman, Molecular and Human Genetics, Baylor College of Medicine, Houston, TX
Spero Manson, Ph.D., Colorado Trust Chair in American Indian Health, University of Colorado, Aurora
Jay Shendure, M.D., Ph.D., Professor of Genome Sciences, University of Washington School of Medicine, Seattle
M. Roy Wilson, M.D., M.S., President, Wayne State University, Detroit, MI
Barbara Wold, Ph.D., Professor of Molecular Biology, California Institute of Technology, Pasadena

NIH

Michael M. Gottesman, M.D., Deputy Director for Intramural Research
Michael S. Lauer, M.D., Deputy Director for Extramural Research and Director, Office of Extramural Research
Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy and Acting Chief of Staff

Executive Summary

The 120th meeting of the Advisory Committee to the Director (ACD) of the National Institutes of Health (NIH) took place virtually on June 11–12, 2020, via videoconference. The meeting was open to the public and webcast live. NIH Director Francis S. Collins, M.D., Ph.D., announced new members of the NIH leadership team and described some notable awards and events at NIH over the past 6 months. Associate Budget Director Neil Shapiro, J.D., M.B.A., and Legislative Analyst Adrienne A. Hallett, M.T.A., provided updates.

Anthony Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases, gave an overview of current COVID-19 science and described his Institute's strategic plan for COVID-19 research. NIH leadership outlined plans for the Accelerating COVID-19 Therapeutic Interventions and Vaccines program, a public–private partnership to standardize and share research methods. Key personnel guiding the Rapid Acceleration of Diagnostics (RADx) program summarized its four arms: RADx Tech (supporting early innovation), RADx Advanced Technology Program (advancing existing efforts), RADx Radical (promoting long-term, nontraditional approaches), and RADx for Underserved Populations.

Diana Bianchi, M.D., Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, described rapid efforts to initiate research on multisystem inflammatory syndrome in children at risk for or exposed to COVID-19. She also summarized investigations of drugs to treat children with COVID-19 and a large retrospective analysis of pregnant women to assess COVID-19's impact on pregnancy. Other NIH leaders presented NIH's activities to address COVID-19 on its campuses and through intramural research and the lasting impact of the pandemic shutdown on extramural research.

The ACD approved the list of external awards to NIH employees that had been vetted by Lawrence A. Tabak, D.D.S., Ph.D., NIH's Principal Deputy Director, and selected ACD members. Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy at NIH and Cochair of the HeLa Genome Data Access Working Group (WG), presented a new request for access to HeLa genome sequencing data, for which the ACD unanimously recommended approval.

Barbara Wold, Ph.D., Cochair of the ACD WG on Enhancing Rigor, Transparency, and Translatability in Animal Research, related the highlights of the WG's discussions and the key themes it plans to put forth in a report and recommendations by December. Dr. Wolinetz described initial implementation of the ACD's 2019 recommendations to end sexual harassment, bullying, and retaliation in the scientific research environment. Michael Lauer, M.D., Deputy Director for Extramural Research at NIH, updated the ACD on NIH's work to root out foreign threats to research, in response to recommendations made by the ACD WG on Foreign Influences on Research Integrity in 2018.

M. Roy Wilson, M.D., M.S., Cochair of the ACD WG on Diversity, expressed the importance of continuing to address inequities and work toward diversity in the scientific workplace despite the pandemic. WG Cochair Hannah Valantine, M.D., laid out the plans of the WG and described progress on programs implemented by the Office of Scientific Workforce Diversity.

Meeting Summary
Thursday, June 11, 2020

Open Session: Welcome and National Institutes of Health (NIH) Director's Report

Francis S. Collins, M.D., Ph.D., Director, NIH

The 120th meeting of the NIH Advisory Committee to the Director (ACD) took place virtually on June 11 and 12, 2020, via videoconference. Dr. Collins called the meeting to order at 1:00 p.m. The meeting was open to the public and webcast live. Dr. Collins thanked his staff for figuring out how to bring the ACD together virtually and for juggling NIH's many important priorities despite the challenges posed by the COVID-19 pandemic.

Dr. Collins announced that Rick Woychik, Ph.D., was named Director of the National Institute of Environmental Health Sciences. Joshua Denny, M.D., M.S., began his tenure as Chief Executive Officer (CEO) for the *All of Us* Research Program. John Ngai, Ph.D., was named Director of the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative.

In December, NIH held its annual meeting with the Bill & Melinda Gates Foundation to discuss next steps for their partnership. In the past 6 years, the partnership has created working groups (WGs) on 10 topics to advance biomedical research. High-profile visitors to the NIH campus included First Lady Melania Trump and Maryland First Lady Yumi Hogan, who visited the Children's Inn on separate occasions in February.

COVID-19 has been a full-time concern of NIH since being recognized as a pandemic in early March. Some intramural laboratories have retooled to address the virus, and others have been working on the front lines to develop vaccines and therapeutics. Anthony Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases (NIAID), has served on the White House Task Force on COVID-19 since its inception, and Dr. Collins joined the Task Force recently. President Trump visited the NIH campus in early March and heard from scientists leading the Dale and Betty Bumpers Vaccine Research Center's efforts. Also in early March, Dr. Collins testified at a congressional budget hearing. He pointed out that NIH continues to have strong bipartisan support from Congress, reflected in budget increases in each of the past 5 years.

NIAID supported clinical trials showing that the antiviral drug remdesivir shortens the hospital stay for COVID-19 patients by 31% and may reduce mortality. To develop new approaches to COVID-19 testing, Congress tasked NIH and the Biomedical Advanced Research and Development Authority (BARDA) with leading the Rapid Acceleration of Diagnostics (RADx) program. In May, the White House announced Operation Warp Speed, an effort to coordinate work across the U.S. government on COVID-19 vaccines, therapeutics, and diagnostics, with attention to scaling up and manufacturing products quickly. In June, White House Task Force members Deborah Birx, M.D., and Jared Kushner toured NIH and discussed diagnostics further with Dr. Collins and colleagues.

Dr. Collins acknowledged the challenges that NIH staff is facing during the pandemic, with most NIH offices and laboratories closed. He particularly sympathized with trainees who have lost out on opportunities to pursue their work, and he said NIH will do what it can to support them. Much work has continued successfully through virtual mechanisms. The NIH Clinical Center has remained open, with restrictions, to serve patients. NIH testing facilities identified more than 200 people with COVID-19; they were quarantined immediately, and most did not require hospitalization. NIH has a staged plan for returning staff to work that includes closely monitoring for infection and maintaining protective practices.

NIH has already held three virtual town hall meetings, involving as many as 20,000 participants, to field questions about COVID-19 and to come together to grieve the more than 100,000 deaths to date. Dr. Collins praised Dr. Fauci for his excellent and extensive work communicating candidly about the pandemic with the public.

Dr. Collins announced that Diana Bianchi, M.D., Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), was awarded an honorary doctorate from the University of Amsterdam in January and Nora Volkow, M.D., Director of the National Institute on Drug Abuse, received the American Medical Association's Dr. Nathan Davis Award for Outstanding Government Science. A number of awards within the Department of Health and Human Services (HHS) recognized NIH employees. Five NIH representatives were named as finalists for the Samuel J. Heyman Service to America Medals.

Budget Update

Neil Shapiro, J.D., M.B.A., Associate Director for Budget, NIH

Mr. Shapiro explained that NIH received nearly all of its funding at the beginning of fiscal year (FY) 2019, which was unusual. For FY 2020, NIH operated under partial funding through a continuing resolution. NIH's type 1 diabetes research is funded through a separate mechanism, which was partially funded through late May 2020. In March, Congress completed the FY 2020 funding for NIH and finalized a partial funding resolution for type 1 diabetes research for FY 2021 through November.

The total budget for FY 2020 ($41.7 million) represents a 6.4% increase over the budget for FY 2019. With that and the increases provided for the past 4 years, NIH has restored its purchasing power to within 5% of what it was in 2003. The budget includes targeted increases for Alzheimer's disease and dementia research and National Cancer Institute awards. The *All of Us* Research Program and the BRAIN Initiative now have $500 million each in annual funding. The budget includes $100 million for NIH buildings and facilities to address a backlog of maintenance projects. The Investigation of Co-Occurring Conditions Across the Lifespan to Understand Down Syndrome (INCLUDE) Project and research related to the Childhood Cancer Survival, Treatment, Access, and Research Act also received substantial funding.

The President's FY 2020 budget proposal to fold the Agency for Healthcare Quality and Research into NIH was not enacted. Congress directed HHS to spend $225 million of its

nonrecurring expenses fund on NIH building and facilities projects, which will allow the construction of a new surgery, radiology, and laboratory medicine wing for the Clinical Center.

Mr. Shapiro summarized the funding allotted to NIH so far through Congress and HHS emergency funding for COVID-19 research, totaling more than $3.5 billion. The President's proposed budget for FY 2021 originally recommended a cut to NIH, but after the pandemic started, the proposal was revised to recommend the same level of funding for FY 2021 as FY 2020. The FY 2021 proposal again recommends moving the Agency for Healthcare Quality and Research into NIH. The proposed 2021 budget would add another $100 million for buildings and facilities and give NIH authority to move money from the accounts of Institutes and Centers (ICs) to supplement funding for maintenance backlogs or large facilities projects. The proposal targets high-priority areas, including artificial intelligence for addressing chronic disease, neonatal research, and methamphetamine research. Funding levels for research on opioids and pain relief, pediatric cancer, and influenza would be maintained.

Legislative Update

Adrienne A. Hallett, M.T.A., Associate Director for Legislative Policy and Analysis and Director of the Office of Legislative Policy and Analysis, NIH

Ms. Hallett reviewed the timeline of congressional budget activity since February. Both houses of Congress have returned to session, but with different procedures for voting. Congress moved quickly to pass legislation providing money for the COVID-19 response, including $3.6 billion for NIH research. The House passed the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act. The Senate agrees on the need for additional funds but wants to limit the total dollars and suspend negotiations until after the July 4 holiday, Ms. Hallett said.

Appropriations bills must move forward or the government will run out of money, but the processes and timing for marking up the bills and voting are uncertain. Ms. Hallett suspected that both houses would move forward in early July, around the same time as the HEROES Act, likely resulting in some confusion around spending.

Ms. Hallett noted that FY 2021 is the last year that Congress must abide by statutory spending caps for non-defense-related spending. An amendment passed in 2019 provides about $12 billion to address non-defense-related spending in FY 2021. The Department of Veterans Affairs Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act expires in 2020 and requires $11 billion to continue. Ms. Hallett believes the MISSION Act will be exempt from the budget caps. She also noted discussion about the national debt increasing, driven by the pandemic and its effect on the economy.

The impact of the debt and the pandemic on the November 2020 elections is unknown. The pandemic may limit in-person campaigning, and it is not clear whether Congress will stay in session longer if members do not need to return to their districts to campaign in

person. The results of the elections will determine whether Congress tries to complete legislation before the end of the year or leave it for the next Congress.

Statement on Racism and Inclusivity

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins acknowledged the turmoil of recent weeks as protests erupted around the world in response to the killings of George Floyd, Breonna Taylor, Ahmaud Arbery, and others. He recognized the pervasiveness of racism, which many try not to see, that has persisted since slavery was introduced in America. He called for deep introspection about racial injustice across the board, including within the biomedical community. Dr. Collins called on himself and others to create a more inclusive culture, to work harder to nurture the diversity of the workforce, and to redouble efforts to minimize disparities as current events shine a light on what was already known.

As the leading biomedical research organization in the world, NIH must look unflinchingly at its culture, embrace the challenge, and enlist those who can bring their experience to bear, including those who have studied racial disparities and violence and also lived it. Dr. Collins said the biomedical community is capable, resilient, remarkably visionary, and diverse in many ways. Diversity fuels creativity and drives innovation. He urged the community to embrace the moment and not let it pass. The ACD, NIH staff, and others should consider what they can do to end the scourge of racism and related health disparities, a goal that is part of NIH's mission. Dr. Collins said he has felt anger, grief, and distress over the events in the news. He believes that NIH must address racism in new and productive ways with the many tools and resources it has.

Statement from the ACD Members

Brendan Lee, M.D., Ph.D., Chairman, Molecular and Human Genetics, Baylor College of Medicine, Houston, TX; ACD Member

Speaking on behalf of the ACD members, Dr. Lee said that the ACD joins with numerous scientific organizations and leaders in the biomedical community in expressing concern about the motivation for terminating NIH funding to Peter Daszak, who headed EcoHealth Alliance. The move circumvented the normal peer review process and contradicts long-held NIH traditions and policies. The ACD recommends that the termination be reviewed and that, if flaws in the process are revealed, NIH reverse the decision and implement mechanisms to avoid repeating them. Dr. Lee said 15 of the ACD's members endorsed the recommendation, and two abstained.

COVID-19 Science

Anthony S. Fauci, M.D., Director, NIAID, NIH

Dr. Fauci described the emergence of COVID-19, the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), so named because of its similarity to severe acute respiratory syndrome (SARS), identified in 2002. At the time of his talk, about 7 million people around the world ad been diagnosed with COVID-19 and 400,000 had died. In the United States, 2 million people had been diagnosed so far, and 116,000

had died. New York City was particularly hard hit; cases there are decreasing now but are offset by rises in infections in Louisiana, Arizona, North Carolina, and other states. Deaths from COVID-19 are decreasing. As the country moves to reopen, it is not known whether infections and deaths will increase.

Some symptoms of COVID-19 look like typical influenza, while others do not. The disease manifests in many ways, which Dr. Fauci called puzzling. People infected may be asymptomatic or experience anything from a mild influenza-like illness to severe disease to death. Scientists now estimate that about 25% to 45% of people infected are asymptomatic or presymptomatic, a finding that is critical to learning about the spread of infection and the effectiveness of contact tracing. Among the populations at high risk for severe illness are those who are obese or have other chronic diseases, including cardiovascular disease, chronic kidney disease and diabetes.

Clear racial and ethnic disparities in disease have been reported in various cohorts. Dr. Fauci said that African Americans and other racial and ethnic minorities are disproportionately impacted by certain social determinants of health, including employment that places them at greater risk. They also have a higher prevalence than whites of underlying conditions associated with COVID-19 infection.

Dr. Fauci summarized NIAID's strategic plan for COVID-19 research:

- **Improve fundamental knowledge** of the disease by supporting basic research intramurally and extramurally, including studying the virus's molecular structure and mechanism of action; making viral isolates and reagents widely available to the research community; conducting research to identify animal models of disease; and supporting epidemiological research.
- **Develop diagnostics and assays** by validating novel and existing tests and facilitating the RADx initiative.
- **Characterize and test therapeutics**, including remdesivir and other antivirals, convalescent plasma and hyperimmune immunoglobulins, repurposed drugs, host modifiers and immune-based therapies, and monoclonal antibodies (mAbs). Building on early findings that remdesivir has a modest effect, research is assessing the combination of remdesivir with baricitinib. NIAID also has created treatment guidelines for COVID-19 that will be updated as new findings emerge.
- **Develop safe and effective vaccines** by partnering with BARDA to advance promising candidates, including some developed at NIH's Vaccine Research Center (e.g., Moderna's mRNA-based vaccine), and supporting Operation Warp Speed.

NIH's strategic approach to vaccine development was published in *Science* in May. In April, NIH launched Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV), a public–private partnership to standardize and share research methods, an effort to maximize clinical trial capacity. As a member of the White House COVID-19 Task Force, Dr. Fauci has presented information and research from NIH's work to the President and Vice President.

ACTIV Partnership

Dr. Collins explained how ACTIV was created through rapid national and international cooperation, and he described its organizational structure. He said the planning stage was a useful framework for working through what needs to be accomplished, such as how to prioritize treatments for clinical trials, map clinical trial capacity across sectors, and coordinate vaccine development efforts, as well as the need for in vitro assays and animal models.

Overview

John R. Mascola, M.D., Director, Dale and Betty Bumpers Vaccine Research Center, NIAID, NIH

Dr. Mascola said ACTIV brings biotech and pharmaceutical companies together with federal research entities in an extraordinary environment to tackle a disease about which little is known. Operation Warp Speed is a subset of ACTIV. Because of the amount of vaccine needed and the number of people who must be vaccinated to stop the spread of COVID-19, there is strong interest in developing multiple vaccines and platforms. ACTIV is supporting research on vaccines involving traditional proteins, nucleic acids (e.g., mRNA, DNA), and live replicating vectors, all of which are in various stages of development.

NIAID is coordinating plans for Phase III clinical studies for some vaccine candidates, with extensive input from industry, regulators, and other government entities. Dr. Mascola expects several Phase III trials to begin in the next few months. NIH will set up a central data safety monitoring board to oversee the trials. All Phase III studies will collect similar data on endpoints to support product comparison across studies. Dr. Mascola projected that results of vaccine efficacy trials could be available by the end of 2020 if assumptions about the incidence of COVID-19 play out and subject enrollment is successful.

Types of Therapeutics in Development

H. Clifford Lane, M.D., Deputy Director for Clinical Research and Special Projects, NIAID, NIH

Dr. Lane described three passive immunotherapy approaches under study that use antibodies against SARS-CoV-2. These include single-donor convalescent plasma, hyperimmune IVIg and monoclonal antibodies.

A number of evaluations of single-donor convalescent plasma are being conducted with approval from the Food and Drug Administration (FDA). The majority of these infusions were initially provided under single-patient emergency investigational new drug approvals. This has recently evolved to an expanded access protocol run out of the Mayo Clinic. Close to 100 additional studies are also underway, among them a limited number of randomized, controlled trials. Of these, 8 trials are comparing high-titer versus low-titer plasma, which Dr. Lane thought was the approach most likely to provide results. A

large program at the Mayo Clinic has already reported data on the first 5,000 patients. From the Mayo Clinic experience of their first 5,000 patients on the expanded access program, 36 experienced a serious adverse event within 4 hours of transfusion, including 15 deaths categorized as possibly or probably related to the plasma treatment.

At this point a variety of mostly small and observational studies have suggested that convalescent plasma has some benefit. Thus far, robust data are lacking. In general, convalescent plasma has not been shown to be very effective for disease when evaluated in randomized, controlle trials. An exception to this is the treatment of Argentine Hemorhagic Fever where treatment within 8 days of symptoms led to a statistically significant decrease in mortality.

Hyperimmune intravenous immunoglobulin derived from genetically engineered cattle or human convalescent plasma is another approach being explored with studies anticipated to be launched in late summer. Hyperimmune Ig from humans has the potential to be a standardized product that could be widely distributed.

At least 21 mAb products are in development, most targeting the coronavirus spike protein. Phase I clinical trials are being planned for later this summer for both treatment and prevention of COVID-19.

Rapidly Advancing Understanding, Prevention, and Treatment of COVID-19–Associated Coagulopathy (CAC)

Gary H. Gibbons, M.D., Director, National Heart, Lung, and Blood Institute (NHLBI), NIH

Dr. Gibbons explained that CAC manifests in many ways and appears to increase the risk of severe disease and death. There is no clear standard of care or evidence-based guidance for treating patients with CAC. Under the ACTIV partnership, NHLBI and NIAID are looking at treatment options across various stages of COVID-19, from asymptomatic to convalescent patients. Dr. Gibbons said the key might lie in identifying what triggers the clotting phenomenon. He hoped findings would guide therapy, which is critically needed in the absence of a vaccine.

The impact of CAC underscores the importance of having a nimble, adaptive clinical trial platform. Investigators are learning about the disease as it unfolds, and ACTIV provides mechanisms for testing new treatments, such as antithrombotics, as they become available. The partnership also takes advantage of existing clinical trial platforms across NIH. Various projects are working together in real time, providing an exciting opportunity for advancement, Dr. Gibbons noted.

A master protocol for the first open-label protocol comparing blood clotting regimens in patients with COVID-19 is in the final stages of approval. The adaptive platform will allow investigators to consider other anticoagulant and antiplatelet agents. Studies should also reveal risk profiles that can help with risk stratification, which will further contribute

to treatment guidelines. Dr. Gibbons said the research is one step under toward short-term treatment options while a vaccine is developed.

Discussion

Dr. Mascola said BARDA is primarily responsible for creating mechanisms to scale up and manufacture a COVID-19 vaccine rapidly. Dr. Collins added that Operation Warp Speed will manufacture promising candidates, even if the findings are not finalized. He added that different vaccines will require different manufacturing capacity, which further complicates the process.

Dr. Collins said ACTIV's Preclinical WG seeks to determine the utility and availability of tools to assist with preclinical research. For example, the National Center for Advancing Translational Sciences is gathering relevant assays, identifying approved drugs that may be useful, and assessing animal models. Dr. Lee noted the need to validate findings to inform future work.

Dr. Gibson observed that data from a New York City hospital found that COVID-19 patients who were on anticoagulants were less likely to be admitted for intensive care and had better survival rates than others, which hints that coagulopathies might increase morbidity and mortality. An RCT is needed to test the hypothesis. Understanding the cell types affected and how they respond over time may inform research on host-directed therapies.

RADx Initiative

Dr. Collins explained that the RADx initiative has four arms addressing different diagnostic needs, plus funding dedicated to data management and support across the program.

RADx Tech

Bruce J. Tromberg, Ph.D., Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB), NIH

The RADx initiative aims to increase testing capacity broadly, for various settings and populations, necessitating multiple strategies. Congress allotted $500 million to RADx Tech to foster innovation in the development of COVID-19 diagnostics and optimization of their use. Dr. Tromberg said the availability of testing and platforms for analysis should not be the limiting factor in broad testing goals. At present, most tests require laboratory analysis; over time, point-of-care testing will become more widely available and easier to use, possibly as soon as early 2021.

NIBIB's Point-of-Care Technologies Research Network is anchored by the Center for Integration of Medicine and Innovative Technology (CIMIT). RADx Tech relies on CIMIT to evaluate applications for likelihood of success (going beyond an assessment of readiness) and then links applicants to a team of experts from various fields for further discussion about whether to proceed. Most proposals have come from small businesses, but other types of applicants are well represented. The sampling approaches proposed and

the types of support requested indicate a robust and varied response to the RADx Tech call for innovation.

RADx Tech is made up of three cores that oversee test validation, clinical trials, and large-scale operations. Notably, the test validation core, which involves FDA and academic partners, will provide independent validation that normally would be done by the test maker. Dr. Tromberg said the RADx Tech approach, facilitated by Operation Warp Speed, is critical to derisking the research and matching the technology to the appropriate user community. He also noted that the various RADx components complement each other to move diagnostics from concept to deployment.

RADx Advanced Technology Platforms (RADx-ATP)

Rick A. Bright, Ph.D., Senior Advisor to the Director, NIH

RADx-ATP seeks to optimize throughput of point-of-care diagnostics by identifying and advancing existing technology or promising products in late stages of development. Candidates could be identified through RADx Tech applications, BARDA-supported projects in progress, or outreach to industry, for example. Dr. Bright hoped to identify three to five candidates suitable for immediate scale-up to expand test availability and testing capacity by the end of fall 2020.

In addition, RADx-ATP will assess whether large, platform-based technologies already in laboratories can be boosted to increase throughput. Some research has already demonstrated such capacity. The effort will also explore the creation of a diagnostic innovation hub to identify developments on the horizon that could benefit from optimization and accelerate research into innovative technologies, such as next-generation sequencing. RADx-ATP received $230 million from Congress and is working closely with the other arms of RADx.

RADx Radical (RADx-rad)

Tara A. Schwetz, Ph.D., Associate Deputy Director, NIH; Acting Director, National Institute of Nursing Research, NIH

RADx-rad allots $200 million to focus on nontraditional approaches to testing. Unlike the other arms of RADx, it provides a longer timeline for development, with emphasis on platforms that could be applicable to detect other viruses, including as-yet-unknown threats. Suggestions were solicited from all NIH ICs, and a subset of IC directors weighed in to identify the best ideas to pursue. Dr. Schwetz said a cohesive research plan is being developed. A portion of funding will be set aside to give NIH flexibility to adapt the program to meet future needs.

RADx-rad will support efforts to apply existing diagnostic technologies in new ways and to develop unconventional technologies, such as biomarkers that can predict severity of disease or mechanisms to reveal the presence of SARS-CoV-2 virus in wastewater samples. Research could yield complex screening panels that identify COVID-19 along with other infectious diseases. RADx-rad will establish a data coordinating center that links to the broader NIH COVID-19 data management and coordination effort. Funding

opportunity announcements (FOAs) will be released this summer, and awards will be made beginning in late 2020.

RADx for Underserved Populations (RADx-UP)

Eliseo J. Pérez-Stable, M.D., Director, National Institute on Minority Health and Health Disparities, NIH

Dr. Pérez-Stable appreciated that NIH is acknowledging the health disparities spotlighted by the pandemic and other current events. In addition to facing longstanding structural disparities, racial and ethnic minorities have higher rates of comorbid conditions that place them at higher risk for COVID-19. Moreover, racial and ethnic minorities tend to work in public-facing jobs that have been considered essential during the pandemic, increasing the likelihood of exposure to the virus. Many underserved persons live in crowded housing and communities. Dr. Pérez-Stable said it is imperative to implement prevention and health care strategies aligned with the needs of racial and ethnic minority communities to address effects of the pandemic and underlying inequities.

Cases of COVID-19 are distributed unequally across the United States, and the distribution changes daily. RADx-UP seeks to better understand the factors contributing to disparities and implement interventions to reduce them. It will expand the capacity to test broadly for viral nucleic acids in the populations most affected, including testing people who are asymptomatic. RADx-UP will put mitigation strategies in place based on isolation and contact tracing to limit community transmission. It will anticipate opportunities to evaluate and distribute vaccines and therapeutics through networks. It also offers an opportunity to deploy validated point-of-care tests, including self-test methods and use of saliva samples for testing. FOAs for RADx-UP will be released shortly, and initial awards will be made by the end of September.

With $500 million from Congress, RADx-UP will begin with a project to leverage existing community partnerships to implement culturally relevant testing strategies in underserved and vulnerable populations. In its first phase, a central data coordination and collection center will be established, followed by a network of research centers with experience in community engagement and a track record of working with vulnerable and minority populations. A second phase of funding will renew and expand awards on the basis of the evolution of the pandemic.

Multisystem Inflammatory Syndrome in Children (MIS-C)

Diana Bianchi, M.D., Director, NICHD, NIH

Dr. Bianchi described emerging awareness of a spike in Kawasaki disease–like symptoms in children who were infected with or exposed to COVID-19. Most children initially had mild illness that progressed to full-blown MIS-C. Federal partners collaborated to establish a research platform to study children who are at risk for or have MIS-C to better understand the disease. The platform will test the leading hypothesis that there is a genetic predisposition to a vigorous immune response, which is thought to be distinct from the initial illness. The platform will also follow a cohort over the long term to assess

ongoing complications, such as the impact of cardiac involvement. The project emphasizes the importance of sharing data, especially given the small number of cases, and includes funding for a data coordination center.

A pediatric trials network will assess the pharmacokinetics and safety of drugs not typically used in children and determine the appropriate dosing for children with COVID-19. Another effort will use existing infrastructures supported by NIH to gather information on up to 10,000 children with COVID-19 to use as a control group for comparison with those who develop MIS-C.

Dr. Bianchi said NICHD is also using its existing networks to study COVID-19 in pregnancy. NICHD will gather information from a racially and ethnically diverse sample of 21,000 pregnant women at 12 study sites to assess the effects of COVID-19 on prenatal care, maternal health complications, cesarean delivery rates, and maternal mortality, comparing 2020 and 2019 data over the same period (March through December). The study will also encompass an evaluation of the natural history of COVID-19 in pregnancy to assess the potential for vertical transmission and fetal complications. Dr. Bianchi noted that NICHD is working to ensure that pregnant women, children, and people with developmental disabilities are included in ACTIV and RADx studies so that they will benefit from the research.

Discussion

Dr. Bianchi said the immediate concerns of the pediatric studies are sharing data and biospecimens to facilitate research that can improve understanding of MIS-C. The studies also incorporate adaptive design so that investigators can compare new approaches to treatment as they emerge.

Francis Cuss, M.B. B.Chir., said the enormous number of COVID-19 studies underway will generate an avalanche of data, which he hoped would be used to drive new guidelines for care. He also hoped NIH would ensure that patients have a voice in the process so that guidelines are clear. Specifically, pregnant women and new mothers should provide feedback on guidelines for treating COVID-19 in pregnancy. Dr. Bianchi responded that NICHD's advisory councils invite input from study participants and others to ensure they get needed insights. She noted that the results from studies conducted by NICHD's Maternal–Fetal Medicine Units Network, which is facilitating the study of COVID-19 in pregnancy, frequently show up in professional guidelines for care, and the Network is in a position to address immediate concerns.

Wendy Chapman, Ph.D., emphasized the need to translate the data into guidance for health care providers and information that consumers can use to make decisions about their behavior. She called for better clinical decision support tools, integrated into electronic health record systems; tools for virtual health tracking; and more communication with health care providers. Lawrence A. Tabak, D.D.S., Ph.D., noted that many ICs have expressed a renewed interest in telehealth, and there is a new urgency around integrating electronic health records.

Dr. Collins agreed that there are lots of efforts around data and technology integration. He also said that NIH is crafting guidelines for health care providers that it anticipates revising frequently; patients' perspectives will inform those guidelines. Dr. Collins said that for most conditions, NIH has input from patient advocacy organizations. He apologized for not pursuing patients' input more aggressively for COVID-19.

Closing Remarks and Adjournment

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins gave an overview of the agenda for the next day. He thanked the speakers and recessed the meeting for the day at 4:26 p.m.

Friday, June 12, 2020

Open Session: Opening Remarks

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins called the meeting to order at 1:00 p.m. and reviewed the agenda for the day.

NIH Administrative Response to COVID-19

Addressing Safety on Campus

Alfred C. Johnson, Ph.D., Deputy Director for Management, NIH

Dr. Johnson described challenges facing NIH, such as bringing staff who were on travel or working overseas back to the United States when the pandemic broke out and shifting most staff to telework. His office also coordinated volunteers to work with other government agencies in response to the pandemic.

To date, more than 2,700 tests for COVID-19 have been conducted on campus, followed by contact tracing as needed. As plans develop for a phased approach for staff to return to work, NIH is addressing safety on campus with additional cleaning and decontamination, as well as more testing at all of its campuses. NIH created a tracker to identify where COVID-19 cases occurred that is used to guide evaluation and cleaning protocols. NIH has added physical barriers where appropriate and bought personal protective equipment in bulk to meet staff needs.

Travel is now limited to mission critical efforts and must be approved by Dr. Johnson. NIH has eliminated paper processing for paying invoices. As of June 12, about 5,000 of the Bethesda campus's 25,000 staff are on site each day, and more will return to their offices in the coming weeks. The phased plan includes criteria that must be met and maintained for a few weeks before proceeding to the next step.

Intramural Research

Michael M. Gottesman, M.D., Deputy Director for Intramural Research, NIH

The Office of Intramural Research responded to the pandemic by quickly establishing a COVID-19 scientific interest group with subject matter experts from various fields to identify scientific activities to address the pandemic. The Office also created a dashboard with links to 357 COVID-19–related intramural projects underway (representing 250 principal investigators [PIs]). Its website directs users to reagents and repositories for research, as well as a weekly clinical series. With NIAID funding, NIH is supporting novel intramural research on approaches to COVID-19. A central review committee evaluates the research proposals to ensure they are highly applicable and conducted safely.

NIH has maintained 60 beds at the Clinical Center to provide continuous care. It is increasing capacity now, aiming for 90 to 100 beds. Clinical Center staff, patients, and visitors are tested frequently for COVID-19. NIH recently bought equipment that will increase throughput, which may allow NIH to test substantially more people. The Clinical

Center is conducting the clinical trial comparing remdesivir with and without baricitinib in infected patients. In addition, NIH is maintaining animal research colonies to ensure the well-being of the animals, support mission critical and COVID-19 research, and ensure colonies are available for research when laboratories are fully reopened.

Extramural Research

Michael Lauer, M.D., Deputy Director for Extramural Research, NIH

The pandemic forced a lot of research to suspend or shut down activities, causing substantial and possibly lasting disruption to the field of biomedical research. NIH estimated that COVID-19 might cost the field $10 billion in lost productivity. Dr. Lauer said NIH has received more applications for funding than last year and will be issuing more awards than last year, so staff have been working remotely to process applications, coordinate virtual peer review, and prepare new FOAs.

In response to the pandemic, NIH has made accommodations to allow for flexibility in the following research areas:

- Application deadlines
- Donation of research supplies
- Salaries and stipends
- Human subjects research and clinical trials
- Animal research and oversight
- Reporting requirements and expenditures
- Loss of time

The Office of Extramural Research's website provides advice for applicants and grant recipients and strongly encourages people to contact staff with questions. Dr. Lauer said the situation has caused unprecedented stress, and concerns persist about the pandemic's long-term impact on the biomedical research workforce, especially for people in the early stages of their careers, underrepresented groups, and women (particularly those affected by the lack of child care options).

Discussion

Dr. Lauer noted that early-stage investigators (ESIs) can apply online for an extension of their status that takes into account time lost during the pandemic shutdown. The committee that reviews the applications has been very flexible in its determinations. Applicants can propose what accommodations they think they need. Roberta Diaz Brinton, Ph.D., stated that the pandemic reveals the challenges of sustaining a system that is structured to support ESIs until they get their own grants. Dr. Lauer said that the topic has been discussed as part of the Next Generation Researchers Initiative and that NIH has committed to funding ESIs. Under current conditions, NIH is doing all it can with the flexibility it has.

Dr. Lee pointed out that the problems caused by the pandemic and the lockdown are likely to continue. He suggested the research community look at the long-term impact, including assessing the opportunity costs for at least the next 2 years.

Dr. Lauer noted that surveys are being considered to shed light on the impact of the pandemic on researchers (especially women) who have young children so that steps can be taken to mitigate the impact on their careers. Hannah Valantine, M.D., said her office anticipates that women and underrepresented groups will be disproportionately affected by the career disruptions, so data on the topic are being collected.

Kristina Johnson, Ph.D., asked for guidance on the use of pool testing of samples in higher education settings. Dr. Gottesman said NIH is considering pooling samples, as analysis indicates that such testing can be sufficiently sensitive. Dr. Tabak and Dr. Johnson agreed to exchange relevant data on pool testing.

Review of Outside Awards for ACD Approval

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH

Dr. Tabak explained that NIH employees may not receive additional, outside payment for their work, so selected ACD members work with the NIH Ethics Program staff to screen all outside awards. Dr. Tabak asked the ACD to consider the list of awards to NIH employees who are deemed eligible by the NIH Ethics Program.

Vote: ACD members approved the awards unanimously.

HeLa Genome Data Access WG

Spero Manson, Ph.D., Colorado Trust Chair in American Indian Health, University of Colorado, Aurora; WG Cochair
Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH; WG Cochair

Dr. Wolinetz explained that the HeLa Genome Data Use Agreement (DUA) is an agreement between the NIH and the family of Henrietta Lacks that provides a way for whole genome sequence data generated from HeLa cells to be used to advance research, while respecting the family's privacy and interests. The HeLa Genome Data Access Working Group (WG) evaluates requests to access HeLa cell genome data for consistency with the terms of the DUA and reports its findings to the ACD. Per the DUA, investigators (requestors) requesting access to HeLa whole genome sequence agree to not make contact with the Lacks family, only use the data for biomedical research, disclose commercial plans, include an acknowledgment in publications and presentations, and deposit future whole genome sequence data into the database of Genotypes and Phenotypes (dbGaP).

Of the 89 requests evaluated and the findings reported to the ACD by the WG, 82 have been approved by the NIH Director to date. At this ACD meeting, the WG presented its findings of one new request; the WG reported that the pending request was consistent with the DUA.

Vote: The ACD voted unanimously in favor, informed by the findings of the WG, of recommending that Dr. Collins approve the pending request.

ACD WG on Enhancing Reproducibility and Rigor in Animal Research (Interim Report)

Barbara Wold, Ph.D., Professor of Molecular Biology, California Institute of Technology; WG Cochair
Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; WG Cochair

To better reflect its charge, the WG was renamed to the ACD WG on Enhancing Rigor, Transparency, and Translatability in Animal Research. Dr. Wold reiterated the extensive charge to the WG and described its membership, major discussion topics, and subgroups.

Animal research is often the foundation for clinical trials. If translation is the goal, closer attention must be paid to the standards for design and analysis of the studies, the utility of preregistration, and the role of studies that reproduce or replicate the findings. The Vocabulary Subgroup pointed out that a binary approach to reproducibility is not helpful, nor is it useful to conclude that findings from one setting are equally applicable in all settings. Scientific rigor and transparency are the building blocks for consistent results across studies. The Vocabulary Subgroup outlined one approach, adapted from Goodman, Steven N., Daniele Fanelli, and John PA Ioannidis. "What does research reproducibility mean?." *Science translational medicine* 8.341 (2016): 341ps12-341ps12, that identifies three categories of reproducibility, all of which are important:

- *Methods reproducibility* requires full transparency about the details of the work so that it can be replicated by others.
- *Results reproducibility* refers to the capacity of other researchers to obtain the same results using procedures as close as possible to the original; expectations should be clear from the outset, and statistical analysis should be well defined up front to avoid data manipulation.
- *Inferential reproducibility* draws similar conclusions from different experiments that center around the same question; it requires complete data availability.

Statistical significance is not enough to demonstrate reproducibility, Dr. Wold emphasized.

The WG heard input from invited experts on selection of models, improving and finding alternatives to animal models, and use of preregistration to improve study design. Selection of an animal model should take into account how well the model addresses the research question. Dr. Wold noted that the WG's recommendations would not list the best animal models for specific human disease research, because the research question matters. Furthermore, if the work is intended to be translational, the data collected must be appropriate to the goal. Improving model selection will require cultural change at all levels so that researchers focus on what works for a given question, rather than selecting models based on tradition or convenience.

NIH can play a role by creating incentives to develop new models as needed. The National Institute of General Medical Sciences (NIGMS) tackled this concept by

focusing on the failure of animal models to advance research on sepsis. It convened a WG that made recommendations to develop better models and support alternative approaches, and those recommendations led to changes in the field.

Nonanimal models, such as organoids and tissue-on-a-chip approaches, merit more attention and funding. These models can catalyze intense interdisciplinary work and incorporate systems design principles.

Preregistration—or publishing the hypothesis, methods, and design of proposed research—can inform the field about work underway. If done well, it forces investigators to design studies better. Preregistration of exploratory research is allowed and encouraged as long as researchers clarify their intentions. Preregistration requires additional administrative work, and there is no consensus on what type of research plans should be published or at what stage in the research process preregistration should occur. Other questions to consider are whether preregistration should be mandatory, what role it plays in peer review, what minimum elements should be required, and how intellectual property can be protected. The WG intends to continue to explore the role of preregistration as it finalizes its recomendations.

The Financial Implications Subgroup, led by Dr. Lauer, is assessing the impact of potential WG recommendations on NIH resources. The Subgroup is focusing mostly on immediate preclinical work and seeks to estimate the costs of increasing sample sizes, training and hiring more specialized statisticians, requiring more replication, encouraging preregistration, and standardizing meta-analyses. Using a random set of approved grant applications, the Subgroup seeks to compare the administrative data, research proposals, and subsequent publications to determine whether the awardees described a rigorous methodological approach and whether published results reflected that methodology. The Subgroup will also gather input from other entities that have analyzed the financial implications of raising the bar for rigor and reproducibility.

NIH will publish a request for information inviting input on enhancing rigor, transparency, and translatability in animal models, specifically requesting comments on optimizing the relevance to human biology and disease and improving the research culture.

The WG plans to refine the following themes in its report:

- Selecting or developing the most appropriate animal or other model for human disease to address the question of interest
- Strengthening experimental design and analysis, with appropriate expectations for reproducibility
- Recognizing the impact of animal care and husbandry on experimental outcomes
- Enhancing transparency, recognizing that digital publishing allows for publication of more detailed background and supplemental materials
- Training and continuing education, including vocabulary, around animal research
- Measuring and evaluating the effects of any interventions
- Tackling the cultural incentives that maintain the status quo

Dr. Wold concluded that the WG will present its final report and recommendations to the ACD at the December 2020 meeting.

Discussion

Dr. Brinton suggested the WG mention in its report that including clinicians on the research team (whether the research is basic, clinical, or translational) is a key element to successful translational research. She added that selecting a contract research organization that engages in the work like a true partner is also important to success. Dr. Brinton noted that the Alzheimer's Drug Discovery Foundation developed a list of recommended contract research organizations on the basis of input from the Alzheimer's research community.

Dr. Brinton observed that, in epigenetics research, clinical trials of pharmaceuticals often do not carry out good research to determine whether the trial compound reaches the target, an issue that speaks to an important aspect of the interface between basic and clinical research. Dr. Wold said the issue reflects the need to ensure that the data collected are appropriate to the research question. It is one of many areas that would be improved by increased transparency, and NIH can incentivize steps in that direction, said Dr. Wold.

Dr. Lee hoped the WG would offer guidelines on selecting models and determining endpoints that answer the research question. Case studies may be helpful in that regard.

Dr. Collins asked whether the WG has considered distinguishing the different types of research (e.g., exploratory and hypothesis-generating experiments) from the perspective of interpreting the results. Dr. Wold said the WG is wrestling with the issue. Ultimately, the research community at all levels—including researchers who review grant applications and submissions for journal publication—must become better educated and more sophisticated in understanding the types of research and outcomes.

Dr. Wold clarified that scientific rigor is as important as translatability. Dr. Brinton pointed out that translatability and validity are part of the long journey from planning to results, and rigor and reproducibility are incorporated and expanded along the way.

ACD WG on Changing the Culture of Science to End Sexual Harassment

Carrie D. Wolinetz, Ph.D., Associate Director for Science Policy, NIH; Sexual Harassment WG Cochair

Dr. Wolinetz reiterated the themes and conclusions of the WG's report and recommendations, which were accepted by the ACD in December 2019 and immediately approved by Dr. Collins. Dr. Wolinetz said NIH not only has a moral obligation to end the culture of sexual harassment in biomedical research but also recognizes that safe and harassment-free research environments are essential for conducting high-quality science.

In 2019, NIH evaluated 115 reports of sexual harassment. So far in 2020, it has evaluated 27 cases. Reports have come from 71 institutions, and 14 PIs have been removed as a

result. Many incidents are still being investigated. Dr. Wolinetz summarized some progress toward NIH's goals, emphasizing that much more work lies ahead. Internally, NIH's ICs have tailored plans to address the culture and instated best practices to address sexual harassment, including a consistent approach to disciplinary actions. These efforts were informed by the results of NIH's climate survey.

The 2019 report recommended creating a parallel process that treats professional misconduct (including sexual harassment) as seriously as research misconduct and establishing mechanisms to address it. NIH is publishing guidance for extramural institutions that speaks to these recommendations and seeks to close some loopholes. NIH has updated policies to indicate that researchers who have committed professional misconduct, including sexual harassment, may not participate in NIH peer review or advisory groups. Steps are also being taken to support research on policies that model and promote a positive workplace climate, including a stakeholder workshop, the outcome of which could ultimately be used by funding agencies to support effective approaches.

Toward the goal of restorative justice, NIH has established new incentives and funding opportunities for people whose careers have been affected because they were targeted for harassment or bullying. Several new mechanisms are in development to fund some trainees directly as a way to promote a safe research environment. Release of the Katz Award to enable ESIs to pursue work that differs from their training focus was delayed because of COVID-19 but will take place in the fall. Other NIH entities are evaluating the use of career development (K) and fellowship (F) awards to provide direct funding. NIH has taken a number of steps to clarify that standards of professional conduct for NIH-funded researchers apply to other settings, particularly conferences.

The NIH Center for Scientific Review is finalizing a report on a study to assess gender bias in peer review. NIH is offering administrative supplements to extend projects that promote diversity in research settings.

Dr. Wolinetz said NIH is seeing a worrisome trend: When an incident is reported, investigated, and found to be credible, some extramural institutions acknowledge the findings and remove the individual from training and supervisory responsibilities but request that NIH make no changes to the grant and retain the PI. This approach supports the perception that institutions protect their highly funded researchers even if they compromise the safety of the research environment, and NIH believes it is not in keeping with good stewardship of public funds.

Dr. Wolinetz noted that a lot of work is underway across HHS and in partnership with the National Academies of Science, Engineering, and Medicine. The pandemic has slowed progress. There have been conversations about how the pandemic will affect workforce diversity and the research environment.

Discussion

Dr. Cuss, who cochaired the WG, said he was disappointed but not surprised that extramural institutions are adapting to the new reality. The WG anticipated resistance and believes that the recommendations may need to include stronger consequences. In

addition, said Dr. Cuss, it has become clear that COVID-19 affects women in science differently, as the number of scientific publications by women has already gone down. He hoped NIH would consider the long-term impact on women's careers. Dr. Johnson, also a cochair, said that her institution has responded to the pandemic by extending the clock for tenure and applying that across the board, with an opt-out provision for people who did not wish to extend so that it would not be perceived as a stigma.

Dr. Wolinetz pointed out that once NIH reframed sexual harassment and other misconduct as a threat to workplace safety, it was able to use its existing authority to move forward on many fronts. Some of the recommended actions remain difficult to achieve, but NIH is not giving up on them, she said. Dr. Wolinetz clarified that in all of its efforts, NIH defines professional misconduct as including not just sexual harassment but other forms of bullying and retaliation as well. She hoped to have more details to report on revisions to F and K awards in the future. Dr. Collins concluded that it is not easy to change culture, but NIH is taking the recommendations seriously and believes that diversity correlates with scientific productivity.

Update: ACD WG on Foreign Influences on Research Integrity

Michael Lauer, M.D., Deputy Director for Extramural Research, NIH

Dr. Lauer recapped the concerns that led to formation of the WG and its recommendations, approved by the ACD in December 2018 and implemented by NIH. He highlighted some notable civil, criminal, and compliance cases. For example, six prominent scientists at the Moffitt Cancer Center, including the CEO, who had substantial undisclosed ties to China's Thousand Talents Program were removed for various instances of receiving unreported personal payments, benefits, and research support.

NIH is aware of nearly 400 scientists of concern, identified through tips, self-disclosure, or discrepancies between grant applications and public reporting; most are linked to China. NIH has reached out to 189 institutions. Significant violations were found in more than 80% of cases. Of the 189 institutions involved, 41% have been removed from NIH-funded activities.

Dr. Lauer noted that violations have occurred across the country, in all areas of biomedicine. Most of the work involves animal research. Among institutions that NIH contacted about concerns, about half have instituted new measures to protect research integrity. A recent article on the Thousand Talents Program points out that moving one's research is not in itself illegal but does transfer intellectual property created with U.S. tax dollars to another country. The author recommended more transparency and more dialogue between China and America.

Dr. Lauer concluded that the WG's recommendations were implemented and have yielded results, including a lot of self-disclosure and more cooperation with other agencies and stakeholders. He stressed that NIH believes that foreign researchers contribute to biomedical science and that the climate must not be unwelcoming to them.

Discussion
Dr. Lauer pointed out that the Thousand Talents Program is substantial and has been involved in most of the cases of concern. NIH is looking into threats from Russia and elsewhere, but they occur on a much smaller scale.

Dr. Lauer said the number of scientists of concern has risen since the WG's recommendations were made, in part because institutions are discovering and revealing problems. He said it will take many more months to understand the full extent of the issue. The Thousand Talents Program has gone dark; there is evidence that China has instructed participants not to name the program in email or other communications, and it is not clear whether China is still recruiting scientists for the program.

Update: ACD WG on Diversity

M. Roy Wilson, M.D., M.S., President, Wayne State University; WG Cochair
Hannah Valantine, M.D., Chief Officer for Scientific Workforce Diversity, NIH; WG Cochair

Dr. Wilson said that the lack of diversity in biomedical and scientific research workforce has been recognized for some time, but recent events, specifically the pandemic and the murder of George Floyd, have brought racial injustice into sharp focus and increased the urgency of the WG's work. The WG held two virtual meetings in recent months to discuss how to sustain diversity efforts amid the pandemic rather than back off.

COVID-19 has been devastating to the African American community, Dr. Wilson observed, and so has police brutality, which represents another public health crisis. The root causes of both involve systemic racism, poverty, and unequal education and opportunity—all of which have also stymied diversity in the biomedical workforce. Dr. Wilson said the impact of COVID-19 is high but still represents only half the number of African American men who are likely to die at the hands of police officers. The WG believes it must not shirk its responsibility to address underlying inequities. Speaking for all the WG members, Dr. Wilson said the WG feels a sense of urgency and also cautious optimism. NIH has been a strong leader, and some extraordinary steps have been taken. The WG will continue, Dr. Wilson concluded.

Dr. Valantine said the WG has had meaningful discussions raising various important points. The field of science needs to do some soul searching and correct inequities. One key step is to openly acknowledge the problems faced by Black people in science. (Dr. Valantine recognized that other underrepresented groups also have unique experiences and problems in the field, but now is the moment to act on issues specific to Black people.) Black peer support is vital during this time of turmoil and hopelessness exacerbated by COVID-19. Admission and selection committees must revise their criteria to cast a broader net. As with sexual harassment, acts of racial bias should be reported and perpetrators held accountable. Recognizing implicit bias is important, but explicit racism remains. Allies should be empowered to be actively anti-racist, or they risk falling back into complicity.

The WG identified three priorities for 2020:

1. Develop a plan to communicate NIH's progress on enhancing diversity to the larger community, for ACD's consideration.
2. Help update NIH's 5-year Scientific Workforce Diversity Strategic Plan (2021–2025), encompassing actionable steps for implementing 2019 recommendations, for ACD's consideration.
3. Coordinate a subset of ACD WG members to prepare a white paper on individuals with disabilities in the scientific workforce, in their individual capacities.

For the communication plan, the WG identified target audiences that would benefit from education and more awareness of NIH programs, tools, resources, and activities around diversity, but progress stalled when the pandemic hit. The WG decided to monitor the impact of COVID-19 on diversity and inclusion efforts. The WG is also moving forward with updating the strategic plan and creating a subgroup to address issues faced by people with disabilities.

Among NIH activities to implement ACD recommendations on diversity is the Faculty Institutional Recruitment for Sustainable Transformation program. One intramural pilot program has demonstrated success in changing the demographics of tenure-track investigators. The first FOA for the Faculty Institutional Recruitment for Sustainable Transformation program will go out this summer, with awards announced in summer 2021. Also, an online training module on implicit bias will be available soon through NIH's learning portal.

NIH's COVID-19 Action Plan targets the ways in which the pandemic contributes to a less diverse workplace culture and places added burden on women and African Americans. As a first step, NIH will leverage existing flexibility and accommodations in extramural programs to mitigate these effects. It will collect data about the workforce and seek other trans-NIH approaches. A survey is planned for July, and Dr. Valantine hoped it would provide information that could inform evidence-based interventions by the fall.

Discussion

Dr. Valantine clarified that NIH's cohort model for diversity measures productivity and time at the individual level to attain an independent grant or tenure, then compares those findings with a control group. Another key measure is the extent of diversity among the faculty cohort and whether that affects the diversity of the department. Another indicator of success is a shift in institutional culture, which Dr. Valantine hoped to measure with a standardized tool. She stressed the importance of evaluating the models rather than dictating actions to the community. Dr. Wilson added that previous NIH diversity programs may have lacked sufficient rigor in measurement, so there is a strong emphasis now on measurement. Dr. Valantine also pointed out that evaluation will be conducted by the Coordination and Evaluation Center, not the individual institutions involved in the model, and the model was designed to capture comparisons.

Dr. Valantine sits on a federal interagency scientific workforce group that includes representatives from the Department of Education and is seeking to improve diversity and engagement starting in preschool. NIH has a number of programs that target K–12 education, but much more needs to be done. Dr. Collins noted that K–12 education is seen as the job of the National Science Foundation, so NIH's role is limited. Dr. Brinton said her institution takes advantage of the mentoring requirements in training grants to reach out to underserved elementary and high school science students. Dr. Valantine agreed to raise the idea for further consideration. NIGMS recently expanded mentoring requirements to take into account the diversity of mentors and their ability to connect across different cultural backgrounds, and the new approach has been very effective.

Closing Remarks and Adjournment

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins thanked the ACD members for their valuable insight and NIH staff for their hard work in organizing and preparing for this meeting. The next ACD meeting is scheduled for December 10–11, 2020, and will likely take place virtually. Dr. Collins adjourned the meeting at 4:00 p.m.

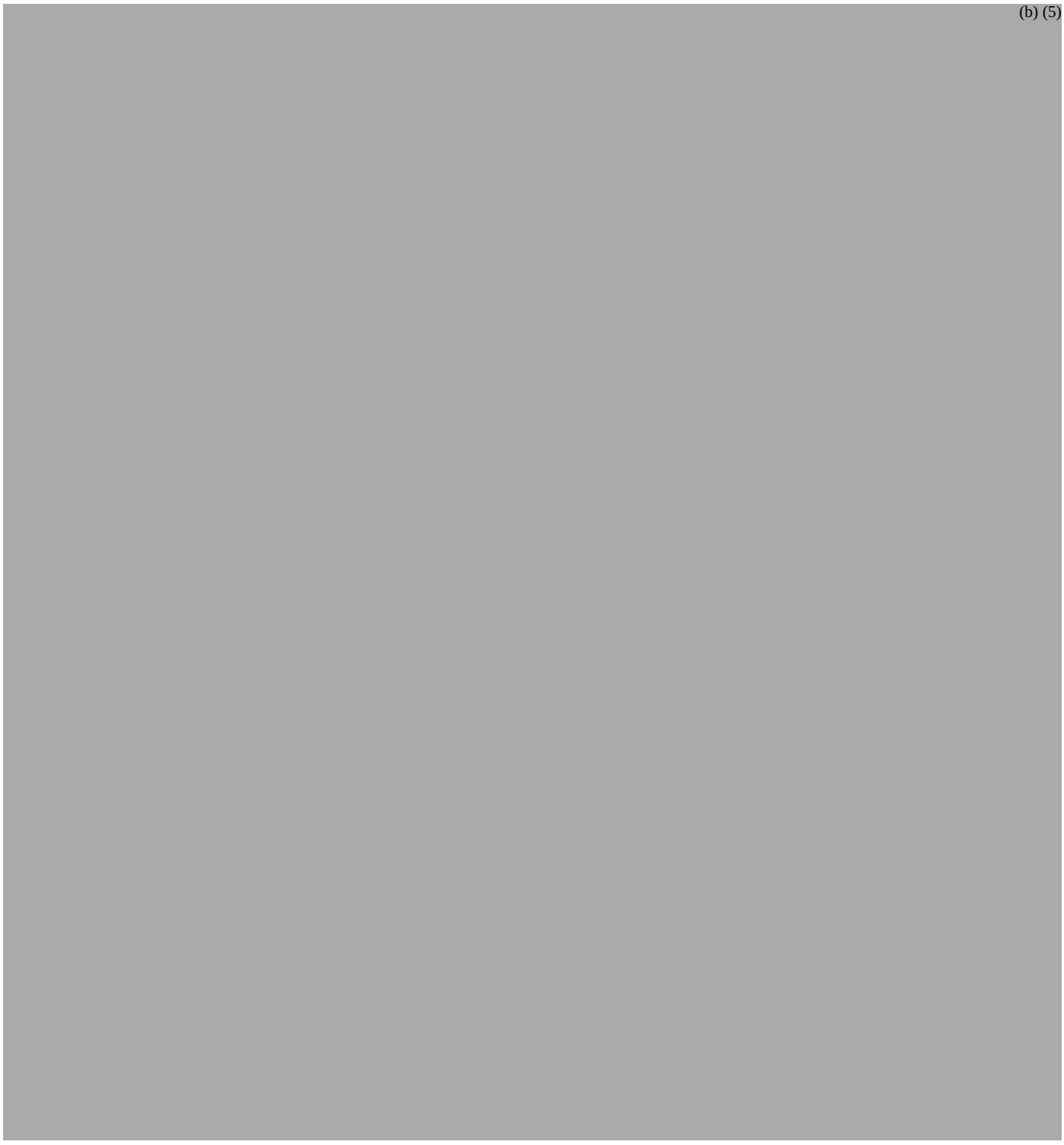
Lawrence A. Tabak, D.D.S., Ph.D.
Executive Director, Advisory Committee to the Director
Principal Deputy Director, NIH

Francis S. Collins, M.D., Ph.D.
Chair, Advisory Committee to the Director
Director, NIH

Abbreviations and Acronyms

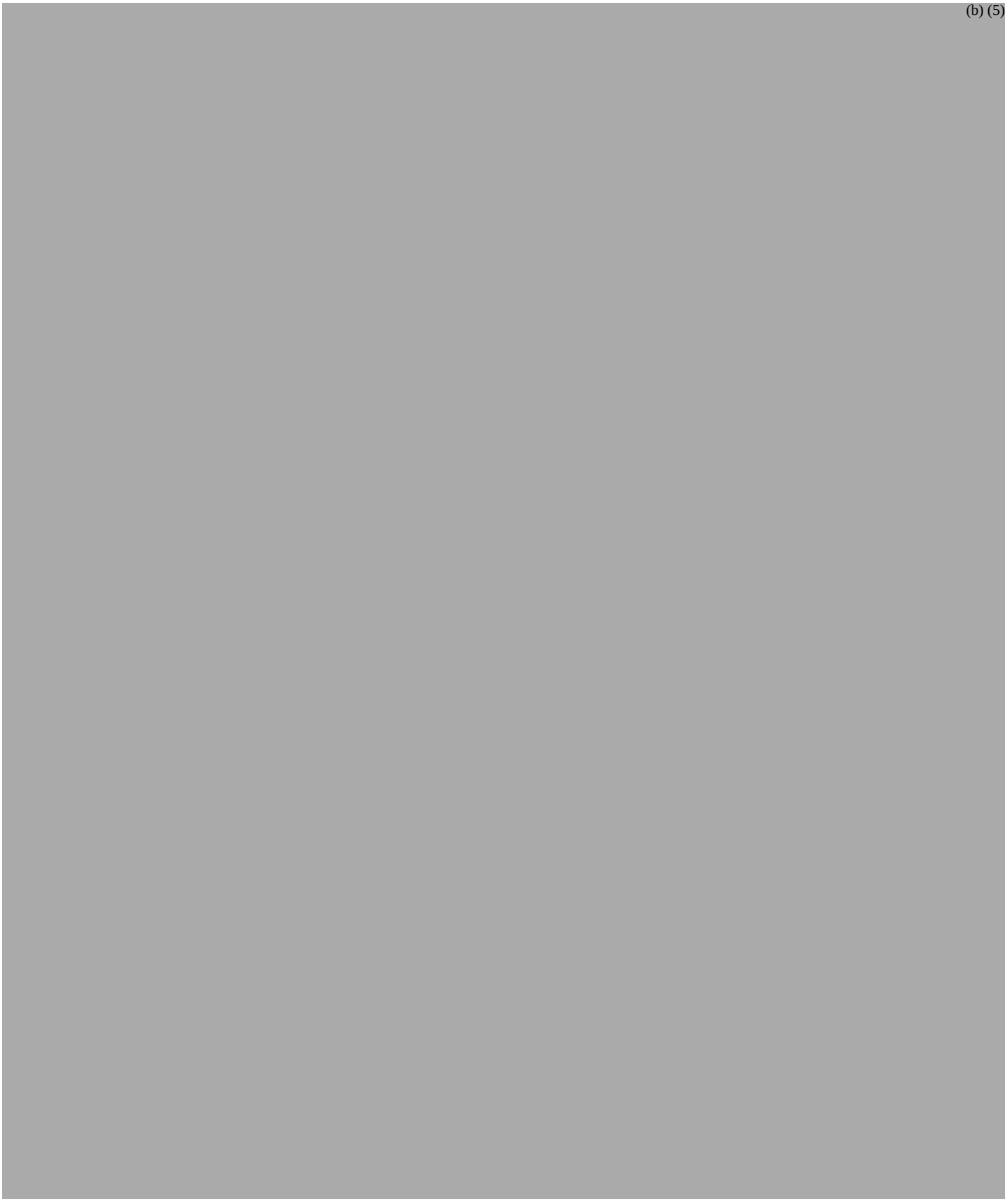
ACD	Advisory Committee to the Director
ACTIV	Accelerating COVID-19 Therapeutic Interventions and Vaccines
BARDA	Biomedical Advanced Research and Development Authority
BRAIN	Brain Research Through Advancing Innovative Neurotechnologies
CAC	COVID-19-associated coagulopathy
CEO	chief executive officer
DUA	data use agreement
ESI	early-stage investigator
FDA	Food and Drug Administration
FIRST	Faculty Institutional Recruitment for Sustainable Transformation
FOA	funding opportunity announcement
FY	fiscal year
HEROES (Act)	Health and Economic Recovery Omnibus Emergency Solutions
HHS	Department of Health and Human Services
ICs	Institutes and Centers
mAb	monoclonal antibody
MIS-C	multisystem inflammatory syndrome in children
MISSION (Act)	Maintaining Internal Systems and Strengthening Integrated Outside Networks
NHLBI	National Heart, Lung, and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
PI	principal investigator
RADx	Rapid Acceleration of Diagnostics
RADx-ATP	Rapid Acceleration of Diagnostics Advanced Technology Program
RADx-rad	Rapid Acceleration of Diagnostics Radical
RADx-UP	Rapid Acceleration of Diagnostics for Underserved Populations
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
WG	working group

(b) (5)

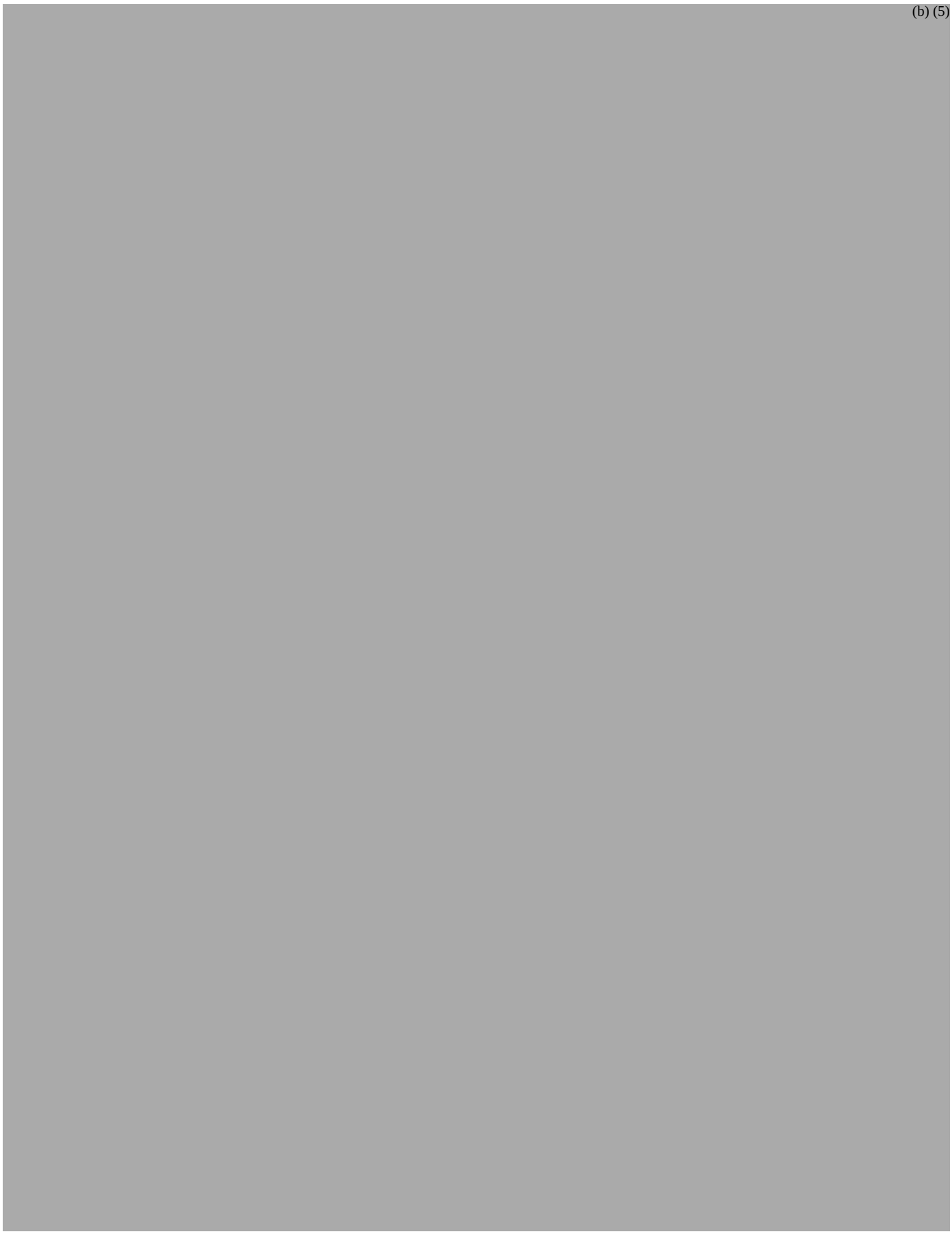


(b) (5)

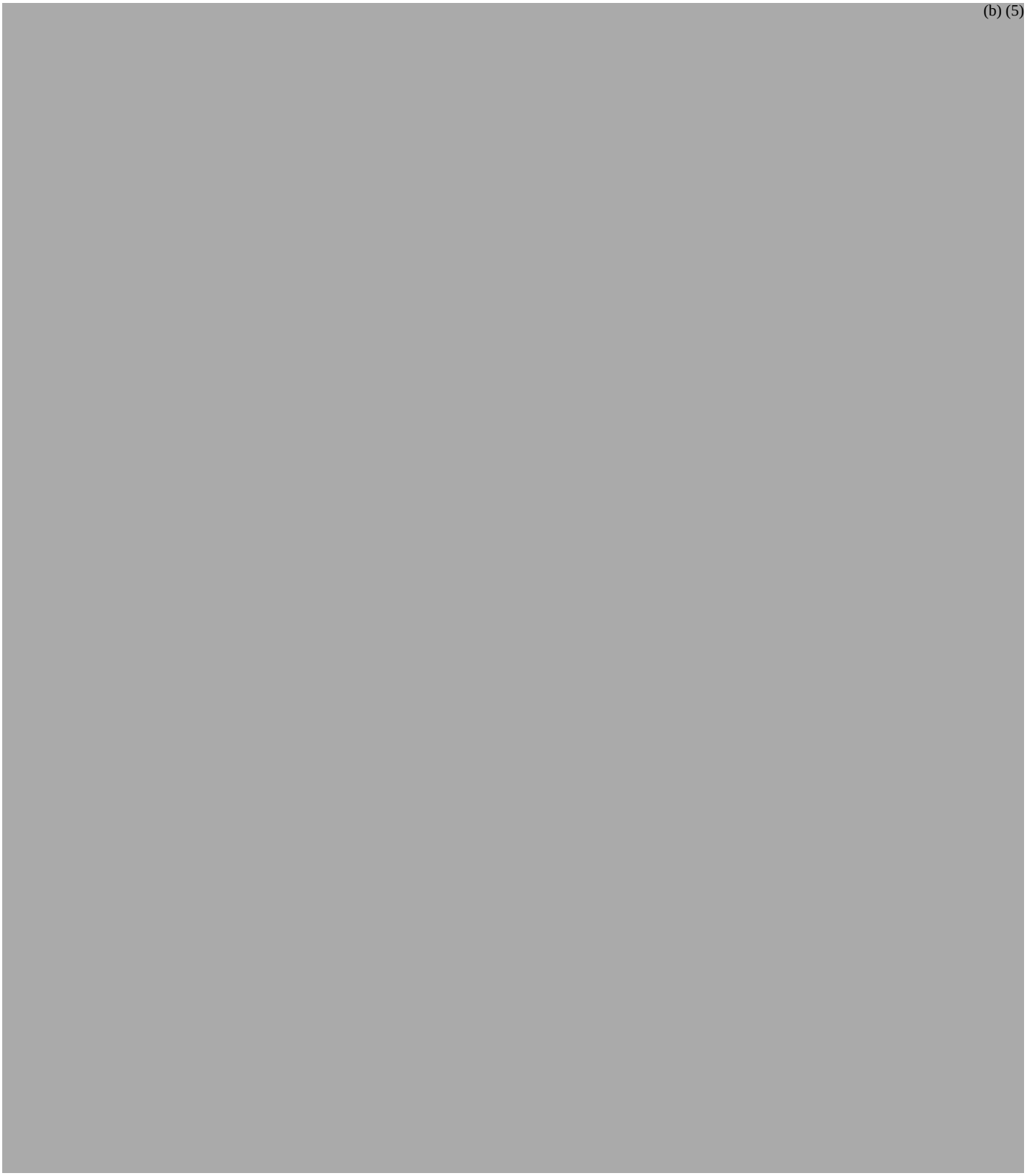
(b) (5)

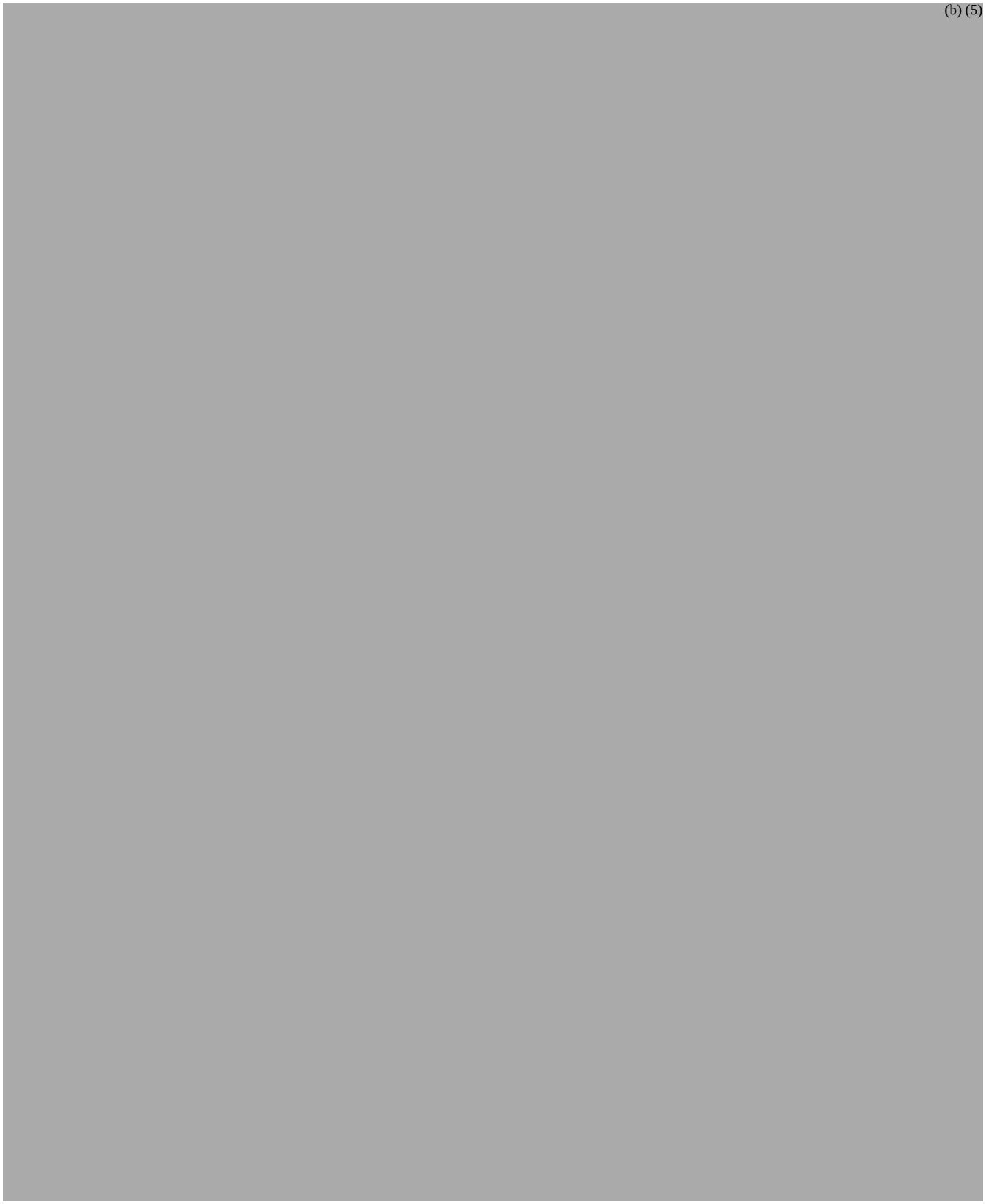


(b) (5)



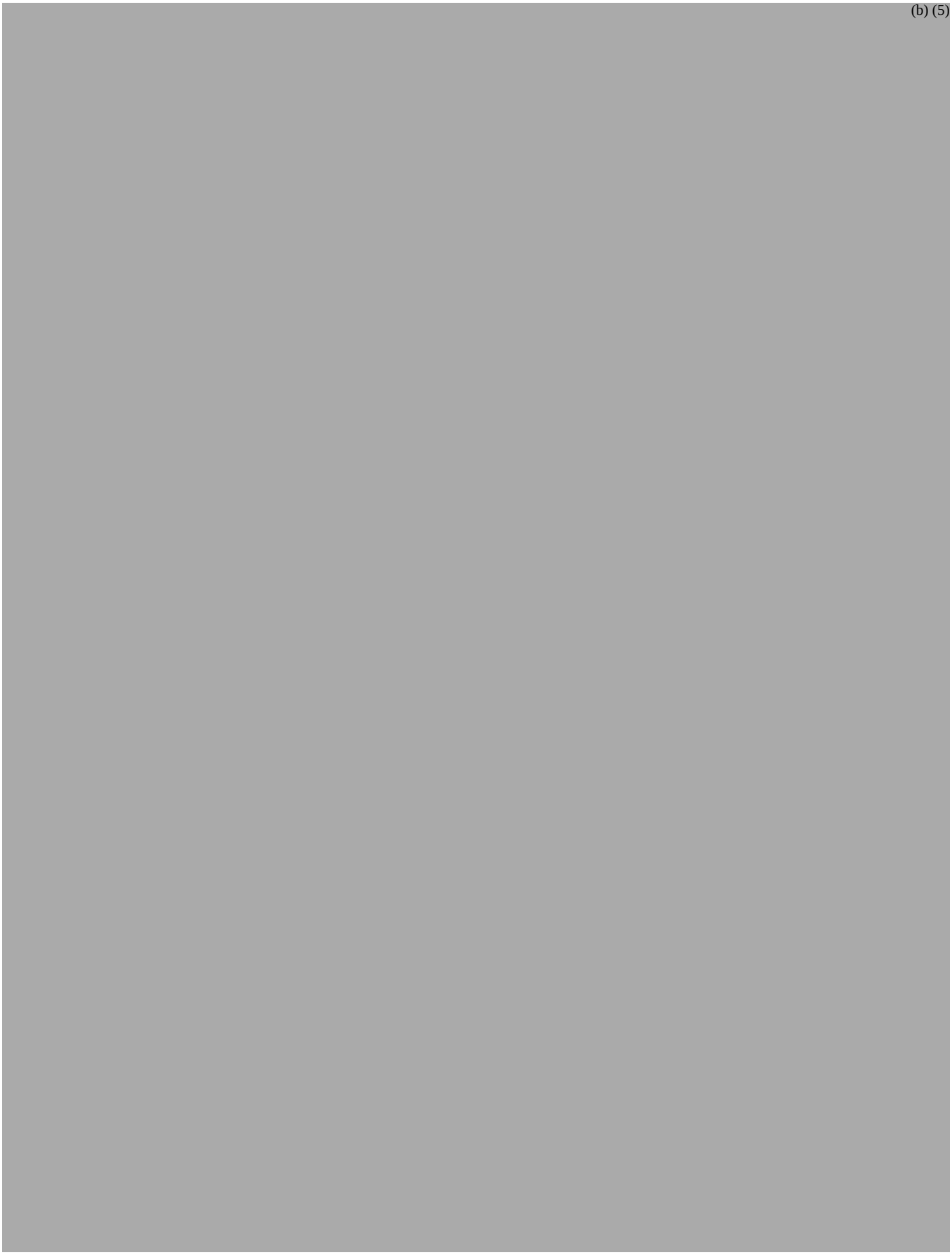
(b) (5)




(b) (5)

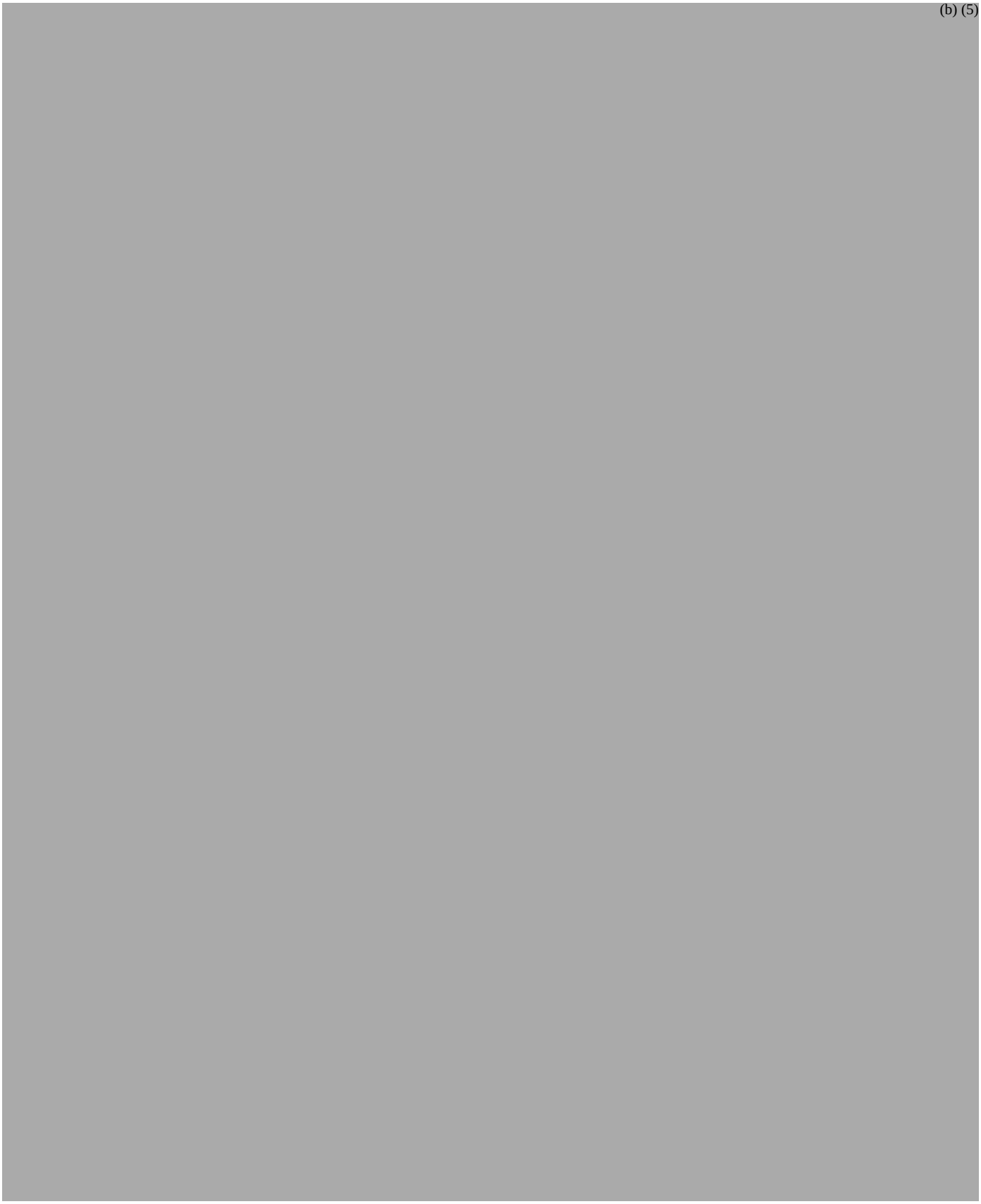

(b) (5)

(b) (5)



(b) (5)

(b) (5)



(b) (5)

U.S. Department of Health and Human Services

National Institutes of Health

Fifteenth Meeting of the Clinical Center Research Hospital Board

July 17, 2020

Contents

Clinical Center Research Hospital Board

Laura Forese, M.D., M.P.H., Executive Vice President and Chief Operating Officer, NewYork–Presbyterian Hospital; and Chair, National Institutes of Health (NIH) Clinical Center Research Hospital Board (CCRHB)

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH; and Executive Director, CCRHB

Francis S. Collins, M.D., Ph.D., Director, NIH; and *Ex Officio* Member, CCRHB

Ellen Berty, Special Education Teacher, Book Author, and Former NIH Research Participant

Brig Gen James Burks, M.B.A., M.M.A.O.S., U.S. Air Force (Ret)

Jeanette Ives Erickson, D.N.P., RN, FAAN, Chief Nurse Emerita, Massachusetts General Hospital; and Executive Committee Chair, Commission on Magnet Recognition, American Nurses Credentialing Center

*Julie Freischlag, M.D., Wake Forest University School of Medicine

Steven I. Goldstein, M.H.A., President and Chief Executive Officer, University of Rochester Medical Center

William Hait, M.D., Ph.D., Global Head of External Innovation, Johnson & Johnson

Stephanie Reel, M.B.A., Chief Information Officer Emerita, Johns Hopkins University and Health System

Richard Shannon, M.D., Executive Vice President for Quality and Transformation, Duke Health

Ruth Williams-Brinkley, M.S.N., President and Chief Executive Officer, Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.

*Absent

Executive Summary

The Clinical Center Research Hospital Board (CCRHB) of the National Institutes of Health (NIH) convened its 15th meeting via videoconference on July 17, 2020. The meeting was open to the public and was webcast live. A video recording of the meeting is available online.

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork–Presbyterian Hospital; and Chair, CCRHB, called the meeting to order at 9:00 a.m. ET. She welcomed new Board members Steven I. Goldstein, M.H.A., President and Chief Executive Officer (CEO) of the University of Rochester Medical Center; and William Hait, M.D., Ph.D., Johnson & Johnson's Global Head of External Innovation. Julie Freischlag, M.D., Wake Forest University School of Medicine, was absent.

The Board and NIH staff honored two former Board members, Beatrice Bowie and Paul O'Neill, who recently passed away.

Francis Collins, M.D., Ph.D., NIH Director, greeted the CCRHB members and highlighted NIH and other agencies' activities focused on the pandemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public–private partnership aims to speed the development of the most promising treatments and vaccines for coronavirus disease 2019 (COVID-19). In addition to private firms and NIH, the Department of Veterans Affairs, the Department of Defense, the Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention, and other federal entities are collaborating within the framework of Operation Warp Speed. Dr. Collins also outlined the many provisions aimed at keeping Clinical Center employees safe during the current pandemic.

James Gilman, M.D., CEO, NIH Clinical Center, announced several changes in Clinical Center leadership and noted the precipitous drop in the hospital census because of the pandemic. The phased approach for bringing NIH employees back to the Clinical Center was also discussed. Dr. Gilman announced the new Blood and Immune Deficiency–Cellular Therapy Program at NIH, which consolidates three or four separate inpatient services. New initiatives to improve employee safety have been launched. The Behavioral Emergency Response Team (BERT) responds to disruptive or violent behavior by providing verbal or physical crisis de-escalation. The Anti-Harassment Response Team (AHaRT) addresses inappropriate behavior and harassment by patients and visitors toward Clinical Center staff. The Clinical Center is improving the hospital's simulation capabilities and establishing a clinical simulation center. Dr. Gilman also explained new Clinical Center systems to support telehealth visits. In closing, he spoke of the movement inside and outside NIH calling for social justice and rejecting racism in all its forms.

Laura Lee, RN, Chief, Office of Patient Safety and Clinical Quality, briefed the CCRHB on patient and employee safety data, noting several recent encouraging trends. She also explained the Trigger Tool, a qualitative peer review of factors that contribute to individual patient harm events. Madeleine Schuyler Deming, M.D., Staff Clinician and Assistant Research Physician, Clinical Center Internal Medicine Consult Service, presented three cases that were analyzed by the Trigger Tool team. These deep-dive peer reviews have highlighted some systems issues and led to several organizational changes.

Gwenyth Wallen, Ph.D., RN, Chief Nurse Officer, Clinical Center Nursing Department; and Rachel Coumes Perkins, M.S.N., RN, Nurse Consultant, Clinical Center Nursing Department, described the Clinical Center's journey to become a Magnet Recognition Program® hospital. Ms. Perkins is serving as the Magnet Recognition Program® manager, coordinating with nursing staff and an analyst as NIH develops a plan for achieving Magnet status.

Dr. Gilman; Ann Marie Matlock, D.N.P., RN, NE-BC, Chief, Medical–Surgical Specialties Clinic, and Captain, United States Public Health Service; Karen Frank, M.D., Chief, Clinical Center Department of Laboratory Medicine (DLM); and Tara Palmore, M.D., Chief, Clinical Center Hospital Epidemiology Service, outlined in detail the provisions in place for screening and testing staff and patients for SARS-CoV-2. They also provided information on the testing setup in the DLM as well as data on Clinical Center test results to date.

Meeting Summary
Friday, July 17, 2020

Welcome and Board Chair's Overview

Laura Forese, M.D., Executive Vice President and Chief Operating Officer, NewYork–Presbyterian Hospital, and Chair, Clinical Center Research Hospital Board (CCRHB)

The 15th meeting of the National Institutes of Health (NIH) CCRHB took place on July 17, 2020. The meeting participants convened via videoconferencing. The meeting was open to the public and webcast live. A video recording of the meeting is available online.

Dr. Forese called the meeting to order at 9:00 a.m. ET and welcomed everyone. Dr. Forese announced that CCRHB member Julie Freischlag, M.D., Wake Forest University School of Medicine, was absent.

Dr. Forese asked the meeting participants to observe a moment of silence to honor one of the Board's first members, Beatrice Bowie, who passed away several weeks ago. Ms. Bowie was a vital participant. She never missed a meeting and took every opportunity to provide a patient's perspective on the NIH Clinical Center's efforts to ensure patient safety and provide top-notch care in the world's largest hospital dedicated to biomedical research.

The Board welcomed new members Steven I. Goldstein, M.H.A., President and Chief Executive Officer (CEO) of the University of Rochester Medical Center; and William Hait, M.D., Ph.D., Johnson & Johnson's Global Head of External Innovation.

NIH Director's Remarks

Francis S. Collins, M.D., Ph.D., Director, NIH; and Ex Officio *Member, CCRHB*

Dr. Collins thanked Dr. Forese for her continued service as leader of the Board and welcomed the new members.

The Clinical Center has experienced stresses during the pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), as has every other medical organization during recent months. Dr. Collins said that his days have been very long and packed with meetings and decisions. He also spoke of the enormous responsibility of bringing the best science forward to end the crisis in this nation and around the world.

Dr. Collins reflected on Ms. Bowie's contributions to the Board and to NIH as a whole. Ms. Bowie frequently reminded everyone that patients are the point behind this research enterprise. Dr. Collins acknowledged Ellen Berty, who now is assuming the sole responsibility for reminding the Board and others that patients should be front and center.

Dr. Collins also acknowledged the recent death of former Board member Paul O'Neill, M.P.A., who was a real force for patient and employee safety.

Dr. Collins also spoke about the role of Anthony Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases (NIAID), in promoting the science of SARS-CoV-2 while

communicating about what is known as well as knowledge gaps. Dr. Fauci is resilient and will continue to tell the stories of coronavirus disease 2019 (COVID-19) and scientific progress.

Update from the NIH Clinical Center CEO

James Gilman, M.D., CEO, NIH Clinical Center

Dr. Gilman thanked the Board members for their guidance to the Clinical Center (CC). He acknowledged the passing of former members Ms. Bowie and Mr. O'Neill.

Hospital Census

One of the goals of the Clinical Center Strategic Plan is to increase utilization of the Clinical Center. The inpatient census was trending upward, but then the pandemic struck, and the census has been declining since mid-March. NIH supported plans to defer elective clinical and research procedures and Clinical Center staff developed strategies to prepare for a possible influx of COVID-19 patients. Many research participants were discharged to home, and others were advised to defer plans to come to the Clinical Center. Since mid-May, the census has been slowly rising, but is likely influenced by patients' reluctance to travel and enter hospitals unless absolutely necessary. In the meantime, transplants and surgeries have resumed, but the census has not bounced back yet. Compared with 2019, admissions are down 28% and outpatient visits are down 30%.

Leadership Changes

Two national searches, for a new chief medical officer and for the chief of the Transfusion Medicine Department, are nearing completion.

NIH has made further changes in the leadership of the Clinical Center Pharmacy Department. CAPT Richard DeCederfelt, Pharm.D., is now Acting Chief of the Pharmacy Department. He previously ran the pharmacy's procurement division. A national search will be launched to fill the position permanently. Marilyn Farinre, Pharm.D., M.B.A., DPLA, has stepped in as the Chief of Pharmacy Operations Service. She came to NIH from Sibley Memorial Hospital. Marcus Ferrone, Pharm.D., J.D., was recruited from the University of California, San Francisco, where he was an R01-funded investigator. He filled a quality control role initially but is now the Chief of the Clinical Pharmacy and Investigational Drug Research Unit.

Blood and Immune Deficiency–Cellular Therapy Program

The new Blood and Immune Deficiency–Cellular Therapy Program at NIH consolidates four former separate inpatient services. The National Heart, Lung, and Blood Institute (NHLBI); the National Institute of Allergy & Infectious Diseases (NIAID); the National Cancer Institute (NCI); and the National Human Genome Research Institute (NHGRI) are working together, combining their -bone marrow transplantation programs and sharing ideas. Theresa Jerussi, M.S., PA-C, of the NIH Clinical Center is Chief Operating Officer of the program, which began about a year ago.

The idea behind the consolidation is to build a transplant and cell therapy community based on best practices with the goal of providing the highest-quality and safest care, optimize resource utilization of the Clinical Center and the NIH Institutes and Centers (ICs), leverage expertise to

optimize the design of clinical trials, ensure physician competency in the fields of bone marrow transplantation and cell therapy, and increase efficiency and clinical care experience among clinicians previously practicing separately.

Clinical Center 2020 Priorities

Dr. Gilman outlined five goals for 2020:

- Achieve Magnet recognition, as was discussed later during the meeting.
- Improve detection of neurologic effects of medications. Avindra Nath, M.D., Intramural Clinical Director of the National Institute of Neurological Disorders and Stroke, is taking part in this effort, along with nursing staff.
- Implement two initiatives focusing on staff safety (i.e., Anti-Harassment Response Team [AHaRT] and Behavioral Emergency Response Team [BERT]).
- Improve talent management.
- Focus on clinical simulation and telemedicine.

Employee Safety

Although NIH is well protected from outside threats, sometimes patients or visitors exhibit disruptive or violent behavior that may be an effect of diseases or treatments. To deal with these incidents, NIH launched the Behavioral Emergency Response Team (Code BERT) in February 2020. When a Code BERT is called, the team helps with patients (or visitors or family members) to manage uncontrolled, escalating, disruptive, or violent behavior if efforts by the primary team have been ineffective or medical and nursing teams need support in managing a patient. A trained team arrives to provide verbal or physical crisis de-escalation. After each Code BERT incident, a debriefing takes place. Since Code BERT's launch, the team has been called upon seven times—more often than anticipated. Clinical Center staff are partnering with a simulation expert to prepare for BERT events.

CAPT Antoinette L. Jones, MSOD., RN, is leading the CC **Anti-Harassment Response Team** (AHaRT), established to address inappropriate behavior and harassment by patients and visitors toward Clinical Center staff. Disruptive behavior affects staff and the care of other patients. To date, 16 reports of verbal abuse (e.g., yelling, profanity, disparaging remarks), involving two pediatric patients and three adults, have been dealt with. One patient was referred for care elsewhere.

New Clinical Simulation Program

The 2019 Strategic Plan identified the need to standardize and improve the hospital's simulation capabilities and establish a clinical simulation center. To meet these needs, the Clinical Center has enlisted the services of Mabel Gómez Mejia, M.Sc., who completed a medical simulation fellowship at Harvard Medical School. NIH clinicians perform a great deal of high-complexity, low-volume work; simulations may be beneficial for training and maintaining skills. In addition, simulations may help people learn how to request autopsies and communicate with families. Dr. Gilman presented the four proposed work streams for the simulation center: clinical simulation, translational simulation, research simulation, and innovations in simulation.

Telehealth and Telemedicine at the Clinical Center

The CC selected the Microsoft® Teams platforms for telemedicine resources, which has substantial privacy protections. A new policy was developed in just 3 weeks as a strategy to cope with the coronavirus pandemic. During May and June this year, 785 telehealth visits took place. The Clinical Center Health Information Management Department provides telehealth concierge services, which manages all the technology and coordination aspects of telemedicine. Telehealth services at NIH are likely to expand—a positive outcome of the pandemic because of the convenience for patients and providers. The plan is to move to a long-term solution in 2021 that fully integrates with NIH's electronic health record system.

Grieving Loss and Confronting Social Injustice

Two years ago, Dr. Gilman reported that more than 2,000 NIH employees had completed implicit bias training, but much more needs to be done. Following the tragic death of George Floyd and the subsequent outcry across the country, there has been a movement inside and outside NIH to address social justice and racism in all its forms. As Dr. Gilman wrote in an email to Clinical Center staff, "We must do more than wait for this to pass. This time we need to be better than that. This time I must do more. This time I must be better than I have in the past."

Racism must be confronted as a public health concern: "Public health is called upon to recognize the pervasive role of racism in public health and to reshape our discourse and agenda so that we all actively engage in racial justice work."[1]

Returning to Work

Dr. Gilman underscored the importance of ensuring the safety of patients and staff asNIH implements guidance on provisions for safe return to work, during whichfacial coverings are required. Campaigns on hand hygiene and coughing/sneezing hygiene are in place. Employees are returning to work in phases, and the inpatient census will slowly rise. No more than 10 people may be in a room at any time and a team of a given service is always sequestered at home so that not all service staff are potentially exposed.

To bolster employee morale, music performances are recommencing in the atrium of the Clinical Center, where there is a grand piano. Although vocal music, woodwinds, and brass are contraindicated, strings, percussion, and keyboards will be performing.

Discussion

Dr. Hait asked about the role of diagnostic testing in decisions about returning to work. He also noted that people are often good about safety practices at work, but they ride in carpools, dine in restaurants, and engage in other risky activities when they are outside of the workplace.

Dr. Gilman said NIH is testing about 1,000 staff members every week with next-day turnaround. Every patient and visitor is tested. The rates of asymptomatic infections have been very low for staff and nil for patients. Increased infection rates in Montgomery County, MD, are raising questions about returning more staff to the workplace.

---

[1] García JJ-L, Sharif MZ. Black Lives Matter: A Commentary on Racism and Public Health. *Am J Public Health*. 2015;105(8):e27-e30. doi:10.2105/AJPH.2015.302706. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4504294/. Accessed July 29, 2020.

Richard Shannon, M.D., expressed his support for the simulation program, which could be transformative in terms of safety. Team preparation and training are instrumental; simulations will be a major enhancement.

Dr. Shannon thought that the multi-Institute collaboration on cellular therapies and transplantation was an important advance. Many organizations are creating service lines, in which people from different disciplines come together to build an excellent service. Dr. Shannon recommended establishing metrics to document success.

Dr. Shannon said that the reduced census was to be expected during the pandemic, but he asked about the consequences of deferring care for patients whose clinical needs are being met to some extent through their participation in research. Dr. Gilman noted that investigators have had to be more selective about procedures. Some surgeries were postponed for a week or a month with no discernable impact on outcomes. Transplant communities implemented some temporizing measures. If clinicians think a procedure should not be delayed, they may reach out to Dr. Gilman. When investigators make a sound case for clinical urgency, requests are usually approved. Investigators have been very forthright in their assessments of patients whose procedures could not be delayed. Dr. Gilman said that one positive outcome of the pandemic is improved lines of communication, including with the nursing department. Dr. Gilman has been updating Dr. Tabak weekly. The 17 ICs that contribute patient resources to the Clinical Center were very cooperative.

Jeanette Erickson, D.N.P., RN, FAAN, is looking forward to Shannon N. Zenk, Ph.D., M.P.H., RN, FAAN, joining NIH as the incoming Director of the National Institute of Nursing Research (NINR) in the fall of 2020. Dr. Zenk's research focus is on inequities and disparities in health which will be an asset as she helps shape/influence intramural research.

Follow-Up Items:

- Be explicit about success measures for the Blood and Immune Deficiency–Cellular Therapy Program in terms of efficiencies, cost, and clinical outcomes.
- Follow up with the Board about the possible consequences of deferred care for patients who normally would receive some clinical care at the Clinical Center.

Patient Safety and Clinical Quality Update

Laura Lee, M.S., RN, Director, Clinical Center Office of Patient Safety and Clinical Quality; and Madeleine Schuyler Deming, M.D., Staff Clinician and Assistant Research Physician, Clinical Center Internal Medicine Consult Service

Performance Metrics

Ms. Lee highlighted several performance metrics from the ***Executive Dashboard*** for the Clinical Center:

- *Patient perceptions:* Inpatients and outpatients have a consistently positive perception of the Clinical Center, and most would recommend the Clinical Center to others. Both measures were well above the benchmarks.

- *Infection control metrics:* Handwashing compliance consistently hovers around 90%. The central line–associated bloodstream infection (CLABSI) rate reached 0% in the first quarter of 2020. In the intensive care unit, the CLABSI rate and the catheter-associated urinary tract infection (CAUTI) rate have remained at 0% for more than a year. For the surgical oncology service, the CAUTI rate had been at 0%, but in the fourth quarter of 2019, the rate jumped to 9 infections per 1,000 Foley catheter days. Ms. Lee reviewed the cases. Surgical site infections are down, but the rate remains above benchmarks.
- *Inpatient falls:* Ms. Lee reported a slight upward trend in falls and falls with injury, but rates remain below national benchmarks.
- *Pressure injuries:* After a couple of quarters' reductions in pressure injuries, a slight uptick in the prevalence of pressure injuries has occurred since the third quarter of 2019. Prevalence remains well below benchmarks, however. Two patients had stage 1 or 2 injuries that resolved; no stage 3 or 4 pressure injuries were reported.
- *Medication administration barcode compliance:* Compliance is 99%, just shy of the 100% goal. Per the CCRHB's request, Ms. Lee did not include data from hospital areas that do not use barcode scanning.
- *Blood and blood product use:* The goal for the Clinical Center's crossmatch-to-transfusion ratio is 2 or less. This goal is consistently met, which is important for ensuring that blood is not held unused in reserve when it could be available for another patient. Transfusion reactions occur in less than 0.5% of transfusions; the majority of reactions are of the febrile, nonhemolytic type. The percentage of blood bank specimens that were improperly collected or labeled has remained under 2.0% with the exception of the second quarter of 2019, when it approached 2.5%.
- *Occupational injury and illness:* The most important metric is "days away, restricted, or transferred (DART)." Numbers have ranged between 9 and 23 per quarter for the past five quarters. Musculoskeletal injuries are most often reported (43% of occupational injuries and illnesses). Wounds (24%) are almost always minor cuts, scratches, and sterile needle sticks.

Accreditation Activities

Ms. Lee announced that the Clinical Center is within the 18-month window for the next Joint Commission assessment. The last survey occurred in July 2018. The Clinical Center undertakes an annual self-assessment to check adherence with more than 1,400 individual standards of performance. During the most recent self-assessment, four noncompliant standards (i.e., findings) were identified.

A review of pain management data revealed a lack of a systematic way to look at the pain management from an aggregate or organizational perspective. A system is being set up to present to the Joint Commission. Also, for graduate medical education, the assessment indicated a need for written descriptions of the roles, responsibilities, and patient care activities of the participants of the graduate education program. This deficiency has already been corrected.

Patient Safety Event Reporting

Ms. Lee presented the dashboard for the Safety Tracking and Reporting System (STARS), which is used to identify trends in patient safety events. This electronic reporting system is available to all staff to share information about errors, near misses, process issues and instances of high-quality service. Ms. Lee reviewed some recent STARS data.

Of 4,000 reports between October 2019 and July 2020, nearly 8% were high-quality service reports. Very few anonymous reports are submitted, which Ms. Lee attributes to a healthy reporting culture that makes people comfortable about reporting safety events. The top 10 general events include meals/fluids, laboratory/specimens, and clinical care and treatment. The main specific events include orders not entered into the Clinical Research Information System (CRIS), incorrect blood draw volumes, and Code Blue events.

Medication delays used to be the most common safety event, but pharmacy and nursing staff have collaborated to improve medication delivery. These delays are now fourth in terms of frequency, and pressure events are the most common.

Harm Outcomes Assessment: The Trigger Tool

The Trigger Tool is a qualitative peer review of factors that contribute to individual patient harm events. In 2017 Ms. Jerussi convened the Trigger Tool group, a facilitator role assumed by Drs. Madeleine Deming and Naomi O'Grady in June 2019.Ms. Lee relies on the Trigger Tool team to understand the state of care in the Clinical Center.

Dr. Deming stated that the Trigger Tool group has reviewed three cases in depth every two weeks between June 2019 and March 2020; a total of 47 deep dives performed over this timeframe.

These deep-dive peer reviews have highlighted some significant systems issues and led to some significant organizational changes. Each trigger case is categorized by clinical performance level:

- Level I: Most providers would have handled the case similarly.
- Level II: Some providers would have handled the case differently.
- Level III: Most providers would have handled the case differently.

Dr. Deming screened and performed a preliminary review of 453 intensive care unit (ICU) admissions between July 2019 and March 2020.

The 287 planned admissions (mainly postoperative admissions following uneventful surgeries) and 90 unplanned Level I admissions during this period reflect the high complexity of Clinical Center cases. During this time frame 25 (6%) ICU admissions were deemed to be a Level III. Associated harms with each of these occurrences included: 18 attributed to clinical management, 4 attributed to system failures, 2 were attributed to adverse events related to a medication side effect or procedural intervention, and one each 1 attributed to a patient factor (noncompliance with a care plan) or disease progression.

Over this 8-month review, there were a total of 19 ICU admissions which were both Level III and unexpected. Most of these cases included a harm event attributed to clinical management. The Trigger Tool team found that Level III harm events were spread among 13 Institute branches, 17 attending teams, and multiple care units in the hospital, so no clear trends emerged. The team identified some common themes associated with Level III harms: protocol research-attending physician engagement, handoff lapses during transitions of care, and delays in recognizing acute clinical changes. Dr. Deming provided three case examples of the themes and described mitigation efforts:

- An I-PASS system in CRIS to improve patient handoffs
- A new clinical decision document for electrolyte management
- Neurologic assessment training for clinical staff

Dr. Deming stated that the Trigger Tool team and the Office of Patient Safety and Quality are working together to identify and address important opportunities for improving clinical care and hospital systems. Their efforts are leading to systems improvement, with the overarching goal of improving patient safety and quality of care.

In the News

Ms. Lee announced that a manuscript about the Clinical Center's suicide risk screening program had been accepted for publication.[2]

Discussion

Dr. Forese remarked that she was struck by themes that are common to the Clinical Center and other major academic medical settings.

Ms. Berty commented on the Clinical Center's continued improvements in safety and quality indicators.

Ms. Erickson said that the dashboard data would serve as very helpful evidence to support the Clinical Center's submission for the Magnet Recognition Program®.

Dr. Goldstein -commented on the "clear and impressive" Clinical Center data, given the number of ICs that use Clinical Center resources and potential problems with communication and patient handoffs. He noted that historical silos posed issues in the past but these data reflect no impact currently

Ruth Williams-Brinkley, M.S.N., spoke about the remarkable culture of safety for patients and employees that has been built and is continuing at the Clinical Center.

[2] Snyder DJ, Jordan BA, Aizvera J, et al. From Pilot to Practice: Implementation of a Suicide Risk Screening Program in Hospitalized Medical Patients. *Jt Comm J Qual Patient Saf*. 2020;46(7):417-426. doi:10.1016/j.jcjq.2020.04.011

Launching the Journey for Magnet Recognition Program® Accreditation

Gwenyth Wallen, Ph.D., RN, Chief Nurse Officer, Clinical Center Nursing Department; and Rachel Coumes Perkins, M.S.N., RN, Nurse Consultant, Clinical Center Nursing Department

Dr. Wallen introduced Ms. Perkins' role as the Magnet Recognition Program® manager who is working with nursing staff and with an analyst to get NIH into planning mode for achieving Magnet recognition. The American Nurses Credentialing Center (ANCC) established the program to recognize "health care organizations that truly value nursing talent…. Magnet Recognition is…proof of a hard-earned commitment to excellence in health care, with contented nurses at its heart."

Dr. Wallen reviewed the components of Magnet accreditation and noted that process and structure were the traditional focus, but now empirical outcomes comprise the core of the Magnet model. Why is the Clinical Center embarking on a Magnet journey? Dr. Wallen said that Magnet hospitals:

- Have better patient outcomes—lower rates of mortality, falls, failure to rescue, and nosocomial infections
- Attract and retain high-quality providers through better nurse satisfaction, along with lower rates of turnover and burnout
- Improve quality and safety, with better support for evidence-based practice, higher quality of care, and higher patient ratings
- Realize financial benefits in terms of lower nurse turnover and shorter lengths of stay for patients

Dr. Wallen listed several potential benefits for the NIH Clinical Center, including having a rigorous and data-driven analysis of hospital and patient outcomes, an opportunity to identify gaps in quality while developing strategies for improvement, a more collaborative culture, and enhanced public visibility to showcase clinical research and attract high-quality candidates in nursing and medicine.

Many nurses, fellows, and physicians wonder why the Clinical Center is not already a Magnet hospital. Staffneed to feel the pride of working in a center of excellence.

Gap Analysis

A recent Gap Analysis confirmed the Clinical Center Nursing community excels in many areas, including a robust shared governance structure, a highly visible chief nursing officer, and an impressive nursing research portfolio. Ahe comprehensive analysis also identified areas for focused improvements., For example, the Clinical Center offers many opportunities for academic and professional development, but they are not equally accessible to all staff. Sometimes, nurses are so involved with their work that they underestimate the importance of their stories about the work. Staff are now starting to write and save their stories. Similarly, stories are needed from patients, and plans are underway to engage the Patient Advisor Group soon. Dr. Wallen also envisions increasing her visibility, and that is already happening through Microsoft Teams meetings and other platforms.

The NIH CC Magnet Journey in 2020

Dr. Wallen's team has met four times with the ANCC Senior Magnet Program Analyst. Based on those discussions, she anticipates that it will take about 3 years to develop and submit documents in support of the Clinical Center's application for Magnet status. Information about the Magnet journey is posted on the electronic information boards in the Clinical Center. Because it is very important that all nursing staff "own" this effort, Magnet Ambassador teams will be set up. James Gulley, M.D., of NCI is the first physician ambassador. Patients and stakeholders will be included to gather their input.

Dr. Wallen clarified that nurses who work directly for ICs are not under her direct supervision, but she does credential and privilege all the registered nurses for NIH. IC nurses will be part of the Magnet journey, too.

Future tasks will include integrating the model of care for clinical research nursing with a professional practice model to come up with a model that makes sense for patient care and for clinical research. Although NIH has very structured annual nursing goals, there is no nursing strategic plan. The idea is to develop a plan that cascades from the NIH Clinical Center Strategic Plan.

Dr. Wallen announced that the Magnet kickoff event slated for October 2020 will probably take place online.

Discussion

Ms. Erickson congratulated Dr. Wallen, Ms. Perkins, and Dr. Gilman on their progress toward Magnet recognition. She said that everyone with the Magnet program is very excited that our nation's research hospital is on this journey, and she offered to help in any way needed. Ms. Erickson recommended focusing on the inter-professional team; the whole infrastructure of the Clinical Center will come to bear.

Ms. Erickson recommended holding the virtual kickoff as planned. All site visits are now conducted virtually.

Dr. Forese reported that her hospital is getting ready for a virtual Magnet visit; the Joint Commission assessment was also done virtually. Dr. Forese also commented that the work to-date on this effort is impressive and inspirational, with clarity that leadership made the difference and there has never been a better time to get focused. Dr. Gilman recognized the importance of the Nursing Department. The Clinical Center nurses are well led. Dr. Gilman supports the Magnet journey because it is good for patients. It is easy to get the idea that Magnet is all about nursing, but the program is really focused on patients. Dr. Forese noted that being a Magnet hospital makes the whole team, not just nurses, better.

Dr. Hait asked about the event that triggered this journey as he suggested the CC could have completed this in the past. Two reasons that Dr. Gilman hired Dr. Wallen as the Chief Nurse Officer were her focus on patients and community and her desire to achieve Magnet status, a longstanding goal for Dr. Wallen. Dr. Wallen also acknowledged the important roles that Dr. Gilman as CEO and the CCRHB have played in supporting this goal.

Ms. Berty suggested collecting stories from patients in addition to those from nurses. Dr. Wallen agreed, saying that the core team plans to attend a future meeting of the Patient Advisory Group. Patients are partners in this effort. Ms. Berty also expressed support for having a patient on the core team.

Stephanie Reel, M.B.A., has taken part in Magnet reviews in the past. One hospital was struggling with several issues but decided to embark on a Magnet journey anyway. The hospital staff discovered that the journey encouraged teamwork in unexpected ways. There is never an ideal time for the journey, but striving for Magnet status is the right thing to do for the hospital, the team, and patients.

On behalf of the CCRHB, Dr. Forese expressed support for the NIH Clinical Center pursuing Magnet recognition. The Board believes strongly that the time is right to forge aheadDr. Wallen said she appreciated the support.

Dr. Shannon said that Magnet Recognition is an important step toward becoming a high-reliability organization. Many hospitals that have gone through the process tapped consultants to help build necessary capabilities. Dr. Shannon volunteered to connect the Clinical Center's core team with his organization's leaders who could share their insights and serve as informal consultants.

Follow-Up Items:

- Maintain the current goal of holding the Magnet kickoff meeting in October 2020.
- Identify the Magnet Recognition Program® staff person who will be working with the Clinical Center.
- Dr. Shannon is willing to connect NIH Magnet core team members with leaders at his organization who have gone through Magnet reviews previously.

Clinical Center Activities Regarding the Novel Coronavirus Pandemic

James Gilman, M.D., NIH Clinical Center CEO; Ann Marie Matlock, D.N.P., RN, NE-BC, Chief, Medical–Surgical Specialties Clinic, and Captain, United States Public Health Service, Clinical Center; Karen Frank, M.D., Chief, Department of Laboratory Medicine (DLM), Clinical Center; and Tara Palmore, M.D., Chief, Hospital Epidemiology Service (HES), Clinical Center

Dr. Gilman presented some data from the Coronavirus Resource Center, which was established by the Johns Hopkins University Center for Systems Science and Engineering. Early in the pandemic, scientists were surprised by the rapid spread of the virus; that knowledge galvanized actions at NIH. The number of patients seen at NIH has remained low consistent with trends in Maryland, which has flattened the curve to the extent that the state has thus far avoided abrupt saturation of hospital resources, such as hospital beds, ICU beds, and ventilators.

Protecting Patients and Staff

Dr. Gilman said that NIH is committed to its existing patients, many of whom have immune disorders or are transplant recipients, and others develop immunosuppression because of treatments. The threat of infections is of great concern for these patients. Also, the NIH

investigator population and the Clinical Center staff population are slightly older than national averages, putting them at greater risk.

The issues facing the Clinical Center are very similar to those confronting all U.S. hospitals: shortages of personal protective equipment (PPE), a shortage of testing reagents, and a lack of training and preparation from a personnel standpoint. While Ebola virus disease patients were treated here>5 years ago, the clinical care model was different as clinicians caring for the Ebola patients volunteered for that duty and with COVID-19, not all the clinicians would be volunteers.

Dr. Gilman outlined some measures at NIH that help people keep safe:

- The building was designed for single-pass air without recirculation of air.
- The Special Clinical Studies Unit has state-of-the-art infrastructure that allows for isolation capabilities and infection control.
- NIH's HES is excellent.
- Strong SARS-CoV-2 testing support (multiple platforms, rapid results) is available through the DLM.
- Numbers of inpatient admissions and outpatient visits have been drastically reduced.
- Visitors are not allowed, with a few exceptions, such as for patients at the end of life and parents of pediatric patients.
- Everyone—patients, staff, and visitors—entering the building is screened.
- Everyone must wear a mask for source control.
- Masks plus face shields are required for people who have close contact with patients.
- Elective procedures are being deferred.

Pandemic preparations at the Clinical Center, including practicing procedures while wearing PPE, started at the end of January. The hospital centralized PPE and put it under tight control.

NIH testing platforms support up to 1,800 tests per day, and capacity can be multiplied tenfold through pooled testing.

The Clinical Center provides employees with well-being and resilience resources. Psychosocial well-being is critical as employees cope with pivotal events, such as the current pandemic and the Black Lives Matter movement. Seeking help is a sign of strength and should not be stigmatized.

Dr. Gilman extended his thanks to Bernard Harper and the entire Materials Management and Environmental Services (MMES) team. The crew has done an excellent job of ensuring that staff have PPE to keep safe.

Building 10 Entry Point Screening

CAPT Matlock said that the 165 entry points for Building 10 have been reduced to 3, in the south lobby, the north lobby, and the P1 parking ramp/lobby. All people entering the building at any time are screened. The PHS officers performing the entry point screening identified the first positive patient. A total of 12,500 people are being screened each week.

The symptom screening is based on guidance from CDC. The list consists of new cough, new fever, shortness of breath or difficulty breathing, muscle aches, chills, diarrhea, recent loss of taste or smell, headache, and sore throat.

Starting on April 2, 2020, people who screen negative have been given surgical masks to wear while in the building. The symptom screening process entails screening questions for everyone entering, and for individuals other than employees, a temperature check.
People who screen negative receive a sticker and mask after the staff confirm that they have an appointment at the Clinical Center. A body temperature above 37.5°C is considered a positive screen. Patients who screen positive are escorted to the fifth floor for testing. Visitors are screened the same way, but if their test result is positive, they are referred to local health providers.

The only employees allowed into Building 10 are those involved in animal or patient care or in direct COVID-19 research. Employees do not have their temperatures checked; they are only asked about symptoms. Employees with positive symptom screens exit the building, call their supervisors, and go to the car line for testing. As of July 1, 2020, more than 200,000 screenings have been performed.

Asymptomatic Testing

CAPT Matlock explained that routine staff testing is necessary to increase the hospital census and staffing in the Clinical Center. Testing has three phases: the sampling production line, the DLM phase, and follow-up and contact tracing.

Testing is required for all Building 10 employees and contractors. After registering in the testing system, agreeing to the conditions of use, and providing a personal email address, employees can set up a patient portal for test results. Self-scheduling is used for testing appointments, which occur between 7:30 a.m. and 4:30 p.m. in 15-minute blocks on weekdays. Appointments are also available in the evenings and on weekends.

CAPT Matlock presented the plan of the fifth floor, which has been set up to allow social distancing and can accommodate up to 49 people in line at any one time. She also listed the resources required for the testing program in terms of space, supplies, and personnel. As of July 9, 2020, nearly 1,900 tests of asymptomatic people have been performed.

DLM Phase

Dr. Frank presented a schematic showing how different countries use different SARS-CoV-2 gene targets in their testing platforms.[3] The World Health Organization published a polymerase chain reaction (PCR) assay on January 13, 2020. The U.S. Food and Drug Administration approved the CDC assay on February 4, 2020, but there were problems with the reagents. NIH received its first kits from CDC and began testing on February 28, 2020.

[3] Ahn D-G, Shin H-J, Kim M-H, et al. Current Status of Epidemiology, Diagnosis, Therapeutics, and Vaccines for Novel Coronavirus Disease 2019 (COVID-19). *J Microbiol Biotechnol*. 2020;30(3):313-324. doi:10.4014/jmb.2003.03011

Early in the pandemic, tests were in short supply. NIH investigators donated their RNA extraction kits and test platforms. NIH performed many test validations and found that the Abbott ID NOW™ system has a lower sensitivity (81%) compared with NIH running the CDC kit. (ID NOW is used by the White House.) The Cepheid assay gives rapid results in 1 hour, but these tests are in very limited supply and are being reserved for urgent staff and patient needs.

On May 21, NIH started pooling up to 10 specimens from asymptomatic employees. The DLM's validation tests demonstrated a slight loss of sensitivity with pooled samples (four cycle threshold levels), but very low viral loads could still be detected. NIH's testing capacity is now up to 18,500 per day with pooling in batches of 10. Current test volume is about 1,000 per week, although the theoretical maximum approaches 130,000. Availability of instruments is no longer a limiting factor, but staffing is. Staff have been approved but are not yet hired or trained.

According to Dr. Frank, three testing instruments are in use at the Clinical Center. The Applied Biosystems™ 7500 Fast Dx instrument has been the DLM's workhorse thus far. Dr. Frank reported that the Hologic Panther Fusion® System went live in June and the Roche COBAS® 6800 System was scheduled to go live in the Department of Tranfusion Medicine under the direction of Dr. Cantilena at the end of July 2020.

In terms of sample collection, Dr. Frank said that nasopharyngeal swabbing is the gold standard, but NIH has changed to a slightly less invasive collection method—mid-turbinate swabs—for testing asymptomatic employees. Nasal swabs have not been used because of reduced sensitivity.

The Institutional Review Board approved a protocol to collect samples and assess sensitivity of saliva testing, but because of the currently low prevalence in Maryland, the number of available samples is insufficient. Results of saliva testing at other centers have been mixed. Staff are collecting some saliva samples from the car line at NIH. NIH is collaborating with the Maryland Department of Public Health and the Washington Hospital Center emergency department to obtain additional samples.

HES

Tara Palmore, M.D., said that HES has been working closely with the Occupational Medical Service (OMS) during the pandemic. So far:

- Sixteen Clinical Center patients have tested positive.
- Twenty patients with COVID-19 have been admitted to the Clinical Center. Eleven were brought to NIH to participate in COVID-19 studies, and two preexisting NIH patients enrolled in NIAID's COVID-19 clinical trial.)
- A total of 256 NIH employees and contract staff members, including 43 healthcare personnel, have tested positive. Seven staff members (five asymptomatic, one symptomatic, and one presymptomatic) have tested positive via asymptomatic surveillance testing. Once a clinical staff member has tested positive, Dr. Palmore queries them about symptoms and HES starts contact tracing. OMS does the same for nonclinical staff.

PPE Timeline

According to Dr. Palmore, since late March 2020, all patient care staff have been required to wear masks, and on April 1, the requirement extended to all Building 10 staff and patients. Inpatients are asked to don masks when healthcare personnel enter their room. On June 26, providers started using face shields over surgical masks for essentially all patient encounters. At each phase, MMES ascertained that supplies were adequate and could be maintained at par levels given the burn rate.

Screening and Testing of Patients for COVID-19

Ahead of appointments or admissions, the appropriate study team asks patients by telephone about their symptoms and exposures. Upon arrival at the Clinical Center, patients are screened and given masks. Patients who have a fever or two symptoms of COVID-19 are directed to the negative-pressure units on the fifth floor for testing. People whose screens are negative proceed to the clinic, where they are rescreened. Those who are scheduled for aerosol-generating procedures undergo pre-procedure testing.

Dr. Palmore reported that 35 contact studies were completed over the course of 3 months. HES does the investigations for patients and healthcare personnel, and OMS does the tracing for nonclinical staff. HES has undertaken about 15% of contact investigations. Four secondary cases have occurred among clinical staff, and no secondary cases have been found among patients. One employee was infected by a patient, and three were infected by other staff members. Three of the secondary infections occurred before universal masking.

Discussion

Dr. Hait asked whether HES has started modeling to identify prevalence rates in the community that would raise a red flag and, if so, what might be done differently in the Clinical Center, short of closing the facility. Dr. Palmore said that only Group A staff are working at NIH at the moment—this group comprises essential staff for patient and animal care. Groups B and C staff are not yet entering the campus. Decisions about when to bring in Groups B and C will be based on thresholds in the community.

Dr. Tabak said that he; David Henderson, M.D. (a consultant to HES); and Steven Holland, M.D. (Director of NIAID's Division of Intramural Research), meet with Dr. Collins every morning to discuss the situation. Currently, the rate of positive tests is about 7%; if the rate rose to, say, 10%, that would be a major cause for concern. Other important factors include the percentage of ICU beds occupied by COVID-19 patients in the area. At the beginning of the pandemic, the Clinical Center reduced the census to 20% by discharging patients. When Group A employees returned to campus, the census grew to 30%. When Group B staff return, the census could grow to 35%. Dr. Tabak underscored the need to maintain a safe environment. Employees' roles have figured prominently in NIH's stratification plan for returning to work. About 60% of staff can work effectively via telework; the likelihood of bringing them back to NIH is low for the time being. NIH staff come from the District of Columbia, Maryland, and Northern Virginia.

Dr. Gilman added that staff who have symptoms are asked to stay home. They are denied entry into the Clinical Center, but if someone who has symptoms comes to an entry point, they are not criticized. Messaging focuses on getting tested through the car line or through OMS. Dr. Tabak

further explained that NIH is using a text and email prompt system. If someone is symptomatic, they are directed to fill out the Research Electronic Data Capture (REDCap) survey. Survey responses have led to detection of a few positive cases. A discussion about implementing an app-based system is underway.

Ned Sharpless, M.D., Director of NCI, said that NCI, the National Institute of Biomedical Imaging and Bioengineering (NIBIB), and CareEvolution have been working on a novel approach to symptom screening and contact tracing using a web-based app. Some other countries are using similar apps. CareEvolution supports the *All of Us* Research Program, the Framingham Heart Study, and other major research initiatives. The NCI–NIBIB effort to develop a web-based app has been challenging because of privacy considerations, but these problems are being worked on. The plan is to roll out the app at NCI soon. The Google/Apple contact tracing system will be added later as part of a research effort. Dr. Sharpless volunteered to provide additional information to anyone interested in learning more.

Dr. Forese commented that she does not know of any medical center in New York City that is testing all employees. Contact tracing is also an issue in New York, where testing supplies are again low.

Ms. Berty asked whether patients can self-refer for a COVID-19 test if they do not have symptoms. Dr. Gilman clarified that tests need to be ordered by medical providers.

Dr. Shannon asked about the potential use of next-generation sequencing technologies for prevalence studies and contact tracing as a means to track the virus and its mutations. Dr. Black reported that this was discussed with Dr. Henderson and with NHGRI staff recently. The question is whether such testing would add value; that is, what are people finding at a large scale when they use these systems? Also, whole genome sequencing (WGS) and bioinformatics take time. Dr. Gilman said that Dr. Palmore has worked with NHGRI using WGS to track clusters of hospital infections; that research is of academic interest but limited practical utility.

Dr. Sharpless mentioned a *60 Minutes* program on using artificial intelligence to track epidemics. Universities might be good settings for using digital tools for contact tracing, but they would need to be powered with adequate testing.

John I. Gallin, M.D., Chief Scientific Officer and Scientific Director of the Clinical Center, said that NIH has 40 clinical protocols on COVID-19, including 29 taking place at the Clinical Center. He noted that the sharing of specimens among investigators has been extremely helpful in driving knowledge about treatments and the pathobiology of the disease as well as. Dr. Tabak remarked on extramural investigations of new technologies for point-of-care testing. Some candidate technologies have been identified that could be scaled up to handle millions of tests.

Dr. Gilman mentioned the challenge of modifying the many contracts that NIH has in place to permit testing of contract staff. Housekeeping staff and some nursing personnel are working under contracts. Testing is still voluntary. Saliva testing would make more people feel comfortable about getting tested.

Follow-Up Item:

- Anyone interested in learning more about the NCI–NIBIB web-based app for screening and contact tracing should contact Dr. Sharpless.

Adjournment

Dr. Forese said that the Board is very impressed with what is going on at NIH and is proud to be connected with the NIH Clinical Center. Dr. Forese thanked Gretchen Wood and other NIH team members who support the CCRHB.

The next meeting of the CCRHB is scheduled for October 16, 2020.

Dr. Forese adjourned the meeting at 12:55 p.m.

_____

Laura Forese, M.D., M.P.H.

Chair, NIH Clinical Center Research Hospital Board

Executive Vice President and Chief Operating Officer, NewYork–Presbyterian Hospital

_____

Lawrence A. Tabak, D.D.S., Ph.D.

Executive Director, NIH Clinical Center Research Hospital Board

Principal Deputy Director, NIH

_____

Francis S. Collins, M.D., Ph.D.

Ex Officio Member, NIH Clinical Center Research Hospital Board

Director, NIH

Abbreviations and Acronyms

ADC	average daily census
AHaRT	Anti-Harassment Response Team
ANCC	American Nurses Credentialing Center
BERT	Behavioral Emergency Response Team
CAUTI	catheter-associated urinary tract infection
CCRHB	Clinical Center Research Hospital Board
CDC	Centers for Disease Control and Prevention
CEO	chief executive officer
CLABSI	central line–associated bloodstream infection
COVID-19	coronavirus disease 2019
CRIS	Clinical Research Information System
DART	days away, restricted, or transferred
DLM	Department of Laboratory Medicine
HES	Hospital Epidemiology Service
ICs	Institutes and Centers

ICU	intensive care unit
MMES	Materials Management and Environmental Services
NCI	National Cancer Institute
NHGRI	National Human Genome Research Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NIH	National Institutes of Health
OMS	Occupational Medical Service
PPE	personal protective equipment
REDCap	Research Electronic Data Capture [software]
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
STARS	Safety Tracking and Reporting System
WGS	whole genome sequencing

From: Hallett, Adrienne (NIH/OD) [E]
To: Collins, Francis (NIH/OD) [E]
Cc: Lauer, Michael (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Allen-Gifford, Patrice (NIH/OD) [E]; LaMontagne, Karen (NIH/OD) [E]
Subject: Re: EcoHealth Response Letter
Date: Saturday, August 15, 2020 8:22:31 AM

I will suggest that to ASL.

> On Aug 15, 2020, at 7:52 AM, Collins, Francis (NIH/OD) [E] < (b) (6) wrote:
>
> (b) (5)
>
> FC
>
> **From:** Lauer, Michael (NIH/OD) [E] < (b) (6)
> **Sent:** Friday, August 14, 2020 1:59 PM
> **To:** Hallett, Adrienne (NIH/OD) [E] < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6)
> **Cc:** Allen-Gifford, Patrice (NIH/OD) [E] < (b) (6) LaMontagne, Karen (NIH/OD) [E] < (b) (6) Lauer, Michael (NIH/OD) [E] < (b) (6)
> **Subject:** Re: EcoHealth Response Letter
> Hi Francis, Larry, and Adrienne – late yesterday we received a "response" from EcoHealth Alliance counsel. Briefly, they are refusing to answer the questions. I've forwarded the materials to OGC for their review. (b) (5)
>
> Thanks, Mike
>
> **From:** "Hallett, Adrienne (NIH/OD) [E]" < (b) (6)
> **Date:** Friday, August 14, 2020 at 12:44 PM
> **To:** "Collins, Francis (NIH/OD) [E]" < (b) (6) "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Lauer, Michael (NIH/OD) [E]" < (b) (6)
> **Cc:** "Allen-Gifford, Patrice (NIH/OD) [E]" < (b) (6) "LaMontagne, Karen (NIH/OD) [E]" < (b) (6)
> **Subject:** EcoHealth Response Letter
>
> FC,
> Well, we finally got a draft back from ASL. It is attached.
> Please let me know if you have any concerns.
> Adrienne

From: Allen-Gifford, Patrice (NIH/OD) [E]
To: Whitfield, Michelle D. (NIH/OD) [E]
Cc: Cool, Mariko (NIH/OD) [C]
Subject: FW: EcoHealth Response Letter
Date: Thursday, August 27, 2020 12:30:32 PM
Attachments: 06.26.20 SST EC Letter to HHS[1][1].pdf
Eco Health Lab letter July 8.pdf
SST and EC EcoHealth Alliance response[1].docx

I think the first attachment is it.

From: Lauer, Michael (NIH/OD) [E] (b) (6)
Sent: Friday, August 14, 2020 1:59 PM
To: Hallett, Adrienne (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Tabak, Lawrence (NIH/OD) [E] (b) (6)
Cc: Allen-Gifford, Patrice (NIH/OD) [E] (b) (6); LaMontagne, Karen (NIH/OD) [E] (b) (6) Lauer, Michael (NIH/OD) [E] (b) (6)
Subject: Re: EcoHealth Response Letter

Hi Francis, Larry, and Adrienne – late yesterday we received a "response" from EcoHealth Alliance counsel. Briefly, they are refusing to answer the questions. I've forwarded the materials to OGC for their review. Since EcoHealth Alliance has not responded to our questions, (b) (5)

Thanks, Mike

From: "Hallett, Adrienne (NIH/OD) [E]" (b) (6)
Date: Friday, August 14, 2020 at 12:44 PM
To: "Collins, Francis (NIH/OD) [E]" (b) (6), "Tabak, Lawrence (NIH/OD) [E]" (b) (6), "Lauer, Michael (NIH/OD) [E]" (b) (6)
Cc: "Allen-Gifford, Patrice (NIH/OD) [E]" (b) (6), "LaMontagne, Karen (NIH/OD) [E]" (b) (6)
Subject: EcoHealth Response Letter

FC,

Well, we finally got a draft back from ASL. It is attached.

Please let me know if you have any concerns.
Adrienne

Congress of the United States
House of Representatives
Washington, DC 20515

June 26, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar,

We write with strong concerns surrounding the Administration's termination of the National Institutes of Health (NIH) grant to EcoHealth Alliance on April 24, 2020.[1] In the letter communicating the grant's termination, NIH Deputy Director for Extramural Research, Dr. Michael Lauer, wrote that "At this time, NIH does not believe the current project outcomes align with the program goals and agency priorities."[2] However, press reports indicate that the grant was canceled because a small portion of the funding was to be given to the Wuhan Institute of Virology for on-the-ground sample collection and analysis.[3] Given the potential for this study to inform our knowledge of coronavirus disease 2019 (COVID-19) transmission, it is deeply concerning that it may have been canceled for political reasons in the midst of the current pandemic.

It is always important that federal research priorities are driven by science-based decisions. This is especially true in a time that requires unparalleled investment in research that may help bring an end to this public health crisis. It is therefore troubling that this abrupt grant cancellation came just a week after President Trump announced that the Administration was looking into "grants going to that area" and continued that "we will end that grant very quickly."[4] This was in response to a reporter referencing false claims that COVID-19 "likely

[1] Sharah Owermohle, "Trump cuts U.S. research on bat-human virus transmission over China ties," *Politico*, April 27, 2020, accessed here: https://www.politico.com/news/2020/04/27/trump-cuts-research-bat-human-virus-china-213076
[2] Nurith Aizenman, "Why The U.S. Government Stopped Funding A Research Project On Bats And Coronaviruses," *NPR*, May 1, 2020, accessed here: https://www.npr.org/sections/goatsandsoda/2020/04/29/847948272/why-the-u-s-government-stopped-funding-a-research-project-on-bats-and-coronaviru
[3] *Id.*
[4] Clip of President Trump with Coronavirus Task Force Briefing, *CSPAN*, April 17, 2020, accessed here: https://www.c-span.org/video/?c4869590/user-clip-us-2015-grant-wuhan-lab-question

came from a Level 4 lab in Wuhan."[5] The Administration has been pushing this theory[6] despite scientific experts saying this path of transmission would be virtually impossible given what is known about the virus and lab safety protocols.[7] If this theory is the basis for the grant termination, it would be an egregious example of the Administration politicizing scientific decision making in order to further a politically convenient narrative.

EcoHealth Alliance's grant was renewed in 2019 after an initial five-year grant on the same topic. The grant it received was extremely competitive – only 22 percent of proposals were funded in 2019.[8] The July 2019 project proposal was titled, "Understanding the Risk of Bat Coronavirus Emergence."[9] In the midst of the COVID-19 pandemic that has taken over 115,000 American lives, it is inconceivable that this project would no longer "align with the program goals and agency priorities" of NIH. Any termination of a grant that has gone through NIH's rigorous scientific review process must be adequately justified on a scientific basis – particularly a grant which would appear to be so relevant to understanding our current health crisis.

As the Committees of jurisdiction over public health and science, we need to better understand the decision to terminate EcoHealth Alliance's NIH grant. We are especially concerned given Dr. Anthony Fauci's, Director of NIH's National Institute of Allergy and Infectious Diseases, assertion at a Committee on Energy and Commerce hearing on June 23 that "the grant was canceled because NIH was told to cancel it."[10] In order to understand how this decision was reached, we request a briefing to be delivered by July 15, 2020. At this briefing, we ask that you be prepared to address the following questions:

1. When the decision was made to terminate the grant to EcoHealth Alliance;

2. Who at HHS was involved in the decision to terminate the grant;

3. Whether entities outside HHS, including but not limited to the White House, the State Department, the National Security Council, and intelligence agencies, were involved in this decision;

---

[5] *Id.*

[6] Mark Mazzetti, Julian E. Barnes, Edward Wong, and Adam Goldman, "Trump Officials Are Said to Press Spies to Link Virus and Wuhan Labs," *New York Times*, April 30, 2020, accessed here: https://www.nytimes.com/2020/04/30/us/politics/trump-administration-intelligence-coronavirus-china.html

[7] Geoff Brumfel and Emily Kwong, "Virus Researchers Cast Doubt On Theory Of Coronavirus Lab Accident," *NPR*, April 23, 2020, accessed here: https://www.npr.org/sections/goatsandsoda/2020/04/23/841729646/virus-researchers-cast-doubt-on-theory-of-coronavirus-lab-accident

[8] Research Grants: Competing Applications, Awards, and Success Rates, National Institutes of Health, January 2020, accessed here: https://report.nih.gov/nihdatabook/category/6

[9] "Understanding the Risk of Bat Coronavirus Emergence," National Institutes of Health Research Portfolio Online Reporting Tools, July 2019, accessed here: https://projectreporter.nih.gov/project_info_description.cfm?aid=9819304&icde=49752569

[10] House Committee on Energy and Commerce, Testimony of Anthony S. Fauci, M.D., Director, National Institute for Allergy and Infectious Diseases, *Oversight of the Trump Administration's Response to the COVID-19 Pandemic*, 116th Cong. (Jun. 23, 2020).

4. The analysis conducted to determine that the EcoHealth Alliance grant's project outcomes did not align with program goals and NIH priorities;

5. Any analysis conducted to determine EcoHealth Alliance's alleged improper disbursal of NIH funds to the Wuhan Institute of Virology;

6. Any other decision NIH has made to terminate grants since January 1, 2020; and

7. Any further action NIH is considering taking regarding EcoHealth Alliance or any other grant holder regarding alleged relationships with international laboratories.

In addition to the briefing, we request the following materials be provided to the Committees no later than July 10, 2020. Please provide these materials in a searchable electronic format.

1. All documents and communications relating to the cancellation of EcoHealth Alliance's grant, including the notification to and any response from EcoHealth Alliance;

2. All documents and communications regarding any potential direction from outside entities, including the White House or other Agencies or Departments, to terminate grants based on suspicion of collaboration with international laboratories;

3. All documentation of audits or other analyses conducted to determine improper disbursement of federal grant money from grant-holding institutions to other entities; and

4. The criteria that NIH used to assess the EcoHealth Alliance grant and determine that such grant merited cancelation, and documentation thereof.

Any decision to terminate a research grant should be conducted in a deliberative and transparent process that adheres to the highest standards of scientific integrity. Especially in this unprecedented time, it is important that our public health and science agencies remain free from political pressure and be allowed to pursue federally-funded research based on scientific merit.

Thank you for your attention to this matter. We look forward to speaking with you and reviewing the relevant materials.

Sincerely,

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space,
and Technology

Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce

Bill Foster
Chairman
Subcommittee on Investigations and Oversight

Diana DeGette
Chair
Subcommittee on Oversight and Investigations

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,

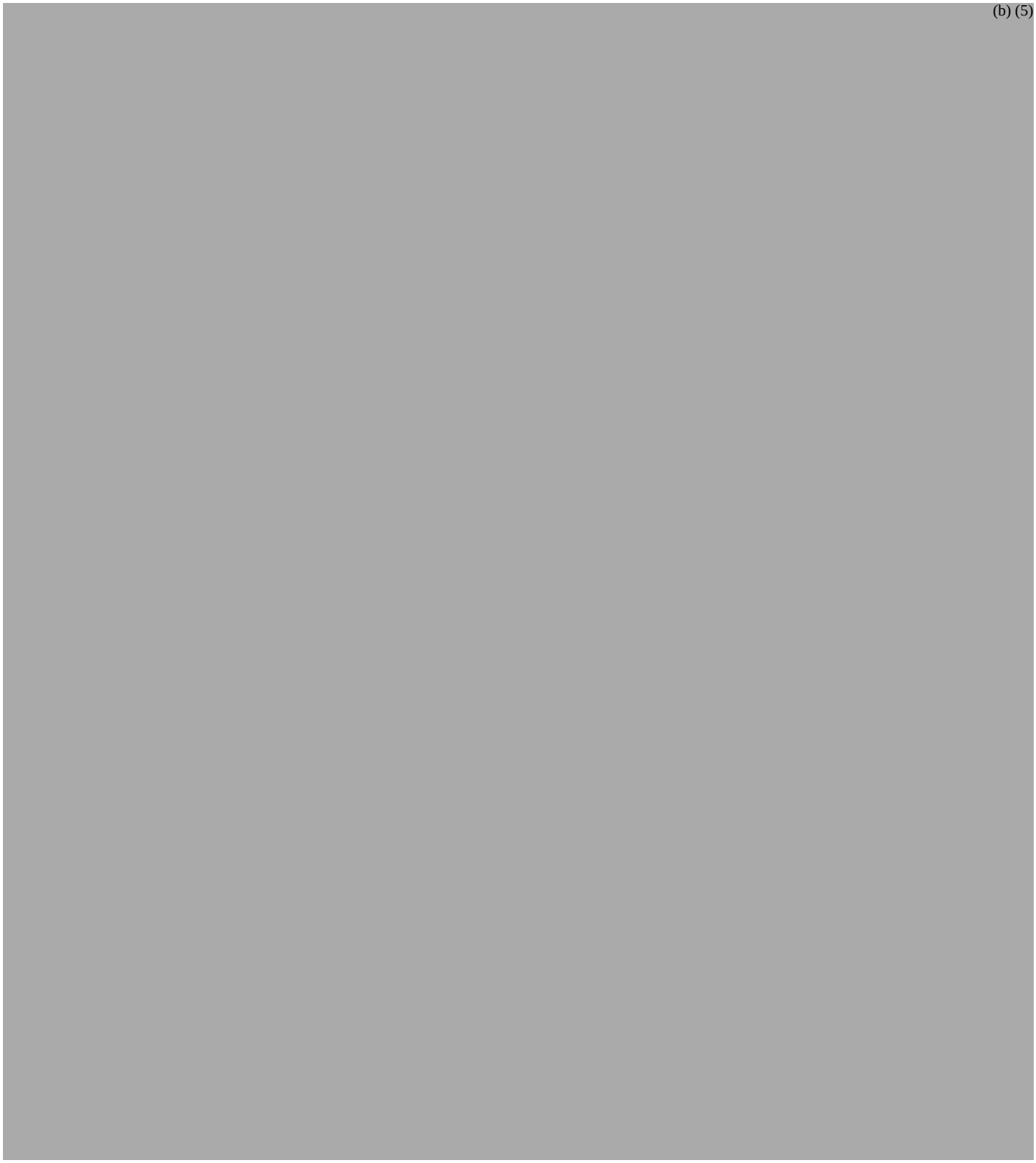
Michael S Lauer, MD
NIH Deputy Director for Extramural Research
Email: (b) (6)

cc: Dr. Erik Stemmy
Ms. Emily Linde

Letterhead

The Honerable Eddie Bernice Johnson
Chairwoman, Committee on Science, Space, and Technology
United States House of Representatives
Washington, D.C. 20510-2102

(b) (5)



From: Collins, Francis (NIH/OD) [E]
To: Fine, Amanda (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]
Cc: Burklow, John (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]
Subject: RE: Interview request for Dr. Collins: Jon Cohen
Date: Sunday, September 20, 2020 5:11:00 PM

I can't make the time for this.

From: Fine, Amanda (NIH/OD) [E] (b) (6)
Sent: Sunday, September 20, 2020 3:55 PM
To: Collins, Francis (NIH/OD) [E] (b) (6) Wood, Gretchen (NIH/OD) [E] (b) (6) McManus, Ayanna (NIH/OD) [E] (b) (6)
Cc: Burklow, John (NIH/OD) [E] (b) (6) Myles, Renate (NIH/OD) [E] (b) (6) Wojtowicz, Emma (NIH/OD) [E] (b) (6)
Subject: Interview request for Dr. Collins: Jon Cohen

Interview Request for Dr. Collins
September 20, 2020

Request: Topic – COVID-19/pandemic

Deadline: 1 hour, Wednesday September 23, requested in person with film crew

Additional information:
Jon Cohen requested an in-person filmed interview with Dr. Collins for two separate projects.

The first is a documentary that will air in 2022 that Jon is co-executive producing with David France (How to Survive a Plague, 2012) that will air on HBO. They are filming interviews now in "real time" of the event (i.e. COVID) happening, rather than doing retrospective interviews.

The second is an interview for Science on several COVID0-19 related topics. He said the film crew wants to film him interviewing people and requested to film this interview as well. He would like to ask Dr. Collins about the following topics:

- Details around the announcement of the convalescent plasma EUA.
- What happened with EcoHealth Alliance?
- Were these two events because of pressure from the White House?
- Vaccine development details.
- How is ACTIV working with OWS?
- Recruitment of minorities into trials.

For additional background, Jon will be with Moncef Slaoui and Moderna in Cincinnati on Thursday for an event.

Recommendation:
We recommend Dr. Collins decline. OCPL let Jon know that he could check back after the election on his request for the documentary, but that we would put forth his request for the Science article.

Submitted by:
Amanda Fine, (b) (6)
NIH News Media Branch

Contact information:
Jon Cohen
Science
jcohen@aaas.org

Other important notes:

Accept: ____
Decline: ____
Need more information: ____